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[2]Handin RI — Bleeding and thrombosis. In: Wilson JD, Braunwald E, Isselbacher KJ, Petersdorf RG, Martin JB, Fauci AS, *et al* editors—Harrison's Principles of Internal Medicine. Vol 1. 12th ed. New York: Mc Graw Hill Inc, 1991: 348-53.

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[3]National Statistics Online—Trends in suicide by method in England and Wales, 1979-2001. www.statistics.gov.uk/downloads/ theme_health/ HSQ 20.pdf (accessed Jan 24, 2005): 7-18.

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Contents

Editorial

The Nuances of Nurture : Unraveling Facts and Myths of Breastfeeding

As we celebrate the advancements in infant nutrition, breastfeeding remains a cornerstone of early childhood development, shrouded in both scientific fact and societal myth. The discourse surrounding breastfeeding is complex, influenced by cultural norms, medical research and personal choice. This editorial aims to dissect the facts from the myths, providing clarity for new parents navigating this critical aspect of childcare.

Fact : Breast Milk as the Gold Standard

Breast milk is widely recognized as the optimal nutrition source for infants. Rich in antibodies, enzymes, and nutrients tailored to a baby's developmental needs, breast milk enhances immune system development, reduces the risk of infections, and supports cognitive development. The World Health Organization recommends exclusive breastfeeding for the first six months, underscoring its significance in early life.

Myth : Breastfeeding is Always Easy and Natural

Contrary to popular belief, breastfeeding is not always a smooth process. Many mothers face challenges such as latching issues, nipple soreness, and milk supply concerns. These difficulties can lead to frustration and feelings of inadequacy. Support from lactation consultants and healthcare providers is crucial in overcoming these hurdles and ensuring a successful breastfeeding experience.

Fact : Benefits Extend Beyond Infancy

The benefits of breastfeeding extend well beyond infancy, impacting both mother and child. For infants, breastfeeding has been linked to lower risks of chronic diseases such as obesity, diabetes, and asthma. Mothers benefit from reduced risks of postpartum depression, breast and ovarian cancers, and a quicker return to pre-pregnancy weight. These long-term advantages highlight the profound impact of breastfeeding on health.

Myth : Formula Feeding is Inferior

While breast milk is ideal, formula feeding is a viable and nutritious alternative for mothers who cannot breastfeed or choose not to. Modern infant formulas are designed to mimic the nutritional profile of breast milk as closely as possible, providing essential nutrients for growth and development. The decision to formula-

feed can be influenced by various factors, including medical conditions, work commitments, or personal preference, and should be respected without judgment.

Fact : Societal Support is Crucial

The success of breastfeeding often hinges on societal support and workplace accommodations. Countries with robust maternity leave policies and breastfeeding-friendly workplaces see higher rates of breastfeeding. Public health initiatives and education campaigns play a vital role in normalizing breastfeeding and providing the necessary support for new mothers.

Myth : Breastfeeding is a Private Matter

Breastfeeding in public remains a contentious issue, often subject to societal scrutiny. However, laws in many regions protect a mother's right to breastfeed in public spaces. Normalizing breastfeeding in society can help alleviate the stigma and discomfort associated with nursing in public, ensuring that mothers feel supported and empowered.

Conclusion

The debate surrounding breastfeeding is multifaceted, encompassing both evidence-based benefits and deeply ingrained societal myths. By understanding the facts and dispelling the myths, we can better support new mothers in their feeding choices, whether breastfeeding or formula-feeding. Ultimately, the goal is to ensure that every infant receives the best possible start in life, nurtured by informed and supported caregivers.

Hony Editor, JIMA **Kakali Sen**

Original Article

A Clinical Study of Mental Depression in Diabetes Mellitus

Vasudha Vidyadhar Sardesai[1], Jay Chudasama[2], Shashikala Sangle[3]

Abstract

Background : Diabetes and mental depression occur together twice as common. With both present, Quality of Life is decreased, diabetes self-management gets impaired, the incidence of complications is increased and all this leads to reduced life expectancy of patients.

Aims and Objectives : To study the prevalence of depression in diabetic patients, its impact on Quality of Life and association with physical parameters as well as treatment modalities.

Settings and Design : Cross-sectional, interview based, prospective study.

Materials and Methods : Diagnosed type1 and 2 diabetic patients for minimum one year, aged 15 to 75years; capable of independent communication and informed verbal consent, treated on out-patient basis; willing to participate were included. Patients treated for any psychiatric illness, with comorbidities other than diabetes; aged otherwise; not capable of independent communication, refusing to participate were excluded. Data collected using structured interviewer administered questionnaire. Patients evaluated for mental depression by nine-item Patient Health Questionnaire (PHQ- 9). Statistical analysis used - Chi- square test.

Results : Prevalence of depression in diabetics is 74%. There is no association of age or waist hip ratio of diabetic patients with depression but there is significant correlation with body mass index, waist circumference, duration of diabetes, use of insulin preparation alone or with oral hypoglycaemic agents.

Conclusions : Prevalence of mental depression is higher in diabetic individuals. Body mass index, waist circumference, duration of diabetes, use of insulin preparations alone or with oral hypoglycaemic agents is associated with depression.

Key words : Diabetes Mellitus, Mental depression, PHQ-9.

Diabetes affects approximately 8.3%population and depression affects approximately 10% population of the world[1]. Epidemiologic studies have shown consistently that the diabetes and depression occur together approximately twice as common as would be predicted by chance alone due to depression or diabetes[2]. There is evidence from different studies suggesting that treatment of depression improves glycaemic control[2]. When both conditions are present together, they worsen the outcome of each other. Quality of life is decreased, diabetes self-management is impaired, the incidence of complications is increased and ultimately patient's life expectancy is reduced[3]. Eventually the costs of treatment rise for both individual patients and health economies but these costs do not necessarily result in significant improvement in disease or Quality of Life outcome[4].

The study was undertaken to evaluate depression in diabetic patients. Its correlation with physical parameters of patients as well as treatment modalities was also studied.

Editor's Comment :

- As the prevalence of mental depression is high in diabetic patients, all diabetic patients should be screened for it.
- Depression and diabetes affect each other adversely hence addressing depression is an essential part of diabetes management in such patients.

Materials and Methods

One hundred patients with type 1 or type 2 diabetes with good glycaemic control based on laboratory results (Fasting Blood Sugar <140, Post Prandial Blood Sugar <200 and/or HbA1c <7%) and stable clinical findings for at least one year, were included in the study. These patients were between the age group 15-75 years and were capable of independent communication. All were taking treatment on out-patients basis. Patients already taking treatment for mental depression or any other psychiatric illness were excluded from the study. Patients having any other major comorbidity like cancer, recent major

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surgery, stroke or recent myocardial infarction were also excluded from the study. Quantitative and qualitative data was collected by using structured interviewer administered questionnaire. The Patient Health Questionnaire-9 (PHQ-9)[5] was used to evaluate depression status of patients. The questionnaire was used in local language. The collected data was evaluated by statistical analysis.

Results: In this study overall prevalence of depression was 74%. Prevalence of mild depression was 55%, moderate depression 14%, moderately severe depression 2%, severe depression 3%.

Out of 100 patients, 58 patients were male and 42 patients were female. Most of the patients from male and female group had mild depression with respective percentage of 30% for male and 25% for female. Majority patients with depression were from age group 40-60 indicating no corelation of age with severity of depression (p-value = 0.057) (Table 1). Among patients with higher body mass index (BMI >25), 18% patients had no depression, but 72 % patients had mild to severe depression (p-value <0.001) (Table 2). Among patients with abnormal waist circumference, 8 patients were without depression as compared to 31 patients with depression (p-value = 0.010).

Waist-to-hip Ratio (WHR) of diabetic patients was abnormal in 20 nondepressed patients as compared to 64 patients with depression but it was found to be statistically insignificant (p- value = 0.602).

In the present study, 7 patients without depression had duration of diabetes >5 years, but at the same time 44 patients with depression had duration of diabetes >5 years (p value = 0.003) (Table 3).

In the present study, 78 patients were on Oral Hypoglycaemic Agents (OHA) and 22 patients were either on insulin alone or insulin with OHA. Out of these 22 patients, 21 patients were found to have mental depression. Thus, there was significant correlation between severity of depression and use of insulin alone or OHAs plus insulin than OHAs alone (p-value <0.001). 48 patients on OHA had mild depression, but 11 patients out of 22 on insulin alone or OHA with insulin had moderate depression.

Table 1 — *Correlation of age and PHQ-9 score in diabetic patients*

Age group	PHQ-9 group						P-value
	≤4	5-9	10-14	15-19	≥20	Total	
≤40	9	7	5	0	2	23	
41-50	8	18	3	1	0	30	
51-60	6	19	3	0	0	28	0.057
61-70	2	10	3	1	0	16	
>70	1	1	0	0	1	3	
Total	26	55	14	2	3	100	

Table 2 — *Correlation of BMI and PHQ-9 score in diabetic patients*

BMI	PHQ-9 group						P-value
	≤4	5-9	10-14	15-19	≥20	Total	
<18.5	0	1	0	0	0	1	
18.5-24.99	8	0	1	0	0	9	
25.00-29.99	12	17	1	0	0	30	<0.001
≥30.00	6	37	12	2	3	60	
Total	26	55	14	2	3	100	

Discussion

Comorbid diabetes and depression is a challenging and under-recognized clinical problem. Depressive symptoms affect up to one-third of people with diabetes and not only impair quality of life but also add to the difficulties experienced in diabetes self-management. Diabetes and depression occur together approximately twice as frequently as would be predicted by chance alone[6].

In our study, relation of age of diabetic patients is not correlating with severity of depression (p-value = 0.057) (Table 1). Zhao, *et al*[7] studied a total of 53072 people aged 20-64 years in the analysis and found that the association is stronger among young adults than among older adults. In our study we didn't find this significant correlation due to small sample size.

In the present study 58% patients were male and 42% patients were female and there is no statistically significant difference between depression in both sexes.

Studies by Anderson and Freedland[8] showed that the odds of depression were significantly elevated in both women and men with diabetes compared with control subjects. This study showed similar results like present study showing no significant difference between male and female diabetics with relation of depression (p-value = 0.691).

This study shows a strong relation between Body Mass Index (BMI) and depression in diabetic patients

Table 3 — *Correlation of duration of diabetes and PHQ-9 score*

Duration of DM	PHQ-9 group						P-value
	≤4	5-9	10-14	15-19	≥20	Total	
≤5	19	23	11	1	2	56	0.003
6 -10 years	4	26	1	0	0	31	
11 -15years	3	1	1	0	1	6	
>15 years	0	5	1	1	0	7	
Total	26	55	14	2	3	100	

(p-value <0.001). In a study by Raval, *et al*[9] total of 300 Type 2 Diabetics including 147 (49%) men and 153 (51%) women were evaluated and strong association with Type 2 Diabetes and central obesity was found.

From this study we can conclude that there was significant association between waist circumference and prevalence and severity of depression in diabetic patients (p-value = 0.010). Zhao G, *et al*[7] study has also shown significant association of central obesity and depression among 2,439 US adults (1,325 men and 1,114 non pregnant women) aged ≥20years who were either overweight or obese with BMI of ≥25.0 kg/m^2.

In this study Waist-to-hip Ratio (WHR) of diabetic patients was not related to prevalence and severity of depression (p- value = 0.602). Zheng, *et al*[10] has done similar study to explore the relationship between depressive symptoms assessed by the Patient Health Questionnaire-9 (PHQ-9) diagnostic algorithm and waist-to-hip ratio, dyslipidaemia, glycaemic levels and blood pressure among 2,511 diabetic and 9,397 non-diabetic Chinese women and have observed no significant relationship between WHR and depression in diabetic women.

This study shows duration of diabetes is strongly related to severity of depression (p-value = 0.003). Almeida, *et al*[11] has done Cross-sectional study of a community-derived sample of 5462 men aged 70-89 years suggesting that longer duration of diabetes is more frequently and more severely associated with depression.

There is significant correlation between severity of depression and use of insulin alone or OHAs plus insulin than OHAs alone (p-value <0.001). Higher grade of depression and greater prevalence of depression is associated with use of insulin or OHAs plus Insulin than OHAs alone. In a study by Noh, *et al*[12] among 204 type 2 diabetics, the insulin group showed a significantly higher frequency of depressive symptoms (p<0.01) compared to the oral drug group.

Conclusion

Hence the study concludes that, prevalence of depression is higher in diabetic individuals. Age of the patients and gender difference in diabetics is not associated with prevalence of depression. Body mass index, waist circumference and duration of diabetes of diabetic patients are strongly associated with prevalence and severity of depression.

Use of insulin alone or insulin with OHAs is significantly associated with prevalence and severity of depression in diabetic patients.

Overall diabetes is associated with higher prevalence and severity of depression in diabetic patients.

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Original Article

Prevalence and Risk Factors Associated with Non-communicable Diseases among Non-teaching Employees in a University : A Cross Sectional Study of Vadodara City in Gujarat, India

Koustav Ghosh[1], Stuti Mayankkumar Trivedi[2], Annie Kuruvilla[3], Sonal Mishra[4]

Abstract

Background : Non-communicable Diseases (NCDs) like cardiovascular diseases, cancer, respiratory diseases and diabetes accounted for 80 percent of total deaths in the world. NCDs were more likely among non-teaching employees as compared to teaching employees. So, the current study aims to determine the prevalence of risk factors and their association with NCDs among the non-teaching members of an institutional setup in Vadodara, Gujarat.

Materials and Methods : The research relied on primary source data using a structured questionnaire. Bivariate analysis, Chi-square tests and binary logistic regression were performed using STATA 14 to identify risk factors for NCDs.

Results : Overall, 10.8 percent of the non-teaching staff suffer from at least one NCD in the university. The prevalence of diabetes, cardiovascular diseases, and cancer among non-teaching employees is 8 percent, 3.8 percent and 0.5 percent, respectively. The risk of NCDs is higher among permanent employees (AOR=3.35, 95% CI=1.56-2.59), family history of chronic diseases (AOR= 2.61,95% CI=0.98-2.56), overweight (AOR=9.32, 95% CI=1.63–12.21) and obese employees (OR=17.20, 95% CI=2.24-21.24). The results also showed that the risk of NCDs is increasing with consumption of butter daily (OR: 2.47; CI: 1.25-1.78) and consumption of extra salt with food (AOR:2.51;95% 1.16-2.99), increasing the risk of NCDs. On the other hand, vigorous-intensity activity helps reduce the risk of NCDs.

Conclusion: It is proposed that university administrators develop NCD surveillance systems to better prevention and control. In order to reduce NCD incidence rates and postpone NCD onset, they should take actions to eliminate NCD risk factors and encourage healthier lifestyles.

Key words : Cardiovascular Diseases, Cancer, Diabetes, Prevalence, Risk Factor.

Non-communicable Diseases (NCDs) are one of the major concerns and public health issues in the world[1-2]. Nearly 41 million people die due to NCDs and responsible for more than 75 percent of global death across the world. Around 15 million deaths occurred due to NCDs between 30 to 69 years of age, 85 percent of them were from low-and middle-income countries[1]. Moreover, NCDs like cardiovascular diseases, cancers, respiratory diseases and diabetes accounted for 80 percent of total deaths in the world[1]. India, which has a population of about 1.3 billion, is responsible for more than two-thirds of all NCD-related deaths in WHO's South-East Asia Region (SEAR)[3]. Obesity, raised blood glucose, high BP, high cholesterol levels, physical inactivity, sedentary behaviour, alcohol consumption and smoking behaviour are the major risk factors of NCDs[4-6]. A study based on Ahmedabad city in Gujarat shows the risk factors of teaching employee for the NCDs are tobacco consumption, job stress, physical inactivity, overweight and obesity[7].

Editor's Comment :

- Non-communicable Diseases (NCDs) are significantly prevalent among non-teaching staff in institutional settings, with key risk factors including obesity, unhealthy dietary habits, and physical inactivity.
- Targeted interventions and regular NCD surveillance are essential to reduce the disease burden and promote healthier lifestyles within such populations.

Because more people live in cities and change the way they live, university workers are likely to be at risk for NCDs. To promote health and happiness at work, it's important to figure out how big the risks are for this group. NCDs were more likely among non-teaching employees as compared to teaching employees[8]. So, the current study aims to determine the prevalence of risk factors and its association with

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NCDs among non-teaching members of an institutional setup of Vadodara city in Gujarat.

Materials and Methods

Data :

A primary data was collected using a structured questionnaire. The WHO STEP-wise risk factor surveillance manual (WHO STEP-wise risk factor surveillance handbook, 2017) was used to conduct a situational analysis to evaluate the health condition of university personnel[9]. The institutional Ethics Committee for Human Research (IECHR), Faculty of Family and Community Sciences, Maharaja Sayajirao University of Baroda, Vadodara, accepted the study with the ethical permission number IECHR/FCSC/MSc/2021/101. A cross-sectional survey with 1025 participants (teaching & non-teaching) was done over seven months across fourteen faculties and three colleges of the university[8]. From 1025, we have taken 581 non-teaching employee as a sample for our analysis.

All of the people who took part in the study gave their written permission and were assured that their answers would be kept secret. No one was pushed to take part in the study. A pre-tested questionnaire was used to get specific information about the socioeconomic situation, family history of NCDs, and social and lifestyle risk factors (such as smoking, drinking alcohol, eating habits, level of physical exercise, etc). Anthropometric measures included weight, which was taken with an electric scale, and height, hip and waist circumferences, which were taken with a measuring tape that didn't stretch. The OMRON digital sphygmomanometer was used to measure blood pressure[10]. In person, all measures were taken. Using data on height and weight from physical measures, Body Mass Index was calculated. Participants were then put into[11] underweight, normal, overweight, or obese groups based on Asia Pacific norms[12].

Methodology :

In our questionnaires, we ask three morbid conditions, including medicine consumption: "Has anyone who works at the university ever been diagnosed with heart disease, cancer, lung disease, or diabetes?" NCDs patients don't include people who don't get drugs. To figure out how common NCDs are, we make a "1" or "0" variable out of the set of chronic disease variables. "1" means that an employee has at least one NCD, while a "0" means that an old person doesn't have any NCDs. Finally, we used the logistic regression models to establish the association between the prevalence of NCDs and their contextual determinants.

$$\Pr(yj \neq 0 \mid x_j) = \frac{(\exp(x_j\beta))}{(1+\exp(x_j\beta))} \quad \ldots\ldots\ldots \quad (1)$$

Data obtained were analysed using STATA 14. To show the prevalence and association of NCDs with background characteristics, bivariate analysis along with Chi-square tests has been performed. A p-value <0.05 indicates a significant relationship between the variables.

The independent variable includes socio-economic characteristics, substance abuse behaviour, dietary pattern, physical activity & sedentary lifestyle, and anthropometrics & clinical Characteristics (Table 1).

Results

Prevalence of NCDs among non-teaching employees: The prevalence of diabetes, cardiovascular diseases, and cancer among non-teaching employees is 8.1 percent, 3.8 percent and 0.5 percent, respectively. The overall prevalence of NCDs in the study population was 10.8 percent.

Prevalence and Association of NCDs with Background Characteristics :

Among non-teaching employees, 13% of males and 5% of females were found to suffer from NCDs, with prevalence increasing with age. Permanent employees (21%) and those educated up to HSC (12%) reported higher prevalence. Furthermore, a significant association was found between family history of chronic diseases (17%) and NCDs. Moreover, lifestyle factors such as smoking (14%), tobacco chewing (15%) and alcohol consumption (13%) were linked to higher NCD prevalence compared to their counterparts. Additionally, dietary habits such as frequent eating out, daily consumption of maida (20%), butter (12%), ghee (10%) and regular use of salt with food (18%) were significantly associated with NCDs.

Physical inactivity also contributed to increased prevalence, with non-walkers/cyclists (11%) and those not engaging in vigorous activities (11%) more affected. Furthermore, nutritional status and blood pressure showed significant associations, with the highest prevalence among obese (16%) and hypertensive individuals (14%), compared to overweight (7%), underweight (2%), and normotensive employees (9%). Additionally, employees at risk based on waist circumference (WC) and waist-hip ratio (WHR) showed greater NCD burden.

Determinants of NCDs among Non-teaching Employees :

The logistic regression was used to identify the risk factors associated with NCDs among non-teaching

Table 1 — *Prevalence and risk factors associated with NCDs*

Background Characteristics		[a]Prevalence of NCDs N (%)	AOR [95% CI]
(A) Socio-Economic Characteristics :			
Residence	Gujarat	59(10.7)	Ref.
	Non-Gujarat	4(12.9)	2.03[0.51-2.95]
Sex	Male	54(13.2)	Ref.
	Female	9(5.2)	0.4[0.21-1.71]**
Age Groups	Up to 30	5(5.1)	Ref.
	31-40	8(5.4)	1.04[0.84-0.04]
	41-50	10(6.9)	0.74[0.58-0.38]
	>50	40(21.1)	0.62[0.51-0.57]
Marital status	Married	60(12.4)	Ref.
	Unmarried	3(3.1)	1.02[0.78-0.02]
Education Status	Up to HS	32(12)	Ref.
	More Than HS	31(9.8)	1.12[0.46-0.29]
Type of Employees	Temporary	25(6.3)	Ref.
	Permanent	38(20.5)	3.35[1.56-2.59]**
Family History of Chronic Diseases	No	29(7.7)	Ref.
	Yes	34(16.7)	2.61[0.97-2.96]**
(B) Substance abuse behavior :			
Smoking Behavior	No	58(10.6)	Ref.
	Yes	5(13.9)	1.34[0.38-2.1]
Tobacco Consumption	No	51(10.2)	Ref.
	Yes	12(14.5)	1.24[0.61-0.44]
Alcohol Consumption	No	56(10.6)	Ref.
	Yes	7(12.7)	0.69[0.45-0.96]
(C) Dietary Pattern			
Daily Ghee consumption	No	37(12.6)	Ref.
	Yes	26(9)	0.68[0.27-0.97]
Daily Butter Consumption	No	52(10.7)	Ref.
	Yes	11(11.6)	2.47[1.25-2.78]*
Breakfast	No	6(7.8)	Ref.
	Yes	57(11.3)	1.38[0.75-1.58]
Lunch	No	2(10.5)	Ref.
	Yes	61(10.9)	2.36[2.50-0.81]
Snacks at office	No	29(11.6)	Ref.
	Yes	34(10.3)	1.06[0.39-1.06]
Use of extra salt	Never	43(10.2)	Ref.
	Always/Often	7(17.9)	2.81[1.89-3.53]
	Sometimes	13(10.8)	2.51[1.16-2.99]**
Eating outside meal	Daily	12(15.8)	Ref.
	Weekly	10(21.2)	0.44[0.27-1.29]
	Sometimes	41(11.7)	0.72[0.35-0.66]
Frequency of coarse grains	Never	5(10.2)	Ref.
	Daily	11(17.5)	1.96[1.46-2.9]
	Weekly	23(10.6)	1.1[0.75-1.14]
	Sometimes	24(9.5)	1.09[0.73-2.12]
Frequency of consumption of Maida	Never	23(19.2)	Ref.
	Daily	4(20)	1.78[1.46-0.7]
	Weekly	13(9)	0.32[0.17-2.14]**
	Sometimes	23(7.7)	0.23[0.10-3.22]***
(D) Physical Activity & D. Sedentary lifestyle :			
Daily walking/ bicycle	No	27(11.3)	Ref.
	Yes	36(10.5)	0.61[0.23-1.27]
Vigorous-intensity Activity	No	54(10.9)	Ref.
	Yes	9(10.5)	0.39[0.22-1.65]*
Moderate-intensity Activity	No	53(10.6)	Ref.
	Yes	10(12.5)	2.26[1.31-2.4]
(E) Anthropometrics & Clinical Characteristics :			
Waist Circumference (WC)	At risk	42(11.7)	Ref.
	Not at risk	21(9.4)	1.6[0.74-1.81]
Waist-to-hip Ratio (WHR)	At risk	54(12.1)	Ref.
	Not at risk	9(6.7)	0.97[0.50-1.05]
Nutrition Status	Underweight	1(2)	Ref.
	Normal	13(7.4)	10.13[1.79-13.1]*
	Overweight	7(7.4)	9.23[1.63-12.21]*
	Obese	42(16)	17.2[2.24-21.24]**
Blood pressure	Normal	29(8.6)	Ref.
	Hypertensive	34(13.9)	2.76[1.10-2.54] *
Dyslipidemia Status	No	61(10.6)	Ref.
	Yes	2(25)	3.31[1.11-3.58]
	Total	63 (10.8)	-
	Observation (N)		581
	Pseudo R2	=	0.15

*Note : [a]Row percentage; AOR; Adjusted Odds Ratio; CI=Confidence Interval; * p<0.05; ** p<0.01; *** p<0.001; Ref.=Reference category*

(Table 1). The results showed that the odds of NCD conditions among females (AOR: 0.40; CI: 0.22-1.71) are lower than males. Moreover, the risk of NCDs among permanent employees was 3.35 times higher (AOR:3.35; CI: 1.56-2.59) as compared to temporary employees. Family history of chronic diseases showed a 2.61 times higher risk (AOR: 2.61; CI: 0.98-2.56) of NCDs as compared to those who did not have any history of chronic diseases. In the case of the dietary patterns, the use of butter and extra salt showed significant relationships with NCDs. It showed that the risk of NCDs is 2.47 times higher among those who take butter daily (AOR: 2.47; CI: 1.25-1.78) as compared to those who do not take butter. Similarly, consumption of extra salt with food (AOR: 2.51; CI: 1.16-2.99) increased the risk of NCDs as compared to those who did not consume salt with food. Among anthropometric and clinical characteristics, nutrition status and blood pressure showed a significant relationship ($p<0.05$) with NCDs. The risk of NCDs among overweight (AOR: 9.32; CI: 1.63-12.21) employees and obese employees (AOR: 17.20; CI: 2.24-21.24) is 9.23 and 17.20 times higher as compared to underweight employees. Moreover, the odds among hypertensive employees are 2.76 times higher as compared to normal BP employees.

