

## ORIGINAL ARTICLE

# What Patients Expect to be Consented Versus What Doctors Tend to Inform for Preauricular Sinusectomy

Dong-Hee Lee

Department of Otolaryngology-Head and Neck Surgery, College of Medicine, The Catholic University of Korea, Seoul, Korea

**Objective:** This prospective controlled study's aim is to identify the difference between patients' and doctors' perspectives regarding risks or complications of preauricular sinusectomy.

**Study Design:** Prospective, questionnaire-based survey and IRB-approved study. Setting; At university-based, secondary referral hospital.

**Subjects and Methods:** Thirty patients who underwent preauricular sinusectomy were surveyed about what they expected to be consented for prior to surgery. These results were compared to 20 surgeons' answers on what they routinely emphasize to patients preoperatively.

**Results:** This study demonstrated a difference in what patients expect to be informed of and what doctors actually consent to. While patients expected to be informed of the many risks or complications, doctors tended to inform patients based on what they wanted to say.

**Conclusions:** This study identified the aspects of informed consent that patients and doctors consider important before preauricular sinusectomy, which is one of the simplest and least morbid operations.

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## 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," according to the Medical Subject headings (MeSH) of the United States National Institutes of Health.

The process of informed consent is complex and continues to evolve. The coordination between patients' rights and doctors' obligations has been considered to be important, but now it needs to be matched by the development of patients' obligations and doctors' rights. This is because our present society considers informed consent as a process of shared decision making. In addition, the recent legal system in most countries does not accept medical paternalism any more and emphasizes a doctor's obligation in the partnership between the patient and the doctor. Therefore, it is very important to identify a difference in what patients expect to be informed of and what doctors actually obtain consent for.

## Materials and Methods

### Study design

The participants in this study were 30 consecutive patients who were scheduled for preauricular sinusectomy at a secondary referral hospital. Prior to requesting their informed consent, the patients were interviewed using a survey questionnaire. If the patient was younger than 19 years old, his or her parents were surveyed. The patients' mean age was 13.8 years old (standard deviation 8.3 years). Fifteen were male and 15 were female.

The postal questionnaire asked 20 surgeons (14 otolaryngologists and 6 plastic surgeons) in the capital region of Korea. Their mean period of in-service as surgeon was 6.9 years (standard deviation 2.2 years) and their mean frequency of preauricular sinusectomy was 18.7 cases per year (standard deviation 6.4 cases per year).

The survey questionnaire used for patients and doctors was an anonymous, paper-based, structured, and self-administered questionnaire for data collection.

### Corresponding address:

Dong-Hee Lee,  
Department of Otolaryngology-Head and Neck Surgery, Uijeongbu St. Mary's Hospital, The Catholic University of Korea,  
#65-1 Geumo-Dong, Uijeongbu City, Gyeonggi-Do, 480-717, Korea.  
Telephone : +82-31-820-3564, Fax : +82-31-847-0038, E-mail : leedh0814@catholic.ac.kr

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### **Questionnaire**

The survey questionnaire contained 8 questions: <sup>[1]</sup> major risks or complications including recurrence and keloid scar; <sup>[2]</sup> minor risks or complications including stitch abscess and scar; <sup>[3]</sup> consequences of not undergoing the preauricular sinusectomy; <sup>[4]</sup> alternative options; <sup>[5]</sup> technical details of the preauricular sinusectomy; <sup>[6]</sup> risks or complications of anesthesia used; <sup>[7]</sup> immediate effects (postoperatively up to 1 month); and <sup>[8]</sup> late effects (postoperatively from 1 month onwards) of the preauricular sinusectomy on patients' quality of social life.

The Visual Analogue Scale (VAS) was used to test the importance of each question to the patients. The VAS ranged from 0 (not important at all) to 10 (extremely important) for each question.

Demographic data were collected on age and sex of patients. Data on years of in-service as surgeon, average frequency per year of preauricular sinusectomy, and professional specialty such as otolaryngology or plastic surgery were also collected. In this study, a doctor's career was defined as a product of years of in-service as surgeon and average frequency per year of preauricular sinusectomy.

### **Ethics**

This survey study was approved by the Institutional Review Board (IRB) of Uijeongbu St.Mary's hospital. Informed consent for preauricular sinusectomy was obtained all the patient participants.

### **Data collection and Statistical analysis**

The data were retrieved by the author and encoded in a Microsoft Excel sheet. Data were transferred to SPSS for statistical analysis. SPSS 13.0 for Windows was used for data analysis. Descriptive statistics included means, standard deviation (SD), and confidence intervals (CIs). CIs were calculated at 95%. P value less than 0.05 was considered significant (two-tailed significance). Nonparametric test (Mann-Whitney U test) was used to detect a difference between patients and doctors groups, between children and adult groups, and between male and female groups. Spearman's rank correlation coefficient test was used to determine bivariate correlation significance.

