Harmonic scalpel versus conventional tonsillectomy: A double-blind clinical trial

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Abstract
We conducted a prospective, double-blind clinical trial to evaluate the differences in operating time, intraoperative blood loss, postoperative pain at 3 hours and 1 week, and delayed (>24 hr) bleeding associated with ultrasonic harmonic scalpel tonsillectomy and conventional tonsillectomy. The study was carried out on 28 patients with recurrent tonsillitis and/or adenotonsillar hypertrophy who underwent harmonic scalpel tonsillectomy on one side and cold dissection tonsillectomy with suction electrocautery hemostasis on the other. The harmonic scalpel was associated with significantly less intraoperative blood loss (mean: 6.2 vs. 58.8 ml; \(p < 0.0001\)) and less early (3 hr) postoperative pain as determined by scores on a 10-point visual analog scale (mean: 3.5 vs. 4.4; \(p = 0.0042\)); although the difference in early pain scores is statistically significant, it is probably not clinically significant. Pain scores at 1 week were nearly identical (mean: 2.7 vs. 2.6; \(p = 0.9246\)). The length of operating time was similar (mean: 10.9 vs. 7.7 min; \(p = 0.0022\)). An unanticipated finding was the fact that delayed bleeding, which occurred in 3 patients (10.7%), occurred only on the harmonic scalpel side. We conclude that the only clearly demonstrable advantage that the harmonic scalpel had over cold dissection was that it caused less intraoperative blood loss.

Introduction
Despite refinements in surgical technique, instrumentation, and anesthetic delivery for tonsillectomy, two areas of concern—bleeding and postoperative pain—remain significant challenges for the surgeon and the patient. The medical literature contains conflicting reports on the effect that the type of surgical technique has on these two parameters.\(^1\)\(^-\)\(^4\) Immediate (<24 hr) and delayed (>24 hr) postoperative bleeding rates of 2 to 5% are considered acceptable; postoperative pain, while variable in intensity and duration, typically lasts for 7 to 10 days after surgery and is moderately severe.\(^5\) Certainly, otolaryngologists would want to investigate the feasibility of any new instrumentation that would demonstrably decrease the morbidity of tonsillectomy, even if it were relatively expensive.

The ultrasonic harmonic scalpel (Ethicon Endo-Surgery; Cincinnati) has been used for a variety of surgical procedures, primarily intraabdominal, intrathoracic, and gynecologic.\(^6\)\(^-\)\(^8\) It has been promoted as having certain advantages over other tonsillectomy procedures, as well, including less intraoperative blood loss and less postoperative pain.

The harmonic scalpel is equipped with a 10-cm dissecting hook blade that is attached to a ceramic piezoelectric connector that converts electrical energy to mechanical energy and generates a longitudinal blade motion of 55,500 cycles per second. The rapid, low-amplitude motion of the blade’s tip (maximum longitudinal displacement: 60 to 100 \(\mu\)m) has a cavitation effect on tissue. The blade simultaneously cuts and coagulates tissue by breaking hydrogen bonds, denaturing protein, and creating a sticky coagulum, thus coagulating the small blood vessels. This is accomplished at a relatively low temperature (50° to 100°C), which limits damage to adjacent tissue.\(^9\)

In this article, we describe a study designed to determine if the harmonic scalpel had any advantages over conventional dissection with respect to the length of operating time, the amount of intraoperative blood loss, the degree of postoperative pain, and the incidence of delayed bleeding.

Patients and methods
Our study population was made up of 28 patients—10 males and 18 females—aged 6 to 40 years (mean: 17). The indications for surgery were recurrent tonsillitis (23 patients [82.1%]), adenotonsillar hypertrophy (2 [7.1%]), and both (3 [10.7%]). Our protocol involved using the harmonic
scalpel to remove the tonsil on one side of each patient and conventional tonsillectomy to remove the other. We obtained appropriate informed consent and briefly described the instrumentation to each patient, but we did not inform patients or the nurses providing postoperative care which procedure was performed on each side. The decision as to which procedure would be performed on each tonsil was made randomly by the surgeon. Harmonic scalpel surgery was performed on the left side in 15 patients and on the right side in the remaining 13.

