Original Article

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Does Harmonic Scalpel Tonsillectomy Have Better Postoperative Outcomes Than Cold Dissection Technique in Adults? Results of A Randomized Double-Masked Study

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Abstract:

Objective: To compare postoperative pain, intraoperative blood loss, operating time, time needed to return to a normal diet, and activity between harmonic scalpel and cold dissection tonsillectomies.

Material and Methods: In this prospective, double-blind study, eligible patients aged 18 and above (n=88) were randomized to receive either harmonic scalpel tonsillectomy (n=44) or cold steel tonsillectomy (n=44). Pain was assessed using the visual analogue scale (VAS) on days 1, 4 and 7, respectively. Intraoperative bleeding was measured by intra-suction blood and the weight of tonsil swabs.

Results: On postoperative day one, the mean pain score in the harmonic scalpel group was 4.6±1.4 (range, 2-7), and in the cold steel group, it was 7.2±1.7(range, 4-10): (p-value<0.001). The mean pain score on the 7th postoperative day in the harmonic scalpel group was 2.3±1 (range, 1-4), and in the cold steel group, it was (2.6±1.3, range 1-6) (p-value=0.145). The mean intraoperative bleeding in Group 1 was 8±1.9 (range, 5-12 cubic centimeter (cc)), and in Group 2 was 66.3±8.1 (range, 58-90 cc): (p-value<0.001). The mean duration of surgery in Group 1 was 14.5±3.5 (range, 11-28 minutes) and in Group 2 was 27.4±4.4 (range, 22-38 minutes) (p-value<0.001). The mean time taken to return to resume daily activities in the case of harmonic scalpel was 7.6± 0.8 days, whereas in cases of the cold steel method it was 8.8±0.9 days (independent t-test, p-value=0.050).

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Conclusion: Harmonic scalpel tonsillectomy has less postoperative pain compared to the cold dissection technique. Additionally, there is less intraoperative blood loss and a reduced incidence of delayed haemorrhage.

Keywords: chronic tonsillitis, cold dissection, harmonic scalpel, tonsillectomy

Introduction

Surgical removal of the tonsils (tonsillectomy) is a commonly performed procedure by otolaryngologists. The procedure itself can be performed in different ways, depending upon the technique, surgical skill, experience, and individual preference[1].

In tonsillectomies, the pharyngeal mucosa is cut with scissors and the tonsil is subsequently dissected from the lateral pharyngeal wall. This 'blunt' dissection is done under general anaesthesia and haemostasis can be achieved via ligature, sutures, or cautery (monopolar and bipolar diathermy)[2]. In general, clinical outcomes of cold knife dissection are good; however, there may be significant blood loss during the procedure[3].

Tonsillectomies are commonly performed for recurrent or chronic tonsillitis, peri-tonsillar abscess and adenotonsillar hypertrophy, leading to airway obstruction and obstructive sleep apnoea[4].

The harmonic scalpel is an ultrasound-based dissector that cuts through the tissues and coagulates blood vessels at the same time. The vibrating frequency of this sharp blade is 55,500 Hz. Haemostasis is achieved by superficial denaturation and coagulation of the proteins at a low temperature (50 ºC to 100 ºC). This offers the advantage of precise dissection, good haemostasis and less thermal damage to tissues[5,6].

Tonsillectomy complications, such as bleeding and pain, can occur during both procedures (cold knife dissection and electrocautery). Bleeding may occur during surgery, within the first 24 hours postoperatively, or after 24 hours; necessitating secondary intervention.

Postoperative pain remains a major concern and, at times, may be severe enough to prolong the length of hospital stay or may require readmission[7,8]. Pain following tonsillectomy assumes significance as there may be difficulty in swallowing, risk of dehydration, infection, and secondary haemorrhage[9].

This present, randomised controlled trial compared harmonic (ultrasonic) scalpel to the classical tonsillectomy technique in adults undergoing tonsillectomy for postoperative outcomes, including pain, blood loss during surgery and frequency of secondary haemorrhage.

