

ORIGINAL RESEARCH

Comparison of Posttonsillectomy Pain Using the Ultrasonic Scalpel, Coblator, and Electrocautery

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OBJECTIVE: To compare postoperative tonsillectomy pain between 3 commonly used surgical devices: the Harmonic Ultrasonic Scalpel (Ethicon Endo-Surgery, Cincinnati, OH), the Coblator (ArthroCare Corp, Sunnyvale, CA), and electrocautery.

STUDY DESIGN AND SETTING: A prospective, randomized trial. One hundred thirty-four patients were randomly assigned to receive a tonsillectomy with 1 of 3 surgical devices. All patients were asked to fill out a postoperative diary.

RESULTS: Statistically significant differences in pain scores were revealed between the Coblator and electrocautery ($P = 0.02$) and between the Coblator and the Ultrasonic Scalpel ($P = 0.003$), with the Coblator having lower pain scores. Electrocautery and the Ultrasonic Scalpel did not differ significantly from each other. The Coblation method showed a strong trend toward quicker return to normal diet.

CONCLUSION: Patients undergoing tonsillectomy with the Coblator device reported less pain over a 10-day period than patients undergoing tonsillectomy with electrocautery or the Ultrasonic Scalpel. Pain after tonsillectomy remains a major issue for our patients. The choice of surgical instrument appears to be one way to reduce this pain.

EBM rating: A-1b

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Tonsillectomy is one of the most common procedures performed in otolaryngology practice. Although of significant benefit to the patient, it is a very painful procedure. The pain can be severe, and patients are often unable to perform in work or school or eat regular food for a number of days after surgery. Dehydration (secondary to painful swallowing) is a significant concern, and some children must be readmitted to the hospital for intravenous hydra-

tion. Many patients are also reliant on narcotic pain medication for several days and may experience side effects of sedation and constipation.

In the United States, the most common instrument used for tonsillectomy currently is the electrocautery device. Two devices introduced more recently are the Harmonic Ultrasonic Scalpel (Ethicon Endo-Surgery, Cincinnati, OH) and the Coblator (ArthroCare Corp, Sunnyvale, CA); these instruments are now commonly used for tonsillectomy procedures. These instruments operate at much lower temperatures and in theory cause less collateral tissue damage and less postoperative pain.

Electrocautery has been the standard surgical technique at our institution for a number of years. It works by using intense local heat to destroy tissues and cause “obliterative coagulation.” Monopolar cautery uses 2 electrodes placed far apart on the patient (1 electrode is the grounding pad and the other is the handheld tip). Electrical current must travel through the body between these 2 electrodes. The density of electrical current is directly related to the size of the electrode; therefore, the tiny Bovie tip generates a lot of heat (temperatures of 400°-600°C),¹ whereas the large grounding pad generates very little heat.

Some of the newer surgical instruments such as the Harmonic Ultrasonic Scalpel, and the Coblator device operate at much lower temperatures (60°-100°C),^{2,3} theoretically inducing less thermal injury to the tissues and resulting in less pain. The Harmonic Scalpel works by vibration of its blade at ultrasonic frequencies (55,000 Hz). Various power settings can be achieved by changing the amplitude of blade vibration. The vibration (invisible to the human eye) trans-

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fers energy to the tissue, providing simultaneous cutting and coagulation.

The Coblator device works by passing a bipolar radio-frequency current through a medium of normal saline. This creates a plasma field of sodium ions. As the energy is transferred to the tissue, ionic dissociation occurs, which results in vaporization of tissue and coagulation of vessels at low temperatures (60°C).⁴ There is minimal thermal damage to surrounding tissues. Coblation causes a low temperature molecular disintegration of tissue.

Aside from pain, hemorrhage is the other major concern when performing tonsillectomy. Other studies have compared the rates of posttonsillectomy hemorrhage for the surgical devices used in this study.⁵⁻⁹ Although results have varied,^{7,9} in general the postoperative hemorrhage rates have been similar for electrocautery, Harmonic Scalpel, and coblation. Our incidence of bleeding was documented; however, it was not the purpose of this study to compare bleeding rates in a statistically significant fashion.

