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Comparison of Coblation Tonsillectomy and Electrocautery Tonsillectomy in Pediatric Patients

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by

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TAU Committee

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Invitation.

This document was developed to assist decision-making in the McGill University Health Centre. All are welcome to make use of it. However, to help us estimate its impact, it would be deeply appreciated if potential users could inform us whether it has influenced policy decisions in any way.

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GLOSSARY

CI	Confidence Interval
CRD	Centre for Reviews and Dissemination
INAHTA	International Network of Agencies for Health Technology Assessment
CADTH	Canadian Agency for Drug and Technologies in Health
MUHC	McGill University Health Centre
MCH	Montréal Children's Hospital
NICE	National Institute for Health and Clinical Excellence
OSA	Obstructive Sleep Apnea
RCT	Randomized Controlled Trials
T&A	Tonsillectomy and Adenoidectomy
TAU	Technology Assessment Unit

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EXECUTIVE SUMMARY

Objective: To compare coblation tonsillectomy to electrocautery tonsillectomy, the procedure commonly used at the MUHC (McGill University Health Centre).

Methods: A systematic literature review was carried out to identify randomized controlled trials comparing coblation to electrocautery tonsillectomy among children. Data on duration of surgery, blood loss during surgery, post-operative pain, time to return to a normal diet or normal activity level, intra- or post-surgical complications and results of tonsillar tissue examination were extracted. For outcomes measured in a comparable manner, meta-analysis was used to pool results across studies. In addition the budget impact of coblation was estimated.

Results: Four studies met our inclusion criteria. Their quality ranged from 3-5 on the 5 point Jadad scale. Two studies had small sample size(<40), and three had poor rates of follow-up (~50%). With coblation; average operation time (3 studies) was 5.18 minutes longer (95% confidence interval (CI): 0.39, 9.97 minutes); average intra-operative blood loss (2 studies) was 9.83 ml greater (95% CI: 0.29-19.38 ml), and average post-operative pain scores (2 studies) were 1 or 4.72 points lower on a 10 point scale. In 2 of 4 studies the median number of days to return to normal diet was fewer by 5.2 and 3.5 days, respectively, while in two studies there was no significant difference. There was no significant difference in the time to return to normal activity (3 studies) or in post-operative analgesia use. There was also no difference in the rate of complications, including hemorrhage. Examination of tonsillar tissue revealed significantly less damage following coblation than electrocautery.

A technology assessment by NICE and a systematic review by the Cochrane Collaboration both included adult and pediatric patients. Both concluded that there was insufficient evidence of a benefit of coblation over electrocautery tonsillectomy.

The cost of coblation, from the point of view of the MUHC is approximately $210 per child compared $25 for electrocautery. Thus use of coblation for the projected 490 procedures (or 67% of 731) tonsillectomy cases at the MUHC would result in an increased cost of 90,607 CAD $ (year 2008).

Conclusion: The available evidence suggests coblation tonsillectomy may be associated with less post-operative pain and a more rapid return to normal diet, though it is unclear if the magnitude of the benefit is clinically significant. The two techniques do not differ significantly in terms of post-operative blood loss or return to full activity. This benefit can be achieved at a net cost of $185 per procedure.

Recommendation: Considering the evidence and opportunity costs involved, the committee concluded that the small though measurable reduction in post-operative pain did not justify the additional cost. Accordingly, they recommend that the hospital should not authorize purchase of this technology. However, they strongly urge the department of pediatric otolaryngology to carry out a research study to evaluate it.

INTRODUCTION

Tonsillectomy is one of the most common surgical procedures in children. A number of different techniques may be employed for this surgery, including cold-dissection, guillotine, electrocautery (bipolar or monopolar), harmonic scalpel and laser. None of these techniques is considered clearly superior and all are accompanied by post-operative pain, with restriction of normal activity for approximately 2 weeks(Temple and Timms, 2001). Serious side-effects, though relatively rare, include hemorrhage during and after surgery and post-operative dehydration.

In electrocautery tonsillectomy (or diathermy) electric current from a radiofrequency generator is passed through the tissue between two electrodes. The resulting high temperature (400º-600ºC) cuts the tissue and simultaneously seals the blood vessels(Canadian Agency for Drugs and Technologies in Health, 2006;Parsons *et al.*, 2006). The advantage of this procedure compared to traditional methods like cold-dissection, is the lower risk of intra-operative bleeding and the shorter duration of surgery(Mowatt *et al.*, 2005). However, this approach is associated with more post-operative pain attributed to the spread of thermal injury due to the high temperatures used(Pinder and Hilton, 2001). There is also an increased risk of post-operative hemorrhage. Monopolar electrocautery tonsillectomy is the standard surgical technique at the MUHC. It is the most common method of tonsillectomy in the United States used by more than 50% of pediatric otolaryngologists (Krishna *et al.*, 2004;Walner *et al.*, 2007). In this method the electric current passes from the surgical instrument through the patient to a remote electrode placed typically on the thigh(Canadian Agency for Drugs and Technologies in Health, 2006). In bipolar electrocautery, the current passes through the tissue between electrodes located in the tips of a pair of forceps or scissors(Canadian Agency for Drugs and Technologies in Health, 2006).

Coblation is a relatively new surgical technique that uses a radiofrequency electrical current that passes through a saline solution to dissect tissue at much lower temperatures (60º-100ºC) than electrocautery(Parsons *et al.*, 2006), thereby theoretically reducing damage to healthy tissue and lowering pain(Mowatt *et al.*, 2005). The first and second generations of coblation were introduced in 1998 and 2003, respectively, by ArthroCare Corporation(Burton and Doree, 2007). One survey of members of the American Society of Pediatric Otolaryngologists showed a sharp increase in the use of coblation during the last 5 years with 16% of pediatric otolaryngologists using it for tonsillectomy procedures in the fall of 2005(Walner *et al.*, 2007). The National Prospective Tonsillectomy Audit (NPTA) carried out in England and Northern Ireland during the period July 2003 to September 2004 found that 1,565 out of 33,921 (4.6%)

patients (children and adults) of tonsillectomies were by coblation(Mowatt *et al.*, 2005).

