Structured Preoperative Phone Counseling by Junior Medical Staff for Improving the Consent Process for Tonsillectomy

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Abstract

Objective. To assess the effectiveness of preoperative phone counseling by junior medical staff for improving the standard of informed consent for tonsillectomy.

Study Design. Prospective randomized controlled trial.

Setting. District general hospital.

Subjects and Methods. A total of 43 patients undergoing tonsillectomy were randomly allocated to 2 groups. Group A (n = 25) underwent the conventional consent process by the consultant ear, nose, and throat surgeon at the time of assessment (which generally takes place 6 to 12 months prior to surgery due to wait-list times). Group B (n = 18) underwent this same consent process but received a structured preoperative phone call 2 to 3 weeks prior to the day of surgery. A preoperative questionnaire assessing the knowledge of tonsillectomy, perioperative course, and risks was completed on the day of surgery.

Results. Group B had a better recall of the risks of tonsillectomy, recalling 7.1 of the 10 most significant risks, compared with 4.6 for group A (P = .017). Group B had a better awareness of tooth damage (78% vs 30% of patients, P ≤ .001), voice change (61 vs 19%, P = .005), and burns to lips and mouth (44% vs 8%, P = .005). Finally, 35% more patients from group B rated their understanding of tonsillectomy as good or very good (P = .017).

Conclusion. Preoperative phone counseling by junior medical staff closer to the time of surgery reinforces and clarifies the information previously provided by senior consultants at the time of initial consent for tonsillectomy.

Keywords
informed consent, tonsillectomy, preoperative counseling

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between preoperative counseling for consent and the day of surgery. These previous studies on informed consent for tonsillectomy have shown that no single intervention is superior for fulfilling the desired role of informed consent; rather, they are useful adjuncts to the consent process and, when combined, could make a significant difference to patient understanding and satisfaction with the consent process. We aimed to improve on this process by investigating if structured preoperative phone counseling by junior medical staff close to the time of surgery can improve patient understanding and satisfaction with the current consent process for tonsillectomy. This intervention combines the use of structured counseling by junior medical staff and a decrease in the time between preoperative counseling and the day of surgery, both of which have been shown to be associated with improved knowledge retention.

**Methods**

**Ethical Considerations**

Institutional Review Board approval for this project was authorized (project 0715-062C) by the NSW Health Central Coast Local Health District Research Committee, and this project was registered with the NSW Health Central Coast Local Health District Clinical Governance Office. This study adhered to CONSORT 2010 reporting standards for randomized controlled trials.

**Participants and Recruitment**

A prospective randomized controlled trial design was employed for our study. Patients who were undergoing tonsillectomy were recruited preoperatively from Gosford District Hospital and randomized to 1 of 2 groups. When the patient was <18 years old, the questionnaire was completed by the parent.

**Group A: Conventional Consent.** Informed consent was obtained from this group by the otolaryngologist–head and neck consultant surgeon or the registrar, using a standard nonspecific NSW Health consent form. In our local health district, the waiting time for surgery is frequently between 6 and 12 months, which is similar to other hospitals in Australia. This is longer than the waiting times reported in the recent report by the NHS, although previous publications from the United Kingdom seem to indicate a similar waiting period for tonsillectomy as our hospital.

**Group B: Structured Preoperative Phone Call by Junior Medical Staff.** Group B underwent the same initial consent process as group A. Approximately 2 to 3 weeks prior to planned surgery, the patients of group B received a phone call from junior medical staff in the Otolaryngology, Head and Neck Surgery department. These phone calls were approximately 5 minutes. Using a structured interview method developed by the consultant surgeon and senior registrars, junior medical staff discussed the upcoming operation and its risks, planned outcomes, and postoperative care. Before junior medical staff were permitted to make the preoperative phone calls, senior staff directly observed them discussing the operation with patients for a minimum of 5 encounters. The junior medical staff involved in this study were second-year surgical residents undertaking a 10-week rotation in the Otolaryngology, Head and Neck Surgery department. They were not currently on the accredited otolaryngology–head and neck surgery training program.

All patients were given the Royal Australasian College of Surgeons–approved information pamphlet on tonsillectomy at the time of original consent.

**Outcome Measure**

A questionnaire based on similar studies was developed to assess the patient’s or guardian’s understanding of the procedure, the associated risks and perioperative care, and their satisfaction with the consent process. The person signing the consent form was approached on admission and asked to complete the questionnaire.

A planned sample size of 20 participants for each group was chosen after power analysis to detect a 5% difference between groups with a significance level of 0.05 and a power of 0.8. To account for loss to follow-up, an additional 5 participants were added to each group.