Discussion

The prevalence of diabetes, cardiovascular diseases, and cancer among non-teaching employees is 8.1 percent, 3.8 percent, and 0.5 percent, respectively. Overall, 10.8 percent of the non-teaching staff suffer

from at least one NCD in the university. The prevalence of NCDs was higher in males. Interestingly, the family history of any chronic disease is significantly associated with NCDs. Employee who has a family history are 2.61 times more likely to suffer from NCDs as compared to employees whose families don't have any chronic disease history. Our finding is similar to a previous study[8].

The prevalence of NCDs is higher among smokers as compared to non-smoker employees. Similarly, it is also higher among people who chew tobacco as compared to those who do not chew tobacco. Moreover, the prevalence is also higher among those who consume alcohol as compared to non-consumers. Our study findings indicate, eating outside meals, daily consumption of maida, butter, and ghee were significantly associated with NCDs. Our study highlights that walking or bicycling and vigorous-intensity activities reduced the risk of NCDs. This finding aligns with previous research[13-14].

Furthermore, the prevalence is highest among obese employees, followed by overweight and underweight employees, respectively. Similarly, hypertensive people suffer more NCDs as compared to normal people[8,15]. Among the socio-economic variables, sex, type of employment, and family history of any chronic disease showed a significant relationship with NCDs. The results show that females are less likely to risk of NCDs as compared to males. On the other hand, the risk of NCDs is 3.35 times higher among permanent non-teaching employees as compared to temporary employees.

Conclusion

The current study examines the prevalence of and risk factors for NCDs among university non-teaching employees. The current study's findings revealed that a family history of NCDs, obesity and overweight, hypertension, daily butter consumption, and taking extra salt raise the risk of NCDs. On the other hand physical activity and a healthy diet can reduced the risk of NCDs. It is suggested that university officials create surveillance systems for NCDs in order to better prevention and control. They should take steps to eliminate NCD risk factors and promote healthier lives in order to lower NCD incidence rates and postpone NCD onset.

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Original Article

Acute Kidney Injury Management — 15 Year Experience at A Tertiary Care Teaching Hospital in South India

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Abstract

Background : There is paucity of published data from Andhra Pradesh, India regarding aetiology, clinical presentation, outcome and temporal trends in patients presenting with Acute Kidney Injury (AKI) requiring hospitalisation. Hence, this study is submitted.

Materials and Methods : We retrospectively reviewed the case records of 1734 AKI patients managed at Sri Venkateswara Institute of Medical Sciences (SVIMS), a tertiary care teaching hospital in Tirupati, Andhra Pradesh State, South-India from the year 2002 to 2016, a fifteen year study.

Results : There were 1734 patients of AKI included in this study (0.62%) from among total hospital admissions (n=2,81,805) during the study period; 1710 (98.6 %) were having community acquired AKI (CAKI) and 24(1.4%) were having Hospital Acquired AKI (HAKI). Infectious etiology (77.9%, n=1351) was the most common cause of AKI. Their mean age was 49.92 ± 16.03 years; males were 1127 (65%). Majority of the cases of AKI occurred in monsoon season (38.5%, n=668). Oliguria at the time of hospitalization was present in 756 (43.6%) patients. Hemodialysis was required in 639 (36.9%) and peritoneal dialysis in 24 (1.4%) patients. Of the 1734 patients, 361(20.8%) died, which accounted for 2.07% of total hospital deaths (n=17, 439) during study period. The survived patients were 1373 out of 1734 AKI patients (79.18%). Of the survived patients progression to Chronic Kidney Disease (CKD) was observed in 133 patients (9.6%). The AKI to CKD progression was noted in most of the patients who required dialysis (p value <0.001), those with diabetes mellitus (p value <0.001) and hypertension (p value <0.001).

Conclusions : This study highlights the presentation of AKI as CAKI, HAKI and their outcomes, temporal and seasonal trends of AKI emphasizing the importance of infection as cause of AKI in monsoon and also the progression of AKI to CKD in the survived patients on follow up (9.6%).

Key words : Acute Kidney Injury, Management, South-India.

Acute Kidney Injury (AKI), which was previously called as Acute Renal Failure (ARF), has been a problem of global concern affecting around 13.3 million subjects annually with mostly being reported from developing countries. AKI is defined as any of the following: Increase in serum creatinine by ≥0.3 mg/dl (≥26.5 ìmol/l) within 48 hours; or increase in serum creatinine to ≥1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or Urine volume <0.5 ml/kg/h for 6 hours[1].

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Editor's Comment :

- AKI continues to be a challenging problem in tropics.
- Infections especially during monsoon period present as tropical AKI is a significant burden.
- Timely referral to advanced centers with critical care supports help in reducing the morbidity, progression to CKD and mortality in these patients.

Even in terms of mortality, low and middle income countries has the highest burden with 1.4 million deaths out of 1.7 million deaths annually[2]. In view of the alarming numbers of AKI, International Society of Nephrology (ISN) launched “0by25” initiative in 2013 with aim of eliminating preventable deaths from AKI by 2025[3].

AKI in most parts of developing world remains under diagnosed. Aetiology, presentation, complications, management and outcome are quite different in developing countries as compared to developed world and it is particularly challenging to rely on global data regarding them. As the diagnosis of AKI depends on laboratory parameters rather than clinical symptoms,

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such that the spectrum of disease ranges from asymptomatic elevation of serum creatinine to oliguria which often occurs at a much later stage of disease. It is of special concern as major portion of cases remains undiagnosed at community level, which is much evident in low and middle income countries.

Aetiology of AKI varies by geography as well as with socioeconomic differences between different parts of world. In high income countries, acute tubular necrosis resulting from one or more insultssuch as sepsis, renal ischemia from shock, bleeding, toxic effects of drugs, radio-contrast agents and pigment injury from haemoglobin or myoglobin are predominant causes of AKI, mostly affecting elderly age population[4,5]. In middle and low income countries, among rural areas aetiology of AKI is much different as infectious causes like acute gastroenteritis or tropical infections like malaria, dengue fever, leptospirosis, respiratory tract infections, native medication intake were most common, predominantly affecting young population. Venomous snake bite and traditional medication intake are among other causes in African and south-east Asian regions. Obstetric related renal injury although declining, contributes to AKI in low income countries. Other causes of pregnancy related AKI include postpartum haemorrhage and puerperal sepsis[5-7].

Multiple factors leads to progression of AKI to Chronic Kidney Disease (CKD), which include presence of comorbidities, nature of the aetiology leading to AKI, ineffective timely management of the initial event leading to AKI, severity of the disease at the time of presentation to hospital and requirement of dialysis and elderly age[8]. Even with trivial causes like acute gastroenteritis without timely intervention, can lead to greater morbidity as well as mortality[9,10].

Sparse published data are available regarding aetiology, clinical presentation, outcome and temporal trends in patients presenting with AKI from the state of Andhra Pradesh. Hence the present study was done retrospectively to find aetiology, comorbidities, seasonal and temporal changes in the incidence of AKI, outcomes and factors leading to progression to Chronic Kidney Disease (CKD) for one and half decades in patients presenting with AKI at our tertiary care teaching hospital.

Material and Methods

We retrospectively reviewed the case records of patients presenting with AKI to Sri Venkateswara Institute of Medical Sciences (SVIMS), a tertiary care teaching hospital in Tirupati, Andhra Pradesh State, Southern India from the year 2002 to 2016. The SVIMS caters to the a population of around seven hundred and fifty thousands[11] not only from Andhra Pradesh State, but also from the border areas of neighbouring four states of Tamil Nadu, Karnataka, Telangana and Orissa. The study was approved by the Institutional Ethics Committee. Hospitalised patients diagnosed to have AKI according to Risk, Injury, Failure, Loss of kidney function and End stage kidney disease (RIFLE), Acute Kidney Injury Network (AKIN) and Kidney Disease Improving Global Outcomes (KDIGO) criteria had been included in this study keeping in view of the study population belonging to a period of one and half decades during which time the diagnostic and the staging of AKI changed from RIFLE criteria to AKIN criteria to KDIGO criteria[1,12,13]. Patients with known CKD prior to admission and patient records not containing required information were excluded.

Demographic, clinical and laboratory data for all participants were collected at the time of study inclusion. Demographic data included age, gender, seasons, date of admission and discharge. Clinical data included aetiology of AKI, presence of oliguria, comorbid diseases, use of nephrotoxic agents, treatment, complications due to AKI and outcome. Laboratory data included urine routine-microscopy, serumcreatinine level and ultrasonography of renal system.

The primary outcome studied was morbidity and mortality of AKI during the course of illness. Secondary outcome studied was progression to CKD. Further the study also included details related to type of AKI (Community or hospital acquired AKI), oliguric or non oliguric AKI patients and management based on dialysis requirement. During study evaluation, important entities such as seasonal variation, temporal trends, elderly age group, pregnancy related AKI were also considered.

Definition :

AKI definition and staging has been changing from time to time in the literature over the study period of 15 years. Initially it was RIFLE criteria (2004), followed by AKIN (2007) and latest being KDIGO (2012) and our patient population were staged accordingly appropriate to the time[1,12,13].

Patients with AKI at the time of admission were considered to have community acquired AKI (CAKI). Patients without AKI on admission who subsequently developed AKI during the hospitalization (≥48 hours after admission) were considered to have hospital acquired AKI (HAKI)[14].

De novo CKD was defined per the KDIGO guidelines as the persistence of eGFR< 60 mL/min per 1.73 m^2 for atleast 3 months[1] from the time of AKI event or from the time of admission (in those without AKI). Oliguria is defined as reduction in urine output of <400 ml/24 hours[15]. Elderly people were taken as population ≥60 years of age[16]. As per India meteriological department - climate profile of India, four seasons were considered, ie, winter (January, February), Summer (March, April, May), Monsoon (June, July, August, September) and Postmonsoon (October, November, December)[17]. Urine was considered abnormal in our study if there is any presence of proteinuria, hematuria or presence of casts.

Comorbidities noted in the study were diabetes mellitus, hypertension, ischemic heart disease, heart failure, vascular disease, malignancy, cerebro-vascular accident, liver disease and respiratory diseases.

Statistical Analysis :

Data were recorded on a pre-designed proforma and managed using Microsoft Excel worksheet (Microsoft Corp., Redmond, WA). All the entries were double checked for any possible error. Descriptive statistics for categorical variables were performed by computing the frequencies (percentages) in each category. For the quantitative variables, approximate normality of distribution was assessed. Variables following normal distribution were summarised by mean ± standard deviation; the remaining variables were summarised as median [interquartile range (IQR)]. Categorical variables were reported as percentages.

The association between two categorical variables were evaluated by Chi-square (χ^2) test or Fisher's exact test as appropriate. Student's 't'-test or Mann-Whitney U test, as appropriate, was used to compare continuous variables between the groups. Correlation was done between outcome (alive or dead)/CKD as the dependent parameters with other patient parameters like age, gender, aetiology, presence or absence of oliguria, urinalysis, USG abdomen and treatment. "Worst case-scenario" analysis[18] was done wherein, the Discharged Against Medical Advice (DAMA) patients were considered to have died. Age was categorised as <60 years and ≥60 years. A two-tailed P-value of <0.05 was considered statistically significant.

The statistical software IBM Statistical Package for Social Sciences (Version 20, IBM Corp., Somers NY, USA); and MedCalc Version 19.1(MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org;2016) were used for statistical calculations.

Results

In the duration of 15 years spanning from January, 2002 to June, 2016, 1734 patients satisfying inclusion criteria were considered for analysis. During this time the patients of AKI studied were 1734 among the total hospital admissions of 2,81,805, amounting to AKI incidence of 0.62%. Their mean age was 49.92 ± 16.03 years. There were 1127 (65%) males and 607 (35%) females. Of 1734 patients studied, 1710 (98.6%) were having Community Acquired AKI (CAKI) and 24(1.4%) were having hospital acquired AKI (HAKI). Gender predilection for females was observed in HAKI patients and this was statistically significant (n=14, 2.3%, p value= 0.02).Over the past one and half decade number of admissions in SVIMS with AKI is increasing with peak cases observed in 2010 (n=218) and 2014(n=207). Majority of the cases of AKI occurred in monsoon season (38.5%, n=668) followed by post monsoon (25.5%,n=442), summer (22.1%,n=384) and winter(13.8%,n=240) respectively. CAKI was more common in monsoon season (n=660) followed by post monsoon (n=432), summer (n=380) and winter (n= 238). Almost similar trend was observed in HAKI ie, it was more common in post monsoon (n=10) followed by monsoon (n=8), summer (n=4) and winter (n=2).

Out of 1734 studied 756 (43.6%) patients presented with oliguria, out of which 482 (63.8%) were males and 274(36.2%) were females. 43.7% CAKI patients and 37.5% HAKI patients presented with oliguria. Of the 756 patients who presented with oliguria, 448 (59.26%) showed urine abnormality (p value< 0.001). Requirement of dialysis was significant in patients presented with oliguria (n=404, 60.9%, p value <0.001).

Infectious aetiology (77.9%, n=1351) was the most

common cause of AKI. 46 (2.7%) patients were using nephrotoxic agents such as NSAIDS (n=31,1.8%), native medication (n=12,0.7%), amphotericin B(n=1,0.1%), aminoglycosides (n=2,0.1%). Most common cause of AKI in oliguric patients were infectious diseases (75.3%, n=570) followed by toxic nephropathy (10.3%, n= 78). Similarly in patients with AKI requiring dialysis infectious diseases (n=482, 72.7%) followed by toxic nephropathy (n=96, 14.4%) were found to be the most common causes. Aetiological details of AKI in the present study were shown in Table 1.

Comorbidities like diabetes mellitus and hypertension were present in 284 (16.4%) and 247(14.2%) patients respectively. Among patients presenting with comorbidities CAKI was more significant than HAKI (n=532, 99.6%, p value =0.01). Among oliguric patients 101 (13.3%) had hypertension and 115(15.2%) had diabetes mellitus. Other comorbidities noted in this study were Chronic Liver Disease (CLD) in 27 patients, hypothyroidism in 23 patients, chronic obstructive pulmonary disease in 30 patients, old pulmonary tuberculosis in 10 patients, coronary artery disease in 47 patients, cerebrovascular accident in 31 patients, carcinoma in 21 patients, congestive heart failure in 17 patients, Systemic Lupus Erythematosis (SLE) in 2 patients and HIV in 2 patients.

Table 1 — *Aetiology of patients presenting with AKI*

Aetiology	No	(%)
Infectious causes	1351	77.9
Acute gastroenteritis	506	29.2
UTI	129	7.4
Leptospira	128	7.4
Malaria	120	6.9
Sepsis with MODS	111	6.4
LRTI	94	5.4
Pyelonephritis	89	5.1
Cellulitis	69	4
Pancreatitis	21	1.2
Viral fever	21	1.2
Cholecystitis	12	0.7
Scrub typhus	7	0.4
Spleenicabcess	6	0.3
Liver abcess	6	0.3
Filaria	2	0.1
HIV(AN)	1	0.1
Hydatid cyst	1	0.1
Chest wall abcess	3	0.2
Meningitis	2	0.1
Peritonitis	7	0.4
Gluteal abcess	5	0.3
Scrotal abcess	4	0.2
Renal related	153	8.8
(A) Glomerulonephritic	24	1.4
(B) Toxic nephropathy	129	7.4
Snake bite	93	5.4
Rhabdomyolysis	12	0.7
Contrast induced nephropathy	5	0.3
Scorpion sting	1	0.1
Poisoning	10	0.6
Transfusion related AKI	8	0.5
Pregnancy related	50	2.9
Puerpueral sepsis	36	2.1
PPH	2	0.1
Eclampsia	12	0.7
Surgical causes	60	3.5
Obstructive uropathy	34	2
Prostectomy	7	0.4
Femur fracture	4	0.2
Obstructive jaundice	1	0.1
GE bleed	2	0.1
Unknown	120	6.9

Among AKI patients 639(36.9%) patients required hemodialysis, 24(1.4%) patients treated with peritoneal dialysis and 30(1.7 %) patients underwent urological interventions like Double J (DJ) stenting for obstructive uropathy. Of the 1734 patients studied, 663(38.2%) required dialysis out of this 424(64%) were males and 239(36%) were females. Among females requiring dialysis 37% (n=88) were in middle age group. In this study, it was observed that 38.3% (655 out of 1710) of CAKI and 33.3 % (8 out of 24) of HAKI patients required dialysis. Of the 1734 patients 1373 (79.2%) survived and 361(20.8%) died, which accounted for 2.07% of total hospital deaths (n=17,439) during study period. Mean age of patients in death group was 51.85±16.61. Death was more significant in HAKI (p value=0.001), in elderly people of age ≥60 years (p value=0.009), in patients presented with oliguria (p value<0.001), in patients having hypertension(p value=0.01).Details were tabulated (Table 2).

Upon discharge patients were followed for 3 months. We noticed progression to CKD in 133(9.7%) subjects out of 1373 survived AKI patients. Eight patients (6%) progressed from AKI to CKD directly without a period of recovery in between (representing category E in RIFLE). Patients of AKI secondary to renal related diseases showed predilection to progression to CKD (p value=0.03).Progression to CKD from AKI was noted in elderly (p value<0.001), in oligurics (p value<0.001), those patients who required dialysis (15.7%, p value<0.001), those with diabetes mellitus (16.4%, p value<0.001) and hypertension (19%, p value <0.001).We also found a correlation between the presence of urinary abnormality with requirement of dialysis (n= 393, p value <0.001), progression to CKD (n= 97, p value< 0.001) and death (n= 194, p value < 0.001).

Table 2 — *Comparison of characteristics between CAKI and HAKI*

	CAKI	HAKI	P-value
Age in years (Mean)	50.01±15.94	43.20±20.68	
Gender :			
Male	1117	10	
Female	593	14	0.029
Definition :			
Oliguria	747	9	
Non-oliguria	963	15	0.680
Diabetes Mellitus :			
Present	284	0	
Absent	1426	24	0.023
Hypertension :			
Present	247	0	
Absent	1463	24	0.039
Urine analysis :			
Normal	941	10	
Abnormal	769	14	0.218
Renal Ultrasonography :			
Normal	993	14	
Abnormal	717	10	1.000
Treatment :			
Dialysis	655	8	
Nondialysis	1055	16	0.678
Outcome :			
Alive	1361	12	
Dead	349	12	0.001

CAKI = Community Acquired Acute Kidney Injury,
HAKI = Hospital Acquired Acute Kidney Injury

Comparison of the results of the present study with previously published studies from other developed and developing countries is shown in Table 3[19-22].

Discussion

AKI is a clinical syndrome denoted by an abrupt decline in Glomerular Filtration Rate (GFR) sufficient decrease in the elimination of nitrogenous waste products (urea and creatinine) and other uremic toxins. AKI is an important cause of morbidity and mortality in patients requiring hospitalization especially in the developing nations. Inspite of fact that AKI is one of the leading cause of morbidity and mortality, it largely remains underdiagnosed and under reported in the developing nations. Our study is one such attempt to know the demographic details, type (CAKI, HAKI), presentation (oliguric or non-oliguric), etiology, dialysis requirement, progression to CKD and mortality at a tertiary care centre in southern part of India, which can serve as a platform for future studies.

Most of the patients in the present study belong to fifth decade, men outnumbered women, is similar to the other studies from developed and developing countries. The putative reasons for male predominance could be that as men tend to stay outdoors and they are at a higher risk of exposure to a wide variety of infectious agents and men seeking medical attention earlier.Infectious causes emerged as most common etiology in the present study in comparision to developed countries where renal vascular related conditions such as diabetes and hypertension leading to AKI and further progression to CKD is much common (Table 3)[19-22]. In the present study AKI is more common in monsoon season, reflecting the increased incidence of infectious aetiology in monsoon season, where as in developed nations it is due to high incidence of cardiovascular and pulmonary diseases in winter seasons[23]. Mortality

Table 3 — *Comparison of present study with other studies*

Variable	Study (reference)				
	Wang 2012[19]	Challiner R 2014[20]	Yousif 2018[21]	Arshad 2020[22]	Present study
Period of study	2009-2010	2013	2013-2014	2017	2002-2016
Place of study	Birmingham, USA	England, UK	Soba Uni-versity Hospital (SUH), Khartoum state, Sudan	Aga Khan University Hospital, Karachi, Pakistan	SVIMS, Tirupati, Andhra Pradesh, India
Study setting	Tertiary care centre	Tertiary care teaching hospital	Tertiary care teaching hospital	Tertiary care centre	Tertiary care teaching hospital
Study design	Retrospective	Retrospective	Prospective	Retrospective	Retrospective
Study subjects	4,365	745	71	134	1734
Age (years)	56.8±16.9	ND	54.0	60 ± 11.7	49.92 ± 16
Gender distribution (male:female)	51.9:40.1	54.6:44.4	66:64	55.2:44.8	65:35
Aetiology	Circulatory diseases (25.4%) and infection (16.4%)	ND	Intrinsic renal disease (25.34%)	Sepsis (45%)	Infectious causes (77.9%)
Progression to CKD	ND	ND	27 (38%)	ND	133 (9.6%)
Mortality	10.8%	11.4%	10 (14.1%)	ND	361 (20.8%)

ND = Not Described

was higher in patients with HAKI as well as those who presented with oliguria in the present study; similar trends were observed in the studies from other parts of the world[24,25]. Progression to CKD is much less when compared to other studies from the world[19-22].

Conclusion

This study represents a fairly good data of AKI patients from southern-India from 2002 to 2016 emphasizing it's incidence as 0.62%, types including CAKI and HAKI, presentation as oliguric and non-oliguric, infections as leading etiology in patient population predominantly in the fifth decade, with hypertension and diabetes mellitus as co-morbidities and in men. Mortality due to AKI was 2.07% among hospital deaths between 2002 to 2016. The progression of AKI to CKD was 9.6% of the survived AKI patients in the follow up reiterating the importance of periodic follow-up after the discharge to enable early detection and to implement effective measures to retard progression to CKD. "A STITCH IN TIME SAVES NINE".

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Original Article

Menstrual Abnormalities Post COVID-19 : Reality or Myth

Rashi Manocha[1], Himadri Bal[2], Hetal Rathod[3], Deepu Palal[4]

Abstract

Background : Many women with a history of COVID were reporting menstrual abnormalities post infection. The possibility of this development being linked to COVID-19 became the genesis of this study.

Aims : To find out the prevalence and nature of menstrual function abnormalities in women of reproductive age, who have recently recovered from COVID-19 infection.

Objectives : Questionnaire based retrospective, analytical study was carried out at a Tertiary Care Hospital in western Maharashtra among 300 women of reproductive age group with history of COVID-19 infection with no recent delivery or not on Oral Contraceptive Pills.

Materials and Methods : Analysis was done in MedCalc v18.2.1 and SPSS v26.0. Categorical variables in frequency and percentage; continuous variables as mean (Standard Deviation, SD). McNemar test and McNemar-Bowker Test for statistical significance. P<0.05 to be statistically significant.

Results : 143 (47%) women noticed changes in their menstrual cycles post covid; change in frequency of cycle in 24% participants, alteration of menstrual flow in 15.6% and 22% reporting a change in severity of dysmenorrhea were the statistically significant findings. However, these changes were very random and did not show any definitive pattern. The average duration for menstrual patterns to revert back to normal was 2.52 (SD=1.33) months.

Conclusions : COVID-19 definitely had an impact on menstruation. Whether these changes are directly linked to the infection or other associated factors like social and psychological will remain a moot question.

Key words : Prevalence, Dysmenorrhea, Menstruation, COVID-19, Menstrual Cycle, Prevalence, Surveys and Questionnaires.

This research topic occurred to us after personal experience with several females reporting insidious onset of menstrual abnormalities. Despite some inconsistencies, we were able to see a pattern emerge in their clinical complaints – they all were in post covid recovery phase.

The possibility of these menstrual abnormalities being linked to COVID-19 in these patients was intriguing. This research was taken up to discover the existence of such an association.

