

Molecular Resonance vs. Coblation Tonsillectomy in Children

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Background: Quantum molecular resonance coagulation is an innovative technology that uses molecular resonance to cut and coagulate precisely, cleanly, and hemostatically at low tissue temperature levels. This technology offers a new possibility for tonsillectomy.

Objectives: To compare molecular resonance (MRT) with coblation (CAT) devices for pediatric tonsillectomy.

Study Design: Prospective, two-group, randomized trial in a tertiary care pediatric institution. One hundred fifty-seven children for whom tonsillectomy was indicated were randomly assigned to receive MRT (n = 79) or CAT (n = 78). Main outcome measures included intraoperative time, blood loss, postoperative pain, and weight loss. Histopathologic examination was performed on all excised tonsils. Patients, parents, and pathologist were blinded to surgical modality.

Results: Histopathologic evaluation revealed significantly reduced thermal injury with MRT than with CAT (43 microns vs. 126, respectively, $P < .001$), and was statistically associated with reduced muscular, blood vessel, and nerve fiber damage. No intraoperative blood loss was observed in patients following MRT. Statistically significant reduced pain scores were related to the MRT ($P < .002$). In addition, the MRT method showed a quick return to normal diet with even weight gain during the 10-day postoperative period. One child in the CAT group experienced delayed bleeding and required readmission.

Conclusions: Molecular resonance for pediatric tonsillectomy resulted in significantly reduced histopathologic thermal injury and lower pain scores compared with coblation. Further studies are advised to support these data.

Key Words: ● ● ●

Laryngoscope, 000:000–000, 2009

INTRODUCTION

Tonsillectomy is one of the most frequently performed procedures in pediatric otolaryngology practice worldwide.¹ Although considered a simple procedure, tonsillectomy is an operation associated with almost certain morbidity in children and which concerns virtually every pediatric otolaryngologist.² The ideal tonsillectomy procedure should achieve a safe, atraumatic, painless, and bloodless removal of the tonsils. This procedure should also be simple to perform with reliable results among surgeons. The cost of surgical instrumentation and the speed of the procedure should also be considered. Innovations in technology and techniques have been proposed over the years, including lasers,^{3,4} microbipolar cautery,⁵ electrosurgical scissors,⁶ ultrasonic^{7–9} or argon plasma¹⁰ scalpels, coblator,^{11–14} microdebriders,^{15,16} and bipolar radiofrequency.¹⁷ Currently, monopolar cautery (MC) tonsillectomy is one of the most common modalities utilized.^{1,14,17,18} This technique gives the advantages of speed, ease of use, and low intraoperative blood loss. Some believe it to cause greater postoperative pain compared with the classical “cold” sharp dissection, although Wexler demonstrated that MC tonsillectomy in children has little effect on pain and recovery compared with cold dissection.¹⁸

Coblation technology seems to offer improvements in postoperative recovery in patients receiving coblation-assisted tonsillectomy (CAT).^{12,13} The coblator device works by passing a bipolar radiofrequency 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) with minimal thermal damage to surrounding tissues.^{12–14}

Recently, quantum molecular resonance (QMR) technology has been introduced as a new tool in general surgery.^{19,20} QMR is generated by means of alternate current, high-frequency electron waves, characterized by a precisely and well-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 posed to resonance—the QMR—and

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Editor's Note: This Manuscript was accepted for publication January 13, 2009.

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subsequent bond breakage occurs with minimal temperature rising.^{19–21} QMR can be delivered through the tips of standard bipolar forceps or the tip of a regular pencil-like monopolar electrode. The forceps are manipulated as usual and are used to gently grasp and dissect tissues, while the monopolar electrode is used like the standard MC pencil. The first author (R.D.E.) had performed several MR tonsillectomies when the technique was introduced into clinical use. The MR technique seemed to offer several advantages over the CAT method: ease of use, high precision during dissection, minimal tissue damage, and a virtually bloodless surgical field. However, at that time there was only one published report on MR tonsillectomy.²² The aim of this study was to assess recovery after MR tonsillectomy in children compared with CAT and to compare its morbidity with the CAT procedure in two separate groups of pediatric patients. In addition, histopathologic examination was performed to assess depth and pattern of thermal damage on all excised tonsils.

