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Living with COVID-19: Herd immunity to appropriate behavior to vaccine

The Ministry of Health and Family Welfare, Government of India, has reported 8.3 million COVID-19 cases and 0.12 million deaths as of November 05, 2020. Since the past 7 weeks, India is showing a decreasing trend in daily cases. Compared to the peak of 97,894 cases on September 17, India has reported 50,210 cases on November 05 (a decrease of around 50%).[1] India's 7-Day Moving Average daily test positivity rate is 4.6%.[2] India continues to occupy the top position globally in terms of COVID-19 recoveries while the total number of active cases has witnessed a sustained downward trend, with its percentage having reduced more than thrice in just 2 months as per the statement given by the Union Health Ministry.[3] Public health experts have opined that India is at the verge of the flattening COVID curve. Although India's COVID-19 trajectory shows a downward trend, there is no scope of complacency. **Jan Andolan campaign** must be executed in true spirit.

The challenge for the nation is to find a balance between reviving the economy and protecting people's health as the Government of India has been lifting the lockdown in a phased manner since June 2020. The onus of containing the spread of the virus now lies majorly on every individual of the country along with the government and the health-care team. The tools for the humankind to fight with the virus include developing vaccine, achieving herd immunity, developing effective treatment protocols, adopting COVID-appropriate behavior, and to wait till the virus stops naturally.

There is little evidence to suggest that the spread of SARS-CoV-2 might stop naturally before at least 50% of the population has become immune. For COVID-19, which has an estimated infection fatality ratio of 0.3%–1.3%, the cost of reaching herd immunity through natural infection would be very high, especially in the absence of improved patient management and optimal shielding of individuals at risk of severe complications. Allowing the virus to effectively run its course and infect such huge percentages could only increase the casualty risk and mass suffering. As the long-term complications of COVID-19 are still unclear, the concept of herd immunity is debatable. The safest way to reach herd immunity is again developing an effective vaccine.[4]

The big question now is when a vaccine will be available? According to the WHO, there are currently more than 100 COVID-19 vaccine candidates under development, with a number of these in the human trial phase.[5] India currently has three COVID-19 vaccines, including two indigenously developed candidates, that are being tested across the country. Covishield, jointly developed by the Oxford University and AstraZeneca, has advanced the farthest in clinical studies in India. The Oxford COVID-19 vaccine candidate, which is being handled by the Serum Institute of India, has entered the Phase 3 trials in the country. The other two candidates, COVAXIN being developed by the Bharat Biotech in partnership with the ICMR and Zy-CoV-D developed by Zydus Caldia, are undergoing Phase 2 human trials. Recently, the Drugs Controller General of India has granted permission to Dr. Reddy's Laboratories to conduct the Phase 2/3 clinical trials of the Russian Sputnik-V, the world's first registered vaccine against COVID-19, in the country. The vaccine is expected in the late December or January if the trials are proven successful.[6] The vaccine against COVID-19 is likely to be anywhere between 50% and 100% effective as per the ICMR. The Government of India had already started groundwork to vaccinate its people against coronavirus. In an advisory to states on setting up coordination committees for distribution of the COVID-19 vaccine, the health ministry has said that the introduction of the shots will span over a year with multiple groups being included sequentially, starting from health-care workers, while also asking governments to be vigilant about disinformation on social media.[7] It may take a couple of years to know whether the vaccines are robust or not.

Some of the European countries and also few states in India such as Kerala, West Bengal, Karnataka, Andhra Pradesh, Tamil Nadu, and Delhi have reported a spurt in cases, which can be attributed to the opening of public places, transport, and also laxity on the part of people who are now shunning distancing and mask rules due to pandemic fatigue.[8] According to the statement given by the Centre for Cellular and Molecular Biology Hyderabad, there is a possibility of a second or a third or even further waves in the near future which are severe than the first one. We have to be extremely watchful and need to delay or reduce

the amplitude of further waves by practicing appropriate COVID-19 behavior.[9]

The overwhelming message is that the evil is still out there and here to stay, which means we have to learn to live with it and it is the only immediate option we have right now.

Living with corona demands three important practices – wearing a mask, maintaining social distancing, and timely hand washing or sanitization. Never before have we wanted to change behaviors in such a compressed time and at such a large scale. The need of the hour is to bring behavioral change among the people and to address the challenges in the way of promoting healthy behavior.

Although COVID-appropriate behavioral practices look like simple measures, the extent to which people adopt and implement these practices is questionable in a country like India. At times, it becomes difficult to maintain social distance in the public places and transport as the density of the population is high. People who are more stressed about their financial situation may compromise with the protective measures. Social and religious gatherings are the other areas where the preventive measures are at times compromised. People who feel a false sense of security due to the relaxation of restrictions, are less likely to wear masks and avoid large gatherings.

There is an urgent need to address the hurdles in adopting and practicing preventive measures and make the people to realize that it is every individual's responsibility to follow COVID-appropriate behavior in order to protect their health, their family health, neighborhood, and community as well. People should be sensitized to be cautious about the virus and to take preventive measures as much as possible. When people cannot afford to buy masks, they can use clean cloth as a mask.

As festivals and the winter season are approaching and the economy is also being unlocked, our honorable Prime Minister Sri. Narendra Modi launched **Jan Andolan campaign** on October 8, 2020, to encourage people's participation in following COVID-appropriate behavior. "Wear mask, follow physical distancing, maintain hand hygiene" is the key message of the campaign. The campaign will focus on awareness raising through all media such as television, hoardings, wall paintings, audio messages, pamphlets, brochures, mobile vans, and social media which is a strong communication channel.

The world is thrown into a tricky situation, where every individual has to think about the risk of corona in every step they take. The ability to co-exist with SARS-CoV-2, as the virus is known, will increasingly ride on how individuals assess risks and make decisions. Currently, the humankind is left with two options – living with corona and living for corona. With the relaxation of restrictions, knowingly or unknowingly, most of the people are living for corona by not following the preventive measures out of carelessness and ignorance. The health-care team at all levels, nongovernmental organizations, teachers, and leaders should take an active role to promote COVID-19-appropriate behavior intensively through various information, education and communication activities to turn the people living for corona into the people living with corona.

The war is not over and the future is unpredictable. It requires efforts by every single citizen to win this war. The humankind's existence depends on adopting to the change. It is time to accept and adopt the new normal way of living as a responsible citizen and live with corona till the dream of an effective vaccine is fulfilled.

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Perspective

Psychological impact of COVID-19 pandemic on healthcare workers and strategies to mitigate them

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Abstract

The outbreak of a novel coronavirus starting from December 2019 and reaching pandemic proportions has raised concerns as to the ability of current protective measures and the health-care system to handle such a threat. Health-care workers may experience considerable psychological distress as a result of the COVID-19 pandemic due to providing direct patient care, vicarious trauma, quarantine, or self-isolation.

Keywords: Health-care workers, pandemic, professionals, psychological, SARS-COV-2

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INTRODUCTION

Since December 2019, the world has been facing the outbreak of a novel infectious disease known as coronavirus disease (COVID-19) starting from Wuhan city of China and rapidly spreading to other countries around the globe which has been declared as a pandemic by the World Health Organisation.[1] Its spread and lethality in terms of absolute numbers is proving to be higher than previous epidemics on account of international travel density and immune naivety of the population[2] triggering urgent, draconian public health measures in most of the countries around the globe. Many accomplishments on COVID-19 including virus information, clinical features, and diagnosis have been achieved, but no effective treatment is available yet.[3-7] The disease, COVID-19, has caused an unprecedented situation for citizens, policymakers, politicians, and health-care professionals, with the pandemic being described as the worst public health crisis in a generation.

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Frontline health workers are integral to the global response to COVID-19. In hospitals, clinics, and homes around the world, health workers are taking on significant personal risk and too often working without adequate equipment to ensure all can receive the care they need.

The mental and physical toll this crisis is having on our frontline health workers is rapidly becoming an epidemic itself. Every new COVID-19 diagnosis means longer hours, less sleep, and sporadic meals which leads to weakened immune systems.

In brief, they are exposed to a protracted source of distress which may exceed their individual coping skills, being, according to a clinometric definition, in allostatic load, which is likely to result in overload with protracted time.[7]

Facing this large-scale infectious hazard, people are under increased psychological pressure. Patients with mental health conditions, such as depression and anxiety, have

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been reporting relapses in their mental state, such as fear-triggered panic attacks or resurface of psychosomatic symptoms; patients with medical comorbidities, such as cardiovascular disease, have been expressing distress and associated worsening of symptoms, in particular, angina and worsening of heart failure status. Even though children who have been reported to be less susceptible to COVID-19 infection[8] are witnessing considerable psychological implications, the shutting down of schools and playgrounds and the restriction of outdoor activities alongside their parents' fears of contamination have been triggering manifestations of anxiety, such as panic attacks and psychosomatic symptoms.

PSYCHOLOGICAL IMPACT ON HEALTH-CARE PROFESSIONALS AND WORKERS

The general population, however, are not the only ones at risk for psychological distress during this pandemic. Experiences from previous SARS and H1N1 epidemics underline that the psychological strain on health-care workers, who find themselves at the frontline of attempts to quell the outbreak, is significant.[9,10]

During the COVID-19 pandemic, clinicians are confronted with mounting challenges that have not been faced ever before. Decisions have to be made fast, ranging from efficiently triaging and isolating patients with suspicion of infection, to deciding whether to shut down departments and operating theatres when a patient or staff test positive; all this while being on limited resources and protective equipment particularly personal protective equipment (PPEs) in most of the countries round the globe. The pressure to act timely and to successfully diagnose, isolate, and treat has been overwhelming, especially among intense public and media scrutiny. This phenomenon is being seen across many countries.[11] In addition, due to the increased risk of exposure to the virus, the frontline doctors, nurses, and health-care workers fear that they may contract COVID-19 themselves. They worry about bringing the virus home and passing it on to loved ones and family members-elderly parents, newborns, and immunocompromised relatives. The use of protective equipment for long periods causes difficulties in breathing and limited access to toilet and water, resulting in subsequent physical and mental fatigue. Such experiences of health-care personnel are being recorded in the emerging scientific literature[12] and media reports.

Hence, health-care professionals dealing with COVID-19 are under increased psychological pressure and experience high rates of psychiatric morbidity, resembling the situation during the SARS and H1N1 epidemics.[9,13] A recent study among health-care professionals in a tertiary infectious disease hospital for COVID-19 in China revealed a high incidence of anxiety and stress disorders among frontline medical staff, with nurses having a higher incidence of anxiety than doctors.[14] Another observational study of 180 health-care workers providing direct care to patients with COVID-19 found substantial levels of anxiety and stress that adversely influenced sleep quality and self-efficacy.[15] Importantly, those who reported a strong social support network had a lower degree of stress and anxiety and a higher level of self-efficacy.[15] A qualitative study of medical residents during the 2003 SARS outbreak in Toronto showed that anxieties around personal safety and risk of contagion to loved ones conflicted with their professional duty to care.[16] This highlights the complexity of issues faced by health-care workers and the dissonance they are required to reconcile.

Health-care providers not directly caring for patients with COVID-19 are not immune to psychologic effects and may have vicarious trauma at levels similar to the general public.[17] It has been postulated that this may relate to their concerns for patients with the disease, their at-risk colleagues, and for themselves and their families.[17] The disruption of routine clinical practice, the sense of loss of control, and the subsequent fear of potential destabilization of the health services, have provoked "overflowing" anxiety and depression among health-care professionals, a feature which is not uncommon of epidemics.[13,18] Depression is associated with poor medication adherence[19] which may increase morbidity among older health-care workers with coexisting medical conditions.

A recent COVID-19 study demonstrated that frontline nurses had significantly lower vicarious traumatization scores than nonfrontline nurses and the general public.[17] Simialrly, another study from Singapore comparing anxiety level in medical and nonmedical health care personnel found a higher prevalence of anxiety among the nonmedical health-care workers.[20] Reasons for this may include reduced accessibility to formal psychological support, less firsthand medical information on the outbreak, less intensive training on PPE, and infection control measures.

MITIGATING THE NEED OF PSYCHOLOGICAL SUPPORT FOR HEALTH-CARE WORKERS

On a positive note, experience so far across the globe indicates that willingness of health-care staff to work has not been really affected, in line with reports from previous pandemics.[9] Despite the initial shock, the

health professionals appeared to exhibit high levels of commitment and professionalism. Confidence in safety, risk perception, and confidence in skills are proven facilitators for willingness to work in health-care workers.[21] Hence, increasing knowledge about preventing and dealing with the disease and the development of more specific procedural and treatment protocols, alongside educational activities, will contribute in enlightening the morale and confidence of the health-care workers dealing with the pandemic. However, considering the increased psychological pressure of frontline health-care staff, measures for psychological support and interventions to protect their mental health should be adopted promptly, as depicted from previous experience[9,14] and emerging initiatives and literature.[12,13,21]

Few past experiences from literature describe measures to mitigate the psychosocial impact on health-care workers and have identified themes that commonly arise in pandemic situations.[22,23] Clear and rapid hospital communication was helpful to address the reactions of health-care workers based on uncertainty or fear.[23] Frequent communications, without being overly reassuring, were also identified as helpful in previous outbreaks.[16,22,23]

Psychiatric support was offered to health-care workers during the SARS outbreak, at first informally and then through confidential telephone lines and drop-in centers.[23] The current need for physical distancing necessitates adjustments to these supportive interventions by leveraging today's technology (e.g., online video and audio capabilities). System-level changes (i.e., safe hospital policies and adequate resource provision) are likely to have more far-reaching effects than individual support, especially since capacity to counsel large numbers of affected health-care workers may be inadequate in most of the places.

A review of existing evidence found that health-care workers who are self-isolating or under quarantine report symptoms of posttraumatic stress disorder, depression, stigmatization, and fear of financial loss.[24] Failure to ensure appropriate support could result in underreporting of symptoms and increase the risk of in-hospital transmission from those who continue to work while being sick. A strong social support network can offset feelings of isolation.[24] Video calls and virtual meetings allow for the maintenance of social relations while preserving physical distancing. Other mitigating interventions may include delivery of general and medical supplies, limiting isolation to the shortest duration necessary, and emphasizing that altruism and serving of the greater good are core values of the profession.[24] All these interventions can reduce the effect of quarantine or isolation and help to preserve wellness and fitness in health-care workers so that they can return to work with full efficiency when they are out of it.

CONCLUSION AND RECOMMENDATIONS

We are facing exceptional circumstances never seen before; the current biothreat is the most serious global crisis of our generation. Health-care staffs are in the frontline of this fight, which is taking a serious psychological toll; supporting health-care workers in all aspects is vital to sustaining a healthy workforce during the pandemic which would eventually help in containing the pandemic.

- Each and every health-care professional and worker involved directly or indirectly with patient care should not ignore symptoms of any mental health problem such as low mood, lethargy, anxiety, impending doom, panic attacks, and nightmares as a consequence of working in stressful situations during the pandemic
- Help in the form of counseling services and break from their work should be offered to every health-care professional or worker who requires them. A help desk or a helpline number in every hospital providing care to COVID-19 patients may be dedicated for the purpose.

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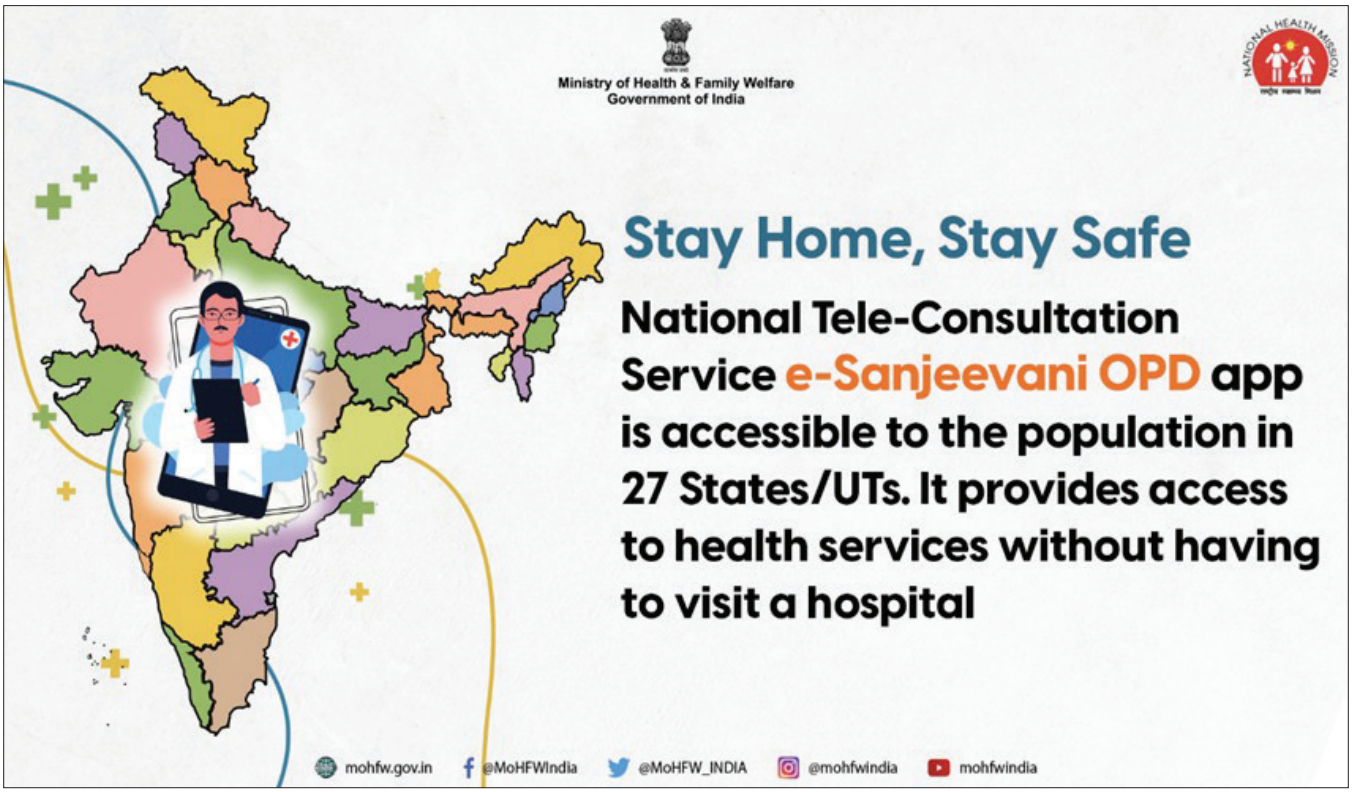

Review Article

Determinants of COVID-19 transmission in India: Issues and challenges

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Abstract

The recent increase in trend of COVID-19 cases in India is an important public health issue. Cases reported vary in calendar time in different states and regions. Case presentations, its determinants and mediators such as behavioral and social factors may be different across and within countries. Although agent, host and environmental factors play a major role, there are other influencing factors for transmission of infection. Appropriate cost-effective prevention strategies such as social distancing, use of face mask and its implementation in the Indian context is a big challenge. Recent data available on the public domain was reviewed on various issues and challenges related to determinants of COVID-19 and its transmission in the Indian context. This review emphasizes to further strengthen prevention of infection transmission strategies at regional and state level by a combination of multiple strategies and robust surveillance system.

Keywords: COVID-19, determinants, India

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INTRODUCTION

Recent data on COVID-19 cases in India show that there is an increase in the trend, but it differs across states and regional level. There is also a difference in the number of cases reported across countries. Although international and interstate travel was the main reason for its transmission at the initial stage, there will be other important determinants which influence morbidity and mortality at the state or regional level of each country. Recent articles highlighted the limits of Public Health Science related to COVID-19. It cautioned the usefulness of mathematical models of infectious disease transmission in various countries.[1] The four factors namely rate of tests performed in the population, calendar time of occurrence of events, use of linier scale, and population of each country affected may not be addressed in these models. Although initially, Kerala reported more cases, afterward more cases reported from Maharashtra, Delhi, Gujarat and Tamil Nadu and other states. About 80%–90% of all cases report it as mild or asymptomatic, and severe cases in 10%–20% cases. Overall and age-specific case fatality rate differs across counties and it could be over 15%.[2] There is also variation in case of fatality rate across states in India with Kerala reporting <1%.[3] There are variations in the epidemiology of COVID-19 morbidity and mortality across countries. Therefore, situational analysis of its determinants in Indian context across state and regional level is an important health issue to be discussed so that appropriate intervention measures may be adopted to

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control the spread of infection. With this background, this review critically discusses various possible determinants of COVID-19 in the Indian context and its public health issues and challenges.

METHODOLOGY

Recent data were collected from Medline and other sources. Information gathered was summarized for the Indian context and analyzed for discrepancies. Information was presented under categories of various determinants and challenges to address the problem in the country.

DETERMINANTS

Social distancing

As the country proceeds from the local transmission to wider spread, there are various factors influencing this through contact between infected and uninfected people. Basic Reproduction Number (R_0) which determines the communicability of disease varies widely, which again depends on many factors like infectivity of virus, its structural variation and environmental factors.[2] Social distancing is an effective method of prevention of droplet transmission. Countrywide lockdown since March 25, 2020 contributed in substantial reduction in cases in the initial phase without going to the stage of community transmission. However, there are instances where its guidelines were not followed. In many states, vegetable and fruit market is one of the important areas where people gather without maintaining social distance and thus spreading the infection.[4] Some religious events like held in Delhi just before the lockdown period with international delegates may be another reason in India favoring the spread of COVID-19 in the initial period.[5] Social customs, including marriage and social gathering held in many parts of India without following rules which is another reason of worry for its rapid spread.[6]

There may be differences in factors influencing disease transmission in urban, rural, and tribal areas which needs to be addressed. It is the lack of awareness in the community about its mode of transmission where people may not consider the seriousness of this disease. For example, in Mumbai, thousands of people especially those in the slums rushed to pick up their food package without maintaining social distancing.[7] Poverty, unemployment and migration affects the transmission. Food or ration may be served to the houses of this vulnerable population by proper planning and distribution system. In these slum areas, it is difficult to follow social distancing measures. All concerned stakeholders and people should be trained through awareness generation about this effective social vaccine method for prevention of transmission of COVID 19 disease.

In Germany, the case fatality rate was lower with 1.2% as on April 2, 2020.[8] People when voluntarily adhere to guidelines of strictly following social distancing norms like done in Germany may help to contain the spread of disease. Taking appropriate early actions to prevent social or public gathering in business or market areas and schools is another important step required. Since health is a state subject, they may take early actions unilaterally whichever is required to contain the spread of disease similar to actions taken by Germany's 16 states. Mandating isolation of people who had COVID-19 positive and quarantine of contacts is also an important step required. It requires improving the testing capacity and robust health care system to find out the eligible group for testing by field surveillance for influenza-like illness or by aggressive contact tracing as done in Germany.[8] There is a need for monitoring of social distancing norms to understand on to what extent these guidelines were adhered in various regions in India.

Kerala model worked well at the initial stage in the drastic reduction of reporting of new cases because of strict adherence to these guidelines with community involvement. "Break the chain" campaign with focusing on social distancing, hand washing, and sanitizing was a success story.[9] There may be other factors also like less dense population in cities which reduce the spread of disease. In slum areas of major cities where following social distance is difficult, it requires to adopt multiple other approaches by concerned health stakeholders to contain the spread of disease. Behavioral change on prevention measures of COVID-19 requires awareness generation and motivation of people with community participation.

HAND AND PERSONAL HYGIENE

Water scarcity is one of the important issues in urban and rural areas of India. For example, in the village of Kaithi, in the Bundelkhand region in north-central India, there is one shared tap for every five households.[10] This may lead to crowd around the tap for washing their hands. In slum and rural areas where access to piped water supply and soap availability is not there, it may become one of the important reason for transmission of COVID-19 infection if not taken care of. Alcohol-based hand rub is an alternative to the use of soap. In the absence of licit liquor, there are incidents in Karnataka that people have reportedly resorted to consuming alcohol-based hand sanitizers.[11] There have been some reports in the UK and USA of patients drinking

alcohol-based hand rubs. However, in the Indian context where water is available, it is better to wash hands with soap and water frequently which is cost-effective and sustainable, while in water deficit area hand sanitizers may be advised temporarily taking necessary precautions. We need to address the risks involved in the use of hand sanitizers.[12]

Hand washing practice with or without soap varies in different circumstances. In urban slums, the availability of adequate water is a problem. In Dharavi, Mumbai slums where more 168 cases have been reported as on April 20, 2020, along with social distancing, hand hygiene also will play a big role in the transmission of disease.[13] A study in India highlighted that extent of desirable practices regarding hand washing is lacking and needs to be emphasized in the urban and rural community[14] But to what extent in the current scenario according to COVID 19 guidelines people use hand and personal hygiene practices may be understood by further research in different regions of the country.

USE OF MASK AND PERSONAL PROTECTIVE EQUIPMENT

Although there is controversy when to use mask for community people, it is a welcome step that India has made the wearing of face masks mandatory when people leave their homes. Ministry of Health and Family Welfare (MoHFW) guidelines mention the use of homemade protective cover for face and mouth for people who are not suffering from medical conditions or having breathing difficulties. They may use handmade reusable face cover, particularly when they step out of their house. This will help in protecting the community people by preventing the transmission from asymptomatic people at large. This face cover is not recommended for either health workers or those working with or in contact with COVID 19 patients or are patients themselves as these categories of people are required to wear specified protective gear.[15]

Public health professionals, health-care managers, health care, and community health workers have to wear different types of mask depending on exposure risk.[16] Availability of personal protective equipments (PPEs) for the health care workers was an issue during the pandemic as all government rushed stocking PPEs. Also, to reduce common breaches in biosafety during donning and doffing of PPE, proper training is an important aspect to be considered.[17] Recent spread of COVID-19 to health staffs are a major cause of concern whether PPE was used properly according to guidelines or not. About 89 personnel of the Madhya Pradesh health department, including four IAS officers and a few doctors, who have been playing a vital role in the fight against COVID-19, have tested coronavirus positive in the state.[18] Health care personnel in the private sector involved in managing noncovid conditions also been infected and deaths have been reported. There is no data on the availability of PPEs and their usage in the private sector. Facilitating the availability and use of masks or PPE in both government and private sector will help in continuing health care services for routine outpatient and inpatient health care services and emergencies. In this regard, we need to address these aspects to prevent the transmission of COVID-19 to health personnel.

HOST FACTORS

A recent study in China showed that older age, male and presence of hypertension were independently associated with severe disease at admission, irrespective of adjustment of time to admission.[19] Case fatality rate also different across counties may be due to different factors like diverse age distribution, different definition of COVID-19– related deaths, country-specific strategy in testing and proportion of asymptomatic cases.[20] The morbidities vary among COVID-19 hospitalized cases.[21,22] In India, we need to assess the independent effect of host factors by comparing among COVID-19 and non-COVID-19 patients on morbidity severity and mortality by further follow-up studies. Serological surveys using antibody tests will assess the herd immunity status, which is also one of the important determinants of transmission of disease.

TEMPERATURE AND HUMIDITY

A study from China showed that meteorological factors may play an independent role in the COVID-19 transmission after controlling population migration. Local weather condition with low temperature, mild diurnal temperature range, and low humidity likely favor the transmission.[23] Another study found that no association of COVID-19 transmission with temperature or UV radiation in Chinese cities.[24] Indonesia study found only temperature average (°C) was significantly correlated with COVID-19 pandemic.[25] However, COVID-19 cases increased in summer season in contrast to Severe Acute Respiratory Syndrome (SARS).[26] We do not know whether temperature and humidity act in interaction with host factors and at what level of exposure to these factors. Earlier China study found that SARS outbreaks were significantly associated with the temperature and its variations, but there may be fallacy and the uncontrolled confounding effects which might have biased the findings and the possibility of other meteorological factors having an affect on the SARS outbreaks.[26] Similarly, in the case of COVID-19 also, we need to address confounding factors

for showing an increase in trend even in the summer season. In the present context, there may be other influencing factors like virus characteristics, host factors along with control strategies adopted which may strongly favor the transmission of COVID-19. We need to address these issues while interpreting the effect of temperature and humidity on COVID-19 transmission in India.

SCREENING AND CONTACT TRACING

Testing in India currently not detecting all infected people. Since the community spread is in initial phase, not detecting this group may be one of the important determining factors for transmission of COVID-19 infection. Although the positivity rate in the testing population is important factor for it, there may be other influencing factors which need to be addressed. Contact tracing and testing strategy should be strengthened along with other control strategies. Epidemiological investigation and surveillance of cases is important to understand the transmission dynamics and monitoring of disease.

Arogya Setu App development and use is a welcome step in this regard.[27] It can help people stay safe and adopt necessary precaution in some areas where there are cases and accordingly prevent community transmission by identifying "hotspots." It also educates on handwashing practices, sanitize surfaces diligently and avoids stepping out of the house, unless important, importance of the use of mask, taking care of high-risk groups like elderlies, children and those with the underlying medical conditions.

PROPHYLAXIS

Availability of chemopropylaxis is a proven determinant in cutting down the transmission. However, there is no chemoprophylaxis for COVID-19 though Indian Council of Medical Research (ICMR) recommends chloroquine for health care workers. Results of the trials focusing on prevention of transmission, which includes hyrdoxycholoroquine and BCG vaccine will guide us on this aspect.

CHALLENGES

1. Understanding the situational analysis of the implementation of various determinants related to COVID 19 transmission by concerned stakeholders and appropriate, timely interventional measures
2. Community participation in following the guidelines. Economically disadvantaged people may violate lockdown. Poverty, reduction of job opportunity in unorganized sector and industries affected the livelihood of the people
3. Strengthening multisectoral coordination on matters related to determinants is also another important area to be considered. In addition to the health sector, services and cooperation of other sectors such as home affairs, education, revenue, civil supplies, transport, water supply and sanitation, labor, agriculture, social welfare, information technology, etc., should be strengthened
4. Advocacy for improving the system and services
5. Resource allocation and workforce availability for planning and implementation of above-mentioned measures. There are substantial regional disparities in health-care resource availability and accessibility in China[28]
6. Provision of social assistance package to the vulnerable groups
7. Mental health issues due to financial burden and lockdown
8. Health-care workers fatigue and burnout due to long working hours
9. Shortage of trained epidemiologists at the state level to guide state governments[29]
10. Population Bed ratio in India
11. Costs of testing and treatment in the private sector and regulation required
12. Research is essential at the regional and state level to understand the contribution of determining factors for COVID-19 transmission.

The robust surveillance system, timely appropriate corrective actions, planning and implementation of all challenges related to determinants at various levels of administration is important in this regard.

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Conflicts of interest
There are no conflicts of interest.

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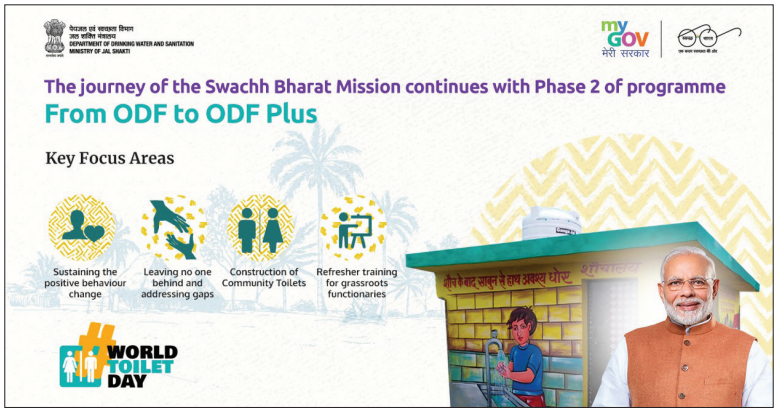

Review Article

Role of ayurvedic intervention in the management of anemia

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Abstract

Anemia is an important public health problem in India. Complementary and alternative systems/traditional medicines can also be explored for the control of anemia apart from the existing platforms. Interventions with various herbal and iron formulations have been reported in Ayurveda. Hence, this review was aimed to explore the effect of various ayurvedic drugs on anemia from the existing literature. Literature was searched in PubMed, Google Scholar, Cochrane Library, Medline (Ovid), IndMed and by cross-referencing the articles. Key words used included "Pandu Roga," "Anemia" and "Ayurveda." The search was restricted to original research articles published in the English language from January 2005 to June 2018 among human subjects. Randomized and nonrandomized control trials were included in this review, which assessed the effectiveness of ayurvedic drugs on improvement in hemoglobin as well as subjective parameters such as weakness, anorexia, and pallor. Effectiveness of 17 different Ayurvedic preparations was assessed in the studies. The maximum increase in hemoglobin was observed by the drug Sarva-juara-hara-lauha in a dose of 500 mg (145.55 mg elemental iron), when administered daily for 30 days using honey as a vehicle. Increase in hemoglobin from 7.3 ± 1.9 to 12.1 ± 1.6 g/dL was observed. All studies that assessed the effect of the drugs on the basis of subjective parameters reported a decreased percentage of complaints by the patients. No adverse reactions were reported. In conclusion, administration of ayurvedic drugs is an effective and safe approach for prevention and management of anemia in various population groups. However, larger multicentric studies are required to assess the exact potential of these drugs in the control of anemia.

Keywords: Anemia, Ayurveda, Pandu Roga

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INTRODUCTION

Anemia is an important public health problem throughout the world. Globally, around 1.62 billion people are affected by anemia which corresponds to one-fourth of the world's population.[1] The World Health Organization (WHO) defines anemia as "a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiologic needs."[2] The global prevalence of anemia 2011 estimated that the prevalence of anemia among children (42.6%) was the highest followed by pregnant women (38.2%) and women of reproductive age group (29.4%).[2] The burden of anemia is relatively high in Low and Middle Income Countries (LMIC) where malnutrition and infections like malaria and soil-transmitted helminths play a major role. The National Family Health Survey-4 (NFHS-4) reports, 58.5% of under-five children and half of the pregnant women are anemic in India.[3] According to the WHO's classification of countries, anemia

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is a serious public health problem in India. Iron deficiency is the most common cause of anemia in LMICs, however micronutrient deficiencies such as folate, Vitamin B12 and Vitamin A deficiencies and other conditions such as inflammation, parasitic infections and inherited disorders can also cause anemia.[4] Consumption of diet rich in iron could be the ideal way for control of anemia in the majority of the population. However, poor intake of dietary iron and the presence of iron absorption inhibitors necessitates iron supplementation.[5] In India, oral Iron-Folic Acid (IFA) tablets are supplemented to high-risk populations such as pregnant and lactating women, under-five children (IFA syrup), children of 6–10 years, adolescents and women of reproductive age group.[6] However, the undesirable side effects of oral IFAs, such as epigastric discomfort, nausea, gastritis, diarrhoea, or constipation, leads to poor adherence to oral IFA supplements.[7] The poor adherence to IFA tablets was evidenced by studies conducted in various parts of India and also in NFHS-4 where only 30% of the pregnant women consumed at least 100 IFA tablets.[3,8,9] Therefore, there is a dire need for alternative methods of oral iron supplementation with lesser side effects to increase the adherence among the target population.

Complementary and Alternative Medicines or Traditional Medicines, which includes Ayurveda, Unani, Siddha, and Homeopathy (AYUSH) has been widely in India since the ancient period. Acknowledging the wider acceptance of AYUSH, Government of India has integrated the traditional systems of medicine (AYUSH) with the allopathic system, especially in rural areas.[10] Each public health sector facility has a separate department for AYUSH and the AYUSH medical officer manages a wide range of diseases.[11] Among the AYUSH system of medicines, Ayurveda refers to "Science of life" or "Science of longevity," which is being practiced in India since 2500 BC.[12] Around 70% of the rural population in India follows the Ayurvedic system of medicine.[13] Hence, the Ayurvedic system can be explored for control of high burden of anemia in India. In Ayurvedic classical texts, anemia is referred to as "Pandu" meaning pallor, which is one of the common symptoms of anemia.[14] An Ayurvedic drug "Tablet Punarvadu Mandur (ISM Preparation of Iron)" has already been added in Accredited Social Health Activist (ASHA) drug kit for management of anemia in pregnancy.[15] The ayurvedic system has also indicated the use of various iron-containing and noniron containing herbal formulations for the management of anemia. Hence, this review aims to explore the effect of various ayurvedic preparations in management anemia.

METHODOLOGY

Search strategy

Literature search was carried out by two authors in PubMed, Google Scholar, Cochrane Library, Medline (Ovid), IndMed and also by cross-referencing the articles. Key words used for the purpose of this review included "Pandu Roga," "Anemia," "Ayurveda" and the search strategy included the Boolean operator - "Ayurveda and Anemia" and also "Ayurveda and Pandu Roga." Specific key words for restricting the search to interventional studies were not used to avoid missing of relevant literatures. The literature search was done from June to July 2018 and the articles published during the period of 2005 to June 2018 were included.

Selection criteria

Search was restricted to intervention studies published in the English language. Original research involving human subjects were only included in the review. Both Randomized Control Trials (RCTs) and nonrandomized trials based on community/hospital/other facilities were included.

Data extraction

Articles were screened by examining the titles and abstracts and were excluded at this stage. The following articles were excluded:

1. Articles with full text not accessible
2. Duplicated articles
3. Review articles and editorials
4. Studies without any intervention
5. Abstract only articles or conference papers.

Full-texts of eligible articles were accessed and read for the purpose of this review. A data extraction sheet was used to extract details such as study title, author name, year of publication, objectives, study participants, interventions, and outcomes.