METHODS

This was a prospective, randomized trial in a tertiary-care medical center associated with the Indiana University School of Medicine. The majority of the procedures were performed at a single hospital where one of the authors is an attending otolaryngologist (SRC). All patients undergoing tonsillectomy or adenotonsillectomy between December 2002 and December 2004 were invited to participate. This included both adult and pediatric patients. Before enrolling any patients, approval was obtained from the Indiana University Purdue University—Indianapolis and Clarian Institutional Review Board. Informed consent was obtained from all patients before enrolling them in the study.

All patients enrolled in the study were randomly assigned to receive a tonsillectomy with 1 of the 3 surgical devices (electrocautery, Harmonic Ultrasonic Scalpel, or Coblator). Patients were blinded as to which device was used. All study participants were asked to fill out a daily pain diary for 10 consecutive days postoperatively. The daily diary included a commonly used, standardized pain scale (Wong-Baker FACES pain rating scale), which is a 0 to 10 numerical rating scale with correlating faces (from happy to sad) to allow both children and adults to reliably record their pain. Children were asked to provide the information whenever possible, and a parent provided the information for those children too young to comply. The diary also included questions about food intake, activity level, need for pain medication, and any complications experienced by the patient. Patients were given a postage-paid envelope to return the pain diary after it was completed.

The surgeries were performed using standard surgical techniques for adenotonsillectomy. The surgeons included postgraduate year 3 and 4 otolaryngology residents, always

with close supervision by the attending otolaryngologist. Operative time was recorded as the number of minutes from insertion of the mouth gag to removal of the mouth gag and thus included time for both the adenoidectomy and the tonsillectomy. It was believed that the adenoidectomy time would be similar across the 3 groups and thus not affect the final results. Estimated blood loss was recorded for each patient.

Adenoidectomy was performed using mirror visualization and a “cold” adenoid curet. Nasopharyngeal hemostasis was achieved with a temporary gauze pack followed by monopolar suction cautery as needed. Tonsillectomy was performed using the randomly assigned device (Coblator, electrocautery, or Harmonic Scalpel). The assigned device was used on both the right and left tonsils. The surgical dissection technique was the same for all 3 devices and involved a subcapsular dissection of the tonsil for complete excision of the tonsil, with effort made to preserve as much pharyngeal mucosa as possible. Power settings for each device followed recommendations of the manufacturer. The device used for dissection was also used for control of bleeding. If “rescue” electrocautery was needed during the tonsillectomy to control bleeding, it was recorded (ie, if the ultrasonic device or Coblator was unable to control bleeding, monopolar suction cautery was then used to control the bleeding). All patients were given similar prescriptions for postoperative antibiotics and pain medication (acetaminophen/codeine), based on age and weight. Most patients went home on the day of surgery, after a period of observation.

RESULTS

One hundred thirty-four patients agreed to participate in the study. Sixty-one patients returned a completed diary. There were 43 patients in the electrocautery group, 44 patients in the Harmonic Scalpel group, and 47 patients in the Coblator group (Figs 1 and 2). The 3 groups did not differ statistically with regards to age, gender, indication for surgery, and return rate of the pain diary. Of the 134 patients, 127 underwent adenotonsillectomy and 7 underwent tonsillectomy alone. Statistical analysis was performed on pain rating, food intake status, and activity level.

Statistical Methods

The 3 groups (coblation, ultrasonic, and electrocautery) were compared for their demographic characteristics (age and gender), preoperative diagnoses, length of surgery times, estimated blood loss, and postoperative bleeding status. We used 1-way analysis of variance (ANOVA) to compare the continuous variables and χ^2 tests (or the exact tests if any of the expected counts were less than 5) for categorical variables.

