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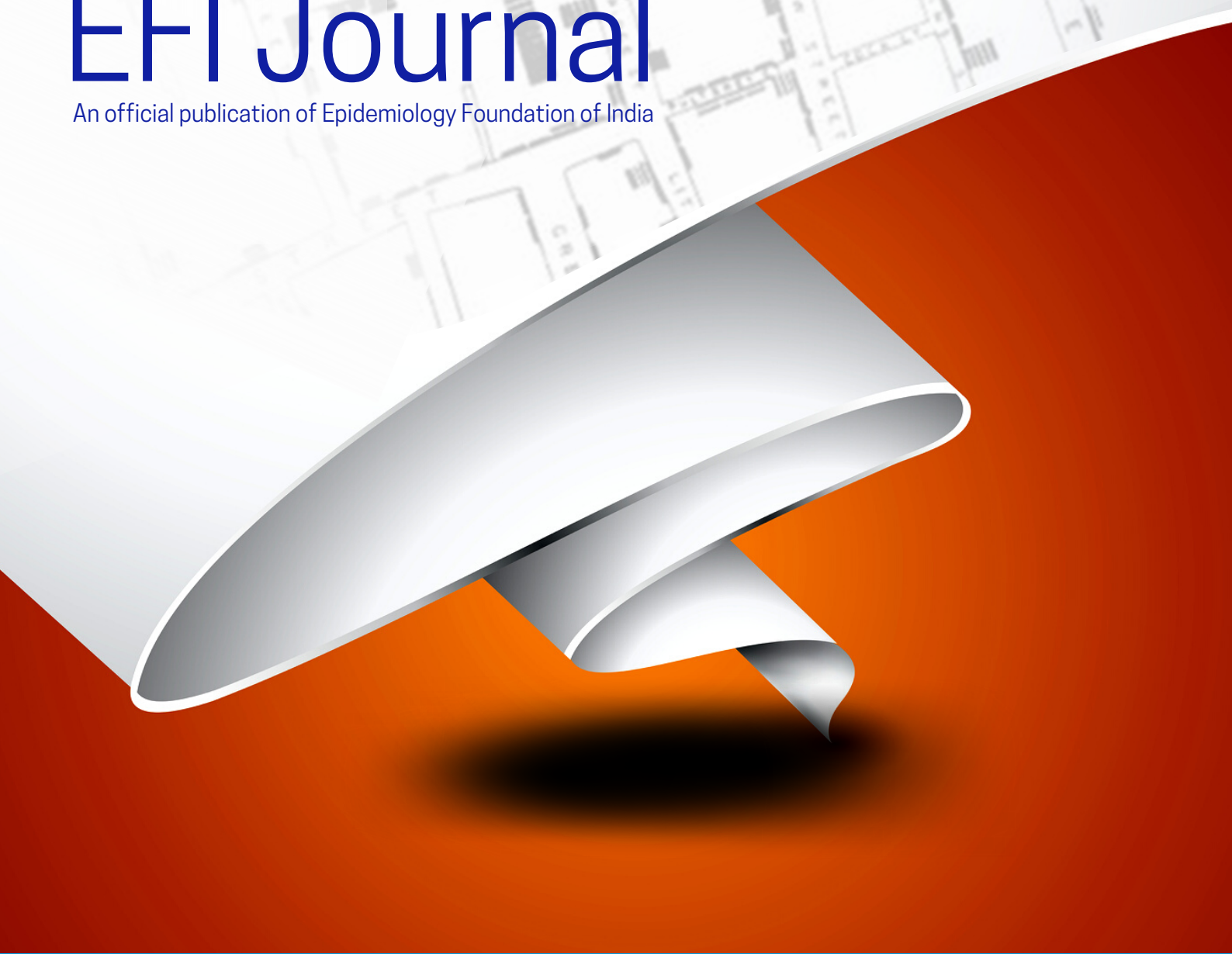

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EDITORIAL

Artificial Intelligence (AI) in Community Medicine and Public Health: Current Applications and Future Prospects.

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Artificial intelligence (AI) has been transforming the healthcare industry over the past decade. One area of medicine where AI has the potential to make a significant impact is community medicine. Community medicine focuses on the health of populations rather than individuals and involves preventative measures to promote healthy lifestyles, disease control, and health education.(1)

AI can be applied in various ways in community medicine to improve health outcomes for populations. One way is through predictive modeling, where AI algorithms can analyze data from electronic health records (EHRs), social determinants of health, and environmental factors to predict the likelihood of disease outbreaks or health risks in a particular community. This can help public health officials to develop targeted interventions and prevent the spread of disease.(2)

Another way AI can be used in community medicine is through natural language processing (NLP). NLP is the ability of machines to understand human language and can be used to analyze patient notes and other medical records to identify patterns and trends in health outcomes. This can help healthcare providers to identify at-risk populations and develop targeted interventions to improve health outcomes.(3)

AI can also be used in community medicine to improve the accuracy of diagnoses and treatment plans. AI algorithms can analyze large amounts of medical data to identify patterns and make predictions about the best treatment options for a particular patient. This can help healthcare providers to develop personalized treatment plans that are more effective and efficient.(4)

Moreover, AI can be used to improve patient engagement in community medicine. For example, AI-powered chatbots can be used to provide patients with personalized health information, answer questions, and offer support. This can improve patient outcomes by increasing patient engagement and reducing healthcare costs.

In conclusion, AI has the potential to revolutionize community medicine by improving health outcomes for populations. AI can be used to predict disease outbreaks, identify at-risk populations, develop personalized treatment plans, and improve patient engagement. While AI is not a replacement for human healthcare providers, it can be a valuable tool to support their work and improve the health of communities.

Here are some examples of how AI is being used in public health:

Disease surveillance: AI can be used to analyze data from a variety of sources, including social media, search engines, and electronic health records, to identify outbreaks of infectious diseases or other health threats. This can help public health officials to

respond more quickly and effectively to these threats and prevent them from spreading(5).

Vaccine development: AI can be used to accelerate the development of vaccines by analyzing large amounts of data on the structure and function of viruses and bacteria. This can help researchers to identify potential targets for new vaccines more quickly and to develop them more efficiently(6).

Disease diagnosis and treatment: AI can be used to improve the accuracy of disease diagnosis and to develop personalized treatment plans based on individual patient data. This can help to improve health outcomes and reduce healthcare costs.(7)

Health behavior change: AI can be used to analyze data on health behaviors and to develop targeted interventions to promote healthy behaviors. For example, AI-powered chatbots can be used to provide personalized health information and support to individuals, encouraging them to adopt healthier behaviors.(8)

Environmental monitoring: AI can be used to analyze data from environmental sensors and other sources to identify health risks associated with air and water pollution, climate change, and other environmental factors. This can help public health officials to develop targeted interventions to reduce these risks and improve health outcomes for communities.(9)

While AI has tremendous potential to transform public health, there are also important ethical and privacy considerations that must be addressed. It is important to ensure that the use of AI in public health is transparent, accountable, and protects the privacy and confidentiality of individuals' health data.

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REVIEW ARTICLE

Interim Analysis: Insights and its importance in clinical research

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ABSTRACT

In resource limited situations, interim analysis helps in decision making process of an interventional study. Interim analysis enables researchers to rethink about the sample size, modify the study design, terminate an ongoing trial, or declare success for a new intervention or drug. Interim analysis should be planned at the very beginning of the study during the protocol development and setting confidence level. Rational use of interim analysis can lead to justifiable conclusion of study with available resources. Unplanned and irrational interim analysis shows false superiority of intervention over control. Besides, it leads the researchers to oversee the progression of a properly designed interventional study. This review tries to put some light over the rationality, advantages and pitfalls of interim analysis in clinical trials.

KEYWORDS

Research Design; Longitudinal Studies; Research Personnel; Decision Making; Review Literature as Topic

INTRODUCTION

Many times, in clinical trials and other scientific studies, researchers perform an analysis of data before data collection for the expected sample size has been completed, known as interim analysis. It is defined as pre planned examination of the data conducted prior to the final planned analysis, allowing investigators and/or funders to assess the likelihood of the study's success or failure while effectively managing statistical errors.(1) Also known as early or intermediate analysis, it offers an opportunity to assess trial progress and outcomes before the study's completion. This enables researchers and stakeholders to make informed decisions and potentially modify the trial protocol or treatment strategy based on emerging data.

