Int. Adv. Otol. 2012; 8:(1) 78-86

ORIGINAL ARTICLE

What do patients really want to know in informed consent for non-morbid otologic surgery?

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Objective: To identify which information patients really want to know in an informed consent for mastoid surgery.

Study design: Prospective study; questionnaire survey.

Setting: University-based, secondary referral hospital

Materials and Methods: 50 patients who underwent the mastoid surgery including canal wall up or canal wall down mastoidectomy were enrolled to the analysis. Patients who underwent the mastoid surgery were asked to identify which information of mastoid surgery they considered to be important for the informed consent prior to the surgery. One month after the discharge, they were asked again to identify which information they considered to be important information for patients to know prior to undergoing mastoid surgery.

Results: Postoperative survey showed that patients considered information on the general outline of their disease and treatment process, to be more important than information on postoperative complications. These include: patients' disease status, purpose of the surgery, technical details of the surgery, details of the postoperative course and consequence of non-surgery. The importance of quality of life associated with the surgery was not increased after the surgery. The importance of intracranial infection, CSF leakage and risk of general anesthesia was decreased after the surgery.

Conclusion: Most patients want more information about the general outline of their disease and treatment process, than about specific and narrow items like postoperative risks or complications. They were more interested about their disease status, purpose of the surgery, consequence of not doing the surgery, technical details of the surgery and details of postoperative course.

Submitted : 16 May 2011 *Accepted : 26 December 2011*

Introduction

Informed consent is defined as "voluntary authorization, by a patient or research subject, with full comprehension of the risks involved, for diagnostic or investigative procedures, and for medical and surgical treatment" and classified into "jurisprudence" as well as "patient rights" according to the Medical Subject headings (MeSH) of the United States National Institutes of Health. Even though the process of informed consent is complex and time-consuming, it is imperative that this process be observed so that patients will be informed on matters of their concern, more than mere information that doctors think should be provided. There are many potential risks or complications in undergoing mastoid surgery, which is one of the most common otologic operations. Their incidence is variable and their severity ranges from minor to life-threatening. Like in other major surgical procedures, the informed consenting process is a vital part of patient preparation. Mein et al 1 first reviewed the informed consent from the viewpoint of patients who have undergone the mastoid surgery. They surveyed which risks of mastoid surgery they felt were important to be informed on prior to the surgery. They concluded that surgeons should not omit information on intracranial complications for the reason of its rarity and potential distress of patients.

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Most studies that deal with the informed consenting procedure are performed prior to the surgery, coming from either the viewpoint of doctors or of patients. However, patients are not experts in medicine and they can have preconceptions about potential risks or complications of the surgery. Therefore, what patients consider to be important before surgery is not always what they consider to be important after the surgery. If patients are not sufficiently informed on issues that they will consider important after the surgery, this misinformation may lead to post-op issues and medico-legal disputes. The severity of risks or complication of the mastoid surgery that surgeons consider is not exactly agreed with what patients consider.

Evaluating the risks or complications that patients consider to be important before and after the surgery, we identified which information patients really want to know and should be sought consented for in informed consent prior to mastoid surgery. To our knowledge, this is the first study in Korea.

Materials and Methods

Study design

The participants in this study were 50 patients who were scheduled for the mastoid surgery at university-based, secondary referral hospital. Only cases which involve middle ear surgery including canal wall up (CWU) or canal wall down (CWD) mastoidectomy were included. Cholesteatoma cases were included while cases of middle ear surgery without mastoidectomy were excluded. Revisional cases and cases with extra- and intracranial complications of chronic inflammatory disease were also excluded. Prior to informed consent, the patients were interviewed using a survey questionnaire. If the patient was younger than 19 years, his or her parents were surveyed. On outpatient visit 1-2 month after the discharge, they were interviewed using the same questionnaire.

Questionnaire (Table 1)

The patients were asked to indicate how important each question was with respect to the mastoid surgery. The Visual Analogue Scale (VAS) was used to test the importance of each question to the patients. The patients were requested to give a score between 0 (not important at all) and 10 (extremely important) for each question.

