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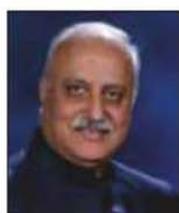


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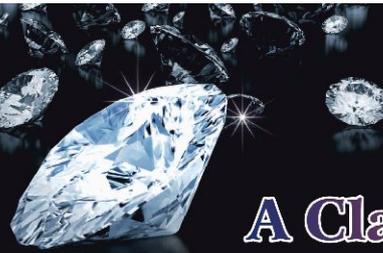
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## JIMA January, 2023 Issue Release Ceremony



In presence of Dr Sarad Kumar Agarwal, National President, Indian Medical Association & Office Bearers of JIMA, Your Health of IMA and IMA HQ, Kolkata at IMA HQ, Kolkata Office on 11-02-2023

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Ref: 1. Diabetes Ther (2022) 13; 1097-1114 **TECOS**- Trial Evaluating Cardiovascular Outcomes with Sitagliptin **MACE**- Major adverse cardiovascular events  
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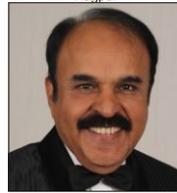
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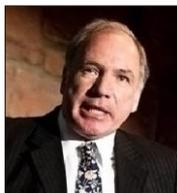
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<sup>2</sup>Handin RI — Bleeding and thrombosis. In: Wilson JD, Braunwald E, Isselbacher KJ, Petersdorf RG, Martin JB, Fauci AS, *et al* editors—Harrison's Principles of Internal Medicine. Vol 1. 12th ed. New York: Mc Graw Hill Inc, 1991: 348-53.

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**S**cientific publication is an essential tool for propagation of knowledge and dissemination of newer evidences into the medical community. It is through published literature that humanity comes to know about disease profiles around the world, newer diagnostic and therapeutic modalities and eventual outcomes. However, any research nowadays is accomplished by the conjoint efforts of many individuals, through multidisciplinary teams, acquiring information from diverse origins. There is also a scholarly hierarchy in research projects where students function under the guidance of seniors. It becomes important to give credit to each and every person involved. Thus gone are the days when a single person would write a paper on a discovery he or she has made his was in vogue till the 1920s after which multiple authorship took over.

The manuscript prepared for documenting work also involves multiple persons in the analysis and interpretation of data followed by drafting , revision and final approval before publication.

The International Committee of Medical Journal Editors (ICMJE) has developed four definite criteria for authorship , all of which need to be satisfied for an individual to be designated as author . It is mandatory that the group of authors should be able to take public responsibility for their work and vouch for the accuracy and integrity of the work of co-authors.

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The quality and quantity of effort put into the research and manuscript preparation is to be taken into account and this decision should be taken even before the work has actually begun by allotment of specific responsibilities. Collective discussion is very important in avoiding dissent and bitterness.

Of all the authors, the corresponding author plays a vital role in communicating with the journal, responding to queries about the publication during the review process and also afterwards should there be any need for additional data. All documents, like the details of authorship, ethics committee approval, clinical trial registration and relevant disclosures also need to be furnished by the corresponding author.

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The guest authors are usually influential people whose inclusion in the byline may be a way to increase the credibility of the publication.

Gift authors are people who feature in the list due to some personal rapport, senior authors might want to reward someone who has helped them in the past or gratify co-workers to maintain cordial relations with them. At times junior authors may put a senior colleague's name with the hope of favourable consequences regarding review and publication.

What are the motivations behind publications and why is authorship important? Communication to the scientific world about one's own research work is the most important, but at times it may be a pressure to increase chances of getting research grants, promotions in academic career or tenure positions. All this leads to a large number of authors in publications, a condition called hyperauthorship.

However it should be kept in mind that though an authorship may bring reputation to a person, it also entails responsibilities of defending the intellectual content of the manuscript, concede any error publicly and in case of fraud state publicly its extent and nature and why it occurred.

Awareness about the criteria and responsibility of authorship is becoming very essential nowadays. The author should know, understand and adhere to recommendations laid down by ICMJE. Some journals require the corresponding author to specifically indicate the contributions of individual authors in the manuscripts so that there is no ambiguity about their inclusion and order of placement. This also leads to abiding to publication ethics. The Committee On Publication Ethics (COPE) has guidelines, advisories for authors as well as journal editors for guidance regarding various responsibilities of authors. Flowcharts for detecting authorship problems, should disputes arise, are also readily available. All information about recommendations and guidelines of ICMJE and COPE are available on the public domain and may be downloaded for personal upgradation and knowledge before one embarks on the next manuscript preparation.

#### FURTHER READING

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## Original Article

# Role of Counselling and its Impact on the Dietary Habits, Glycemic Control and Diabetic Awareness of Newly Diagnosed Type 2 Diabetes Mellitus Patients

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**Background** : Type 2 Diabetes Mellitus is a lifestyle disorders and it leads to complications that are life threatening which can be prevented by proper Counselling and Diet monitoring of patients.

**Objective** : To evaluate effect of Counselling on the Glycemic control, Dietary habits and Diabetes awareness of type 2 DM patients.

**Method** : A randomized clinical trial was conducted at a tertiary hospital. 96 subjects were randomized and baseline data was gathered from all patients included in the study. Out of these 48 patients were given Counselling on various aspects of Diabetes including diet, complications, medication, lifestyle modifications, exercise etc. Lab investigations and Diet calculations were done on first and 4 months later to measure the effect of Counselling on patient's Diet and Glycemic control and Diabetes awareness.

**Results** : Diabetic awareness was measured in terms of number of correct responses which increased from 325 to 542 in Intervention group and from 357 to 402 in Control group. The increase in intervention group (22.60%) was more than that of the Control group (4.59%). The amount of calories in the diet of intervention and control group was respectively 2322±371 and 2334±460. Post Intervention it was 2344±400 and 2056±267 respectively. Before intervention the difference in the amount of Calories, FBS, PP2BS between the 2 groups was statistically insignificant. But after intervention the difference with reference to total calories ( $p=0.0003$ ), FBS ( $p=0.01$ ) and PP2BS ( $p=0.0001$ ) became statistically significant.

**Conclusion** : Counselling led to a significant improvement in the Diabetic awareness, Glycemic control and Dietary habits of patients in terms of caloric intake.

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**Key words** : Counselling, Diabetes Mellitus, Diet, Glycemic control.

The prevalence of Diabetes is increasing all over the world. According to an estimate 285 million people were suffering from Diabetes in the world in 2010. 90% of them were Type 2 Diabetes Mellitus (DM) patients. The world diabetic population is estimated to reach 366 million by 2030<sup>1</sup>.

Management of DM includes both Pharmacotherapy and Counselling the patient about lifestyle changes. Lifestyle changes (eg, dietary regulations, exercise, self-care) are cheap, help in reducing doses of oral hypoglycaemic drugs and delay shifting of Pharmacotherapy from oral hypoglycaemic drugs to Insulin. Thus patient education, involvement and awareness about these aspects are paramount for the successful care of diabetes.

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### Editor's Comment :

- Regular counselling of type 2 diabetes leads to improvement in diabetes awareness, change in choosing food items such as cutting the carbohydrate intake and this leads to overall glycemic control.

Diet, especially excessive caloric intake is a major driving force behind the escalation of obesity and Type-2 Diabetes worldwide. In particular, higher dietary Glycemic Index, Glycemic Load (GL)<sup>2,3</sup> and trans-fats are associated with increased diabetes risk, whereas greater consumption of cereal fibre and polyunsaturated fat is associated with decreased risk. Diligent Counselling of patients, with the aim of improving their awareness and encouraging early incorporation of lifestyle changes especially dietary changes might help enhance Glycemic control, quality of life and delay disease progression.

Therefore, the present study was performed to evaluate the role of Counselling and its impact on the diabetes awareness, Dietary habits and Glycemic control of newly diagnosed Type 2 DM patients visiting a Tertiary hospital.

## MATERIALS AND METHODS

### Sampling :

From August, 2014 to December, 2015, an RCT (Randomised control trial) was conducted for which Type 2 DM patients were selected from the patients visiting the diabetic clinic and medical OPD in a tertiary care hospital. Expecting a 40% increase in the number of patients with "good Glycemic control" in the Intervention group and 10% increase in the Control group from baseline and by keeping alpha risk at 5% and power at 90%, the calculated sample size was 78,39 in each group. By adding around 20% loss to follow up, the sample size increased to 96, 48 in each group. So 96 subjects were randomized and included in the study, 48 in each group. Sample size calculation was done using software Medcalc (version 12.5.0).

Newly diagnosed patients of Type 2 DM in the age group of 25 to 65 years were included in the study. Pregnant females, patients unwilling to take part in the study, patients with diagnosis duration <1 month or >4months and those with physical deformities or severe disease other than DM were not included in the study. Patients who had changes in their pharmacological prescription before the second visit, those with past history of Ketoacidosis or severe complications eg, Nephropathy, Neuropathy or CAD were excluded.

A list of newly diagnosed patients was drawn from the medical OPD register. As number of registered patients whose diagnosis was made in the last 2 to 4 months was less than our required sample size, we continued tracing patients from the register till actual sample size of 96 was achieved. Then these 96 patients were listed and randomized using random numbers generated by the software Epi info 7. Thus, patients were divided into separate groups – intervention and control group with 48 patients in each. But 16 patients left the study and did not return for follow up (dropout rate of 16.66%), so further study was carried out with 40 patients in each group. Registration numbers of the patients selected from the diabetic clinic and medical OPD were used for personal information, clinical profile, lab diagnosis and other details.

### Diabetes Awareness :

To assess and measure the baseline understanding and practice of all the participants of both the groups, they were asked to fill a questionnaire (Table 1) which was imparted in a language intelligible to the patient (Gujarati) at 0 month. After filling the questionnaire all subjects of intervention group were counselled. Questionnaire similar to previous kind was given to the patients of both the groups on a follow up visit (after 4

month) to assess and measure improvement in the awareness if any. Some of the question had one correct option and some had multiple correct answers. Patients were given 20 minutes to mark correct answers.

### Diet Calculation and Lab Investigations :

Diet evaluation of the patients was done at 0 and 4th month of both the groups. Diet calculation was done by 24 hours recall method provided that pt has taken his regular diet on the previous day of Counselling. Answers of question 22 and 23 (Table 1) were derived from the diet calculation data only. For fat intake the cut off was set at 20% of total calories.

During first visit and at the 4th month Weight, Height, BMI and Blood Pressure were measured of all patients. Anthropometric measurements like Weight and Height were taken using standard techniques and standardised instruments. BMI was calculated using formula  $\text{Weight in Kg}/(\text{Height in meters})^2$ . Obesity's WHO criteria for was used to define obese. ( $\text{BMI} > 25 \text{ kg/m}^2$  is Overweight).

Laboratory investigations namely Post Prandial Blood Glucose (PP2BS), Fasting Blood Glucose (FBS) and Random Blood Glucose (RBS) were done in both the groups. All these investigations were done in SSG hospital only. Blood samples from the both groups were drawn under a complete aseptic precaution, after obtaining complete informed consent. For estimation of Blood Glucose a fluoride vacuumed evacuated tubes were used. Blood Glucose was measured by Glucose Oxidase-Peroxidase Enzymatic Method.

### Counselling :

Components of Counselling comprised general information about Diabetes and its complications, diet modification, physical activities, medication and its side effects, danger signs and symptoms of Hypoglycaemia. Patients were first introduced to a video of about 15 minutes that contained all the above mentioned information and then the patient was counselled for 7-15 minutes. At the end of first session, take home material on Diabetes was provided to the patients in form of leaflets/ booklets. Patients were given skill based training on how to do Blood Glucose monitoring by glucometer and Uri-stick.

Diet calculation was done on first and last visit for both the groups to measure the effect of Counselling on patient's diet. It was calculated by using a diet calculator (developed by Dr Raja Namidi, National Institute of Nutrition, Hyderabad), which uses raw material, cooked food and actual food consumption. Change in diet related practice in terms of Carbohydrate, Protein and Fat was also calculated & Post Counselling differences between two groups was measured.

### Ethical Issues :

The standard drug therapy that was prescribed by a Physician in the medical OPD was not changed in the both groups. Apart from this, the intervention group received additional Counselling on Diabetes. The study was approved by Institutional Ethics Committee for Human Research (IECHR). After completion of the study, patients of the control group were contacted telephonically and called for Counselling. They were then given the same Counselling and information booklets as the intervention group.

### Operational Definitions :

- **Type-2 Diabetes Mellitus** : group of disorders characterized by variable degrees of insulin resistance, impaired insulin secretion and increased Glucose production.

#### Criteria for Diagnosis of Diabetes Mellitus

**Symptoms of DM** : Polydipsia, Polyuria and unexplained weight loss & Random Blood Glucose concentration  $\geq 200$ mg/dl)<sup>a</sup>

OR

Fasting Plasma Glucose  $\geq 126$  mg/dL)<sup>b</sup>

OR

HbA1C > 6.5%<sup>c</sup>

OR

Two-hour Plasma Glucose  $\geq 200$ mg/dL) during an oral Glucose Tolerance Test (GTT)<sup>d</sup>

<sup>a</sup>Random is defined as without regard to time since the last meal.

<sup>b</sup>Fasting is defined as no caloric intake for at least 8 h.

<sup>c</sup>The test should be performed in laboratory certified according to A1C standards of the \*Diabetes Control and Complications Trial.

<sup>d</sup>The test should be performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water, not recommended for routine clinical use.

- **Exposure / Exposed** : Here "Exposure" means "Counselling. Exposed means participants who got counselled in the first visit. ie, Intervention group.

- **Good Outcome (Glycemic control)** : patient having FBS < 126 mg/dl and PP2BS < 200 mg/dl

- **Bad Outcome (Glycemic control)** : patient having FBS > or = 126mg/dl or PP2BS > or = 200 mg/dl

### RESULTS

In the study population mean age of intervention and control were 48.63±7.32 and 49.08±6.48 respectively. Number of females in the Intervention Group was 16 (40%), while in the control group there were 22 females (55%). Mean age of female in intervention and Control Groups were 50.43±8.27 and 48.77±5.30 respectively. Mean age of male in intervention and Control Groups were 47.42±6.51 and 49.44±7.83 respectively.

4 patients (10%) in Intervention Group and 3 patients (7.5%) in Control Group had their age below or equal to 40 years. In the age group of 41 to 50 years, intervention group had 22 (55%) participants and control group had 21 (52.5%) participants. Intervention Group had 14 (35%) patients above the age of 50, while Control Group had 16 (40%).

Both the groups had equal number of Hindus 36 (90%) and Muslims 4 (10%). None of the participant belonged to any other religion.

Socio-economical classification of the participants was done using modified Prasad's Classification. 6 (15%) participants of an Intervention and 9 (22.5%) participants of a Control Group were from upper class. In the Intervention Group 20 (50%), 12 (30%) and 2 (5%) participants belonged to upper-middle, middle-middle and lower-middle class respectively. Similarly in the Control Group 16 (40%) and 15 (37.5%) belonged to upper-middle and middle-middle class respectively, while none of the participants was from lower-middle class. Also none of the participants belonged to lower class in either group.

2 (5%) participants from the Intervention and 3 (7.5%) participants from the control group were uneducated. 18 (45%) and 22 (55%) participants in Intervention and Control Group respectively had completed primary schooling. In Intervention Group 19 (47.5%) and 14 (35%) from Control Group completed secondary or higher-secondary school. Two participants, one participant from the Intervention Group and one from the Control Group, were graduates.

To check if after the randomization both the groups were comparable with regards to Age, Sex, Religion, Socio-economic class and Education, difference between proportions and means for all mentioned variables of both the groups was calculated. This difference was statistically insignificant ( $p > 0.05$  for each variable).

Means of Height, Weight and BMI of Intervention group were 67.00 ± 13.12, 160.20 ± 11.35 and 26.19 ± 5.21. Means of these factors in Control Group, in that specific order, were 66.35 ± 10.69, 160.37 ± 8.94 and 25.72 ± 3.11. Systolic BP of intervention group was 135.55±17.86 and that of control group was 131.15 ± 12.59. Similarly Diastolic BP of intervention group was 82.85 ± 8.59 and that of Control Group was 81.90 ± 9.83. Difference between both groups with respect to each of these variables was measured to see if both the groups are comparable.

42.5% (n=17) patients of Intervention Group and 47.5% (n=19) patients of Control Group had their BMI in normal range, while 52.5% (n=21) of the participants of intervention group and 52.5% (n=21) participants of

Control Group were above the normal limit of BMI (either overweight or obese). None of the participants in Control Group and only 2 participants of intervention group had their weight below normal. Proportion of the Hypertension in the Intervention Group was 35% (n=14), while in Control Group it was 30% (n=12). The difference was not statistically significant.

When asked about presence of Diabetes in family, only 5 (6.25%) said that at least one of their blood relative had Diabetes, out of these 4 were from Intervention Group and only one was from Control Group. Fisher's exact test was applied to see the difference between both the groups with respect to presence of family history. Difference was not statistically significant ( $p < 0.36$ )

Only 6 patients were put on mono-therapy with Metformin (MT) and all of them got allocated to the control group. 85% (n=34) participants in the Intervention Group and 80% (n=34) patients in the Control Group were prescribed Glipizide (GPZ) and Metformin. 6 patients of Intervention Group and one patient of control group were prescribed Glimiperide (GMP) and Metformin. Three drugs of Glipizide, Metformin and Voglibose (VGB) were prescribed to only one patient of control group. These drug groups were rearranged and only two groups were made according to their capability to reduce Blood Sugar – group 1 included MT or GPZ+MT which had less capacity to reduce Blood Sugar than group 2 which included patients on MT+GMP or GPZ+MT+VGB. A chi squared test was applied to see the difference between these two groups. This difference came statistically insignificant.

When patients were asked if they took their medicines regularly, 42.5% (n=17) from the Intervention Group and 47.5% (n=36) patients from the Control Group said "no". This difference was statistically insignificant.

10 participants (25%) of the Intervention Group had one or more type of addictions majority 30 (75%) of patients had none. 9 participants (22.5%) of the Control Group had one or more type of addictions while majority 31 (77.5%) of patients had

none. Thus, 61 (78.25%) participants were neither alcoholic nor using any form of tobacco. None of the participants were addicted to any other substance.

The proportions of correct responses to the questions in the questionnaire in Intervention and Control Group before after Counselling are shown in Table 1. At baseline the number of correct responses was more in Control Group than intervention group but this difference was statistically not significant. Before intervention in an Intervention Group, out of possible 960 correct responses only 325 (33.85%) were registered. This number of correct responses rose to 542 (56.45%) after intervention. Before intervention in a Control Group, out of possible 960 correct responses only 357 (37.18%) correct responses were registered, the number of correct responses rose to 402 (41.87%) on the second visit. Even though the number of correct responses in absolute terms increased in both the groups, Intervention group showed much more increase (22.60%) than the Control Group (4.59%).

At baseline patients in both Intervention and Control Group had poor knowledge about the various

Table 1 — Level of Awareness in both Groups (Corrected Responses) (N=80)

No	Question	Pre-intervention		Post-Intervention	
		I	C	I	C
1	normal blood glucose level (RBS)	09	14	35	25
2	Normal HbA1c level	02	04	19	08
3	Diabetes outcome. (Curable/non-curable/controlled by lifestyle modifications and medicines)	20	19	36	23
4	Effect of exercise on blood pressure and sugar	06	03	14	04
5	Type of exercise	22	19	26	19
6	Complications of diabetes (Cardiac diseases, Renal, Neurological, Foot complications, Eye complications)	00	01	07	03
7	Foot complications and sequelae	01	12	02	11
8	Importance of regular blood sugar measurement	12	03	22	06
9	Treatment during the days of fever, diarrhoea and infections	03	03	05	02
10	Eye check-up	07	18	13	11
11	Immediate symptoms of hypoglycaemia	02	01	07	02
12	Healing of wounds in diabetes	08	06	15	10
13	Medicines should be stopped once level of sugar is below 140 mg% /regular doctors visits helps in drugs dose regulation/ those who take medicines doesn't need to take care of their diet.	16	14	24	21
14	How would you tackle an attack of hypoglycaemia?	06	09	26	13
15	How do you feel about including following food items in your diet?	05	02	09	03
16	What type of exercise one should do in terms of duration, type and frequency?	24	29	34	28
17	How should a diabetic patient take his diet in terms of quantity, frequency and amount?	07	18	18	14
18	Takes drugs/insulin regularly?	23	21	39	31
19	Alcohol addiction	34	39	34	39
20	Smoking addiction	34	35	38	35
21	Do you do exercise regularly?	00	00	17	05
22	Kcal in a daily diet (<30kcal/kg)	06	08	23	11
23	% of fat in a diet (<20% of total calorie intake)	38	39	39	38
24	Regular blood sugar check-up?	40	40	40	40
Total correct responses = 960		325	357	542	402

complications of Diabetes as well as management of hypoglycaemic episodes. Awareness about these aspects showed an increase at 4 months in both intervention and control group. Patients in both the groups at 0 months had knowledge about different types of exercises but this knowledge was not implemented as none of the patients were actually doing any regular exercise. At 4 months, the number of patients doing regular exercise increased in both Intervention and Control group, with more increase in intervention as compared to control group.

An unpaired t-test was applied to check the difference between diet of two groups. The results showed that before intervention the amount of calories ( $p=0.89$ ) and fat percentage ( $p=0.50$ ) both were statistically not different between the 2 groups. But after intervention the difference with reference to total Calories ( $p=0.0003$ ) and Fat percentage ( $0.013$ ) became statistically significant between intervention and control group (Table 2).

Paired t-test was used to see if there is any statistical difference in the Intervention Group as well as in the Control Group with respect to total calories intake and fat %.

The difference was statistically significant for total calories intake in the intervention group. ( $p=0.0025$ ). For the fat % the difference was there in the means but the paired t-test suggested that this difference was statistically insignificant. ( $p=0.15$ ) (Table 3).

The difference in the Control Group in pre and post-intervention data was statistically insignificant with respect to total calories intake ( $p=0.82$ ) and fat % ( $0.07$ ). It is important to notice that the percentage of fat derived energy out of total energy increased in control group in second visit (Table 2).

Metabolic control of Diabetes was measured by doing Plasma Glucose measurement. For this purpose RBS, FBS and PP2BS were done. Means of Blood Glucose measurements were calculated. Paired t-test in a Control Group showed significant difference for FBS ( $p=0.0006$ ) but the difference with respect to RBS ( $p=0.06$ ) and PP2BS ( $p=0.052$ ) was statistically insignificant. For intervention group before and after difference with respect to all three parameters RBS ( $p=0.0005$ ), FBS ( $p<0.0001$ ) and PP2BS ( $p<0.0001$ ) was statistically significant (Table 4).

After intervention 20 participants from Intervention Group and 35 participants from the Control Group had either their FBS level above the normal levels (126 mg/dl) or their PP2BS levels above normal levels ( $\geq 200$  mg/dl). While before Intervention these numbers for Intervention and Control Group were 37 and 35 respectively. Thus before intervention 92.5%

Table 2 — Diet Comparison between Two Groups

Pre-Intervention (Unpaired t-test)			
Diet component	Control group	Intervention group	P value
Calories Kcal	2322 ± 371	2334 ± 460	P=0.89
Fat% of total Kcal	13.89 ± 3.25	14.39 ± 3.39	P=0.50
Post-Intervention (Unpaired t-test)			
Diet component	Control group	Intervention group	P value
Calories Kcal	2344 ± 400	2056 ± 267	*p=0.0003
Fat% of total Kcal	15.09 ± 3.08	13.45 ± 2.68	*P=0.013

Table 3 — Diet Comparison in Each Group

Control group (Paired t-test) (n=40)			
	Before Intervention	After intervention	Paired t-test
Calories Kcal	2322 ± 371	2344 ± 400	P=0.82
Fat% of total Kcal	13.89 ± 3.25	15.09 ± 3.08	P=0.07
Intervention group (Paired t-test) (n=40)			
	Before Intervention	After intervention	
Calories Kcal	2334 ± 460	2056 ± 267	*P=0.0025
Fat% of total Kcal	14.39 ± 3.39	13.45 ± 2.68	P=0.15

participants of intervention group had poor Glycemic control and 87.5% participants of control group had poor Glycemic control.

In other words 50% patients from Intervention Group and only 12.5% patients from the Control Group could achieve good Glycemic control. Relative Risk (RR) of poor Glycemic control with respect to Counselling was 1.75. Attributable Risk (AR) of poor Glycemic control with respect to FBS in non-intervention participants was 42.86%.

Table 4 — Effect of Counselling on the Blood Sugar Levels

Before Intervention			
Test	Intervention group Mean ± SD (CI)	Control group Mean ± SD (CI)	t-test
RBS (mg/dl)	259.15 ± 144.17 (213.04-305.26)	240.40 ± 90.24 (211.54-269.26)	p=0.4877
FBS (mg/dl)	178.92 ± 66.87 (139.35-187.64)	171.25 ± 51.22 (154.87-187.63)	p=0.5663
PP2BS (mg/dl)	290.35 ± 70.74 (257.02-298.00)	303.55 ± 101.24 (271.17-335.93)	P=0.5011
After Intervention			
Test	Intervention group Mean ± SD (CI)	Control group Mean ± SD (CI)	
RBS (mg/dl)	174.10 ± 36.49 (162.43-185.77)	209.92 ± 47.57 (194.71-225.14)	*P=0.0003
FBS (mg/dl)	124.00 ± 22.36 (116.85-131.15)	138.37 ± 28.09 (129.38-147.36)	*P=0.0134
PP2BS (mg/dl)	205.90 ± 45.96 (191.20-220.60)	264.12 ± 75.49 (239.98-288.26)	*P=0.0001
Before and After Intervention in Intervention group			
Test	Before Counselling	After counselling	
RBS (mg/dl)	259.15 ± 144.17 (213.04-305.26)	174.10 ± 36.49 (162.43-185.77)	*P=0.0005
FBS (mg/dl)	178.92 ± 66.87 (139.35-187.64)	124.00 ± 22.36 (116.85-131.15)	*P<0.0001

## DISCUSSION

Diabetes is a chronic, incurable condition that has considerable impact on the life of each individual patient. WHO projects that Diabetes will be the 7th leading cause of death in 2030. Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use can prevent or delay the onset of Type2 Diabetes<sup>4</sup>. The vast majority of day-to-day care in Diabetes is handled by patients and/or families, so Counselling the patients to improve self-management should be a central component of any effective treatment plan. Educational programs with in-home reinforcement can improve the self-management of Diabetes and lead to improvement in health indicators<sup>5</sup>.

In our study effect of Counselling the patients about self-management was measured with respect to the change in diabetic awareness, dietary patterns of the participants and Glycemic control.

Patients' level of awareness about Diabetes was measured in terms of number of correct responses to the questions in Table 1. At the end of the study period the total number of correct responses increased in both the groups, but the intervention group showed greater increase than the control group and this difference was statistically significant. This implies that Counselling did improve the patients understanding about DM especially its complications, the management of hypoglycemic episodes and the importance of doing regular exercise. Several studies using such questionnaires also reported a similar positive impact of Counselling on patients knowledge about DM and its implementation in everyday life<sup>6-10</sup>.

At baseline patients in both intervention and control group had poor knowledge about the various complications of Diabetes as well as management of hypoglycaemic episodes. Awareness about these aspects showed an increase at 4 months in both intervention and control group. Patients in both the groups at 0 months had knowledge about different types of exercises, but this knowledge was not implemented as none of the patients were actually doing any regular exercise. At 4 months, the number of patients doing regular exercise increased in both intervention and control group with more increase in intervention as compared to control group.

Table 2 results shows that the difference between both the groups for total calories intake and % fat intake was statistically insignificant at the beginning of the study. The amount of K cal a diabetic takes during the whole day should be less than 2200 or 30 kcal/day. These means suggest that the caloric intake of participants in both the groups was on a higher side.

So the Counselling regarding this was very necessary. The energy derived from fat in these groups were within normal limits (<20%).

After the counselling the intervention group showed the improvement in terms of total energy intake ( $p=0.0025$ ). But the Control Group did not show any improvement, rather the average Calorie intake slightly increased. Change in terms of fat in both the groups was not seen. And whatever change seen in an intervention was statistically insignificant in a group ( $p=0.15$ ), while in the control group the % fat intake increased by a statistically significant amount ( $p=0.07$ ). Since all the values of pre and post intervention for % fat intake are less than 20, we can say that the amount of energy derived was within normal limits.

Post Intervention difference between both the groups in terms of Calories ( $p=0.0003$ ) and % Fat ( $p=0.013$ ) was significant. Patients in the Intervention group were taking more healthy diet and they did modify their diet according to their needs. Since both groups were taking amount of fats within the recommended limits, there was still a scope for Carbohydrate reduction in some patients of the control group. Thus educating the patient about dietary changes did produce an improvement in their dietary patterns. This is similar to the results obtained in a study conducted by Krishnan D, Gururajan R, *et al* which showed that participants who received both dietary and exercise Counselling with periodic follow-up were generally likely to follow dietary principles more carefully and were more involved with their interactions with the Counsellor<sup>11</sup>.

The effect of Counselling on Glycemic control was measured by comparing calculated means of RBS, FBS and PP2BS of the participants in both the groups. The analysis was done similar to the diet analysis. Results showed that the baseline (before Counselling) Blood Sugar in terms of RBS, FBS and PP2BS were comparable as there was no statistical difference. Paired t-test results showed improvement in all three Blood Sugar parameters in an intervention group, while the control group showed improvement in only RBS ( $p=0.0625$ ) and FBS ( $p=0.0006$ ) and not in PP2BS ( $p=0.51$ ) levels. This might be due to improper knowledge and practice regarding the diet in a Control Group. Post intervention difference in the Blood Sugar parameters was significant for all three, RBS ( $p=0.0003$ ), FBS ( $p=0.013$ ) and PP2BS (0.0001). Thus there was a better Glycemic control in intervention group than Control Group (Table 3).