Since a large number of the female population has been infected with COVID-19, there is a need to expand our perception on effects of COVID-19 on reproductive health, and menstruation as a significant marker of this entity.

Editor's Comment :

- Post COVID-19, women were found to have significant ($p<0.05$) change in the quantum of bleeding (hypomenorrhea or menorrhagia) as well as the frequency of their menstrual cycle (10% Change).
- These changes could be attributed to either the infection and/or associated stress.
- A larger controlled study may validate these findings.

Aims :

To find out the prevalence and nature of menstrual function abnormalities in women of reproductive age, who have recently recovered from COVID-19 infection.

Objectives :

(1) Compare the menstrual cycle pattern pre- and post COVID-19.

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(2) To detect changes in cycle frequency, duration and blood loss.

(3) To estimate the time taken to revert back to pre-COVID menstrual state.

Materials and Methods

A Retrospective analytical study was conducted at Tertiary Care Hospital in Western Maharashtra after the approval of the institutional ethics subcommittee. Data collection was done from June, 2021 to October, 2021. Assuming the menstrual cycle change from normal to abnormal is 12% between pre and post COVID-19. Entering this data in WinPepi v11.65, within 95% CI and power of 80% the minimum required sample size is calculated to be 247. Data collection was done on 300 women. Women in reproductive age group who had a positive history of COVID-19 infection were included in the study. Exclusion criteria were Pregnant/Lactating women, recent postpartum women, women on oral contraceptive pills/ other hormonal pills.

The google form link shared with the participants began with the participant information sheet and participant consent. By accepting and proceeding to the next section, 347 participants consented to the study. If participants did not wish to proceed, they were able to decline consent and exit the survey. 300 women of reproductive age group were recruited on a continuous basis satisfying the inclusion and exclusion criteria. Information obtained was depersonalized and maintained confidentiality. A detailed menstrual history including frequency, duration of blood flow, presence or absence of dysmenorrhea and passage of clots in both pre and post COVID phase along with the sociodemographic details was elicited and documented. The severity of COVID-19 (as classified by the treating physician) as well as the mental state during COVID-19 were also recorded.

Data Analysis :

Data was analysed using MedCalc v18.2.1 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2018), and SPSS v26 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). Categorical variables are expressed in terms of frequency and percentage. Continuous variables were expressed as mean (Standard Deviation, SD) & Median (Interquartile Range, IQR). Normal distribution was verified by Shapiro-Francia test. McNemar test and McNemar-Bowker Test were applied to check for statistical significance. In all the tests performed, $P<0.05$ was considered to be statistically significant.

Results

342 (Three Hundred Forty-Two) participants consented to the study and filled a questionnaire in the form of an online survey (google forms), out of which 42 participants were excluded not fulfilling the inclusion criteria.

34% of the participants were 14-20 years old, 58.67% 21-40 years old and 7.33% 41-51 years old. 55.33% [49.51-61.05], 38.67% [33.13-44.43] and 6.00% [3.59-9.32] participants had mild, moderate and severe COVID-19 respectively.

On being questioned about changes in their menstrual patterns post COVID, 87 (29%, 23.93%-34.49%) women responded with “yes” while 56 (18.67%, 14.42%-23.54%) and 157 (52.33%, 46.52%-58.10%) with “Not Sure” and “No” respectively.

Out of 300 women, 282 (94%) did not have any change in duration of bleeding post COVID-19. Whereas 4.64% (N=13) women shifted from normal to abnormal. The difference in change pre- and post COVID-19 infection was only 2.67% [-0.089 to 5.42] which is not statistically significant ($p = 0.0963$).

Whereas, the change in frequency of cycle was much more drastic wherein 24% (72/300) of the participants had a change. Among 222 women who had normal cycle frequency before COVID-19 infection, 51(23%) drifted to abnormal whereas of 78 with abnormal frequency, 21 (26.90%) rectified. This difference in proportion post COVID-19 was 10.00% [4.57 to 15.43] which is statistically significant ($P=0.0005$).

Among 281 females who experienced no clots/small clots before COVID-19 infection, 276 (98.20%) denied experiencing any significant change in clots post COVID-19 infection. Similar was the case in a group of 19 with abnormal clots pre COVID where 84.2% remained unchanged. The difference in proportion of participants experiencing clots pre and post COVID was only 0.67% [-1.18 to 2.51]. This was not statistically significant ($p=0.72$).

Initially 246 (82%) people had normal flow Pre-COVID-19 which changed to 220 post COVID (210

from normal, 7 from heavy and 3 from scanty). Whereas 40 women who had heavy flow pre-COVID-19 became 50 (33 from heavy, 16 from normal and 1 from scanty) while 14 women who had scanty flow pre-COVID-19 increased to 30 (10 from scanty and 20 from normal). The flow change post COVID-19 is statistically significant (McNemar- Bowker Test = 17.087, df=3, P=0.001)

Out of 300 participants,166 had mild dysmenorrhoea, which changed to 134(123 from mild, 11 from moderate).116 had moderate dysmenorrhoea changed to 136(97 from moderate, 35 from mild and 4 from severe). 18 had severe dysmenorrhea which rose to 30 (14 from severe, 8 each from mild and moderate). The change in severity post COVID is statistically significant (McNemar- Bowker Test = 21.855, df=3, P<0.001).

The mean (SD) duration for menstrual patterns to revert back to normal was 2.52(1.33) months [Min 1 month, Max 6 months] (Table 1).

Discussion

The COVID-19 pandemic led to worldwide lockdowns which imposed the shutdown of all commercial, industrial and transport activities[1]. People were confined to their homes during this period for the longest time. Many lost their jobs and others constantly under the stress of having their livelihoods at stake, students were unable to attend school. As everyone sat through this devastating period of massive job losses, shrinking economies and loss of livelihoods[2], the worst to be impacted seem to be women. During the lockdown, women were victims of domestic violence, overburdened domestic work (unpaid care), in addition to threats to their financial independence. Lack of financial security, social isolation, coupled with lack of awareness, fear and stigma of a new disease has been responsible for inducing a lot of stress and mental trauma.

Table 1 — *Changes in Menstrual cycle duration, Frequency and Clots Pre- and Post COVID-19*

Menstrual Pattern	Post COVID Normal N (%)	Post COVID Abnormal N (%)	Total N (%)%	McNemar Test P value, Change [95% CI]
Duration of cycle (Pre-COVID) :				
Normal	267(95.40)	13(4.60)	280(93.33)	P=0.0963,
Abnormal	5(25.00)	15(75.00)	20 (6.66)	2.67%
Total	272(90.70)	28(9.30)	300(100)	[-0.089 to 5.42]
Cycle Frequency (Pre-COVID) :				
Normal	171 (77.00)	51 (23.00)	222 (74.00)	P=0.0005,
Abnormal	21 (26.90)	57 (73.10)	78 (26.00)	10.00%
Total	192 (64.00)	108 (36.00)	300 (100.00)	[4.57 to 15.43]
Clots (Pre-COVID) :				
Normal	276 (98.20)	5 (1.80)	281 (93.60)	P=0.7266,
Abnormal	3 (15.80)	16 (84.20)	19 (6.33)	0.67%
Total	279 (93.00)	21 (7.00)	300 (100)	[-1.18 to 2.51]

The responses in this survey were collected from participants through a google-form based questionnaire, which extended from demographic details to detailed information on menstrual patterns pre- and post COVID-19. Details reflecting severity of the infection and perceived mental state were also collected.

55.33% [49.51-61.05], 38.67% [33.13-44.43] and 6.00% [3.59-9.32] participants had mild, moderate and severe COVID-19 respectively.

Majority (59%) of the participants were between the age of 21-40 years. The highest education level of participants varied from primary schooling to postgraduate level. Most of the participants (58%) were undergraduate students. Since the majority of the participants were college going and above, it was presumed that their responses would be reliable.

The normal menstrual cycle frequency is 21-35 days, lasts for 2-7 days, with an average blood loss of 30-35 ml per cycle[3]. Clotting of menstrual blood is a marker of excessive bleeding as it results from the quantum of bleeding surpassing the capacity of the fibrinolytics released to liquefy menstrual blood for easy passage.

The results show that there was a significant impact of COVID-19 infection on the female reproductive system in the form of menstrual abnormalities. Significant menstrual changes were noted in frequency, flow and severity of dysmenorrhea. The change in all parameters was bidirectional. However, the change in duration of flow and passage of clots were not significant. Although the said changes were well appreciated by the participants on individual

levels, collectively the findings did not follow any particular pattern and were random.

In an observational study conducted by Phelan, *et al*[4] on 1031 women, there was no significant effect of COVID-19 on change in days of menstruation. However, the change in cycle length though significant was bidirectional with 28% and 29% participants experiencing increase and decrease respectively. The study also showed that 49% women reported painful periods, 7% more than the pre-pandemic. 30% reported new onset painful periods and 12% showed resolution of dysmenorrhoea during the pandemic. Our study also showed significant changes in dysmenorrhea post COVID-19. Study by Phelan also shows that heavy periods increased from 42% to 47% in COVID times which is consistent with our study where heavy flow increased from 13.33% to 16.66%. Overall, Phelan, *et al* concluded that COVID-19 pandemic has a significant impact on the reproductive health of women. The conclusion was consistent with the findings of the present study.

Cross Sectional study by Georgie Bruinvels, *et al*[5] titled "How lifestyle changes within the COVID-19 global pandemic have affected the pattern and symptoms of the menstrual cycle" on 749 women of reproductive age. They found that more than half (52.6%) had change in length of menstrual cycle (either increase and decrease), 36% participants had change in the duration of bleeding. Although change in cycle length was significant in women using oral contraceptives compared to non-users, both the groups had experienced changes. Only 16.1% of the study participants had a positive COVID-19 diagnosis or had symptoms of COVID-19 in the study. The study also states that the menstrual changes might be due to increased stress or job insecurity.

In a study by Omer Demir, *et al*[6] on 283 women where only 1.4% women contracted COVID-19. The study found no significant difference between the frequency of menstrual cycle, severity of dysmenorrhoea pre and during COVID-19 where no factors other than stress were at play. However, a significant change was noted in duration of bleeding and amount of bleeding even though only a minority of participants had contracted COVID-19.

In a retrospective study conducted by Kezhen Li, *et al*[7] on analysis of sex hormones and menstruation in COVID-19 women of child-bearing age. Out of 177 women who were included in the menstrual analysis, 25% of the patients had change in menstrual volume, of which 20% had a decrease whereas only 5% had increased volume. However, the study had also shown the change in menstrual volume with respect to the severity of the infection was not significant. When compared with age matched controls, it was found there is significant change in menstrual volume and duration of cycle. Hormonal evaluation showed no significant difference between sex hormones of COVID-19 patients and control group.

With the current results, it is difficult to arrive at any definitive conclusion on the effects of COVID-19 on menstruation. It is also not certain whether the changes we found were due to covid or other factors associated with the pandemic such as those covered by Niahm, *et al*[4] study like weight gain, psychological stress, lack of physical activity, diet changes, changes in work schedule etc.

The most probable explanation as inferred from existing studies is that these changes could be a result of the extreme mental stress patients underwent due to the associated panic created by this pandemic. According to our study 7% [4.39%-10.50%] of the participants were in a mental state of happiness, 42.67% [37.00-48.48%] were neutral and 50.33% [44.53-56.13%] in a stressed and anxious state.

A study conducted by Noelle, *et al*[8]. implies that the pandemic of COVID-19 might have a direct contribution to menstrual cycle irregularities in women experiencing moderate and high levels of stress and the stress could put women at high risk for endocrine dysregulation.

Nazish, *et al*[9] from Bin Faisal University that surveyed 738 young female students studying health sciences found strong positive correlations between stress and various menstrual irregularities with 4, 2.8, and 2 times Odds Ratio for experiencing amenorrhea, pre-menstrual syndrome and dysmenorrhea in women with high stress. Another study by Ansong, *et al*[10] established a relationship between menstrual irregularities and stress, where various menstrual disorders such as abnormal flow, premenstrual symptoms and dysmenorrhea were common amongst those with high stress levels. A study conducted by Shazia Iqbal[11] showed significant correlation between anxiety and duration of the bleeding phase, severity of bleeding and missed periods. Whereas, S Nagma's[12] study on 100 female medical undergraduate students found that high

stress levels (PSS>20) had association with only irregular menstrual cycles, but not with dysmenorrhoea, amount of flow or duration.

Limitation :

Few limitations of our study were that only women who had positive history of COVID-19 were invited to participate, due to which it is uncertain whether the COVID infection was responsible for these changes or the psychosocial stress associated with the pandemic caused them. Secondly, due to subjectivity of the individual responses it was not possible to reliably quantify the responses. However, a larger study under controlled settings could throw more light on the effect of COVID on menstrual physiology.

Conclusion

The study was conceptualised when a number of women who had gone through the agony of COVID-19 infection reported to us with recent onset menstrual problems. The significant impact was noted in the change of cycle frequency in both directions, heavier blood loss, and increase in severity of dysmenorrhoea post COVID. Whether these changes were a direct fall out of the infection or related to the frequent association of morbidities like social and psychological stress with COVID-19, will remain a moot question.

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Original Article

Introducing Multiple Assessment in Skill Training Modules on the Skill “Anterior Nasal Packing"

Sumit Sharma[1], Adarshlata Singh[2], Vaibhav Anjankar[3]

Abstract

Background : Introducing multiple assessment methods in anterior nasal packing training enhances proficiency and ensures comprehensive competency. This critical procedure for managing epistaxis requires precise technique and anatomical understanding. Traditional single-format assessments may not fully capture skill development.

Aims and Objectives : A multi-method approach – using formative assessments, peer reviews, self-assessments, and OSCEs at various learning stages – offers a more robust evaluation.

Materials and Methods : Formative assessments provide continuous feedback for skill refinement. Peer reviews encourage collaborative learning and critical evaluation. Self-assessments promote reflection, helping learners identify strengths and areas for improvement. OSCEs offer standardized, objective competency measures.

Conclusions : This diverse assessment strategy supports different learning styles, deepens understanding and ensures learners are prepared for real-world clinical scenarios. By combining theory, technical skill and adaptability, it produces confident, competent practitioners. Ultimately, this holistic approach improves training outcomes and fosters excellence in clinical practice.

Key words : Anterior Nasal Packing, Skill Training, Multiple Assessment Method, Reflective Practice, OSCEs evaluation, Clinical Skills Development, Multi-Faceted Evaluation.

The National Medical Commission (NMC) introduced Competency-Based Medical Education (CBME) in 2019, requiring Indian medical graduates to demonstrate practical competencies based on Miller’s Pyramid. To support this, skill labs were mandated in all medical colleges, offering structured, supervised training with feedback. This study aims to develop a validated skill-specific module for anterior nasal packing using low-stakes, multiple assessments with timely, constructive feedback. This approach promotes self-reflection, gradual skill acquisition, and better retention. It aligns with CBME’s goal of producing confident, practice-ready graduates capable of applying skills effectively in real-world clinical settings.

Review of Literature :

Simulation is a key learning strategy in medical education, allowing students to engage in real-life clinical scenarios within a controlled, supervised environment[1,2]. It supports the development of critical skills such as communication, ethical reasoning, and crisis management[3,4]. The National Medical Commission (NMC) mandates skill lab training using structured modules to ensure standardized, competency-based education[6]. With Competency-Based Medical Education (CBME), assessment and feedback have become central, leading to the adoption of Programmatic Assessment (PA) – a method involving multiple, low-stakes assessments over time with constructive feedback, enhancing deeper learning[7].

Editor's Comment :

- Integrating multiple assessments in skill lab training enriches student learning by offering a comprehensive, engaging, and real-world-oriented evaluation process. When guided by clear objectives, balanced methods, and continuous feedback, this approach not only strengthens practical competencies but also elevates the overall quality of education

Aims and Objectives

To introduce multiple assessment strategies (including WPBA components) in teaching anterior nasal packing in the skill lab.

(1) Develop a content-validated skill module for

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anterior nasal packing.

(2) Assess learners after didactic sessions.

(3) Assess learners post-practice sessions.

(4) Analyze feedback from faculty and students post-certification.

Materials and Methods

The Methodology flow is as below :

Assessment Method	Group A (NMC Module)	Group B (Present Study)
Making of the Checklist for the module	No Validation	Validation by faculty members
Pre-test	Both Groups subjected to the same Pre-test	
Briefing of the students with the Checklist	Yes	Yes
PPT presentation about the Theoretical component of the module	No assessment	MCQ's based assessment
Demonstration of the Video component of the Module	No assessment	MCQ's based assessment
Practical training sessions of the students on the model for Anterior nasal packing	No assessment	Formative Assessment of the students after training sessions using DOPS
OSCE based summative assessment after adequate practice sessions - Certification.	Both Groups subjected to similar OSCE based summative assessment	
Post-test	Both Groups subjected to the same Post-test	
Both the groups will subsequently be trained in both the methods		
Feedback given	Yes	Yes

Data Analysis : Both qualitative and quantitative data analysis was done. Feedback analysis qualitative and assessment comparison 'T' test and ANOVA.

Observations

Faculty members (n=3) expressed positive feedback on the new skill module, agreeing that the objectives and checklist were adequate with no changes needed. They praised its practical approach, interactive elements, and real-world relevance, noting it effectively enhances student engagement, critical thinking and readiness for professional skill application.

In the present study we had taken a total of 50 students divided equally in two groups – Group – A and Group B (Table 1).

Students of both the groups were made to give a Pre-test and students of both the groups scored 75% in an MCQ based test consisting of 20 questions (Table 2).

Students of Group B were made to give a Post-test following PPT presentation (MCQ Based), Video demonstration (MCQ Based) and after Practice sessions which was Mini-Cex based. Students of Group B scored 65%, 70% and 75% respectively (Table 3).

Since students of Group B was not subjected to Post test after PPT presentation, Video demonstration and after Practice sessions the average number of attempts taken by them to complete the skill as per OSCE checklist was 4.5 as compared to Group B who were subjected to Post test after each stage who took on an average of 2.5 attempts to complete the skill as per OSCE checklist, which is a significant difference (Table 4).

After the summative assessment students of both the groups were then subjected to a post test and average score of all the students in group A was 80% and that of Group B was 95% in an MCQ based evaluation (Table 5).

Statistical Analysis :

Average scores after Post-test of group A is 80 out of 100 in an MCQ based examination, the standard deviation is 16.67, and the p value is 0.003 while average

Table 1 — *Details of the students participated in the study (MBBS 2021-22 batch)*

Group A (n=25)		Group B (n=25)	
Male	11	Male	11
Female	14	Female	14

Table 2 — *Average Pre-test scores of the two groups*

Group A (n=25) Max Marks: 100	Group B (n=25) Max Marks: 100
75 (75 %)	75 (75%)

Table 3 — *Average scores after PPT presentation and Video demonstration and Practice sessions (Only Group B)*

Group B (n=25) Max Marks: 100	
PPT presentation (MCQ Based)	65%
Video demonstration (MCQ Based)	70%
Practice sessions (DOPS/ Mini-Cex)	75%

Table 4 — *Number of attempts taken by the students for completing the skill as per OSCE checklist (Practice sessions)*

Group A (n=25)	Group B (n=25)
4.5	2.5

Table 5 — *Average scores after Post-test of both groups*

Group A (n=25) Max Marks: 100	Group B (n=25) Max Marks: 100
80 (80%)	95 (95%)

scores after Post-test of group B is 95 out of 100 in the MCQ based examination the standard deviation is 14.25 and the p value is 0.0015. The p-value for the test comparing the average scores of Group A and Group B, given the provided standard deviations and sample sizes, is approximately 0.0015. This indicates a significant difference between the two groups' scores at a common significance level (eg, 0.05).

Discussion

In skill training, particularly within skill labs, the implementation of multiple assessment strategies is pivotal. These assessments evaluate student progress, proficiency and preparedness while also offering insights into the effectiveness of training modules and highlighting areas for improvement. This discussion explores various assessment types used in skill training, their benefits, challenges, and best practices for implementation.

Multiple faculty feedback enhances skill acquisition by providing diverse perspectives and nuanced guidance (Hattie & Timperley, 2007)[8]. Faculty with different expertise can identify varied strengths and weaknesses, enriching the learning experience (Sadler, 1989). Such varied input fosters a well-rounded skill set and encourages critical thinking and adaptability (Nicol & Macfarlane-Dick, 2006; Boud & Molloy, 2013). Consistent feedback from multiple sources also aids retention through repetition and reinforcement (Shute, 2008).

Theoretical training using PowerPoint (PPT) presentations improves skill acquisition by presenting information in a clear, organized manner (Mayer, 2009). Visual aids such as diagrams and images cater to visual learners and help simplify complex concepts (Gagné, *et al* 2005)[10]. Bullet points and concise text highlight key concepts and improve focus and retention (Sweller, *et al* 2011)[11]. Interactive PPT elements like embedded quizzes further enhance engagement and promote active learning (Clark & Mayer, 2016)[12]. PPTs are also flexible, easily updated, and tailored to specific learner needs.

Video demonstrations enrich skill training by delivering dynamic, visual, and auditory content that caters to diverse learning styles (Mayer, 2009). Watching skilled performers allows learners to observe critical techniques and replicate them more accurately (Bandura, 1986)[13]. Features like pausing, replaying, slow motion, and close-ups help students grasp difficult steps (Sweller, *et al* 2011)[11]. Videos also reduce learning anxiety by allowing learners to review at their own pace (Clark & Mayer, 2016)[12], which is especially helpful in self-directed learning environments.

A variety of assessments enhance skill training by offering comprehensive evaluation and promoting continuous learning:

Formative Assessments (eg, DOPS, Mini-CEX) monitor progress and provide real-time feedback, helping identify learning gaps and improve outcomes (Black & Wiliam, 1998)[14]. Structured feedback methods like the Sandwich technique or Pendleton's Rules enhance effectiveness (Hattie & Timperley, 2007)[8].

Summative Assessments evaluate competence at training completion. Harlen and James (1997)[16] stressed combining them with formative assessments for best results. Brookhart (2010)[17] recommended scenario-based tasks to assess higher-order thinking.

Performance-Based Assessments evaluate real-world skill application, fostering deeper learning and professional readiness (Wiggins, 1993)[18]; Gulikers, *et al* 2004)[19].

Portfolio Assessments offer a holistic view of long-term learning and development.

Together, these assessment types ensure thorough, practical and reflective evaluation of student competencies.

Benefits of Multiple Assessments :

Multiple assessments offer several advantages —

Holistic Evaluation across cognitive, psychomotor, and affective domains (Black & Wiliam, 1998)[14].

Enhanced Learning through ongoing feedback and adaptive teaching (Hattie & Timperley, 2007)[8].

Adaptability and Personalization in instructional methods (Tomlinson, 2001)

Increased Engagement from varied and interactive assessments (Fredricks, *et al* 2004)[15].

Challenges in Implementing Multiple Assessments :

Despite their benefits, multiple assessments pose several challenges —

Resource Intensiveness in terms of time, faculty, and infrastructure (Brookhart, 2010)[17].

Consistency and Standardization difficulties in subjective assessments (Sadler, 2005).

Student Anxiety due to frequent evaluations (Cassady & Johnson, 2002)[20].

Technical and Logistical Issues in scheduling, assessment execution, and result tracking (McMillan, 2013).

Best Practices for Implementation :

To overcome these challenges, several best practices are recommended —

Clear Objectives and Criteria : Marzano (2006) emphasized defining clear learning targets and assessment criteria.

Balanced Assessment Plans : Guskey (2003)[21] recommended integrating formative and summative assessments to support both learning and accountability.

Continuous Feedback : Shute (2008) stressed the value of timely, specific feedback in enhancing student outcomes.

Training and Support for Instructors : Darling-Hammond & Richardson (2009)[22] highlighted the need for faculty development to ensure quality assessment.

Student Involvement : Boud & Falchikov (2007) advocated involving students in their assessment process to enhance autonomy and engagement.

Conclusion

The use of multiple assessments in skill labs provides a robust framework for evaluating and enhancing student learning. Despite implementation challenges, their benefits – holistic evaluation, improved engagement, adaptability, and deeper learning – are substantial. By following best practices such as setting clear objectives, using balanced assessment plans, providing continuous feedback, training instructors, and involving students, educators can optimize learning outcomes. This comprehensive approach better prepares students for real-world clinical practice while fostering meaningful, engaged learning. Skill labs that adopt these strategies can significantly enhance the effectiveness and impact of skill training modules.

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Original Article

Prevalence and Determinants of Non-communicable Disease Risk Factors using WHO STEPS Approach among Adult Population in Rural and Urban Area of Salem — A Comparative Study

S Sangeetha[1], M Vijayakarthikeyan[2], P Swarna Latha[3], R Shankar[4]

Abstract

Background : Non-communicable Diseases (NCDs) pose a significant and growing challenge to public health worldwide, given their substantial contribution to morbidity and mortality rates. This trend is particularly pronounced in India, where NCD prevalence is escalating at an alarming rate across both urban and rural regions. Comprehensive findings of the prevalence and determinants of NCD risk factors is imperative to devise and implement effective prevention and control strategies.

