

Patients' Expectations on Informed Consent before ENT Surgery

Prakash Adhikari*, Rabindra B. Pradhananga.**

* Dr. Senior Medical Officer.

** Dr. Senior Resident In Otorhinolaryngology.

Address Dr. Prakash Adhikari, M.B.B.S. Medical officer, Department of Ear Nose Throat and Head & Neck Surgery (ENT), Tribhuvan University Teaching Hospital, Kathmandu, Nepal. Tel: 977-14414191. Fax: 977-14414191. Email: prakash_ooz@hotmail.com

Este artigo foi submetido no SGP (Sistema de Gestão de Publicações) da R@IO em 10/2/2007 e aprovado em 14/2/2007 12:11:46

RESUMO

- Objetivo:** Analisar as informações esperadas pelos pacientes/responsáveis antes da assinatura do termo de consentimento de diferentes procedimentos otorrinolaringológicos.
- Método:** Um total de 100 pacientes foram entrevistados através da utilização de um questionário padrão antes de qualquer procedimento cirúrgico no departamento de Otorrinolaringologia e Cirurgia de Cabeça e Pescoço do Hospital Universitário da Tribhuvan University entre setembro e novembro de 2006. Todas as questões foram respondidas de forma escrita. Os formulários foram analisados utilizando-se de método manual simples usando frequência e porcentagem.
- Resultados:** A maioria (96.0%) dos pacientes ficou satisfeita com a informação dos médicos assistentes sobre o procedimento cirúrgico, antes de serem submetidos à cirurgia. Entretanto, 8.0% dos entrevistados procuraram mais informações através da internet, revistas e conversas com pacientes previamente operados. O tempo médio de espera para cirurgia foi de 4.2 meses. Em torno de 77.0% dos pacientes não foram relatadas quaisquer complicações. Informações sobre qualquer complicação cirúrgica conhecida foi solicitada por 90% dos pacientes.
- Conclusão:** As expectativas dos pacientes foram altas e a maioria procurou ser informada acerca de qualquer complicação cirúrgica conhecida. Apesar do questionamento se o termo de consentimento deve conter todas as informações sobre o procedimento cirúrgico, o mesmo deve conter todas as principais complicações cirúrgicas.
- Palavras-chave:** consentimento informado, expectativa, procedimento cirúrgico.

SUMMARY

- Objective:** To observe the information expected by patients/caretakers before signing consent form for different ENT surgical procedures.
- Methods:** Altogether 100 patients were interviewed with a standard questionnaire prior to any surgical procedure in department of ENT and Head and Neck Surgery of TU Teaching Hospital from September to November 2006. All questions were answered in written form. These records were analyzed by simple manual analysis using frequency and percentage.
- Results:** Majority (96.0%) of patients were satisfied with the information given by doctors about their surgical procedure before doing surgery. However, 8.0% respondents looked for further information regarding their surgery in internets, various magazines, and talking to previously operated individuals. The mean waiting time for surgery was 4.2 months. There were 77.0% patients who could not list any complications. Ninety percent want to be informed about all known complications.
- Conclusion:** Patients' expectation was quite high and majority of them wanted to be informed about all known complications. Whether Informed consent should include all the information regarding the surgical procedure is still debatable. However, it must include major complications after surgery.
- Key words:** informed consent, patients' expectation, surgical procedure.

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. The amount of detail that is to be included in the informed consent process is inexact (1,2). Some states have enacted the "prudent patient standard," in which the physician must disclose all risks that a reasonably prudent patient would consider material to the decision to undergo or refuse a particular procedure (2,3,4). Other states support that a reasonably prudent physician would disclose to his or her patient (3,4). The purpose of this study is to assess the knowledge and information expected by patients/caretakers before signing consent form for different ENT surgical procedure.

METHODS

This study was conducted in 100 patients undergoing elective surgery in ENT and head and neck surgery department at TU Teaching Hospital from September to November 2006. The mean waiting time from out patients booking to date of operation was also noted. All patients were interviewed with a standard questionnaire and all answered in written form. Questions include the knowledge of informed consent, frequency of complications that patients expected to know, sources of additional information regarding surgical procedure. These records were analyzed by simple manual analysis using frequency and percentage.

RESULTS

Results showed that 55.0% male and 45.0% female, children (18.0%), adults (82.0%). Thirty one percent patients were illiterate (Table-1). The mean waiting time for surgery was 4.2 months. The various types of surgical procedures were given in Table-2.

There were 96.0% patients satisfied with the information given by doctors about their surgical procedure before doing surgery. However 8.0% respondents looked for further information (source internet, various magazines, and talking to previously operated individuals.). Around 94.0% patients understand what informed consent is. There were 77.0% patients who could not list any complications. The most common complications listed by our patients were bleeding (8.0%) and wound infection (7.0%) (Table-3). However, 90.0% of patients expect to know all known complications.

Table 1. Educational status of the participant.

Education Level	Number(Percentage)
Illiterate	31 (31%)
Less than 10 class	38 (38%)
Intermediate	22 (22%)
Bachelor	9 (9%)
Total	100 (100%)

Table 2. List of surgical procedure.

