

# Randomized Controlled Study of Ultrasonic Scalpel Tonsillectomy Versus Cold Dissection Tonsillectomy

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## ABSTRACT

### Background

The purpose of this study is to compare two different techniques of tonsillectomy, the ultrasonic scalpel, and the cold dissection tonsillectomy. In this study, the duration of the surgery, intra-operative blood loss, post-operative pain and post-operative hemorrhage rate will be compared.

### Material and Methods

This is a randomized controlled study involving 72 patients within the age of 3-40 years old with history of recurrent tonsillitis or tonsillar hypertrophy with obstructive symptoms. The patients are randomized to have both tonsils removed either by cold dissection method or ultrasonic scalpel method. During the surgery, operative time and intra-operative blood loss will be documented. The post-operative pain score was documented by the patient using the visual analog pain score. Post-operative hemorrhage will also be documented if present.

### Results

The data collected will be analysed statistically. The duration of surgery for ultrasonic scalpel tonsillectomy was significantly shorter (mean 14.11 minutes versus 29.09 minutes,  $p < 0.001$ ) and intra-operative bleeding was also significantly lower (mean 9.58 ml versus 87.57 ml,  $p < 0.001$ ). There were no significant mean differences of post-operative pain score between cold dissection and ultrasonic scalpel in first 6 hours up to day 6 of post-surgery. However, post-operative pain score for cold dissection tonsillectomy was significantly less on the 7th day of post-surgery.

### Conclusions

There was no documented post-operative hemorrhage. Ultrasonic scalpel tonsillectomy is more superior compared to cold dissection tonsillectomy in terms of operative time and intra-operative blood loss, however there is no difference in the post-operative pain score.

### Keywords

cold dissection; operative time; post-operative pain; tonsillectomy; ultrasonic scalpel.

## INTRODUCTION

One of the most common surgical procedures in the field of otorhinolaryngology is the removal of the tonsils, or tonsillectomy. With nearly a quarter of a million performed each year, tonsillectomies rank as the third most common surgery performed in the United States.<sup>1</sup> Numerous methods and tools for tonsillectomies have been developed over the years. These include tonsillectomy by cold dissection, tonsillectomy by electrocautery, tonsillectomy by coblation, tonsillectomy by Pulsed Electron Avalanche Knife (PEAK) plasma blade, tonsillectomy by ultrasonic scalpel, and tonsillectomy by microdebrider.<sup>2,3</sup> The debate remains on the optimal method that has the least intraoperative and post-operative morbidity.

Complications of tonsillectomy can range from common issues like postoperative

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infection, bleeding, and edema to more rare and serious complications such as atlantoaxial subluxation, mandible condyle fracture, pneumothorax and to the most commonly miss concerned complication by the local community, which is the loss of voice, concluded by Lea et al., to be objectively negative during objective voice assessment.<sup>4,5</sup> These complications highlight the importance of careful consideration and monitoring during and after tonsillectomy procedures to ensure patient safety and optimal outcomes.

In our centre, the routine method performed is the traditional cold dissection tonsillectomy.

Cold dissection tonsillectomy remains the standard technique in most centres. All trainees who wish to pursue their career in otorhinolaryngology should master this tonsillectomy method before learning any other methods.<sup>6</sup> Under general anaesthesia, a cold dissection tonsillectomy is carried out. The tonsils are carefully pulled medially with Luc's forceps to reveal their loose areolar tissue plane. An incision is made along that plane with a curved set of Metzenbaum scissors. Using a Mollison's tonsillar dissector, the tonsil is divided along the plane until the inferior pole is reached after the tonsillar capsule is exposed. A bipolar cautery is used to achieve haemostasis.<sup>7</sup>

