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Research Article

Blood Glucose

Study of knowledge, perception, and practice of patients regarding fasting requirements for blood glucose testing

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Background: Patient preparation is one of the least standardized parts of the preanalytic phase of testing. Fasting blood glucose requires fasting for 8-12 hours as per various guidelines and also has several other requirements. Lack of communication, understanding, or compliance regarding hours-of-fasting, water-intake, avoidance of caloric snack/beverage, the sudden change in smoking, exercise, alcohol, medication, etc. introduces preanalytic errors. **Method:** To evaluate awareness, understanding, and compliance with fasting requirements, a face-to-face survey was done on outpatients in a Government Hospital in Pali, Rajasthan, India. Relatively more educated internet users were surveyed as controls through an online SurveyMonkey tool. **Results:** 98 patients and 187 controls participated in the study. Perception about fasting requirements ranged from 0-17 hours. 71% of patients and 35% of controls perceived that nobody explained to them the duration or nature of fasting. The different sources of information had been used in different proportions by patients and controls. For imparting understanding and compliance about duration, and other requirements of fasting, the instruction was usually incomplete but still much more effective (p-value=0.000002) than formal education level (p-value=0.024). **Conclusion:** 71% of patients and 35% of controls did not receive instructions for fasting. 40% of those instructed showed better compliance, but awareness was incomplete. The instruction was more effective than formal education in improving awareness and compliance. Improved awareness was strongly associated with receiving instruction and weakly associated with formal education but financial status showed only a weak negative association.

Keywords: Fasting for Diagnostic Laboratory Tests, Patient Preparation, Under-fasting and Over-fasting

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Introduction

The preanalytic phase, i.e. the series of steps before the actual testing of a laboratory investigation, is known to incur significantly more errors (50-70%) than the analytic (5-15%) and the post-analytic phases (10-30%) [1]. The regulated environment of the laboratory and the implementation of rigorous quality controls have more than decimated the analytic errors. However, the pre-analytic and post-analytic phases are much less regulated, especially at the extreme ends of the process loop (the brain-to-brain loop) [1,2]. A particularly problematic area of the preanalytic phase involves those requiring patient preparation [3].

Fasting is the most well-known type of patient preparation for diagnostic medical testing. Though a multitude of laboratory parameters are significantly affected by fasting state, e.g. glucose, triglyceride, insulin, alkaline phosphatase, bilirubin, iron, C-Reactive Protein, alanine aminotransferase, albumin, calcium, sodium, magnesium, potassium, uric acid, some of the routine hematology count parameters, etc. [4-7] it is glucose for which fasting measurement is most common patient preparation asked by a medical laboratory. Under-fasting and over-fasting, both are detrimental to glucose measurements, for diagnostic as well as monitoring purposes [8].

Fasting requirements are not comprehensively defined in most of the guidelines themselves [9] and are not adequately communicated or explained to patients [10,11]. "Fasting" in laboratory science is not merely a term that is intuitive from its face value and is different from other forms of medical fasting eg “Nil Per Oral (NPO)” before surgery or endoscopic procedures etc. Depending on the test, fasting requires specifying the duration and a list of allowed/desired and prohibited types of activities before and during the fast [4].

For example, the fasting duration for fasting blood glucose may vary from 8-12 hours (usually overnight) depending on country and guideline [4,12]. It also requires 24 hours of alcohol restriction. Any caloric intake in the form of solid or liquid is prohibited during the total duration of fasting. Smoking, exercise, chewing gums, and taking nonessential medication in the morning before sampling is discouraged [13]. However, hydration in the form of clear water is allowed or rather encouraged, and thus it is very different from NPO.

When fasting blood glucose is a part of an OGTT, it needs to be even more stringent [14]. WHO recommends OGTT to be administered in the morning after three days of caloric unrestricted diet (daily >150 g of carbohydrate) along with usual physical activity, and a moderate (30-50g) carbohydrate-containing meal in the evening before the test day. In addition to all the usual specifications of fasting, WHO recommends documenting additional factors for OGTT e.g. medications, inactivity, infection, etc. which could affect the interpretation of the test.

