Postoperative Morbidity and Histopathologic Characteristics of Tonsillar Tissue Following Coblation Tonsillectomy in Children: A Prospective Randomized Single-Blind Study

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ABSTRACT

The aim of this prospective randomized single blind study was to determine the depth of thermal damage to tonsillar tissue due to coblation, and to compare it with thermal damage to tonsillar tissue following conventional tonsillectomy; to correlate the depth of thermal damage to tonsillar tissue with the parameters of postoperative morbidity, to compare intraoperative blood loss, postoperative pain severity, time to resuming normal physical activity, and incidence of postoperative bleeding between two groups of tonsillectomized children aged up to 16 years. 72 children aged 3–16 years scheduled for tonsillectomy randomly assigned into two groups submitted either to conventional tonsillectomy with bipolar diathermy coagulation or to coblation tonsillectomy, with a 14-day follow up.Statistically significant differences were observed in the depth of thermal damage to tonsillar tissue (p<0.001), intraoperative blood loss (p<0.004), in postoperative pain severity (p<0.05) and in time to resuming normal physical activity between the two groups (p<0.001). There was no case of reactionary or secondary bleeding in either group. In this paper for the first time we have correlated postoperative morbidity.

Key words: tonsillectomy, radiofrequency, coblation, blunt dissection, postoperative bleeding, pain

Introduction

Tonsillectomy is one of the most common operative procedures in childhood¹. At the ENT Department, Mayo Clinic, Rochester, Minnesota, USA, 4662 tonsillectomies were performed during a 12-year period; at the University Department of ENT, Head and Neck Surgery, Split University Hospital, Split, Croatia, 3619 tonsillectomies were performed during a four-year period². Tonsillectomy has been practiced for more than 2000 years (Celsus, 30 B.C.)^{1,3}. Historically, opinion concerning the indications for tonsillectomy has changed from one extreme to another. According to one opinion, tonsills should be removed in every child, thus preventing tonsillar disease and all potential associated sequele. Another school of thought advocates that tonsils should not be removed because they have a role to play in immunity, irrespective of their condition³. Although tonsillectomy may be perceived as a straightforward procedure, it is associated with considerable postoperative morbidity including severe postoperative pain and both reactionary (<24 h) and secondary (>24 h) postoperative hemorrhage¹. A study conducted under the auspices of the American Academy of Otorhinolaryngology and Head and Neck Surgery (AAO-HNS) has pointed to pain being the major problem and concern in more than 90% of tonsillectomized children's parents⁴. Faster post-tonsillectomy recovery with reduced postoperative morbidity is a challenge to every pediatric ENT specialist^{5,6}. A number of operative methods have been investigated in terms of these issues, however, none yielding satisfactory results in all respects^{5,7,8}. In contrast to the majority of operative

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procedures associated with primary wound closure, tonsillectomy leaves an open wound that undergoes healing by second intention, thus opening the possibility of postoperative complications. Pain is the result of lesions of the mucosa, muscle and nerve endings of the $9^{\rm th}$ and $10^{\rm th}$ cranial nerves, leading to inflammation and spasm of the pharyngeal musculature, which in turn entails ischemia and intensifies the sense of pain. Pain completely resolves only after 14–21 days, when full re-epithelization has occurred ^{7,9}.