Demographic data were collected on age, sex and profession by questions positioned intentionally at the

Table 1. Questions asked to patients how important each question was with respect to the mastoid surgery they need to undergo. The Visual Analogue Scale (VAS) from 0 to 10 was used.

Questions
A. Current status of the disease
B. Detailed purposes of the procedure
C. Technical details of the procedure
D. Anesthesia, analgesia or sedation used
E. Details of postoperative management and course
F. Major risks or complications of undergoing the procedure
F.1. Recurrence
F.2. Facial paralysis
F.3. Intracranial infection; meningitis, brain abscess, etc
F.4. CSF leakage
F.5. Risks of general anesthesia
G. Minor risks or complications of undergoing the procedure
G.1. Tinnitus
G.2. Vertigo
G.3. Taste change
G.4. Wound problem; bleeding, hematoma, infection, dehiscence, scar
H. Consequences of not undergoing the procedure
I. Alternative options
J. Effects of the procedure on quality of life during hospitalization
K. Effects on quality of life in the short-term (up to 3 month) postoperatively
L. Effects on quality of life in the long-term (from 3 month onwards) postoperatively

end of the questionnaire. The survey questionnaire used was a paper-based, structured and self-administered questionnaire for data collection.

Ethics

This survey study was approved by the Institutional Review Board (IRB) of Bucheon St. Mary's Hospital that all cases were recruited from (IRB policy number; HC09FZZZ0050). Informed consent for the mastoidectomy was obtained for all the patient participants.

Data collection & Statistical analysis

The data were retrieved and were entered into Microsoft Excel sheet by one (J-H.S.) of the authors. SPSS 13.0 for Windows (Somers, NY, USA) was used for data analysis by one (D-H.L.) of the authors. Mann-Whitney test was used to compare the difference between two groups and Wilcoxon signed ranks test was used for the comparison of pre and postoperative data. P value less than 0.05 was considered significant (two-tailed significance).

Results

Epidemiology

Fifty patients (19 males and 31 females) were included in this study. Their median age was 51.8±11.8 years-old. The median age of male was 51.0±12.0 years-old and that of female was 53.6±11.9 years-old. The causative disease of the mastoidectomy was chronic suppurative otitis media without cholesteatoma in 26 cases and with cholesteatoma in 24 cases. In male patients, chronic suppurative otitis media without cholesteatoma was in 11 cases and with cholesteatoma in 8 cases. In female patients, chronic suppurative otitis media without cholesteatoma was in 15 cases and with cholesteatoma in 16 cases.

Patients' grading of the perception of importance before and after the operation (Table 2 and 3, Fig 1)

For questions that patients thought to be least important in preoperative survey, the first-ranked questions were "taste change (36%)" and "alternative options (36%)". The first-ranked questions in male patients were "tinnitus (14%)", "wound problem (14%)" and "alternative options (14%)" and "taste change (24%)" in female patients.

Table 2. Patients' grading of the perception of importance (preoperative survey).

Groups	Ranks	Questions which importance was lower than the average importance of each patient
Total (n=50)	1st	Alternative options, Taste change
	2nd	Vertigo, Wound problem
	3rd	Technical details of the procedure
Male (n=19)	1st	Alternative options , Tinnitus, Wound problem
	2nd	Technical details of the procedure, Recurrence, Vertigo, Taste change
	3rd	Effects on quality of life in the short-term postoperatively, Facial paralysis
Female (n=31)	1st	Taste change
	2nd	Alternative options, Vertigo
	3rd	Effects of the procedure on quality of life during hospitalization, Wound problem

Groups	Ranks	Questions which importance was higher than the average importance of each patient
Total (n=50)	1st	Detailed purposes of the procedure
	2nd	Current status of the disease, Anesthesia, analgesia or sedation used
	3rd	Details of postoperative management and course, Risks of general anesthesia
Male (n=19)	1st	Detailed purposes of the procedure
	2nd	Current status of the disease
	3rd	Details of postoperative management and course, Effects of the procedure on quality of life during hospitalization, Risks of general anesthesia
Female (n=31)	1st	CSF leakage
	2nd	Intracranial infection, Risks of general anesthesia, Wound problem
	3rd	Alternative options, Effects of the procedure on quality of life during hospitalization

Table 3. Patients' grading of the perception of importance (postoperative survey).

