Tonsillectomy in Children: A Five-Factor Analysis Among Three Techniques— Reporting Upon Clinical Results, Anesthesia Time, Surgery Time, Bleeding, and Cost

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Objectives: Improved technology claims better clinical results for adenotonsillectomy (T&A) in children, and promoters of each technique announce many virtues over one another, year after year. However, cost remains one variable that is not always thoroughly addressed. In this study, monopolar cautery (MPC) T&A was compared with coblation (CAT) and molecular resonance (MR) techniques in a pediatric population.

Study Design: Prospective analysis of 96 patients (32 for each surgical modality: MPC, MR, or CAT).

Setting: Tertiary care pediatric institution.

Subjects and Methods: Clinical results, anesthesia and surgery time, bleeding, and cost among these three established techniques were compared. *P*-values of P < .05 were considered significant for all comparisons.

Results: The CAT and MPC had similar operative times (mean 19.2 and 21.1 minutes, respectively, P = NS), whereas the MR group had overall saving of 7.8 minutes in surgery (P < .05). In terms of cost of technology, the cost of the MPC and MR groups was 90.6% and 83.7% less than the CAT group, respectively.

Conclusions: This study demonstrated that MR technique of T&A enabled the surgical team to save a significant amount of time, whereas CAT added substantial costs, compared to MR and standard cautery techniques.

Key Words: Molecular resonance, tonsillectomy, children.

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INTRODUCTION

Tonsillectomy is one of the most frequently performed surgical procedures in children, with an

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estimated 263,000 tonsillectomies performed each year on children in the United States.¹ Under appropriate indications, this procedure yields satisfactory results such as in sleep disorders due to tonsillar hypertrophy or in recurrent tonsillar infections.²

Different tools and techniques are currently utilized with reported good results among surgeons.²⁻⁶ Cold knife tonsillectomy has been the standard technique for many years,^{7,8} but surgical modalities have evolved from cold techniques to electrosurgical ones.^{8,9} In addition, the development of new instruments used for adenotonsillectomy is constant, with an overall feeling to achieve better results in terms of patient's outcome and surgeon's satisfaction.^{3-6,8,9} In recent years, there has been a moving trend toward monopolar cautery (MPC) and coblation tonsillectomy.¹⁰ MPC is one of the most common modality to perform adenotonsillectomy (T&A) because its low cost, speed and ease of use, and its advantage of improved hemostasis.^{7,11} However, MPC generates temperatures as high as 400-600°C,¹² with an increased thermal spread over surrounding tissues resulting in an increased postoperative morbidity.^{11,12} Coblation technology for tonsillectomy (CAT) utilizes dissociation of isotonic saline between coblator electrodes. These sodium ions break molecular bonds between cells with dissection claimed to be at a thermal effect of 45-85°C, thus reducing thermal injury to surrounding tissue.¹³ More recently, molecular resonance (MR) technology has been introduced as a new tool in otolaryngology.^{14,15} MR is generated by means of alternating current (AC), high-frequency electron waves, characterized by a defined major wave at 4 MHz, followed by subsequent well-defined 8, 12, and 16 MHz waves with decreasing amplitudes. Electron energy quanta (EEQs) are thus obtained and calibrated for human tissue. As these EEQs are delivered, cell molecular bonds are placed into resonance-the MR-and subsequent bond breakage occurs, with an increase in temperature as low as 45°C.

However, all these improvements in technology along with claimed better outcomes have a cost, that is not always thoroughly addressed. On this light we

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Fig. 1. Main image shows the bipolar forceps used with the molecular resonance generator. The fine tips allow gentle grasping along with delicate dissection of tissue. Inset shows the EVAC 70 bendable wand for coblation T&A. Simultaneous irrigation and suction provide a clean surgical field, although the large tip offers less precise delivery of energy to tissue.

designed a prospective, randomized, blinded study to investigate the morbidity and associated costs of three established tonsillectomy techniques: MPC, CAT, and MR. We studied the differences in surgical technique, operating room (OR) times, duration of anesthesia, and additional costs of technology, and we evaluated potential savings of one technology over the others.

METHODS

Study Design and Recruitment

This was a prospective, randomized, single-blinded study performed at a tertiary care pediatric institution performed from September 17, 2007 through April 28, 2009 at Vicenza Civil Hospital, Italy. The study protocol was approved by the Ethical Committee of the Institution and followed the CONSORT recommendations.¹⁶ Patients were randomly assigned to each treatment group (MPC, CAT, or MR). Randomization was obtained with a computer-generated table, and the allocated procedures were placed in a numbered container to be opened by the scrub nurse upon preparation of the OR table the day of surgery. The allocation sequence was therefore concealed until surgery took place.