During 1960s, as clinical trials were the benchmark for Evidence-Based Medicine, the National Institutes of Health [NIH], established a dedicated committee to tackle the various challenges encountered in the design, execution, monitoring, and analysis of trials, especially those involving complex multi-institutional studies. (2) The report emphasizes the fundamental principle that clinical trials should prioritize participant safety and avoid unnecessary prolongation. Additionally, it highlights the importance of establishing independent committees to diligently monitor accumulating data.

Why to plan interim analysis?

There are multiple reasons which demand the researcher to look at the data collected and see whether a meaningful inference can be made without making any false assumptions. The interim analysis presents a range of options and

opportunities for the trial, exemplifying potential avenues for further exploration, for example:

- An opportunity to re-estimate the sample size
- An opportunity to modify the trial design
- An option to stop the trial for efficacy or futility

Three major reasons for which an interim analysis is planned are as follows:

1. Ethics

There are two compelling ethical reasons that mandate the cessation of a trial:

- When interim analysis demonstrates the superiority of one intervention over the other, it becomes ethically imperative to halt the study e.g. In the ASCOT-BPLA study for comparison of amlodipine and atenolol based anti-hypertensive regimes for non-fatal and fatal coronary artery disease. The experiment was terminated after a total of 19,257 patients were monitored for a median of 5.5 years, as all cause death [738 vs. 820, p = 0.02], cardiovascular death [263 vs. 342, p = 0.001], stroke [327 vs. 422, p = 0.0003], and death from any cause [738 vs. 820, p = 0.02] were all considerably lower in the amlodipine group. (3)
- When interim analysis shows evidence indicating safety concerns and the potential for undue risk to participants, it becomes ethically imperative to terminate the trial and prevent further exposure e.g. BART study conducted to compare tranexamic acid, aprotinin and aminocaproic acid in patients undergoing high-risk cardiac surgery. The study focused on two important outcomes: massive postoperative bleeding and 30-day mortality. The analysis revealed a statistically significant increase in 30-day mortality associated with the use of aprotinin compared to the other two drugs, with a relative risk of 1.53 (95% CI 1.06-2.22). These concerning findings regarding safety led to the early termination of the study. (4)

2. Lack of difference

When the data indicates a lack of significant difference between the two treatments, it becomes desirable, from both ethical and cost perspectives, to discontinue the study e.g. PRESENT study - This multicenter, randomized, double-blind controlled study enrolled 758 women with early-stage node positive breast cancer and low to intermediate HER-2 neu expression. Participants were randomly assigned to receive either a novel vaccine called Nelipepimut (designed to stimulate cytotoxic T lymphocytes for the destruction of HER-2 neu expressing cancer cells) in addition to standard of care, or a vaccine adjuvant alongside standard of care. However, the study was halted for futility by the Data and Safety Monitoring Committee (DSMC). The DSMC concluded that continuing the study would not have demonstrated a significant difference between the two treatment arms, rendering further investigation unnecessary (5)

3. Slow accrual

When participant enrolment in a study is significantly slow for any reason, a decision can be made to either continue the study if the research holds substantial importance or discontinue the study due to futility.

When to conduct an interim analysis?

The trial protocol should explicitly outline the timing, frequency, and methods for conducting the analysis prior to commencing the study. Depending on the number of subjects and the specific drug or device under investigation, there may be one or multiple analyses conducted at different time points. It is crucial to time the analysis when a sufficient number of subjects are enrolled in the trial to detect meaningful signals. Insufficient data makes it challenging to identify significant findings. However, conducting the analysis too late in the study diminishes its value, hence striking the right balance is essential.

An illustration of multiple interim analyses in a comparative trial, where the efficacy of two treatments is being compared, can be outlined as follows:

$H0: p2 = p1$

$H1: p2 > p1$

In a standard design, considering 80% power with an alpha of 0.05, it is estimated that around 100 patients per arm are needed based on assumptions of p2 = 0.50 and p1 = 0.30, resulting in a difference of 0.20. However, what if we encounter a situation where we observe $P < 0.05$ before all patients are enrolled? Why is it not appropriate to examine the data multiple times during the trial and conclude that one treatment is superior if we observe $P < 0.05$?

As it is observed that every time data is looked and researcher considers stopping, there is a chance of rejecting the null hypothesis falsely. If data is looked at multiple times, and alpha of 0.05 is used as

criterion for significance, there is 5% chance of stopping each time and total probability of stopping with increased number of looks. (6)

Hence it becomes of utmost importance that results of interim analysis should be interpreted cautiously and we should keep alpha according at each time of analysis to minimise the chances of committing Type I error while rejecting the null hypothesis. How we set alpha in a planned interim analysis is discussed in the next section.

Planned and Unplanned Interim analysis (Interim analysis in RCTs)

Investigators typically have three choices when it comes to interim analyses: they can choose to entirely avoid them, analyze the data whenever they desire without considering the potential for inflated type-1 errors, or opt for a more structured approach by adopting a theoretical framework of sequential designs with continuous data monitoring. Given the availability of statistical methods, it is generally recommended to incorporate planned interim analyses rather than relying on unplanned assessments.

- Planned Interim Analysis:
  Three points to be kept in mind when planning for interim analysis are: 1) which endpoint(s) to analyse; 2) how many interim analyses to plan and 3) which group sequential procedure to adopt. (7) On the basis of these questions, different approaches are used to set the alpha value during the interim analysis which is discussed in the next section.
- Unplanned Interim Analysis:
  Many trials with no formal plans for interim analyses, often request for interim analysis whenever it seems “something interesting” is going on. Such scenarios present a dilemma to the collaborating statistician who is aware of biases involved as treatment differences may be grossly exaggerated because interim analysis is “data provoked.” Consequently, conducting an unplanned interim analysis using conventional significance testing raises the risk of encountering false positive findings that are unlikely to withstand scrutiny over time.(7)

Approaches for setting alpha error

Investigators cannot disregard interim analyses when data monitoring is warranted. However, conducting multiple interim analyses without accounting for multiplicity concerns escalates the risk of false-positive errors. While planning for a trial an appropriate sample size is estimated considering the four elements – alpha error, beta error, expected variability and magnitude of difference known as effect size. The alpha error, typically set at 5%, is allocated across all planned analyses when multiple looks at the data are intended. This adjustment ensures that the alpha is appropriately distributed or spent over the course of all the analyses.

When a researcher intends to exhaust the entire alpha of 5% in each analysis conducted, there is a significant risk of inflating the alpha level and subsequently increasing the likelihood of a false positive error. Even if the alpha is adjusted at each analysis point, it is crucial to acknowledge that the sample size at each look is considerably smaller than the final sample size, as the final sample size calculation typically considers a beta error of 10% or 20%. Thus, it is essential for statisticians to adopt an approach that takes into account both factors, as there is no reason to believe that one error is inherently more severe than the other. However, in practice, greater emphasis is often placed on the alpha error due to the potentially more serious implications associated with a false positive finding.

The subsequent section delves into the adjustment and prudent utilization of the alpha level across the planned interim analyses.

1. **O’Brien and Fleming approach:**
   A widely employed and straightforward approach involves allocating a small portion of the alpha for the initial stages of the study and reserving a larger portion for the final analyses. This allocation strategy ensures that it is more challenging to reject the null hypothesis in the early stages, while making it comparatively easier to do so later on.(1)
2. **Pocock approach:**
   It uses the same significance level at each interim analysis point. Of all the approaches, it provides the best chance of early trial termination.
3. **Haybittle Peto approach:**
   This approach employs an exceedingly small allocation of alpha during the initial interim analyses, significantly lower than the O'Brien and Fleming approach. However, in contrast, the final analysis consistently utilizes the entire 5% alpha level. Therefore this methods allows the researcher to utilize full 5% alpha at the end like

traditional designs but at the same time extremely low alpha at the interim analysis stages makes it almost impossible to stop the study at an early time point. (8)

The aforementioned three approaches are commonly referred to as Frequentist approaches due to their rigid nature in accommodating changes during the study. In contrast, in this particular approach, prior information is considered as a supplementary factor rather than an integral part of the formal analysis, and the initial model remains unaltered at the point of data analysis.(9)

To overcome drawbacks of frequentist approach alpha spending function approach was developed.