Monopolar diathermy is one of the most widely used method of tonsillectomy worldwide, which can significantly reduce the operative time and intraoperative hemorrhage by its haemostatic effect but does not contribute to the reduction of postoperative pain and time to complete wound healing ^{5,7,10–13}. Coblation surgery, as one of different types of radiofrequency surgery, is a novel surgical technique that was first introduced in ENT practice in late 1990s for the operation of head and neck soft tissues ^{7,14}. Radiofrequency was already recognized as very potent surgical tool in modern cardiology and abdominal surgery^{15,16}.In contrast to diathermy, characterized by direct lead - tissue contact producing local tissue temperature of up to 400 to 600 °C, coblation will not cause tissue temperature to exceed 60 to 70 °C, as there is a space filled with saline between the ending tip and the tissue. It is in this plasma field that the ions responsible for destruction of intercellular bonds in tissues undergo dissociation. The principle action of radiofrequency energy is based on molecular dissociation rather than vaporization, as in diathermy^{1,10,11,17}. Thermal damage to the surrounding tissues is minimal owing to the relatively low temperatures developed during the procedure, coupled with continuous irrigation of the operative field with cold saline^{1,8,11,18}. Similar histopathologic tissue changes are observed with the use of harmonic scalpel¹⁹. The operative technique of coblation tonsillectomy is based on the standard technique of dissection in the relatively bloodless tonsillo-muscular plane, with the tonsillectomy hand piece tip directed toward the tonsil in order to avoid damage to tonsillar arches and tonsillar fossa. An operative microscope can also be employed for better precision, recording and teaching^{1,8}.

The aim of the present study was to determine the depth of thermal damage to tonsillar tissue due to radiofrequency ablation, and to compare it with thermal damage to tonsillar tissue following conventional tonsillectomy; to correlate the depth of thermal damage to tonsillar tissue with the parameters of postoperative morbidity; to compare intraoperative blood loss, postoperative pain severity, time to resuming normal physical activity, and incidence of postoperative bleeding between two groups of tonsillectomized children aged up to 16 years.

Subjects and Methods

This single-blind, prospective, randomized study included 72 children aged 3–16 years, scheduled for tonsillectomy at the University Department of ENT, Head and Neck Surgery, Split University Hospital, Split, Croatia. Inclusion criteria were age 3-16 years and indications for tonsillectomy according to the guidelines issued by the Ministry of Health and Social Welfare of the Republic of Croatia (upper airway obstruction, recurrent tonsillitis -7 inflammations per one year, or 5 inflammations per year in 2 subsequent years, or 3 inflammations per year in 3 subsequent years, recurrent peritonsillar abscess, obstructive sleep apnea and suspected malignant tonsillar disease). Exclusion criteria were absolute and relative contraindications for operative procedure (e.g., acute infection of upper airways, coagulation disorders (hemophilia), leukemia, uncontrolled diabetes mellitus, active tuberculosis, agranulocytosis, etc.). Randomization was done by use of computer generated random number which used for selection children and separate them into groups from large ENT database containing children assigned for tonsillectomy by 2nd author. Children's parents did not know what specific procedure (of two possible) was perform on their child. Study subjects were divided into two groups: one group operated on by the radiofrequency method using the ArthroCare Evac 70 Arthro Wand (ArthroCare Corp., Sunnyvale, CA, USA), and the control group undergoing conventional cold steel tonsillectomy with bipolar diathermy coagulation using reusable surgical accessories. All patients were operated on University Department of ENT, Head and Neck Surgery, Split University Hospital by the same surgeon (first author) and anesthesia was administered by the same anesthesiologist by use of a Primus device (Draeger Medical AG&Co. KG, Lübeck, Germany). Inhalational anesthesia were administrated (NO, O₂ and sevofluran) followed by intravenous boluses of fentanyl according body mass (kg). All children were discharged from hospital on the first postoperative day with the same instructions for the use of analgesics and diet.

Outcome measures

The primary outcome was depth of thermal damage to tonsillar tissue. Histopathologic examination of the operated tonsils was performed at the University Department of Pathology, Forensic Medicine and Cytology, Split University Hospital, and included determination of the depth of thermal tissue damage. The entire operatively removed tonsil was cut longitudinally, fixed for 24 h in 4% buffered formalin, and then embedded in paraffin. Paraffin blocks were cut in 3- to 5-um sections and stained by standard hematoxylin-eosin. Each microscopic preparation was examined for the width of thermal lesion at three sites by use of an Olympus BX41 light microscope and computer software for image analysis (Program Analysis, Soft Image System GmbH, Münster, Germany). The width of thermal lesion corresponds to the area of tonsillar tissue destruction caused by heat and is measured from the preparation surface to the border of normal tonsillar tissue. We assumed that the damage to the tonsil is proportional to the damage of the underlying bed of tonsillar fossa. Taking a specimen from the tonsillar fossa cutting the normal tissue would be highly unethical.