Material and Methods

Study design

A randomized, doublemasked, interventional study was conducted at two teaching hospitals. The research was part of a dissertation for a postgraduate student. The institutional review boards and the local ethics committee approved the trial. Written informed consent was obtained from all patients participating in the study. The study followed the tenets of the Declaration of Helsinki.

Patient selection

In this study, harmonic scalpel tonsillectomies were compared to cold steel tonsillectomies. Patients of either gender, above 18 years of age, who presented for tonsillectomy were prospectively evaluated.

Tonsillectomies were performed for recurrent acute tonsillitis, obstructive sleep apnea and clinically suspected neoplasm. A history of recent surgery, tonsils hypertrophy, acute tonsillitis, peritonsillar abscess, mental or language

dysfunction and patients with bleeding disorders were excluded from the study.

Randomization, masking, and sample size calculation

The sample size was calculated using the principle of inference for means, comparing two independent samples. To calculate the sample size and compare the mean difference pain score (VAS score) between the harmonic scalpel (Group 1) and cold steel group (Group 2), a pilot study was first conducted on 10 subjects.

The mean reduction in VAS score (from 1st to 7th PO day) in Group 1 was 1.3 and, in Group 2 it was 1.6. The standard deviation was 0.5. Assuming 1:1 randomization, 80% power (alpha = 0.05), and a precision error of 5%, to detect a difference of 20% or more in VAS score between the two groups, the estimated sample size in each group was calculated to be 44 (www.stat.ubc.ca/;rollin/stats/ssize/n2.html). As dissertation needs to be completed in a limited time span (15 months), an overall sample size of 88 (44 in each group) was justifiable.

The procedures were performed by one of two surgeons, with both being well-versed in the procedures. A disk operating system-based software in the Department of Community Medicine at our institute was used to generate allocation codes. The process was stratified according to the clinical center, utilizing a permuted block method with randomly chosen block sizes. Allocation of patients was performed randomly to one of the two surgical groups via parallel assignment. The codes were sealed in green envelopes, and healthcare personnel not involved in patient care opened the envelopes 10 minutes prior to surgery.

Surgical technique

With the neck in slight extension, the patient was placed in a supine position on the operation table. With forceps, the tonsil(s) was grasped and drawn medially. The harmonic scalpel was adjusted at the level 2 position for the machine and an incision was made, cutting the mucosa at the superior pole near the anterior pillar. After dissection, the tonsillar capsule was exposed, and the dissection was continued along the surface of the tonsil, separating it from the constrictor muscles. Using the broad surface of the blade, the dissection was extended near the tonsil. The connection between the lower pole of the tonsil and the base of the tongue was also divided. The flat surface of the blade was applied to the source for 5–10 s to achieve haemostasis for small vessel bleeds. The power adjustments, blade edge, tissue tension, grip force and pressure all controlled the cutting speed and coagulation. Additionally, it is prudent to keep the blade as close as possible to the capsule of the tonsil throughout the procedure. In the cold procedure, the tonsils were dissected out by cold steel instruments, and haemostasis was secured by bipolar diathermy.

Postoperative analgesia

In both interventional groups, paracetamol and ibuprofen were prescribed to the patients. Additionally, patients in the cold steel group received codeine phosphate for pain relief. Equal doses of acetaminophen were prescribed to all patients after surgery. On the first postoperative day, an acetaminophen suppository, 325 mg every 8 hours, was followed up with acetaminophen syrup (10 mL), administered 6 hoursly.

Measurement of blood loss

The bleeding during surgery was calculated by measuring blood collected at suction and the weight of tonsil swabs (as a rule, the weight of each swab was considered as about 1g and, when completely wet, having approximately 5 mL of blood). No topical or surface anesthesia, or other oral or injectable analgesics were prescribed prior to surgery.

Pain assessment

A visual pain measurement scale (VAS) was used to assess postoperative pain. Overnight hospital stay was mandatory for all, and patients were discharged home the next day. At discharge, patients were administered a questionnaire relating to pain, the intake of analgesics, and return to normal diet and activity (1st, 4th, and 7th days after the operation), and pain scores were compared between the two interventional groups.

