

Patients' perspective on informed consent in ear surgery

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Background: Informed consent is required before any surgical procedure. This study was done to assess patient's expectations before signing consent forms for ear surgery.

Methods: This study was done in Department of ENT and Head and Neck Surgery, T U Teaching Hospital from August to December 2006. All patients attending to OPD for appointment of surgery were randomly selected and were explained verbally about the possible complications of surgery, by the first author. There were 100 patients and they were interviewed with a standard questionnaire just one day before surgery. Answers were written by the first author on a standard questionnaire form. All those 100 patients who were informed previously about the possible complications were included in the study. Informed consent was obtained from all patients for the study. Data analysis was done statistically using frequency and percentage.

Results: Ninety five percentages of patients were satisfied with the information given by doctors before ear surgery. There were very few patients (7.0%) who looked for further information. Only 27.0% patients could tell complication of ear surgery. Among them, 5.0% patients could list more than one complication. The common complications listed by our patients before ear surgery were: bleeding (10.0%), infection (9.0%). Around 96.0% want to be informed all known complications even if the incidence was less than one percent.

Conclusion: The information given by the doctors might not meet the expectation of the patients of twenty first century as they have a high expectation. However, the doctors should give a sufficient time to explain about the surgical procedure and they should not miss a common and important complication of surgery.

Keywords: Informed consent, Patients expectation, Ear surgery.

Introduction

Informed consent is the process of explaining a procedure and its risks, benefits and alternative treatments that allows patients to make educated decision about treatment. Ear surgery is one of the most common surgical procedures performed by Otorhinolaryngologists in Nepal. It is the surgeon's responsibility to the patient to discuss procedures

risks preoperatively so that the patient can make an appropriately informed decision.¹ In T U Teaching Hospital; informed consent is required before any surgical procedure. The way of taking informed consent in T U Teaching Hospital and other hospitals of Nepal are same. Patient's party will be given to sign a consent form where the risk of surgery is explained. But the details of the risk are not written in that form. If needed, the surgeon explains the details

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complication of the procedure.

Patients demonstrate a range in terms of the depth in which they wish to discuss potential risks during the informed consent process.² The amount of detail that is to be included in the informed consent process is inexact.^{1,3} This study was done to assess the patient's desires and expectations in the informed consent process before ear surgery.

Materials and Methods

This study was done in Department of ENT and Head and Neck Surgery, T U Teaching Hospital from August to December 2006. All patients attending to OPD for appointment of surgery were randomly selected and were explained verbally about the possible complications of surgery, by the first author. There were 100 patients and they were interviewed with a standard questionnaire just one day before surgery. Answers were written by the first author on a standard questionnaire form. All those 100 patients who were informed previously about the possible complications were included in the study. Informed consent was obtained from all patients for the study. In children and illiterate patients, it was taken from the guardians or caretakers. Data analysis was done statistically using frequency and percentage.

Results

There were 64.0% male and 36.0% female. Around 40.0% were children so their forms were filled up by their parents/guardians. Thirty five percent patients were illiterate.

Table: 1 Educational status of the participants

Educational Level	Number of patients (%)
Illiterate	35 (35.0)
Less than class 10	41 (41.0)
More than class 10	24 (24.0)
Total	100 (100.0)

Ninety five percent were satisfied with the information given by doctors prior signing to consent form for ear surgery. There were 7.0% patients who looked for further information from the previously operated patients and searching internets and magazines. Seventy three percent were unable to list any complications of the surgery they were undergoing. There were 5.0% patients who could tell more than one complication. Common complications listed by them were bleeding (10.0%), Infection (9.0%). Around 96.0% wish to know all complications even if the incidence was less than one percent.

Table: 2 Complications listed by patients

Complication listed by patients	Number of patients (%)	Total (%)
No complications listed	73 (73.0)	73 (73.0)
One complication listed	22 (22.0)	—
More than one complication listed	5 (5.0)	—
Complications listed (Total)	—	27 (27.0)
Total	100 (100.0)	100 (100.0)

Table: 3 Types of complications listed by patients

Types of complications	Number of patients (%)
Bleeding	10 (10.0)
Infection	9 (9.0)
Facial palsy	4 (4.0)
Taste change	3 (3.0)
Further hearing loss	3 (3.0)
Red eye and swelling	3 (3.0)

Discussion

Patients receive information about their treatment from the time of initial consultation to just before signing their consent form.⁴ In T U Teaching Hospital of Kathmandu, for elective ear surgery, there is a long gap between the date booked for surgery and the day of operation. It ranges from 2-3 months up to even a year. All patients attending to ENT and Head and Neck Surgery OPD for appointment of surgery were explained verbally about the possible complications of surgery, by the first author. So, even if the doctors had explained before about the complications of ear surgery, the patients might have recall poorly. This might be the reason that though majority (95.0%) of our patients were satisfied with given by doctors, only 27.0% could list complication. Among them, 5.0% could list more than one complication. This might be also due to lower educational status, lower socioeconomic status and longer time gap between the date booked for surgery and the operation day.

Pre-operative information sheets will improve patients' understanding of their condition and treatment as well as compliance.⁵ Paul Burns et al study revealed that two third of patients sought information elsewhere prior to signing their consent form.⁴ Houghton et al also emphasized that patients' expectation had increased in recent times.⁶ Dawes et al also showed an increase in complication disclosure among

British Otolaryngologists, reflecting the increase in both doctor and patients awareness.⁷ However, our study showed that 7.0% patients sought for further information.

Defining which risks are significant is arguably the most crucial aspect of informed consent law.^{4,8} Paul Burns et al study showed that 90.0% of subjects claimed to be happy with the information they receive in out-patients, while over half of these could not list even one complication prior to signing their consent form.⁴ Seventy three percent of those questioned expected to be informed of all known complications, even if the incidence was less than one percent.⁴ However, our study had a different results. Majority of our patients expected from the doctors to know all complications even if the incidence was less than one percent. This expectation was higher than the study done by Bowden et al⁹ (85.0%) and Jeffrey S et al study¹ (44.0%). The common complications listed by our patients before ear surgery were- bleeding (10.0%), infection (9.0%) etc. Although most patients incorrectly believe that informed consent serves only to protect a physician's right, the informed consent gives patients an understanding of a procedure.¹⁰ So that they can adequately make an informed decision.

Conclusion

The information given by the doctors might not meet the expectation of the patients of twenty first century as they have a high expectation. However, the doctors should give a sufficient time to explain about the surgical procedure and they should not miss a common and important complication of surgery.

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