Outcome

Outcome indicators to assess the impact of Ayurvedic intervention were subcategorized as -

- Primary outcome
  - Effect on hemoglobin level
- Secondary outcome
  - Effect on other hematological and biochemical parameters such as serum ferritin, Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin Concentration (MCHC) and MCH and Total Iron-Binding Capacity (TIBC)
  - Effect on subjective parameters of anemia such as Dourbalya (weakness), Aruchi (anorexia),

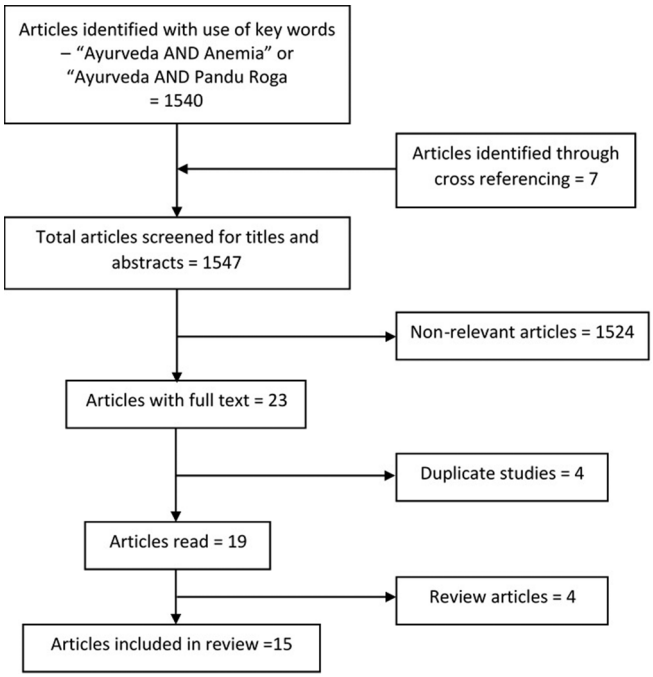

Figure 1: Search strategy for selection of articles

Arohanayasa (exertional dyspnea), Angamarda (fatigue), Hriddava (palpitation), Shiroruja (headache), Pandutva of Netra (pallor), Rukshangata (dryness), Shotha (edema), and Alasya (lassitude)

- Adverse events following Ayurvedic drug administration.

RESULTS

In total, 1547 articles were obtained using the search strategy. Of them, 1532 were excluded; they were observational studies or conference proceedings (1524), duplication studies (4) and review articles (4). In total, 15 studies were included in this review and the process is depicted in Figure 1. No restriction was placed for the geographical region of the studies; however, only Indian studies were found pertinent. Community or facility-based trials published during years 2005–2018 were reviewed.[16-30]

Type of studies

Seven were RCTs[18,19,23-25,29,31] and the remaining 8 were quasi-experimental trials (before and after intervention).[16,17,20,22,26-28,30] Of the 15 studies, 12 were from outpatient or inpatient departments of hospitals, two from schools or colleges and study site was not clearly mentioned in one study. Of the 12 studies from hospitals, 11 were from Ayurvedic health centres.

Study population and sample size

The individuals with anemia identified from outpatient or inpatient departments or from schools and colleges were included in the trails. Sample size in the selected trials varied from 25 to 1646. Of the total studies reviewed, six were among adults,[17,19,20,28,29,31] three among adolescents,[23-25] four among pregnant women,[16,26,27,30] one each among children aged 1–16 years,[18] and geriatric (50–80 years) patients.[22]

Intervention

Both iron containing and non-iron containing Ayurvedic preparations were studied to assess their effect on anemia [Table 1]. All ayurvedic drugs were produced in a laboratory and were provided to the participants.[16-20,22-28,30,31] However, in one study, the participants were asked to purchase the drugs.[29] Of the seven RCTs, two compared iron-containing Ayurvedic preparations with an allopathic oral IFA tablet[23,29] and three RCTs compared noniron containing Ayurvedic preparations with oral IFA tablet.[19,24,25] One RCT compared Ayurvedic iron preparation with a non-Ayurvedic iron preparation.[31] All eight non-RCTs used iron-containing Ayurvedic drug without any control group. The content of iron was mentioned in one RCT and two non-RCTs. A study on children decided the dosage of the drug according to body weight,[18] while a fixed dosage was prescribed to all participants in the rest of the studies. The drugs in some studies were administered along with a vehicle to enhance iron absorption and increase digestibility. Various vehicles used included lemon water,[30] buttermilk,[16,22,23,29] honey,[19,29] ghee[19,29] and ginger extract.[29] The duration of intervention ranged from 28 to 120 days and the duration of observation after intervention ranged from 28 days to 180 days. Deworming before the intervention was done among the study participants in all the studies. To ensure compliance, weekly,[24,25] fortnightly[18,20] and monthly follow-ups[23] were done in a few studies.

Hemoglobin estimation

The method used for hemoglobin estimation varied between studies. Dacie and Lewis method was used in one study,[29] cyan-meth hemoglobin in two studies[24,25] and the method of hemoglobin estimation was not mentioned in other studies.

Outcome assessment

Eleven out of fifteen studies assessed the effect of ayurvedic drug based on both objective and subjective parameters[16-19,22,23,26-28] and the remaining studies assessed only the objective parameters.[24,25,29,31] Objective parameters include various haematological parameters-hemoglobin, serum ferritin, MCV, MCH, MCHC and TIBC. Subjective parameters were the symptoms of "Pandu," anemia, which include, Dourbalya (weakness), Aruchi (anorexia), Arohanayasa (exertional dyspnoea), Angamarda (fatigue),

Table 1: Summary of literature on ayurvedic preparations for anemia

Title, author and year of publication	Type of study and duration of intervention	Sample size	Intervention	Assessment	Findings
Title: Effect of Ayurveda Medications (Kasīsa Bhasma and Dhātrī Avaleha) onIron Deficiency Anemia: A Randomized Controlled Study[31] Author: Tubaki *et al*. (2016)	Randomized controlled, open label, parallel group study, 60 days of intervention Study duration: 60 days Study site: OPD and IPD of the SDM College of Ayurveda, Udupi, Karnataka, India	*n*=40 individuals aged 20-60 years of either sex with Hb - 5-8 g/dl	2 group Group D (*n*=20): 10 g Dhātrī avaleha (noniron drug) twice a day after food Group K (*n*=20): capsules of Kasīsa bhasma 125 mg thrice a day Iron content of drug of Kasīsa bhasma: not given Intervention: 30 days Follow-up=30 days	Assessment at baseline, 30th and 60th days Primary outcome: Hb Secondary outcome: RBC indices, total RBC count, PCV and peripheral blood smear study	From baseline to 60th day Group D: Hb increased from 6.98 to 8.96 g/dL (P<0.05) Group K: Hb increased from 7.33 to 10.48 g/dL (P<0.05) Group K: Showed better results compared to Group D in all hematological parameters (P<0.001) Adverse event of the drugs: Not mentioned Loss to follow-up: 3
Title: Scientific Evaluation of some Ayurvedic Preparations for Correction of Iron Deficiency and Anemia[29] Author: Sharma *et al*. (2007)	Comparative follow-up study Study duration=30 days Study site: OPD of Ayurvedic Hospitals	*n*=140 Adult patients (male - 49, female - 91) aged 16-41 years Moderate to severe iron deficiency	7 groups (*n*=20 in each) Control group-given allopathic drug (ferrous fumarate, elemental iron 115 mg, Vitamin C, folic acid and Vitamin B12) for 30 days, 1 capsule/day Ayurvedic drug groups: 6 groups 6 most commonly prescribed drugs (elemenatal iron content in each capsule: Navayasa Curna 120 mg Punarnavadi Mandura 100 mg, Dhatri Lauha 102 mg, Pradarantaka Lauha, (14.8 mg) Sarva-Juara-Hara Lauha (145.5 mg) and Vrihat Yakrdari Lauha (69.4 mg) given in a dose of 2 tablets twice a day (500 mg of tablet/day)	Assessment after 30 days Hb, PCV, TRBC, MCV, MCH MCHC PI, TIBC, PS of iron and Plasma ferritin were determined Loss to follow-up: Nil	Statistically significant rise all hematological and iron parameters in all 7 groups TIBC decreased significantly SJHL was the drug of choice as improvement in Hb was highest 0.16 g/dl/day. Hb increased from 7.35±1.86 at baseline to 12.11±1.65 g% at endline in SJHL group, which is higher than allopathic effect Adverse event: None in ayurvedic drugs but 14 out of 20 people who received oral IFA had side effects like nausea, gastritis and vomiting
Title: Integration of Ayurvedic Formulations with Iron Folic acid in the Treatment of Nutritional Anemia among School Going Adolescents of Dehradun District[25] Author: Prakash *et al*. (2016)	Single blinded, randomized controlled clinical trial Study duration=270 days Study site: students from various government schools and colleges of Raipur, Maldevta, Miyawala, Shyampur, Bahadur, Gujrada and Chaktunwala	*n*=820 adolescent anemic students aged 11-18 years	4 groups Group I (control): Starch Group II: (SR 250 mg + SC 400 mg) Group III: 100 mg elementary iron and 500 μg FA Group IV: (SR 250 mg + SC 400 mg) along with IFA Treatment for 90 days and followed till 270 days Iron content: both are noniron containing formulations SR ootshekhar SS: SC	Blood samples were drawn on the 1st day and then on 30th, 60th and 90th, 170th, 270th day respectively for Hb estimation	Mean gain in Hb in the groups from day 0 to day 270 in g/dl Group II: 0.46±0.04 Group III: 0.14±0.03 Group IV: 1.01±0.06 Increase in Hb levels in group IV (SR+SC) was significantly higher (1.01±0.06 g/dl) than any other group Adverse event: None
Title: A Comparative Clinical Study to Evaluate the Effect of *Tanduliyaka* in *Garbhini pandu* w. s. r. to Anaemia During Pregnancy[30] Author: Singh *et al*. (2017)	Controlled clinical trial with pre and posttest design Study duration: 90 days Study site: OPD and IPD of Rishikul Ayurvedic College and District Women hospital Haridwar	40 pregnant women of 20-35 years of age with 16-24 weeks of gestation and Hb 6-10 g/dl	Treated with two *Amaranthus viridis* capsules 500 mg thrice a day with lemon water Iron content: 61.58 mg/100 m of *Amaranthus*	Subjective and objective parameters were captured Subjective: Dourbalya, Aruchi, Arohanayasa, Angamarda, Hriddava, Shiroruja, Pandutva of netra, Rukshangata, Shotha, Alasya Objective: Hb, RBC count, Haematocrit, MCV, MCH, MCHC Loss to follow-up: Nil	Hb increased from 8.1±1.1 at baseline to 9.5±0.9 at endline Statistically significant improvement was observed in other objective parameters and subjective parameters Adverse event: None

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Title, author and year of publication	Type of study and duration of intervention	Sample size	Intervention	Assessment	Findings
Title: A Clinical Study on Iron Deficiency Anaemia with Bioiron[20] Author: Majeed *et al*. (2016)	Nonrandomized, open-label, clinical trial Study duration=63 days Study site: Male and female outpatients of age 18-55 years attending Life Care Hospital, Bangalore, India	*n*=30 Male and female aged 18-55 years, suffering from IDA	Self-administration of 900 mg tablets twice a day before food for 56 days Iron content: (Elemental iron in 900 mg tablet) BioIron: 8.5 mg; (iron from green gram) BioPerine: 2.5 mg (extract from black pepper)	Assessment: Screening, baseline, 14th, 28th, 56th day and 63rd day Food intake recorded in patient diaries provided at visit 1 Parameters: CBC, RBC indices, ESR, serum iron, TIBC and serum ferritin were evaluated Health assessment using SF-36 questionnaire and fatigue severity scale Loss to follow-up: Nil	Mean change in Hb: 11.45 g/dl (screening) to 12.45 (visit 5) (P<0.001) TIBC: 452.7 μg/dL (screening) to 437.3 μg/dL (visit 5) Slight increase in serum ferritin Mean change in SF-36 questionnaire: 52.23-59.12 Change in mean fatigue severity scale: 4.09 at screening to 3.02 at visit 5 Adverse event: None
Title: Sustainable Effect of Ayurvedic Formulations in the Treatment of Nutritional Anemia in Adolescent Students[24] Author: Prakash *et al*. (2010)	Single-blinded, randomized, controlled study Study duration in days=270 (treatment=90, Follow-up=180) Study site: school students from Government Girls Inter College, Rajpur Road, Government Inter College, Nathuvawala and Government Inter College, Maldevta, Gujarat	*n*=1646, both boys (*n*=319) and girls (*n*=1327) of 11-18 years of age with Hb 7-12 g/dl were included SR plus SC	*n*=1121 adolescent anemic students randomly divided into 5 groups Group I (control): Starch Group II: SR 125 mg+SC 500 mg daily Group III: SR 250 mg+SC 400 mg daily Group IV: SR 250 mg+SC 400 mg weekly Group V: IFA tablet daily Iron content: both are noniron containing formulations	Blood samples were drawn for Hb estimation on day 0, 30, 60, 90, 170 and 270 Loss to follow up Group I: 34 Group II: 35 Group III: 30 Group IV: 25 Group V: 31 Total: 155	Baseline Hb mean (SD) - 9.7±1.3 g/L Endline: the mean (SD) gain of Hb: (g/dL) Group I: 1.7±0.4 Group II: 2.3±0.4 Group III: 6.9±0.6 Group IV: 1.4±0.5 Group V: 3.6±0.5 The maximum Hb gain was noted in Group III. All groups - P<0.05 Adverse event: None
Title: Study to Evaluate Efficacy of Vajravatakmandura in Iron Deficiency Anemia[23] Author: Pareek *et al*. (2018)	Open label RCT Study duration: 8 weeks Study site: OPD/IPD of Kaumarabhritya, PG Department of National Institute of Ayurveda, Jaipur and from various schools situated in Jaipur	*n*=100 Adolescent girls of 12-15 years with Hb 8-12 g/dl were included Groups=2	Group A (*n*=50): Trial drug (Vajravatakmandura) 500 mg in 2 doses Vehicle: Buttermilk Group B (*n*=50): Control drug (IFA tablet) 100 mg elemental iron + 500 mcg folic acid Vehicle: Water Iron content: Not mentioned	Subjective parameters: Clinical features of anemia (modern and ayurveda parameters) Objective parameters: Hb%, CBC, PBS, Stool routine and microscopic.(before and after) Loss to follow-up: Nil	Drug was found effective over subjective parameters with percentage gain-weakness (Group A: 38.4%, Group B: 39.8%), palpitation (Group A: 37.8%, Group B: 39.3%), pallor (Group A: 36.8%, Group B: 39.2%) and loss of appetite (Group A: 36.9%, Group B: 38.1%) Objective parameters Mean (SD) increase in Hb: Group A: 1.0 (0.9), Group B: 1.1 (0.1) Similarly, other parameters also showed significant improvement except for RBC count in Group A. Adverse event: None
Title: A Clinical Study on Pandu Roga, Iron Deficiency Anemia, with Trikatrayadi Lauha Suspension in Children[18]	Randomized double-blind placebo-controlled clinical study	*n*=123 children in the age group of 1-16 years with Hb 6-11 g/dl	2 groups Group A: Trikatrayadi Lauha, 0.5 mg/kg body weight in two divided doses	Clinical assessment Vaivarnata (pallor) Daurbalyata (weakness) Shrama (fatigue) Aruchi (anorexia) Kopana or Adhirata (irritability), Shwasa (dyspnea)	Relief in pica Group A: 89.29% Group B: 61.54% Group A showed faster improvement in clinical features Statistically significant increase of hematologic values, such as blood Hb%, Total RBC, PCV, MCV. MCH, MCHC, etc., observed

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Title, author and year of publication	Type of study and duration of intervention	Sample size	Intervention	Assessment	Findings
Author: Kumar *et al*. (2012)	Study duration: 10 weeks Study site: Not mentioned clearly		Group B: Placebo drug Trikatrayadi Lunha: 1.049 mg elemental iron per milliliter of suspension	Hridayaspandana (palpitation), Shotha (edema) Laboratory Total RBC count, Hb, PCV, MCV, MCH, MCHC, PBS, ESR, serum iron level, TIBC, and serum ferritin	Mean increase of Hb ingroup A 1.94 g/dl in 5 weeks 3.33 g/dl in 10 weeks At the end of 10 weeks mean increase in Hb was 39.10%: Group A 3.33%: Group B Adverse event: None Lost to follow-up Group A: 6 Group B: 10
Title: Clinical Efficacy of Amalaki Rasayana in the Management of Pandu (Iron Deficiency Anemia)[19] Author: Layeeq *et al*. (2015)	Randomized controlled open clinical trial Study duration: 45 days Study site: IPD/OPD of Institute for Postgraduate Teaching and Research in Ayurveda Hospital, Jamnagar, India	*n*=25 patients (16-60 years) with Hb <12 g/dl (among females) and Hb <13 g/dl (among males) and serum iron <50 mg/dl with symptoms of Pandu were included Number of groups=2	Group A (*n*=14): 2 g of Amalaki Rasayana thrice a day with the unequal quantity of honey and ghee for 45 days Group B (*n*=11): 150 mg ferrous fumarate + 1500 mcg folic acid (standard control) once a day with water for 45 days Iron content: Noniron containing drug	Assessment: baseline and the end line at 75 days Subjective parameters: Panduta, Daurbalya, Shirahshoola, Shwasa, Hridspandan, etc. Objective parameters: Hb %, RBC count, HCT, MCV, MCH, MCHC, serum iron and TIBC Loss to follow-up: one in each group	Both groups showed significant improvement in subjective and objective parameters compared to respective baseline data There was no significant difference between Group A and Group B in the endline, except transferrin saturation which was better in Group B (P<0.05) Side effects: None
Title: A Clinical Study of Punarnava Mandura in the Management of Pandu Roga in Old Age (Geriatric Anemia)[22] Author: Pandya *et al*. (2014)	Before and after interventional study Study duration: 120 days Study site: OPD of Kayachikitsa, Institute for Postgraduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India	*n*=50 (50-80 years) Geriatric individuals with anemia (Hb: Men: 7-13 g/dl, women: 7-12 g/dl) were included	Patients given 2 tablets (250 mg each) of Punarnava Mandura twice a day after lunch and dinner with the Anupana of 100 ml of Takra (freshly prepared buttermilk) for 90 days Iron content: Not mentioned	Assessment: Before and 30 days after the intervention Subjective parameters: Signs and symptoms of Pandu Roga, Symptoms of Dhatu Kshaya, Scoring of health, wellness and QOL questionnaire, Assessment of Deha Bala, Agni Bala and Sattwa Bala Objective parameters: Hb%, serum iron and TIBC Loss to follow-up: 10 (due to personal reasons)	Significant decrease in most of the subjective parameters (P<0.001) There was no significant improvement in hematological parameters (P>0.05) Overall QOL improved from 37.40% to 45.45% Stress and life enjoyment relieved from 32.50% to 27.68% Adverse event: None
Title: Dhatrilauha: Right Choice for Iron Deficiency Anemia in Pregnancy[26] Author: Roy *et al*. (2014)	Quasi-experimental trial Study duration: 45 days Study site: OPD of Prasuti Tantra, Faculty of Ayurveda, Sir Sundarlal Hospital, IMS, BHU, Varanasi, Uttar Pradesh, India	*n*=58, Pregnant women in 4^{th}–7^{th} month of pregnancy, confirmed with a diagnosis of IDA Hb 7-10 g/dl were included	Dhatrilauha: 500 mg was given in two divided doses after food with normal potable water for 45 days (3 followups, each of 15 days intervals) Iron content: not mentioned	Assessment after 45 days Subjective parameters: weakness, fatigue, palpitation, effort intolerance, breathlessness, heartburn, pallor, and constipation were assessed Objective parameters: Hb, RBC, HCT, MCV, MCHC, RDW, RPV, serum iron, TIBC Loss to follow-up-Nil	Statistically significant improvement (P<0.001) in signs and symptoms was found (weakness, fatigue, palpitation, effort intolerance, breathlessness, swelling feet, heartburn, pallor, and constipation) Increase in Hb by 1.13 g/dl (P<0.001) Significant improvement in all hematological parameters including serum ferritin Adverse event: None
Title: Clinical efficacy and Safety of Punarnavadi	Prospective open-label multicenter trial	*n*=103 adults aged 15-60 years of either sex	Punarnavadi mandura: 2 tablets of 250 mg given twice daily with water and	Assessment: Baseline and at 84th day	Hb increased from 9.29 g/dl to 9.40 g/dl (P>0.05) Serum iron from 41.13 μg/dl to 50.02 μg/dl (P=0.005),

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Title, author and year of publication	Type of study and duration of intervention	Sample size	Intervention	Assessment	Findings
Mandura and Dadimadi Ghrita in the Management of Iron Deficiency Anemia: A Prospective Open-Label Multicenter Study[28] Author: Sannd *et al*. (2017)	Study duration: 84 days Study site: 3 peripheral centers of the Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH	Hb: 8-11 g %	Dadimadi ghrita: 10 g twice daily before food with lukewarm water Punarnavadi Mandura: is an iron preparation (iron content not mentioned) Dadimadi Ghrita responsible for Agni deepan and thus increases the absorption of Punarnavadi Mandura	Primary outcome measure-Hb Secondary outcome measure-Ferritin level and various symptoms like weakness, fatigue, irritability etc., (baseline to 84th day) Loss to follow-up: 13	similarly serum ferritin also showed a significant increase Significant decrease in percentage complaints (weakness, fatigue, and headache) of common symptoms of IDA Adverse event: None, no elevation of renal or liver parameters
Title: Clinical Efficacy of Punarnava Mandura and Dhatri Lauha in the Management of Garbhini Pandu (Anemia in Pregnancy)[16] Author: Khandelwal *et al*.(2015)	Comparative clinical trial Study duration: 90 days Study site: OPD of Stree Roga and Prasooti Tantra of Institute for Postgraduate Teaching and Research in Ayurveda (IPGT and RA) Hospital, Jamnagar	*n*=24 PW aged 18-40 years with clinical signs and symptoms of Garbhini Pandu, in 2nd or 3rd trimester of pregnancy with 6-10 g/dl of Hb and microcytic hypochromic RBC in peripheral smear	Group A (*n*=15): Punarnava Mandura, 2 tablets (each of 500 mg) thrice a day with 100 ml of buttermilk Group B (*n*=9): Dhatri Lauha, 2 tablets (each of 500 mg) thrice a day with lukewarm water was administered for 90 days Iron content- not mentioned	Assessment: subjective parameters such as pallor, general weakness, dyspnea, etc., and objective parameters such as haematological parameters Time: Baseline and 90 days after of intervention	Subjective parameters: Group A statistically significant (P<0.05) difference than B on relieving Aruchi and Pindikodweshtana Rest of other symptoms-both groups are equally effective Objective parameters: On comparing Group A and B, statistically significant (P<0.05) difference in Hb%, MCV, MCH, and MCHC Group A is better than Group B in relieving above parameters However, none of the patients showed complete remission or marked improvement in any of the groups Moderate improvement Group A: 46.67% Group B 44.44% No improvement Group A: 13.33% Group B: 22.22% Adverse event: None
Title: A Comparative Study on the Effect of Pandughnivati and Dhatrilauhavati in the management of Garbhinipandu (Iron Deficiency Anemia)[27] Author: Rupapara *et al*. (2013)	Comparative clinical trail Study duration: 90 days Study site: Patients attending the OPD of Streeroga and Prasootitantra, Gujrat	PW in 2 or 3 trimester with Hb% 6.5-10 g % and microcytic hypochromic appearance of red blood cell in peripheral smear	Group A: 2 tablets of Pandughnivati (500 mg) tds, before the meal with luke warm water for 90 days (*n*=12) Group B: 1 tablet of Dhatrilauhavati (500 mg) tds, before the meal with luke warm water for 90 days (*n*=10) Iron content: Dhatrilauhavati: iron containing drug, content not mentioned Pandughnivati: noniron containing drug	Assessment: subjective parameters such as pallor, general weakness, dyspnea, etc., and objective parameters such as hematological parameters Time: Baseline and after of intervention	There was a significant improvement in subjective parameters in both the groups No improvement in objective parameters Group A: 83.33% and in Group B 90% patients remained unchanged in terms of objective parameter Adverse event: None
Title: Efficacy of Trikatrayadi Lauha in Panduroga with Reference to Iron Deficiency Anemia[17]	Comparative clinical trail Study duration: 60 days	*n*=56 IDA patients of both sexes aged 16-70 years with Hb 6-12 g/dl	Group-A (*n*=34) Trikatrayadi lauha, 250 mg. Q. I. D. in the form of Vati, before and after lunch and dinner with water	Assessment Subjective and objective parameters	Subjective parameters: Both drugs showed significant effect on all subjective parameters

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Title, author and year of publication	Type of study and duration of intervention	Sample size	Intervention	Assessment	Findings
Author: Khan *et al*. (2012)	Study site: OPD and IPD of Hospital at IPGT and RA, GAU, Jamnagar, Gujarat		Group-C: (*n*=22) Fersolate-CM, 1 tablet TID. before meal with water, allopathic drug	Time: Baseline and after of intervention	Objective parameters Trikatrayadi Lauha provided significant results on Hb g %, RBC, PCV, MCV, serum iron, percent transferrin saturation and TIBC Fersolate-CM provided significant results on Hb g %, RBC, PCV, MCV, MCH, serum iron, percent transferrin saturation and TIBC Adverse event Fersolate-CM-nausea, salivation, sour belching (hyper acidity), epigastric pain, flatulence, uneasiness, pain abdomen, liquid stool (diarrhoea), vomiting, loss of appetite and constipation Trikatrayadi Lauha: None

OPD: Out-patient department, PW: Pregnant women, IDA: Iron deficiency anemia, IPD: In -patient department, Hb: Hemoglobin, RBC: Red blood cells, PCV: Packed cell volume, MCH: Mean corpuscular hemoglobin, MCHC: MCH concentration, MCV: Mean corpuscular volume, PS: Percent saturation, IFA: Iron and folic acid, SJHL: Sarva-Juara-Hara Lauha, SR: Sootshekhar Rasa, SC: Sitopaladi Churna, SF: Short form, QOL: Quality of life, HCT: Hematocrit, RDW: RBC distribution width, RPV: Rat parvovirus, SD: Standard deviation, TIBC: total iron-binding capacity, AYUSH: Ayurveda, Unani, Siddha, and Homeopathy

Hriddava (palpitation), Shiroruja (headache), Pandutva of netra (pallor), Rukshangata (dryness), Shotha (oedema) and Alasya (lassitude).

Effect on hematological parameters

All studies have assessed the effect of Ayurvedic drugs on hemoglobin concentration and reported an increase in hemoglobin level after the intervention. However, increase in hemoglobin was not statistically significant in four studies.[19,22,27,28] Sharma *et al.* reported a maximum increase by *Sarva-juara-hara-lauha,* which contained 145.5 mg elemental iron and was administered with honey as a vehicle for 30 days. Increase in hemoglobin from 7.3 ± 1.9 to 12.1 ± 1.6 g/dL was observed in this drug.[29] Other significant improvement in hemoglobin concentration was observed in *Kasisa Bhasma* (1.88 g/dL) and *Dhatri Avaleha* (1.2 g/dL).[31]

Effect on other hematological and biochemical parameters

Other parameters such as serum iron, serum ferritin, TIBC, MCH, MCHC, and MCV were assessed in 12 studies and nine of them have reported significant improvement in the haematological and biochemical parameters.

Effect on subjective parameters

Subjective parameters of anemia such as Dourbalya (weakness), Aruchi (anorexia), Arohanayasa (exertional dyspnoea), Angamarda (fatigue), Hriddava (palpitation), Shiroruja (headache), Pandutva of netra (pallor), Rukshangata (dryness), Shotha (edema), and Alasya (lassitude) were assessed in eleven out of 15 studies included in the review. The objective parameters were also assessed in those studies. Of the eight studies, six reported significant improvement in both objective and subjective parameters, while five studies reported statistically significant improvement only in subjective parameters after the intervention. Eight studies attempted to assess the effect of therapy on signs and symptoms of anemia on a Likert scale in which the severity was ranged from one to four.[16-19,22,23,26,27,30]

Adverse effect

Eleven studies have reported the details on observation of any adverse event following Ayurvedic drug administration. No adverse event was observed during the study period in those studies. The studies have reported mild to moderate gastrointestinal adverse effect for the allopathic oral IFA tablets in the comparative group.

DISCUSSION

In total, 15 studies were included in this review to assess the effectiveness of Ayurvedic preparations on the management of iron deficiency anemia. The studies included both randomized and non-RCTs conducted across various age groups with different ayurvedic preparations and dose, with varied effects on anemia. Both iron-containing and

noniron containing Ayurvedic preparations were assessed in the studies. The effect of Ayurvedic drug compared to oral IFA tablets varied across the studies. Significant improvement in subjective parameters of anemia was reported in all the studies and more than one-third of the studies reported improvement in hematological parameters of anemia. Although four studies had reported significant improvement in subjective parameters, there was no improvement in hematological or biochemical parameters. None of the studies of reported serious adverse effect following administration of Ayurvedic preparations.

A literature review conducted by Prajapati and Acharya found that there are around 176 Ayurvedic formulations with 37 different dosage forms are available for management of anemia (Pandu).[12] Around 17 Ayurvedic preparations with different dosage have been used in the studies included in the current review. The mode of action of Ayurvedic preparations and their components were mentioned in all the 15 studies. However, few studies which included iron-containing Ayurvedic preparations have not mentioned the iron content explicitly. Studies have mentioned that the vehicle which is administered along with the Ayurvedic preparation has substantial role on the effect of the drug. However, the effect of vehicle has not been explored in any of the studies. Samal J had conducted a similar review on Ayurvedic preparations on the management of anemia, included studies published till 2014.[32] The newer studies included in the current review has relatively shorter intervention period (30–90 days) and tried to compare the effectiveness of iron-containing and noniron-containing iron preparations with oral IFA tablets. Ayurvedic drugs were found to have similar effects as IFA tablets with less side effects.

Ayurvedic preparations such as Kasīsa bhasma, Navayasa Curna, Punarnavadi Mandura, Dhatri Lauha, Pradarantaka, Lauha, Sarva-Juara-Hara Lauha, Vrihat Yakrdari Lauha, Sootshekhar Rasaootshekhar plus Sitopaladi Churna, *Amaranthus viridis*, BioIron, Vajravatakmandura, Trikatrayadi Lauha, and Amalaki Rasayana reported significant improvement in hematological parameters compared to the baseline values or control group. The noniron containing Ayurvedic preparation Dhātrī avaleha, also showed significant improvement in hematological parameters after the intervention. However, Punarnava Mandura, Pandughnivati, and Dhatrilauhavati, which are iron-containing Ayurvedic preparations have not shown significant improvement in hematological parameters. Punarnava Mandura, an Ayurvedic preparation which is included in ASHA's drug kit under National Health Mission, showed significant improvement in hematogical parameters in two studies[16,29] but failed to show such effect in two other studies.[22,28] The difference in study population, duration of intervention and dosage of the Ayurvedic preparation could be the reason for such variation. The studies without significant improvement in hematological parameters provided only half of the dose of Ayurvedic drugs, compared to the studies with significant improvement. The duration of dosage was either same or more and included geriatric patients in the previous one. The subjective symptoms of anemia improved in all the studies, though there no improvement in hematological parameters in a few studies. This difference could be due to multiple facts such as nonblinding, social desirability bias and the detection bias in the trials.

The studies included different age group population such as children, adults, pregnant women and also geriatric population. The Ayurvedic preparations were found to be palatable among children and also had components with laxative effect to relieve constipation among the elderly. The most common and undesirable adverse event, gastrointestinal disturbance associated with oral IFA intake was not reported in any of the Ayurvedic preparations. Indeed, none of the studies have reported any adverse event. However, few case studies have reported lead toxicity associated with Ayurvedic preparations used for the management of fertility, low back pain, arthritis, and diabetes from various parts of the world.[12,33,34] None of the studies included in this review mentioned about monitoring for heavy metal poisoning. Exploring the risk of heavy metal poisoning and standardization of Ayurvedic preparations is very crucial to include this traditional system of medicine in routine care for the management of anemia. Further research on Ayurvedic preparations in the management of anemia from community-based studies are also required. Furthermore, the role of the vehicle with different Ayurvedic preparations and cost-effectiveness compared to oral IFA should also be explored.

Findings of this review have few important public health implications. The Ayurvedic system of medicine is followed by more than one-third of the rural population in India and also gaining popularity in urban areas. Research evidence suggests that Ayurvedic preparation can improve the hemoglobin level and other hematological parameters of anemia across various age groups, including pregnant women and children. Therefore, Ayurvedic preparations could be effective in reducing the burden of anemia in India, where medical pluralistic culture is prevalent. However, public health policy measures are required to implement, regularize and monitor the Ayurvedic preparations for control of anemia.

The review has a few limitations. All the studies included in this review were from India. Hence the study results cannot be generalizable to other high or low- and middle-income countries. However, the traditional systems of medicines are indigenous to each country; therefore, nongeneralizability to other countries need not to be taken with serious concern. Second, all the studies have been conducted in controlled settings such as Ayurvedic health facilities or other facilities such as schools and colleges, where the acceptance and adherence to the prescribed medications could be different from the general population. The results have to be interpreted with caution because of the limited sample size, study site, design, and the bias associated with the studies.

CONCLUSION

This review concludes that the administration of ayurvedic drugs could be an effective approach for prevention and management of anemia in various age groups. Major advantage with ayurvedic formulations is that they are considered to be safe and do not result in any adverse reactions. They can be incorporated and promoted at all levels of health care along with the allopathic drugs for control of anemia. However, larger multicentric studies are required to assess and prove the exact potential of these drugs.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Inventory management of drugs at a secondary level health-care center in Odisha

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Abstract

Introduction: Planning the recurring purchases in the pharmacy results in efficient functioning of a health-care facility. Limited studies have explored the inventory management at secondary-care settings. The objective of this study was to analyze the annual drug expenditure of Community Health Centre (CHC), Tangi during the year 2017-2018.

Material and Methods: The annual procurement of, and expenditure incurred on drugs for financial year 2017-2018 drugs was analyzed at the secondary level CHC always, better, control (ABC) analysis, vital, essential, desirable (VED) analysis and combination matrix of ABC-VED which are inventory management techniques based on expenditure, criticality, and combination of both.

Results: Total expenditure for the year 2017–2018 on 232 drugs was 4,606,487 rupees. According to ABC analysis, Category A, B and C constituted 8.6%, 19.4%, and 72% accounting for 70%, 20%, and 10% of the total expenditure. VED analysis showed 21%, 66%, 13% items as Vital, Essential, and Desirable, accounting for 14%, 67%, and 19% of annual expenditure. On ABC-VED matrix analysis, 24.1%, 66.8%, and 9.1% drugs were found to be Category A, B and C, accounting for 74.7%, 24.6%, and 0.7% of annual expenditure.

Conclusion: ABC-VED matrix analysis can be used for effective management of inventory at a secondary level healthcare centre.

Keywords: Annual expenditure, consumables, drug distribution, supply management, stocking cost

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INTRODUCTION

Pharmacy stores are very essential supportive service of any hospital.[1] The pharmacy is one of the most extensively used therapeutic facilities of the hospital and one of the few areas where a large amount of money is spent on purchases on a recurring basis.[2] In a study, it was revealed that about one-third of the annual hospital budget is spent on buying material and supplies, including medicines.[3] There is need for planning, designing and organizing the pharmacy in a manner that results in efficient clinical and administrative services.[4] The goal of the hospital supply system is to ensure that there is adequate stock of the required items.[5] An inventory is a detailed itemized list of assets held by an organization or institution. The

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inventory can provide financial information to support economic and budget assessments. Inventory management is a method of maintaining stock of items at a level of lowest purchasing and stocking costs without interference with supply.[6] Inventory management helps in designing appropriate corrective measures so that an uninterrupted supply of such items is maintained. This is of particular importance in resource constraint settings like India where resources are limited, and existing resources must be utilized appropriately.[7]

There are various methods for inventory management. These are Eyeballing technique, Double shelf method or A/B method, Modern techniques: always, better, control (ABC), vital, essential, desirable (VED), fast-moving, slow-moving, nonmoving, scarce, difficult, easy, high, medium, low and season-off-season.[8]

The commonly used techniques are ABC analysis, VED analysis, and ABC-VED matrix analysis. ABC analysis, also known as "Always Better Control," is an important tool used to identify items that need greater attention for control. According to it, 10% items account for 70% of budget (Category A). Next 20% account for 20% of the budget (Category B) and the remaining 70% account for just 10% of the budget (Category C).[9] The limitation of ABC analysis is that it is based only on monetary value and cost of consumption of items. Some items of low monetary value are vital or life-saving. Their importance cannot be overlooked simply because they are not in Category A.

Therefore an additional parameter of assessment is their criticality by doing a VED analysis. "V" is for vital items without which a hospital cannot function "E" for essential items without which a hospital can function but may affect the quality of the services and "D" stands for desirable items, unavailability of which will not interfere with functioning. VED analysis cannot be considered alone as some of the desirable drugs despite being costly could get included as a priority drug. To overcome the limitations of ABC analysis and VED analysis an ABC-VED matrix is prepared, and drugs are categorized as Category A, B, and C [Figure 1].

MATERIAL AND METHODS

Study site

The study was conducted at Community Health Centre (CHC) in Tangi Block of Khordha district which serves a population of approximately 169,000. CHC, Tangi Block is the field practice area of All India Institute of Medical Sciences, Bhubaneswar [Figure 2].

It has a store pharmacy and a Drug Distribution Centre. Drugs and consumables from the store Pharmacy are distributed to different PHCs and Sub-Centers. Drugs from Drug Distribution Centre are dispensed to out-patients and in-patients.

Drugs and consumables are procured on a yearly basis at the CHC and supplied by the Odisha State Medical Corporation Limited yearly to the CHC.

Methodology

All the oral and parenteral drugs along with the consumables procured during the financial year 2017-2018 were included for the analysis. Details of methodolgy are shown in Figure 3.

RESULTS

Total expenditure for the year 2017-2018 was 46,06,487. Total of 232 consumables were analyzed. According to ABC analysis there were a total of 20 drugs in Category A, 45 in Category B, and 167 in Category C. Thus, 8.6% of the items cost 70% of the expenditure, while 72% of the items cost only 10% of the expenditure [Table 1]. According to VED analysis, 48 drugs were classified as Category "V," 153 as Category "E" and 31 as Category "D." Around 14% of budget was spent on Category V, 67% on Category E and 19% on Category D drugs [Table 2]. In ABC-VED matrix analysis, around 24.1% of drugs were in Category A, 66.8% in Category B, and 9.1% in Category C. The expenditure in Category A, B, and C were 74.7%, 24.6%, and 0.7% of total expenditure, respectively [Table 3].

DISCUSSION

The total cost incurred for procurement of drugs at CHC, Tangi was Rupees 4,606,487 for the financial year 2017-18.