Patients and parents were blinded as to which device was used. One-hundred three patients undergoing tonsillectomy with adenoidectomy were enrolled in this prospective study. Indications for T&A were recurrent tonsillitis and/or airway obstruction caused by adenotonsillar hypertrophy. The study was explained to parents, and written informed consent was obtained for all participants the study. Ninety-six patients accepted to participate and were randomly assigned to receive MCP, CAT, or MR tonsillectomy. If concurrent adenoidectomy was indicated, this was performed via curette in MCP and MR. Hemostasis was obtained with suction cautery in MCP, and MR bipolar cautery in MR. In CAT patients, coblation adenoidectomy was performed. No other concurrent procedure was performed in all enrolled children. Exclusion criteria included bleeding disorders, craniofacial malformations, previous adenotonsillectomy, suspected lymphoma, and mental retardation. Postoperative analysis was performed as elsewhere.¹⁷ In summary, the Wong-Baker FACES pain scale¹⁸ was provided to families to assess pain after surgery. Parents and children were taught how to fill in the questionnaire. Pain was assessed first thing in the morning, and for each day parents recorded information on medication doses, diet, voice, activity, and to circle any complication occurred such as bleeding or behavioral changes. All patients received a follow-up examination at postop day 10, and filled questionnaires were returned to the office.

Surgical Procedure

All patients were operated on under general anesthesia by the same attending surgeon (R.D.E.) who was blinded to type (i.e.,

MPC, CAT, or MR) of surgical procedure until entering the operating room. The involved surgeon had an experience of 12 years in ENT surgery, with at least 8 years of experience on the three surgical modalities of the present study. Patients were operated under general anesthesia and endotracheal intubation, and were placed in the standard supine position with the Boyle-Davis gag and a shoulder roll. All patients were received the same anesthesia protocol and were anesthetized by the same pediatric anesthesiologist and nurse anesthetist. No local anesthesia was applied in either group. All patients received simultaneous removal of adenoids and tonsils, so an adenotonsillectomy was perfomed. No partial, subtotal or intracapsular tonsillectomy was performed. Prior to surgery all patients received an i.v. dose of Amoxicillin/clavulanate (50/mg/kg). If patient proved to be penicillin allergic, then another comparable antibiotic was applied. After induction and prior to surgery, all patients were given a dose of betamethasone (0.1 mg/kg i.v., max. 4 mg) and a rectal acetaminophen loading dose (20 mg/kg).

In the MPC system group, the Force TriverseTM FT 3000 with the EDGETM Safety SleeveTM insulated blade (mod E1544B-4) electrode and the Force TriadTM generator (Valley-lab, Tyco Healthcare Corp., Boulder, CO) were used with a power setting of 10 W. In MPC tonsillectomies the mucosa of the anterior tonsillar pillar was incised with the flat-tipped electrocautery blade, electrically insulated down to the tip in the ValleylabTM mode. The dissection proceeded along the plane of the tonsillar capsule, and suction spot cautery (10 W) was applied to any remaining bleeding sites. Adenoidectomy was performed by means of "cold" curette under direct vision, and suction spot cautery was applied to any remaining bleeding sites (10 W as tonsillectomy).

In CAT, the EVAC 70^{TM} handpiece (ArthrocareENT, Sunnyvale, CA) (Fig. 1, see inset) was applied. The tonsil was gently medialized with a grasping forceps with noncutting edges, and ablation was obtained with the wand skimming the tonsil/anterior pillar interface under continuous saline irrigation, starting at the inferior tonsillar pole and proceeding toward the upper pole, with the wand set at the "coblate 9" setting. Hemostasis, if required, was obtained with the wand set on the "coagulate 5" setting. Adenoidectomy was performed with the same EVAC 70^{TM} bendable wand under mirror vision as well.

