

Effect of patient information leaflet on working pattern and patient satisfaction level in a busy Indian day care operative theater complex

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Abstract

Background and Aims: In a day care setting, communication of preprocedure instructions prior to general anesthesia (GA) is critical. Verbal information may be inadequate at times leading to unnecessary rescheduling. The aim of the study is to evaluate the use of patient information leaflet (PIL) and its impact on rescheduling and patients' satisfaction levels.

Material and Methods: Adult ASA I-III patients scheduled for elective day care Head Neck procedures such as direct laryngoscopy, examination under anesthesia, and biopsy under GA were recruited. In the outpatient department (OPD), the attending surgeons verbally instructed the patients as well as handed them the PIL. The process was streamlined over a month and thereafter patients' satisfaction levels and rescheduling rates were captured over 2 months. This was compared to the data from the pre-PIL phase.

Result: Prior to PIL, 12% cases were rescheduled due to avoidable causes. After introducing of the PIL, only 8% case were rescheduled ($P = 0.02$). There was a significant improvement seen in patient satisfaction with 89% patients reporting that the PIL was good or better while 77% were willing to recommend it to the others.

Conclusion: PIL is an effective way of imparting perioperative instructions to patients which will improve not only satisfaction but also reduce patient rescheduling. The institution is in the process of implementing PIL to provide instructions to patient posted for day care procedures.

Keywords: Day care surgery, patient information, patient satisfaction

Introduction

Day care procedures are well accepted in the west and are becoming increasingly popular in our country.^[1] The key to successful functioning of a daycare surgical unit is proper patient selection and adequate preparation. This requires good patient education.^[2] Patient information and effective

communication is a critical part of patient education, especially for procedures requiring general anesthesia (GA). The patient and relatives need clarity of the pre and postoperative process on the appointed day.

There are several common patient screening methods for ambulatory surgery. These include facility/office visit prior to the day of procedure or preoperative screening on the morning of procedure.^[3] Each system has its own merits

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and limitations.^[3] Screening on the day of the procedure can make the preoperative assessment and optimization challenging.^[4]

In our hospital, a premier tertiary level cancer hospital in India, we perform a large number of diagnostic procedures and minor surgeries on a day care basis. Patients receive verbal instructions from surgical colleagues in the out-patient department facilities (OPD). These patients are then seen by the anesthesiologist on the day of the procedure. Due to various reasons, important instructions with respect to the day care procedure such as starvation, medications, or particular investigations are often not adhered to by the patient. This could result in either delay of procedure by a few hours and rarely, rescheduling of cases.

As seen in the literature, verbal information is often inadequate and reinforcement using printed material is found to be helpful.^[5] However, there is limited evidence evaluating the benefit of printed material in the working pattern or efficacy of a day care center. In our previous study, patient information leaflet (PIL) was designed, translated in regional languages (Hindi, Marathi, and Bengali), and validated in patients for its content and readability.^[6] Reading of the PIL had positive feedback and improvement in patients' knowledge about preoperative and postoperative instruction to be followed in minor operation theater (MiOT) complex. We planned this interventional study to establish the benefit of the PIL in reducing rescheduling of cases and to understand its impact on patient satisfaction.

Material and Methods

The study was approved by our Institutional Review Board and registered with Clinical Trials. Gov (NCT03011840). All adult patients (>18 years of age), with (ASA) grade I-III, undergoing elective therapeutic/diagnostic head and neck procedures under GA on a day care basis, in MiOT complex, e.g., direct laryngoscopies, excision biopsy, examination under anesthesia, and laser surgeries were included. Patients undergoing emergency procedures, those planned for admission postprocedure, or patients admitted pre procedure were excluded.

The study was conducted in two phases. During 1st phase (Jan 2017–March 2017), the number of cases done under GA in the MiOT and number of rescheduled cases were noted. In this study, “Avoidable rescheduling” was defined as an event when the patient planned for a procedure in the MiOT was deferred on account of inadequate starvation, inadequate investigations, or if medications were not taken

as advised. Cases rescheduled in view of non-availability of equipment, requiring second opinion, lack of time, or detection of new clinical finding needing further optimization were not included.