Table 1: Always, Better, Control analysis of showing cost incurred by different category of items

Category	Total number (%)	Total cost in rupees (%)
A	20 (8.6)	32,44,487 (70)
B	45 (19.4)	9,43,417 (20)
C	167 (72)	4,18,882 (10)
Total	232 (100)	46,06,487 (100)

A: Always, B: Better, C: Control

Table 2: Vital, Essential, Desirable analysis of showing cost incurred by different category of items

Category	Total number (%)	Total cost in rupees (%)
V	48 (21)	6,93,499 (14)
E	153 (66)	33,06,350 (67)
D	31 (13)	9,46,866 (19)
Total	232 (100)	46,06,487 (100)

V: Vital, E: Essential, D: Desirable

Figure 1: Always, better, control-analysis, vital, essential, desirable matrix analysis showing different categories

ABC/VED	A	B	C
V			
E			
D			

Category A	Needs close monitoring and control
Category B	Moderate control
Category C	Minimal degree of control

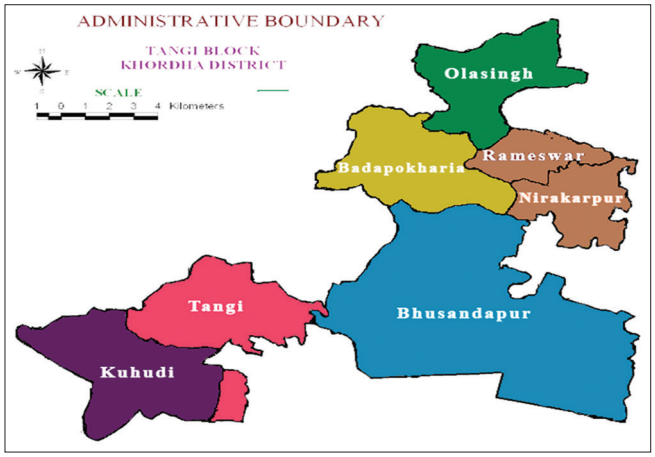

Figure 2: Map of Tangi block showing different sectors

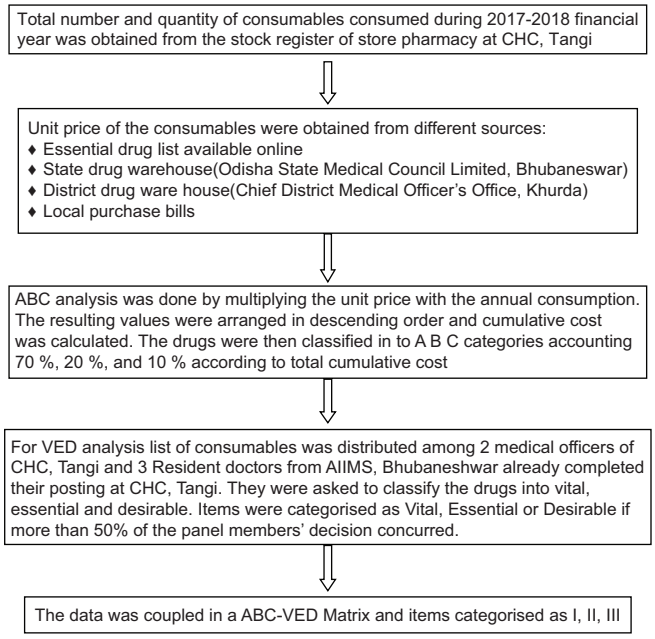

Figure 3: Methodology flow diagram

This study shows that out of 232 items, 20 (8.6%) items consume 70% (Group A) of the total budget, 45 (19.4%) consume 20% of total budget (Group B) and the rest 167 (72%) drugs consume just 10% of the total budget (Group C) Table 1. In our study, 48 (21%) were categorized as Vital, 153 (66%) as Essential and 31 (13%) as Desirable Table 2. On ABC-VED matrix analysis [Table 4], 24.1%

Table 3: Costs incurred by different categories of items in Always, Better, Control -Vital, Essential, Desirable analysis

Category	Total number (%)	Total cost in rupees (%)
I	56 (24.1)	34,39,200 (74.7)
II	155 (66.8)	11,31,805 (24.6)
III	21 (9.1)	35,779 (0.7)

Table 4: Always, Better, Control - Vital, Essential, Desirable analysis matrix showing the total number of items in each category

VED/ABC	A	B	C	Total
V	4	3	33	40
E	14	37	113	164
D	2	5	21	28
Total	20	45	167	232

VED: Vital, Essential, Desirable, ABC: Always, Better, Control

of the items were in Category A, 66.8% in Category B, and 9.1% in Category C [Table 3].

In a tertiary care teaching hospital, study conducted by Wandalkar *et al.* showed that the total Annual Drug Expenditure (ADE) was Rs. 6, 98, 74, 457. It is more compared to our study which was done at a secondary level care institution. By ABC analysis, it was found that 13.4%, 16.5% and 70.1% items belonged to A, B and C Category respectively, accounting for 69.1%, 19.2%, and 11.7% of ADE which is similar to our findings. VED analysis showed that 50.9%, 40.2% and 8.9% were V, E, and D Category items, respectively, accounting for 55.2%, 41.5% and 3.3% of ADE. By ABC-VED matrix analysis, 57%, 35%, and 8% were found to be Category A, B, and C items, respectively, accounting for 85.3%, 14.2%, and 0.5% of ADE.[6]

Another study conducted in a tertiary care teaching hospital by Gupta *et al.* the total cost of drugs used was Rupees 5,523,503. Of these 325 drugs, 47 (14.4%) drugs were Category A consuming 70% of total expenditure, 73 (22.46%) drugs Category B consuming 20% and rest 205 drugs (63.7%) Category C drugs cost only 10% of expenditure, which is almost similar to the ABC management of inventory. VED categorization done by consensus opinion of medical officers, found 24 (7.3%) drugs vital, 160 (49.3%) essential and rest 141 (43.3%) desirable. On coupling the two techniques ABC-VED matrix was made and drugs were classified in to Category A (AV + BV + CV + AE + AD) comprising 68 drugs, Category B (BE + CE + BD) 159 and Category C (CD) 98 drugs, being the essential list of drug highest is comparable to our study.[8]

Similarly, another study at tertiary care teaching hospital, PGI conducted by Singh *et al.*, the total ADE on items

issued in 2008–2009 and 2009–2010 was Rs 6.04 crores and Rs 4.84 crores, respectively, which is much higher as it is one of the apex institutions of India. ABC analysis of pharmacy store for the year 2008–2009 revealed 11.23%, 24.60%, and 75.4% items as A, B, and C Category items, respectively, accounting for 70.19%, 19.83% and 9.98% of ADE of the pharmacy. It is almost as per the ABC matrix of inventory. VED analysis showed 12.30%, 61.5%, and 26.2% items as V, E, and D Category items, respectively, accounting for 19.56%, 71.12%, and 9.33% of ADE of the pharmacy. However, ABC analysis of pharmacy store for the year 2009-10 revealed 11.08%, 22.16% and 66.75% items as A, B, and C Category items, respectively, accounting for 70.04%, 19.93%, and 10.02% of ADE of the pharmacy. VED analysis showed 12.40%, 60.16%, and 27.44% items as V, E, and D Category items, respectively, accounting for 25.05%, 66.91% and 8.04% of ADE of the pharmacy.[2]

In a study conducted in a secondary health-care center by Kant *et al*., the total annual expenditure on 182 drugs was Rs 6,495,785 amounting to 21% of hospital budget for the financial year 2013-2014. It is much higher than our study as it is a secondary care institute attached to AIIMS New Delhi. ABC analysis revealed 10.4%, 19.8%, and 69.8% drugs as A, B, and C Category, respectively, accounting for 69.7%, 21.2% and 9.1% of annual expenditure which is as per the ABC system of inventory management. VED analysis showed 31.9%, 53.3% and 14.8% items as V, E, and D Category, respectively, accounting for 12.1%, 84.5% and 3.4% of annual expenditure. The results are very much comparable to our study. On ABC-VED matrix analysis, 40.6%, 46.7%, and 12.7% drugs were found to be Category A, B, and C, respectively, accounting for 77%, 21.8%, and 1.2% of annual expenditure.[4]

CONCLUSION

Category A drugs were only 8.6%. Hence, supervision of those 20 drugs would result in control of over 70% of the drug budget. In VED analysis 32% of drugs were categorized as vital and 13% as Desirable. In a resource constraint setting it is necessary that most of the budget was spent on the "vital" and "essential" category of the drugs rather than the "desirable" category. As only 0.7% of the drug budget was spent on Category C drugs, it can be said that inventory management practice was appropriate. To bring about substantial savings without affecting patient care, rational use of drugs along with restriction on nonessential drugs (Category C) and imposition of fixed budget to this category is expected.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

External rapid convenience monitoring of measles–rubella campaign 2017 and lessons learned: Study from a hilly district of North India

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Abstract

Introduction: The most recent vaccine incorporated in the Universal Immunization Program of India is measles-rubella vaccine, introduced as a catch-up campaign to eliminate measles and control rubella by the year 2020. The success of any immunization campaign lies on its meticulous planning for areas such as trainings, cold chain management, advocacy, and social mobilizations. Rapid convenience monitoring (RCM) was done in nine health blocks of a hilly district of Himachal Pradesh, pertaining to various campaign activities, for determining vaccine coverage and side effects.

Material and Methods: Standardized formats developed by the World Health Organization for RCM of the quality of activity at session sites which included information regarding vaccinating teams, immunization sites, logistics used, cold chain and aseptic condition management, waste disposal, and record maintenance were used. School and house-to-house visits were conducted randomly to check the indelible ink mark/vaccination cards to find out any missed child.

Results: A total of 107 immunization sessions were observed for compliance. We assessed 1182 children between the age group of 9 months and 15 years for determining vaccine coverage during the measles–rubella campaign in September–October 2017. Compliance to various aspects of the campaign was found very good, exceeding 90% in almost all the domains. The total vaccination coverage was 98.1%. Schools and health-care providers were the major source of information for this campaign. No severe adverse events following immunization were reported during the survey.

Conclusion: Activity compliance and vaccination coverage were found high. Adequate supply of indelible ink pens and functional hub cutters needs to be ensured. There should be revision of incentives to team members with increased involvement of accredited social health activist workers in such campaigns.

Keywords: Measles–rubella campaign, measles–rubella vaccine, rapid convenience monitoring, vaccination coverage

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INTRODUCTION

The most recent addition to the India's Universal Immunization Program is the combined measles–rubella (MR) vaccine introduced as a catch-up campaign.[1] Compared to the routine immunization (RI), such campaigns have many technical and operational issues. The major challenges faced are a huge target group to vaccinate, requirement of a large pool of trained vaccinators, and giving an injectable vaccine in schools and outreach sessions.[2] During the previous rounds of MR campaign in other states, it was found that training of health workers, the timing of campaign, inadequate social mobilizers and vaccinators, inadequate and incomplete micro-planning, and overall human resource and logistic constraints were the limiting factors.[3,4]

Therefore, the success of any immunization campaign lies on its meticulous planning such as trainings, logistics, cold chain management, advocacy, and social mobilizations. Monitoring of these activities during the campaign by internal and external observers is essential to identify any constraints that are likely to affect the implementation of the program. Their feedbacks provide valuable inputs and solutions to remove any bottlenecks and provide future recommendations.[2-5]

Himachal Pradesh along with seven other states conducted this MR campaign from August to October 2017.[6] At the request of the World Health Organization (WHO) state surveillance office, external monitoring of this campaign was done by the Department of Community Medicine, Indira Gandhi Medical College, Shimla. The process of external monitoring itself provides an opportunity to assess as well as support in the field. Hence, accordingly, we planned this study to assess the immunization sessions and determine the vaccine coverage. We also wanted to identify and disseminate the barriers, and give suggestions to help in better vaccination coverage in the subsequent phase as well as in other campaigns.

MATERIAL AND METHODS

MR campaign was conducted in Himachal Pradesh for 5 weeks with effect from August 30, 2017 to October 3, 2017. Three specialists from the community medicine department were deputed for monitoring of immunization sessions and assess coverage of the campaign. The checklist used was standardized formats developed by the WHO for rapid convenience monitoring (RCM) of the quality of activity in an area.[4] External monitors were briefed about the methodology of monitoring (RCM) by the WHO surveillance medical officer before the start of the campaign. The checklist included information regarding vaccinating teams, immunization sites, logistics used, cold chain and aseptic condition management, waste disposal, and record maintenance. Prior approval for conducting the study was taken from the institutional ethics committee of Indira Gandhi Medical College, Shimla. Informed consent/assent was taken from all the participants, and confidentiality of all the participants was ensured. We conformed to all the ethical guidelines as per the Helsinki declaration.

All the nine health blocks of Shimla district were visited by the external monitors. There were an estimated 189,030 children (between 9 months and 15 years of age) eligible for vaccination in Shimla district. A total of 1752 sessions were planned which included 1135 schools, 480 outreach, 113 fixed, and 24 high-risk areas. Mobilization of children was ensured through information, education, and communication activities via mass media. Awareness messages were relayed through radio, television, local cable networks, newspapers, posters, banners, and miking at periodic intervals. Community-level workers such as accredited social health activists (ASHA), anganwadis, auxiliary nurse midwives, and school staff were also looped in for delivering sensitization talks in the schools. Data collection was done concurrently to the immunization campaign. The RCM coincided with the immunization sessions in schools and outreach sites.

During the first 2 weeks, RCM was done in schools, followed by monitoring of outreach sessions in the next week, and house-to-house visits were conducted in the last 2 weeks. In schools, the children were assessed by physical verification for presence of the indelible ink mark. A child was considered unvaccinated if the mark was absent. During household visits on regular school days, their vaccination status was assessed indirectly through the inspection of vaccination cards. Both the school/outreach site and household survey was conducted in different geographical areas to prevent overlapping or duplication of effort. The number of children covered and left out was noted. Due to logistic and managerial issues, it was very difficult to conduct repeat school or outreach sessions, so the parents of left-out children were requested to take their children to the nearest fixed site/hospital for vaccination. There was a maximum gap of 1 week between vaccination and assessment of vaccination coverage in the field or schools.

The schoolchildren and teachers/principals were also asked about the feedback or constructive suggestions, in case a

similar activity has to be undertaken in the near future. Regarding house-to-house visits, the standard methodology of selecting the households, that is, going to the center of the village, rotating a pen, and then starting from the first house which the pen tip pointed, was followed. The house visits were done till we managed to cover twenty children in each village in rural areas, or a ward in urban areas. The members of the family were also asked about the sources of information about the campaign and the side effects encountered after vaccination.

The aforesaid methodology ensured assessment of quality and completeness of vaccine coverage. Prompt remedial action was taken for any deficiency or deviation observed. Onsite supportive supervision and hand holding of the vaccinating teams was done. The various problems such as technique of vaccination, requirement of additional teams for sudden unexpected rush of children, malfunctioning hub cutters, shortage of insulin syringes, and some teams not using the full volume of diluent for reconstitution of vials were identified during the course of monitoring and were rectified or handled appropriately.

The checklist used for RCM has eight specific domains, and each domain is represented by multiple items (44 items in all).[4] Out of the eight domains, we have left out the first and seventh, that is general information and the school-specific domain. Hence, we have presented the data of six domains which were assessed for compliance at the immunization sessions [Table 1].

Activity compliance, vaccine coverage, and side effects were expressed in frequency proportion tables. Regular inputs and feedbacks were collected by the external monitors throughout the campaign and these inputs have been categorized according to various activity domains.

RESULTS

A total of 107 different immunization sessions were monitored for compliance during the campaign. Compliance regarding different domains was in excess of 90% except for injection practices which were found adequate at 88.8% of the session sites observed. Compliance for safe injection practice during the campaign was only 70% at health facilities [Table 2].

A total of 1882 children (1162 at school and 720 at household level) were assessed for vaccine coverage. All children in the schools were assessed by physical verification; while out of 720 at the household level, 308 were assessed through physical verification and rest through vaccine card, 35 children were found unvaccinated during the survey, accounting for the overall vaccine coverage of 98.14% [Table 3].

Schools (77%) and health-care providers (72%) were the major source of information regarding MR campaign. Mass media approach such as television/radio/miking (18%) and newspaper/poster/banner (22%) were the source of information in limited population [Figure 1].

Sickness during the period of MR campaign was mentioned as the most common reason (15/35) for noncompliance among the unvaccinated children. Nine unvaccinated children provided family refusal as the reason for noncompliance. Seven children avoided vaccination because of the fear of side effect of the vaccine [Figure 2].

Mild pain was reported by 12% of the children, while 2% had swelling at the site of injection. A few others reported excessive crying (4%), headache (4%), pain abdomen (2%), and fainting (2%) [Figure 3].

Feedbacks collected during the campaign are summarized in Table 4. Although it was generally positive except for few incidences of programmatic error and complacency at certain session sites, we have laid stress on the negative points so that it may help program managers and planners to avoid such obstacles and take care of these things in future.

Table 1: Checklist used for rapid convenience monitoring (RCM)

Domains	Compliance (national operational guidelines)
Adequate workforce	Adequate team (vaccinator and mobilizers) assigned as per the no. of beneficiaries present at the session site
Vaccine and logistics	Adequate vaccine vials, AD syringes, reconstitution syringes, hub cutters, and indelible ink marker as per beneficiaries were present.
Cold chain	Alternate vaccine delivery system, proper transportation and storage of diluents and vaccine, no vial in unusable stage in the vaccine carrier
Injection practices	One vial constituted at a time by using the whole of diluents, time of constitution noted on the vial and kept in a well of ice pack, vaccinator following aseptic measure and right technique of vaccination, not recapping the needle, and syringe being cut by hub cutter and disposed
AEFI management	AEFI management kit and referral site present and vaccinators have the knowledge of various guidelines for its use
Mobilization	Visible banners present, house visits done by mobilization team

AD: Auto disable, AEFI: Adverse events following immunization

Table 2: Compliance to various aspects of vaccination during the measles- rubella campaign

Compliance	Locality		Type of session site		Overall compliance (cumulative sites: 107), *n* (%)
	Rural (total sites observed: 85), *n* (%)	Urban (total sites observed: 22), *n* (%)	School (total sites observed: 97), *n* (%)	Health facility (total sites observed: 10), *n* (%)	
Domains					
Adequate workforce	81 (95.3)	22 (100)	94 (96.9)	9 (90)	103 (96.3)
Vaccine and logistics	79 (92.9)	21(95.4)	92 (94.8)	9 (90)	100 (93.4)
Cold chain	78 (91.8)	21(95.4)	91(93.8)	8 (80)	99 (92.5)
Injection practices	75 (88.2)	20 (90.9)	86 (88.6)	7 (70)	95 (88.8)
AEFI management	77 (90.6)	20 (90.9)	89 (91.7)	8 (80)	97 (90.6)
Mobilization	77 (90.6)	20 (90.9)	88 (90.7)	9 (90)	97 (90.6)

AEFI: Adverse events following immunization

Table 3: Vaccination status of children surveyed for assessing coverage

	Total children observed	Number of vaccinated children	Number of unvaccinated children	Percentage coverage
School survey	1162	1134	28	97.59
Household survey	720	713	7	99.02
Total	1882	1847	35	98.14

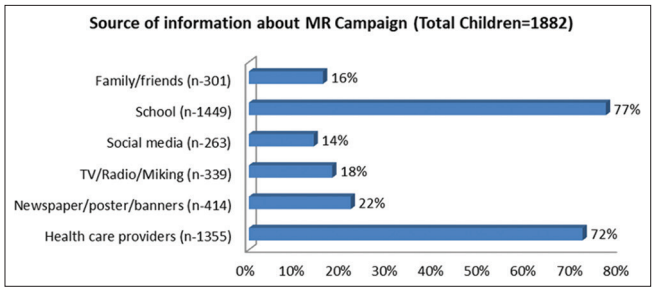

Figure 1: Source of information about the measles–rubella campaign

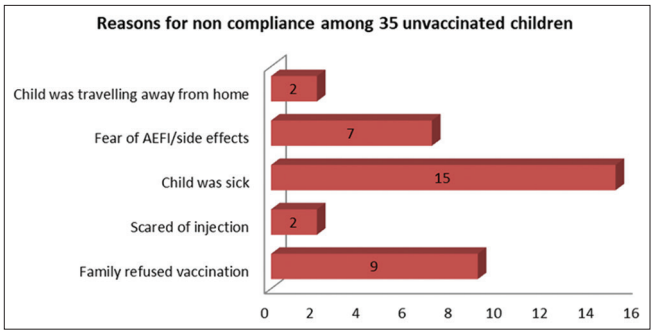

Figure 2: Reasons for noncompliance

DISCUSSION

RCM has been used as a primary method for monitoring mass vaccination campaigns. Its effectiveness and contribution to increasing campaign quality has been documented previously.[7]

Compliance to various aspects of vaccination campaign was found very good, exceeding 90% in almost all the domains. Adequate workforce was present in 96.3% of the session sites observed. Around 90% of the session sites were compliant with safe injection practices, proper cold chain maintenance, and Adverse Events Following Immunization (AEFI) management preparedness. Deviation of the activities from standardized guidelines was very small (<10%) in the current surveys, which indicates a successful planning and execution of the campaign.

Vaccination coverage in this survey was 98.1% for MR vaccine. Routine measles vaccination coverage reported by the National Family Health Survey-4 in Himachal Pradesh for 2015–2016 was 87.4%.[8] Bhardwaj *et al*. in their survey reported routine vaccination coverage of 82.7% for measles in 2016.[9] The vaccination coverage in the present study was similar to that of RCM in Nepal and Bhutan where 95% and 98.17% of children were vaccinated, respectively.[10,11] The estimated national coverage with MR vaccine in Haiti was 79.2% in 2007–2008.[12] The high vaccination coverage reflects the strong health infrastructure and efficient health-care delivery system existing in this hilly state. Acceptance for such mass immunization campaigns involving a number of stakeholders from various sectors is quite remarkable and further solidifies the concept of intersectoral coordination.[13]

Mass campaign of a vaccine requiring an injection at sites away from health institutes always instills fear among children, parents, teachers, and even health-care providers. Despite this, noncompliance was very low in the present study and the most common reason reported was current sickness, which is acceptable and can be rectified in RI sessions. The second most common reason was refusal from family, most probably because they had already vaccinated their children with the vaccine and had feared hyperimmunization. No severe AEFI was reported during the survey. Mild side effects such as local pain and swelling were reported by 12% of the children. Other side effects such as excessive crying, headache, fainting, and fever were reported within the expected limits, which assures the safety of this vaccine.

Table 4: Feedbacks received during the campaign from external monitors

Activity domains	Feedbacks
Preparedness/training	Precampaign sensitization should be done at least once in all schools when there is maximum attendance such as during parent- teacher meetings and school maintenance committee meetings
	It should be in the beginning of the school academic session
	Timings of immunization should be flexible as per school hours and government and private school should have separate sessions
	Students/parents should be strictly instructed not to erase the indelible ink mark as they were seen trying to erase it
	A part of the budget should be spent on giving some sort of refreshments to the students. In addition, the incentive for vaccinating team was found dismissive
	As most routine immunization sessions are conducted by the ANMs, the male health workers deployed for vaccination were out of practice and hence they were having difficulty in vaccination with proper technique
Logistics inputs	Same worker who is issuing vaccines for different teams (at cold chain point) also had to reach his/her session sites on the same day, indicating poor management
	Indelible ink pens were not sufficient at few sites
	Hub cutters should be tested before handing them over to the vaccinating teams
	Due to miscommunication, some parents brought their under-5 children at the school session instead of outreach session, which led to sudden rush that overburdened the vaccinating teams and caused temporary vaccine shortage
Vaccination process	Full diluent (5 mL) was not being used for reconstituting the vaccine vials
	Time of opening of the vial was not being written on it at some places
	Contrary to the instructions, thumbs were being marked before vaccination, these too were being done randomly, either left or right
	Vials not kept in the well of ice pack at few places
	Vaccinators were not discarding needles and other waste by themselves (instead using help from other team members)
	A few parents did not have faith in the government process and were discouraged to vaccinate by the private practitioners
	There were some (mis)communications about the adverse effects of extra dose. Some parents and teachers perceiving half hour observation period as recovery time from strong dose, percolating a wrong message
	There was a good example of NSS volunteers regulating the immunization session at few sites. They were seen counseling and encouraging the junior schoolchildren to get the shot
Record maintenance and data flow	After the vaccination, the vaccination cards were still present in the school
	They were not handed over to children/parents at some places
	Records at some sites were completed at the end of the entire session
Miscellaneous/others	Insulin syringes for adrenaline injection were missing at a few places
	ASHA workers were not involved/present with the teams at few places

ANM: Auxiliary nurse midwife, ASHA: Accredited social health activist, NSS: National service scheme

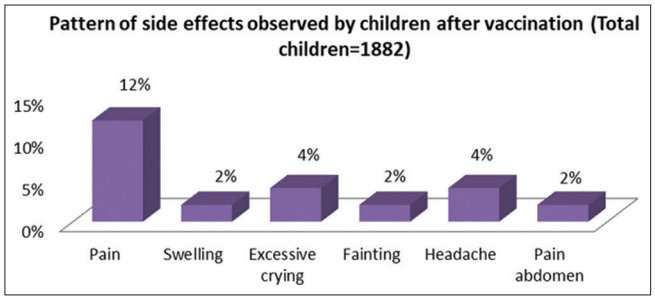

Figure 3: Pattern of side effects observed by the children after vaccination

Vaccination process especially safe injection practice and maintaining cold chain is the backbone for any campaign, which not only ensures high sero-conversion but also reduces the chance of unwanted side effects. Small mistakes or complacency was observed at certain session sites, which needs to be stressed upon during the preparedness or training stage.

Communication plays a vital role in the success of such mass campaigns, and it is important that a right message is conveyed to a right person through a right medium.[14] A lot of miscommunications or misinterpretations tend to arise in such situations, which has to be addressed in the preplanning period as well as during the ongoing activities. Schools and health-care providers were the major source of information for this campaign. Mass media had limited role as a primary source of information in this campaign, which can be utilized in a better way in the near future. Higher enrollment of children in schools and a large pool of health workers had been utilized effectively.

Another important aspect of the campaign was record maintenance and fluent data flow from ground level to higher authority. Complacency has been observed at certain points that necessitates the role of strict vigilance and supervision.

Dedication of the vaccinating teams is quite evident from the very high compliance rate and vaccination coverage. At present, in low- and middle-income countries, a number of public health interventions are being carried out regularly in the form of campaigns. Hence, in order to keep them motivated, their hard work needs to be appreciated. Better incentives and recognition for their work are recommended at various platforms.

CONCLUSION

During this RCM, important feedbacks were collected from the children, vaccinating teams, teachers, parents, and external monitors. Overall, a positive feedback was received regarding the conduct of the campaign. However, few instances of programmatic error and complacency were also noticed. A few such as inadequate supplies of indelible ink pens and functional hub cutters have already been documented in literature. During the training of vaccinators, emphasis has to be laid on the importance of using the full amount of diluents.

The male health workers who otherwise do not take part in RI sessions need to be given refresher training regarding the correct immunization technique before holding such campaigns. There should also be revision of incentives for the vaccinating teams along with more involvement of ASHA workers in such campaigns in future. Similar studies in other states are advised, which will shed more light on region-specific issues. This activity has reinforced the role of strict monitoring and supervision. In the long run, it will help program managers and planners to avoid such hindrances and help in smooth running of such campaigns.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

A discrepancy in logistics and supply chain management: Findings from national iron plus initiative process documentation in Odisha

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Abstract

Introduction: Anemia is highly prevalent in India affecting all age groups. In 2016, process documentation program was done in Odisha by Department of Health and family Welfare, Government of Odisha with the aid of UNICEF and All India Institute of Medical Sciences, Bhubaneswar to assess National Iron Plus Initiative program. The objectives were to assess facilitating factors and hindrances in implementation of program. In the present study, hurdles in logistics and supply chain management are discussed.

Material and Methods: A mixed-methods study was done among four districts (3 poor performing and one good performing) based on Iron folic acid tablets consumption. Two blocks from Keonjhar and Jagatsinghpur and one block from Bhadrak and Kalahandi were selected. In depth interviews and Focus group discussion were done among 170 respondents (officials and beneficiaries). By probability proportion to size, 50 sub-centres were chosen and front line workers interviewed. Data was collected by survey team and analysis was done using Nvivo qualitative research software program for qualitative surveys and Microsoft Excel for quantitative surveys.

Results: It was seen that there were discrepancies in the method (bypassing officials), frequency of indenting (quarterly, bi-annual and annual), supply chain, stock out management (informal methods) and flow of supply (prolonged quarantine period). It was also seen that only 41% of sub-centres had IFA tablets at the time of survey.

Conclusion: Logistics and supply chain management play a crucial role in the success of any program. Timely and orderly management, centralised method and formal approach need to be incorporated.

Keywords: Anemia, logistics, National Iron Plus Initiative, Odisha, stock management, supply chain

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INTRODUCTION

Anemia, a condition defined by the decrease in the number or the oxygen carrying capacity of red blood cells,[1] is an issue of concern since ages. Although, India is growing economically and politically, the burden of anemia still persists with negligible decline over the decades. Improved

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living conditions, financial stability, sanitation and hygiene, and educational status of people have ceased to show any influence on this major nutritional deficiency. National Family Health Survey-4 reveals that the prevalence of anemia is high ranging from 53% in women of 15–49 years of age to 58.5% in children of 6–59 months of age.[2] Anemia has profound ill effects on health varying from shortness of breath, fatigue, headache to irregular heartbeat, and arrhythmia. Furthermore, anemia accounts for decreased school performance and productivity. Hence, this preventable cause of nutritional deficiency needs to be addressed. National iron plus initiative (NIPI) is one such program designed to combat anemia through the life cycle approach. Supplementing iron and folic acid (IFA) and Albendazole to 6 months to 19 years of age, women in reproductive age group, and pregnant and lactating females, this program strives to overcome anemia.[3]

NIPI was launched in 2013.[3] In the year 2016, with 3 years into the launch of the program, a process documentation program to investigate the progress and assess the hurdles in the ground level implementation was planned. Odisha was chosen to assess the process documentation as the prevalence of any anemia and severe anemia is very high in the state. Hence, Department of Health and Family Welfare, Government of Odisha in collaboration with UNICEF and All India Institute of Medical Sciences (AIIMS), Bhubaneswar, planned to review the process documentation in March–May 2016. The objectives of the process documentation were to evaluate the key state and district experiences in implementing NIPI, success factors and challenges in provision of IFA to children, adolescents, pregnant and lactating women, explore the programmatic lapses and suggest future recommendations.

For successful implementation of any supplementation program, special emphasis should be placed upon monthly monitoring of stocks at each level of distribution, scheduling of orders to ensure regular supply, and quality control measures by periodic sample checking.[4] In Odisha, OSMCL was established in 2013 for ensuring procurement and supply of high quality drugs in the state. All the information related to indent, purchase order, quality control and supply chain is entered online in "e-Aushadhi" system of OSMCL. Distribution of drugs is ensured down till block level with the help of several vehicles. However, the monitoring and tracking of supply and utilization of drugs at grass-root level remains a big constraint.[5]

In this present article, we intend to discuss the procurement and supply chain management issues incurred during the process documentation of NIPI.

MATERIAL AND METHODS

A mixed methods approach was adopted for conducting process documentation in NIPI.

Selection of study site

Among 30 districts of Odisha,[6] four districts were planned to be a part of the study based on the IFA consumption by mothers and children as assessed by Annual Health Survey 2012–2013.[7] One poorest performing district from each revenue division (three districts: Bhadrak, Keonjhar, and Kalahandi) was selected, and the overall best-performing district (Jagatsinghpur) was selected as the fourth to assess the differences among poor and best performing districts. From the districts selected, one good and one bad performing block were selected from Keonjhar and Jagatsinghpur. However, as much data variability did not occur among the blocks of the district, only one block each was selected in Bhadrak and Kalahandi.

Surveys

Both qualitative surveys to assess the perceptions of the respondents (n = 170) toward NIPI program and quantitative surveys to compute the outputs and outcomes were undertaken. As a part of qualitative survey, in depth interviews (IDD) were purposively conducted among state (n = 12) and district level officials (n = 27) from the departments of Health, Education, and Integrated Child Development Services (ICDSs). District officials were chosen evenly across the four districts, and block and sector officials (n = 32), field workers (n = 49), and beneficiaries (n = 34) were chosen evenly across the six blocks. Both IDD and focus group discussions (FGDs) were conducted among respondents at block, sector/cluster, and field level. Among beneficiaries, only FGDs were conducted as a part of process documentation. For quantitative survey, facility-based survey was done to understand the supply chain management. From four districts, 8 community health centers and 24 primary health centers were included. Based on probability proportion to size sampling method, 50 sub-centres, 99 schools, 90 Anganwadi centers, and 48 village health and nutrition day (VHND) sites were further selected. From these centers, 245 anganwadi workers (AWWs), 235 Accredited Social Health Activists (ASHA), and 39 auxiliary nurse wid-wives (ANM) were interviewed.

Questionnaire development

Facility survey questionnaires were designed according to the platform (health centres, schools, and VHND) of IFA interventions and survey team administered the same.

Data collection

Data collection for qualitative surveys was done by a survey team who were trained in a 6 day phase wise training method. Following training, the survey team conducted IDDs either in offices or in private places, depending on the availability of the official. FGDs were conducted in the group of 12–15 years. A review meeting was held every day to discuss the obstacles faced and reforms needed for further data collection. Supervisory visits were done by the investigators intermittently to monitor the survey team and ensure the smooth conduct of the process documentation. All the qualitative interviews and FGDs were tape recorded and labelled with time, date, and place.

Data analysis

The transcripts were later entered into Nvivo qualitative research software program. Analysis was done under 15 different arenas which included logistics procurement and supply chain.

Ethical clearance

Ethical clearance was obtained from ethical committee of AIIMS, Bhubaneswar. Written informed consent was obtained from the participants, and their identity was kept confidential.

RESULTS

Evaluation of indenting mechanisms and supply chain management were among the other subsets of the process documentation of NIPI. The existing mechanisms in the field and differences in regard to the routine indenting mechanisms were evaluated by IDDs of various health officials and stake holders. The indent orders are made by Health and Family Welfare department based on the number of students enrolled in the school at the beginning of an academic year and bi-annual household survey by AWWs.

Qualitative surveys

Assessment of drug requirements

Various stakeholders including ANMs were interviewed as they are the first contact of health care for the population. Regarding IFA requirement of pregnant women, they had two schools of thoughts. One group assumed that most of the pregnant women are anemic and needed 2 doses of IFA per day. Another group assumed that 80% of women are anaemic and need 2 doses of IFA per day and 20% need one IFA tablet. When Medical Officer Incharges (MO I/Cs) were interviewed, it was revealed that a surplus of 10% stock is ordered.

These different school of thoughts lead to over/under estimation of stock requirement.

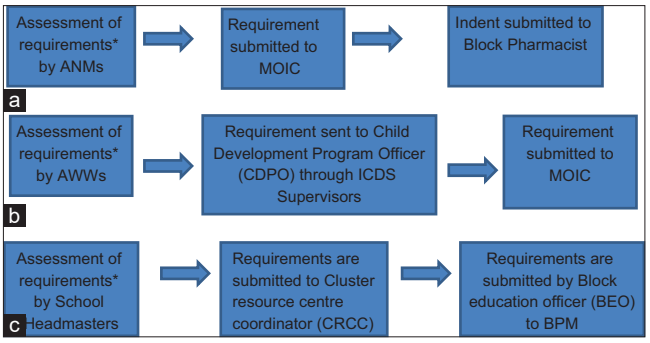

Figure 1: Flow of indenting of IFA and albendazole at various health sectors. (a) Health officials indenting. *Requirements (iron and folic acid and Albendazole) of pregnant women and children from 6 to 59 months are assessed. (b) Integrated Child Development Service indenting. *Requirements of iron and folic acid tablets and Albendazole for out of school adolescent girls and children of 6 months to 5 years are assessed. (c) Education officials indenting. *Requirements of iron and folic acid tablets (pink and blue) for in school children of 5–10 years of age (standard 1–5) and adolescent girls and boys is done

Method of drug indenting

Flow of indenting was consistent in all the four districts [Figure 1]. The indent request from MO I/C and BPM, with the help of Block Pharmacist is sent to Chief District Medical Officer (CDMO) through District Pharmacist. The CDMO is then entrusted with the responsibility of sending the indent to State Drug Management Unit/OSMCL.

It was seen that the indent requirement for the health department bypassed Lady Health Visitor and MOIC received directly from health workers. In one district, the indent was once sent directly to sector supervisors from ANMs without consulting MOIC. Another major discrepancy was seen in Bhadrak district wherein indent was being prepared by ICDS workers and officials rather than health workers. For the ICDS, the Child Development Program Officer (CDPO) prepared the indent for MOIC rather than District Social Welfare Officer. For the Education department, the BEO compiled the report for BPM rather than for District Education Officer (DEO) as per the guidelines.

Frequency of indenting

Most of the officials reported annual indenting. Few exceptions were noted as some officials reported bi-annual indenting, one CDPO and ANM reported quarterly indenting and one group of ANMs reported stock based indenting (indent whenever there is stock out).

Receipt of drug supply

OSMCL officials reported that supply is received in 2–3 instalments of 30%, 30%, and 40%. According to them, the receipt of supply depends on the requirement and

storage space at warehouse. At the level of district, field and block, officials mentioned that supply is bi-annual. The receipt of supply stock at the field level however varied with one CRCC notifying as yearly and the other as quarterly. Two ANMs reported as receiving the stock in every quarter.

Another issue of concern is the poor storage conditions for drugs at warehouses of OSMCL (lack of ventilation and sufficient space).

Flow of supply

The flow of supply was consistent among the four districts.

As per Health officials, for pregnant women, supply was sent from CDMO/District Pharmacist to CHC Pharmacist/MOIC/BPM and then to ANM. Similar mechanism is maintained for children 6 months to 5 years. ANM later distributes the stock to ASHA (for children <3 years) and AWW (for children 3–5 years). ICDS officials revealed that from CHC, the supplies are sent to CDPO, then to ICDS supervisors and AWW and ASHA. Education department officials revealed that the supply from CHC is sent to BEO and then to CRCC and headmasters of schools.

However, in three districts, the District Pharmacist transported to CHC/Block and in one district the Block Pharmacist collected it from District Pharmacist. The District Pharmacist supplied directly to schools in one district. Irregularities were seen in distribution from CRCC to head masters. Various officials said that the supply takes 2–4 months to reach from district to block after clearance of quarantine (for every new batch of IFA), and it usually takes 10 days for the supply to be delivered from block to CDPO/CRCC/Sub-centre.