This is similar to result obtained in an interventional study done by Renuga E, Vanitha Rani N, *et al* in 2014 in India stated that "There was a reduction in the

mean FBS from baseline to the follow-up in both the groups but a statistically significant higher reduction in the mean FBS was found in the Intervention Group from baseline to the final follow-up when compared to the control group ( $p < 0.001$ ).<sup>12</sup> In another study conducted by Ahmed MM, Degwy HME, *et al* statistically significant improvement was found in the mean levels of HbA1c and FBS after application of face to face diabetic education<sup>13</sup>.

Several other studies also showed that Counselling led to better Glycemic Control measured in terms of Glycated Haemoglobin(HbA1c)levels<sup>14-18</sup>. A study by Norris S L, Lau J, Jay Smith J S, *et al*/showed that self-management education improves Glycated Hb levels at immediate follow up and increased contact time increases the effect. The benefit declines 1-3 months after the intervention ceases, however, suggesting that learned behaviours change over time. They also stated that further research is needed to develop interventions effective in maintaining long-term Glycemic control<sup>19</sup>.

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## Original Article

# High Fear & Stress in the Quarantine Population of COVID-19 in Southern Rajasthan : A Survey

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**Background :** The advent of the COVID-19 pandemic has caused a significant psychological impact on the General Public, Health Care Workers, Elderly, High-risk groups, etc. Higher fear is likely among the quarantine population.

**Aim of this study :** To evaluate the fear and stress of individuals in quarantine; to determine the possible factors that are influencing the Psychological reactions of the individuals in quarantine compared to the general population; to provide a basis for future Government policies.

**Methods :** A semi-structured questionnaire that included a pre-tested, 7-item Fear of COVID-19 Scale (FCV-19S) was used for data collection. A total of 245 responses were received. Through random sampling, 50 participants each were chosen from the general and quarantine populations. p-value <0.05 was considered significant.

**Results :** Individuals in quarantine had a greater fear of COVID-19 compared to the general population (p=0.0059). Symptomatic fears like clammy hands (p=0.032), sleep disturbance (p=0.00026) and heart palpitations (p=0.000034) were commoner in the quarantine population. The younger age group in the quarantine population was comparatively more affected by News and Social media (p=0.00018). Getting a negative screening test resulted in lesser fear both in the quarantine (p=0.017) and general populations (p=0.002).

**Conclusion :** The individuals under quarantine have greater fear possibly due to stressors like transmitting the infection to family, working on the frontlines, being in high-risk groups, losing jobs, and exposure to social media. However, negative screening tests were shown to reduce the fear.

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**Key words :** COVID-19, Fear of pandemic, Psychological fear, Quarantine.

COVID-19 is a new respiratory infection outbreak that started in China in December, 2019. As of 4th May, 2020, a total of 42,533 cases and 1373 deaths were reported in India and 3,435,894 cases and 239,604 deaths all around the world<sup>1</sup>. By 12th November, 2021, the total number of confirmed COVID cases in India rose up to 34, 414, 186 and the total deaths reached to 462, 690<sup>2</sup>. The epidemic brought not only the risk of death from the viral infection but also unbearable Psychological pressure to people in China and the rest of the world. There have been reports on the Psychological impact of the COVID-19 pandemic on the Frontline Workers<sup>3</sup>, Students<sup>4</sup>, Health Care Workers<sup>5</sup>, Elderly<sup>6</sup>, etc.

Quarantine is the separation and restriction of movement of people who have potentially been exposed to a contagious disease to ascertain if they become unwell, hence reducing the risk of them infecting others. This definition differs from isolation, which is the

### Editor's Comment :

- COVID-19 exacerbated fears Worldwide which is higher in who quarantine.
- The stressors which contributed to increase fear were losing jobs, economic crisis, transmitting infection to family members, social stigma high risk for future/ life threatening, and these people need counselling/ psychological support.

separation of people who have been diagnosed with a contagious disease from people who are not sick<sup>7</sup>.

The Fear of COVID-19 Scale (FCV-19S) is a reliable and valid tool to assess fear as a Psychological reaction to the COVID-19 pandemic which is proven by studies in multiple Countries<sup>8</sup>. Fear of COVID-19 Scale is a seven-item, unidimensional scale with robust psychometric properties. It has been proven that the English version of the COVID-19S is a sound unidimensional scale with robust psychometric properties that can be used with confidence among English-speaking populations<sup>9,10</sup>. Moreover, total scores on the FCV-19S are comparable across the Country, Gender and Age which suggests that it is a good Psychometric instrument to be used in assessing and allaying fears of COVID-19 among individuals<sup>8,11</sup>. However, no detailed study comparing the mental health status of the population under quarantine with the normal population has been conducted to date.

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The purpose of our study is :

(1) To evaluate the fear and stress of individuals in quarantine.

(2) To determine the possible factors that are influencing the Psychological reactions of the individuals in quarantine compared to the general population.

(3) To provide a basis for future Government policies.

**Materials and Methods:** This analytical research study was conducted at RNT Medical College, Udaipur (Rajasthan), for which the data was collected during May - June 2020. The study protocol was approved by the Institutional Ethical Committee. [RNT/STAT/IEC/2020/426 Dated 18/05/2020]

A cross-sectional survey was conducted, using a semi-structured, pre-tested questionnaire that obtained Socio-demographic information (like gender, age, residence, educational status, occupation), medical history and information regarding the COVID screening test (RT-PCR). Moreover, a previously validated and standardized instrument, the 7-item Fear of COVID-19 Scale (FCV-19S) was used to evaluate the levels of fear<sup>8,12,9</sup>. The FCV-19S includes seven items that can be subdivided into 4 items based on emotional fear reactions and 3 items based on symptomatic expressions of fear. Respondents report their symptoms using a 5-item Likert rating scale that ranges from 1 (*strongly disagree*) to 5 (*strongly agree*), such that the total score ranges from 7 to 35<sup>11</sup>.

The questionnaire along with the consent form was distributed through digital media and the data was collected via google forms. Appropriate ethical approval procedures were followed while taking consent from subjects and also in conducting the research. A total of 245 responses were received. Using the inclusion and exclusion criteria, the respondents were subdivided into quarantine and general. The inclusion and exclusion criteria comprised of :

**Inclusion criteria :** Age between 18 & 60 years.

The quarantine population comprised individuals who had stayed under quarantine due to history of recent travel or history of contact with a COVID-19 patient or history of contact with a COVID-19 suspected patient. The general population comprised of individuals who had not stayed under quarantine.

**Exclusion criteria :** The participants with pre-existing or previously diagnosed mental health disorders or history of treatment for any mood/anxiety disorder or symptoms of upper respiratory tract infection or a positive screening test for COVID-19 were excluded from the study.

**Statistical Analysis :** *Slovin's formula* [ $N / (1 + Ne^2)$ ] was applied to calculate the sample size for the

quarantine population in the institute. Taking the confidence level as 95% the resulting sample size for the quarantine population was 50 with a margin of error of 10%. After implementing the inclusion and exclusion criteria, 50 participants were selected in the quarantine population through random sampling and for effective comparison, 50 participants were similarly selected in the general population. The collected data were analyzed with SPSS v22.0 software (IBM Corp, Armonk, NY). The means and Standard Deviation were calculated and compared using a two-tailed t-test. p-value < 0.05 was considered statistically significant.

## RESULTS

Table 1 — Demographic profile

Demographic		General (n= 50)	Quarantine (n= 50)
Sex	Male	30 (60%)	37 (74%)
	Female	20 (40%)	13 (26%)
Age	18 – 30 Years *	34 (68%)	33 (66%)
	31 – 44 Years	14 (28%)	13 (26%)
	45 – 60 Years	2 (4%)	4 (8%)
Education	Undergraduate	27 (54%)	21 (42%)
	Postgraduate	13 (26%)	17 (34%)
	Others	10 (20%)	12 (24%)
Occupation	Health Care Workers	19 (38%)	43 (86%)
	Others	31 (62%)	7 (14%)
Screening test done	Yes	16 (32%)	34 (68%)
	No	34 (68%)	16 (32%)

\* Most of the respondents were between the age of 18 and 30 years and majority were males. Among the sample of the quarantine population, 86% were Health Care Workers (Table 1).

The quarantine population reported to have higher rates of symptomatic fear - clammy hands, sleep disturbance, Heart palpitations. Moreover, news and Social media had a significantly higher impact on the fear of COVID-19 among the quarantine population. There was no significant difference in the average scores between the quarantine population and the general population with regards to being afraid of COVID-19 and losing life to COVID-19 (Table 2).

Overall, there was a significant difference ( $p=0.0059$ ) in the fear of COVID-19 between the quarantine ( $14.96 \pm 5.510$ ) and the general population ( $12.48 \pm 2.908$ ) on the FCV-19S.

Both males and females in the quarantine population had higher fear compared to the males and females in the general population,  $p=0.032$  and  $p=0.022$  respectively ( $p < 0.05$ ) (Table 3).

In both the general and the quarantine populations, the females showed higher levels of fear ( $13.35 \pm 2.54$  &  $17.23 \pm 6.56$  respectively) compared to the males ( $11.9 \pm 3.03$  &  $14.16 \pm 4.95$  respectively). However, the results were not significant.

The 2 ends of the age groups (18 - 30 years and 45

Question	Category	Average Score	SD	p value
I am most afraid of COVID-19	Quarantine	2.52	1.07	0.57
	General	2.64	1.08	
It makes me uncomfortable to think about COVID-19	Quarantine	2.54	1.15	0.04
	General	2.12	0.96	
My hands become clammy when I think of COVID-19	Quarantine	1.66	0.85	0.03
	General	1.36	0.48	
I am afraid of losing my life because of COVID-19	Quarantine	1.82	0.83	0.90
	General	1.84	0.91	
When watching news and stories about COVID-19 on social media, I become nervous or anxious	Quarantine	2.68	1.2	0.002
	General	2.02	0.91	
I cannot sleep because I'm worrying about getting COVID-19	Quarantine	1.72	0.83	<0.001
	General	1.22	0.42	
My heart races or palpitates when I think about getting COVID-19	Quarantine	2.02	1.09	<0.001
	General	1.28	0.49	

population that stayed in quarantine and explore different factors that are influencing their levels of fear. This study indicates that the average score in terms of fear of COVID-19 was higher in the quarantine population ( $14.96 \pm 5.51$ ) compared to the general population ( $12.48 \pm 2.908$ ).

Reports indicate that various factors like

- 60 years) showed higher fear in the quarantine population as compared to the general population ( $p=0.000969$ ,  $p=0.0048$ ). Whereas the 31- 44 years group showed no difference in the levels of fear between the general population and the quarantine population ( $p = 0.24$ ). In addition to that, on comparing the scores for the question - "When watching news and stories about COVID-19 on Social media, I become nervous and anxious" in the 18-30 years age group, the quarantine population was more affected by news and social media compared to the general population ( $2.71 \pm 1.159$  versus  $2.0 \pm 0.862$ ,  $p = 0.00018$ ).

The Postgraduates and Undergraduates in the quarantine population had higher levels of fear compared to the general population ( $p = 0.036$ ,  $p = 0.020$ ) while those classified as "others" (which included respondents who have done diploma course or attended high school only) had no difference in the level of fear between the quarantine and the general population ( $p = 0.94$ ). Similarly, the Health Care Workers and other occupational categories showed greater fear in the quarantine population ( $p = 0.037$ ,  $p = 0.029$ ). The respondents who had not taken a screening test for COVID-19 had higher levels of fear in the quarantine population compared to those in the general population ( $p = 0.0000302$ ) (Table 4).

On comparing respondents within the same population, those who had taken a screening test for COVID-19 showed lesser fear both in the quarantine and the general population. Since our study did not include COVID-19 positive patients, those respondents who took a screening test and received negative results eventually had significantly less fear of COVID-19 ( $p=0.017$ ,  $p=0.002$ ) (Table 5).

## DISCUSSION

The main goal of this study is to compare the psychological reaction and fear arising from the COVID-19 outbreak between the general population and the

unpredictability, uncertainty, seriousness of the disease, misinformation and Social isolation play a role in contributing to stress and mental morbidity<sup>13</sup>. Similarly, studies on the Psychological impact of the quarantine suggested that not being able to see friends and family members, worry of infecting their family members and confinement also play a role in the psychological effects of the quarantine population<sup>14</sup>.

Table 3 — Average score comparison of the same sex group between the quarantine population and the general population

Category	Male		Female	
	Quarantine	General	Quarantine	General
Count (%)	37 (74%)	30 (60%)	13 (26%)	20 (40%)
Average	14.16	11.9	17.23	13.35
SD	4.95	3.03	6.56	2.54
p value	0.03	0.02		

Table 4 — Average score comparison based on demographics between the general and the quarantine population

Average Scores	Quarantine	SD Q	General	SD G	p value
Age Groups :					
18 – 30 years	16.24	5.3504	12.74	2.49	< 0.001
31 – 44 years	10.77	4.418	12.57	3.48	0.21
45 – 60 years	18.00	2.449	7.50	0.707	0.004
Education :					
Undergraduate	16.00	5.723	12.08	3.353	0.03
Postgraduate	15.81	5.785	12.81	2.632	0.02
Others	12.00	3.766	12.10	3.213	0.94
Occupation :					
Healthcare Workers	14.77	5.433	11.89	3.381	0.03
Others	16.14	6.283	12.84	2.570	0.02
Screening Test Done :					
Yes	13.71	5.541	10.69	3.572	0.05
No	17.63	4.530	13.32	2.114	< 0.001

Table 5 — Screening test comparison within the same population

	Screening Test Done	Average	SD	p value
General	Yes	10.697	3.572	0.002
	No	13.32	2.114	
Quarantine	Yes	13.71	5.541	0.01
	No	17.63	4.530	

When considering the fear of COVID-19 in relation to the various demographic factors, while some studies showed higher levels of fear and a greater Psychological impact on females<sup>15</sup>, others did not show a significant difference in the Psychological impact between males and females<sup>4</sup>. In our study we did not find a significant difference between the fears of the males and females within the same population. This can be due to the difference between the number of males and females both in the quarantine (males 74% females 26%) and the general population (males 60%, females 40%).

However, when we compared the males and females in the general population with the males and females in the quarantine population respectively, significantly higher levels of fear were seen in the quarantine population for both males ( $p = 0.032$ ) and females ( $p = 0.022$ ).

On comparing different age groups, we found that age ranges depicted a variation in the level of fear between the quarantine and the general population. While the age groups of 18-30 years ( $p=0.000969$ ) and 45-60 years ( $p=0.004$ ) had a much higher level of fear in the quarantine population, there wasn't a significant difference in the level of fear in the age group of 31-44 years. This is supported by a previous study which states that the younger population are much more exposed to Social media than the middle aged and the elderly which can contribute to a greater Psychological impact<sup>16</sup>. In our study this is explained by comparing the results of the 18-30 years age group's average score for the question - "When watching news and stories about COVID-19 on Social media, I become nervous or anxious". This had a significantly higher average value ( $p = 0.00018$ ) in the quarantine population compared to the general population. It is suggested that young people can easily trigger stress as they tend to collect information from social media<sup>17</sup>. The quarantine population were Health Care Workers and their higher levels of fear can be attributed to seeing their patients die, worry about their own safety, exhaustion due to increased duration of work and fear of other colleagues who have tested positive for COVID-19<sup>4</sup>. Along with this, it is reported that the Social disconnectedness and perceived isolation can result in higher levels of anxiety and depression in the elderly<sup>6</sup>. The elderly, are at a heightened risk of the Psychosocial outcomes of the COVID-19 pandemic<sup>18</sup>, which was also observed in our study.

The educational groups (Undergraduates and Postgraduates) reported having higher fears in the quarantine population. This stems from their awareness about the gradually increasing distances between the people resulting from the quarantine, the effect of the virus on their studies and future employment<sup>4</sup>.

Occupationally, both Health Care Workers ( $p=0.037$ ) and individuals from other occupations ( $p=0.029$ ) had significantly higher levels of fear when staying under quarantine. The Psychological impacts on the Health Care Workers are largely supported by various studies that highlight that the Health Care Workers are afraid due to multiple reasons. Some of them include the high risk of the infection and inadequate protection from contamination, frustration, isolation, lack of contact with family<sup>5</sup> and the fear of infecting their families or seeing their patients die<sup>3</sup>.

Similarly, studies during the SARS outbreak report: acute stress in the quarantine population can be attributed to getting back in quarantine after resuming work as a Health Care Workers on the frontlines and the duration of quarantine<sup>19,14</sup>. The participants from other occupational categories who were under quarantine also showed higher fears which might be related to the future employment opportunities<sup>3</sup>, economic crisis<sup>20</sup>, and the stigma associated with COVID-19.

Getting a screening test has been attributed to lesser fear both within the quarantine ( $p = 0.017$ ) and the general population ( $p = 0.002$ ). Similarly, when we compared respondents between the quarantine and the general population based on whether or not they have taken a screening test for COVID-19, there was a significantly higher fear in the quarantine population ( $p = 0.0000302$ ) who had not yet taken a screening test for COVID-19. But there was no significant difference in the fear of the respondents who had already taken the screening test and eventually tested negative. A screening test that confirms the negative status of the infection is helpful in reducing the stress and fear levels. Similar to this, previous studies in China found that fabricated or false reports about COVID-19 infection resulted in worse Psychological outcomes<sup>21</sup>.

Our study suggests that the quarantine population has greater fears and anxiety compared to the normal population due to COVID-19 related stressors. These include close contact with a positive or a suspected patient, working on the frontlines, economic stressors and being in the high risk age groups. The symptomatic fear like disturbance in sleep, heart palpitations and clammy hands were found to be of significant intensity in the quarantine population compared to the general population.

News and Social media play a major role in the Psychological reaction of the younger individuals; measures to censor the News and Social media platforms regarding COVID-19 related information should be taken. Increasing the number of screening tests can help in flattening the curve of the infection and at the same time, it can help in reducing the stress

and fear among the individuals. Since isolation and quarantine can be fearful, proper counselling and support should be provided to those staying in quarantine. The availability of proper protective equipment and scales to evaluate the mental health of Health Care Workers with appropriate counselling and therapy can be helpful. High risk groups such as the elderly should be screened for mental health problems, provided Psychosocial support and Psychoeducation.

**Limitations :** The FCV-19S is based on Likert-scale which provides 5 choices to the respondents and it is likely that people avoid choosing the “extreme” options on the scale, because of the negative implications involved.

However, the scale is generalizable and has proven reliability and validity<sup>7</sup>.

**Conclusion :** The emergence of COVID-19 has exacerbated fears Worldwide which is even higher in those who are staying in quarantine due to a history of travel or contact with suspected or positive patients. There are stressors which have contributed to increased fear and anxiety in the quarantine population. These stressors include situations like losing jobs, economic crisis, transmitting infection to family members, being in the high risk age group, working on the frontlines, exposure to media and societal stigma. However, negative screening test results have reduced anxiety and fear.

The mental health of the individuals in quarantine is significantly affected in the COVID-19 pandemic compared to the general population and they require attention, help and support from their families and the society. The Government should work towards providing timely Psychological services to those staying in quarantine.

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## Original Article

# Morbidity Pattern among the Farm House Residents in Vijayapur District, Karnataka — A Cross Sectional Study

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**Background :** Agriculture Workers have a multitude of health problems, a fact which is often forgotten because of widespread misconception that occupational health is mainly concerned with industry and industrialized countries. The health problems of workers in agricultural field may be accidents (Snake and insect bites), toxic hazards (chemical exposure and insecticide poisoning), physical hazards (extreme conditions and solar radiation) and respiratory problems (farmer's lung and occupational asthma).

**Objectives :** To study the morbidity pattern among the Farm house residents.

**Material and Methods :** A cross sectional study was conducted among the farm house residents in rural areas of Vijayapura district. A Sample of 450 farm house residents were interviewed by pre-structured proforma containing information regarding Socio demographic profile, present and past six months morbidities. In each Taluka, the selection of households was done by considering villages as the Primary Sampling Unit (PSU). PSUs were selected with probability proportional to size sampling and 5 households in a selected PSU were selected by random sampling. All characteristics were summarized descriptively, Chi-square ( $\chi^2$ ) test was employed to determine the significance of differences between groups for categorical data.

**Results :** The findings of the present study among Farm dwellers in the rural area of vijayapura district revealed that majority at the time of study were having Anaemia followed by Respiratory Infection and majority of Farm dwellers in past six months were having Dental carries as a morbidity followed by Respiratory infection.

**Conclusion :** The present study concludes that overall majority of the Farm house residents presently suffering from Non-communicable Diseases (54%) followed by Communicable Diseases (46%).

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**Key words :** Morbidity pattern, Farm house, Household, Agriculture.

Agriculture is an art/practice of cultivating land. Agriculture sector occupies a key position in our Country. It provides employment to about 65% of the working population of India. Agricultural Workers constitute by far the largest segment in the unorganized sector. Agriculture workers constitute the most neglected classes in the Indian Rural structure. Their income is low and irregular. They do not possess any skill and training and have no alternate employment opportunities<sup>1</sup>.

Agriculture is essential for good health as it produces food, fibre and materials for shelter along with medicinal plants. It is also an important source of livelihood in many of the middle and lower income countries<sup>2</sup>. Agriculture as an occupation differs from another occupation in that, workers work in the open fields, exposing themselves to extremes of climates and also there are no 'Labour laws' in practice. The

### Editor's Comment :

- Agriculture is the backbone of the country as Agriculture sector occupies a key position in our country so farm house residents health is utmost important.

health problems of workers in agricultural field may be accidents (Snake and insect bites), toxic hazards (chemical exposure and insecticide poisoning), physical hazards (extreme conditions and solar radiation) and respiratory problems (farmer's lung and occupational asthma)<sup>3</sup>.

### According to the Karnataka Land Revenue (Amendment) Act, 2015 :

"Farm Buildings" or "Farm house" means a house attached to a farm and constructed in a portion of an agricultural land, used for the residence of the agriculturist or used for the purpose of keeping Agricultural equipment's and tethering cattle. The house shall be used by a farmer for his own use and it shall not be let out for commercial activities to any individual or agency. "Amendment of section 95.- Inside section 95 of the principal Act, - (a) after sub-section (1) state Farm building or Farm house so erected shall

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not be more than ten percent of his holding subject to a maximum of such extent of land as may be prescribed<sup>4</sup>. The Farm house workers are so remotely dispersed in Rural area that the health services may not reach them. Data regarding morbidity pattern among Farm house dwellers is very sparse. Community based study can only reflect the true picture of morbidity pattern in a given Community. Hence the present study was undertaken to explore the morbidity pattern among the Farm house residents of Vijayapura District.

#### MATERIALS AND METHODS

This was a descriptive cross-sectional study conducted among the Farm house residents of Vijayapura District. The study was done over a period of one year (June, 2017 – May, 2018).

After obtaining ethical clearance from the Institutional Ethical Committee the study was conducted in Vijayapura District. Geographically Vijayapura District has been divided into five Talukas, namely Vijayapur, Indi, Sindgi, Basavana Bagevadi and Muddebihal. Within each Taluka, the selection of households was done in different stages considering villages as the Primary Sampling Unit (PSU)<sup>5</sup>. Villages, where the number of households was less than 5 were not considered in the selection of samples and removed from the list. Allocation of the total sample population of 384 (~400) in Farm households is done in proportion to their population. Households have been selected in two stages. PSUs were selected with Probability Proportional to Size (PPS) sampling and 5 households in a selected PSU were selected by random sampling.

The List of Households Staying in Farm was taken from the Government Primary Health Centre and chits containing the head of the family were made. Total 5 chits from each village were selected randomly and included in the study.

From each household four participants randomly were interviewed regarding morbidity pattern. If any selected household did not contain 4 participants, was excluded and new household was selected randomly. The Household members were reached with the help of ASHA / Health worker of PHC which helped to develop rapport with people staying in the household. The purpose and overview of the study was explained at the time of the interview and interviewers were informed that their participation was entirely voluntary, their anonymity would be assured and consent was taken.

#### Distribution of Sample :

Mean number of person per household (HH) = 4 (on the basis of pilot observation in a nearby village)

Hence, Total number of HH in Farm houses =  $400/4 = 100$

Mean number of HH in farm houses per village = 4.7 (~ 5) (on the basis of pilot observation in a nearby village)

Total number of PSU (Villages) =  $100/4.7 = 21$

The sample size was calculated based on the formula.  $n = z^2pq/d^2$ . Due to lack of information on morbidity among the farm house residents in the study area, the calculation was based on the assumption of prevalence to be 50%. Assuming a confidence level of 95% and at a precision of 5%, the total sample size was 384 farm house residents. A round of sample of 384 (~400) was taken for the study, but the collected sample size was 450. The Study was conducted in Vijayapura District, situated in the Northern part of Karnataka. Farming and agriculture related business is the main occupation for many people in the district. People residing in Farm houses for less than 6 months were excluded from the study. Investigation like Haemoglobin estimation by using Mission HB instrument And Blood Sugar Estimation by Using Accu-Chek Active Glucometer. All characteristics were summarized descriptively, Chi-square ( $\chi^2$ ) test was employed to determine the significance of differences between groups for categorical data. Data were analysed using SPSS software v.23.0.

#### RESULTS

A total of 450 were the study participants, majority of male participants belonged to age group of 41-50 (21.4%) years and female participants belonged to age group of 11-20 (21.7%) years. The major proportion of males (97.8%) and female participants (96.8%) belonged to Hindu religion. 58.1% of male and 62.9% female participants belonged to nuclear family followed by 29.7% male and 25.8% female participants belonged to joint family. The majority of male (49.8%) and female (48.9%) participants were illiterates. More than 50% of the participants belonged to class V Socio-economic status (Table 1).

Among Study participants (n=450), 66% were presently suffering from various diseases, Among which majority of the participants 54% were having Non Communicable Diseases like Anaemia, Hypertension, Diabetes Mellitus, Accidents, Arthritis and 46% were having Communicable Diseases like Gastro-enteritis, Respiratory infections, Dental caries, Fever.

Majority of participants 58% in the last six months had suffered from various diseases, Among which majority of the participants 57% were having Communicable Diseases like Gastro-enteritis, Respiratory infections, Dental caries and Fever. 43%

Table 1 — Distribution of respondents according to Socio-demographic variables

Parameters	Male		Female		Total	
	N	%	N	%	N	%
<b>Age :</b>						
≤10	19	8.3	31	14.0	50	11.1
11-20	36	15.7	48	21.7	84	18.7
21-30	41	17.9	31	14.0	72	16.0
31-40	40	17.5	46	20.8	86	19.1
41-50	49	21.4	39	17.6	88	19.6
51-60	23	10.0	19	8.6	42	9.3
61-70	9	3.9	7	3.2	16	3.6
>70	12	5.2	0	0.0	12	2.7
<b>Religion :</b>						
Hindus	224	97.8	214	96.8	438	97.3
Muslims	5	2.2	7	3.2	12	2.7
<b>Type of family :</b>						
Nuclear	133	58.1	139	62.9	272	60.4
Joint	68	29.7	57	25.8	125	27.8
Three Generation	28	12.2	25	11.3	53	11.8
<b>Educational Status :</b>						
Illiterate	114	49.8	108	48.9	222	49.3
Primary	81	35.4	80	36.2	161	35.8
Secondary	31	13.5	30	13.6	61	13.6
PUC And Above	3	1.3	3	1.4	6	1.3
<b>Occupation :</b>						
Student	43	18.8	69	31.2	112	24.9
Labour	10	4.4	9	4.1	19	4.2
Household Activities	6	2.6	18	8.1	24	5.3
Farmer	170	74.2	125	56.6	295	65.6
<b>SE-Status :</b>						
Class Iv	111	48.5	101	45.7	212	47.1
Class V	118	51.5	120	54.3	238	52.9
<b>Total</b>	<b>229</b>	<b>100.0</b>	<b>221</b>	<b>100.0</b>	<b>450</b>	<b>100.0</b>

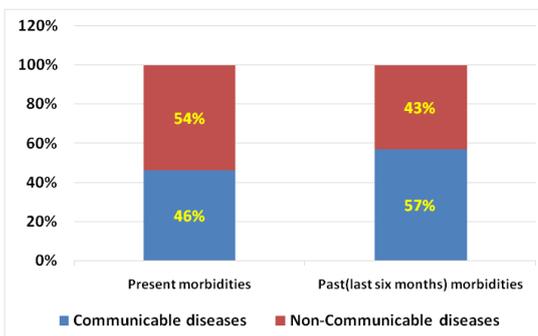


Fig 1 — Proportion of present and past morbidities (last six months) among study participants

Fever (18). Non-communicable was the commonest condition associated with the participants of 41-50 years age group who were illiterate and lived in nuclear families. The statistically significant association was observed between present morbid conditions with related to age, sex, type of family, educational status, occupation (Table 2).

In our study, we recorded past 6 month morbid condition also, 18.6 % of the female participants and 13.5% of male participants reported Dental caries. H/o known case of Hypertension was present among 4.3% and 1.3% of male and female participants respectively. Similarly H/o of Diabetes Mellitus was present among 3.7% and 1.3% of male and female participants respectively. Scorpion bite (7.7%) and Snake bite (4.1%)

were having Non Communicable Diseases like Hypertension, Diabetes Mellitus, Accidents, Arthritis, Scorpion bite, Snake bite, Cataract, Corneal scar, Hearing loss, Skin diseases (Fig 1).