Aims and Objectives : (1) To Compare the Prevalence of Non Communicable Disease risk factors among the adult population residing in Rural and Urban field practice area. (2) To determine the factors associated with Non-communicable Disease risk factors among the adult population residing in Rural and Urban field practice area.

Materials and Methods : A cross sectional study was carried out among 400 adults (≥18 years). Semi structured questionnaire was used to collect data and the World Health Organization-STEPS methodology was used to document behavioural risk factors, biochemical risk factors and physical measurements. Continuous and categorical data were represented as mean and proportion respectively. Strength of Association was determined using Odds Ratio and Adjusted Odds Ratio.

Results : Mean age of the participants was 43.8±14.9, about 58.3% of them were females. In our study males exhibit higher rates of tobacco (71.8%) and alcohol (74.4%) use whereas females are more prone to physical inactivity (56.1%), Unhealthy diet (55.7%) and overweight or obesity (61.3%). Binary Logistic Regression analysis reveals that individuals aged over 40 years emerge as a significant predictor of hypertension. Additionally, being male and holding skilled occupations are significantly associated with diabetes.

Conclusions : Identifying risk factors early through screening and embracing healthy lifestyle choices can help alleviate the burden.

Key words : Unhealthy Diet, Dyslipidemia, Hypertension, Diabetes Mellitus.

Non-communicable Diseases (NCDs) claim 41 million lives annually, accounting for 74% of global deaths. Alarmingly, 17 million people die from NCDs before age 70 each year, with 86% of these premature deaths occurring in low- and middle-income countries. Furthermore, an overwhelming 77% of all NCD-related fatalities occur within these same regions[1]. Non-Communicable Diseases (NCDs) are the leading cause of mortality in the South-East Asia Region, resulting in approximately 8.5 million deaths annually. Alarmingly, one-third of these deaths are premature, significantly impacting labor supply and economic productivity in the region[2]. In India, NCDs are estimated to account for 66% of all deaths[2].

Editor's Comment :

- Adults over 40 years are disproportionately affected by NCD risk factors.
- Modifiable risks like tobacco use and unhealthy lifestyles drive obesity, hypertension, diabetes and dyslipidemia.
- Targeted interventions in both urban and rural areas are essential to mitigate the growing NCD burden.

The WHO highlights four key Non-communicable Diseases (NCDs) : diabetes, cardiovascular disease, chronic respiratory disease, and cancer, largely driven by modifiable behavioural and metabolic risk factors. These factors include tobacco use, excessive alcohol consumption, poor diet, physical inactivity, high blood

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pressure, obesity, elevated blood sugar, and abnormal lipid levels. Addressing these risks is critical to curbing the rising prevalence of NCDs globally[3]. When an individual experiences the simultaneous presence of two or more of these factors, it's termed as the clustering of risk factors. This clustering substantially heightens the likelihood of developing Non-communicable Diseases (NCDs)[4].

Currently, a larger proportion of the global population resides in urban areas compared to rural ones, with 55% of the world's population living in urban settings as of 2018. This marks a substantial increase from 1950 when only 30% of the population was urban. Projections indicate that by 2050, urban dwellers will make up 68% of the global population. However, it's important to note that urbanization rates vary significantly across different geographic regions, reflecting diverse levels of urban development worldwide[5]. In the context of Non-communicable Diseases (NCDs), there's a growing concern regarding the impact of urbanization and rural-to-urban migration on population exposure to risk factors. This heightened exposure can be attributed to various factors, including variations in access to motorized transportation and pollution, disparities in occupational physical activity levels, differences in marketing strategies and varying accessibility to tobacco, alcohol and processed food products[6]. Enhancing our comprehension of the determinants of Non-communicable Diseases (NCDs), including disparities between urban and rural areas, is crucial for effective NCD prevention efforts. This understanding enables prioritization of actions and facilitates the customization of strategies based on the resources available[7]. With this background the study was carried out —

- To Compare the Prevalence of Non Communicable Disease risk factors among the adult population residing in Rural and Urban field practice area.
- To determine the factors associated with Non Communicable Disease risk factors among the adult population residing in Rural and Urban field practice area.

Materials and Methods

Study Design : Community based analytical cross sectional study

Study Setting : This study was conducted in the field practice area affiliated with the Rural and Urban Health and Training Centre of VMKV Medical College & Hospital, Salem.

Study Duration : The study was conducted over a period of 6 month period from July, 2023 – December, 2023 following Institutional Ethical Committee approval.

Study Participants : The research focused on adults ≥18 years residing in the field practice areas of the Rural and Urban Health Training Centre of Medical College & Hospital.

Inclusion criteria : Adults aged over 18 years who provided written informed consent were included in the study.

Exclusion criteria : The study did not include adults with intellectual disabilities, cognitive impairments or serious illnesses, as well as pregnant or lactating women.

Sample size calculation : The sample size was calculated using the formula Z^2PQ / L^2, based on a prevalence of 36% from a study by Rawal, *et al*. With Z = 1.96, P = 36, Q = 64, and L = 5% (absolute precision), the calculation yielded a sample size that was further adjusted for a 10% non-response rate. The final sample size was determined to be 400, with an equal distribution of 200 participants from rural and urban areas.

Sampling technique : Adults were listed from family folders at our health centers and serially numbered. Simple random sampling was used to select study participants.

Informed Consent : Informed consent was prepared in the local language and written consent was obtained from each participant before data collection, ensuring their voluntary participation in the study.

Ethical clearance : Ethical clearance was obtained from the institution and proceeded with the data collection.

Data Collection : Face-to-Face interviews were conducted to gather information on socio-demographic characteristics and behavioral risk factors including tobacco and alcohol use, physical activity, diet and family history. Standardized instruments like portable stadiometer, electronic weighing scale and non stretchable measuring tape were used to measure Height, Weight, Waist and hip

circumference. Participants were instructed to remove footwear and bulky items to ensure accuracy. Blood pressure was measured using an automated monitor. Following an overnight fasting period, a 5-mL venous blood sample was drawn by a skilled phlebotomist from the anterior cubital vein for the assessment of lipid profile and blood sugar levels, including fasting plasma glucose, triglycerides, total cholesterol and high-density lipoprotein, using a chemical autoanalyzer. All instruments were regularly calibrated for accuracy during the data collection period.

Statistical Analysis : Data collected was entered into Microsoft Excel and analyzed using SPSS software. Descriptive statistics included frequencies and percentages for categorical data, and mean with standard deviation for numerical data. Chi-square test was used to determine the significance of findings ($p<0.05$ considered significant). Binary logistic regression assessed the strength of association, with adjusted prevalence ratios and corresponding 95% confidence intervals computed after adjusting for confounding variables, identifying independent associations with risk factors.

Operational Definitions :

Tobacco Usage : Current tobacco smokers are those who have smoked tobacco products at least once in the last 30 days[9].

Alcohol consumption : Current episodic heavy drinking defined as consuming six or more drinks on any day in the past 30 days[9].

Insufficient Fruit and Vegetable Intake : Participants consuming less than 5 servings of fruits and vegetables per day will be considered to have insufficient fruit and vegetable intake[9].

Physical activity : World Health Organization recommends a minimum of 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity for adults.[10]

Obesity : Participants were classified based on BMI[10] as: Obese : ≥30.0 kg/m²
Overweight : 25.0-29.9 kg/m²

Raised blood pressure - Blood pressure is considered raised if Systolic BP≥140 mmHg and or Diastolic BP≥90 mmHg or being previously treated for hypertension[10].

Hyperglycemia will be defined as a plasma glucose level ≥7.0 mmol/L (> 126 mg/dL), and also recorded if the participant is currently on medication for DM. The prediabetes stage will be defined as a plasma glucose level between 5.5 and 7.0 mmol/L (100-125 mg/dL)[11].

Dyslipidemia will be defined as any of the followings: elevated TC (≥200 mg/dL), high LDL (≥160 mg/dL), low HDL (<40 mg/dL in men and <50 mg/dL in women), or elevated TG (≥150 mg/dL)[11].

Results

Table 1 shows the distribution of socio-demographic variables among individuals residing in rural and urban areas. The mean age of the study participants was 43.8 years and standard deviation of 14.9.

The analysis reveals notable gender differences in health behaviours and risk factors. Males have higher tobacco and alcohol use, hypertension and triglyceride levels, while females are more prone to inactivity and obesity. Hypertension is linked to age >40, higher socio-economic status, unhealthy diets and tobacco use. Diabetes, obesity and dyslipidemia are more common among males, skilled/unskilled workers and tobacco users.

Table 2 Binary Logistic Regression analysis reveals significant associations between factors and health conditions. Age over 40 predicts hypertension, while male gender and skilled occupations associate with

Table 1 — *Socio-demographic Characteristics*

Variable	Rural (n=200)		Urban (n=200)	
	Male	Female	Male	Female
Age :				
>40 years	52(44.8)	64(55.2)	51(48.6)	54(51.4)
≤40 years	31(36.9)	53(63.1)	46(48.4)	49(51.6)
Religion :				
Hindu	78(43.3)	102(56.7)	91(50.3)	90(49.7)
Christian / Muslim	5(25)	15(75)	6(31.6)	13(68.4)
Education :				
≥Higher Secondary	25(58.1)	18(41.9)	20(55.6)	16(44.4)
<Higher Secondary	58(36.9)	99(63.1)	77(47)	87(53)
Occupation :				
Skilled worker & above	46(64.8)	25(35.2)	46(64.8)	25(35.2)
Below skilled worker	37(28.7)	92(71.3)	51(39.5)	78(60.5)
Marital Status :				
Married	63(46.3)	73(53.7)	71(51.1)	68(48.9)
Others[#]	20(31.3)	44(68.8)	26(42.6)	35(57.4)
Type of Family :				
Nuclear	53(38.1)	86(61.9)	69(45.7)	82(54.3)
Joint	30(49.2)	31(50.8)	28(57.1)	21(42.9)
SES :				
Upper / Middle	43(43.4)	43(56.6)	37(51.4)	35(48.6)
Lower	50(40.7)	73(59.3)	60(46.9)	68(53.1)

#Others – Single, Widow, Divorced

Table 2 — *Binary Logistic Regression findings*

Variable	HTN	
	P value	APR (CI)
Age	<0.001**	1.227(1.014 - 3.836)
	DM	
Sex	0.014*	1.634(1.411-1.993)
Occupation	0.011*	1.551(1.348-1.871)
	Overweight	
Tobacco	0.034*	1.641(1.039-2.592)
	Dyslipidemia -High Cholesterol	
Age	0.002*	1.984(1.293-3.044)
Occupation	<0.001**	2.654(1.576-4.467)
SES	<0.001**	3.092(1.238-3.647)
	Dyslipidemia – Low HDL	
SES	0.012*	1.561(1.357-3.883)
Tobacco usage	0.015*	1.568(1.361-2.895)

Only the significant association has been presented in the Table
**p value < 0.05, **p value <0.01*

diabetes. Tobacco use is linked to overweight, and dyslipidemia predictors include age over 40, male gender, higher socio-economic status, and tobacco consumption.

Discussion

A cross-sectional survey conducted in South India, using the WHO-STEPS methodology, has provided insights into the risk factors associated with Non-communicable Diseases (NCDs) in the region. One significant finding of the survey is the notable differences in tobacco use prevalence between urban and rural areas. In our study, the prevalence is higher in urban areas at 34.5% compared to rural areas at 22%. This contrasts with findings from other regions such as Kerala[12], where tobacco use prevalence is higher in rural areas (45%) compared to urban areas (43%) and Chennai,[13] where rural areas (23.7%) exhibit higher prevalence than urban areas (19.4%).

Moreover, the survey shows that alcohol consumption in rural areas is 17.5% and 22% in urban areas, contrasting with the Tamil Nadu IDSP survey[14], where the rates were higher - 39.7% in rural areas and 31.7% in urban areas. These variations highlight the complex interplay of different factors influencing alcohol and tobacco use.

In both rural and urban areas of our study the prevalence of overweight and obesity stands significantly high at 62% and 60%, respectively. These rates markedly exceed those reported by Oomen, *et al*[15]. Furthermore, consistent with findings from Venkatrao, *et al*[16] our research demonstrates a higher prevalence of overweight and obesity among females compared to males. Specifically, in rural areas, the prevalence is higher in females at 69.3% compared to males at 30.7%, while in urban areas, the prevalence is 53.3% in females versus 46.7% in males. These results highlight the critical need for targeted interventions to address the burgeoning issue of overweight and obesity, particularly among females, in Tamil Nadu.

This study confirms that people in Tamil Nadu don't eat enough fruits and vegetables like in other states[17]. Particularly rural women seem to eat the least amount of fruits and vegetables in line with findings from Geetha, *et al*[18]. This demonstrates a significant difference from urban settings and emphasizes the need to inform and inspire rural women about the advantages of eating a balanced diet[19]. Moreover, the prevalence of diabetes (51% rural, 39% urban) exceeds the figures reported for Tamil Nadu in the multi-centric ICMRINDIAB study[20]. (7.8% rural, 13.7% urban). The increase in unhealthy habits among Indians, coupled with the higher chance of pre-diabetes turning into diabetes, could be the reason for the significant rise in high fasting blood sugar levels[17].

The prevalence of hypertension among adults is high among urban when compared to that of rural areas, with rates standing at 49% in urban areas and 41.5% in rural areas which is similar to that of Bhagyalaxmi, *et al*[19].The high number of tobacco users in urban areas may be the cause of the high risk of hypertension[21]. These figures complement the estimates for India (33% urban, 25% rural) and South India (32% urban, 21% rural)[22] among adults aged 18 years and above.

Conclusion

The study uncovered a significant prevalence of behavioural and metabolic risk factors, showcasing variations among adults in both rural and urban areas. These findings underscore the necessity for robust public health strategies aimed at fostering healthier lifestyles and preventing the emergence of NCDs in the community. Future research endeavours and longitudinal studies are imperative to track trends over time and evaluate the efficacy of intervention initiatives in addressing NCD risk factors in Salem and comparable locales.

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Original Article

Prevalence of Candiduria in Patients Admitted in Tertiary Care Hospital in Western Maharashtra

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Abstract

Background : Viral pneumonia frequently results in bacterial and fungal infections, particularly in individuals who are critically ill. Prolonged ICU stay is a risk factor for the development of nosocomial candidemia. Candida spp. account for almost 10-15% of nosocomial Urinary Tract Infections (UTIs). The most frequent illness linked to healthcare is nosocomial UTI. Candida species are becoming a more significant cause of nosocomial urinary tract infections.

Aims and Objectives : (1) The prevalence of Candiduria in COVID-19 and non-COVID-19 patients. (2) Age wise and gender wise distribution and antifungal susceptibility pattern of yeast isolates and (3) To compare the prevalence of Candiduria between COVID-19 positive and negative patients.

Materials and Methods: The sampling frame consisted of all isolates in COVID-19 positive and negative patients admitted in ICU with signs of UTIs. After getting Ethics committee approval, patients were screened for presence of COVID-19 using RT-PCR and candiduria by performing urine culture.

Results/Observations : In a total of 100 COVID-19 positive ICU patients, 58% and 42% patients were tested COVID positive and negative respectively, 68% were men. Average age was 49±17.8 years. Gender, age and isolate wise no significant difference was found between COVID positive and negative patients. Study reported, each ICU admitted patient had one of the eleven isolates. The common Isolates present in the study population and in COVID population were Tropicalis (37 /23), Albicans (34 /17), Parasitosis (16/12). The pandemic has highlighted the possible variability of prevalence of Candiduria fungal infection.

Conclusion : Hospital acquired infections are of great concern in hospital infection prevention and control. The presence of bacterial and or fungal secondary infection or coinfection is likely an important factor affecting mortality. Screening the ICU admitted COVID patients for UTI will help in early diagnosis of isolates and are valuable in guiding treatment of COVID-19 to control co-infection/superinfection. It would serve in controlling Catheter Associated Urinary Tract Infection (CAUTI) which is more common in COVID patients because of long ICU stay, indiscriminate use of antibiotics, overuse of steroids and the disease itself.

Key words : Nosocomial Infections, Candida albicans, Candiduria.

Maharashtra state in India had maximum number of COVID-19 cases (8142059) and maximum number of deaths (148435) compared to all other states in India[1]. The most frequent source of secondary infections in COVID-19 is bacterial infections; however, new reports from India have raised concerns about an increase in systemic fungal infections, especially invasive mold[2]. Up to 8% of COVID-19 patients have bacterial and fungal co-infections[3]. Candiduria or presence of Candida spp. in the urine is very uncommon in healthy individuals. Because hospitalized patients have a number of predisposing conditions, the prevalence of true infection has dramatically grown in recent years. Urinary tract instrumentation, previous antibiotic usage, extended hospitalization, extremes of age, diabetes mellitus, female sex and immuno-suppressive medication use

Editor's Comment :

- Hospital acquired infections are of great concern in hospital infection prevention and control. In this era of emerging non albicans candida group, screening the ICU admitted patients for UTI will help in early diagnosis of isolates and are valuable in guiding treatment to control co-infection/superinfection.

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are predisposing variables commonly linked to candiduria. Many experts have noted that a more aggressive therapy is necessary because candiduria in the presence of risk factors predisposes the patient to widespread candidiasis.

Candida spp. account for almost 10-15% of nosocomial Urinary Tract Infections (UTIs)[4]. Explicit research has not been done on the prevalence of urinary tract co-infections in COVID-19 patients. Pneumological co-infections were the subject of most of the reviewed publications. Nonetheless, several of the evaluated studies allow for the extrapolation of the prevalence of UTI co-infections in COVID-19 patients. According to a recent study, UTIs were likely overdiagnosed in over 60% of patients hospitalized with COVID-19 and urinary tract co-infections. Therefore, it appears that the actual prevalence of UTI linked to COVID-19 is quite modest.

Researchers have looked at the risk factors for candiduria. According to Carol Kauffman, Increased age, female sex, use of antibiotics, urinary drainage devices, previous surgical procedures, and diabetes mellitus are risk factors for candiduria. Further it is observed that Candiduria due to either species (Candida glabrata or Candida albicans) was associated with female gender, Intensive Care Unit (ICU) prolonged stay and antibiotic use[6]. Microbiologist Rasmi Chaudhari says, caution has to be maintained in reporting candida from urine and advices not to ignore Candiduria, since it may even be a marker of disseminated candidiasis[7]. Further she stated, isolation of C albicans in urine represents contamination. Candiduria can also be a sign of invasive renal candidiasis or candidemia. Renu Yadav's, "Study of candiduria in neonates" is one of the few studies to report incidence of candiduria. The study was conducted with neonates in ICU. After collecting and analyzing urine samples, 3.25 percent of people had candiduria. The most commonly isolated species from the newborn samples in the wards was Candida albicans, while Candida tropicallis was from the infants in ICU (43%)[8]. Many studies have looked at candidemia in non-COVID-19 and some in COVID-19 positive patients. However, only a few studies have been done on candiduria in COVID -19 patients. Some studies have reported Candida can be one of the causes of fungal UTI infection. Hence, it is very important to know the candida species as a fungal pathogen in UTI. In view of this, a study was planned at Department of microbiology, DY Patil Medical College, Hospital and Research Centre at Pune to determine, (1) The prevalence of Candiduria in COVID-19 and non-COVID-19 patients. (2) Age wise and gender wise distribution and antifungal susceptibility pattern of yeast isolates and (3) To compare the prevalence of Candiduria between COVID-19 positive and negative patients.

Materials and Methods

This was a cross-sectional observational study performed during a period of June, 2021 to June, 2022. Ethical committee clearance for th study was taken by the Institutional Ethics Committee (IEC/204/150). A total of 100 participants were enrolled. The sampling frame consisted of all isolates in COVID-19 positive and COVID-19 negative patients admitted in critical care unit with signs of UTI collected at Tertiary care centre based in Pune. All participants undergoing this study signed written informed consent. The asymptomatic patients and bacterial isolates were excluded from the study.

Inclusion Criteria : All patients admitted in ICU with symptoms of UTI

Exclusion Criteria : All asymptomatic patients of UTI and bacterial isolates around 10ml of urine was collected as per standard guidelines for collection of urine in catheterized patients. Utmost care was taken in collection of the samples. Samples once collected were sent to the laboratory immediately. The staffs collecting the specimens were also trained for the same. Routine microscopy of wet mounts wase done on the sample to see the presence of pus cells etc. The specimens were inoculated immediately on a Cysteine Lactose Electrolyte Deficient (CLED) agar with the help of a calibrated double loop inoculator. Plates further incubated for 18-24 hours in an incubator at 37ºC. Gram stain was done and then if budding yeast cells were seen, inoculated on Sabouraud's dextrose agar, Hichrom agar and Corn meal agar was done to identify the isolates. All study isolates were tested for Germ tube tests and speciation was done. Relevant patient related demographic information was collected and used for further demographic co-relation and covid and non-covid status of the patients. Data was entered on the Microsoft Excel sheet. Appropriate statistical tests such as t test or analysis of variance was used for testing the difference in mean values across *Candida* species for continuous variables and

Fisher's exact test or χ^2 test, as appropriate, was used for testing associations between categorical patient characteristics and *Candida* species.

Results

68% were men and 32% were women. The mean age was little less than 50 years (49±2)40% patients were in 40 to 60 years of age group. More male than female patients were COVID +ve. Age wise one-third patients in each age category (1 to 40, 40 to 60 and above 60 years) were COVID positive. Age and gender wise there no significant difference was observed between COVID positive and negative groups.

Common Isolates present in the study population were *C tropicalis* (37), *C albicans* (34), and *C parasilosis* (16). More Covid positive patients were observed with the infection of these isolates compared to covid negative patients except for C albicans. But the difference was not significant (Table 1).

Gender, age and isolate wise no significant difference was found between COVID positive and COVID negative patients.

We combined the isolates those were small in number and created "Others" category. Table 3 is derived from Table 2.

Table 1 — *Sex and Age by COVID Status (Sex : P = 0.135, Age : P =0.335)*

		Status		Total
		COVID Positive	COVID negative	
Sex	F	22 (37.9)	10 (23.8)	32 (32.0)
	M	36 (62.1)	32 (78.2)	68 (68.0)
P = 0.135 ns				
Age	1 to 40	19 (32.8)	13 (31.0)	32 (32.0)
	40 to 60	20 (34.5)	20 (47.6)	40 (40.0)
	Above 60	19 (32.8)	9 (21.4)	28 (28.0)
P = 0.334 ns				
	Mean ± std	49.62 ±18.92	48.38 ±16.30	49 ± 17.79

Table 2 — *Isolate by COVID Status P = 0.239*

	COVID Status		Total
	COVID Positive N (%)	COVID negative N (%)	N (%)
Isolate :			
C Tropicalis	23 (39.7)	14(33.3)	37(37.0)
C Albicans	17 (29.5)	17 (40.5)	34 (34)
C Parapsilosis	12 (20.7)	4 (9.5)	16 (16.0)
C Glabrata	2 (3.4)	3 (7.1)	5 (5)
Candida Rugosa	1 (1.7)	1 (2.4)	2 (2.0)
C Kefyr	1 (1.7)	0 (0)	1 (1.0)
C Auris	1 (1.7)	0 (0)	1 (1.0)
Candida Guilliermondii	0 (0)	1 (2.4)	1 (1)
Candida Lusitaniae	0 (0)	1 (2.4)	1 (1.0)
Cryptococcus Laurentii	1 (1.7)	0 (0)	1 (1.0)
Trichosporon Asahii	0 (0)	1 (2.4)	1 (0)
Total	58 (100)	42 (100)	100 (100)

Table 3 — *Isolate by COVID-19 Status P = 0.166*

	COVID Status		Total
	COVID Positive N (%)	COVID negative N (%)	N (%)
Isolate :			
C tropicalis	23 (39.7)	14(33.3)	37(37.0)
C albicans	17 (29.5)	17 (40.5)	34 (34)
C parasilosis	12 (20.7)	4 (9.5)	16 (16.0)
Others	6 (10.3)	7 (16.7)	13 (13)
Total	58 (100)	42 (100)	100(100)

Discussion

Although, the incidence of UTI is very common in females, but in contrast, in this study, 68% were men and 32% were women, which is consistent with the sudy of[7] (56.8%in males, 43.2% females) it may be because the men were moving more out of the home for work and in lockdown period it was more expected. Common Isolates present in the study population were *C tropicalis* (37), *C albicans* (34), and *C parasilosis* which was consistent with the study of Shah Dharati, *et al*[9] & Santana, *et al*[10,7]. Although Candida albicans is the most commonly reported species in cases of candidal UTI, numerous research have shown that non-albicans Candida species are also becoming more common as UTI causative agents. Non-albicans species that cause candiduria include Candida tropicalis, Candida glabrata, Candida parapsilosis, Candida lusitaniae, Candida guilliermondii, and Candida krusei[5].