Stock–out of drugs

Most of the interviewees revealed that there were no experiences of major stock out. Most of them perceived that the supply was good, and this is a positive sign.

However, few experiences of stocks outs did occur at some places. Stock out of IFA for out of school adolescent girls occurred in two districts (4–5 months in one block and 10 months in another block) as told by ICDS supervisors and officials. Drugs were not available even at the time of interview. Lack of IFA (blue tablets) supply was observed for a year after the implementation of NIPI in one cluster of a district as told by CRCC. Shortage of supply was also seen in schools of one block as said by a DEO and an ANM at the time of interview. Lack of supply was seen in one PHC as explained by MOI/C and Pharmacist. They perceived that the PHC was not a priority destination for implementation of NIPI programme, and hence, there was no supply. ASHA, ANMs, and AWWs reported stock out for 2–4 months. Even in early 2016, stock outs occurred in three districts. Women in one of these districts also mentioned that there was no IFA supply for their young children.

An episode of stock out of Albendazole occurred in two districts as told by a BEO. Another episode occurred wherein Albendazole ran out of supply amidst distribution as told by Block Pharmacist and CRCC.

Management of stock-outs

In times of crisis, supply sent to the peripheries is less than the demand placed. A Block Pharmacist told that "*Requirement could be more but as per the availability of the drug, they send accordingly.*" When interviewed, an AWW also expressed the same. Another mechanism is to procure from areas where buffer stock is kept as said by a Block Pharmacist and PHC Pharmacist. A CRCC expressed that "*If no one is able to give, we bring it from PHC*". Another mechanism which is most commonly practiced and expressed through interviews was informal i.e., local sharing of stock followed by AWWs and ASHA in accordance to ICDS supervisors. Another mechanism which involves technical inputs is cross district sharing requiring access to online drug portal (e-Aushadi) of OSMCL. A pharmacist in one district had shared the experience of sharing stocks across another district using this interface. Also, lack of adherence to drug formulations during stock out phases was observed.

Expiry of received supply

From the officials interviewed, there were hardly any reports of receipt of expired stock. If occurred, they are aware that the stock expired should be returned. However, fear of expiry of IFA tablets was expressed countless times by teachers, head masters, CRCC and frontline workers.

Distribution of drugs

As told by a block Pharmacist, supply of IFA and Albendazole was received prior to the assessment made by survey report. Hence, difficulty occurred in distribution of supplies. One CRCC mentioned that it can take 1 month to distribute stock within a cluster due to transportation issues. Education department officials said that difficulties occurred in delivery of supply to schools as the CRCC is often not available to receive the supply from Block Pharmacist. In one instance, the time taken for quarantine clearance of supply was as long as 4 months. Many

pharmacists expressed dissatisfaction over prolonged time taken for clearance.

Receipt of drugs by beneficiaries

When beneficiaries were interviewed, it was seen that a group of adolescent girls received IFA only once, and in another district, the college girls received IFA from AWC rather than from the college.

Quantitative surveys

From the quantitative surveys, it was seen that 41% of subcenters had a stock of IFA syrup, 63% had IFA tablets, and none had iron injections at the time of survey. Regarding PHCs, none had the stock of IFA syrup, only 8% had IFA for therapeutic purposes, and only 5% had iron injections. Only 25% of CHCs had stock of IFA syrup, and only 75% had stock of IFA tablets. The low stock of IFA syrup in CHCs is consistent with reports of qualitative surveys as the supply is transported down to ANMs. When enquired, only a small proportion of frontline workers thought that stocks were adequate. It was seen that 15% of ASHAs in Kalahandi and 49% in Keonjhar perceived that stocks for children under 3 years were adequate. Varied responses were received from AWWs regarding adequacy of supply. For children of 3–5 years, 4% AWWs in Kalahandi, and 45% in Bhadrak perceived the stock to be adequate. For adolescent out of school girls, 13% of AWWs in Kalahandi and 64% in Jagatsinghpur perceived the stock to be adequate. For junior college girls, 4% of AWWs in Kalahandi and 36% in Jagatsinghpur perceived the stock to be adequate.

DISCUSSION

From the process documentation, it is evident that a well-networked supply chain management operates for NIPI implementation. Howsoever, it was enumerated from qualitative surveys that two instances of stock outs did occur. The reasons varied as inadequate procurement by state and inadequate indenting below district level. Stock outs affect the implementation of program. A qualitative study in Pondicherry reported that regular supply of IFA was one of the facilitators for successful iron supplementation.[8] A captivating mechanism was seen in the field as front line workers act as agents of support and share stocks locally to avoid stock outs. Bossert *et al.* reported that "inventory management" function better when centralized rather than decentralized.[9] Hence, this mechanism of informal stock sharing can be harnessed and introduced into the routine implementation of programme. All the front-line workers and pharmacists can be educated about the use of electronic supply chain software and overcome crisis in critical phases of stock outs. Another area of concern was the limited storage space for IFA and Albendazole supply. In a process documentation done in Bihar, similar constraints of limited supply and unhygienic storage area leading to stock damage were reported.[10] Regarding indent placement, it was seen that discrepancies occurred in the flow of indenting at various levels. Uniform methods should be encouraged across the districts to avoid under or over placement of indent. Another major area of concern was the transportation of supply to schools from CRCC. The issues of accessibility should be assessed further and alternate delivery mechanisms in hard to reach areas should be formulated. Majority of the pharmacists expressed discontentment over the prolonged time for quarantine clearance of every new batch. Strict regulations should be in place to avoid delays and ensure timely dispatch of the supply.

With the launch of Intensified NIPI (I-NIPI) under Anaemia Mukt Bharat, concerted efforts are made to effectively decrease the prevalence of anemia.[11] From the findings of this study, various loopholes observed in the administrative and management aspect of program implementation can be taken care of in effective implementation of I-NIPI. Periodic surveys involving both qualitative and quantitative aspects are needed to monitor functioning of the I-NIPI program and address the drawbacks without delay.

CONCLUSION

Logistics and supply chain management plays a pivotal role in the success of any program. Timely and orderly management of logistics and stock, being the core elements of program implementation should be focused upon. From the present mixed methods analysis of NIPI process, documentation few shortcomings are observed. Few recommendations are suggested henceforth in parallel with the study findings. Mechanisms (electronic preferably) should be in place to check the possible stock outs in any region at a given point of time. Real-time monitoring of logistics and stock and thereby tracking of supply chain below sub-district level should be developed and monitoring to be done accordingly. Management of stock outs should be more formalised enabling hassle free transfer in case of need. Furthermore, expansion and improvement of storage space for stock are required at all levels of distribution. Training and periodic meetings to ensure appropriate supply and distribution of IFA, manage online transfer of stocks, and efficient procurement should be reinforced. The impact of anemia on overall health and economy of nation should be emphasized through

these trainings. This will enable them to take ownership and thereby optimally engaged to combat anemia. With the suggested recommendations and inputs from process documentation of NIPI, the drawbacks in program implementation can be addressed and the vision of "Anemia Mukht Bharat" can be made possible.

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Conflicts of interest

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Original Article

Adherence to iron with folic acid supplementation in women attending an antenatal clinic at a low-income urban area in Delhi, India

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Abstract

Introduction: Adherence to Iron-Folic Acid Supplementation (IFAS) in pregnant women can safeguard them against nutritional anemia and the related adverse pregnancy outcomes. The objective of this study was to assess the adherence to oral IFAS in women attending an antenatal clinic in an urban resettlement colony of Delhi, India.

Material and Methods: We conducted a cross-sectional study and enrolled 211 antenatal women through consecutive sampling during a 4-month period from December 2018 to April 2019. IFAS adherent status was defined as women taking ≥80% of their prescribed IFAS in the previous 7 days, equivalent to IFAS intake for at least 6 days in the previous week. We also estimated adequacy of IFAS drug stocks with the patient during the past 30 days. The data were analyzed using IBM SPSS Version 25. A $P < 0.05$ was considered statistically significant.

Results: The mean (± standard deviation) age of the women was 24.6 (±3.4) years, ranging from 19 to 35 years. Median years of education was 11, and all the women were currently married. A total of 54 (25.6) women reported being non-adherent to their prescribed IFA medication. Only 175 (82.9%) women had adequate IFAS stocks during the past 30 days. On adjusted analysis, running out of IFAS stocks was a significant predictor of IFAS non-adherence ($P = 0.004$).

Conclusion: The present study indicates that adherence to IFAS among pregnant women is suboptimal. Non-adherence was usually because of running out of drug-stocks but rarely due to drug side-effects.

Keywords: Adherence, antenatal women, iron-folic acid supplementation

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INTRODUCTION

Anemia in pregnancy is a major public health challenge worldwide with an estimated 38.5% prevalence, affecting >56.4 million women.[1,2] Nutritional anemia due to Iron Deficiency Anemia (IDA) is the predominant cause of anemia in the developing world.[3] Anemia during pregnancy is considered as a hemoglobin concentration <11 g/dl, with >10 g/dl as mild anemia, between 7 and 9.9 g/dl as moderate anemia and <7 g/dl as severe anemia.[4] Factors such as dietary deficiency, iron inhibitors in diet, poor iron stores in childhood and adolescence, iron losses during postpartum hemorrhage, teenage pregnancy,

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repeated pregnancies with inadequate spacing and poor sanitary conditions increase the risk of IDA in women undergoing pregnancy in the developing world.[5]

The National Family Health Survey 4 (NFHS 4) reported 50.3% of pregnant women in India were anemic. Mild, moderate and severe anemia was observed in 24.5%, 24.6%, and 1.3% of the women, respectively. In the Indian capital city, Delhi, the prevalence of anemia among pregnant women was 45.1%.[6]

It is well-established that IDA causes multiple adverse outcomes for both the mother and infant, including an increased risk of hemorrhage, sepsis, maternal mortality, perinatal mortality, and low-birthweight.[7] Furthermore, anemia in pregnant women is estimated to contribute to >115,000 maternal deaths and 591,000 perinatal deaths globally per year.[8] Anemia is also considered as the underlying cause for 20%–40% of maternal deaths in India.[5]

Iron requirements in pregnancy increase by an estimated 850 mg for red cell expansion, growth of the fetus, placenta, and the uterus, additional needs that cannot be met by diet alone and require the utilization of body iron stores.[9] Current prevention and control strategies for IDA for women in India are therefore focused on iron-folic acid supplementation (IFAS) during pregnancy after the first trimester as means of preventing anemia and related complications.[10] However, poor adherence to IFAS is a major challenge in Indian health settings. Findings from the NFHS-4 reveal that only 52% of women took the recommended 100 IFA pills during their previous pregnancy.[6]

There is a paucity of Indian studies which have assessed factors associated with poor IFA intake during antenatal care. We conducted the present study with the objective of assessing the adherence to oral IFAS in pregnant women attending an antenatal clinic in an urban resettlement colony of Delhi, India.

MATERIAL AND METHODS

Study site

We conducted a cross-sectional study in the antenatal clinic of an urban primary health center, run by the government of National Capital Territory, Delhi and located in an urban resettlement colony in the North-East district of the state from December 2018 to April 2019. The area was selected as it constitutes the field practice area of a government medical college in the city. The antenatal clinic is conducted once a week and provides antenatal care services to around 500 pregnant women annually, mostly residents of the area. Service delivery is through a team of resident doctors, medical interns, two public health nurses, and a government medical officer.

Standard care

All the pregnant women attending the clinic are prescribing only folic-acid during the first trimester of their pregnancy. From the second-trimester onward, the women are prescribed iron-folic acid (IFA) tablets containing 100 mg elemental iron and 500 μg folic acid. The IFA tablets were provided free of cost to all the beneficiaries at the health facility. Women without anemia (Hb ≥11 g) were prescribed once daily IFA tablet while those with anemia (Hb <11 g) were being prescribed twice daily IFA tablet. Women detected with severe anemia (Hb <8 g) were referred to a higher center to provide for specialist obstetrics care.

Selection criteria

We included all adult pregnant women with ≥16 weeks amenorrhea attending the antenatal clinic. We excluded those women who were previously detected having severe anemia, anemic women on parenteral iron therapy or those who received blood transfusion during their current pregnancy and finally those anemic women who were previously diagnosed with non-IDA.

Sample size and sampling strategy

At 95% confidence level, 7% margin of error, with expected prevalence of IFA adherence being 52%,[6] and accounting for 10% non-response, the sample size was estimated to be 215. We selected the participants applying the consecutive sampling method, i.e., all the women meeting the selection criteria and willing to participate were enrolled into the study, one after the other, until a maximum of 10 women had been enrolled in a single session.

Methodology

We interviewed the women using a patient interview schedule. We collected information on sociodemographic variables, knowledge, attitude and adherence practices relating to the participant's IFAS intake. We determined the drug adherence rates in the previous seven days, by dividing the ([total number of IFA tablets prescribed–total number of missed IFA tablet doses]/[total number of IFA tablets prescribed]) × 100.

Standard definitions

IFAS adherent status was defined as women taking ≥80% of their prescribed IFAS in the previous 7 days, equivalent

to IFAS intake for at least 6 days in the previous week. We estimated the adequacy of drug stocks present with the women by calculating the proportion of days with IFA coverage in the last 30 days and classifying it as adequate if drug coverage was ≥90%. Among the women who were non-adherent to their prescribed IFAS, we also ascertained the reasons for medication non-adherence. Furthermore, we obtained participants perspectives relating to IFA intake through means of in-depth interviews in 10 women with moderate anemia (HbA1c 8–10 g%).

Statistical analysis

We analyzed the data using IBM SPSS Statistics for Windows, Version 25.0. (Armonk, NY: IBM Corp). Data were expressed in frequency and proportions. Chi-square test was used to find an association between categorical variables. A $P < 0.05$ was considered as statistically significant.

Ethics

The study was approved and exempted from full review by the Institutional Ethics Committee of the medical college. We collected data from the women after obtaining their written and informed consent. All the women were provided health education relating to anemia, the need for IFAS and its good adherence through individual counseling after the interviews.

RESULTS

Sociodemographic

We enrolled a total of 211 pregnant women with 100% response rate. The mean (±standard deviation) age of the women was 24.6 (±3.4) years, ranging from 19 to 35 years. The median years of education of the women were 11 years. All the women were currently married. All the women had received at least two antenatal visits at the time of enrolment into the study. One hundred and three (48.8%) women were primigravida, while 122 (57.8%) did not have any previous children.

Iron-folic acid supplementation adherence

The IFA tablets were prescribed once daily to 173 (82%) women that were nonanemic and twice daily to 38 (18%) women who were anemic. A total of 54 (25.6) women reported being nonadherent to their prescribed IFA medication in the previous 7 days. There were also 50 (23.7%) women who did not take their IFAS on the last day. One hundred and seventy-five (83%) women had adequate IFAS stocks during the last 30 days.

Thirty-four women took their IFA pills before their meals, six took it with their meals while the rest took it appropriately after their meals.

Reasons for non-adherence to IFAS were reported by the women to be forgetfulness 43 (20.4%), side-effects 7 (3.3%) and running out of IFA pill stocks 28 (13.2%).

The importance of high adherence to IFAS during pregnancy was perceived to be very important by 102 (48.3%), quite important by 66 (31.3%), important by 24 (11.4%), somewhat important by 10 (4.7%), and not at all important by 9 (4.2%) women.

None of the sociodemographic and clinical variables was found to be significantly associated with nonadherence to IFAS on either bivariate or adjusted analysis [Table 1]. However, women reporting inadequate IFAS stocks at home in the previous month were three times more likely to be nonadherent to IFAS compared to the women having adequate IFAS coverage ($P = 0.004$).

Perspectives of women having moderate anemia during pregnancy was favorably inclined toward IFAS intake, which indicated their perception of increased susceptibility to adverse health outcomes in case of nonadherence. A respondent replied, "the IFA pills are useful during pregnancy…they protect my health…. I take them regularly." However, there were four primigravida women who reported never having previously received IFA either through frontline health workers or at school; "we have never been given iron pills before our pregnancy." None of these women had been previously diagnosed with anemia by any medical practitioner either.

DISCUSSION

Adherence to IFAS in pregnant women can safeguard them against nutritional anemia and the related adverse pregnancy outcomes. The present study revealed that nearly one in four pregnant women were nonadherent to their IFA medication, while nearly one in five women lacked adequate IFA stocks. However, the rates of IFAS adherence among antenatal women observed in our study are significantly higher compared to those reported by some recent studies conducted in Africa.[11-14] Another study in an urban area of Southern India by Mithra *et al*. found 64.7% adherence to IFAS.[15] The improved adherence rates in our study are probably due to urbanization and better healthcare access due to the central location of the health facility near a busy marketplace. Nevertheless, the definition of IFAS nonadherence employed by the different researchers indicates considerable methodological heterogeneity due to which the outcomes in terms of IFAS adherence rates may not be comparable across studies.

Table 1: Iron-folic acid supplementation adherence in antenatal women in Delhi (*n*=211)

	Total	IFAS nonadherence	Adjusted odds (95% CI)	*P*
Age (years)				
<25	115 (54.5)	34 (29.5)	0.59 (0.3- 1.1)	0.13
≥25	96 (45.5)	20 (20.8)	1	
Number of children				
None	122 (57.8)	28 (23)	1.6 (0.83- 3.1)	0.16
≥1	89 (42.2)	26 (29.2)	1	
Anemia status				
Present	39 (18.5)	14 (35.9)	0.51 (0.23- 1.1)	0.10
Absent	172 (81.5)	40 (23.2)	1	
Education (years)				
<10	77 (36.5)	18 (23.4)	1.2 (0.63- 2.5)	0.49
≥10	134 (63.5)	36 (26.8)	1	
Knowledge of IFA				
Incorrect	40 (18.9)	10 (25)	1	0.64
Correct	171 (81.1)	44 (25.7)	1.2 (0.53- 2.8)	
IFA stock				
Adequate (≥90%)	175 (83)	38 (21.7)	1	0.004
Inadequate (<90%)	36 (17)	16 (44.4)	3.1 (1.4- 6.8)	

IFA: Iron-folic acid, IFAS: Iron-folic acid supplementation, CI: Confidence interval

In this study, none of the sociodemographic and birth variables was associated with nonadherence to IFAS. Previous studies have, however, indicated these variables influencing IFAS adherence.[14,15] Our results are probably due to the homogeneous population of the study area and the improved service quality blunting the detrimental effect of adverse sociodemographic parameters.

We found running out of IFA pill stocks was a significant predictor of nonadherence in the present study, which could be either due to missed appointments, dispensing of inadequate IFAS or drug stock-outs at the health facility. Similarly, a previous study conducted in the urban slums of Delhi also observed high antenatal care coverage but the delivery of an inadequate ANC package to the beneficiaries.[16] The study by Varghese *et al.* in a North Indian state also attributed low intake of IFAS by pregnant women due to them having low stocks.[17]

Dyspepsia and gastritis are frequent side-effects of IFAS that can result in lower adherence.[15] However, in this study, this was reported by very few women, which probably occurred, since the majority of women were taking their IFAS appropriately after their meals. Another study in Northern India also reported that nonconsumption of IFAS by pregnant women was not due to the perceived side-effects of the drug.[17]

There are certain limitations to the study. First, the cross-sectional study design precluded the possibility of detecting any change in IFAS adherence prospectively during the course of the women's pregnancy. Second, it was a clinic-based study which limits its generalizability to other antenatal women in the community who did not report to the health facility. Third, although IFAS was provided at the health facility, we did not assess the drug inventory control methods at the health center, which in case of poor stock control could result in the incomplete dispensing of the prescribed drugs. We also did not collect data pertaining to missed or delayed appointments among the women. Both these factors resulting in nonreplenishment of IFA drug stocks could cause nonadherence in case of the women failed to procure the drugs from alternative sources or through out-of-pocket purchase. Fourth, the possibility of the participants over-reporting their drug adherence due to any social-desirability bias cannot be ruled out.[18]

CONCLUSION

The present study indicates that adherence to IFAS among pregnant women is suboptimal and often results from them running out of drug-stocks. Ensuring IFAS coverage for the women through regular home delivery of IFAS by frontline health workers may be beneficial in this regard. Furthermore, since, forgetfulness is a major reason for IFAS nonadherence, the utilization of modern tools such as mHealth/eHealth and digital technology for the provision of effective reminders promoting IFAS adherence also warrants exploration.

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Conflicts of interest
There are no conflicts of interest.

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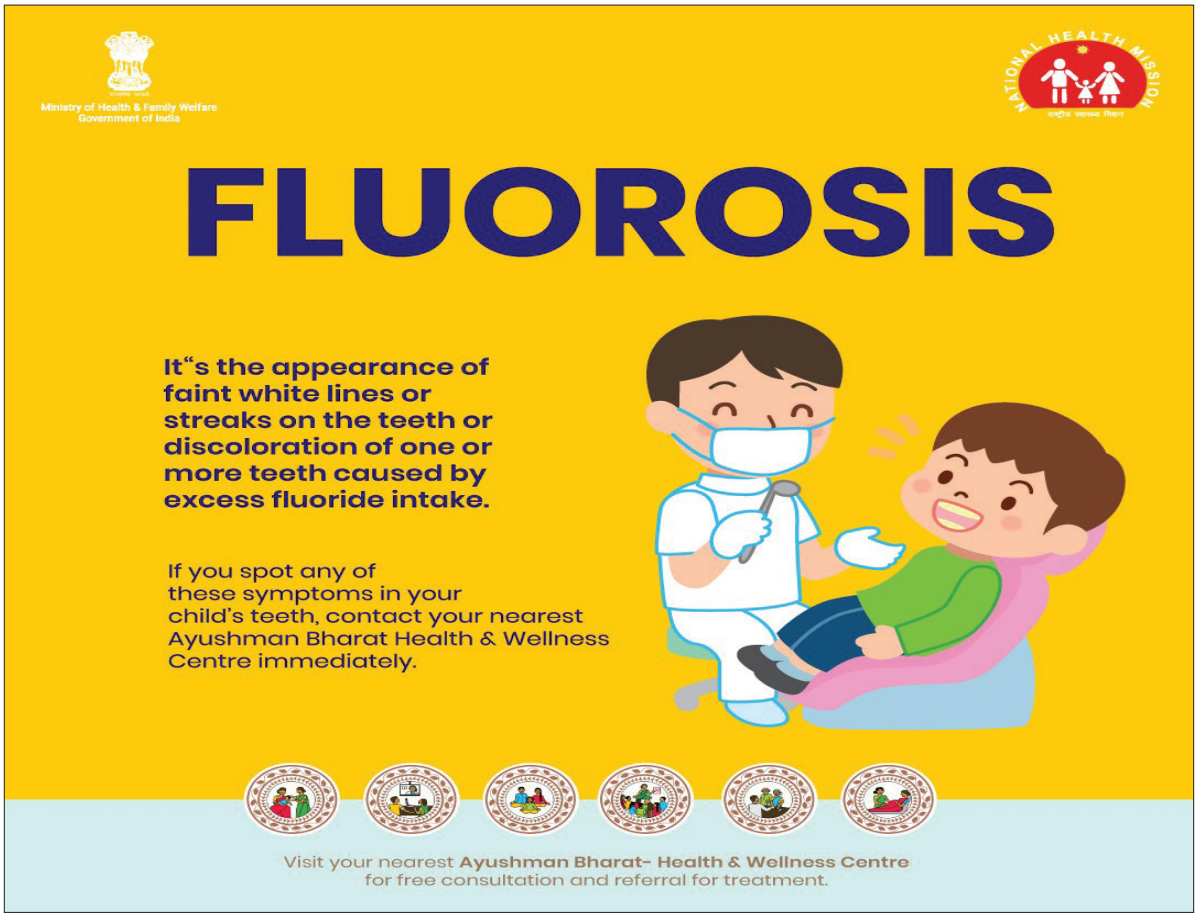

Original Article

Quality of life among people living with HIV/AIDS receiving highly active anti-retroviral therapy: A domain-based analysis

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Abstract

Introduction: With the highly effective antiretroviral treatment, HIV is transforming into a chronic condition, whose management is now experiencing problems of other chronic diseases, where quality of life (QoL) plays a central role. This study was conducted with the objective of determining the QoL among people living with HIV/AIDS (PLHA) taking Anti-Retroviral Therapy (ART) and examine the factors affecting it.

Material and Methods: A cross-sectional study was conducted at ART center, Aligarh. 434 PLHA on antiretroviral therapy, were interviewed using a pretested questionnaire, assessing QoL with the World Health Organization (WHOQoL) HIV-BREF. For domain-based analysis, we examined the association of various factors with the individual domain. The $P < 0.05$ was considered statistically significant.

Results: The mean score in all the domains of WHOQoL was maximum for the level of independence (15.7 ± 2.6) followed by the physical domain (15.5 ± 3.0), while environment domain (11.7 ± 1.8) had the least mean. All the domains, including overall QoL scored above average QoL. This study also showed that a strong relationship exists between QoL with lower socioeconomic status, presence of side effects from ART and depression.

Conclusion: The QoL of HIV patients taking ART from Aligarh was adequate, reflecting the efforts of NACO and other agencies in managing the disease. With respect to its determinants, providing good family support, better employment opportunities, reducing stigma, and proper and timely management of side effects and depression could further increase levels of QoL.

Keywords: Antiretroviral therapy, HIV/AIDS, people living with HIV/AIDS, quality of life, World Health Organization quality of life

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INTRODUCTION

With the adoption of test and treat policy in 2017, Government of India strengthened its strategy of controlling the HIV/AIDS by extending provision of treatment to each and every person with HIV, irrespective of their clinical stage or immunity.[1] In pursuit to ending the AIDS epidemic by extending care, support and treatment

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to all the People Living with HIV/AIDS (PLHA), this was based on the recommendations of the Joint United Nations Programme on HIV and AIDS. This universal access to comprehensive care aims to further strengthen the fight against AIDS. Despite the absence of cure for the disease, the Highly Active Antiretroviral Therapy (HAART) has transformed HIV/AIDS management, increasing life expectancy and survival of the patients like any other chronic disease, requiring a long-term care.[2] However, it remains to be seen whether this has successfully transformed the Quality of Life (QoL) of PLHA or not. While extension of HAART provisioning is laudable, due attention to QoL will further enhance the HIV/AIDS care that PLHA deserve.

The WHO defines QoL as "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." Comprehensive care with support and treatment as the program envisions, should be efficient in improving the health status of PLHA. The advancement of QoL depends on multiple factors such as patients clinical condition and treatment as well as demographic and social-economic conditions. However, conflicting findings have been reported in many of these QoL related factors in different populations.[3-9] While all these studies document some improvement in QoL with treatment, side effect from these long term use of drugs have been a deterrent in some cases.[10,11] With limited literature on QoL and its relation to treatment, especially from North India, we conducted this study to measure QoL among PLHA receiving anti-retroviral therapy (ART) and examine the factors affecting it.

METHODS

Study design, setting and sample size

A cross-sectional study over a period of 12 months was conducted at ART centre, Jawaharlal Nehru Medical College, Aligarh. All adult HIV/AIDS patients registered to the ART center were eligible. Inclusion criteria were all adult PLHA (>18 years) taking ART for >6 months from the selected ART center. We excluded patients with (1) acute medical condition during the study, (2) any past, present or family history of a psychiatric condition, and (3) any bereavement or significant loss of property or sickness/death of any close relatives within the past 3 months.

The sample size was calculated taking the expected confidence interval (σ) and mean from a previous study,[4] with 95% confidence level and within variability (ε) of 3% of expected mean (μ). It was calculated as 440, using the equation for calculation of sample size for continuous response variables, $n = z^2\sigma^2/\varepsilon^2\mu^2$.[12] The eligible population was sampled by systematic random sampling, preparing sampling frame from the list of the patients coming to ART center on the day of data collection, which was done thrice a week. Considering total study population (2323), data collection visits and average daily attendances at ART center (≈50), the sampling interval was calculated to be 10. The first sample was chosen randomly and every tenth patient in the sampling frame was selected.

Study instruments

We conducted face-to-face interview using a predesigned and pretested questionnaire administered in the local language (Hindi), recording information regarding selected socio-demographics, clinical and social factors. QoL was measured by the World Health Organization (WHOQoL) HIV-BREF questionnaire, which is 31-item self-reported questionnaire having 29 specific facets covering six domains -physical, psychological, independence, social relationships, environment, and spiritual, religion and personal beliefs (SRPBs); and two facets for global QoL and general health.[13] Physical domain has facets which measure pain, discomfort, fatigue and symptoms from the disease. Psychological domain measures how a person feels and thinks along with their self-esteem. Level of independence domain has multiple facets measuring mobility, daily activity, drug dependence and work capacity. Social relationships reflect personal relationships, social support and sexual activity. Environment domain includes factors relating to physical safety and security, home and work environment and transportation, while SRPB domain includes factors-related religiousness, belief and suicidal tendency. The patients were asked to focus on their experiences in the past 2 weeks. The facets scored from 1 to 5, with a higher score indicating a better QoL.[13] To compare different domains with each other, the scores of all the domains were transformed to reflect a 4–20 scale by multiplying the average scores for all facets in the domain by 4. Overall QoL was estimated by averaging of all domains. A score of 4–9.9 was treated as low, 10–14.9 as satisfactory and 15 or more as good level of QoL. Physical Health Questionnaire-9 (PHQ-9) was used to screen and diagnose depression. The PHQ-9 consists of nine measures based on the criteria for the diagnosis of depressive disorders according to the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV.[14]

Data management and statistics

The data were entered and analyzed using the IBM Statistical Package for the Social Sciences version 20 (SPSS Inc.,

Armonk, NY, USA). Descriptive statistics were presented as mean and standard deviations in continuous variables and percentages/proportions in qualitative variables along with their 95% confidence intervals. Statistical significance was tested by the Spearman's rank correlation, unpaired *t*-test for two independent variables, and analysis of variance for more than two independent variables. If applicable, Tukey's honest significance difference test was used as *post hoc* test. A value of $P \leq 0.05$ was considered significant.

Ethics

The study was part of MD thesis, submitted in 2017 and was approved by the Institutional Ethics and Research Advisory Committee, JN Medical College, Aligarh. All patients gave written informed consent. Before the start of interview, individual rapport-building sessions were held explaining the purpose of the research and its implications and ensuring confidentiality. Appropriate health education, counseling and appropriate referral was provided to all the patients after the interview.

RESULTS

During the study period, 440 patients were interviewed, of which six patients did not complete the interview. Thus the final analysis was done on 434 sample.

Sociodemographic and clinical characteristics

We interviewed a total of 434 patients (262 males, 170 females and 2 transgender) during the study period. Mean age was 39.02 ± 9.82 years. Majority of them were married (65.4%), lived in a rural area (73.7%) and in a nuclear family (62.7%). Only about two-third patients were literate, and the same number were employed. About two-third participants (66.4%) belonged to the lower socialeconomical class. Most of the participants (249/434) were asymptomatic (WHO staging I), with a mean CD4 cell count of 384.57 ± 179.54 mm^3. Side effects from antiretroviral were reported by 18.7% of the participants during the previous 30 days [Table 1].

Table 1: Sociodemographic characteristics of the HIV/AIDS patients taking Antiretroviral therapy

Pattern of depression	Frequency (%)	95% CI
Age		
18- 30	93 (21.4)	17.8- 25.5
31- 40	169 (39.0)	34.5- 43.6
41- 50	119 (27.4)	23.4- 31.8
51 and above	53 (12.2)	9.4- 15.7
Sex		
Male	262 (60.3)	55.7- 64.9
Female	170 (39.2)	34.7- 43.8
Intersex	2 (0.5)	0.1- 1.7
Religion		
Hindu	386 (88.9)	85.6- 91.6
Non-Hindu	48 (11.1)	8.4- 14.4
Residence		
Urban	114 (26.3)	22.3- 30.6
Rural	320 (73.7)	69.4- 77.7
Marital status		
Never married	32 (7.4)	5.2- 10.3
Married	284 (65.4)	60.8- 69.8
Widowed, separated, divorced	118 (27.2)	23.2- 31.6
Education		
Illiterate	140 (32.2)	28.0- 36.8
Primary	130 (30.0)	25.8- 34.4
Secondary	125 (28.8)	24.7- 33.2
Graduation and above	39 (9.0)	6.6- 12.1
Present occupation		
Unemployed	144 (33.2)	28.9- 37.7
Employed	290 (66.8)	62.3- 71.1
Socioeconomic status*		
I	23 (5.3)	3.5- 7.9
II	48 (11.1)	8.4- 14.4
III	66 (15.2)	12.1- 18.9
IV	158 (36.4)	32.0- 41.0
V	139 (32.0)	27.8- 36.6
Economic dependency		
Independent	287 (66.1)	61.6- 70.4
Dependent	147 (33.9)	29.6- 38.4
Type of family		
Nuclear	272 (62.7)	58.0- 67.1
Joint	162 (37.3)	32.9- 42.0

*Mod BG Prasad Classification

Quality of life in different domains

The mean scores in the six domains of QoL were maximum for the level of independence (15.7 ± 2.6) followed by the physical domain (15.5 ± 3.0), while environment domain (11.7 ± 1.8) had the least mean. Other domains were psychological (14.6 ± 2.0), social relationship (13.0 ± 2.9) and SRPB domain (13.1 ± 2.8). All the domains, including overall QoL scored better than previous studies, showing an above-average QoL of PLHA from Aligarh [Figure 1]. Domain-based analysis of the WHOQoL showed an adequate internal consistency (Cronbach's $\alpha = 0.660$) and

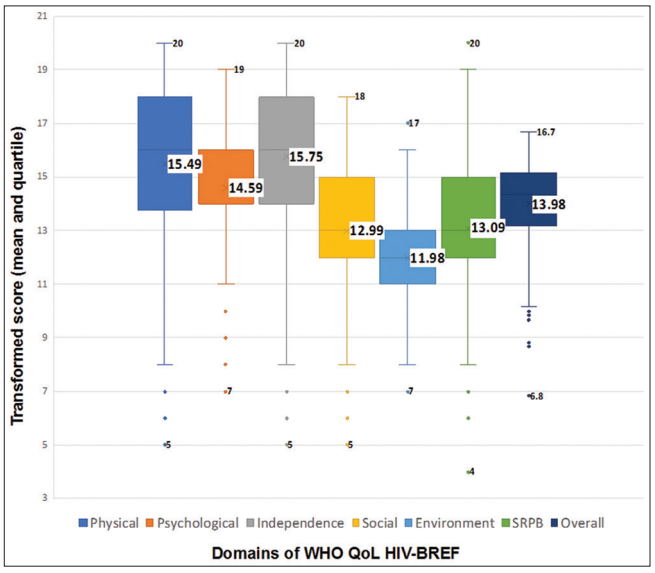

Figure 1: Boxplot of World Health Organization quality of life HIV-BREF domains

moderate-to-strong positive correlation ($r = 0.307–0.756$) among all the domains except social relationship, which had mild to no correlation with other domain scores. Table 2 shows the distribution of QoL scores across various factors of HIV/AIDS patients.

DISCUSSION

We observed in our study that the PLHA from Aligarh were having adequate to a good level of QoL. These scores are higher in comparison with studies from Nepal

Table 2: Distribution of scores of quality of life domains across various social-economic and clinical factors

Variable	Mean±SD					
	Physical	Psychological	Independence	Social	Environment	SRPB
Age						
<35	15.6±2.9	14.5±1.3	16.4±2.5**	13.2± 2.6	11.9±1.8	11.6±2.5***
35+	15.4±3.0	14.7±1.9	15.5±2.7**	12.9±3.0	11.7±1.8	13.7±2.6***
Sex^						
Male	15.2±3.1*	15.0±2.1***	15.7±2.8	13.2±2.9	12.2±1.6***	13.2±2.6
Female	15.9±2.7*	14.0±1.7***	15.8±2.3	12.7±2.9	11.1±1.8***	12.8±2.9
Transgender	15.5±3.5	14.0±0.6	15.0±0.0	10.0±5.7	9.8±0.4	14.5±4.9
Martial status						
Married	15.3±2.9	14.4±2.0***	15.7±2.7	13.6±2.5***	11.9±1.6**	12.9±2.7*
Not married	15.8±3.1	15.1±2.0***	15.7±2.6	11.9±3.3***	11.4±2.0**	13.5±2.8*
Residence						
Rural	15.5± 2.9	14.5±2.0	15.8±2.5	13.0±2.8	11.5±1.7***	13.2±2.7
Urban	15.6±3.2	14.9±2.0	15.6±2.9	12.9±3.1	12.5±1.8***	12.9±2.9
Socioeconomic status*						
I, II, II	16.1±2.5**	15.4±1.9***	16.5±2.2***	12.4±3.1**	12.9±1.7***	13.2±2.7
IV and V	15.2±3.2**	14.3±2.0***	15.4±2.8***	13.2±2.8**	11.2±1.5***	13.1±2.8
Family type						
Nuclear	15.3±3.1	14.4±2.1**	15.6±2.8	12.9±2.9	11.7±1.8	13.0±2.7
Joint	15.8±2.7	15.0±1.9**	16.0±2.4	13.1±2.9	11.7±1.7	13.2±2.8
Family support						
Satisfied	15.6±2.9	14.7±2.0	15.9±2.6*	13.5±2.6***	11.9±1.7***	13.2±2.6
Dissatisfied	14.9±3.4	14.2±2.4	15.1±2.9*	10.1±3.1***	10.8±1.6***	12.4±3.3
Literacy						
Illiterate	15.5±3.2	14.2±1.9**	15.6±2.9	12.9±2.9	10.6±1.6***	13.1±2.7
Literate	15.5±2.9	14.8±2.1**	15.8±2.5	13.0±2.9	12.3±1.6***	13.1±2.8
Employment						
No	15.3±3.2	13.8±1.8***	14.9±2.8***	13.2±2.8	11.3±1.7**	12.9±3.0
Yes	15.6±2.9	15.0±2.0***	16.2±2.4***	12.9±2.9	11.9±1.7**	13.2±2.6
Social support						
Present	15.3±3.2	14.6±2.1	15.9±2.9	12.8±2.9	12.2±1.6**	13.0±3.2
Absent	15.5±2.9	14.6±2.0	15.7±2.6	13.0±2.9	11.6±1.8**	13.1±2.6
Distance						
50 or less	15.3±3.0	14.6±2.0	15.7±2.7	12.9±3.0	12.4±1.5***	12.9±2.9
>50	15.7±2.9	14.6±2.1	15.8±2.6	13.2±2.6	10.5±1.5***	13.4±2.5
Felt stigma						
Yes	14.6±3.6*	13.9±2.5**	15.2±3.1	11.2±2.8***	11.6±1.7	11.5±3.3***
No	15.7±2.8*	14.8±1.9**	15.8±2.5	14.3±1.8***	11.9±1.8	13.4±2.5***
Services satisfaction						
Satisfied	15.5±3.0	14.6±2.1	15.8±2.6	13.0±2.9	11.8±1.7**	13.1±2.8
Dissatisfied	15.8±3.4	14.7±1.8	15.7±3.0	12.2±2.9	10.9±1.8**	13.5±2.1
Side effects						
Yes	13.8±3.5***	13.6±2.4***	14.4±3.0***	12.9±3.0	11.3±1.7*	11.9±3.0***
No	15.9±2.7***	14.9±1.9***	16.0±2.4***	13.0±2.9	11.8±1.8*	13.4±2.6***
Time since diagnosis (years)						
<5	15.3±3.0	14.5±2.1	15.6±2.6	12.9±2.9	11.8±1.9	12.4±2.6***
>5	15.8±2.8	14.8±1.9	16.1±2.7	13.2±2.9	11.6±1.5	14.5±2.6***
WHO staging						
I (asymptomatic)	17.2±1.6***	14.9±1.9***	16.8±1.9***	12.8±2.8	11.7±1.8	13.3±2.6*
II, III and IV	13.2±2.8***	14.2±2.2***	14.4±2.9***	13.3±2.9	11.8±1.7	12.8±2.9*
CD4 cells counts						
200 or less	13.4±3.4***	14.4±2.3	13.1±2.2***	13.6±2.9	11.8±1.8	12.9±3.1
>200	15.9±2.7***	14.7±2.0	16.3±2.4***	12.9±2.9	11.7±1.8	13.1±2.7
Depression						
Present	11.6±3.0***	12.1±2.0***	12.5±2.8***	12.1±3.1*	11.6±1.7	9.3±2.6***
Absent	16.2±2.3***	15.1±1.6***	16.4±2.1***	13.1±2.8*	11.8±1.8	13.8±2.1***

*$P<0.05$; **$P<0.01$; ***$P<0.001$, ^Tukey HSD test. SRPB: Spirituality/religion/personal belief, SD: Standard deviation

and Bangladesh, as well as other parts of India.[3-5,15-17] However, recent studies from South India and West Bengal have also observed a good level of QoL.[6,18] In terms of QoL, these findings convey an encouraging message for the HIV care, support and treatment under NACP. The free provisioning of drugs with physician consultations from the ART Centres established in almost all of the districts in India may have contributed to better QoL. In our domain-based analysis, we observed there is a need for more attention toward environment and social relationship domain as compared with other domains. Out of six domains, physical and level of independence had higher scores, while the scores of psychological, social relationship, environment and spiritual domain were lower, but within the adequate level of QoL. The internal consistency between the six domains were found to be adequate, with a moderate-to-high correlation among themselves, except the social domain.

