Tonsillectomy by Means of Plasma-Mediated Ablation

Prospective, Randomized, Blinded Comparison With Monopolar Electrosurgery

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Objective: To compare plasma-mediated ablation (PMA) with monopolar electrosurgery (MES) for pediatric tonsillectomy.

Design: Prospective, randomized, blinded study.

Setting: Academic children’s hospital.

Participants: Thirty-four children, aged 4 to 7 years.

Interventions: Tonsillectomy by means of PMA (n=17) or MES (n=17).

Outcome Measures: We measured surgical efficacy, estimated blood loss, and surgical time during tonsillectomy and morphine use, immediate postoperative pain, and recovery scores after tonsillectomy. Parents recorded recovery of normal diet and activity and their own return to work for 10 days after surgery. Histopathologic evaluation of excised tonsils was performed. We reviewed medical records and attempted follow-up telephone contact.

Results: With no significant difference in blood loss compared with MES, PMA was effective for tonsillectomy. Performance of PMA took longer (24 vs 16 minutes; P=0.002). Results of histopathologic evaluation showed less thermal injury with PMA than with MES (P=0.03). Morphine consumption, pain, and recovery scores were equivalent between groups. We found no significant difference in recovery of normal diet and activity or parental return to work. Patients undergoing PMA had a greater number of perioperative complications than those undergoing MES, including 2 patients in the PMA group (compared with none in the MES group) who required unplanned admission for postoperative airway obstruction.

Conclusions: Plasma-mediated ablation for pediatric tonsillectomy resulted in less histopathologic thermal injury than MES, but did not show a statistically faster recovery to normal activity and diet or parental return to work. In addition, PMA took longer to perform, and had more complications. Therefore, PMA should not replace MES for pediatric tonsillectomy. The reduced thermal injury with PMA supports investigation into other means of using plasma ablation to treat tonsillar hypertrophy.

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Tonsillectomy in children is most often performed today using monopolar electrosurgery (MES) or cold instruments (knife or scissors). Electrocautery is favored for its hemostasis,1 whereas advocates of cold tonsillectomy believe that reduced thermal injury to the pharynx results in less postoperative pain.2

Monopolar electrosurgery excises tissue by using radiofrequency current to burn soft tissue. Plasma-mediated ablation (PMA) energizes protons to break molecular bonds between tissues. Tissue removal using PMA leaves less heat in tissue, and so reduces thermal injury.3,4 This reduced thermal effect with PMA has resulted in the term cold ablation or Coblation (ArthroCare Corp, Sunnyvale, Calif). Plasma-mediated ablation has been offered for tonsillectomy since 1998 as a means of creating less thermal injury than that seen with MES, while achieving better hemostasis than with cold instruments alone.

Our previous experience in children showed that PMA was effective for tonsillectomy to treat lymphoid hyperplasia in children older than 3 years,5 with reduced gross and histopathologic thermal damage and less ability to provide hemostasis than that seen with MES.6 Despite these promising initial results, no evidence to date supports the claim that reduced thermal injury translates into improved outcomes for children and families.

We undertook this investigation to determine the efficacy, benefits, and risks of
PATIENTS AND METHODS

We recruited children aged 4 through 7 years, who were scheduled for day-surgery adenotonsillectomy (T&A) to treat adenotonsillar hypertrophy, from August 10, 1999, through April 26, 2000. Parents provided informed consent. Children 3 years and younger were excluded because of their higher risk for perioperative complications, severe obstructive sleep apnea, craniofacial syndrome, developmental delay, expressive language disorder, hematologic wound-healing disorder or necrotizing dermatosis, implanted electrical device, and mucopolysaccharidosis. Parents and patients were unaware of the surgical technique.

The primary outcome measure was the score on the Bieri Faces Pain Scale. Because sample size calculation is not straightforward for noncontinuous measures, various scenarios were tested. The most optimistic yielded a P value of .008 and the most pessimistic, a P value of .03 for a sample size of 30 control subjects and 30 children in the experimental group.

Prospective randomization determined whether PMA or MES was used for tonsillectomy. Adenotonsillectomy was performed under a standardized regimen of general anesthesia. After adenoedectomy by means of curette, tonsillectomy was performed by means of MES, using an electrocautery pencil (Valleylab, Boulder, Colo), or by means of PMA, using the ArthroWand (ArthroCare Corp). Hemostasis after excision was achieved by means of suction electrocautery for both groups. Intravenous antibiotics and dexamethasone sodium phosphate (dose determined by body weight) were administered.

