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ORIGINAL ARTICLE

A Prospective, Randomized, Double-Blind Study of Coblation versus Dissection Tonsillectomy in Adult Patients

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Abstract This randomized double blind study was conducted prospectively to determine whether coblation tonsillectomy fared better than the conventional dissection method in terms of postoperative pain, bleeding, and rapidity of healing in adult Indian patients undergoing tonsillectomy. Sixty adult patients undergoing tonsillectomy for benign indications were randomized to have one tonsil removed by subcapsular radiofrequency ablation method and the other by conventional dissection method. The operative time and blood loss was noted for each side. Patients were evaluated at 6, 12, 24, 48, 72 h and then on 7th and 20th postoperative day for postoperative pain (by visual analog scale), bleeding, and tonsillar fossa healing. Statistical comparison was done using appropriate tests. The two groups were demographically matched. It took longer to perform the coblation procedure (15 *vs* 11 min) ($P > 0.05$). The operative blood loss on the radiofrequency side was 11 ml, vs 34 ml on the conventional side ($P = 0.009$). 77% patients said that the coblation side was less painful for the overall 20-day recovery period. There were significant differences seen at 6, 12, 24, 48, and 72 h in terms of postoperative pain scores. Beyond that, the pain was consistently less on the coblation side, but the difference was not significant. There was no case of reactionary or secondary hemorrhage in either arm. The healing took longer on the radiofrequency side. Coblation tonsillectomy is an easy to learn technique with significantly reduced operative blood loss and postoperative pain. Longer operative times maybe further reduced with experience.

Keywords Coblation · Tonsillectomy · Randomized · Blinded

Introduction

Tonsillectomy is one of the most common surgical procedures performed worldwide. Over the years, various techniques and instruments have evolved to accomplish this operation and have a long history.

Unlike most operative procedures, which are closed primarily, tonsillectomy produces an open wound that heals by secondary intention. The major postoperative morbidity problems are pain and secondary hemorrhage. The pain is the result of disruption of mucosa and glossopharyngeal and/or vagal nerve fiber irritation followed by inflammation and spasm of the pharyngeal muscles that leads to ischemia and a protracted cycle of pain; it does not completely subside until the muscle becomes covered with mucosa 14–21 days after surgery. The postoperative secondary hemorrhage is due to secondary infection of the tonsillar fossa resulting in disruption of vessels and bleeding [1].

The various methods described in literature for tonsillectomy are dissection, guillotine, cryosurgery, monopolar and bipolar diathermy dissection, suction diathermy dissection, bipolar scissor dissection, ultrasonic removal, radiofrequency surgery and laser surgery [2–10]. Any improvement of these procedures should have one or more of

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the following advantages–decrease in the operating time, reduction in the intraoperative and postoperative blood loss, and reduction in postoperative morbidity (mainly pain).

Coblation is a relatively new technique that was started in 1997, and involves passing a radiofrequency bipolar electrical current through a medium of normal saline, resulting in a plasma field of highly ionized particles, which in turn break down intercellular bonds and thus melt tissue at around 70°C (c.f. electrocautery which cuts tissues at 400°C or greater). There are two different techniques for coblation tonsillectomy: (1) Subtotal, intracapsular ablation in which some tonsil tissue may be left behind; and (2) Total, subcapsular dissection of tonsils, in which the entire tonsil is removed by dissecting between the tonsillar capsule and the surrounding pharyngeal muscle. In concordance with other studies [11], which state that a subtotal tonsillectomy may not be the best technique to use in adults with chronic tonsillitis because tonsillar tissue is left behind and could result in recurrent infections, we have adopted the subcapsular technique at our institute.

There are various studies describing the use of coblation in tonsillectomy with varying conclusions regarding intraoperative blood loss, postoperative hemorrhage rates, postoperative pain, and healing rates [12–24].

Five studies in adults have assessed postoperative pain after tonsillectomy in patients who had coblation compared with another technique. In most of these studies, postoperative pain was significantly less in the coblation group [11, 13, 18, 24]. A fifth study showed no difference in pain between the two procedures [23].

One study reports intraoperative blood loss value of 24 ml on an average per tonsil with coblation subcapsular adult tonsillectomy [24]. Postoperative hemorrhage rates after coblation subcapsular tonsillectomy has been reported in two studies. Noon et al. [16] reported a relatively high postoperative bleeding rate of 22.2% in patients undergoing coblation tonsillectomy in a retrospective study of 36 patients. Belloso et al. [17] prospectively compared two cohorts (pediatric and adult patients) for differences in postoperative hemorrhage. Postoperative hemorrhage rates were 2.25% in the coblation group and 6.19% in the bipolar group.

One study of 10 adult patients assessed postoperative healing rates between coblation and electrocautery (bipolar). These authors reported that at 9 days after tonsillectomy, 7 of 10 coblation patients had fully healed fossae, whereas none of the electrocautery patients had fully healed in the same time interval [13]. Although these studies address and answer many questions about coblation tonsillectomy, there is still controversy over which is the most optimal technique of tonsillectomy.