Counseling patients and clarifying their doubts in their language is necessary to improve perception and compliance regarding the above factors. However, this step is often missed or remains inadequate, due to a multitude of logistic issues. Delivery of the information is controllable and is a relatively standardizable part of the process. However, what is not exactly controllable is the level of understanding, subjective perceptions, and compliance of the patient, which might potentially be affected by the education or socioeconomic status of the patient.

The primary aim of this study was to evaluate the awareness perception and compliance about the duration and nature of fasting required for fasting blood glucose testing among patients accessing the hospital laboratory. The current study intended to identify the types of gaps in the communication, and instructions that are more frequently missed, which could help predict corrective interventions.

The current study also planned to assess the impact of education, income, and other factors on understanding and adherence to the instruction. To this end, a control group was recruited from educated (>10th pass) adult internet users from the same locality, who were competent to respond to a similar online questionnaire but were not themselves medical professionals.

Materials and Methods

The study was conducted after permission from the Institutional Ethics Committee and the study adhered to the Principles of Geneva Council for International Organizations of Medical Sciences. A pre-tested face to face anonymous questionnaire-based survey was conducted on ambulatory patients waiting for phlebotomy in the out-patient section of Government Bangur Hospital, Government Medical College Pali, Rajasthan.

Patients were selected using a convenient sampling method. After obtaining informed consent from the patient, the survey was administered non-judgmentally in the native language of the patients (Hindi or Marwari).

A comparable Online SurveyMonkey tool (SurveyMonkey, San Mateo, CA, USA) [15] was used to survey adult internet users from the same locality, who completed school education or more. This questionnaire was in English.

Mentally incapable, deaf, or dumb patients were excluded from the face-to-face survey. Fully trained Health professionals e.g. doctors, technicians, nurses, etc. were also excluded from both forms of survey.

The questionnaire included questions on

- Basic demographic data including age, gender, locality
- Formal education level
- Financial status (family annual income)
- Perception of hours of fasting required
- Perception about whether to restrict
  - Water intake
  - Beverage
  - Light breakfast
  - Religious eatables e.g. Prasad for Hindu worship or Sehri (pre-dawn meal) for Ramadan etc.
  - Smoking
  - Drinking alcohol
  - Medication
  - Exercise during the fasting
  - Change of, in the previous three days, exercise habit, food
  - Instruction/explanations about fasting received
    - Whether instructed at all
    - Who instructed
    - Verbal or in writing
    - What was the number of hours they fasted in practice
  - Did they take any edibles in the morning
  - What food or beverage they ate before starting the fasting

For financial status, an annual income classification 1-5 was adapted in a way similar to a modified Kuppuswami scale 2019 update [16] (Table 2) to cover the range of annual income of affluent patients and controls.

The education levels were numerically categorized 0-4 (Table 1) based on a schema adapted from ISCED (International Standard Classification of Education) and modified according to the prevailing nomenclature of our country. The patients were chosen randomly, thus had varied education levels. But the control group, by definition, completed school education, i.e. passed a "School-Leaving" board examination or Matriculation or equivalent. Data processing and statistical analysis were done with Microsoft Excel, IBM SPSS 23.0, and R 4.0.3. with Rcmdr.

Results

For the survey, 310 subjects, including 110 patients and 200 controls, were approached and were informed about the details of the questionnaire. The response was received from 285 subjects (92% response) including 98 patients (89% response) and 187 controls (93% response) who consented to participate in the survey. Control: The patient ratio was 1.9:1 among respondents. The patients included 54 (55%) females and 44 (45%) males and controls included 103 (55%) females and 83 (45%) males. Male to Female ratio 1.25 in both groups. The age range was 18-82 years (Mean± SD=42.9±17.8y) in the patient group and 18-52 years (21.1±6.5y) in the control group. Education information was not provided by 2 patients (2%), and financial information was not provided by 7 patients (7%) and 12 controls (6%).

Table-1: Educational stratification of patients and controls.

Education: Categories		Group		Total (%)
		Control (%)	Patient (%)	
Uneducated	0		40 (42%)	40 (14%)
Primary School (Class I-V)	1		14 (15%)	14 (5%)
Secondary School (Class VI-X)	2		21 (22%)	23 (8%)
Matriculated (Passed Secondary Board)	3	56 (30%)	10 (10%)	64 (23%)
Graduate or Pursuing Bachelor or higher education	4	131 (70%)	11 (12%)	142 (50%)

Total	187	96	283
Education levels are stratified into 5 categories and the number of patients and controls in each. By design, the control group consisted of people who have passed high school and thus did not have any population in the first three education categories.			