Future Prospects

It is evident from various previous research studies and newer studies that pathogenesis of hematogenous seeding of Candida species to the kidney was well established[4-7]. In the largest series, only 11% of 861 patients with candiduria were without any predisposing factors but Eighty-three percent of patients had long-term indwelling urethral catheters or other urinary drainage devices[1]. It was also observed from various studies that most patients were converted from asymptomatic to symptomatic candiduria; In one major multicenter trial, just 4% of patients showed symptoms that suggested a UTI, but in another smaller series, 14% did. This observation

emphasis on that the clinician to make a early diagnosis of asymptomatic candiduria, comparable to asymptomatic bacteriuria, so no additional testing or care should be necessary. In neonatesUrine containing candida species is typically indicative of hematogenous spread to the kidneys and is mostly linked to the formation of many blocking fungal balls in the collecting system. For most people, candiduria does not indicate candidemia. Just 7 (1.3%) of 530 patients with candiduria who were monitored for 12 weeks in a major prospective research went on to develop candidemia; in a smaller retrospective analysis, 11 (10.5%) of 105 patients with candiduria did the same[6].

Conclusion

The current study highlights the importance of taking candiduria into account as a new and significant element in the current environment. A second clean catch urine culture should be performed to confirm the existence of candiduria, which poses a therapeutic challenge for the doctor. It is crucial to identify candida species and perform an antifungal profile since our research suggests that some species may become resistant to the antifungal drugs currently in use[7]. Since many non-albicans Candida species are resistant to fluconazole treatment, understanding Candida species is crucial for the appropriate management of UTIs[6]. Hospital acquired infections are of great concern in hospital infection prevention and control. One significant factor influencing mortality is probably the existence of a secondary infection or coinfection caused by bacteria and/or fungi.In this era of emerging non albicans candida group, screening the ICU admitted patients for UTI will help in early diagnosis of isolates and are valuable in guiding treatment to control co-infection/superinfection.

Limitations : Small sample size, single hospital, no follow-up, patient were not asked about their comorbidities, antifungal susceptibility test was not carried out.

The pre-eminent issue with regard to candiduria is to develop methods to distinguish infection from colonization and to differentiate upper from lower urinary tract involvement.

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Ethical Statement : Ethical approval was obtained from the Institutional Sub-ethical Committee, Dr D Y Patil Medical College, Hospital and Research Center, Dr D Y Patil Vidyapeeth Pimpri, Pune.

Conflict of Interest : The authors do not report any financial or personal connections with other persons or organizations.

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Review Article

Sphingomonas paucimobilis — Related Central Nervous Infection : A Systematic Review

Darshan Rajatadri Rangaswamy[1], Niranjan Kamble[2], Kiran Kavatagi[3]

Abstract

Background : Sphingomonas paucimobilis is a gram-negative bacterium that is an emerging human pathogen that causes both community-acquired and nosocomial infections. It can affect various sites, including the central nervous system. The prognosis is typically favourable, although it has been linked to a few severe events, including death.

Aims and Objectives : The discuss about all the cases of Sphingomonas paucimobilis infections of the Central Nervous System (CNS) in the general population that have been established by bacteriology.

Materials and Methods : *Data sources* - Pubmed, Cochrane library and Directory of Open Access Journals.

Eligibility Criteria - Studies mentioning CNS infections due to S paucimobilis in humans.

Synthesis methods - PRISMA

Results : There were 9 papers covering 12 patients enrolled, 4 patients of which were part of a study for which individual information were not available. Meningitis, which was largely community acquired and seen among immunocompetent adults, was the most prevalent diagnosis among the remaining 8 cases. All patients were treated with antibiotics with an average duration of 21 days. 3 developed complications out of which two expired, the remaining had good outcome.

Limitations : Small sample size and incomplete clinical details from one study.

Conclusion : Sphingomonas paucimobilis is an occasional human pathogen causing infection including CNS. Though most of the cases have favourable outcome but complications and death have been noted. The infection responds effectively to antibiotics, hence early identification would be lifesaving.

Key words : Sphingomonas paucimobilis, Meningitis, Cns Infection, Ventriculitis.

Sphingomonas paucimobilis is a gram-negative, non-fermentative, low motility bacillus that is an emerging human pathogen[1]. Though most infections caused by it have favourable prognosis few instances of fatal outcomes have been reported[2-4]. Despite causing mortality on a few occasions, little is known about its effect on the central nervous system.

The purpose of this study was to conduct a systematic review of Sphingomonas paucimobilis infections of the Central Nervous System (CNS) in the general population that have been established by bacteriology. A secondary goal was to characterise the clinical traits, diagnostic, treatment approaches, and outcomes of individuals with S Paucimobilis-related CNS infections.

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Editor's Comment :
- Sphingomonas paucimobilis is a rare but can potentially be a serious human pathogen.
- Early recognition and prompt antibiotic therapy are crucial, as timely treatment can lead to favorable outcomes and prevent complications or death.

Materials and Methods

Pubmed (https://www.ncbi.nlm.nih.gov/pubmed/), Cochrane Library (http://www.cochranelibrary.com/) databases and Directory of Open Access Journals (till October 10, 2023) were systematically searched for studies reporting Central Nervous System infection caused by Sphingomonas paucimobilis. We used the search phrases [(pseudomonas paucimobilis) or (Sphingomonas paucimobilis)] and [(meningitis) or (cns infection) or (central nervous system infection) or (ventriculitis) or (encephalitis)] to find clinical studies to review. The titles and abstracts of the retrieved publications were reviewed for eligibility. The following inclusion criteria were used to select studies for further analysis: (1) full-text publication/abstract reporting at

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least one Sphingomonas paucimobilis-related CNS disease, (2) enrolling human subjects and (3) In English language. Conference reports, remarks, and findings from studies using animals or cell lines were removed. Citations selected were included in the final analysis if these following data were available: documentation of CNS infection and confirmation of S paucimobilis detection by cultures.

All data were independently abstracted in triplicate by three investigators (DRR, NK, KK) according to the inclusion criteria. The first author's last name, the publication year, the age of the reported patients, their diagnosis, mode of acquiring the infection, their immune status, the complications encountered, the method of bacterial isolation, the bacterial antimicrobial susceptibility and resistance profiles, the initiated treatment, as well as the outcomes were all information that was retrieved from each publication. SPSS1 version 24 was used to do descriptive analysis on the extracted data (IBM, Armonk, NY, USA).

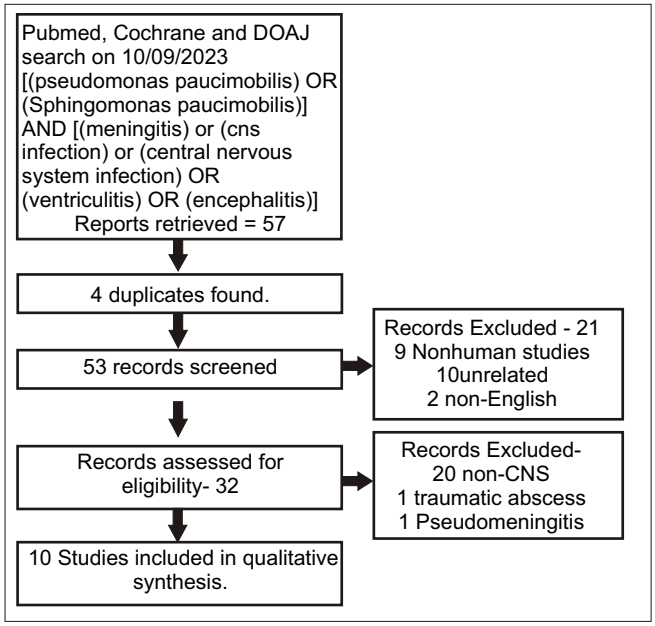

Fig 1 — PRISMA flow diagram of describing inclusion and exclusion criteria for experimental studies
DOAJ - Directory Of Open Access Journal,
CNS - Central Nervous System

Results

Our literature review yielded 17 publications from Pubmed, none from Cochrane library and 40 from DOAJ, of which 4 were duplicates hence removed. Out of these we excluded 21, as 9 were non-human studies, 10 were unrelated and 2 were in English language. Out of the remaining studies after eligibility checkup, 20 of them were found to be non-CNS infections, 1 case was a post traumatic abscess and 1 case was having pseudomeningitis hence were not included. The remaining 10 publications were further evaluated. A flow-diagram summarizing the literature research approach is shown in Fig 1. A triplicate screening was done and all the 9 were found to be meeting our inclusion criteria and hence were analysed for our systematic review.

We were able to find out a total of 13 cases of S paucimobilis infection of central nervous system. Bayram N, et al in his study form 2013, analysed the S paucimobilis infections among 24 children, out of which there was one case with CNS infection [5]. Complete details of this patient were not available. Similarly, Rohilla, et al in their study done in 2021 from a teaching hospital in India reported 4 cases of S paucimobilis isolated from CSF among a total of 49 isolates[6]. The details of each patient however were not available for this review. Of the other 8 cases the most frequent diagnosis was meningitis (7 patients, 88%, diagnosis was not specified for 1 case[3]) and only one case had associated ventriculitis.

All patients were adults with a mean age of 46 years (median age 45 years, range 30-66 years) and 4 of 8 were females. Majority of the patients were immuno-competent (6 patients, 75%), one article by Marincu N, et al did not mention about the immune status[7]. In 5 patients were noted to have underlying illness. The median duration of symptoms was 7 days (range of 1-21 days), Bolen, et al and Marincu, et al did not mention the duration of illness. In 7 cases were community acquired (88%), however Bolen, et al dint mention about the same[7,8].

The common method used to isolate the bacteria was conventional with Vitek 2 (50%) however one study each used MALDITOF[8] and BacT Alert[6] methods. One case had a simultaneous CNS infection with Mycobacterium tuberculosis, 7 rest all grew single organism from CSF.

Two patients had concomitant blood culture growths, one yielded S paucimobilis[9] and the other was listeria monocytogenes[10]. All the patients were treated with antibiotics and 2 of them received steroids. The average duration of antibiotics noted among those who survived was 21 days. The commonest complication noted was hydrocephalus (3) followed by ventriculitis and IVH (1 each). 4 patients underwent

surgical intervention, of which 3 were External Ventricular Drain (EVD)[3,4,10] and 2 Ventriculo-Peritoneal (VP) shunt[10,11]. Out of 9 patients, 6 had recovery among which one was recovering and was bedridden without neurological deficits10 however 2 patients did not survive[3,4].

Discussion

The genus Sphingomonas was described by Yabuchi, *et al* in 1900 and emended by Takeuchi et al in 1993, comprises of 12 species among which Sphingomonas paucimobilis is an occasional human pathogen, formerly known as CDC group IIk, biotype 1 then later on it was named as Pseudomonas paucimobilis in 1977[1,12,13]. In 1990, this organism received its own genus Sphingomonas based on the type of strain of the genus. It shares similar biochemical properties, fatty acid content with flavobacterium.

The first case of P paucimobilis was reported in 1979 in a sailor with leg ulcer and was isolated in pure culture. Subsequently many more infections with Sphingomonas have been reported[6,14,15].

Sphingomonas can be divided into four phylogenetic groups each representing separate genus these are, Sphingobium, Novosphingobium, Sphingophyxis along with Sphingomonas[1].

There are three species of Sphingomonas - Sphingomonas parapaucimobilis[1], Sphingomonas mucosisimma[16] and Sphingomonas adhesive[17] which have been reported to cause infections in humans.

Sphingomonas paucimobilis is a straight gram negative, non-sporing rods with single polar flagellum. (Fig 2)[1,13,18]. However when incubated at 18 to 22°C, it is motile on wet mount and motility medium, and is non-motile in 37°C hence the name paucimobilis due to difficulty in demonstrated motility in laboratory[1,18]. It lacks lipopolysaccharide in its outer capsule[12]. Instead it possesses two different kinds of Sphingolipids (hence the name Sphingomonas). Sphingolipids are unique sphingoglycolipid with long chain base di-hydrosphingosin, ubiqioune 10 Q-10 and hydromyristic acid 2-OH C 14:0 and absence of 3- hydroxy fatty acids (Fig 3)[19].

These are oxidase and catalase positive. On Sheep blood agar it grows as deep yellow colony with optimum growth seen at 30°C in 5 % CO_2 or ambient air, also grows in 37°C but do not grow at 42°C. It

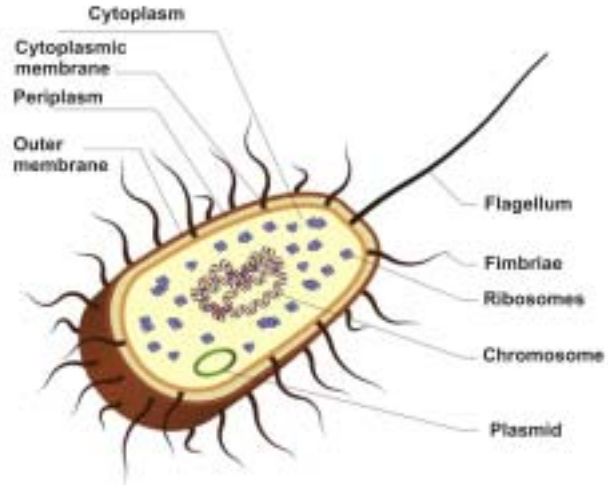

Fig 2 — Microscopic representative image of Sphingomonas paucimobilis

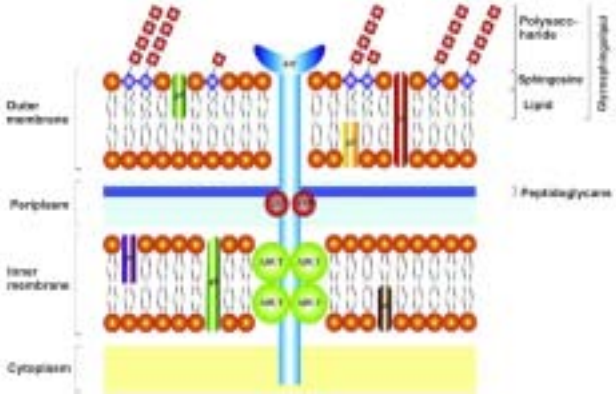

Fig 3 — Bacterial cell wall

does not grow on MacConkey agar (90% does not grow, 10% grow as non-Lactose Fermenters). It utilizes glucose, xylose and sucrose oxidatively, strongly esculin hydrolysis positive, urease negative and indole negative, produces a zone a inhibition around vancomycin disk places in BAP. It is susceptible to polymyxin B, which differentiates it from Sphingobacterium. Sphingomonas paucimobilis have been isolated from blood, CSF, urine, wounds, vagina, cervix and hospital environment. Most strains are susceptible to tetracycline, chloramphenicol, trimethoprim-sulfamethoxazole and amino-glycosides[1,13,18].

The organism is mostly acquired from the community[2], but it has also been linked to nosocomial infections and has been isolated from hospital equipment, water source and devices[6,15].

Only a few case reports and short case series have

described S paucimobilis's pathogenicity in humans, and one systematic review linked it to infections of the bones and soft tissues[15]. The organism is associated with infections of various sites[6] with a predilection to bone and soft tissue and only 12 cases noted to infect CNS[15]. Most of the cases of CNS infections were noted to be community acquired. The organism has been reported to cause infections in all age groups including children and neonates[5,20] however we noticed that all our patients reported with CNS infections were adults. It was intriguing to notice that most patients with CNS infections were immunocompetent, even though it was previously known to infect immunocompromised patients because of its poor virulence. In majority of S paucimobilis infections the prognosis is favourable however it has caused morbidity as well as mortality[2] in a limited number of instances. Most of the cases noted in our review had acute history and predominantly were adults with a few cases being senior citizens. The organism is easily identifiable using conventional and Vitek 2 method of isolation. There were few occurrences of coinfections, one patient had Listeria monocytogenes bacteraemia[10] and one had mycobacterium tuberculosis meningitis[7]. All the patients were treated mainly with antibiotics with an average duration of 21 days, ceftriaxone and meropenem were among the ones commonly administered, only two cases received additional steroids. Ventriculitis, hydrocephalus and IVH were the noted complications needing surgical interventions for EVD placement and VP shunting. Although they were immunocompetent and had no concomitant conditions, two individuals with hydrocephalus who had undergone EVD placement had a catastrophic outcome.

The antibiotic susceptibility pattern differed greatly throughout the case reports, indicating the importance of personalised decision making when treating CNS infections. Most of the isolates were sensitive to aminoglycosides, cephalosporins (3rd and 4th generation) and meropenem. Colistin was frequently encountered to be resistant.

The study undertaken by Bayram N, *et al* included a total of 24 children, one of which had CNS infection but lacked comprehensive clinical information. Similarly, another research with four instances of CNS infection lacked a clear description of the patient features, limiting the ability to analyse those cases[5,6].

Our review had few limitations, we attempted to include all literature relating to CNS infection caused by S paucimobilis, although several studies did not offer a full description of the patients. Our extremely small sample size made it difficult to generalise our results, which was another downside. The strength of this study is that we attempted to analyse the limited literature extensively to help disseminate the information to help aid in the treatment of subsequent cases. Our review would signify the importance of early recognition and treatment of a condition which can at times be fatal. Further prospective studies are needed to better understand the clinical implications of this organism.

Conclusion

Sphingomonas paucimobilis is an occasional human pathogen. The bacteria can cause both nosocomial and community-acquired infections. It has been implicated to affect humans irrespective of their immune status. S Paucimobilis can cause infections of various organs however there are only 13 cases of infections of CNS in the searched literature. Though most of the cases have favourable outcome but the organism can cause complications like hydrocephalus and intraventricular haemorrhage and can be fatal leading to death. The infection responds well to antibiotics thus emphasising on the need for early identification and initiation of appropriate antibiotics in suspected cases.

Conflict of interest : None of the authors have any conflicts of interest associated with the work presented in this manuscript.

Ethics approval and informed consent According to regional regulations, there was no need for ethical approval for this evaluation.

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Data availability All data generated or analyzed during this study are included in this article.

Further enquiries can be directed to the corresponding author.

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Review Article

Proposed Algorithm for the Diagnosis and Management of Functional Dyspepsia-Gastroesophageal Reflux Disease Overlap in the Indian Clinical Setting

V G Mohan Prasad[1], B Ravi Shankar[2], Showkat Ali Zargar[3], Nitesh Pratap[4], Chetan Bhatt[5], Rajesh Puri[6], Jejoe Karankumar[7]

Abstract

Background : Functional Dyspepsia (FD) and Gastro-esophageal Reflux Disease (GERD) are common gastrointestinal disorders worldwide, impacting Quality of Life and healthcare costs. FD is characterized by epigastric pain and discomfort without organic causes, while GERD is marked by heartburn and acid reflux. In India, there is a high prevalence of FD-GERD overlap, often influenced by *Helicobacter pylori* infections and unique cultural factors. To address these challenges, an algorithm for managing FD-GERD overlap in India has been developed that will assist clinicians in accurate diagnosis and treatment, with the aim to reduce burden and improve patient outcomes. After several national and regional discussions amongst groups of Gastroenterologists across India, an algorithm was finalized for careful and thorough clinical evaluation of patients presenting with chronic dyspepsia and reflux symptoms. The algorithm highlights the role of endoscopic evaluation, *H. pylori* infection, and gastric pH monitoring in the diagnosis of FD-GERD overlap, along with the role of Proton Pump Inhibitors (PPIs) and prokinetics in its treatment. Among the various prokinetics, the experts agreed that itopride improves gastrointestinal motility in FD and is reported to be efficacious and well tolerated.

Key words : Functional Dyspepsia, Gastroesophageal Reflux Disease, Gastrointestinal Disorders, Algorithm, Prokinetics.

Functional Dyspepsia (FD) and Gastro-esophageal Reflux Disease (GERD) are common gastrointestinal disorders that significantly affect Quality of Life and increase healthcare costs[1]. According to Rome IV criteria, FD is defined by chronic or recurrent epigastric pain or discomfort without identifiable organic cause, often with early satiety, postprandial nausea, and bloating[1]. FD, a diverse condition is classified into Postprandial Distress Syndrome (PDS) and Epigastric Pain Syndrome (EPS), with or without overlapping features[2]. On the other hand, GERD is characterized by heartburn and regurgitation due to acid reflux, often accompanied by a bitter taste, chest pain and substernal burning and pain[1]. GERD includes Erosive Reflux Disease (ERD) and Non-erosive Reflux Disease (NERD) with nearly 70% of cases being NERD, where typical symptoms occur without visible mucosal damage on endoscopy[3].

Editor's Comment :

- FD-GERD overlap is common and challenging to manage. Accurate diagnosis is essential and prokinetics play a key role in treatment by addressing motility-related symptoms. Prokinetics like itopride can effectively relieve overlapping dyspeptic and reflux symptoms, improving patient outcomes in this complex condition.

Although FD and GERD are distinct gastrointestinal disorders, considerable symptom overlap is common, leading to diagnostic and therapeutic challenges[3-5]. Most existing data are based on studies from Western populations, with limited research from India. The prevalence of FD-GERD overlap in Indian studies is reported at 59%. In a study by Shankar, *et al* around 60% of Physicians observed 20-40% of their patients exhibiting overlapping symptoms, with 5-20% newly diagnosed[6]. In India, Helicobacter pylori (*H pylori*) is a key contributor to dyspeptic symptoms in FD but it may reduce severity of GERD disease[7,8]. Hence,

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testing for *H. pylori* is important in FD-GERD overlap for optimal management. The clinical presentation in India is shaped by a complex interplay of *H. pylori* infection, cultural and physiological factors, dietary patterns, genetic and environmental influences.[5-8]

Effective management of FD-GERD overlap necessitates a comprehensive approach involving accurate diagnosis, evidence-based treatment, and individualized care[1,4]. However, guidelines and recommendations specifically tailored for the Indian set-up are currently missing. Thus, there is a need for algorithm development that can aid healthcare professionals in accurately identifying and managing FD-GERD overlap cases in India.

Hence, to develop a structured algorithm for the diagnosis and management of FD-GERD overlap, focus-group discussions were conducted with 50 Gastroenterologists from across India. Consensus was achieved on all key components, including patient history, physical examination, identification of alarm symptoms, relevant laboratory investigations, endoscopy, *H. pylori* testing, and the overall management strategy.

This review presents the resulting expert consensus algorithm tailored to the Indian context. It aims to facilitate timely and accurate diagnosis, reduce the Socio-economic burden, and improve patient outcomes by integrating clinical evidence, expert opinion, and population-specific considerations.

Diagnosis of FD-GERD Overlap :

The experts recommended looking for overlapping symptoms of GERD and Functional Dyspepsia (FD), such as epigastric pain, early satiety, bloating, nausea, and vomiting (FD), and heartburn, regurgitation, acidic or bitter taste, chest pain, and substernal burning (GERD)[1,3]. They also emphasized identifying atypical or extra-esophageal manifestations including non-cardiac chest pain, otitis media, asthma, chronic sinusitis, dental erosions, aphthous ulcers, halitosis, pharyngitis, laryngitis, laryngospasm, globus, postnasal drip, frequent throat clearing, tracheobronchitis, chronic cough, aspiration pneumonia, pulmonary fibrosis, chronic bronchitis, bronchiectasis and sleep apnea[9].

History-taking and clinical examination :

Evaluation of patients should begin with detailed history taking, clinical examination and initial investigations, including an Ultrasound Examination (USG) for ruling out potential causes other than FD and GERD. This should also help identify the presence of any alarm symptoms (Table 1), related to malignancies that help in further investigations and treatment.

Investigations :

The initial investigations include a Complete Blood Count, Serum Electrolytes, Fasting Blood Glucose, Renal Function Tests, Thyroid Function Tests, Liver Function Tests and USG to determine patient's overall health, with additional investigations like celiac serology in high prevalence areas[5]. Endoscopy remains essential to confirm FD by excluding organic disease[4].

For some patients with reflux esophagitis, a meal can produce gastric distension contributing to postprandial fullness. Duodenal eosinophilia, increasingly reported in FD, may explain the overlap, with research indicating that FD, especially PDS, is linked to increased GERD risk when duodenal eosinophilia is present, which can be identified via duodenal biopsy[4,10]. Additionally, duodenal hypersensitivity, plays a role in FD symptoms. This complex interplay between impaired gastric function, duodenal eosinophilia, and hypersensitivity contributes to the shared clinical manifestations in FD and GERD patients.[10] The assessment of gastrointestinal motility encompasses techniques like manometry of the esophagus and/or antro duodenum, Electrogastrography (EGG), radioisotopic assessment of gastric emptying, expiration testing for gastric emptying capacity, and Ultrasonography to observe gastric emptying and duodeno-gastric reflux. Computed Tomography (CT) scan and EGG may help rule out other causes of dyspeptic and reflux symptoms; experts also recommend duodenal biopsy, fundic accommodation tests, and evaluation of duodenal hypersensitivity to identify specific pathologies in rare situations.

Table 1 — *Alarm symptoms to investigate in patients with dyspepsia*[7,13]

■ Age >45 years (in areas with a high prevalence of gastric cancer: >37 years)*
■ Recurrent vomiting
■ Weight loss
■ Dysphagia
■ Evidence of GI bleeding
■ Family history of cancer
■ Hematemesis, Melena*
■ New onset dyspepsia in the subjects • >40 years of age in a population with a high prevalence of upper gastrointestinal malignancy and • >45 and >50 years in populations with intermediate and low prevalence, respectively.