Procedures	Number(Percentage)
Myringoplasty	28 (28%)
FESS	18 (18%)
Mastoid surgery	14 (14%)
Septoplasty	12 (12%)
Adenotonsillectomy/Tonsillectomy	6 (6%)
Grommet insertion	5 (5%)
Tracheostomy	3 (3%)
Posterior Nasal Packing	3 (3%)
Inferior turbinate hypertrophy reduction	2 (2%)
Septorhinoplasty	2 (2%)
Thyroidectomy	1 (1%)
Conservative Parotidectomy	1 (1%)
Excision of sinus Neck	1 (1%)
Endoscopic resection of Nasal mass	1 (1%)
Stapes surgery	1 (1%)
Lymph Node excision	1 (1%)
D/L Biopsy of Carcinoma Glottis	1 (1%)
Total	100 (100%)

Table 3. Complications listed by patients.

Complications	Number(Percentage)
No complications listed	77 (77%)
Bleeding	8 (8%)
Wound infection	7 (7%)
Pain	4 (4%)
Facial Palsy	3 (3%)
Tasting Loss	2 (2%)
Subconjunctival hemorrhage	1 (1%)
Drooping of shoulder	1 (1%)
Tracheostomy	1 (1%)

DISCUSSION

The elements of informed consent include a description of the patient's condition and the treatment, the benefits of proposed treatment and the discussion of alternative treatment, including the implications of no treatment. Though majority of our patients were satisfied with the information given by doctors before surgery, 77.0% could not list even a single complications. Even after a relatively short time patients can have poor recall of information they have been given, and in elective surgery

Performa on Informed Consent.	
1. Patient Name: _____	Date: _____
2. Guardian Name (If children) _____	Relation: _____
3. Operation Name: _____	Waiting time: _____
4. Were U satisfied with the information given to u by your doctors about your operation? Yes () No ()	
5. Have U looked for further information regarding your operation? Yes () No () Source _____	
6. Do U know what surgical/informed consent is? Yes () No () Details _____	
7. Did your doctor explain the complications of your procedure? Yes () No ()	
8. Can you list any complication regarding your operation? Yes () No () List: _____	
9. How U know about these complications? _____	
10. How common complications you expect to know from your doctors? < 1%, 1-5%, 5-10%, 10%, 20%, 50%, ALL.	

there can be a considerable time gap (3,5) between the date booked for surgery and operation day. In our study, we found low educational status, long time gap and less enthusiasm to search for further information regarding their surgery, as the factors that patient cannot give information properly. Only 8.0% of patients looked for further information regarding surgical procedure. But study by PAUL BURNS et al showed that two third of patients sought information elsewhere prior to signing their consent form (3). This showed that we need to increase the awareness and interest of our patients though patients' expectations had increased in recent times in developed countries. On asking what informed consent is almost all patient replied that they knew it. This was similar to other study (3).

Defining which risks are significant is arguably the most crucial aspect of informed consent law (3,6). Study by PAUL BURNS et al showed that 73.0% of those questioned expected to be informed of all known complications, even if the incidence was less than one percent. But our study had a different result. Almost all patients expected from doctors that all known complications should be informed.

Although most patients incorrectly believe that informed consent serves only to protect a physicians right the process of informed consent gives patients an understanding of a procedure (7). So that they can adequately make an informed decision. Mention extremely rare complication such as death would only serve to unjustly increase patient anxiety; however the argument that stating uncommon risks may cause undue patient anxiety has been disproved (7). 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 our patients wish to be informed all known complications, we should not miss major complications before surgery.

CONCLUSION

Patients' expectation was quite high and majority of them patients wanted to be informed about all known complications. Whether Informed consent should include all the informations regarding the surgical procedure is still debatable. However, it must include major complications after surgery.

REFERENCES

1. Wolf JS, MalekZadeh S, Berry JA, O'Malley BW. Informed consent in FESS. *Laryngoscope* 2002; 112:774-8.
2. Jeffrey S. Wolf, Alexander G. Chiu, James N. Palmer, Bert W, O'Malley, Kimberlay Schofield et al. Taylor. Imformed consent in endoscopic sinus surgery: the patient perspective. *Laryngoscope* 2005; 115:492-494.
3. Paul Burns, Ivan Keogh, Conrad Timon. Informed consent: a patient's perspective. *J Otolaryngol* 2005; 119:19-22.
4. Baker C. Informed Consent: Obligation on opportunity. *J Health Hospital Law* 1993; 26:214-215.
5. Robinson G, Nerov A. Informed consent: recall by patients tested postoperatively. *Ann Thoracic Surg* 1976; 22:209-11.
6. Palisamo D, Laeve R. Informed Consent update for Louisiana: reducing the risk of malpractice suits. *J La State Med Soc* 1994; 146:399-401.
7. Stanley B, Walter D, Maddern G. Informed consent: how much information is enough? *Aust NZ J Surg*. 1998; 68:788-91.