The ultrasonic scalpel was introduced as the harmonic scalpel in 1993 by Ethicon® Endo-Surgery. Over the last few years, the ultrasonic scalpel has been widely used in urologic, thoracic, hepatic, laparoscopic, and gynaecologic procedures at Hospital Universiti Sains Malaysia (HUSM). This scalpel is also widely used in head and neck procedures such as thyroidectomy, laryngectomy, and tonsillectomy in HUSM. This device works by using ultrasound energy to excise tissues while at the same time closing the surface of the cut. Using ultrasonic scalpel has the benefit over diathermy in that it produces less smoke and can sever thicker tissues. While an ultrasonic scalpel coagulates as it cuts, surgical diathermy can coagulate bleeding tissue at any moment. The ultrasonic scalpel cuts tissue by vibrating at a rate of roughly 55 kHz per second; the edges are then sealed by protein denaturation.<sup>8</sup> The reasons for the increasing popularity of the ultrasonic scalpel are its known associations with less post-operative pain and an earlier return to oral intake and regular activities.

The debate over the optimum tonsillectomy technique has been well-documented, with discussions focusing on issues such as blood loss during the procedure, length of stay, and pain following the surgery. With differing outcomes, several studies have contrasted tonsillectomy using an ultrasonic scalpel with alternative techniques. According to Akural et al., compared to a cold dissection tonsillectomy with electrocoagulation, ultrasonic scalpel tonsillectomy demonstrated a decrease in intraoperative blood loss and less pain the day following surgery.<sup>9,10</sup> According to Sood et al., an ultrasonic scalpel tonsillectomy is a quick treatment with little blood loss and less pain thereafter.<sup>11</sup>

When compared to bipolar diathermy, there was no benefit in terms of operating time, post-operative morbidity, or bleeding from using an ultrasonic scalpel. Similar conclusions were found from a randomised control trial carried out by Leaper et al. on 204 youngsters.<sup>12,13</sup> There was less intraoperative blood loss using an ultrasonic scalpel than with a cold dissection tonsillectomy, according to research by Collison et al. and Basu et al.<sup>14,15</sup> According to Kamal et al., the tonsillectomy group that underwent ultrasonic scalpel surgery had a similar mean operative time as the tonsillectomy group that underwent cold dissection tonsillectomy; however, the ultrasonic scalpel tonsillectomy group experienced much reduced intra-operative blood loss. The study also found that, compared to the cold dissection tonsillectomy group, post-operative pain was experienced by all patients in the ultrasonic scalpel tonsillectomy group, albeit to a lesser degree.<sup>6</sup> Ali et al. conducted a study comparing harmonic scalpel tonsillectomy with electrocautery and discovered that the former caused reduced discomfort only in the early postoperative period. However, there were no noteworthy changes observed in terms of intraoperative bleeding, operative time, or subsequent haemorrhage.<sup>16</sup>

Based on the above-mentioned studies, there is conflicting evidence as to whether the method of ultrasonic scalpel tonsillectomy really carries significant advantages when compared with cold dissection tonsillectomy. Therefore, the research question is whether ultrasonic scalpel tonsillectomy is better than cold dissection tonsillectomy in several key areas that are of importance to both surgeons and

patients, specifically in the reduction of post-operative pain, intra-operative blood loss, duration of surgery, and incidence of post-operative hemorrhage.

## MATERIAL AND METHODS

This was a prospective, single-blinded, randomised controlled trial that was carried out at Hospital Universiti Sains Malaysia. A total of 72 patients aged 3 to 40 years who fulfilled the criteria for tonsillectomy based on the tonsillectomy guidelines published by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNS) in 2011 were included in this study.<sup>11</sup> The patients who were indicated for tonsillectomy were divided into 2 groups: those who underwent cold dissection tonsillectomy and those who underwent ultrasonic scalpel tonsillectomy. Simple randomization of the subjects was carried out by drawing lots. Indications for tonsillectomy in this study included patients aged 3 to 40 years with either a history of recurrent tonsillitis or tonsillar hypertrophy with obstructive symptoms.