Table-2: Financial stratification of Patients and Controls.

Annual Income: Financial Category		Group		Total
		Control (%)	Patient (%)	
<2.5 Lakh	1	35 (20%)	8 (9%)	43 (16%)
2.5-5 Lakh	2	40 (23%	16 (18%)	56 (21%)
5-7 Lakh	3	39 (22%)	10 (11%)	49 (18%)
7-10 Lakh	4	26 (15%)	28 (31%)	54 (20%)
>10 Lakh	5	35 (20%)	29 (32%)	64 (24%)
Total		175	91	266
Financial status was assessed as per the annual family income and stratified into 5 categories. Annual income was noted in Indian National Rupees (INR) Lakhs per year. 1 Lakh = 100,000. Note that patients are significantly more affluent than the controls: N=266, Pearson Chi-Square=20.563, df=4, p-value=0.00038.				

Perception and practice of fasting duration varied from 0 hours to 17 hours in both groups. A staggering 71% (70/98) of the patients and 35% (65/187) of educated respondents perceived that nobody instructed or explained to them anything about the nature of the fasting.

Table-3: Number (%) of patients, controls, and total, that were instructed or aware of fasting.

Group	Patient	Control	Total
N	98	187	285
Instructed	30 (31%)	122 (65%)	135 (47%)
Aware that some fasting is needed for some tests	43 (44%)	148 (79%)	191 (67%)
No knowledge about fasting duration or conditions for blood glucose test	53 (54%)	80 (43%)	133 (47%)
Fasting duration known for blood glucose test	15 (15%)	65 (35%)	80 (28%)
Fasting conditions (other than duration) for blood glucose test known	23 (23%)	86 (46%)	109 (38%)
Fasting duration and conditions for glucose test all known	0 (0%)	36 (19%)	36 (13%)

Among patients, 11% of the uninstructed knew the fasting duration right, whereas 40% of instructed patients knew the fasting duration right. The instruction did make a significant improvement in awareness about the duration (N=98, Pearson Chi Square=5.321, df=1, p-value=0.021).

Of the instructed patients, 46% knew the fasting conditions (other than duration) right and of those not instructed only 14% knew them, i.e. instruction again had a very significant impact (N=98, Pearson Chi-Square=11.504, df=1, p-value=0.001).

Since both the outcomes, right duration, and right conditions, were improved by the instructions, the overall knowledge was improved even more significantly. In the total population N= 285, Pearson Chi-Square=29.463, df=3, p-value=1.79*10-6.

Among controls, 26% of uninstructed and 39% of instructed knew the fasting duration right. The impact of instruction was not significant (Chi-square p-value=0.071). On the other hand, 51% of instructed controls and 37% of uninstructed controls knew the fasting conditions (other than time) right. Impact of instruction again was not significant (Chi-square p-value= 0.69). However, among controls impact of instruction on knowing fasting duration and conditions all right was significantly associated with instructions (N=187, Pearson Chi-Square=8.435, df=1, p-value=0.004).

Perception of fasting duration on the average was lower than the proper target (8-12h) in both patients and controls (i.e. under-fasting), but patients (3.4±4.9h) had a significantly lower duration in their perception than controls (5.4±3.7h) and the difference was highly significant (Student's t-test p-value=0.0004). Among controls, 79% and patients 44% were aware that some fasting is necessary for some tests in general.

Table-4: Source of Information in Patients and Controls.

Sources	Sources for Patients	Sources for Controls
Doctor, Verbal	17%	36%
Doctor, Written	2%	
Doctor gave literature		
Another patient	13%	
Internet	11%	20%
Phlebotomist, after mistake	9%	5%
This questionnaire		15%
Previous mistake		5%
Nurse		3%

Relative usage of the information sources reported by patients and controls. The percentages represent what proportion of patients or controls accessed these sources of information to learn about fasting. Multiple sources could be reported per individual for these mutually nonexclusive sources; thus, the total would add up to more than the total instructed% i.e. 31% and 65% in Patients and Controls respectively.

The commonest sources of information for patients were doctors (17% verbal instructions, 2% written instruction, Printed reading material not received by any).

