Objectives/Hypothesis: Monopolar cautery is the most commonly used technique for tonsillectomy. The aim of the present study is to compare postoperative pain using a new technology, PlasmaKnife tonsillectomy (PKT), in comparison with monopolar cautery tonsillectomy (MCT).

Study Design: Prospective, randomized, single-blinded, self-controlled study using paired organs.

Methods: Thirty-two adult patients, aged 18 to 30 years, scheduled for tonsillectomy for recurrent tonsillitis were included. Patients were randomly assigned to undergo PKT on one side and MCT on the opposite side. The primary outcome was self-rated daily pain assessed by using a 10-point scale. Patients were provided 21-day pain diaries and were phoned twice weekly by a research assistant to assess pain and remind them to complete diaries. Secondary outcomes included comparisons of operative time, blood loss, and postoperative complications.

Results: Repeated measures analysis of variance comparing PKT to MCT during the 21-day postoperative period revealed no difference in postoperative pain between the two groups (P = .131). In addition, total operative time (P = .276) and blood loss (P = .418) did not differ significantly between PKT and MCT.

Conclusions: Adult subjects undergoing PKT do not experience less postoperative pain in comparison to MCT.

Key Words: Tonsillectomy, PlasmaKnife, Bovie, postoperative pain.

Level of Evidence: 1b.

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INTRODUCTION

Tonsillectomy continues to be among the most common procedures performed by otolaryngologists in the United States. Despite the frequency and long history of tonsillectomy, otolaryngologists continue to seek improved methods for its performance. Adult tonsillectomy, in particular, is known to cause substantial postoperative pain and morbidity and is often associated with greater blood loss than pediatric tonsillectomy. The reason for this is thought to be the presence of increased fibrosis from previous infections combined with large blood vessels. As a result, more cauterization is typically required to control bleeding and may contribute to postoperative pain. Methods of adult tonsillectomy commonly used include “cold techniques” (snare, guillotine), Bovie monopolar electrocautery (Valleylab, Inc., Boulder CO), Harmonic scalpel (Ethicon Endo-Surgery, Cincinnati, OH), and Coblation (ArthroCare Corp., Sunnyvale, CA). Recently, the PlasmaKnife (Gyrus ENT, Bartlett, TN) has been introduced for performing tonsillectomy. The PlasmaKnife (Fig. 1) is a single-use, low-temperature, bipolar electrosurgical instrument. This device uses a technology referred to by the company as “PlasmaCision,” which employs local tissue electrolytes and low voltage to generate a local plasma field that causes tissue disruption. Because of the relatively low temperatures involved, the PlasmaKnife has been reported to cause less collateral tissue damage. This claim is supported by histologic evidence from a porcine model that compared several technologies including monopolar electrocautery and the PlasmaKnife. In this study, the investigators demonstrated a more precise incision with only localized thermal damage in the PlasmaKnife incisions compared to the other methods. The device also features a suction-bipolar cautery function that is claimed to achieve coagulation by tissue-resistive heating using low voltage. This method is distinguished from monopolar cautery tonsillectomy, which uses much higher voltages to excise and cauterize tonsil tissue, thereby producing collateral thermal damage and, presumably, more postoperative pain.
MATERIALS AND METHODS

Study Subjects and Design

We designed a prospective, randomized, single-blinded, self-controlled study to compare PlasmaKnife tonsillectomy (PKT) to standard Bovie monopolar electrocautery tonsillectomy (MCT). The study protocol was approved by the Naval Medical Center Portsmouth Institutional Review Board. Adult patients from 18 to 30 years of age undergoing tonsillectomy for recurrent tonsillitis were invited to participate. Exclusion criteria included history of peritonsillar abscess, severe unilateral tonsil enlargement concerning for neoplasia, obstructive sleep apnea, and pregnancy or lactation. Each patient that agreed to participate underwent MCT on one side and PKT on the opposite side. Randomization was performed by using a computerized random number generator to select the side allocated to receive PKT, with the opposite side receiving MCT for each subject. In this way, each subject served as their own control. The side receiving PKT was revealed to the surgeon at the time of surgery by using sealed, opaque, sequentially numbered envelopes and was never revealed to the subject. All patients received standardized postoperative narcotic analgesic medication consisting of 60 analgesic medication consisting of acetaminophen 325 mg with oxycodone 5 mg tablets.