We observed current morbidity status of participants, majority of the male participants (54.7%) and female participants (15.9%) were diagnosed as anaemia. Respiratory infection in 7.9% of males and 10.9 % females' participants. Accidents were reported among 3.9% of male participants only (Fig 2).

The maximum proportion of participants were suffering presently from Non-communicable Diseases like Anaemia (127) arthritis (18), Accidents (9), Hypertension (5) and Diabetes mellitus (2) followed by Communicable disease like Respiratory infection (49), Gastro-intestinal infection (40), Dental caries (29),

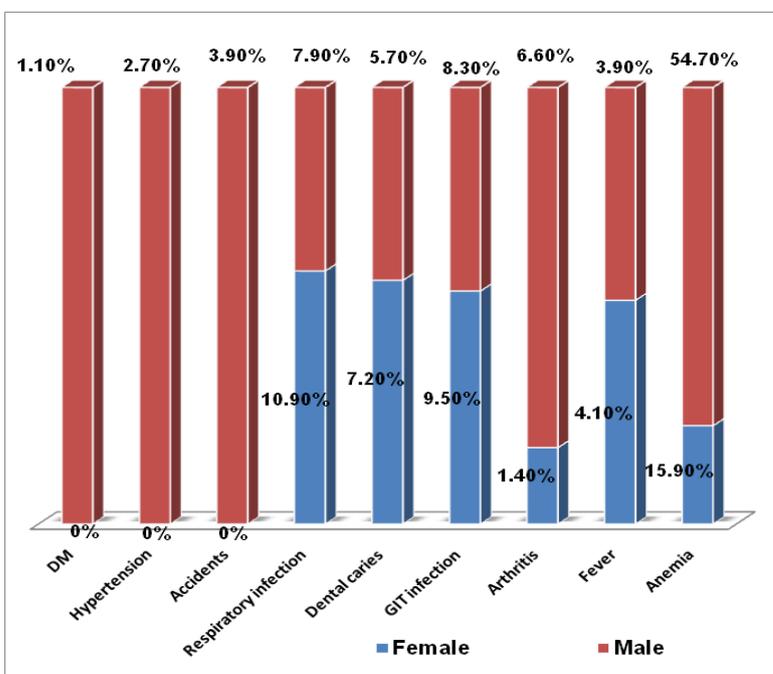


Fig 2 — Gender-wise distribution of present morbid status of the respondents

Parameters	Communicable diseases	Non-Communicable diseases	X <sup>2</sup> & P Value
Age :			
≤10	19	3	37.289
10-20	27	11	< 0.0001
21-30	21	24	
31-40	27	29	
41-50	23	46	
51-60	9	24	
61-70	4	12	
>70	6	12	
Sex :			
Male	62	132	43.119
Female	74	29	< 0.0001
Religion :			
Hindus	129	158	2.443
Muslims	7	3	0.1180.
Type of Family :			
Nuclear	88	81	8.137
Joint	38	54	0.0171.
Third Generation	10	26	
Education :			
Illiterate	81	98	10.696
Primary	33	53	0.0135.
Secondary	20	7	
Puc and Above	2	3	
Occupation :			
Student	37	7	41.994
Labour	12	8	<0.0001
Household Activities	8	2	
Farmer	79	144	
Se Status :			
Class Iv	72	67	3.799
Class V	64	94	0.0513
TOTAL	136	161	

Note: \*significant at 5% level of significance (p<0.05)

reported more among females compared to male participants (Fig 3).

During last six months morbid condition, the majority of participants had Communicable disease like Dental caries (72) followed by Respiratory infection (49), Gastro-intestinal infection (19) fever (9) followed by Non-Communicable disease like Accidents (20), Scorpion bite (27), Snake bite (12), Arthritis (12), Hypertension (10), Diabetes Mellitus (9), Cataract (9), Skin Disease (9), Corneal Ulcer (3), Hearing Loss (3).

Communicable Diseases were the commonest condition associated with the participants of 31-40 years of age group who were illiterate and were farmers living in nuclear families and maximum number of females suffered from Communicable Diseases compared to male's participants. This statistically significant association was observed between last six months morbid conditions and Age, Sex, Education,

Occupation & Socio-economic status (Table 3).

### DISCUSSION

Farming is a lifelong occupation. The farmers live near the Farm land and are often exposed to the environmental hazard throughout their life. Agricultural work tends to be a family occupation and all members of a family are involved in field activities. Rapid technological development in the Agricultural Sector has tremendously improved in last 25 years. The new innovations have increased production. They have also given rise to new variety of problems related to safety and health. Broadest and most extensive exposure to injury, diseases are suffered by Agricultural Workers.

In present Study, Maximum proportion of participants had Anaemia (36.9%) followed by Respiratory infection (9.3%), Gastrointestinal infection (8.9%), Dental caries (6.4%), Fever (4%), Arthritis (4%), Accidents (2%), Hypertension (1.5%), Diabetes Mellitus (0.6%). Majority of male participants (54.7%)

Parameters	CD	NCD	X <sup>2</sup> & P value
Age:			
≤10	14	10	33.079
10-20	31	13	<0.0001
21-30	24	5	
31-40	36	28	
41-50	34	26	
51-60	7	14	
61-70	3	8	
>70	0	10	
Sex :			
Male	69	70	5.906
Female	80	44	0.0151
Religion :			
Hindus	144	112	0.6392
Muslims	5	2	0.4240
Type of Family :			
Nuclear	98	69	0.9239
Joint	37	31	0.63.1
Third Generation	14	14	
Educational status :			
Illiterate	80	67	10.801
Primary	38	39	0.0128
Secondary	28	8	
Puc And Above	3	0	
Occupation :			
Student	39	23	13.545
Labour	12	0	0.0036
Household Activities	5	9	
Farmer	93	82	
SE Status :			
Class Iv	65	68	6.635
Class V	84	46	0.01
TOTAL	149	114	

Note : \*significant at 5% level of significance (p<0.05)

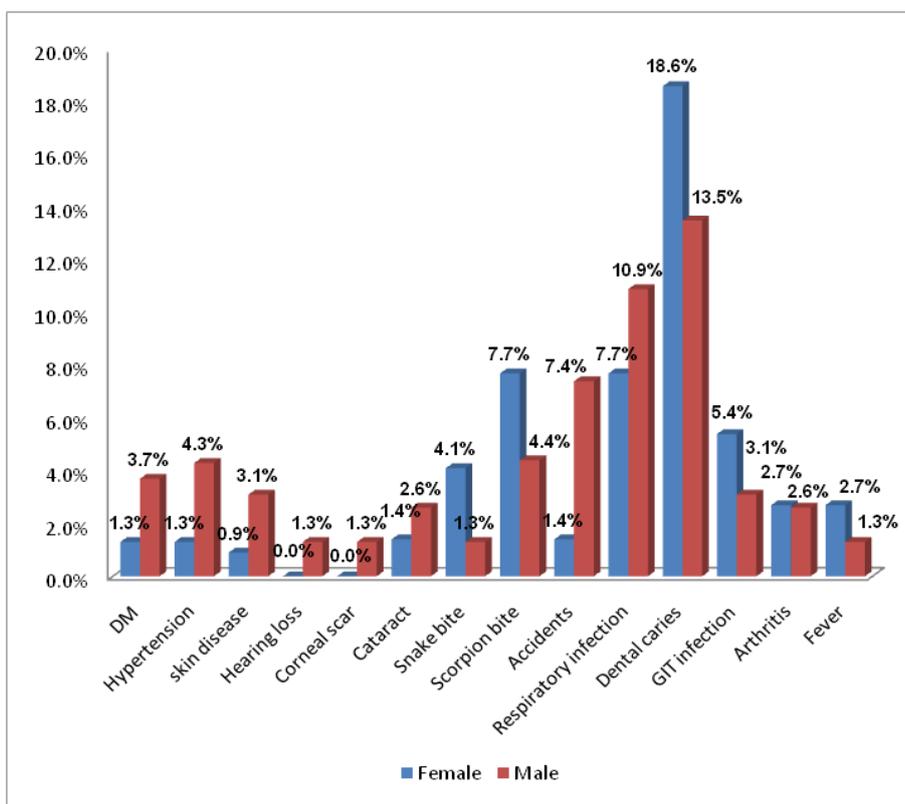


Fig 3 — Gender-wise distribution of past (last six months) morbid status of the respondents

reported with Anaemia compared to female participants (15.9%) and maximum number of females suffered from Respiratory infection compared to males participants respectively. Accidents were reported among 3.9% of male participants only. Verma V, *et al*, in Rural area of Allahabad District of Uttar Pradesh observed that Overall, most prevalent diseases were linked to Ocular, Musculoskeletal, Psychological system, Gastrointestinal System and Dental Disorder affecting 274 (68.5%), 239 (59.75%), 119 (29.75%), 100 (25%), 94 (23.5%), of elderly respectively. The prevalence of Anaemia (43%), Under-nutrition (38.5%) and Respiratory problems (16%) were more in Rural aged<sup>6</sup>. Sharma D, *et al*, in Rural area of north India reported the morbid condition like Musculoskeletal problems (56.5%), Hypertension (25%), Cataract (37%), Dental problems (33%), Asthma (4%), Corneal opacity (1.5%) and a significantly higher proportion of women suffered from Musculoskeletal problems (females: 66.7% *versus* males: 42.7%), Hypertension (females: 48% *versus* males: 32.7%), Diabetes (females: 7.8% *versus* males: 3.6%), while chronic Obstructive Pulmonary Disease (males: 14.3% *versus* females: 0.4%) was observed more in men<sup>7</sup>. According to DLHS IV survey Karnataka, reported that prevalence

of morbidity in Rural area was mainly injury (3.4%), acute illness (5.7%) and chronic illness (5.3%)<sup>8</sup>. Gupta SK, *et al*, in Rural area of Madhya Pradesh found that the prevalence of Anaemia was 42%. However, the prevalence of Anaemia was high in females (82%) compared to males (18%)<sup>9</sup>.

The proportion of Anaemia was more in males compared to female participants probably due to walking barefoot in field area may leads to worm infestations. The percentage of females suffering from Respiratory infection was more compared to male participants would be due to use of smoke forming challohs in Farm house. Accidents were reported among the male participants probably due to use of farming tools & machineries.

Among Last six months morbidity condition, majority of participants had Dental caries(16%) followed by Respiratory infection (9.3%), Accidents (4.4%), Scorpion bite (6%), Gastrointestinal infection (4.2%), Snake bite (2.7%), Fever (2%), Arthritis (2.7%), Hypertension (2.9%), Diabetes Mellitus (2.6%), Cataract (2%), Skin Disease (2%), Corneal Ulcer (0.7%), Hearing Loss (0.7%). A study done by Rahman SJ, *et al* in a Rural block of Jorhat District, Assam revealed that, (54.25%) of the farmers suffering from Respiratory Tract Infections followed by Musculoskeletal problems (23.25%) and Gastrointestinal Tract Ailments (11.75%)<sup>10</sup>. According to Hameed S, *et al* Study reported that the proportion of Arthritis, Anaemia and Obesity were significantly higher among females than among male participants<sup>11</sup>.

Ahmeed SM, *et al* in his study showed, there was significant association found between Fever, Skin, Eye, Ear problems with Age and Gender<sup>12</sup>. A study done by Kulkarni RR, *et al* in a Rural area of Belgaum District observed majority of Agriculture Workers were having Dental caries (25.50%), Dental stains (21.75%), followed by Musculoskeletal System (21.75%) and Respiratory System (19%)<sup>13</sup>. Kansal S, *et al*, in Rural community of Eastern Uttar Pradesh revealed that

Respiratory diseases (18%) followed by Fever (15.4%), GIT Diseases (11.4%), Bone and Joint problems contributed the principle cause of morbidity in the study population<sup>14</sup>.

### CONCLUSION AND RECOMMENDATIONS

The Farm house workers are a special group, who are remotely dispersed in Rural areas which makes that the health services may not accessible to them. The present study concludes that overall majority of the Farm house residents presently suffering from Non-communicable Diseases (54%) followed by communicable Diseases (46%). Among last –six months morbidity status, majority suffered from Communicable Diseases (57%) followed by Non-communicable Diseases (43%).

Farmers should be advised regarding use of protective measures like using masks for protection from hazards of fertilizers and pesticides, by wearing gloves while handling manure, by wearing long boots while walking in the fields. Also training for the use of agricultural equipment, as per instruction manuals.

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## Original Article

# Study of Effectiveness of Convalescent Plasma-therapy in Moderate to Severely ill COVID-19 Patients

Manoj Saluja<sup>1</sup>, Prakarsh Sharma<sup>2</sup>, Sidharth Sharma<sup>3</sup>, Saurabh Chittora<sup>4</sup>, Deelip Meena<sup>5</sup>, Gaurav Bhargava<sup>5</sup>

**Background :** Convalescent Plasma-therapy, a classic adaptive immunotherapy used in the treatment of SARS, MERS and 2009 H1N1 pandemic with acceptable efficacy and safety in the past. Convalescent Plasma-therapy was taken into consideration in management of COVID-19 disease during the initial days of pandemic but was withdrawn later due to its doubtful beneficial role. This study aims to explore the beneficial role of Convalescent plasma and to determine whether Convalescent Plasma-therapy holds a second chance in treating SARS-CoV-2.

**Methods :** This cross-sectional observational study includes 82 cases of moderate to severely ill COVID-19 patients who received Convalescent Plasma-therapy and 41 controls who didn't. regular monitoring of Total Leukocyte Count (TLC), PaO<sub>2</sub>/FiO<sub>2</sub> (PaO<sub>2</sub> is partial pressure of Oxygen in arterial blood, fractional inspired oxygen (P/F ratio), Neutrophil to Lymphocyte Ratio (N/L ratio) inflammatory markers, respiratory rate, oxygen saturation, ABG and Radiological Imaging was done for comparative analysis.

**Results :** In case group 39 patients (47.56%) were on oxygen mask, 17 patients (20.73%) on Non-invasive Ventilation (NIV), 9 Patients on Non-rebreather Mask (NRM) (10.97%), 16 patients (19.51%) on room air, 1(1.21%) on High Flow Nasal Cannula (HFNC) initially. After 7<sup>th</sup> day of Convalescent Plasma-therapy 49 patients (59.75%) were on room air which suggests significant improvement in mode of ventilation in case group as compared to Control Group. Mean respiratory rate in case group was 30.46 Cycles Per Minute (CPM) initially and 24.7 CPM on day 7<sup>th</sup> of Plasma-therapy which is statically significant.

**Conclusion :** Plasma-therapy is effective if given in early stage of disease and Convalescent Plasma donors having adequate antibody titre.

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**Key words :** Convalescent plasma-therapy, COVID-19, P/F ratio, Mode of ventilation.

An epidemic of Severe Acute Respiratory Syndrome coronavirus-2 (SARS-CoV-2) emerged in Wuhan, China. It was named as Coronavirus Disease 2019 (COVID-19) by World Health Organization (WHO). This epidemic spread Globally at great pace and within 3 months it was declared a pandemic by WHO on March 11, 2020. As of now on August, 2021, 21.9 crore cases with 45 lakh deaths have been recorded worldwide. India also has its fair share with 3.3 crore cases and 4.4 lakh deaths owing to this pandemic<sup>1-3</sup>. SARS-CoV-2 transmits through inhalation or direct contact with droplets of infected people with an incubation period ranging from 2 to  $\geq 14$  days.

Convalescent Plasma (CP) therapy, a classic adaptive immunotherapy, is used in prevention and treatment of many infectious diseases. Convalescent plasma delivers passive immunity in form of neutralizing antibodies.

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### Editor's Comment :

- In the present times when mutated variant strains are emerging at a phenomenal pace, mRNA vaccine based on specific protein antigens may not conquer immunity against newer variants whereas convalescent plasma with its natural antibodies carries potential to offer broad immunity against all variants.
- Plasmatherapy instead of being outrightly excluded from therapeutic armamentarium against Corona Virus, needs a re-evaluation as afresh so that its therapeutic potential may be exploited for the benefit of Corona Virus victims.

Convalescent Plasma is donated by recovered cases of COVID-19. It is the acellular component of blood that contains antibodies which specifically recognizes SARS-CoV-2. These antibodies are thought to exert an antiviral effect by suppressing virus replication. Virus-specific antibodies from recovered persons are often the first available therapy for an emerging infectious disease, till new antivirals and vaccines are being developed<sup>4-6</sup>.

Convalescent Plasma is relatively safe, with comparable risk to that of non-immune plasma. Known general risks of Plasma-therapy includes allergic reactions, Transfusion-Associated Circulatory Overload (TACO), and Transfusion-Associated Acute Lung Injury (TRALI). On August 23, 2020, the US FDA granted Emergency Use Authorization (EUA) of CP in

hospitalized individuals with COVID-19<sup>7-11</sup>.

However, some recent studies show no benefit of Plasma-therapy in COVID. In May 2020, ICMR had started a study regarding the efficacy of Plasma-therapy in COVID patients known as PLACID trial<sup>12</sup>. This study showed no role of Convalescent Plasma-therapy in disease progression and mortality. There are some limitations made out from this study. Most of the Plasma donors had only mild disease and around 2/3<sup>rd</sup> of these donors had median titre value of 1:40 which is way lesser than FDA recommended 1:160 neutralising titre. In some donor's antibody titres were not measured due to unavailability of antibody titre kit or faulty kits. From several studies it is observed that there is a positive correlation between magnitude of neutralising antibody response and disease severity in recovered COVID-19 patients<sup>13-14</sup>. Convalescent Plasma-therapy used in the treatment of SARS, MERS, and 2009 H1N1 pandemic with acceptable efficacy and safety in the past.

#### MATERIALS AND METHODS

This study is a cross-sectional observational study performed during a period of July, 2020 to Jan, 2021 at Government Medical College, Kota and attached hospitals. Subjects falling in inclusion criteria were lab-confirmed RT-PCR positive for nasopharyngeal swab according to CDC criteria. Moderate to severely ill admitted patients were included.

This study includes 82 cases of moderate to severely ill COVID-19 patients who received convalescent Plasma-therapy and 41 controls of moderate to severely ill COVID-19 patients who did not receive Convalescent Plasma-therapy. Moderately ill COVID-19 patients were those who had Respiratory Rate between 24-30 per minute and spo<sub>2</sub> of 90-94% on room air. Severely ill defined as respiratory rate >30 and SpO<sub>2</sub> of <90% on room air.

Patients who were asymptomatic or with mild symptoms, pregnant & lactating women, having known hypersensitivity to blood products and recipients of immunoglobulins in past 30 days were excluded. Patients who were critically ill PaO<sub>2</sub>/ FiO<sub>2</sub> <100 or in shock requiring vasopressors to maintain a Mean Arterial Pressure (MAP) of ≥65 mm Hg or MAP of <65 mm Hg were also excluded.

After admission, each patient was monitored till the end of hospital stay/ demise by a multispecialty team. Temporal assessment of the patient's profile was ensured by regular monitoring of vitals, daily assessment of the patients, and serial blood biochemistry, inflammatory markers, ABG and radiological imaging. Baseline parameters were taken before giving Convalescent Plasma-therapy (Day 0) and

data was collected after giving Plasma-therapy on day 3, day 7 and comparative analysis was done.

#### Convalescent Plasma Donors :

Potential donors must have had documented SARS-CoV-2 infection (either nasopharyngeal swab positivity or serologic positivity), be symptom-free for at least 14 days and meet standard blood donor eligibility requirements. Currently, individuals who themselves were treated with Convalescent Plasma for their own COVID-19 illness are not allowed to donate blood products, including Convalescent Plasma, for 3 months. Donations can occur as frequently as weekly for several months following clearance of infection before antibody titres begin decreasing<sup>15</sup>.

#### Statistical Methodology :

Statistical analysis was performed using Statistical Package for Social Science (SPSS) Version 22.0. Quantitative Continuous variables data were expressed as Mean ± Standard Deviation whereas Quantitative discrete variables data were expressed as frequencies are expressed as number (%). The Qualitative data were expressed in Medians with interquartile ranges. The student's t-test and  $\chi^2$ -test were used to compare the difference for means between two or more than two groups or to compare categorical variables, while continuous variables were compared using the Mann-Whitney U test. All statistical tests were two-tailed. Statistical significance was taken as p<0.05.

#### RESULTS

This study included 82 participants who received Plasma-therapy. Patients who were critically ill were excluded. There were 41 patients in the Control Group which received the same treatment as of case group except Convalescent Plasma. Out of 82 patients of case group, 60 was male and 22 were females with mean age of 55.6±14.6 years (age range 26-85). 75 patients (91.46%) got discharged and 7 patients (8.54%) died. Co-morbidities (pre-existing illness) were present in 45 patients (54.88%).

Table 1 shows no statistical difference among the case group and Control Group patient with respect to gender and age. Further the both Case and Control group found statistically similar on the basis of outcome and co-morbidity.

It is observed from Table 2 that there is no statistical difference among the case group and control group patient with respect to Total Leukocyte Count (TLC), Oxygen saturation, duration of hospitalisation and inflammatory markers measured on Day 0, Day 3, Day 7.

**In case group N :** L value increases on day 3 from the baseline and significantly decreases on day 7. However, in Control Group it decreases on day 3 &

Table 1 — Comparison between COVID-19 Patients with CP treatment (case group) and COVID-19 patients without CP treatment (control group)

Demographic Factors	Case Group (N=82)	Control Group (N=41)	T test	Chi square test	P value
Gender :					
Male	60 (73.17%)	29 (70.73%)		0.08	0.77
Female	22 (26.83%)	12(29.27%)			
Age, year :					
Mean ± SD	55.6±14.6	56.8± 16.7	0.399	0.689	
Outcome :					
Discharged	75(91.46%)	36(87.80%)		0.416	0.51
Expired	7(8.54%)	5(12.20%)			
Comorbidity :					
COPD	1(1.21%)	3(7.31%)		3.23	0.07
CVA	0 (0%)	2(4.87%)		0.158	0.69
HTN	29(35.36%)	16(39.02%)		0.676	0.41
T2DM	24(29.27%)	15(36.58%)		0.051	0.47
IHD	3(3.63%)	2(4.87%)		0.504	0.477
CKD	1(1.21%)	2(4.87%)		2.446	0.117
Hypothyroidism	5(6.05%)	4(9.75%)		0.051	0.47
Asthma	1(1.21%)	0(0%)		1.537	0.215
Obesity	2 (2.42%)	0(0%)		0.051	0.47
Post Renal Transplant	1(1.21%)	0(0%)		1.537	0.215
None	37(45.12%)	18(43.90%)		0.016	0.899

Values are presented as number (%) or Mean ± SD

day 7 respectively. There is significant improvement in P: F value in both the groups.

Further, both Case and Control Group found statistically similar on the basis of saturation % and inflammatory markers.

Case group shows significant improvement in mode of ventilation and respiratory rate as compared to controls.

Table 3 shows comparison among variables day 0, day 3 and day 7 in case group before and after giving Convalescent Plasma-therapy.

Table 4 shows comparisons among variables in control group.

Fig 1 shows no significant difference in mean PF value post Plasma-therapy in cases when compared to control group.

Fig 2 shows significant difference in change of mode of ventilation post Plasma-therapy in cases as compared to controls.

**DISCUSSION**

Our study explores the effectiveness of Convalescent Plasma-therapy in moderate to severely ill COVID-19 patients. We have taken 82 cases of COVID-19 and each of these were given 200-400ml of CP and effect of this was noted in different variables at 3<sup>rd</sup> and 7<sup>th</sup> day. 41 controls were taken which includes the COVID-19 patients who received all standard care except Convalescent Plasma.

The variables included were as follows :-

1. TLC count [effect noted as decrease or increase in TLC count], 2. N/L ratio (effect noted as whether there

is decrease or increase in this ratio), 3. P/F ratio (with the help of ABG we have calculated Pao2 and then we calculated Pao2/Fio2 ratio), 4. Oxygen Saturation (SpO2), 5. Mode of ventilation, 6. Respiratory rate and 7. Duration of hospital stay.

Previous studies have reported the use of Convalescent Plasma transfusion in treatment of various infections. Convalescent Plasma obtained from COVID-19 recovered patients who had established humoral immunity against the virus, contains high neutralizing antibodies. These antibodies are capable of neutralizing SARS-CoV-2 and eradicating the pathogen from blood circulation and Lung tissues. In our study we have included the donors who were recently recovered from COVID-19 and had high titres of neutralizing antibodies.

We have found from our study that in cases there is significant improvement in all these variables in form of decreased TLC count, decrease in N/L ratio, increased P/F ratio, decrease in Respiratory Rate, improvement in Saturation and change in Mode of ventilation (patients wean off from oxygen support) on day 3 and day 7 after giving Convalescent Plasma-therapy when no comparison was made to Control group.

To increase the validity of our study we have also included 41 controls who received all standard care except Convalescent Plasma. We have compared the

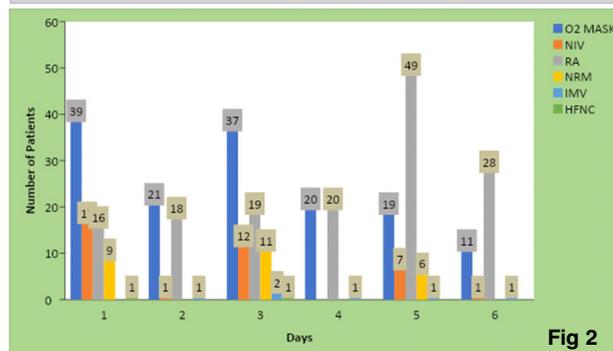
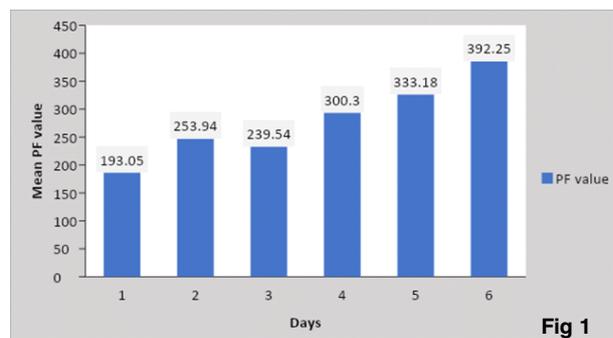


Table 2 — Comparison between COVID 19 Patients with CP treatment (case group) and COVID 19 patients without CP treatment (control group)

Clinicopathologic Factors		Case Group (N=82)	Control Group (N=41)	T test	Chi square test	P value
TLC value on Day 0	Mean ± SD	9.09 ± 4.17	10.05±6.10	1.026		0.30
TLC value on Day 3	Mean ± SD	10.78 ± 5.43	9.50±4.35	1.313		0.192
TLC value on Day 7	Mean ± SD	9.32 ± 4.26	9.32±4.95	0		1.0
NL Ratio value on Day 0	Mean ± SD	11.97 ± 10.43	10.65±12.30	0.352		0.725
NL Ratio value on Day 3	Mean ± SD	17.27 ± 19.2	10.18±13.87	2.104		0.03
NL Ratio value on Day 7	Mean ± SD	12.91 ± 11.93	7.95±10.78	2.243		0.02
PF value on Day 0	Mean ± SD	193.05 ± 92.64	253.94±90.89	3.458		0.00
PF value on Day 3	Mean ± SD	239.54±117.64	300.39±103.76	2.809		0.00
PF value on Day 7	Mean ± SD	333.18±149.09	392.25±144.21	2.094		0.00
Mode of Ventilation on Day 0	O2 MASK	39(47.56%)	21(51.41%)		19.207	0.00
	NIV	17(20.73%)	1(2.44%)			
	RA	16(19.51%)	18(43.90%)			
	NRM	9(10.97%)	0 (0%)			
	IMV	0(0%)	1(2.44%)			
Mode of Ventilation on Day 3	O2 MASK	37(45.12%)	20(48.78%)		17.733	0.01
	NIV	12(14.63%)	0 (0%)			
	RA	19(23.17%)	20(48.78%)			
	NRM	11(13.41%)	0 (0%)			
	IMV	2(2.42%)	1(2.44%)			
Mode of Ventilation on Day 7	O2 MASK	19(23.17%)	11(26.83%)		5.281	0.25
	NIV	7(8.53%)	1(2.44%)			
	RA	49(59.75%)	28(68.29%)			
	NRM	6(7.31%)	0 (0%)			
	IMV	1(1.21%)	1(2.44%)			
Respiratory Rate (CPM) value on Day 0	Mean ± SD	30.46± 3.36	27.32±2.81	5.148		0.00
Respiratory Rate (CPM) value on Day 3	Mean ± SD	27.68 ± 4.07	24.73±3.24	4.042		0.00
Respiratory Rate (CPM) value on Day 7	Mean ± SD	24.70 ± 4.82	23.07±5.27	1.714		0.08
Saturation% on Day 0	Mean ± SD	93.72 ± 3.96	93.07±3.38	0.899		0.37
Saturation% on Day 3	Mean ± SD	94.87 ± 3.18	94.53±2.14	0.618		0.53
Saturation% on Day 7	Mean ± SD	95.29 ± 2.35	95.68±2.42	0.859		0.39
Duration of Hospitalization	Mean ± SD	10.162±6.19	9.27±3.84	0.793		0.43
Inflammatory Markers	Normal	2(2.42%)	0(0%)		1.017	0.06
	Raised	80(97.58%)	41(100%)			

Values are presented as number (% or Mean ± SD

Table 3 — Correlation between clinicopathologic factors of case group before & after convalescent plasma-therapy using one way ANOVA

Clinicopathologic factors	Day 0	Day 3	Day 7	F Test	P value
	Pre-Plasma	Post Plasma	Post Plasma		
TLC value	9.09 ± 4.17	10.78 ± 5.43	9.32 ± 4.26	3.186	0.043
NL Ratio	11.97 ± 10.43	17.27 ± 19.2	12.91 ± 11.93	3.172	0.043
PF value	193.05 ± 92.64	239.54±117.64	333.18±149.09	28.066	0.000
Respiratory Rate	30.46± 3.36	27.68 ± 4.07	24.70 ± 4.82	39.833	0.000
Saturation%	93.72 ± 3.96	94.87 ± 3.18	95.29 ± 2.35	5.2149	0.006

Values are presented as number (%) or Mean ± SD

baseline characteristics of both case and control group. Both groups are almost similar in age and sex characteristics. These controls were selected from those COVID-19 patients who had not received Convalescent Plasma due to unavailability of donor or cross matched Plasma or who didn't give the consent.

