Effect of pre-operative educational counseling about routine elements of perioperative care on patient's experience through their first surgical journey: A randomized control trial



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ABSTRACT

Background: Pre-operative counseling improves patient's care experience. The trial studied the effect of pre-operative counseling about non-procedural elements of perioperative care, on patients undergoing their life's first surgery. Aims and Objectives: The aim of our study was to investigate whether educating patients on supporting elements of perioperative care inherent to all surgical procedures, but often unaddressed, have a role in improving patient's overall surgical experience, especially through their first surgical journey. The objective was to study the effect of a single structured pre-operative educational counselling session about supporting elements of peri-operative care inherent to all surgical procedures in a tertiary care center, on the patient's personal experience as they journeyed through their first surgical treatment. Materials and Methods: Patients undergoing their first-ever surgery were randomized into test Group A and control Group B. Surgical experience was recorded at 48 h through a regional-language questionnaire. Results: Groups A and B had mean overall surgical experience scores of 71.78 and 62.93, respectively (mean difference (MD) 8.85; P<0.001; the overall surgical experience score was measured using a validated questionnaire). Mean scores in pre-, intraoperative, and post-operative domains were 33.31 versus 30.27 (MD 3.05; P<0.001), 14.47 versus 12.30 (MD 2.15; P<0.001); and 24.00 versus 20.37 (MD 3.63; P<0.001) for the groups, respectively. Significant difference favored the test group in overall surgical experience and specified perioperative periods. Conclusion: Educating patients undergoing their first surgery about elements of perioperative care inherent to hospitalization for any surgery, decreases the anxiety of the patient, and improves patient satisfaction and patients' care experience in their surgical journey.

Key words: Patient-reported outcome measure; Patient empowerment; Patient satisfaction; Questionnaire

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INTRODUCTION

Surgery can be daunting for patients, especially their first experience. Pre-operative counseling refers to an educational intervention before surgery with the aim of improving patient's knowledge, health, and outcome.¹ This usually happens as part of informed consent. The patient is given information specific to the procedure and expected procedure-related benefits, risks, safety, and care arrangements available to ensure safe treatment.

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Despite such procedure-specific counseling being standard practice, patients often suffer peri operative anxiety which overwhelmingly comes to define their experience with surgical care despite good treatment outcomes. Several international studies have looked into the effect of preoperative counseling on individual aspects such as anxiety, ^{2,3} length of stay, ³ and pain. ² However, there is a lack of data on the effect of pre-operative counseling about routine peri-operative hospital processes on the overall experience of the patient through their first-ever surgical care journey.

The lack of evidence led us to null hypothesize that pre-operative counseling about routine non-procedural elements of perioperative care would have no impact on patient's overall surgical experience, through their first surgical journey.

Aims and objectives

The aim of the study was to determine whether preoperative counselling about routine non procedural elements of perioperative care could improve patient's overall surgical experience, through their first surgical journey.

MATERIALS AND METHODS

After seeking clearance from the institutional ethics committee and institutional review board (IRB), the trial was registered in the Clinical Trial Registry. Patients charted for the first surgical procedure in their life, who satisfied our inclusion criteria were enrolled in the randomized Control Trial of parallel design.

Inclusion criteria

Inpatients admitted to surgical wards for general surgical and urology procedures at a tertiary care teaching hospital in the region with the following attributes.

- a) Age group: 18–80 years
- b) Charted for their life's first surgical procedures under general and spinal anesthesia.

Exclusion criteria

- Patients undergoing major surgeries requiring postoperative intensive care other than immediate recovery from anesthesia
- b) Patients undergoing minor surgeries under local anesthesia
- c) Patients undergoing emergency surgical procedures
- d) Patients who have had previous surgical experience apart from obstetric procedures.