Other common sources included another patient (13%), the internet (11%), explanation by phlebotomists after improper fasting (9%), counseling after this questionnaire (6%), and nurses (2%). Top sources for the control were doctors (36%), Internet (20%), this questionnaire (15%), nurses (5%), and previous improper fast (4%).

In the patient group, of those instructed 83% were aware and 72% were compliant in practice about avoiding light snacks during fast. Whereas, among uninstructed patients, 48% claimed to be aware and only 15% were compliant about light snacks. Awareness and compliance about avoidance of tea/coffee was 67% and 44% for instructed vs 30% and 0% for the uninstructed respectively.

An alarming 33% of the instructed patients continued to perceive that religious food could be taken in the morning, and 11% even consumed religious food. As much as 55% of the uninstructed patients perceived religious food was allowable and 19% consumed them. Interestingly 100% of both instructed and uninstructed claimed to be aware of alcohol and smoking. Their compliance was close to 95%.

Even among the controls, 30% thought tea/coffee is allowed, 10% thought snacks are allowed and 3% thought religious food was allowed. Only 35% of controls could guess the correct fasting duration for glucose despite their higher formal educational status.

Among patients, the commonest sources (nonexclusive) of information were: doctors (17% verbal, 2% written, 0% print), another patient (13%), internet (11%), phlebotomist (9%), counselling after this questionnaire (6%). Top information sources for controls were: doctors (36%), Internet (20%), this questionnaire (15%), nurses (5%), and previous improperly prepared tests (3%). Among the instructed controls 83% understood and 72% were compliant about light snacks. Among un-instructed controls, 48% claimed to be aware and 15% adhered to the requirement to avoid snacks.

Awareness and compliance about tea/coffee among patients was 67% and 44% for instructed vs 30% and 0% for the uninstructed. As much as 33% of instructed patients thought religious food could be taken in the morning during fasting, and 11% took them.

On the other hand, 55% of the uninstructed patients thought it was allowable and 19% took them. 100% of both instructed and uninstructed patients claimed to be aware of alcohol and smoking restrictions and compliance was close to 95%. Among the controls 27% thought tea/coffee is allowed, 10% thought snacks are allowed and 3% thought religious food was allowed. Thus, controls also had misconceptions, but to a much smaller extent than patients.

Table-5: Perception of what is allowed during fasting among patients and controls.

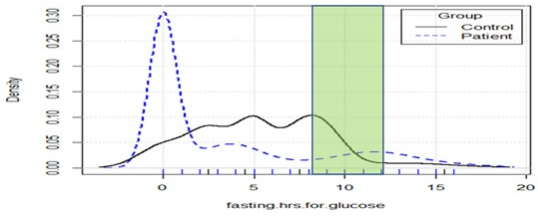
Activities perceived as acceptable during fasting	% of Patients	% of Control
Water	92.93	87.77
Tea/Coffee	67.68	26.6
Prasad/Ramadan Sehir	34.34	3.72
Light Snacks	41.41	10.11
Smoking	2.02	1.06
Alcohol consumption	1.01	1.6
Mild Exercise	17.17	27.66
Severe Exercise	23.23	5.32
Morning Medication	31.31	21.81

Perception of patients and controls about activities they believed were allowed during the fasting for glucose testing.

Among patients, awareness and compliance about tea coffee were 67% and 44% respectively for the instructed vs 30% and 0% for the uninstructed. Even 33% of instructed thought religious food could be taken, and 11% took them. In contrast 55% of the uninstructed thought they were allowable and 19% consumed them. Interestingly 100% of both instructed and uninstructed claimed to be aware of alcohol and smoking and compliance was close to 95%.

Among controls 30% thought tea/coffee is allowed, 10% thought snacks are allowed and 3% thought religious food was allowed. Only 20% of controls could guess the correct range for fasting duration for glucose.

Fig-1: Density histograms of Perception of Fasting duration in patients versus controls.