**Opinion of the experts*

Prasad VGM, *et al.* Proposed Algorithm for the Diagnosis and Management of Functional Dyspepsia-Gastroesophageal Reflux Disease.

In Asia, where gastric cancer is more common and occurs at a younger age, relying solely on *H. pylori* eradication without endoscopy may risk missing malignancies. Early upper GI endoscopy is recommended for dyspeptic patients over 40 to exclude organic causes, including gastric cancer[2].

Experts noted that *H. pylori* can be assessed via Rapid Urease Tests (RUT) or gastric/duodenal biopsies, though RUT has limited validation. The C^{13} breath test is costly and scarce in India, while the C^{14} test is banned due to radiation risks. Experts recommend endoscopy and *H. pylori* testing if alarm symptoms are present or initial therapy fails, to identify and treat any underlying organic cause.

Management of FD-GERD

The comprehensive management of GERD and FD overlap requires both pharmacological therapy and lifestyle modifications to address risk factors[1,3].

Acid-suppressing and neutralizing agents :

Acid-suppressing agents such as PPIs, are very commonly given empirically in patients with GERD, on account of their very low toxicity profile and good efficacy for suppressing gastric acid secretion and symptom relief. However, the coexistence of FD or IBS and the absence of esophagitis or the presence of FGIDs is linked with diminished response or PPI failure in patients with GERD. The effectiveness of H2RAs in treating FD is debatable and are not the preferred initial choice for FD treatment, still commonly used in case of PPI failure[11]. There is also empirical evidence supporting the potential amelioration of GERD-related symptoms with alginate-based treatments[3].

Prokinetics :

Prokinetic agents comprise a diverse group of compounds that target various receptors, such as 5-hydroxytryptamine 4 (5-HT4) receptor agonists, Dopamine2 (D2) receptor antagonists, and motilin and ghrelin receptor agonists. They are suggested to alleviate symptoms of GERD by boosting esophageal motility and facilitating gastric emptying[12]. Prokinetics, when used alongside PPIs, contribute to a decrease in reflux episodes, resulting in a more significant improvement in symptom scores and a potential enhancement in patients' Quality of Life[13]. Itopride, a D2 antagonist possessing anticholinesterase properties, expedites gastric emptying by its dual mechanisms of action, targeting both dopaminergic and acetylcholinesterase pathways. Typically used in patients with FD, it has demonstrated notable effectiveness in addressing sensations of postprandial fullness and early satiety. The therapeutic benefits of itopride may stem from its effects on brain-gut communication, visceral hypersensitivity, gastric accommodation, distension-induced adaptation, and TLESRs[12] Shankar, *et al* in their survey found that approximately 80% of participating Indian Physicians reported highly favorable effectiveness of itopride, and 81.5% expressed similar sentiments regarding its safety. Furthermore, a notable 88.4% of Physicians utilize a once-daily sustained-release formulation of itopride[6]. Itopride was found comparable in efficacy to domperidone in relieving symptoms and was devoid of cardiac side effects[14]. For patients with non-ulcer dyspepsia, a study reported higher complete symptomatic relief rates with itopride (81%) compared to domperidone (70%). In another study, itopride demonstrated significantly greater moderate to complete symptomatic relief (90%) in comparison to levosulpiride (83.3%) in patients with non-ulcer dyspepsia (p=0.0146). Among the array of prokinetics utilized for FD, itopride emerges as a preferable choice, particularly for vulnerable populations like the elderly and individuals with diabetes[13]. It produces no undesirable cardiac effects due to its lack of affinity for the 5-HT4 receptors in the heart and no hyperprolactinemia[15]. The pronounced polarity of itopride hinders its ability to penetrate the blood-brain barrier, rendering it free from Central Nervous System (CNS) side effects. This characteristic establishes itopride as a safer choice compared to alternative prokinetics. Furthermore, the pharmacokinetic profile of itopride is such that it does not have any drug-drug interactions with CYP450 enzyme inhibitors, such as macrolides and azole antifungals, enabling concurrent administration with these medications[16]. As per the consensus guidelines from the Association of Physicians of India-Indian Society of Gastroenterology (API-ISG), individuals dealing with both GERD and overlapping symptoms of FD, including volume reflux and signs of delayed gastric emptying, could potentially find value in incorporating prokinetic medications into their treatment. In a recent meta-analysis of nine placebo-controlled trials involving 2,620 individuals with FD, itopride (1,372 subjects) was compared to domperidone, mosapride, or placebo (1,248 subjects). The itopride group reported significant improvements in PDS Relative Ratio (RR): 1.21; 95% Confidence Interval (CI): 1.03-1.44; p=0.02), early satiation (RR: 1.24; 95% CI: 1.01-1.53; p=0.04), and Global patient assessment scores (RR: 1.11; 95% CI: 1.03-1.19;

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p=0.006) compared to the Control group[6].

The experts agreed that itopride improves gastrointestinal motility in FD and that it is efficacious and well tolerated[17]. Among other prokinetics, the experts advised caution with the use of levosulpiride and suggested counselling of patients and follow-up to check for extrapyramidal side effects, especially in older populations and those with a positive family history of Parkinsonism.

In patients without alarm symptoms, experts suggest initiating PPI and prokinetic therapy for 4 weeks to manage suspected FD-GERD overlap[1]. If symptoms persist, further evaluation is needed[3]. With normal endoscopy, empirical PPI therapy and lifestyle changes are recommended. Persistent symptoms despite high-dose PPI may indicate refractory GERD, requiring manometry, pH monitoring, and possibly EGG or gastric scintigraphy[18-20] (Fig 1).

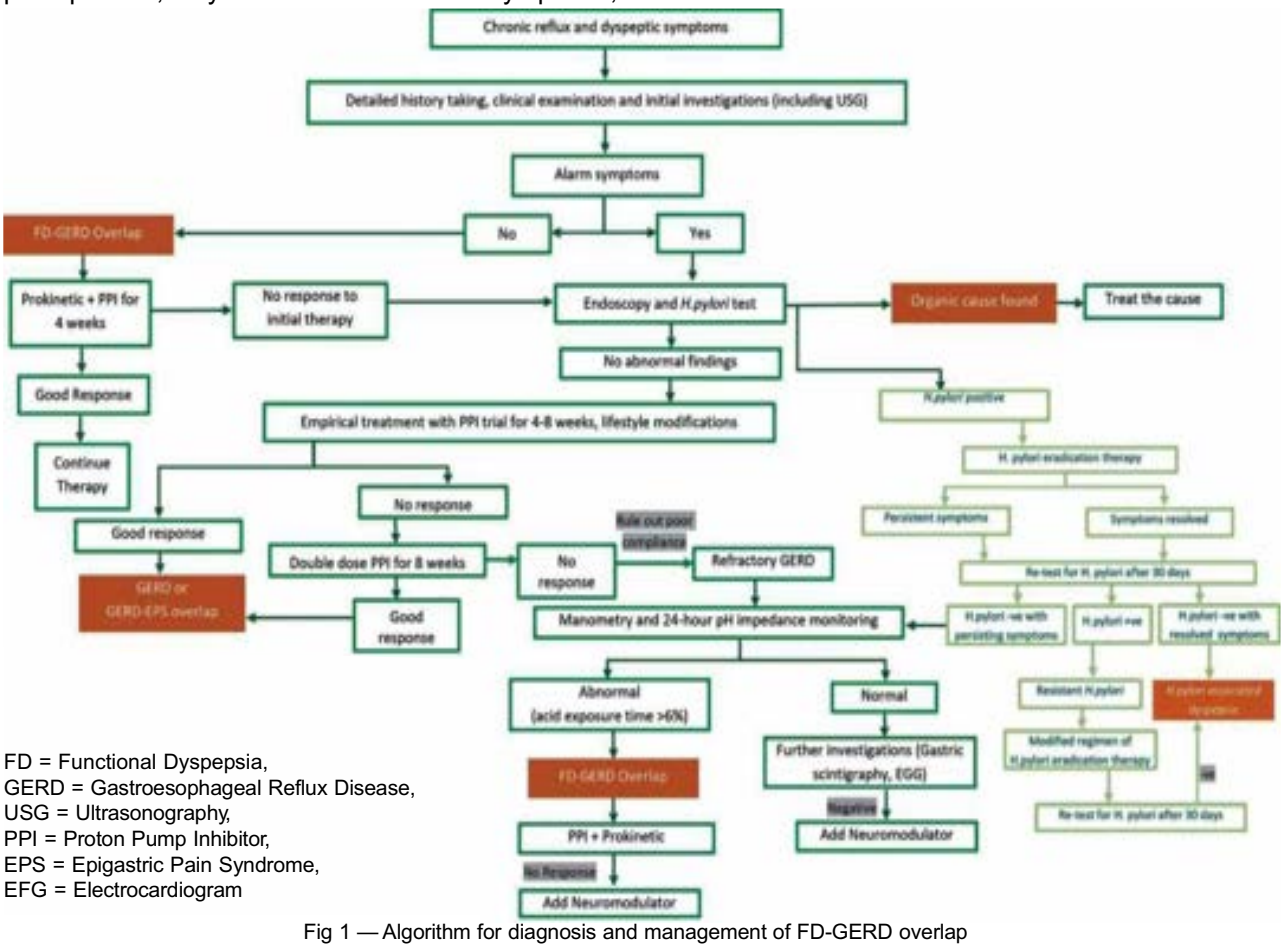
Neuromodulators :

Amitriptyline, especially when combined with pantoprazole, may relieve FD and GERD symptoms, including ulcer-like pain, bloating, and impaired gastric accommodation[10]. Experts suggested adding neuromodulators such as amitriptyline, mirtazapine, SSRIs, or SNRIs, if there is no response to PPIs and prokinetics or if EGG and scintigraphy are negative.The various treatment options are listed in Table 2.

Table 2 — Treatment options for patients with FD-GERD overlap

Acid suppressing and neutralizing therapies	Proton pump inhibitors and PCABs H2 receptor antagonist (H2RAs) Alginates, antacids and sucralfate	
Prokinetics	Idopride Cinitapride Acotiamide^ Baclofen^	Domperidone Levosulpirid* Prucalopride Metoclopramide
Neuromodulators	Amitriptyline Mirtazapine Selective Serotonin Reupake Inhibitors (SSRIs) Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)	

^Useful for fundus relaxation/PDS type of FD only.
*Caution is advised with the use of levosulpiride. Counsel patient and follow-up to check for extrapyramidal side effects, especially in older population.



FD = Functional Dyspepsia,
GERD = Gastroesophageal Reflux Disease,
USG = Ultrasonography,
PPI = Proton Pump Inhibitor,
EPS = Epigastric Pain Syndrome,
EFG = Electrocardiogram

Fig 1 — Algorithm for diagnosis and management of FD-GERD overlap

Prasad VGM, et al. Proposed Algorithm for the Diagnosis and Management of Functional Dyspepsia-Gastroesophageal Reflux Disease.

Proposed Algorithm for the Diagnosis and Management of FD-GERD Overlap :

The expert consensus algorithm for diagnosing and managing FD-GERD overlap, shown in Fig 1, outlines a systematic approach for patients with chronic reflux and dyspeptic symptoms. It emphasizes thorough initial evaluation, identification of alarm symptoms, and key investigations such as upper GI endoscopy, *H. pylori* testing, esophageal manometry, and 24-hour pH impedance monitoring, to help in the diagnosis of FD-GERD overlap. Given the high prevalence of *H. pylori* in India, eradication therapy is included for *H. pylori*-positive patients. In the absence of endoscopic abnormalities, empirical treatment with PPIs, prokinetics, and neuromodulators is recommended based on symptom profile.

Conclusion :

The significant convergence between two distinct conditions, FD and GERD, poses several challenges in terms of diagnosis and treatment. Indian research focusing on FD, GERD and conditions that exhibit overlapping symptoms is scarce, leading to reliance on data from clinical studies with Western populations. In the Indian population, the complex interplay of cultural, physiological, infectious, dietary, genetic and environmental factors presents unique challenges in managing the overlap between FD and GERD. The experts aimed to bring out a comprehensive approach for accurate diagnosis and specific interventions involved in the management of FD-GERD overlap. The consolidated views and recommendations from these Indian experts are expected to guide Clinicians in reducing the socioeconomic impact of FD-GERD overlap in India.

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Case Series

Varied Presentation of Guillain-barre Syndrome : Case Series and Review of Literature

Sumanyu Saxena[1], Prakhar Kumar[2]

Abstract

Background : We encountered a few cases with varied clinical presentation of Guillain-Barre Syndrome (GBS) in a Tertiary Care Centre and they were analysed to correlate certain clinical features with outcome at discharge.

Materials and Methods : Out of all the GBS patients admitted in the medical wards, 5 patients with varied presentation were analysed. Detailed history and physical examination was taken and necessary lab investigations were done including CSF study and Nerve conduction study.

Results : All the patients included in the study, irrespective of the clinical presentation and varied symptoms were diagnosed early with prompt initiation of treatment, were discharged with no or minimal residual symptoms.

Conclusion : There is a high percentage of Motor axonal variant of GBS in this study. There is predominance of Male patients and that too in a young adult age group.

Key words : Guillain-Barre Syndrome, Albumino-Cytologic Dissociation, Polyradiculopathy.

Guillain-Barré Syndrome (GBS) is an eponym, which contains multiple acute immune mediated poly neuropathies, although rare but serious post-infectious neuropathies. Resulting from autoimmune nerve destruction in the peripheral nervous system, it causes symptoms such as tingling, numbness, weakness and can even progress to quadriparesis[1]. GBS is one of the causes of acute, acquired flaccid, neuromuscular paralysis. Considered to be immune-mediated neuropathies, GBS and its variants are theorized to be post-infectious. Molecular mimicry is believed to play a key role in pathogenesis, as evidenced from animal models, where epitopes on peripheral nerve are targeted by and cross react with an immune response to an antecedent infection or other event[2]. For example, the lipo-oligosaccharide present in the outer membrane of Campylobacter jejuni is similar to gangliosides, which are components of peripheral nerves. Therefore, an immune response to C jejuni gastrointestinal infection can lead to a cross-reaction on host nerves[3]. GBS has been linked to numerous infections, most common being gastrointestinal or pulmonary illnesses. C jejuni can generate antibodies to specific gangliosides, including GM1, GD1a, GalNac-GD1a, and GD1b, which are strongly associated with AMAN and AMSAN. A large proportion of patients, up to 70% report an antecedent illness in the 1-6 weeks prior to presentation of GBS[4].

Editor's Comment :

- Although GBS and its variants may present with numerous presenting complaints, a strong suspicion based on detailed history and examination along with support from Electrodiagnostic studies and Lab evaluation, the precise diagnosis can be made out in time before it becomes life-threatening and hinders day to day life.

Other common infections like Influenza A & B, Cytomegalovirus, HIV, COVID-19 and Zikavirus have also been associated with GBS. Patients with the common Acute Inflammatory Demyelinating Polyneuropathy (AIDP) form have prominent demyelination on electro diagnostic studies and lymphocytic infiltration on sural nerve biopsies, while those with other forms such as Acute Motor Axonal Neuropathy (AMAN) form have prominent axonal loss without lymphocytic infiltration or complement activation and few degenerating nerve fibres. Demyelination is thought to start at the level of the nerve roots where the blood-nerve barrier is deficient. The breakdown of the blood-nerve barrier at the dural attachment allows transudation of plasma proteins into the cerebrospinal fluid. Demyelination blocks electrical saltatory conduction along the nerve. This causes conduction slowing and leads to muscle weakness. Distribution of GBS is worldwide with

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overall incidence ranging from 1 to 2 cases per 1,00,000 per year, incidence being slightly higher in males than in females[5].

Case Series

Case 1 :

A 24-year-old male presented with complaints of 1 episode of fever (unrecorded, low grade not a/w chills or rigor) around 10 days back, then he developed insidious onset weakness in Right upper limb. Two days later he developed weakness in Left upper limb and then 4 days later he developed weakness in bilateral lower limbs. This weakness was progressive in nature such that initially he could perform all the activities but within 2 days of onset of weakness he was even unable to hold food items in both his hand, comb his hair or wear his clothes. He was also unable to walk without support or get up from squatting position. Along with the weakness patient also developed pinching type of pain in his upper back area which was non-radiating and not associated with any hand or shoulder movement. There was no history of any sensory deficit, bladder or bowel incontinence. There was no history of any trauma or antecedent diarrhoea.

Examinations — On examination, patient was conscious and all higher functions and cranial nerves were intact. Single Breath Count (SBC) test was 16. On inspection, spine was normal and no deformity was apparent. On motor system examination, bulk, tone and nutrition was normal in both upper limbs. Power was 3/5 in both UL at shoulder, elbow and wrist in all range of motion. Hand grip was significantly reduced. In both lower limbs also, bulk, tone and nutrition was normal whereas power was 4/5 in both LL at hip, knee and ankle in all range of motion. All the deep tendon reflexes (biceps, triceps, supinator, knee and ankle) were mute bilaterally and plantar reflex was bilaterally flexor. Sensory examination including cerebellar signs was unremarkable.

Patient was investigated thoroughly including routine investigations which were normal. Radiographs of D/L and L/S spine were normal. Serum vitamin B12 levels were normal. CSF examination showed a total cell count of 02 cells and a protein level of 50mg/dl. Patient underwent Nerve Conduction Study(NCS) of all 4 limbs was done which showed CMAP amplitude was depressed in B/L median, ulnar, peroneal and tibial nerves, prolonged distal motor latency. F-wave and H-reflex was absent in all tested nerves. These findings were consistent with Acute Motor Axonal Neuropathy (AMAN) and patient was started on Intravenous Immunoglobulin (IVIG) at 2gm/Kg over 5 days. Patient showed improvement in his weakness by 4th day of treatment and backache was also improved. On 8th day of admission power in all 4 limbs had improved and he could walk without support and was able to perform personal activities. On a 2 week follow up patient was stable and had no residual weakness.

Case 2 :

A 14-year-old Male presented with the complaints of fever (unrecorded, low grade not associated with chills or rigor) around 4 days back, following which he developed insidious onset weakness in bilateral lower limbs resulting in difficulty in walking. One day later he also developed complaint of tingling sensation in both his upper limbs however there was no complaint of loss of power or restriction of any activities. He also complaint of pain abdomen and unable to micturate.There was no history of bowel incontinence or antecedent diarrhoea. There was no history of any backache or trauma.

Examinations — On examination, patient was conscious and oriented to time, place and person. All higher functions and cranial nerves were intact. Single breath count test was 22. On motor system examination, bulk, tone and nutrition was normal in both upper limbs. Power was 5/5 in both UL at shoulder, elbow and wrist in all range of motion. Hand grip was normal. In both lower limbs also, bulk, tone and nutrition was normal whereas power was 3/5 in both LL at hip, knee and ankle in all range of motion. All the deep tendon reflexes in all 4 limbs (biceps, triceps, supinator, knee and ankle) were absent. Plantar reflex was absent. Sensory examination including cerebellar signs was unremarkable.

Patient's investigations revealed normal serum B12 level, normal MRI Brain with spine screening. NCS revealed CMAP amplitude was depressed in B/L median, ulnar, peroneal and tibial nerves and prolonged distal motor latency. F-wave was inconsistent in all the tested nerves. These findings suggested a diffuse motor axonal neuropathy. CSF analysis showed total cells 10 and albumin level of 168mg/dl. Patient was started on IVIG at 2gm/Kg over 5 days. Patient showed improvement in his weakness by 6th day of treatment such that Patient could walk without support. On a 2 week follow-up patient had no residual weakness.

Case 3 :

A 33-year-old Male presented with the complaints of acute onset weakness of bilateral lower limbs for 2 days which was progressive in nature such that within a period of 2 days he was unable to walk without support and couldn't rise up from squatting position. Patient also complaint of weakness in both upper limbs for 2 days such that he could not perform his personal activities or raise his arms above his head. Patient also developed complaint of slurring of speech for 12 hours however there was no history of drooling of saliva. Patient had a history of painful lesions on his trunk 1 week back which was consistent with Herpes Zoster. There was no history of bowel or bladder involvement or any antecedent diarrhoea.

Examinations — On examination, patient was conscious and oriented to time, place and person. All higher functions were intact. There was loss of naso-labial fold prominence on the left side and slurring of speech, suggesting Facial nerve involvement. However taste sensation was intact. Single breath count test was 17. On motor system examination, bulk, tone and nutrition was normal in both upper limbs. Power was 4/5 in both UL at shoulder, elbow and wrist in all range of motion. Hand grip was normal. In both lower limbs also, bulk, tone and nutrition was normal whereas power was 4/5 in both LL at hip, knee and ankle in all range of motion. All the deep tendon reflexes in all 4 limbs (biceps, triceps, supinator, knee and ankle) were absent. Plantar reflex was flexor. Sensory examination including cerebellar signs was unremarkable.

Patient's investigations revealed normal routine investigations. B12 levels were normal. CSF analysis showed Total cells 25 with N20L80 differential and CSF albumin level was 800mg/dl. NCS of all 4 limbs showed Axonal changes in upper limb nerves involving motor and sensory fibres with prolonged distal motor latency and either absent or impersistent F-wave and H-reflex, suggesting radiculopathy. Patient was diagnosed as a case of Post Herpes Zoster Acute Inflammatory Demyelinating Polyradiculopathy with Facial nerve involvement and was started on IVIG at 2gm/Kg over 5 days. Patients weakness and speech improved after 7 days and was discharged on 9th day witch no residual paralysis or difficulty in speech.

Case 4 :

A 36-year-old Male presented with complaints of bilateral lower limb weakness for the last 5 days which was progressive in nature such that he could not walk without support within a span of 5 days. There was also difficulty in passing urine and stools for 2 days. Patient had a history of fever with chills 10 days back and was tested positive for NS1 Antigen and was conservatively managed.

Examinations — On examination, patient was conscious and oriented to time, place and person. All higher functions and cranial nerves were intact. On motor system examination, bulk, tone and nutrition was normal in both upper limbs. Power was 4/5 in both UL at shoulder and 3/5 in elbow and wrist in all range of motion. Hand grip was normal. In both the lower limbs, bulk and nutrition was normal whereas tone was decreased. Power was 2/5 in both LL at hip, knee and ankle in all range of motion. All the deep tendon reflexes in all 4 limbs (biceps, triceps, supinator, knee and ankle) were absent. Plantar reflex was flexor. Sensory examination including cerebellar signs was unremarkable.

Patient's investigations revealed normal routine investigations. MRI brain was normal. CSF analysis revealed total cell count 02 cells and protein 100mg/dl. Nerve conduction studies of bilateral ulnar, median and tibial nerve showed prolonged distal motor latency. CMAP amplitude and F-wave absent in b/l peroneal nerve and depressed in bilateral median, ulnar and tibial nerve. H-reflex bilaterly absent. Patient was diagnosed as a case of Post Dengue Fever Guillain-Barre Syndrome. Patient was started on IVIG at 2gm/Kg over 5 days. Two days after admission, patient developed weakness in bilateral upper limbs and difficulty in breathing and was placed onto Mechanical Ventilation. As the weakness persisted even after complete course of IVIG, patient was started on alternate day Plasmapheresis. Meanwhile tracheostomy was done. After 2 sessions patient showed improvement in weakness and patient was weaned off from ventilator after 4th session of plasmapheresis (15th day). Patients power improved to 4/5 in all limbs was discharged 5 days later.

Case 5 :

A 25-year-old Male presented with the complaints of acute onset weakness in all 4 limbs. Weakness was initially noticed by him in the R lower limb, which progressed to L upper limb, then the L lower limb and then to the R upper limb all within 9 days. Patient was unable to walk even without support or do any of his personal activities. There was no history of any

antecedent fever, diarrhoea or trauma of any kind. There was no history of any back pain. There was no history of bowel or bladder incontinence.

Examinations — On examination, patient was conscious and oriented to time, place and person. All higher functions and cranial nerves were intact. Single breath count test was 20. On motor system examination, bulk, tone and nutrition was normal in both upper limbs. Power was 2/5 in both UL at shoulder, elbow and wrist in all range of motion. Hand grip was weak. In both lower limbs also, bulk, tone and nutrition was normal whereas power was 2/5 in both LL at hip, knee and ankle in all range of motion. All the deep tendon reflexes in all 4 limbs (biceps, triceps, supinator, knee and ankle) were absent. Plantar reflex was flexor. Sensory examination including cerebellar signs was unremarkable.

Patient's routine investigations were normal. Serum B12 levels were normal. CSF analysis was done which showed total cell count of 5 and a protein level of 29mg/dl. NCS of all 4 limbs was done which showed prolonged distal motor latency of bilateral median, ulnar and tibial nerve. CMAP amplitude and F-wave absent in b/l peroneal nerve and depressed in bilateral median, ulnar and tibial nerve in both motor and sensory fibres. Patient was diagnosed as a case of AMSAN variant of GBS. Patient was started on IVIG at 2gm/Kg over 5 days. Patient showed improvement in his weakness by 4th day of treatment such that Patient could walk without support and was discharged on 8th day of admission with no complaints.