The pain scores were treated as continuous values, and repeated-measures ANOVA was used to compare the 3 methods for differences in pain scores and investigate the

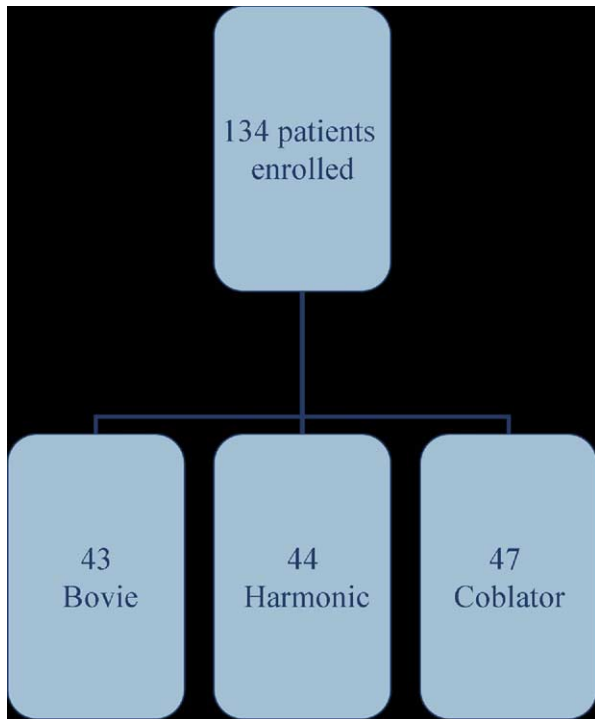


Figure 1 Randomization of study patients.

pain trends for each method over the 10 days. The repeated-measures model allows taking account of correlation in the pain scores over time reported by the same subject. Comparisons of the 3 groups for differences in number of days to first “yes” to normal food intake/activity level were made using Kaplan-Meier plots and survival analysis (log-rank tests). Summary statistics for pain scores and distribution of number of days to first “yes” to normal food intake/activity level were provided. Also, comparisons were made through nonparametric Kruskal-Wallis tests for differences in number of postoperative days (out of 10) recorded as “normal” for diet and activity level. All tests were conducted as 2 sided at an alpha level of 0.05 for statistical significance.

RESULTS

Comparison of the 3 Groups in Demographic Characteristics, Preoperative Diagnoses, and Postoperative Events and Description of Usage of Rescue Cautery in the Ultrasonic Group

Table 1 shows data from all enrolled patients, and Table 2 shows data from the subgroup that provided the 10-day pain diary. Comparison of the 3 groups within each of these tables shows that they were similar to each other in term of age, gender, preoperative diagnoses, estimated blood loss and delayed postoperative bleeding (return visit to the operating room).

Surgery time was found to be significantly different among the 3 groups. Although there was no difference

between the Coblator and Harmonic Scalpel, surgery time for electrocautery seemed to be significantly less (Table 3).

As seen in Table 2, the association was found to be marginally significant ($P = 0.053$) between the surgical instruments and whether a patient makes postoperative telephone calls or visits to the physician; 52.6% of the patients in the electrocautery group, 24.0% in the coblation group, and 17.7% in the ultrasonic group called their physician’s office within 10 days after their surgeries. The odds of a patient in the electrocautery group calling his/her physician after surgery increases 5.19 times (95% confidence interval, 1.11-24.14) compared with a patient in the ultrasonic group.

The use of electrocautery for rescue hemostasis among the coblation and Harmonic Scalpel groups was evaluated. The coblation group required the use of rescue electrocautery in 4 of 47 patients (8.5%), all of which were early on in our experience with it. In the Harmonic Scalpel group, 19 of 44 patients (43.2%) received some amount of rescue cautery. Eleven patients (25.0%) needed minimal rescue cautery, 6 (13.6%) needed moderate rescue cautery, and 2 (4.6%) needed a large amount of rescue cautery.

Pain Scores

Mean pain scores were computed for each patient over the 10 days, and summary statistics were obtained for the 3 groups as shown in Table 4. The initial repeated-measures ANOVA model contained effects for methods, days after surgery, and the interaction between method and days. Pain trends over the 10-day period were similar for the 3 methods, and this was therefore dropped in the final model.