In this report we will focus on the comparison in children between coblation and either bipolar or monopolar electrocautery tonsillectomy.

METHODS

A systematic literature search of articles in English and French was performed using PubMed, MEDLINE and EMBASE databases. We used the key words (coblation OR plasma mediated ablation OR tonsillar ablation OR cold ablation OR ionised field ablation OR radiofrequency ablation) AND (tonsillectomy OR adenotonsillectomy). We limited our search to randomized controlled trials (RCTs) among children published before September 30, 2008. For our technology assessment, we included only RCTs of "coblation tonsillectomy versus electrocautery tonsillectomy" in pediatric patients. We also searched the databases maintained by the International Network of Agencies for Health Technology Assessment (INAHTA), the Canadian Agency for Drug and Technologies in Health (CADTH), the Centre for Reviews and Dissemination(CRD), and the Cochrane Collaboration, using the key words above in order to identify health technology assessment reports and systematic reviews of coblation for tonsillectomy. A further search was conducted by tracking references in publications identified. We also reviewed an article documenting the risk of complications following electrocautery tonsillectomy documented at the Montreal Children's Hospital.

We extracted outcomes reflecting the safety and efficacy of coblation and electrocautery tonsillectomy. These included: i) surgery time, ii) blood loss during surgery, iii) post-operative pain, iv) time to return to a normal diet, v) time to return to normal activity level, vi) analgesic use, vii) postoperative haemorrhage, viii) other complications, and ix) results of tonsillar tissue examination. We used random effects meta-analysis (Julian PT Higgins and Sally Green, 2006) to estimate the overall effect of coblation for the two outcomes that were measured using the same metric across all studies – time of surgery (minutes) and blood loss (ml). Study quality was evaluated using the Jadad scale(Jadad *et al.*, 1996), with the modification that studies were required to be single-blinded, i.e. the individual measuring the outcome should have been blinded to the group to which the patient had been randomized. This scale ranks studies from a low of 0 indicating poor quality to a high of 5 indicating high quality.

Budget impact was considered from the point of view of the Montreal Children's Hospital (MCH) of the McGill University Health Centre (MUHC). We consulted

Linda Sand, the nurse manager of the MCH, for cost estimates and data related to the current practice of tonsillectomy at the MCH. We estimated the net annual budget impact of adopting coblation at the MCH.

Statistical analyses were performed using Review Manager 5.0 and Excel 2003.

RESULTS

Four RCTs in pediatric patients(Temple and Timms, 2001;Shah *et al.*, 2002;Stoker *et al.*, 2004;Parsons *et al.*, 2006), one technology assessment report from the National Institute for Health and Clinical Excellence (NICE) (Mowatt *et al.*, 2005) and one systematic review from the Cochrane collaboration (Burton and Doree, 2007) were identified. A flowchart summarizing the selection process for the RCTs is given in Figure 1. A brief description of the 4 RCTs is given in Table 1. We included one study that did include adult subjects because the majority of subjects (numbers not provided) appeared to be children(Parsons *et al.*, 2006).

Based on the Jadad scale (0= poor, 5= high), the study of least quality was the earliest RCT(Temple and Timms, 2001), with a score of 3 (Table 2). The remaining studies received scores of 4 or 5. The Jadad scale focuses on reporting of randomization, blinding and dropout rate, all of which were done by most studies. However, this does not reflect the fact that two studies had small sample sizes (Temple and Timms, 2001;Shah *et al.*, 2002) and three had poor follow-up rates (Temple and Timms, 2001;Shah *et al.*, 2002;Parsons *et al.*, 2006;Burton and Doree, 2007) .

We found that the aims of the NICE and Cochrane reports were somewhat different from ours. While our focus was the comparison between coblation and electrocautery in pediatric patients, these reports compared the performance of various surgical techniques including coblation in children and adults. The NICE report included both randomized studies as well as observational studies in its assessments. Therefore, we summarize the conclusions of these reports separately from those of the RCTs at the end of this section.

Clinical outcomes

i) Surgery time (minutes): Three out of 4 studies reported the surgery time(Shah *et al.*, 2002;Stoker *et al.*, 2004;Parsons *et al.*, 2006). The average surgery time of coblation tonsillectomy ranged from 22.7 to 28.9 minutes across studies, compared to 16.2 to 23 minutes for electrocautery. The pooled mean difference (coblation-electrocautery) between the two techniques was estimated

to be: 5.18 minutes (95% confidence interval (CI): 0.39, 9.97; p value: 0.03). See Table 3.

ii) Estimated blood loss during surgery (ml): Three out of 4 studies reported the estimated blood loss during surgery(Shah *et al.*, 2002;Stoker *et al.*, 2004;Parsons *et al.*, 2006). Stoker et al. (2004) (Stoker *et al.*, 2004) reported that one patient had more than 30 ml operative bleeding in the coblation group, but most (coblation: 98%; electrocautery: 89%) had no more than 15 ml blood loss. Mean estimated blood loss in the coblation group was 21.5ml and 90.9 ml in the remaining two studies. Based on the meta-analysis, the overall blood loss during coblation tonsillectomy was more than that during electrocautery tonsillectomy (mean difference (95% CI): 9.83 ml (0.29, 19.38); p value: 0.04). See Table 4.

iii) Post operative pain: Three studies reported on post-operative pain(Temple and Timms, 2001;Stoker *et al.*, 2004;Parsons *et al.*, 2006), but since each used a different measurement of pain, meta-analysis was not possible. In two studies pain was measured daily during the follow-up period using a validated 10-point rating scale (Temple and Timms, 2001;Parsons *et al.*, 2006) . Both studies found significantly less pain following coblation, though the magnitude of the benefit was considerably different. One study found a mean improvement of 0.99 point improvement (Parsons *et al.*, 2006) while the other found a mean improvement of 4.72.