Kernel density function output of Fasting duration (Hours) in Patients and Controls is plotted together. Blackline is Controls and Blue line is Patients. Green Zone (8-12hr) is the proper duration of fasting. Note that the major density peak of patients is non-fasting (<2 hours) whereas the majority of controls are under-fasting (<8 hours)

Only 15 (15%) patients and 65 (35%) controls recalled fasting for the proper duration. Though the control group was also grossly improper, mostly under-fasting, they had statistically better performance than patients in terms of hours of fasting required. When plotted as a continuous variable, perception of hours of fasting duration needed for glucose was lower than the target (8-12h) in both patients and controls (i.e. majority reported under-fasting), but patients (3.4±4.9h) had a significantly lower duration than controls (5.4±3.7h) and the difference was highly significant (Student's t-test p-value=0.0004)

Table-6: Fasting Duration Categories in Patients versus Controls.

		Fasting duration proper	Fasting duration improper			Total
		Fast 8-12hr	No Fast (<2hr)	Under fast (2-8hr)	Overcast (>12h)	
Group	Control	65	28	82	12	187
	Patient	15	59	17	7	98
Total		80	87	99	19	285

Table 6: Patients and controls stratified by fasting duration: proper fasting duration (8-12 hours), not fasting (<2 hours), under-fasting (2-8 hours), and over-fasting (>12 hours). The difference between the two groups in the distribution of the discontinuous duration categories was also significant: N=285, Chi-Square= 64.816, df=3, p-value=5.491* 10-14.

In the combined population of patients and controls, educational categories were cross-tabulated against fasting duration categories.

Table-7: Fasting duration versus education categories.

		Fasting Duration				Total
		Fast 8-12hr	No Fast (<2hr)	Overfast (>12h)	Underfast (<8hr)	
Education Category	.0	4	28	3	5	40
	1.0	2	9	2	1	14
	2.0	7	8	1	7	23
	3.0	22	16	3	23	64
	4.0	45	25	10	62	142
Total		80	86	19	98	283

Fasting duration categories were cross tabulated against education categories. N= 283, df=12, Pearson Chi-Square=55.545, p-value=1.45*10-7.

Table-8: Proper Fasting duration cross-tabulated against Education categories.

		Fasting Duration Proper		Total
		.0	1.0	
Education Category	.0	36	4	40
	1.0	12	2	14
	2.0	16	7	23
	3.0	42	22	64
	4.0	97	45	142
Total		203	80	283

Fasting for 8-12 hours was considered proper fasting duration and the rest were clubbed into improper fasting duration. Education categories were cross-tabulated against proper fasting duration. N=283, Pearson Chi-Square= 9.983, df=4, p-value=0.041.

Chi-Square analysis (Table 7 and 8) showed that knowledge of proper fasting duration had a significant association with a better education. However, clubbing the different types of misconceptions about durations into a single improper duration category leads to a partial loss of significance, mainly because the relatively more educated people tended to cluster within one subtype (under-fasting) of the improper duration of fasting, and less educated people had higher tendency to be in another subtype (non-fasting).

Overall knowledge was classified into 4 ordinal categories: scored as 3 if conditions and duration both all known, 2 if conditions were known but duration not known, and 1 if only duration known and 0 if neither is known.

Table-9: Instruction and overall knowledge about fasting for a glucose test.

		Overall Knowledge of fasting				Total
		0	1	2	3	
Instructed	.0	83	18	28	6	135
	1.0	49	26	45	30	150
Total		132	44	73	36	285

The overall knowledge is cross-tabulated against instructed status. Overall knowledge was categorized as 3 if all correct, 2 if fasting conditions correct, 1 if duration only correct and 0 if all wrong. N=285, Pearson Chi-Square=29.463, df=3, p-value= 1.79*10-6.

Table-10: Education and overall knowledge about fasting for the glucose test.

		Overall Knowledge of fasting				Total
		0	1	2	3	
Education Category	.0	29	3	7	1	40
	1.0	10	2	2	0	14
	2.0	11	3	5	4	23
	3.0	22	14	20	8	64
	4.0	59	22	38	23	142
Total		131	44	72	36	283

Education Categories cross-tabulated against overall knowledge. Overall Knowledge categorized as 3 if all correct, 2 if fasting conditions correct, 1 if duration only correct and 0 if all wrong. N=283, Pearson Chi-Square 23.491, df=12, p-value=0.024.