The poor QoL was observed among participant belonging to the rural area, who had poor transport facilities, which is consistent with many reports.[4,17] A significant relationship was found between socioeconomic status, literacy and employment with the QoL domains. A poor score of QoL domain was observed in patients belonging to a lower socioeconomic class, who were illiterate and unemployed. This finding is consistent with previous researches.[15,17,19-22] We observed that lower socioeconomic status was associated with poorer QoL in all domains, with the exception of spirituality, while employment status was seen having an effect in psychological, independence and environment domain. These findings highlight the need to improve the overall social and economic status, by providing employment opportunities, social security and financial assistance to PLHA. HIV/AIDS is an important hurdle in finding employment, on the other hand, being employed act as a positive enforcement of usefulness for the individual.[22] Literate patients, apart from better job opportunities, have better attitude toward the disease understanding, its prevention and management, and have a better comprehend to compliance and side effects– which was also found to be an important determinant of poor QoL in our study. Although contrarily to our finding of positive relation of literacy and QOL, which is also observed in others studies,[15,21,23] a study from West Bengal and from Ghana, observed no relationship, while Nigerians PLHA showed higher QoL with no or primary education.[6,8,11]

The social domain related findings in our study is along the lines of previous studies from South India,[23,24] and other developing countries including Nigeria, China, and Brazil.[11,20,25] The relatively poorer social domain reflects the persistence of social isolation, stigmatization and marginalization of PLHA leading to a poor social relationships. While this has improved from previous studies, it still needs to be addressed.[3,15] We observed a significant association between dissatisfaction from family support and social domain– which has been documented in previous studies.[5,26] Contrary to our expectation and previous research,[22,27] presence of social support was not found to be an important determinant of QoL in our study setting, as it was associated only with environment domain. A good and supportive family environment would help the patient feel better and have healthy personal relationships and daily activity, and peer and social support groups may mitigate psychosocial consequences.[26] The studies have observed perceived stigma predicts a poor QoL,[4,9,28] which was also documented in our study population. Thus interventions designed to decrease felt stigma and strengthen positive enforcement against discrimination would improve QoL.

The environment domain had the least score in our study. This is presumably due to the sociodemographic characteristics of the study population as most of the patients belonged to lower socioeconomic class and were unemployed. On top of that, many had to traverse a long distance to collect their monthly supply of antiretroviral medications. The environmental domain had the lowest score in another study from New Delhi.[5] We observed environment domain to be significantly lower in females, unmarried, patients from rural areas who have to travel large distances, illiterate and unemployed with lower socioeconomic status, presence of side effects, dissatisfaction from family, social support as well as services. A study from South India has shown female to have a lower mean of QoL in all domain,[23] while few international studies have documented better QoL in female HIV patients.[16,17]

Most patients in our study were stable, asymptomatic and on long-term treatment, with minimal side effects affecting their daily activity. This is the reason why the physical domain-largely associated with clinical factors, and the domain related to the level of independence were found to have a good score. However, while the physical domains were least affected by sociodemographic factors; higher age, lower socioeconomic status, unemployment along with clinical factors affected the independence domain. While, the psychological domains had satisfactory levels, the SRPB domain had a lower score with further worsening in those reporting higher felt stigma and depression. This is another arena that needs attention. We observed that older patients had significantly better QoL in a spiritual domain. Studies done elsewhere have also observed younger age to be

associated with poor QoL.[4,11] As older patients may be on treatment for long, they may have better cope up with their condition, highlighted by a higher score in QoL, especially in the spiritual domain. Among the clinical factors, similar to previous findings, we found side effects from ART and presence of depression to be significantly effecting all the domains of QoL except for social relationship.[10] These two factors along with low socioeconomic status, were the most important determinants of QoL in our study. Although severity of the side effects has drastically reduced in newer drugs,[29] we inferred from our finding that even mild side effects hamper QoL of patients and should not be ignored. The QoL in HIV patients was adversely affected by the concurrent presence of depression which is consistent with several other studies in different part of the world.[20,22,30,31] Apart from the environmental domain, the presence of depression among HIV/AIDS patients was highly associated with all domains of WHOQoL HIV-BREF. A study from South India found depression to be the strongest negative predictor of the QoL, while another observer those with lack of/mild symptoms of depression experiences 4.91 times good QoL.[10,18] While a high prevalence of depression is enough to incorporate mental healthcare with screening, improving the access to effective depression management might provide an opportunity to raise QoL as well. It was expected that HIV symptoms would adverse QoL of HIV patient, which was confirmed in our study as symptomatic patients had poor QoL in physical, psychological, independence and spiritual domain. These findings support a study from Iran which observed the clinical stage of the disease to be the strongest predictor of QoL in multivariate analysis.[19] While a study from Uttar Pradesh has reported an inverse relationship between different stages of HIV infection with all six domains, it was significant only in Psychological and independence among PLHA from Nepal and with overall QoL in Ghana.[8,16,32] Similarly, we found lower CD4 counts to be associated with physical and level of independence, which has been reported in the literature to affect one or more domains of QoL.[7,11,16,20,23,25] Some of the literature in this is contradictory. It may be due to the different classification of CD4 groups, deferring population as well as different assessment instruments, thereby limiting comparisons between results.[5,33] All these reinforce the importance to comprehensive care support and treatment of PLHA which are now incorporated in test and treat Policy of NACO.[1] Contrary to previous literature,[7,25] we did not find significant association of years of diagnosis and domains of QoL except spiritual domain.

There were a few limitations in our study. The present study was a cross-sectional study based in a hospital setting. As QoL is a dynamic phenomenon and not a constant state, it cannot be assessed in a cross-sectional study. We also refrain from making any causal associations, as the temporality cannot be ascertained, a prospective study needs to be conducted to confirm the findings of this study. It was not a community-based study, opening the gates of selection bias, although most of the PLHA in India avail treatment from these ART centers. Furthermore, we have included the PLHA who were on treatment, that too for > 6 months, which might have excluded a lot of patients, although they are unlikely to be a chronically managed patient, in whom we wanted to observe the QoL. Finally, there might be a limitation of recall biased as the WHOQoL HIV-BREF instrument measures QoL within 4 weeks before the interview.

CONCLUSION

An important contribution of this study to the literature is that the QoL of HIV patients is improving. This was possible because of the long and steady efforts of NACO, and other agencies in managing the HIV/AIDS problem. This study also showed that a significant relationship exists between QoL with sociodemographic variables, economic and clinical factors. In this respect, patients belonging to lower socioeconomic class, having side effects due to ART and presence of depression were found to be the most important in lowering the QoL of the PLHA. In addition, providing good family support, better employment opportunities and reducing stigma could increase levels of QoL of PLHA.

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Conflicts of interest
There are no conflicts of interest.

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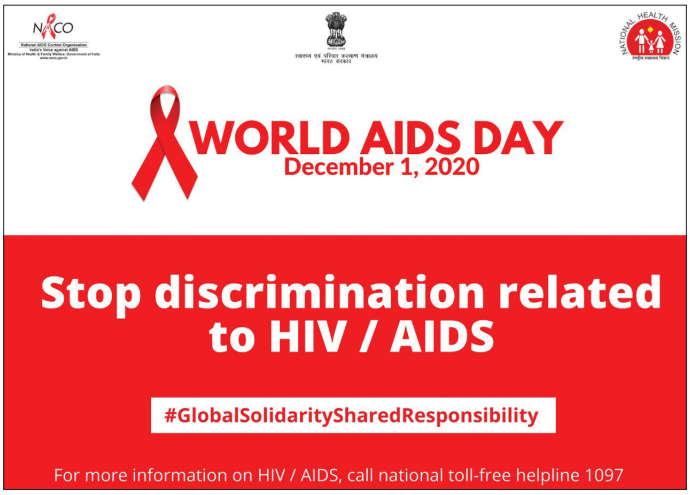

Original Article

A cross-sectional study on parental awareness for newborn screening and assessment of the burden of congenital hypothyroidism and glucose 6-phosphate dehydrogenase deficiency

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Abstract

Introduction: Newborn Screening (NBS) has been one of the most successful health programs and of most paramount importance worldwide but not so in India. Due to the lack of awareness and paucity of laboratory facilities, the disease burden in our population has not yet been established.

Aim and Objective: The aim and objective of the study was to assess the burden of Congenital Hypothyroidism (CH) and Glucose 6-Phosphate Dehydrogenase (G6PD) deficiency in this area by NBS tests and to assess the impact of awareness sessions on the response rate of parents for NBS.

Material and Methods: The screening was conducted in 474 babies of age 48 h up to 8 weeks. The dried blood spots collected were subjected to the following analytical protocol. Thyroid-stimulating hormone (TSH) level and G6PD enzyme activity were analyzed by immunofluorescence method-based neonatal kits. All babies with a positive screening test for G6PD deficiency and CH were asked for venous confirmatory testing after 7 days.

Results: The efficiency of the program for all live birth babies delivered in the institute was 92% (n = 410/445). It was 82% in the first phase of the study period and 98.5% in the second phase. Repeated training of nursing professional reduced the sampling errors from 14.7% in the first phase to 6.1% in the second phase. A total of 11 samples reflected high TSH values, of which one baby confirmed for CH. Of the 24 babies who screened positive for G6PD, four were confirmed for the same. The prevalence for CH and G6PD deficiency was, respectively, 1 in 462 (2/1000) and 4 in 462 (8.7/1000).

Conclusion: Development of expansion of NBS program in the state should be made mandatory for all newborns. The recommendations include awareness among parents, during antenatal and postnatal period and also to health professionals and provision for laboratory facilities for NBS testing at low cost.

Keywords: Congenital hypothyroidism, efficiency, glucose 6-phosphate dehydrogenase, prevalence, recall response, sampling errors

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INTRODUCTION

Newborn screening (NBS) has been one of the most successful health programs and of most paramount importance worldwide but not so in India.[1] The obstacles to access for NBS are enormous, and thus, developments for the program are slow and partial. One of the two major limitations is the cost, as these testing facilities are mainly catered by private laboratories. The diagnostic facilities in India are not available at primary health-care centers. Very few government medical colleges and hospitals provide the facilities for the same and that through by pilot projects or small-scale studies only.[2-4] There are no such related published studies in the state of Chhattisgarh.

The second challenge is the lack of awareness regarding the Inborn Errors of Metabolism (IEM) and NBS program in the Indian population.

The basic requisite for a disorder to be included in the screening program is that there should be enough epidemiological data regarding the disease burden. Besides, there should also be adequate knowledge of natural history; a sensitive diagnostic test which is cost-effective should be available and more importantly, treatment should be effective.[5,6]

Congenital Hypothyroidism (CH) is considered the most common of all IEM. A study by Sanghvi and Diwakar revealed an incidence of 2.1/1000 among inborn term infants.[7] The second most common is glucose 6-phosphate dehydrogenase (G6PD) deficiency in Central India, the percentage varies from 3.4% to 21.3% in tribal population of Bhils and Gonds.[8]

Due to the paucity of laboratory facilities, the disease burden in our population has not yet been established. Hence, the aim of the study was to assess the burden of CH and G6PD deficiency in this area by newborn screening tests.

MATERIAL AND METHODS

The study was conducted in the department of biochemistry with collaboration with the department of pediatrics of our institute. It was a cross-sectional study. As the prevalence of IEM is very less, sample size calculation is not feasible. Our institute is a newly established institute with tertiary care facility. Department of obstetrics was newly established and catered nearly 100 deliveries per month (during the study period: 2017–2018) inclusive of normal and high-risk pregnancy cases. The small size sample population is definitely the major limitation, but the said factors might not affect the prevalence of inborn errors of metabolic disorders. Hence, a convenient sampling method was applied for the study and 474 newborns were recruited for the study. All babies after 48 h up to 8 weeks of age delivered in the institute or attending at the pediatric Outpatient Department (OPD) and admitted in ward for treatment purposes were included in the study. For babies with any sort of complications, sampling was done on the day of discharge. Written informed consent was obtained from the parents of babies after educating regarding the advantages of newborn screening in the ward.

Under strict aseptic precautions, capillary blood was obtained by heel prick and two spots were collected on an adsorbent filter paper (Whatman 903) so that the drop evenly filled the entire circle and equally soaked on both sides of the spot. Once collected, the cards with Dried Blood Spots (DBS) were air-dried at room temperature for 4 h and then transported to the laboratory for analysis in a zipper plastic bag. Criteria for exclusion were as follows:

1. Any sample not fulfilling the above procedure
    i. The circle not evenly filled the entire circle
    ii. The spot not soaked equally on both sides
    iii. The spot not adequately dried
    iv. The DBS sample not transported in a zipper plastic bag.

The parents were called for repeat sampling in case the laboratory receives any improper samples as mentioned above. Samples of those babies who responded to the recall, were re-collected under supervision to be included and processed; however, those who did not respond were considered withdrawn and excluded from the analysis.

The DBS collected were subjected to the following analytical protocol. Thyroid-stimulating hormone (TSH) level and G6PD enzyme activity were analyzed by immunofluorescence method-based Neonatal kits by Labsystems Diagnostics Oy, VANTAA, Finland. Cutoff value considered for TSH was 10 mIU/L and that for G6PD was 3 U/Gm of Hb. Babies with TSH values above 10 mIU/L and G6PD values <3 U/GmHb were immediately informed and called for confirmation. To perform confirmatory tests, venous blood sample was collected in plain vacutainer (one ml for serum TSH and T4 estimation) and in ethylenediaminetetraacetic acid vacutainer (one ml for whole blood G6PD estimation). Confirmatory test for serum TSH along with T4 levels was estimated by chemiluminescence method in Advia Centaur XP and quantitative G6PD activity in whole

blood using enzyme kinetic method by G-Six kit from Tulip Diagnostics.

During the entire study period of 8 months, counseling and awareness programs were conducted in antenatal OPD and postnatal wards and all parents were provided with information brochures regarding NBS and its importance. Similarly, all nursing personals were also made aware of the significance of NBS and frequent training sessions were organized for heel prick collection of DBS samples. One counseling session for each mother was conducted in the postnatal ward prior to signing written informed consent. It included one-to-one conversation, distribution of handout materials in regional languages, and video of the procedure for needle prick.

Counseling and training sessions were also conducted for 16 nursing staffs of postnatal and pediatrics neonatal wards in a batch of four in each month for 4 months. A small batch was deliberately chosen for efficient skill-based hands-on training so that they become competent enough for counseling parents and sample collection. For each batch, 1 h training was conducted for three consecutive days, followed by weekly supervision throughout the sampling period. The training sessions included PowerPoint presentation and printed handouts along with hands-on training for each nursing staff. The study period was divided into two phases, 4 months in each phase. Two phases differed by the fact that in the first phases, the nursing staff were not much aware of NBS and procedure for DBS sampling as compared to the second phase. The first phase is basically the preparatory phase and the second one is the postpreparatory phase to see the effectiveness of preparatory phase. To see the effect of the awareness program and training sessions, a comparison study between the first and second phase of the study was done with respect to the consent of parents for the enrollment of their babies in the study, recall response of parents, and proper sampling of DBS by nursing personals.

RESULTS

The total number of babies enrolled in the study was 474. For the institutional deliveries, the response rate of the parents for consent to enroll their babies in the study for the screening of CH and G6PD deficiency varied from 72% to 89%, average of 82% [n = 142/173; Table 1] in the first 4 months. In the next phase, the efficacy for counseling for enrollment increased to 95%–100% for all the institutional live births delivered. The response rate was observed to be 100% for parents of neonates admitted through OPD [Figure 1]. A total of 43 DBS samples

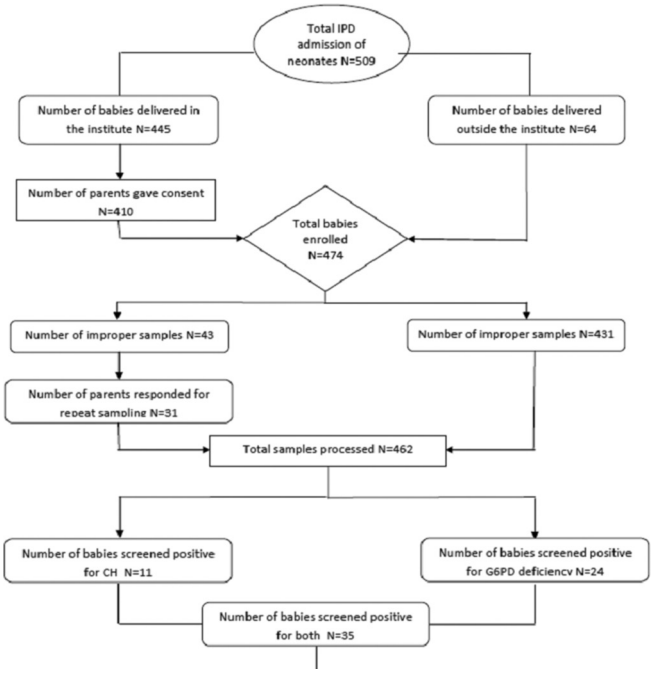

Figure 1: Flowchart depicting the study setting and the sampling

were considered improper during the study period. The response for recall for repeat sampling was about 71% (31 parents of the 43 were responsive). Hence, 12 (2.5%) DBS samples could not be analyzed due to improper sampling and were considered withdrawn. Of the total 462 samples analyzed, 11 babies were found to have raised TSH levels (>10 mIU/L) and 24 were detected as G6PD deficient (<3U/gmHb) in the first screening. The serum TSH and T4 levels confirmed for CH in one baby and the blood G6PD activity in four babies were confirmed to be low. Thus, the prevalence of CH in the studied population was found to be nearly 1 in 462 (0.2%, 2/1000) and that of G6PD deficient was nearly 4 in 462 (0.9%, 9/1000). All the G6PD deficient cases were males and only two presented with hyperbilirubinemia. These babies had no history of ABO or Rh incompatibility.

DISCUSSION

A cross-sectional study was conducted on 474 neonates to estimate the burden of congenital hypothyroidism and G6PD deficiency in this area. The prevalence of CH and G6PD deficiency was found to be 2/1000 and 9/1000 live births, respectively.

The newborn screening program was started as a pilot project to assess the burden of CH and G6PD deficiency in the babies delivered or attending our institute. The efficiency of the program for all live birth babies delivered in the institute was 92% [n = 410/445; Figure 1]. It was

Table 1: Comparison of the laboratory evaluation for newborn screening during the study period

	First phase of 4 months	Second phase of 4 months	Total
Number of institutional deliveries (live births)	173	272	445
Number of live birth babies enrolled from institutional postnatal ward	142	268	410
Response of parents for NBS (only for institutional live birth babies)	82% (142/173)	98.5% (268/272)	92.1% (410/445)
Number of babies delivered outside and admitted in the institute	21	43	64
Total babies enrolled	163	311	474
Number of babies enrolled		410 + 64 = 474	
Improper samples received	14.7% (24/163)	6.1% (19/311)	9.1% (43/474)
Response to recall for repeat sample	75% (18/24)	68.4% (13/19)	72.1% (31/43)
Withdrawal of subjects due to nonresponse to recall for repeat samples	1.3% (6/474)	1.3% (6/474)	2.5% (12/474)
Total number of samples processed	163−6=157	311−6=305	474−12=462
Number of samples with high TSH values	4	7	11 (2.4%)
Number of samples with high G6PD	15	9	24 (5.2%)
Response to recall for confirmatory tests	52.6% (10/19)	81.3% (13/16)	65.7% (23/35)
Confirmed for CH	0	1	1 (0.2%)=2/1000 live births
Confirmed for G6PD deficiency	1	3	4 (0.9%)=9/1000 live births

NBS: Newborn screening, TSH: Thyroid-stimulating hormone, CH: Congenital hypothyroidism, G6PD: Glucose 6-phosphate dehydrogenase

82% in the first 4 months of the study period and 98.5% after that. The main reasons were unwillingness of parents for a prick of their newly born baby and early discharge of mothers due to limited beds available in the ward. The increase in response could be achieved by creating awareness among parents during the antenatal visits and also in the postnatal stay in the ward. All parents were distributed with the basic information sheet during the counseling. Almost none of the parents were familiar to NBS. Not only parents but also repeated attempts to visit the clinicians were made to update them regarding the current practices for NBS. Davis *et al.* in their study also had confirmed regarding lack of awareness for NBS in parents and clinicians and recommended that adequate knowledge of the health-care providers could be essentially the best way to create awareness among parents.[9] The 100% response observed in parents who admitted their babies through OPD could be due to the fact that they were already anxious and were readily willing to go for such health-care facility.

Nearly 9% samples of the study subjects were considered to be improper and the parents were informed and called for repeat sampling. However, the percentage of improper sampling was reduced by about 58% in the second phase. This could be accomplished by providing repeated training to the residents and nursing professionals for sampling. It is of utmost importance to ensure proper sampling because the response to recall for repeat sample was found to be very poor in both the phases of comparison. Parents were tried to be contacted over phone, but many times the contact number was not proper or the number was not attended. If at all contacted, the parents would give consent for sampling during the first immunization schedule, but they did not turn up. On the other way round, some parents were so concerned that they ask for duplicate sampling during their first immunization schedule, even if the first test was normal.

A total of 11 (2.4%) samples reflected raised TSH values. Of these, 6 cases had a history of intrauterine growth retardation, 3 were preterm, 8 babies were low birth weight, and in 4 cases, mother had thyroid dysfunction. One baby (0.2%) was confirmed for the CH with increased trapping function of the thyroid gland due to raised TSH as detected by ^{99}Tc pertechnetate thyroid scan. Kapil *et al.* in their study reported an incidence of 1 in 23 (4.4%) in 613 babies screened in Kangra valley, Himachal Pradesh.[10] Sanghvi and Diwakar in Chandigarh and Shriraam *et al.* in Tamil Nadu, in their studies, had published an incidence of CH of 1:500 (0.2%) and 1:900 (0.1%), respectively.[7,11]

G6PD deficiency was detected in 5% (n = 24) of the population in the initial screening. However, only four (0.9%) got confirmed. All the affected babies were male. Two babies had hyperbilirubinemia during the stay. The babies were re-confirmed for G6PD deficiency after 1 month, during the immunization visit. Kaur *et al.* had revealed 0.8% prevalence in 6813 babies screened in Chandigarh.[12] On the other hand, an incidence of 16.7% was reported by Mohanty *et al.* in 191 babies screened in Orissa.[13] The low prevalence of G6PD observed in our study could be attributed to the low influx of tribal families to our tertiary care center and the prevalence of G6PD deficiency is known for its prevalence in the tribal community.[8]

The response to recall for confirmatory tests was 50 times more in the second phase of the study. Repeated telephonic conversation and counseling played a key role for the recall response. It was made a mandatory to visit the pediatrician during the first immunization schedule so that they can be counseled for NBS if they did not have the report.

During the later stage of the study period, a 7-month child in the OPD (delivered in our institute) was diagnosed with CH with features of delayed milestone and lethargy. The case could have been diagnosed early provided the parents would have given consent for the NBS when asked for consent.

Strengths and limitations

For the first time, a study was conducted on laboratory screening of newborns for CH and G6PD deficiency in a government hospital in this state. Our institute is the first government institute to provide laboratory diagnostic facility for newborn screening in the state. The major limitation of the study is the low sample size. However, 1 case of CH in 462 reflects a very high incidence which cannot be ignored. The toll could have been more provided there was a better response by parents for confirmatory tests and re-sampling. A high rate of improper sampling and incorrect contact number had also influenced the evaluation of NBS program.

Interpretation and implication

The study was first of its kind in assessing the burden of CH and G6PD deficiency in the area. Although the diagnostic facilities are available in a few private laboratories, this is a step forward to provide the state-of-art facility in laboratory testing to the people of Chhattisgarh, at a minimal cost. The patient will be directly benefitted as the treatment and management can be started at an earlier stage for the patient.

Controversies

There are no controversies except that the incidence of G6PD deficiency in newborns was very low (0.9%). This could be ascribed to the fact that the study population consisted of institutional deliveries and those attending OPD. As per the study on district-wise distribution of G6PD deficiency in different states, the prevalence in the tribal population ranged from 10% to 20%.[8] Being in the urban locality, the tribal inflow to the hospital is not enough to predict a high incidence of the disorder.

Future research

Large-scale studies or task force projects, including various urban and rural hospitals and primary health-care centers, in different districts of the state, can be endorsed for mapping of the actual burden of inborn born errors of metabolism with more parameters.

CONCLUSION

Development of expansion of NBS program in the state should be made mandatory for all newborns. The recommendations include awareness among parents, during antenatal and postnatal period and also to health professionals and provision for laboratory facilities for NBS testing at low cost.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

A study of factors influencing academic performance of undergraduate medical students

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Abstract

Introduction: An important indicator of quality of medical education is students' academic performance and the study of factors which influence the academic performance of medical students is important as it can provide information to improve educational programs.

Material and Methods: This was a cross-sectional study involving medical students who passed their final professional examinations and were about to start their internship training. They were asked to complete an anonymously administered feedback form which contained questions regarding the academic performance of students in all the professional examinations of MBBS along with background characteristics of students. Data entry and statistical analysis was carried out using statistical software SPSS version 12. The primary outcome was the proportion of students in different levels of academic achievement. The secondary outcome was the factors associated with different levels of academic achievement. Descriptive statistics were used to describe the distribution of all variables. For finding out the association, an analysis using Chi-square test was done for qualitative data.

Results: The mean age of participants was 22.7 ± 0.67 years (range 21–25). About 43.6% of the students had scored <60% marks, while 56.4% had scored more than that. High-performing students were found to spend more time on hobbies as well as on physical activities and less time on social networking sites as compared to the average-performing students. Study and sleep habits of high performers were significantly different from average performers.

Conclusion: Many factors were found to have a significant association with academic performance of students such as residence, having a doctor parent, spending time on personal hobbies and social networking sites, time spent on study, and duration of sleep a day before examination.

Keywords: Academic performance, examination, factors, medical students

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INTRODUCTION

The primary aim of undergraduate medical education is to generate doctors who are competent enough to carry out their duties and responsibilities. In the past few years, there has been an increased focus on the shortage of doctors in our country and the need for increasing the number of medical seats. As a result, the number of undergraduate

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medical seats has increased considerably, but the quality of medical education is facing challenges. As medical teachers, our focus should be to identify these challenges and rectify them wherever possible.

An important indicator of the quality of medical education is students' academic performance which is a known predictor of professional competence in long-term careers. Research has shown that students with poor academic performance are at increased risk of subsequent professional misconduct.[1] The study of factors which influence the academic performance of medical students becomes more important under these circumstances as it can provide information to improve educational programs.

Objectives

- To study the pattern of academic performance of undergraduate medical students
- To study the association between different factors and academic performance of study subjects.

MATERIALS AND METHODS

A cross-sectional study was conducted by the department of community medicine of a premier medical institute of Delhi in the last week of December 2017. The study participants included all the medical students who passed their final professional examinations held in November–December 2017 and were about to start their internship training from January 01, 2018. They were informed about the purpose of the study and explained that their participation is purely voluntary and they can opt out of the study if they feel so. They were asked to complete a feedback form which was self-administered and filled anonymously. This feedback form contained questions regarding the academic performance of students in all the professional examinations of MBBS along with background characteristics of students like the place of residence, schooling, education, and occupation of parents. Academic performance was measured by average marks obtained in all the university professional examinations. The students were categorized into two groups based on the average marks obtained by them. Those who obtained more than 60% marks were categorized as high performers and the students having 50%–60% marks were included in the average performer category. In addition, information regarding time spent by students on extracurricular activities such as hobbies, physical activities, television, social media, and study was also recorded. They were inquired about their habits and pattern of study and sleep, on routine days as well as a day before examinations.

Data entry and statistical analysis was carried out using statistical software SPSS version 12. The primary outcome was the proportion of students in different levels of academic achievement. The secondary outcome was the factors associated with different levels of academic achievement. Independent variables which were assessed include background characteristics of students such as age, place of residence, education of parents, their schooling, coaching taken for clearing entrance examination, and other factors like time spent on hobbies, physical activities, social networking sites, and on study. The dependant variable includes academic performance. Descriptive statistics were used to describe the distribution of all variables. For finding out the association, an analysis using Chi-square test was done for qualitative data.

Ethical consideration

The feedback forms were collected anonymously without any identifying information of the respondents. The students filled the forms voluntarily and their confidentiality was maintained. As the information collected was totally anonymous, permission for data analysis and presentation along with waiver of written consent was obtained from the Institutional Ethics Committee.

RESULTS

The proforma was completely filled by 110 interns who were included in the final data analysis. The mean age of participants was 22.7 ± 0.67 years (range 21–25). The students were divided into high performer and average performer groups based on the average marks obtained during all the MBBS professional examinations taking 60% as cutoff point. About 43.6% of the students had scored <60% marks, while 56.4% had scored more than that.

All of the students had undergone some coaching for clearing the pre-medical entrance test. The majority of the students (92.7%) belonged to urban areas. A considerably large proportion of students did their schooling from private schools. Nearly 78.2% had studied in private schools till middle school level and 80.9% had studied from private schools after senior secondary school level. Almost 90% of the students' fathers were educated up to a minimum of graduate level, while mothers of 70% of the students had studied up to graduation or higher level. About 13.6% of the students had at least one parent who was doctor. On relating students' performance with the occupation of both father and mother, it was found that the proportion of students with doctor parents

was significantly higher in high-performing students as compared to average-performing ones. Almost two-fifth of the participants were day scholars and the rest were staying in the college hostel. We did not find any significant association between the place of living and academic performance [Table 1].

We found that medical students do not devote much time to their hobbies. The frequency of time the students spent on hobbies was quite less in both the groups, but the high-performing students were found to spend time on hobbies significantly more frequently as compared to the average-performing students ($P < 0.05$) [Table 2].

The time spent on physical activities by the students is also very less with a slightly less than one-fourth of the students never doing any physical activity. High-performing students were found to spend more time on physical activities as compared to average-performing students, although it is not statistically significant [Table 2]. Similarly, watching TV is not very popular among medical students, and it was not found to have any significant relationship with academic performance ($P > 0.05$).

However, using social networking sites was found to be quite popular among the students. The high-performing students used to spend significantly lesser amount of time on social

Table 1: Demographic profile of average- and high-performing students

Background characteristics	Average performers	High performers	Total	*P*
Residence				
Urban	41 (85.4)	61 (98.4)	102 (92.7)	<0.05
Rural	7 (14.6)	1 (1.6)	8 (7.3)	
Schooling upto middle				
Government	12 (25.0)	12 (19.4)	24 (21.8)	>0.05
Private	36 (75.0)	50 (80.6)	86 (78.2)	
Schooling senior secondary and after that				
Government	10 (20.8)	11 (17.7)	21 (19.1)	>0.05
Private	38 (79.2)	51 (82.3)	89 (80.9)	
Education of father				
Below graduate	5 (10.4)	6 (9.7)	11 (10.0)	>0.05
Graduate and above	43 (89.6)	56 (90.3)	99 (90.0)	
Education of mother				
Below graduate	18 (37.5)	15 (24.2)	33 (30.0)	>0.05
Graduate and above	30 (62.5)	47 (75.8)	77 (70.0)	
Occupation of father				
Doctor	2 (4.2)	14 (22.6)	16 (14.5)	<0.01
Any other	46 (95.8)	48 (77.4)	94 (85.5)	
Occupation of mother				
Doctor	2 (4.2)	12 (19.4)	14 (12.7)	<0.05
Any other	46 (95.8)	50 (80.6)	96 (87.3)	
Place of living				
Hostel	32 (66.7)	33 (53.2)	65 (59.1)	>0.05
Home	16 (33.3)	29 (46.8)	45 (40.9)	

Table 2: Time spent on extracurricular activities among average- and high-performing students

	Average performers	High performers	Total	*P*
Time spent on hobbies				
Everyday	3 (6.3)	11 (17.7)	14 (12.7)	<0.05
At least twice a week	2 (4.2)	8 (12.9)	10 (9.1)	
At least once a week	18 (37.5)	27 (43.5)	45 (40.9)	
At least once a month	21 (43.7)	11 (17.7)	32 (29.1)	
Never	4 (8.3)	5 (8.1)	9 (8.2)	
Time spent on physical activities				
Everyday	3 (6.3)	9 (14.5)	12 (10.9)	>0.05
At least twice a week	4 (8.3)	10 (16.1)	14 (12.7)	
At least once a week	13 (27.1)	16 (25.8)	29 (26.4)	
At least once a month	14 (29.2)	16 (25.8)	30 (27.3)	
Never	14 (29.2)	11 (17.7)	25 (22.7)	
Time spent in watching TV per day				
Do not watch	24 (50.0)	28 (45.2)	52 (47.3)	>0.05
<2 h	19 (39.6)	28 (45.2)	47 (42.7)	
>2 h	5 (10.4)	6 (9.7)	11 (10.0)	
Time spent on social networking sites per day (h)				
<2	14 (29.2)	33 (53.2)	47 (42.7)	<0.01
2-4	19 (39.6)	26 (41.9)	45 (40.9)	
>4	15 (31.2)	3 (4.8)	18 (16.4)	

networking sites than the average-performing students ($P < 0.01$). More than half of high performers spent <2 h in a day, while almost one-third of average performers spent more than 4 h/day on social networking sites. This shows that spending too much time on social networking sites negatively impacts academic performance [Table 2].

Almost all of the high-performing students used to study daily on routine nonexamination days with a very large proportion studying for more than 2 h daily, whereas in the average performing group, approximately one-fourth of the students did not study daily on nonexamination days and only one-third used to study for more than 2 h daily. This difference was found to be statistically highly significant ($P < 0.001$). When asked about the time spent on studying a day before examination, the maximum number of high-performing students (88.7%) reported studying for 10–15 h, while in case of average-performing students, they studied either < 10 h (39.6%) or more than 15 h (35.4%) with only one-fourth of the students studying for 10–15 h. The two groups differed significantly in this aspect also ($P < 0.001$) [Table 3].

As far as the preferred time for study is concerned, almost two-third of the students preferred to study late night. The proportion of students who preferred to study early morning was slightly higher (35.5%) in the high-performing group as compared to the average-performing group (27.1%). A majority of students (64.5%) preferred to study alone rather than group study. We did not find any significant association of academic performance of students with preferred time or preferred method of study ($P > 0.05$) [Table 3].

This study shows that a majority of students in both average- and high-performing categories slept for more than 6 h on routine days. Almost two-third of the students (67.7%) from high-performing group and half (50%) from average-performing group reported sleeping for 6–8 h on nonexamination days. Students from both the groups used to sleep for lesser time on the day before examination as compared to routine days. However, a majority of high-performing students slept for 4–6 h, while the majority of average performers slept for less than 4 h. This difference between the two groups was found to be statistically highly significant ($P < 0.01$) [Table 4].