In the study of Temple et al the statistical significance is questionable, for reasons noted in Table 5(Temple and Timms, 2001). However, the magnitude of the difference in the daily mean pain scores (4.72 on a scale of 1-10) is unlikely to be affected.

In one study(Stoker *et al.*, 2004) in which the time to achieve complete freedom from pain was recorded, there was no significant difference in the median time between the two approaches. See Table 5.

iv) Recovery time to normal diet: All 4 studies reported the time to return to a normal diet(Temple and Timms, 2001;Shah *et al.*, 2002;Stoker *et al.*, 2004e;Parsons *et al.*, 2006). In three of these (Temple and Timms, 2001;Shah *et al.*, 2002;Parsons *et al.*, 2006) the median time was significantly shorter, ranging from roughly 2-5 days shorter, following coblation, although this difference was not statistically significant in one of the studies(Shah *et al.*, 2002). In the remaining study(Stoker *et al.*, 2004) there was no clinically or statistically significant difference between the two groups. See Table 6.

v) Recovery time to normal activity: Three out of 4 studies reported the number of days to recover to a normal activity level(Shah *et al.*, 2002;Stoker *et*

al., 2004;Parsons *et al.*, 2006). Shah et al. reported that children in the coblation group returned to normal activity 2 days earlier than the electrocautery group, though this result was not statistically significant(Shah *et al.*, 2002). The two other studies found no difference between the two treatments(Stoker *et al.*, 2004;Parsons *et al.*, 2006). See Table 7.

vi) Analgesic use: Three out of 4 studies reported medication use(Temple and Timms, 2001;Shah *et al.*, 2002;Stoker *et al.*, 2004). One study found no difference in morphine use between the two groups(Shah *et al.*, 2002). One study found that children in the coblation group stopped use of narcotic analgesics 1.5 days earlier than the electrocautery group(Stoker *et al.*, 2004). The study by Temple et al. did not have a systematic record of analgesic use, though the authors reported “many parents from the coblation group returned the analgesics unopened.” See Table 8.

vii) Postoperative haemorrhage: Three out of 4 studies reported the incidence of postoperative haemorrhage(Shah *et al.*, 2002;Stoker *et al.*, 2004;Parsons *et al.*, 2006). Across these studies 6 cases of postoperative bleeding were reported out of 107 patients in the coblation group compared to 4 cases out of 103 patients in the electrocautery groups. Only one patient required readmission for heavy bleeding after surgery (electrocautery) (Stoker *et al.*, 2004). See Table 9.

viii) Other Complications: In one study no complications were reported in either group(Temple and Timms, 2001). Typical complications reported in the other 3 studies(Shah *et al.*, 2002;Stoker *et al.*, 2004;Parsons *et al.*, 2006) included pain, dehydration and vomiting. Two cases required postoperative admission for airway obstruction in the coblation group in the study by Shah et al.(Shah *et al.*, 2002). For this reason, the trial was terminated with 34 patients. Shah et al. reported a greater percentage of complications in the coblation group than the electrocautery group (24% vs. 12%)(Shah *et al.*, 2002). Because the definitions of complications varied across studies, overall complication rates are not comparable. See Table 9.

ix) Health services use: Only the study by Stoker et al. reported the number of post-operative physician contacts(Stoker *et al.*, 2004). They found that there were fewer physician visits or calls in the coblation group compared to the electrocautery group (32% vs. 51%). However, the percentage of complications resulting in readmission was the same in both groups at around 2% (1/45). See Table 9.

x) Examination of tonsils: Three out of 4 studies examined the tonsillar tissue following the surgery(Temple and Timms, 2001;Shah *et al.*, 2002;Stoker *et al.*, 2004).

In Shah et al.(Shah *et al.*, 2002), the mean depth of injury was 0.63±0.25 mm and 0.13±0.12 mm in 4 tonsils from the electrocautery group and 3 tonsils from the coblation group, respectively. The tonsils were selected randomly. The authors concluded that tonsils in the coblation group had less thermal damage. In addition there was tissue charring and basophilic infiltrate at the excision margin in electrocautery group, but almost no evidence of this in the coblation group.

Temple et al. (Temple and Timms, 2001)reported a great difference in healing of tonsillar fossa. At 9 days after surgery nearly all fossae were healed in the coblation group, but considerable extensive areas of slough were present in electrocautery group.

Stoker et al. (Stoker *et al.*, 2004)reported that following coblation a lower proportion of patients were found to have anterior pillar swelling (5% vs. 21%), posterior pillar swelling (2% vs. 16%) and palatal swelling (7% vs. 16%). However, a higher proportion of patients in the coblation group were found to have eschar present (right tonsil: 76% vs 60%; left tonsil: 64% vs 53%).