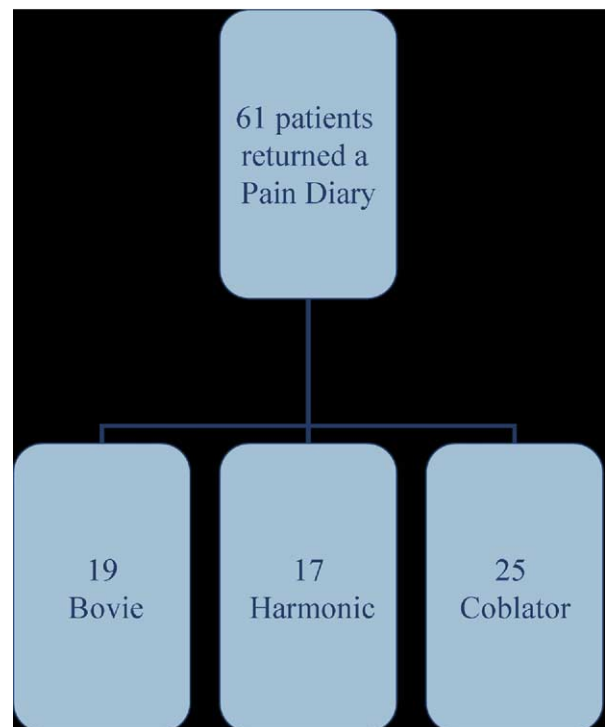


Figure 2 Breakdown of patients in study.

Among the 3 methods, coblation was associated with the lowest mean pain level ($P = 0.007$). Pairwise comparisons were made among these 3 groups, and significant differences in pain scores were revealed between the coblation and electrocautery methods and between the coblation and Ultrasonic Scalpel methods. Electrocautery and Ultrasonic Scalpel methods did not differ significantly from each other (Table 5).

Food Intake

Within 10 days after the surgery, 80.3% of the patients were able to achieve normal food intake. The Kaplan-Meier plot (Fig 3) of first day to normal food intake was obtained for the 3 groups. Visual examination suggests that coblation might be associated with fewer recovery days in terms of food intake compared with electrocautery and the ultrasonic scalpel. However, the log-rank test only detected a marginally significant difference among these 3 methods ($P = 0.08$). Pair-wise comparisons were made between the coblation and ultrasonic methods and between the coblation and electrocautery methods and the differences were also found to be marginally significant (P values are 0.07 and 0.08, respectively).

Activity Level

Within 10 days after the surgery, 91.8% of the patients were able to reach a normal activity level. The Kaplan-Meier plot

(Fig 4) of first day to normal activity level was obtained for the 3 groups. The 3 survival curves intertwine with each other, which suggests no differences among the 3 methods in terms of the time to resume normal activity level. The large P value from the log-rank test ($P = 0.96$) confirmed this finding.

Power Analysis

The sample size in the coblation, electrocautery, and ultrasonic groups was 25, 19, and 17, respectively. Assuming an SD of pain scores to be 1.45 (as found in our study), the pairwise comparisons among the 3 techniques for difference in postoperative pain have at least 80% power to detect the differences we found, with a 0.05 2-sided significance level.

Using a 0.05 significance level, 2-sided log-rank test to calculate the power of our sample size for normal food intake, our sample size has at least 60% power to detect the difference between coblation and electrocautery, 41% power to detect the difference between coblation and ultrasonic scalpel, and only 6% power to detect a difference between electrocautery and ultrasonic scalpel for time to normal food intake.

Table 1
Comparison of the three groups in demographic characteristics, preoperative diagnoses, and postoperative events using all patients (N = 134)

Variables	Coblation (N = 47)	Electrocautery (N = 43)	Ultrasonic (N = 44)	P value*
Age				
N	46	43	44	0.720
Mean (SD)	9.5 (7.3)	10.1 (9.0)	10.9 (8.8)	
Min, max	2.0, 32.0	1.9, 42.0	1.9, 33.0	
Gender				
Female	28	20	21	0.386
Male	19	23	23	
Preoperative diagnoses infectious				
Yes	12	15	13	0.625
No	35	28	31	
Preoperative diagnoses obstructive				
Yes	40	31	35	0.315
No	7	12	9	
Preoperative diagnoses other				
Yes	1	2	1	0.692
No	46	41	43	
Postoperative bleeding				
Yes	1	2	1	0.692
No	46	41	43	
Surgery time (min)				
N	42	42	44	<0.001
Mean (SD)	28.9 (13.5)	21.0 (6.7)	31.5 (9.9)	
Min, max	1.0, 66.0	11.0, 42.0	17.0, 65.0	
Estimated blood loss (ml)				
N	46	43	44	0.149
Mean (SD)	21.5 (32.6)	11.3 (12.8)	18.2 (24.5)	
Min, max	1.0, 150.0	0.0, 50.0	1.0, 150.0	

*Results from χ^2 tests or exact tests for categorical measures and 1-way ANOVAs for numeric measures.