Age/ Sex	Antece-dent Infection	Type of Weakness	CSF (Albumin/ Cells)	NCV Findings	Treatment Given	Outcome
24/M	N/A	Descending	40/02 (WNL)	AMAN	Inj IVIG	Cured
14/M	N/A	Ascending + Urinary Retention	168/08 (Albumino-cytologic dissociation)			
33/M	Herpes Zoster	Ascending + Facial Nerve Paralysis	800/15 (Albumino-cytologic dissociation)	AMAN	Inj IVIG	Cured
36/M	Dengue Fever	Ascending +B/B Involvement+ Respiratory Paralysis	100/02 (Albumino-cytologic dissociation)	AMAN	Inj IVIG+ Plasmapheresis +Mechanical Ventilation	Cured
25/M	N/A	Ascending +Sensory Involvement	29/05 (WNL)	AMSAN	Inj IVIG	Cured

Typical features of GBS include progressive and symmetric muscle weakness and absent /depressed deep tendon reflexes, may also have sensory symptoms and dysautonomia. Present within a few days-week after onset of symptoms, progressing over a period of two weeks. By 4 weeks, more than 90% of patients have reached the nadir of the disease. Weakness may vary from mild difficulty in walking to near complete paralysis of all limb, facial, respiratory, and bulbar muscles, depending on disease severity and clinical subtype. Classically, there is flaccid proximal and distal arm and leg weakness. Weakness is usually symmetric, starting in legs, but begins in arms or facial muscles in 10% of patients. Most patients progress to weakness in both arms and legs by the nadir. Facial nerve palsies occur in more than 50% with AIDP and oropharyngeal weakness eventually occurs in 50%. Occulomotor weakness occurs in about 15% of patients. Decreased or absent deep tendon reflexes in the arms or legs are found in approximately 90% of patients at presentation[4]. Most patients will develop hyporeflexia as symptoms progress to the nadir. Autonomic dysfunction may also develop in some patients with AIDP and may be prominent features in some variant forms of GBS. Paresthesias in the hands and feet are reported by more than 80% of patients, but sensory abnormalities on examination are frequently mild. Pain due to nerve root inflammation, typically located in the back and extremities, can also be a presenting feature and is reported during the acute phase by two-thirds of patients with all forms of GBS[6]. The prevalence of autonomic dysfunction ranges from 38 to 70% of patients with GBS[7], including Ileus, Hypertension, hypotension, Fever, tachycardia or bradycardia or Urinary retention. Patients with dysautonomia tended to have more frequent cardiogenic complications, hyponatremia and a higher burden of disability. Unusual features of GBS include papilledema with severely elevated Cerebro-spinal Fluid (CSF) protein, facial myokymia, hearing loss, meningeal signs, vocal cord paralysis, and mental status changes[8].

Common variant forms include : Acute Motor Axonal Neuropathy (AMAN), Acute Motor And Sensory Axonal Neuropathy (AMSAN).

Other rarer forms are Miller Fisher syndrome (MFS) & Bickerstaff Brainstem Encephalitis (BBE), Acute pan dysautonomia, Pure sensory GBS, Facial diplegia and distal limb paresthesia and Acute bulbar palsy.

Diagnosis of GBS in suspicious cases is based on

clinical features that are consistent with the syndrome and supported by diagnostic testing such as Electrodiagnostic Studies (EDx) and Cerebrospinal Fluid (CSF) analysis. Diagnostic criteria for GBS, originally proposed for research in 1978 by the National Institute of Neurological Disorders and Stroke (NINDS) [140], are widely used in clinical practice. CSF protein elevations may vary from 45 to 200 mg/dL for most patients, but protein elevations as high as 1000 mg/dL (10 g/L) have also been described. In one-third to upto one-half of patients, if CSF analysis is done earlier than one week from symptom onset, a normal CSF protein can be seen and therefore does not exclude the diagnosis of GBS. CSF cell count in GBS is usually normal (ie, <5 cells/mm^3). The albuminocytologic dissociation varies by time since symptom onset. In the first week of illness, it may be present in 50-66% of patients and in the third week in ≥75% of patients[9]. Electrodiagnostic studies commonly suggest Prolonged or absent F waves and absent H reflexes as the earliest findings, conduction blocks and Increased distal latencies with temporal dispersion of motor responses, Significant slowing or absent response on nerve conduction velocities not seen until the third or fourth week. Needle EMG of weak muscles show reduced recruitment or denervation[10].

Diagnostic imaging is typically reserved for patients with atypical symptoms to exclude alternative causes.

All patients with GBS should be monitored for deterioration with supportive care to address symptoms or their progression. Progressive neurologic weakness may help identify patients at risk for respiratory failure. More frequent neurologic evaluations (eg, every four to eight hours) are performed for those at high risk for deterioration and for those who may be rapidly worsening. For DVT prophylaxis, we use low molecular weight heparin and intermittent pneumatic compression or compressive stockings until patients are able to walk independently, unless a contraindication exists. Pain occurs in approximately two-thirds of patients with acute GBS and those in the recovery phase. Pain in GBS may be both somatic, related to inflammation of nerves, and neuropathic, secondary to axonal degeneration and can be managed by gabapentin, NSAIDs, opiods or morphine. Disease-modifying treatment in GBS include immunotherapy with either Plasma Exchange (PLEX) or Intravenous Immune Globulin (IVIG) and both are found to be effective[11]. The time to onset of recovery may be shortened by approximately 40 to 50% by treatment with PLEX or IVIG. For non-ambulatory adult patients with GBS who are within four weeks of symptom onset, we recommend treatment with PLEX or IVIG. When both therapies are equally available and there are no contra-indications for either, we prefer treating with IVIG because it is generally better tolerated and easier to administer than PLEX[12]. The choice between PLEX and IVIG is dependent on local availability and on patient preference, risk factors, and contra-indications[13]. Usual dosing of IVIG is 0.4 g/kg per day, given for 5 days to patients within four weeks of onset of GBS. Usual protocol for PLEX is four to six sessions over 8 to 10 days to patients within four weeks of onset of GBS. There are no trials comparing IVIG with placebo for the treatment of GBS; rather, the trials have compared IVIG with PLEX; IVIG and PLEX appear to have similar efficacy[14]. Acute-phase rehabilitation should include an individualized program of gentle strengthening involving isometric, isotonic, isokinetic, and manual-resistive and progressive-resistive exercises[15]. Rehabilitation should emphasize proper limb positioning, posture, and orthotics as well as nutrition. A device to help with communication may be necessary for patients with bulbar weakness. The long-term prognosis is favourable for most patients with GBS. Approximately 80% of patients are able to walk independently and more than half recover completely by one year[16]. However, severe motor impairments persist in more than 10%. Approximately 5 to 10% of patients with GBS have a prolonged course with several months of ventilator dependency and very delayed and incomplete recovery[17]. Mortality risk appears highest during recovery. In one study of 527 patients with GBS, the median time from symptom onset to death was 76 days, most frequently from respiratory or cardiovascular complications[18]. Approximately 3 to 7% of patients with GBS die despite intensive care[19]. Among patients who become ventilator dependent, mortality is approximately 20%. Causes of death include acute respiratory distress syndrome, sepsis, pulmonary emboli, and unexplained cardiac arrest.

Conclusion

GBS despite being an acute, life-threatening condition, may be cured if diagnosed early and prompt initiation of treatment is given. Practical conditions in developing countries may hinder this and may have

an impact on favourable outcome. After giving the treatment, the residual weakness if any, must be treated by physiotherapy regimens.

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Case Report

Deliberate Self Harm due to Ingestion of Oleander Seeds Presenting as Cardiac Toxicity

Saurabh Puri[1], Ashok Kumar Grover[2], Pankaj Nand Choudhry[3], Arjun Prem Gupta[4], Praveen Sangwan[5]

Abstract

Background : Kaner, an ornamental shrub seen all over the world. All parts of the plant contain cardiac glycosides, so are toxic and present with gastrointestinal and cardiac symptoms. We present the case of a young male presented with dizziness along with nausea and vomiting after 24 hours of self ingestion of oleander seeds.

Key words : Oleander, Kaner, Poisoning, Self Harm, Atropine.

Kaner *(Cascabela thevetia)* is an ornamental small shrub commonly seen all over the world. It is one of the most common poisonous plant containing non digitalis cardiac glycosides ie, neriifolin, thevetins A and B. All parts of the plant contains these glycosides and can be isolated from it.

We report a case of a young male with deliberate ingestion of oleander seeds presenting with gastrointestinal and cardiac symptoms and was managed promptly with good outcome.

Case Report

A 34-year-old male was admitted in emergency with complaints of nausea, vomiting and dizziness 24 hours after self ingestion of 8 seeds of yellow oleander (Cascabela thevetia) commonly called kaner, after having some family dispute. Initial examination revealed vitals as followed, pulse rate 42/min which was irregular with blood pressure 100/60 mmHg. He was having vomiting which caused dehydration and he looked toxic. Rest of the general & physical examination were normal. Irregular rhythm with S1S2 were heard on cardiovascular examination. Inverted P wave was seen in inferior lead in Electrocardiograph and PR interval was prolonged (0.30s) QRS duration normal & with AV blocks (Fig 1). Complete blood count revealed Hb 13.4 gm/dl, leucocyte count 8.6 x 10^9/L, platelet count 224 x 10^9/L. Liver function test revealed mildly elevated enzymes (SGOT 67U/L, SGPT 78U/L, GGT 72U/L, ALP 66U/L). Renal function test revealed no abnormality (urea 32mg/dl, creatinine 1.0 mg/dl, Na 138 mmol/l, K 4.2 mmol/l). He was managed with supportive measures including 0.6 mg intravenous atropine twice a day along with intravenous fluids. He was discharged after 3 days of admission with sinus node dysfunction however asymptomatic (Fig 2).

Editor's Comment :

- Oleander plant is ubiquitous in the environment making it freely available.
- Physicians should be aware of its poisoning to diagnose it early.

Discussion

Cardiac glycosides containing plants include foxglove and oleander having oleandrin, oleandroside, nerioside, digitoxigenin, thevetin and thevetoxin[1]. Oleander ingestion produces more gastrointestinal effects when compared to Digoxin with symptoms including nausea, vomiting, bloody diarrhoea, mucosal irritation. Mydriasis, confusion, weakness, dizziness, drowsiness & vision disturbances are few cranial manifestations[2]. Most serious side effects are ECG abnormalities which include prolonged PR interval, decreased QRS-T interval & flattened or inverted Twave with cardiac abnormality including ventricular dysahythmias, heart block, tachyarrythmias[1,3].

Patients with Oleander poisoning are managed empirically with hemodynamic support. Supportive management includes administration of atropine for severe bradycardia, phenytoin or lidocaine for dysrhythmias or Digoxin-specific Fab antibody fragments (Digibind)[4]. Removal of toxic substance from stomach can be done by emesis however, stimulation of vagus nerve can worsen the bradycardia, so should be observed. Studies have shown that gastric lavage by activated charcoal can prevent further

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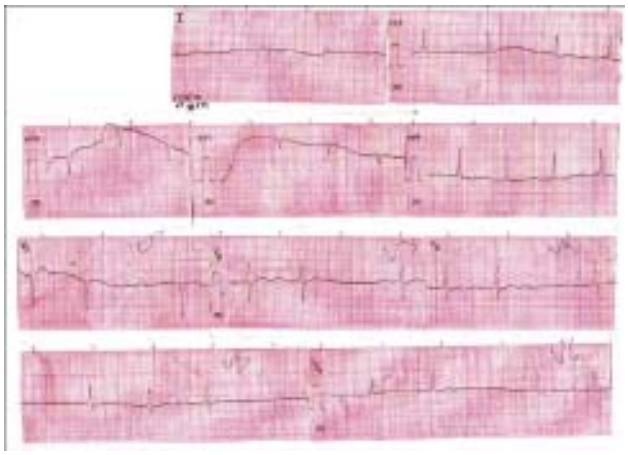

Fig 1 — Electrocardiograph revealed inverted P wave in inferior lead and prolonged PR interval (0.28 s) with

absorption of cardiac glycosides, however our patient presented after 24 hours of ingestion so it was not done.[5]

Conclusion

Ingestion of even a small amount of oleander can be fatal. Lethal dose of oleander leaf was calculated approximately 4 gm by Osterloh and associates[1]. Due to its wide availability throughout the world Physicians should be aware of lethal properties of oleander.

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Conflict of Interest : None

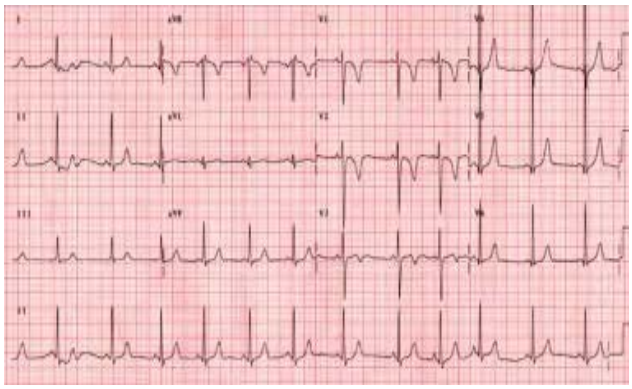

Fig 2 — Electrocardiograph revealing sinus node dysfunction

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Short Communication

Hypertension Management Beyond BP Numbers — Exploring the Novel Calcium Channel Blocker Cilnidipine

Jyotirmoy Pal[1], Nandini Chatterjee[2], Aafreen Naik[3]

Abstract

Background : Hypertension poses a significant public health challenge in India, contributing substantially to cardiovascular and renal morbidity and mortality. The coexistence of hypertension with Type 2 Diabetes Mellitus (T2DM) and Chronic Kidney Disease (CKD) exacerbates the risk of target organ damage. Cilnidipine, a fourth-generation dihydropyridine calcium channel blocker, uniquely inhibits both L-type and N-type calcium channels.

Discussion : This dual action not only facilitates effective blood pressure reduction but also attenuates sympathetic nervous system activity, offering additional cardiovascular and renal protection. Clinical studies have demonstrated cilnidipine's superiority over traditional L-type calcium channel blockers, such as amlodipine, in reducing proteinuria and mitigating sympathetic overactivity. Furthermore, cilnidipine exhibits a favorable safety profile, with a lower incidence of adverse effects like pedal edema and reflex tachycardia, enhancing patient compliance.

Conclusion : Given the high prevalence of hypertension, T2DM, and CKD in the Indian population, cilnidipine emerges as a promising antihypertensive agent that addresses both hemodynamic and neurohormonal aspects of hypertension management. Its incorporation into treatment regimens could lead to improved clinical outcomes and reduced progression of hypertension-mediated organ damage.

Key words : Hypertension, Organ Damage, Chronic Kidney Disease, Diagnosis, Cilnidipine.

High Blood Pressure (BP) is a major public health concern in South Asia, where it ranked as the third leading risk factor for disease burden in 2010. In India, Hypertension (HTN) significantly impacts cardiovascular health and places a considerable strain on the healthcare system. It is directly responsible for 57% of all stroke-related deaths and 24% of deaths due to Coronary Heart Disease (CHD) in the country. Globally, the World Health Organization (WHO) identifies hypertension as one of the most critical causes of premature mortality. According to the Global and Regional Burden of Disease and Risk Factors Study (2001), hypertension in South Asia is second only to childhood undernutrition (measured as underweight for age) in terms of its contribution to death and disease burden[1].

Editor's Comment :

- Hypertension poses a significant public health challenge in India, contributing substantially to cardiovascular and renal morbidity and mortality.
- Diabetes and obesity are the leading co-morbidities seen in Indian Hypertensive patients, which contributes to substantial target organ damage – majorly renal and cardiovascular disease.
- Early and timely evaluation of organ damage is essential for accurate cardiovascular risk stratification and the implementation of effective, targeted treatment strategies. While lifestyle modifications are key in the management of hypertension, pharmacotherapy holds its significance in improving overall hypertension control. Among the Calcium channel blockers, this article focuses on Cilnidipine, a dual L/N-type calcium channel blocker, which has emerged as an ideal antihypertensive agent for Indian patients, offering effective BP control, superior renoprotection, and reduced cardiovascular risk.

Hypertension Prevalence and Epidemiology – India:

Hypertension (HTN) is a growing epidemic in India, affecting approximately 35% of adults aged 25 years and above, with rural areas reporting a prevalence of 25% and urban areas nearing 40%. India also stands at a staggering 11% reported prevalence of Type 2 Diabetes Mellitus (T2DM), which puts the population at a high risk of organ damage mediated by these 2 lifestyle diseases. The India Microalbuminuria Study quotes a prevalence of 27% of microalbuminuria seen in Indian Hypertensive patients[1,2].

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Awareness, Treatment and Control of Hypertension in India[2] :

According to the India Hypertension Control Initiative (IHCI), only 12% of individuals with hypertension in India achieve optimal Blood Pressure (BP) control. This poor control places a significant portion of the population at increased risk for cardiovascular events, stroke, and Chronic Kidney Disease (CKD).

A recent study published in the Lancet (2022) quoted that over 75% of individuals with hypertension are uncontrolled in India. Persistent patterns of undiagnosed, untreated and uncontrolled hypertension significantly elevate the risk of Hypertension-mediated Organ Damage (HMOD).

Hypertension Mediated Organ Damage[3] :

The presence of HMOD is closely linked to increased vascular risk and higher mortality, amplifying the overall burden of hypertension. HMOD commonly affects critical organs such as the heart, kidneys, brain, and eyes. Early and timely evaluation of organ damage is essential for accurate cardiovascular risk stratification and the implementation of effective, targeted treatment strategies.

The Coronary Artery Risk Development in Young Adults (CARDIA) study revealed that individuals who developed hypertension before the age of 35 faced a significantly higher risk of target organ damage in midlife – including Left Ventricular Hypertrophy (LVH), coronary artery calcification, and left ventricular diastolic dysfunction – compared to those who developed hypertension at or after the age of 45. Notably, the study consistently identified the highest burden of organ damage across all evaluated systems in those with early-onset hypertension. The India Microalbuminuria Study also noted that >35% of young Indian hypertensive patients present with microalbuminuria to the physicians' clinic, with an overall 27% of hypertensive Indians suffering from some extent of kidney damage.

Hypertension Mediated Organ Damage in the Heart:[3]

Hypertension exerts continuous pressure on the heart, leading to both structural and functional changes that are often asymptomatic in the early stages. However, these changes substantially increase the risk of future cardiovascular events, including heart failure with preserved or reduced ejection fraction (HFpEF/HFrEF), Atrial Fibrillation (AF), Coronary Artery Disease (CAD) and Sudden Cardiac Death (SCD).

The 2023 European Society of Hypertension (ESH) Guidelines for the Management of Arterial Hypertension define cardiovascular Hypertension-mediated Organ Damage (HMOD) as the presence of increased arterial stiffness, non-hemodynamically significant atheromatous plaques detected on imaging, and Left Ventricular Hypertrophy (LVH). The guidelines further characterize preclinical or asymptomatic hypertensive heart disease by the presence of LVH, changes in left ventricular geometry, impaired diastolic and systolic function, left atrial enlargement, and a heightened risk of arrhythmias.

Hypertension Mediated Organ Damage in the Kidneys[3] :

Hypertension is recognized as the second most common cause of Chronic Kidney Disease (CKD) and can also develop because of primary renal disorders. Kidney function is primarily assessed through estimated Glomerular Filtration Rate (eGFR) and the presence of microalbuminuria – both key indicators of Hypertension-mediated Organ Damage (HMOD) in the kidneys.

Renal HMOD is diagnosed when eGFR falls below 60 mL/min (corresponding to KDIGO stages III-V) or when urinary albumin excretion exceeds 30 mg/g. According to the 2023 European Society of Hypertension (ESH) Guidelines – endorsed by the European Renal Association – renal HMOD is defined as CKD stage G3 (eGFR 30 – 59 mL/min/1.73 m^2), or stages G1–G2/A2 (eGFR $\geq$60 mL/min/1.73 m^2 with albuminuria between 30 and 300 mg/g). Additional markers of systemic organ damage include an Ankle-brachial Index (ABI) of less than 0.9 and the presence of advanced hypertensive retinopathy. Illustrated in Tab. 01 are some markers to detect early HMOD (Table 1).

A Step Forward in Hypertension Management: Cilnidipine: A Novel L and N-type Calcium Channel Blocker

Considering the high prevalence of hypertension and associated co-morbidities like diabetes, CKD in India, it is crucial to choose antihypertensive therapies that not only effectively lower BP but also provide cardiovascular and renal protection.

Amongst the multiple classes of anti-hypertensive medications available, Calcium Channel Blockers (CCBs), Renin-Angiotensin-Aldosterone System Inhibitors (RAASi) and Diuretics are recommended as first line therapy according to the recent guidelines

Table 1 — *Tools for assessment of HMOD as per the European Society of Hypertension (ESH) (Adapted from Nath, Dorairaj, Nair 2025)*

A Step Forward in Hypertension Management: Cilnidipine: A Novel L and N-type Calcium Channel Blocker

Tools for assessment of HMOD	Aim
Basic screening test recommendes for HMOD recommendated for all hypertensive patients	
12 lead ECG	Measure HR and AV conduction, detect cardiac arrhythmias, myocardial ischemia and infarction, screen for LVH
Urine albumin creatinine ratio (UACR)	Direct and classify CKD
Serum creatinine and eGFR	Detectedand classify CKD
Extended screening for HMOD	
Echocardiography	Evalute the structure and function of the ventricles and left atrium, detect vascular disease. aortic root diameter and ascending aneurysm.
cfPWV or baPWV	Evaluate aortic / large artery stiffness
Carotid artery ultrasound	Determine carotid intima-media thickness, plaque and stenosis
Coronary artery calcium scan	Determine the presence and extent of coronary calcium to predict CAD events
Abdominal aorta ultrasound	Screen for aortic aneurysm
Kidney ultrasound	Evaluation size and structure of the kidney, detect renovascular disease, determine RRI
Spectral Doppler ultrasonography	Diagnosis of renovascular disease and determination of RRI
ABI	Screen for LEAD
Retina microvasculature	Detect microvascular changes
Cognitive function testing (MMSC, MoCA)	Screen for early stages of dementia
Brain image (CT, MRI)	Direct structural brain damage

AV=Atrioventricular; CAD=Coronary Artery Disease; CKD=Chronic Kidney Disease; CT=Computed Tomography; ECG = Electrocardiogram; HMOD=Hypertension-Mediated Organ Damage; LEAD=Lower Extremity Artery Disease; LVH=Left Ventricular Hypertrophy; MMSE=Mini-Mental State Examination; MoCA=Montreal Cognitive Assessment; MRI=Magnetic Resonance Imaging; RRI=Renal Resistive Index.

for elevated BP and hypertension by the European Society of Cardiology (ESC)[4].

CCBs play a pivotal role in hypertension management especially in Indians and the South-east Asian population. Their favourable safety profile and well-understood mechanisms of action support their prominent role in hypertension management[5].

CCBs are broadly categorized into two types: dihydropyridines and non-dihydropyridines. Non-dihydropyridine CCBs primarily target voltage-dependent L-type calcium channels in cardiac and smooth muscle, leading to reduced myocardial contractility and heart rate. In contrast, dihydropyridines exert their effect mainly through vasodilation of the peripheral vasculature, helping to lower blood pressure. Calcium Channel Blockers (CCBs) are among the most extensively studied antihypertensive agents and are widely recommended as first-line therapy, either as monotherapy or in combination with other drug classes[5].

When greater blood pressure control is required, combination therapy that includes a CCB with either an Angiotensin Receptor Blocker (ARB) or an Angiotensin-converting Enzyme (ACE) inhibitor has shown superior efficacy in recent meta-analyses, making it a preferred dual-therapy option. Within CCBs, amlodipine has been a cornerstone for decades. However, the emergence of newer generation DHP-CCBs like Cilnidipine has established the molecule far and wide due to its novel and unique pharmacological properties.

Cilnidipine, a fourth-generation DHP-CCB, exerts its antihypertensive effect by blocking both L-type and N-type calcium channels. The L-type calcium channel blockade reduces peripheral vascular resistance, lowering BP effectively. Simultaneously, the N-type calcium channel blockade suppresses sympathetic nerve activity by inhibiting norepinephrine release, preventing reflex tachycardia and reducing sympathetic overdrive[6].

This dual action makes cilnidipine particularly effective in Indian hypertensive patients, who often present with high sympathetic activity, contributing to increased cardiovascular and renal risk. The major advantage of Cilnidipine over other CCBs is the significant reno-protective benefits it offers due to its N-channel blocking abilities, thereby reducing albuminuria and slowing the progression of CKD.

