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A Randomized Study to Evaluate Effectiveness of Verbal *vs*. Written Peri-operative Information Developed by Quality Improvement (QI) Module for Assessing Patient Satisfaction and Quality of Life

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Abstract

Background: Adequate and effective information to the patient on their disease and proposed surgery is an important component of surgical care. This study is a collaborative effort for developing a Quality Improvement (QI) module using Plan-Do-Check-Act (PDCA) approach and to evaluate its effectiveness in a randomized trial, to standardize the process of passing information to patient in a more systematic way.

Materials and Methods: This study was conducted in single surgical unit of tertiary care hospital in two phase and all patient undergoing laparoscopic cholecystectomy and inguinal hernia repair were included. In phase I QI module was standardized by PDCA approach. The effectiveness of QI module was tested by a randomized study in phase II. The patients were randomized in two groups, control group (regular protocol) and study group (QI module in addition to the regular protocol) in preoperative period. The patient satisfaction and perception of care were assessed at the time of discharge and after 30 days using a predefined questionnaire on Likert scale (1-10). Quality of Life (QOL) was assessed by WHOQOL BREF.

Results: QI module was standardized after three PDCA and FGD after improving the patient satisfaction of more than 95%. In phase II there was significant improvement in patient satisfaction in various aspects in PSS (p=0.025), improvement of QOL (p=0.02), satisfaction of health (p=0.005) and psychological health in WHOQOL BREF of study group (p=0.002).

Conclusion: The verbal preoperative information augmented with QI module improved the patient satisfaction, quality of life and perception of care in surgical patients.

Keywords: Quality improvement; PDCA approach; Patient satisfaction and Quality of life

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Introduction

Communication in all spheres of medicine has gained importance in recent times. Effective communication skills are now being taught in the undergraduate curriculum now in many medical universities. Adequate and effective information to the patient about their disease and proposed surgery is an important component of surgical care. Information is essential not only for patient's knowledge and satisfaction; it allays anxiety and is also important from medico-legal aspect. Research has shown that providing adequate preoperative information to the patient's results in shorter hospital stay, less analgesia requirement in postoperative period and increased satisfaction of the patient with the care provided [1]. Lack of information is one of the important sources of patient dissatisfaction and studies have shown that patients want more information than they received and they received less information than their surgeons believed they were providing [2,3]. Preoperative information about the disease, procedure and potential complications ensure that patients no longer reach the operation table frightened and unaware of what will happen to them [1].

In our system most of the information related to disease and procedure is informed to patient by residents or nursing officer in wards. However, most of the time patients are inadequately informed

due to paucity of time and resident not understanding the value of communication with the patient. Treating faculty plays the role of mentor to the resident and comes into the picture only when rare diagnosis is made or unusual events happen during surgery. There is a need to develop system involving paramedical staff like nurses, clinician assistants as in western countries who pass information related to the disease and procedure to the patients in a more effective and structured format. Quality Improvement (QI) initiatives have enormous potential to improve delivery of care especially in the providing effective communication, but well publicized research successes have proved difficult to replicate outside the trial setting [4,5]. The successes of QI initiative on a wider scale remain poorly understood, but two key factors that often noted are the engagement of paramedical staff in the broader initiative, and the context in which it takes place. Involvement of clinical staff and detailed understanding of the content and logistical issues are pivotal for successful QI initiative [6,7]. Plan- Do-Check-Act (PDCA) is a well-recognized way to develop QI initiative which has various advantages. PDCA cycles provide one such method for structuring iterative development of change, either as a standalone method or as part of wider Quality Improvement (QI) approaches, such as the Model for Improvement (MFI), Total Quality Management, Continuous QI, Lean, Six Sigma or 'Quality Improvement Collaborative'. Some PDCA approaches have been demonstrated to result in significant improvements in care and patient outcomes [8]. The present project was a collective effort of the treating surgeons, nursing care staff, psychiatrist and quality improvement expert to develop a QI module by PDCA cycle, to standardize the process of passing information to patients regarding their disease, surgery and post-operative outcome and care in a more systematic way. The effectiveness of this QI module in patient's satisfaction and perception of care was evaluated by a pilot randomized trial.

