Informed Consent in Pediatric Surgery
Do Parents Understand the Risks?

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Objective: To investigate parent understanding of the risks of pediatric ear, nose, and throat surgery after counseling with and without the use of informational aids.

Design: Prospective, randomized trial.

Setting: Academic tertiary care center.

Participants: Parents of children undergoing ear, nose, and throat surgery.

Interventions: Parents were randomized to receive standard informed consent with or without detailed informational aids.

Main Outcome Measures: Parents completed identical questionnaires testing their general procedure knowledge and their recall of 9 specific surgical risks both immediately after counseling and on the day of surgery.

Results: Thirty-four parents enrolled in and completed the study (18 in the control group and 16 in the test group). The mean time from informed consent to surgery was 6.3 days (range, 1-22 days). Parents in the test group scored significantly higher on identifying the 9 risks on both the preoperative questionnaire (mean score, 6.00 vs 4.44; P = .007, 2-tailed t test) and the postoperative questionnaire (6.25 vs 4.17; P < .001). There was a negative correlation (inverse relationship) between parent education score and risk recall, with parents with lower education levels scoring higher on both the preoperative (Pearson r = -0.36; P = .04) and the postoperative (r = -0.35; P = .04) surveys. The maternal parent recalled risks significantly better than the paternal parent, with surgical risk recall scores of 5.46 out of 9 vs 3.67 out of 9 (P = .02, 2-tailed t test).

Conclusions: Parents of children undergoing ear, nose, and throat surgery recall far less than 100% of counseled risks. The use of detailed surgical risk counseling improves measured parental understanding of surgical risk. Parental educational level and maternal vs paternal parent may affect risk counseling recall.


Performing surgical procedures is often a routine event for the operating surgeon; however, surgery is anything but routine for patients and especially for parents of pediatric patients who are undergoing surgery. While under the influence of general anesthesia, patients are completely vulnerable to the experience and expertise of the surgeon. Significant trust must be developed between a patient and his or her surgeon for the patient to completely expose himself or herself to the surgical team under such conditions. To put the well-being of one’s child in the hands of a relative stranger, with the child under general anesthesia, requires an even greater level of trust between parent and physician. Therefore, it is absolutely crucial that patients be well informed before they undergo any surgical procedure so that they can truly make an informed decision regarding surgical interventions. Pediatric patients pose the unique challenge of not being able to give consent on their own. Instead, the consenting individual is a parent or a legal guardian.

Informed consent, as defined by the ethics committee of the American Academy of Otolaryngology–Head and Neck Surgery, consists of 4 key elements: disclosure, comprehension, competence, and voluntary choice. To meet these criteria, the physician must openly communicate to the patient a clear description of the procedure and the goals and benefits of that procedure as well as the risks of, and all alternatives to, surgery. In the case of pediatric patients, the parents or

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legal guardians must be counseled concerning their child’s surgery. Consent practices vary greatly from physician to physician, and although the general definition of informed consent is well established, no clear-cut consensus exists as to what specific information should be passed to patients regarding a given surgical procedure. There are a limited but growing number of reports in the literature regarding consent practices, the majority of which have been published outside the United States. Most of these studies involve only adult patients, and, to our knowledge, there are no studies involving pediatric patients in the otolaryngology literature. Adenotonsillectomy and insertion of tympanostomy tubes are the 2 most common surgical procedures performed in pediatric patients. In fact, otitis media is the most common pediatric diagnosis encountered during physician visits after the common cold. The primary objective of this study was to evaluate the informational recall of the key surgical risks and general surgical information of parents whose children are undergoing common ear, nose, and throat operations (eg, insertion of ear tubes, bilateral myringotomy with tympanic tubes [BMTT], or tonsillectomy and adenoidectomy [T&A]) with and without informational aids. A secondary objective was to evaluate the effect of parental demographic information and other factors on informational recall of informed consent counseling.

METHODS

This study was reviewed and approved by the institutional review board of Walter Reed Army Medical Center, Washington, DC. Parents and/or legal guardians of children who met clinical indications for T&A and/or BMTT were enrolled, and verbal consent was obtained by the primary (D.P.N.) and senior (S.E.B.) authors. Routine subject data were collected during the preoperative visit to include patient and parent or guardian age, sex, race, education level, military rank, and any prior counseling and/or education that they received regarding their child’s surgical procedure before surgery. Parents and/or legal guardians were then stratified by the type of procedure (adenotonsillectomy vs tubes) and then randomized to either a control or a treatment counseling group. The parents were counseled regarding the surgical risks of their child’s surgery (T&A and/or BMTT) with or without the use of a standardized surgical risk data sheet. After completing preoperative counseling, the parents were asked to complete a preoperative surgical risk questionnaire.

The parents were provided a control surgical data sheet, which included general surgical information only (the current standard in our institution), or a test surgical risk sheet plus the control sheet, which listed specific surgical risks for T&A and/or BMTT after they completed all preoperative surgical risk survey materials to ensure that the data sheets were not used to answer the questions. Also, in the test group, the counseling physician used the informational aid as a checklist to ensure that there were no oversights during the counseling session. An identical postoperative surgical risk questionnaire was completed by the parent on the day of surgery (Figure 1).