In the absence of a suitable questionnaire in the regional language, one was developed, validated by an expert committee of 9 members (including 6 doctors, 2 nurses, and a counselor),

and statistically validated by a qualified bio-statistician using Cronbach's alpha. The questionnaire comprised 15 questions divided into three sections of 5 questions each to cover three periods of their surgical treatment journey; (domain 1: preoperative experience, domain 2: Operation theatre experience, and domain 3: postoperative experience) marked on a 5-point Likert scale (Annexure 1).

Sample size (n=62) was calculated based on a pilot study on twenty patients accepting type I error α at 5% and type II error β at 20% and a standard deviation of 5 using the formula.

$$n = \frac{2\sigma^2 (Z\alpha + Z1 - \beta)^2}{\frac{1 - 2}{\mu_d^2}}$$

 $Z_{_{1\text{-}\alpha/2}}=1.96$ [at 5% α] $Z_{_{1\text{-}\beta/2}}=1.84$ [at 20% β] $\sigma=SD$ $[\sigma_{_1}\text{-}\sigma_{_2}]$ $\mu_{_d}^2=$ clinically significant difference = 5.

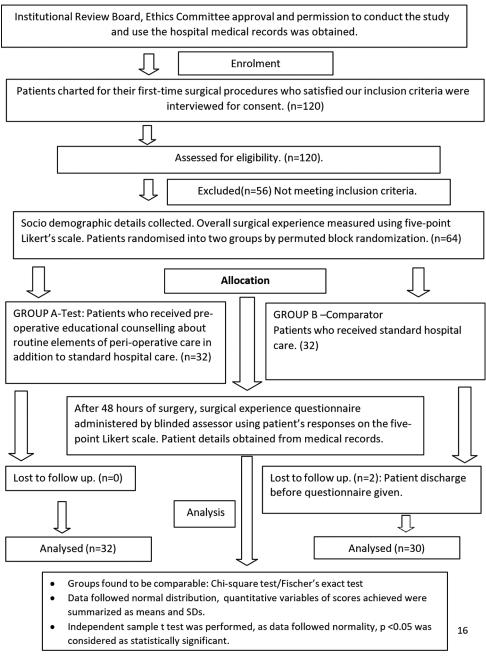
Patients were randomized into two groups by permuted block randomization with allocation concealment using closed envelopes to eliminate recruitment bias with an allocation ratio of 1:1. Envelopes were opened only after eligibility and consent from the subject being enrolled were confirmed. Random allocation envelopes were prepared by an individual not involved in recruitment or assessment.

Blinding of participants was achieved by the recruiting investigator spending equal time speaking with subjects from both groups after group allocation to avoid subjective bias among the recruited subjects admitted to the same ward. Double blinding was achieved by ensuring the delivery of the experience assessment questionnaire 72 h after surgery by an assessor blinded to the allocation.

Statistical analysis of the data was done using R software and Chi-square test calculator from Social Science Statistics (https://www.socscistatistics.com/tests/chisquare2/default2.aspx).

OBSERVATIONS AND RESULTS

Based on the defined criteria, 62 subjects were randomized to the Test group (n=32) and control group (n=30) (Annexure 1: Consort Flow chart). The trial was to be conducted as per institutional mandate between February and April 2020 but was rescheduled till the relaxation of COVID-19 restriction in March 2021 for 3 months. IRB and CTRI were duly notified of these unavoidable changes. Recruitment was stopped when the desired sample was reached. Male-to-female ratio was 59.4: 34.3, and 63.4: 36.5



Annexure 1: Study flow diagram (following consolidated standards of reporting trials guidelines)

in the test and control groups, respectively. (P<0.05) Majority of the participants in both groups had an educational qualification equivalent to a high school degree or higher degree. 56.2% of the participants in the test group and 63.3% of the participants in the control group underwent minimally invasive surgical and urological procedures (P<0.05) (Table 1).

The test and compared groups were compared for confounding factors such as influence of type of procedure and comorbidities and were found to be comparable in all other aspects other than the intervention under study using the Chi-square test.