Materials and Methods

This study was conducted in a single surgical unit of a tertiary care hospital after clearance from the Institute ethics committee. All patients undergoing elective surgery for gall stone diseases and inguinal hernia under general anesthesia were included. Patients undergoing emergency surgery, re-operation, having a post-operative hospital stay less than 12 h or more than 7 days and procedures under local anesthesia were excluded from the study. A written informed consent was taken from all the patients. The study was conducted in two phases. In the first phase a Quality Improvement (QI) module was developed with the help of PDCA cycle and in the second phase patients were randomized to evaluate the effectiveness of the QI module. This was a pilot study and a sample of convenience of 90 patients was taken for development of quality improvement module and another 60 patients were randomized for evaluation of quality improvement module.

1st Phase

During this phase, a module (printed patient information sheet) to improve the delivery of information to hospitalized surgical patients regarding their disease and treatment was developed by quality improvement team. The effectiveness of the QI module after each Plan-Do-Check-Act (PDCA) cycle was assessed using Patient Satisfaction Scale (PSS) on a Likert scale (1-10). The questionnaire used to asses' patient's satisfaction and perception of care was used earlier by Specht et al. [9] to evaluate the patient's satisfaction after knee replacement which was partially modified for the present study

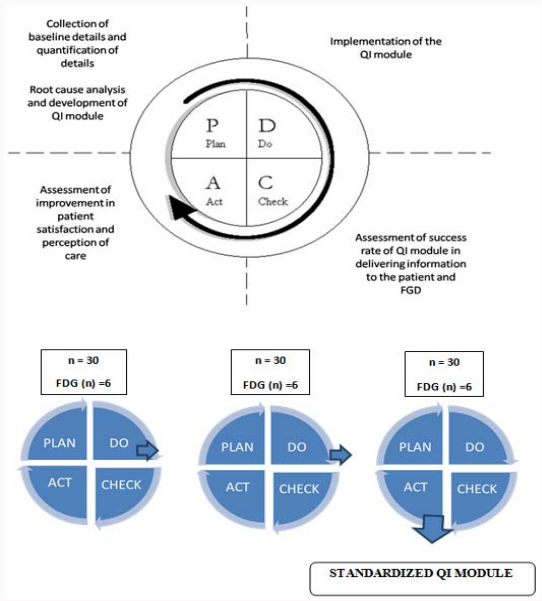

Figure 1: Schematic diagram of phase I of the study.
Phase 2: Evaluation of the Quality Improvement (QI) module in improvement of patients' satisfaction and perception of care by a randomized trial.

(Figure 1). The development process of the QI module constituted the following PDCA steps:

Plan: Collection of base line details, root cause analysis and development of Quality Improvement module (QI module).

The treating surgeon, quality improvement specialist, psychiatrist, surgical residents and nursing staff collectively constituted a QI team. Thirty patients who fulfilled the inclusion and exclusion criteria were enrolled for this study. Details about demographics, disease, education, occupation and monthly income were collected. The patients underwent the surgery and were discharged without any intervention. Patient were given a questionnaire at the time of discharge to assess how much information was provided to them about the disease and procedure for surgery by the operating team pre-operatively (Figure 2). QI team designed the first draft of QI module (PIS) based on the information given by the patients and possible root causes of failure in delivering adequate information were analyzed by the team and ways to overcome it were discussed and added in the QI module. All efforts were made by the QI team to make the module easily adoptable and sustainable.

Do: Quantification of the problem and Implementation of the QI module.

The first draft of QI module was implemented in 30 pre-operative patients.

Check: Assessment of success rate of QI module & Focused Group Discussion (FGD).

The success rate of QI module was evaluated using Patient Satisfaction Score (PSS) (Figure 1) on a Likert scale (1-10) at the time of discharge. First FGD was organized between the QI team and randomly selected 5 to 6 patients enrolled during implementation of 1st draft of QI module and the problem in the QI module and patient's expectation were discussed.

