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Informed Consent In Patients Undergoing ENT Surgery: What Do Patients Want To Know?

ABSTRACT

Objective: To determine patient satisfaction with the informed consent process in ear, nose and throat (ENT) diseases requiring surgery. Specifically, to determine relationships between educational levels of patients and their satisfaction with information given by doctors versus self-gathered information; whether complications of the operation were explained to, and could be listed by patients; the types of complications patients expected to be informed about and the importance of this information to them; their familiarity with the term “informed consent” and their preference for written or spoken information; and whether they were convinced about what they consented to.

Methods:

Design: Cross-sectional Descriptive study

Setting: Tertiary Public Hospital

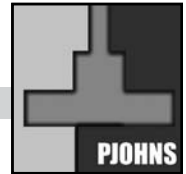
Population: One Hundred

Results: There were 55 males and 45 females (average age 26.7 years, range 4 - 74 years). Ten percent (all children) had no formal education, 56% had primary to high school education, 23% had certificate level education and 11% had a baccalaureate or masters degree. Ninety-five percent claimed they knew what informed consent was. Ninety percent were satisfied with the information given to them by doctors. Eighty percent, mainly with educational levels of high school and above preferred to receive written information from doctors. Twenty three percent accessed other sources of information. Those with certificate level education talked with previously operated patients (10%) or read magazines (2%) while the internet was favored by almost all of those with baccalaureate degrees (8%) and all those with masters degrees (2%). Of those who accessed self-gathered information, 21% were not satisfied while only 2% were satisfied. Seventy percent considered the information given by doctors very important. Similarly, seventy percent (mostly from the higher educational levels) considered the impact of information provided by the doctor completely convincing for decision making while 30% (mostly from lower educational levels) only found the information partly convincing. Forty nine percent (again from the lower educational levels) could not list even a single complication. Nineteen percent with educational levels of certificate and above wanted to know all complications of surgery including those that were very rare while 56% wanted to know most of the complications.

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Conclusion: We should not underestimate the importance of the outpatient consultation, the importance of written material and non medical information sources as patients' expectations are quite high and the majority of them want to be informed about most complications. We should also find ways to improve the provision of patient information where possible and appropriate as per specific patient groups.

Keywords: *Informed consent, otorhinolaryngology, surgical procedures.*

Informed consent is the permission given by the patient/relatives after being given appropriate information about a proposed medical/surgical intervention. The process is called the informed consent process.¹ It may be obtained in one sitting or over a period of time, either orally or in writing or as a combination of the two.² Studies suggest that in practice only minimal formal efforts are made to obtain informed consent for routine interventions.^{3,4} Some have suggested using the "prudent patient standard," in which the physician must disclose all risks so that a reasonably prudent patient would make a decision whether to undergo or refuse a particular procedure.^{5,6,7} Others have hypothesized that better informed consent could improve the patient-physician relationship, establish trust, increase patient compliance, and provide information that could reduce medical error.^{2,8} Still others state support that a reasonably prudent physician would disclose to his or her patient.^{6,7} The informed consent process may be influenced by the educational level of the patient. Studies have suggested that patients with higher education levels tended to have better understanding of informed consent, grasped more information and also had better recall than those with no formal education.^{9,10}

The aim of this present study was to determine patient satisfaction with the informed consent process in ear, nose and throat (ENT) diseases requiring surgery. Specifically, the study sought to determine relationships between educational levels of patients and their satisfaction with information given by doctors about their recommended operation versus self-gathered information (if any); whether complications of the operation were explained to, and could be listed by patients; the types of complications patients expected to be informed about and the importance of this information to them; their familiarity with the term "informed consent" and their preference for written or spoken information; and whether they were convinced about what they consented to.

METHODS

This study was carried out among 100 patients in the Department of ENT, Kathmandu University Hospital, Dhulikhel from January to May

2010. All the patients posted for elective surgery were included. The study was performed in the following phases:

Questionnaires were constructed inspired and based on the study performed by Adhikari *et al.*¹¹ and Albera *et al.*¹² A statistician and the Department of Community Medicine were consulted regarding the validity and reliability of the questionnaire but no pre-tests were conducted. The survey questionnaires were framed in English and translated into native Nepali but were not back-translated. Questions covered demographic data and satisfaction with information obtained from doctors; whether complications of the operation were explained by doctors and could be listed by patients; the types of complications patients expected to be informed about and the importance of this information to them; knowledge of the term "informed consent," whether they were convinced about what they consented to; whether they looked for further information regarding the surgical procedure; the sources of and satisfaction with self-gathered information; and modes of information patients prefer from doctors (*Appendix*). Patients who opted for modalities of management other than surgery were excluded from the study.

During the outpatient examination, the patients were given explanations about their disease, the risks and benefits of the recommended surgery, alternative methods of management and costs of surgery to reach the ultimate decision. Questionnaires were handed over to nursing staff with clear instructions on how to complete them for patients to complete prior to discharge. Patients with no formal education and children whose parents had no formal education were assisted in accomplishing the questionnaires. These records were collected and analyzed by simple manual analysis using frequencies and percentages.