### **Results**

Difference between patients and doctors (Table 1)

This study showed a significant discrepancy between

patients and doctors in all questions except one, which was about immediate effect on patients' quality of social life ( $p=0.173$ ). This meant that both patients and doctors considered this aspect not to be important (VAS score of patients =  $3.7\pm1.8$  and VAS score of doctors =  $2.7\pm1.5$ ).

In this study, most patients considered consents for minor risks and consequences of not undergoing the operation to be very important to them. Contrary to this, most doctors emphasized only consent for major risks such as recurrence or keloid scar. Although VAS scores were not high enough, many patients were more interested than doctors were in alternative options, technical details, risks of anesthesia, and late effects on their quality of social life. These differences were significant.

Analysis according to characteristics of patients: age and sex (Table 2)

To analyze any difference according to a patient's age, the patient group was divided into 22 children (younger than 19 years) and 8 adult (19 years or older) patients. Only two aspects showed significant differences between the two groups: risks or complications of anesthesia used and immediate effect on patients' quality of social life. Many parents of child patients wanted to be consented for the former aspect and many adult patients wanted to be informed of the latter aspect. This resulted from public conviction that general anesthesia might be more dangerous for children than for adults. Because preauricular sinusectomy needs no admission or very short admission of 1–2 days, if necessary, adult patients were stressed by the burden that he or she must return to daily activity including working places soon after the operation.

Only two aspects showed significant differences between 15 male and 15 female patients. Female patients wanted more detailed information on minor risks or complications including scar and alternative options to surgical treatment. This was due to the fact that female patients were more sensitive to the cosmetic aspect of surgery than males. Because preauricular sinusectomy can cause a scar on the face, female patients worried about this and wanted to be informed of other possible bloodless and scarless treatment options such as laser therapy.

Analysis according to characteristics of doctors: experience and specialty

**Table 1.** Statistics of Visual Analogue Scale (VAS) scores of importance of questions to 30 patients and 20 doctors.

Number of questions	Patients			Doctors			p value
	Mean	SD	CI	Mean	SD	CI	
Q1. Major risks or complications including recurrence and keloid scar	2.9	0.9	2.89 -2.91	6.2	1.2	6.18 -6.22	0.000
Q2. Minor risks or complications including stitch abscess and scar	6.9	2.1	6.88 -6.92	4.3	1.0	4.24 -4.26	0.000
Q3. Consequences of not undergoing the preauricular	5.2	1.5	5.18 -5.22	1.7	0.7	1.69 -1.71	0.000
Q4. Alternative options	3.6	1.3	3.62 -3.65	0.5	0.5	0.44 -0.46	0.000
Q5. Technical details of the preauricular sinusectomy	4.3	1.3	4.29 -4.31	2.7	1.0	2.64 -2.66	0.000
Q6. Risks or complications of anaesthesia used	3.8	1.6	3.75 -3.79	1.1	0.8	1.04 -1.06	0.000
Q7. Immediate effect of the preauricular sinusectomy on patients' quality of social life	3.7	1.8	3.65 -3.69	2.7	1.5	2.68 -2.72	0.173
Q8. Late effect of the preauricular sinusectomy on patients' quality of social life	2.3	0.9	2.32 -2.34	0.7	0.7	0.69 -0.71	0.000

SD = standard deviation; CI = confidence interval (calculated at 95%).

To evaluate any difference according to a doctor's characteristics, the data were analyzed according to a doctor's career and professional specialty. In this study, Spearman's rank correlation coefficient test did not demonstrate any significant correlation between a doctor's career and VAS scores of each question (Table 3).

This study did not demonstrate any significant difference between 14 otolaryngologists and 6 plastic surgeons (Table 2). However, otolaryngologists were more interested in major risks or complications including recurrence, immediate effects, and late effects on patients' quality of social life. Plastic surgeons were more interested in minor risks or complications including scar and technical details of the preauricular sinusectomy.

## Discussion

Patients in this study considered many questions posed to be important. Furthermore, patients differed in their desire for information, with one significant minority favoring little or no discussion of risk and another wishing detailed consideration of specific risks. This difference might result from patients' difference in individual circumstances and daily activity. Therefore, the system of informed consent that reflects a patient's perspective can better suit the patient's wishes than a doctor-specified agenda.

In this study, doctors were even concerned least about alternative options and late effects on patients' quality of social life, which many patients were interested in. These might result from the bias that all doctors that were recruited into this study were surgeons.