After the process of informed consent, feedback forms were collected from all patients enrolled in the study. The feedback form [Annexure 1] besides basic demographics included four questions on whether the patient had been instructed on starvation, investigations required for the procedure, medication schedule, and information about postprocedure course. Patients were asked to rate their satisfaction on the information provided to them on a Likert scale from excellent to very poor. The feedback form was available in four languages: English, Hindi, Marathi, and Bengali.

After 1st phase, the patient information leaflet (PIL) was introduced in all head and neck (HN) surgical OPDs. The PIL contained relevant information that any patient undergoing procedure under GA is expected to know and included preoperative instructions, postoperative instructions, and a few of the expected adverse effects and alerts postprocedure, refer Annexure 2. In addition, the PIL also had two checklists for the caregivers. It was made available in four languages: English, Hindi, Marathi, and Bengali.

The leaflet, in the language best understood by the patient/relative, was handed over by the attending surgical registrar to all patients planned for procedure in MiOT under GA, in addition to verbal instructions. Patients were instructed to read the PIL carefully, comply with it. A break period of 1 month was given to ensure adequate compliance with use of PIL in all HN OPDs.

In 2nd phase (Apr 2017–June 2017), the impact of use of PIL was assessed by noting the number and reason for cases rescheduled in MiOT as in 1st phase. Feedback form was similarly collected. In the 2nd phase in addition to the feedback about information, few questions pertaining to the PIL were included [Annexure 1-part B].

For our preliminary review, the avoidable rescheduling rate was around 20%. We aimed for 50% reduction after introduction of PIL. Group sample size of 199 in either group (Pre and Post-PIL) achieved 80% power to detect a 50% difference. Two-sided Z-test with pooled variance was used with significance level of 0.05.

On an average 250 head and neck cancer patients undergo procedure under GA every month. With due consideration of our inclusion criteria for assessing feedback on patient satisfaction and accounting for

variation in number of patients scheduled on a daily basis, a 2-month recruitment period pre and post intervention was considered adequate.

Primary end point was the number of cases rescheduled which was compared using Chi-square test. All demographic details and patients' response with respect to information and patient satisfaction in both groups were compared using Chi-square test. Opinion about PIL was expressed in percentages. The satisfaction levels of the patients were compared by applying the McNemar test. All data was analyzed using SPSS software version 21, P value < 0.05 was considered as statistically significant.

Results

Reschedule rate

In the 1st phase (pre PIL) among 472 patients scheduled for procedures in the MiOT complex, 97 patients were rescheduling [Table 1]. In the 2nd phase (post PIL) among 573 patients scheduled for procedures, 73 were rescheduled which was a significant reduction ($P = 0.02$) compared to 1st phase.

Feedback response

In 1st phase, 350 feedback forms were distributed of which 232 patients (66%) responded. In 2nd phase of the 360 feedback forms distributed, 217 patients (60%) responded.

Demography

Demographic details such as age, gender, and education of patients who participated in the feedback process were comparable in both phases [Table 2]. However, the data was missing in post-PIL phase with respect to details of person filling the form, and we had more first timers to MiOT complex in the post-PIL phase.

The patients' response regarding the information

provided about preprocedure starvation and investigations was similar for both phases. There was a significant improvement with respect to information provided about medications to be taken/avoided ($P = 0.005$) and about the further course action for patient's treatment ($P < 0.001$), refer to Table 3.

Eighty-nine percent of the participants were of the opinion that the patient information leaflet was very good/good and 77% of patients were willing to recommend the leaflet to others. The patient satisfaction about information regarding the instructions to be followed before the procedure ($P = 0.008$) as well as information to be followed after the procedure ($P = 0.001$) was significantly better [Figure 1].