While on comparing with Control Group (41 in number) the difference is significant only in improvement in Respiratory Rate and change in Mode of Ventilation. Otherwise, there is no significant difference in TLC count, N/L ratio, P/F ratio, and saturation between Case and Control group.

In Case group 39 patients (47.56%) were on Oxygen mask, 17 patients (20.73%) on NIV, 9 Patients on NRM (10.97%), 16 patients (19.51%) on room air, 1(1.21%) on HFNC initially. After 7<sup>th</sup> day of convalescent Plasma-therapy 49 patients (59.75%) were on room air which suggests significant improvement in mode of ventilation in case group as compared to control group.

Similarly mean Respiratory Rate in Case group was 30.46 CPM initially while in Control group it was 27.32 CPM and this difference was statistically significant. On day 7 mean respiratory rate was 24.7 CPM in case group while it was 23.07CPM in control group and the difference was statistically insignificant. It implies that there is significant improvement in respiratory rate in case group.

**Comparison with other studies :**

A large observational study finds the usefulness of Convalescent Plasma for treatment of COVID-19 patients. It shows that 7-day mortality and 30-day mortality were lower in those patients who received Convalescent Plasma within 3 days of onset of symptoms. The conceived trial from Netherlands was terminated early because they could not find any effect on mortality at 60 days, hospital stay or severity at 15 days. A randomised control trial of 103 patients

with severe COVID-19 in China shows no effect of Convalescent Plasma on time to clinical improvement. However, in that trial a subgroup of 45 patients with severe disease showed clinical improvement. One retrospective observational study conducted in South-West China explored the potential efficacy and safety of Convalescent Plasma treatment in 8 critically and severely ill patients which suggest early administration of Convalescent plasma may beneficial in improvement of clinical features. In a study conducted by ICMR (placid trial) did not show any benefit of giving Convalescent Plasma transfusion in disease progression and mortality. By using proper Convalescent Plasma collection with high neutralising antibody titre and timing of giving Plasma-therapy might hasten it being a more potential COVID-19 treatment.

#### Limitations of our study :

There are some limitations of this study. First, except for Convalescent Plasma, patients also received other standard care like antiviral treatment despite the uncertainty of the efficacy of the drug used. These antivirals might contribute to the recovery of patients or synergize with the therapeutic effects of Convalescent Plasma. Most of the patients received glucocorticoids which might interfere with Immune System and can cause delay in viral clearance<sup>16,17</sup>. Second is small sample size of the study group.

Despite of these limitations our study shows Convalescent Plasma might be a beneficial option for treating moderate to severely ill COVID-19 patients.

#### CONCLUSION

It is observed from this study that there is improvement in Lung Function (respiratory rate and mode of ventilation) whereas no significant effect on duration of hospital stays, laboratory parameters and mortality benefit. As there is development of variant SARS-CoV-2 strains, Convalescent Plasma donated by variant strain affected population may prove beneficial. Furthermore, evaluation and studies are required to see the long-term benefits like prevention of restrictive pattern and Fibrosis of lung by Convalescent Plasma-therapy. Plasma-therapy still holds a chance if given in early stage of disease and Convalescent Plasma donors having adequate antibody titre.

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Table 4 — Correlation between clinicopathologic factors of control patients at different days using one way ANOVA

Clinicopathologic factors	Day 0	Day 3	Day 7	F Test	P value
TLC value	10.05±4.35	9.50±4.35	9.32±4.95	0.216	0.805
NL Ratio	10.65±12.30	10.18±13.87	7.95±10.78	0.558	0.573
PF value	253.94±90.89	300.39±103.76	392.25±144.21	15.30	0.000
Respiratory Rate	27.32±2.81	24.73±3.24	23.07±5.27	12.153	0.000
Saturation%	93.07±3.38	94.53±2.14	95.68±2.42	9.589	0.000

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## Original Article

# Study of Hindrances in Sustaining — Body Donation Programme in COVID-19 Era

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**Rationality :** During the COVID-19 pandemic, there has been widespread confusion regarding the acceptance of donated bodies, especially those of COVID-19 unknown status. The present study aims to (1) quantify the fall in the body donation in COVID pandemic times & (2) explore the perception of the recipients of body donation (Anatomy faculties) and the facilitators of body donation (NGO members), regarding the problems they faced.

**Materials and Methods :** A cross sectional study using a pre designed study schedule was conducted over period of two months. 30 Anatomy faculties from 3 Medical Colleges in Kolkata and 20 members from 2 NGOs were interviewed. The actual numbers of the body donation received has been documented from record in Anatomy Departments and actual numbers of the body donation facilitated by NGOs has been obtained from record maintained in NGO office. The responses were analysed accordingly.

**Results :** There was significant decline in body donation activity in all the Medical Colleges during COVID times. 80% Anatomy faculties and 60% NGO members recommended posthumous RTPCR tests for COVID-19 unknown bodies. 93.33% faculties and 60% NGO members also wanted the Government to publish directives for posthumous RTPCR tests in donor's body. Most faculties (83.33%) were unsure as to whether embalming fluid can neutralize COVID-19 virus or not.

**Conclusion, Limitation & Future Scope :** This study explored the hesitations, its causes and remedial measures of hindrances in body donation program in COVID times. Being an ICMR STS project, authors needed to wrap up it by only two months time; but it can be used as the pilot to continue same in larger scale. Further researches are required to assess the lethality of embalming fluid on COVID-19 virus in this perspective.

[J Indian Med Assoc 2023; 121(2): 38-40]

**Key words :** COVID-19, Body donation, Lockdown times.

In the process of the "Body donation" after death, usually the body of the deceased is brought in the Department of Anatomy by his/her legal heirs. So the faculties/staff of the Anatomy Department remains in the recipient end of the Body Donation Programme, where the Society remains in donor end of the process. There are many Social Welfare Organizations who promote the Body donation service and they actively participate to coordinate the procedure.

According to a Government of India directive, embalming was debarred for known COVID positive bodies. So naturally for those bodies, donations have been halted. Donation of non-COVID deaths were attempted to avoid due to confusions, lack of knowledge, evidences among the recipients & donors<sup>1</sup>.

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### Editor's Comment :

■ The study demonstrated a significant fall of body donation in COVID-19 times. The cause of hindrances of the COVID-untested bodies was mainly lack of evidence of lethality of embalming fluid on Sars-CoV-2 virus and resulting fear of transmission from the Covid unknown cases. In the present day it is true that the COVID pandemic has passed away, but lessons we learnt can be utilized in future administrative planning.

Earlier studies revealed that most Universities refused Body donations and stopped all dissection research and training during that period<sup>2-4</sup>. Even we can see that there is much confusion prevailing around the question - whether embalming fluid can neutralize SARS-CoV-2 virus or not. Only if it does, the COVID-19 unknown bodies can be accepted directly without performing any posthumous test; in literatures as were searched for<sup>5-8</sup>.

### Objective :

(1) To compare the frequency of 'Body donation' activities held in the Anatomy Departments of Medical Colleges during Covid-times with pre-Covid time.

(2) To explore the perception of 'recipients of body donation' in accepting Body donation of COVID-19 unknown cases.

**MATERIALS AND METHODS**

**Type of study :** Field Operational Research.

**Study Design :** Cross sectional observational study.

**Study duration :** This was an ICMR- STS (Short term studentship) project. After obtaining necessary approvals from ICMR, Institutional Ethics Committee; data collection was done in 2 months of time period within the months of August & September 2022.

**Study setting :** The study was conducted under purview of Department of Anatomy of IPGME&R, Kolkata.

**Study population :** faculties of the Department of Anatomy(s) who were in the recipients end of the “body donation” programme and Exclusion criteria: Who did not give informed written consent to participate in the study.

**Sampling technique :** Non-randomized feasibility sampling

**Sample size :** Considering the feasibility, data was collected from 30 faculties from three (3) different Medical Colleges of Kolkata.

**Study technique :**

Data was collected by

- (a) Analysis of the maintained records in the office
- (b) Face to face interviews with the participants.

**Materials used :**

- (a) An interview guide
- (b) Informed consent form
- (c) Records maintained in Anatomy Departments(s)

**Data collection procedures :**

After approval from ICMR, necessary permissions were taken from Institutional Ethics Committee (IPGME&R/IEC/2022/309 dated 30/06/2022), HODs, President of ASI- WB Chapter, NGO officials. Data on numbers of Body donation accepted by Medical College- has been obtained from the register maintained in the Department(s). For feasibility, period of March, 2019 to February, 2020 has been considered as “pre-COVID times” & period of March 2020 to February, 2021 has been considered as body donation in “COVID period”. Perception of the recipients of Body donation- has been obtained by the face to face in-depth interview with the faculties in Department of Anatomy; using the interview guide after obtaining informed consents from them.

**Data analysis procedures:**

The data collected was checked for completeness and consistency. Then the data was entered in Microsoft Office Excel 2010 (Microsoft Corporation, Redmond, WA, USA), SPSS version 20 and analysed.

**RESULTS**

In total thirty faculties of Anatomy Departments of three different Medical Colleges of Kolkata have finally participated in the study. The records have well shown the vivid fall of the Body donation in the COVID period than usual times (Table 1/Fig 1).

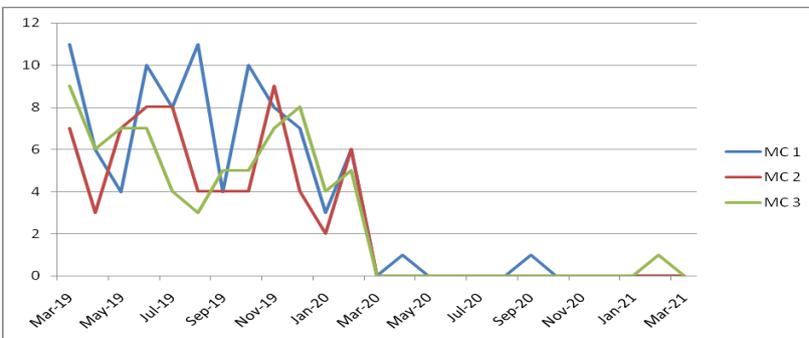
On interviewing with the faculties, it became evident that during the COVID-19 times majority (83%) had no knowledge regarding the lethality of the embalming fluid of SARS-CoV-2 virus; so they (76%) would to prefer for the COVID RTPCR test with 72 hrs of validity and if needed for the posthumous RTPCR testing (10% opined) to overcome hesitation to accept the body of COVID-19 unknown cases (76.6%)(Table 2)

**DISCUSSION**

The numbers of Body donation in a Medical College depends upon its location, social reputation as well as the trend of donation from its service area<sup>9,10</sup>. The difference in findings can be explained by the fact that trends in Body Donations vary a lot from time to time, and from institute to institute. Similar trends were observed by some researchers in Organ donations and Organ transplantations<sup>11,12</sup>. However, no research in our knowledge has yet been conducted to find out the status of Body donations in West Bengal in COVID-

Table1, Fig 1 — Comparison of ‘acceptance of body donation’ in preCOVID with COVID times

Pair	Monthly body donation	Mean	STD Deviation	T value (paired sample t test)	Significance (2 tailed)
Medical College 1	Pre-Covid times	7.33	2.807	8.332	0.000
	Covid times	0.17	0.389		
Medical College 2	Pre-Covid times	5.50	2.276	8.37	0.000
	Covid times	0.00	0.00		
Medical College 3	Pre-Covid times	5.83	1.801	10.682	0.000
	Covid times	0.08	0.289		



From above diagram it becomes evident that during Covid times, there was significant decrease of body donation in all the three Medical Colleges.

19 pandemic era. Majority of the faculties (83.33%) confessed they don't know whether embalming fluid can kill COVID-19 virus or not and that more research is required in this field. Now that COVID-19 cases are regressing, adequate measures must be taken by the authorities to remediate the gaps, so that proper coordination exists in the noble process of Body donations, and the hindrances in body donations are gradually erased.

#### CONCLUSION & FUTURE SCOPE

The study demonstrated significant fall of body donation in COVID-19 times. The cause of hindrances of the Covid-untested bodies was mainly lack of evidences of lethality of embalming fluid on SARS-CoV-2 virus and resulting fear of transmission from the Covid unknown cases. In present day it is true that the Covid pandemic has passed away, but lessons we learnt can be utilized in future days administrative planning.

#### Limitations :

Time- it was a Short term studentship project; so within a span of two months data collects were done. For which authors were compelled to restrict in smaller group of population. In future days, same study can be carried on in larger group of populations spanning all over the state even the country. Secondly, the lethality of embalming fluid on SARS-CoV-2 virus was also felt needed evidence. The work can be carried on in liaison with Department of Microbiology.

#### ACKNOWLEDGEMENT

The researchers are sincerely indebted to Indian Council of Medical Research to grant their kind permission for the Short Term Studentship Program project. The authors convey their gratefulness to the members of the (a) Institutional Ethics Committee of the institute, (b) Prof Abhijit Bhakta, the President of the Anatomical Society of India West Bengal Chapter, (c) Head of the Department of Anatomy of IPGME&R, Kolkata; Medical College Kolkata & NRS Medical College Kolkata, Prof. Soma Saha of Department of Anatomy, Medical College, Kolkata; for providing necessary permission & kind help to carry on the work. The author expresses their gratitude to all the participants who provided their valuable time to allow them interviewed.

**Conflict of Interest :** None declared for

**Source of fund (grants) :** Self

Table 2 — Perceptions of the faculties of Anatomy departments

Perception of Anatomy faculties [N=30]	Type of response	No of respondents(%)
What was your perception on receiving the offer for body donation in Covid unknown cases – during COVID pandemic?	to accept directly	4 (13.33%)
	To prefer for the Covid RTPCR report, if negative, to accept	23 (76.67%)
What was your acceptable time-window, for the Covid RTPCR test in these cases?	to refuse directly	3 (10%)
	After death it would be carried on	3 (10%)
	24 hr from the time of body donation	3 (10%)
	48 hr from the time of body donation	1(3.33%)
According to you, who would to arrange for the RTPCR test, in these cases?	72 hr from the time of body donation	23 (76.6%)
	From donor's family	21 (70%)
	From recipient department	7 (30%)
What is your knowledged on lethal potency of embalming fluid to inactivate COVID-19 virus?	It inactivate surely	5 (16.67%)
	It not inactivates	0 (0%)
	I don't know	25 (83.33%)

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## Original Article

# Dyslipidemia in Patients with Tuberculosis and Diabetes Mellitus

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**Aims :** To calculate the prevalence of Dyslipidemia in patients with Mycobacterium Tuberculosis infection (Mtb) and Diabetes Mellitus (DM).

**Materials and Methods :** A study done on 294 patients infected with Mtb were enrolled in the study. Patients infected with Tuberculosis (TB) were selected from Medicine and Pulmonary Medicine Departments in MLN Medical College Prayagraj. Patients were segregated into two groups on the basis of glucose tolerance; Abnormal Glucose Tolerance (AGT) and Normal Glucose Tolerance (NGT).

**Results:** A total of 294 patients with TB were taken in the study, 143 patients in AGT group and 151 patients in NGT group. The average age of the patients in AGT group was 47.91 years. Among AGT and NGT, Dyslipidemia was found to be statistically significant among AGT group ( $p=0.01$ ). Mean Serum Triglycerides (209.8,  $p<0.004$ ) and LDL Cholesterol (144.3,  $p<0.0001$ ) in AGT group.

**Conclusion :** Patient with TB DM are more prone for Dyslipidemia and atherogenicity.

[J Indian Med Assoc 2023; 121(2): 41-3]

**Key words :** Dyslipidemia, Tuberculosis, Diabetes, Atherosclerosis.

According to The Global Tuberculosis Report 2019, majority of TB cases in 2018 were in the South-East Asian region (44%). Eight countries contributed for two thirds of the Global total: India (27%), China (9%), Indonesia (8%), the Philippines (6%), Pakistan (6%), Nigeria (4%), Bangladesh (4%) and South Africa (3%)<sup>1</sup>.

Insulin Resistance (IR) has been implicated in various diseases, such as Cardiovascular Disease (CVD)<sup>2</sup>, Hypertension<sup>3</sup>, Polycystic Ovarian Syndrome (PCOS)<sup>4</sup>, Type 2 Diabetes (T2DM)<sup>5</sup>, Obesity<sup>6</sup>, and Metabolic Syndrome (MetS)<sup>3</sup>. The prevalence of MetS in India has been documented to be from 11% to 41% across this vast country with numerous Socio-cultural varieties<sup>7</sup>.

The population in both Urban and Rural areas have increase chances of having DM. A recent review found that DM ranged from 3% to 12% across different Rural areas of the country with an expected rate of increase of 2.0 per 1000 population per year<sup>8</sup>.

Interestingly, the causative agent of TB, Mycobacterium tuberculosis (Mtb), has been shown to rely heavily on host derived lipids for its survival<sup>9-11</sup>. Mtb induces the formation of lipid-loaded foamy macrophages, similar to atherosclerotic lesions and exploits these cells as its primary niche for replication. Several studies have identified high Cholesterol levels as risk factor for TB<sup>12-14</sup> and reducing Cholesterol

### Editor's Comment :

- Lipids plays an important role in development of both diabetes and tuberculosis. Hence it may be beneficial to control lipid profile in patients with TB-DM and further research is required to know its effect on treatment in patients with TB-DM.

levels using statins was beneficial in Mtb infected macrophages, mice<sup>15</sup>.

### MATERIALS AND METHODS

A Total of 294 patients infected with Mtb were enrolled in the study. Patients of TB were selected from Medicine and Pulmonary Medicine Departments in MLN Medical College Prayagraj. All Consecutive adults with TB infection determined Bacteriologically, Histologically, clinically or Radiologically were recruited after informed consent. Patients with serious life threatening TB infection, pregnant women, patients on steroid therapy, those unwilling for study, MDR / XDR TB, HIV, Patient taking lipid lowering agents were excluded.

Informed consent was taken and demographic characteristics, anthropometry and details of the diagnosis of Tuberculosis were obtained. Patients with self-reported history of previous diagnosis of Diabetes and those on treatment with anti-diabetic agents were considered to have DM and no need to have any further testing other than A1C. Patients of DM not previously diagnosed, samples were drawn for A1C and on a subsequent day had an Oral Glucose Tolerance Test (OGTT) on a fasting state. For all the patient's Serum Fasting Lipid Profile was drawn to assess lipid status. Patients were grouped into, either having AGT or NGT. AGT group included patients with Impaired Glucose Tolerance (IGT) and DM.

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**RESULTS**

A total of 294 patients with TB were taken. Of them 143 patients had AGT group, and 151 patients had NGT group. The mean age of the patients in AGT group was 47.91 years while in NGT group was 37.05 years. Majority of patients were male in both the groups.

Maximum patients of AGT and NGT group had a BMI in normal range value ie, 46.8% and 52.3% respectively. On comparison the odds of Glucose intolerance were less in underweight patients (OR=0.45; 95% CI 0.20-1.01; p=0.05) whereas Obese patients had higher odds of Glucose Intolerance (OR = 4.20; 95% CI 0.86-20.4; p=0.05).

Among AGT and NGT, Dyslipidemia was found to be statistically significant among AGT group (p=0.01). Correlation between age and Dylipidemia was calculated and was found to be equal in both the groups( correlation coefficient 0.28 in AGT and 0.27 in NGT group; p<0.001) suggesting age as a non-confounding variable in our study. Mean Serum Triglycerides was 209.8 mg/dl in AGT group and 170.93 mg/dl in NGT group (p <0.004). The LDL Cholesterol in AGT group was 144.3 mg/dl and 97.03 mg/dl in NGT group(p<0.0001) (Tables 1&2 and Figs 1&2).

**DISCUSSION**

A total of 294 TB patients with DM were taken up for study and status of Lipid Profile was determined at

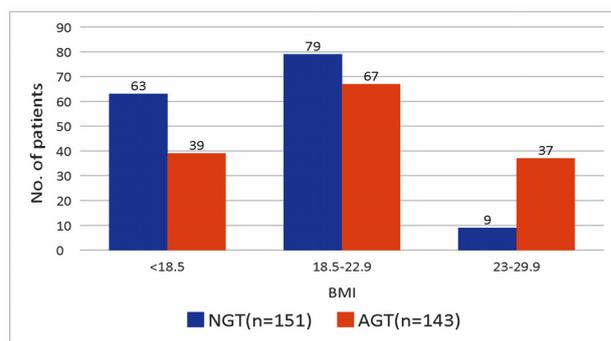


Fig 1 — BMI and glucose intolerance

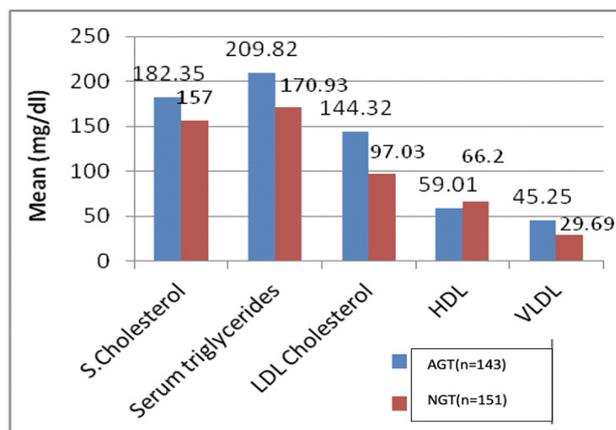


Fig 2 — Association of dyslipidemia in patients with TB and DM

the time of admission. It was found out that mean age in patients with TB and AGT group was significantly higher (47.91 years) as compared to those with TB alone (37.05years, p=0.0001). Gadallah, *et al*<sup>16</sup> in a nationwide population-based study found that screening for DM among 1435 TB patients with no history of DM detected 30 new cases of DM, with a case detection rate of 2.09%. It was found out that majority of patients in AGT group had Dyslipidemia as compared to NGT group which was statistically significant (p=0.01). Mean Serum Triglycerides level and LDL Cholesterol were (209.82 ± 68.03, p<0.004) and (144.32± 24.83, p<0.0001) respectively in AGT group. In this study HDL values were lower and VLDL values were higher in AGT group even though they were not statistically significant. In a similar study done by Vrieling, *et al*<sup>17</sup> on 177 patients it was observed that DM patients had Dyslipidemia as evidenced by high levels of VLDL, Triglycerides and low HDL Cholesterol. They concluded that TB-DM patients possess a distinctive Plasma Lipid Profile with pro-atherogenic properties. Several studies conducted in the past showed

Characteristics	AGT(n=143)	NGT(n=151)	<sup>2</sup>	p -Value
Age :				
<50 years	70(48.9%)	123(81.45%)	34.41	<0.001
>50 years	73(51.1%)	28(18.54%)		
Gender :				
Male	100(69.9%)	92(60.9)	2.6	0.11
Female	43(30.1%)	59(39.1%)		
Residence :				
Rural	100(69.9%)	64(42.4%)	22.59	<0.001
Urban	43(30.1%)	87(57.6%)		
Education :				
Below High school	124(86.7%)	110(72.8%)	8.69	0.003
Above High school	19(13.3%)	41(21.2%)		
Age (Years)	47.91 ± 15.32	37.05 ± 13.58		0.0001
Hb (g/dl)	10.66± 1.61	10.53 ± 1.58		0.08
Serum creatinine (mg/dl)	1.28 ± 0.52	0.95 ± 0.29		0.0001

Lipid profile	AGT(n=143)	NGT(n=151)	p value
S Cholesterol (mean ± SD)	182.35 ±32.26	157 ± 42.37	0.15
S Triglycerides (mean ± SD)	209.82 ± 68.03	170.93 ±85.19	0.004
LDL Cholesterol (mean ± SD)	144.32 ±24.83	97.03 ±41.69	0.0001
HDL Cholestrol (mean ±SD)	59.01 ± 27.94	66.20 ± 26.03	0.18
VLDL (mean ±SD)	45.25 ± 51	29.69 ± 11.89	0.23

the benefits of using statin therapy for decreasing the incidence of TB in elderly population with DM. A study done by Lee, *et al*<sup>18</sup> among 27,958 patients age >65 years and were followed up from 1998 to 2009. A total of 13,981 Type 2 diabetic patients were chosen. Calcium channel blocker, beta blocker, and statin users exhibited a reduced independent association after controlling for age, sex, other co-morbidities, and medications, with risk ratios of 0.76 (95 percent CI, 0.58-0.98), 0.72 (95 percent CI, 0.58-0.91) and 0.76 (95 percent CI, 0.60-0.97), respectively. Calcium channel blocker, beta blocker, and statin medication may reduce TB infection in older Taiwanese patients with Type 2 Diabetes, according to the researchers. Lai, *et al*<sup>19</sup> did another trial with 8098 new TB cases and 809 800 control individuals. Statin users had a lower chance of active Tuberculosis, according to the researchers. Statin use for more than 90 days in a year was linked to the lowest unadjusted risk of Tuberculosis (RR 0.74; 95 percent CI 0.63 to 0.87). After correcting for individual confounders (RR 0.66; 95 percent CI 0.56 to 0.78) and DRS adjustment, the protective effect of active TB persisted (RR 0.66; 95 percent CI 0.56 to 0.78) (RR 0.62; 95 percent CI 0.53 to 0.72). The result of their study showed that patients with Dyslipidemia had reduced chances of infection with active Tuberculosis who were on stations, and the duration of stations offered prevention from Tuberculosis. In a similar study by Liao, *et al*<sup>20</sup> to identify 8,236 patients above 20 years with recent infection of Pulmonary Tuberculosis. Odds Ratio (OR) of Pulmonary Tuberculosis was 0.67 for patients who had been taking statins (95% CI 0.59, 0.75). The adjusted ORs of Pulmonary Tuberculosis were 0.87 (95% CI 0.69, 1.10) for patients with total duration of statins use <3 months, 0.77 (95% CI 0.58, 1.03) for 3-6 months, and 0.59 (95% CI 0.51, 0.68) for ≥6 months, compared with subjects who never used statins. They concluded statins use correlates with a small but statistically significant risk reduction of Pulmonary Tuberculosis. The protective effect is stronger for prolonged use of statins.

### CONCLUSION

In this study it was observed that patients with TB-DM are more prone for Dyslipidemia as compared to patients with TB alone.

**Limitation :** This was a small population study.

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## Original Article

# Profile of Patients with Hypoglycemia Presenting to the Emergency Medicine Department of a Tertiary Care Hospital

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**Background :** Hypoglycemia is a common treatable endocrinological emergency. This study is aimed at profiling patients with Hypoglycemia presenting to the Emergency Department.

**Materials and Methods :** This is a prospective study aimed to know the clinical profile of patients more than 18 years of age presenting with Capillary Glucose Random Blood Sugar value less than 70mg/dl from the period of September, 2018-May, 2020. Results: 123 participants were included in the study among which 69.1% of them were known Diabetes Mellitus with mean duration of 6.9 years. Using the American Diabetes Association (ADA)/ European Association for Study of Diabetes (ESAD) definitions 71.5% presented with severe Hypoglycemia. Neuroglycopenic symptoms were the most common presenting symptom among the diabetics however, autonomic symptoms were the most predominant symptom among non-diabetic population. Drug induced Hypoglycemia was the most common cause among diabetic population accounting for 43.5% and among non-diabetic group 28.9% it was probably due to food intake secondary to fasting. Modified Clarke's score of more than 4 indicated impaired awareness of Hypoglycemia.

**Conclusion :** Education about the prevention of hypoglycemia needs to be initiated from the Emergency Room. Spontaneous Hypoglycemia indicates impaired glucose tolerance. Development of risk stratification score helps in accurate disposition of patients from Emergency Room.

[J Indian Med Assoc 2023; 121(2): 44-8]

**Key words :** Modified Clarke's score.

**D**ietary Mellitus is the most common Metabolic Disorder which presents to the Emergency Department with life threatening emergencies and are important contributors to morbidity and mortality. Hypoglycemia is the most common diabetic emergency and is associated with adverse outcomes<sup>1</sup>. According to the Endocrine Society Guidelines Hypoglycemia is defined as a documented alert value of less than 70mg/dl; while the American Diabetes Association (ADA) stresses that a documented value of 54mg/dl whether symptoms are present or not, denotes clinically important Hypoglycemia<sup>2</sup>.

The International Hypoglycemia Study Group proposed the levels of Hypoglycemia, which included level 1 is glucose alert value of 70 mg/dL or less, level 2 is glucose level of 54 mg/dL is sufficiently low to indicate serious, clinically important Hypoglycemia and level 3 being severe Hypoglycemia, as defined by the ADA denotes severe cognitive impairment requiring external assistance for recovery<sup>3</sup>. Hypoglycaemic coma occurs when Blood Sugar is less than 50mg/dl<sup>4</sup>.