Generally, surgeons tend to be more interested in surgical treatment, rather than other medical treatment. However, this study showed that surgeons must keep in mind that patients are eager to know overall treatment options. Therefore, even surgeons should explain to the patients about the treatment options in multidisciplinary fashion even in the case of surgically-curable disease.

Although not significant statistically, this study showed some differences between otolaryngologists and plastic surgeons. In Korea, most otolaryngologists are not skillful cosmetic surgeons. Because some complicated preauricular sinus involves broad area on a face, most patients, especially younger patients and female patients, worry about postoperative scar on their face and visit plastic surgeons to get a preauricular sinusectomy and to minimize the scar. So, plastic surgeons might be more interested in minor risks or complications including scar. However, the patients with recurrent preauricular sinus want to get revisional operation from otolaryngologists. This might be because otolaryngologists know more about the anatomy and pathophysiology of preauricular sinus and get more experience of preauricular sinusectomy than plastic surgeons in Korea. So, otolaryngologists might be more interested in major risks or complications including recurrence.

Recently, there have been important changes in what is perceived as informed consent in society and legal system and these changes have been reflected by many medical literatures. Of course, otolaryngology is not an exception to this trend<sup>[1-5]</sup>. The key point of this trend is that the Bolam principle<sup>6</sup> or medical paternalism is no longer acceptable. Recent trends warn doctors not to make assumptions about patients' views on informed

consent; for example, withholding frank information from patients may be helpful in reducing their psychological distress or giving patients excessive information about the risks may cause them to refuse the treatment. Currently, informed consent is a process of shared decision making between patients and doctors, and not merely a process of providing information by doctors. Although some patients adhere to the old adage of 'ignorance is bliss,' the active process of informed consent is still important and doctors should involve such patients in sharing of information and decision making.

The importance of proper informed consent has been extensively reported in the literature. A number of earlier reports have been made in the United Kingdom, which resulted from the model consent forms that the British Department of Health issued in 2001<sup>[1-4]</sup>. However, the change in informed consents has become a worldwide trend largely in response to pressure from the media and the public in many countries, including Korea. This is the first report that surveyed patients of the otolaryngology department in Korea.

Although recent society and laws emphasize the role of patients on informed consent and decision making as described above, most of the previous reports focused on the doctors' perspective<sup>[3-5]</sup>. A proper study that focused on patients' perspective and on the patient-doctor partnership was found only in one literature on otolaryngology<sup>[1]</sup>. This is in contrast to other medical fields that deal with more serious diseases and more morbid operations.

To the author's knowledge, there have been several reports that surveyed the informed consent of procedures with high risk or high cost, which demonstrated that patients considered major

**Table 2.** Statistics of Visual Analogue Scale (VAS) scores according to patients' age and sex as well as doctor's speciality. The question numbers are matched to those of Table 1.

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Children vs Adult	0.836	0.909	0.063	0.765	0.836	0.000	0.000	0.565
Male vs Female	0.305	0.000	0.116	0.026	0.775	0.902	0.412	0.233
Otolaryngologist vs Plastic surgeon	0.153	0.397	0.659	0.841	0.494	0.904	0.353	0.547

**Table 3.** Spearman's rank correlation coefficient test between doctor's career and VAS scores. The question numbers are matched to those of Table 1.

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
correlation coefficient	-0.389	0.334	-0.351	0.14	-0.072	0.095	0.208	0.295
p value	0.090	0.150	0.130	0.557	0.763	0.691	0.379	0.20

complications, effects of not undergoing the procedure, effects on the future management of the condition, and long-term effects on work as the most important factors<sup>[7,8]</sup>. Interestingly, the present study showed results different from those earlier reports. The patients surveyed considered major risks and late effects on their quality of social life as unimportant. This difference may result from the difference in the surveyed procedures. Because preauricular sinusectomy is one of the simplest and least morbid operations in otolaryngology, patients often have the preconception that major risks such as recurrence may be not important in such a simple procedure.

Considering that patients differ in their motivations for consent, and that no significant difference was observed according to the characteristics of doctors (experience and specialty), it is suggested that the process of informed consent should be tailored according to the needs of each individual patient, rather than that of the doctors.

### **Conclusions**

In informed consent, the doctor and the patient enter into a trust-based relationship, where the doctor is expected to do his or her best for the patient. This study demonstrated a difference in what patients expect and what doctors actually obtain consent for. Patients are becoming increasingly involved with decisions regarding their health and the recent legal system appears to support this trend. For this reason, health professionals need to obtain detailed, tailored, and honest consent from each individual patient about any planned surgery, even when it is a common, simple, and slightly morbid operation such as preauricular sinusectomy. It is now becoming more important to minimize the discrepancy between the opinions of patients and doctor.

### **Acknowledgments**

Nothing to Declare

### **Conflicts of Interest**

Nothing to Declare

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