Randomized, Controlled, Multisite Study of Intracapsular Tonsillectomy Using Low-Temperature Plasma Excision

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Objective: To determine the efficacy of intracapsular tonsillectomy using low-temperature plasma excision for improving the quality of the postoperative experience and for treating obstructive symptoms through 12 months postoperatively.

Design: Prospective, randomized, controlled, single-blind study.

Setting: Multiple private or institutional otolaryngology clinics.

Patients: Fifty-five children (aged 3-12 years) with obstructive tonsillar hypertrophy.

Intervention: Patients were randomly assigned and blinded to undergo either intracapsular tonsillectomy using low-temperature plasma excision (n=27) or total tonsillectomy using conventional electrosurgery (n=28).

Main Outcome Measures: Operative data, 14-day recovery variables, and obstructive symptoms were prospectively collected through 12 months.

Results: During the first 14 days, significantly fewer children in the intracapsular group reported nausea (P=.01) or lost weight (P=.003). The intracapsular group had a significantly faster resolution of pain (P=.01), had an earlier return to a normal diet (P=.004), ceased taking pain medication sooner (P=.002), and returned to normal activity sooner (P=.04). Postoperatively, the intracapsular group had more residual tonsil tissue than the total tonsillectomy group (P=.002 for the 3- and 12-month visits). However, the incidence of recurring obstructive symptoms, pharyngitis, and antibiotic use was similar in both treatment groups during the 12 months.

Conclusions: Postoperative morbidity normally associated with traditional (total) tonsillectomy was significantly reduced after intracapsular tonsillectomy using low-temperature plasma excision. The residual tonsillar tissue associated with this technique was of no clinical consequence.

Arch Otolaryngol Head Neck Surg. 2004;130:1303-1307
coblation and ionized field ablation. It has been applied successfully in several different applications for soft tissue removal. Its mode of action differs from the commonly used conventional electrosurgery (“Bovie”) approach in that radiofrequency energy is used to excite the electrolytes in a conductive solution, such as isotonic sodium chloride, to create a precisely focused plasma field. The energized particles in the plasma have sufficient energy to break molecular bonds, excising soft tissue at relatively low temperatures (40°C-70°C) while minimizing damage to adjacent tissue. Previous clinical study of total tonsillectomy with low-temperature plasma excision has shown that postoperative recovery is of significantly better quality than that following conventional electrosurgery. For intracapsular tonsillectomy, past investigators have reported its safety in a clinical study of more than 500 patients and its effectiveness in a retrospective study through the immediate postoperative period.

Previous clinical studies of low-temperature plasma excision for intracapsular tonsillectomy were conducted using a single-site retrospective or prospective case series study design. To our knowledge, the examination of longer-term outcomes has not been performed. This study evaluates the utility of using low-temperature plasma excision for intracapsular tonsillectomy compared with conventional electrosurgical tonsillectomy in a controlled, multisite, prospective, clinical setting. It was also our intention to determine the efficacy of this approach for 12 months from the time of surgery.

METHODS

PATIENTS

Patients from 4 clinical centers were considered for participation in the study. All candidates approached for participation were aged between 3 and 12 years, had longer than a 6-month history of obstructive symptoms, reported 2 or fewer episodes of streptococcal pharyngitis per year, and had physical findings consistent with tonsillar hypertrophy. Children were enrolled after meeting the inclusion criteria and obtaining parental consent. Excluded patients had active pharyngitis, prior tonsillar surgery, a history of a peritonsillar abscess, systemic diseases, suggestion of a tonsillar neoplasm, coagulopathy, or a craniofacial anomaly, or were judged unable to convey pain or discomfort to the caregiver. Study participants were randomly assigned (1:1 ratio) to undergo either intracapsular tonsillectomy using low-temperature plasma excision or total tonsillectomy using conventional electrosurgery. Assignment was conducted by coin toss, in blocks of 6 (3:3 ratio). The sponsor maintained the randomization schedule and specific assignment made immediately following enrollment of each individual patient. The institutional review board at each clinical site approved the study protocol. All patients were enrolled into the study between September 17, 2001, and June 3, 2002.

SURGICAL PROCEDURE

The surgical procedure was standardized across clinical sites. All patients received an intraoperative corticosteroid and an antiemetic. Clinical investigators were allowed to use additional medications, with the exception of local anesthetic infiltration at the operative site. Intracapsular tonsillectomy was defined as removal of the tonsillar tissue without violating the capsule. Although the exact amount of tonsillar tissue removed could not be accurately measured, it was estimated that approximately 90% or more of the total amount was removed. The intracapsular tonsillectomy was performed using a wand (EVac 70 Plasma Wand; ArthroCare Corp, Sunnyvale, Calif); no adjunctive cautery device was used unless it was clinically necessary. Patients in the total tonsillectomy group underwent standard monopolar electrosurgical dissection with suction cautery hemostasis as necessary. Any adenoidectomy was performed using an adentome with suction cautery for hemostasis. All patients were kept in the postanesthesia unit until adequately hydrated and recovered, as noted by the nursing staff. The patients were discharged home with oral amoxicillin, 45 mg/kg per day, for 10 days and a supply of acetaminophen with codeine elixir.