Educational categories had a significant association with better overall knowledge which however was not as significant as the impact of instruction. There was a positive Spearman Correlation of +0.185 between education categories and overall knowledge, which was very significant (p-value=0.002)

In contrast to instruction and educational categories, financial categories did not have any significant association with fasting duration (N=266, Pearson Chi-Square=11.990, df=12, p-value=0.446), but there was a mildly significant association with knowing other conditions right (N=266, Pearson Chi-Square=10.796, df=4, p-value=0.029). On a closer look, the association showed a weak negative Spearman correlation (R= -0.112) however the correlation was not statistically significant (p-value=0.068).

Table-11: Financial category and overall knowledge about fasting for a glucose test.

		Overall Knowledge of fasting				Total
		0	1	2	3	
Financial Category	1.0	17	4	13	9	43
	2.0	27	9	11	9	56
	3.0	16	10	19	4	49
	4.0	31	11	8	4	54
	5.0	33	8	17	6	64
Total		124	42	68	32	266

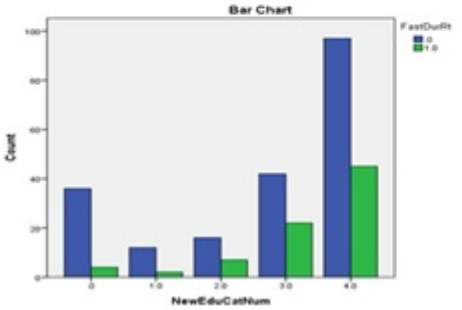
Financial categories cross-tabulated against overall knowledge. Overall Knowledge categorized as 3 if all correct, 2 if fasting conditions correct, 1 if duration only correct and 0 if all wrong. N=266, Pearson Chi-Square 19.675, df=12, p-value=0.073.

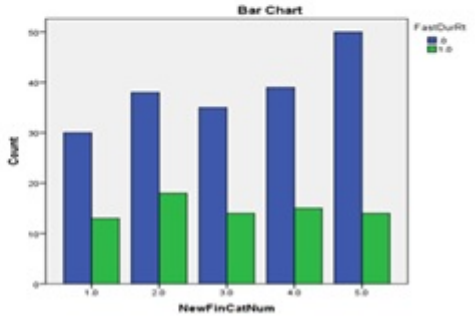
		FastDurRt		
		.0	1.0	Total
NewEduCatNum	.0	36	4	40
	1.0	12	2	14
	2.0	16	7	23
	3.0	42	22	64
	4.0	97	45	142
Total		203	80	283

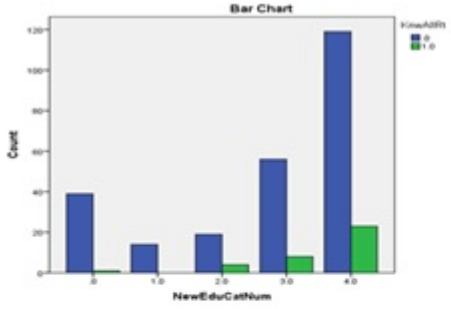
2A: Spearman Correlation +0.130, p-value=0.029*

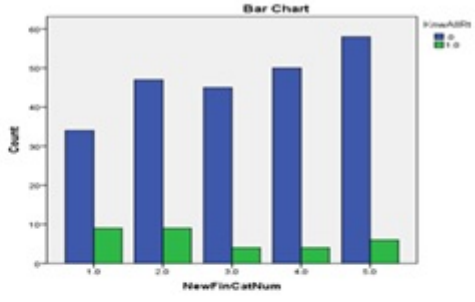
		FastDurRt		
		.0	1.0	Total
NewFinCatNum	1.0	30	13	43
	2.0	38	18	56
	3.0	35	14	49
	4.0	39	15	54
	5.0	50	14	64
Total		192	74	266

2B: Spearman Correlation -0.073, p-value= 0.235









2C: Spearman Correlation +0.131, p-value=0.027*

		KnwAllRt		
		.0	1.0	Total
NewEduCatNum	.0	39	1	40
	1.0	14	0	14
	2.0	19	4	23
	3.0	56	8	64
	4.0	119	23	142
Total		247	36	283

2D: Spearman Correlation -0.127, p-value=0.039*

		KnwAllRt		
		.0	1.0	Total
NewFinCatNum	1.0	34	9	43
	2.0	47	9	56
	3.0	45	4	49
	4.0	50	4	54
	5.0	58	6	64
Total		234	32	266

Fig-2: Spearman Correlation of Educational Status and Financial Status against the knowledge of Fasting Duration and Total Knowledge of Fasting.