RESULTS

Results were obtained from the sample of 100 subjects. There were 55 males and 45 females with an average age of 26.7 years and a range of 4 to 74 years. Seventeen percent were children. Ten percent (all children) had no formal education, 56% had primary to high school education, 23% had certificate level education, and 11% had a baccalaureate or masters degree. (*Table 1*) Ninety-five percent of the patients claimed they knew what informed consent was. (*Table 2*) Ninety percent of our patients were satisfied with the information given to them by doctors. (*Table 3*) Eighty percent of patients, mainly with educational levels of high school and above, preferred to receive written information from doctors. (*Table 4*) Twenty three percent of patients accessed other sources of information. Those with certificate level education talked with previously operated patients for information (10%) or read magazines (2%), while the internet was

Table 1. Educational Level of Patients-Participants, n = 100

Level of Formal Education	Number of Patients per Level
No formal education	10
Primary/High School	56
Certificate	23
Baccalaureate	9
Masters	2
TOTAL	100

Table 2. Patient Awareness of the Informed Consent Process, n =100

Level of Formal Education	Aware	Not Aware	Total
No formal education	5	5	10
Primary/High School	56	0	56
Certificate	23	0	23
Baccalaureate	9	0	9
Masters	2	0	2
TOTAL	95	5	100

Table 3. Patient Satisfaction with Information Provided by the Doctor, n=100.

Level of Formal Education	Satisfied	Not Satisfied	Total
No formal education	10	0	10
Primary/High School	56	0	56
Certificate	17	6	23
Baccalaureate	6	3	9
Masters	1	1	2
TOTAL	90	10	100

Table 4. Patient Preference for Mode of Delivery of Information , n=100.

Level of Formal Education	Mode of Delivery			Total
	Written	Spoken	No particular preference	
No formal education	-	8	2	10
Primary/High School	46	10	-	56
Certificate	23	-	-	23
Baccalaureate	9	-	-	9
Masters	2	-	-	2
TOTAL	80	18	2	100

Table 5. Other Sources of Information Accessed by the Patients-Participants, n=100

Level of Formal Education	Other Patients	Magazines	Internet	Total
No formal education	-	-	-	-
Primary/High School	-	-	-	-
Certificate	10	2	-	12
Baccalaureate	-	1	8	9
Masters	-	-	2	2
TOTAL	10	3	10	23

favored by almost all of those with baccalaureate degrees (8%) and all those with masters degrees (2%). (Table 5) Of the patients who accessed self-gathered information, 21% were not satisfied while only 2%, (both with certificate educational level) were satisfied. (Table 6) Seventy percent considered the information given by doctors very important, 29% considered such information important and only one considered it somewhat important. More importance seemed to be accorded by those with higher educational levels. (Table 7) Similarly, 70% of the patients (mostly from the higher educational levels) considered the impact of information provided by the doctor completely convincing for decision making, while 30% (mostly from lower educational levels) only found the information partly convincing. (Table 8) Forty nine percent of patients (again from the lower educational levels) could not list even a single complication while an increasing number of complications could be listed by those with increasing levels of education (Table 9). Nineteen percent of our patients with educational levels of certificate and above wanted to know all complications of surgery including those that were very rare while 56% wanted to know most of the complications. (Table 10)

DISCUSSION

The components of informed consent include a description of the patient's condition and the proposed treatment, the benefits of proposed treatment and the discussion of alternative treatment including the implications of no treatment. Almost all our patients replied that they knew what informed consent was, echoing findings of other studies.^{6,11} The majority of our patients (90%) were satisfied with the information given by doctors before surgery, similar to findings in previous studies by Adhikari *et al.*¹¹ and Albera *et al.*¹² On the other hand, 80% of our patients preferred to receive written information from physicians, in complete contrast to another study¹² which showed that only 20% preferred the written form. It may be because our patients think that the written form of information instilled trust and hope.

Less than one fourth (23%), mainly the well-educated patients, looked for further information regarding the surgical procedure. These are less than the figures of Burns *et al.*⁶ where two thirds of patients sought information elsewhere prior to signing their consent form, but more than those of Adhikari *et al.*¹¹ and comparable to those of Lavelle –Jones *et al.*¹³ This may suggest a need to increase awareness and interest among our patients and exert more effort to help non-formally educated patients understand their disease. Obtaining proper informed consent and good communication should be practiced not only because it forms a part of a good medical practice; it also reduces legal problems. Although the problem of litigation in Nepal is not very high, there recently seems to be an increasing trend in this direction.