This study was designed to determine whether coblation tonsillectomy fared better than the conventional dissection method in terms of postoperative pain, bleeding, and rapidity of healing in adult Indian patients undergoing tonsillectomy.

Materials and Methods

This comparative interventional study was conducted in the Department of Otorhinolaryngology, and Head & Neck Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, India on 60 patients between 18 and 50 years on both male and female patients between November 2008 and March 2010 after ethical and scientific committee clearance. Only patients 18 years of age or older were enrolled in this study. Indications for tonsillectomy in this study were: (1) Recurrent tonsillitis ($\geq$3 episodes in the last year), (2) Tonsillar hypertrophy resulting in snoring but no sleep apnea, and (3) Halitosis or persistent foul taste due to chronic tonsillitis which is not responding to medical therapy. Patients with a history of unilateral peritonsillar abscess, unilateral tonsil hypertrophy (warranting investigation for neoplastic process), or a known bleeding disorder were excluded from the study.

Patients were randomized to have one tonsil removed using coblation (Surgitron FFPF EMC, Ellman Inc, USA) and the other using conventional dissection method. Through this randomization process, half of the patients had their right tonsil removed with coblation and left tonsil by dissection. The other half of the patients had the left tonsil removed with coblation and right tonsil by dissection.

Patients were blinded with regards to the technique used to remove each tonsil. Thus, patients became their own controls in terms of postoperative pain, wound healing, and bleeding. The coblation device was set to a level of 6 or 7 during the surgeries. All surgeries were performed by a single experienced otolaryngologist, who had performed at least ten coblation tonsillectomies before beginning this study. Outcome measures of time needed to perform surgery for each side, blood loss during surgery, patient-reported pain, postoperative hemorrhage, and amount of wound healing at 20 days after surgery were recorded by an independent otolaryngologist blinded to the technique used to remove each tonsil. Postoperative care was the same for all patients. Postoperative pain was assessed at 6, 12, 24, 48, 72 h and then on 7th and 20th postoperative day. The pain was assessed using visual analog scale (VAS) on a scale of 0–10. Patients were also asked which side hurt more overall during the first postoperative week. Even if the difference was very small, the patients were asked to choose the less painful side. The area of slough in each tonsillar fossa was assessed by direct visual examination. The surgeon estimated the amount of healing within the tonsillar fossa by recording the percentage of the fossa

that had remucosalized. Also, all episodes of postoperative bleeding from the tonsillar fossae were documented, including the side and day on which it occurred, and the interventions required to stop it.

Statistical analysis was performed with SPSS software ver. 17 (SPSS Inc., Chicago, IL). Comparison of pain scores was performed with a two-way analysis of variance. Categorical data analysis was performed with χ^2 techniques. Pearson correlation coefficients and *t*-tests were performed wherever appropriate. Differences were considered significant when the *P* value was <0.05.

Results

Demographic Data

There were 32 males and 28 females between 18 and 28 years, averaging 21.56 years. The two groups were matched in terms of sex and age distribution.

Surgical Time

The mean operation time from giving incision on the tonsil to achieving complete hemostasis for conventional technique was 11 min and that for the radiofrequency technique was 15 min (Table 1). Thus it took an average of four minutes longer to perform the coblation procedure compared to the conventional technique, but this difference did not reach statistical significance ($P > 0.05$). Also, the operative time did not correlate with postoperative pain scores in either arm.

Intraoperative Blood Loss

The total blood loss during the procedure was measured by weighing the swabs before and after the procedure separately on each side, and that in the suction apparatus. The amount of blood lost on an average on the radiofrequency side was 11 ml, and on the conventional side was 34 ml (Table 1). This difference was found to be statistically significant ($P = 0.009$, independent *t*-test).

Table 1 Comparison of operative time (mean) and intraoperative blood loss (mean ± standard deviation) between the coblation and conventional tonsillectomy arms

	Coblation arm ($n = 60$)	Conventional arm ($n = 60$)	*P* value
Operative time (min)	15	11	NS
Intraoperative blood loss (ml)	11 ± 7.87	34 ± 12.89	0.009

NS not significant

Postoperative Pain

Seventy-seven per cent of patients said that the side that underwent coblation was less painful for the overall 14-day recovery period than the side on which dissection was used. The other 23% said that the dissection side was less painful, and this was statistically significant ($P = 0.01$).

Pain was observed by VAS. The data recorded from various groups was put to statistical analysis and '*P*' value was calculated using independent *t*-test. The mean pain score for coblation averaged over 14 days was 2.76 and was 4.84 for conventional technique (Table 2). When pain scores were compared between the two techniques for each individual evaluation, there were significant differences seen at 6, 12, 24, 48 and 72 h. Beyond that, the pain was consistently less on the coblation side, but the difference was small and not significant.

Postoperative Bleeding

There was no case of reactionary or secondary hemorrhage in either arm.