We measured time to perform T&A and estimated blood loss. The surgeon assessed PMA for ease of use, ability to excise tissue, and hemostasis. Randomly selected tonsils were sent from both groups for histopathologic evaluation by a pathologist masked to surgical technique.

A standardized medication regimen was administered in the postanesthesia care unit by nurses masked to the surgical technique. Use of morphine sulfate was recorded. Nurses rated pain using the Bieri Faces scale, a visual analog scale intended for children aged 3 to 7 years. Pain was scored at 15-, 30-, and 60-minute intervals. Steward scores, measuring readiness for discharge, tracked consciousness, airway patency, and ability to move. Nurses recorded scores at 30 and 60 minutes.

Parents were asked to record postoperative progress on a checklist, tracking return to normal activity and diet and parental return to work. Parents scored activity (1, none; 2, very little; 3, mostly normal and 4, normal), diet (1, liquids and soft diet only; 2, some solids; 3, mostly solids; and 4, normal diet), and commented on missed work (yes, no, and would not have worked anyway [with separate responses for father and mother]). Medical records were reviewed for complications, and telephone follow-up was attempted. The study was to be stopped if significantly more postoperative hemorrhages required reoperation in the PMA group than the 2.7% that is typical at this institution. The Institutional Review Board of The Children’s Hospital of Philadelphia, Philadelphia, Pa, approved this study. Unless otherwise indicated, data are given as mean ± SD.

Table 1. Operative Measures

<table>
<thead>
<tr>
<th>Variable</th>
<th>MES Group (n = 17)</th>
<th>PMA Group (n = 17)</th>
<th>All Patients</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated blood loss, mL</td>
<td>83.8 (46.4)</td>
<td>90.9 (35.3)</td>
<td>87.3 (40.7)</td>
<td>.51</td>
</tr>
<tr>
<td>Surgical time, min</td>
<td>16.2 (3.2)</td>
<td>23.8 (7.9)</td>
<td>20.2 (7.2)</td>
<td>.002</td>
</tr>
</tbody>
</table>

*Data are given as mean (SD). MES indicates monopolar electrosurgery; PMA, plasma-mediated ablation.
†Value compares MES group vs PMA group.

We enrolled 34 children undergoing tonsillectomy: 17 by means of MES, and 17 by means of PMA. Average age of the 6 girls and 11 boys in the MES group was 5.4 years; of the 6 girls and 11 boys in the PMA group, 5.2 years. The MES group averaged 22.2 kg in weight; the PMA group, 21.7 kg. Because of 2 airway complications in the PMA group, one of us (U.K.S.) chose to terminate the study at 34 patients, rather than to complete enrollment to 60 patients.

Tonsillectomy in all cases was possible with PMA. Subjectively, ease of use and hemostasis were equivalent for MES and PMA. Hemostasis with PMA was possible for vessels less than 1 mm in diameter. One important finding, confirming previous experience, is that the plasma wand ablated 2 to 3 mm in advance of the instrument tip. The ability to excise tissue was subjectively rated better with PMA (P < .02). Mean surgical time was 16.2 ± 3.2 minutes for MES and 23.8 ± 7.9 minutes for PMA. This difference was statistically significant (P = .002). Surgical time for patients in the PMA group for whom ability to provide hemostasis was subjectively assessed as similar to MES was an average of 20.9 minutes, compared with an average of 25.7 minutes for patients with less hemostasis. This difference in time approached statistical significance (P = .05). Mean estimated blood loss was 83.8 ± 46.4 mL for the MES group and 90.9 ± 35.3 mL for the PMA group (P = .51) (Table 1).

Results of histopathologic evaluation showed that 4 tonsils from the MES group had a mean depth of injury of 0.63 ± 0.25 mm. In contrast, 3 tonsils from the PMA group showed a mean depth of injury of 0.13 ± 0.12 mm. These differences were statistically significant (t = 3.11; P = .03) (Figure 1).

Total morphine consumption and the Faces and Steward scores were not significantly different between the MES and PMA groups (Table 2).

Complications were seen in 2 patients after MES, related to hydration in both. Four children had perioperative complications after PMA. Two children required postoperative admission for airway obstruction; both required supplemental oxygen, and 1 required a nasal airway. The third child required readmission for dehydra-
tion, and the fourth experienced a delayed posttonsillectomy hemorrhage that was managed surgically.

The families of patients in the MES and PMA groups returned 8 (47%) of 17 forms from each group. No statistically significant difference in recovery of diet, activity, or parental return to work was seen (Figures 2, 3, and 4).