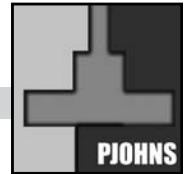


Table 6. Satisfaction with Self-Gathered Information, n=100

Level of Formal Education	Satisfied	Not Satisfied	Total
Certificate	2	10	12
Baccalaureate	0	9	9
Masters	0	2	2
TOTAL	2	21	23

Table 7. Importance Given by Patients to the Information Provided by Doctors, n = 100

Level of Formal Education	Very Important	Important	Somewhat important	Not Important	Total
No formal education	-	9	1	-	10
Primary/High School	36	20	-	-	56
Certificate	23	-	-	-	23
Baccalaureate	9	-	-	-	9
Masters	2	-	-	-	2
TOTAL	70	29	1	-	100

Table 8. Impact of Information Provided by the Doctor on Decision-Making, n = 100

Level of Formal Education	Completely convincing	Partly Convincing	Not Convincing	Total
No formal education	-	10	-	10
Primary/High School	36	20	-	56
Certificate	23	-	-	23
Baccalaureate	9	-	-	9
Masters	2	-	-	2
TOTAL	70	30	-	100

Table 9. Patient recall of the possible complications explained by the doctor, n=100.

Level of Formal Education	Recall of Complications				Total
	Cannot recall any	Can recall only 1	Can recall 2	Can recall at least 3	
No formal education	10	-	-	-	10
Primary/High School	39	17	-	-	56
Certificate	-	16	7	-	23
Baccalaureate	-	-	8	1	9
Masters	-	-	-	2	2
TOTAL	49	33	15	3	100

Table 10. Number of Patients who would like to be told of surgical complications whose incidence rates fall within a certain range only, n = 100.

Level of Formal Education	Incidence Rate of Complications					Total
	50-75%	25-50%	10-25%	5-10%	All	
No formal education	-	5	4	1	-	10
Primary/High School	41	15	-	-	-	56
Certificate	15	-	-	-	8	23
Baccalaureate	-	-	-	-	9	9
Masters	-	-	-	-	2	2
TOTAL	56	20	4	1	19	100

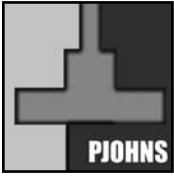
Interestingly, our results showed that patients were not satisfied with self-gathered information compared to information provided by doctors, reminiscent of findings by Georgalas *et al.*¹⁴ It may be because they believe more in the information provided by doctors rather than that acquired from other sources. Moreover, the risk with this self-gathered type of information is that it frequently is of variable quality, and patients in another study graded it as the worst quality among all the information sources.¹⁴

Also consistent with the literature¹² were our findings that 70% of patients believed it was very important for them to be informed about their procedure and 70% of patients were completely convinced about what they consented to. This may be because our patients had trust in their doctors.

Almost half (49%) of our patients, mainly those with no formal education and educational levels of primary/high school could not list even a single complication while 33% who listed one complication only mainly had primary/high school and certificate level education. Only 3% listed 3 complications and they had either master or baccalaureate level education, consistent with the findings of Gongal *et al.*⁹ and Hekkenberg *et al.*¹⁵ which showed better levels of understanding in patients who had higher education.

Defining which risks are significant is arguably the most crucial aspect of informed consent law.^{6,16} Adhikari *et al.*¹¹ showed that 90% expected to know all complications, while Burns *et al.*⁶ showed that 73.0% of those questioned expected to be informed of all known complications, even if the incidence was less than one percent. Our study showed that only 19% who were among the more educated expected to know all complications even if rare. It may be because our patients had less enthusiasm and more anxiety about knowing the rarest complications. Most patients incorrectly believe that informed consent serves only to protect a physician's right but the process of informed consent gives patients an understanding of a procedure¹⁷ so that they can adequately make an informed decision. While mention of extremely rare complications such as death may only serve to unjustly increase patient anxiety; the argument that stating uncommon risks may cause undue patient anxiety has been disproved.¹⁷ When discussing complications with a patient, it is not clear whether one should present his or her incidence of a complication or that found in the literature. Though only few of our patients wish to be informed of all known complications, we must raise awareness of patients and improve our communication regarding most major complications.

We should not underestimate the importance of the outpatient consultation, the importance of written material and non-medical information sources. It is up to us to understand and use these



alternative information channels appropriately. Patients' expectations are quite high and the majority of them want to be informed about most complications. We should also find ways to improve the provision of patient information where possible and appropriate as per specific patient groups.

APPENDIX
Questionnaire

Name: _____
Age: _____
Sex: _____
Religion: _____
Education: _____
Guardian name (if children): _____ Relation: _____
Operation name: _____ Date: _____

- 1. Were you satisfied by the information given to you by the doctors about your operation?
Yes () No ()
2. Have you looked for any further information regarding your operation?
Yes () No () List: other patients (), Magazines (), Internet ()
3. Were you satisfied with self-gathered information?
Yes () No ()
4. Do you know what informed consent is?
Yes () No ()
5. Did your doctor explain the complications of your procedure?
Yes () No ()
6. Can you list any of complications regarding your operations?
Yes () No () List: _____
7. How frequent the complications you expect to know from your doctors?
<1%, 1-5%, 5-10%, 10-25%, 25-50%, 50-75%, ALL.
8. How important is it for you to be informed about:
a. Very much b. Enough c. A little d. Not at all
9. Were you convinced about what you consented to?
a. Yes, completely b. yes, partly c. No
10. Would you prefer to receive written or spoken information from the doctor?
a. Written b. spoken c. it's the same.

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