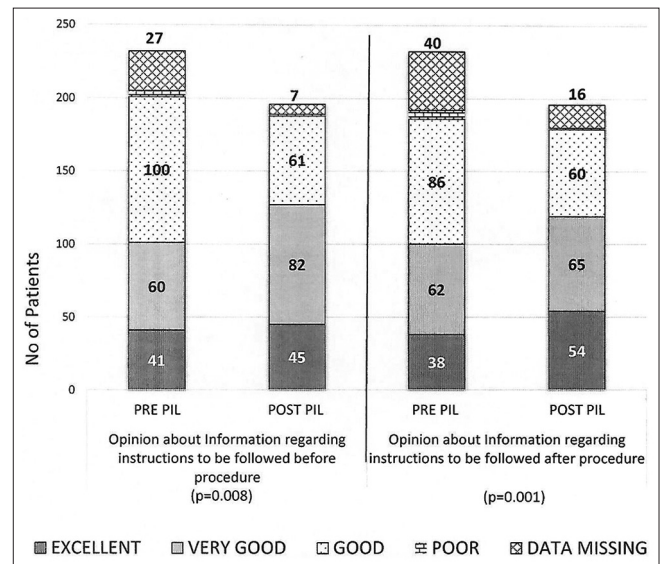


Figure 1: Bar graph comparing patient satisfaction with information provided before and after introduction of PIL. PIL-Patient information leaflet. Satisfaction was measured on a five-point Likert scale ranging from excellent to very poor. P values of Chi-square (in brackets) comparing satisfaction between pre and post-PIL group reveal a significant improvement in the post-PIL phase, $P < 0.05$ -significant

Table 1: Details of postponement/rescheduling of cases

Causes	Pre-PIL n=472	Post-PIL n=573
Avoidable	56	44
Inadequate starvation	26	18
Medications not taken/avoided	11	6
Investigations not available (MRI/CT PLATE/ECG)	19	20
Other reasons (excluded for analysis of primary endpoint)		
Senior surgeon not available	11	5
Instrument not available	4	1
Patient's medical condition needing optimization	24	19
Consent for procedure not given	1	2
Inadequate time	1	2
Total postponements	97	73

Table 2: Comparison of sociodemographic data of patients participating in the feedback process

Variable	Subgroup	pre PIL (n=232)	post-PIL (n=196*)	P
Age	18-44 years	57 (24.6%)	37 (18.9%)	0.38
	45-59 years	79 (34.1%)	74 (37.8%)	
	60 years and above	84 (36.2%)	68 (34.7%)	
	Data missing	12 (5.1%)	17 (8.6)	
Sex	Male	176 (75.9%)	148 (75.5%)	0.93
	Female	36 (15.5%)	34 (17.3%)	
	Data missing	20 (8.6%)	14 (7.2%)	
Education	Illiterate	38 (16.4%)	27 (13.7%)	0.29
	School	71 (30.6%)	74 (37.8%)	
	Graduate	46 (19.8%)	31 (15.8%)	
	Post graduate	18 (7.8%)	11 (5.6%)	
	Data missing	59 (25.4%)	53 (27.1%)	
Person filling form	Patient	53 (22.8%)	43 (21.9%)	0.007#
	Attendant	116 (50%)	73 (37.2%)	
	Data missing	63 (27.2%)	80 (40.8%)	
Previous procedure in minor OT	No	172 (74.1%)	161 (82.1%)	0.000 ^s
	Yes	53 (22.8%)	27 (13.8%)	
	Data missing	7 (3.1%)	8 (4.1%)	

*Out of the 217 patients who responded, feedback from 21 patients were excluded as they didn't receive the PIL. #Data missing in post PIL phase with respect to details of person filling the form. ^sSuggests more first timers in post PIL phase

Table 3: Comparison of patients' response regarding the information provided

Question	Response (in percentage)								P
	Pre-PIL				Post-PIL				
	Yes	No	Not sure	DM	Yes	No	Not sure	DM	
Were you adequately informed with regard to the fasting, pre-surgery (What to eat/drink)?	75	16	2	7	79	12	3	6	0.67
Were you informed about any tests (blood tests, ECG, scans, X-ray, etc.) that were necessary before the procedure?	92	3	1	4	89	6	2	3	0.31
If you take any medicine on a regular basis, were you informed about which medicines to continue or to avoid on the day of surgery?	52	34	3	11	66	20	5	9	0.005*
Did you receive enough information about the future course of action about your treatment (includes when to expect the result of today's procedure, future treatment, and follow-up)?	48	28	7	17	67	17	8	8	<0.001*