The NICE and Cochrane reports

The NICE report included 50 studies with randomized and non-randomized designs, and studies of both adults and children (Mowatt *et al.*, 2005). Based on the results of randomized controlled trials, non-randomized comparative studies and case series, no significant differences were found in the rates of secondary haemorrhage (> 24 hrs post-surgery) requiring return to theatre [0.5% (95% CI: 0.2%, 1.2%) and 0.9% (95% CI: 0.6%, 1.3%) in coblation and electrocautery groups, respectively]; in rates of primary haemorrhage (< 24 hrs post-surgery) requiring return to theatre [0.3% (95% CI: 0.1%, 1.0%) and 0.2% (95% CI: 0.1%, 0.4%) in coblation and electrocautery groups, respectively]; or in the rate of all primary haemorrhage [1.5 (CI: 0.9%, 2.4%) and 0.7% (CI: 0.5%, 1.1%) in coblation and electrocautery groups, respectively]. However, rates of all secondary haemorrhage (irrespective of severity) favoured coblation [4.1% (CI: 3.0%, 5.5%) and 9.4% (CI: 8.4%, 10.4%) in coblation and electrocautery groups, respectively].

The NICE report also reviewed the results of the National Prospective Tonsillectomy Audit (NPTA) (N=33,921) and the Wales Single use Surveillance Program (SISP) (N=3690) of all tonsillectomies carried out in England and Northern Ireland between July 2003 and February 2004. As with the results from individual studies, the population registries also suggest that there is no difference between coblation and electrocautery in primary hemorrhage or secondary hemorrhage requiring a return to theatre. However, the rate of all secondary hemorrhage (irrespective severity) was lower in the coblation group.

The NICE report concluded that in general electrosurgery dissection (either coblation or electrocautery) was associated with a greater risk of

secondary haemorrhage compared to cold steel dissection. The latter, on the other hand, was associated with a greater risk of primary haemorrhage.

The Cochrane report included randomized controlled trials of either adults or children comparing coblation tonsillectomy to any other technique(Burton and Doree, 2007). The four studies we have identified in this report were all included in the Cochrane report. The report concluded that there was an absence of evidence establishing whether or not coblation tonsillectomy was an improvement over conventional techniques for most outcomes, including pain and bleeding. They recommended that the use of coblation be confined to well designed randomized controlled trials involving well-trained surgeons.

Experience at the Montreal Children's Hospital

Abou-Jaoude et al. (Abou-Jaoude *et al.*, 2006) reported the risk of short-, medium- and long-term complications among consecutive patients operated between 1997 and 2003 using electrocautery tonsillectomy at the Montreal Children's Hospital. Patients were classified as being high risk (N=390) or normal risk (N=1537). The high risk population consisted of children who had craniofacial malformations, bleeding disorders, moderate to severe obstructive sleep apnea (OSA), sickle cell phenotype or some form of systemic disease, or were less than 3 years of age.

In the high risk group, intra-operative or peri-operative complications resulted in the unplanned admission of 21% of patients. Most of the complications were in children with OSA (~70%). The remaining complications were in children less than 3 years of age, consisting of pain or inadequate oral intake or due to other gastroesophageal complications (vomiting, dehydration) or bleeding. In the normal risk group, intra- and perioperative complications resulted in the unplanned admission of 3% of patients. Once again the most common reasons for admission were airway related or gastroesophageal complications.

In the high risk group, 9.7% of patients returned to the emergency room for minor complications, and 2.5% returned for major complications requiring admission. The majority of the readmissions (60%) were related to bleeding. In the normal risk group, 6.8% of patients returned to the emergency room for minor complications, and 2.6% were admitted for major complications. Once again, the majority of readmissions were due to bleeding.

By comparison with other similar cohorts, the authors concluded that electrocautery tonsillectomy was safe and reduces the risk of post-operative complications compared to the traditional technique of cold knife dissection. However, they concluded that there was room for improvement with a need to lower the risk of respiratory complications.

Budget impact

Unit cost: Coblation and electrocautery tonsillectomy involve the same resource costs, except for the purchase cost of the disposable hand piece for electrocautery (CAD $ 25 per patient) and for coblation (CAD $ 210)(Sand, 2008b). For purposes of net budget impact from the point of view of the hospital, the two procedures were assumed to be identical in terms of severe complications rates and medication use. Cost estimates do not include the costs of training otolaryngologists and nurses in using coblation. We also did not take into account any costs incurred by the patients or their caregivers.

In 2007 731 T&A(Tonsillectomy and Adenoidectomy) procedures were carried out at MCH(Sand, 2008 personal communication). We assume that the number of T&A cases per year and purchasing costs of hand piece of electrocautery/coblation are constant. If all cases were carried out by coblation tonsillectomy, the net annual budget impact would be 135,235 CAD $. If coblation partly replaces electrocautery, the net annual budget impacts of 33%, 50% and 67% T&A operations using coblation would be 44,628 CAD $, 67,618 CAD $, and 90,607 CAD $, respectively.

DISCUSSION

The quality of the RCTs we evaluated was good as regards randomization, blinding and reporting of results. However, all studies either had a small sample size or a large number of losses to follow-up. The Temple et al study(Temple and Timms, 2001) that reported the greatest benefit of coblation used simplistic statistical analysis techniques that may have contributed to their obtaining statistically significant results. There was a lot of heterogeneity between the studies in terms of quantifiable benefit of coblation. This may of course partly be explained by the different metrics used in each study, the different technologies used both for coblation (generations I vs II) and electrocautery (monopolar vs. bipolar), or differences in the extent of training with coblation tonsillectomy.