Groups	Ranks	Questions which importance was lower than the average importance of each patient
Total (n=50)	1st	CSF leakage
	2nd	Wound problem, Effects of the procedure on quality of life during hospitalization
	3rd	Alternative options
Male (n=19)	1st	Effects of the procedure on quality of life during hospitalization and in the short-term postoperatively
	2nd	Wound problem, Alternative options
	3rd	CSF leakage, Vertigo, Taste change
Female (n=31)	1st	Anesthesia, analgesia or sedation used
	2nd	Current status of the disease
	3rd	Details of postoperative management and course, Effects of the procedure on quality of life during hospitalization, Risks of general anesthesia

Groups	Ranks	Questions which importance was higher than the average importance of each patient
Total (n=50)	1st	Consequences of not undergoing the procedure
	2nd	Current status of the disease, Detailed purposes of the procedure
	3rd	Technical details of the procedure, Details of postoperative management and course
Male (n=19)	1st	Detailed purposes of the procedure
	2nd	Consequences of not undergoing the procedure
	3rd	Current status of the disease
Female (n=31)	1st	Current status of the disease
	2nd	Detailed purposes of the procedure, Consequences of not undergoing the procedure
	3rd	Technical details of the procedure, Details of postoperative management and course

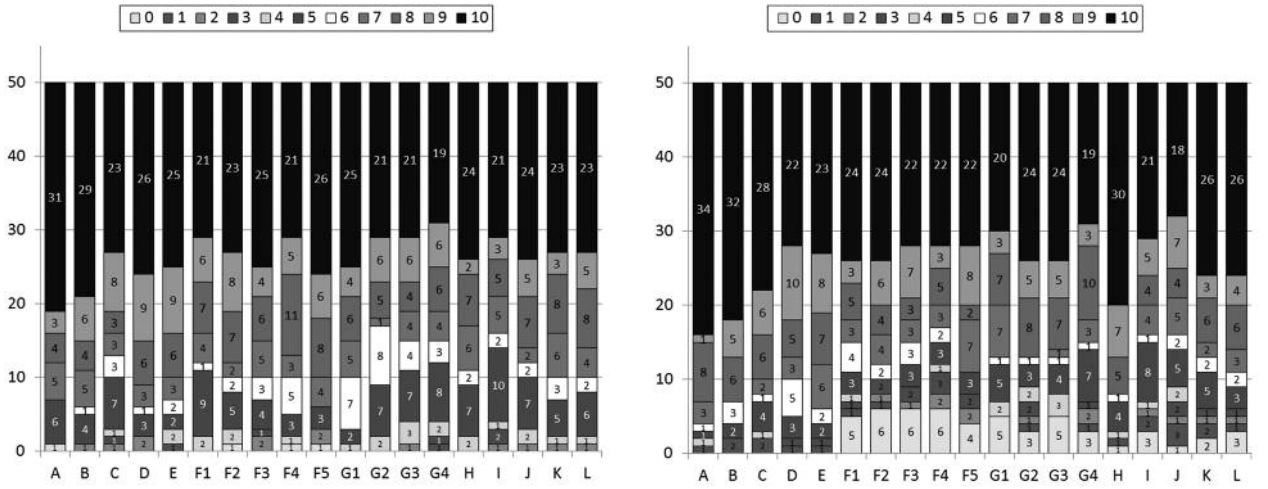

Figure 1. Number of patients scored 0-10 according to questions in (A) preoperative and (B) postoperative survey.

On the other hand, for questions that patients thought to be most important in preoperative survey, the first-ranked question was "detailed purposes of the procedure (48%)". The first-ranked question in male patients was "detailed purposes of the procedure (22%)" and "CSF leakage (34%)" in female patients.

Forty percent of patients considered "CSF leakage" as a question that they thought to be least important in postoperative survey. The first-ranked questions in male patients were "effects of the procedure on quality of life during hospitalization (14%)" and "effects on quality of life in the short-term postoperatively (14%)" and "anesthesia, analgesia or sedation used (30%)" in female patients.