Surgical Technique

All tonsillectomies were performed by either the principal investigator or an associate investigator. Before the study, each investigator had performed at least five PlasmaKnife tonsillectomies and received guidance from the manufacturer (Gyrus) representative on recommended starting device settings. PlasmaKnife settings ranged from 80/20 to 95/5 (coagulation to cutting ratio) using the Gyrus ENT workstation as the power source. The decision regarding which setting to use was based on the investigator’s judgment during the course of surgery.

MCT is the standard method of tonsillectomy at our institution and was performed using the Valleylab electrosurgical handpiece with guarded flat blade on a setting of 15 W in the coagulation mode. Following each tonsillectomy, bleeding was controlled by using the PlasmaKnife bipolar cautery function for the PKT side or the suction Bovie on a setting of 15 W coagulation for the MCT side. In cases where bleeding could not be controlled by using the PlasmaKnife bipolar cautery, adjunctive suction cautery (suction Bovie) was used. For each tonsillectomy, blood loss was measured by using separate suction canisters. Irrigation volume was standardized and subtracted from each canister to ensure that blood within the suction tubing was accurately measured. Operative time for each tonsillectomy was also separately recorded. These data, including the PlasmaKnife settings, were recorded on individual data collection forms for each subject.

Outcome Measures

The primary outcome of interest was self-rated daily pain assessed using a 10-point scale. All subjects were discharged to home on the day of surgery and were each provided a 21-day pain diary and given detailed instruction on its use. Each of the 21 segments of the diary contained two 10-point pain scales labelled “left side” or “right side.”

Patients were also phoned twice weekly by a research assistant to separately assess pain and remind patients to complete diaries. The research assistant used standardized questions in communications with patients to prevent introduction of bias. Patients were also given a follow-up appointment at 3 weeks, and the diaries were collected at that time. Secondary outcomes included comparisons of operative time, blood loss, and postoperative complications related to each tonsillectomy technique.

Statistical Analysis

Group sample sizes of 19 tonsillectomies per group (PKT and MCT) were initially calculated to achieve 81% power to detect a difference of −0.6 between the group means. Statistical significance was set at $P < .05$. Because of the change in the instrument design during the study, the sample size was increased by nine tonsillectomies per group (total sample size of 28 subjects undergoing 56 tonsillectomies). To allow for dropouts, we estimated our enrollment to be 32 subjects (64 individual tonsillectomies). Statistical tests were performed using SPSS Version 12.0 statistical software (SPSS Inc., Chicago, IL).

Pain scores were treated as continuous variables, and a repeated-measure analysis of variance (ANOVA) was performed comparing PKT to MCT. Also, three-way ANOVA was used to compare PKT, mPKT, and MCT. Differences in operative time and blood loss between PKT and MCT were evaluated by using the Student $t$ test, and adjunctive cautery use between PKT and mPKT were compared using $\chi^2$ analysis.

RESULTS

Thirty-two subjects were enrolled and underwent tonsillectomy for recurrent tonsillitis. The subject...
characteristics are contained in Table I. Four subjects (12.5%) were noncompliant or lost to follow-up. Twenty-eight subjects (56 individual tonsillectomies) completed the study. Randomization resulted in 16 (57.1%) right tonsils and 12 (42.9%) left tonsils removed by PKT and 12 right (42.9%) and 16 left (57.1%) removed by MCT. As a result of the design modification of the Plasma-Knife during the study, 10 patients underwent surgery with the older device (PKT) and 18 patients had the newer device (mPKT).

