

Study Title

**Effect of Patient Information Leaflet on working pattern and patient satisfaction level
in a busy Indian day care operative theatre complex**

Investigators

Dr. Sumitra Bakshi

MD, DNB (Anaesthesiology)

Professor

Department of Anaesthesia, Critical Care and Pain

Dr. Amit Raja Panigrahi

Post-graduate Student,

Department of Anaesthesia, Critical Care and Pain

Dr. Akash Tambule

Post-graduate Student,

Department of Anaesthesia, Critical Care and Pain

Dr. Prathamesh Pai

M.S.

Professor

Department of Surgical Oncology

Institution

Tata Memorial Hospital,

Mumbai-400 012

Table of Contents

- 1. Study summary**
- 2. Introduction**
- 3. Aims and objectives**
- 4. Inclusion and exclusion criteria**
- 5. Material and methods**
- 6. Measurements**
- 7. Statistical analysis**
- 8. References**

Annexure form 2.1

Annexure form 2.2

Study title: Effect of Patient Information Leaflet on working pattern and patient satisfaction level in a busy Indian day care operative theatre complex

**Investigator: Dr Sumitra Bakshi, Dr Amit Raja Panigrahi, Dr Akash Tambule,
Dr Prathamesh Pai**

Study Site: Department of Anaesthesia, Critical Care and Pain, Tata Memorial Hospital,
Parel, Mumbai 400 012.

INTRODUCTION:

Patient Information is one of the key determinants of patient satisfaction. Adequate information about the disease condition, treatment plan, waiting times and ‘what to do next’ affects patients’ overall satisfaction level. Good quality information not only reduces patient anxiety and stress but also reduces unreasonable expectations and misperceptions. Patient satisfaction has always remained an important and commonly used indicator for measuring the quality in health care.

In the recent years there is a gradual upward trend in day care surgeries all across the globe; an estimated 83% of the surgeries in the United States being performed on an ambulatory basis¹. In India, about 20 percent of all surgical procedures are performed on outpatients. It is estimated that by 2020, 75 percent of all surgical operations in India will be carried out in ambulatory surgery centers². The increasing trend of ambulatory surgeries has emerged from advances in anesthesia and surgical techniques. Patient information and effective communication is critical in these surgeries especially the ones that need General Anesthesia. Provision of information is one of the mainstays of effective day surgery management. This needs to cover not only what to do preoperatively and postoperatively, but also what will happen on the day of surgery. There are several ways of providing information like written information, using a video, over telephone or by patient interviews before and

after surgery. Verbal information alone is inadequate and must be reinforced with well-presented printed material³.

Tata Memorial hospital is a premier tertiary level cancer hospital in India. Around 140-150 patients undergo minor surgical procedures (diagnostic and therapeutic) in our hospital's Minor OT complex every day. About 30-40% of surgeries belong to the Head & Neck region alone. About 40-50% of these surgeries are done under General Anaesthesia. At present the communication with patients in the busy outpatient department is mainly verbal. Due to time constraints, lack of a responsible attendant with the patient, important information with respect to the day care procedure is often not effectively delivered. This leads to patients not following instruction adequately with respect to starvation, medications to be taken on the day of the procedure and also not carrying all essential documents. This leads to delays, rescheduling of cases and rarely postponement of procedures.

Does an information leaflet provide an effective way of communication in the peri-procedure period? Will it help in better information delivery and hence reduce the number of avoidable postponements and delay. And does this translate to better patient satisfaction is what this study aims to see. The study is restricted to patients undergoing Head & Neck procedures under General Anaesthesia, as they form the major bulk of patients in our minor OT complex and for logistic reasons to start with a defined group of patients.

AIMS AND OBJECTIVES:

1. To reduce postponement of cases due to lack of information to patients in the pre-operative period
2. To compare satisfaction levels between patients , pre and post introduction of information leaflet

Primary end point:

To reduce postponement of cases due to lack of information to patients in the pre-operative period

Co Primary end point:

To compare satisfaction levels between patients, pre and post introduction of information leaflet.

Design of the study: Pre and post interventional model

INCLUSION CRITERIA:

All adult patients (> 18yrs), ASA I-III, undergoing elective therapeutic/diagnostic Head & Neck surgeries under General Anaesthesia in the Minor OT complex and discharged on the same day will be included. The surgeries will include Head & Neck surgeries like DL scopies, laser surgeries, EUA, excision biopsies etc.

EXCLUSION CRITERIA:

1. Patients refusing to take part in study
2. Patients undergoing emergency surgeries
3. ASA IV patients, or high risk patients planned for admission
4. Admitted patients for minor OT procedure
5. Patients not getting the Information leaflet due to any reason (in 2nd half of study)
6. Patient and his attendant, both illiterate

MATERIAL AND METHODS

After Institutional Review Board approval, all adult patients meeting inclusion criteria and undergoing surgeries in the Minor OT complex during a 6 month period will be enrolled in the study. The study will be done in two parts.