OUTCOME MEASURES

The primary objectives were as follows: (1) to evaluate the operative variables and the quality of postoperative recovery and (2) to assess the efficacy for ameliorating obstructive symptoms associated with tonsillar hypertrophy through 1 year postoperatively. Clinical data were prospectively collected at baseline, at surgery, during the 14 days following surgery, and at the 3- and 12-month postoperative visits. Intraoperative outcome measures included operative time, blood loss during the tonsillar portion of the procedure, and device effectiveness for hemostasis. During the first 14 postoperative days, parents completed a daily diary to report pain status, return to normal diet, return to normal activity, and cessation of pain medication. The Wong-Baker FACES Pain Rating Scale was used to rate pain; all other measures were reported as “yes” or “no.” At the 14-day visit, patients were weighed and the presence of eschar on tonsillar fossae was noted by the clinician. At the 3- and 12-month visits, the clinician graded the amount of residual tonsil tissue. At these same postoperative points, parents completed a form to rate the frequency of 13 obstructive symptoms, including snoring, choking at night, sweating at night, restless sleep, stopping breathing, frequent awakenings, needing frequent naps, behavioral problems, poor attention span, mouth breathing, poor appetite, choking with eating, and eating slowly. Symptoms were rated using a 5-point scale, with end points corresponding to “never” and “every day/night”; this information was also collected at baseline. In addition, information on the incidence of sore throats and antibiotic use since the last physical examination was collected from parents.

STATISTICAL ANALYSIS

The study sample size was estimated to test the null hypothesis, “The mean number of days till return to normal diet will be no different for treatment groups during the 14-day postoperative period,” against the 2-sided alternative hypothesis. By estimating a common SD of 2.1 days and setting the type I error rate at 5%, a sample size of 24 patients in each treatment group would have 80% power to detect a difference in means of 1.7 days.

Nonordered categorical data were statistically evaluated using the χ² or Fisher exact test, and ordered categorical data were examined using the Wilcoxon rank sum test. Normally distributed continuous data were tested using an independent t test. Although the protocol called for comparing mean times (days) to freedom from pain, freedom from pain medication, return to normal diet, and return to normal activity during the 14-day postoperative period, for technical reasons (last observation was censored, leading to biased estimates of means), medians were
RESULTS

Fifty-five children (intracapsular group, n=27; and total tonsillectomy group, n=28) were enrolled. At the 14-day physical examination, 25 (93%) of the patients in the intracapsular group and 25 (89%) of the patients in the total tonsillectomy group were seen. The corresponding numbers for the 3-month physical examination were 21 (78%) and 24 (86%); and for the 12-month physical examination, 22 (78%) and 21 (75%). Baseline demographic characteristics, medical history, and pertinent findings were similar for the treatment groups (Table).

INTROOPERATIVE FINDINGS

The intracapsular tonsillectomy procedure time (mean±SD, 19.5±10.9 minutes) was significantly longer (P=.005) than the total tonsillectomy procedure time (mean±SD, 11.2±8.7 minutes). Operative blood loss (P=.77) and device effectiveness for hemostasis (P=.13) did not differ significantly between treatment groups. Two device failures and 3 cases of excessive device clogging were noted with the intracapsular procedure. No episodes of immediate postoperative bleeding occurred in either group.

THE 14-DAY POSTOPERATIVE PERIOD

During the 14-day postoperative period, intracapsular tonsillectomy patients had significantly faster recovery (P<.04, all comparisons) than total tonsillectomy patients; all comparisons were made using median time values and time-to-event curves (Figure). Intracapsular tonsillectomy patients were free from pain at (median) 6.5 days and had ceased pain medication use at 6.4 days compared with 10.0 and 11.0 days, respectively, for total tonsillectomy patients. Intracapsular tonsillectomy patients returned to a normal diet at (median) 4.4 days and to normal activity at 4.1 days compared with 7.5 and 8.0 days, respectively, for the total tonsillectomy patients. Significantly fewer intracapsular tonsillectomy patients reported postoperative nausea (4 vs 14 patients; P=.01). Two hospital readmissions occurred in the total tonsillectomy group: one for dehydration (at 2 days) and the other for delayed postoperative hemorrhaging (at 5 days). In addition, significantly fewer intracapsular tonsillectomy patients had eschar than total tonsillectomy patients (4 patients [16%] vs 13 patients [52%]; P=.007).