Patients were not informed which technique would be used to remove their tonsils until the first follow-up. In this manner, patients served as their own controls, regarding their post-operative pain and bleeding. Once agreeable, informed consent was taken from the patients, and they were registered with regards to age, gender, race, pre-tonsillectomy grading, indication of surgery, and the method of surgery. During the procedure, the operative time taken was documented in minutes, and the intra-operative bleeding rate was documented in millilitres (ml). Patients were advised on how to fill up the post-operative pain score sheet, and the sheets were returned during the first follow-up following surgery.

All surgeries were performed by a single surgeon. The ultrasonic scalpel tonsillectomy was performed under general anaesthesia using the Ethicon® Endo-Surgery handpiece. The upper poles were dissected using the harmonic scalpel set on 40% power. Medial traction on the tonsil was applied, and the tonsil was dissected, staying as close as possible to the capsule. A cold dissection tonsillectomy was also performed under general anaesthesia. Using Luc's forceps, the tonsils were gently retracted medially, exposing their loose areolar tissue plane. Using a curved pair of Metzenbaum scissors, an incision was made along that plane. The tonsillar capsule was exposed, and the tonsils were dissected along the plane until the inferior pole of the

tonsil was reached using a Mollison's tonsillar dissector. Haemostasis was achieved using a bipolar cautery.

The operative time was recorded from the time the Boyles-Davies gag was inserted until haemostasis was secured. Intra-operative blood loss was documented in several ways, depending on the surgical technique used. If the surgical procedure involved tonsillectomy alone, only one suction jar was used, whereas if the surgical procedure involved adenotonsillectomy, two suction jars were used (one suction jar was used for adenoidectomy and the other for tonsillectomy). Standard tonsil gauzes were used. These swabs were counted and weighed toward the end of the procedure. Each piece of gauze, when fully soaked, weighs 5 g and contains approximately 5 ml of blood. The post-operative pain score was evaluated using a standard visual analogue pain score that is currently practised in Ministry of Health (MOH) hospitals across Malaysia. A pain score ranging from 0 to 10 was documented, where 0 indicated no pain and 10 indicated the most severe pain. As for younger age groups where pain scores could not be assessed using the analogue pain score, the Wong Bakers Faces Pain Rating Scale was used instead.<sup>14</sup> Patients' parents or legal guardians were taught how to use the pain score pre-operatively. The feedback forms were given to the patient during discharge and reviewed during the first clinic follow-up. Episodes of post-operative haemorrhage were documented on the feedback form and analysed during the first clinic follow-up.

The collected data were entered and analysed using IBM SPSS version 22 predictive analysis software. The methods practiced in this study have met the ethical principles stated in the Declaration of Helsinki developed by The World Medical Association (WMA).

## ETHICAL CLEARANCE

This study was approved by the Human Ethical Committee of the School of Medical Sciences, Universiti Sains Malaysia (USM/JEPeM/15120563).

## RESULTS

A total of 72 patients were recruited in this study. Thirty-six patients underwent a cold dissection tonsillectomy, and 36 patients underwent an ultrasonic scalpel tonsillectomy. There was a significant difference in the mean intra-operative time between cold dissection and ultrasonic scalpel tonsillectomy (mean difference

(95% CI): 14.98 (12.96, 16.99);  $p < 0.001$ ) (Table 1). Patients with cold dissection procedures had a longer mean intra-operative time (29.09 minutes) compared to patients who underwent ultrasonic scalpel procedures, which had a mean intra-operative time of 14.11 minutes. There was also a significant difference in the mean intra-operative bleeding between cold dissection and ultrasonic scalpel (mean difference (95% CI): 77.99 (72.42, 83.56);  $p < 0.001$ ) (Table 2). Patients with cold dissection procedures had more intra-operative bleeding (87.57 ml) compared to patients who underwent ultrasonic scalpel tonsillectomy (9.58 ml).

