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Molecular Resonance Tonsillectomy in Children: Comparative Study over Standard Techniques in an 11-Year Study

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Abstract

Objectives. Learn the molecular resonance (MR) technology for tonsillectomy. An analysis of outcomes of MR compared to standard cold-knife (CK) and monopolar cautery (MPC) for pediatric tonsillectomy offers new possibilities, lowering postoperative morbidity.

Study Design. Eleven-year, prospective, randomized, 3-group trial.

Setting. Tertiary care pediatric institution.

Subjects and Methods. Eight hundred and seventy-three children undergoing adenotonsillectomy were randomly assigned to MR (n = 283), CK (n = 279), or MPC (n = 279) techniques. Outcome measures included intraoperative time, blood loss, postoperative pain, weight loss, and histopathologic examination on excised tonsils.

Results. Histopathologic evaluation revealed reduced thermal injury with MR over MPC (43 μ m vs 186, $P < .001$), statistically associated with reduced muscular, blood vessel, and nerve fiber damage compared to CK ($P < .001$). Blood loss was minimal in MR. Significant reduced pain scores were related to MR ($P < .002$). Two MR, 15 CK, and 12 MPC patients experienced delayed bleeding.

Conclusion. MR for pediatric tonsillectomy resulted in reduced histopathologic thermal injury, lower pain scores, and reduced postoperative morbidity compared with CK and MPC techniques in an 11-year study.

Keywords

tonsillectomy, adenotonsillectomy, molecular resonance, children, prospective trial

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Introduction

Adenotonsillectomy (T&A) is a common procedure in pediatric otolaryngology. An estimated 530,000 patients undergo this procedure annually in the US.^{1–5} T&A is considered a

simple procedure, although every pediatric otolaryngologist bears in mind its associated potential morbidity.^{5–7} Ideally, tonsillectomy should be safe, atraumatic, painless, achieving a bloodless removal of tonsils; procedure should be simple, without associated cost due to technology, with reliable and easily reproducible results. In reality, common postsurgical condition may include pain, fever, and uvular edema.² Complications may include dehydration, postoperative hemorrhage, velopharyngeal insufficiency, nasopharyngeal stenosis, atlantoaxial subluxation (Griesel's syndrome), and psychological trauma.^{2,8–11} Incidence of mortality after T&A is variable and has decreased over time.^{2,9–11} However, excluding anesthetic-related deaths, mortality should be virtually avoidable.^{11,12}

Popular T&A techniques include standard “cold” and electrocautery techniques.² Innovative techniques and emerging technologies are proposed every year, including coblator,^{13–15} microdebriders,^{16,17} ultrasonic scalpel,^{5,17} bipolar radiofrequency,^{5,18} microbipolar cautery,¹⁹ PlasmaKnife,²⁰ and even daVinci robot.²¹ Currently, monopolar cautery (MPC) is the one of the most common modalities,^{3–5,18,20} given the advantages of speed, ease of use, and low intraoperative blood loss. Some believe it to cause greater postoperative pain, compared to cold-knife (CK) dissection, although Wexler demonstrated that MPC tonsillectomy in children has little effect on pain and recovery compared to CK.⁴

Coblation technology seems to offer an improved postoperative recovery after coblation-assisted T&A (CAT)^{13–15} and has raised in frequency of use in the US.¹⁵

Recently, molecular resonance (MR) technology has been introduced as a new surgical tool.^{22,23} MR is generated by means of alternate current, high-frequency electron waves, with a precisely and well-defined major wave at 4 MHz, followed by 8, 12, and 16 MHz waves with decreasing amplitudes. Electron energy quanta (EEQs) are thus