Table 2
Comparison of the 3 groups using patients that completed the 10-day diary (N = 61)

Variables	Coblation (N = 25)	Electrocautery (N = 19)	Ultrasonic (N = 17)	P value*
Age				
N	25	19	17	0.440
Mean (SD)	10.0 (7.5)	10.1 (8.8)	13.2 (9.3)	
Min, max	2.0, 32.0	1.9, 38.0	2.0, 30.0	
Gender				
Female	15	10	10	0.878
Male	10	9	7	
Preoperative diagnoses infectious				
Yes	8	7	6	0.942
No	17	12	11	
Preoperative diagnoses obstructive				
Yes	22	13	13	0.281
No	3	6	4	
Preoperative diagnoses other				
Yes	0	1	0	0.590
No	25	18	17	
Postoperative bleeding				
Yes	1	1	1	1.000
No	24	18	16	
Postoperative telephone calls				
Yes	6	10	3	0.053
No	19	9	14	
Surgery time (min)				
N	24	19	17	0.003
Mean (SD)	31.4 (14.7)	20.0 (7.1)	30.4 (8.5)	
Min, max	12.0, 66.0	11.0, 42.0	20.0, 49.0	
Estimated blood loss (cc)				
N	25	19	17	0.214
Mean (SD)	27.5 (38.4)	10.4 (12.5)	22.4 (36.2)	
Min, max	1.0, 150.0	1.0, 50.0	1.0, 150.0	

*Results from χ^2 tests or exact tests for categorical measures and 1-way ANOVAs for numeric measures.

DISCUSSION

Postoperative pain continues to be a major drawback to tonsillectomy surgery. One of the first and most commonly quoted articles in the literature regarding the benefits of coblation tonsillectomy was authored by Temple and Timms in 2001.¹⁰ Their results from a group of 38 children (and in a later study of 10 adults⁴) showed a marked difference in postoperative pain and return to normal diet in favor of coblation. Several prospective, randomized controlled studies have since been published with various results. Back et al¹¹ found no significant difference in pain scores among 40 patients comparing coblation with the cold

dissection/electrocautery hemostasis method. Stoker et al¹² found that coblation tonsillectomy patients appeared to experience a better quality postoperative course than electro-surgery tonsillectomy, in terms of the patient's subjective rating of the experience, postoperative nausea, and the number of physician contacts postoperatively. However, they were unable to show a difference in pain.

Fenton and Long¹³ in Toronto published a retrospective study of 25 cases of ultrasonic tonsillectomy in 2000. They compared these cases to a previous group of cold dissection/Bovie hemostasis tonsillectomies. They believed there may be less postoperative pain in the ultrasonic cases, but their

Table 3
Pairwise comparisons for surgery time using all patients

Pair	Difference (min)	Standard error	P value
Coblation vs electrocautery	7.9	2.3	0.001
Coblation vs ultrasonic	-2.5	2.2	0.257
Electrocautery vs ultrasonic	-10.5	2.2	<0.001

Table 4
Comparison of the 3 groups for mean pain scores

Method	N	Mean	Median	SD	Minimum	Maximum
Coblation	25	3.27	2.90	1.42	1.20	6.90
Electrocautery	19	4.30	4.20	2.10	1.25	7.70
Ultrasonic	17	4.66	4.60	1.67	0.10	6.50

Coblation had the lowest mean pain scores ($P = 0.007$).

data could not show a statistically significant difference. Akural et al¹⁴ compared the ultrasonic tonsillectomy to blunt dissection in 32 patients. Their results showed significantly different pain scores. The ultrasonic method was associated with decreased pain on the day of surgery but increased pain during the second postoperative week. Walker and Syed⁶ reported a prospective study comparing ultrasonic tonsillectomy with electrocautery. Three hundred sixteen patients were randomized into the 2 methods. The ultrasonic scalpel method showed a significantly earlier return to normal activity and diet.