Our analysis focused strictly on the comparison between two tonsillectomy technologies, coblation and electrocautery. We used only randomized controlled trials to avoid the problem of confounding in observational studies. A particular concern with tonsillectomy techniques is the learning curve and the preference of traditional techniques such as cold-dissection and electrocautery among more senior surgeons(Brown *et al.*, 2004;Krishna *et al.*, 2004;MacFarlane *et al.*, 2008;Carney *et al.*, 2008). We excluded studies of adults as the pattern of postoperative morbidity and risk of complications, particularly hemorrhage, are different for adults than for children(Burton and Doree, 2007), and we also excluded studies of intra-capsular tonsillectomy as this was not a technology of interest to our consultants due to the risk of tissue re-growth(Anna H.Messner,

2005). A more complete cost-effectiveness analysis would take into account the societal perspective. This may be particularly relevant in the case of tonsillectomy where the direct benefit due to an early return to normal activity would affect patients and their parents, for example, in terms of fewer days of school/work lost. However, our mandate was to make a recommendation based on the opportunity cost of this technology to the MUHC.

Compared with electrocautery tonsillectomy, coblation results in significantly less scarring of tissue, and marginally improves the quality of life, particularly by lowering post operative pain and accelerating return to normal diet. The magnitude of the benefit varied considerably across studies. There was no clear benefit in terms of the time to return to normal activity or the use of analgesics. There was no significant difference in risk of complications between the two procedures. Coblation substantially increases the surgery cost, due to the incremental purchase cost of 185 CAD $ per case for the disposable hand piece. It also appears to be associated with a slightly longer surgery time.

Reducing the rate of readmission, particularly among high risk patients, is an important goal, but this was not reported in any of the studies we reviewed. Though one study suggested that health services use was significantly lower in the coblation group, this seems to primarily pertain to minor complications that do not require readmission. Moreover, this study did not include children with obstructive sleep apnea or those aged less than 3 years, the two groups at highest risk of readmission at our institute. Better randomized controlled trials with larger sample sizes and high follow-up rates are needed to improve our understanding of the potential benefit of coblation tonsillectomy.

Future studies should consider health services use for major and minor complications as important outcomes, as these are more reliably measured than subjective outcomes, such as pain and return to normal diet, in young children. Future studies should make a special effort to include high risk groups such as children with OSA and children less than 3 years of age.

CONCLUSIONS

The available evidence suggests coblation tonsillectomy may be associated with less post-operative pain and a more rapid return to normal diet, though it is unclear if the magnitude of the benefit is clinically significant. The two techniques do not differ significantly in terms of post-operative blood loss or return to full activity. This benefit can be achieved at a net cost of $185 per procedure.

RECOMMENDATIONS

After reviewing the evidence and considering the opportunity costs involved, the committee came to the conclusion that the small though measurable reduction in post-operative pain did not justify the additional cost of $185 per procedure. Accordingly, they recommend that the hospital should not authorize the purchase of this technology. However, they recognize that there is a need for improved randomized controlled trials and urge the department of pediatric otolaryngology to pursue a research study to compare coblation to electrocautery tonsillectomy.

REFERENCE LIST

Abou-Jaoude,P.M., Manoukian,J.J., Daniel,S.J., Balys,R., bou-Chacra,Z., Nader,M.E., Tewfik,T.L., and Schloss,M.D. (2006). Complications of adenotonsillectomy revisited in a large pediatric case series. Journal of Otolaryngology *35*, 180-185.

Anna H.Messner (2005). Tonsillectomy. Operative Techniques in Otolaryngology *16*, 224-228.

Brown,P. *et al.* (2004). Tonsillectomy technique as a risk factor for postoperative haemorrhage. Lancet *364*, 697-702.

Burton,M.J. and Doree,C. (2007). Coblation versus other surgical techniques for tonsillectomy. Cochrane Database of Systematic Reviews.

Canadian Agency for Drugs and Technologies in Health. Hot Techniques for Tonsillectomy. 2006. 9-30-2008.Available from: http://www.cadth.ca/media/pdf/E0003_tonsillectomy_cetap_e.pdf .

Carney,A.S., Harris,P.K., MacFarlane,P.L., Nasser,S., and Esterman,A. (2008). The coblation tonsillectomy learning curve. Otolaryngology-Head and Neck Surgery *138*, 149-152.

Jadad,A.R., Moore,R.A., Carroll,D., Jenkinson,C., Reynolds,D.J.M., Gavaghan,D.J., and Mcquay,H.J. (1996). Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Controlled Clinical Trials *17*, 1-12.

Julian PT Higgins and Sally Green. Cochrane Handbook for Systematic Reviews of Interventions.2006. 10-15-2008. Available from: http://www.cochrane.org/resources/handbook/Handbook4.2.6Sep2006.pdf .

Krishna,P., Lapage,M.J., Hughes,L.F., and Lin,S.Y. (2004). Current practice patterns in tonsillectomy and perioperative care. International Journal of Pediatric Otorhinolaryngology *68*, 779-784.

MacFarlane,P.L., Nasser,S., Coman,W.B., Kiss,G., Harris,P.K., and Carney,A.S. (2008). Tonsillectomy in Australia: An audit of surgical technique and postoperative care. Otolaryngology-Head and Neck Surgery *139*, 109-114.

Mowatt,G., Cook,J., Fraser,C., and Burr,J. Systematic review of the safety and efficacy of electrosurgery for tonsillectomy. 2005. Available from: http://www.nice.org.uk/nicemedia/pdf/ip/Tonsillectomy%20post%20IPAC%20version%20June%202005.pdf.

Parsons,S.P., Cordes,S.R., and Comer,B. (2006). Comparison of posttonsillectomy pain using the ultrasonic scalpel, coblator, and electrocautery. Otolaryngology-Head and Neck Surgery *134*, 106-113.

Pinder,D. and Hilton,M. (2001). Dissection versus diathermy for tonsillectomy. Cochrane Database Syst. Rev. CD002211.

Shah,U.K., Galinkin,J., Chiavacci,R., and Briggs,M. (2002). Tonsillectomy by means of plasma-mediated ablation - Prospective, randomized, blinded comparison with monopolar electrosurgery. Archives of Otolaryngology-Head & Neck Surgery *128*, 672-676.