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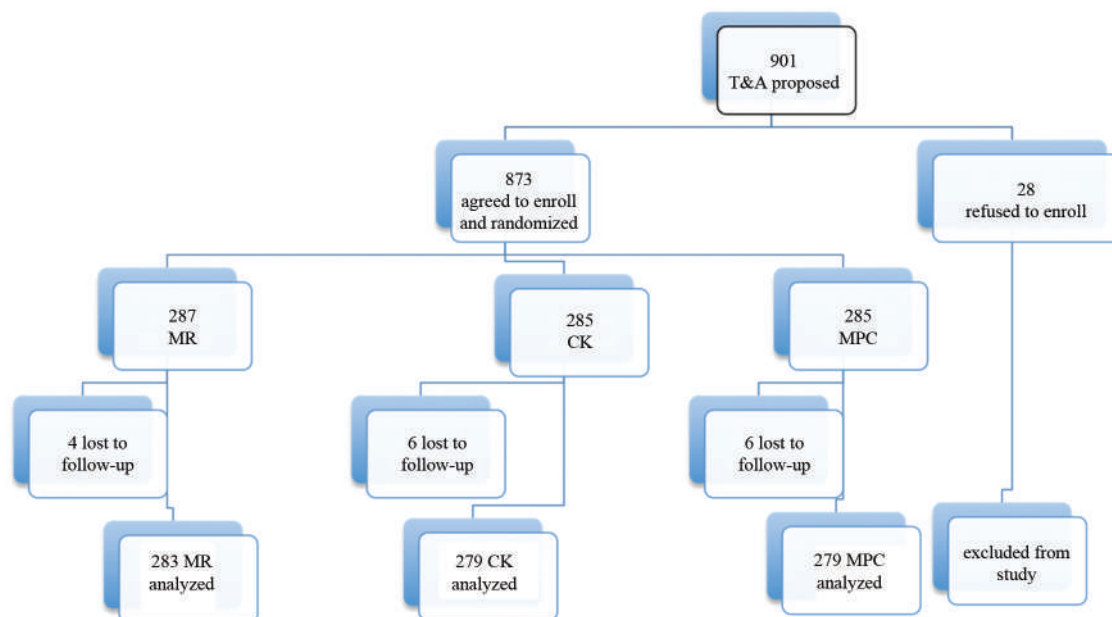


Figure 1. CONSORT randomization diagram. Abbreviations: CK, cold-knife; MPC, monopolar cautery; MR, molecular resonance; T&A, adenotonsillectomy.

obtained and calibrated for human tissue. As these EEQs are delivered, cell molecular bonds are placed into resonance—the MR—and bond breakage occurs with minimal temperature rising.²³⁻²⁵ MR can be delivered through the tips of standard bipolar forceps or the standard pencil-like MPC electrode.

MR technique seemed to offer several advantages over the CK method: ease of use, high-precision dissection, minimal tissue damage, and a virtually bloodless surgical field. MR tonsillectomies revealed reduced charring over the tonsillar bed during surgery when compared to standard MPC technique. However, at that time there was only 1 published report on MR adenoidectomy²⁴ and 2 only on MR tonsillectomy.^{25,26} Aims of this study were: (1) assess recovery after MR tonsillectomy as compared to CK and MPC in children, (2) compare its morbidity with CK and MPC procedures, and (3) perform histopathologic examination to assess depth and pattern of thermal damage on randomized excised tonsils.

Methods

This is a prospective, single-blinded study, performed from September 3, 2002, to October 23, 2013, at a tertiary-care pediatric institution. The study protocol followed the CONSORT guidelines^{27,28} and was approved by the Institutional Review Board (VCZ.H-IRB). Eight hundred seventy-three children undergoing T&A alone were included in this prospective study in a single-blinded, randomized fashion (**Figure 1**). Statistical analysis and sample size were conducted by intention to treat; power, number needed to treat (NNT), number needed to harm (NNH), and estimate hazard ratio were calculated. Sample size was 270 patients for each arm of the study ($z = 1.96$, $NNT = 2$ for MR-arm). Enrolled patients were randomly assigned to