Repeated-measures ANOVA was performed on the postoperative-pain data, comparing the two groups (PKT and MCT) for 21 days. No significant difference was seen between the two techniques \((P = .131)\), and no interaction effect was seen \((P = .910)\). Pain scores decreased for both the PKT and MCT groups over time (Fig. 2). A three-way ANOVA was then performed on the data to statistically evaluate for any differences between MCT, PKT, and mPKT. Again, all pain scores decreased over time in all three groups \((P < .001)\) but at an equal rate \((P = .871)\), and there were no differences between the groups \((P = .306)\) (Fig. 3). To compare surgical time and blood loss between the PlasmaKnife and monopolar cautery, the Student \(t\) test was used. The mean operative time was 8.9 minutes for PlasmaKnife and 7.4 minutes for monopolar cautery. The mean operative blood loss was 11.3 mL for PKT and 17.7 mL for MCT. Neither the operative time \((P = .276)\) nor the blood loss \((P = .418)\) differences were significant. The data were again stratified to compare PKT, mPKT, and MCT. No significance was noted for either time \((P = .164)\) or blood loss \((P = .721)\). Finally, because adjunctive (suction Bovie) cautery was required in about half of the Plasma-Knife tonsillectomies, a \(\chi^2\) test was used to compare pain differences in these two groups. Again, the difference was not significant \((P = .513)\).

**DISCUSSION**

Tonsillectomy continues to rank as one of the most common surgical procedures performed in the United States, with more than 600,000 performed annually.\(^2\) The most common indications include recurrent tonsillitis and obstructive tonsillar hypertrophy. Additional indications include asymmetry, peritonsillar abscess, and keratosis pharyngeus.\(^5\) Although this is a relatively short surgery that is typically performed on an outpatient basis, the morbidity from adult tonsillectomy can be substantial. Postoperatively, adult patients are likely to experience moderate to severe odynophagia to the extent that dehydration may occur. In addition, bleeding, nausea, and airway complications are established complications. Consequently, the recovery period can be quite difficult for adult patients, resulting in suffering and loss of productivity with a typical period of convalescence of approximately 14 days.\(^5\)

With such morbidity for a common procedure, the surgeon is obligated to select a technique that provides for a safe operation with the least morbidity. This decision will ultimately be made based on clinical judgement,

<table>
<thead>
<tr>
<th>Characteristics of Study Patients.</th>
<th>Early PlasmaKnife (10)</th>
<th>Modified PlasmaKnife (18)</th>
<th>Combined (28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, yrs</td>
<td>27.5</td>
<td>24.1</td>
<td>25.3</td>
</tr>
<tr>
<td>Male, no. (%)</td>
<td>7 (70.0)</td>
<td>7 (38.9)</td>
<td>14 (50.0)</td>
</tr>
<tr>
<td>Female, no. (%)</td>
<td>3 (30.0)</td>
<td>11 (61.1)</td>
<td>14 (50.0)</td>
</tr>
<tr>
<td>PlasmaKnife, on right, no. (%)</td>
<td>4 (40.0)</td>
<td>12 (66.6)</td>
<td>16 (57.1)</td>
</tr>
<tr>
<td>PlasmaKnife, on left, no. (%)</td>
<td>6 (60.0)</td>
<td>6 (33.3)</td>
<td>12 (42.9)</td>
</tr>
<tr>
<td>Dropouts, no. (%)</td>
<td>3 (9.4)</td>
<td>1 (3.1)</td>
<td>4 (12.5)</td>
</tr>
</tbody>
</table>

Fig. 2. Pain outcomes for 21 days following tonsillectomy for PlasmaKnife tonsillectomy versus Bovie monopolar cautery tonsillectomy \((P = .131)\). Knife = PlasmaKnife tonsillectomy; SE = standard error; VAS = visual analog scale.
With this goal in mind, many strategies have been tried to reduce the postoperative pain and length of recovery following tonsillectomy. These include such adjuvants to surgery as topical anesthetics, postoperative antibiotics, corticosteroids, and nonsteroidal antiinflammatory medications. In addition, some investigators have evaluated modified techniques such intracapsular tonsillectomy or “tonsillotomy” for selected indications with the promise of improved morbidity.