Cross-tables and clustered bar charts, with green bars indicating correct knowledge and blue bars indicating incorrect knowledge. A. knowledge of fasting duration tabulated and plotted against educational status, B knowledge of fasting duration tabulated and plotted against financial status, C. total knowledge about fasting (duration and conditions) tabulated and plotted against education status, D. total knowledge about fasting (duration and conditions) tabulated and plotted against financial status. Spearman correlation showed that the educational Status correlated positively (green font) and significantly (* signifies $P<0.05$) with (A) knowledge of fasting duration and (C) total knowledge (duration and condition); whereas financial status did not correlate with (B) knowledge of duration and (D) had a weak negative (red font) correlation with total knowledge (duration and condition).

Discussion

Though the exact degree of reliance on medical decisions on laboratory investigations is difficult to delineate [17] its criticality is unquestionable. Poor investigation results lead to misdiagnosis and contribute to the burden of morbidity and mortality in many ways. Preanalytic variability, though relatively less standardized than the analytic phase, has several components that have been investigated for decades. However, patient preparation, though the most obvious and unavoidable, is still one of the most neglected components of the pre-analytic phase [18].

India is the "diabetes capital of the World" [19] with 45 million diabetics (15% of the world's burden) living in this country. Rajasthan is the largest state in India that historically had a very low prevalence of diabetes (<5% in 1990). However, Rajasthan has shown an alarming jump in diabetes prevalence, increasing by 28-36% in the period 1990-2016 [20]. Diagnosis and monitoring of diabetes become all the more important in this context, which critically depends upon the quality of glucose testing, which includes the quality and duration of the fasting.

In this study, it was found that a large majority (71%) of our patients and a third of our educated controls did not remember receiving fasting instructions for glucose. Patients are on average less educated in formal school education (Table 1) but more affluent (Table 2) than the control group. So, as expected, patients had less knowledge or baseline understanding about duration and other conditions of fasting compared to controls and the majority came in improper fasting state quantitatively or qualitatively. Controls, though better by statistical significance, also were not properly prepared (Figure 1 and Table 6).

Education and instruction both make a significant impact and are associated with a better understanding of duration and other conditions.

However, the uniqueness of the present study is that the ability to see the significance levels of the impacts. It was found that instruction was way more significant (Table 9: p-value=0.00000179) than formal education (Table 10: p-value=0.024) in imparting the awareness about specific medical information regarding fasting.

In contrast to formal education, financial status (Fig. 2) did not have any positive association, but interestingly had a weak negative association with the total knowledge about fasting (Chi-Square borderline significant but Spearman correlation not significant). This finding suggests people who are financially more affluent are likely to be somewhat less complaint.

Instruction overall in the present study had only about 40% final effectiveness which suggests that there is a lot of scope of improvement in improving the content of the instruction and their modality of implementation. The high apparent awareness and compliance about alcohol and smoking found in the present study were likely false due to the shame of disclosure.

The lack of knowledge and poor compliance is partly amplified due to the diffuse responsibility of all stakeholders involved in the total testing process. The poor outcome testifies that, whether the information was provided or not, it was not retained well or adhered to. Some guidelines [3,13] have recently been formulated to standardize the delivery of patient preparation information.

It is counterintuitive that under fasting may not always lead to higher estimates of glucose levels. Reactive hypoglycemia is seen in many conditions including early diabetes where a post-prandial sample may show glucose level relatively lower than fasting [21,22]. Thus the pre-analytic error introduced by the lack of instruction, understanding, or compliance in different aspects of fasting is complex and cannot be normalized post-analytically by some correction formula even if the current study retrospectively knew the exact error in the patient preparation.

The primary way to prevent the error would be to improve the content, quality, intensity, and frequency of the information delivery to the patients and updating the training of their caregivers of all levels through as many means as possible.

While the physicians and policymakers involved in developing guidelines formulate the need for fasting and are responsible for systematically increasing public and professional awareness, it is the Laboratory professionals who implement the preanalytic phase and directly ensure the quality. A review of the guidelines of fasting in different countries [4] showed that the guidelines vary: e.g. for fasting glucose testing the USA, UK, and Italy ask for 8 hours of fasting, the only USA specifies that there should be no food or drink except water.