For descriptive purposes, we reported the mean pain scores over a 10-day period. The use of mean pain scores (as opposed to presenting daily comparisons) may seem less convincing to some readers. However, the pain analyses were performed using repeated measures ANOVA, in which all pain scores were analyzed for method, number of days after surgery, and any interaction between method and day number. This allowed us to use every single pain score in the statistical analysis, and not just a mean value, in essence breaking the pain scores down into 10 different time periods. Pain trends over the 10-day period were similar for the 3 methods, and therefore “number of days after surgery” was dropped in the final model.

An important question has been raised as to whether a statistical difference in posttonsillectomy pain scores is enough to really be clinically significant. Collison and Weiner¹⁵ com-

pared the Harmonic Scalpel to cold dissection and snare with suction cautery. They discovered a measurable difference between the 2 methods regarding pain scores. The difference of 0.9 on a 10-point visual analog pain scale at 3 hours after surgery was statistically significant ($P = 0.004$), but they did not believe it was clinically significant based on other studies in the pain literature that have established various minimum differences on visual analog pain scales to be clinically significant. Small differences in the severity of pain on these scales may be statistically significant but have only trivial or no difference in the patient’s experience of pain. Collison referenced several studies in the pain literature that suggest that a minimum mean change on a 10-point visual analog scale of 1.0 in one study¹⁶ and 1.3 in another study¹⁷ was needed to correlate with subjective clinical improvement in pain. The results of our study meet this minimum suggestion for clinical significance (mean difference in pain scores with coblation versus electrocautery of 1.03 and coblation versus Harmonic scalpel of 1.39).

The dropout rate for this study was higher than one might expect. Sixty-one patients returned a completed diary out of 134 patients who agreed to participate, for a completion rate of 46% and a dropout rate of 64%. Six pain diaries were returned only partially completed or without a name and were not included in the results but when included for dropout analysis yield a return rate of 50%. This study was performed at a county hospital (where the author SRC is on

Table 5
Pairwise comparisons of the 3 groups for mean pain scores

Coblation		Electrocautery		Difference	P value
LS mean	SD	LS mean	SD		
2.85	0.29	3.84	0.33	-0.99	0.0236
Coblation		Ultrasonic		Difference	P value
LS mean	SD error	LS mean	SD		
2.85	0.29	4.20	0.35	-1.35	0.0031
Electrocautery		Ultrasonic		Difference	P value
LS mean	SD	LS mean	SD		
3.84	0.33	4.20	0.35	-0.36	0.4455

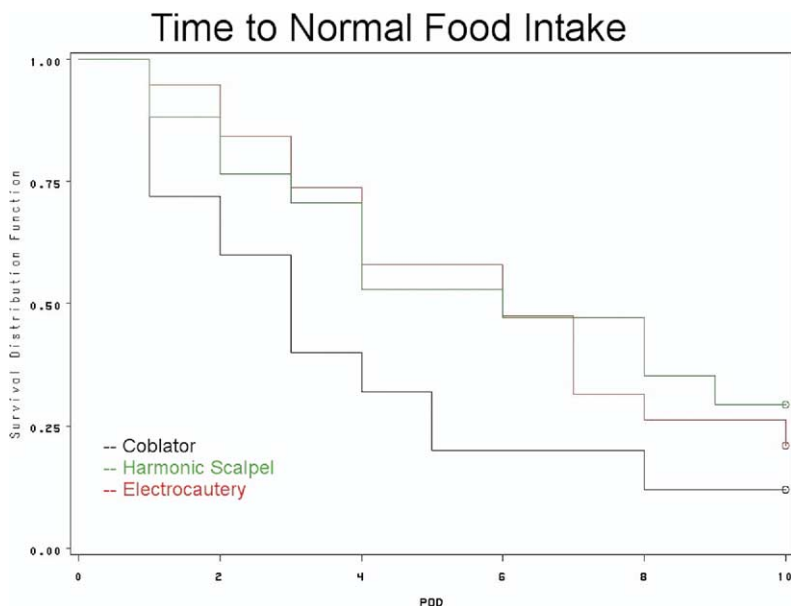


Figure 3 Survival analysis on time to normal food intake. *POD*, postoperative day.