Spontaneous Hypoglycemia a condition referred as the occurrence of hypoglycemia without diabetes, is

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### Editor's Comment :

- Diabetes Mellitus being the most prevalent non-communicable disease the complications of treatment should be identified in emergency room. Prompt recognition prevents the adverse events and helps to eliminate other mimics Hypoglycemic episodes among non-diabetic population may indicate impaired glucose tolerance hence complete evaluation is needed.

a puzzling clinical issue. Reactive Hypoglycaemia a entity of spontaneous Hypoglycemia<sup>5</sup> is defined as postprandial Hypoglycemia seen in non-diabetic individual<sup>6</sup>. But in our Indian background, Sepsis was more commonly associated with Spontaneous Hypoglycemia, however an episode of Spontaneous Hypoglycemia is indicator of Pre-diabetes state<sup>7</sup>.

The body activates defence mechanisms against a hypoglycemic episode by hormonal counter regulation and increased behavioural response, this interplay mechanisms are compromised in advanced Diabetes Mellitus resulting in defective adreno-medullary response and defective neural and sympathetic responses which leads to unawareness of hypoglycemic symptoms. These are components of Hypoglycemia Associated Autonomic Failure (HAAF)<sup>8</sup>. Scoring systems namely Gold and Clarke's score are used to assess the impaired awareness of Hypoglycemia in recurrent episodes of Hypoglycemia, it is evident that high scores individuals have more

neuroglycopenic symptoms than autonomic symptoms<sup>9</sup>.

**MATERIALS AND METHODS**

This is a prospective observational study using a semi -structured questionnaire done in Emergency Room of a Tertiary Care Teaching Institute in Bangalore. All patients above the age of except pregnant women, presenting with Hypoglycemia that is Random Capillary Blood Sugar value less than 70mg/dl to the Emergency department from September, 2018-May, 2020 were included.

**Data and Statistical Analysis :**

The results were averaged (mean ± Standard Deviation) for each parameter for continuous data the percentage for categorical data using student T test, Chi square test and multivariate logistic regression was calculated. In all the above test a “p” value of less than 0.05 was accepted as indicating statistical significance.

**OBSERVATIONS**

Among 123 patients included in the study,85 were already diagnosed Diabetes Mellitus among these patients 95.3% had Type 2 Diabetes Mellitus. The mean duration of Diabetes Mellitus was 6.9 years. According to the ADA/ European Association for Study of Diabetes (ESAD) definition 71.5% presented with severe Hypoglycemia (Fig 1).

The maximum number of Hypoglycemic episodes occurred among 60-69 years of age in diabetic population at 27.6% as compared to 23.7% episodes occurred among 30-39 years in non-diabetic population. The mean age of occurrence of hypoglycemic episode was 58.2±17 years.52.8% of hypoglycaemic episodes occurred in females. In 31.8% among diabetic population hypoglycemic episodes occurred in early morning hours. Among non-diabetic population 39.5% had presented with hypoglycemic episode in timeline of 12pm-6pm (Table 1).

Among the diabetic group 43.5% presented with altered sensorium,34.1% presented with both dizziness and loss of consciousness, 24.7% presented with fever, 22.4% presented with sweating and among non-diabetic population 39.5% presented with sweating, 36.8% with dizziness and 34.2% presented with altered sensorium.

Among 123 participants on comparing the onset of symptoms with different ranges of Glucose Random Blood Sugar (GRBS) values 54.1% presented with altered sensorium within

**PERCENTAGE OF HYPOGLYCEMIA AMONG DIABETICS VERSUS NON DIABETICS**

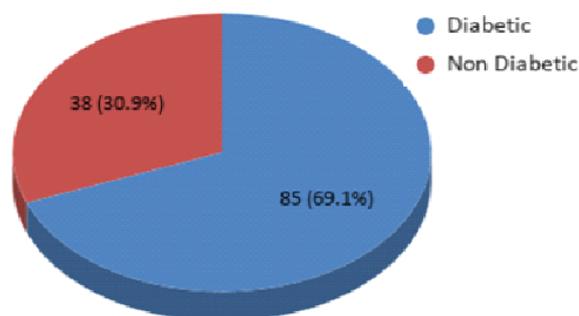


Fig 1 — Distribution of Diabetic Status among Hypoglycemia

GRBS range of 20-30mg/dl. Autonomic symptoms were the presenting symptom in patients with GRBS more than 30 mg/dl.

Most common cause for a hypoglycemic episode among the diabetic was drug induced Hypoglycaemia out of which 32.5% occurred in Oral Hypoglycemic Agents (OHA) users and 20.3% occurred in both oral hypoglycemic and insulin users. It was evident that sulphonylureas and insulin mixtard were the common offending agents. Among the non-diabetic group 28.9% hypoglycemic episodes were due to inadequate food intake, followed by Liver Cell Failure at 18.4%. Sepsis accounted for 15.8% cases of hypoglycemia, among the focus of Sepsis, Urosepsis ranked first followed by Pneumonia which included the COVID 19 infection also (Table 2).

Among the 85, who had already existing Diabetes Mellitus, 33% had a hypoglycemic episode in the past 12 months and all had Modified Clarke’s score of more than 4. The association between onset of Hypoglycemia and Modified Clarke’s scoring was significant.

Among 123 patients 60% were admitted ,44.7% were discharged against medical advice. Among non-diabetic population 28.9% went discharge against medical advice. Died in Emergency Room was 2.6% among non-diabetics.

Table 1 — Demographic Characteristics

Parameter		Diabetic (N=85)		Non-diabetic (N=35)		Total (N=123)		P value
		N	%	N	%	N	%	
		AGE	20-29 years	4	4.7%	6	15.8%	
	30-39 years	0	0.0%	9	23.7%	9	7.3%	
	40-49 years	6	7.1	8	21.1	14	11.4	
	50-59 years	16	18.8	4	10.5	20	16.3	
	60-69 years	28	32.9	6	15.8	34	27.6	
	70-79 years	21	24.7	4	10.5	25	20.3	
	80-89 years	10	11.8	1	2.6	11	8.9	
Gender	Male	43	50.6	15	39.5	58	47.2	0.254
	Female	42	49.4	23	60.5	65	52.8	

Causes	Diabetic (N=85)		Non-diabetic (N=38)		Total (N=123)		P value
	N	%	N	%	N	%	
Inadequate Food Intake	14	16.5%	11	28.9%	25	20.3%	0.112
Sepsis	29	34.1%	6	15.8%	35	28.5%	0.037
Liver Cell Failure	0	0.0%	7	18.4%	7	5.7%	<0.001
Drug Induced (OHA/Insulin)	37	43.5%	1	2.6%	38	30.9%	<0.001
Alcohol Intoxication	1	1.2%	5	13.2%	6	4.9%	0.004
Other Causes							
Carcinoma							
Duodenum	0	0.0%	2	5.2%	1	1.6%	0.001
Idiopathic	0	0.0%	5	13.2%	5	4.1%	
Insulinoma	0	0.0%	1	2.6%	1	0.8%	

**DISCUSSION**

In our study Hypoglycemia was more common in known diabetics than non-diabetic population which is attributed to the fact that most of the patients were on medications for Diabetes Mellitus.

The prevalence of Type 2 Diabetes Mellitus is more than Type 1 Diabetes Mellitus and this was evidenced by the fact that 95.3% were diagnosed Type 2 Diabetes Mellitus and 4.7% were Type 1 Diabetes Mellitus. This was consistent with a retrospective study done by Jordi Caballero, *et al* at Hospital Universitario de Bellvitge in Emergency Room 81.9% episodes occurred in type 2 diabetic and 16.1% occurred in Type 1 Diabetic<sup>10</sup>.

Many studies on Hypoglycemia used the study definition of Hypoglycemia as Glucose Random Blood Sugar (GRBS) <40mg/dl. Hence our data of level 2 Hypoglycemia according to International Hypoglycemia Group classification being the most common at 71.5% was inconsistent (Fig 2).

27.6% of total hypoglycemic episodes occurred in the elderly age group of 60-69 years however, among non-diabetics 23.7% episodes occurred in a young age group of 30-39 years. These findings were almost consistent with a study done by Ohenhen Oluwatoyin Abisoye, *et al* at a Tertiary Health Institution at Nigeria in which among diabetics 38% episodes occurred in 55-64 years of age and 31% occurred in 65-74 years of age<sup>11</sup>.

Among non-diabetic group there were 27 episodes in less than 60 years of age which is consistent with findings done by

Krishnaraj, *et al* in 2010 in which total 108 participants, 61 episodes occurred in less than 65 years of age<sup>12</sup>.

In our study the mean age among diabetic group was 63.9 years which was similar with study done by Satish, *et al* on clinical profile of Hypoglycemia in which the mean age of patients ranged from 61.6 years<sup>13</sup>. The mean age among non-diabetic population was 46.1 years. This was comparable with the finding done by Santra, *et al* in which the mean duration among non-diabetics is 42.84

years<sup>14</sup>.

52.8% participants were female, however among diabetic group the gender distribution was approximately equal among both genders. In our study among non-diabetics 60.5% were females, which was similar to a study done by Ekpebegeh *et al* among 26 non-diabetic patients out of which 65.4% were females<sup>15</sup>.

31.8% participants among known Diabetics Mellitus, had an episode during early morning hours which was in conformity with a study done by Ohenhen Oluwatoyin Abisoye, *et al* among diabetic patients, 51.7% had hypoglycemic episodes in the early morning hours<sup>11</sup>. In our study among the 38 non-diabetics, 39.5% had a hypoglycemic event in noon hours. This is a new finding as no much studies had been done on the time of presentation of non-diabetic hypoglycemia which needs further studies.

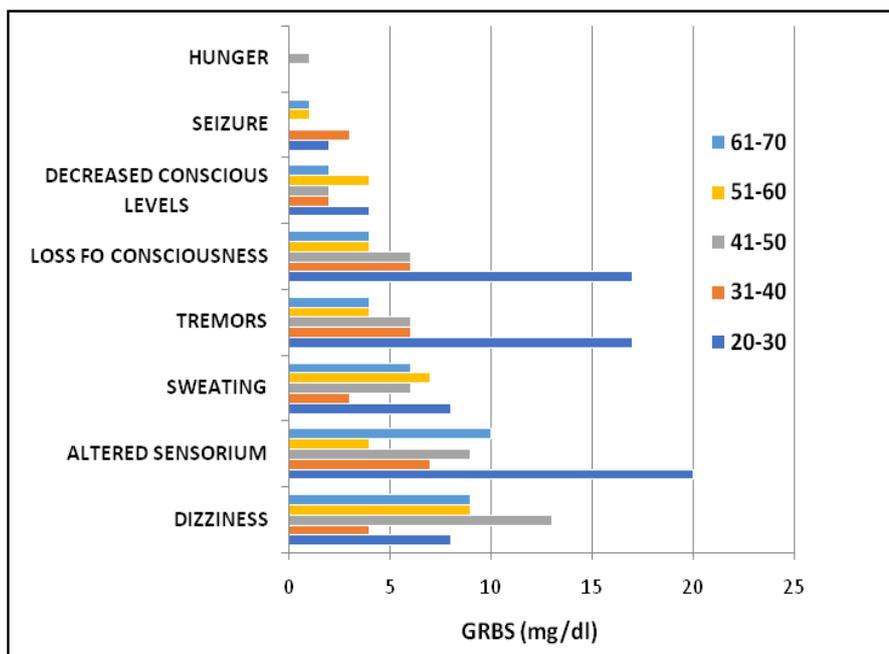


Fig 2 — Association of GRBS with Symptoms of Hypoglycemia

The mean GRBS value among diabetic was 39.7 mg/dl, this value was similar with the study conducted by Satish *et al* in which the mean GRBS was 37.12 mg/dl<sup>13</sup>.

40.7% patients presented with altered sensorium which indicates that neuroglycopenic symptoms are the most common presenting symptoms of Hypoglycemia which was consistent with study done by Kumar, *et al* in which 59.3% presented with decreased conscious levels<sup>2</sup>.

Among 123 participants on comparing the onset of symptoms with different ranges of GRBS values 54.1% presented with a neuroglycopenic symptom, altered sensorium within range of 20-30mg/dl. However autonomic symptoms such as sweating were common in patients with GRBS value >30mg/dl. This implies the importance of counter regulatory hormones in the pathophysiology of Hypoglycemia, which helps to counsel the patients regarding various symptoms onset.

Another than Diabetes Mellitus, among 51% systemic Hypertension was associated comorbidity, which was similar to the study done by Caballero *et al* who found in 73.3% systemic hypertension was the most associated comorbidity<sup>10</sup>.

Among the non-diabetic population malignancy was the most common underlying comorbid conditions. However, in the studies done on non-diabetic Hypoglycaemia, have emphasized on the fact that Hypoglycemia can present as undiagnosed malignancy.

Among non-diabetic group autonomic symptom such as sweating were common at 39.5%. This finding in conformity with a study done Gharbi, *et al* among 40 non-diabetic patients, 82.5% presented with autonomic symptoms<sup>16</sup>.

In our study among 123 participants, 30.9% had a hypoglycemic event secondary to anti-diabetic medication, this finding is consistent with the study done by Kumar, *et al* among 320 diabetics out of which 59.81% were diagnosed drug-induced hypoglycemia<sup>2</sup>.

Among the drug-induced Hypoglycemia 32.5% were OHA user's, followed by 20.3% were on OHA's and insulin, this was consistent with the study done by Ohenhen Oluwatoyin Abisoye, *et al* 60.7% were on OHA drugs and 32.6% were both OHA plus insulin users<sup>12</sup>. Among OHA user's 39% occurred among the diabetics who were on monotherapy, out of which 14.6% were on sulphonylureas closely followed by 13.8% on biguanides which was similar to the study conducted by Eren, *et al* among 225 patients, 64 subjects were using oral hypoglycemic drugs out of

which 43 were on sulphonylureas<sup>17</sup>.

In our study among the non-diabetic group 28.9% of hypoglycemic event was due to inadequate food intake due to fasting among 32% of participants followed by Liver Cell Failure. This was inconsistent with the study done by Ekbepegh, *et al* in which the main cause for Hypoglycemia was hypercortisolism attributed to underlying retroviral status of the patient<sup>15</sup>.

In our study by correlating the most common time of presentation of Hypoglycemia being the noon hours and the most common cause being inadequate food intake secondary to fasting the possibility of underlying impaired glucose tolerance among non-diabetic group was found. This is a new finding and further studies are needed regrading Hypoglycemia among non-diabetic population.

In this study among 28.5% the cause of hypoglycemic event was sepsis, out of which 34.1% was in the diabetic group which is inconsistent to the fact that infections are the most common cause for Hypoglycaemia among non-diabetics<sup>12</sup>. This can be due to a smaller number of non-diabetic patients were included in this study. However, considering the focus of Sepsis 32.4% was diagnosed urosepsis, which is consistent with the study done by Indu, *et al* in which among the 10 patients diagnosed Hypoglycemia secondary to infection most common was urosepsis diagnosed in three patients<sup>18</sup>. Also among the causes of sepsis 5.9% had hypoglycemic event due to COVID-19 during the pandemic.

38.5% of them had a previous episode of Hypoglycemia among the 85 already diagnosed Diabetes Mellitus in past 12 months and all had a Modified Clarke's score of more than four indicating that there was impaired awareness of hypoglycemic symptoms and thus this episode is a recurrence of Hypoglycemia. This was correlating with study done by Geddes, *et al* showed strong association between Modified Clarke's score and impaired awareness thus recurrent Hypoglycemia<sup>9</sup>.

In 55.3% patients the outcome from Emergency Room was admission for further management It was also noted that in non-diabetic group discharged against medical advice was most common outcome. There were two deaths, with sepsis accounting for 1.6%. This is consistent with the study done by Makoto, *et al* among patients with Sepsis had increased mortality among hypoglycemic group<sup>19</sup>.

#### Limitations :

- It is a single center study.
- Difficulty in taking history from the patient himself, more reliability on the attender's history which

can be a source for information bias.

- Among the non-diabetic with hypoglycemia most of them went discharge against medical advice which attributes to missing out the etiology.

### CONCLUSION

71.5% presented at level 2 Hypoglycemia and above, but considering the non-diabetics level 1 Hypoglycemia was the commonest. Neuroglycopenic symptoms occurred in Capillary Blood Sugar levels of 20-40 mg/dl while autonomic symptoms were the presenting symptom above 30mg/dl. Sulphonylurea induced hypoglycemia was the most common cause for hypoglycemia among the diabetics. In the non-diabetic group, it was evident that more hypoglycemic episodes occurred during noon hours which raise the concern for pre-existing impaired glucose tolerance. Hypoglycemia among the non-diabetic population needs further studies. Hypoglycemia was also the presentation for COVID-19 in diabetic population. The Modified Clarke's scoring system evaluated in patients proved that a score of more than 4, indicates impaired awareness and recurrent Hypoglycaemia. The overall death was 2.6% in Emergency Room due to Multiorgan Failure due to Sepsis.

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## Original Article

# A Study on Sexually Transmitted Infections Using Syndromic Approach among Patients Attending Suraksha Clinic at a Tertiary Care Hospital of West Bengal

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**Introduction** : A proper understanding of different aspects of Sexually Transmitted Infections (STIs) in different regions of a country like India is very essential for STI control.

**Objectives** : To assess pattern of STIs using Syndromic approach among patients attending at Suraksha Clinic and to find out treatment seeking behaviour among them.

**Material and Method** : A cross-sectional study was conducted at a Tertiary Care Hospital of West Bengal. This retrospective study was done selecting all patients who attended the Clinic for first time from 1<sup>st</sup> May, 2020 to 30<sup>th</sup> April, 2021. Relevant records were reviewed. Descriptive statistics and chi-square test were used.

**Observations** : In present study Suraksha Clinic attendees were mainly comprised of female (95.8%); while 65.8% and 64.2% of patients were suffering from Lower abdominal pain and Cervicovaginal discharge respectively. Nearly one-third of them (37.9%) were suffering from more than one disease. About one-fourth of patients (28.2%) accessed the STI/RTI/Suraksha Clinic directly. The treatment seeking behaviour was significantly associated with gender and education of patients.

**Conclusions** : This Tertiary Care Hospital based study highlighted higher prevalence of certain STIs among attendees to Suraksha Clinic as well as lower proportion of male and directly walk-in patient.

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**Key words** : Suraksha Clinic, Syndromic approach, Treatment seeking behaviour.

Group of illnesses which are caused by infections, transmitted by sexual contact through exchange of semen, vaginal fluid, blood and other fluids, are called Sexually Transmitted Infections (STIs); it also transmitted by direct contact with the affected body areas of people with STIs. No doubt that it leads to huge Psycho-social consequences both at the individual as well as at the community levels<sup>1</sup>. It also plays an important role in the acquisition and transmission of HIV<sup>2</sup>. Besides its contribution to the substantial burden of mortality and morbidity, have made it as one of the major public health problems affecting both developing and developed countries<sup>1,3</sup>.

The pattern of STIs is found usually to vary from region-to-region, especially in large nations like India<sup>3</sup>. In our country, the assessment and management of patients is still largely based on syndromic approach suggested by the National AIDS Control Organization (NACO)<sup>4</sup>. Thus the information regarding the profile of STIs relies essentially on syndromic diagnosis<sup>5</sup>.

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### Editor's Comment :

- The local epidemiology of STIs addressing lower male attendees to Suraksha clinic and higher prevalence of certain STIs, would be better explored through research with help of grass-root Health workers.

Control Society (WBSAP&CS) is going to ensure better access of STI/RTI related services to the people in need by establishing the 'Suraksha Clinics' at all those hospitals which are not covered by STI Services under NACP-IV, as new initiative. Therefore, new STI clinics are going to be established at Sub-division Hospitals & State General Hospitals also. At present, total 46 (fourty six) STI Clinics are currently running by WBSAP&CS in this State<sup>6</sup>.

In order to plan and implement successful targeted interventions and to combat problem of STIs, availability of current baseline information of STIs in the various parts of the country is essential. Literature review shows that information regarding Suraksha Clinic as well as pattern of STIs is scarce in West Bengal. So, present study was planned among patients attending at Suraksha Clinic, to generate valuable information regarding the pattern of STIs using syndromic approach and to find out treatment seeking behaviour of them.

### MATERIAL AND METHOD

A retrospective study with cross-sectional design

was conducted with help of the relevant records of STI patients at Suraksha Clinic of a Tertiary Care Hospital of West Bengal over the period of past one year from 1<sup>st</sup> May, 2020 to 30<sup>th</sup> April, 2021. Complete enumeration technique was followed to select all study subjects who visited the Clinic for first time during study period. Data were collected through careful review process of counsellor's patient register and clinical records of STI patients.

Data were collected after scientific review and ethical approval of the synopsis by Institutional Ethics Committee. Confidentiality and anonymity of patients' information was assured. Patients were categorized mainly as per the NACO guidelines<sup>7</sup> into Genital Ulcerative Disease-Herpetic (GUD H), Genital Ulcerative Disease Nonherpetic (GUD NH), Cervicovaginal discharge, Lower abdominal pain and Urethral discharge.

Collected data were checked for completeness and consistency and then the data were entered in the computer on Excel data sheets (Microsoft Excel, 2013). The principles of descriptive statistics were applied to organise and present the data in tables and diagrams. Proportions in relation to different outcome variables were also calculated. Data were analysed using Statistical Package for Social Sciences [IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, New York, United States]. Appropriate statistical tests such as Chi-square test were applied.

### OBSERVATIONS

Overall 4348 patients visited at Suraksha Clinic of the Tertiary Care Hospital in West Bengal during study duration, while 2132 study subjects visited for the first time. These patients with first time visit at the Suraksha Clinic were included in present study. Among the total patients more than half were (57.7%) were belonging to 25 to 44 years age group, nearly one-twentieth (4.2%) were male. Overall three-fourth of patients (75.8%) were formally educated while 2.9% were illiterate and 21.3% were non-formally educated. Majority of the patients (71.8%) were referred and 28.2% accessed the STI/RTI clinic directly.

Majority of them were suffering from lower abdominal pain (65.8%) followed by Cervicovaginal discharge (64.2%), GUD-Non herpetic (3.1%), GUD-Herpetic (2.8%)(Table 1). On further analysis, it was noted that 808 (37.9%) patients had more than one STI. Only two study subjects were found to be HIV-positive.

Addressing treatment seeking behaviour among patients whether suraksha clinic was accessed directly or referred, it was explored that

Table 1 — Distribution of study subjects according to certain characteristics (n=2132)

Characteristics	Frequency	Percent
<b>Age (years) :</b>		
<20	435	20.4
20-24	390	18.3
25-44	1231	57.7
>44	76	3.6
<b>Gender :</b>		
Male	90	4.2
Female	2042	95.8
<b>Education :</b>		
Illiterate	63	2.9
Non-formally educated	455	21.3
Class I - Class IV	460	21.6
Class V - Class VIII	1078	50.6
Class IX and above	76	3.6
<b>Direct walk-in/ Referred :</b>		
Direct walk-in	602	28.2
Referred	1530	71.8
<b>Syndromic diagnosis* :</b>		
Cervicovaginal discharge	1369	64.2
GUD-Non herpetic	66	3.1
GUD-Herpetic	59	2.8
Lower abdominal pain	1402	65.8
Urethral discharge	17	0.8
Other STIs	25	1.2

Note : \* Multiple responses

the behaviour was significantly associated with gender (<0.001) and education (<0.001) of patients (Table 2).

### DISCUSSION

Present study revealed that major issues among study subjects were Lower abdominal pain (65.8%) and Cervicovaginal discharge (64.2%). Corroborating with present study Cervicovaginal discharge was noted as most common problem among patients at STI-clinic of a Tertiary Care Hospital of Rajasthan (38%)<sup>4</sup>. Sharma S, Tiwari S, Paliwal V, *et al* noted in a study of patterns of Sexually Transmitted Diseases using a Syndromic approach from a Tertiary Care Hospital of the Northern India that vaginal/cervical discharge (13.4%) was remarkable problem<sup>5</sup>. In addition to this, among females of STI-clinic, Cervicovaginal discharge constituted the maximum proportion of cases at a Tertiary Care

Table 2 — Association between treatment seeking behaviour and certain characteristics of patients

	Direct walk-in [No (%)]	Referred [No (%)]	Chi-square test
<b>Age (years) :</b>			
≤24 years	242 (30.1)	563 (69.9)	2.128 (1) 0.145
>24 years	360 (27.1)	967 (72.9)	
<b>Gender :</b>			
Male	81 (90.0)	9 (10.0)	176.899 (1) <0.001
Female	521 (25.5)	1521 (74.5)	
<b>Education :</b>			
Illiterate and Non-formally educated	110 (21.2)	408 (78.8)	16.550 (1) <0.001
Others	492 (30.5)	1122 (69.5)	

Hospital of the Northern India (61.04%)<sup>5</sup> and at a Tertiary Care Hospital of Eastern India (29.9%)<sup>8</sup>. However, Genital Ulcer Disease-herpetic was reported as most common problem among patients of STI-clinic at a Tertiary Care Hospital of North India (21.75%)<sup>3</sup>, at a Tertiary Care Hospital of Eastern India<sup>8</sup> as well as among male patients at a Rural-based Tertiary Care Center (24.37%)<sup>9</sup>. Again a study on patterns of Sexually Transmitted Diseases using Syndromic approach from a Tertiary Care Hospital of the Northern India explored that the overall most common STI was balanoposthitis (39.62%)<sup>5</sup>.

Lower abdominal pain was noted in very lower proportion than present study (65.8%) at a Tertiary care Hospital of Rajasthan (2.3%)<sup>4</sup>, at a Tertiary Care Hospital of the Northern India (2.66%)<sup>5</sup>. Such variation in observation might be explained by the way of diagnosis (ie, syndromic approach, investigation based), Socio-economic diversity across the country, sampling technique of different studies and comparatively less male participants in present study.

In present study only two study subjects were found to be HIV-positive. On the contrary, newly diagnosed HIV cases were noted 0.4% in such a study at a tertiary care hospital of Rajasthan<sup>4</sup> as well as HIV prevalence was reported as widely varied proportion (2.48% to 10.59%) in different studies at STI-clinic in tertiary care hospital across the country<sup>3,5,8,9</sup>.

In present study majority of the patients (71.8%) were referred. On the contrary, Suvirya S, Singh R and Senthamizh P, *et al* in a study regarding treatment seeking behaviour of STI clients in a Tertiary Care Centre of North India found that majority of the patients (84.7%) accessed the STI/RTI clinic directly and only 15.3% were referred<sup>10</sup>.

Pearson's Chi-square test revealed in present study that treatment seeking behaviour had a significant association with gender and education but not with age of patients. The study regarding treatment seeking behaviour of STI clients in a Tertiary Care Centre of North India showed similar significant association with age, gender and education of patients<sup>10</sup>.

### CONCLUSIONS

This Tertiary Care Hospital based study highlighted higher prevalence of certain STIs among attendees to Suraksha Clinic, among whom majority were female and referred patient. The treatment seeking behaviour was significantly associated with gender and education of patients. The local epidemiology of STIs would be better understood through research with help of grass-root health workers. Such further exploration regarding STIs may help us to implement STI control programs successfully as well as to address the Global efforts to combat HIV/AIDS.

### Recommendations :

Information, Education and Communication (IEC) techniques need to be strengthened to spread awareness about STI-clinics among general population as well as to increase utilization of such clinics at Tertiary Care Centre by them through direct walk-in. Besides proper training of the Health Care Providers, condom promotion, partner notification and partner management, persuasive counselling to attendees may motivate their peer group to avail the Suraksha Clinic facilities provided by the NACO.

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## Original Article

# Aesthetic Reconstruction of Scrotum after Fournier's Gangrene using Laterally based Medial Thigh Fasciocutaneous Flap

Aravind Lakshmana Rao<sup>1</sup>, Vishnu PS<sup>2</sup>

**Introduction :** Fournier's Gangrene is a rapidly progressive necrotising fasciitis affecting the genital region, perineum, perianal region and the abdominal wall. It can have an adverse effect on the functional and psychological aspects of the patient. Many flaps are available for the defect coverage.

**Aim :** The aim of this prospective study was to analyse the effectiveness of laterally based medial thigh flap for scrotal reconstruction. This is a fasciocutaneous flap just below the Scrotum which covers moderate to large sized scrotal defects successfully.

**Methods and Materials :** This study was done at a teaching hospital in South India on patients with major scrotal defects secondary to Fournier's Gangrene. Ten patients with major scrotal defects secondary to Fournier's gangrene were subjected to reconstruction of scrotum by medial thigh fasciocutaneous flap.

**Results and Conclusions :** All ten flaps survived and provided a durable and aesthetic cover for exposed testes. Only one flap had necrosis of distal 2cm, which was successfully managed by secondary suturing. The donor areas were primarily covered with placement of a small graft near the base of the flap, which healed well with an inconspicuous scar. In conclusion, the laterally based medial thigh fasciocutaneous flap provides excellent closure for extensive scrotal skin loss. It is a robust flap, easy to mobilise, rarely undergoes necrosis, provides a sensate cover with excellent aesthetic results. The technique is simple, less time consuming and can be easily incorporated by plastic Surgeons and General Surgeons.

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**Key words :** Fournier's Gangrene, Fasciocutaneous flap, Scrotal reconstruction, Medial thigh flap.

Fournier's Gangrene is an acute, rapidly progressive and potentially fatal, infective necrotising fasciitis affecting the external Genitalia, perineal or perianal regions<sup>1</sup>. Fournier's gangrene was first described by Jean Alfred Fournier in 1883<sup>2</sup>. Injury to the perineal area continues to be the most frequent reason for the entry of bacteria that mediates the infectious process<sup>3</sup>.