*-patients received better information in the post-PIL phase with respect to changes in medication, and future course of action, $P < 0.05$ is significant

Discussion

In 1st Phase, 12% cases were rescheduled due to avoidable causes and the introduction of PIL in the 2nd Phase helped in significantly reducing it to 8%. In addition, a significant improvement was seen in patient satisfaction with the information provided in PIL. 89% patients felt that the PIL was good/very good and 77% of patients were willing to recommend it to the others.

Absenteeism in day care surgeries is not unknown. A previous study reported 54.3% cancellations due to various causes ranging from lack of awareness of date of surgery, clinical problems like respiratory tract infections and social/economic reasons.^[7] In our hospital as in other Indian studies,^[8] due to sheer patient volumes, patients' absenteeism is not as much a concern, as is overbooking of theater time. Hence, it is important for high volume centers

to optimize theater time by reducing avoidable causes for rescheduling.

Many studies have looked at written information and its impact on knowledge.^[9,10] All studies support the use of standardized written and/or pictorial information documents to improve patient knowledge, skill, and compliance for the given treatment/instructions. PIL are currently being administered for providing information regarding drugs^[11,12] and few chronic diseases. These PIL proved to be very satisfying and effective in providing understanding about the disease and drug therapy schedule.^[13-16]

However, there is limited literature which looks at influence of PIL on work efficacy and rescheduling rates.^[17] Our study is among the few studies looking at impact of PIL on work pattern. While we aimed at reducing rescheduling linked to preprocedure instruction compliance, we also found an overall reduction in both avoidable and unavoidable causes. Hawthorne effect, leading

to vigilance and reduction of other causes of postponement by ensuring availability of equipment and expertise for cases planned for the day, cannot be ruled out.^[18]

In a high-volume center like ours, busy outpatient services restrict the time of interaction between attending doctor and patient, resulting in patient being inadequately instructed. In our study, PIL helped in improving patients' information which improved their satisfaction. Similar findings have been reported in the past.^[19] However, it has also been observed that though information leaflets help patients get involved in the decision-making process, they may not influence outcome or satisfaction metrics.^[20]

Traditionally, information gain has been shown to reduce patient anxiety.^[19] Interestingly, Gillies and Baldwin reported that if provided in an inappropriate form, information leaflet can lead to anxiety.^[21] Our study did not assess patient anxiety and is one of its limitation. Though not formally studied, we feel anxiety may not have been a significant contributing factor as 89% of patients ranked the PIL as good/very good and 76% of patients were happy to recommend the PIL to others.

In post-PIL phase, 37% of the questionnaire were filled by attendants suggesting satisfaction improved among patients as well as caregivers. One expects patients' satisfaction with respect to information provided to improve with repeated visits to MiOT. In our study, the satisfaction level was higher in the post-PIL group, despite the number of patients visiting the MiOT for the second time was higher in the pre-PIL group. This contrary finding reinforces the benefits of the PIL. Most of our patients were planned for diagnostic procedures. As we wanted to incorporate a common leaflet with focus on the peri-procedure instructions, information about individual disease type and its management were not incorporated. Leaflet is available in only 4 languages which caters to 95% of our patients. With the encouraging results of our study, our center has incorporated this leaflet in routine patient care.

Conclusion

Patient information leaflet (PIL) is effective in reducing rescheduling of cases in a busy day care center by increasing patient's compliance to instructions such as starvation, carrying appropriate documents, and alteration in basic medications. Patient satisfaction with respect to information provided in the peri-procedure period is better with effective use of PIL.

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Conflicts of interest

There are no conflicts of interest.

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Annexure 1.