In the First half of study- planned over 2 months (Nov-Dec), feedback forms will be collected from patients at the end of minor OT procedure (Annexure 2.1) All patients, meeting inclusion criteria, at the end of the procedure prior to discharge from the minor OT will be explained about the study and they shall be given a feedback form to be filled and submitted. Also the number of postponement or rescheduling of cases will be noted.

Postponement or rescheduling of case is defined as an event when the patient who is called for his turn in minor OT is deferred for any amount of time in account of starvation not adequate, investigations not brought, medications not taken as prescribed. Any postponement in view of awaiting opinion from senior consultant , special equipment or any investigations called in view of patients clinical conditions which was not anticipated in the OPD by the surgical colleague, or due to lack of OT time will not be included.

After the initial collection of feedback over 2 months, the patient information leaflet (PIL) will be handed over to all patients planned for procedure in the minor OT complex (Second half of study). This leaflet will be handed over by the attending doctor in the Head neck OPD. The checklist pertaining to counselling at the Head neck OPD will be ticked after they are carried out. The patient will be instructed to read leaflet carefully and carry the leaflet on the day of Minor OT procedure. In the minor OT the discharge checklist in the PIL would be carried out by all concerned including the surgical, anesthesia and nursing team. A period of 1 month (Jan) will be allowed to streamline the use of patient information leaflet.

In the subsequent 2 months, Feb - Mar, the impact of use of PIL will be assessed. Firstly by noting the number of postponement or rescheduling of cases. In addition all patients meeting inclusion criteria will be given the feedback form (Annexure 2.2) at the end of their procedure in minor OT.

For patients coming to minor OT without a patient information leaflet- one would ascertain if the leaflet was handed in OPD and not brought to minor OT or if the leaflet was not handed at all. The numbers of such misses will be recorded. Patients who did not get the leaflet in the OPD will be excluded from study.

Sample size calculation:

For our preliminary review of postponement rate as defined in our study is around 20%. We aim for a reduction of such postponement by 50%. Group sample sizes of 199 in group 1 and 199 in group 2 achieve 80.007% power to detect a difference between the group proportions of -0.1000. The proportion in group 1 (the treatment group) is assumed to be 0.2000 under the null hypothesis and 0.1000 under the alternative hypothesis. The proportion in group 2 (the control group) is 0.2000. The test statistic used is the two-sided Z-Test with pooled variance. The significance level of the test is 0.0500. Considering a 20% loss to follow up from OPD to minor OT, the sample size needed is 480 patients. On an average at least 250 patients of head neck patients undergo procedure under general anesthesia, per month (12-15 patients /day x 20 working days). With due consideration of our inclusion criteria, a two month recruitment period pre and post intervention should be adequate.

MEASUREMENTS

- No. of cases postponed pre and post introduction of the leaflet and reasons behind them
- Primary data collected will be patient satisfaction levels after the procedure (both pre and post PIL) on a 5 point Likert scale (Ranging from very poor = 0 to Excellent = 4)
- No of patients who did not receive the patient information leaflet in the OPD
- No of patients who received the PIL but did not get it along to the minor OT

STATISTICAL ANALYSIS

All Data will be analyzed using SPSS software. Likert scores will be treated as ordinal data. Proportions will be compared using chi square analysis. Additionally Multivariate logistic regression analysis will be used to assess the contribution of possible covariates, including age sex and patient knowledge on patient satisfaction. For all data P-value < 0.05 will be considered as statistical significant.

REFERENCES:

1. Beverly K. Philip MD, Day Care Surgery: The United States Model of Health Care IAAS Journal/17.4/PHILIP17.4.pdf
2. Emerging Trends in Healthcare A Journey from Bench to Bedside 17 February 2011;KPMG/ASSOCHAM
3. Jarrett, P. E. M, Day care surgery ;European Journal Of Anaesthesiology November 2001 - Volume 18 - Issue - p 32–35
4. Shah U, Wong DT, Wong J Patient satisfaction and positive patient outcomes in ambulatory anesthesia 9 April 2015 Volume 2015:2 Pages 29—37 dovepress.com

Annexure 2.1

You are invited to take part in this study & help us improve the quality of services provided to you. Your participation is completely voluntary & it will not alter the treatment given to the patient in any way. Please base your answers on today's experience at this MINOR OT COMPLEX. Just mark the option which the patient thinks is correct.

1. Patients age _____ Gender _____

2. Education: Illiterate/ school/ graduate/ post graduate (please tick patients 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 & 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

Annexure 2.2

You are invited to take part in this study & help us improve the quality of services provided to you. Your participation is completely voluntary & it will not alter the treatment given to the patient in any way. Please base your answers on today's experience at this MINOR OT COMPLEX. Just mark the option which the patient thinks is correct.

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 & follow up)
Yes No Not sure
9. 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
10. What is your opinion about the leaflet?
Very Good Good Average Bad Very Bad
11. Would you recommend this leaflet to others?
Strongly recommend / will Recommend/ Neutral /recommend reluctantly/ not recommend at all
12. How was your overall satisfaction with respect to the information you were provided before the surgery?
Excellent Very good Good Poor Very Poor
13. How was your overall satisfaction with respect to the information you were provided after the surgery?
Excellent Very good Good Poor Very Poor

Version1

Dtd. 12/08/2016