Cilnidipine – Evidence

BP and Proteinuria Reduction :

In multiple trials and observational studies, Cilnidipine has shown to reduce proteinuria notable of which is the CARTER Study published in 2007, which compared Cilnidipine to Amlodipine in Hypertensive-CKD patients, who were already taking ARBs. In this study, the BP reduction in both the groups was similar.

However, the Urinary Protein-to-creatinine Ratio (UPCR) decreased significantly more in the cilnidipine group compared to the amlodipine group, where an increase in the UPCR was observed. Cilnidipine demonstrated a superior antiproteinuric effect, even among patients whose blood pressure had fallen below the target level. These findings suggest that cilnidipine, when used in combination with a Renin-Angiotensin System (RAS) inhibitor, is more effective than amlodipine in preventing the progression of proteinuria in hypertensive patients. Table 2 summarises the key trials with cilnidipine in BP reduction and renoprotection.

Beneficial Effects on Reducing Sympathetic Overdrive :

Cilnidipine inhibits both L-type and N-type calcium channels. While L-type blockade leads to vasodilation, N-type inhibition suppresses the release of norepinephrine from sympathetic nerve endings, thereby reducing sympathetic nerve activity. Clinical studies have demonstrated that cilnidipine significantly lowers markers of sympathetic activity, such as plasma norepinephrine levels, especially in hypertensive patients with T2DM. Cilnidipine has shown to improve the parasympathetic nerve activity and baroreflex control in patients with hypertension.[13] The ACHIEVE-One trial demonstrated the benefits

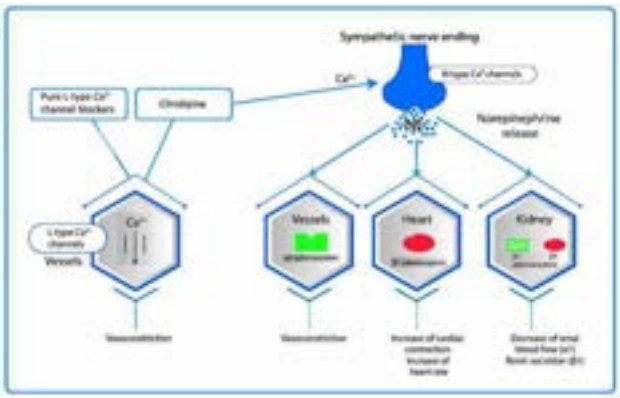

Fig 1 — Cilnidipine Mode of action
[Adapted from Chandra and Ramesh 2013]

of Cilnidipine in reducing morning BP and PR [~9.7 bpm reduction] in patients, especially in those who had higher morning SBP and PR[9] (Fig 1).

Safety and Tolerability of Cilnidipine :

L-type CCBs (eg Amlodipine) may effectively control BP but are often associated with pedal edema, reflex tachycardia, and sympathetic overactivation – side effects that are poorly tolerated by many Indian patients. Cilnidipine, due to its N-type calcium channel blockade, mitigates these side effects, leading to better compliance and improved patient outcomes. Studies conducted in hypertensive patients have shown that cilnidipine not only maintains BP control

Table 2 — Key Evidences of Cilnidipine in Reno-protection, Cardio-protection and Neuro-protection[7-12]

Trial Name / Study	Number of Patients	Key Findings	Published in
CARTER Study	339	Cilnidipine exerted a greater antiproteinuric effect than amlodipine even in the subgroup whose blood pressure fell below the target level. This study suggests that cilnidipine is superior to amlodipine in preventing the progression of proteinuria in hypertensive patients when coupled with a renin-angiotensin system inhibitor.	Kidney International
CLEARED Study	90	Cilnidipine has anti-albuminuric effects in diabetic hypertensives; switching from amlodipine to cilnidipine improved albuminuria.	Diabetes Research and Clinical Practice
J-CIRCLE Study	70	Switching from amlodipine to cilnidipine results in a significant reduction in urinary ACR as well as significant reduction in uric acid production. Thus, cilnidipine is more useful than amlodipine in improving albuminuria and uric acid metabolism in hypertensive patients with chronic kidney disease.	Journal of Clinical Hypertension
ACHIEVE-ONE Trial	2319	Cilnidipine reduced both morning SBP and PR more markedly in patients with higher baseline morning SBP , and also reduced both morning PR and SBP more markedly in patients with higher baseline morning PR (0.6 beats per minute and -15.6 mm Hg in <70 beats per minute, and -9.7 beats per minute and -20.2 mm Hg in ≥85 beats per minute). Cilnidipine significantly reduced BP and PR in hypertensive patients at the clinic and at home, especially with higher BP and PR in the morning.	Journal of Clinical Hypertension
CA-ATTEND Study	2667	Cilnidipine was effective in treating uncontrolled blood pressure and was well tolerated in Japanese post-stroke hypertensive patients, over 12 months, in a real-world clinical setting.	Clinical and Experimental Hypertension
CA-ATTEND Study [Sub-set]	603	Cilnidipine promoted the regression of common carotid IMT in post-stroke hypertensive patients, especially in the thick group. Cilnidipine also reduced the IAD in both normal and thick groups.	Journal of Atherosclerosis and Thrombosis

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comparable to amlodipine but also reduces heart rate by 5-9 bpm (as also described in the ACHIEVE-One study) and significantly lowers the incidence of pedal edema (6% with cilnidipine *versus* 63% with amlodipine)[14].

With its growing evidence base, the molecule finds recommendations through leading Indian Guidelines (RSSDI 2023 and API-ICP 2024) in the management of Hypertension in T2DM, in combination with ARBs[15,16].

Conclusion :

Cilnidipine, with its dual L/N-type calcium channel blockade, emerges as an ideal antihypertensive agent for Indian patients, offering effective BP control, superior renoprotection, and reduced cardiovascular risk. In comparison to older L-type CCBs (eg Amlodipine), cilnidipine provides better safety, fewer adverse effects, and enhanced tolerability, making it a preferred choice for Indian patients with hypertension, diabetes, and CKD. As India grapples with a rising burden of hypertension and associated organ damage, cilnidipine holds promise in achieving better patient outcomes in the long term.

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Conflict of Interest : None

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Commentary

Evaluation of "cadaveric oath ceremony" as a part of AETCOM teaching in Anatomy Teaching-Learning program for Phase 1 MBBS Students — A proposed methodology (protocol)

Hironmoy Roy[1], Shweta Parwe[2], Kuntala Ray[3]

Abstract

Background : After the implication of the AETCOM module by NMC (erstwhile MCI), the AETCOM classes are regularly arranged for the Phase 1 MBBS Anatomy students. Module no 1.5, "cadaver is the first teacher" is usually get taught by two successive sessions- lecture followed by 'cadaveric oath ceremony' where after an oath taking led by the Head of the Department, students offers floral tribute to the cadaver and promises for respectful handling in their dissection demonstration classes. In attempt to evaluate their learning, literature says that authors did upto level 2 Kirkpatrick's analysis. But their actual behavior in handling cadaver during their dissection class (work-placed based) has never been assessed. In this protocol, out of the acceptable modes of Work-placed based assessments, Direct Observation of Non-clinical Skill (DONCS) is planned to be conducted, if needed in modified versions, considering all feasibilities. So, this protocol is aimed to assess the students' behavior during their actual Anatomy classes.

Key words : cadaveric oath ceremony, AETCOM Session, Reflection Writing, DONCS.

AETCOM module was implemented since 2019 MBBS entrant batch as a part of Competency-based Medical Education (CBME). Alongwith the teaching learning methods, the assessment plans are also mentioned in each module. During the Phase 1 MBBS, when a student first time starts the dissection classes in Anatomy, a ***cadaveric oath ceremony*** is used to be hosted in all medical college of the state of West Bengal to show the tribute to the cadaver and the human remains, as a part of the training of AETCOM module "Cadaver is your first teacher". This practice is going on for the last four years. During the ceremony all the students get oriented about the importance of cadaver in the teaching of Anatomy and the medical science, following which the 'cadaveric oath' get read out by the Head of the department and students offer their tribute[1].

As till date no evaluation has been done on the said programme in the state so far the literature is reviewed, for which this endeavor is been taken to evaluate the impact of such programme among the students of Anatomy, in this institute, based of Kirkpatrick's model.

Editor's Comment :

- This is a project proposal (protocol), which is framed in the year 2023, approved by IEC on February, 2024; to evaluate the AETCOM teaching learning in Anatomy for the 1st year MBBS students. Here first time, as available in literature, 'does' level of Millar's pyramid is been proposed to be addressed (for Anatomy students).

The Kirkpatrick's model[2] is basically five-levelled approach, which is recommended to evaluate any educational programme. The levels of the model is summarized as —

Levels	What to evaluate	How to evaluate
1	Whether participants have liked the programme?	Feedback regarding the programme
2	What the participants can learn from the programme?	Pre-post test/ Reflection writing/ Question-Answer session after the programme
3	How far their behaviour get changed?	Work placed based assessment (WPBA)
4	What is the long term effect in society?	Portfolio of the participants/ various social indicators
5	What is the return of investment?	Formula for cost-effectiveness assessment

As in this case, we intend to assess students' behavior for how they are handling cadaver in Anatomy, so it becomes to address the 'DOES' level of Millar's Pyramid. So, the assessment tools becomes – Work Placed Based assessment.

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(a) Mini-CEX cannot be done in this case, as it not clinical cases.

(b) Multisource feedback (MSF *alias* 360 degree evaluation) also cannot be done as to get feedback from the patient's relatives as well as the patient himself. Here in maximum we can arrange the MSF stations with feedback from the teacher, peer as well as the dissection hall attendant. So, this plan also aborted.

(c) Direct observation of Procedural Skill (DOPS) also cannot be undertaken as there would not be any procedure of skill domain.

(d) The Kalamazoo scaling, cannot be taken as it not encounter any live patient.

So, considering all feasibilities, the Direct Observation of Non Clinical Skill (DONCS) with certain modifications may be planned of, which needs only the trainee-trainer interaction[3].

Research Gap analysis :

In 2017, a study from Pondicchery[4] with 150 Anatomy students of Phase 1 MBBS, have explored students' reflection of the 'cadaveric disrobing ceremony'; where the ethical concerns and moral aptitudes of the students got exposed in form of narratives.

Study by Singal A, *et al*[5] in 2020 have explored students perception for the utility of the cadaver in Anatomy learning in the 'thanks-giving ceremony' to the cadaver even amidst the lockdown times. They have expressed their gratitude to their silent-mentor in form of poem, gift cards. Study published in similar times with 220 students in JNMC Wardha[5] has explored the students' gratitude and empathy to the cadaver when they were provided with the predesigned questionnaire after the cadaveric oath ceremony.

Later, a study from Chennai[7] with 250 UG students has established students' concerns about the empathy and gratitude to the cadaver when they were taken into the session of 'donor is the first teacher'. Almost in similar time a in a different study from Hyderabad the result of a case-control pattern was explored. There 100 students were exposed to the cadaveric oath and 100 were not. All the students were made exposed to a questionnaire regarding the importance of the cadaver in learning of Anatomy. Students, who have taken the oath expressed better sense of bioethics, humanities to the altruism of the donor[8].

A recently published article (2023) from Andhra Pradesh[9] have expressed the students' perception of importance of the cadaveric oath ceremony when they were interviewed with predesigned questionnaire after the event.

So, till the literature have searched for, everywhere the 'immediate feedback' (ie, the Reaction- level 1 of Kirkpatrick evaluation ladder) or maximum to the "attitude to the result of learning" ie, the Learning- Level 2 of Kirkpatrick evaluation ladder have been assessed. None of the work could enlighten the higher level, ie, actual work-place based survey of the skill (Level 3-Behaviour), which would be tried in our present work.

Till the literature searched for no WBPA assessments were been explored for the Phase 1 Anatomy students on the issue of handling cadaver during their Anatomy teaching-learning programme. DONCS, which was found to be used for assessing non-clinical skills as chairing a meeting with a range of senior stakeholders, managing differing or opposing viewpoints effectively, managing conflict with a colleague or person receiving care etc. There was the trainee-trainer feedback session after the over of the event. But in nowhere in literature it was found to assess the behavior of the learner while handling cadaver during Anatomy class[10].

Reseach Question :

Whether the "Cadaveric Oath Ceremony" conducted as the part of AETCOM training in Anatomy, makes the impact in attitude and behavior of the students while handling cadaver/ human remains like viscera, bones etc. during their Anatomy practical classes?

Aims and Objectives

Aim :

This study aims to explore effectiveness of "cadaveric oath ceremony" for Phase 1 MBBS Anatomy students in attitude and behavior to handle cadaver/ human remains during their classes.

Objective :

(1) To explore the reaction of students for the cadaveric oath ceremony.

(2) To analyse the learning of the students in handling the cadaver or human remains.

(3) To measure the behavior of the students while handling cadaver or human remains in their practical/ demonstration classes.

Materials and Methods

Place of study : The study will be carried out in a government medical college of Kolkata.

Study design : Exploratory- Action research.

Study period : It will be carried on next 12 months.

Period required for data collection : 08 months

Study setting : The study will be carried on in the Department of Anatomy of a government medical college of Kolkata.

Sampling frame : Students of Phase 1 MBBS.

Sample size : all students will be approached. So expected sample size would be 200.

Inclusion criteria : The students, who will provide the informed consents, will be incorporated in the project.

Exclusion criteria : Students not consented to participate and/or not attended either of the sessions (cadaveric oath ceremony/ assessment programmes) will be excluded.

Study tool (Table 1) **:**

IEC clearance : Approval has been obtained (IPGME&R/IEC/2024/0031 dt. 08/02/2024

Making & validating the tool : Necessary approval has already been obtained from the Institutional Ethics Committee as well as from the administration.

At first the two tools will be made and validated.

(a) For the feedback-questionnaire, which would be placed just after the "cadaveric oath ceremony" will be formed and validated by the MEU/CC members of the institute and the subject experts from outside the institute.

(b) Secondly a one day one hour session will be arranged for the faculties of the department of Anatomy to prepare the blueprint of the DONCS (Directly observed non clinical skill) stations. That will also be validated by the MEU faculties and CC faculties respectively.

Proposed method of data collection — Now, the work will start from the upcoming 'cadaveric oath ceremony' programme. When in the academic calendar the respective event will be scheduled as the part of AETCOM teaching programme in Anatomy for UG Phase 1 MBBS students; just after the cadaveric oath gets over, the immediate feedback of the students will be obtained by using the 'feedback questionnaire'. On requisite analysis this will reflect the Level 1 of the Kirkpatrick's tier (Fig 1).

After one week, one session will be carried on for 'how to write reflection' and students will be asked to submit their reflections of the AETCOM class and cadaveric oath ceremony. Qualitative ananlysis will be carried on for those reflective writings and Kirkpatrick's level 2 is expected to be assessed.

During the departmental assessment events, separate station will be framed for the assessment of how they are handling cadaver by using DONCS schedule made within the department. Students will be provided requisite feedback for their necessary rectifications. By this the 'workplace based assessment' level will be attempted to assess.

Statistics : The data collected will be checked for completeness and consistency. The quantitative parts of the data will be analysed Microsoft Office Excel 2010;

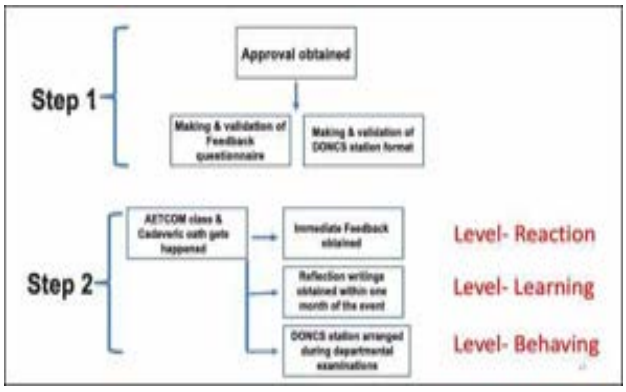

Fig 1 — Representing the plan of work

Table 1 — Showing Study Tool

Kirkpatrick Levels	What to evaluate	How to evaluate	Study tools proposed to be used
1	Whether participants have liked the programme?	Feedback regarding the programme	Feedback questionnaire after the cadaveric oath ceremony
2	What the participants can learn from the programme?	Pre-post test/ Reflection writing/ Question-Answer session after the programme	(1) Reflection essays gathered from the students (2) Theory questions on AETCOM in examinations
3	How far their behaviour get changed?	Work placed based assessment (WPBA)	Directly observed Non clinical skill (DONCS)

Table 2 — *Showing Statistics of Data Collection*

	Data	Proposed source	Proposed tool statistics	Proposed use of
1	How the students' liked the cadaveric oath ceremony?	Departmental record	Feedback form filled up just after the session	Quantitative analysis (descriptive statistics)
2	What the students' learnt from the cadaveric oath ceremony	Departmental record	Narrations in the reflective writings	Qualitative analysis (thematic)
3	How the students behaved actually while handling the cadaver	Scores in upcoming formative assessments	DONCS	Qualitative analysis (descriptive)

and the qualitative part of the data will be analysed thematically. Descriptive statistics including frequencies and will be used to summarise the findings (Table 2).

Discussion

As this is a project-protocol only, so at present this section can not be built up. will be done on the basis of observation and analysis data.

Conclusion

It will be drawn on the basis of Observation and Results.

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Letter to the Editor

[The Editor is not responsible for the views expressed by the correspondents]

Citations update in the Article only from same Indexing Journal : Is it not unfair to other Indexing ?

Sir, — The last two to three decades have seen a rise in experimental research and publications. The quantity and caliber of research studies and publications have both increased. Before that, the procedure of publishing a paper took a long time, and the popularity of high-impact journals was less widespread[1]. The circumstance has now improved. The majority of people seek to publish their findings in journals that are listed in prestigious databases like Scopus, Medline, and Web of Science. The top three are reliable indexing bodies that are acceptable to significant accrediting and ranking organizations. Any researcher who has their research published in an indexed journal feels proud and satisfied with their work[2].

Once the research is published, other researchers may read it and be motivated to conduct similar or slightly modified research in their institute or region. They used the published research work as a review of literature or reference for this study. The second author cites the influential study in their bibliography or references list when writing the article. Published articles receive citations whenever someone uses them as references in their research. Before good indexing journals, candidates' profiles also grew stronger based on the number of publications and citations, High impact factor journals and citations too[3].

Anyone who has publications with high impact factors or more citations is considered to have a notable profile. The citation index known as the h-index, i5, i10, the index gives an idea about how many research manuscripts are used as a reference by various other researchers. While the author profiles on Google Scholar display citations from every publication, the author profiles on Scopus/Web of Science/Medline include only citations from articles that were published in the same indexed journal. This circumstance prohibits some article citations from being included in the author id for the indexing database[4].

We comprehend that the indexing server is unable to link publications and citations when the corresponding data has not yet been updated on their server or website. However, this strategy results in authors losing their citations. Although Scopus is a high-quality and well-regarded indexing body for journals, this does not imply that alternative indexing bodies cannot meet the standards and quality that Scopus indexing journals have. Medline and web of science are also appreciable and standard indexing bodies. If any articles from Medline or Web of Science indexing journals mentioned Scopus indexing journal articles as references, Scopus indexing journals' cite score will also increase. Since Scopus does not have to maintain its citation monopoly, authors are deterred from submitting their work to other high-caliber indexing journals[5,6].

We are not advocating that Scopus should change its policy; rather, we are proposing that Scopus should enhance it more inclusive by adding additional high-quality indexing journals, at least for the Scopus article and author citation index. Additionally, the journal's cite score and impact factors will rise significantly.

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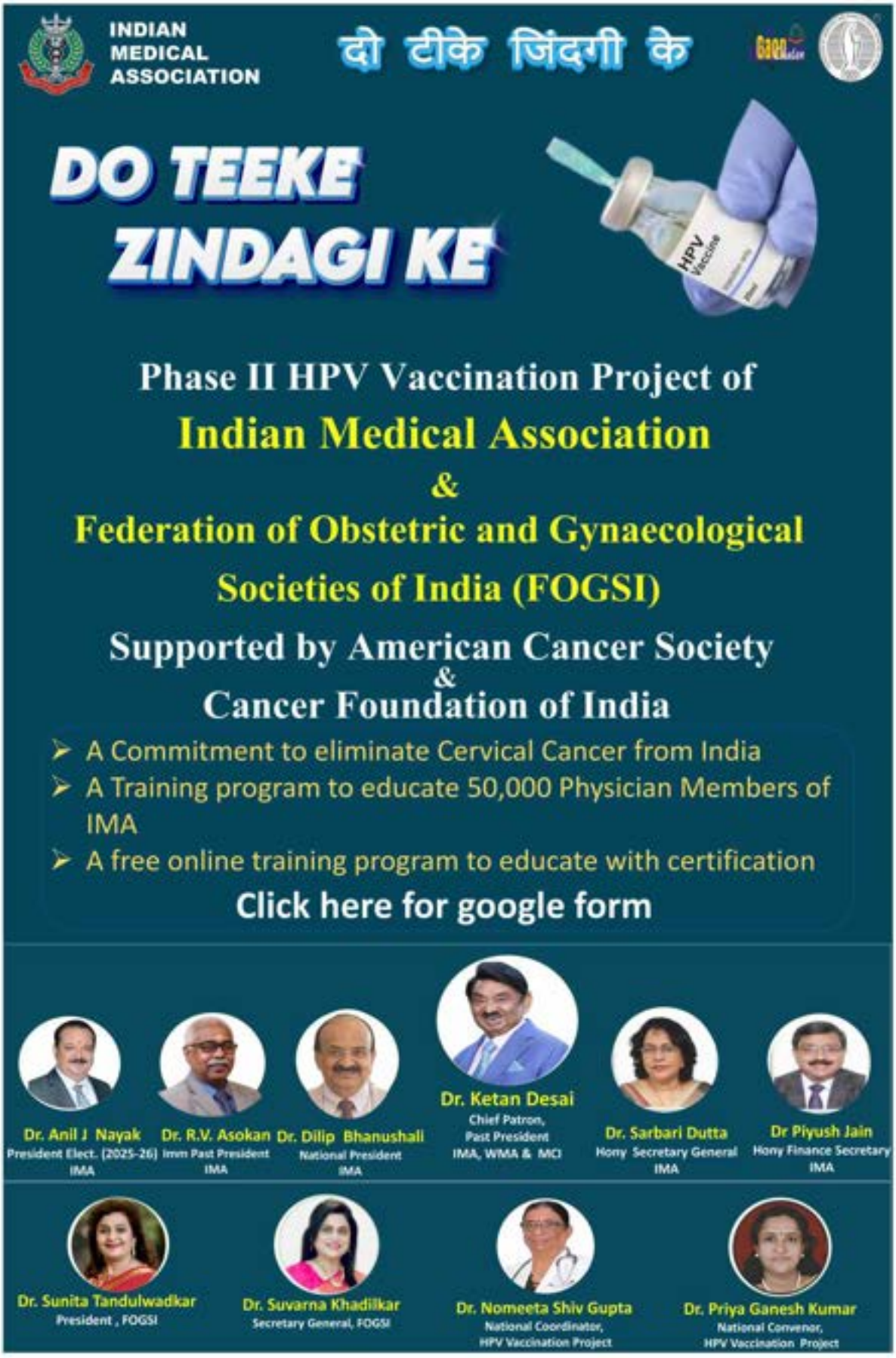
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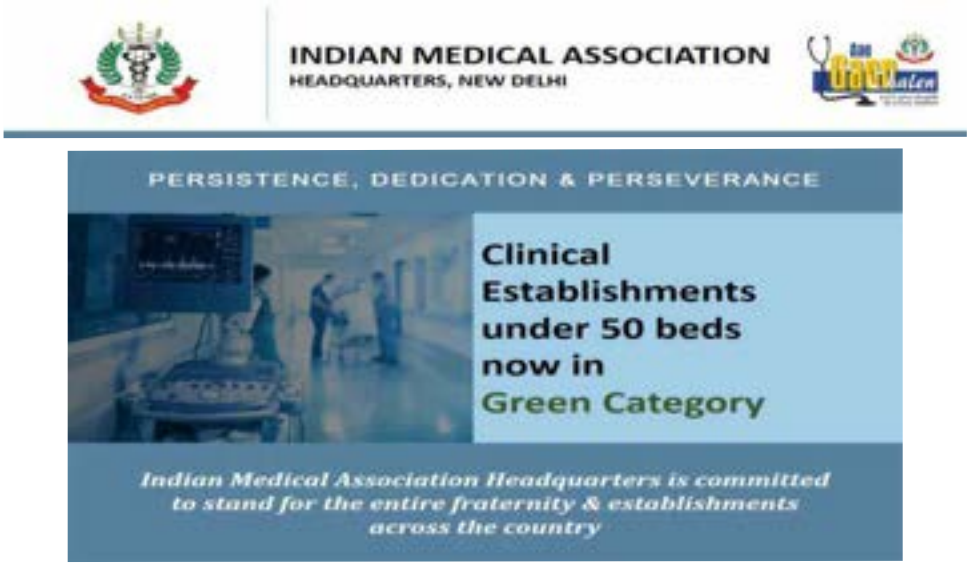
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