receive CK, MPC, or MR T&A. After computer-generated randomization, the allocated procedures were placed in a numbered container opened by the scrub nurse upon preparation of the OR table the day of surgery. Allocation was concealed until surgery. Patients were blinded as to which device was used. Indications for the procedure were airway obstruction caused by adenotonsillar hypertrophy and/or recurrent tonsillitis. The study was explained to the parents (signed informed consent was obtained for all participants), who were asked to complete a 10-day questionnaire after surgery to be returned at the prescheduled 10-day follow-up examination. Patients could withdraw from the study at any time. The same attending surgeon performed all procedures. Patients were operated under general anesthesia and endotracheal intubation, in the standard supine position with the Boyle-Davis gag and a shoulder roll. No local anesthesia was applied. No partial, subtotal, or intracapsular tonsillectomy was performed. Prior to surgery, all patients were given a dose of dexamethasone (0.1 mg/kg IV, maximum 4 mg), a rectal acetaminophen “loading” dose (20 mg/kg), and a perioperative intravenous (IV) course of antibiotics (Amoxicillin-Clavulanate: 50 mg/kg/day). If patient proved to be penicillin allergic, an appropriate comparable antibiotic was applied. An antibiotic course was prescribed for a standard oral (PO) 10-day regimen. Children began an identical pain control protocol of PO acetaminophen (15 mg/kg) TID for 4 days, then as needed (PRN) for 10 days after surgery. All patients were treated on an inpatient basis with an overnight observation without restrictions on food or fluid intake.

MPC Procedure

The Force Safety Sleeve insulated blade and the Force TX generator (Valleylab, Tyco Healthcare Corp, Boulder,

Colorado) were used with a power setting of 10 W. The mucosa of the anterior tonsillar pillar was incised with the flat-tipped insulated electrode, in the coagulation mode. 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. Suction spot cautery was applied if needed (10 W).

MR Procedure

The tonsil was gently medialized with grasping forceps with noncutting edges, 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 (mod. MX 90, Telea Engineering, Vicenza, Italy) was set at 30, and dissection proceeded along the plane of the tonsillar capsule, starting at the superior pole. MR-bipolar cautery was applied to any remaining bleeding sites with same power level (see Supplemental Video). Adenoidectomy was performed as in MPC patients, with MR-bipolar spot cautery applied if needed.

CK Procedure

The tonsil was gently medialized as previously described; the anterior tonsillar pillar was carefully incised with a No. 11 tip blade, followed by blunt dissection along the tonsillar capsule plane. Suction spot cautery (10 W) was applied if needed. Adenoidectomy was performed as in MPC.

Blood loss was estimated on the scale of the suction collection canister in all cases, separating the collected volumes for tonsillectomy and adenoidectomy. The anesthetist nurse recorded values. Exclusion criteria included: bleeding disorders, craniofacial malformations, previous T&A, suspected malignancy, and mental retardation. Postoperative analysis was performed as elsewhere²⁹ with the Wong-Baker FACES pain scale.^{29,30} Pain was assessed first thing in the morning, and for each day parents recorded information on medication doses, diet, voice, activity and circled any complication that occurred (ie, bleeding). A staff physician assessed any occurring bleeding during the 24-hour admission period. An ENT staff physician upon readmission evaluated any parental reported bleeding from postoperative day (POD) 2 through 10, severe enough to require readmission. All patients received a follow-up examination at POD 10; filled questionnaires were returned to the office.

Histopathologic evaluation was randomly performed in excised tonsils. Specimens were fixed in 4% formalin after removal, embedded in paraffin, and stained with hematoxylin and eosin (H&E). Depth of thermal damage from the cut edge in the specimens was measured under a magnification of $\times 100$ using microscope's calibrated lens. Even under the same modality (CK, MPC, or MR) and with the same settings, the depth of thermal damage may vary in the same specimen; so 20 measurements in randomly selected areas were performed. The same pathologist (unaware of the surgical modality) performed all measurements.

