Patient Education and Informed Consent in Head and Neck Surgery

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Objective: To examine the effects of an educational intervention, in the form of printed material, on patient knowledge and recall of possible risks from parotidectomy or thyroidectomy.

Design: Prospective, randomized, controlled study conducted during a 9-month period.

Setting: Head and neck surgery clinic of an academic tertiary care hospital.

Patients: One hundred twenty-five consecutive patients older than 16 years who were undergoing thyroidectomy or parotidectomy at the head and neck surgery clinic were recruited. Four patients were excluded from analysis because their follow-up interview was not within the required limits.

Intervention: At the preoperative visit during the routine consent process, both groups received a verbally delivered checklist of risks specific for the surgery to be performed. The intervention group was also given a pamphlet with written information accompanied by illustrations.

Main Outcome Measures: The effectiveness of the educational intervention was determined by comparing the average rate of risk recall between the intervention and control groups. The effects of age, sex, level of education, and time between the consent and recall interviews on recall rate were also assessed.

Results: The overall risk recall rate for both procedures was 39.1%. The recall rate of the intervention group was 50.3% compared with 29.5% for the control group ($P<.001$).

Conclusions: The intervention consistently improved risk recall for all patients regardless of age, sex, and level of education. Patients' ability to recall potential risks was significantly increased by an educational intervention; all patients would benefit from this intervention.


CONSENT EPITOMIZES one of the most important doctrines in the delivery of health care because obtaining a patient's consent is a daily routine for all physicians. Informed consent involves the explanation by a physician, in an understandable manner, of information that a patient requires to make a knowledgeable decision regarding a recommended course of medical or surgical intervention. The term informed consent was formally introduced in the California Appeals Court in 1957. In this judicial pronouncement, Justice Bray mandated that a patient must receive sufficient information to balance the benefits against the risks before consenting to a medical procedure. In 1980, the Supreme Court of Canada changed the focus of the informed consent law from one of standard professional disclosure to one that required information a “reasonable patient” would need to know to make an informed decision. Physicians have a legal and moral obligation to disclose specific information, including the nature and purpose of treatment, its benefits and potential risks, the consequences of not receiving it, and any alternative therapies available.

The rote dissemination of a set of facts or the mere action of signing a consent form cannot replace ongoing dialogue between the physician and the patient. Patients are entitled to make decisions about their medical care, and consent represents a means by which they may protect themselves from unwanted treatments; it also ensures that they take responsibility for their decisions. Appropriately obtained consent may also act as a shield for the physician, protecting him or her from litigation. Treating a patient without con-
sent constitutes battery, while providing treatment with inadequate informed consent is considered negligence.³

Many patients, unfortunately, do not understand and may forget much of the information disclosed to them. This problem underscores the need to improve communication techniques. Lavelle-Jones et al⁴ demonstrated that patients’ recall of information was best immediately after signing the consent document, and that the recall rate decayed steadily with time. Several other studies⁵⁶ in the surgical literature have also reported the lack of recall of the preoperative interviews by patients. In a previous study⁷ at Princess Margaret Hospital, University Health Network, the effectiveness of the informed consent process in head and neck surgery was evaluated and results showed that the overall patient recall rate of potential surgical complications was 48%. Patient age and educational level had influences on recall. In light of these findings, the present study investigates a potential intervention method that may improve patient recall ability.

METHODS

All consecutive patients older than 16 years seen at an academic tertiary care center and undergoing thyroidectomy or parotidectomy were eligible for inclusion in this prospective study. The inability to communicate in English and additional surgical procedures constitute the exclusion criteria. One hundred twenty-five patients provided consent and were enrolled.

The patients were randomized into either an educational intervention or a control group. At the preoperative visit, the 4 participating surgeons (J.C.I., L.E.R., D.H.B., and P.J.G.) were given a specific checklist of risks to outline to the patient according to the planned surgical procedure, with an equal emphasis on each risk. The educational intervention group was also given a pamphlet with written information accompanied by illustrations (Figure 1A and B), in addition to the verbal checklist. During the consent process in both groups, any additional questions posed by the patients were answered. After the discussion, the patients were asked to sign a standard surgical consent document. The specific complications discussed with patients undergoing parotidectomy were facial scar, facial nerve weakness or paralysis, greater auricular nerve paresthesia, and Frey syndrome. Patients undergoing thyroidectomy were informed of the potential risks of a neck scar, recurrent laryngeal nerve weakness or paralysis, and hypocalcemia. Within 3 to 7 weeks after the initial visit, the patients in both groups were interviewed by telephone and asked to recall the specific risks of their operation.