1. Alpha spending approach:

This approach is more flexible and provides both academic and industry sponsored trials with a convenient way to monitoring accumulating results. This approach offers flexibility to accommodate varying timing and additional data assessments beyond the original plan. Researchers have the freedom to allocate their alpha as they see fit while ensuring that the total alpha spent remains within the predetermined limit, such as 5% or any other specified value set at the beginning of the trial.(10)

Advantages: Interim analysis can help re-estimating the sample size of large clinical trials. The study design can be modified based on the result of a well-planned interim analysis. Interim analysis gives insight into efficacy of new drug or intervention, as well as futility of the study. Interim analysis also tells if the study should be continued or not. Interim analysis reveals significance of new intervention before the entire sample size is reached, and hence helps in making key decisions early.

Pitfalls of doing an interim analysis: Several factors need to be considered when analyzing data from early patients in a trial. These include the potential lack of representativeness of early patients compared to later patients, the possibility of a small number of events, and the potential for randomization to not have yet achieved balance between treatment groups. Planning for interim analysis is extremely crucial for any clinical trial because unplanned interim analysis can influence the researcher to prematurely stop the study or wrongly interpret the results. Also there is chance that after looking at the data research may bring bias to the study therefore blinding becomes utmost important in such conditions.

Challenges and way forward: Researchers often lack knowledge of doing interim analysis. Researchers motivated by business profit can use irrational use of interim analysis and prematurely terminate a properly designed clinical trial. Members of data safety and monitoring committee (DSMC) should stay unblinded in due course of study, but it is not seen in most of the cases and this can influence the decision to terminate or continue the study. (11) Though interim analyses provides evidence to researchers to help decision process to terminate a trial earlier than planned but there are other factors to consider along with it such as, baseline comparability, treatment compliance, outcome ascertainment, benefit to risk ratio, and public impact of the decision.

Rational use of interim analysis is vital for clinical trials where there is anticipation of clinical significance being accepted more than statistical significance. Interim analysis is mainly done in ongoing clinical trials to see the significance of results. Interim analysis should always be planned in the protocol stage of any clinical trial. Unplanned interim analysis can lead to wrong conclusion of a systematically conducted clinical trial. It should me made sure that interim analysis to be done in classical randomized double blinded clinical trials. It should not be done for any business interest or profit. Role of data safety and monitoring committee stays very crucial in interim analysis. A properly planned interim analysis helps avoiding unnecessary delay in drawing conclusion of an interventional study.

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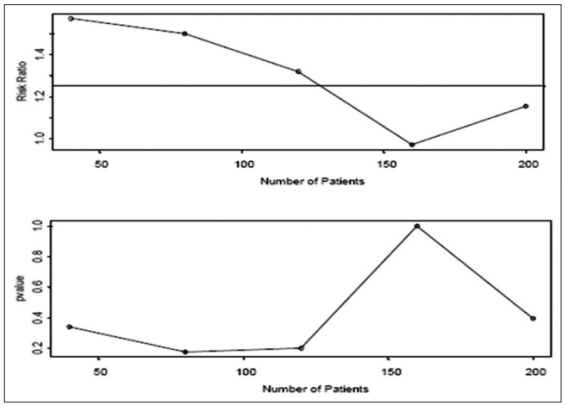
FIGURES

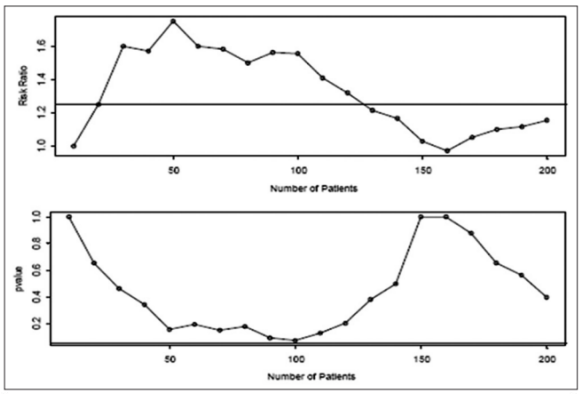
Figure 1 Example of a comparative trial in which two treatments are being compared for efficacy with having different frequency of interim analysis.

A)



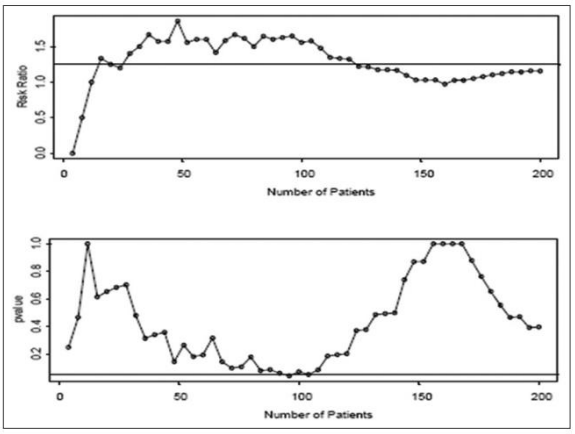
Scenario 1:
When conducting interim analyses after every forty patients, the scenario arises where neither treatment would warrant termination based on the observed results. However, if we were to wait until the completion of the trial with a sample size of 200, the calculated P-value indicates a significant difference of 0.40 between the treatments. (Fig. 1A)

B)



Scenario 2:
By conducting interim analyses after every ten patients, we observe a scenario where the study would not be stopped until all 200 patients are observed. In this case, the analysis would yield a non-significant difference with a calculated P-value of 0.40, leading to the conclusion that there is no significant difference between the treatments. (Fig. 1B)

C)



Scenario 3:

By conducting interim analyses after every four patients, the observed scenario indicates that the study would be stopped at 96 patients. At this point, the analysis would reveal a significant difference between the intervention and control groups, leading to the conclusion that there is a statistically significant distinction between the two treatments. (Fig. 1C)

Figure 2 Comparing the alpha values of three approaches for interim analysis, namely the O'Brien Fleming, Haybittle-Peto, and Pocock approaches revealing their distinct differences.

Number of analyses	1	2	3	4	5
Method of analysis					
	Alpha value of 5% distributed at each analysis				
O'Brien Fleming					
2	0.0054	0.0492	-	-	-
3	0.0006	0.0151	0.0471	-	-
4	0.00005	0.0039	0.0184	0.0412	-
5	0.000005	0.0013	0.0085	0.0228	0.0417
Haybittle – Peto					
2	0.01	0.05	-	-	-
3	0.01	0.01	0.05	-	-
4	0.001	0.001	0.001	0.05	
5	0.001	0.001	0.001	0.001	0.05
Pocock					
2	0.0294	0.0294	-	-	-
3	0.0221	0.0221	0.0221	-	-
4	0.0158	0.0158	0.0158	0.0158	-
5	0.0158	0.0158	0.0158	0.0158	0.0158

CME

Non-alcoholic Fatty Liver Disease (NAFLD): An 'Ongoing Silent' Epidemic

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Liver diseases are considered as one of the leading global health priorities. Fatty liver is categorized into two main types. One is non-alcoholic fatty liver disease (NAFLD) and other is alcoholic fatty liver disease (ALD); also known as alcoholic steatohepatitis. The pathogenesis of build-up of excess fat being different in these two conditions however both are significantly changing the burden of liver diseases worldwide.[1] Readily accessible calorie-dense food and sedentary lifestyle together with the modern epidemics of diabetes mellitus (DM) and obesity have propelled non-alcoholic fatty liver disease (NAFLD) into a substantial public health problem in India as well as globally.[2] NAFLD has emerged as one of the leading causes of cirrhosis, hepatocellular carcinoma (HCC), and liver transplant in India.[3]

Considering enormous population, the burden of NAFLD in India is likely to be substantial, which may significantly burden health-care systems and causing substantial economic and well-being losses.

Non-alcoholic fatty liver disease (NAFLD) was first described as a distinct clinical entity four decades ago in the 1980s. Due to its high prevalence and growing contribution to the burden of end-stage liver disease, the condition has become the centre of attention within hepatology.[4] NAFLD is an umbrella term that describes a histological spectrum ranging from excess fat deposits in the liver (steatosis) to the more aggressive non alcoholic steatohepatitis (NASH), which is characterized by hepatic inflammation (steatohepatitis) that prompts scarring of liver tissue (fibrosis).[5]

NAFLD is also a potential contributor to an important burden of extra-hepatic chronic complication. Alongside the progressive liver damage, NAFLD is becoming an established risk factor for the leading causes of death and disability in the modern era, namely cancer, cardiovascular disease and type 2 diabetes mellitus. Previous literature has established the complex relationships between NAFLD, obesity and many modifiable risk factors, such as sedentary lifestyle, lack of exercise, and has also started to elucidate some of the genetic drivers of NAFLD.[6]

Stages of non-alcoholic fatty liver disease (NAFLD)

Development of NAFLD most likely occurs in four main stages. Most people will only ever develop the first stage without realising the disease. However in a few cases it can progress and if not detected and managed timely, may lead to permanent liver damage.[7]

The main stages of NAFLD are:

1. **Simple fatty liver (steatosis)** – This stage is mostly harmless and characterized by building up of fat in the liver cells. There are often no symptoms in this stage, therefore many people

are unaware that they have a fatty liver and it is usually diagnosed accidently.