Stoker,K.E., Don,D.M., Kang,D.R., Haupert,M.S., Magit,A., and Madgy,D.N. (2004). Pediatric total tonsillectomy using Coblation compared to conventional electrosurgery: A prospective, controlled single-blind study. Otolaryngology-Head and Neck Surgery *130*, 666-675.

Temple,R.H. and Timms,M.S. (2001). Paediatric coblation tonsillectomy. Int. J. Pediatr. Otorhinolaryngol. *61*, 195-198.

Walner,D.L., Parker,N.P., and Miller,R.P. (2007). Past and present instrument use in pediatric adenotonsillectomy. Otolaryngology-Head and Neck Surgery *137*, 49-53.

Walner,D.L., Parker,N.P., and Miller,R.P. (2007). Past and present instrument use in pediatric adenotonsillectomy. Otolaryngology-Head and Neck Surgery *137*, 49-53.

Figure 1: Flowchart summarizing literature search and study selection

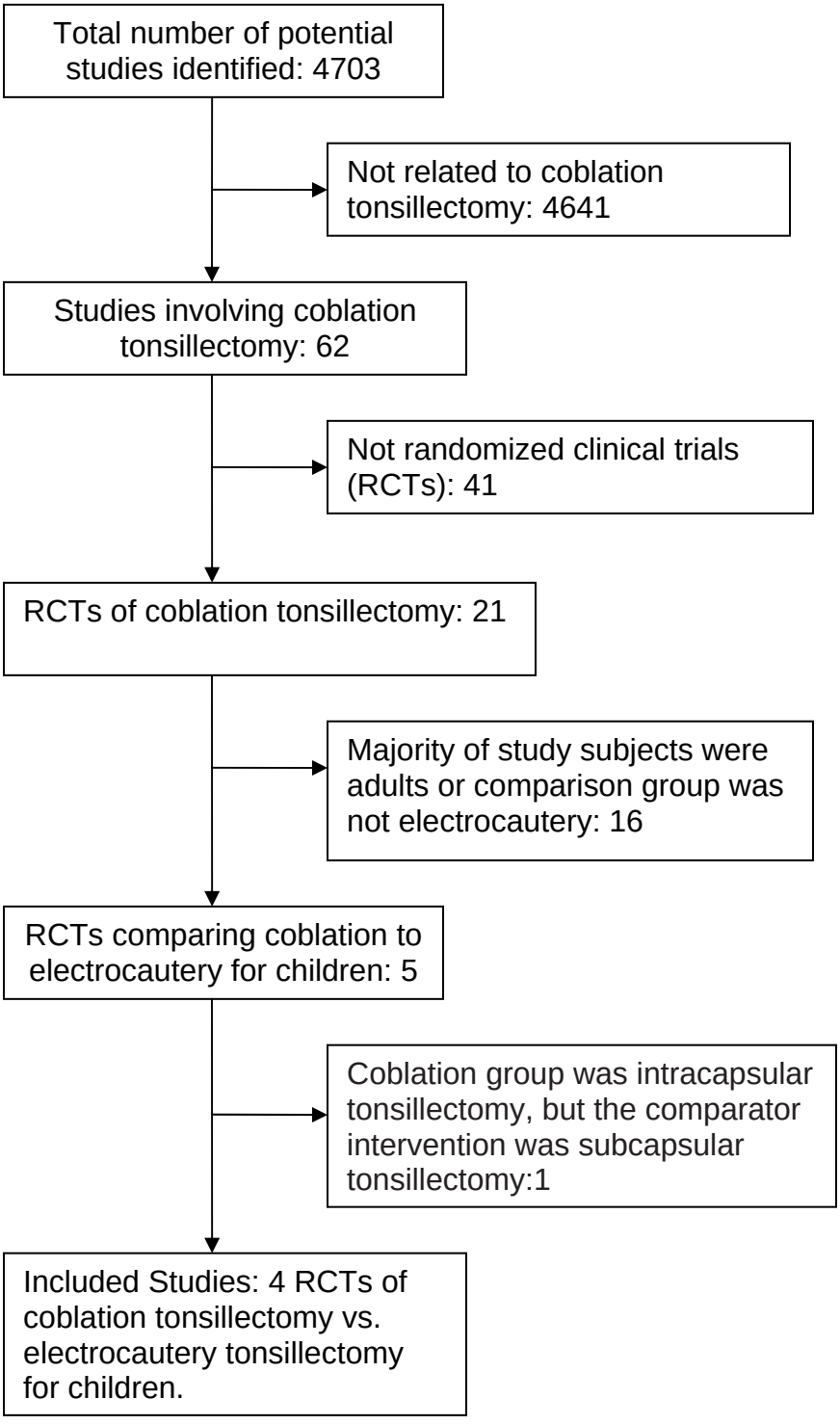

Table 1: Description of the included randomized controlled trials

Author (year)	Type of device (coblation vs. electrocautery)	Sample size and study subjects	Length of follow-up	Loss to follow-up
Temple et al. (2001) (Temple and Timms, 2001)	Bilateral coblation vs. bilateral standard bipolar dissection	38 pediatric patients, aged 4 to 12 years with a history of recurrent tonsillitis (but without tonsillitis within the 3 weeks prior to surgery), or obstructive symptoms related to tonsillar hypertrophy	14 days	47%
Shah et al. (2002) (Shah *et al.*, 2002)	Plasma-mediated ablation vs. monopolar electrosurgery	34 pediatric patients, aged 4 to 7 years scheduled for day-surgery adenotonsillectomy (T&A)	6 months	53%
Stoker et al. (2004) (Stoker *et al.*, 2004)	EVac 70 Plasma Wand vs. monopolar radiofrequency	89 children, aged 3 to 12 years with history of tonsillar infection and/or obstructive tonsillar hypertrophy	16 days	4.5%
Parsons et al. (2006) (Parsons *et al.*, 2006)*	Coblation vs. monopolar electrocautery	134 patients undergoing tonsillectomy or adenotonsillectomy. Mean (standard deviation) of age of coblation and electrocautery groups were 9.5 (7.3) and 10.1 (9.0), respectively	10 days	54.5%

*This study included both children and adults. Due to low mean age of 9.5 and 10.1 in the two groups we chose to include this study.