As a result of these efforts, multiple techniques are currently available to the otolaryngologist. Methods of adult tonsillectomy in common use include “cold” techniques (snare, guillotine), monopolar electrocautery (Bovie), Harmonic scalpel, and Coblation. In the United States, many otolaryngologists use monopolar electrocautery because it reduces intraoperative bleeding compared to traditional cold dissection. Unfortunately, this advantage comes with the cost of increased postoperative pain.

Traditional monopolar electrocautery involves the transmission of electrical current from a single electrode via a return path through the patient. Concentrated electrical current results in a burn that coagulates tissue and stops bleeding, resulting in eschar formation. Bipolar electrocautery is a widely accepted alternative to monopolar surgery but is not an effective way to make a surgical incision and cannot stop bleeding over a large area. Both techniques coagulate at high temperatures of up to 400°C, which causes substantial collateral damage to surrounding tissue. In an effort to reduce postoperative tonsillectomy pain, several companies have developed alternative instruments that generally aim to provide dissection and coagulation at lower temperatures. The expectation is that this will limit tissue damage and therefore improve recovery. Radiofrequency devices such as the Coblator and the PlasmaKnife produce less heat and thus potentially result in less collateral tissue damage. Coblation passes radiofrequency bipolar electrical current through a medium of normal saline resulting in a plasma field of ionized particles able to break down intercellular bonds and divide tissue at a temperature of 70°C. One study of 48 patients comparing Coblation to monopolar electrocautery found that Coblation subcapsular tonsillectomy resulted in less postoperative pain when compared to electrocautery tonsillectomy. In this same study, no difference was seen in operative blood loss and postoperative hemorrhage rates between the two techniques. Similarly, in a study of 17 patients undergoing tonsillectomy, investigators found significantly less pain with Coblation compared to monopolar electrocautery. These findings suggest that the method by which tonsillectomy is performed can reduce postoperative pain. Our study looked at a similar technology, the PlasmaKnife, which is claimed to be an excisional rather than ablative instrument with the potential for even less collateral damage to tissue.

The PlasmaKnife is a single use instrument that produces a highly ionized gaseous state, or “plasma,” around the active electrode through the use of local tissue electrolytes. This highly excited tissue state requires less electrical current to achieve molecular dissociation. The net result is less thermal injury and char formation because of the lower working temperatures (60–90°C) compared to the higher temperatures (>120°C) that result from monopolar electrocautery. Although no published studies have compared the PlasmaKnife to electrocautery, one study compared the PlasmaKnife to bipolar electrodissection in a pediatric population. In this European double-blinded, randomized controlled trial, the investigators found that the PlasmaKnife group had more pain in the early postoperative period and that the bipolar dissection group returned to normal activities in a larger proportion than the PlasmaKnife group by postoperative day.14

Fig. 3. Comparison of postoperative pain between Bovie monopolar cautery, PlasmaKnife, and modified PlasmaKnife tonsillectomy for 21 postoperative days (P = .306). Old Knife = PlasmaKnife tonsillectomy; New Knife = modified PlasmaKnife tonsillectomy; SE = standard error; VAS = visual analog scale.
As part of the military healthcare system, we perform many tonsillectomies in young adults. Therefore, we were interested in investigating the potential benefits of the PlasmaKnife in comparison to monopolar electrocautery for adult tonsillectomy with regard to safety, efficiency, and postoperative pain using a prospective, randomized, single-blinded, self-controlled study. To achieve this goal, we used a paired-organ study design, in which patients serve as their own control. This design is not uncommon in studies comparing tonsillectomy techniques because it allows for the elimination of the potential confounding influences of age, sex, and subjective response to pain. The premise of this design is that patients are able to locate, differentiate, and grade pain within the oropharynx. Previous tonsillectomy studies as well as studies of other paired organ surgeries such as bilateral carpal tunnel repair have used this type of self-control design. We believe it to be an appropriate method for assessing postoperative pain where paired organs are involved.