Fournier's Gangrene presents with major soft tissue loss and may even be lethal<sup>4</sup>. Since the testes have an independent blood supply, they are spared and remain exposed<sup>5</sup>. Fournier's Gangrene can lead to an extensive skin loss involving the Scrotum, Penis, Thighs and Lower abdomen. After thorough surgical debridement, major scrotal and perineal defects along with exposed testes have to be dealt by Plastic Surgeons<sup>6</sup>.

Different surgical procedures were used to cover the exposed testes. Earlier methods for testicular salvage were: covering with skin grafting, burying them

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### Editor's Comment :

- Aggressive debridement and appropriate antibiotic cover followed by regular dressings is the mainstay of management in Fournier's Gangrene involving scrotum.
- Durable and aesthetic cover of the exposed testicles is the need of the hour after proper debridement.
- Laterally based Medial thigh flap is a suitable option to cover the exposed testicles and also gives good aesthetic outcome.

underneath the medial thigh skin, tissue expansion of adjacent tissues and use of local fasciocutaneous or musculocutaneous flap<sup>4</sup>.

Reconstruction of the Scrotum is important for Functional, Cosmetic and Psychological reasons<sup>7</sup>. The scrotal region requires durable coverage as it is an essential gland that produces sperm and is the representative organ of masculinity<sup>8</sup>. Early scrotal coverage with single-staged sensate flap that provides complete and adequate protection of exposed testicles is the ideal choice<sup>9</sup>.

The aim of the present study was to evaluate the effectiveness of laterally based medial thigh fasciocutaneous flap in reconstruction of Scrotum in patients with Fournier's Gangrene.

### MATERIALS AND METHODS

This prospective study involves ten patients of

Fournier's Gangrene undergoing laterally based medial thigh fasciocutaneous flap for reconstruction of Scrotum. Ethical Committee clearance was taken from the institution before commencement of the study. All patients were referred from the Department of General Surgery after thorough debridement and proper antibiotic treatment. The patients were aged between 38 and 62 years with the average being 51.3. Among the subjects, seven also had involvement of other areas like perineum, perianal region and lower abdomen along with exposed testes. Five patients had associated Diabetes Mellitus. Three with extensive perianal and lower thigh involvement had undergone Diversion Colostomy to accelerate wound healing. Consent was taken from all the subjects for inclusion in the study.

### Pre-operative Preparation :

Antibiotics were administered as per Culture and Sensitivity Reports. Diabetes was controlled using insulin therapy. Thrice daily saline dressing was done to reduce the bacterial colonisation of the wound before Surgery. All the subjects were catheterised using Foley's indwelling catheter. Groin area was inspected to rule out bacterial or fungal infection. Bowel preparation was done in all except those who had Colostomy.

### Surgical Technique :

Patient was made to lie down in supine position and a folded linen or sand bag was placed below the same thigh for comfortable access to medial aspect of thigh. Thorough saline wash was given to scrotal, perineum and perianal region. Wound margin was freshened (Figs 1a & 1b). Dimensions of the defect were measured in two dimensions. Template was designed as per the dimensions of the defect. Before making incision for the flap, reverse planning was done several times using the template, to confirm the reach of the flap. Template was placed just below the defect over the medial thigh. The flap margins were marked. The superior margin of the flap corresponded with inferior border of the defect. The medial vertical margin was also marked as per template. The inferior margin was marked parallel to the superior margin. Lignocaine and adrenaline injection was infiltrated beneath the

flap to reduce bleeding. The flap elevation was started from medial to lateral direction. Deep fascia was incised; tagging sutures were taken between deep fascia and dermis to prevent shearing of septo-cutaneous perforators. Flap was raised above adductor muscle of the thigh. Septo-cutaneous perforators, while elevating the flap were cauterised using bi-polar diathermy. After sufficient elevation of the flap, it was inset to the scrotal defect. A dependent suction drain was used routinely in all cases. In the donor area, distal portion was primarily closed and proximal part near the base of the flap was grafted. Bolster dressing was applied over skin graft. Remaining defects over thigh, perianal, or lower abdomen were either closed primarily or skin grafted. Padded scrotal dressings were applied (Figs 2a & 2b).

### Postoperative Care :

The patients were positioned in the supine position to avoid compression and traction on the flap. Flap was inspected on second day; however, the graft bolster dressing was kept undisturbed. Graft dressing was opened on fifth day and staples were removed and patient was discharged with regular follow-up. All the cases were followed for six months (Figs 3a, 3b & 3c).

### RESULTS

Ten laterally based medial thigh fasciocutaneous flaps were performed to reconstruct Scrotum in patients



Fig 1a — Scrotal defect



Fig 1b — Flap marking



Fig 2a — Elevation of the flap



Fig 2b — Flap inset

with Fournier's Gangrene. The subjects were followed up for six months. The wounds healed satisfactorily in all patients included in the study. There was partial flap necrosis of two cm in one patient requiring



Fig 3a — Defect exposing testes



Fig 3b — After flap cover



Fig 3c — Follow up after 6 months

debridement and secondary suturing. Minor graft loss over the donor area was noticed in one patient, which healed by secondary intention in three to four weeks. Sutures were removed after two weeks. Flap fused well with the native Scrotum and suture line was inconspicuous after six weeks. The suture line mimicked the normal anatomical median raphe in those patients, where half of the Scrotum was reconstructed by flap. The crude touch and pressure sensation over the flap was almost equal to that of native Scrotum. Normal hair growth was noticed on the flap after four weeks. All subjects were happy about the cosmetic appearance of the Scrotum. The details of patients are mentioned in Table 1.

#### DISCUSSION

Many surgical options have been used to reconstruct exposed Testes in Fournier's Gangrene. Reconstruction of the Scrotum is vital for functional, aesthetic and psychological reasons<sup>6</sup>. The ideal reconstructive approach would seem to incorporate the following flap features: A single stage procedure, excellent flap reliability, sensate flaps with potential for normal function, minimal donor-site morbidity and simplicity<sup>6</sup>.

Scrotal cover using split skin grafting leads to graft loss and subsequently shrinkage of Testicles<sup>4</sup>. Aesthetically, skin graft is not acceptable to the patients and skin graft will remain as an anaesthetic patch. Moreover, normal hair growth will not be present over grafted skin. The placement of Testes in medial

thigh leads to exposure of Testes to core body temperature and may affect Spermatogenesis. Other issues like dragging pain while walking and cycling and later leading on to Testicular Atrophy has been reported<sup>10</sup>.

The problems associated with this procedure are constant pain caused by mechanical trauma and Testicular Atrophy<sup>11</sup>. Laterally based medial thigh flap is a reliable fasciocutaneous flap, which can be performed in reasonable short operative time for defects of any size. The donor scar and grafted areas are hidden in the medial aspect of the thigh.

The fasciocutaneous flap of the medial thigh has rich blood supply due to the presence of branches of the femoral artery (internal and circumflex pudendal), making the flap very safe even in diabetic and vasculopathic patients<sup>11</sup>.

Flap should be planned immediately at the lower border of the defect; the inferior margin of the defect forms the superior border of the flap. This step prevents the skin bridge between the defect and the flap. The width of the flap corresponds to the width of the defect.

The minor drawback of this technique is that, the inset of the flap is deficient at the root of the Scrotum. Postoperatively, patient experiences serous discharge from this part for a period of two to three weeks. Some patients also complained of mild dragging pain in this region due to attachment of the flap medially. Flap division and inset done under Local Anesthesia relieved both the above problems.

In the surgical technique explained by Ayad, *et al*<sup>6</sup>, the dominant pedicle is located over the apex of the femoral triangle 6-8 cms below the inguinal ligament. There is a need for Doppler examination before starting the procedure to locate the pedicle. After elevation of the flap from distal to proximal direction, careful dissection is required to prevent the injury to the pedicle. Our technique does not require either Doppler examination or

Table — Patient demographics of Fournier's Gangrene in our hospital

Age	Site	Flap dimension)	Complications	Hospital stay
44	Scrotum	8 X 5 cm	Nil	18
42	Scrotum & penis	9 X 4 cm	Nil	13
38	Scrotum	7 X 5 cm	Nil	10
48	Scrotum & abdomen	8.5 X 5.5 cm	2cm flap necrosis	16
56	Scrotum & perineum	7.5 X 5 cm	Nil	18
61	Scrotum, perianal & ABD	9.5 X 6 cm	Partial graft loss	12
58	Scrotum & penis	8 X 6.5 cm	Nil	19
54	Scrotum	6 X 3.5 cm	Nil	11
50	Scrotum, perineum & penis	8.5 X 5 cm	Nil	14
62	Scrotum, ABD & perineum	9 X 5.5 cm	Nil	16

meticulous dissection of the flap.

Mageed, *et al*<sup>4</sup> have explained their technique of anteromedial fasciocutaneous thigh flap in which the flap is proximally based and longitudinally oriented and the base of the flap was drawn on the anteromedial aspect of thigh at the level of the inguinal crease. The vascular supply to this flap is the rich suprafascial plexus of vessels present at the anteromedial thigh. However, this technique requires bilateral flaps to cover larger defects.

Pudendal thigh flap provides good quality skin and good support. Even though there is need for bilateral flaps, primary closure of the donor area is an additional advantage of this flap<sup>10</sup>. Fasciocutaneous thigh flaps can cover medium to large-size defects. The pedicled antero lateral thigh perforator flap is another good alternative for reconstruction of extensive defects of penoscrotal area<sup>2</sup>. Fasciocutaneous medial thigh flap was sufficient for the defects in our study group.

The advantages of our technique are :

- Single stage reconstruction of scrotal defect of any size using one flap only.
- Restoration of normal skin color and hair on the Scrotum, as the flap is designed from adjacent area.
- Preservation of sensation over the flap.
- Donor area is hidden in the medial aspect of the Thigh.
- Durable cover to the exposed Testicles.
- Good aesthetic result.

#### CONCLUSION

Early recognition and diagnosis, followed by Emergency Surgery, are the keys to treating these cases and for prevention of Systemic Sepsis, Potential Organ Failure and Death<sup>12</sup>. The laterally based medial thigh fasciocutaneous flap provides excellent cover for

extensive losses of scrotal skin. It is a very robust flap, can be easily mobilized, rarely undergoes Necrosis, and provides sensate cover and excellent Aesthetics. The technique is simple, less time consuming, does not require complex flap planning, and hence can be easily incorporated by Plastic Surgeons and General Surgeons as well.

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— Hony Editor

## Review Article

# Off-Pump Coronary Artery Bypass Grafting Surgery : A Narrative Review

Mansour Jannati<sup>1</sup>, Fatemeh Jannati<sup>2</sup>

Coronary Artery Bypass Grafting (CABG) Surgery is considered the standard treatment for revascularization in Coronary Artery Disease. The Off-Pump Coronary Artery Bypass Graft (OPCAB) which evades the use of Cardiopulmonary Bypass (CPB) became a popular CABG procedure, due to the adverse effect of CPB. Hypothetically, OPCAB may improve the rates of perioperative Myocardial Injury, Neurocognitive Impairment, Stroke and Mortality. However, some studies showed no superior outcomes for OPCAB compared to on-pump CABG. This study aims to evaluate the short-term and long-term outcomes of OPCAB versus On-Pump CABG. The results showed that OPCAB is probably a safe procedure for patients, especially for those with high-risk conditions. OPCAB procedure showed superior short-term outcomes in terms of Myocardial Infarction, Systemic Inflammatory Response, Postoperative Cognitive Dysfunction, Renal Failure, Stroke, Pulmonary Complication, Postoperative Transfusion, Hospital stay length and infection than On-pump CABG. However, regarding long-term outcomes, Off-Pump CABG had a higher rate of incomplete revascularization and repeat revascularization and a higher risk of long-term mortality as well as lower graft patency. Furthermore, the result showed that the higher experience of the surgeons in OPCAB improves the outcome of the Surgery.

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**Key words :** Off-Pump Coronary Artery Bypass Grafting Surgery, OPCAB, Short-term Outcomes, Long-term Outcomes.

Coronary Artery Disease (CAD) is the main reason for death Globally and AHA estimated that CAD leads to more than 360,000 deaths each year<sup>1</sup>. Coronary Artery Bypass Grafting (CABG) considers the main standard treatment for CAD<sup>2</sup>. The first CABG was done in the 1960s as the only treatment method for Ischemic Heart Disease<sup>3</sup>. Developments in Cardiopulmonary Bypass (CPB) have improved Cardiac Surgery; however, the non-physiological effect of CPB leads to organ dysfunction and tissue injury. In addition, cerebrovascular events related to CPB are a significant problem<sup>4,5</sup>. As the number of patients undergoing CABG increases, solutions to reduce the alleged adverse effects of CPB due to aortic manipulation and clamping have been evaluated. Therefore, Off-Pump CABG (OPCAB) became popular in the 1990s<sup>6</sup>. In the United States, OPCAB peaked in 2002 and almost 25% of all CABG in operations were done Off-Pump<sup>6</sup>. In Japan, in 2000, and after the emersion of the stabilizer, OPCAB has become a prevalent practice for CABG, and now about 65% of CABG cases are done by OPCAB<sup>7</sup>.

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### Editor's Comment :

- The comparison of Off-Pump CABG and On-Pump CABG has yielded mixed results.
- Off-Pump procedure is safer with lesser short term complications though long term outcomes like incomplete revascularization, repeat revascularization and poor graft patency is more in off pump revascularization.

After many years of using the OPCAB procedure and publishing many trials and meta-analyses about the benefits of this method, there is still controversy on the outcomes and advantages of Off-Pump CABG. The present review summarizes the most recent and relevant data about this method and evaluates the short-term and long-term outcomes of Off-Pump CABG.

### MATERIALS AND METHODS

In this review study, all articles on Off-Pump Coronary Artery Graft surgery were evaluated from the year 2000 to 2021. Articles were searched through databases such as PubMed, Web of Science, Scopus, Google Scholar, Science Direct and Cochrane library using the keywords "Off-Pump Coronary Artery Graft Surgery", "OPCAB", "Short-term outcomes" and "long-term outcomes". A total of 167 articles were extracted in an initial search. After reviewing the abstract of these articles, finally, 68 articles that met the necessary criteria of the present review were selected and evaluated completely.

### OPCAB in High-Risk Patients :

In a meta-analysis by Kowalewski, *et al*, it was shown that the odds of Cerebral Stroke are significantly decreased in OPCAB in comparison to conventional CABG in high-risk patients. Furthermore, they showed that there is a significant association between patients' risk profile and benefits from OPCAB in Myocardial Infarction (MI), Death and Cerebral Stroke, proposing that in high-risk patients, OPCAB must be toughly considered. Therefore, they concluded that OPCAB improves the short-term outcomes in high-risk patients<sup>8</sup>. In a prospective randomized trial study on 411 patients, it was found that OPCAB decreases primary mortality as well as morbidity in high-risk patients<sup>9</sup>.

In Kerendi, *et al* study it was revealed that the risk-adjusted outcomes for mortality and morbidity endpoints in high-risk patient populations were superior after OPCAB versus On-Pump CABG<sup>10</sup>. The result of Rastan, *et al* study on high-risk patients demonstrated that patients with reduced left ventricular function and multi-risk patients benefit from OPCAB in terms of perioperative mortality and morbidity. Furthermore, in patients with major extracardiac risk factors, OPCAB reduced the rate of Perioperative Stroke. In individuals with Pulmonary or renal Dysfunction, OPCAB resulted in a reduction in the failure of the organ. OPCAB resulted in a lower need for transfusion in high-risk populations<sup>11</sup>.

### Morbidity and Mortality after OPCAB :

In a study on 118,140 CABG procedures, that 11,717 cases of them were OPCAB, the use of the OPCAB method was related to a reduction in risk-adjusted operative mortality from 2.9% with the On-Pump method to 2.3% in the OPCAB group. Also, the risk-adjusted morbidity rate was reduced from 14.15% with On-Pump CABG to 10.62% in OPCAB group<sup>12</sup>. Bittner, *et al* evaluated 57 multivessel diseases OPCABG cases for 2 years and reported that Off-Pump CABG can be done with rational low morbidity and mortality in high-risk patients<sup>13</sup>. Vettath, *et al* also showed that Off-Pump CABG resulted in an improvement in the mortality rate over time<sup>14</sup>. Takagi, *et al* studied eight medium- to large-size RCTs including 8780 patients with long-term follow-up OPCAB versus on-pump CABG and revealed that OPCAB rises long-term (5 years or more) mortality in comparison to On-Pump CABG (ONCAB)<sup>15</sup>. In another study, they demonstrated that OPCAB is related to an increase in very long-term, 10 years and more, all-cause mortality in comparison to ONCAB<sup>16</sup>.

### OPCAB and Systemic Inflammatory Response :

The systemic inflammatory response is probable after CABG using CPB which comprises the

complement and Leukocyte activation, pro-inflammatory cytokines releasing Nitric Oxide metabolism changes, and an increase in the free radical's Oxygen production that may lead to organ dysfunction and coagulation conditions<sup>17</sup>. Schulze, *et al* showed that the OPCAB revascularization process and not using CPB significantly diminishes the Systemic Inflammatory Response Syndrome and the need for primary catecholamine. This can help to the improvement of Organ Function, also improvement of recovery from surgery<sup>18</sup>. Neshar, *et al* study demonstrated that Serum cytokine levels (IL-6, IL-8 and IL-10) in the OPCAB method were lower in comparison to the on-pump method<sup>19</sup>. In another study, OPCAB attenuated the systemic release of IL-8 and IL-10, whereas no difference was seen in the release of IL-6, CRP and Neutrophils. Signs of cytokine uptake were seen in the Lungs by OPCAB<sup>20</sup>. In Meng, *et al* study, the analyses presented that the concentration of IL-10 was significantly lower after OPCAB in comparison to on-pump CABG. But, for IL-6 and IL-8 no significant differences were observed in the two groups<sup>21</sup>.

### Postoperative Cognitive Dysfunction in OPCAB :

Cerebral Dysfunction including Postoperative Cognitive Dysfunction (POCD), delirium and stroke after Cardiac Surgery remains a devastating problem, especially in the older age group. They may happen as a result of cerebral emboli, inflammation, or hypoperfusion<sup>22</sup>.

In Sun *et al.* study, a Meta-analysis of 13 randomized controlled trials on 2326 patients it was demonstrated that the occurrence of POCD was significantly lower following OPCAB than On-Pump in 1-2 weeks and at 3 months after Surgery<sup>23</sup>. In a study by Szwed, *et al*, it was shown that anaortic OPCAB significantly reduced the rate of postoperative cognitive dysfunction and delirium compared to conventional OPCAB<sup>24</sup>. Schmitz, *et al* also found that postoperative neurocognitive function significantly improves by OPCAB<sup>25</sup>. In another study, Off-pump CABG decreased postoperative Neuropsychological dysfunction in elderly cases in comparison to on-pump CABG<sup>26</sup>. However, in Lund, *et al* study, long-term cognitive function after OPCAB was similar to on-pump coronary Artery Bypass Grafting Surgery<sup>27</sup>. Similarly, Marasco *et al* meta-analysis indicated no significant neurocognitive advantage while using OPCAB in comparison to on-pump CABG<sup>28</sup>.

### Postoperative Renal Dysfunction and OPCAB :

Postoperative Renal Dysfunction is a significant complication of CABG and is associated with the

patient's clinical condition, CPB-related events, renal hypoperfusion, hypotension, hypothermia, microemboli, and stimulation of the inflammatory response<sup>29,30</sup>. According to Umit, *et al* study, the Off-Pump CABG offers excellent renal protection and a significantly lower risk of Renal Dysfunction compared with conventional CABG<sup>31</sup>. Abu-Omar *et al* in a study on 1580 patients showed that Off-pump CABG is associated with a decrease in postoperative renal damage<sup>32</sup>. Rocha, *et al* reported that OPCAB is related to improving in-hospital renal outcomes in patients with moderate renal failure, but is not related to the long-term cumulative occurrence of end-stage renal failure which needs permanent Dialysis<sup>33</sup>.

#### Postoperative Pulmonary Dysfunction and OPCAB:

One of the prevalent difficulties after CABG is pulmonary complications associated with surgical procedures, anaesthesia procedure effects, and Cardiopulmonary bypass pump<sup>34</sup>.

A study by Staton *et al.* reported that OPCAB was associated with a greater decrease in postoperative respiratory compliance compared to the on-pump method. Moreover, OPCAB resulted in superior gas exchange and earlier extubation<sup>35</sup>. According to Raja *et al.* study, based on available evidence from RCTs, OPCAB reduces Postoperative Pulmonary Dysfunction and is more effective than On-Pump CABG for Chronic Obstructive Pulmonary Disease (COPD) patients<sup>36</sup>. Silva, *et al* study also revealed that patients in the OPCAB group had higher improvement in pulmonary function after Surgery than On-Pump group<sup>37</sup>. However, in Montes, *et al* study Off-pump CABG in comparison to the On-Pump method did not result in important protection from postoperative pulmonary dysfunction<sup>38</sup>.

#### OPCAB and Postoperative Arterial Fibrillation :

Postoperative Atrial Fibrillation (AF) is a common arrhythmia that happens after CABG. OPCAB is considered to be a less invasive technique and is believed to reduce the rate of AF, however, there is inconsistency in obtained data. Athanasiou, *et al* demonstrated a reduction in the occurrence of postoperative AF with Off-Pump CABG techniques. However, they suggested that the results should use with caution<sup>29</sup>. Lewiki *et al.* reported no difference between the incidence of AF after OPCAB and ONCAB surgeries. Böning *et al.* also showed no alteration in the rate of postoperative AF by using OPCAB<sup>39</sup>. In the Junior, *et al* study, Off-pump CABG did not decrease the occurrence of postoperative AF. They also defined age >70 years old and preoperative AF as risk factors

for postoperative AF<sup>40</sup>.

#### Incomplete Revascularization in OPCAB :

In this Cohort Ji, *et al* on 1,349 patients with a triple-vessel lesion, the occurrence of Off-Pump incomplete revascularization was 19.9%<sup>41</sup>. In a report on 41,139 patients with the left main and three-vessel lesion, the rate of incomplete revascularization in 6,367 OPCAB patients was about 29.0%<sup>42</sup>. In a SYNTAX trial by Head, *et al*, the incomplete revascularization rate was 36.8% after OPCAB<sup>43</sup>. Another study including 7,427 OPCAB cases and 7,128 on-pump CABG cases demonstrated that the incomplete revascularization rate of the Off-Pump method was 13.3%<sup>44</sup>.

#### Repeat Revascularization and OPCAB :

Takagi, *et al* analysis showed that OPCAB may raise the rate of repeat revascularization by 38% over ONCAB<sup>45</sup>. In a meta-analysis study by Zhou, *et al*, it was found that OPCAB increases the rate of repeat revascularization in comparison to ONCAB at 1-year follow-up, but not at 5-year follow-up<sup>46</sup>.

#### Graft Patency After OPCAB :

Hattler *et al.* study demonstrated significantly lower graft patency for OPCAB than On-Pump CABG<sup>47</sup>. Parolari, *et al* study in a meta-analysis of randomized studies showed a reduction in postoperative graft patency of Coronary Artery Bypass Grafts done by OPCAB methods<sup>48</sup>. Another study by Houliand, *et al* found that graft patency after Off-Pump CABG was lower than the On-Pump method even with heparinization protocols<sup>49</sup>. However, Puskas, *et al* reported that graft patency was similar for OPCAB and on-pump CABG at 30 days and one year<sup>50</sup>. Hu, *et al* also revealed no significant differences in graft patency between OPCAB and ONCAB GROUPS in Triple Vessel Coronary Artery Disease patients<sup>51</sup>.

#### Conversion in OPCAB :

Regardless of the popularity of OPCAB and its benefits, in a small number of patients, conversion to on-pump CABG may be required due to reasons including hemodynamic disturbance, physical difficulty in grafting, ischemia, or arrhythmias. Chakravarthy *et al.* reported that conversion in OPCAB is related to significant mortality raise. Increased left ventricular end-diastolic pressure, women's gender and pre-operative need for Intra-aortic balloon are indicators of amplified mortality risk in conversion<sup>52</sup>. According to Tariq, *et al* study, emergency conversion from OPCAB to on-pump is the most disastrous occurrence leading to higher morbidity and mortality. Conversion as a result of

arrhythmias was the main cause (rate: 9%) and patients with higher New York Heart Association status and Chronic Obstructive Pulmonary Disease had a higher risk of emergency conversion. Therefore, they suggested that the decision for OPCAB should be made with caution for each patient<sup>53</sup>. In Keeling, *et al* study, intra-operative conversion from OPCAB to on-pump was reported to be a morbid incident. They recommended that elective ONCAB should be selected for those with a higher risk for conversion. They also found that older age, preoperative intraaortic balloon pump placement, ejection fraction <35%, increasing number of involved vessels, Heart Failure and emergent procedural condition were independent markers for conversion<sup>54</sup>.

### OPCAB and Surgeons' Experience :

The important role of Surgeons' experience in OPCAB was highlighted frequently by professionals in the field. Benedetto, *et al* showed that mortality was reduced after OPCAB when done by high-volume surgeons in high-volume OPCAB centers and in contrast the mortality risk increased when OPCAB was done by surgeons in low-volume centers<sup>55</sup>. In the Glance *et al.* study it was found that for On-Pump CABG Surgery, higher surgeon case volumes are related to lower rates of mortality<sup>56</sup>. In another study by Chen, *et al*, it was shown that by Increasing the experience of a surgeon the rate of blood transfusion was reduced by about 33%<sup>57</sup>. Hsu, *et al* evaluated the proficiency of surgeons for OPCAB by the following quality indicators, the revascularization index, and the conversion rate. They reported that a revascularization index of  $\geq 1.4$  and a conversion rate of  $\leq 5\%$  show the proficiency of surgeons for OPCAB<sup>58</sup>. Hemil, *et al* reported that the occurrence of emergency conversion during OPCAB has reduced with raising surgeons' experience; however, in these patients, the rate of morbidity remained unaffected<sup>59</sup>.

### Short-term Outcomes of OPCAB :

In a meta-analysis, by Reston, *et al* the results showed that rates of perioperative myocardial Infarction, Reoperation for bleeding, Renal failure, Stroke and Mortality were lower after OPCABG than after CABG. They also showed a decrease in hospital stay length, AF and wound infection related to OPCABG, however, the differences were not statically significant<sup>60</sup>. In a study by Elmahrouk, *et al* on 450 patients, it was found that the rate of early postoperative AF and Renal Failure was decreased in the Off-Pump group. But, no statistically significant difference was observed in neurologic complications, AML, or early mortality between Off- or On-Pump groups<sup>61</sup>. Gao, *et al* evaluated the short-term outcome

in 318 high-risk patients who underwent CABG and found that the OPCAB group had significantly decreased ventilator support time, Postoperation ICU time, operative mortality and morbidity<sup>62</sup>. Guan, *et al* performed a meta-analysis and systematic review on 32,354 patients and reported a significant benefit from OPCAB in terms of 30-day mortality, MI, stroke, renal failure, Infection, Pulmonary complication, Postoperative transfusion, and reoperation bleeding. They showed no significant difference in AF and Neurological Dysfunction<sup>63</sup>. Kowalewski, *et al* performed a meta-analysis on 100 studies (19,192 patients) and demonstrate a significant decrease in the odds of cerebral stroke in the OPCAB group compared with on-pump CABG<sup>8</sup>.

### Long-term Outcomes of OPCABG :

In Luo, *et al* study on seven RCTs and 9,128 patients, in long-term follow-up OPCAB had a significantly higher rate of revascularization (OR=1.45; p=0.04) than on-pump CABG<sup>64</sup>. Chikwe *et al.* evaluated long-term results on 6,950 who underwent Off-Pump CABG and reported a rise in repeat revascularization, incomplete revascularization and mortality at 10 years in comparison to ONCAB<sup>65</sup>. A meta-analysis by Takagi, *et al* on 22 studies, and more than 100,000 patients, disclosed that OPCAB is probably related to worse long-term survival (5 years or more) compared with ONCAB<sup>66</sup>. In another study on 13 studies including 13,234 patients, Off-pump CABG increased the risk of all-cause death and repeat bypass surgery at long-term, more than 4-year follow-up<sup>67</sup>. In a study on 5,203 patients by Kim, *et al* it was reported that for overall mortality, patients who underwent Off-Pump CABG had a significantly higher risk of mortality (HR: 1.43; p<0.0001) in comparison to those who underwent ONCAB<sup>68</sup>.

### CONCLUSION

OPCAB is probably a safe substitute for On-Pump CABG for patients, especially with high-risk conditions. OPCAB procedure showed superior short-term outcomes in terms of Myocardial Infarction, renal Failure, Stroke, Pulmonary Complication, Postoperative Transfusion, Hospital stay length and Infection than On-Pump CABG. Also, it was shown that the OPCAB revascularization process significantly diminishes the systemic inflammatory response syndrome. In addition, OPCAB significantly reduced the rate of early postoperative cognitive dysfunction compared to conventional OPCAB. However, regarding long-term outcomes Off-Pump CABG had a higher rate of incomplete revascularization and repeat revascularization and a higher risk of long-term mortality

as well as lower graft patency. Furthermore, the result showed that the higher experience of the surgeons in OPCAB improves the outcome of the surgery.

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## Review Article

# A Study of the Epidemiology of Childhood Blindness and Plan of Action in Bihar

**Vishwa Ratan<sup>1</sup>**

Vision Disorders are among the most common disabilities to affect children. Childhood Blindness is an important Public Health Problem due to inequalities in the Social and Economical conditions of Bihar State.