The data of results were confirmed to follow a normal distribution (Kolmogorov–Smirnov test). An independent sample T-test was performed between the groups to check for the significance of the difference in the mean overall surgical experience score as well as the mean of domain scores covering three periods of their surgical treatment journey facilitated by the design of the questionnaire. It was observed that surgical experience score of the test group was 71.78 (SD=3.2) and the control group was 62.93 (SD=6.44) with a mean difference 8.85 (95% CI [6.21–11.49] P<0.001) (Table 2).

We also observed that there was a significant difference in the average score between the control group and experimental group in all the 3 domain scores namely preoperative, operation theater, and post-operative experience score with mean differences of 3.05 (95% CI [1.43–4.67] P<0.001), 2.17 (95% CI [1.39–2.95] P<0.001), and 3.63 (95% CI [2.69–4.58] P<0.001), respectively (Table 3).

A subgroup analysis of the questionnaire response revealed that the sum of scores of the patients of agreement in principle to the positively worded questions (agree+strongly agree) and disagreement in principle to the negatively worded questions (disagree+strongly disagree) in the control group agreed in principle to the statement that they felt confident in going ahead with the surgery with no disagreement in principle in either group to that question.

When similar scores were considered for strong agreement

and strong disagreement with the same questions considered above, a significant difference was observed between the 2 groups. 96.8% of the test group as against 66.7% of the control group strongly agreed with the statement that they felt confident in going ahead with the surgery.

DISCUSSION

Surgery, however, vital and well performed, has an undeniable effect on the emotional health of a patient, which can in turn affect post-operative physical recovery and compliance to future medical treatments.⁴

Patient satisfaction is as important as the clinical outcome from surgery in terms of service delivery and planning.

Table 1: Demographic comparability						
Variables	Groups		Chi-square/fishers exact test	P-value		
Sex	A: Test	B: Control	0	1		
Male	21 (59.4)	19 (63.4)				
Female	11 (34.3)	11 (36.5)				
Education			4.34	0.23		
Graduate/PG	15 (46.9)	8 (26.7)				
Higher sec school (A level)	3 (9.4)	4 (13.3)				
High school (GCSE)	7 (21.9)	13 (43.3)				
Primary school	5 (15.6)	4 (13.3)				
No formal education	2 (6.2)	1 (3.3)				
Occupation			Fishers exact test	0.1		
Employed	10 (31.2)	11 (36.6)				
Professional	5 (15.6)	2 (6.7)				
Retired	3 (9.4)	0				
Self employed	1 (3.1)	6 (20)				
Unemployed	13 (40.6)	11 (36.7)				
Co-morbidities			0.522	0.47		
Absent	24 (75)	20 (67)				
Present	8 (25)	10 (33)				
Surgery type			Fishers exact test			
Lap	5 (15.6)	7 (23.3)				
Min. Invasive (urology)	18 (56.2)	19 (63.3)				
Open	9 (28.1)	4 (13.3)				

Table 2: Mean surgical experience score test versus control group							
Variable	Group	n	Mean	Mean difference	T-statistic	P-value	95% CI
Overall surgical experience score	Test Control	32 30	71.78 62.93	8.85	6.76	<0.001*	6.21–11.49

CI: Confidence interval. P<0.05 was considered as statistically significant

Variable	Group	n	Mean	Mean difference	T-statistic	P-value	95% CI
Presurgical experience score	Test	32	33.312	3.05	3.76	<0.001*	1.43-4.67
	Control	30	30.27				
Experience score during surgery	Test	32	14.468	2.17	5.60	<0.001*	1.39-2.95
	Control	30	12.300				
Postsurgical experience score	Test	32	24.000	3.63	7.76	<0.001*	2.69-4.58
	Control	30	20.366				

A key determinant of patient satisfaction is patient education.^{5,6} A common method of coping with an anticipated life event is by obtaining information which reduces the degree to which it is perceived as being stressful.²

The standard process of consenting for surgery focuses on treatment options, benefits versus risks of the proposed procedure, steps taken to ensure safe outcomes, and expected recovery process including return to normal work and life.