Responses of diet scores show that on average, children in the PMA group did better than those in the MES group after day 3. The first day at which diet for more than half of the respondents was mostly normal or normal was not seen during the 10 days of responses for the MES group, whereas it was seen at 7 days for the PMA group. These differences were not statistically significant.

Graphs of averaged activity scores show children in the PMA group with higher average activity scores after day 7 compared with those in the MES group. The first day at which activity for more than half of the children was mostly normal or normal was 10 days for the MES group and 8 days for the PMA group.

Nearly all parents missed work on the day of surgery. By the end of the first week, most parents could return to work if needed (Figure 4).

Twelve (71%) of 17 patients in each group were reached by telephone for follow-up at an average of 178 days. One child in the MES group complained of persistent snoring. Three children in the PMA group (3/17 [18%]) each had 1 of the following complaints: velopharyngeal insufficiency, drooling and poor speech clarity, and 2 episodes of pharyngitis after tonsillectomy.

COMMENT

The plethora of techniques applied for tonsillectomy argues against the clear superiority of any single method. In the first century AD, Celsus removed diseased tonsils using blunt finger dissection or a sharp hook and knife. The fauces were then "washed out with vinegar and painted with a medication to reduce bleeding." From the mid-19th century until the earlier part of the 20th century, a knife, dissectors, scissors, a tonsillotome, or a guillotine was used for the sharp, complete (tonsillectomy) or partial (tonsillotomy) removal of the tonsils,10,11 with the patient awake or under local anesthe-

<table>
<thead>
<tr>
<th>Variable</th>
<th>MES Group</th>
<th>PMA Group</th>
</tr>
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<tbody>
<tr>
<td>Mean (SD) Steward score</td>
<td>5.5 (1.1)</td>
<td>5.4 (1.1)</td>
</tr>
<tr>
<td>30 min†</td>
<td>60 min</td>
<td>5.7 (1.0)</td>
</tr>
<tr>
<td>Mean total morphine PACU, mg</td>
<td>1.1 (0.8)</td>
<td>1.2 (1.1)</td>
</tr>
<tr>
<td>Mean Faces score‡</td>
<td>15 min</td>
<td>3.6</td>
</tr>
<tr>
<td>30 min</td>
<td>4.5</td>
<td>5.0</td>
</tr>
<tr>
<td>60 min</td>
<td>2.8</td>
<td>2.9</td>
</tr>
<tr>
<td>No. of perioperative complications</td>
<td>2§</td>
<td>4</td>
</tr>
<tr>
<td>Mean length of follow-up, d (range)</td>
<td>176.3 (52-442)</td>
<td>170.3 (5-529)</td>
</tr>
</tbody>
</table>

*MES indicates monopolar electrosurgery; PMA, plasma-mediated ablation; and PACU, postanesthesia care unit.
†Described in Steward. Lower Steward scores indicate less ready for discharge and more discomfort.
‡Described in Bieri et al. Lower Faces scores indicate less discomfort.
§Indicates dehydration in both patients.
||Indicates bleeding in 1 patient, posttonsillectomy hemorrhage in 1, and airway obstruction in 2.
We have investigated PMA for tonsillectomy since 1998, when it was offered as a means of bridging the gap between cold and hot techniques. Plasma-mediated ablation promised better hemostasis with excision than cold methods, while leaving less heat to the pharynx than MES.4,5

We compared PMA with MES, our standard technique for tonsillectomy, to determine whether PMA in vivo would demonstrate less histopathologic thermal injury, and whether this reduced thermal injury was sufficient to result in a faster, less painful recovery. We used a randomized, prospective, partially blinded protocol. This report of 34 patients is the largest prospective series comparing MES and PMA to date. This series showed that PMA was effective for tonsillectomy and demonstrated less histopathologic thermal injury, but that PMA took longer to perform and did not offer statistically significant improvement in recovery for children or families compared with MES.

Tonsillectomy was possible in all cases with PMA, which was believed to allow better excision than MES, and was equivalent to MES for ease of use and hemostasis. Plasma-mediated ablation required on average of 7.6 minutes longer than MES (Table 1). Surgical inexperience cannot be blamed, as the learning curve was broached during previous work by the same surgeon. The longer surgical time most likely did not relate to reduced hemostasis of PMA, as hemostasis (subjectively) and recorded estimated blood loss were equivalent. For those cases in which PMA resulted in worse hemostasis than would have been expected with MES, however, surgical times were longer, with near statistical significance (P = .05). Most likely, the longer surgical time of PMA relates to instrumentation and technique. Extra irrigation and tubing is required for water delivery for PMA. The time difference of more than 30% may also reflect the greater care required during tonsillectomy with PMA to avoid lateral injury due to the 2- to 3-mm zone of ablation in front of the tip of the plasma wand. Appropriate use of the instrument, in our experience to date, has been without significant problems.