3-MONTH VISIT

No residual tonsillar tissue was found in 7 (33%) of the 21 patients followed up in the intracapsular group and in 19 (79%) of the 24 patients followed up in the total tonsillectomy group. Significantly more intracapsular tonsillectomy patients had at least some residual tonsillar tissue (P=.002). Although this was most commonly graded as less than 10% (in 12 [57%] of the intracapsular group vs 5 [21%] of the total tonsillectomy group), 2 (10%) of the intracapsular patients had residual tonsillar tissue graded as greater than 10%. For these 2 subjects, obstructive symptoms were improved over baseline in 12 of 13 measures in 1 subject (1-level increase in night sweating) and in 11 of 13 measures in 1 subject (1-level decrease of appetite and eating slowly). When intragroup evaluations were performed, the intracapsular and total tonsillectomy groups reported worsening of obstructive symptoms in at least 1 of the 13 obstructive measurements in 10 subjects (48%) and 6 subjects (25%), respectively. Improvement in obstructive symptoms from baseline did not differ statistically between treatment groups. In addition, treatment groups did not differ in the incidence of sore throat or antibiotic use between the 14-day and 3-month visits.

Table. Patient Demographic Characteristics, Baseline Medical History, and Pertinent Findings

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intracapsular Tonsillectomy Group (n = 27)*</th>
<th>Total Tonsillectomy Group (n = 28)*</th>
<th>Difference, Mean (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>16 (59)</td>
<td>16 (57)</td>
<td>2 (−32 to 28)†</td>
</tr>
<tr>
<td>Age, y</td>
<td>6.4 ± 2.8‡</td>
<td>5.9 ± 2.2‡</td>
<td>0.5 (−0.8 to 1.9)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>26.7 ± 12.7‡</td>
<td>23.3 ± 10.2‡</td>
<td>3.4 (−2.8 to 9.6)</td>
</tr>
<tr>
<td>History (&lt;2 episodes/y) of pharyngitis</td>
<td>1 (4)</td>
<td>2 (7)</td>
<td>−3 (−19 to 12)†</td>
</tr>
<tr>
<td>Tonsil size, right + left‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+2</td>
<td>6 (11)</td>
<td>6 (11)</td>
<td></td>
</tr>
<tr>
<td>+3</td>
<td>27 (50)</td>
<td>27 (50)</td>
<td></td>
</tr>
<tr>
<td>+4</td>
<td>21 (39)</td>
<td>21 (39)</td>
<td></td>
</tr>
<tr>
<td>Inferior turbinate hypertrophy</td>
<td>4 (15)</td>
<td>3 (11)</td>
<td>4 (−17 to 25)†</td>
</tr>
<tr>
<td>Snoring</td>
<td>4.8 ± 0.5‡</td>
<td>4.7 ± 0.7‡</td>
<td>0.1 (−0.2 to 0.5)</td>
</tr>
<tr>
<td>Choking at night</td>
<td>3.0 ± 1.7‡</td>
<td>2.6 ± 1.5‡</td>
<td>0.4 (−0.4 to 1.2)</td>
</tr>
<tr>
<td>Restless sleep</td>
<td>3.9 ± 1.2‡</td>
<td>3.4 ± 1.6‡</td>
<td>0.5 (−0.3 to 1.3)</td>
</tr>
<tr>
<td>Mouth breathing</td>
<td>4.4 ± 1.0‡</td>
<td>4.1 ± 1.1‡</td>
<td>0.2 (−0.4 to 0.9)</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage) of each group unless otherwise indicated.
†Data are given as percentages.
‡Data are given as mean ± SD.
§For both groups, n = 54; missing data for this variable, n=1.

Footnotes:
- Data are given as mean ± SD.
- For both groups, n = 54; missing data for this variable, n=1.

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12-MONTH VISIT

At 12 months, physical findings were similar to observations at 3 months. No residual tonsillar tissue was found in 6 (27%) of the 22 patients followed up in the intracapsular group and in 16 (76%) of the 21 patients followed up in the total tonsillectomy group. Significantly more intracapsular patients had at least some residual tonsillar tissue ($P = .002$). Those with residual tonsillar tissue graded as less than 10% included 14 (67%) of the intracapsular patients and 5 (24%) of the total tonsillectomy patients. Residual tonsil tissue was rated as greater than 10% in 1 (5%) of the intracapsular patients; this individual was not 1 of the 2 patients noted at 3 months. This patient reported more frequent restless sleep, but no other symptoms. Improvement in obstructive symptoms did not differ statistically between treatment groups. Worsening of at least 1 of the 13 obstructive measurements was also noted in both study groups at the 12-month visit when intragroup evaluations were conducted, similar to the 3-month visit. Treatment groups did not differ in incidence of sore throat or antibiotic use between 3 and 12 months postoperatively.