Secondary outcome were: intraoperative blood loss, postoperative pain severity, time to resuming normal physical activity, and incidence of postoperative bleeding. The intraoperative blood loss was measured by volume of suction aspirate. Parents were given a questionnaire with precise instructions in the form of two tables: one to enter data on the use of analgesics on demand for 14 days after the surgery; and another one to enter the postoperative day of the child's resuming normal preoperative physical activity (normal eating, drinking, sleeping, playing). A 14-day follow up period was chosen because postoperative bleeding as an operative complication is not expected to occur beyond this time. The rate of postoperative hemorrhage was monitored by use of data on this operative complication in the admission log-book kept at University Department of ENT, Head and Neck Surgery, Split University Hospital, backed up by information from parents at two- week follow up.

The study was approved by the Split University Hospital Medical Ethics Committee.

Statistics

A sample size of 18 patients per group was calculated for 5 % of statistical significance to reveal a clinically significant and expected 100% difference in blood loss between two operation techniques. In our study the mean intraoperative blood loss of children operated by blunt dissection was more then 100% higher than in the group of children operated by coblation tonsillectomy. The power calculation after t-test on this mean difference and sample size was 1. Statistical analysis was carried out using Statistica 7.1 (StatSoft Inc, USA). χ^2 test was used for statistical evaluation of differences between two groups of patients in descriptive characteristics. Mann-Whitney U test was used for statistical evaluation of the differences in analgesics consumption and recovery speed with p<0.05 accepted as statistically significant. T-test for independent samples was used to evaluate differences in intraoperative blood loss and depth of the thermal damage. We computed the Pearson's product-moment correlation for analysis of correlation between the depth of the thermal damage and postoperative analgesics consuption.

All statistical values were considered significant at the p level of 0.05.

Results

We enrolled 102 eligible participants in our study. Thirteen were excluded (three because they did not meet inclusion criteria and 10 refused to participate). There were 89 patients randomly assigned to coblation tonsillectomy (n=45) and blunt dissection with bipolar diathermy hemostasis (n=44). In coblation tonsillectomy group 44 patients received allocated intervention, and one did not due to fever and vomiting just before the pro-

 TABLE 1

 COMPARISON OF POSTOPERATIVE MORBIDITY PARAMETERS

 AFTER BLUNT DISSECTION AND COBLATION TONSILLECTOMY

 MEASURED DURING THE STUDY (MEDIAN-RANGE)

Main outcome measures	CB	BD	p-value*
Number of analgesic applications	8 (0–21)	10 (1-20)	0.014
Days on analgesics	4 (0–9)	5 (1-8)	0.043
Return to normal activity	2(1-7)	4 (1–9)	< 0.001
Postoperative hemorrhage	0	0	

*Mann-Whitney U test

CB - coblation tonsillectomy, BT - blunt dissection

cedure. In blunt dissection tonsillectomy group all patients received allocated intervention.

In each group eight patients were lost to follow-up. Thirty-six patients in each group completed the study protocol (Figure 1).

Between February and December 2006. thirty-six patients were operated on by the conventional method of blunt dissection with bipolar diathermy homeostasis, and thirty-six patients by coblation technique. Forty-one (57 %) patients were male and 31 (43%) were female. The mean age for both groups was 6 (range 3–15 for conventional method group; range 3–14 for coblation group). There is no statistically significant difference between the groups by age (p=0.891) or gender (p=0.811).