**Table 1:** Comparison of the intra-operative time between cold dissection and ultrasonic scalpel tonsillectomy

Method	Mean (SD)	Mean difference (95% CI)	t-statistic (df)	p-value <sup>a</sup>
Cold dissection (n = 35)	29.09 (5.20)	14.98 (12.96, 16.99)	14.88 (53.47)	< 0.001
Ultrasonic scalpel (n = 36)	14.11 (2.95)			

<sup>a</sup>Independent t-test applied, normality assumption met, and unequal variances assumed.

**Table 2:** Comparison of the intra-operative bleeding between cold dissection and ultrasonic scalpel tonsillectomy

Method	Mean (SD)	Mean difference (95% CI)	t-statistic (df)	p-value <sup>a</sup>
Cold dissection (n = 35)	87.57 (15.83)	77.99 (72.42, 83.56)	28.35 (37.90)	< 0.001
Ultrasonic scalpel (n = 36)	9.58 (3.85)			

<sup>a</sup>Independent t-test applied; normality assumption met, and unequal variances assumed.

There were no significant differences in the mean post-operative pain score between cold dissection and ultrasonic scalpel at six hours, days 1, 2, 3, 4, 5, and 6. However, at day seven, there was a significant difference in the mean post-operative pain score between these two procedures (mean difference, 95% CI): -0.74 (1.22, -0.27);  $p$ -value = 0.003. The mean (SD) post-operative scores for cold dissection and ultrasonic scalpel at day

seven were 1.03 (0.71) and 1.77 (1.22), respectively (Table 3). There were no documented post-operative haemorrhages in either of the tonsillectomy techniques.

**Table 3:** Comparison of the post-operative pain score between cold dissection and ultrasonic scalpel tonsillectomy

Time	Mean (SD)		Mean difference (95% CI)	t-statistics (df)	p-value <sup>a</sup>
	Cold dissection (n = 35)	Ultrasonic scalpel (n = 36)			
6 hours	8.23 (1.09)	8.22 (0.96)	0.01 (-0.48, 0.49)	0.03 (69)	0.979
Day 1	6.91 (1.20)	7.25 (1.30)	-0.34 (-0.93, 0.26)	-1.13 (69)	0.261
Day 2	6.09 (1.12)	6.47 (1.56)	-0.39 (-1.03, 0.26)	-1.20 (63.63) <sup>b</sup>	0.234
Day 3	5.00 (1.16)	5.44 (1.52)	-0.44 (-1.09, 0.20)	-1.38 (69)	0.172
Day 4	4.20 (1.13)	4.81 (1.51)	-0.61 (-1.24, 0.03)	-1.91 (69)	0.060
Day 5	3.03 (1.22)	3.58 (1.42)	-0.56 (-1.18, 0.07)	-1.76 (69)	0.083
Day 6	2.20 (1.32)	2.61 (1.18)	-0.41 (-0.96, 0.14)	-1.50 (69)	0.139
Day 7	1.03 (0.71)	1.77 (1.22)	-0.74 (-1.22, -0.27)	-3.13 (54.64) <sup>b</sup>	0.003

<sup>a</sup> Independent t-test applied

<sup>b</sup>Equal variances not assumed.

## DISCUSSION

The cold dissection method of tonsillectomy was first described in the 20th century by Worthington and Vaughn.<sup>17</sup> The favoured technique for tonsillectomies has been cold dissection tonsillectomies, which have been performed extensively for many years. One advantage of the cold dissection technique is that it preserves the oral mucosa to the greatest extent possible, which promotes faster healing and reduced pain.<sup>18,19</sup> Since its introduction in the late 1990s, the ultrasonic scalpel has grown in popularity as a tool for tonsillectomies. There are several benefits to tonsillectomies performed with an ultrasonic scalpel, including the fact that the

procedure is bloodless, takes less time, results in less pain after the procedure, and facilitates a quicker return to normal activities.<sup>20,21</sup> These two methods were assessed in terms of several aspects: intra-operative duration, intra-operative bleeding, post-operative pain score, and post-operative hemorrhage.