2. **Non-alcoholic steato-hepatitis (NASH)** – This stage is considered as a more serious form of NAFLD, where the inflammation of liver gets started.
3. **Fibrosis** – In this stage there is formation of scar tissues around the liver and nearby blood vessels due to persistent and progressive inflammation, but the liver still may be able to function normally.
4. **Cirrhosis** – The most severe stage that occurs after many years of inflammation, where the liver gets shrink and becomes scarred and lumpy. This damage is permanent which leads to liver failure and liver cancer.

It can take several years for progression from steatosis to fibrosis or cirrhosis. It's important to make lifestyle changes to prevent the permanent damage to the liver.

Disease burden and Prevalence of NAFLD

Non-alcoholic fatty liver disease (NAFLD) is estimated to affect approximately 1 billion individuals worldwide. The worldwide prevalence of NAFLD is about 25%, ranging from 13% in Africa to 23% in Europe and 32% in the Middle East.[8] Non-alcoholic fatty liver disease (NAFLD) is emerging as an important cause of liver disease in India. Epidemiological studies suggest prevalence of NAFLD in around 9% to 32% of general population in India with higher prevalence in those with overweight or obesity and those with diabetes or prediabetes.[9]

NAFLD is a very common disorder affecting as many as 20-30% of the general population all over the world. About 2 to 5 % of adults and up to 20% of those who are obese may develop NASH. Several factors contribute to the development of NAFLD or NASH and subsequent Hepato-Cellular Carcinoma (HCC) development. The presence of diabetes, hypertension, and dyslipidemia ,male sex, older age , diet, lifestyle, obesity, genetic risk factors including a family history of NAFLD or metabolic syndrome, are the most important risk factors for HCC.[10]

Over the past 20 years, the global burden of NASH has more than doubled from 40 lakh prevalent cases of compensated cirrhosis in 1990, to 94 lakh cases in 2017. This disease is highly prevalent with 10-30 per cent of the global population being affected by it.

The prevalence of NAFLD among the general population in India ranges from 9% to 53%. Previous research suggests that differences in diagnostic techniques for NAFLD may attribute for the wide variation in reported prevalence. Additionally there is evidence of rural-urban as well as geographical variations[11]

Diagnosis of non-alcoholic fatty liver disease (NAFLD)

NAFLD is often diagnosed after an abnormal liver function test and other liver conditions, such as hepatitis. Serum markers like aminotransferases (AST, ALT), are mild to moderately elevated or may be normal. In patients with NAFLD, ALT elevations are more common than elevations of AST. ALT levels tend to be higher in NASH than in simple steatosis.[12] However blood tests do not always pick up NAFLD.

Various imaging modalities can be used to substantiate the diagnosis, however none of them are routinely used for differentiating between (histological) subtypes of NAFLD or NASH.[13] Imaging findings in patients with NAFLD include increased echogenicity on ultrasound, decreased hepatic attenuation on CT, and an increased fat signal on MRI. Due to diffuse fatty infiltration, ultrasound scan often reveals a hyperechoic texture or a bright liver. The sensitivity and the specificity of ultrasound are 89% and 93% respectively in detecting increased fibrosis and steatosis.[14] Further tests may be needed to determine the staging of disease once the person is diagnosed with NAFLD. This may involve a special blood test or having another type of elastography scan (Fibroscan). Fibroscan measures the scarring by determining the stiffness of liver tissue.

Currently, the only reliable method of telling whether a patient has NASH or simple fatty liver is liver biopsy, where a small sample of liver tissue is taken using a needle and further analysed in a laboratory.[11]

Treatment for non-alcoholic fatty liver disease (NAFLD)

Most people with NAFLD will not develop any serious problems, however if someone is diagnosed with the condition it's a good idea to take further steps to stop it getting worse. There's currently no specific medication for NAFLD. Lifestyle interventions are the primary modality for the management of NAFLD and have been shown to improve biochemical and histological outcomes in Indian patients.[3] With the growing obesity pandemic and the rising prevalence of co-morbid conditions like Type 2 diabetes mellitus

and NAFLD, the management of these patients has become even more complex.[15]

The Ministry of Health and Family Welfare, Government of India has undertook a leading step by integrating Non-Alcoholic Fatty Liver Disease (NAFLD) into the National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), a way forward towards addressing India's non-communicable diseases (NCDs). India has become the first country to do so and has created a sense of urgency in addressing the ongoing epidemic of NAFLD and NASH in India. Now there is need of further convergence in the approaches with clear risk stratification and implementation in mission mode for prevention, early diagnosis and management of NAFLD.

Health education regarding lifestyle modifications to children, adolescents in schools and colleges may be the need of the hour. A broad-based integrated approach that incorporates social, behavioural as well as biological targets need to be undertaken at a health system level along with strong efforts are also required to change the perception and mindset of clinicians as well as the public toward this ongoing but silent epidemic.

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COMMENTARY

Family adoption program: A way forward to community based medical education, challenges ahead

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ABSTRACT

Medical education in India is based predominantly on hospital environments and specialist services covering a narrow spectrum of health problems, with especially dependent on technology. A significant reorientation is needed in medical education, to allow students to understand people in their social contexts in a more holistic way, rather than seeing them merely as parts of a biological machine. National Medical Commission (NMC) in their recent notification included Family Adoption Program (FAP) in the undergraduate curriculum to provide a learning opportunity towards community-based health care to Indian Medical Graduates.

KEYWORDS

Medical Education, Family Adoption Program (FAP), Curriculum

INTRODUCTION

Medical education in India is based predominantly on hospital environments and specialist services covering a narrow spectrum of health problems, with especially dependent on technology. A significant reorientation is needed in medical education, to allow students to understand people in their social contexts in a more holistic way, rather than seeing them merely as parts of a biological machine [(1)] National Medical Commission (NMC) in their recent notification included Family Adoption Program (FAP) in the undergraduate curriculum to provide a learning opportunity towards community-based health care to Indian Medical Graduates. [(2)] The NMC documented its vision as "to provide for medical education system that improves access to quality and affordable medical education, ensures availability of adequate and high-quality medical professionals in all parts of the country; that promotes equitable and universal health care that encourages community health perspective and makes services of medical professionals accessible to all citizens; that promotes national health goals…"[(3)]. Vanikar et al had depicted the road map of this FAP, where one village outside the Rural Health Training Center (RHTC) will be allotted to every new batch of a medical college assigning 5 households to each student. The orientation to the rural health problems with rural health infrastructure will start from the very beginning of the foundation course in the first professional year. Assistant professors and senior residents of Department of Community Medicine will act as the mentors and will coordinate with Gram Sabha and local villagers with local ASHA workers, Anganwadi Worker (AWW) and medical social workers. The students will collect data from the households by visiting them physically, besides they will also take part in the outreach health and awareness camps. As a step towards environmental consciousness, the students will be encouraged for

trees/ medicinal tree plantation[4] Several studies envisaged the advantages of learning in 'the community as a classroom' as achieving communication skills; understanding the customs and cultural beliefs of the rural population, learning to be humane and develop empathy; inculcate leadership skill; working as primary consultants for the households; and learning basic skills of diagnosing and managing health problems, ultimately having training in family medicine.[4-6] Examples of participation of medical students in community health activity are not scarce. The Social Service Camps with village adoption program was running in Mahatma Gandhi Institute of Medical Sciences (MGIMS), Sewagram, Wardha, Maharashtra, successfully for few decades to expose the students to a value based and cost-effective medical education in resource constrained rural areas. They have developed an interface between community, health system & the institute to discharge its role in social responsibility in short term & social accountability as a long-term goal. [7,8] The term Community Based Medical Education (CBME) is also vogue, which refers to learner's clinical training at the community setting and utilized by health science faculties worldwide to provide a relevant primary care experience for students and a service to underserved communities.