Act: Changes in QI module

Patient's problems, their expectation, pitfalls of the QI module

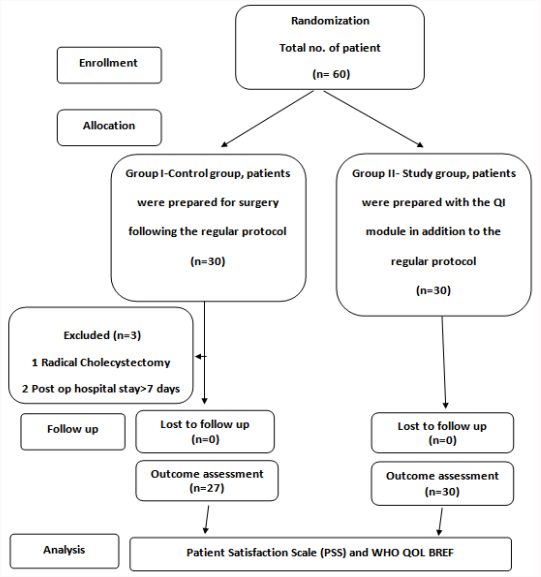

Figure 2: Consort Diagram of phase 2 of the study.

were also critically evaluated by the QI team and a revised QI module was developed based on the feedback received in FGD. The revised QI module was again assessed using similar PDCA cycle and FGDs and a final QI module was developed which consistently provided information about the disease, treatment and more than 90% of hospitalized patients were satisfied with the information provided. Three PDCA cycles were conducted to achieve this. The QI module was then standardized for phase 2 of the study.

2nd Phase

In this phase an evaluation of the Quality Improvement (QI) module was done by a randomized trial. The study was conducted as per CONSORT guidelines after due clearance from the Institute Ethics Committee. ICMR/GCP guidelines for a randomized trial were followed.

Consecutive patients who underwent laparoscopic surgery for gall stone disease or inguinal hernia and meeting the inclusion criteria were randomized by computer generated random numbers using block randomization (www.randomization.com) in sealed opaque envelopes and were divided into two groups, Group I - Control group, patients were prepared for surgery following the regular protocol (spoken information) and Group II - Study group, patients were prepared with the QI module (printed PIS) in addition to the regular protocol (spoken information) in preoperative period. The treatment received by both the groups was similar in preoperative preparation, surgery and postoperative care. The patient's satisfaction and perception of care were assessed at the time of discharge from the hospital and after 30 days using the patient satisfaction score (Figure 1) on a Likert scale (1-10). Quality of life was assessed by WHO QOL BREF; preoperatively as well as 30 days following surgery and the data was analyzed.

Statistical analysis

The data were entered into Microsoft excel software and were analyzed by using SPSS version 15. The statistical method applied was student t - test/Mann Whitney U test, whichever was applicable to compare the continuous data between the two groups and the categorical variables were compared using Chi - Square test/Fisher exact test. A p-value of <0.05 was considered as significant.

Results

Phase I was an observational study. The QI module was developed and effectiveness and validity tested with Patient Satisfaction Scale (PSS) in ninety patients (n=90) who were planned for laparoscopic cholecystectomy and laparoscopic mesh repair for inguinal hernia in three PDCA cycles. In the first PDCA cycle 30 patients were included, PSS score was 5.4 ± 0.3 (Table 1). Six patients were called randomly for the first Focus Group Discussion (FGD). With the feedback during FGD, the facts that were added to the QI module after 1st FGD, were articles used in operation (mesh and drains), the terminology was changed to simple language and the language of the consumables for surgery were included in the QI module. In the 2nd PDCA cycle, modified QI module was given to another thirty patients (n=30) and the response was evaluated with PSS. The overall satisfaction score improved to 8.3 ± 0.6 (Table 1). Second Focus Group Discussion (FGD) was done and six patients were called randomly. The timing of operation and the probability of cancelation of the surgery were added to the QI module after 2nd FGD. In the 3rd PDCA cycle QI module was further modified and conducted on another thirty patients (n=30) and PSS further improved to 9.3 ± 0.3 (Table 1). After the 3rd FGD, post-operative dietary plan and time to return to normal activities were included. The QI module was standardized after reaching PSS of more than 90%. In Phase II, 60 patients were randomized. Out of these 3 were excluded (one patient underwent radical cholecystectomy and 2 patients had post-operative hospital stay of more than 7 days). Fifty-seven patients were included in the final analysis. Twenty-seven in control group (conventional protocol, spoken information) and thirty patients in study group (spoken information supported with

Table 1: Patient Satisfaction Scale (PSS), Phase 1.

