No clinical advantages of coblation tonsillectomy compared with traditional tonsillectomy

Lise Moesgaard & Frank Mirz

ABSTRACT

INTRODUCTION: Tonsillectomy may be performed by several methods. It is continuously being discussed which method is preferable with regard to postoperative haemorrhage, pain, activity and nutrition.

MATERIAL AND METHODS: The present study is a prospective non-randomized study of tonsillectomy. It included 198 patients aged 14-40 years who either underwent coblation tonsillectomy or traditional “cold” tonsillectomy after random allocation to different surgeons. A total of 51 patients underwent coblation tonsillectomy and 147 patients underwent traditional tonsillectomy. We tested the hypothesis that there is no difference in postoperative pain experience between the two surgical techniques. The patients were followed for nine days postoperatively. They filled in a questionnaire on postoperative pain score, activity level and food intake.

RESULTS: We found no statistically significant difference in pain perception between the two groups and there was no difference in their levels of activity. The intraoperative haemorrhage was significantly reduced in the coblation tonsillectomy group, but there was no difference in postoperative haemorrhage between the two groups.

CONCLUSION: The overall results of this study suggest that neither coblation tonsillectomy nor traditional tonsillectomy enjoys an advantage over the other in patients aged 14-40 years.

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Tonsillectomy is a very common surgical procedure in children and young adults. Several surgical techniques for tonsillectomy exist, but differences in their clinical performance are not well described. The purpose of the present study was to compare the clinical performance of coblation tonsillectomy (COT) and traditional “cold” tonsillectomy (TT). We tested the hypothesis that there is no difference between the two surgical techniques regarding postoperative pain experience. We also compared COT and TT in terms of their effect on postoperative food intake, activity level and haemorrhage.

MATERIAL AND METHODS

This prospective, non-randomized clinical study was performed in conformity with the standards of the Danish ethical committee.

The study included 198 patients aged 14-40 years listed for complete tonsillectomy for tonsillar hypertrophy, recurrent acute tonsillitis and chronic tonsillitis. All procedures were performed from 1 February 2006 to 31 July 2007. Exclusion criteria were use of anticoagulants, known non-steroidal anti-inflammatory drugs (NSAIDs) allergy or intolerance, regular use of analgesics due to chronic pain, and known or suspected malignancy. Two surgeons (one resident and one consultant) performed COT. Eleven surgeons performed TT. No randomization was performed. The patients were blinded to the operative technique.

Postoperatively, the patients once a day filled in a questionnaire about their pain experience, use of analgesics, food intake and activity level. The patients were followed for nine days (the day of surgery was referred to as day one). We evaluated data from day 2 to day 9. The severity of pain was scored on a visual analogue scale (VAS), where the patients scored their pain experience on a line connecting the two extremes: “no pain” and “worst thinkable pain”.

Food intake was registered as either: a) normal eating and drinking, b) limited eating, normal drinking, c) limited eating and drinking, d) no eating, limited drinking, or e) no eating or drinking. Activity was registered as either: a) normal activity, b) sub-normal activity, c) limited activity, d) very limited activity, or e) confined to bed. The patients were recommended regular intake of paracetamol and NSAIDs. Intake of analgesics was registered.

Surgical techniques

TT was performed with traditional dissection using standard specified tonsillectomy instruments (tonsil forceps, scalpel, dissectors, pillar retractors, tonsil snares, bipolar diathermy, etc.), according to the preference of the individual surgeon. Coblation equipment, including coblation wand (ArthroCare, Evac-70) and tonsil forceps, was used for COT (Figure 1). Coblation is a technique for soft tissue surgery where an electrical field of sodium ions in saline water is created at the tip of a wand. This plasma field of sodium ions is able to dissociate soft tissue at degrees of only 40-70°C as opposed to bipolar diathermy where the temperature needed may reach approx. 400°C.
Coblation tonsillectomy performed with a coblation wand and tonsil forceps.

Statistical analysis
The data obtained were analysed using the statistical programs EpiData Analysis (version 2.2, EpiData Association, Odense, Denmark 2001-2009) and Epilinfo (Epi Info, version 3.5.1, 2008, United States Department of Health and Human Services, Centers for Disease Control and Prevention). Descriptive statistics were used to individually analyse the COT group and the TT group. Fisher’s exact test was used for statistical evaluation of COT versus TT regarding nominal data. The Mann-Whitney test was used for statistical evaluation of COT versus TT in terms of rank ordinal data and VAS scales. p < 0.05 was considered statistically significant.