Diab et al in a qualitative study in South Africa had cited the short term benefits the community achieved from community based education (CBE) as improved service delivery, reduction of hospital referrals, community oriented primary health care, improved communication with patients and long-term benefits included improved teaching through a relationship with an academic institution, students' participation in community upliftment projects thereby acting as agents of change in these communities [4] Experience from Australia and Canada showed through Longitudinal integrated Clerkships (LICs), year-long community-based placements, students gain strong communication skills and excellent clinical reasoning and management skills, which they described as 'Meaningful personal learning experiences[9]

But implementation of this FAP poses a challenge in India. This needs good infrastructure of each medical college at the RHTC like human resources, vehicular support, funds as well as good accommodation facilities. The renowned well established private medical colleges had built their rural infrastructure on their own or in collaboration with Government settings with an objective of conducting the students/ internship training program, as well as attracting the patient pool for curative services in the hospitals. But most of the Government & private medical colleges are in back foot, not having adequate human resources to run the FAP at rural areas, will have to depend solely on the district health infrastructure. What a herculean task, it is when one medical college with 150 students will have to select at least 750 households per year. ASHA workers working at grassroots level are already overburdened with their routine activities and motivation without incentives will create a problem to engage them in FAP activities. In most of the medical colleges we don't have Medical Social Worker posted in the department who can be the main pivot for making all collaboration with Gram Panchayat and Village Health Sanitation & Nutrition Committees. Dept of Community Medicine is having faculties as per the NMC norms, but they are engaged in teaching and training activities throughout the year from 1st to 3rd Professional MBBS with multiple batches, along with implementation of national programs and participation in administrative activities at college level.

Apart from this National Medical Commission (NMC) has reduced the faculty required in the department of community medicine with replacement of Assistant professor with (MO/IC) Medical officer in charge of RHTC & UHTC (Urban Health Training Centre) which would be one of greatest concern in moderating this family adoption programme for 3-4 MBBS batches impacting the outcome & assessment.

Moreover, as per NMC, the villages to be adopted will be outside the field practice area of RHTC and repetition of villages should be avoided. In spite of having NMC norms for nonmedical/ paramedical manpower in urban and rural field, most of the medical colleges have not employed these designated personnel. In this context, the sole responsibility will lie on the Assistant Professor at RHTC without support of adequate manpower (Post graduate trainees are not present in many medical colleges) to build liaison with the villagers, Gram Panchayat or local NGOs. College to college

variations exist in respect to number of students, strength of faculty and support staff, distance of RHTC from Medical Colleges etc, therefore FAP application cannot be uniform everywhere, so this needs flexibility in its implementation. In the competency based medical education, NMC has provided the curriculum planning how these competencies to be achieved in 1st to last professional MBBS to remain throughout the curriculum. Within the 1-year span of 1st Professional, the students have to pay 9 visits (27 hours duration) to complete the competencies, for which they have to know the survey methodology, PRA techniques, communication skill, history taking, clinical examination, management of illnesses which seemed to be impossible without any clinical exposure and in an overburdened situation to grasp the 1st Professional subjects. Moreover, clarification is lacking about incorporation of the allotted hours of family visits throughout the year in the routine of the whole curriculum. NMC should get thanks for taking an initiative to make the curriculum of community medicine more community oriented. In Indian context, if this FAP can be implemented successfully, this will be a great achievement for the country. The IMGs engaged in both community and hospital setting will understand the health problems in real context, will develop the essential attitude and communication skill needed for a family practitioner, might choose the career options in rural setting. Success of FAP will depend on intersectoral collaboration, logistics, support system & motivation of faculties & students. The colleges or state will have to provide necessary support; otherwise sustainability will be a great question.

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COMMENTARY

Finding 'a risk factor for a risk factor': Universal screening recommendations for non-communicable diseases are not immune to risks of overdiagnosis

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Sharmila Devi wiped her brow with her saree pallu as she served water to the ASHA worker, Sarita, who was visiting her home in Mataundh village, UP. She gazed at Sarita's forms and registers placed carefully on the floor where they sat and exchanged pleasantries. 'We have been asked to test blood sugar and measure blood pressure for everyone in the village over the age of 30 years' said Sarita reaching for her bag. Sharmila Devi, who had been told by Sarita to remain fasting that morning, got a blood test for fasting blood sugar. Sarita raised her eyebrows as she looked at the reading on the glucometer: 135 mg/dl. She advised Sharmila Devi to meet the medical officer in the nearby primary health centre.

Next morning, Sharmila Devi finished her household chores early to line up at the primary health centre to meet Dr Sanjay Kumar. On asking if anything is wrong, Dr Sanjay told her that her blood sugar was in the 'pre-diabetes' range. He advised her to get an HbA1c from a lab nearby. Sharmila Devi returned the next day with her HbA1c report: 6.4%. Dr Kumar saw the report and nodded, yes, Sharmila Devi was pre-diabetic; 'borderline diabetic' he called it.. Sharmila Devi asked him what this means. He told her that she had an increased risk of developing diabetes. Worried that she is now 'at risk', she asked what she could do about it. She was encouraged to modify her diet, increase her exercise, and consider a drug to prevent diabetes and its complications. She made a few changes to her diet and started taking metformin. She experienced side effects from the metformin but was happy when her next HbA1C test result was 5.9%.

But the question to ponder is: Has this patient experienced an early diagnosis or overdiagnosis?
Overdiagnosis is the diagnosis of a condition, that would otherwise not cause symptoms or harm to a patient during his or her lifetime.[1] It has been recognized as a consequence of cancer screening, and was discussed in an article in a previous issue of the *EFI Bulletin*.[2] However, overdiagnosis should be acknowledged as an important consequence of any diagnostic testing in the absence of symptoms. In fact, in the context of primary health care, the concept of overdiagnosis remains largely unrecognized.

Overdiagnosis represents an unwarranted diagnosis. It detracts health care resources from being spent on genuine problems, and leads to unnecessary stress, costs and labeling of individual patients.

With respect to the scenario above, the case of pre-diabetes illustrates the potential for overdiagnosis that exists in any screening scenario. Though it first received attention in the context of cancer screening,[3] the potential for overdiagnosis accompanies screening for most asymptomatic non-communicable diseases, such as hypertension, hyperlipidemia, osteopenia, etc. Some level of overdiagnosis is unavoidable, as perfect tests do not exist, and all diseases occur across a diseases spectrum. Limiting screening to high risk individuals may to some extent minimize overdiagnosis and increase benefit. But it is still impossible to identify with 100% accuracy the cases with disease that would threaten health and do genuinely require treatment. To some extent, screening will identify persons with slowly progressive or non-progressive diseases where treatment will not benefit patients but expose them to potential harms.

The Government of India has recently launched the '75 by 25 initiative', i.e., screening and putting 75 million persons on standard care for diabetes and hypertension by 2025. While it a great public health measure, a dialogue must be intiated on the harms of overdiagnosis for more circumspect policy formulation. Though inevitable to some degree, it is important to understand the factors that drive overdiagnosis so that efforts may be made to minimize it at the population level.

Widening disease definitions

Disease cut-off points are usually selected with the aim of minimizing under-diagnosis, with the expense of high rates of overdiagnosis.[3] Over the years, the definitions of many diseases have changed and become more inclusive, shifting the dividing line between normal and abnormal. This has been the case with hypertension, diabetes, osteoporosis, high cholesterol, obesity, and cognitive impairment. Considering our case scenario above, 'pre-diabetes' in effect broadened the pool of patients diagnosed with 'diabetes' of some form. It is important to remember, however, that diagnostic tests such as HbA1c and blood glucose have variable accuracy and performance characteristics.[4] A low diagnostic threshold for pre-diabetes leads to more people being diagnosed and a lesser proportion of them developing diabetes. Also inherent in this phenomenon is the mistaken assumption that all patients with 'pre-diabetes' will go on to develop diabetes.

The notion of creating a 'at risk' group is also seen in conditions such as hypertension and hyperlipidemia. In the case of hypertension, creation of this 'pre' group has also led many patients to be administered treatment without benefit.[5]

Public health screening programs

Population based interventions such as universal screening presume that screening will reduce the adverse outcomes from unidentified diseases. However, screening will identify persons along the whole spectrum of disease, including those with indolent, non-progressive and slowly progressive diseases that are not destined to harm the patient in any way in the long run. For this reason, screening for breast cancer and prostate cancer are classic examples where the harms of mass screening present a close call between benefits and harms.[6]

According to a systematic assessment of breast cancer screening, for a 40- or 50-year-old woman undergoing 10 years of annual mammograms, about 19% of the cancers diagnosed would not have become clinically apparent without screening.[7] This means that for three women that clearly benefit as a result of screening, 104 will be overdiagnosed with breast cancer and will undergo treatments such as surgery, chemotherapy and radiotherapy for a disease that was never destined to cause harm.