DISCUSSION

The present study focused on the factors that affect the academic performance of medical students. More than half (56.4%) of the students had scored more than 60% average marks in MBBS. A majority of students did their schooling from private schools. The proportion of students studying from private schools is larger after senior secondary level as compared to the middle level. This shows that more students prefer to study in private schools after middle school level. The reason for this may be that private schools are supposed to provide academically better environment which will, in turn, help in clearing medical entrance examination. Kumwenda *et al*. have reported that students from independent private schools performed better than students from state-funded schools.[2]

The parents of majority of students had studied at least up to graduation level. We did not find any association of educational status of father or mother with the academic performance of the students. However, out of the high performers, fathers of one-fourth of the students and mothers of one-fifth of the students were doctors, while this proportion was significantly less in average-performing group. The reason may be that doctor parents can give better guidance and support to their children studying medicine as compared to parents from other professions. Our findings

Table 3: Pattern of study habits among average- and high-performing students

	Average performers	High performers	Total	*P*
Time spent on study during nonexamination days				
Do not study daily	13 (27.1)	01 (1.6)	14 (12.7)	<0.01
<2 h	18 (37.5)	3 (4.8)	21 (19.1)	
2-4 h	13 (27.1)	45 (72.6)	59 (53.6)	
>4 h	4 (8.3)	13 (20.9)	17 (15.5)	
Time spent on study a day before examination				
<10 h	19 (39.6)	4 (6.5)	23 (20.9)	<0.01
10-15 h	12 (25.0)	55 (88.7)	67 (60.9)	
>15 h	17 (35.4)	3 (4.8)	20 (18.2)	
Preferred time for study				
Early morning	13 (27.1)	22 (35.5)	35 (31.8)	>0.05
Late night	35 (72.9)	40 (64.5)	75 (68.2)	
Preferred method for study				
Studying alone	30 (62.5)	41 (66.1)	71 (64.5)	>0.05
With a friend	12 (25.0)	18 (29.1)	30 (27.3)	
Studying in groups	6 (12.6)	3 (4.8)	9 (8.2)	

Table 4: Pattern of sleep habits among average- and high-performing students

	Average performers	High performers	Total	*P*
Duration of sleep on nonexamination days (h)				
<6	5 (10.4)	5 (8.1)	10 (9.1)	>0.05
6-8	24 (50.0)	42 (67.7)	66 (60.0)	
>8	19 (39.6)	15 (24.2)	34 (30.9)	
Duration of sleep a day before examination (h)				
<4	34 (70.8)	2 (3.2)	36 (32.7)	<0.01
4-6	5 (10.4)	57 (91.9)	62 (56.4)	
>6	9 (18.8)	3 (4.8)	12 (10.9)	

are in accordance with the results of another study involving medical students conducted in the Netherlands which shows that most students had parents with a higher level of education, and approximately 13% of the students had at least one parent with a medical background.[3]

A slightly more than half of the students from high-performing group lived in hostels as compared to two-third of average performers, but there was no significant relationship between the place of living and academic performance. Similar results have been reported by other researchers as well.[4-6]

We assessed the time spent by the students on their hobbies. Interestingly, a larger number of high-performing students (17.7%) spent time on their hobbies daily as compared to average performers (6.3%). Almost two-third of the high performers spent time on hobbies at least once a week or more, while almost half of the average performers did so. This difference was found to be statistically significant. This shows that spending time on hobbies has a positive association with academic performance. Hence, medical students should be encouraged to spend some time on their hobbies and recreational activities which would be expected to improve their academics, although others authors have reported no significant association between time spent on personal hobbies and academic performance of medical students.[4]

As far as time spent on physical activities is concerned, high-performing students spent more time on physical activities as compared to average-performing students, although it is not statistically significant. Overall, this shows that medical students lead a very sedentary life which may not be a healthy practice. Results of another study by Stroebele *et al.* show that less physical activity by students is related to lower academic performance.[7]

Almost half of the participants did not watch TV and a slightly lower proportion watched it for <2 h in a day. We did not find any association of spending time watching TV and academic performance. Similar results have been reported from other studies,[4] but one study shows the association of hours of TV watching with academic performance.[7] We found that watching TV is not very popular among our study participants and only a minority of students watched TV for more than 2 h in a day.

However, in our study, students reported that they spent a considerable amount of time on social networking sites. All the students were active on these sites. The high-performing students used to spend a lesser amount of time on social networking sites than the average-performing students. We found this association highly significant ($P < 0.001$). It can possibly act as a distraction from academics and would lead to a wastage of time which could better be utilized for academic purposes by the students. This aspect needs further exploration, and there is a need to conduct extensive research in this area to identify not only the extent of the problem but also the reasons and remedies for it. Al Shawwa *et al.* have also found similar results stating that the amount of time spent on social networking had a significant effect on students' performance.[4] Another study by Rithika and Selvaraj shows that students use social media extensively, and there is a significant relationship between social media usage and student's academic performance.[8]

A maximum proportion of high-performing students reported studying more than 2 h a day on routine nonexamination days, while almost one-third of the students in the average-performing group did so. The proportion of average-performing students who studied <2 h daily and who do not study daily is quite large as compared to high-performing students. This difference was found to be statistically highly significant. This clearly reflects that spending more than 2 h a day on the study on a regular basis is a positive predictor of better academic performance and irregular study habits deteriorate students' performance in examination.

We also found a statistically significant difference in the time devoted to studying on the day before examination in both the groups. While a majority of high performers typically spent 10–15 h on study, a large proportion of average performers spent either <10 h or >15 h on study on the day before examination. These findings are

in contrary to another research which shows no effect of duration of study prior to examination and number of hours of studying on the day before examination on academic achievement.[4] Our results might reflect that not studying on regular basis and spending excessive time on study (more than 15 h) on the day before examination has a negative effect on academic performance of students which is also there when students devote <10 h to studying before examination. Our results are consistent with findings of Alos *et al*. who have concluded that it is important to study over a period of days rather than waiting and leaving everything till the last minute.[9]

A major proportion of students preferred to study late night than early morning, but no significant difference was found in the two groups with regard to the preferred time of study and preferred method of study which included studying alone, studied with a friend, or studying in groups, although a larger proportion of students in both the groups preferred to study alone rather than with friends. These findings are in accordance with the results of a similar research conducted in Iran.[10] Other studies have reported a significant difference in the method of study where high-performing students preferred to study alone, and students with lower performance preferred group study.[4,11]

This study shows that a lack of sleep a day before examination adversely affects the academic performance and sleeping for a duration of >6 h before examination also results in decline in academic performance. This may be because of the vast medical curriculum which requires a long time for revision, for which the students have to compromise their sleep, but sleep duration of <4 h may result in mental exhaustion, thereby adversely affecting the recall capacity during the examination, which will ultimately deteriorate students' performance. Similarly, Shareef *et al*. have reported that to comply with large academic load, many of medical students do not devote much time to rest or sleep, especially when it is close to their examinations.[12] Veldi *et al*. have reported that complaints about sleep problems are common in young medical students and sleep quality is significantly associated with academic progress.[13]

A study conducted by Al Shawwa *et al*. in Saudi Arabia also shows that a significantly higher proportion of medical students with low grade point average tend to sleep for longer duration a day before the examination as compared to students with high grade point average.[4]

In contrast to our findings, Reddy *et al*., from Uttrakhand, have found no correlation between the duration of sleep before the examination and academic performance.[14] Another study conducted among school students shows that sleeping for >9 h/night is associated with better grades. This difference could be due to the difference in course standards.[7]

CONCLUSION AND SUGGESTIONS

The study participants had an overall good academic performance, with 56% scoring more than 60% marks. Many factors were found to have a significant association with academic performance of students like residence, having a doctor parent, spending time on personal hobbies, spending time on social networking sites, time spent on study, and duration of sleep a day before examination. We found that not studying on a regular basis and spending excessive time on study and sleeping <4 h a day before examination has a negative effect on academic performance. We did not find any association of schooling, parents' education, place of living, time spent on physical activities, and watching TV and preferred time and method of study on academic achievement of medical students. We suggest that to improve academic performance, medical students should be encouraged to spend some time regularly on extracurricular activities like hobbies. They should also devote a minimum of 2 h daily to studying on a regular basis and sleep for 4–6 h on the night before examination. Excessive use of social networking sites should be discouraged, as it may interfere with academics.

Limitations of the study

- The academic performance of students was measured by the information self-reported by the students themselves and could not be cross-verified
- We studied only some of the factors affecting academic performance. To make better inferences, we need a more comprehensive evaluation by including more variables
- We have done a univariate analysis in this study. Multivariate analysis could have been done.

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Conflicts of interest

There are no conflicts of interest.

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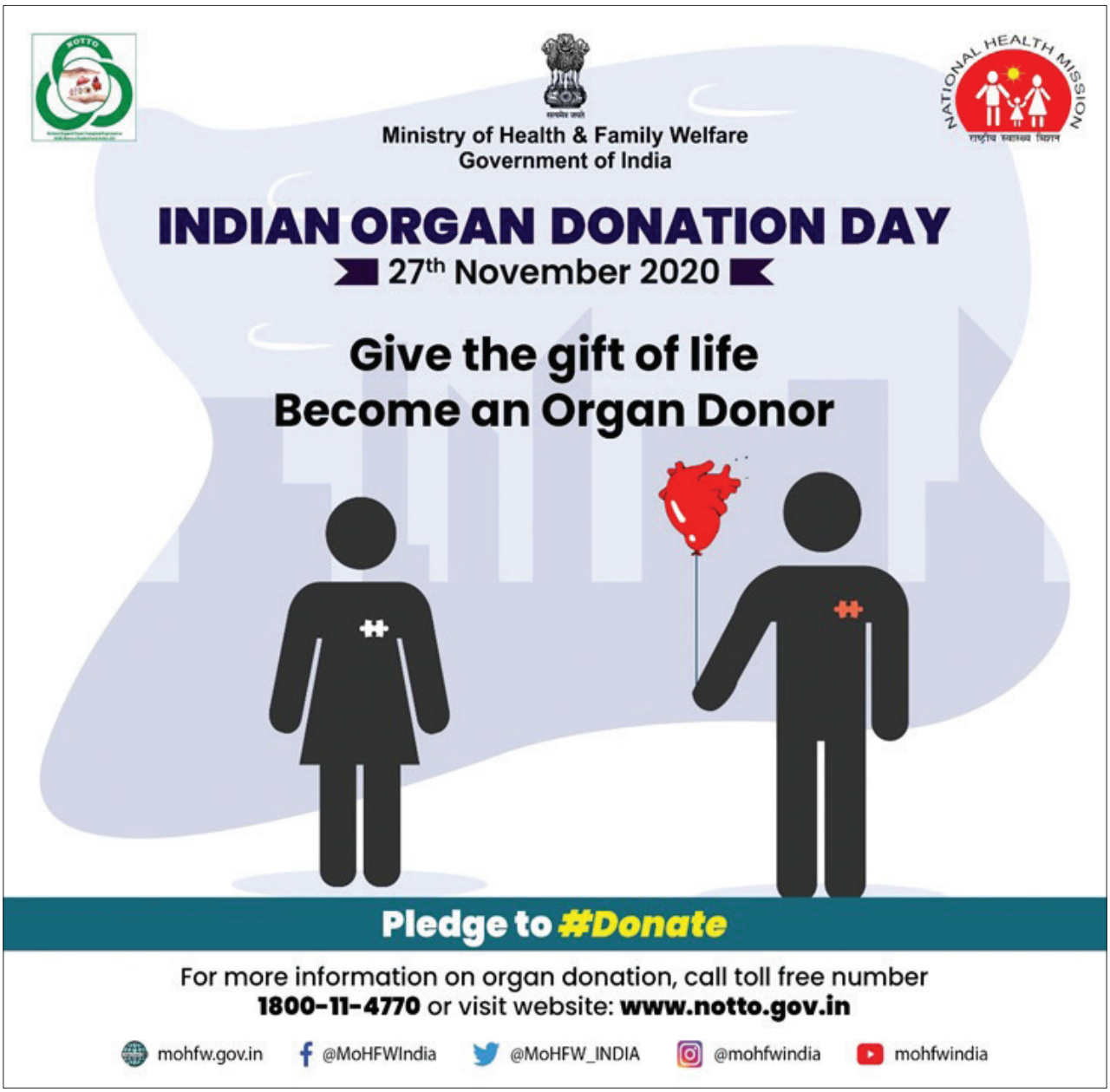

Original Article

Determinants of injectable depot medroxyprogesterone acetate contraception among women of reproductive age: A study from Southern Haryana, India

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Abstract

Introduction: The safety and effectiveness of Depot Medroxyprogesterone Acetate (DMPA) (available by the name of "Antara" in Government of India supply) has resulted in inclusion of this injectable contraceptive in the basket of family planning choices and thus has opened the way for clients to avail of a safe, effective, and hassle-free method with full confidentiality, which is also free of cost in public health facilities all over India.

Material and Methods: This community-based study with cross-sectional design was conducted during April 2019–October 2019. During first 3 months of the study, all the females who adopted the DMPA contraception were included in the study and the factors for opting DMPA were assessed.

Results: Among those who had previously used contraceptives, oral pills were the most prevalent method. Most of the clients who opted to DMPA agreed that they switched because of privacy and confidentiality attached to DMPA. The side effects were reported by more than four-fifth of subjects, and the most common side effects were irregular spotting per vaginally, amenorrhea, and weight gain.

Conclusion: The present study has shown some light regarding the factors responsible for injectable DMPA uptake as a family planning method and the facilitators and barriers to consistent injectable DMPA use. The study findings are expected to be utilized for framing policies to improve compliance of DMPA and making it more acceptable, client-friendly initiative.

Keywords: Confidential, discontinuation, health-care worker, side effects

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INTRODUCTION

India was the first country in the world to launch a family planning program, as early as 1952, with the main aim of controlling its population. An expert committee of the WHO, in 1971, defined family planning as, "a way of thinking and living that is adopted voluntarily, upon the basis of knowledge, attitudes and responsible decisions by individuals and couples, in order to promote the health and welfare of family groups and thus contribute effectively to the social development of a country."[1] In April 1976, the country framed its first "National Population Policy," which was subsequently revised in 2000 and is now running

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under RMNCH+A (Reproductive, Maternal, Newborn, Child, and Adolescent Health, 2013) strategy, so that each and every couple of India get awareness of the need of the family planning methods. India's population has already reached 1.26 billion, and considering the high decadal growth rate of 17.64, the country's population is slated to surpass that of China by 2028.[2]

Over the years, the National Family Planning Programme too has evolved with a shift in focus from merely population control to more critical issues of saving the lives and improving the health of mothers and children through use of reversible spacing methods leading to reduction in unwanted, closely spaced, and mistimed pregnancies and thus avoiding pregnancies with higher risks and chances of unsafe abortions.[3] The widespread adoption of family planning, in a society, is an integral component of modern development and is essential for the integration of women into social and economic life.

The contraceptive prevalence rate provided in National Family Health Survey-4, 2015-2016 (NFHS) among the currently married women is 53.5%, which has decreased from 56.3% reported in NFHS-3.[4] In 2011, the couple protection rate was about 40% for India, which is still far behind to achieve the 60% couple protection rate goal.[5] At present, the spacing options are limited to condoms, intrauterine contraceptive device (IUCDs), and oral pills contributing to 5.9%, 1.9%, and 4.2% share of modern contraceptive prevalence rate, respectively. Development of a long-acting reversible contraceptive such as depot medroxyprogesterone acetate (DMPA) was a goal of family planning researchers for many years.[6]

It is estimated that currently, an estimated forty-two million women worldwide use injectable contraceptives as a method of choice. DMPA is the fourth most prevalent contraceptive and is widely used as an effective, safe, and acceptable method of contraception across the world. DMPA is a private and confidential method, convenient, and easy to use (does not require daily routine or additional supplies); acts for 3 months with a grace period of 4 weeks; completely reversible; does not interfere with sexual pleasure or intercourse; pelvic examination is not required before use; suitable for women who are not eligible to use an estrogen-containing contraceptive; suitable for breastfeeding women (after 6 weeks postpartum) as it does not affect quantity, quality, and composition of breast milk; provides immediate postpartum (in nonbreastfeeding women) and postabortion contraception; and may be used by women at any age or parity if they are at risk of pregnancy.[7]

With a standard regimen, the 1st-year effectiveness is 99.7% when the drug is used correctly. The perfect use failure rate of 0.3% is lower in comparison to 0.5% of female sterilization, 0.8% of IUCD, and 3% of combined oral contraceptives (COCs).[8] A WHO study in more than 3 million woman months of DMPA use has reassured that DMPA does not increase the risk of overall cancers, congenital deformities or infertility and keeps the fertility intact. However, it usually takes about four months longer for a woman to achieve pregnancy after discontinuing DMPA than after discontinuing other reversible contraceptive methods.

The safety and effectiveness of DMPA (available by the name of "Antara" in Government of India supply) has resulted in inclusion of this injectable contraceptive in the basket of family planning choices and thus has opened the way for clients to avail of a safe, effective, and hassle-free method with full confidentiality, which is also free of cost in public health facilities all over India. In Nuh (earlier Mewat) district, the contraceptive use among currently married women is lowest (15.5%) among all districts of Haryana and only 0.2% are using injectables as contraception method while unmet need is very high (31.0%).[4] Taking into consideration the above factors, this study is planned to be conducted in rural area with the objectives to assess the factors responsible for injectable DMPA uptake as a family planning method among eligible couples (married women 15–45 years of age) and to assess the facilitators and barriers to consistent injectable DMPA use.

MATERIAL AND METHODS

Study duration

This community-based study with cross-sectional design was conducted during April 2019–October 2019. During the first 3 months of the study, all the females coming to Primary Health Center (PHC) for opting the DMPA as family planning option were included in the study and the factors for opting DMPA were assessed. Participants opting for injectable contraceptives were screened based on the checklist by the medical officer for the contraindications and then injection DMPA was administered 150 mg deep intramuscular in the gluteal region and next doses were given at an interval of 3 months. Over the next 1 month of the study, the facilitator factors were assessed for those who were coming for the second dose of DMPA, and in the last 2 months of the study, females who remained drop outs for DMPA (who do not turn up for the next dose of DMPA in grace period, i.e. within 4 weeks of due date) were enlisted and home visits were made to contact them to assess the reasons and barriers responsible for

discontinuation of DMPA. Ethical approval was obtained from the Institutional Ethical Committee of SHKM Government Medical College, Nalhar, Nuh, Haryana.

Study setting

The study was conducted in the area catered by PHC, Nagina of district Nuh of Haryana state. PHC, Nagina, is the field practice area of Department of Community Medicine, SHKM Government Medical College, Nalhar.

Study size and sampling

The study included all the eligible couple visiting PHC Nagina to opt for DMPA as a family planning method during the first 3 months of study. At Nagina PHC, nearly 40–50 females/month were opting DMPA as family planning method, so the total study sample size estimated was 120–150 females. In the present study, 124 females those who were willing to participate in the study could be enrolled.

Study participants

The study participants were females those who are currently married and of 15–49 years of age, those who were visiting to PHC Nagina for opting DMPA as a family planning method. They were interviewed at different points of period to assess factors responsible for injectable DMPA uptake and subsequently to assess the facilitators and barriers related to DMPA use.

Exclusion criteria

Females not willing to give verbal informed consent and with contraindications to DMPA were excluded from the study. Among dropouts, the individuals who were not available even after paying three home visits were excluded from the study.

Data collection

Informed written consent was obtained from all the study participants. A pretested, predesigned questionnaire was used by the investigator to interview the selected study participants. The questionnaire included the information regarding age, education, family size, caste, per capita income, facilitators, and barriers related to DMPA.

Statistical analysis

The responses to the schedule by each participant was entered into excel sheet, the data were tabulated, and the data were analyzed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp. Armonk, NY, USA). All the tests were performed at significance level of 5%; thus, an association was significant if the "*P*" <0.05. Categorical variables were presented as percentage (%). The variables with quantitative data were presented as mean (standard deviation). The Pearson's Chi-square test was used for categorical variables and Student's *t*-test for quantitative data.

RESULTS

In the present study, nearly one-third of subjects were having age more than 30 years and one-third of subjects belonged to 26–30 years' age group. More than two-fifth of subjects (43.5%) were illiterate and around only one-tenth of subjects were graduate or diploma or above. More than 90% of subjects were homemakers and around 60% of subjects were staying in joint family. As the Nuh district is Muslim dominated, in the present study, most of the subjects were Muslims (82.3%) and around two-fifth of subjects (38.7%) belonged to lower-middle socioeconomic class [Table 1].

Obstetrics details showed that more than half of the study subjects (54.8%) got married at the age of <21 years, and due to lower age of marriage, majority of them were having family size of four or more. The present study revealed that around one-third of subjects had history of one or more miscarriage or abortion [Table 2].

Out of the total study subjects who came for DMPA, 77.4% were not having any previous contraceptive history. Among those who had previously used contraceptives, oral

Table 1: Sociodemographic characteristics of study subjects (*n*=124)

Characteristic	*n* (%)
Age (years)	
<21	12 (9.6)
21-25	25 (20.3)
26-30	43 (34.6)
More than 30	44 (35.5)
Education	
Illiterate	54 (43.5)
Primary or middle school	28 (22.5)
High school or senior secondary	25 (19.2)
Graduate or diploma or above	17 (13.8)
Occupation	
Homemaker	112 (90.3)
Working	12 (9.7)
Religion	
Hindu	22 (17.7)
Muslim	102 (82.3)
Type of family	
Nuclear	43 (34.7)
Joint	72 (58.1)
Extended	9 (7.2)
Socioeconomic status*	
Upper class	6 (4.8)
Upper-middle class	32 (25.8)
Middle class	33 (26.7)
Lower-middle class	48 (38.7)
Lower class	5 (4.0)

*Udai Pareek socioeconomic status scale

pills were the most prevalent method. Most of the clients who opted to DMPA (82.1%) agreed that they switched because of privacy and confidentiality attached to DMPA. The firsthand source of information or guidance for DMPA was most commonly through health-care workers and friends or social media [Table 3].

During the follow–up, 54.8% of women continued the use of DMPA while more than two-fifth of subjects discontinued the DMPA, i.e., they did not turn up for the second dose of DMPA. The most common reasons for continuation of DMPA were husband unawareness and it does not interfere with sexual intercourse/pleasure. The spouse insistence and side effects were among the frequent reasons for the discontinuation of DMPA [Table 4].

Table 2: Previous obstetrics details of study subjects (*n*=124)

Obstetrics details	*n* (%)
Age at marriage (years)	
<21	68 (54.8)
21-25	39 (31.5)
26-30	12 (9.6)
More than 30	5 (4.1)
Family size	
One	9 (7.3)
Two	11 (8.7)
Three	39 (31.6)
Four or more	65 (52.4)
Gender of children	
Male	75 (60.5)
Female	49 (39.5)
Number of miscarriage/abortions	
Nil	88 (70.9)
One	26 (20.9)
Two or more	10 (8.2)

Table 3: Previously used contraceptives among study subjects

Previous contraceptive details	*n* (%)
Used contraceptives previously (*n*=124)	
Yes	28 (22.6)
No	96 (77.4)
Method used as previous contraceptive (*n*=28)	
Cu-T	7 (25.0)
Oral pills	12 (42.9)
Barrier method	9 (32.1)
Reason for initiating/switching to DMPA* (*n*=28)	
Side effects	15 (53.6)
Spouse insistence	13 (46.4)
A private and confidential method	23 (82.1)
Firsthand source of information or guidance for DMPA* (*n*=124)	
TV	26 (20.9)
Radio	43 (34.7)
Newspapers/magazines	66 (53.2)
The health worker (doctor/midwife/nurse/pharmacist)	99 (79.8)
NGOs	6 (4.8)
Family	36 (29.1)
Friends/social media	80 (64.5)
Neighbor	31 (25.0)

*Multiple choices available. DMPA: Depot medroxyprogesterone acetate, NGOs: Nongovernmental organizations

The side effects were reported by most of the study subjects (84.6%), and the most common side effects were irregular spotting per vaginally, amenorrhea, and weight gain. Around 50% of subjects were convinced with the DMPA use and they were in favor of recommending it to the family members and friends [Table 5].

DISCUSSION

DMPA as a family planning method is being made widely available at free of cost by the Government of India at public health institutions. The acceptance of DMPA as family planning method in Western countries is widespread due to its safety and effectiveness. As per NFHS-4 (2015–16) in Mewat region, the acceptance to

Table 4: Follow-up details of study subjects for depot medroxyprogesterone acetate

Follow-up details	*n* (%)
Continuation of DMPA (*n*=124)	
Yes	68 (54.8)
No	56 (45.2)
Reason for continuation of DMPA* (*n*=68)	
Convenient and easy to use	39 (57.3)
Long term contraceptive	34 (50.0)
Completely reversible	36 (52.9)
A private and confidential method	36 (52.9)
Does not interfere with sexual intercourse/pleasure	56 (82.3)
Safe during breastfeeding	11 (16.2)
Husband unawareness	59 (86.8)
Few side effects than previous contraceptive	46 (67.6)
Reason for discontinuation of DMPA* (*n*=56)	
Side effects	26 (46.4)
Planning conception	6 (10.7)
Spouse insistence	40 (71.4)
Husband away	33 (58.9)
Out of pocket costs/distance from home	21 (37.5)
Health worker (not maintained privacy/not told side effects/benefits)	24 (42.8)
Switched to other contraception methods	10 (17.8)

*Multiple choices available. DMPA: Depot medroxyprogesterone acetate

Table 5: Side effects of depot medroxyprogesterone acetate among study subjects (*n*=124)

Side effects among study subjects	*n* (%)
Side effects of last DMPA use (*n*=124)	
Yes	105 (84.6)
No	19 (15.4)
Side effects of last DMPA use* (*n*=105)	
Irregular spotting PV	73 (69.5)
Amenorrhea	18 (17.1)
Mood changes	9 (8.5)
Weakness	6 (5.7)
Scanty periods	10 (9.5)
Backache/headache	7 (6.6)
Weight gain	17 (16.2)
Will you support and recommend the family and friends to use DMPA? (*n*=124)	
Yes	59 (47.5)
No	65 (52.5)

*Multiple choices available. DMPA: Depot medroxyprogesterone acetate, PV: Per vaginal

any family planning methods is poor.[4] The prevalence of injectable contraceptive use is 3.5% worldwide. It is 15% for Sri Lanka, 10% for Nepal, 7% for Bangladesh, 5.9% for Bhutan, and 2.7% for Pakistan, whereas nationally the current use of DMPA is 0.1%.[8,9]

In the present study, the firsthand source of information or guidance for DMPA was most commonly came through health-care workers and friends or social media. Furthermore, there is local radio station for Mewat, where the health talks are being delivered by faculties of medical college, that is why the radio was one of the source of information regarding DMPA contraception. Similarly, in a study conducted by Taklikar *et al.*, doctors were the most common source of information regarding contraception among the users. In the present study, nearly two-third of subjects were having age more than 26 years who opted for DMPA as family planning method. Similarly, in most of the studies, maximum contraceptives were utilized by the eligible couples of 26–33 years' age group.[10-13]

In this study, the most common reasons for continuation of DMPA were husband unawareness (privacy) and it does not interfere with sexual intercourse/pleasure. Furthermore, health education imparted through local radio station was among the reasons for acceptance of DMPA contraception. In a study by Burke *et al.*, the reasons for acceptance were privacy, convenience, free of hassles of daily intake, and coitus independent.[14]

In the current study, more than two-fifth of subjects discontinued the DMPA, i.e., they did not turn up for the second dose of DMPA. Various studies have shown discontinuation rate of DMPA in the range of 42.5%–70%.[15] Most discontinuations were reported after 1st or 2nd injection when the menstrual irregularities are at their peak. Major reasons for discontinuation were irregular vaginal spotting, amenorrhea, and influence of spouse against the injectable.

In the present study, the side effects were reported by more than four-fifth of subjects, and the most common side effects were irregular spotting per vaginally, amenorrhea, and weight gain. Various other studies had shown similar side effects; those studies had also reported advantages of DMPA use such as no significant effect on blood pressure in postpartum women and lactation remained unaffected.[14,16-18]

Acceptance and continuation can be increased by proper selection of clients thorough counseling, appropriate timing of injections, and good supportive care. Standardized protocols for counseling, periodic orientation for providers, diligent follow-up, and surveillance for side effects are some of the suggestions to sustain and continue DMPA contraceptive program.[19] In Mexico, the continuation rate was high in women who had received in-depth counseling compared to women who received only routine counseling and some general information about DMPA in the first visit. In-depth counseling consisted of detailed information of the drug along with emphasis on how to handle the side effects and this was given at each reinjection visit every 3 months. As a result, at the end of 1 year, only 6% discontinued in this group compared to 27% in the routine counseling group.[20]

CONCLUSION

As single DMPA injection provides contraception for 3 months with minimal side effects, this family planning method might have had higher acceptance level compared to other existing contraceptive methods. The present study revealed that most of the client got the information regarding DMPA contraception through health-care workers and friends or social media. Privacy and no interference in sexual pleasure were responsible for its continuation, while spouse insistence and menstrual irregularities were the most of cause of its discontinuation.

Limitations

Limitation of the present study is that it included clients attending only single health center, so multicentric studies with larger sample size are recommended to develop a suitable program to improve acceptance and remove barriers for DMPA use. Furthermore, the studies on DMPA determinants are very confined in India, so the relevant comparisons of determinants were done using the studies from other developing countries.

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Conflicts of interest

There are no conflicts of interest.

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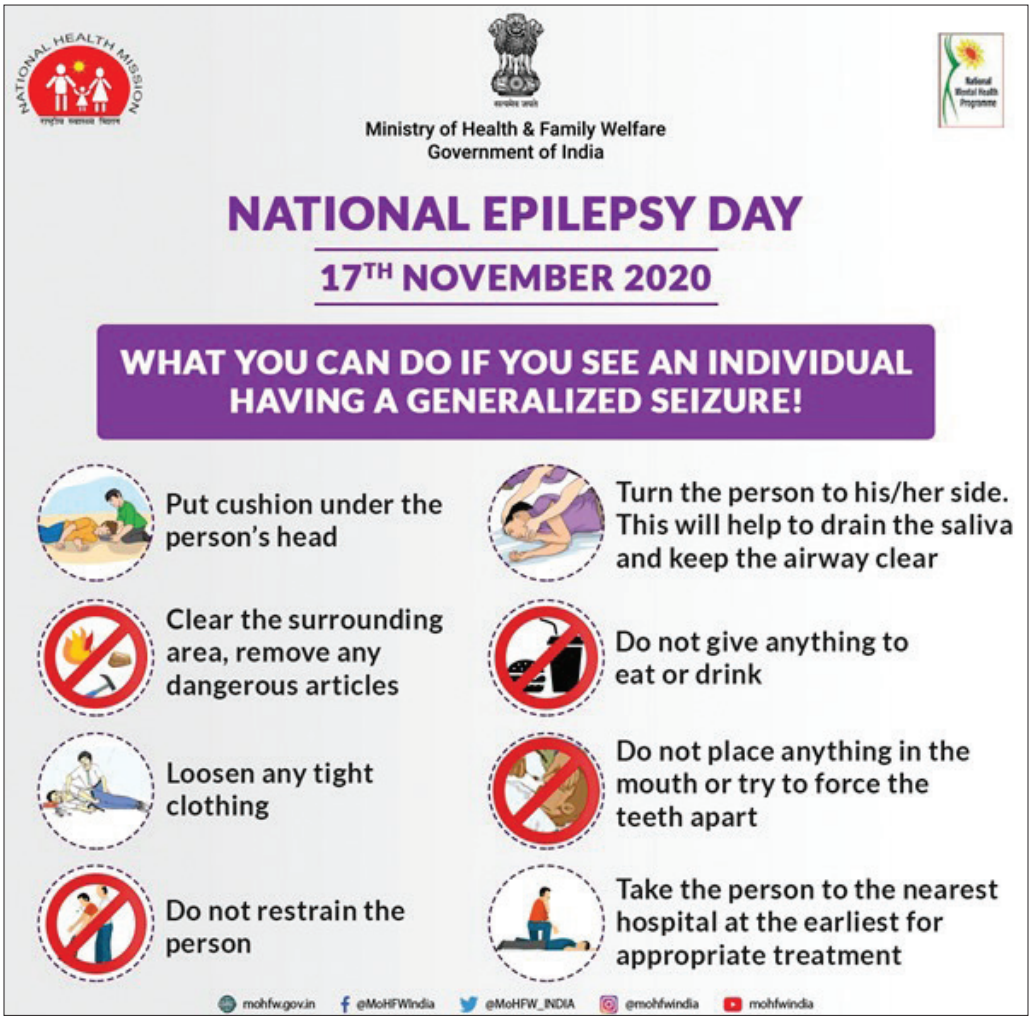

Original Article

Assessment of the relation between obesity, serum lipids, and dietary intake of vegetable oils

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Abstract

Introduction: The study was conducted to assess the association between consumption of particular variety of cooking oil and its effect on serum lipid profile and also on body mass index (BMI).

Material and Methods: The study was conducted at one of the tertiary care hospitals, Ahmedabad city, India. Patients with ≥18 years age who were undergoing "lipid profile" test at central laboratory department of selected hospital and giving consent were the study participants. Details of serum lipid profile were taken from report along with which anthropometric measurements were done and details of diet were taken. Data were entered into MS Excel and were analyzed by frequency, contingency coefficient, and Fisher's exact test.

Results: Total 1000 participants were included in the study, among which 274 (27.4%) had raised lipid levels and 729 (72.9%) were preobese or obese. Association between variety of cooking oil used and cholesterol-high-density lipoprotein ratio revealed contingency coefficient value of 0.042 with *P* value of 0.416. Association between BMI and variety of cooking oil used revealed Fisher's exact value as 83.015 with $P < 0.001$.

Conclusion: Statistical association was not found between serum lipid profile and type of oil used for cooking. Obesity indices revealed significant statistical association with both variety of cooking oil used and serum lipid profile. Dyslipidemia was found to have statistical significant association with raised blood pressure and raised blood glucose.

Keywords: Body mass index, cholesterol, cooking oil, obesity, serum lipids

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INTRODUCTION

Cardiovascular diseases are leading cause of death worldwide due to increase in their prevalence in low-to-middle-income countries.[1] In India, it is increasing at an alarming rate that it accounts for 24% of total deaths among adults aged 25–69 years.[2] Joshi *et al.*[3] in their similar research in India found that 79% of participants had abnormalities in one of the lipid parameters, with 13.9% having hypercholesterolemia. Excessive level of blood cholesterol speeds up the atherogenesis and lowering the level of blood cholesterol reduces incidence of Coronary Heart Disease (CHD).[4] In case of CHD, low-to-very-low-fat and

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high-carbohydrate diet is usually recommended; however, there is strong support that moderate-fat diet can be as effective or even better than usual trend.[5,6] Moreover, at present, available options for reducing obesity and improving blood lipid levels such as dietary therapy and physical exercise are long-term option and hence there is poor adherence.[7] Hence, a novel, effective, and safe strategy such as use of oil with specific fatty acid such as medium-chain fatty acid and mono- and polyunsaturated fatty acid has demonstrated antiobesogenic effect.[8]

Vegetable cooking oils are one of the most common food item consumed in India. Various types of oil are available such as cottonseed, groundnut, soybean, palm, and sunflower. Foods from animal source have cholesterol and rich in saturated fat, but foods from plant source such as vegetable oils do not have cholesterol and they contain more of unsaturated fatty acid.[9] It is generally believed that vegetable oils decrease plasma cholesterol levels although they differ in their cholesterol-lowering capacity. Further research suggests that it is not the amount of fat in diet that matters but it is the type of fat in diet.[10] Quite a few researches can be found which try to establish a relation between consumption of cooking oil and cholesterol level/anthropometric measurement. It is commonly observed in clinical practice that lean and thin individuals have dyslipidemia and obese persons may have normal lipid profile though both consuming the same type of oil. Hence, the present study was planned to find triangular relationship between obesity, serum lipids, and consumption of particular kind of oil with the following objectives.

Objectives

1. To determine the prevalence of dyslipidemia among participants
2. To assess the association between consumption of particular variety of cooking oil and its effect on lipid profile and also on body mass index (BMI)
3. To assess the association between BMI and lipid profile.

MATERIAL AND METHODS

The present study was a cross-sectional study, conducted at one of the tertiary care hospitals of Ahmedabad city, India. Necessary approval was sorted from the institutional ethics committee. A pretested questionnaire was used for data collection. Patients with ≥18 years of age who were undergoing "lipid profile" test at the central laboratory department of the selected hospital were the study participants. Inclusion criteria included all patients aged ≥18 years, referred by any specialty of selected tertiary care hospital to the central laboratory for lipid profile, and willing to give informed oral consent. Patients who were below 18 years or not willing to give informed oral consent were excluded from the study. Duration of the study was from July 2016 to November 2018. The sample size was predefined purposively as 1000 participants.

A pretested questionnaire was used to fill in details of study participants, which included their sociodemographic details, anthropometric measurements, and their investigation reports of blood test. Data were entered into MS Excel and were analyzed using IBM SPSS Statistics for Windows, Version 20.0., IBM Corp., Armonk, NY, USA.