The harmonic scalpel was set to power level 2 as recommended by the manufacturer. Conventional tonsillectomy involved cold dissection and snare with suction cautery (Aspen Excalibur with a Conmed handpiece; Soma Technology; Cheshire, Conn.) at a setting of 35 for hemostasis. The length of operating time and the estimated amount of blood loss were recorded for each side. In a double-blind manner, nurses in the Ambulatory Surgery Unit assessed each patient’s degree of postoperative pain on each side 3 hours postoperatively by means of a 10-point visual analog scale. All patients were discharged on the day of surgery with an antibiotic, an analgesic, and standard instructions for diet and activity limitation.

All patients were reexamined 1 week later, and their pain was reassessed by the same method. Any episodes of postoperative bleeding were also noted, and the amount of bleeding was estimated on the basis of the history, physical examination, measurement of expectorated blood, and changes in hematocrit level.

A Student’s paired t test was used to compare the length of operating time and the estimated intraoperative blood loss. Pain scores were compared by the Wilcoxon signed rank test. Values were expressed as a mean ± confidence interval (CI), and the threshold for statistical significance was 0.05.

Results

Operating time. The length of operating time was similar, ranging from 5 to 25 minutes (mean: 10.9) with the harmonic scalpel and from 5 to 16 minutes (mean: 7.7) with dissection-cautery ($p = 0.0022; 95\% \text{ CI}: ±1.66$ and $±1.20$, respectively) (figure 1). The length of time required to perform the harmonic scalpel procedure decreased slightly with continued use. In 7 of the 28 patients (25.0%), cautery was required on the harmonic scalpel side to coagulate one or two larger vessels.

Intraoperative blood loss. The estimated amount of blood lost during surgery was significantly less on the harmonic scalpel side ($p < 0.0001$). Estimates ranged from 0 to 50 ml (mean: 6.2) with the harmonic scalpel and 7 to 125 ml (mean: 58.8) with dissection-cautery ($p < 0.0001; 95\% \text{ CI}: ±4.14$ and $±11.31$, respectively).

Postoperative pain. At 3 hours postoperatively, pain scores ranged from 1 to 10 (mean: 3.5) on the harmonic
scalpel side and from 0 to 10 (mean: 4.4) on the dissection-cautery side (figure 3). The difference reached statistical significance ($p = 0.0042$; 95% CI: ±0.99 and ±0.94), but we do not believe that it is clinically significant. At 1 week, pain scores ranged from 0 to 9 (mean: 2.7) and from 1 to 10 (mean: 2.6), respectively; this difference is not statistically significant ($p = 0.9246$).

**Delayed bleeding.** There were 3 cases of delayed bleeding (10.7%), all of which occurred on the harmonic scalpel side. This was an unexpected finding. Bleeding stopped spontaneously in 2 patients, but the other patient’s hemoglobin fell to 6.3 g/dl, which necessitated a return to the operating room for hemostasis and transfusion of 2 units of packed red blood cells.

**Discussion**

Otolaryngologists and patients alike would embrace the introduction of any instrumentation that would decrease the morbidity of tonsillectomy and increase its safety. Although numerous articles have been published in the general surgery, thoracic surgery, and gynecology literature on the harmonic scalpel, reports in the otolaryngology literature that specifically address its use for tonsillectomy are limited. Of course, posttonsillectomy care differs substantially from postoperative care of other types of surgery in which a wound is closed and unexposed. Regardless of the specific tonsillectomy procedure that is performed, all patients are left with a relatively large and raw superior constrictor muscle that must heal by secondary intention in the contaminated oropharyngeal environment.

In a pilot study published in 2001, Walker and Syed prospectively evaluated 316 tonsillectomies, 155 of which were performed with the harmonic scalpel. They obtained data on outcome parameters—including the return to regular diet and activity and the use of pain medications—through questionnaires, interviews with surgeons, and chart reviews. Compared with electrocautery tonsillectomy, harmonic scalpel tonsillectomy was associated with a significantly earlier return to normal diet and activity, a similar degree of perioperative blood loss, and a lower rate of delayed bleeding (3.2 vs. 5.6%). The authors called for additional studies to further evaluate this device for tonsillectomy. The same year, Sood et al described their experience with harmonic scalpel tonsillectomy in 59 cases. Their findings with regard to operating time, intraoperative blood loss, postoperative pain, and delayed bleeding were similar to ours, although their series included no controls. They also called for “a formal prospective, randomized, controlled study . . . to confirm our findings and to compare [ultrasonic harmonic scalpel] tonsillectomy with other methods.”