Trial registration: not relevant.

RESULTS
A total of 198 patients (73 male, 125 female) were included of whom 51 underwent COT and 147 TT. The mean age was 23 years. We found no significant differences in age, gender or surgical indication between the COT and TT group (Table 1). We found reduced peroperative haemorrhage in the COT patients compared with the TT patients (p < 0.001). Most patients were discharged after 24 hours of observation. There were no significant differences between the COT and TT group concerning prolonged hospitalisation or readmission rates.

Of the 198 patients included in this study, 28 patients (14.1%) failed to complete the questionnaire (ten COT patients and 18 TT patients). No statistically significant difference between drop-out rates in the two groups was observed.

Pain scores
The VAS scores on day 2-9 are illustrated in Figure 2 (median pain).

No significant difference in pain experience between the COT and TT group was observed from Day 2 to 9. On Day 2, we noted a trend towards less pain in the COT group, but this observation did not reach a level of statistical significance (p = 0.073). We found no significant difference in the intake of either recommended or “extra” analgesics between the two groups.

Food intake and activity scores
Significantly more patients had a normal food intake on Days 7 and 8 in the TT group (p = 0.019, p = 0.011), than in the COT group (Figure 3). No significant difference was found between the two groups concerning their levels of activity (Figure 4).

Postoperative haemorrhage
Three patients (1.5%) experienced primary haemorrhage (within 24 hours), which was treated by bipolar diathermy haemostasis in general anaesthesia. One patient was from the COT group and two were from the TT group. No significant difference in the occurrence of primary haemorrhage between the COT and TT group was observed.

Seven patients (3.5%) experienced secondary haemorrhage (after 24 hours), which was treated in general anaesthesia. Two patients were from the COT group and five patients were from the TT group. There was no significant difference between the groups.

Secondary haemorrhage occurred between Day 3 and Day 12. The two COT patients were bleeding on Day 3 and Day 12, respectively. The five TT patients were bleeding between Day 5 and 11. There was no significant difference between the groups concerning the day of secondary haemorrhage.

DISCUSSION
Tonsillectomy is a very commonly performed procedure. Many surgical techniques have been developed over time, e.g. guillotine tonsillectomy, “cold” dissection tonsillectomy, bipolar and monopolar dissection tonsillec-
tomy, laser tonsillectomy and COT. COT is a relatively new method that was first described in the literature in 2001 [1]. The coblation wand is a disposable piece of equipment that costs 80-90 €. For a new, more expensive surgical technique to be adopted, the advantages that accompany its introduction must be significant. An obvious advantage for the patient is a potential pain reduction, better food intake and earlier return to normal activity. An important surgical factor is a potential reduction in postoperative haemorrhage. Other factors of interest may be economic, such as a reduction of readmissions and earlier return to work.

In our study, we followed the patients for nine days, including the day of surgery. It is hardly reasonable, though, to include the day of surgery (Day 1). First, the patients were not comparable, since surgery was performed at different times of the day. Second, the type and amount of analgesics given during surgery and in the recovery room were not standardized.

We found no coherence between surgical technique and pain score, and there was no difference in activity levels between the patients in our two intervention groups.

Several studies have found an advantage of COT regarding pain score [1-5]. Yet, other studies have found no such advantage [6, 7], or even a disadvantage of COT [8]. In a Cochrane review, eight studies found no significant difference in pain score between COT and “control” tonsillectomy, and one study found an advantage of COT [9].

Evaluating food intake and activity levels, we compared patients who scored these parameters as “normal” with patients who scored them “below normal” (the remaining levels summarized). On Days 7 and 8, more patients in the TT group than in the COT group had a normal food intake, but on Days 1-6 and Day 9, no difference was seen between the two groups. Previous studies found no difference between COT and “control” tonsillectomy regarding food intake or return to normal activity [5, 8]. We found a reduction of intraoperative haemorrhage in the COT patients. This was also found in other studies [5, 7].