The mean depth of thermal damage to tonsillar tissue was $428.58 \pm 47.4 \,\mu$ m and $841.17 \pm 39.7 \,\mu$ m in the tonsils operated on by coblation and by conventional method with bipolar diathermy hemostasis, respectively, yielding a statistically significant difference (t= - 40,1; p<0.001, Figure 2A, B, 3). The mean intraoperative blood loss was



Fig. 1. Flow-chart of a trial of comparison coblation tonsillectomy and blunt dissection tonsillectomy.



Fig. 2. Depth of thermal damage to tonsillar tissue following coblation (a) and conventional tonsillectomy with bipolar diathermy coagulation (b) (H-E, x400).

 10.83 ± 3.41 mL in the group of children operated on by coblation tonsillectomy and 27.08 ± 13.22 mL in the group of children operated on by blunt dissection. The difference was statistically significant (t = -7.14; p<0.001. Figure 4). Children operated on by coblation technique faster resumed normal physical activities in 2 (1–7) *vs.* 4 (1–9) days which is statistically significant (Z=-4.9; p<0.001).



Fig. 3. Depth of thermal damage to tonsillar tissue following coblation (CB) and conventional tonsillectomy with bipolar diathermy coagulation (BD).



Fig. 4. Intraoperative blood loss during coblation (CB) and conventional tonsillectomy with bipolar diathermy coagulation (BD).

The children operated on by coblation used analgesics for a mean of 4 (range 0–9) days postoperatively with 8 (range 0–21) applications per child, and those operated on by the conventional method for a mean of 5 (range 1–8) days postoperatively with 10 (range 1–20) applications per child which was statistically significant (p<0.05, Table 1). There were not instances of early or late postoperative bleeding or infection in either group.

Correlation analysis showed positive association (r=0.28, p=0.017) between the depth of the thermal damage and less postoperative analgesics consuption (Figure 5).

Discussion

In our study, the depth of radiofrequency thermal damage to tonsillar tissue was found to be significantly lower as compared with tonsillar tissue lesion in case of the conventional method with bipolar diathermy coagu-



Fig. 5. Positive correlation between the depth of the thermal damage and number of analgesic application ((r=0.28, p=0.017)).

lation, which is consistent with reports from previous animal models¹⁸. Results in terms of clinical outcome following coblation tonsillectomy vary among different studies²⁰. Unfavorable results primarily refer to an increased frequency of postoperative bleeding. In present study there was no episode of postoperative bleeding in either group. In 2004, the National Postoperative Tonsillectomy Audit reported the prevalence of hemorrhage with »warm« techniques (diathermy and coblation) to be threefold that in »cold« dissection (blunt dissection, scissors or scalpel dissection)¹⁴. Similar results have also been reported by Lee et al found increased rates of hemorrhage when comparing diathermy with cold dissection tonsillectomy²¹. According to Noon and Hargreaves in a small study, coblation tonsillectomy considerably increases the rate of postoperative hemorrhage in adults (22.2 vs. 3.4% in control group)²². In another small series, Windfuhr et al report a higher rate of postoperative hemorrhage in children operated on by the coblation technique (7.9% vs. 0.8% in control group)²³. In contrast to these reports, Divi and Benninger, and Philpott et al. have shown that there was no difference in the rate of postoperative bleeding between patients operated on by coblation and non-coblation techniques in two larger studies^{24,25}. Timms and Temple recorded no case of postoperative bleeding among adults and children operated on by the technique of radiofrequency in their original studies on post-operative pain^{8,10} and in a large study Bellosso et al. showed that the technique of coblation significantly reduced the rate of postoperative bleeding, especially in the pediatric population (0.95% vs. 4.77% in control group)¹.

As in our study, almost all studies agreed that coblation tonsillectomy causes less postoperative pain and faster resuming normal physical activities. As technique pioneers, Timms and Temple, as well as Hasan et al. found that children and adults operated on by coblation suffered statistically significantly less postoperative pain and considerably faster resumption of normal dietary habits^{10,26}. Stoker *et al.* demonstrated the radiofrequency tonsillectomy to be superior to diathermy in terms of reduced postoperative pain and local edema, and faster wound healing¹¹. The same conclusions were reached by Chang¹². Hall et al. also demonstrated a significantly

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Conclusion

Our results support the hypothesis of lower postoperative morbidity after coblation tonsillectomy when compared with the method of blunt dissection tonsillectomy with bipolar diathermy haemostasis.