Moreover it's a significant component of WHO vision 2020 program. By Public Health Interventions, the prevalence of cases of Childhood Blindness can be reduced. With this background, a study was done in assessment of the epidemiology of childhood blindness, with suggestions of plan of actions to reduce the prevalence of childhood Blindness which will lead to educational opportunities and improvement in mental and general health.

This study had limitations due to average Health infrastructures and record keeping from PHC to Medical colleges. But at the same time, still a lot of timely Neonatal Eye Care Services and proper refraction strategies have helped in prevention of Childhood Blindness.

In this study, the principals of epidemiology has been followed, as to finding the answers of "Who, Where and Why" regarding Childhood Blindness in Bihar.

The current prevalence of blindness in children is known to be around 0.6%. Despite various intervention programs. This Public Health Problem a challenge both from epidemiology and care provider point of view.

[J Indian Med Assoc 2023; 121(2): 62-3]

**Key words :** Strong School Health program intervention, Awareness of kitchen gardening.

### Methods :

Information from search engines used included Pubmed, Google scholar. Field visits to different levels of Health infrastructure, like PHC, CHC, District Hospitals and Medical Colleges, while working in a, Govt, UNICEF sponsored project Hospital Records<sup>1</sup>.

### Community Based Survey :

From verbal discussion with Eye Specialists, Program Managers and Health Workers.

From Health Department Records available in State Blindness Control Cell<sup>1</sup>.

### Observations :

The main cause of Childhood visual impairment was Refractive Errors. Under Blindness Control Programme till date 3.5 lacs children have been examined at schools of Bihar over a period of nearly fourteen years from 1999 to 2013. The important observation being that the majority of children suffered from Refractive errors. Random sampling of 15 district records out of total 38 districts were done.

Districts with high percentage of Refractive errors Sharsha, Supual, Madhepura, Rhotas, Kishanganj, Darbhanga, Banka, Madhubani and Sitamadhi. This in terms of percentage is 60% Districts with low

### Editor's Comment :

- School Health Check up program, Should be strengthened and implemented Seriously.
- Awareness about kitchen garden and use of roof tops of the hutments for growing Vegetables.
- Data collection and analysis of childhood blindness should be done on an Annual basis.

percentage of refractive errors Munger, Nalanda, Nawada and Begusarai, Arrah, Gaya. This in terms of percentage is 33.33%

The findings showed that North Districts across River Ganges had more cases of Refractive Errors than Districts of South and Central Bihar.

The possible causes of high percentage in North Bihar Districts being Poverty, Malnutrition.

Yearly floods causing loss of livelihood leading to poor economic status.

The second largest cause of childhood blindness was Vitamin-A deficiency.

The Prevalence of childhood blindness due to Vit-A deficiency per thousand was as follows :

Year	PR
2000	0.40
2005	0.25
2010	0.02

The OPD records on random study of District Hospitals showed that, South Bihar showed a bigger percentage of cases in comparison to North Bihar.

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The possible cause being rich fruit plantation like papaya, mangoes, which are consumed in large children population. Practice of hut roof for agriculture purpose is very common in villages, of North Bihar, where papaya can be grown.

With intervention of Vitamin-A deficiency control program sponsored by UNICEF for nearly five years played a very crucial role in bringing down the prevalence rate of Vitamin-A deficiency cases. Moreover, this program also led to huge reduction in Gastroenteritis cases in children.

**Thus breaking the vicious cycle of —**

Diarrhea-malnutrition- vitamin-A def- blindness<sup>2</sup>.

3. Lately with more access to Health Care Facilities, other causes too were also identified

Coloboma of Iris

Congenital Cataract

Microphthalmos

Possibly, Hereditary reasons are responsible for these ocular morbidity.

Many cases of ocular trauma were also recorded.

**Discussion :**

The impact of Vitamin-A blindness program, supported by UNICEF, had a great impact in Vitamin-A deficiency both in terms of the incidence and prevalence leading to decreasing the burden of Childhood Blindness. After the program, robust immunization programme, which includes Vitamin-A administration to children had also a great impact<sup>2</sup>.

The School Health Check-up Programme, which includes detection of Refractive Errors and general examination of Eye, too had been very successful. A large number of children with Refractive Errors were detected, which was eventually corrected by giving glasses, which can lead to reduction of Amblyopia in future years.

**The observations suggests that —**

Strengthening of refractive services at Primary and Secondary level of school going children.

Screening of Eyes at school levels, as well at health facilities like PHC, CHC, District Hospitals should be done regularly.

Provision of low vision devices at low or free should be done.

**Plan of Actions/ strategy to be adopted for control of childhood Blindness.**

Establishment of Paediatric Ophthalmic Department in Medical and District Hospitals.

Low vision clinics should be provided at District Hospitals.

Training programs in Paediatric Ophthalmology should be carried out regularly<sup>1</sup>.

**Conclusions :**

Regular small survey should be carried out by Ophthalmologist in their respective areas, which will go a long way in prevention of Childhood Blindness. The observations should be documented and published.

There should be continuum of health promotion of Health programs along with Rehabilitation. A comprehensive eye care approach in control of Childhood Blindness should be a priority by the health planners and providers.

**Conflict of Interest :** No financial support

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- 2 UNICEF Supported field visits as State program officer (Control of Blindness).

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## Review Article

# A Study of the Urethral and Stretched Penile Lengths in the Adult, Indian, Male Population

Rishi Amritlal Grover<sup>1</sup>, Hiren Vaidya<sup>2</sup>, Hamir Rajatiya<sup>3</sup>, Mohua Moitra<sup>4</sup>

There are few contemporary studies about the normal Urethral and Penile Length and the paucity of data about the same is surprising. This paper aims to add to the existing sparse anatomical data about the same. 264 male patients (age 18-82 years) admitted at a Tertiary Care Center, for any non-urological indication, between January, 2019 and April, 2020, who fulfilled the inclusion and exclusion criteria, were included in the study. The methodology was based on direct measurement of the Stretched Penile Length (penopubic junction to tip of glans) and estimating the Urethral Length by measuring the exposed segment of an indwelling Foley catheter and subtracting it from the total catheter length (measured from the base of balloon to the 'Y' junction). The mean Urethral Length was 17.8 cm (14-30 cm) and the mean Stretched Penile Length was 7.8 cm (5-12 cm). There was no correlation between the age, BMI and Urethral Length or the Stretched Penile Length.

[J Indian Med Assoc 2023; 121(2): 64-6]

**Key words :** Male Urethral Length, Stretched Penile Length.

The indwelling Urethral Catheter is an ubiquitous device and transurethral access is almost mandatory for Endoscopic Surgeries in Urology. While there are a multitude of studies on penile length in children and adolescents<sup>1-6</sup> and adults<sup>7-9</sup>, there are very few contemporary studies about the Urethral Length<sup>10,11</sup> and the paucity of data about the same is surprising. This paper aims to add to the existing sparse anatomical data.

### MATERIALS AND METHODS

264 male patients at a Tertiary Care Center, admitted for any non-urological indication, between January, 2019 and April, 2020, who fulfilled the inclusion and exclusion criteria, were included in the study.

#### Inclusion Criteria :

All male patients admitted at a Tertiary Referral Center for any non-urological indication.

Only patients who already had an indwelling catheter were included.

#### Exclusion Criteria :

Age less than 18 years

Any prior history of Transurethral, Urinary Bladder,

#### Editor's Comment :

■ This study adds to the scant global data on normal urethral length and almost non-existent data on the normal, adult, penile length in the Indian subcontinent. The findings can be invaluable for optimizing size of urethral devices and especially for customizing penile implants for the Indian population.

Prostate or Penile Surgery (except circumcision).

H/o prior traumatic urethral catheterisation or instrumentation

Any patient where such history was not available, could not be elicited or where immobility or altered sensorium precluded weighing or accurate measurements.

Similarly, any patients with visible orthopaedic prosthetic devices like external fixators were also excluded to avoid skewing of the BMI estimation.

Any patient having a urethral catheter other than a Foley catheter eg, Nelaton catheter or infant feeding tube etc.

Any patient with an endocrine condition (previously known or evident on examination) which could affect development of the genitalia.

Any patient where examination showed anomalies of the external Genitalia or Urethra like hypospadias or epispadias.

No patient was catheterised solely for the purpose of the study. History and informed consent was obtained from the patient and/or an attendant and the penile measurements were all taken with the subjects in supine posture. The brand of the indwelling catheter was noted. The catheter was then held upright without

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traction and the flaccid penile length noted. The penis was then stretched gently and the catheter was marked at the level of the external Urethral Meatus using an indelible marker (mark 'C'). Using a commercially available steel ruler, the Stretched Penile Length was then noted by resting the base of the ruler perpendicular from the pubic symphysis. The length of the catheter from the 'Y' junction of the catheter (marked 'B') to this marking was measured. The length of the Urethra was estimated by subtracting the length 'BC' from the length 'AB'.

Thereafter, the patients were weighed taking care to see that the urine collecting bags were emptied before doing so and the height was measured in erect posture.

**Markings were as follows :**

**A (notional) :** The base of the Foley catheter balloon (which rests at the bladder neck)

**B (actual) :** The 'Y' junction of the Foley catheter

**C (actual) :** The marking on the catheter at the level of the external Urethral meatus

Thus the Urethral Length was calculated as follows:

$$AB - BC = AC \text{ (Estimated Urethral Length)}$$

Where AB is the distance from the Bladder neck to the 'Y' junction of the catheter, BC is the distance from the 'Y' junction till the external meatus and AC is the estimated distance from the Bladder neck till the external urethral meatus (the urethral length) (Fig 1).



Fig 1 — Foley Catheter With Measurement Markings

The data were tabulated, basic statistics derived and statistical analysis done for correlation between the various measurements (Tables 1-4).

**RESULTS**

There was no correlation between the age, BMI and Urethral Length or the Stretched Penile Length. A weak correlation was demonstrated between estimated

Parameter	Median	Mean	Min	Max
Age (years)	38.5	41.4	18	82
Height (cm)	165	163.2	132	190
Weight (kg)	65	63.3	35	98
Body Mass Index (BMI)	23.7	23.8	15.1	36.2
Catheter Size (Fr)	18	16.7	12	18
Length of Urethra (cm)	17	17.8	14	30
Stretched Penile Length (cm)	7.95	7.8	5	12

Table 2 — Age Distribution

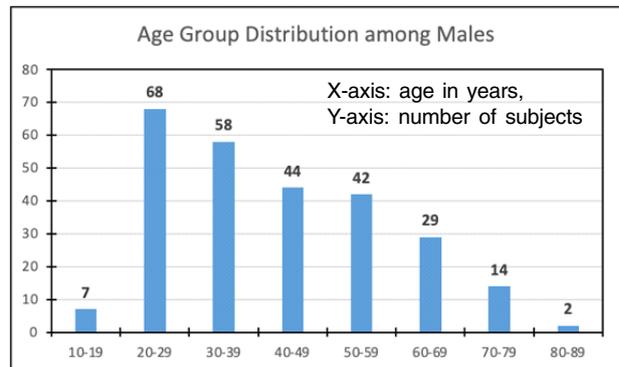
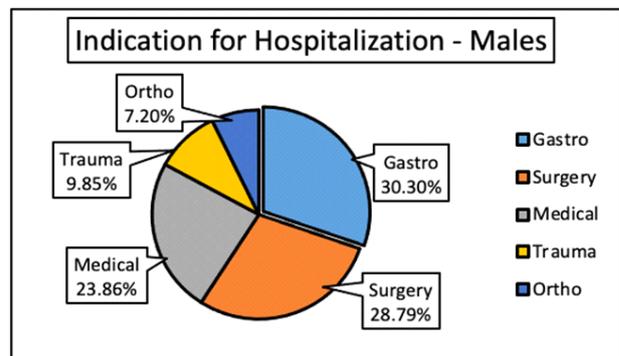


Table 3 — Indication for Hospitalization



Ortho-Orthopedics, Trauma-Any non-urological trauma, Medical-Any medical illness, Gastro-Any medical or surgical gastrointestinal or hepatobiliary pathology, Surgery-Any general surgical procedure

Urethral Length and the Stretched Penile Length. The 'p' value for BMI versus stretched Penile Length was significant (<0.05) but the R/PE value was less than 6, hence the correlation is not considered as significant. This correlates with previously published data<sup>10</sup>.

**DISCUSSION**

MRI has been used to study Urethral Anatomy and has the advantage of being non-invasive and also identifying additional conditions like inflammation, Sinuses, Fistulae or Diverticula<sup>12</sup>. However, it is operator and software dependent. On the contrary, measurements using urethral catheters<sup>10,11</sup> give a direct and more reliable estimate of the urethral length and are less observer dependent.

The advantage of our technique was that neither was any patient catheterised for the sole purpose of the study, nor did the measurement require removal of any indwelling catheter. While due diligence was done during data collection and all the data was collected by the same investigator, the measurements could have been affected by the degree of stretch on the penis and the amount of suprapubic fat.

There is no gold standard or best technique accepted for measuring Stretched Penile Length and we used the penopubic skin junction to glans tip measurements. We did record the flaccid penile girth for all subjects in this series, but did not include it in the analysis

as this correlates poorly with erect measurements<sup>13</sup>. Given the location of the study and the fact that the subjects were catheterised and admitted for some pathology, measurement of erect penile girth or length was not feasible. The pubic bone to tip of glans measurement is more accurate and reliable, while the penopubic skin to glans measurement can be affected by Obesity<sup>14,15</sup>.

Also, we have not taken into consideration the duration of hospital stay at the time of the study which may have had some effect on the weight. Similarly, we have also not taken into account the effect on weight of any debilitating illnesses or malignancies which the patients may have been suffering from. However, since the total number of patients falling into these categories was miniscule, we presume that these did not have a significant bearing on the final results (Table 5).

### CONCLUSIONS

Our data adds to the existing scant information about the male Urethral and Penile Length available in the literature. The same may be applied to optimising the size of Urethral and/or Penile devices or implants for the Indian subcontinent.

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	BMI versus UL		UL versus SPL		BMI versus SPL		Age versus SPL	
R	-0.03	-2.66%	0.24	24.00%	-0.13	-12.64%	-0.12	-11.56%
R <sup>2</sup>	0.00	0.07%	0.06	5.76%	0.02	1.60%	0.01	1.34%
Coeff Alienation(K)	1.00	99.93%	0.94	94.24%	0.98	98.40%	0.99	98.66%
t	-0.43		4.00		-2.06		-1.88	
p value	0.67	66.68%	0.0001	0.01%	0.04	4.01%	0.06	6.07%
Std Error (SE)	0.06		0.06		0.06		0.06	
Probable Error (PE)	0.04		0.04		0.04		0.04	
R/PE	-0.64		6.14		-3.10		-2.82	

BMI : Body Mass Index, UL : Estimated Urethral Length, SPL : Stretched Penile Length

Parameter	Kohler <sup>10</sup>	Krishnamoorthy <sup>11</sup>	Aslan <sup>7</sup>	Spyropoulos <sup>9</sup>	Our study
n=	109	422	1132	52	264
Mean Urethral Length (cm)	22.3	17.55			17.8
Urethral Length range (cm)	15 - 29	14 - 22.5			14 - 30
Stretched Penile Length (cm)			13.7	12.18	7.8

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## Case Report

### Stroke — Next Wave of Complications from COVID-19

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Since the declaration of COVID-19 infection as Pandemic in March, 2020, There has been rise in Multisystem Complications apart from regular Acute Respiratory Syndrome which is hallmark of COVID-19 infection. As the second wave surge of COVID-19 has occurred, most of the patients already suffered from dyspnoea but also rare complications like CVA (Infarct and Haemorrhage), Seizure and altered sensorium related to Hypoxic Brain Injury. COVID-19 frequently presents with a state of altered coagulability which increases the risk of pulmonary embolism and other Thrombotic events such as Cerebrovascular events. This case report is limited to Neurological complications seen in COVID-19 Infected patients.

[J Indian Med Assoc 2023; 121(2): 67-8]

**Key words :** CVA, Acute Respiratory Distress Syndrome, Coagulability, Neurological.

The COVID-19 infection caused by SARS-CoV-2 virus has been declared Pandemic by World Health Organization since March, 2020<sup>1</sup>. The most frequent presentation of the disease is viral pneumonia with fever and dry Cough, Acute Respiratory Syndrome due to COVID-19 infection was primary identified in Wuhan City, China on January, 2020<sup>2</sup>. there is evidence of heterogeneous spectrum of Multisystem involvement due to distribution of ACE receptors over different sites in human body.

COVID-19 frequently presents with a state of altered coagulability which increases risk of Pulmonary embolism and other thrombotic events such as Cerebrovascular events in marked number of COVID patients. Patients present with altered D-dimer, Fibrinogen and Ferritin levels.

Cases discussed in this report were admitted in Lokpriya Hospital (Reg no- RMEE1900995), Meerut – A Primary care facility (COVID Section) in western UP which is primarily a Sugarcane belt of India where most Patients are Uneducated and belong to lower Socio-economic status.

#### Case 1 :

Hb	13.7	D-Dimer	1084.37
TLC	12.8	LDH	878
Neut.	94	FERRITIN	388.18
Lympho.	6	HBA1C	7.1
Urea	39	PT/INR	12.4/1.06
Creat	1.2	CRP	103.7
Na	136		
K	3.9		

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#### Editor's Comment :

- As COVID pandemic still running Globally so clinician should also aware other manifestations other than Respiratory system.

A Male patient 51 years (UHID-11106) came with c/o difficulty in Breathing x 6days, with vitals, PR 100/min, BP 132/86mmhg, RR 34/min temperature 98.4F Spo2 74% in RA. No history of any comorbidities. Patient's COVID Antigen test was done, which came out to be positive and patient was admitted in COVID Section for further management. Patient was taken on continuous O2 support via NRBM and maintained Spo2 90-92%, Relevant investigations are-



Fig 1 — HRCT chest S/O CTSI 18/25.

During the Course of treatment, On 3<sup>rd</sup> day, patient started complaining of weakness in Right Upper Limb

and Lower Limb, on examination, plantars were found extensor on right side and flexor on left side, B/L pupil were normal size normal reactive. Power in Right Upper Limb was 3/5 and Lower Limb 4/5. After which immediate NCCT head (Fig 1a) was done. Which were suggestive of SUBTLE HYPODENSE AREA OF MEAN 20HU NOTED INVOLVING LEFT OCCIPITAL, THALAMUS AND CORONA RADIATA REGION/ ISCHEMIC INFARCT, patient's blood thinner were increased after taking Neurology opinion.

Patient was then managed conservatively. Patient was then discharged with stable vitals at room air with COVID RTPCR negative report., with existing Neurological deficit and mild Post COVID symptoms.

3 more Cases are discussed in this Case report showing CNS related complications in Admitted COVID Infected patients.

### DISCUSSION

Even though, most common manifestation of COVID-19 is Respiratory Failure, but during the Second wave Patients had constellation of Neurological manifestations like headache, vertigo, dizziness, loss of smell and taste, as mild symptoms and Major complications like Seizures, CVA (infarct / bleed) has been present in COVID-19 patients.

The pathophysiological mechanisms that underlie Cerebrovascular events in COVID-19 could potentially be related to vasculopathy<sup>4</sup>. In addition, there is an increase of conventional Stroke risk during Sepsis<sup>5</sup>, comorbidities, such as Diabetes, Hypertension, Dyslipidemia enhance expression of Angiotensin-converting enzyme2 receptors in the Brain and neurotropism of SARS-CoV-2 virus<sup>6</sup>.

The above cases discussed shows that without any prior Neurological history, patient presented or developed these Neurological complications, attributed to the SARS-CoV2 infection. Therefore, multidisciplinary approach needed in management of COVID-19 patients.

From the beginning of COVID-19 Pandemic, potential Central Nervous System involvement has been hypothesized through various etiological mechanisms, including direct Neuroinvasion<sup>7</sup>, parainfectious autoinflammatory involvement<sup>8-11</sup>, endothelial dysfunction<sup>12</sup> and indirect involvement due to altered homeostasis such as altered coagulative states that cause an increase in ischaemic hemorrhagic lesions<sup>13-18</sup>.

Further studies are needed to determine whether these Neurological complications are more due to Thrombo Inflammation caused by SARS-CoV-2 virus due to enhance expression of ACE-2 receptors in the brain or due to Prophylactic/overuse of anticoagulant therapy in hospitalized patients.

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## Case Report

# Dancing Feet Syndrome in Diabetes : Para-ballism and Para-chorea in a Diabetic Patient with Diaphragmatic Myoclonus

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While movement disorders in Diabetes have long been recognized, the terminology of diabetic striatopathy is relatively more recent. Herein, we report a rare case of diabetic striatopathy in a 62-year-old woman with uncontrolled Type 2 Diabetes Mellitus who presented with Para-ballismus and Para-chorea along with diaphragmatic Myoclonus, a constellation of rarely reported before simultaneously in a hyperglycemic state. While these movement phenomena are extremely rare, the case also highlights they may persist even after acute control of hyperglycaemia, emphasizing on the need for achieving long term Glycemic control for its management. [J Indian Med Assoc 2023; 121(2): 00-00]

**Key words :** Striatopathy, Para-ballismus, Para-chorea, Myoclonus, Diabetes.

### CASE REPORT

A 62-year-old known diabetic patient on oral anti diabetic drugs for 1 year presented with acute onset abnormal movements of her Left Lower Limb for 1 month. These movements which she described as involuntary jerky and dance like movements soon involved the Right Lower Limb and sequentially the upper limbs within the next 15 days. No history of any Focal Limb weakness, Sensory, Cranial Nerve or Sphincter abnormalities was present. Fever, headache, loss of consciousness, alteration of sensorium or specific drug use apart from oral anti diabetic drugs were not reported. Family history of movement disorders was not present.

On Examination she had a Glasgow coma Scale score of E4V5M6 with no significant cognitive impairment. Cranial nerve, sensory and autonomic examination were within normal limits. Motor examination was significant for abnormal, involuntary, hyperkinetic movements in the form of rapid, high amplitude and arrhythmic, flinging movements of both Lower Limbs suggestive of Para-Ballismus. Abnormal involuntary movements of distal muscles of Bilateral Lower Limb were also observed that were brief, random and without purpose, suggestive of Chorea. Additionally, there were also abnormal, involuntary, arrhythmic, undulating, inward and outward movements of the abdominal wall suggestive of diaphragmatic myoclonus. No abnormal movements were noted in the Upper Limbs. There was no muscle wasting anywhere. The tone and power of Bilateral Lower Limbs could not be assessed due to abnormal involuntary movements. The tone and power of Bilateral Upper Limbs were normal. Deep tendon reflexes were 2+ in Bilateral Upper and Lower

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### Editor's Comment :

- Diabetes is a multisystem disorder affecting the whole body, Central Nervous System is also not an exception.
- Diabetes presenting with a movement disorder is very rare but is being noticed nowadays with increasing proportions.
- Any movement disorder presenting acutely it is a good habit to check the capillary blood glucose, which can be easily managed & patient will get immediate relief.

Limbs, Plantar reflexes were bilateral flexor. Cerebellar function testing (finger-nose, finger-nose-finger) revealed no abnormality. No abnormal orolingual movement was observed. Meningeal signs were absent.

In view of the acute nature of the dyskinesias possibilities including metabolic and acute onset structural lesion (likely vascular) affecting the basal ganglia or its connections were considered. Bedside Capillary Blood Glucose (CBG) done immediately was found to be 170 mg/dl. However, she was found to have uncontrolled Blood Glucose levels with a Fasting Blood glucose level of 540 mg/dl and HBA1c 10.38. As euglycemia was achieved with Insulin and OADS, the dyskinesia decreased in intensity and persisted only present in Bilateral Lower Limbs. Arterial Blood Gas (ABG) analysis was done next which did not reveal acidosis and she had normal serum osmolarity. Urine dipstick test revealed glucosuria, but no ketone bodies. All other tests of the metabolic panel, Complete Hemogram, Serum Electrolytes, Renal, Liver and Thyroid Function Tests and Autoimmune profile were within normal limits. NCCT Brain showed bilateral caudate nucleus hyperdensity. MRI brain showed bilateral T1 and T2 hyperintensity of caudate and putamen. EEG was normal (Figs 1&2).

### DISCUSSION

With the ever expanding knowledge of the impact of diabetes on different organ functions, brain changes in diabetes is being increasingly recognized. Movement disorder is one amongst the myriad neurological presentations of Diabetes. While movement disorders have long been described, the terminology of "diabetic striatopathy" is relatively more recent<sup>1</sup>. Diabetic striatopathy

is defined as a hyperglycemic condition associated with either both or one of the following conditions (1) chorea/ballism (2) striatal hyperdensity on CT or hyperintensity on T1 weighted MRI which can be reversible<sup>1</sup>. 4 main hypotheses to explain the pathogenesis resulting in striatal abnormalities on imaging include petechial haemorrhage, mineral deposition (Calcium or Magnesium), myelin destruction and infarction with astrocytosis (gemistocytopathy). In non-ketotic hyperglycaemia a shift in Brain metabolism to the alternative anaerobic pathway in Krebs Cycle leads to depletion of Gamma-aminobutyric Acid (GABA) a inhibitory neurotransmitter, consequently resulting in disinhibition of subthalamus and basal ganglia that translates into hyperkinetic movements. On the contrary, in Ketosis, GABA can be resynthesized using acetoacetate produced in the Liver to prevent its reduction, thus causing lesser incidence of movement disorder<sup>1</sup>.

The movement disorders commonly associated with Hyperglycaemia can be Hemichorea-hemiballismus [HB-HC], Monoballismus, Myoclonus, Hemifacial spasm, paroxysmal kinesogenic dyskinesia (PKD) and several partial seizures<sup>2,3</sup>. Overall, these are usually more frequently observed in a background of non Ketotic hyperglycaemia rather than that with ketosis<sup>1,2</sup>. However, Paraballism-Parachorea that is ballismus and choreiform involvement of both lower limbs as a primary manifestation is rare, as is diaphragmatic Myoclonus.

Ballismus are large amplitude wild flinging incessant purposeless movements that are typically seen affecting one half of the body. The pathologic abnormality lies in the subthalamic nucleus and its afferent or efferent connections. Very rarely can they be Bilateral /involving both legs which is known as PARA BALLISMUS. As early as 1965 Hemiballismus was described as (1) Hemiballismus, typical (well localized lesion in the contralateral sub thalamic nucleus) (2) Hemiballismus, atypical (involving connections of the subthalamic nucleus, usually internal capsule) (3) Para-ballism (bilateral ballistic activity usually as a part of encephalitic sequelae with corpus luyii seemingly normal)<sup>4</sup>.

Chorea is described as an involuntary irregular, random, non-rhythmic, purposeless movements, caused by involvement of the caudate nucleus. Variable in their distribution, they can affect a single extremity, one half of the body (hemichorea) or be generalized. Characteristically involving the distal extremities, it may also affect the proximal parts, lower extremities, trunk, face, tongue lips and Pharynx de Jong<sup>5</sup>.

Diaphragmatic myoclonus also known as belly dancers' dyskinesia, is a form of segmental myoclonus caused by rhythmic, involuntary contractions of the diaphragm resulting in undulating, rhythmic movements of the abdomen. Its generator source is believed to lie in the rostral medulla. It can be due to central causes such as Encephalitis and extra pontine myelinosis. Peripheral causes include Phrenic nerve injury /irritation, Spinal cord

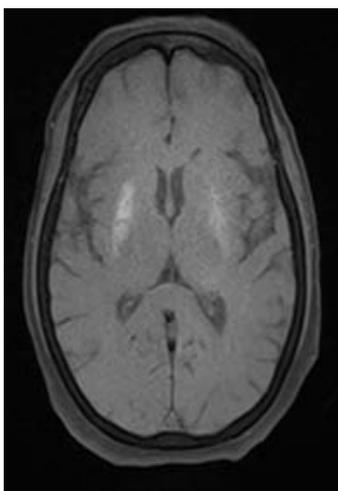


Fig 1 — MRI Brain in T1 weighted image shows Bilateral hyperintensities in putamen & caudate nucleus

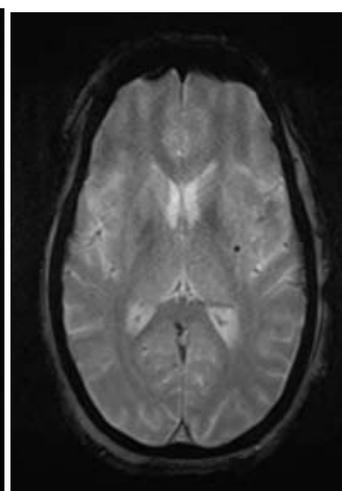


Fig 2 — MRI Brain in T2 weighted image shows Bilateral Hyperintensities in caudate nucleus and putamen

lesions. They may also be drug induced or psychogenic, however, majority of the cases are idiopathic<sup>6</sup>. Diaphragmatic Myoclonus has been reported only once before as a reversible manifestation of uncontrolled hyperglycemic state<sup>7,8</sup>. Often mistaken for hiccups, it is a less recognized phenomenon, the identification of which is thus crucial for suspecting and treating underlying hyperglycaemia<sup>9</sup>.

In this case we observed Para-ballismus and parachorea. Bilateral chorea/ballismus has been reported twice before in a background of non Ketotic Hyperglycaemia.

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## Case Report

# Atypical Presentation of Anti-phospholipid Syndrome with Triple Antibody Positive (ATAP) Syndrome Presented as Non-healing Foot Ulcer in a Middle-aged Adult Female

Amishi Nitin Rathod<sup>1</sup>, Vishal Nitin Rathod<sup>2</sup>, Sunil M Shahane<sup>3</sup>

Middle aged women presented with non-healing ulcer over foot following trivial injury. She was not having any co-morbid condition. Investigations revealed APLA Syndrome with triple antibodies positive (Lupus anticoagulant, Anticardiolipin antibody and anti B2-glycoprotein antibodies). Patient responded well with anti-platelet and skin grafting at local site.