MATERIALS AND METHODS

This is a prospective, single-blinded study, performed from January 5, 2005 to January 9, 2008 at a tertiary care pediatric institution. The study protocol followed the CONSORT guidelines^{23,24} and was approved by the Institutional Review Board (IRB) from the first author's institution's ethics committee.

One hundred fifty-seven pediatric patients undergoing tonsillectomy alone—without adenoidectomy or other procedures—were included in this prospective study in a single-blinded, randomized fashion. All patients enrolled in the study were randomly assigned to receive tonsillectomy with coblator or MR surgical devices. 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. Indications for the procedure were airway obstruction caused by tonsillar hypertrophy and/or recurrent tonsillitis. The study was explained to the parents, and signed informed consent was obtained for all participants. The study participants were asked to complete a 10-day questionnaire after surgery to be returned to the office at the prescheduled 10-day follow-up examination. Parents were also instructed on the meaning of the questions and given the opportunity to ask questions to the attending surgeon. Patients could withdraw from the study at any time.

All procedures were performed by the same attending surgeon (R.D.E.), who was blinded to the procedure until entering the OR. 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. No local anesthesia was applied in either group. After induction and prior to surgery, all patients were given a dose of betamethasone (0.1 mg/kg IV, max. 4 mg) and rectal acetaminophen (20 mg/kg).

In CAT procedures, either the EVAC tonsillectomy and adenoidectomy (T&A) or EVAC 70 handpieces (Arthrocare/ENT, Sunnyvale, CA) were 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.

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—were placed in contact with the anterior tonsillar pillar mucosa. The MR generator (MX 90, 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. Bipolar MR spot cautery was applied to any remaining bleeding sites at the same power level. Blood loss was estimated on the scale of the suction collection canister. No additional preparation for the patient was needed.

All patients started a preoperative intravenous (IV) course of antibiotics (amoxicillin-clavulanate or clindamycin if proven allergy), which was then prescribed for a standard 10-day course per os (PO). No other medication was used after completion of the procedure in any patients. Patients in both the CAT and MRT groups began a standard pain control protocol of three-times-a-day (TID) oral acetaminophen (20 mg/kg) for 4 days, then as needed for 10 days after surgery. All patients were treated with an overnight observation. There were no restrictions on food or fluid intake.

The Wong-Baker FACES pain scale²⁵ was provided to the families to assess pain rate after surgery. Both children and parents were taught, during the preoperative visit and after surgery, how to reliably fill out and circle in the questionnaire. Pain was to be assessed first thing in the morning, prior to drug administration. For each day, parents recorded information on medication, diet, voice, and activity. They were also asked to circle any complication in a list of the possible complications that might occur during the first 10 postoperative days. Identical single-day pages were to be filled; each was to be completed without referring to the previous days' sheets. Every patient had a follow-up examination at day 10 after surgery, and the completed questionnaires were returned to the office.

Histopathologic evaluation was performed in all excised tonsils. Collected specimens were fixed in 4% formalin solution right after removal, embedded in paraffin, and stained with hematoxylin and eosin (H&E). The depth of visible thermal damage from the cut edge in the specimens was measured under a magnification of $\times 100$ using the calibrated lens of the microscope. Even under the same modality (i.e., CAT or MRT) and with the same settings, the depth of thermal damage may vary from site to site in the same specimen, so 20 measurements in randomly selected areas of the specimen were carried out. All measurements were performed by the same pathologist (L.B.), who was unaware of the surgical modality.

Data with discrete and skewed distributions were analyzed with a nonparametric test, the Mann-Whitney U statistic, while parametric tests such as *t* test were applied for data that followed a normal distribution. Because there were many possible comparisons, a conservative significance level of 0.01 was used. The data were analyzed using the statistical package SAS, version 9.1 (SAS Institute Inc., Cary, NC).