In the study, cutoff for lipid profile results were based on report of the National Cholesterol Education Program Expert panel on detection, evaluation, and treatment of high blood cholesterol in adults.[11]

Similarly, formula to calculate and determine cutoff for various anthropometric measurements/obesity indices such as BMI, Broca's index, Lorentz index, Corpulence index, waist circumference, waist–hip ratio was taken from Park's Textbook of Preventive and Social Medicine, while for Ponderal index, it was obtained from Online Ponderal Index Calculator.[12,13]

Criteria for diagnosing diabetes were based on the WHO recommendations for diagnostic criteria for diabetes and intermediate hyperglycemia.[12] Similarly, for diagnosing of hypertension, Government of India's developed Hypertension guidelines were used.[14]

For statistically testing the association between BMI/type of cooking oil used and lipid profile, cholesterol-high-density lipoprotein (HDL) ratio was taken as gold standard indicator. This is because studies have suggested these atherogenic disturbances may not be adequately reflected by variation in low-density lipoprotein (LDL)-HDL ratio or other indicators.[15,16] The Socioeconomic Classification was done as per modified prasad classification. The value of All India Consumer Price Index for Industrial worker (AICPI - IW) was taken for June 2018 - the declared value was 291 by labour bureau, Govt.of India.[17]

RESULTS

In the present study, 1000 participants were interviewed and assessed. Sociodemographic profile of all participants is shown in Table 1. The mean age of participants was

Table 1: Sociodemographic profile of the study participants (*n*=1000)

Variable	Category	Frequency (%)
Age (completed years)	<30	136 (13.6)
	30-40	125 (12.5)
	40-50	232 (23.2)
	50-60	275 (27.5)
	>60	232 (23.2)
Gender	Male	413 (41.3)
	Female	587 (58.7)
Residence	Urban	493 (49.3)
	Urban slum	448 (44.8)
	Rural	59 (5.9)
Education	Illiterate	140 (14.0)
	Primary	392 (39.2)
	Secondary	258 (25.8)
	Higher Secondary	119 (11.9)
	Graduate and above	91 (9.1)
Occupation	Student	28 (2.8)
	Business	104 (10.4)
	Service	188 (18.8)
	Laborer	92 (9.2)
	Farmer	19 (1.9)
	Retired	100 (10.0)
	Unemployed	11 (1.1)
	Homemaker	458 (45.8)
Socioeconomic class (as per Modified BG Prasad)[#] (*n*=926)	Upper class	52 (5.6)
	Upper-middle class	295 (31.9)
	Middle class	258 (27.9)
	Lower-middle class	241 (26.0)
	Lower class	80 (8.6)
Reason for undergoing lab investigation	Referral from clinical department	929 (92.9)
	Self-referral	71 (7.1)

[#]AICPI (IW) June 2018: 291[17]

Table 2: Lipid profile of the study participants (*n*=1000)

Investigation	Category	Frequency (%)
Serum cholesterol	Desirable	726 (72.6)
	Borderline high	191 (19.1)
	High	83 (8.3)
Serum triglyceride	Normal	704 (70.4)
	High	165 (16.5)
	Hypertriglyceridemia	128 (12.8)
	Very high	3 (0.3)
Serum HDL	Less than normal	174 (17.4)
	Normal	682 (68.2)
	More than normal	144 (14.4)
Serum LDL	Optimal	391 (39.1)
	Near/above optimal	348 (34.8)
	Borderline high	190 (19.0)
	High	52 (5.2)
	Very high	19 (1.9)
Serum VLDL	Normal	812 (81.2)
	More than normal	188 (18.8)
Serum cholesterol/HDL ratio	Optimal	434 (43.4)
	Moderate risk	494 (49.4)
	High risk	72 (7.2)
Serum LDL/HDL ratio	Optimal	612 (61.2)
	Moderate risk	329 (32.9)
	High risk	59 (5.9)

HDL: High-density lipoprotein, LDL: Low-density lipoprotein, VLDL: Very LDL

47.86 ± 13.868 years. A detailed lipid profile of all the participants is described in Table 2.

Out of 593 participants having undergone fasting blood glucose level examination, 340 (57.3%) had normal level, 81 (13.7%) had impaired fasting blood glucose level, and 172 (29.0%) had uncontrolled fasting blood sugar level. Out of 294 participants having undergone postprandial blood glucose level examination, 91 (31.0%) had normal level, 40 (13.6%) had impaired postprandial blood glucose level, and 163 (55.4%) had uncontrolled postprandial blood sugar level. Out of 57 participants having undergone random blood sugar investigation, 54 (94.7%) had normal level and 3 (5.3%) had uncontrolled random blood sugar level. Hemoglobin A1c (HbA1C) report was done by 178 participants; out of which, 39 (21.9%) had normal level, 28 (15.7%) had well-controlled report, and 111 (62.4%) had poorly controlled HbA1C report. On examining blood pressure, 390 (39.0%) had raised blood pressure. In that, 116 (29.7%) had only raised systolic blood pressure, 75 (19.2%) had only raised diastolic blood pressure, and 199 (51.1%) had both systolic and diastolic raised blood pressure.

Obesity indices of all participants are shown in Table 3.

On inquiring about personal history of participants, 615 (61.5%) participants were pure vegetarians, 7 (0.7%) were eggetarians, and 378 (37.8%) consumed all kinds of food. 281 (28.1%) participants had in the past or at present were having addiction, among which 278 used product containing tobacco and 15 told of consuming alcohol. 352 (35.2%) participants informed of having stress in their life. On asking history of present/past noncommunicable diseases (NCDs), 489 (48.9%) participants had positive history of any NCDs. Total 206 participants were suffering from hypertension, 114 had diabetes, while 100 individuals had both hypertension and diabetes. Among total, 69 participants were suffering from other health-related conditions with or without having diabetes and/or hypertension. Other category includes diseases such as hypothyroidism, migraine, dyslipidemia, cardiovascular disease, cerebrovascular accident, and asthma.

From all of the participants, 344 (34.4%) participants had heard of 'cholesterol', among them 327 (95.1%) knew about its relation to health, out of which 323 (98.8%) knew that above normal limit of cholesterol is harmful.

The belief about some effect of alternatively changing variety of oil on health was existed among 122 participants. Out of them, 56 believed that it was harmful while 66 believed that it was helpful for health. The most commonly used cooking oil was cottonseed (56.2%), followed by groundnut (25.1%), sunflower or safflower (9.3%), and

Table 3: Distribution of the study participants according to various obesity indices (*n*=1000)

Variable	Category	Frequency (%)
Quetelet's index (BMI)	Underweight (<18.5 kg/mt^2)	39 (3.9)
	Normal (18.5-22.9 kg/mt^2)	232 (23.2)
	Preobese (23.0-24.9 kg/mt^2)	127 (12.7)
	Obese (>25.0 kg/mt^2)	602 (60.2)
Broca's index	Ideal weight	310 (31.0)
	Overweight/obese	690 (69.0)
Lorentz formula	Ideal weight	220 (22.0)
	Overweight/obese	780 (78.0)
Ponderal index	Underweight (<11.0 kg/mt^3)	22 (2.2)
	Normal (11.0-14.0 kg/mt^3)	214 (21.4)
	Overweight (>14.0 kg/mt^3)	764 (76.4)
Corpulence index	Normal (≤1.2)	615 (61.5)
	Overweight/Obese (>1.2)	385 (38.5)
Waist circumference	Normal (<102 cm for male and <88 cm for female)	451 (45.1)
	>Normal (≥102 cm for male and ≥88 cm for female)	549 (54.9)
Waist hip ratio	Normal (≤1.0 for male and ≤0.85 for female)	425 (42.5)
	>Normal (>1.0 for male and >0.85 for female)	575 (57.5)

BMI: Body Mass Index

soybean (2.5%). Other oils such as mustard, corn, sesame, rice bran, palmolein, and coconut were used by only 4% of participants. Out of total, 29 (2.9%) participants practiced changing of cooking oil. Method of changing cooking oil was alternate in 15 (51.7%) participants. The found determinants for changing oil were according to the type of food being prepared and type of oil available from nearby shop in 8 (27.6%) and 6 (20.7%) participants, respectively.

A total of 971 participants informed that they did not change the type of cooking oil since many years. Various reasons given by participants for not changing oil were lack of knowledge that oil should be changed in 520 (53.6%), economical constraint to buy other costly oils in 402 (41.4%), family head does not allow changing of oil in 25 (2.6%), spouse does not allow in 10 (1.0%), belief of "there is no health benefit by changing oil" in 6 (0.6%), family members do not like taste of food if oil is changed in 5 (0.5%), and a belief "oil changing is dangerous for health" in 3 (0.3%) participants.

Out of total, 493 participants used to repeatedly heat the same oil for frying. Of these participants, 181 informed that there is some effect of repeated using the same oil for frying on health, of which 169 (93.3%) believed that it had harmful effect and 12 (6.7%) believed that it had helpful effect on health.

On assessing the association between type of cooking oil (2 variables: only one type used and changing variety of cooking oil used) and cholesterol-HDL ratio (3 variables: optimal, moderate risk, and high risk), it was revealed the contingency coefficient value of 0.042 with $P = 0.416$. Hence, no statistical association was obtained between changing variety of cooking oil and cholesterol-HDL ratio.

Statistical association was obtained between BMI and cholesterol level. As BMI increases, cholesterol level also increased. Statistical association was also obtained between BMI and cholesterol-HDL ratio. As BMI increases, cholesterol-HDL ratio also increased. Statistical association was obtained between type of cooking oil used and BMI [Table 4].

No statistical association was obtained between type of cooking oil used and cholesterol-HDL ratio (Fisher's exact value = 11.510; P value = 0.319).

On performing Multivariate analysis between BMI, Lipid profile and type of cooking oil used, No statistical significance was found [Table 5].

Statistical association was obtained between raised blood pressure and cholesterol-HDL ratio (contingency coefficient value = 0.094; P value = 0.012). Cholesterol-HDL ratio was poor in participants who had raised blood pressure. Similarly, statistical association was obtained between raised blood sugar and cholesterol-HDL ratio (contingency coefficient value = 0.214; $P \leq 0.001$). Cholesterol-HDL ratio was poor in participants who had raised blood sugar.

DISCUSSION

Majority of participants had normal level of serum cholesterol (72.6%) and normal level of serum HDL (68.2%), but serum cholesterol-HDL ratio was optimum in only 43.4% of participants. Hence, it supports the conclusion of various studies that cholesterol-HDL ratio is a more sensitive indicator compared to other indicators.[15,16]

Majority of participants were overweight-obese based on various obesity indices such as BMI (72.9%), Lorentz (78.0%), Broca's (69.0%), and Ponderal index (76.4%). However, according to Corpulence index, only 38.5% were having more than normal weight. More than half (57.5%) the number of participants had more than normal waist–hip ratio.

Most participants used cottonseed oil (56.2%) for cooking, followed by groundnut (25.1%), sunflower or safflower (9.3%), and others. Only 2.9% of participants consumed combination of oil. Alternatively changing variety of oil (51.7%) was most preferred method by

Table 4: Association of body mass index with other risk factors of cardiac diseases

Association between BMI and cholesterol level					
BMI category	Cholesterol level			Total	Fisher's exact value (*P*)
	Desirable	Borderline high	High		
Underweight	39	0	0	39	37.430 (<0.001)
Normal	184	31	17	232	
Overweight/preobese	96	30	3	129	
Obese	413	124	63	600	
Total	732	185	83	1000	
Association between BMI and cholesterol-HDL ratio					
BMI category	Cholesterol-HDL ratio			Total	Fisher's exact value (*P*)
	Optimal	Moderate risk	High risk		
Underweight	34	5	0	39	49.498 (<0.001)
Normal	122	96	14	232	
Overweight/preobese	53	70	6	129	
Obese	225	323	52	600	
Total	434	494	72	1000	
Association between BMI and variety of cooking oil used					
Type of cooking oil used	BMI			Total	Fisher's exact value (*P*)
	Underweight	Normal	Overweight	Obese		
Cottonseed	23	126	83	330	562	83.015 (<0.001)
Groundnut	16	92	29	114	251	
Soybean	0	1	3	21	25	
Sunflower or safflower	0	6	6	81	93	
Mustard or corn or sesame or rice bran or palmolein or coconut	0	4	5	31	40	
Mixed	0	3	3	23	29	
Total	39	232	129	600	1000	

BMI: Body mass index, HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Table 5: Multivariate analysis between body mass index, lipid profile, and type of cooking oil used

BMI	Cholesterol-HDL ratio	Type of cooking oil used		Total	Fisher's exact, *P*
		Single variety	Mix variety		
Underweight	Optimal	34	0	34	1.000
	Moderate risk	5	0	5	
	High risk	0	0	0	
	Total	39	0	39	
Normal	Optimal	116	3	119	0.371
	Moderate risk	100	0	100	
	High risk	13	0	13	
	Total	229	3	232	
Preobese	Optimal	50	0	50	0.352
	Moderate risk	69	3	72	
	High risk	5	0	5	
	Total	124	3	127	
Obese	Optimal	218	8	226	0.331
	Moderate risk	311	15	326	
	High risk	50	0	50	
	Total	579	23	602	

BMI: Body mass index, HDL: High-density lipoprotein

participants. The most common reason provided by participants regarding changing the variety of cooking oil was lack of knowledge about benefits of changing the oil (53.6%), followed by economic constraints in buying other variety (41.4%).

It is common nowadays that many people suggest about changing variety of cooking oil. Many articles are published advising people about changing variety of cooking oil.[18] In a three-county collaborative study, it was found that certain variety of cooking oil significantly altered lipid profile.[19] In another study done among rats in Pakistan, it was found that different varieties of cooking oil had different effects on lipid profile of rats.[20] In a review article published, it was found that all oils had beneficial effect on health and no specific detrimental effects of oil on health were found.[21] However, in a trial done among hen, it was found that different cooking oils did not have any effect on lipid profile.[22] In the present study also, no statistical association was obtained between changing variety of cooking

oils used and cholesterol level (contingency coefficient value = 0.047; $P = 0.335$) as well as cholesterol-HDL ratio level (contingency coefficient value = 0.042; $P = 0.416$). This may suggest that only changing variety of cooking oil does not affect an individual's lipid profile. It is the genetic constitution, physical exercise, stress, and other factors that would influence an individual's lipid profile. Moreover, advantages of individual oil are provided in various researches, but no specific combination that should be used is suggested.

Statistical association was obtained between variety of cooking oil and BMI (Fisher's exact = 83.015; $P = 0.000$). BMI was more severe in participants consuming soybean, sunflower or safflower, mustard, sesame, etc., compared to cottonseed and groundnut. This may have occurred as those participants may have recently changed type of oil used for cooking, as their previous oil consumption was not known.

An ICMR study done in India concludes a strong association between obesity, dysglycemia, and hypertension with dyslipidemia.[3] The present study also shows similar association.

Statistical association was also obtained between BMI and cholesterol level (Fisher's exact = 37.430; $P = 0.000$) as well as cholesterol-HDL ratio level (Fisher's exact = 49.498; $P = 0.000$). There was dyslipidemia more in overweight and/or obese participants compared to underweight or normal weight participants.

In a study done by Singh *et al*.,[23] it was found that there is an association between blood glucose and serum lipid level. Also in other study done among Asian population, it was found that diabetes is associated with dyslipidemia.[24] Another study which concluded the same association was done in Turkey.[25] In the present study, statistical association was obtained between blood glucose and serum lipid level. In the present study, statistical association was obtained between blood pressure and serum lipid level. This is in line with other studies done by Choudhury *et al*.[26] in Bangladesh and by Asviandri *et al*.[27] in Indonesia.

CONCLUSION

The prevalence of dyslipidemia was found to be in quarter of patients having undergone serum lipid profile testing. Statistical association was not found between serum lipid profile and type of oil used for cooking. Obesity indices revealed significant statistical association with both, variety of cooking oil used, and serum lipid profile. Dyslipidemia was also found to have statistical significant association with raised blood pressure and raised blood glucose.

Limitation of the study

The association between BMI and variety of cooking oil was established in the current study but per capita amount of cooking oil used/consumed could be proved a better association with BMI rather than only type of cooking oil used. The same was not assessed in this research project.

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Conflicts of interest

There are no conflicts of interest.

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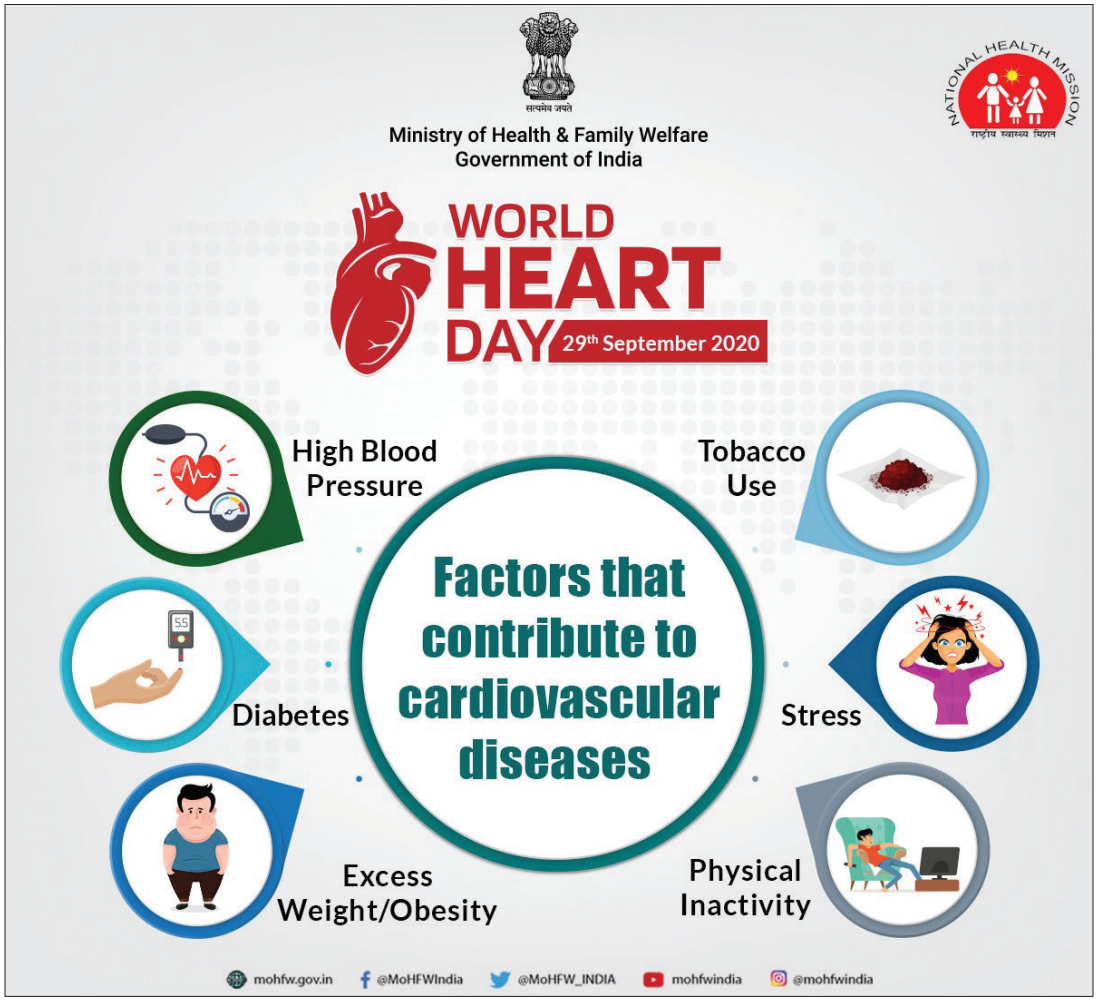

Original Article

Self-esteem and body-image dissatisfaction among adolescents: A cross-sectional study

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Abstract

Introduction: Adolescence is the time period in which the values about themselves will be created. Hence, self-esteem and correct perception about own body are an important context in their life.

Objectives: The objective of this study is to find out the degree of dissatisfaction with their body size (DDBS) among adolescents and to analyze the influence of it on self-esteem.

Material and Methods: This study was cross-sectional done among the undergraduate students in a private medical college and students of high-school section of the government school. A questionnaire was used to document the sociodemographic details, subjective assessment of body image, and self-esteem.

Results: In this study, majority of the students had high (93; 50.8%) self-esteem and moderate self-esteem (62; 33.9%). Out of 183 samples, 53 (29%) were satisfied with body contour based on DDBS. In those who were underweight, it is shown that 48 (54.5%) wanted to increase their body weight, and in normal body mass index (BMI) category, 50% of participants wanted to lose their body weight. Age and BMI were significantly associated with self-esteem and body-image perception.

Conclusion: The concept of body image has to be modified to reduce the risk of overweight, obesity, and eating disorders. This, in turn, can increase and sustain the self-esteem of adolescence.

Keywords: Adolescence, body image, dissatisfaction, perception, self-esteem

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INTRODUCTION

Adolescence is defined as the period between the age group of 10–19 years.[1] India has the largest adolescent population in the world, comprising 250 million adolescents who contribute to 21% of the total population.[2] Adolescence is a vital moment in the profound development of physical and psychological health.[3] This is the time in which adolescents grow physically, mentally, and psychologically. The perception that creates during the time remains more or less similar throughout their life. This is the time where the adolescents start to value themselves, own ideas, and try to stand and pursue it. The changes in the body and own perception give confidence at the same time mistrust or skepticism about oneselves [Figure 1].

During the growth spurt, as noteworthy changes occur in the body, weight perception is also influenced. Bodyweight perception refers to one's estimate of body image with all of

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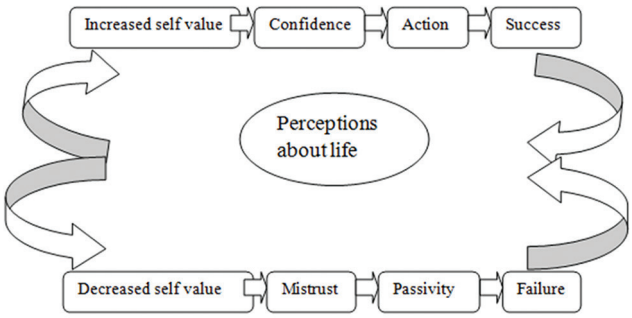

Figure 1: Perceptions and its effects

the accompanying feelings, attitudes, and thoughts concerning weight, size, shape, and appearance.[4-6] Bodyweight perception plays a significant role in weight management. A previous study has concluded that body weight perception is a better predictor of body management and related behaviors than Body Mass Index (BMI), i.e., actual weight status.[7] Almost one-third of adolescents misperceive their body weight; moreover, compared to boys, girls are more likely to hold misperceptions. In a previous study, 42.2% of girls had misperceptions compared to 7.3% boys.[8]

The term self-esteem means "reverence for self." The "self" pertains to the values, beliefs, and attitudes that we hold about ourselves. Having a strong will and self-confidence, decision-making power and originality, creativity, sanity, and mental health are directly related to self-esteem and sense of self-worth. It also refers to an individual's sense of his or her value or worth, or the extent to which a person values, approves of, appreciates, prizes, or likes him or herself.[9] There are many studies showing a decreased self-esteem for those with overweight or obesity.[10,11] As suggested four major factors which are important in the development of self-esteem: (1) treatment and acceptance received from significant others in life, (2) a person's past successes, (3) the values and aspirations which modify and interpret a person's experiences, and (4) how a person responds to devaluation.[12] Hence, the presence of altered perception leads to dissatisfaction and defamation from others leading to lowered self-esteem.

The aim of this study was to find out the Degree of Dissatisfaction with their Body Size (DDBS) among adolescents and to analyze the influence of it on self-esteem. Furthermore, wanted to assess the change of perception between early and late adolescents in terms body size dissatisfaction and self esteem.

MATERIAL AND METHODS

We conducted a cross-sectional study for a period of 1 month among the undergraduate students in a private medical college and students of high-school section of government school. This study was initiated after obtaining the Institution Ethics Committee approval and necessary permission from the authority.

The sampling method followed was convenient sampling, and the school was selected on a convenient basis to access early adolescents. Similar late adolescent group was accessed from the early year of medical college.

A structured interview schedule was administered to the study population. The interview schedule consisted of two parts. The first part included sociodemographic detail of the participants, including age, gender, type of family, number of family members, education, and occupation of parents. Physical parameters such as height, weight, BMI, and waist circumference were also assessed.

The second part has subjective self-assessment of body image.

The figure rating scale adapted by childress and coworkers consists of eight figures representing several children's and adolescents' body outlines, ranging from very slim (contour 1) to obese (contour 8). This was available for both boys and girls.[13] From the eight outline figures available, the schoolchildren chose the one that matched their Current Body Size (CBS – the figure showing the contour they believe they have) and the one matching their ideal body size (IBS – the figure showing the contour the child would like to have); this was done in a private room, the children having had prior individualized explanation given by the chief researcher. DDBS) was obtained by subtracting the CBS from the IBS. The DDBS score showed the degree of dissatisfaction with body shape; the magnitude may be positive when the individual wishes to increase their body size and negative if they wish to reduce their size. To characterize body dissatisfaction, regardless of whether individual wishes to increase or reduce their contour, (a dissatisfied individuals with DDBS >/<0 and b) satisfied – individuals with DDBS = 0. The part 3 has the assessment of self-esteem.[14]

Rosenberg Self-esteem Scale (10 items) was used to assess self-esteem. There were five items for positive self-esteem and five items for negative self-esteem. They were scored for positive self-esteem as 3 for strongly agree, 2 for agree, one for disagree, and zero for strongly disagree. Reverse scoring is done for negative self-esteem. The total score of self-esteem ranged from 0 to 30 for 10 items. Levels of self-esteem were classified as very high self-esteem (25–30), high self-esteem (19–24), moderate self-esteem (13–18), low self-esteem (7–12), and very low self-esteem (0–6).

After obtaining formal administrative approval and necessary consent from school authorities and assent from children, the questionnaire was administered by the researchers. Necessary physical and general examinations were done to record the anthropometric measurements. Each part of the questionnaire was explained to the students in the local language and filled by the researcher based on their answers.

The purpose and objectives of the study were explained for the late adolescent group (1st year MBBS students) and motivated for the self-completion of questionnaire. The doubts were cleared, and physical and general examinations were done to record the anthropometric measurements

The data collected were entered in Microsoft Excel and analyzed using the SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. (Chicago, USA, SPSS Inc.). The descriptive analysis was analyzed using frequencies, mean, standard deviation, and proportions. Appropriate statistical tests were conducted to find further association.

RESULTS

The mean age of the study population was 15.3 ± 3.32 years. The youngest study subject was 11 years of age, and the oldest study subject was 19 years of age. In the study population, 107 (58.3%) were females. Among the population, 110 (60.1%) belong to the early adolescent group, i.e., from 10 to 13 years [Figure 2]. Majority (126; 68.9%) belonged to the nuclear family. In this study, 31 (16.9%) had more than five members in the family.

In this study, most of the participant's parents were graduates (24% paternal and 19.7% maternal). In the occupation pattern, most (35%) of the fathers were daily wagers, and mother's (63.4%) were homemakers. Among the study population, 88 (48%) were underweight according to the WHO BMI classification [Figure 3].[15]

In this study, majority of the students had high 93 (50.8%) self-esteem and moderate esteem 62 (33.9%). Both for girls (52; 48.6%) and boys (41; 53.9%), majority had high self-esteem [Table 1]. Out of 183 samples, 53 (29%) was satisfied with body contour based on DDBS [Figure 4].

Association was done between BMI and DDBS. In those who are underweight, it is shown that 48 (54.5%) wanted to increase their bodyweight, and in normal BMI category, 50% of participants wanted to lose their bodyweight. In the overweight category, majority 13 (76.5%) wanted to lose their body weight. This difference was statistically significant [Table 2].

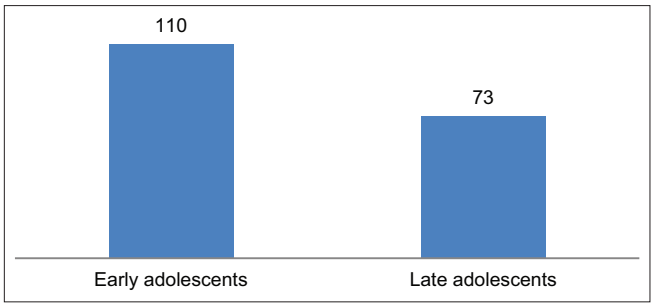

Figure 2: Age distribution of the study population

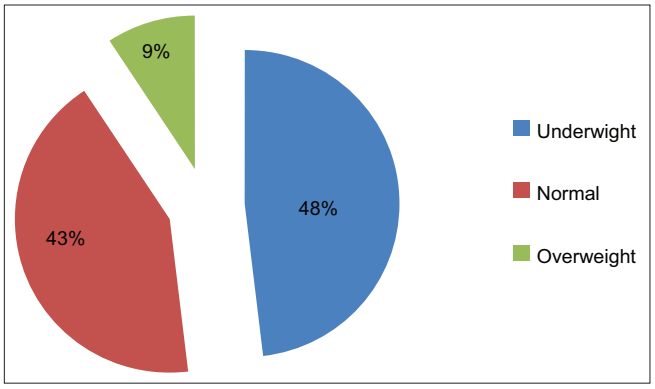

Figure 3: Distribution of body mass index among the population

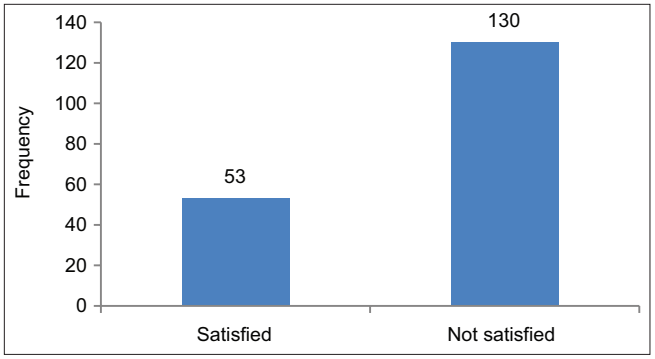

Figure 4: Degree of dissatisfaction with body size

Table 1: Self-esteem according to the Rosenberg Self-esteem Scale(*n*=183)

	Boys (%)	Girls (%)
Low self-esteem	5 (6.6)	8 (7.5)
Moderate self-esteem	25 (32.9)	37 (34.6)
High self-esteem	41 (53.9)	52 (48.6)
Very high self-esteem	5 (6.6)	10 (9.3)

Table 2: Body dissatisfaction distribution (*n*=183)

Body mass index	Ideal - current <0	Ideal - current =0	Ideal - current >0
Underweight (%)	14 (15.9)	26 (29.5)	48 (54.5)
Normal (%)	39 (50)	26 (33.33)	13 (16.7)
Overweight (%)	13 (76.5)	1 (5.9)	3 (17.6)

Fischer's exact value=44.66, $P<0.001$ (significant)

The variables self-esteem and DDBS were subjected to inferential statistical tests with other sociodemographic

variables (age categories [early and late], gender, type of family, number of family members, education and occupation of father and mother, and BMI) to find any associations.

The table shows that the association between age and DDBS was statistically significant. Among the early adolescents, 84 (76.36%) were not satisfied with their body image compared to 46 (63.01%) of late adolescents [Table 3].

Age as a continuous variable and total self-esteem score was correlated to see any significant result. It was found that as age increases self-esteem decreases. There exists a weak negative correlation between age and self-esteem ($r = 0.24$, $P = 0.001$). In early adolescents, the number of participants with moderate and high self-esteem was high than in late adolescents. There was no significant association between DDBS categories and self-esteem categories ($\chi^2 = 4.78$, $P = 0.18$).

Our study shows that self-esteem was negatively correlated with BMI (self-esteem weak correlation [Correlation coefficient = −0.15, $P = 0.03$]). Furthermore, we did not find any significant association between degree of dissatisfaction and self-esteem categories. However, we could see that 69.2% of participants who had low self-esteem had dissatisfaction with their body size.

DISCUSSION

The objective of our study was to find out the DDBS among adolescents and to analyze the influence of it on self-esteem. In this study, majority of the students had high 93 (50.8%) self-esteem and moderate esteem 62 (33.9%). Out of 183 samples, 53 (29%) is satisfied with body contour based on DDBS.

Adolescents during their period always are at conflict of views even in their body image perception. The way they look at themselves matters the most in their physical and psychological health. Furthermore, these perceptions affect their self-evaluation which emerges as the single strongest pointer toward their self-esteem. Adolescents with a negative body image concerns are also more likely to have psychological symptoms such as depression, anxiety, and suicidal tendencies than those without dissatisfaction over their appearance, even when compared to adolescents with other psychiatric illnesses.

Table 3: Association between age and degree of dissatisfaction with body size

Variable	Category	Degree of dissatisfaction with body size		χ^2	*P*
		Satisfied (%)	Not satisfied (%)		
Age	Early adolescence	26 (23.64)	84 (76.36)	3.8	0.049*
	Late adolescence	27 (36.99)	46 (63.01)		

*Chi-square test $P<0.05$ was significant

In our study, most 130 (71%) of the adolescents were not satisfied with their CBS. This finding is similar in studies[16] where 77.6% and 81%[17] were not satisfied with their body size. In our study, 66 (36.1%) want to lose the body weight to reach an ideal size, and 64 (35%) want to gain weight to reach an ideal size. Twenty-nine (38.2%) boys want to gain weight to reach ideality, and 40 (37.4%) girls want to lose weight to reach ideal size. The dissatisfaction difference based on gender was not significant in our study. However, many studies have shown increased dissatisfaction among girls compared to boys.[17-20] Girls during their adolescence perceive different body images. It can be easily influenced by external media and peer pressure. The perception is far more easily influenced and changed than a boy.

In our study, the early adolescents 84 (76.36%) were not satisfied with their body image compared to 46 (63.01%) of late adolescents. This finding is comparable to a study where they analyzed body image perception at different periods of adolescence where fund that younger adolescents had higher dissatisfaction than their peers.[21] However, a study showed that younger adolescents were found to be least dissatisfied.[22]

In our study, we have found that as BMI increases, DDBS decreases. It shows that people with overweight BMI want to have a lean body weight compared to lesser BMI participants. In those who are underweight, it is shown that 48 (54.5%) wanted to increase their bodyweight, and in normal BMI category, 50% of participants wanted to lose their bodyweight. In overweight category, majority 13 (76.5%) wanted to lose their bodyweight. This finding can also be noted in other studies.[16,19] These results suggest a strong affinity toward thin shape even when the subject has normal BMI.

Self-esteem is the attitude toward oneself and can act as a pointer toward mental well-being. Hence, in adolescence as compared to any other age group, the presence self-esteem is highly linked to the physical appearance. In our study, we found that majority of the students had high 93 (50.8%) self-esteem and moderate esteem 62 (33.9%). The presence of high self-esteem in our study is comparable with other studies.[23-25] The self-esteem decreases as age progresses. May be the overload of responsibilities and other duties which bestowed as age progresses reduced the self-esteem. Furthermore, the presence of academic achievement in school increases self-esteem among a person. The decrease in self-esteem as age progresses is also noted by many studies.[26,27] This can be

also be attributed to maturity, acculturation, peer interaction, responsible role acquisition, peer pressure, inferiority complexes psychological, and physical upheaval (storm and stress period) during the age spectrum.

In our study, we did not find any association between self-esteem and body dissatisfaction. From our study, it was found that even though 71% is dissatisfied with the body image (29% satisfied with the image), only 7% had low self-esteem. This shows that physical appearance single handily does not influence self-esteem, but it is a cumulative dominion of inter-woven elements of various realm. There are many studies which showed negative association with both. The studies showed the negative effect of body dissatisfaction on self-esteem in adolescents, which confirmed that a negative discernment of one's body leads to low self-esteem resulting in psychological distress.[22,28,29]

Studies[9,16,23,27] have shown that family size, type, and education of parents influence both the body dissatisfaction and self-esteem, which is not found in our study.

Recommendations and limitations

The adolescence is a delicate time which has to be handled in such a way that positive attitude about oneself has to be installed first. The influence of media on these body image perceptions has to be taken care of and should impart a healthy concept instead of beauty. Active part has to be taken by community, family, and parents to build self-confidence, courage to resist both external and internal pressure about negative perceptions and provide support to raise their self-esteem. The school teachers can also be a supporter to deviate the young minds to more fruitful ideas. We should create a mind that loves own body or self which reciprocates to others.

This study was limited to few adolescents which reduces the results completeness. Furthermore, adolescents from different streams such as rural/urban, government school/private school, arts/science, medical/engineering, and socioeconomic groups should have been compared to get an extraimage of the current situation. Furthermore, gender reverse questionnaire should have been included to discuss what other gender feels about. Qualitative questions would have added more value the study.

CONCLUSION

In this study, majority of the students had high (93; 50.8%) self-esteem and moderate esteem (62; 33.9%). Out of 183 samples, 53 (29%) is satisfied with body contour based on DDBS. The distorted body-image perceptions among adolescences have to be considered as a serious issue, and strategies have to be made to increase the understanding of the actual size of the body. There should be an awareness drive about healthy body not outward beauty body.

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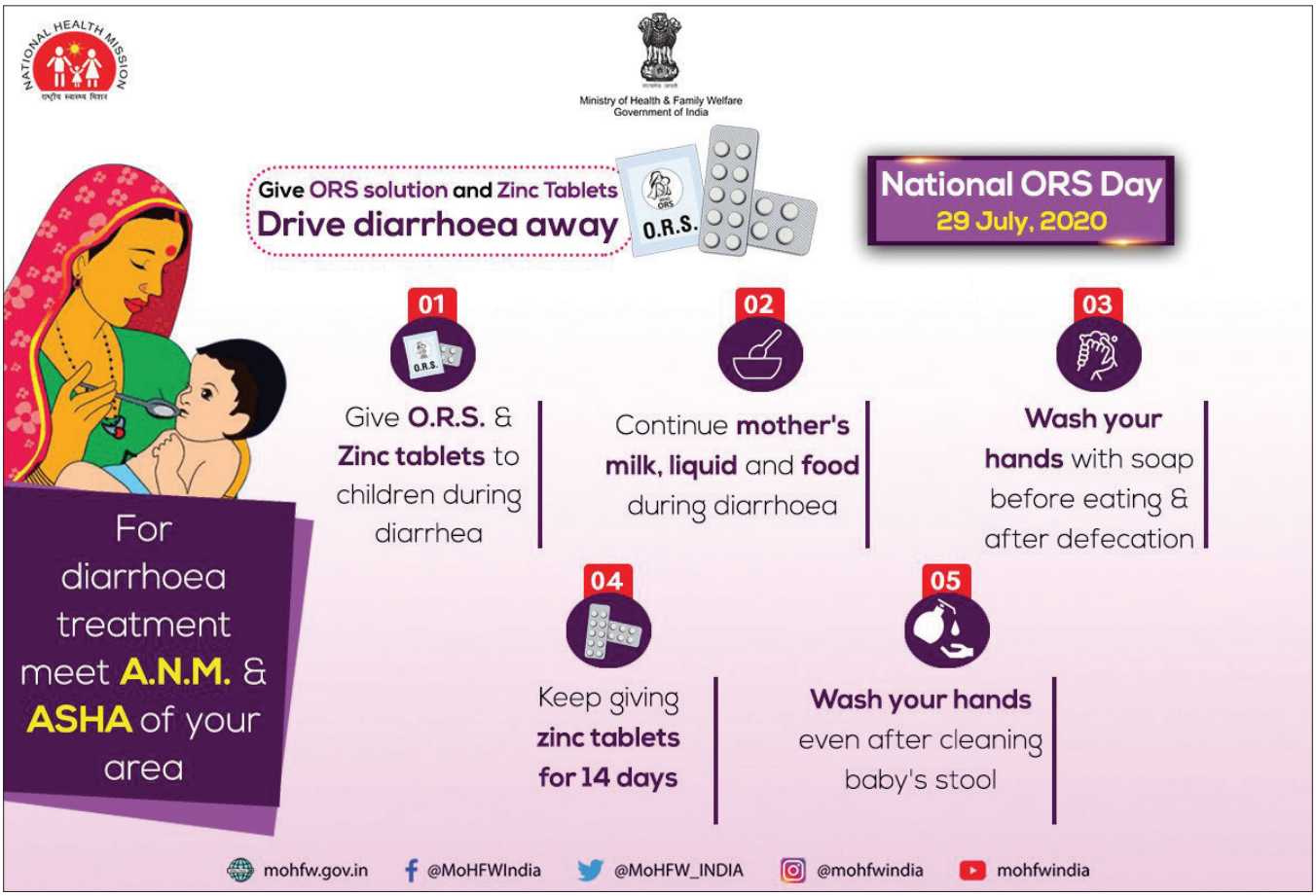

Primary Health Care "approach" and Medical Education: New opportunities for revitalizing the bond

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Abstract

The importance of primary health care (PHC) has once again been reiterated in the Astana Declaration of 2018. PHC is an approach to health systems development rather than just a level of health-care service delivery. Understanding the PHC "approach" is crucial for doctors, across specializations and levels, as they are one of the prominent players in the country's health system. Undergraduate medical education offers an ideal window of opportunity to do so. The medical education policy, time and again, has acknowledged this need and has created mechanisms to fulfill it. The role of departments of community medicine has been kept central in these policy prescriptions. This, in practice, has led other departments to play only a weak role in the teaching and application of PHC. The Medical Council of India's new competency-based medical curriculum, with a renewed focus on integrated teaching, offers fresh opportunities to change this situation.