COMMENT

Intracapsular tonsillectomy using low-temperature plasma excision was efficacious for treating children with tonsillar hypertrophy, with no adverse clinical consequences resulting from the residual tonsil tissue during the 12-month postoperative period. Similar to traditional monopolar electrosurgical total tonsillectomy, obstructive symptoms were relieved, although intracapsular tonsillectomy provided the additional benefit of better-quality postoperative recovery. The improved 14-day recovery profile of the intracapsular tonsillectomy group was supported by physical findings, specifically, a significantly lower incidence of eschar formation at 14 days and fewer cases of reported nausea and weight loss during the recovery period.

We attribute the low morbidity in the intracapsular tonsillectomy group to the surgical approach and the technology used in this study. The lower morbidity observed with intracapsular tonsillectomy agrees with the reports of other investigators.3-6,20 This is most likely related to the fact that the tonsillar capsule is not violated with intracapsular tonsillectomy. Just as important, although the temperature delivered by the low-temperature plasma excision technique is sufficient to achieve hemostasis, this approach results in less thermal damage to the tissue (ie, the musculature adjacent to the tonsillar capsule) than traditional electrosurgery.17,18

From a surgical standpoint, intracapsular tonsillectomy took longer to perform than total tonsillectomy. We ascribe this to the procedure learning curve because most of the participating investigators had not routinely per-

formed intracapsular tonsillectomy using this technique before the study. There were 5 reported cases of device complications with intracapsular tonsillectomy, 3 of which were attributed to device clogging. Because this issue was well recognized in the field, newer versions of the device used in this study provide improved suction capability. Nevertheless, this did not adversely affect overall operative outcomes. Operative blood loss and device capability for performing hemostasis were similar for both surgical methods. Excellent safety was demonstrated with the intracapsular approach, supporting the results of a previous larger-scale prospective case series clinical study.8

Fear of tonsil tissue regrowth and recurring symptoms, similar to that observed with the guillotine tonsillectomy, has prevented widespread acceptance of the intracapsular technique. The residual tonsil tissue observed in intracapsular tonsillectomy patients, which was fully anticipated, seemed to be of no clinical consequence. These patients demonstrated no evidence of recurring obstructive symptoms and no sign of increased incidence of pharyngitis or antibiotic use compared with total tonsillectomy patients through 12 months postoperatively. Our results concur with those of Densert et al,6 who reported no difference in the recurrence of obstructive symptoms after tonsilotomy using the carbon dioxide laser through 2 years postoperatively.

Two recent studies reported individual cases of tonsil tissue regrowth after intracapsular tonsillectomy. Koltai and colleagues21 reported one case after retrospective study of partial tonsillectomy performed using the endoscopic microdebrider, and Linder et al20 reported one case after intracapsular tonsillectomy using the carbon dioxide laser. However, the amount of residual tonsil tissue left behind following these intracapsular procedures was not clear. By using the low-temperature plasma excision approach for intracapsular tonsillectomy, 90% or more of the tonsil tissue was removed in 90% or more of the cases. The worsening of obstructive symptoms in intragroup evaluations at the 3- and 12-month visits for both study groups most likely was because of the ability of parents to rate the severity of symptoms without regard to a comparison with the preoperative state, an intrinsic problem of the patient symptom survey form. We maintain that because intergroup comparisons of the 13 obstructive symptoms were not significantly different at the 3- and 12-month visits, the intragroup variability was of little clinical relevance.

Nevertheless, the present study does not establish whether this approach is efficacious in preventing the future incidence of streptococcal disease or is indicated for use in patients undergoing tonsillectomy for streptococcal disease. Furthermore, this study was not meant to address the cost-benefit attribute of this device. The retail cost of this device is $140. Future studies in these areas may be useful.

Intracapsular tonsillectomy using low-temperature plasma excision is a reasonable alternative to the traditional approach for performing monopolary total tonsillectomy to treat tonsillar hypertrophy. The safety record and improved postoperative pain profile of intracapsular tonsillectomy make it suitable for the pediatric population.

Submitted for Publication: January 14, 2004; final revision received June 15, 2004; accepted July 16, 2004.

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Funding/Support: This study was supported in part by a research grant from the ArthroCare ENT Division of ArthroCare Corp, Sunnyvale, Calif.

Previous Presentation: This study was presented at the American Society of Pediatric Otolaryngology Annual Meeting, May 4, 2003; Nashville, Tenn.

Acknowledgment: We thank Dan Bloch, PhD, for statistical analysis and critical scientific suggestions in the preparation of the manuscript and Tami Crabtree, MS, for data management and statistical analysis.

REFERENCES