For purposes of pain assessment during the postoperative period, we used daily, self-rated pain assessment based on a 10-point scale for 21 days after surgery. Here, we differed from many previous studies that only assessed pain for 14 days, the most common timeframe before patients return to work or activity. In our practice, we have found that postoperative pain following tonsillectomy in adults frequently lasts longer than 2 weeks. We also found it useful to employ a research assistant to phone twice weekly, assess pain, and remind patients to complete diaries. The research assistant used standardized questions to help eliminate bias. Of the 32 patients who underwent tonsillectomy in our study, 15 (46.8%) required adjunctive monopolar cautery. Of those, seven were from cases using PKT and eight were from cases using mPKT. Even after correcting for the greater number of cases done by mPKT, the difference was not significant, suggesting that mPKT was just as likely to require adjunctive cautery as PKT.

Additional factors that should be considered when using new technology include operative time and blood loss. Most surgeons performing tonsillectomy today would agree that cold techniques result in greater blood loss than monopolar cautery. In fact, one study demonstrated the mean intraoperative blood loss to be 10 mL with electrocautery versus 190 mL with sharp dissection. The PlasmaKnife appears to provide similar benefits in terms of reduced blood loss, but it operates at much lower temperatures than electrocautery. In our study, blood loss was 17.7 mL for monopolar cautery compared to 11.3 mL for the PlasmaKnife. This difference was not significant. With regard to operative time, the mean elapsed time for monopolar cautery was 7.4 minutes compared to 8.9 minutes for the PlasmaKnife. Again, this difference was not significant.

At least two limitations of this study should be considered. First, we did not anticipate the manufacturer’s design change when the study began. Although the changes were small, we needed to consider the possibility that the earlier version of the instrument was flawed in a way that led to greater use of adjunctive monopolar cautery. In theory, this would defeat the benefit of the PlasmaKnife technology. However, by increasing the sample size and conducting a separate analysis where we compared pain scores, bleeding, and operative time, of the three techniques (PKT, mPKT, MCT), we still found no significant difference in these outcomes (Fig. 2). In addition, we compared the use of adjunctive monopolar cautery between the mPKT and PKT and found no significant difference. Therefore, we concluded that the design change did not impact our results.

A second limitation is related to the device settings. The device allows for a range of settings from 60/40 (i.e., 60% coagulation with 40% cutting) to 100/0. Most of the PlasmaKnife tonsillectomies in this study were performed on the 80/20 or 85/15 setting. In our experience, we found that the lower-cut/higher-coagulation settings impaired hemostasis. The study-related concern is that, had we consistently used higher coagulation settings
such as 90/10 or 95/5, we might have observed overall lower postoperative pain scores in the PKT group compared to the MCT group. However, we felt that for the study to be clinically useful, the instrument should be evaluated in the manner that it would be used by the surgeon. We believed that one standardized setting to control for variables that might produce better pain outcomes would not reflect real clinical practice.

CONCLUSION

Based on the findings of our study, the PlasmaKnife does not seem to offer a better solution to the elusive goal of minimizing pain after tonsillectomy in the adult patient. Although the PlasmaKnife appears to be equal to monopolar cautery in terms of intraoperative hemorrhage and operative time, in this study population our findings suggest that there is no added benefit in regard to postoperative pain. As a single use, disposable instrument that adds substantial cost to tonsillectomy without clear benefit, we do not feel that its use for adult tonsillectomy can be justified.

Acknowledgment

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BIBLIOGRAPHY