Demographic information, such as sex, age, highest level of education attained, and occupation, in addition to the type and date of surgical procedure, were collected using a standardized form. This form was also used to record the number of risks recalled by the patient at the follow-up interview.

The effectiveness of the educational intervention was determined by comparing the mean rate of complication recall between the intervention and control groups. For each subject, the percentage of complications recalled was calculated. For those undergoing parotidectomy, the percentage recalled was calculated of a possible 4 complications; and for those undergoing thyroidectomy, of a possible 3 complications. In this way, the data from both procedures could be pooled. The recall rates were compared between the intervention and control groups using the t test.

Cochran-Armitage tests for trend were used separately for each surgical procedure to test whether the distribution of the number of risks recalled differed between the intervention and control groups. The proportions recalling each of the individual complications were compared between groups using Fisher exact (FE) tests. The percentage of risks recalled was not normally distributed, so for modeling purposes, they were dichotomized into less than 50% or 50% or greater. Logistic regression models were fit to see if recalling 50% or more of the risks was related to the various demographic variables, including patient age, sex, and highest level of education attained; the surgical procedure undergone; and the time from the consent interview to the recall interview. These variables were also examined to determine whether they altered the intervention effect. The data were also split at the level of 67% recall, but the results did not differ significantly from those derived by dividing the data at the level of 50% recall and are, therefore, not presented herein.

RESULTS

One hundred twenty-five patients were enrolled in this prospective study. Four patients were excluded from the analysis because their follow-up interview was less than 3 weeks (n=3) or at 12 weeks (n=1) after their initial visit. Inclusion of these patients did not substantively alter any results. Of the 125 patients, 89 were female and 36 were male. The average age was 47 years (range, 18-86 years). Sixty-three percent of the patients had a postsecondary degree, 26% had a high school education, and 11% had less than a high school education. Ninety-five thyroidectomies and 30 parotidectomies were performed by the 4 surgeons (J.C.I., L.E.R., D.H.B., and P.J.G.) involved in the study. The mean length of follow-up was 33 days (range, 22-53 days).

Of the 121 patients included in the analysis, 56 (46%) received educational intervention pamphlets and a verbal checklist of possible complications of the surgery, while 65 (54%) received only oral communication of the same information. The demographic information for the intervention and control groups is summarized in the Table. Seventy-seven percent of the patients in the intervention group were female compared with 66% of those in the control group. The average age was 46 years in both groups. The 2 groups had comparable numbers of patients with a postsecondary education; and the mean length of follow-up was 33 days in each group.

The overall mean recall rate of potential complications for both procedures, regardless of group, was 39.1% (95% confidence interval, 34.0%-44.2%). The mean recall rate was significantly higher for the intervention group (50.3%; 95% confidence interval, 42.6%-58.0%) compared with the control group (29.3%; 95% confidence interval, 23.6%-35.4%) (P<.001, t test). When this comparison was repeated for each procedure individually, the results demonstrated that the subjects who underwent thyroidectomy in the control group (n=48) had a mean recall rate of 30.6%, compared with 50.4% for those in the intervention group (n=43) (P<.001, t test). The subjects who underwent parotidectomy and received only verbal information (n=17) had a mean recall rate of 26.5%, compared with 50.0% for those who received a pamphlet (n=13) (P=.03, t test). The results for the 2 procedure subgroups were similar, and the differences in the P values are largely due to the difference in sample size between the 2 groups.


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The recall success for each of the 2 procedure subgroups was also evaluated by comparing the intervention and control groups for each procedure according to the number of complications they recalled. For the patients who underwent thyroidectomy and who were in the intervention arm (n=43), 5 (12%) recalled 3 of 3 complications, 18 (42%) recalled 2 of 3 complications, 14 (33%) named 1 of 3 complications, and 6 (14%) remembered no complications (percentages may not total 100 because of rounding). Patients who underwent thyroidectomy and who were in the control group (n=48) had a different distribution (P=.001, Cochran-Armitage test) (Figure 2A). None of the controls recalled all 3 complications, 11 (23%) recalled 2 of 3 complications, 22 (46%) could name 1 of 3 complications, and 15 (31%) remembered no complications. The parotidectomy subgroup showed a similar trend (P=.03, Cochran-Armitage test) (Figure 2B). None of the patients in the no-pamphlet group (n=17) recalled 4 of 4 complications, compared with 2 (15%) of the intervention group (n=13). Of the patients in the intervention arm, 3 (23%) recalled 3 of 4 complications, 1 (8%) recalled 2 of 4 complications, 7 (54%) recalled 1 of 4 complications, and 0 recalled no complications. For the patients who underwent parotidectomy and who were in the control group, 1 (6%) recalled 3 of 4 complications, 5 (29%) each recalled 2 of 4 complications, 11 (41%) could name 1 of 4 complications, and 24 (89%) remembered no complications.