On the other hand, Australia and the Czech Republic recommend 8-10 hours of fasting, and Germany requires 12 hours of fasting overnight. Despite a few newer guidelines [13,23], this field is still far from harmonization. Unless there is detailed research about the bottlenecks in the implementation, policymakers would not know the ground reality of how well the preanalytic guidelines are being implemented and where it needs to be improved.

Some of the limitations of the study include cross-sectional design, inherent limitations of the survey as a tool (e.g. recall bias), and an unusual combination of the financially affluent but educationally diverse patient population in the catchment area of the hospital. These findings need to be replicated and corroborated and generalized by larger studies in a country like ours, which is heterogeneous in percolation of resources including information availability, health care facilities, and training of personnel as well as the level of education of the local population. The high apparent impact of instruction in patients was because the baseline level of knowledge was low. Also, because of the relatively affluent financial status of the average patients and the relatively small sample size, the current study did not have sufficient representation of the very poor or most underprivileged segment of the population in the Indian context.

There remains an unmet need to improve awareness on this topic at multiple levels, that needs to be done multi-modally including printed leaflets, posters, and audio-visual aids in addition to verbal reminders.

In the future, locally the current study planned to administer corrective actions both in the training of staff as well as the improvement in information content, administration, and reinforcement modalities, and check the effectiveness of these interventions and their evolution in time. At a larger level, it was planned to hold bigger systematic surveys and sensitize the policymakers Nationally and Internationally.

This study is going to contribute to the field of pre-analytic clinical chemistry in India and Internationally in many ways. On one hand, it addresses a lack of harmonization in guideline content Nationally and Internationally, on the other hand, it also brings to attention the poor state of implementation of the guideline that perpetuates poor awareness which in turn amplifies the problem of quality delivery of medical services in multiple ways.

It should add to the literature used to formulate better harmonized preanalytic guidelines, and also it should lead to quality improvement interventions aimed at better percolation and implementation of the guideline at the grassroots levels.

Regarding patient preparation aspects of preanalytic clinical biochemistry, there are no published studies from India and very few studies exist Internationally [24,10,18,11,25]. One of the very few studies on a related topic from another Lower Middle Income Country (LMIC) [26] that could be located was Pant et al study from Nepal, [25] also points to a lack of harmonized definition and protocol for fasting.

A preanalytic survey done by one of the leading groups of the European Federation of Laboratory Medicine (EFLM) [10] found 52% of the patients were not informed about fasting and the rest 48% were also only partly informed.

The present study contrasts with this European study where baseline awareness for fasting was much higher, and rather some of the European subjects believed fasting was necessary for all tests. Another study from Australia [24] found that the female gender was associated with better patient understanding but the female gender did not show any difference in the present study.

A 2012 report by the European Commission [27] showed that the communication barrier between physicians and their patients was partly due to physicians' availability or time to explain.

Laboratories also are supposed to have updated, clear, and understandable written instructions which unfortunately are rarely created or maintained. There should be clear policies for sample acceptance rules for fasting samples. "No-sample is better than a bad-sample" principle should be strictly enforced and re-training of the laboratory personnel should include an emphasis on this.

What does the study add to the existing knowledge?

The current study raises an alert that the present system of information delivery to patients is not able to achieve its intended goal. Revised recommendations should be more harmonized and include precise and practically executable requirements for patient preparation. For fasting blood glucose testing, the time of the day (7-9 AM), the exact range of fasting duration (8-12hours), and water consumption ad libitum, should be specified. At least verbal explanations to avoid religious snacks during fasting should be provided to help clarify the difference between medical fasting and religious fasting. Alcohol avoidance for 24 h, abstinence from cigarette smoking and avoiding exercise in the morning, and strict restriction of calorific or stimulating beverages including tea, coffee, etc. should be promulgated.

Author contributions

Dr. Asmita Hazra: Study conceptualization and design, data collection

Dr. Saptarshi Mandal: Analysis and interpretation

Dr. Seema L. Jawalekar: Review and authorization

Dr. Jairam Rawtani: Review and authorization

Ms. Minal Marlecha: Data collection

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