	1st cycle (n=30)	2nd cycle (n=30)	3rd cycle (n=30)
	Mean ± SD	Mean ± SD	Mean ± SD
Q1. How satisfied were you with the information you received about your disease?	5.7 ± 0.7	8.9 ± 0.4	9.8 ± 0.4
Q2. How satisfied were you with the information you received about the surgery you had undergone?	5.8 ± 0.8	8.3 ± 0.6	9.4 ± 0.4
Q3. How satisfied were you with the information you received about the postoperative outcome?	5.2 ± 1.1	8.2 ± 0.8	9.1 ± 0.3
Q4. Were you satisfied with the length of your stay in hospital?	5.1 ± 1.1	6.7 ± 1.0	8.6 ± 0.5
Q5. How well informed did you feel about the time after discharge?	5.1 ± 1.2	8.3 ± 0.7	9 ± 0.2
Q6. How satisfied were you with your discharge procedure?	5.4 ± 0.8	8.4 ± 0.6	9.3 ± 0.4
Q7. How satisfied were you throughout the few weeks after discharge?	5.3 ± 0.7	8.5 ± 0.7	9.4 ± 0.5
Q8. How was your overall satisfaction with the entire process?	5.9 ± 0.75	9.1 ± 0.5	9.8 ± 0.4
Q Total	5.4 ± 0.31	8.3 ± 0.6	9.3 ± 0.3

Table 2: Demographic Profile, Phase 2.

S.N.	Parameters	Control group n=27	Study group n=30	p value
		Mean ± SD	Mean ± SD	
1	**Age (years)**	41.9 ± 16.9 (17-78)	43.5 ± 14.4 (17-72)	0.7
2	**Gender**			1.0
	Male	13 (48.1%)	15 (50%)	
	Female	14 (51.8%)	15 (50%)	
3	BMI	22.2 ± 1.4 (18.3-26.1)	22.2 ± 1.3 (18.7-25.3)	0.9
4	**Education**			0.8
	Uneducated	6 (22.2%)	5 (16.6%)	
	Primary (1-4)	4 (14.1%)	4 (13.3%)	
	Secondary (5-10)	11 (40.7%)	11 (36.6%)	
	Higher	6 (22.2%)	10 (33.3%)	
5	**Income**			0.7
	Lower	6 (22.2%)	4 (13.3%)	
	Middle	19 (70.3%)	24 (80%)	
	Upper	2 (7.4%)	2 (6.6%)	
6	**States**			0.1
	Delhi	19 (70.3%)	15 (50%)	
	Others	8 (29.6%)	15 (50%)	
7	**Surgery**			0.7
	Lap cholecystectomy	16 (59.2%)	19 (63.3%)	
	Lap mesh repair	11 (40.7%)	11 (36.6%)	
8	**Hospital stay (days)**	3.1 ± 1.1 (2-6)	3.40 ± 1.3 (2-6)	0.5

quality improvement module, leaflet) and were followed up for 30 days post operatively. No patient was lost to follow up. At follow up, interview was taken directly or telephonically and data was analyzed. The demographic profile was similar between the two groups (Table 2). Average length of hospital stay was similar in both the groups (3.14 ± 1.9 days *vs.* 3.40 ± 1.3 days). The Patients Satisfaction Scale (PSS) showed significant improvement in the study group as compared to the control group in the all aspects of information given to the patient (Table 3). Overall satisfaction with the entire process (9.6 ± 0.4 *vs.* 9.2 ± 0.9, p=0.025) was significantly higher in study group than in control group (Table 3). The base line quality of life was evaluated in both the groups with pre-operative WHO-QOL BREF. The QOL was similar in the pre-operative in both the groups. However, there was a significant improvement in scores for quality of life (p=0.02) and satisfaction with health (p=0.005) in post-operative period (Table 4, 5). In the post-operative period score for the psychological health (57.3 ± 7.8 *vs.* 65.8 ± 11.7, p= 0.002) and overall score (208.5 ± 22.2 *vs.* 249 ± 39.0, p=0.01) showed significantly better score in the study group (Table 6).