[J Indian Med Assoc 2023; 121(2): 71-2]

**Key words :** Triple antibody positive.

### CASE REPORT

39-year-old female presenting with complain of non-healing wound on the lateral aspect of the right foot for 2 months. Patient was alright 2 months ago, when she sustained minor blunt trauma to right foot resulting in mild swelling followed by small Ulcer. It increased in size over 2 months period. There was no history of motor or sensory system disturbance in lower extremities, no history of bleeding or discharge from the wound. There is no Hyperpigmentation/ Varicose Vein or raised temperature of the skin around the wound. There was no history of skin rash, oral ulceration, photosensitivity, or bleeding from any other site. Patient did not give any history of co-morbid condition or Collagen Vascular Disorder /Inflammatory Bowel Disease. She does not give history of significant weight loss. She refused any history of medication taken for illness. she is non-smoker and non-alcoholic. Patient underwent debridement of the wound 1 month ago and wound did not heal even after 2 months of proper dressing, antibiotics and anti-inflammatory drugs (Figs 1&2).

**Examinations** — On examination, patient hemodynamically stable. All the peripheral pulses were palpable. One large Ulcer over lateral malleolus and another small Ulcer adjacent to it were present without any changes of the surrounding skin. The Ulcers were oval in shape with size of 9x4 cms and 2x1 cms respectively. The ulcer had an indurated margin with Floor of the wound covered with slough. There was no active discharge. Abdominal examination revealed no splenomegaly or hepatomegaly. Central nervous system

### Editor's Comment :

■ Middle age female presenting as a non healing ulcer after ruling out common causes like Vasculitis and Pyoderma Gangrenosa, Antiphospholipid Antibody Syndrome should be considered.

did not reveal any sensory or motor deficit or Peripheral Nerve thickening or tenderness.

**Investigations** — The hemogram showed Hemoglobin of 9.4g/dL, a Leucocyte Count of 9030/L, Platelet count: 169X 10<sup>9</sup>/L. The Random Blood Sugar was 111mg/dL. The Blood Urea Nitrogen was 38mg/dL and serum Creatinine 1.24mg/dL. The serum Sodium-138.0 mEq/L, Potassium - 3.85 mEq/L, Chloride-101.8 mEq/L. The Prothrombin time 14seconds and INR were 1.35 seconds. The HBsAg, HCV and HIV were negative. The CRP- 3.74 mg/L and ESR-75 mm respectively. Pus culture grown pseudomonas aeruginosa of non-significance. No fungal elements or acid-fast bacilli seen.

The Anti CCP Antibodies were negative (2.00 U/ML). The sickling test was also negative. The Anti-Nuclear Antibody (ANA) with titer (1:1000) was positive with a homogeneous pattern (Immunofluorescence method) cytoplasmic positivity seen. THE C-ANCA was Negative but P-ANCA was Positive. Based on the clinical profile of the patient with investigations, diagnosis of Vasculitis Ulcer was made. Color Doppler of bilateral lower limbs and abdomen was normal with no evidence of arterial blockage or Varicose Vein. The lupus anticoagulant, anti cardiolipin antibodies IgG 97U/ml (positive >40), anti-beta-2 glycoprotein of IgG 124.46 RU/ml (positive >20) was positive. Biopsy from the edge of the wound revealed granulation tissue with infiltration of Lymphocytes, Plasma cells and few Neutrophils, no granulomas or fungal elements seen. Histopathological diagnosis was Necrotic Foot Ulcer.

Considering clinical presentation along with specialized investigations, non-healing ulcer with APLA Syndrome diagnosed. Patient was given anti-platelet

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Fig 1 — Non healing ulcer over Right foot.

and skin grafting done. Patient improved and discharged from hospital.

### DISCUSSION

Antiphospholipid Syndrome is Autoimmune Disorder, resulting due to autoantibodies against anticardiolipin and lupus anticoagulant present on the Plasma membrane causing a hypercoagulable state<sup>1</sup>. Although the exact etiology of APS is still not clear, genetics is believed to play a key role in the development of the disease, Genetic Markers: HLA-DR4, HLA-DR7 and HLA-DRw53 It is more common in women than in men<sup>2</sup>. Clinically important anti-phospholipid antibodies are associated with Thrombosis and Vascular disease. In pregnant women affected by APS, there is an increased risk of miscarriage and intrauterine growth retardation<sup>3</sup>. The Anti-phospholipid Syndrome responsible for most of the miscarriages in later trimesters. It is estimated that the incidence of APS is approximately 5 cases per 100,000 persons per year and the prevalence is approximately 40-50 cases per 100,000 persons.

It is very rare to have APLA Syndrome with non-healing ulcer as present in our case report. Treatment includes wound care, pain management, Anti-platelet agents, Blood thinner if major artery or venous blockage, warfarin is used, the INR is kept between 2.0 and 3.0<sup>4</sup> in case of triple positive instead of warfarin directly acting oral anticoagulant are used<sup>5</sup> and skin grafting for non-healing



Fig 2 — Non healing ulcer after skin grafting

ulcer. In refractory cases Plasmapheresis may be considered.

### CONCLUSION

Middle aged women present with evidence of arterial, venous blockage or repeated miscarriage and occasionally present with non-healing ulcer then Antiphospholipid antibody (APLA) Syndrome should be suspected.

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## Case Report

### Hydrophilic Intraocular Lens Opacification — A Case Report

Shivcharan Lal Chandravanshi<sup>1</sup>, Shashi Jain<sup>2</sup>, Divya Tripathi<sup>3</sup>, Divya Ramraika<sup>4</sup>

**Purpose :** To report a case of late opacification of the hydrophilic acrylic Intraocular Lens (IOL) after uneventful Cataract Surgery.

**Methods :** A 60-year-old male presented with chief complaint of gradual diminution of vision in right eye over the past one year. He was Normotensive, Non-diabetic and had a normal Lipid Profile. History revealed that he underwent uneventful phacoemulsification with posterior chamber hydrophilic intraocular in the bag implantation for pre-senile cataract in his Right Eye ten years ago. He had the best corrected visual acuity of 6/6 in his Right Eye for nine years Post Cataract Surgery. Slit-lamp examination confirmed Intraocular Lens Opacification.

**Results :** Intraocular Lens exchange was performed in his Right Eye. The hydrophilic IOL was replaced with poly methyl methacrylate intraocular lens. The explanted IOL showed uniform grayish-white opacification. Post operative period was uneventful. Intraocular pressure by applanation tonometry was 16.4 mm Hg in both the eyes. Patient's best corrected visual acuity was 6/6 with -1 D Cyl. at 90 degree, Postoperatively. Over a follow up period of one year, the patient did not develop complications like posterior capsular IOL opacification.

**Conclusion:** Intraocular Lens opacification is an extremely rare late postoperative complication of Phacoemulsification which can be managed effectively by IOL exchange procedure in cases of opacified IOL optics causing visual morbidity.

[J Indian Med Assoc 2023; 121(2): 73-4]

**Key words :** Calcification, Hydrophilic intraocular lens, Intraocular lens, Posterior capsule opacification, Intraocular lens opacification, Tertiary cataract.

Intraocular Lens (IOL) opacification is an extremely rare unilateral or sometimes bilateral IOL related complication of Cataract Surgery which may affect the surfaces (anterior, posterior or both) or the material of the optic, haptics, or whole lens. Intraocular Lens opacification is postulated to be caused mainly by calcification. Calcification of IOL may be of primary or secondary types. Primary calcification results from the problems of IOL itself in the absence of other significant causes. Secondary calcification of IOL occurs in the presence of pre-disposing factors such as Diabetes, Uveitis and following Vitreoretinal or Keratorefractive surgeries. Patients usually present to the Ophthalmologist with complaints of diminution of vision. Intraocular Lens exchange is universally accepted and safe procedure to restore vision in these cases. This case study aims to report a rare case of Hydrophilic Intraocular Lens opacification in the absence of any risk factors.

#### CASE REPORT

A 60-year-old male presented with chief complaints of right eye gradual painless diminution of vision since one year. He gave history of right Eye Phacoemulsification

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#### Editor's Comment :

- Intraocular Lens opacification is a rare complication. It is more common in hydrophilic intraocular lenses.
- The ophthalmologists must be aware of this complication and patients to be well informed about Postoperative IOL opacification to avoid litigation.

with Hydrophilic Intraocular Lens implantation 10 years back, elsewhere. There was a negative history of Diabetes, Uveitis or any Keratorefractive or Intraocular Retinal Surgeries. On initial pen light examination, there was Leucocoria in his Right Eye. His best corrected visual acuity was 6/24 in the right eye and 6/9 in the Left Eye. Slit lamp examination disclosed pseudophakia with opacified intraocular lens in the Right Eye while nuclear sclerosis grade II in the Left Eye. Dilated Slit-lamp examination confirmed opacification of both the optic and haptics sparing posterior capsule. No deposits were seen on Intraocular Lens surface on 40X magnification. The patient was posted for exchange of opacified IOL with Polymethyl Methacrylate Intraocular Lens. Postoperative visual acuity was 6/6 with -1 cylinder at 90°. The explanted IOL was sent for light microscopy examination with special stains for detection of Calcium coupled with scanning electron microscopy which did not reveal any deposits over IOL surface. However, special stains, Alizarin red S was positive while Von Kossa was negative for calcium. Postoperative period was uneventful. Postoperative visual acuity in the Right Eye at one month follow-up was 6/6 with -1D cylinder at 90° (Figs 1&2).

#### DISCUSSION

The Intraocular Lens opacification is an extremely rare

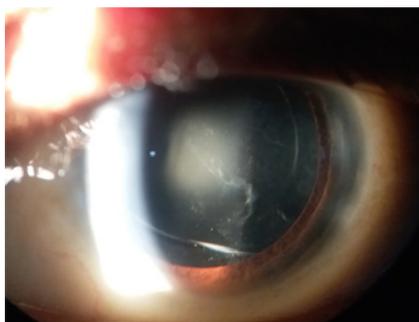


Fig 1 — Slit-lamp photograph showing grayish white opacification of intraocular lens



Fig 2 — Slit-lamp optical section photograph showing grayish white opacification of intraocular lens

late Postoperative complication after Cataract Surgery with IOL implantation which usually occurs in the late postoperative period in Hydrophilic IOLs. Intraocular Lens opacification in Hydroview IOLs after Cataract Surgery was first reported by Chang *et al* in 1999<sup>1</sup>. The incidence of IOL opacification ranges from 1.1% to 14.5% depending on the presence of risk factors in the patient<sup>2</sup>. Duration of IOL opacification ranges from one year to seven years or more. Silicone, Acrylic and Poly Methyl Methacrylate (PMMA) IOLs have been reported to undergo opacification. Hydrophilic acrylic IOLs have greater tendency of opacification in comparison with hydrophobic acrylic IOLs<sup>3</sup>. Patients with IOL opacification usually present with complaints of gradual painless loss of vision after Cataract extraction with IOL Implantation Surgery, decreased contrast and glare<sup>4</sup>. Sometimes patient may also present with Leucocoria, poor vision in dim light and hazy or foggy vision.

Various risk factors for IOL opacification have been described in the literature such as Diabetes, Uveitis, Asteroid Hyalosis, Breakdown of blood aqueous barrier intraoperatively in procedures such as Parsplana Vitrectomy (PPV) with intraocular gas or air injection, penetrating keratoplasty, Descemet Membrane Endothelial Keratoplasty (DMEK) and descemet stripping (automated) Endothelial Keratoplasty (DSEK/DSAEK)<sup>5-6</sup>. In present case study, no such risk factors are present for IOL opacification.

Mechanism of IOL opacification is not well established. Various mechanisms have been proposed by numerous researchers. Different patterns of IOL opacification have been noted in different IOL substances such as snowflake opacification in PMMA IOLs, discoloration/clouding in silicone IOLs, calcification (hydroxyapatite, dicalcium phosphate, octacalcium phosphate, or hydroxyapatite deposition) in hydrophilic acrylic IOLs and glistening or subsurface nanoglistenings in Hydrophobic acrylic IOLs<sup>7</sup>.

Diagnosis of IOL opacification is easily made by Slit-lamp Biomicroscopy. Sometimes, it may mimic a lamellar cataract. Anterior Segment Optical Coherence Tomography offers help in detection of IOL-capsular bag adhesions. Scanning laser electron microscopy and X-ray diffraction examination of an explanted IOL may be helpful in understanding the mechanism of IOL

opacification. Both the techniques show Calcium deposition over IOL surface. Von Kossa stain is useful in IOL surface calcification while Alizarin red is used for entire IOL material calcification<sup>8</sup>.

Explanation of an opacified IOL and reimplantation of new IOL made up of different material is the procedure of choice for the treatment of opacified IOL at present<sup>9</sup>. However, IOL exchange procedure may become risky in patient who has had Nd-YAG laser capsulotomy in the past. In such cases, capsular bag damage, complete dehiscence of bag, vitreous prolapse, zonular dehiscence, IOL drop, IOL decentration may be the common complications. Scleral fixated IOL, anterior chamber IOL, sutured iris fixated IOL, iris claw IOLs and retro pupillary iris claw IOL are also other viable options in case of capsular bag damage/dehiscence<sup>10</sup>. Majority of IOL exchange procedures have excellent Postoperative visual outcome if posterior segment is healthy.

## CONCLUSION

Incidence of IOL opacification is extremely low; the patient should be warned in advance of the remote possibility of IOL opacification in long term. This aspect of IOL related complication and the likelihood of repeat surgery for the same, should be mentioned in the informed consent in order to avoid litigation in the future.

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## Image in Medicine

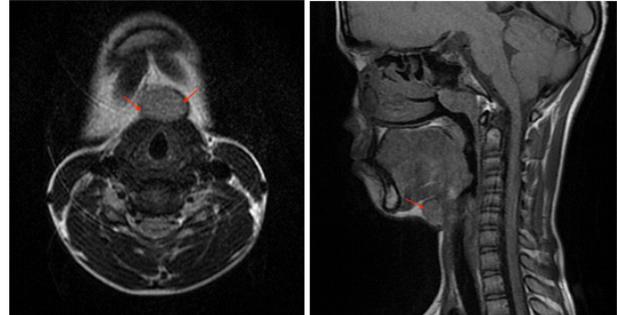
Bhoomi Angirish<sup>1</sup>, Bhavin Jankharia<sup>2</sup>

### Quiz 1

**A 13-year-old female presented with painless midline neck swelling. On clinical examination, the swelling elevates on protrusion of tongue.**

#### Questions :

- (1) What is the diagnosis ?
- (2) What is the locations of this lesion ?
- (3) What are the other differential diagnosis of midline neck swelling ?



#### Answers :

(1) A well defined cystic lesion is seen in midline at the base of tongue ( red arrow). A thin linear track (yellow arrow) is seen which represents failure of normal developmental obliteration of the thyroglossal duct. These findings are suggestive of suprahyoid thyroglossal duct cyst.

(2) The thyroglossal duct cysts can occur anywhere along the course of the thyroglossal duct from the foramen cecum to the thyroid gland. The common locations are : (A) Suprahyoid; (B) At the level of hyoid bone; (C) Infrahyoid How to differentiate this condition from its mimics?

They are typically located in the midline, while those off-midline are characteristically adjacent to the thyroid cartilage.

(3) The common differential diagnosis of midline neck swelling are – brachial cleft cyst, delphian lymph node, epidermoid cyst, thyroid lesions, laryngocele, ranula, parathyroid adenoma, ectopic thyroid.

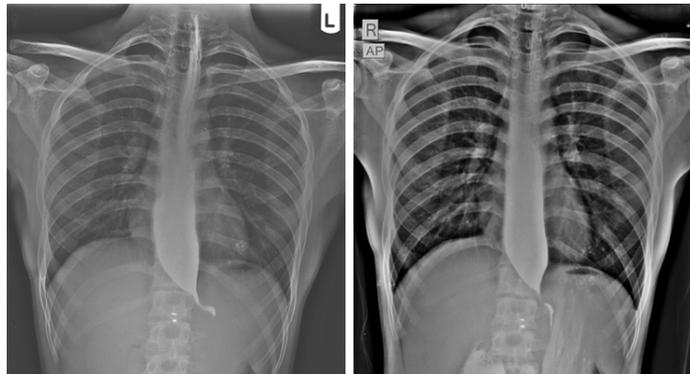


### Quiz 2

**Barium swallow images of a 20 year old male who presented with dysphagia and regurgitation.**

#### Questions :

- (1) What is the diagnosis?
- (2) How to differentiate this condition from its mimics?



#### Answers :

(1) There is significant dilatation of esophagus with smooth tapering seen in the lower esophagus (bird beak / rat's tail sign) suggestive of achalasia.

(2) Achalasia (primary achalasia) results from failure of organized esophageal peristalsis causing impaired relaxation of the lower esophageal sphincter. This is due

to loss/destruction of neurons in the myenteric plexus.

Obstruction of the distal esophagus from other non-functional etiologies, may have a similar presentation and is termed "secondary achalasia" or "pseudoachalasia". Some of the causes of pseudoachalasia are malignancy, scleroderma, esophageal stricture, chagas disease.

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## Letters to the Editor

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

### **Manuscript Writer : Are they Eligible for Authorship in Scientific Article ? If yes then which place ?**

SIR, — Reading, writing and speaking are the skill which can be developed by personal interest and training. Everyone doesn't have skill and all person cannot have all skills. Good writing with appropriate words makes excellent effect on the readers and reviewers too. Previously writing was not much important but in current busy world, writing gets more weightage compare to past decades. Many people who have that good writing skill, can convert it into their profession which is a good use of the skill<sup>1</sup>.

Research works are being done for benefits to human and other lives, it will be a success when it reaches to other people, not from same institute or same city but whole globe, so we need to publish the data. With the help of internet, that work has become rather easy as compared to past decades<sup>2</sup>. Though it has their own drawbacks like copy the idea, plagiarism, fake data etc. Various journals are rejecting the manuscript in first screening, if it has plagiarism more than their set limits or not written in proper way. All clinical researcher and scientist don't have the skill of good writing and presentation. To publish the data and findings, they are taking the help of the medical or research writer. Those writers use their skill with available data and present it with good writing and nice way which can be accepted in the journal easily<sup>3</sup>.

Everyone has rights to use their skill for their self-use. Professional Manuscript writers are doing writing work either for some economic purpose or for some ethical purpose. There are many professionals who are available who are writing on behalf of the authors and submit it to appropriate journals. Data owner just have to give the data and have to explain the concept to the writer. This type of professional asks only for money and they do not want any authorship. Many journals asked about the medical writer details during the manuscript submission. Those journals are taking consent for same from all/ corresponding authors. We are also recommended that professionals are not eligible for authorship in any type of manuscript<sup>4</sup>.

Another non-professional medical writer who writes for that friends/relatives/departments or else. Those are eligible for authorship as and when all investigators agreed to give authorship. We know that writer is not a part of investigator team but to write they have to search and read the many related articles. They give their efforts without any economic benefits. So, to write it they are fitted in to international journal authorship criteria. However, there are some types of articles doesn't require medical writer. Original article, case reports, case series or brief reports are based on the departmental data where medical writer doesn't have to allowed to front authorship. Their name can be added after giving departmental authors their due. Letter to editor or concept discussion doesn't require medical writer, it is mostly by avoid writers<sup>5</sup>.

So, we suggest that writers cannot be eligible for the first authorship because they are using someone else's concepts. If

writer is not a part of data collection. Sample selection, concept and study designing, analysis or investigator, not eligible for first place authorship. As per the guidelines, innovative concept and idea given authors are most appropriate for the first author. Only searching review of literature and writing from data (Supplied by principal investigator) doesn't make sense to appoint as first author. If all cases/ patient's investigation and data collection done before the involvement of writers, he/she are eligible for back side place not for first authors. Person can be a corresponding author between the journal and investigator team. We hope everyone will agree with us.

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### **What is Essential to know in Heart Failure Patients**

SIR, — As heart failure prevalence increases globally, there is a growing need for new innovative solutions. Nearly 64 million people worldwide are living with Heart Failure (HF). It is estimated that half of patients living with HF will die within five years of diagnosis. It creates divesting impact on healthcare systems and the global economy.

Heart failure is a complex syndrome with current treatments helping to slow HF risks and progression in some, but not all patients. These unmet medical needs underscore the urgency to increase awareness, early detection and development of life-saving medicines to address these complexities with straightforward solutions. It is crucial to develop and deliver innovative solutions to

address the gaps that currently exist in the treatment of heart failure. So it is imperative to be aware of what is essential to know in heart failure patients for proper care.

In many clinical trials it has been revealed that Torsemide was not superior to furosemide in improving survival among patients treated for decompensated HF. For diuretics it has shown there are no differences in cardiovascular outcomes between chlorthalidone and HCTZ among elderly veterans with HTN. Patients suffering from bad lipid profile Pemafibrate did not improve cardiovascular outcomes among patients with diabetes and hypertriglyceridemia.

Iron deficiency is a very common symptom among HF patients for them, Iron (ferric derisomaltose) infusion is not superior to usual care. Empagliflozin has salutary effects on renal function and CV mortality among patients with CKD, with or without DM, who are already on appropriate doses of ACEi/ARB. Highly purified eicosapentaenoic acid showed borderline statistical sig in reducing the risk of adverse CV events in Japanese w/ c/c CAD who were being treated with statins, whereas Olpasiran significantly reduced lipoprotein (a) in established ASCVD. Rosuvastatin 5 mg daily lowered LDL-C significantly >placebo, fish oil, cinnamon, garlic, turmeric, plant sterols in those with increased 10-year risk for ASCVD.

For invasive cardiac procedures, Radial artery bypass graft improves adverse CV outcomes v/s R internal thoracic artery BG. Hypertension management protocol of 4 drugs, quarter-dose BP-lowering combination of candesartan, amlodipine, indapamide and bisoprolol led to a greater reduction in change in BP from baseline to 12 weeks compared with standard-dose ARB immunotherapy in patients with mild to moderate HTN. Adults with HTN who participated in a mindfulness behaviour program for 8 weeks had significantly lower BP levels & greatly reduced sedentary time, at 6 months follow-up V/S those who received enhanced usual care (home BP monitor/BP edu/facilitated access to a physician).

Systematic use of a hospital-based POC tool to support clinical decision-making, followed by rapid follow-up in an outpatient clinic, led to a lower risk of death or hospitalization for CV causes within 30 days among patients with acute HF seeking emergency care. A single IV infusion of NTLA-2001, a novel gene-editing therapy based on CRISPR/Cas9, significantly reduced abnormal levels of the TTR protein by > 90% in patients with ATTR amyloid CM after 28 days. Routine collection of patient-reported health status using KCCQ-12 in the HF clinic improved accuracy of clinician assessments of patients' health status.

Prophylactic methylprednisolone in infants undergoing cardiopulmonary bypass heart surgery did not improve post-operative outcomes compared with placebo.

Bivalirudin w/ a median 3hr post-PCI high-dose infusion significantly reduced the 30d composite rate of all-cause mortality/ BARC types 3-5 major bleeding compared with heparin monotherapy in Chinese patients with STEMI undergoing primary PCI w/ radial artery access.

DAPT with indobufen plus clopidogrel significantly reduced the risk of 1 year net clinical outcomes in Chinese patients with negative cardiac troponin undergoing DES implantation, compared to conventional DAPT of aspirin plus clopidogrel. A personalized "precision" testing approach led to more efficient evaluations for cardiovascular disease risk and improved diagnosis and treatment

of CAD when compared to usual care in more than 2,000 adults with stable chest pain. Early initiation of rivaroxaban, prescribed for 35 days in non-hospitalized patients with symptomatic COVID-19 at-risk for thrombosis, was not found to reduce a composite endpoint of venous and arterial thrombotic events, hospitalization, and death. A universal EHR integrated CDS tool using a validated VTE risk model significantly increased rates of in-hospital appropriate thromboprophylaxis & significantly reduced major thromboembolic events w/o an increase in major bleeding at 30d post-discharge VS usual care.

First-line catheter ablation was associated with a significantly lower progression to persistent Afib, when compared to initial antiarrhythmic drug therapy. No significant differences in the rate of postoperative Afib in cardiac surgery patients who received either 125U or 250U doses of botulinum toxin type A (AGN-151607) compared with placebo. Implementation of a novel shared decision-making toolkit designed for low health literacy achieved significantly lower decisional conflict and improved preparation for decision-making compared to usual care in patients with AFib. Among patients with resistant HTN, Aprocitentan resulted in short-term and sustained BP-lowering effects. Among patients with treatment-resistant HTN aldosterone synthase inhibition with Baxdrostat led to dose-dependent reductions in SBP.

In patients with CLTI surgical revascularization with a great saphenous venous conduit was superior to endovascular intervention in reducing major adverse limb events or death. Greater QOL improve in those undergoing endovascular interventions versus surgery. Etripamil nasal spray was effective in termination of spontaneous PSVT in patients experiencing an episode in an at-home setting. Catheter ablation reduces the incidence of persistent AFib/recurrent atrial tachyarrhythmia v/s antiarrhythmic therapy.

An intensive treatment strategy of rapid up-titration of GDMT and close follow-up after an acute HF admission reduced symptoms, improved QOL and reduced the risk of 180-day all-cause death or HF readmission compared with usual care. Among patients with stable ischemic heart disease and moderate to severe ischemia on non-invasive stress testing, routine invasive therapy failed to reduce major adverse cardiac events compared with optimal medical therapy.

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### **The Road not Taken : A Perspective of a Medical Professional's Inability to Choose between Clinical Practice or Postgraduation Degree after Internship**

SIR, — A Postgraduation (PG) degree has almost become a requisite to pursue medical profession in India. A major part of such degrees rely on the clinical mastery of the doctors but to our dismay, the clinical exposure we get during our MBBS courses and

internship does not adequately prepare us for such bigger roles. Patients' outlook has gradually changed over time and it has been often seen that a doctor with a MD or DM degree is preferred over a "suboptimal" MBBS degree, as stated by a few patients. This has subjected the young doctors into a fierce academic competition to crack entrance examinations like NEET, INICET etc. The race is getting tougher day by day in a constant crescendo so much so that it has almost become a norm to dedicate a year or two only for "PG preparation". A vast majority of the aspirants are getting enrolled in various online courses completely sacrificing the clinical exposure of working in a hospital. The internship courses showcase a mere orientation programme with scanty clinical exposure. In most of the hospitals internees are made to fill up charts, perform phlebotomy, insert catheter, write requisitions etc and are almost never a part of the clinical decision making process. After completing the internship, if we are again detaching ourselves from clinical exposure and devoting years to post graduation entrance, is it compromising our clinical acumen further? Having said that, now if we take into account a budding doctor's point of view, the need for post-graduation in India has outweighed the requirement of clinical practice in a doctor's career. The question pattern keeps changing every now and then, leaving them with meagre time to balance between their yearning for clinical experience and simultaneously preparing for the mutating Multiple Choice Question (MCQ) pattern. For example, just a few years ago image based questions were rarely asked but with the commencement of computer based tests, questions with CT scan, Xray, clinical images are commonly asked and without a rigorous practice it is not possible to get success in these entrance tests. After getting into a MD course it is very difficult to have the necessary experience of the other specialities, which is a sine-qua-non to become a successful physician of any speciality. After joining a PG course in a clinical branch the doctors with sparse clinical experience are suddenly given the huge responsibility of treating patients which ultimately results in compromised patient-care at times. Moreover, there is heterogeneity in the work culture or duties of internees in different states. So, the degree of clinical exposure keeps varying from one Post Graduate trainee to another. The regulatory authority should take this issue into account to ensure optimum patient care. A mandatory and uniform clinical orientation course for the post graduate trainees all over India can probably bridge the gap of clinical experience and align them better into the clinical practice.

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### Monkeypox as a Global Health Emergency — A Threat after COVID-19 Pandemic

SIR, — Monkeypox is a rare zoonotic disease caused by the monkeypox virus that belongs to the Poxviridae family (1). While the source of infection is primarily zoonotic, and the disease

condition is usually seen in Central and West Africa since the 1970s. Recently, there is a rapid spread of Monkeypox all over the world due to climatic change, widespread global travel, and waning herd immunity due to the cessation of smallpox vaccination (2). Re-emergence of monkeypox across nations had made World Health Organization declare it a public health emergency of international concern (PHEIC) in July 2022 (3). As the disease is mild and not fatal, there are debates on declaring it as a PHEIC as it creates panic among the public but considering the reservoir of infection, pandemic potential and susceptible population declaring monkeypox as PHEIC is the need of the hour. India has reported nine confirmed cases of Monkeypox, including one death (4<sup>th</sup> August 2022) (4). In India, the recent COVID-19 pandemic has equipped us to battle any outbreaks in the future. As we expect more emerging and re-emerging infections in the future, strengthening molecular laboratories will help in the early detection of the disease and containment. Currently, around 70% of the human population is susceptible to Monkeypox infection (2). During the COVID-19 pandemic, a significant gamechanger in controlling the outbreak was a quick roll-out of mass vaccination campaigns. As per the CDC recommendations, two FDA-approved vaccines namely JYNNEOS (Imvamune or Imvanex) and ACAM2000 may be used for the prevention of Monkeypox infection (5). But the data regarding the effectiveness of these two vaccines in the current outbreak is not available. Hence it is imperative that budget allocation for conducting vaccination effectiveness studies should be implemented in endemic countries where we have an increased incidence of Monkeypox infection.

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