RESULTS

A total of 157 tonsillectomies were performed and corresponding questionnaires were administered to the families. All but nine questionnaires (five in the MRT group, four in the CAT group) were returned completed. One hundred forty-eight diaries were subsequently analyzed. Surgical indications were obstructive tonsillar hypertrophy and/or recurrent tonsillar infections. Seventy-nine MRT and 78 CAT were performed over a 36-month period by the same attending surgeon. In each

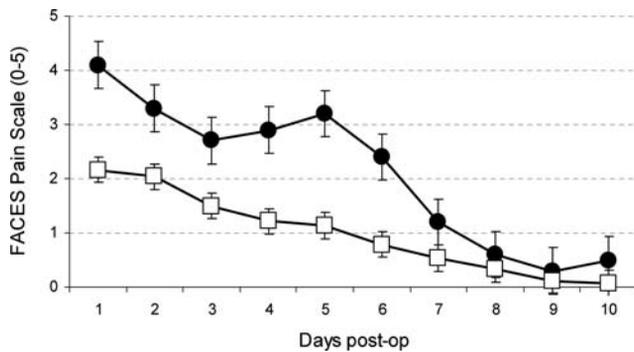


Fig. 1. Course of recovery from postoperative pain over time. Closed circles indicate coblation-assisted technique (CAT) and open squares represent molecular resonance tonsillectomy (MRT). Mean scores on the Wong-Baker FACES scale are shown. There was significantly less pain for MRT than for CAT.

group, the median age was 5 years, with a range of 3 to 11 years.

Mean pain scores were computed for every single patient during the 10 postoperative days. Pain levels were consistently lower for the MRT than for the CAT group (Fig. 1). Even from postoperative day 2, most MR patients had scores of 0 (“No pain”) or 1 (“Hurts a little bit”) on the Wong-Baker FACES pain scale. Because the data had a skewed distribution, having only discrete values of 0, 1, 2, ..., nonparametric tests such as Mann-Whitney U test and χ^2 test were applied. The MRT group averaged only 0.7 day with pain greater than 2, significantly less than the 3.4 days for the CAT group ($P < .001$).

Weight loss is a sign of discomfort after T&A, as consequence of poor food intake due to postoperative pain. We observed even weight gain (mean, 0.7 kg; median, 0.43 kg; range, -0.2 kg–+1.5 kg) in the MRT group, while children in the CAT group experienced a median weight loss of 0.9 kg (mean, 0.8 kg; range, 0.5–1.2 kg).

The difference in pain was also reflected in reduced medication requirements for the MRT group. Because analgesic medication was on a fixed regimen through day 4, only the data for as needed (PRN) medication—days 5 to 10—were analyzed. The MRT group averaged 0.12 doses per day of acetaminophen compared with 1.1 doses for the CAT group ($z = 4.01, P < .0001$). Multiple awakenings during the night are another sign of discomfort. The MRT group averaged 0.85 nights with more than one awakening compared with 3.54 for the other group ($P < .001$).

Voice changes during the recovery period are to be expected. The MRT group was not significantly less affected at the 0.01 level—an average of 1.2 days compared with 0.9 days for the CAT patients ($P = .02$); some voice disturbances may occur when using the MRT as with the CAT method. No significant differences between groups were found for nausea, vomiting, or changes in behavior.

Intraoperative blood loss was calculated for both groups. The blood lost during the procedure was recorded by an independent nurse and entered in the

electronic OR records. In MRT, blood loss was minimal (mean, 3 mL; median, 6 mL; range, 0–12 mL), while CAT tonsillectomy averaged 5 mL blood loss (median, 8 mL; range, 0–19 mL). Despite the reduced blood loss for the MRT group, this finding did not reach statistical significance.

No early hemorrhage occurred during the first 24 hours of hospital stay, and no late hemorrhage was reported by parents during the subsequent 10-day period of observation in the MRT group. Only one child in the CAT group experienced late bleeding (post-op day 6) that required readmission in the OR to be controlled. There were no deaths in our study, and neither dehydration