Figure 1. Schematic representations of the printed material containing the risks for thyroidectomy (A) and parotidectomy (B) given to patients at the preoperative visit.
membered 2 and 1 of 4 complications, and 6 (35%) could name no complications (percentages may not total 100 because of rounding).

The individual recall rates for each potential complication were also assessed. The intervention group, although not always statistically significant, had a higher recall rate for every complication (Figure 3A). Among the patients who underwent thyroidectomy, 36 (84%) of 43 subjects in the intervention group could name a laryngeal nerve injury, compared with 29 (60%) of 48 subjects in the control group ($P = .02$, FE test). While 23 patients in the intervention group (53%) recalled hypocalcemia as a possible complication, only 13 controls (27%) could remember it ($P = .02$, FE test). Recall rates for the third potential complication of scar formation are 14% (6 of 43 patients) for the intervention group and 4% (2 of 48 patients) for the control set ($P = .14$, FE test).

For the 30 patients undergoing parotidectomy, 12 (92%) of 13 in the intervention group recalled a facial nerve injury, whereas only 11 (65%) of 17 in the control group did ($P = .10$, FE test) (Figure 3B). Similarly, 6 patients (46%) in the intervention group recalled the potential of a greater auricular nerve injury, compared with 3 (18%) in the control group ($P = .12$, FE test). Four subjects (31%) in the intervention arm could name the Frey syndrome as a possible complication, as could 4 (24%) in the control arm ($P = .70$, FE test). Furthermore, none of the subjects from the control group could recall scar formation, compared with 4 (31%) in the intervention group ($P = .03$, FE test).

The results of logistic regression modeling showed that age ($P = .37$), sex ($P = .48$), type of surgical procedure ($P = .80$), and time from consent until recall inter-

### Patient Characteristics According to Randomization Assignment

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention Group (n = 56)</th>
<th>Control Group (n = 65)</th>
</tr>
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<td></td>
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<tr>
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<td>22 (34)</td>
</tr>
<tr>
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<td>41 (63)</td>
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<tr>
<td><strong>Operation</strong></td>
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<tr>
<td>Thyroidectomy</td>
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<td>48 (74)</td>
</tr>
<tr>
<td>Parotidectomy</td>
<td>13 (23)</td>
<td>17 (26)</td>
</tr>
<tr>
<td><strong>Time between consent</strong></td>
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<td></td>
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<tr>
<td>and recall, mean (SE), d</td>
<td>32.8 (0.6)</td>
<td>33.3 (0.6)</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage) of patients unless otherwise indicated. Percentages may not total 100 because of rounding.

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Figure 2. The distribution of the number of risks recalled. A, Patients who underwent thyroidectomy (the total possible is 3 risks). B, Patients who underwent parotidectomy (the total possible is 4 risks).

Figure 3. Recall rate of the specific risks for thyroid surgery (A) and parotid surgery (B). The recall rate in the intervention group is higher than in the control group for all the risks assessed.
view (P = .48) were not related to whether a patient recalled less than 50% or 50% or more of the risks. Patients who had a postsecondary education were more likely to recall 50% or more of the risks (45% [34/76]) than those with a high school education or less (27% [12/45]) (P = .05), as expected from previous analysis. Those who received the pamphlet recalled 50% or more of this risk significantly more often (29 [52%] of 56 patients) than those who did not receive the pamphlet (17 [26%] of 65 patients) (P = .004). This effect remained significant when the previously mentioned variables were controlled for in the model (P < .01 in each case). There were no significant interactions between the intervention and any of the variables considered.

**COMMENT**

A well-recognized problem in the process of obtaining consent for treatment is ensuring that the patients are adequately informed of the nature of therapy, possible outcomes, benefits, risks of the treatment modality, and other alternatives available. Several studies have clearly demonstrated the lack of recall for preoperative instructions presented to the patients during the consent to treatment process. Robinson and Merav showed that patients undergoing thoracic surgery recalled, on average, 29% of the information given during the informed consent discussion. In a series of 100 general plastic surgery patients interviewed within 7 days of the informed consent dialogue, Leeb et al reported an overall retention rate of 35%. Priluck et al found that the overall recall rate of preoperative explanation was 57% in 100 patients undergoing retinal detachment surgery interviewed 2 to 11 days after the initial consent information encounter. Hutson and Blaha tested the recall of preoperative information by 36 patients undergoing total joint replacement surgery immediately after the consent interview, and found a range of 11% to 82% for individual complications. After the initial interview (5-11 months), the percentage of patients recalling potential risks of surgery decreased significantly, to a range of 3% to 28%. A more recent study conducted on a group of general surgery patients undergoing laparoscopic surgery demonstrated a 27% recall rate of preoperative information when patients were questioned 5 days after the surgery.