The 3 groups were compared for their demographic data, length of surgery, days of pain, return to diet and activity, and complications. Two types of variables, categorical and continuous, were used in the analysis. The differences of categorical variables among 3 groups were tested by Fisher's exact test (2-tailed), whereas for continuous variables, nonparametric Kruskal-Wallis test was used to determine overall differences. Because there were many possible comparisons, a conservative significance level of .01 was used. Data were analyzed using the statistical package SAS, version 9.1 (SAS Institute Inc, Cary, North Carolina).

Results

T&A indication was proposed in 901 children during the 121-month period of the study. A total of 873 families agreed to participate the study, and 873 T&As were performed, with corresponding questionnaires administered to the families. All but 16 questionnaires (4 in the MR group, 6 in the CK, and 6 in MPC) were returned completed, so 857 completed diaries were returned and analyzed (**Figure 1**). Surgical indications were as in **Table 1**, and 287 MR, 285 MPC, and 285 CK T&As were performed by the same attending surgeon. The median age was 5.5 years for MPC, 5.9 for CK, and 5.7 for MR, respectively (range, 2-18 years). Mean pain scores were computed for every patient during the first 10 PODs. Pain levels were lower for MR T&A than for CK and MPC (**Figure 2**). Even from POD 2, most MR patients had scores of 0 or 1 on the Wong-Baker FACES pain scale. Because the data had a skewed distribution, having only discrete values, nonparametric Kruskal-Wallis test was applied. The MR group averaged only 0.8 day with pain greater than 2, significantly less than the 3.4 days for the MPC and the 3.1 days in the CK groups ($P < .001$). Weight loss is a sign of discomfort after T&A, as consequence of poor food intake due to postoperative pain. We observed even mild weight gain (mean, 0.4 kg; median, 0.43 kg; range, 0.2 kg-1.1 kg) in the MR group. The MPC group experienced a median weight loss of 0.9 kg (mean, 0.8 kg; range, 0.5-1.2 kg), while the CK group had a median weight loss of 0.7 kg (mean 0.6 kg, range 0.4-1.1 kg). The difference in pain also reflected in reduced pain relief medication requirements for the MR group. Because analgesic medication was on a fixed regimen through day 4, only data for PRN medication—POD 5 to 10—were analyzed. The MR group averaged 0.22 doses/day of acetaminophen compared to 1.80 and 1.21 doses for the CK and MPC groups, respectively ($P < .001$). Multiple awakenings during the night are another sign of discomfort. The MR group averaged 0.85 nights with more than 1 awakening compared with 3.54 for the MPC and 2.96 for the CK groups, respectively ($P < .001$). Voice changes during the recovery period are to be expected. The MR group was not significantly less affected (average of 1.1 days compared to 0.9 days for MPC and 0.8 days for CK; $P < .02$). No significant differences among groups were found for nausea, vomiting, or change in behavior. Intraoperative blood loss was calculated for all groups. In MR, blood loss was

Table 1. Patients' Demographic and Main Outcome.

	Monopolar Cautery (n = 285)	Cold Knife (n = 285)	Molecular Resonance (n = 287)
Gender			
Male	130	142	132
Female	155	143	155
Age (years)			
2	4	7	7
3-11	272	271	273
11-18	9	7	7
Median	5.5	5.9	5.7
Indication for adenotonsillectomy (T&A) surgery			
Hypertrophy	228	226	221
Recurrent tonsillar infection	57	59	66
Time (minutes)			
Tonsillectomy	17.4 (SD = 1.8)	21.2 (SD = 2.1)	13.7 (SD = 1.5)
Adenoidectomy	5.1 (SD = 1.2)	5.0 (SD = 1.1)	5.1 (SD = 1.2)
Blood loss (cc)	15.0	25.3	1.8
Average pain	3.8 (SD = 0.7)	3.5 (SD = 0.6)	1.7 (SD = 0.3)
Average doses pain drugs	1.80 (SD = 0.5)	1.21 (SD = 0.4)	0.22 (SD = 0.1)