In MRT, the tonsil was gently medialized in the same fashion, and the blunt edges of the MR forceps—electrically insulated down to the tip—(nonstick model 2606240) (Fig. 1, main image) were placed in contact with the anterior tonsillar pillar mucosa. The MR generator (Vesalius MC, Telea Engineering, Vicenza, Italy) was set at "Resonance 30," and the dissection proceeded along the plane of the tonsillar capsule, starting at the lower pole, while adenoidectomy was performed by means of "cold" curette under direct vision. Bipolar MR spot cautery was applied to any remaining bleeding sites at the same power level. No patient received local anesthesia infiltration after surgery, and children began an identical pain control protocol of oral acetaminophen (15 mg/kg) three times a day for 4 days, then as needed for 10 days after surgery. All patients were treated on an inpatient basis with an overnight observation. There were no restrictions on food or fluid intake.

Costs (Costs Are Expressed in 2009 U.S. Dollars)

The cost of professional services provided by the anesthesiologist and surgeon were not included. The OR charges were calculated on the time utilized (patient in-patient-out of the OR). Calculation was based on the crude time utilized, and not on 30- or 15-minutes increments as usually happens in private healthcare institutions. These charges covered the use of the OR, surgical equipment, disposable materials utilized. As T&A is a low-complexity case, all T&As incurred in the same rate per minute, as the OR and supplies charges per minute for T&A are identical.

Anesthesia charges for anesthesia time were added the OR costs. These charges were calculated on the costs for the nurse anesthetist, equipment usage, inhalational agents, and nurse service assistance time to the patient in the postanesthesia care unit (PACU). Time was calculated starting with the anesthesiologist's examination of the patient in the preop area, proceeded with patient preparation and entering the OR, duration of the procedure, and ended with the patient out the PACU.

Data Analysis

The three groups were compared for their demographic data, length of surgery, pain levels and doses of pain medication, blood loss, and complications. The differences of categoric variables among the three groups were analyzed with the Fisher's exact test (two tailed), whereas for continuous variables and discrete data with skewed distribution a nonparametric Kruskal-Wallis test was used.

Because there were many possible comparisons, conservative values of P < .05 were considered significant. The data were analyzed using the statistical package SAS, version 9.1 (SAS Institute, Inc., Cary, NC).

RESULTS

Patients Demographics

A total of 96 patients enrolled in this prospective study, and were randomly assigned to receive T&A with standard cautery (MPC = 32), coblator (CAT = 32), and molecular resonance (MR = 32). No patient was lost to follow-up. All 96 patients completed and turned in their diaries.

There was an equal distribution between sex, with an equal distribution among the three groups (Table I). Patient's age range was mainly between 3 and 11 (MPC = 98.1%, CAT = 93.4%, MR = 93.5%). There was no statistical difference among the three groups for age.

Anesthesia and Operative Time

Surgery time was calculated as the time from the mouth gag was placed to removal. The distribution of mean operative time among the three groups is illustrated as in Table I. Mean adenoidectomy time alone

ase of the As T&A same rate annute for	13–18	
	Median	
	Time (min)	
	Tonsillectomy	
dded the ts for the eents, and stanesthe- with the reop area, OR, dura- to out the	Anesthesia	
	Blood loss (cc)	
	Avg pain	
	Avg doses pain drugs	
	Cost (US dollars)	
	Total OR cost	
	Surgical cost	
	Total (surg and OR)	
	OR = operating room.	

Gender Male

Female

Age (years)

<2

3-11

2

was 3.5 minutes in the MPC group, 3.7 in the CAT, and 3.4 in the MR one, and proved to be not significant.

TABLE I.

Patient Demographics, Main Outcome, Cost.

Molecular

resonance

(n = 32)

15

17

0

1

30

1

5.9

13.6

16.1

1.7

1.7

0.22

794

15.60

809.60

Coblation

(n = 32)

16

16

0

1

30

1

6.1

21.1

22.4

5.7

3.7

1.20

1105

200

1305

Monopolar

cautery

(n = 32)

15

17

0

0

31

1

5.6

19.2

25.2

15.0

3.8

1.80

1243

35

1278

In tonsillectomy, the difference between MPC and CAT proved to be not significant, whereas MR time was significantly shorter when compared to MPC and CAT (P < .001 for both comparisons) with an overall time savings of 7.7 minutes on average for the MR group. Anesthesia times were as in Table I. The difference between MPC and CAT was not significant, but MR showed a reduced time when compared with MPC and CAT (P < .05).