Discussion

Preoperative information about the disease, surgery and post-operative course is very crucial for the patient's satisfaction and feeling of receiving quality of care. The information must be comprehended also, coordinated by the patient in spite of an anxiogenic setting, which does not make things simpler. On a social and juridical level, improvement of this information is essential. Health information can be provided to the patient by health care professionals who are in the best position to provide it. Proude et al. [10] suggest that with most of the world population now having access to the World Wide Web, there is risk of accessing information that is wrong, harmful or incomprehensible. It is therefore crucial that clear, precise and accurate information is provided to the patient during his course of treatment and all his queries or concerns are addressed. Memory for medical information is often poor and inaccurate, especially when the patient is anxious. Patient tends to focus on diagnosis related information and fail to register instructions on treatment. Simple and specific instructions are better recalled than general statements. Research has shown that patient remembers only 20% of the verbal information and instructions and forgets half of the information within five minutes [11]. Additional written information can improve retention of information by the patients by 50% [12]. Although written information alone is not adequate enough and can never replace 'one to one' communication between doctor and patient but it acts like a guide to the patient who wants to understand what will happen to them throughout the hospital stay and in post-operative period. As time constraints are going to be more pronounced in coming days with compulsory 48 h working limits and cost cutting in the healthcare sector, the stay in hospital and the time available for patient consultations are becoming even shorter. The development of a system to deliver information on the disease and procedure to the patient in a more effective and structured format is very essential. Giving written information to the patient can reduce the time which a healthcare professional spends with the patient on repetition of routine information and instruction. It is recognized that there is difference in understanding and memorization of information by the patients provided by different means (oral, written text, illustrations, animation). Patient can understand better and memorize for longer period of time when provided with verbal information supported by written information. Written document can act as a consultation

Table 3: Patient Satisfaction Scale (PSS), Phase 2.

	Control group (n=27)	Study group (n=30)	p value
	Mean ± SD	Mean ± SD	
Q1. How satisfied were you with the information you received about your disease?	5.7 ± 2.6	9.6 ± 0.9	0.0001
Q2. How satisfied were you with the information you received about the surgery you had undergone?	6.7 ± 1.2	9.6 ± 0.6	0.0001
Q3. How satisfied were you with the information you received about the post-operative outcome?	5.8 ± 1.5	9.5 ± 0.7	0.0001
Q4. Were you satisfied with the length of your stay in hospital?	4.6 ± 1.3	7.0 ± 1.8	0.0001
Q5. How well informed did you feel about the time after discharge?	6.9 ± 1.1	9.2 ± 0.8	0.0001
Q6. How satisfied were you with your discharge procedure?	7.5 ± 1.3	9.2 ± 0.7	0.0001
Q7. How satisfied were you throughout the few weeks after discharge?	7.4 ± 1.1	9.3 ± 0.7	0.0001
Q8. How was your overall satisfaction with the entire process?	9.2 ± 0.9	9.6 ± 0.4	0.025
Q Total	54.0 ± 6.7	73.4 ± 3.6	0.0001

Table 4: WHOQOL BREF, Phase 2, overall quality of life.

How would you rate your quality of life? Scores	Pre-operative period			Post-operative period		
	Control Group (n=27)	Study Group (n=30)	p value	Control Group (n=27)	Study Group (n=30)	p value
1	0	0	0.3	0	0	0.02
2	0	1		0	0	
3	19	24		13	12	
4	8	5		13	9	
5	0	0		1	9	

Table 5: WHOQOL BREF, Phase 2, satisfaction with health.

How satisfied are you with your health? Scores	Pre-operative period			Post-operative period		
	Control Group (n=27)	Study Group (n=30)	p value	Control Group (n=27)	Study Group (n=30)	p value
1	0	0	0.65	0	0	0.005
2	2	2		1	0	
3	25	28		18	10	
4	0	0		8	14	
5	0	0		0	6	

Table 6: WHOQOL BREF, Phase 2.