Culture of over-medicalization

Physicans and patients tend to be oblivious to the problem of overdiagnosis in general. Screening is generally viewed as a worthy measure in the medical community for its 'yield' and value in bringing more patients into the purview of treatment. Overdiagnosis is a difficult concept to grasp for patients, who are usually grateful for the result of the screening test that 'caught the disease early'.[8] This belief is further corroborated by a lot of experts who have made strong statements about the benefits of screening, such as that for aggressive mammography.

Limited evidence generation and application

Ideally, a screening programme should be subjected to a randomized controlled trial for assessment of its

effectiveness. Detecting a signal in terms of reduction in overall mortality would be of great value in ascertaining that the screening intervention works. However, such evidence is few and far between.

Moreover, physicians that recommend routine screening have limited knowledge in finding and applying the best evidence for a particular screening test. Awareness of prior probabilities, likelihood ratios and measures of diagnostic accuracy remain topics in theory with little or no application in daily practice.[9]

The consequences of overdiagnosis in the context of nation-wide universal screening programmes are not trivial. It is difficult to quantify the measure of psychological harm, labelling, costs of over-treatment and burden on healthcare systems.[10] But it is certain that the effects are multi-faceted, affecting individuals, systems and society at large. It is an ethical obligation of medical community to make attemps to minimize the harms of overdiagnosis. This can be by better understanding of the concept of overdiagnosis, ameliorating disease definitions, gaining knowledge on evidence for a screening test, optimizing risk stratification for screening and considering overdiagnosis when making clinical decisions.

It may not be possible to ascertain if lady in our case scenario is a victim of overdiagnosis or if she will gain long term benefit. However, it unlikely that her physician considered harms of overdiagnosis while advising her initial HbA1c test. A better understanding of overdiagnosis in primary care, along with its harms will lead to more circumspect advice for screening tests, and better care for patients.

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ORIGINAL ARTICLE

Association of Duration of Diabetes with Erectile Dysfunction among Type 2 Diabetes Patients- A Cross Sectional Study In South India

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ABSTRACT

Background: Erectile Dysfunction (ED) is a common complication in Type2 diabetic patients. Patients with Diabetes Mellitus (DM) are prone to get ED due to various factors. Present study was undertaken to investigate the association between duration of diabetes and erectile dysfunction in type 2 diabetic patients. **Methods:** A cross-sectional hospital-based study was conducted at the out-patient unit of Department of Endocrinology of a reputed hospital, Coimbatore. All married men aged 20-60 years with a diagnosis of type 2 diabetes attending the out-patient unit of Department of Endocrinology, PSG Hospitals, Coimbatore during the months of May and June 2019 were studied. Patients with a history of any coronary event (myocardial infarction, coronary artery bypass surgery or coronary angioplasty) in the previous four weeks, liver diseases, renal diseases, and dialysis were excluded. The severity of erectile function was assessed using the validated International Index of Erectile Function (IIEF-5) questionnaire. Duration of diabetes was elicited in an ordinal scale (1-5, 6-10, 11-30 years). All subjects were evaluated for smoking status, alcohol consumption, obesity, physical activity, retinopathy and hypertension. Multivariate logistic regression analysis was used to assess the effect of the duration of diabetes on ED. **Results:** A total of 204 patients were enrolled in which 65 (31.86%) were found to have ED. A significant increase in the prevalence of ED with duration of diabetes was observed. In patients with diabetes; for 1-5 years, the prevalence was 24.1%, for 6-10 years, the prevalence was 27.7% and for 11-30 years, the prevalence was 53.1%. The mean (SD) of ED score for 1-5 years was 25.17(8.66), for 6-10 years was 24.82(8.55) and for 11-30 years was 20.32(9.22), $p<0.01$. The multivariate adjusted odds ratio of erectile dysfunction for 11-30 years duration of diabetes compared to 1-5 years duration of diabetes was 2.505 (95% Confidence Interval (CI) (1.038-6.045), $p<0.05$. **Conclusion:** For type 2 diabetic men, increasing duration of diabetes was positively associated with increasing risk of ED. It also appears that this association persisted despite the prevalence of other co-morbid conditions. Our results are consistent with the hypothesis that at primary health care, ED prevention and diabetic management efforts should go hand in hand. Health care providers who address sexual dysfunction issues with their diabetic patients early may be able to reduce the severity or delay the onset of ED.

KEYWORDS

Type 2 Diabetes, Erectile Dysfunction (ED), Risk factor, Duration of diabetes, Diabetes Mellitus.

INTRODUCTION

Erectile Dysfunction (ED) is the inability to attain and maintain penile erection sufficient enough for satisfactory sexual performance.[1] Diabetes mellitus (DM) can cause ED because it can damage the blood supply to the penis and the nerves that control an erection. Many studies have reported that ED is more prevalent amongst men with diabetes and has negative impact on the quality of life.[2-7].Prevalence of estimated erectile dysfunction among diabetes men ranges from 27 to 75 percent and diabetes hastens the occurrence of ED by 10-15 years.[8-12] Up to 28% of men who complain of ED have DM. To achieve a proper erection good enough for penetrative sex, sexual stimulation is to be initiated. Blood vessels in the corpora cavernosa dilate and leads to increased arterial inflow and reduced venous outflow. Nitric oxide causes the smooth muscle to relax in the corpora cavernosa. Nitric oxide also stimulates guanylate cyclase, which in turn produces increased levels of cyclase guanosine monophosphate. This results in opening of the calcium channels and thus smooth muscle relaxation is induced.[13-15] But when the blood sugar levels get too high, less nitric oxide is produced and low levels of nitric oxide are often found in those with diabetes.

Few studies have observed an association between ED and duration of diabetes.[12] Some studies were reported that ED is progressive in these diabetic patients, with more than 50% of them affected after 10 years of DM.[16-19] In India not much studies were done to investigate the association between duration of diabetes and ED and more studies are needed to investigate the association of duration of diabetes with erectile dysfunction adjusting the effects of other confounding factors. Besides, there is evidence that ED is a risk factor for cardiovascular disease and an early marker for coronary artery disease which is a leading cause of mortality in patients with DM.[5-6] Despite the above mentioned clinical importance of ED, most of the primary care clinicians do not enquire about sexual dysfunction during consultation particularly while evaluating the duration of diabetes. The aim of the present study is to examine the effect of duration of diabetes on erectile function.

MATERIAL & METHODS

The study was initiated after the protocol was approved by the Institutional Human Ethics Committee. All confirmed type 2 diabetic men attending the out-patient unit of Department of Endocrinology, in a reputed hospital, Coimbatore during the months of May and June 2019 were initially enrolled. We have calculated the sample size based on an expected prevalence of ED as 40% and with 20% allowable error of the prevalence, 95% confidence limits and 25% non-responds. Thus, the required sample size for this study was 200. Married male patients diagnosed with type 2 diabetes, aged between 20 years and 60 years, staying with their wife minimum for the past one month were included in the study using non-probability consecutive sampling. Those patients with a history of any coronary event (myocardial infarction, coronary artery bypass surgery, or coronary angioplasty) in the previous 4 weeks, liver diseases, renal diseases, and dialysis were excluded from the study. Thus, a total of 204 patients were included. The patients were interviewed in a separate room after obtaining their informed consent and their details will be maintained discreet.