1. Patients age _____ Gender _____
2. Education: Illiterate/school/graduate/post graduate (please tick patient's highest qualification)
3. Are you filling this questionnaire for self or on behalf of the patient?
If Yes, please tick your highest qualification education: Illiterate/school/graduate/post graduate
4. Is this your first visit to this Minor OT complex? Yes No
If "No," when was the last time you came here? _____
5. Were you adequately informed with regard to the fasting procedure, pre-surgery (What to eat/drink)?
Yes No Not sure
6. Were you informed about any tests (blood tests, ECG, scans, X-ray, etc.) that were necessary before the procedure?
Yes No Not sure
7. If you take any medicine on a regular basis, were you informed about which medicines to continue or to avoid on the day of surgery?
Yes No Not sure
8. Did you receive enough information about the future course of action about your treatment (includes when to expect the result of today's procedure, future treatment, and follow-up)
Yes No Not sure
9. How was your overall satisfaction with respect to the information you were provided before the surgery? Excellent
Very good Good Poor Very Poor
10. How was your overall satisfaction with respect to the information you were provided after the surgery?
Excellent Very good Good Poor Very Poor

Part B (incorporated in second phase of the trial)

- Have you received any Information leaflet at the OPD? Yes/No
 - If "Yes," have you read the leaflet? Yes/No
 - If "Yes," have you understood the information provided in the leaflet? Yes/No
- What is your opinion about the leaflet?
Very Good Good Average Bad Very Bad
- Would you recommend this leaflet to others?
Strongly recommend/will Recommend/Neutral/recommend reluctantly/not recommend at all

Annexure 2: Patient information leaflet (in English)-a 4-page brochure folded in the center. Enclosed is copy of page 4, page 1, page 2, page 3 (in the order specified)

POST-OPERATIVE INSTRUCTIONS

- In the Recovery room you will stay till you are completely awake
- Your BP, oxygen levels and heart rate will be monitored
- Oxygen will be given for some time through a clear mask
- Patient's relatives will be allowed to meet the patient
- If you have any problem inform the attending staff for help
- You will be told when to resume eating/drinking by the doctors
- You may be prescribed medicines (pain killers/antibiotics etc.)
- Follow-up instructions will be given to you by the doctors/nurses
- You will be discharged once you are deemed fit by the doctors

POSSIBLE SIDE EFFECTS OF SURGERY/ANAESTHESIA

- Nausea , vomiting- Dizziness, confusion
- Sore throat- Headache, body ache
- Mild to moderate pain over surgical site

CONTACT IMMEDIATELY AT MINOR OT/CASUALTY IF YOU HAVE ANY OF THE FOLLOWING:

- Persistent vomiting - Pain unresponsive to pain killers
- Breathing problem - Bleeding from surgical site does not stop

POST PROCEDURE CHECKLIST(RECOVERY ROOM)

BY SURGEON (Name _____)

- Airway issues addressed?	Yes	No	NA
- Bleeding under control?	Yes	No	NA
- Follow up instructions given?	Yes	No	NA

BY ANAESTHESIOLOGIST (Name _____)

- Airway unobstructed?	Yes	No	NA
- Pain medication explained?	Yes	No	NA
- Eating/Drinking instruction given?	Yes	No	NA

BY NURSINGSTAFF (Name _____)

- Medication Explained?	Yes	No	NA
- Follow up instruction given?	Yes	No	NA
- Paperwork complete?	Yes	No	NA

PRE-OPERATIVE INSTRUCTIONS

Before surgery

- Make sure you have undergone tests advised to you
- The test reports will be available to us online **except ECG & PFT**
- **Please collect your ECG report/ PFT Report(if done) from respective counters before going to Minor OT**
- If you are on any regular medications you can continue them but **STOP BLOOD THINNERS 5 DAYS BEFORE SURGERY;**
- Continue Aspirin**
- Avoid Alcohol intake/ Smoking or Tobacco in any form as it may lead to cancellation of your surgery
- Avoid Nail paint/Mehendi before procedure