Intraoperative and Perioperative Morbidity

There were neither episodes of intraoperative hemorrhage nor postoperative hemorrhage within the first 24 hours of observation after surgery in all groups. Intraoperative blood loss was calculated after tonsillectomy and as collected in the suction canister for the MPC and MR procedures, whereas in CAT, because saline flow is required, a difference in saline plus blood suctioned and saline alone utilized was calculated in the CAT group. Mean estimated blood loss was 15 cc for the MPC group, 5.7 cc for the CAT, 1.7 cc for the MR (Table I). This difference was significant for CAT and MR versus MPC (P < .001), and for MR versus CAT (P < .005).

Postoperative Morbidity

Pain. Mean pain scores were consistently lower for the MR patients when compared both with the CAT and the MPC groups. By the POD 2, no patient in the MR group registered pain greater than 1 in the Wong-Baker



Fig. 2. Distribution of pain scores during the first 10 postoperative days among the three surgical modalities. See text for abbreviations.

FACES pain scale. The average pain scores were 3.8 and 3.7 for the MPC and the CAT group, respectively, whereas was 1.8 in the MR group (P = .001) (Table I). The difference was not significant between the MPC and the CAT groups (Fig. 2).

Pain medication. The difference in pain reflected in different medication requirements for MR patients. Because the pain relief medication was on a fixed regimen up to the POD 4, only PRN medication data were analyzed from POD 5 to 10. The MR group averaged only 0.22 doses per day of acetaminophen compared to the 1.2 for the CAT and 1.8 for the MPC groups (P <.001) (Table I).

Complications. We had no deaths among our patients, and there was no difference in the occurrence of postoperative complications like immediate hemorrhage in all groups. No patient required suture placement for control of hemostasis, but two patients in the MPC group (one 5-year-old boy and one 6-year-old girl) required readmission to control delayed bleeding in the OR (POD 4 and 7, respectively) with use of suction cautery. One patient (5.5-year-old boy) in the CAT group required readmission for the same complication on POD 5. No patient required blood transfusion. Two patients in the MPC group (two 4.5-year-old girls) were readmitted on POD 3 and 4, respectively, for poor fluid intake and dehydration.

Cost

Tonsillectomy is considered a low-complexity case at our institution, and OR charges are billed in a per-minute basis for T&As. The average OR cost is \$2,960 per hour (\$49.33 per minute), taking into account of the disposable items per such low-complexity cases. The expense of the disposable components of the MPC and the coblator was approximately \$35 for the TriVerseTM spatula and \$200 for the Evac 70^{TM} coblator wand. The MR forceps is a reusable tool and its cost is approximately \$500; it is autoclavable and can be resterilized up to 5 to 600 times. Its ideal duration of use for T&A is about 500 times in the present author's experience, and the cost per patient was subsequently extrapolated by dividing the initial cost of the forceps for the number of patients of the present study, yielding a cost of approximately \$15.6 per patient. In terms of cost of technology alone, the cost of the MC and MR groups was 90.6% and 83.7% less than the CAT group, respectively. We calculated the cost of the procedure per patient and obtained the MCP technique at \$1,278, the CAT at \$1,305, and the MR at \$809 (Table I). This analysis revealed the MR technique the least expensive, whereas the MCP and the CAT at comparable costs.

For the purposes of institutional confidentiality, we did not report the actual charges for anesthesia, but we were allowed to report that the anesthesiologist's fee for such low-complexity cases is on a fixed basis for each patient, regardless the time utilized.

DISCUSSION

Tonsillectomy is a common surgical procedure worldwide, and can be associated to significant morbid-ity and even death.^{19,20} For these reasons, tonsillectomy can always be considered a challenge for the pediatric otolaryngologist. Tools and techniques to obtain faster and simpler procedure along with better recovery are always sought by the ENT surgeon. Traditional "cold" techniques (i.e., Sluder guillotine, snare, scalpel) have been gradually replaced by electrosurgical dissection, being electrocautery the most diffused technique.¹⁰ The use of electrocautery minimizes intraoperative blood loss, is fast, and low cost.^{8,10,17} In addition this technology allows the surgeon to move in a virtually bloodless surgical field, so surgery proceeds with optimal vision of surgical planes along with ease. However, electrocautery is claimed to yield a higher postoperative pain with poor oral intake after surgery and subsequent higher risk of dehydration, prolonged hospital stay, and possibility of hospital readmission,^{21,22} even if Wexler⁸ and Akkielah et al.23 demonstrated that monopolar cautery tonsillectomy is similar to cold-dissection technique with regard to pain in children.