A total of 72 participants were initially recruited for this study period of one year. Participants were randomised into two groups: 36 participants underwent ultrasonic scalpel tonsillectomy, and the remaining 36 participants underwent cold dissection tonsillectomy. However, one participant in the cold dissection group was excluded because the patient defaulted on follow-up.

In our study, we found that the operative time of the patients in the ultrasonic scalpel group was significantly shorter compared with the cold dissection group, with a mean time of 14.11 minutes. This finding is similar to a study by Shinhar et al., which found that the mean operative time for ultrasonic scalpel tonsillectomy (mean = 23.6 minutes) was much shorter compared to cold dissection and hot electrocautery tonsillectomy with the means of 35.3 and 30.2 minutes, respectively. The above-mentioned study included five ultrasonic scalpel tonsillectomies, 37 cold dissection tonsillectomies, and six electrocautery tonsillectomies. The authors also mention several benefits of rapid surgery, which include reduced risk of exposure to surgery and anaesthesia as well as a reduction in the cost of surgery.<sup>22</sup>

According to a different study by Kamal et al., tonsillectomies performed with an ultrasonic scalpel took an average of 15 minutes ( $p = 0.05$ ) to complete, while tonsillectomies performed with the cold dissection approach took an average of 20 minutes.<sup>6</sup> In contrast, there was no discernible difference in operative time between the cold dissection tonsillectomy and the ultrasonic scalpel approach in a prospective single-blind randomised controlled experiment involving children ages five to thirteen.<sup>23</sup> Therefore, more procedures can be completed and at a lower cost with a shorter operating time. Reduction in the chance of anaesthesia problems and surgical site infection is another possible advantage of the shorter operative duration.

A bloodless intraoperative area improves sight during the tonsillectomy surgery, reducing the chance of unintentional damage to nearby structures.<sup>18</sup> Our study found a notable difference when comparing intra-operative blood loss between ultrasonic scalpel and cold dissection tonsillectomies (9.58 ml and 87.57 ml,

respectively) (mean difference (95% CI): 77.99 (72.42, 83.56);  $p < 0.001$ ). In most of the tonsillectomies performed with the ultrasonic scalpel, intraoperative bleeding was almost negligible. Akural et al. reviewed 28 patients who were operated on either side of their tonsils with cold dissection or an ultrasonic scalpel and concluded that intra-operative blood loss was significantly higher on the cold dissection side.<sup>9</sup> Similar findings were also noted in a study by Collison et al., which found that the mean intra-operative blood loss for the ultrasonic scalpel group was 6.2 ml versus 58.8 ml for the cold dissection tonsillectomy group ( $p < 0.0001$ ).<sup>14</sup> Because the ultrasonic blade can simultaneously cut and coagulate tissue as well as generate a mass of coagulated matter, there is virtually no blood loss when using the ultrasonic scalpel. This is likely because of the blade's dual function. The coagulated matter effect, which creates secondary heat that acts to seal bigger blood arteries, then closes off small bleeding vessels.<sup>14,15</sup> This results in dramatically reduced blood loss when compared to a cold dissection tonsillectomy. In the cold dissection method, the surgeon needs to use diathermy to arrest bleeders after removal of the tonsils. Failure to do so causes pooling of blood at the tonsillar bed, making it harder to localise the bleeders.

One of the biggest challenges to a tonsillectomy patient's rehabilitation after surgery is pain. Insufficient control over pain might cause inadequate or postponed oral intake, which can lead to dehydration and inadequate wound healing. Six hours after surgery, until day six, there was no discernible difference in the post-operative pain score between an ultrasonic scalpel tonsillectomy and a cold dissection tonsillectomy. We did note a significant difference in the pain score at day seven; the mean (SD) post-operative scores for cold dissection and ultrasonic scalpel at day seven were 1.03 (0.71) and 1.77 (1.22), respectively. Although this was a small difference statistically, even a slight reduction in pain can make a difference to the patient. In the aforementioned study by Akural et al., the cold dissection group's post-operative pain score was noticeably greater over the first ten hours.<sup>9</sup> However, during the second week after surgery, the post-operative pain score was significantly higher in the ultrasonic scalpel group.<sup>9,15</sup> The author came to the conclusion that the use of an ultrasonic scalpel can be applied to nursery surgery and decrease hospital stays since it lessens the intensity of pain during the early post-operative phase.<sup>7</sup> Daycare surgery allows for better resource utilisation as well as cost savings because an