The smaller depth of thermal tonsillar tissue damage with coblation in comparison to conventional tonsillectomy with bipolar diathermy coagulation, published for the first time in the present study, offers clear correlation between reduced postoperative morbidity with less damage to the adjacent tissues.

The method of coblation tonsillectomy resulted in lower intraoperative blood loss, which is a particular advantage in children, especially those with haemostasis disorders, anaemia and children under to 3 years old. The considerable cost of the disposable coblation wands is a factor to consider, especially in transition countries such as Croatia. However, the 1:50000 risk of vCJD transmission estimated with the use of reusable instruments, helps mitigate against this, as does the possible reduction in absence from work or school⁸.

The results of our study have encouraged us to continue using coblation tonsillectomy, as it proved superior to the conventional tonsillectomy with bipolar diathermy coagulation in all parameters investigated. We do expect even better results when coblation tonsillectomy become the part of surgical routine as well as cold dissection tonsillectomy.

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POSLIJEOPERACIJSKI MORBIDITET I HISTOPATOLOŠKE KARAKTERISTIKE TONZILARNOG TKIVA NAKON KOBLACIJSKE TONZILEKTOMIJE U DJECE: PROSPEKTIVNA RANDOMIZIRANA JEDNOSTRUKO-SLIJEPA STUDIJA

SAŽETAK

Cilj ove prospektivne randomizirane jednostruko-slijepe studije bio je utvrditi dubinu termičkog oštećenja tkiva tonzile koblacijom u odnosu na termičko oštećenje nakon klasične tonzilektomije; korelirati dubinu termičkog oštećenja tonzilarnog tkiva s parametrima poslijeoperacijskog morbiditeta, usporediti intraoperacijski gubitak krvi, poslijeoperacijski intenzitet bola, vrijeme povratka na normalnu tjelesnu aktivnost, i incidenciju poslijeoperacijskog krvarenja između dviju skupina tonzilektomirane djece u dobi od 3–16 godina. 72 djece predviđeno za tonzilektomiju randomizirano u dvije skupine tonzilektomirano je klasičnom tonzilektomijom s bipolarnom dijatermijskom koagulacijom ili koblacijskom tonzilektomijom. Follow-up je bio 14 dana. Statistički značajna razlika utvrđena je u dubini termičkog oštećenja tkiva tonzile (p<0,001), intraoperacijskom gubitku krvi (p<0,004), u poslijeoperacijskom intenzitetu boli (p<0,05) i brzini vraćanja na normalnu tjelesnu aktivnost (p<0,001) između ispitivanih skupina. U nijednoj skupini nije bilo slučajeva ranog ili kasnog poslijeoperacijskog krvarenja. U ovom istraživanju po prvi puta je dokazana korelacija između poslijeoperacijskog morbiditeta i termičkog oštećenja tkiva: manje termičko oštećenje povezano je s manjim poslijeoperacijskim morbiditetom.

Appendix: Questionnaire for the Parents

	1.day	2.day	3.day	4.day	5.day	6.day	7.day	8.day	9.day	10.day	11.day	12.day	13.day	14.day
Ibuprofen														
Dalsy														
Neofen														
Paracetamo	1													
Plicet														
Lupocet														
Lekadol														
Panadol														
2. »GETTING BACK TO NORMAL PHYSICAL ACTIVITY«														
1.dav 2.	dav	3.dav	4.dav	5.dav	6.dav	7.dav	8 dav	9.da	v 10.	dav 11	dav 1	2 dav	3.dav	14 day

1. ANALGESICS CONSUMPTION AFTER PROCEDURE