Statistical analysis

Statistics were perfromed using IBM statistical software, Statistical Package for the Social Sciences (SPSS) Statistics version 29 (IBM Inc., Armonk, New York, USA). Shapiro-Wilk test was used to check data for normality. Visual inspection of boxplots identified the outliers. For all continuous variables, descriptive measures, such as mean with standard deviation (S.D.), were calculated, whereas frequencies and percentages were calculated for all categorical variables. The difference between the means of two independent groups on a continuous dependent variable was calculated using the independent-samples t-test. The association between two categorical variables was evaluated using chi-square tests. Statistically significant differences between the means of two or more independent groups were evaluated using one-way ANOVA. A p-value less than 0.05 was considered statistically significant.

Results

There were 28 males in the harmonic scalpel group (Group 1), with a male female ratio of 1.75:1 and 32 males in Group 2; with male female ratio of 2.7:1. Between the two groups, gender did not differ significantly (chi-square test, p-value=0.493). Table 1 mentions the demographic characteristics of the study subjects.

The mean age of patients in Group 1 was 26.2±6.1 (range, 18-38 years), and in Group 2, it was 24.4±5.1 (range, 18-35 years). The age of patients did not significantly differ between the two groups (independent t-test, p-value=0.073).

Surgical time: Surgical time was recorded from the initial incision to the end of coagulation. The mean duration of surgery in Group 1 was 14.5±3.5 (range, 11-28 minutes), and in Group 2, it was 27.4±4.4 (range, 22-38 minutes). A statistically significant difference was observed in the surgical time between the two groups (independent t-test, p-value<0.001).

Intraoperative bleeding: the mean intraoperative bleeding in Group 1 was 8±1.9 (range, 5-12 cubic centimeter (cc)), and in Group 2, it was 66.3±8.1 (range, 58-90 cc). There was a significant difference in intraoperative blood loss volume between the harmonic scalpel and cold steel techniques (independent-t tests, p-value<0.001).

Table 1 Demographic characteristics

Parameter	Group 1 (n=44)	Group 2 (n=44)	p-value
Age in years*	26.2±6.1	24.4±5.1	0.073
Gender#			
Male	28	32	0.493
Female	16	12	
Length of surgery (minutes)*	14.5±3.5	27.4±4.4	0.001
Time to resume normal diet*	7.3±1.2	8.1±1.4	0.023
Time to resume daily activity*	7.6±0.8	8.8±0.9	0.050

*expressed as mean±S.D., #expressed as frequency and percentage

Delayed bleeding: delayed bleeding was defined as the incidence of bleeding more than 24 hours post-surgery. There was a significantly lower risk of delayed bleeding in the harmonic scalpel group as compared to the cold steel group (p-value<0.001).

Postoperative pain: after tonsil surgery, pain was evaluated on the first, fourth, and seventh days, respectively. On the first postoperative day, the mean pain score in the harmonic scalpel group was 4.6±1.4 (range, 2-7), and in the cold steel group, it was 7.2±1.7(range, 4-10). There was significantly lower pain in the harmonic scalpel group on postoperative day one as compared to the cold steel group (independent-t tests, p-value<0.001).

The pain score (mean) on the 4th postoperative day in the harmonic scalpel group was 4±1.4 (range, 2-6), and in the cold steel group, it was (4.4±1, range 3-6). Between the 2 groups, the pain scores did not differ significantly (independent-t tests, p-value=0.082).

The pain score (mean) on the 7th postoperative day in the harmonic scalpel group was 2.3±1 (range, 1-4), and in the cold steel group, it was (2.6±1.3, range 1-6). On postoperative day 7, the pain score did not differ significantly between the two groups (independent-t tests, p-value=0.145). Figure 1 compares pain scores between the two groups on the 1st, 4th, and 7th postoperative days, respectively.

No other significant intra nor postoperative complications were reported in the two groups. The mean time taken to resume normal diet in the harmonic scalpel group was 7.3±1.2 days and in the cold steel group it was 8.1±1.4 days (independent-t tests, p-value=0.023).