The most common complications of adenotonsillectomy and those tested include bleeding (3%-5%), pain, infection, dehydration, failure to correct the underlying condition, minor injury to the oral cavity structures, voice changes, and velopharyngeal insufficiency. The complications of BMTT included on the survey were continued infections, perforation of the ear drum, tube blockage, cholesteatoma, the need for further surgery, bleeding from the tube, hearing loss, failure to correct the hearing loss, and early or late tube extrusion. The primary outcome measure of the study was parental correct identification (percentage) of these 9 key risks for the procedure of interest (T&A or BMTT). Also, recall of general informational knowledge of the procedure of interest to include typical recovery, diet restrictions, and patient instructions was also tested. Blinded demographic parental information (eg, educational level, age, family size) was recorded to assess the effect of informational recall.

Statistical analysis was performed with the assistance of computer software (Stata Version 8.2; Stata Corp, College Station, Texas). Data analysis was performed by analyzing the mean correct responses of both the surgical risk assessment (9 identified surgical risks) and the general surgical procedural knowledge questions. Statistical analysis was performed using a 2-tailed t test and Pearson correlation coefficient calculation. \( P < .05 \) was considered significant. Forward and backward stepwise multivariate linear regression modeling was also used to assess the effect of various factors on the primary outcome measure of correct identification of key surgical risks.

RESULTS

Thirty-four parents were enrolled in the study: 18 in the control group and 16 in the test group. There were 12 patients in the BMTT group and 22 in the T&A group. The maternal parent completed the survey most of the time (76%) compared with the paternal parent (18%) and other (6%). The sex of children undergoing surgery was 67% male and 33% female. The average number of preoperative visits was 2.26 (range, 1–8 visits). The mean

Figure 1. Flowchart describing study design and patient enrollment methods. BMTT indicates bilateral myringotomy with tympanic tubes; T&A, tonsillectomy and adenoidectomy.
The key outcome measured was the risk recall rate, which was defined as the number of surgical risks correctly identified out of the 9 tested. The overall risk recall rate for all subjects was 5.17 out of 9 (58%) before surgery and 5.14 out of 9 (57%) after surgery, which was notably far less than 100% despite the attention given to informed consent counseling in this study. There was no significant difference between preoperative and postoperative scores. Parents in the test group scored significantly higher on identifying the 9 risks both on the preoperative questionnaire (mean score, 6.00 vs 4.44; \( P = .007 \), 2-tailed \( t \) test) and on the postoperative questionnaire (6.25 vs 4.17; \( P < .001 \)) (Figure 2). Notably, however, the scores in the test group were still far less than the targeted score of 100% (9 of 9 risks identified). There was a significant difference in the general knowledge scores in the preoperative test group (83.8% vs 72%; \( P = .008 \), 2-tailed \( t \) test), and there was a trend toward increased general knowledge scores in the postoperative test group (82.9% vs 75.4%; \( P = .10 \), 2-tailed \( t \) test), but this did not reach formal statistical significance.

Secondary analysis of demographic factors effecting informational recall revealed surprising results. Interestingly, there was a negative correlation (inverse relationship) between parent education score, modeled on a 1 (high school only) to 4 (postgraduate or professional degree) scale, and the preoperative risk recall (Pearson \( r = -0.36 \); \( P = .04 \)) and the postoperative risk recall (\( r = -0.35 \); \( P = .04 \)). Specifically, parents with lower education levels scored higher on risk recall than parents with higher levels of education (Figure 3 and Figure 4). Multivariate regression analysis was performed, and the strongest predictor of preoperative and postoperative risk recall, beyond being in the test or control group, was parent education level, with an inverse relationship being demonstrated (regression coefficient \( \beta = -1.22 \); \( P = .02 \); 95% confidence interval, −2.18 to −0.25). Also of remarkable interest, the maternal parent recalled risks significantly better than the paternal parent, with surgical risk recall scores of 5.46 out of 9 vs 3.67 out of 9 (\( P = .02 \), 2-tailed \( t \) test). Parental age, procedure type (BMTT vs T&A), and days between counseling had no significant correlation with informational recall. There were insufficient data to evaluate the effect on surgical risk recall of a parent having a child who had previously undergone the procedure.

This study shows that parents of pediatric patients who are undergoing ear, nose, and throat surgery recall far less than 100% of identified surgical risks despite formalized counseling before surgery. Although formal counseling with detailed data sheets does improve parent surgical risk recall, no parent was able to recall 100% (9 of 9) of the intended surgical risks. Lower education level and maternal parent participation were associated with improved retention of counseled surgical risks. Clearly, further study is needed to identify factors that may improve patient and parent understanding of surgical risk.