This study confirmed the anticipated reduction in histopathologic thermal injury with PMA compared with MES (Figure 1). Tonsils excised by means of PMA showed only a 0.13-mm depth of histopathologic thermal injury on average, compared with those excised by means of MES, which showed 0.63-mm damage. This difference was statistically significant even for this small sample (P = .03). This reduced thermal effect, however, did not translate into improved recovery. We found no statistically significant difference between groups for morphine consumption in the postanesthesia care unit, the Bieri Faces scale (a visual analog pain scale), and pre-discharge Steward scores (to evaluate readiness for discharge) (Table 2). Once home, the return to normal diet and activity and parental return to work were similar between groups (Figures 2, 3, and 4). The self-reporting format had a poor response rate, with less than half of each group returning surveys. Although the PMA group

Figure 3. Return to normal activity. The difference seen in recovery of activity after tonsillectomy by means of monopolar electrosurgery (MES) vs plasma-mediated ablation (PMA), as reported by parents, was not statistically significant. Scores are described in the "Patients and Methods" section.

Figure 4. Parents who lost days from work. Nearly all parents who worked could not do so on the day of surgery. By the end of the first week, most parents could return to work if needed. The differences seen between children who had tonsillectomy performed by means of monopolar electrosurgery (MES) vs plasma-mediated ablation (PMA) was not statistically significant.
showed an earlier return to mostly normal or normal activity and diet, this difference was not statistically significant. An important message from these responses is the lack of complete recovery even at 10 days after surgery, supporting outcomes measures that track recovery for up to 2 weeks.\textsuperscript{2,13}

The PMA group had a trend to a higher complication rate, including 2 children with airway edema. The airway edema may be due to PMA-related thermal injury, but this is contrary to the reduced thermal injury seen histopathologically. Sealing of lymphatic channels, or an as yet uncharacterized tissue effect of PMA, may be to blame. The airway edema may simply reflect the longer surgical time of PMA. Although our sample size was too small to allow statistical characterization of airway risk due to T&A with PMA, the unplanned admission of 2 children from the PMA group is cause for concern. This study was terminated before complete enrollment because of these airway complications.

The lack of a statistically significant improvement in perioperative measures despite reduced histopathologic thermal injury, and in fact a trend to a higher rate of complications, has several explanations. First, the use of electrocautery to achieve hemostasis after PMA excision of tonsils may undo the benefits of cooler ablation. The advocates of cold tonsillectomy would recommend a controlled trial with PMA for T&A followed by the use of sutures or ligatures for hemostasis, compared with MES or a knife or scissors for excision. Second, although the histopathologic evaluation of thermal injury is considered to be a proxy for presumed thermal injury to the pharynx, this thermal effect on the excised tonsil may not be important to recovery. Third, a yet undefined tissue effect, unique to PMA, might cause neural irritation, or other soft tissue trauma, of which the airway edema seen in 2 children after PMA may be a harbinger.

One extension of this work may be to treat tonsillar hypertrophy by means of delivery techniques other than the plasma wand, and to offer tonsillar reduction (tonsillectomy) rather than resection (tonsillectomy). This concept is particularly valid if pain is due to exposed pharyngeal musculature. Reduction of tonsillar tissue may be possible by laser techniques\textsuperscript{14} or by different delivery systems for PMA. In addition to reduced pain, these methods offer a reduced risk for immediate and delayed postoperative hemorrhage. These methods have not yet been fully investigated in children, and to date, no long-term evaluation of tonsillar regrowth has been performed for these alternatives.

Regardless of the tonsillectomy technique studied, we offer this study as a means of facilitating as objective an analysis as possible of the many factors involved in evaluating new technologies for tonsillectomy in children. Technical factors, tissue effects, perioperative pain scores and medication use, and recovery variables are all important in considering various techniques for this commonly performed surgery.

CONCLUSIONS

Plasma-mediated ablation for pediatric tonsillectomy resulted in less histopathologic thermal injury than MES, but did not show a statistically faster recovery to normal activity and diet or parental return to work. In addition, PMA took longer to perform ($P<.002$) and showed a trend to more complications. This technique as it is presently delivered should not replace MES for routine tonsillectomy. The reduced thermal injury seen with PMA, however, supports current investigations into other means of using PMA to treat tonsillar hypertrophy in children.

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