The variables studied include age in years (<=45, 46-55, 56-60), current smoking status (Yes, No), current alcohol consumption (Yes, No), obesity (Body Mass Index in Kg/m^2) (Yes: BMI>=30, No: BMI<30), physical activity (minutes in an average per day) (Yes: >=40, No: <40), duration of diabetes (the time from which patients were bio-chemically diagnosed and was categorically classified as 1-5 years, 6-10 years and 11-30 years), hypertension (Yes: those with Blood Pressure >=140/90 mmHg or those who have taken anti-hypertensive drugs, No: others), retinopathy (Yes: retinal changes such as aneurysm, haemorrhage, exudates, cotton wool spots or neovascularization, No: others). Everyone was interviewed in person using a validated International Index of Erectile Function (IIEF-5) questionnaire. The six questions in the questionnaire (how often were you able to get an erection during sexual activity?, when you had erections with sexual stimulation, how often were your erections hard enough for penetration?, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner during sexual intercourse?, how often were you able to maintain your erection after you had penetrated (entered) your partner?, during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?, how do you rate your confidence that you could get and keep an erection?) were used to assess erectile

dysfunction. A score of 0 to 5 was awarded to each of these questions with a total score of 30 and patients with low IIEF (International Index of Erectile Function) score (<=14 out of 30) were considered to have erectile dysfunction.[20]A preliminary report on the socio demographic and clinical correlates of ED among type 2 diabetes patients has been published.[21]

Data were analysed using SPSS version 24(SPSS Inc., Chicago, Ill., USA). Mean and standard deviation were calculated for continuous variables and number (percentage) for categorical variables. Analysis of variance was used to compare the mean values. Multivariate logistic regression analysis was used to find the association between duration of diabetes and erectile dysfunction. The factors adjusted in the multiple logistic regression analysis were age, smoking status, alcohol use, obesity, physical activity, hypertension and retinopathy. P value<0.05 was considered as statistically significant.

RESULTS

Sixty-five patients were found to have Erectile Dysfunction and the prevalence of ED in the study population was 31.86%. The demographic and metabolic characteristics of the study population were shown in Table 1. The prevalence was more in those who have obesity (p<0.05), doing less physical activity (p<0.01), having hypertension (p<0.01) and having retinopathy (p<0.001). A significant increase in the prevalence of ED with duration of diabetes was observed. For 1-5 years, the prevalence was 24.1 %(n=26), for 6-10 years, the prevalence was 27.7%(n=13) and for 11-30 years, the prevalence was 53.1%(n=26) (Chi square linear trend was 11.57 with p<0.001). The mean (SD) of ED score for 1-5 years was 25.17(8.66), for 6-10 years was 24.82(8.55) and for 11-30 years was 20.32(9.22) p<0.01. Age adjusted and multivariate adjusted odds ratio with 95% confidence interval was tabulated and is shown in Table 2. The variables adjusted were age, smoking status, alcohol use, obesity, physical activity, hypertension and retinopathy. The age adjusted odds ratio of ED for 11-30 years duration of diabetes compared to 1-5 years duration of diabetes was 4.027 (95% confidence interval (1.834-8.840) which was statistically significant, p<0.05). The multivariate adjusted odds ratio of ED for 11-30 years duration of diabetes compared to 1-5 years duration of diabetes was 2.505(95% confidence interval (1.038-6.045) which was statistically significant, p<0.05). We further stratified the data by hypertension and physical activity status (Table 3). Within the subgroup of men, with type 2 diabetes and hypertension, the odds ratio for 11-30 years duration of diabetes compared to 1-5 years duration of diabetes was 4.167 (95% confidence interval (1.403-12.372) which was statistically significant, p<0.05). It was more than twice the odds ratio of those without having hypertension (odds ratio=1.879, 95% confidence interval (0.610-5.785),p=0.272). Within the subgroup of men, with type 2 diabetes and without physical activity, the odds ratio for 11-30 years duration of diabetes compared to 1-5 years duration of diabetes was 4.607 (95% confidence interval (1.924-11.028) which was statistically significant, p<0.05).It was almost three times the odds ratio of those with physical activity (odds ratio=1.650, 95% confidence interval (0.410-6.646), p=0.481).

DISCUSSION

Erectile dysfunction is a common medical problem affecting approximately 15% of men each year. Over 150 million men worldwide were estimated to have been affected by ED in 1995 and this figure would rise to 320 million by 2025.[22-25] Prevalence estimates of ED among diabetic men range from 27 to 75%. Much of this variability is due to differences in definition of ED as well as duration of diabetes between samples.[13] Diabetes Mellitus (DM) is one of the most common chronic diseases in nearly all countries and it is an established risk factor for sexual dysfunction in men. Moreover, patients with diabetes may have several clinical conditions including hypertension, obesity, cigarette smoking, retinopathy and physical activity which are themselves independent risk factors for sexual dysfunction in men.[26-27] In Massachusetts Male Aging Study, the age-adjusted probability of erectile dysfunction was three times (28%) greater in patients treated with diabetes than in those without diabetes (9.6%).[17,23] Erectile dysfunction was detected in over 50% of men with diabetes in the U.S and in 41% of diabetic men in Netherlands. Many studies conducted in India also reported a significantly greater frequency of ED among patients with type 2 diabetes mellitus.[28,29]

Our study suggests that diabetic men with less physical activity have a higher risk of ED. A study from the University of West in the United Kingdom found that physical activity helped 40 percent of men with ED regain normal erectile function.[30] Several

studies have confirmed that combining two interventions, Mediterranean diet and physical activity, provide additional benefit to erectile function.[31,32] Therefore, physical activity has proved to be a protective factor against erectile problems for type 2 diabetic men with higher duration of diabetes. The presence of retinopathy among type 2 diabetic patients is independently associated with occurrence of ED. Some earlier studies show that the risk of ED is increased by 3 to 4 times in patients with retinopathy than in patients without it.[33]Hence, we recommend that diabetic men with retinopathy should be screened for ED and vice versa. ED is frequently encountered in hypertensive men. 46.1 percent of hypertensive patients have complaints of ED. Hypertension can lead to ED as a consequence of high blood pressure or due to anti-hypertensive treatments.

In our study, the frequency of ED was related to the duration of diabetes for type 2 diabetic subjects. Despite multiple factors that contribute to ED including the age range of the patients, we observed an association between duration of diabetes and ED after adjusted possible confounders. Many studies supported our findings that longer duration of diabetes is the risk of ED among type 2 diabetes patients.[13] It was observed by some researchers that among type 2 diabetic patients, diagnosis within the first 10 years was not significantly associated with an elevated risk of ED whereas for those patients with diagnosis after 10 years, the risk was significantly greater.[12,13]

Within the subgroup of men with hypertension, we found that the association between duration of type 2 diabetes and ED was stronger than in men without hypertension. Men with diabetes and hypertension had ED with a prevalence of 46.1% whereas men with diabetes and without hypertension had lowest rates of ED with a prevalence of 23.4 %.[13,34] Hence, it appears that hypertension increases the prevalence of ED among men with longer duration of diabetes. A similar finding was also observed for lower levels of physical activity.[12]

An review article by Hakim et al. on potential mechanisms for diabetic ED, observed that microangiopathy of the cavernosal artery, corporal veno-occlusive dysfunction and autonomic neuropathy are the primary path physiological pathways for ED.[35] Corporal smooth muscle contraction and relaxation may then be disturbed by reduced nitric oxide action. The observed difference in higher prevalence of ED among hypertensive patients and those who are having lower levels of physical activity may be due to the fact that these factors increase nitric oxide disturbance related to ED in diabetic patients.[35,36]

We were encountered with some limitations. Although patients with major depression and other psychological disorders were excluded from our study. Detailed psychological evaluation could not be considered as we were studying these patients at the out-patient unit. The prevalence of ED is difficult to establish accurately because of limitations related to the populations screened and unreliability of the answers due to personal embarrassment. We were not able to include glycosylated haemoglobin as a measure of glycemic control in our model because of the unavailability of such data among men in this study. Another limitation of our study is that our examination of ED was cross-sectional study in nature. Despite these limitations, the study has several strengths. We have used a validated questionnaire to assess erectile dysfunction rather than subjective evaluation. Besides, we have studied a large number of factors and adjusted their confounding effects to observe the association between duration of diabetes and ED.

In conclusion, the key take home message of our results is that ED is significantly associated with longer duration of diabetes among type 2 diabetic patients. It also appears that hypertension and lower level of physical activity increase the prevalence of ED amongst men with diabetes. It also suggests that there may be an increase in severity of ED among men who have had diabetes for a longer duration, especially among those with hypertension and those who have less physical activity. The prevalence in these scenarios is much higher than in patients who are only diabetic. Our results are consistent with the hypothesis that primary health care providers who address sexual dysfunction issues with their diabetic patients early may be able to reduce the severity or delay the onset of ED in their patients. Further analysis on various medications and its association with ED will be reported in a subsequent paper. Further studies with repeated surveillance of erectile function before and after diabetes diagnosis may produce increased evidence on the association between ED and duration of diabetes.

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TABLES

TABLE 1 Prevalence of Erectile Dysfunction(ED) according to demographic and metabolic parameters.