Keywords: Community Medicine, integrated teaching, pedagogy, re-orientation, undergraduate

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INTRODUCTION

The term "Primary Health Care" (PHC) reflexively evokes the image of a rural primary health center, where a doctor is seeing some patients with common complaints such as cough, cold, fever, or diarrhea; a sub-center from where the auxiliary nurse midwife is going out in the village to administer vaccines; an Anganwadi where a worker is weighing babies; and an accredited social health activist who is visiting houses having antenatal women in her area. However, the classical text of the Alma Ata declaration and its nuanced interpretations posit PHC as an "approach" to overall health systems development, rather than just a level of care with a set of services provided through a team of peripheral workers.[1-3] Thus, the principles of PHC apply as much to the functioning of a medical college (MC) and hospital as to a primary health center and its sub-centers.

The relevance of PHC for India has been well acknowledged in the health policy documents across decades.[4-9] The importance of the approach has once again been re-iterated in the Astana Declaration which calls it "a cornerstone for a sustainable health system for universal health coverage and health-related sustainable development goals."[10] One of the important requirements so as to bring this "approach" into practice is to make the doctors, who are the key functionaries at different levels of the health system, understand the underlying concept in its most comprehensive form.[11] Undergraduate (UG) medical education offers an ideal window of opportunity to do so.

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ADOPTION OF PRIMARY HEALTH CARE IN UNDERGRADUATE MEDICAL EDUCATION

Recognizing the need to include community and preventive aspects in the training of "basic doctors," the Bhore Committee recommended the establishment of departments of preventive and social medicine (PSM) in every MC.[4] The departments were supposed to give a social perspective to health problems and health practices; knit together concepts and methods of public health with those from other related medical disciplines; and interact with teachers of other disciplines to provide a social dimension to their teaching.[12]

In the latter half of the 1970s, a scheme for Re-orientation of Medical Education (ROME) was launched. The objectives of ROME were to give rural orientation to the faculties, students, and interns and to channelize the potential of MCs to improve health-care services in rural areas.[13] Each MC was expected to take administrative charge of three primary health centers where medical students and interns would be posted.

Besides this, the General Medical Education Regulation (1997) stated that "at the end of the undergraduate program, the medical student should be able to recognize "health for all" as a national goal…"[14] The curriculum prescribed for community medicine (CM) under the regulations included teaching of "principles and components of PHC and the national health policy to achieve the goal of "health for all"….".[14] The Medical Council of India's Minimum Standard Requirements for the MC include provision for a rural and an urban health training center under the academic control of the dean.[15]

While several MCs such as CMC Vellore and MGIMS Wardha have been engaged in orienting their medical students on PHC, looking at the larger picture, there are significant challenges.

THE CHALLENGES

Despite the pronunciations in the policy and curriculum, medical education has remained unresponsive to the PHC needs of the country. Graduates are, still, more suited to work in hospitals than in communities.[16] There is a predilection for clinical specialization, "latest technologies," and urban practice.[17] Twenty-four percent (8286/33,968) of sanctioned positions of doctors at primary health centers are vacant, despite more than 60,000 medical seats in the country.[18] Doctors, in general, are seen to be bringing medical bias in public health planning.[19] Research topics selected by the faculty and their postgraduation (PG) students are not found to be innovative or locally relevant.[20] Often, they are found to be influenced by international funding.[21,22] With due regards to exceptions, doctors continue to remain techno-centric. All of these lie diametrically opposite to the position of PHC.

To ensure that medical students come out adequately oriented in PHC is not the responsibility of the departments of CM alone. However, creation of a separate PSM department led to relegation of the teaching on preventive aspects by faculty of other subjects.[12] In most MCs, the responsibility to co-ordinate ROME was given to the PSM department. This made ROME a "PSM activity" in which other specialties did not take much interest.[14,22] The case is no different even at present when the activities at rural and urban health training centers, where they actually exist, are almost exclusively managed by the department of CM. Other departments remain busy in the hospital.

Preliminary findings from an ongoing larger study involving the departments of CM of four MCs inform that integrated teaching has been happening in the lecture halls and in the wards. Institutions, that have incorporated community orientation camps in their UG curriculum, also engage different specialty departments to demonstrate clinico-social history taking at household level. The institutional ethos of holistic health and a supportive management are the enabling factors for such integrated teaching. Still, these activities occur only infrequently, ranging from once a month to once a year. The faculty find it difficult to resolve differences between "public health guidelines" and "clinical protocols," for instance, in the management of neonatal and childhood illnesses. Divergent disciplinary orientation and academic arrogance are the impediments to such reconciliation. Senior faculty who have themselves experienced an integrated pedagogy and who have been able to develop a perspective beyond "the clinical" do justice to such sessions. However, over time, as hospitals have become increasingly complex, their participation in these activities has reduced. They have started sending junior faculty or even PG students, which does not serve much purpose. Given their clinical workload, they see these activities as "additional tasks." And sometimes, things do not happen just because one department is "instructing" the other rather than establishing a dialog.

The departments of CM, in general, may themselves not have been able to make the contribution expected of them toward orienting medical students in PHC. There may be multiple factors responsible for this. The possible actors in

this process include the medical students themselves, who have to be receptive; the CM faculty, who have to absorb and exude the essence of PHC, and remain motivated; the college management, which has to make resources available to the department (such as staff, vehicles, and access to field); the regulatory body, which has to be more flexible with regard to curriculum, pedagogy, and assessment methods; and the professional system in which the medical student would ultimately work. However, even in the best case scenario, the CM departments cannot attain this objective if the other departments of the MC carry on their business as usual.

Recounting their experience of visiting seven MCs in the country, Narayan *et al.* writes, *"Where reorientation was seen as the primary responsibility of one department, or was projected as having to support one departments' training programme…the significance of the reorientation attempt or the enthusiasm of the faculty was being negatively affected"*.[21]

NEW OPPORTUNITIES

In 2018, the Medical Council of India has revamped and repackaged the UG medical curriculum by involving subject experts from different MCs.[23] A list of topics for each subject and a set of competencies for each topic have been put forth along with suggested teaching–learning and assessment methods. Besides, the long talked about "integrated teaching" has been operationalized. For each competency, it mentions the subject(s) that needs to be integrated, in a vertical and/or horizontal framework. Data compiled from the pages dedicated to CM in the curriculum document show that there are around eighty competencies across fourteen subjects which would require integration with CM [Table 1]. Moreover, a similar number of competencies in CM would require integration with nine other subjects [Table 2].

The faculty from different departments are expected to collaborate in the lesson planning and, wherever necessary, to also remain present when these competencies are actually being developed in the students (p35, Vol. II).[23] In either case, it calls for a very close professional interaction between the faculty of CM and those from other disciplines on an equal footing. The two mindsets, one focused on individual patient's disease and the other concerned more about population health, will have to per force sit together and listen to each other. For instance, when the department of obstetrics and gynecology invites faculty of CM to plan/develop competency to "counsel in a simulated environment, contraception, and puerperal sterilization" [Table 1, OG 19.2], there is an opportunity to discuss population control as a developmental issue. Or when the department of CM requests faculty of pediatrics to plan/develop competency to "describe and discuss the importance and methods of food fortification and effects of additives and adulteration" [Table 2, CM 5.8], there is an opportunity to talk about the long-fought struggle against breast milk substitutes.

While the Medical Council of India's renewed focus on integrated teaching should be fully tapped, other

Table 1: Number of competencies in other subjects that would require integration with Community Medicine

Subject	*n*	Example of such competency(s)
Biochemistry	1	Summarize the nutritional importance of commonly used items of food including fruits and vegetables (macro-molecules and its importance) (BI 8.5)
Physiology	1	Enumerate the contraceptive methods for male and female. Discuss their advantages and disadvantages (PY 9.6)
Microbiology	6	Describe the epidemiological basis of common infectious diseases (MI 1.3)
Pharmacology	1	Describe and discuss the following National Health programmes including immunisation, tuberculosis, leprosy, malaria, HIV, filaria, kala azar, diarrhoeal diseases, anaemia and nutritional disorders, blindness, noncommunicable diseases, cancer and iodine deficiency (PH 1.55)
Pathology	3	Define and describe the etiology, types, exposure, environmental influence, pathogenesis, stages, morphology, microscopic appearance and complications of occupational lung disease (PA 26.5)
Forensic Medicine	1	Demonstrate ability to use local resources whenever required like in mass disaster situations (FM 2.33)
Ophthalmology	1	Enumerate, describe and discuss the causes of avoidable blindness and the National Programs for Control of Blindness (including vision 2020) (OP 9.4)
Paediatrics	32	Explain preventive interventions for Child survival and safe motherhood (PE 18.2)
General Medicine	10	Counsel the patient and family on prevention of various infections due to environmental issues (IM 25.13)
Obstetrics and Gynaecology	6	Counsel in a simulated environment, contraception and puerperal sterilisation (OG 19.2)
Respiratory Medicine	9	Demonstrate an understanding of patient's inability to change working, living and environmental factors that influence progression of airway disease (CT 2.27)
Psychiatry	4	Describe the concept and principles of preventive psychiatry and mental health promotion (positive mental health); and community education (PS 19.5)
General Surgery	2	Describe the principles and steps of clinical research in surgery (SU 7.2)
Dermatology, Venerology and Leprosy	3	Classify, describe the epidemiology, etiology, microbiology pathogenesis and clinical presentations and diagnostic features of Leprosy (DR 9.1)

Source: Compiled from Competency-Based Undergraduate Curriculum for the Indian Medical Graduate (MCI, 2018, p51-59, Vol II).[22] The competency codes given in parenthesis in column-4 (like BI 8.5) have been taken from the source

Table 2: Competencies in Community Medicine that would require integration with other subjects

Example of such competency(s)	Subject	Number of such competencies
Describe the role of vectors in the causation of diseases. Also discuss National Vector Borne Disease Control Program (CM 3.6)	Microbiology	9
Describe roles of essential medicine in primary health care (CM 19.2)	Pharmacology	4
Describe and discuss the epidemiological and control measures including the use of essential laboratory tests at the primary care level for communicable diseases (CM 8.1)	Pathology	1
Describe the health hazards of air, water, noise, radiation and pollution (CM 3.1)	ENT	1
Describe and discuss the importance and methods of food fortification and effects of additives and adulteration (CM 5.8)	Pediatrics	22
Describe health problems of aged population (CM 12.2)	General Medicine	32
Describe local customs and practices during pregnancy, childbirth, lactation and child feeding practices (CM 10.3)	ObsGyne	6
Define and describe the concept of mental Health (CM 15.1)	Psychiatry	3
Describe disaster management cycle (CM 13.2)	General Surgery	4

Source: Compiled from Competency-Based Undergraduate Curriculum for the Indian Medical Graduate (MCI, 2018, p41-51, Vol II).[22]
The competency codes given in parenthesis in column-2 (like CM 3.6) have been taken from the source. ENT: Ear, nose, and throat

mechanisms of professional interactions between different departments of the MC should also be activated. They should better engage in delivering clinical services in the outreach, and should collaborate for community-based research. Participating in inter-departmental discussion platforms such as clinico-pathological conferences and involving other departments in clinic–social case presentations can also expose the faculty to each other's perspectives. Organizing continuing medical education sessions on the concept of PHC approach and on ROME may be a good starting point.

The fusion of two different worldviews (medicine: health; patients: population) will enrich both groups of faculty. Especially for the faculty of CM, this will be a stimulus to re-examine and renew their own understanding of the concepts, principles, and operationalization of PHC. Overall, this is an opportunity to revitalize the bond between medical education and PHC, which will help in sowing the seeds of comprehensive PHC approach in the minds of the medical students. Such evolved medical graduates will be a significant contribution of the medical education system toward realizing the ambition, as laid out in the Astana Declaration, of achieving "health and well-being for all, leaving no one behind."[10]

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Conflicts of interest

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Short Communication

Coronavirus disease 2019 pandemic: Strengthening health sector response amidst the background of global economic crisis

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Abstract

The Coronavirus Disease-2019 (COVID-19) pandemic should be looked upon as much more than a public health emergency, as it has significantly impacted the global economy. Owing to the fact that the disease spreads by close contact, many of the nations imposed social restrictions, with an aim to reduce the spread of the disease. However, the bitter truth is that such measures enormously affects the income opportunities of individuals & families, and the financial status of the community and the nation at large. During these difficult times, each nation should start their response by funding all the components of the emergency response plan, strengthen the foundations of the health system and remove the possibility of financial constraints, which can prevent people to access health care. In conclusion, the COVID-19 pandemic has made us to come to a scenario where we have to not only save lives, but even ensure that livelihoods of people are sustained. Thus, the need of the hour is to strengthen the health sector through financial assistance, and simultaneously plan for the release of the lockdown to try to bring our economy back on track.

Keywords: COVID-19 pandemic, economy, health sector, World Health Organization

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INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic should be looked upon as much more than a public health emergency, as it has significantly impacted the global economy and even produced a major impact on the social determinants of health.[1] This has been primarily due to the various measures launched by the national health authorities toward the promotion of social distancing, which in turn has been done due to the sudden rise in the number of cases. Globally, a cumulative total of 2,074,529 cases and 139,378 deaths have been reported, which amounts to a case fatality rate of 6.7%.[2] However, more than these numbers, it is the pace with which the number of cases increases; for instance, in a single day, 82,967 cases were reported, and this huge number is very much enough to outstretch the health system of any nation beyond doubts,

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including the most developed nations and those with the best health system in place.[1,2]

IMPOSITION OF RESTRICTIONS AND THEIR FINANCIAL CONSEQUENCES

Owing to the fact that the disease spreads by close contacts and through droplets, many of the nations have imposed social restrictions, including complete or partial lockdown for varied periods of time. Even though these measures were done to safeguard the citizens and to reduce the spread of the disease, the bitter truth is that such measures enormously affect the income opportunities of individuals and families, and the financial status of the community and the nation at large.[1] Amidst this ongoing pandemic, it is important to note that the impact of the disease has gone beyond the health sector alone, and the public health crisis has affected various other sectors such as education, commerce, travel, and trade. In fact, the financial crisis which has emerged due to the COVID-19 pandemic is predominantly because all these sectors are facing the brunt of the infection.[3]

The International Monetary Fund has estimated that there will be a 5% likelihood that the global growth will fall below −7.4%.[4] The resulting economic crisis has started to show its impact at the local, national, and international levels.[5] From an individual's perspective, the prospects of earning have reduced, predominantly because of the closure of various establishments (such as restaurants, malls, and recreation centers), and this has affected the livelihood of people, especially of the daily wagers and those in lower socioeconomic status group. Commerce or educational industries are finding it hard to pay salary to their employees amidst the various restrictions and recession and thus employees have been laid off from their jobs. At the national and international levels, it is the travel trade sector which has been hit most, as people have started to stay inside home and thus all the national economies have been affected.[5]

HEALTH SECTOR RESPONSE AMIDST THE FINANCIAL CRISIS

Despite these financial developments, it becomes our utmost responsibility to not only continue but also intensify the fight against the COVID-19 pandemic.[4] The best way to deal with this financial crisis and yet continue the battle against COVID-19 will be through ending all forms of restrictions, and simultaneously adopting aggressive and holistic strategies (viz., active case detection, testing, isolation, treatment, contact tracing, quarantine, and infection prevention).[1,5-7] However, all the governments are really concerned about relaxing the restrictions, as it might result in the upsurge of the cases (once people come out in huge numbers), which eventually puts a huge load on the health system, rising number of deaths, and possibly a prolonged and more disastrous impact on the economy.[1]

Acknowledging all these scenarios, the most feasible option at present is to finance the health sector response by ensuring strengthening of all the essential domains of the response, and simultaneously plan for social and economic recovery of the nation by ensuring lifting of the imposed restrictions in a phase-wise manner.[1,3,5] Under these circumstances, the role of various international welfare agencies comes into place, where they can extend the debt relief to the nations and thus minimize the possibility of the downfall of the economy of the affected nations.[3]

PRACTICAL INTERVENTIONS

During these difficult times, each nation should start their response by funding all the components of the emergency response plan as stated above, including the establishment of a risk communication mechanism.[5] The government has appealed to all the stakeholders to voluntarily donate money based on their responsibilities to help the nation to cope up with the pandemic. At the same time, multiple economic provisions have been made to help the vulnerable population groups, the general population, and also to strengthen the health sector response to the COVID-19 pandemic. These emergency responses include creation of temporary facilities for isolation and quarantine facilities for COVID-19 cases in China, importing personal protective equipment by India and Italy, importing hydroxychloroquine by the USA for chemoprophylaxis, and funding research activities to expedite the development of a drug or a vaccine in the Solidarity Trial by the World Health Organization.

All these measures are accompanied with interventions to strengthen the foundations of the health system as a whole, which, in other words, amount to giving salaries to health professionals on time and supplying them with all the essential equipment and personal protective tools to carry out their job without risking their safety.[1] Another important domain will be that the government should ensure that no financial constraints prevent people from accessing health-care services. This is an extremely important area, as if the members of the community don't avail services because they cannot afford, eventually the disease will manifest in huge numbers as the disease transmission will continue to occur in the absence of timely diagnosis, prompt isolation, and provision of appropriate treatment.[1,5]

In fact, many of the nations have made the laboratory test free and some of them have even waived off user fees, and these are all the need of the hour to contain the crisis. This becomes a really important step, as none of the people should be reluctant to avail the health care, especially because of financial constraints, as that might lead to the emergence of a new chain of transmission of infection. At the same time, national leaders should explore the option of cash transfer to the vulnerable population groups, which can support their livelihood during the times of lockdown.[1] Further, many nations and regions have come forward to appeal for financial assistance by donors to support or intensify the ongoing public health response activities.[1,3] For instance, the Pan American Health Organization has appealed for $94.8 million to intensify the COVID-19 response-related activities in nations within the Latin America and the Caribbean.[3] This is the time that all of us should support the ongoing efforts and donate from our side as much as possible to save the lives and reduce the risk of disease transmission.

CONCLUSION

The COVID-19 pandemic has made us to come to a scenario where we have to not only save lives but also ensure that the livelihoods of people are sustained. Thus, the need of the hour is to strengthen the health sector through financial assistance, and simultaneously plan for the release of the lockdown to try to bring our economy back on track.

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There are no conflicts of interest.

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Case Report

Acute fatty liver of pregnancy: A clinical dilemma

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Abstract

Acute Fatty Liver of Pregnancy (AFLP) is a rare and life-threatening obstetric emergency. Although the exact pathogenesis is unknown, the cases of AFLP are believed to be associated with abnormal fatty acid oxidation. The diagnosis of AFLP is a challenging task for the clinicians because of the nonspecific clinical presentation which may mimic conditions such as acute viral hepatitis, preeclampsia or Hemolysis, Elevated Liver Enzymes, and Low Platelet Count (HELLP) syndrome. Early diagnosis, prompt obstetric management, intensive supportive care, and a multidisciplinary approach are the key to a good outcome. We here present two similar cases of AFLP with two different outcomes managed in a tertiary care center of the Andaman and Nicobar Islands.

Keywords: Acute fatty liver of pregnancy, disseminated intravascular coagulopathy, hepatic failure, jaundice

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INTRODUCTION

Acute fatty liver of pregnancy (AFLP) is one of the rare and potentially fatal complications of late pregnancy. The incidence ranges between 1 in 7000 to 1 in 16,000 pregnancies.[1,2] It is an autosomal recessive disorder with inherited mitochondrial abnormalities of fatty acid oxidation. The most common mutations are the G1528C and E474Q mutations of the gene on chromosome 2 that code for long-chain-3 hydroxy acyl-CoA dehydrogenase (LCHAD).[2] The clinical presentation is vivid and may range from a mild asymptomatic case to a severe variety resulting in overt hepatic failure with encephalopathy leading to high maternal and perinatal morbidity and mortality. However, the updated guidelines stressing on early termination of pregnancy and more intensive supportive care protocols have led to the decrease in maternal mortality from 80%–85% to 7%–18% and the fetal mortality rate from 50% to 9%–23%.[1] We, hereby, present two cases of AFLP in which we could save one mother but lost the other one despite intensive obstetric management and support.

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CASE REPORTS

Case 1

A 20-year-old primigravida was admitted at 34 weeks gestation with preterm labor pains along with fever and malaise for 2 days. On examination, she was conscious and well oriented. The temperature was 99.2°F, pulse rate (PR): 88 beats/min, blood pressure (BP): 110/70 mmHg, and sclera was yellow. Systemic examination was within the normal limits and there was no organomegaly. Obstetric examination revealed a single viable fetus of around

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32 weeks. Her laboratory investigations are shown in Table 1.[3] Abdominal ultrasound showed fatty changes with bright echotexture in the liver with ascites. Initially, hemolysis, elevated liver enzymes, and low platelet count (HELLP) syndrome was suspected, but on account of hypoglycemia, hypofibrinogenemia, raised bilirubin, normal BP, and ascites, the diagnosis of AFLP was made. The patient underwent emergency cesarean section for fetal distress. Live male child of 2600 g was delivered. Hemostasis was secured and a prophylactic abdominal drain was kept. The patient received two units of packed cell infusion and four units of fresh frozen plasma (FFP). She was shifted to the intensive care unit (ICU) and managed by critical care specialist and gynecologist. She was shifted to the ward on the 7th postoperative day and discharged on day 12. The mother and baby were healthy on follow-up on day 28. Unfortunately, we could not screen the mother and baby for LCHAD mutation, as this facility was not available in the institute or anywhere else in the island.

Case 2

A 32-year-old primigravida with 37-week gestation was referred to our hospital with complaints of yellow discoloration of urine and eyes and vomiting for 3–4 days. There was no history of pain in the abdomen, leaking or bleeding per the vagina. On examination, she was drowsy. Her BP was 160/100 mmHg, PR: 84 beats/min, and temperature: 99°F. She had icterus and mild pedal edema. Abdominal examination revealed relaxed uterus of 36 week size with the fetus in cephalic presentation and normal fetal heart rate. Her investigations on admission are shown in Table 1. Blood gas analysis revealed metabolic acidosis with respiratory alkalosis. Ultrasound abdomen showed grade 1 fatty changes with moderate ascites.

The patient had spontaneous vaginal delivery of a 2540 g male, stillborn baby, but her condition deteriorated after delivery with rising liver enzymes and deranged coagulation profile despite correction with fresh frozen plasma. She was shifted to the ICU in view of hepatic encephalopathy with coagulopathy and hepatorenal shutdown. She had to be dialyzed and blood component therapy was given to correct coagulation profile. The patient was intubated and started on inotropes later. Despite vigorous management, she could not be revived and expired on the 5th day.

DISCUSSION

AFLP was first described by Stander and Cadden in 1934[4] and later, Sheehan[5] in 1940 gave it the name of acute yellow atrophy – where postmortem examination was performed on 400 obstetric patients and six were found to have significant liver pathology. This entity has a high case fatality rate unless managed intensively and promptly.

The majority of cases of AFLP occur in the late third trimester, commonly in primigravida, multifetal gestation, and with a male fetus.[6] Both our cases were primigravida and had male babies.

The literature suggests that AFLP usually occurs due to the deficiency of LCHAD or mutations in the genes coding for this enzyme. There is not much effect on fatty acid oxidation mechanism under normal physiological conditions; however, when both the parents are heterozygous for this abnormality and the fetus is homozygous, it will not be able to oxidize long-chain fatty acids. The un-metabolized free fatty acids traverse the placenta and saturate the maternal circulation overwhelming the mothers' mitochondrial capacity to oxidize excess fatty acids.[7] Termination of pregnancy will break this chain of fatty acid circulation and diminish the hepatic stress, thereby normalizing the condition postpartum.[8] Newborns with defective mitochondrial fatty acid oxidation may present with

Table 1: On admission laboratory parameters of cases with acute fatty liver of pregnancy

Parameters	Normal reference range in pregnancy (3rd trimester)[3]	Case 1	Case 2
Hemoglobin (g/dl)	>11 g/dl in pregnancy	8.6	6.2
Leukocytes (×10³/mm³)	5.9- 16.9	18.7	23.9
Platelets (×10³/mm³)	1.4- 4.2	0.61	1.6
Bilirubin (total) (mg/dl)	0.1- 1.1	8.8	5
Aspartate aminotransferase (U/L)	4- 32	186	205
Alanine aminotransferase (U/L)	2- 25	210	130
Serum alkaline phosphatase (U/L)	38- 229	502	731
Prothrombin time (s)/INR	9.6- 12.9/.80- .94	34 /2.9	60 / 2.9
Serum lactate dehydrogenase (IU/L)	105- 333/82- 524	942	836
Serum fibrinogen (mg/dL)	373- 619	40	-
D-Dimer (μg/mL)	0.13- 1.7	-	16
Random blood sugar (mg/dL)	-	60	40
Serum urea (mg/dL)	3- 11	55	47
Serum creatinine (mg/dL)	0.4- 0.9	2.6	2.1
Viral hepatitis (A, B, C, E)	-	Negative	Negative

INR: International normalized ratio

hypoglycemia, metabolic acidosis, hepatic failure, and cardiomyopathy and are associated with increased perinatal morbidity and mortality.[1] In an ideal scenario, it is always better to search for this mutation in the mother and the newborn so that we can prognosticate the case and predict about the recurrence in a future pregnancy. However, in our case, we could not get the mutation testing done as it was not available in our setup. Andaman and Nicobar Islands Institute of medical Sciences is the only tertiary referral hospital of the island catering the entire population. The patients who are difficult to be managed due to lack of infrastructure or resources are referred to Chennai or Kolkata on government expense for further management. Our first case, who survived, was given the option of molecular testing at a higher center, but she refused for that.

AFLP is a diagnosis of exclusion. A high index of suspicion is required to diagnose AFLP, as there are no straight forward noninvasive diagnostic tests to make a confirmatory diagnosis. The clinical presentation may be nonspecific. Many case reports have been published describing the myriad presentation of this condition.[9-11] The patient commonly presents with malaise, epigastric pain, nausea, and vomiting followed by jaundice. On laboratory tests, bilirubin levels may be high but are usually not more than 10 mg per dl, liver transaminases may be elevated but not more than 1000 U/L, and renal dysfunction, coagulopathy, hypofibrinogenemia, and hypoglycemia may be present.[6] Both our cases had hyperbilirubinemia, hypoglycemia, hypofibrinogenemia, and raised LDH which favored AFLP. Although one should have a high index of suspicion for AFLP, other pregnancy-related liver conditions that mimic AFLP such as acute viral hepatitis, preeclampsia, HELLP syndrome, intrahepatic cholestasis of pregnancy (IHCP), and cholelithiasis must also be taken into consideration. Differentiation between preeclampsia with liver involvement, HELLP syndrome, and AFLP is a challenging task because of similar clinical and laboratory picture. However, there are some specific patterns which can aid in differentiating them. Women with HELLP usually have high BP and do not have hypoglycemia. Women with AFLP can have preeclampsia, but females with preeclampsia alone are not usually jaundiced and do not usually have hypoglycemia. Severe coagulopathy, jaundice, hepatic encephalopathy, ascites, hypoglycemia, and a mild-to-moderate elevation of transaminase levels are the key features of AFLP and were present in our cases also.

Women with acute viral hepatitis in pregnancy also present with fever, nausea, vomiting, fatigue, and jaundice, but the aminotransferase values are markedly elevated (>1000 U/L) and serology test will be positive. IHCP can cause jaundice as well, but itching is the characteristic symptom with raised serum bile acid levels. After excluding these cases, a clinical impression of AFLP was made in our case.

The specificity and sensitivity of the imaging studies in diagnosing AFLP are insufficient, and the likelihood of false-negative results is high.[6] Liver biopsy is the gold standard test, but it is invasive, risky, and requires a normal coagulation status.

The optimal management of AFLP is prompt delivery and supportive care of the mother. However, many patients may deteriorate even after delivery,[10] as it was seen in our second case where the patient died on the 5th day. The relatives denied postmortem examination. Such severely ill patients may require ICU care including assisted ventilation and dialysis. Aggressive correction of hypoglycemia and coagulation abnormality is the mainstay of treatment. Maternal deaths usually occur due to hemorrhage, gastrointestinal bleeding, sepsis, aspiration, pancreatitis, or renal failure. Surviving patients generally recover with no hepatic sequel.[6]

CONCLUSION

AFLP is a medical and obstetrical emergency. Although in low-resource settings, molecular testing cannot be done, but with a high index of suspicion, early recognition, timely referral, prompt delivery, and aggressive management, morbidity and mortality of AFLP can be greatly reduced.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

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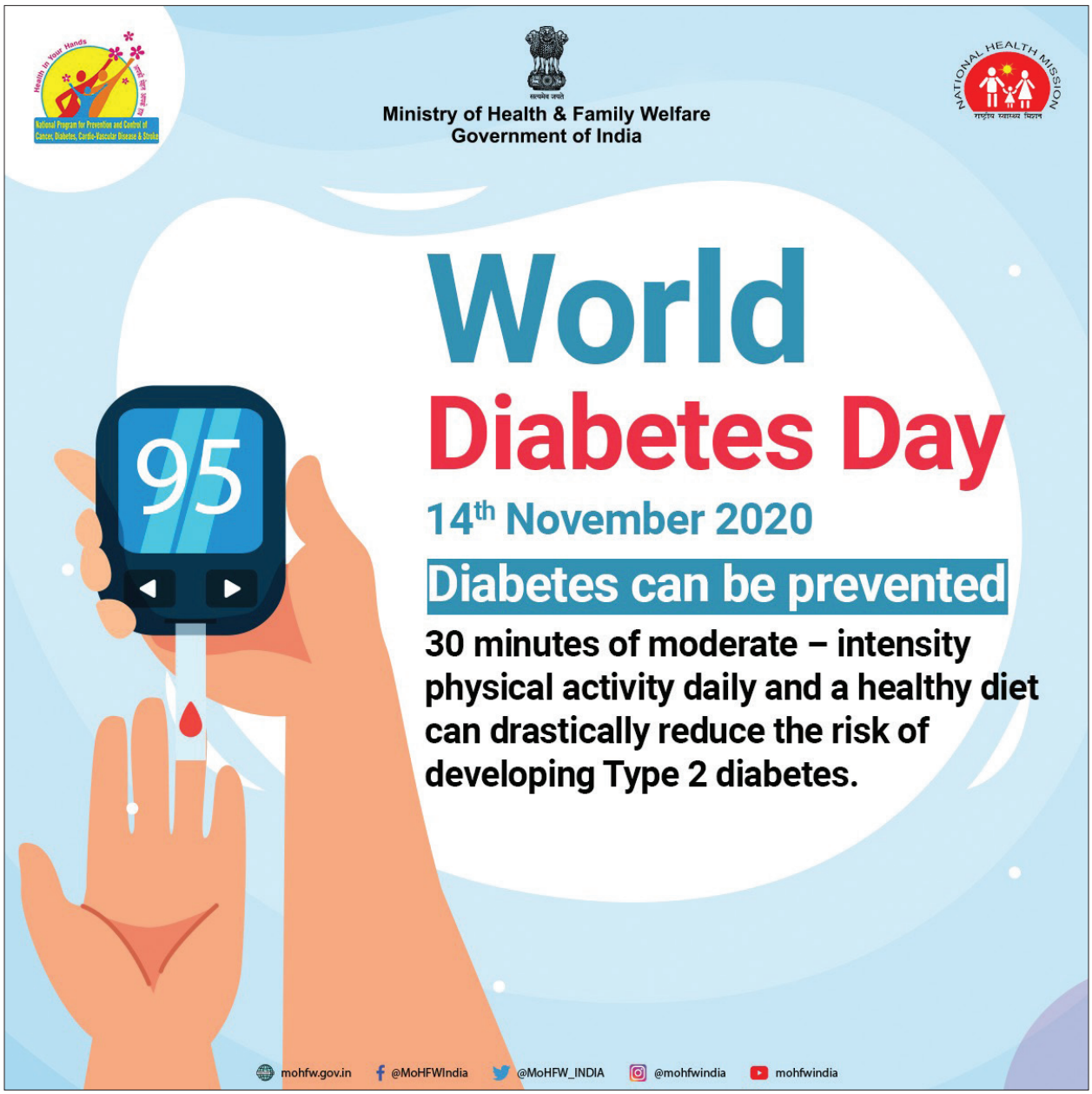

Disinfection of environment in health-care settings: In COVID era

Sir,

Coronavirus disease 2019 (COVID-19) is a respiratory illness caused by SARS-CoV-2. The disease is mainly transmitted by close contact and respiratory droplets, while the role of surface contamination, especially in health-care settings, is not conclusively proven. Keeping in view about the role of fomite transmission in case of other coronaviruses, the World Health Organization has given guidelines about the measures to be taken in health-care settings to avoid such spread. Environmental surfaces, mainly areas where COVID cases are managed, and medical procedures (bronchoscopy, endotracheal intubation, etc.) being carried out are more likely to be contaminated with the virus. Therefore, those areas must be demarcated and disinfected properly as per guidelines in order to avoid further transmission.[1]

First, the environment has to be cleaned with soap and water mechanically in order to remove the dust, debris, and other organic matters. Then, a recommended disinfectant (like sodium hypochlorite) has to be applied in the right concentration (e.g., 1% sodium hypochlorite) and should be left for the recommended contact time (at least 10 min), so as to kill all the microbes. Metallic surfaces like door handles can be disinfected with 70% alcohol where bleach is not suitable. Proper disinfection of the environment involves adequate training, monitoring, and feedback of the staff involved. Appropriate personal protective equipment (PPE) need to be worn while preparing or using disinfectants to avoid exposure to chemicals. PPE which are advised include uniforms with long sleeves, closed work footwear, aprons, heavy-duty rubber gloves, triple-layer medical mask, and face shield.[2] Special care needs to be taken while doffing the PPE so as to avoid self-inoculation with contaminated PPE or hands and a separate doffing room needs to be set up which has to be disinfected regularly.[3]

Hypochlorite products such as sodium hypochlorite solution display a broad spectrum of action against majority of the microbes. As per the recommendations of National Guidelines for Infection Prevention and Control in health-care settings by the Government of India, 1% sodium hypochlorite solution can be used for disinfection of surfaces that might have got contaminated with the organism during patient care. Chlorine solutions decay rapidly in accordance with time and hence have to be prepared daily. Table 1 shows some of the common

Table 1: Guidelines for environmental disinfection in health-care settings

Area/item	Agent	Method
Floors	Warm water, detergent, sodium hypochlorite (1%)	First mop the area with the warm water and detergent solution Mop area again using sodium hypochlorite 1% after drying the area
Doors and doorknobs	Damp cloth or sponge, squeeze mop, detergent (alkylbenzene sulfonates) 70% alcohol	Doors are to be washed with a brush, using detergent and water once a week Door knobs and other frequently touched surfaces should be cleaned daily Metallic surfaces such as door handle and security locks are cleaned with 70% alcohol
Railings	Detergent/sanitizer- warm water, sodium hypochlorite (1%)	Damp dust with warm water and detergent followed by disinfection with hypochlorite
Isolation room	Detergent/sanitizer- warm water, sodium hypochlorite (1%)	Terminal cleaning Three buckets (one with plain water and one with detergent solution); separate bucket for sodium hypochlorite (1%)
Clinical areas/laboratories/ wherever spill care is required	Sodium hypochlorite (1%), absorbent paper, spill care kit, mop, hot water	For large spills, cover with absorbent paper Cover the spill with sodium hypochlorite (1%) for 10- 20 min contact time Clean up spill and discard into infectious waste bin (yellow color), and mop area with soap and hot water
Stethoscope	Alcohol-based rub (70% alcohol)/spirit swab	Should be wiped with alcohol-based rub/ spirit swab before each patient contact
Thermometer	Detergent and water- alcohol rub (70% alcohol) individual thermometer holder	Clean with detergent and tepid water and wipe with alcohol rub in between patient use
Light switches	Damp cloth (never wet), detergent-warm water	Light switches to be cleaned of dust, spots, and finger marks. Clean with a damp cloth (never wet) and detergent

surfaces that could get contaminated with the SARS-CoV-2 and the recommended method of disinfection.[4,5]

Spraying or fogging using some disinfectants is not recommended, because of their ineffectiveness over the organic matter, in addition to the risk of adverse health effects among the workers. Some no-touch disinfectant methods such as ultraviolet irradiation and use of vaporized hydrogen peroxide are being tested and approved in some places but only for terminal disinfection and that too with prior removal of organic matter by cleaning. Furthermore, spraying disinfectants over people need to be avoided under any conditions, as it may lead to serious health consequences. All touchable surfaces have to be disinfected, but those high-touch surfaces (such as bed rails, door handles, and switches) have to be disinfected frequently.[2]

Appropriate disinfectants have to be selected for health-care settings, while taking into consideration their efficacy against other health-care-associated infections too, apart from SARS-CoV-2. Even though there is not much evidence on the role of fomite risk in nonhealth-care settings (such as homes, schools, offices), high-touch surfaces need to be identified and disinfected regularly. Due to the fact that the Coronavirus can survive in the environment for days, disinfection of the environment, especially the health-care settings where COVID-19 patients are managed becomes imperative.[6,7]

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