**Randomization**

Participants were computer randomized in an allocation ratio of 1:1 into the 2 study groups: (1) the group undergoing the conventional consent process and (2) the intervention group receiving an additional preoperative structured phone call by a junior medical staff in addition to the conventional consent process. There was no blinding in this study.

**Statistical Methods**

Data were analyzed with Predictive Analytics SoftWare Statistics 22.0 (IBM, Chicago, Illinois). Normality tests were performed on all continuous variables. Comparisons between groups for normally distributed variables were performed with independent samples t test. Chi-square test was performed on discrete variables.

**Results**

There were a total of 25 patients in group A and 18 patients in group B after 5 patients from group A and 7 from group B were lost to follow-up (Figure 1). There were no significant differences in age, sex, educational levels, or rates of participants having other children who had tonsillectomy (Table 1). Group B had significantly longer waiting periods from time of consent to operation: 6.7 vs 10.4 months, t(41) = 2.223, P = .03.

Of the 10 most common risks of tonsillectomy, group B was aware of 2.49 (25%) more risks than group A (4.62 vs 7.11 risks, χ² = 5.736, N = 43, P = .017; Figure 2). In comparison with group A, group B had 48% more patients aware of tooth damage (30% vs 78%, χ² = 12.836, N = 43, P < .001), 42% more patients aware of voice change, (19% vs 61%, χ² = 8.062, N = 43, P = .005), and 36% more
patients aware of burns to lips or mouth (8% vs 44%, \( \chi^2 = 8.062, N = 43, P = .005; \) Figure 3). The groups had a similar understanding that paracetamol (acetaminophen) was recommended postoperatively (Figure 4). Thirty-five percent more patients from group B believed that paracetamol (acetaminophen) and codeine combinations were recommended postoperatively (15% vs 50%, \( \chi^2 = 5.736, N = 43, P = .017 \)). There was no difference in the number of patients receiving a handout on the procedure or if they felt that the time spent explaining the procedure was adequate (Table 2).

No harms or adverse events were encountered during this study.

**Discussion**

This study shows that preoperative phone counseling by junior medical staff improves participants’ understanding of the risks of tonsillectomy and their satisfaction with the consent process. Group B was aware of more risks than group A and was less likely to consider regular nonsteroidal anti-inflammatory drugs (NSAIDs) as recommended analgesia post-tonsillectomy. The 2011 US guidelines for tonsillectomy in children support the use of ibuprofen in posttonsillectomy pain, and the 2005 Cochrane review on the use of NSAIDs and posttonsillectomy bleeding concluded that NSAIDs did not cause an increase in bleeding and in fact were beneficial in causing less nausea and vomiting as compared with other analgesics. However, in 2013 the Cochrane Collaboration updated its conclusion as follows: “There is insufficient evidence to exclude an increased risk of bleeding when NSAIDs are used in paediatric tonsillectomy.” Our department’s postoperative instructions are for the use of regular paracetamol (acetaminophen) for

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### Table 1. Demographic Data.

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
<th>( \chi^2 )</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group size, n</td>
<td>25</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Mean age, y</td>
<td>9.42</td>
<td>9.44</td>
<td>0.165</td>
</tr>
<tr>
<td>Patient</td>
<td>33.63</td>
<td>33.13</td>
<td>0.148</td>
</tr>
<tr>
<td>Parent/guardian</td>
<td>33.13</td>
<td>1:1</td>
<td>2.891</td>
</tr>
<tr>
<td>Male:female</td>
<td>1:2.6</td>
<td>1:1</td>
<td>0.392</td>
</tr>
<tr>
<td>Education level of person giving consent, tertiary:secondary</td>
<td>1:4.3</td>
<td>1:5.25</td>
<td>0.871</td>
</tr>
<tr>
<td>Any previous children</td>
<td>0.29</td>
<td>0.24</td>
<td>0.058</td>
</tr>
<tr>
<td>Mean time from original consent, mo</td>
<td>6.7</td>
<td>10.4</td>
<td>2.223</td>
</tr>
</tbody>
</table>

*Independent samples t test.*
posttonsillectomy pain. If this is inadequate, patients are then encouraged to discuss with their surgeon the use of NSAIDs or other analgesia options for breakthrough pain.

Group B was more likely to consider codeine combinations as recommended analgesia, although this difference was not seen in the subgroup of patients undergoing tonsillectomy for obstructive sleep apnea. A reason for this relatively high recommendation of codeine combinations is that this study was commenced prior to the Australian Therapeutic Goods Administration’s guidelines being released in October 2015, which advised that codeine is contraindicated in children <12 years and <18 years for those undergoing tonsillectomy for obstructive sleep apnea. When compared with group A, group B was more likely to rate its understanding of the risks of the procedure as good or very good. This was despite both groups having no difference in patients reporting that they understood the discussion of the risks, received a handout for the procedure, or felt that the time taken to explain the risks was adequate.