Table 2: Modified Jadad scores of study quality

	Temple et al. 2001 (Temple and Timms, 2001)	Shah et al. 2002 (Shah *et al.*, 2002)	Stoker et al. 2004 (Stoker *et al.*, 2004)	Parsons et al. 2006 (Parsons *et al.*, 2006)
Was the study described as randomized?	1	1	1	1
Was the study described as single-blind†? (i.e. person measuring outcomes blinded to surgical technique)?	1	1	1	1
Description of withdrawals and dropouts?	0	1	1	1
Method of randomization appropriate?	0	1	0	0
Method of blinding appropriate?	1 *	1 *	1 **	1
Total	3	5	4	4

†: The standard Jadad criteria require that the study is double-blind. It was not possible for the surgeon to be blinded to the tonsillectomy procedure. Therefore, we required that studies were "single-blind", i.e. the person measuring the outcomes was unaware of the intervention.

*: Not clear if parents were blinded.

**: do not mention if nurse/study co-ordinator was blinded

Table 3: Meta-analysis of surgery time (minutes)

Study or Subgroup	Coblation Mean	SD	Total	Electrocautery Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
Shah et al.	23.5	7.9	17	16.2	3.2	17	35.9%	7.30 [3.25, 11.35]	2002
Stoker et al.	22.7	13.5	44	23	11.7	45	30.5%	-0.30 [-5.55, 4.95]	2004
Parsons et al.	28.9	13.5	42	21	6.7	42	33.6%	7.90 [3.34, 12.46]	2006
Total (95% CI)			**103**			**104**	**100.0%**	**5.18 [0.39, 9.97]**	

Heterogeneity: Tau² = 12.36; Chi² = 6.50, df = 2 (P = 0.04); I² = 69%
Test for overall effect: Z = 2.12 (P = 0.03)

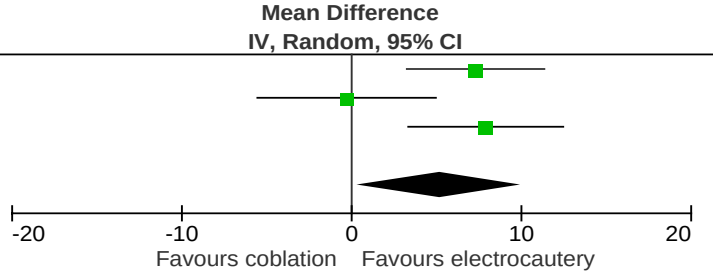

Table 4: Meta-analysis of blood loss (ml) in surgery

Study or Subgroup	Coblation Mean	SD	Total	Electrocautery Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
Shah et al.	90.9	35.3	17	83.8	46.4	17	11.9%	7.10 [-20.61, 34.81]	2002
Parsons et al.	21.5	32.6	46	11.3	12.8	43	88.1%	10.20 [0.03, 20.37]	2006
Total (95% CI)			**63**			**60**	**100.0%**	**9.83 [0.29, 19.38]**	

Heterogeneity: Tau² = 0.00; Chi² = 0.04, df = 1 (P = 0.84); I² = 0%
Test for overall effect: Z = 2.02 (P = 0.04)

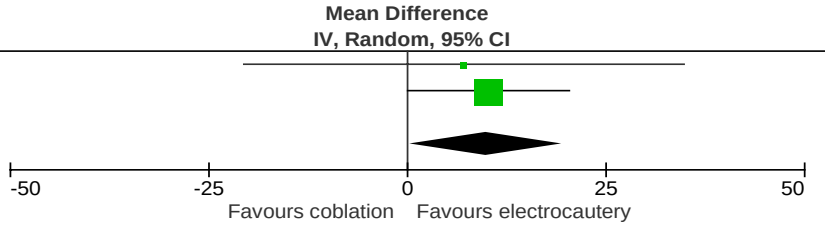

Table 5: Summary of results on post operative pain

Author(year)	Measure of pain[#]	Results
Temple et al. (2001)(Temple and Timms, 2001)	Daily mean pain scores over 9 days on a visual analogue pain score (on a scale of 1–10)	• Daily mean pain scores were significantly* lower in the coblation group. Average difference in the daily mean pain scores over 9 days was -4.72 (95% CI: 3.48, 5.96). Mann-Whitney U test p-value <0.0001. • The mean pain score fell below 4 on day 2 in the coblation group, but not even by day 10 in the electrocautery group.
Stoker et al. (2004)(Stoker *et al.*, 2004)	Days to freedom from pain based on Wong-Baker FACES pain rating scale	• Mean (standard deviation) of days to freedom from pain were 9.8 (1.7) and 10.4 (1.7) in coblation and electrocautery groups, respectively. The median number of days was 10 in both groups. Log-rank test p-value = 0.249.
Parsons et al. (2006)(Parsons *et al.*, 2006)	Overall mean pain scores over a 10 day period on the Wong-Baker FACES pain rating scale (scale of 1–10)	• Mean (standard deviation) of pain scores over 10 days are 2.85 (0.29) and 3.84 (0.33) in coblation and electrocautery groups, respectively. P-value from a repeated measures analysis was 0.024.