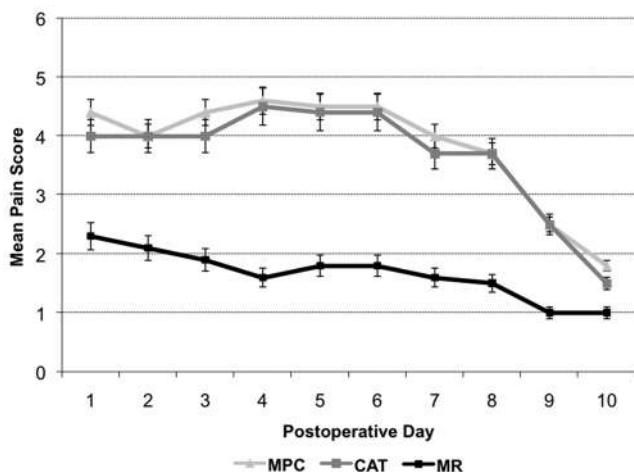


Figure 2. Pain recovery course over time (see text for abbreviations). Mean scores (Wong-Baker FACES scale) are displayed. Pain was significantly less in the MR than in the CK and MPC groups.

minimal (mean, 2.1 mL; median, 1.8 mL; range, 0-5 mL), while CK tonsillectomy averaged 25 mL blood loss (median, 21 mL; range, 0-32 mL) and MPC averaged 15 mL (median, 14, range, 0-21). MR tonsillectomy yielded significant reduced blood loss when compared to CK procedure ($P < .001$). However, this finding did not reach statistical significance ($P < .02$). No early hemorrhage occurred during the first 24 hours of hospital stay in our patients. Delayed, self-limited bleeding was reported by parents in 2 girls (6 years old) in the MR group (POD 5 and 10—no readmission required). Fifteen children (8 males) in the CK group (POD 6) and 12 in the MPC group (6 males—POD 6)

experienced late bleeding that required operating room readmission to be controlled. There were no deaths in our study, and neither dehydration nor poor food intake severe enough to require readmission were observed.

Histopathologic evaluation yielded no thermal damage in CK collected specimens ($n = 82$), as expected (**Figure 3A**). However, some degree of muscular tissue ($112 \pm 13 \mu\text{m}$; $t = 2.55$, $P < .001$) was observed excised with the tonsil, with some blood vessels and small nerve fibers in the surrounding excised tissue. MPC specimens ($n = 86$) displayed a mean depth of thermal damage of $126 \pm 11 \mu\text{m}$ (**Figure 3B**). MR specimens ($n = 91$) revealed a mean depth of injury of $43 \pm 9 \mu\text{m}$ (**Figure 3C**). These differences in thermal spread were statistically significant ($t = 2.71$, $P < .001$). A superficial vacuolization zone was observed in all MPC specimens, sign of high temperature applied on the surface. Even if this zone was limited (mean $40 \mu\text{m} \pm 7 \mu\text{m}$), this was not seen in MR specimens (**Figure 3C**).

Discussion

T&A is commonly performed in pediatric surgery in the US and worldwide,¹⁻⁵ but there is no universal agreement on the surgical method and extent of removal.³¹ The potential for significant morbidity and even death^{2,6,9-11} is inherent in the procedure. Traditional “cold” dissection techniques have largely been replaced with “hot” techniques utilizing MPC to limit intraoperative blood loss.²⁰ MPC is burdened with its own complications of prolonged pain, poor oral intake, risk of dehydration, prolonged hospital stay, and possibility of hospital readmission,^{12,22} although several authors^{4,31} demonstrated that MPC is similar to CK T&A with regard to pain in children. Modifications in