Variables		Total studied	Patients with Erectile Dysfunction	Percentage	p value
Age (in years)	<45	56	15	26.8	0.359
	45-55	71	27	38	
	56-60	77	23	29.9	
Current smokers	Yes	7	3	42.9	0.525
	No	197	62	31.5	
Alcohol	Yes	22	7	31.8	0.996
	No	182	58	31.9	
Obesity(kg/m^2)	BMI>=30	25	13	52	0.021*
	BMI<30	179	52	29.1	
Physical activity (in minutes)	<40	120	48	40	0.003*
	>=40	84	17	20.2	
Hypertension	Yes	76	35	46.1	0.001*
	No	128	30	23.4	
Retinopathy	Yes	35	22	62.9	0.000*
	No	169	43	25.4	
* p <0.05					

TABLE 2 Erectile Dysfunction by duration of type 2 diabetes in unadjusted, age adjusted and multivariate adjusted regression model.

Duration of diabetes (in years)	Unadjusted odds ratio (confidence interval)	Age adjusted odds ratio (confidence interval)	Multivariable[a](confidence interval)
1-5	1	1	1
6-10	1.206(0.555-2.622) P value: 0.637	1.271 (0.574-2.817) P value: 0.555	1.270 (0.528-3.057) P value: 0.593
11-30	3.565(1.746-7.278) P value: 0.000*	4.027 (1.834-8.840) P value: 0.001*	2.505(1.038-6.045) P value: 0.041*
[a] Adjusted for age, current smoking status, alcohol use, obesity (BMI), physical activity, hypertension, retinopathy; * p <0.05			

TABLE 3 Erectile Dysfunction by duration of type 2 diabetes among men with and without hypertension and physical activity in age adjusted regression model

	Total Studied	Number of men with Erectile Dysfunction	Percentage	Duration of diabetes	Age adjusted odds ratio (95% Confidence limits)
Men with type 2 diabetes and hypertension	76	35	46.1	1-5	1
				6-10	1.944(0.539-7.019); P value: 0.310
				11-30	4.167(1.403-12.372); P value: 0.010*
Men with type 2 diabetes and without hypertension	128	30	23.4	1-5	1
				6-10	0.827(0.294-2.325); P value: 0.718
				11-30	1.879(0.610-5.785); P value: 0.272
Men with type 2 diabetes and physical activity	84	17	20.2	1-5	1
				6-10	0.859(0.250-2.955); p value: 0.810
				11-30	1.650(0.410-6.646); p value: 0.481
Men with type 2 diabetes and without physical activity	120	48	40	1-5	1
				6-10	2.178(0.743-6.382); p value: 0.156
				11-30	4.607(1.924-11.028); p value: 0.001*

OPINION

Travel Burnout

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ABSTRACT

There are two counterintuitive fires stoking desires within and decisions from within and without: first one that makes me to travel when I may not need to and second one just because I am traveling despite knowing better. However, I have learnt that I must target to maintain my cruise-control speed of traveling by appropriately breather-spacing before traveling again to sternly silence the expectations of traveling while maintaining my innate sanity when traveling and trotting into the insane world of globe-trotting humanity.

OPINION

My academic mentors expect me to travel [1-2]. My business leaders expect me to travel. My family members expect me to travel [3]. Even my forebears (both mythological ones as well as historical ones) expect me to travel. But how much can I travel? They say that traveling is in my selfish genes by being wired into my cultures because my forebears traveled out-of-Africa to populate the whole world [4-5]. They say that those who did not travel did not evolve just like bonobos still peacefully persisting in their pre-historically natural habitat because we are more like chimpanzees constantly exploring naive habitats before evolving them and turning them into our own newly natural habitats [6-7]. Still how much can I travel before I can say that it is too much [8]? We must ask our academic mentors. We must ask our business leaders. We must ask our family members. We must even ask our forebears (both mythological ones as well as historical ones). It is my assumption that all will unanimously zero in on however much I can stretch thin my personal limits while still safely and peacefully existing despite traveling as much as possible. They all are expecting me to gauge my limits before they all can then push me beyond those limits while hoping that I will not burnout thus defeating their selfish purpose to push me in the first place. But am I burning out too easily and too hastily? Have I not learned from my forebears that whatever did not kill made them stronger? However, it may also be true that whoever survived as our forebears assumed themselves to be stronger than non-survivors only in retrospect when it might have been that they might have been smarter rather than stronger to sneak past their existential threats by freezing, fainting, flooding, fatiguing, fleeing and fawning rather than fighting [9-11] them during their lifetimes so as to be able to self-perpetuate and make the modern humanity an actual momentary reality instead of becoming a lost legendary possibility. Maybe, there are two counterintuitive fires stoking desires within and decisions from within and without: first one that makes me to travel when I may not need to and second one just because I am traveling despite knowing better. Amnesia to incidents in our lives is good so that we do not develop post-traumatic stress disorder and can go on living our lives. However, we also tend to forget cause-and-effect of the amnestic incidents making us prone to endure similar or even same incidents again. But am I listening to my own words? Am I heeding to what I

am saying? Maybe I am a life-long learner and here is what I have learnt [12-18]. I can hitch the ride taking myself for a ride but I must target to maintain my cruise-control speed of traveling by appropriately breather-spacing before traveling again to sternly silence the expectations of traveling while maintaining my innate sanity when traveling and trotting into the insane world of globe-trotting humanity.

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LETTER TO EDITOR

Community medicine and Anaesthesiology: Trending medical streams

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Dear editor,

We read the manuscript "Anaesthesiologists as Community Physicians- Expanding Horizons" with great interest, published in your esteemed journal, EFI Bulletin. 2023;4(1):30-31. (1)

Authors have beautifully narrated the synergy between 19th century Cholera and the 21st century Covid-19 pandemic. They also witnessed the dedicated work of Dr John Snow (15 March 1813 – 16 June 1858), one of the founders of modern Epidemiology. Authors elaborated on the increasing horizon of Anesthesiology from the four walls of operation theatre to their active role in a wide spectrum of community healthcare management. This article favors the concept of intersectoral coordination.

Anesthesiology and community medicine have some common peculiarities and agony. Though Anesthesiology is still regarded as a dependent branch by some ignorant fellows, its broadened scope is being recognized day by day. Moreover, the occurrence of Covid-19 once again reminded the importance and utility of Anesthesiology and critical care specialists. (2) Anesthesiologists were involved in patient care in emergency, intensive care and operative procedures including acute and chronic pain management. They are also involved in the planning of health management and policy making. Anesthesiologists are known for their broad scope in patient management including airway management, infection control and prevention and, life support. In the event of a disaster Anesthesiologists are among the best persons to implement triage and maximize the outcome in terms of reducing mortality, morbidity and disability. Mahajan brothers' "sea to sky" campaign is a beautiful effort of public awareness about CPR (Cardiopulmonary Resuscitation). (3)

Community medicine, previously known as Social and Preventive Medicine is an important component of Indian Medical graduates' curriculum. A two-month mandatory training in preventive and social medicine for newly graduated doctors was proposed by the Bhore Committee Report. Community Medicine personnel are involved primarily in community-oriented works. To obtain the optimal health for an individual and the community as a whole, they set priorities and propose relevant programs. Community medicine specialists are involved in various research works, epidemiological investigations, health management planning and policy making. Community medicine is also among specialties like Microbiology, which is being recognized more in the heat of the Covid-19 pandemic. (4,5)

Certain basic principles of anesthesiology and community medicine are alike and relevant in day-to-day practice. Prevention is an important theme in

community medicine which is efficient (doing things in the most economical way), effective (achieving desired target) and efficacious (capacity of a given intervention under ideal or controlled conditions) virtue. Prevention is also very important in anesthesiology and critical care e.g. drug errors, cardiac arrest, etc. are easy to prevent than to treat. Monitoring and Surveillance are other noteworthy attributes relevant to both streams. Vaccines are among the most cost-effective public health measure of disease control, whereas Anesthesiologists are trained to tackle AEFI (Adverse Effects Following Immunization) as part of their curriculum.

There are certain differences peculiar to each specialty too. Community medicine is mostly involved at the population level while anesthesiology is usually oriented at the individual level. Anesthesiology often has poor control of their work pattern owing to emergency calls and the need to take a rapid decision for managing a patient eg. in operation rooms and intensive care units, on the other hand, community medicine, often provide better work-life balance. Though, community medicine has been comparatively a less trending specialty of medicine. (6)

To conclude, we support the authors' thought that the amalgamation of the principle of community medicine and anesthesiology may help better service to society and help the attainment of UHC (universal health coverage).

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