overnight stay in the hospital is not required.<sup>15</sup>

The authors of a second double-blind clinical trial study with 28 patients who had cold dissection tonsillectomy on one side and ultrasonic scalpel tonsillectomy on the other discovered a statistically significant difference in the early post-operative pain score of 0.9 (on a 10-point scale), but they did not think it was clinically significant. The authors concluded that pain outcome measures were not clinically meaningful when the difference in pain intensity was less than 1, 1.3, or 3.3, respectively, based on three studies that examined the clinical significance of these measures.<sup>14</sup> We found in our study that there was little variation in post-operative discomfort between these two methods. On the other hand, early post-operative pain was somewhat reduced when an ultrasonic scalpel was used. This is most likely caused by the ultrasonic scalpel's mode of operation, which involves less stretching and lessens harm to the tonsillar bed's muscle fibres while simultaneously cutting and coagulating tissue with less heat damage. Consequently, there is a reduction in the direct thermal injury to the nerve terminals in the surrounding peritonsillar tissues since electrocoagulation for haemostasis is not often required.<sup>9,23</sup> Based on our study, we presume that less pain during the initial post-operative stage enabled patients to take oral medications well, and this too may promote the healing process. For the first two days, paracetamol was the only analgesic given to both groups of patients every six hours and on demand for the remaining days. Most of the patients did not require analgesics after the third post-operative day, apart from two patients from the ultrasonic scalpel group who required analgesics up to day nine of post-surgery.

One of the most dreaded complications after tonsillectomy is postoperative haemorrhage. While delayed bleeding was considered to be a problem mostly owing to the shedding of fibrin scabs and not related to the surgeon or surgical technique, early postoperative bleeding was supposed to be caused by insufficient intraoperative haemostatic technique.<sup>24,25</sup> In our study, there were no documented incidences of post-operative haemorrhages with either the cold dissection or the ultrasonic scalpel tonsillectomies. In a study by Kamal et al., the author reported a significant difference between the ultrasonic scalpel group and the cold dissection group in terms of the requirement for hospital admission due to post-operative haemorrhage

whereby no patients in the ultrasonic group required surgical intervention, while three patients in the cold dissection tonsillectomy group required surgical intervention for control of bleeding.<sup>6</sup> The low morbidity rate when using an ultrasonic scalpel was due to the scalpel's low temperature activities, which prevented lateral thermal damage and thus improved post-operative tissue healing.<sup>6,26</sup> In another prospective study by Mitchell et al., the author found that the incidence of reactive and secondary haemorrhage involving the ultrasonic scalpel group was similar compared to the cold dissection control group.<sup>18</sup> However, one of the shortfalls mentioned by Mitchell et al. is that two operators instead of one performed the surgeries, and this could have influenced the results.<sup>18</sup>

## CONCLUSION

Ultrasonic scalpel is becoming increasingly popular for tonsillectomy due to its reduced duration of surgery, negligible intra-operative bleeding, and less post-operative pain. Compared to cold dissection, the ultrasonic scalpel technique appears to be superior in terms of intraoperative time and bleeding.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interests regarding the publication of this paper.

## Authorship Contribution

Authors' contributions to manuscript are as follows, RSHS, RRR, and IM designed research; RSHS and IF conducted research; RSHS analysed data; and RSHS, RRR and IM wrote the paper. RRR had primary responsibility for final content. All authors read and approved the final manuscript.

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