Our study found that the harmonic scalpel was associated with a significant decrease in intraoperative blood loss, a slight decrease in early postoperative pain, and an apparent increase in the risk of delayed bleeding. The difference in early postoperative pain—0.9 points on a 10-point scale—is statistically significant, but its clinical significance, if any, needs to be examined more carefully. The clinical relevance of pain outcome measures has been explored in three studies in the pain literature. The authors of these studies concluded that when differences in pain intensity were less than 1, 1.3, and 3.3, respectively, on a 10-point scale, they were not clinically significant. This finding was confirmed by several different methods, and the results were consistent. The 0.9-point difference in our study fell below the lowest threshold established in the three earlier studies and, therefore, we do not believe that it is clinically significant. The small number of patients in our study (28) might be considered a limitation to determining significance, but our double-blind design, in which each patient served as his or her own control, did confer the advantage of obviating the placebo effect. The 10-point pain scale has been used effectively in a number of other studies in the otolaryngology literature, as has the practice of using patients as their own controls to assess differences in both pain and bleeding. Although the use of a visual analog scale can be criticized as being subjective—as opposed to other determinants such as analgesic intake or return to normal diet and activity—all pain assessments are ultimately subjective, relying as they do on each patient’s perception of and reaction to the sensation.
The harmonic scalpel has also been evaluated in animal studies with respect to hemostasis, bleeding, healing, and adhesion formation, and results have been mixed.\textsuperscript{18,19} We know that energy-based procedures such as laser ablation and electrocautery are generally associated with more scarring, slower healing, and less tensile strength in the wound than is simple incision, depending on how much power is applied.\textsuperscript{20} In the porcine model, the harmonic scalpel appeared to produce fewer adhesions than did other energy sources; this was attributed to less bleeding, the absence of carbonization as a result of lower tissue temperatures (<80°C), and less thermal damage.\textsuperscript{21} In the rat, however, the harmonic scalpel appeared to be associated with more tissue injury than was a regular scalpel.\textsuperscript{19} A fairly thorough discussion of the theoretical advantages of ultrasonic energy technology in surgery has been published by Lee and Park.\textsuperscript{21} They listed several theoretical reasons that the use of the harmonic scalpel would result in less pain, including the fact that, unlike electrocautery, there is no electric current to stimulate nerves and muscles. They also cited some anecdotal reports that the use of the harmonic scalpel was associated with a decrease in postoperative pain among patients who had undergone procedures such as breast biopsy, hernia repair, and prostatectomy. However, none of these differences has ever been proved to be statistically significant.

In information distributed to physicians, Ethicon Endo-Surgery, the manufacturer of the harmonic scalpel, claims that the device is associated with “improved post op outcomes” and “quicker recovery, return to regular diet, and regular activity” when used for tonsillectomy.\textsuperscript{9} The results of our study support some of the claims made by the manufacturer; we did observe significantly less intraoperative bleeding and a comparable length of operating time compared with cold dissection with directed cautery. However, we found no real differences in the degree of early and late postoperative pain and a higher incidence of delayed bleeding (10.7 vs. 0%). In fact, we terminated our study when the trend in delayed bleeding became apparent. Although the number of cases in our study was low, the senior author (P.J.C.) previously reported a series of 217 conventional tonsillectomies in which the rate of delayed bleeding was only 1.8%.\textsuperscript{5} The six-fold difference between that rate and the rate seen with the harmonic scalpel in the current study is both clinically and statistically significant. Further studies would perhaps clarify the issue of delayed bleeding, although any surgeon contemplating such an investigation would have to decide if the benefits of the harmonic scalpel outweigh its limited advantages, possible risks, and higher cost. In the current study, the harmonic scalpel added approximately $300 to the cost of each case, a 10 to 15% increase.

References