On the other hand, 56% of patients considered "consequences of not undergoing the procedure" as a question that they thought to be most important in postoperative survey. The first-ranked question in male patients was "consequences of not undergoing the procedure (22%)" and "current status of the disease (34%)" in female patients.

Changes of patients' grading of the perception of importance before and after the operation (Table 4)

To evaluate the changes of the importance before and after the operation, the difference between pre- and postoperative importance was calculated. Questions in which the difference was outside of its 5- and 95-percentile were selected. The questions where the difference in the importance was under 5-percentile were defined as ones with significant decreases in importance after the operation. The questions of which the difference in the importance was over 95-percentile were defined as the questions with significant increase in importance after the operation.

The first-ranked question of which the importance was significantly decreased after the operation was "intracranial infection" in total (74%), in male (28%) and in female patients (46%). The first-ranked question of which the importance was significantly increased after the operation was "consequences of not undergoing the procedure" in total patients (42%);

Table 4. Changes of the importance before and after the operation.

Groups	Ranks	Questions which the importance was decreased markedly (lower than 5th percentile) after operation
Total (n=50)	1st	Intracranial infection
	2nd	Effects of the procedure on quality of life during hospitalization
	3rd	Anesthesia, analgesia or sedation used
Male (n=19)	1st	Intracranial infection
	2nd	Effects of the procedure on quality of life during hospitalization
	3rd	Anesthesia, analgesia or sedation used, Taste change, Effects on quality of life in the short-term postoperatively
Female (n=31)	1st	Intracranial infection
	2nd	Facial paralysis, CSF leakage
	3rd	Anesthesia, analgesia or sedation used, Risks of general anesthesia, Tinnitus, Wound problem, Effects of the procedure on quality of life during hospitalization

Groups	Ranks	Questions which the importance was increased markedly (higher than 95th percentile) after the operation
Total (n=50)	1st	Consequences of not undergoing the procedure
	2nd	Detailed purposes of the procedure, Vertigo
	3rd	Current status of the disease, Technical details of the procedure, Taste change, Effects on quality of life in the short-term and in the long-term postoperatively
Male (n=19)	1st	Consequences of not undergoing the procedure, Vertigo
	2nd	Current status of the disease, Detailed purposes of the procedure, Intracranial infection
	3rd	Wound problem, Effects on quality of life in the short-term and in the long-term postoperatively
Female (n=31)	1st	Detailed purposes of the procedure, Technical details of the procedure, Taste change, Consequences of not undergoing the procedure, Effects on quality of life in the short-term and in the long-term postoperatively
	2nd	Current status of the disease, Vertigo
	3rd	Effects of the procedure on quality of life during hospitalization

"vertigo" and "consequences of not undergoing the procedure" in male (18%) and 6 questions including "taste change" and "consequences of not undergoing the procedure" in female patients (24%).

Questions which showed the largest difference between pre- and postoperative importance was "intracranial infection" in total (51%), in male (22%) and in female patients (29%). In two-third of these patients, the importance was decreased (in 73% of total, in 64% of male and in 79% of female patients).

Comparison of the importance according to gender, etiology and type of mastoidectomy.

There was no significant difference of the importance between male and female patients in preoperative survey as well as in postoperative survey.

Only "consequences of not undergoing the procedure" was significantly higher in cholesteatoma group (p=0.023) in preoperative survey. There was no significant difference in the importance between chronic otitis media and cholesteatoma groups in postoperative survey. There was no significant difference in the difference between pre- and postoperative importance according to type of etiology.

There was no significant difference in the importance between CWU and CWD groups in preoperative survey. "Taste change", "consequences of not undergoing the procedure", "alternative options" and "effects of the procedure on quality of life during hospitalization" was significantly higher in CWD group (p=0.036, 0.029, 0.042 and 0.041, respectively) in postoperative survey. Only the difference of "consequences of not undergoing the procedure" between pre- and postoperative importance was significantly higher in CWD group (p=0.024) according to type of mastoidectomy.