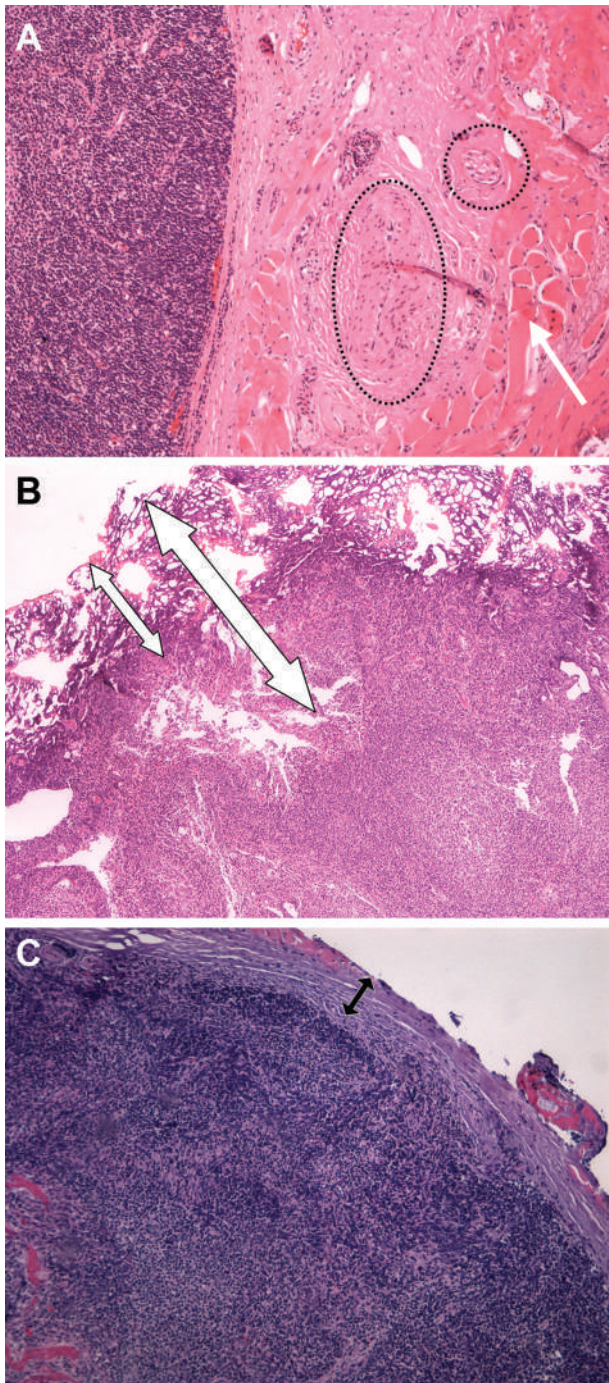


Figure 3. Specimens from (A) cold knife (CK), (B) monopolar cautery (MPC), and (C) molecular resonance (MR) tonsillectomies ($\times 100$, hematoxylin and eosin). (A) Small blood vessel (large oval), nerve fiber (small circle), and muscular tissue are evident (white single arrow). (B) Deep thermal damage zone is evident (long double white arrow). A more superficial charring zone with vacuolization is noticeable (small double white arrow). (C) Depth of thermal damage is reduced (small double black arrow). Tonsillar tissue architecture is better maintained.

tonsillectomy technique have been proposed in recent times. Goals of modifications (ie, intracapsular tonsillectomy, tonsillotomy) aimed to decrease the morbidity and surgical

operative time. Technology offered help with “new” tools over years (ie, lasers, coblator),^{3-6,15,11,18} with rapid rise in CAT²⁰ in the past 3 years, mainly due to its claimed low-temperature tissue disintegration (60°C).¹³⁻¹⁵ Recently, MR technology has been introduced in otolaryngology.^{22,23} MR generator creates EEQs calibrated for the human tissue, separating cell bonds with reduced thermal injury (45°C), so dissection is granted not by thermal vaporization as in traditional MPC techniques.²²⁻²⁶ In our series, there was a significant difference in intraoperative blood loss among MPC, CK, and MR. However, an intraoperative blood loss of 2 mL versus 15 to 20 mL has minimal clinical effect on patient morbidity or postoperative recovery.