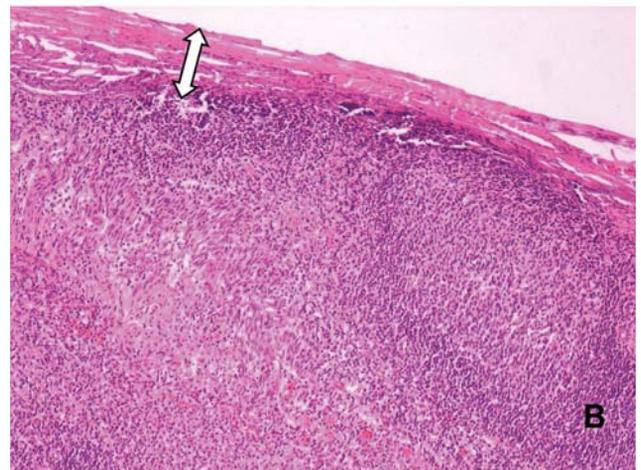
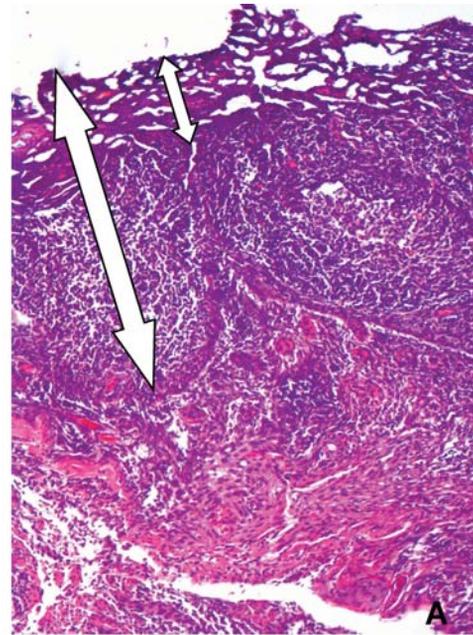


Fig. 2. Collected specimens from CAT (A) and MRT (B) procedures (original magnification $\times 100$, hematoxylin and eosin stain). In the CAT specimen, a deep thermal damage zone is evident (long double white arrow). A more superficial charring zone with tissue vacuolization is visible, a sign of high temperature application on surgical margin (short double white arrow). In the MRT specimen, the depth of thermal damage is markedly reduced (small double white arrow). The overall architecture of the tonsillar tissue is much better preserved.

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nor severe poor food intake serious enough to require prolongation of the hospital stay or readmission were encountered.

F2 Histopathologic evaluation yielded that tonsils from the MRT group showed a mean depth of injury of $43 \pm 9 \mu\text{m}$, while specimens in the CAT group displayed a mean depth of thermal damage of $126 \pm 11 \mu\text{m}$ (Fig. 2A). These differences were statistically significant ($t = 2.71$, $P = .001$). A superficial charring zone was observed in all CAT specimens, a sign of high temperature applied on the surface. Even if the extent of this vacuolization zone was limited (mean, $40 \mu\text{m} \pm 7$), this was not seen in MRT specimens (Fig. 2B). In addition, some degree of muscular tissue was observed to be excised along with the tonsil in the CAT group, while this tissue was not present in specimens collected after MRT procedure.

DISCUSSION

Better recovery after tonsillectomy is a challenge for the pediatric otolaryngologist. For this reason, various tools and techniques are sought by surgeons in the search for an optimal method. Currently, tonsillectomy is mainly performed through cold dissection or bovie cautery.^{14,18} Both techniques present advantages and disadvantages; cold dissection is considered less painful but is associated with longer operative time and higher intraoperative blood loss when compared with bovie cautery. Electrocautery is the most common instrument used for tonsillectomy in the United States,¹⁴ but the tiny bovie tip generates temperatures as high as 400°C to 600°C .^{14,26} Newer instruments such as the coblator device operate at much lower temperatures (from 60°C to 70°C), theoretically causing less thermal trauma and resulting in less pain.¹²⁻¹⁴

AQ3 This prospective study demonstrates that MRT is associated with significantly less postoperative pain than is the CAT technique in a pediatric population. The MR generator allows formation of EEQ calibrated for the human tissue that break molecular cell bindings with minimal thermal damage and no cell death ($<45^\circ\text{C}$).¹⁹⁻²² Dissection is therefore provided not by means of thermal vaporization as occurs while using traditional electrocautery or laser.^{21,22} Deep thermal damage is thus avoided with minimal involvement of nerve ending fibers.