Comparison of the importance according to the category of the questions (Fig 2)

Nineteen questions were categorized into 4 categories according to their characteristics. Category 1 is about focal information restricted to major and minor risk or complications of the operation (G and F questions in Table 1). Category 2 is about technical information limited to the surgery and includes current status of the disease, technical details of the procedure and anesthesia/analgesia/sedation used (A, C and D questions in Table 1). Category 3 is about quality of life associated with the surgery and includes details of postoperative management and course and effects of

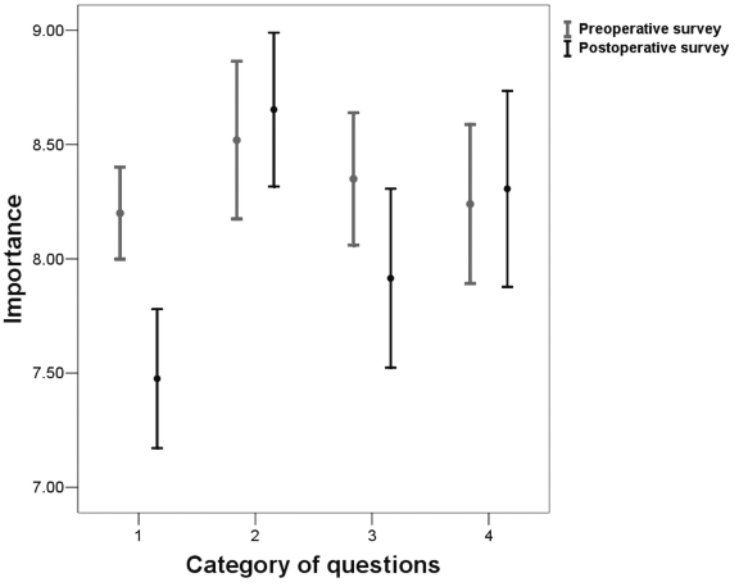

Figure 2. Error bar graph showing the importance of information according to its category. Bar represents 95% confidence interval for mean.

the procedure on quality of life during hospitalization/in the short-term postoperatively/in the long-term postoperatively (E, J, K and L questions in Table 1). Category 4 is about the treatment principles and plans and includes detailed purposes of the procedure, consequences of not undergoing the procedure and alternative options (B, H and I questions in Table 1).

The importance in preoperative survey of category 1 was significantly decreased after the surgery ($p=0.002$) and there was no significant difference of the importance between pre and postoperative survey in other categories ($p=0.227$ in category 2, 0.218 in category 3 and 0.581 in category 4).

The comparison of each categories showed the significant differences between category 1 and 2 in postoperative survey ($p< 0.001$) as well as between category 1 and 4 in postoperative survey ($p=0.014$).

Discussion

Patients are no longer passive recipients of medical information. They want to participate actively in the decisions related to their management. This change is largely due to increased awareness among patients about the disease processes affecting them and increased access on information available on the internet. A wide range of available therapeutic options and detailed discussion of these options has revolutionized the meaning of 'informed consent'.

Today, the actions of doctors have been increasingly challenged and treating a patient with inadequately informed consent constitutes 'negligence' by law. Informed consent should be viewed as part of the patient education process prior to treatment so that the patient becomes well informed, responsible and willing member of the team. Apart from the fact that informed consent process is a legal requirement, it is an important component of the patient–doctor relationship and goes a long way to ensure active participation of patients in the healing process.

However, there are some problems herein. The amount and content of information during informed consent have been decided just by the doctors. Currently there is no clear consensus among the doctors on how much information should be provided to patients. Also, the level of risk disclosure varies between patients and doctors, as well as among individual doctors. Patients themselves also differ widely in their opinion about how much information they want about risks involved in the treatment. Some researchers feel that full informed consent can cause patient anxiety or distress prior to surgery [2,3], but others show that extended informed consent did not cause increased anxiety or depression [4,5]. Therefore, to know what patients want to know and consider to be important is the basic and essential step in taking the informed consent from them. This study is the first systematic research in evaluating patients' need and opinion about the informed consent of mastoidectomy.

Our results showed that our patients want more information about the general outline of their disease and treatment process, than about specific and narrow items like postoperative risks or complications. Patients want to know more about their disease status, purpose of the surgery, consequence of not doing the surgery, technical details of the surgery and details of postoperative course. Detailed information, such as intracranial infection, CSF leakage, quality of life during hospitalization and anesthesia used, were not as important to patients after the surgery. However, information such as: disease status, purpose of the surgery, consequence of not doing the surgery, technical details of the surgery and postoperative quality of life became more important after the surgery. In providing patients with information that they want to know, doctors can help patients become more active participants in their treatment process.