The reduced MR thermal spread probably caused reduced trauma to blood vessels into the tonsillar fossa, and the less necrotizing action had the lesser chance to damage larger vessels coursing into the fossa. The lower temperature generated by MR (45°C) versus MPC (4°C – 600°C) probably played a role between these 2 “hot” modalities. Furthermore, the bipolar forceps tips allowed the surgeon to better control the dissection planes, achieving better tonsillar capsule identification and vessels sparing. Chang and Hah²⁶ reported no difference in pain between MR and standard bipolar cautery. Probably, 2 different techniques placed on the same child were a possible confounding factor, as children are less reliable on reporting the exact pain level on the exact site of surgery, especially if dealing with the oral cavity. In addition, the magnitude of delay of recovery could not be exactly determined because every child has to deal with different types of tonsillectomy wound to heal. Additional bias is the standard cautery devices utilized in these studies (monopolar—the present—vs bipolar²⁶). Further multicenter and multisurgeon studies with large cohorts and similar cautery devices will clarify these issues.

The present study revealed the reduction in histopathologic thermal injury with MR. Tonsils excised by means of MR yielded a shallower thermal damage when compared to MPC specimens. This difference was significant, and this reduced thermal effect translated into reduced pain, as MR seemed to provide an overall better pain outcome in our study. CK specimens revealed no thermal damage, although the amount of tissue surrounding the excised tonsils was deeper as compared to the thermal damage of MR specimens. Moreover, we observed small blood vessels and small nerve fibers in the surrounding excised tissue. This may explain the lesser blood loss and the more favorable postoperative pain course in MR patients. We observed less pain even from POD 1 in our MR children compared with MPC and CK patients (**Figure 1**). Pain recovery after tonsillectomy is proven to have a nonlinear pattern,^{4,13,14,32-34} and an increase of subjective pain at POD 4 is to be expected, regardless of the technique.^{4,13,32-34} This is due to the detachment of eschar from the tonsillar fossa (usually POD 4-5). MR revealed a linear downsloping pattern during the postoperative period of observation. Probably, the minimal thermal injury²³ and the reduced depth of eschar formation contributed to this favorable pain outcome.

Improved surgical precision and reduced tissue trauma of MR are reflected in reduced overall postoperative morbidity in the MR group.

The “learning curves” involved with the use of the CK, MPC, and MR were similar, so comfort and proficiency was analogous. However, only 1 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. The most significant limitation of this study is the potential bias relating to the single surgeon; multi-institutional, or at the very least, multisurgeon studies are necessary in the future to confirm these results.

Cost is always an issue when new technologies are introduced to a well-established and familiar surgical procedure. At the author’s institution, the MR generator, frequently used in other ENT and general surgery procedures (thyroid, neck dissection, neurosurgical, and spine procedures), has comparable cost to MPC device. MR-bipolar forceps are reusable (up to 550-580 T&As), as are other standard bipolar forceps. With a cost of about \$550, the additional cost per patient would be \$1 per case.

Conclusion

This prospective study on MR versus CK and MPC T&As demonstrated a significantly improved postoperative recovery in children after MR T&A. MR can yield reduced intraoperative blood loss, reduced postoperative pain, and minimal weight loss, with less requirements for pain control medications. Histopathologic examination demonstrated reduced thermal injury with MR tonsillectomy. Larger clinical studies will demonstrate if this reduced thermal effect will be significant in wound healing after MR T&A.

Author Contributions

Riccardo D’Eredità, conception and design, acquisition of data, analysis and interpretation of data, manuscript drafting and review, final approval of manuscript version.

Disclosures

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Supplemental Material

Additional supporting information may be found at <http://otojournal.org/supplemental>.

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