Technology in surgery seemed to help T&A with various tools and techniques proposed over years, like lasers, microbipolar scissors, harmonic scalpels, microdebriders, and coblators,^{3-6,10,13,17} and promoters of each technique announce many virtues over one another, year after year. As a matter of fact, in the past 5 there has been a rapid rise in CAT as modality to perform T&As, in large part due to its claimed low-temperature (about 60°C) tissue disintegration.^{10,13} More recently, the MR technology has been introduced in otolaryngology.14,15 The MR generator creates electron energy quanta-EEQs—calibrated for the human tissue, separating cell bonds with reduced thermal injury and no cell death $(<45^{\circ}C)$,^{14,15,20} so dissection is granted not by means of thermal vaporization as occurs in traditional MPC techniques. However, improved technology has additional costs, and in the modern medical practice, concerns over costs have become ubiquitous.

In this prospective, randomized study the rate and degree of intra/post-op hemorrhage of three established surgical technologies for T&A was compared, and evaluation and comparison of the cost of all three modalities was performed. There were no treatment failures in any of the three groups. There was no significant difference in the complication rate, even if two delayed bleedings in the MPC group and one in CAT were observed, whereas no postoperative hemorrhage was observed in the MR group.

There was a significant difference in intraoperative blood loss among MPC, CAT, and MR. CAT and MR yielded 5.7 and 1.7 cc blood loss during surgery, significantly less than 15 cc for the MRT. The reduced thermal spread in the CAT and MR probably caused reduced trauma to the blood vessels into the tonsillar fossa, and the less necrotizing action into tissue had the lesser chance to damage larger vessels coursing into the fossa. The lower temperature generated by MR ($<45^{\circ}C$) versus CAT (up to 60° C) probably played a role in the difference between these two modalities. In addition, the small forceps tips of MR as compared to the relatively larger tip of the CAT wand allowed surgeon to better control the surgical dissection planes, thus achieving better tonsillar capsule identification along with potential bleeding vessels sparing; the grasping action of forceps tips may have added value to this action (Fig. 1). However, although there is a significant difference in intraoperative blood loss, this difference may not be statistically significant due the small amounts of blood encountered.

Improved surgical precision and reduced tissue trauma of MR are reflected in reduced overall surgical times, postoperative pain, and reduced pain control medications requirements in the MR group, compared to MPC and CAT. In addition, the "learning curves" involved with the use of the CAT, MPC, and MRT were similar, so the same level of comfort and proficiency with each of these three instruments was analogous. However, only one surgeon was involved and this might have added limitations to the present study, even if single surgeon user reduces confounding effect of surgical technique from various operators and learning curve. Further studies with multiple surgeons included might clarify on this, in the future.

There does appear to be a cost advantage associated with the MR technique when compared to both the electrocautery and coblator techniques. The primary advantage is the reduced surgical time. This reflects on potential of more cases to be performed if OR charges are calculated on a fixed time frame (i.e., 15- or 30-minute) increments. An additional economic advantage of the MR is the reduced cost for the disposable components over the coblator. The forceps used for the MR procedure are like similar bipolar forceps used in general surgery. They are autoclavable, so they can be easily resterilized, and can be reused up to 5 to 600 times. The only difference is the nonstick feature on forceps tips that yields reduced charring effect and reduced time spent on wiping char off the tips. In this study, the \$500 additional cost has been divided among the number of patients receiving MR adenotonsillectomy (n = 32, \$15.60 charge per case), setting the forceps cost at a level well below \$35 for the TriVerse pencil. However, the complete reuse of the forceps (up to 500 T&As for better results in the author's experience) would have added \$1 only per patient, which would have been much

less than the \$5.60 for the disposable cautery and Teflon tip used on standard bovie cautery T&A.

Based on our findings, there is no significant difference between the cost-per-patient between the coblator and the TriVerse MPC adenotonsillectomies, as the time savings in the CAT patients are overwhelmed by the cost of the coblator wand. However, if a standard MPC pencil would have been applied, the difference between CAT and standard MPC would have been of \$28.10 less per case.

CONCLUSION

This study supports previous reports of efficacy and decreased postoperative morbidity of MR adenotonsillectomy. MR reduced OR time, and reduced intraoperative and postoperative morbidity.

Furthermore, this study demonstrated that MR adenotonsillectomy would enable the Institution to save significant amount of time and cost for children undergoing T&A. However, further studies with larger series will add statistical power to results of the present analysis.

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