Domain	Pre-operative period			Post-operative period		
	Control Group (n=27)	Study Group (n=30)	p value	Control Group (n=27)	Study Group (n=30)	p value
Physical health	54.1 ± 5.2	54.6 ± 4.4	0.68	59.7 ± 4.6	63 ± 9.2	0.1
Psychological health	56.3 ± 4.8	55.9 ± 4.6	0.74	57.3 ± 7.8	65.8 ± 11.7	0.002
Social relationship	52.7 ± 13.3	53.3 ± 13.8	0.86	53.4 ± 13.9	58.9 ± 14.6	0.15
Environmental	43.8 ± 8.6	44.5 ± 5.8	0.72	56.4 ± 7.07	61.5 ± 13.2	0.07
Overall Domain	207.1 ± 19.6	208.5 ± 22.2	0.7	226.9 ± 23.1	249 ± 39.0	0.01

for infinite period of time; whenever patient wants, they can use it as a consultation or re-confirmation. In this study preoperative information was given to the patient in the form of leaflet (QI module) in addition to verbal information which was standardized with PDCA protocol and the efficacy assessed in a randomized study.

There are various studies that evaluate the addition of various multimedia methods (leaflet, audio, and video) to the spoken information. Navipour et al. [13] conducted a study to assess effect of FOCUS PDCA process strategy on patient satisfaction in surgery units of hospitals affiliated to Tehran Medical University and found a significant difference before and after following intervention in patient satisfaction (P>0.0001). Our study showed that there is significant improvement in the level of satisfaction and perception of care with the information provided to the patient in the form of leaflet (QI module) (p=0.025). There was improvement in all domains of WHOQOL BREF (p=0.01) with the use of QI module but improvement in the psychological health was significant (p=0.002). The quality of life (p=0.02) and satisfaction (p=0.005) with health were significantly improved with the use of QI module. There have been no studies in literature in general surgery patients undergoing laparoscopic surgery. Although there are many studies from other specialties which have shown similar results and our outcomes are in accordance with those of different investigations assessing the advantages of written document in preoperative information. Facca et al. [14] estimated in their cohort of 37 patients divided in two groups, who were operated for carpal tunnel syndrome (the first 18 received only oral information and the following 19 received oral, written and visual information) that there is significant improvement in the satisfaction level of the patients receiving written and visual information compared to those who received only spoken information. Similar results were found by Angiolo et al. [15] in a randomized study for preoperative information in patients of gynecologic oncology surgery. They concluded that there is faster recovery, low pain medication uses and better quality of life outcome with the use of preoperative information leaflet. Improving quality of information and customizing it through the leaflet (QI module) fortifies the sentiment of accepting quality care. There is no doubt of the benefit of such written information as a support during the preoperative period, but also as a means of information to enhance memory until the day of the operation. In a study randomized the patients undergoing functional endoscopic sinus surgery in two groups according to mode of preoperative information received, printed leaflet or website [16]. They found that there were similar rates for usability, readability and recall of complications. Merley et al. [17] conducted a randomized control trial in patients undergoing GI surgery for preoperative information about Surgical Site Infection. 207 patients randomized in two groups receiving information in the form of oral or oral and leaflet. There was higher satisfaction level in patient receiving information with leaflet than oral which is in line of our study. There were few limitations of this study. Only those

patients were enrolled who underwent laparoscopic cholecystectomy or lap mesh repair of hernia surgery, so this study fails to express about the patient satisfaction and perception of care for other laparoscopic surgeries as well as open surgeries. As we have already discussed that memorization of information is more in case of oral information supported by written information than in case of oral information only that may lead to some changes in results. It was difficult to collect data from the patients who were illiterate.

Conclusion

In conclusion this study shows that the preoperative information in spoken form augmented with quality improvement module (leaflet), increases the satisfaction of the patients in various aspects. Psychological health, quality of life and satisfaction with health of patient's improved significantly. These forms of QI modules should be developed for all patients undergoing surgery and support and help of paramedical staff especially nursing professional should be used more often in communication with the patient about his disease and course of treatment and post-operative care.

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