Most patients want physicians to disclose the risks of diagnostic or therapeutic interventions before the procedure. Verbal information and advice from the clinician are often the most convenient methods of information dissemination and, hence, they are used most frequently. Unfortunately, oral communications alone are often misunderstood and/or forgotten by patients. Information pamphlets may provide the necessary reinforcement of the verbal communication and improve understanding and recall of the treatment procedure and potential complications. Printed material is a simple and inexpensive tool that is easy to administer in an ambulatory clinical setting, and it has been reported previously to improve patients’ understanding of their treatment. Research studies have also demonstrated that written material may also help reduce anxiety in patients facing stressful events, such as surgery, and improve satisfaction with their treatment. Moreover, Humphris et al demonstrated that an information leaflet significantly increased the knowledge of oral cancer in dental students and members of the general public.

A previous study at Princess Margaret Hospital, University Health Network, evaluated the effectiveness of informed consent in patients undergoing head and neck surgery, and found that the overall recall rate of potential complications was 48.5% and that patients who recalled 50% or more of the complications were younger and better educated. Evidence in the literature provides a rationale for conducting a direct assessment of the effects of an educational intervention on patient recall as a logical progression to the previous study. The information pamphlet was shown to improve risk recall significantly in the intervention group, with an average recall rate of 50.3% compared with the control group rate of 29.5%. This comparison held true when applied to the procedure groups individually. The recall rates for each potential complication of the 2 procedures were also considered individually. Most patients could recall a potential facial nerve or recurrent laryngeal nerve injury. This finding is consistent with a previous study from Princess Margaret Hospital, University Health Network, and suggests that the perceived severity of the potential consequence is likely to impact on patient recall. Results from this study revealed that there is a trend toward an improved recall rate for every complication for both procedures for the intervention group. The effects were not always statistically significant, possibly due to the smaller sample sizes in the subgroups. As in the previous study, patients who recalled 50% or more of the complications were better educated, but in contrast, they were not significantly younger.

The improved recall produced by the educational intervention in this study is in keeping with findings from other reports. Livesley and Rider demonstrated a significant improvement in patients’ understanding of the joint replacement procedures and their management. Moreover, Hawkey and Hawkey found that information leaflets on gastrointestinal diseases increased patients’ knowledge of their conditions. Another study of oral and maxillofacial surgical patients assessed the value of written warnings. It demonstrated that patients’ recall and recognition of important risks were significantly improved by written information. In a population of general otolaryngology patients, Dawes et al showed that a structured interview guided with an information sheet increased the number of complications recalled by the patients without increasing preoperative anxiety. However, the time between the consent and recall interviews was several hours, which is unrealistic given the widespread problem of long surgical waiting times. Most surgical waiting periods for thyroid and parotid surgery are longer than 4 weeks. Because recall of information decays with time, the follow-up interviews were conducted on average at 33 days postconsent to best mimic the actual clinical scenario.

As the complexity of the surgical procedure increases, so do the number and type of complications. Thyroidectomy and parotidectomy are similar in that there are relatively defined and finite complications. However, procedures such as laryngectomy and the extensive proce-
dures required for the treatment of oral cancer (neck dissections, tracheotomies, mandibulotomies, or mandibulectomies) and the reconstruction required for these procedures become highly complex. Clearly, educational interventions for these types of procedures are likely to be beneficial. However, we intentionally chose 2 procedures for which the complications are well-defined, and although it would be expected that these results would translate into a more complex surgery, this is not known. Prospective studies are ongoing at our institution, investigating the benefits for patients undergoing complex oral cancer surgery and facial plastic surgery.

Last, it is apparent that educational interventions may result in improved patient recall of potential surgical risks. Although this may potentially benefit the surgeon with regard to reducing potential medicolegal risks, this is not known.

In summary, the findings of this study indicate that patients’ ability to recall potential complications of surgery was significantly increased by an intervention. The written information consistently improved risk recall; patients of both sexes, of all ages, and with all levels of education will benefit from an educational intervention. This is consistent with results found in previous studies performed on different patient populations. These types of educational intervention studies are crucial for the establishment of a comprehensive patient education approach and for enhanced physician-patient communication.

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