No gender difference was found in our study. It is important for the readers to note that the respondent patients had not experienced serious complications during and after the surgery in this study. Preoperatively, female patients dwelt on specific and morbid postoperative complications, such as CSF leakage, intracranial infection and risk of general anesthesia. However, after the surgery and recovery, they realized that these were not as important as they perceived to be before the surgery. A small perforation of the neodrum that did not require re-operation was

found in 4 patients, tinnitus occurred in 1 patient, tinnitus was aggravated in 1 patient, temporary dizziness was complained by 2 patient, temporary headache was complained by 2 patients and hematoma resolved conservatively developed in 1 patient. Postoperative infection developed but was controlled conservatively in 13 patients. The responses of the subjects may be different had there been cases involving serious complications.

Although this study showed that specific and morbid postoperative complications seemed to be less interested to patients, this result does not mean that these information are not valuable for the informed consent. This means that information about the disease status, purpose of the surgery, consequence of not doing the surgery, technical details of the surgery and details of postoperative course are almost as important as postoperative complications. Surgeons should keep in mind that information on postoperative complications should be given before any surgery for medicolegal reasons.

In preoperative survey, the importance of "consequences of not undergoing the procedure" was significantly higher in choleasteatoma group than in COM group. Because patients with cholesteatoma were generally warned on postoperative scenarios such as: high recurrence rate despite of the surgical treatment, poor prognosis for hearing and poor quality of life resulting from possible CWD mastoidectomy, avoidance of surgical treatment is an option that they seriously consider. However, this difference was lost in postoperative survey and this means that they were satisfied with the surgery outcome.

This trend is also seen in the comparison between CWU and CWD groups. In postoperative survey, the importance of "taste change", "consequences of not undergoing the procedure", "alternative options" and "effects of the procedure on quality of life during hospitalization" was significantly higher in the CWD group, but not in the preoperative survey. We can assume that many discomforts resulting from CWD mastoidectomy including postoperative cavity problems and taste changes may give rise to negative opinion in patients who got CWD mastoidectomy. Considering that the significant difference was not seen in preoperative survey, we can easily know that these discomforts were real problems in patient's life. Therefore, we must keep in mind that even minor information is also important to patients and we try to reduce these postoperative problems during CWD mastoidectomy.

After the surgery, our patients reconsidered the significance of the information about major and minor risk or complications in the whole course of their treatment. They considered the information about the outline of treatment course (category 2) and general principle/plan (category 4) more valuable to them. Surprisingly, the importance of category 3 (questions about quality of life associated with the surgery) was slightly decreased after the surgery. This may be attributed to the minimal effects on the quality of life of patients postoperatively since mastoidectomy is not a serious surgical method. Thus, although literature on informed consent abound in the field of cardiac surgery or cancer treatment [2-5], this is not the case for patients undergoing less-complex surgery.

The results of this study must be considered within its limitations. First, recall bias may have been introduced since the postoperative survey was administered 1-2 month after the surgery. Next, gratitude bias for the surgeons given that there was no case of serious complications during and after the surgery.

The reliable assessment and evaluation of the informed consent process can only be done through patient feedback, since informed consent is patient-centered. Therefore improving the informed consent process requires an understanding of patients' perspective, desires and information needs. When doctors appreciate this patient-centered process of informed consent, then they can better work with their patients as part of the medical team.

Conclusions

Today patients are no longer passive recipients of medical information and they want to participate

actively in the decisions related to their management. If patients are not sufficiently informed on issues that they will consider important, this misinformation may lead to post-op issues and medico-legal disputes. This study found that most patients want more information about the general outline of their disease and treatment process, than about specific and narrow items like postoperative risks or complications. In this study, patients want to know more about their disease status, purpose of the surgery, consequence of not doing the surgery, technical details of the surgery and details of postoperative course. We hope that this study can be contributed to the improvement of doctor's attitude, who prepare and take informed consent from patients who get not too much morbid operation because knowing one will always make you a winner.

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