The mean time to the resumption of daily activities in cases of harmonic scalpel usage was 7.6±0.8 days, whereas in cases utilizing the cold steel method, it was 8.8±0.9 days (independent t-test, p-value=0.050).

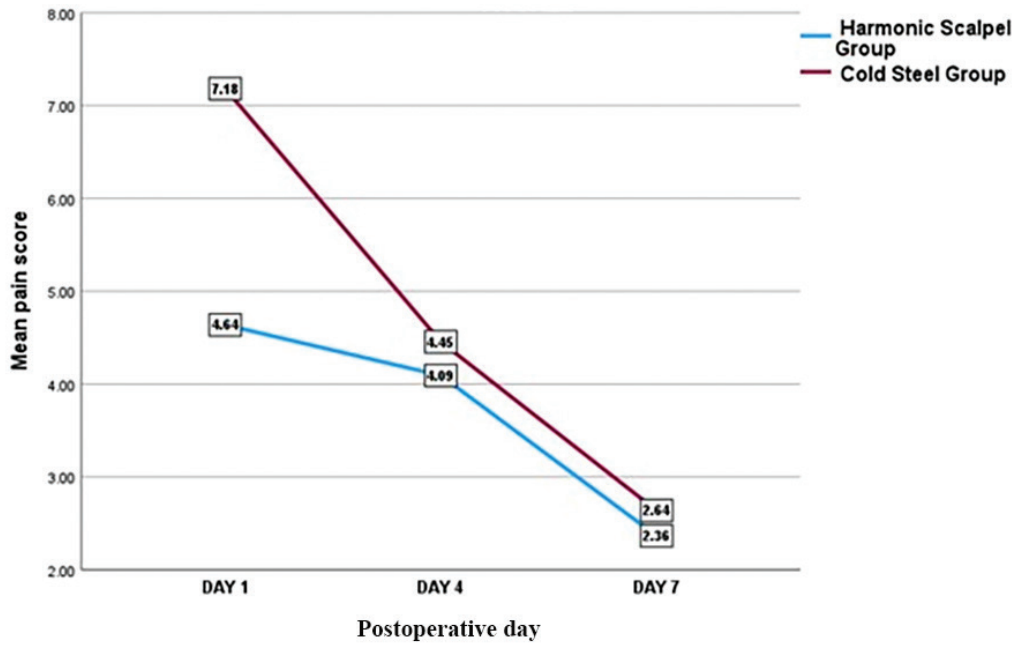

Figure 1 A line diagram showing the mean difference in pain scores on the 1st, 4th and 7th postoperative day between harmonic scalpel and cold dissection methods

Discussion

This prospective, double-masked, randomized study evaluated the differences in operating time, blood loss during surgery, postoperative pain (days 1, 4, and 7), and delayed (>24 hours) bleeding between ultrasonic harmonic scalpel and conventional tonsillectomy. The study was conducted on 88 eligible patients that were randomized to receive either a harmonic scalpel tonsillectomy (n=44) or a cold dissection tonsillectomy (n=44), with suction electrocautery haemostasis.

The results of this study revealed that the harmonic scalpel tonsillectomy had significantly less intraoperative blood loss (8 mL versus. 66.3 mL, p-value<0.001) and significantly less pain on 1st postoperative day. The pain was determined by scores on a 10-point visual analogue scale (mean: 4.6 versus 7.2, respectively, p-value<0.001).

Although pain scores at postoperative day 7 were comparable between the two techniques (2.3 vs. 2.6, p-value=0.145), the operating time was significantly lower in the harmonic scalpel group (14.5 versus. 27.4 min, p-value<0.001).

Despite refinements in instrumentation, techniques of surgery and means of achieving haemostasis, bleeding and pain during postoperative periods remain significant challenges for both the surgeon and the patient during tonsillectomy. Since time immemorial, there has been a constant endeavour by otolaryngologists to adapt to any instrumentation and technique that could potentially reduce morbidity as well as increase the safety margin during tonsillectomies.

The harmonic scalpel has been widely used in intrabdominal, intrathoracic, and gynaecologic surgeries; however, there are limited published studies in the literature that specifically relate to its use in tonsillectomies[10-12].