While there has been recent emphasis on improving patient's pre-operative, operative, and post-operative experience to improve satisfaction and aid recovery there was a dearth of literature on the effect of preoperative educational counseling about routine elements of peri operative care in improving a patient's surgical experience. This study was, therefore, a novel attempt to investigate the effect of educating patients about routine elements of perioperative care inherent to all surgical procedures, but often unaddressed, in improving patient's overall surgical experience during their life's first surgical treatment journey.

We observed from our study that there existed a significant difference in the surgical experience score between test and control groups (P<0.001). A significant difference in the average domain scores between the counseled group and uncounseled group was also noted in all three questionnaire-defined treatment period domains (preoperative, operation theater, and postoperative experience domains). A statistically significant difference was thus observed in the surgical experience score between the groups in favor of the test group validating the effectiveness of the study intervention.

The sub-group analysis of the questionnaire response observed that the sum of overall agreement in principle (agree+strongly agree) and disagreement in principle (disagree+strongly disagree) between both groups were not significantly different. This in all possibility reflects the effect of the robust surgical consenting process which ensured that all the patients were certain beyond doubt that they needed to undergo surgery with all its inherent benefits and risks even though they had less than maximal confidence in their experience reflected in the post-operative questionnaire score.

However, the statistically significant difference in favor of the test groups when responses of strong agreement or strong disagreement were considered clearly reflects the influence of the counseling intervention in boosting the confidence of the patients to certainty as also reflected by other studies that offer similar evidence for the positive effects of preoperative counseling on different variables post operatively.⁷⁻¹⁰

Multiple studies have proven that satisfied patients have better health outcomes because they tend to the obey doctor's advice, refrain from malpractice litigations, comply with treatment regimens, attend follow up appointments, and ask for medical advice when required. 11,12 A metaanalysis of 68 studies undertaken by Hathaway⁸ indicates that patients who receive preoperative education have 20% favorable post-operative outcomes of physiological variables, (length of stay, sedatives used, recovery, and complications) and psychological variables (observed ratings of cooperation, scores of self-reported anxiety inventories, etc.) compared to those patients who did not receive preoperative education.8 These results are comparable to our study wherein in we observed favorable outcomes among the test population in terms of various pre-operative, intraoperative, and post-operative elements.

To balance our conviction based on our observations we would like to also highlight a few studies that show negative or no effect of pre-operative counseling on patient outcomes. 13,14 They report difficulties experienced in counseling or patient's inability to understand or use the information provided as reasons for the contrary results. The high level of literacy in the state of Kerala, delivery of structured information in the patient's mother tongue as well as use of a purpose-designed and validated questionnaire in the regional language allowed us to minimize the effect of these confounding factors experienced by the aforementioned researchers, in the present study.

The restriction on the duration of the trial and permission to recruit beyond minimum calculated sample size due to COVID-related interaction guidance pertaining to non-clinical activity has to be declared as a trial limitation. The achievement of sample size ensured outcomes were unaffected by this limitation.

Limitations of the study

The limitation posed by time restriction on the project only allowed for limited recruitment of subjects to fulfill the statistically required number of subjects for the study. An increase in the number of subjects would have further improved the relevance of the findings.

CONCLUSION

Pre-operative educational counseling about routine elements of peri-operative care in addition to routine surgical consent process significantly improved the patient's experience through their first surgical journey. Routine introduction of such counseling for patients regarding peri-operative care could serve to improve the patient's overall surgical experience and in turn translate to a higher level of confidence among patients to seek treatment when needed without fear, thus improving outcomes.

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FSK- Study design, data collection, writing, data analysis; JEJ- Study design, writing, data analysis, implementation of counselling; SB- Concept, study design, writing, data analysis.

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