In the CAT technique, conductive saline solution in the gap between the device tip and the tissue is converted into an ionized plasma layer. Where this plasma layer meets the tissue, enough energy to detach molecular bonds is achieved, resulting in molecular dissociation. This effect is considered to be achieved at temperatures of 60°C to 70°C , thus thermal injury to the tissue is minimized.^{11-13,26,27}

This study confirmed the anticipated reduction in histopathologic thermal injury with both CAT and MRT. However, tonsils excised by means of MR technique yielded a shallower thermal damage on average when compared with CAT specimens. This difference was statistically significant, and this reduced thermal effect translated into reduced pain, as MRT seemed to provide

an overall better pain outcome in our study. We observed less pain even from postoperative day 1 in our MR children compared with CAT patients (Fig. 1).

Pain recovery after tonsillectomy is proven to have a nonlinear pattern.^{10,18,28,29} An increase of subjective pain at postoperative day 4 is to be expected, regardless of the technique applied.^{11,12,18} This is due to the detachment of the eschar from the tonsillar bed that usually occurs on postoperative day 4, exposing muscular and nerve fibers previously sealed by the procedure. MRT, however, revealed a linear downsloping pattern during the postoperative period of observation. It is probable that the minimal thermal injury ($<50^\circ\text{C}$)²¹ followed by reduced eschar formation and detachment contributes to this favorable pain outcome.

Weight loss is another sign of pain and discomfort. Some reduction of weight is to be expected after conventional tonsillectomy in children.^{14,18} Recent techniques¹⁶ and new tools^{10,12} seem to reduce postoperative weight loss with different mechanisms (i.e., reduced thermal damage, sealing of nerve fibers). In our series, MRT tonsillectomy provided an overall better weight outcome. We observed even weight gain in our MR patients compared with CAT subjects. This low-temperature mechanism obtained by the EEQ below 50°C may have played a role in the reduced pain scores obtained since the first postoperative day, allowing an adequate and early food intake.

The mechanism of electrocautery coagulation is simple: The heat denatures the proteins and forms the coagulum that coopts and tamponades blood vessels.^{3,4,28,30} With the MR instrument, coagulation is obtained by breaking cell molecular bindings, able to trigger proteic fibrinogen denaturation. The process activates a coagulation physiologic cascade without the need for creating a necrotic plug as in warm techniques.^{19,21} A cold cut is thus obtained, thermal damage is minimal, and cut tissue edges present no slough.^{21,22,31} The surgeon is then allowed to work on a really bloodless field with optimal vision of surgical planes. MR tonsillectomy may proceed rapidly, with minimal blood loss. Intraoperative blood loss in the MR procedure was minimal in our study. MRT yielded a reduced blood loss compared with CAT; however, this difference did not reach statistical significance. Probably, a larger series will provide additional data on this issue. In addition, we observed only a late (after 24 hours) bleed in our patients, but larger series may provide better statistical support.

A brief learning curve is always to be considered when a surgeon becomes accustomed to a new surgical tool. However, we found MRT similar to standard bipolar electrocautery tonsillectomies, as the MC and the MRT forceps are almost identical in shape and way of manipulation. Duration of MRT procedure was not among the parameters to be analyzed in this study, but we found reduced duration of procedure on the MRT group (mean, 9.5 minutes) as compared with on CAT (16.2 minutes).

Cost is always an issue when new technologies are introduced to a well-established and familiar surgical procedure. At the first author's institution, the MR generator, which can be frequently used in other standard

ENT procedures (thyroid surgery, head and neck dissection, neurosurgical and spine procedures, etc.), has a comparable cost to the MC device. The MRT bipolar forceps are reusable (up to 550–580 T&A procedures in the first author's experience), as other standard bipolar forceps. With a cost of about \$570, the additional cost per patient would be of one dollar per case. Other economic benefits are less direct. Reduced pain leads to less medication to be used, and the shorter recovery period means earlier return to normal activities such as school or daycare. Parents can resume work sooner as well. Future studies on cost analysis may evaluate the financial impact of this new procedure.

CONCLUSIONS

This prospective, single-blinded, randomized study of MR tonsillectomy versus CAT procedure has demonstrated a statistically significant improvement in the postoperative recovery in children. MRT can yield decreased postoperative morbidity with reduced postoperative pain, minimal or absent weight loss, and less requirement for pain-relief medication. Furthermore, histopathologic evaluation revealed significantly reduced thermal injury with MRT.

MRT may be an effective alternative method to the standard tonsillectomy procedure in children. Time and larger clinical series will tell whether a few degrees of temperature will have this significant an effect on wound healing after tonsillectomy.

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