Irrespective of the type of tonsillectomy, all patients are left with a relatively large, raw superior constrictor muscle that needs to heal by secondary intention in the oropharynx, which is contaminated[13].

Walker and Syed conducted a pilot study (n=316) in patients undergoing tonsillectomies. Out of these, 155 tonsillectomies were performed with a harmonic scalpel. Data were collected on parameters, such as return to regular diet and activity and the use of medications for pain. The authors found that return to normal diet and activities were significantly earlier in harmonic scalpel tonsillectomies. Additionally, although perioperative blood loss was comparable, the delayed bleeding (3.2 vs. 5.6%) rate was lower as compared to electrocautery tonsillectomy[14].

Another study by Sood et al. evaluated outcomes of harmonic scalpel tonsillectomy (n=59) and found that operating time, intraoperative blood loss, postoperative pain and delayed bleeding rates were comparable to this study. However, unlike a randomised controlled trial (RCT) like ours, there was the absence of a control arm[15].

A recent study by Bagherihagh et al. compared outcomes of tonsillectomy in adults (n=50) via harmonic scalpel and classical methods. The authors found that surgical time and the amount of blood loss during surgery were significantly less in the harmonic scalpel method group than in the cold dissection method group (p-value< 0.001). Second, pain on postoperative days 1 and 4 was significantly less in the harmonic scalpel group, whereas pain was comparable on postoperative day 7 between the two groups. These observations are comparable with this study[16].

In contrast, a study by Lachanas et al. found that pain on postoperative day 7 was significantly less in the harmonic scalpel group as compared to the cold steel group[17]. In another study by Kamal et al., 90 patients who underwent tonsillectomy received ibuprofen and paracetamol preoperatively. In addition, patients in the cold steel group received codeine as well. The authors found that postoperative pain in the first week was significantly less in the harmonic blade group[18].

Alexiou et al. conducted a meta-analysis of randomized controlled trials (n=33) comparing technology-

assisted tonsillectomy and conventional tonsillectomy involving 3,139 patients. In their study, surgical time, bleeding (perioperative and postoperative), and postoperative pain were compared. The authors found that perioperative bleeding was significantly less in the harmonic scalpel group as compared to cold steel and/or electrocautery dissection. However, collation and harmonic scalpel techniques do not have any significant advantage over cold steel and/or electrocautery for postoperative pain[19]. Having said this, many of the studies included in the meta-analysis were conducted on patients of different age groups with variable indications, and they differed in timing and dose of painkillers; these differences could have influenced the outcomes. Second, variables such as age, gender, anxiety, and pain thresholds can significantly influence pain scores assessed by a quantitative scale.

A systemic review by Wong and Paddle observed that in comparison to cold steel tonsillectomy, a harmonic scalpel was associated with significantly less blood loss (mean difference=–37.79, 95% CI: –40.78 to –34.80, p-value<0.001). However, there was extreme statistical heterogeneity (I^2=99%); pointing towards a low quality of evidence due to heterogeneity in methodology[20]. Hence, more RCTs are needed, with more comparable methodologies, to provide more comprehensive evidence.

This present study had several limitations and strengths. As the sample size (n=88) was relatively small, this could have led to the possibility of type II error, and consequently overestimation. Second, the use of a visual analogue scale (VAS) has often been criticized as being more subjective as opposed to other determinants, such as analgesic intake and return to normal diet and activity. The randomized study design with concealed allocation, double-blinding and negligible attrition bias were the strengths of this study.

Conclusion

The harmonic scalpel technique is associated with less postoperative pain as compared to cold techniques. This significant difference (p-value<0.05) in pain scores, compared to standard techniques, was observed on the 1st and 4th postoperative days. This technique may also be associated with less blood loss during surgery; however, there was significant statistical heterogeneity among included studies pooled for meta-analysis (I^2=99%). A harmonic scalpel tonsillectomy does demonstrate superiority over blunt dissection ("cold steel technique"), as evidenced by a reduced incidence of delayed haemorrhage.

Conflict of interest

The authors declare no conflicts of interest.

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