#: For all scales higher values were associated with greater pain.
*:The studies by Temple et al used a simplistic statistical analysis that did not account for the correlation between observations on the same child(Temple and Timms, 2001). If this had been taken into account it is possible their results would not have been statistically significant.

Table 6: Summary of results on time to return to normal diet

Author(year)	Measure	Results
Temple et al. (2001)(Temple and Timms, 2001)	Days to return to a normal diet	Day of return to normal diet in coblation group was significantly lower than that in electrocautery group - 2.4 days vs. 7.6 days, respectively (these are probably the median number of days). P-value of Mann Whitney U test <0.0001.
Shah et al. (2002)(Shah *et al.*, 2002)	Days to return to more than half of normal diet	Median number of days to resumption of more than half of normal diet was 7 days for in the coblation group and > 10 days for the electrocautery group. The difference was not statistically significant.
Stoker et al. (2004)(Stoker *et al.*, 2004)	Days to return to a normal diet	Return to normal diet was insignificantly longer following coblation than after electrocautery. The mean (standard deviation) number of days were 7.4 (1.9) days and 6.7 (1.8) days, respectively. Log-rank test p-value=0.40
Parsons et al. (2006)(Parsons *et al.*, 2006)	Days to return to a normal diet	Median number of days to return to a normal diet was 2.5 in the coblation group compared to 6 days in the electrocautery group. Log-rank test p-value=0.08.

Table 7: Summary of results on time to return to normal activity

Author(year)	Measure	Results
Shah et al. (2002)(Shah *et al.*, 2002)	Days to return to a normal activity level	• The median number of days to return to a normal activity level was 8 days for the coblation group and 10 days for the electrocautery group. The difference was not statistically significant. • Coblation patients had higher average activity scores after 7 days.
Stoker et al. (2004)(Stoker *et al.*, 2004)	Days to return to a normal activity level	• The average number of days (SD) of return to normal activity in coblation and electrocautery groups were 7.0 (1.9) days and 6.9 (1.8) days, respectively. P-value of log-rank test = 0.951.
Parsons et al. (2006)(Parsons *et al.*, 2006)	Days to return to a normal activity level	• 91.8% of patients were able to return normal activity level after 10 days. There was no difference between coblation and electrocautery groups.

Table 8: Summary of results on analgesic use

Author(year)	Measure	Results
Temple et al. (2001)(Temple and Timms, 2001)	None	• No systematic record of analgesic use. However, the authors say “many parents from the coblation group returned the analgesics unopened.”
Shah et al. (2002)(Shah *et al.*, 2002)	Total morphine consumption	• Mean (standard deviation) of morphine consumption in the coblation and electrocautery groups was, 1.2 (1.1) and 1.1 (0.8) mg, respectively.
Stoker et al. (2004)(Stoker *et al.*, 2004)	Days until freedom from analgesics	• Days until freedom from non-narcotic analgesics was 6.9 (2.2) in the coblation group vs. 6.9 (2.2) in the electrocautery group. Days until freedom from narcotic. P-value of log-rank test = p=0.965. • Days until freedom from narcotic analgesics was 6.1 (1.9) in the coblation group vs. 7.5 (1.8) in the electrocautery group. P-value of log-rank test = p=0.071. • The coblation group tended to taker fewer daily doses.

Table 9: Summary of complications following coblation or electrocautery tonsillectomy

Author(year)	Results : coblation vs. electrocautery			
Temple et al. (2001)(Temple and Timms, 2001)	No primary or secondary hemorrhage in either group of patients.			
Shah et al. (2002)(Shah *et al.*, 2002)	Electrocautery: 2 patients had complications related to hydration. At follow up, 1 child complained of persistent snoring. Coblation: Four children had perioperative complications. Two required postoperative admission for airway obstruction, one needed readmission for dehydration, and one experienced a delayed posttonsillectomy hemorrhage. At follow up 3 children had complaints, one of velopharyngeal insufficiency, one of drooling and poor speech clarity, and the other one of 2 episodes of pharyngitis. Note: Authors argue that "because of 2 airway complications in the PMA (Plasma-mediated ablation) group, one of us (U.K.S.) chose to terminate the study at 34 patients, rather than to complete enrollment to 60 patients."			
Stoker et al. (2004)(Stoker *et al.*, 2004)		Coblation: N (%)	Electrocautery: N (%)	P value
	Contacting the physician (visit or phone) for postoperative complications#	14(32)	23(51)	0.081
	Cauterization for mild bleeding	1	0	NR
	Readmission for heavy bleeding	0	1	NR
	Mild bleeding	3	1	NR
	Pain	6	11	NR
	Vomiting	4	7	NR
	Fever, dehydration, or no eating	6	7	NR

Table 9: Summary of complications following coblation or electrocautery tonsillectomy (cont-d)

Author (Year)	Results : coblation vs. electrocautery			
		Coblation: N (%)	Electrocautery: N (%)	P value
	Cough, lethargy, confusion, and dizziness	0	8	NR
	Miscellaneous	4	14	NR
	Nausea during the 14-day postoperation	(35)	(62)	0.013
	Mouth odor	(67)	(77)	0.336
	Ear pain	(51)	(64)	0.221
	Bleeding	(7)	(14)	0.313
Parsons et al. (2006)(Parsons *et al.*, 2006)	Postoperative bleeding was reported in 1 case out of 46 in the coblation group and in 2 cases out of 41 in the electrocautery group.			

Abbreviations: N=number; NR=not reported; R=right; L=left.

#: In some cases, individual contacts consisted of more than one concern.