Tonsillar Fossa Healing

Each tonsillar fossa was assessed for healing at the time of each evaluation in terms of per cent of the tonsillar fossa that was covered with slough. Slough formation was early on the radiofrequency side and remained there for a longer duration of time (Table 3). The healing took longer on the radiofrequency side.

Long term Follow up (3–6 weeks)

There was no difference between the two groups. By the third week slough was absent in both groups and a smooth tonsillar fossa was visible.

Table 2 Comparison of pain scores by VAS (out of 10) at successive evaluations between the coblation and conventional sides (mean)

	Coblation side	Conventional side	*P* value
At 6 h	4.0	8.2	<0.001
At 12 h	3.7	7.8	<0.001
At 1 day	3.3	7.1	<0.001
At 2 days	3.1	5.2	<0.05
At 3 days	3.1	3.3	<0.05
At 7 days	2.1	2.3	NS
At 20 days	0	0	NS
Average over 20 days	2.76	4.84	<0.001

NS not significant

Table 3 Comparison of tonsillar fossa healing by per cent of fossa covered with slough at successive evaluations between the coblation and conventional sides (mean)

	Coblation side (%)	Conventional side (%)	*P* value
At 6 h	17.5	0	<0.001
At 12 h	44.1	15.6	<0.001
At 1 day	77.5	33.6	<0.01
At 2 days	100	50	<0.01
At 3 days	100	69.1	<0.01
At 7 days	55.8	10	<0.01
At 20 days	0	0	NS

NS not significant

Discussion

Ideally tonsillectomy should be quick, painless and associated with no blood loss. In reality, however the morbidity of tonsillectomy may be significant. Surgeons must consider hemorrhage, apnea, pain, fever, and poor oral intake as possible effects of the surgery. Surgeons should select the technique that, in their own hands offers the minimum morbidity. In our study we compared the advantages and disadvantages of radiofrequency coblation technique for tonsillectomy versus cold dissection and snare tonsillectomy with ligature hemostasis. Several investigators have explored the intraoperative and postoperative complications including pain, slough and hemorrhage.

Belloso et al. [17] in a prospective observational cohort study found that secondary re-bleed rate with coblation was 2.25% versus 6.19% in the control group. Secondary re-bleed rate in children following coblation was 0.95% versus 4.77% in the control group and was statistically significant. Secondary re-bleed rate in adults following coblation showed evidence of a lower prevalence of secondary hemorrhage in the coblation group (4.40%) versus the control group (8.81%). No difference was found in the primary re-bleed rate between treatment groups. Divi V et al. [19] in a retrospective review of records from Jan'99 to April'03 found no statistical difference between bleed rates for coblation versus non-coblation tonsillectomy techniques. In our study, there were no cases of reactionary or secondary hemorrhage. Primary hemorrhage in either arm was minimal and easily controlled.

N Polites et al. 2006 [25] found that coblation tonsillectomy caused significantly less pain during the first three postoperative days, when compared with cold dissection tonsillectomy. No demonstrable benefit was shown on days 4–10. Timms MS et al. [13] found significant benefits in postoperative pain levels and rates of healing following coblation tonsillectomy as compared to conventional techniques. Temple RH et al. [12] concluded that coblation offers significant advantages in the postoperative period such as more rapid return to normal diet and drastic reduction in analgesic requirements when compared to conventional surgical techniques.

In our study we found that pain was significantly less at 6, 12, 24, 48, and 72 h with *P* values of 0.006, 0.0002, 0.0008, 0.03, and 0.005, respectively. However, on the 7th day postoperative *P* value was just statistically insignificant, although the VAS scores were consistently lower in the coblation arm. Although the pain was significantly less in our study, but the tonsillar fossae healing was delayed on the radiofrequency side as evidenced by the presence of slough in the fossae on day 7 with *P* value of 0.04 which is statistically significant.

Conclusion

It is possible at the end of this prospective randomised double blind study to safely reach the following conclusions

1. Coblation tonsillectomy using radiofrequency ablation is a relatively easy technique to learn and perform, providing a near bloodless field, and causing minimal surrounding tissue damage.
2. The operative time required to perform coblation tonsillectomy is more than that for the conventional method, although this did not reach statistical significance. Also, the longer time did not translate into more postoperative pain. It may be possible to reduce this time further with experience.
3. The preoperative blood loss was significantly less on the coblation side than on the dissection side, and was easily controllable in all cases.
4. Most importantly, postoperative pain scores were significantly lower on the coblation side for the first 3 days, and the trend continued till the last evaluation (at 20 days), although the difference was less after 3 days. This reduced pain may be a result of the reduced temperature used in coblation (60–70°C), and less damage to surrounding tissues. Also, it may translate into an earlier return to work and less income loss to the patients' family, though this was not objectively studied in the present study.
5. Healing was slightly delayed on the radiofrequency side but there was no eventual difference at 20 days in the two groups.

To conclude, coblation tonsillectomy is an easy to learn, safe procedure, with significant advantages in terms of reducing postoperative morbidity, and thus should be routinely used in all cases. Larger randomized studies would be required to confirm or refute the same.

Conflicts of interest None

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