staff) with a largely indigent patient population that is often less compliant than our fully-insured patient population at other hospitals. Although this was a noninvasive study, it did require a significant commitment of completing a diary for 10 days in a row and then submitting it to us. Statistical analysis revealed no difference in demographics between those who completed the study and those who did not.

Our study also evaluated several indirect measures of pain (resumption of a normal diet and normal activity, as well as documenting any telephone calls to the physician). Comparing the 3 groups, we found that patients in the electrocautery group tended to make more postoperative telephone calls to the surgeon's office. Another finding was

that the amount of time to reach a "normal" diet was less for coblation, but this was only marginally significant ($P = 0.08$). In a larger study population, it is possible that these findings would be shown to be more statistically significant.

In our study, the electrocautery method resulted in shorter operative times. We believe that with more experience with either the Coblator or Harmonic Scalpel devices, the surgeons at our institution could equal the operative times of the electrocautery method. Both the Coblator and Harmonic Scalpel have well-designed handheld tips, which are easy to use in the oropharynx, and both dissect tissue quite readily. However, the need for the use of "rescue" electrocautery in 43% of the Harmonic Scalpel cases indi-

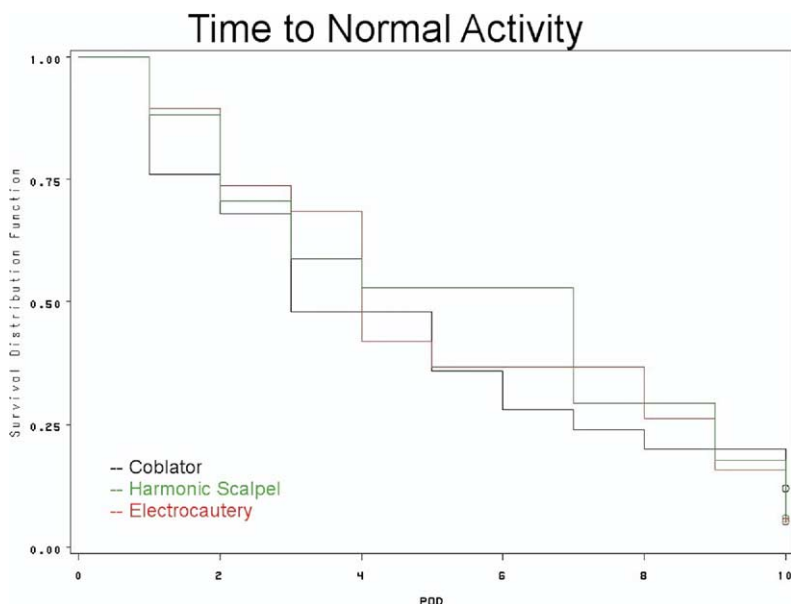


Figure 4 Survival analysis on time to normal activity. *POD*, postoperative day.

cates that this device (at least using the hook tip) does not have the hemostatic ability of the other 2 devices. As one might expect, this difference in hemostatic ability became more apparent in tonsillectomies done for chronic tonsillitis, which tend to have more intraoperative bleeding.

As expected, none of the 3 surgical methods in this study resulted in a pain-free recovery. There are certainly other factors that alter pain aside from the surgical instrument used. Meticulous, gentle surgical technique (staying in the proper surgical plane, gentle handling of tissues, preserving pharyngeal mucosa, and so on) is universally accepted as a significant factor in postoperative pain and healing. But when surgeons use equivalent surgical technique, the instrument used may result in additional benefit to the patient.

CONCLUSION

The current study revealed that coblation tonsillectomy results in decreased postoperative pain compared with electrocautery and Harmonic ultrasonic tonsillectomy. This is based on pain scores analysis and on faster return to normal diet, as well as fewer postoperative telephone calls and visits to the physician.

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