In our study, we included patients aged 14-40 years. We did not include younger children, since we found it important that the patients had a certain age to be able to correctly fill in the questionnaire, particularly regarding the VAS scale.

Patients who are tonsillectomized usually have pain for at least 14 days. We only scored our patients for nine days for practical reasons, since we found it more likely that the patients would show up and return the questionnaire if they had not yet fully recovered. It is possible that those who dropped out of the questionnaire study were those who had least pain and fewest postoperative problems.

As the sizes of the drop-out rates were similar in the COT and the TT group, it is assumed that this applies to both groups, wherefore the comparison remains valid.

Our study is a non-randomized study, which increases the risk of bias. Our small population size lowers the statistical power and induces the risk of type II error. Larger randomized studies are needed.

Tonsillectomy is potentially dangerous because of the risk of postoperative haemorrhage which is accordingly an important parameter in the evaluation of the surgical technique. If a study shows an advantage of a surgical procedure over another and a surgeon considers
to adopt this other technique as a standard procedure, it is important that the disadvantages do not outweigh the advantages. Thus, it would be problematic to adopt a procedure for tonsillectomy that increases the risk of postoperative haemorrhage. In our study, we found no difference in primary or secondary haemorrhage rates between the COT and the control group. This result was also found in previous studies [8-10]. Some studies found a reduction in postoperative haemorrhage rate following COT [11], while others found an increase [12-14]. In a Cochrane review, seven studies revealed no difference between COT and “control” tonsillectomy and one study revealed a reduction of postoperative haemorrhage in the traditional tonsillectomy group [9]. Like most of the studies mentioned above [8-9, 12-13], our study includes a relatively small number of patients. Rare events like postoperative haemorrhage require large patient samples to investigate differences as a primary endpoint. However, it is important that potentially dangerous complications are taken into account as secondary endpoints when other factors, such as pain score, are investigated.

In our study, we found a postoperative secondary haemorrhage rate requiring general anaesthesia in 3.5% of the patients, and we found no difference between the COT and the TT group in this respect. The secondary haemorrhage rates vary in different studies, but the postoperative haemorrhage rate tends to be lower in other studies [9, 15-18] than in ours. All of the studies mentioned also included children. As there is a clear age coherence for secondary haemorrhage rate, with children having a smaller risk than adults [11, 15-18], we expected to have a slightly higher haemorrhage rate since we included only adolescents and adults. Other studies have investigated the postoperative haemorrhage rate of similar age groups and have found frequencies similar to ours [5, 19].

Many studies have investigated the postoperative haemorrhage rate and potential risk factors of tonsillectomy. Haemorrhage requiring reoperation in general anaesthesia is generally the parameter used in these studies of postoperative haemorrhage [15, 16, 19]. The threshold of readmission to hospital for observation of secondary haemorrhage varies greatly between different departments [15, 19]. Even though the threshold for when to operate in general anaesthesia may also vary, this is the best currently available parameter for comparison [17].

In our study, the COT patients were all operated by one of two surgeons, one resident and one consultant. This increases the risk of confounding, since the results might reveal more about the surgeon’s skills than about the effect of the operative technique. COT may have a learning curve as reported in a previous study [20], and it is important to remember that tonsillectomy is usually performed by residents who do not have much surgical experience. In an ideal study, patients would be randomised to either COT or TT to all the surgeons who normally perform tonsillectomy, including the least experienced residents. Apart from this risk of selection bias, we will point out that the COT and the TT groups in our study were otherwise similar and therefore comparable in all other respects.

CONCLUSION

Elective COT for patients aged 14-40 years did not outperform TT in the present study. We found no advantage of COT regarding postoperative pain score and activity level. We found a disadvantage of COT compared with TT regarding food intake later in the postoperative course. There was no difference between the COT group and the TT group regarding postoperative haemorrhage. The postoperative haemorrhage rate in our study matches the haemorrhage rates of other international studies. A large Danish randomised study is required to eliminate bias/confounding.

CORRESPONDENCE: Lis Moesgaard, Øre-, narse- og hals-afdelingen, Regionshospital Holstebro, 7500 Holstebro, Denmark.
E-mail: lismeoesgaard@dadnet.dk

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LITERATURE