What and when to eat/drink


- If Surgery planned in morning; you may eat and drink until midnight, the day before your operation, no solid food after midnight
- If Surgery planned in afternoon (after 12 noon): you can have light breakfast at **6AM** (tea/coffee with little milk and biscuit or plain bread)
- You are allowed to take clear liquids like plain water, coconut water, glucose water, APPY juice **UPTO 2 hours before surgery.**(e.g. if surgery is at 10AM you can drink APPY juice till 8AM but NOT after that)

Continue these medicines on the day of surgery with a small sip of water (if you already take any)

- Blood Pressure (BP) control medicines
- Asthma medication (Inhalers/ Rota caps / Nebulisation etc.)
- Medicine for heart diseases & **Aspirin**
- Thyroid medications
- Fits/Seizure medication
- Acidity/Chest burn medicine
- Steroids

Don't take these medicines before the surgery

- Medicines for Diabetes (tablets/Insulin)
- Blood thinners **except Aspirin**



**PATIENT INFORMATION BOOKLET
FOR ADULT PATIENTS
(FOR PROCEDURES UNDER GENERAL ANAESTHESIA)
AT MINOR OT COMPLEX**

Please read this booklet and if you have any suggestions/queries, discuss with your concerned doctors

GENERAL INFORMATION

- You have been referred to this Minor OT for some procedure/surgery
- This procedure could be Diagnostic or Therapeutic
- **Reporting Time/Date:** _____
- **Reporting Place:**
MINOR OT COMPLEX (ROOM NO.301, 3RD FLOOR GOLDEN JUBILEE BUILDING)

PRE-PROCEDURE CHECKLIST (AT OPD)

- Surgery explained and patient queries addressed?	Yes	No	NA
- Blood work up advised?	Yes	No	NA
- Is ECG advised ^b ?	Yes	No	NA
- Is 2D Echo advised ^c ?	Yes	No	NA
- Imaging advised (X-ray /CT scan/ MRI/ PET-CT)?	Yes	No	NA
- Any other test advised?(Details _____)	Yes	No	NA
- Is PAC clinic reference required ^d ?	Yes	No	NA

a. Any investigations (blood/ecg/x-ray) done in the last 6 months may be accepted provided there is no change in pt. condition or no surgery after that; outside reports may be accepted

b. ECG required in all patients aged >40yrs, patients with h/o heart disease, longstanding diabetic & hypertensives, post Adriamycin chemo etc

c. 2D ECHO required if significant ECG changes, h/o heart disease, post Adriamycin based chemo, pacemaker in situ etc

d. PAC clinic ref: all high risk patients (e.g. uncontrolled Htn/DM, Heart disease, Renal ds, Liver ds, severe COPD/Asthma etc.)

Version 1/12.08.2016

On the day of surgery

- All patients must be accompanied by a responsible adult
- Please handover your file at the registration desk & collect your **Patient identity band**; Patients should wear this band at all times
- After registration your file shall be handed over to the respective unit
- Please ensure that you have read and signed the consent form
- As you await your turn for the procedure, you will be seen by the Anaesthesiologist
- If you are allergic to any medicine/food, please let us know
- Relatives are strictly **NOT** permitted to enter the OT

Don't forget to bring the following

- ID card & File (issued by TMC)
- ECG report/PFT report (if done)
- All x-rays and scans (previous & recent CT/MRI/PET scans if done outside TMH)
- Blood tests & any other tests done outside TMH
- All past medical records (if any)
- All tablets/injections that you take on a regular basis

Remove these before entering the OT

- Artificial dentures - Spectacles, Contact lens
- Mobile, Wallet, Cash, Keys - Hairclips, pins, belts etc.
- Jewellery (bangles, chains, rings etc.)

What happens inside OT

- Inside the OT you shall lie down on the operating table and then your doctor will attach you the following:
- Sticky patches on your chest – to record ECG
- BP cuff around your arm – to record BP
- A clip on your finger – to measure oxygen level in blood
- A small plastic tube will be put in a vein of your hand/arm through which you will receive saline and medications during surgery
- Then you shall be put to sleep using appropriate medicines
- The entire surgery will be painless and you will not feel anything
- After the surgery you will be woken up from sleep and you will be shifted to the Recovery Room for observation

Version 1/12.08.2016