The overall risk recall rate for this study was 57.5%, which is largely disappointing given the effort that was
operative (Pearson with parents with higher education levels at both the pre- and postoperative data sheet to the patient. Counseling of the test group consisted of reading the surgical risk data were provided to both groups; however, surgical risk recall rates of 97% (before surgery) and 91% (after surgery) after detailed counseling sessions been. In our study, the same surgical risk recall with the use of surgical risk data sheets have shown mixed results. Heckenberg et al, Brown et al, and Stanley et al showed no statistically significant improvement in surgical risk recall with the use of patient handouts. However, other studies have shown that surgical risk handouts can improve patient recall. Again, our data are consistent with the latter group. Despite our best efforts in this study, patients and parents clearly do not retain and/or understand the full extent of the surgical risks that were discussed during the informed consent process even though this is the number 1 goal of the informed consent discussion. Clearly, more efforts need to be made by physicians to study this process to better understand the factors that may affect the informed consent process, with the goal of patients and parents being better informed of the basic risks before surgery.

In some of the studies that failed to show improved recall with the use of surgical risk handouts, the handout was the only change in the consent process. In other words, patients were not counseled differently regarding surgical risks. If patients disregard, lose, or simply ignore surgical risk handouts, has a measurable difference taken place between the 2 consenting groups? Is simply handing a patient a piece of paper enough to affect patient understanding of surgical risk? A recent study in the neurosurgical literature presented data showing surgical risk recall rates of 97% (before surgery) and 91% (after surgery) after detailed counseling sessions between the operating surgeon and the patient with the use of detailed information aids. In our study, the same surgical risk data were provided to both groups; however, counseling of the test group consisted of reading the surgical risk data sheet to the patient and then providing the data sheet to the patient.

Parents in our study with lower education levels demonstrated improved surgical risk recall rates compared with parents with higher education levels at both the preoperative (Pearson r = -0.36; P = .04) and the postoperative (r = -0.35; P = .04) surveys. This outcome differs from that in many studies in the reported literature in which a higher patient education level was shown to be associated with improved patient surgical risk recall.2,9,14-16 This may be explained not only by education level but also by certain potential confounding factors that are unique to military life. Active duty enlisted service personnel and their family members may not have had the chance to achieve advanced education early in their careers; however, military life, by its very nature and strict necessity, provides a disciplined and regimented way of life that may foster a greater attentiveness to detail in all aspects of life. Our intent is not to imply that military personnel are smarter or more or less educated than the general public but, instead, that other factors, such as personal discipline, the ability to follow orders, and strict attention to detail, may be significant in affecting surgical risk retention. Furthermore, all military personnel are required to complete a high school education before enlistment. We recognize that this potential selection bias may in fact be excluding those in the true lowest education level, ie, individuals who fail to complete a high school education.

The maternal parent recalled surgical risk significantly better than the paternal parent in our study, with surgical risk recall scores of 5.46 out of 9 vs 3.67 out of 9 (P = .02, 2-tailed t test). These results are limited by the fact that the maternal parent completed the survey most of the time (76%, n = 17) when compared with the paternal parent (18%, n = 4). In fact, analysis of the performance of the maternal vs the paternal parent was included in the regression analysis and showed no significant correlation. These results are again limited by a lack of statistical power owing to low parental parent involvement; therefore, it is difficult to show correlation between a predominant maternal participation and other factors (eg, lower parent education). It is unclear why the maternal parent would consistently perform better than the paternal parent on surgical risk recall regarding their child’s surgery. Could this result from maternal instinct or could the maternal parent be more likely to be more attentive to the needs of and the risks to their children? Clearly, further study is required, and, to our knowledge, there are no reports in the literature comparing individual parental informed consent. Furthermore, there are very few reports addressing informed consent in pediatric surgery overall.

The studies that have shown improved patient risk retention all seem to imply that spending time with the patient seems to affect patient retention in a positive manner. Providing the information alone may be less important to patient retention when compared with the overall impact that physicians can have when they take the extra time to set patients’ minds at ease and to help them really “take in” the information they need not only to make an informed decision but also to prepare for the impact that surgery can have on those patients and their family. It is safe to say that physicians cannot assume that patients and parents of children undergoing surgery understand and retain the information provided during the informed consent process. There is no clear explanation as to why parents do not retain this information. It could be that the process of surgical informed consent is too complex for complete understanding and retention. Maybe parents are too distracted or too trusting of their physicians during the consent process. Other unidentified factors may yet be determined.

Weaknesses of this study include a relatively small sample size and potential confounding owing to a military population and a large predominance of maternal parental participation. Increasing sample size, opening the study to the general civilian population, and comparing and recording time spent during counseling would
likely improve the strength of this study. Attempts to identify other factors affecting informed consent would likely be beneficial as well. Specifically, in the case of pediatric surgery when the parent is the consenting individual, it would be useful to measure the number of distracting factors encountered during the consent process (eg, the number of other children in the examination room and the behavior of the children).

In conclusion, parents of pediatric patients undergoing BMTT and T&A generally recall far less than 100% of the key surgical risks that are communicated during informed consent counseling. Use of a detailed informational aid as a checklist during the counseling session for the physician and a handout to the parent increases recall significantly. Parent educational level may have an unanticipated inverse relationship with surgical risk recall. Maternal parents appear to recall surgical risks significantly better than paternal parents.

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REFERENCES