Our study confirms the findings of previous studies that junior medical staff can improve the consent process for tonsillectomy when they are provided with a structured method for counseling by senior consultants. Our system of preoperative phone counseling several weeks prior to surgery builds on previous studies showing that patient and guardian understanding and knowledge of risks are inversely proportional to the time from consent to the day of surgery. The increase in knowledge caused by our intervention may be actually greater, because group B had a significantly longer period between initial consent and surgery than group A but still had a significant increase in knowledge after the intervention.

Junior medical staff are well placed to provide preoperative phone counseling. Compared with administrative staff, they are often involved in the procedure through either observation or direct contribution to the surgery. This allows them to answer questions using firsthand knowledge of the procedure. Further benefits are that junior medical staff are able to participate and experience the responsibility of the informed consent process in a supervised manner. While our results were obtained only for tonsillectomy, junior medical staff are often involved in the consent for simple procedures in otolaryngology and other surgical specialties. Consultant surgeons may be able to improve the standard of informed consent if they develop local guidelines for junior medical staff to follow when providing preoperative phone counseling or informed consent for procedures in a range of specialties.

This prospective randomized controlled trial involved 43 patients. Despite our results reaching statistical significance,
our study could be improved by increasing the number of patients involved. Furthermore, our study was a single-center trial, and the generalizability of our findings could be improved by a multicenter study design. Barriers to implementation of our intervention include the already busy workload of junior medical staff, and we propose that only simple surgical procedures associated with a long waiting period be trialed with such interventions. Previous studies have looked at the use of video education at the time of consent for tonsillectomy, with minimal improvement, although future directions for our study include investigating the use of video media closer to the time of surgery to reinforce the information provided at the time of original consent.

**Conclusion**

Our study shows that preoperative phone counseling by junior medical staff closer to the time of surgery reinforces and clarifies the information previously provided by senior consultants at the time of initial consent for tonsillectomy. This system is a useful adjunct to the standard consent process, which allows junior medical staff to be involved in a supervised environment and permits consultants to retain responsibility for the initial procedural consent. Such a system would be easy to implement and reproducible in other specialties for simple procedures with long waiting lists. Our study shows that such systems can improve the standard of informed consent and patient satisfaction with the process.

**Acknowledgments**

Dr Sebastian Ranguis, MBBS, was involved in the literature review and design of the original study.

**Author Contributions**

Jonathan Kam, designed study, responsible for acquisition, analysis, and interpretation of data for the work, drafting of work, final approval of the version to be published, agreement to be accountable for all aspects of the work; Elizabeth Harrop, designed study, interpretation of data for the work, critically revising draft for intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work; Priscilla Parmar, designed study, responsible for acquisition, analysis, and interpretation of data for the work, drafting of work, final approval of the version to be published; Nicholas Leith, responsible for acquisition, analysis, and interpretation of data for the work, critically revising draft for intellectual content, final approval of the version to be published; Raymond Kim, acquisition, analysis, and interpretation of data for the work, drafting of work, final approval of the version to be published; Indunil Gunawardena, designed study, interpretation of data for the work, drafting the work and overseeing multiple revisions of the content, final approval of the version to be published, agreement to be accountable for all aspects of the work.

**Disclosures**

**Competing interests:** None.

**Sponsorships:** None.

**Funding source:** None.

**References**


**Table 2. Patient Self-reported Understanding and Satisfaction with the Consent Process.**

<table>
<thead>
<tr>
<th>Group</th>
<th>A, %</th>
<th>B, %</th>
<th>χ²</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were the risks discussed?</td>
<td>88</td>
<td>94</td>
<td>0.461</td>
<td>.497</td>
</tr>
<tr>
<td>Did you understand the explanation?</td>
<td>92</td>
<td>100</td>
<td>1.45</td>
<td>.228</td>
</tr>
<tr>
<td>Understanding of risks? (good or very good)</td>
<td>15</td>
<td>50</td>
<td>5.736</td>
<td>.017</td>
</tr>
<tr>
<td>Handout received?</td>
<td>88</td>
<td>89</td>
<td>0.002</td>
<td>.965</td>
</tr>
<tr>
<td>Time taken to explain was adequate?</td>
<td>88</td>
<td>83</td>
<td>0.19</td>
<td>.663</td>
</tr>
</tbody>
</table>


