Systematic Review

Harmonic scalpel versus other techniques for tonsillectomy: a systematic review and meta-analysis

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Background: The objective of this review was to compare treatment effects of harmonic scalpel tonsillectomy versus alternative techniques on postoperative pain. Secondary outcomes included delayed bleeding and intraoperative blood loss.

Methods: Medline, Embase, and Central were searched for randomized controlled trials where harmonic tonsillectomy was compared to any alternative technique for participants of any age undergoing tonsillectomy. The primary outcome was pain scores using validated pain scores on day 1, day 4, and day 7 postoperatively. Data for postoperative pain scores were synthesized using random effects model and presented as standard mean difference (SMD). All outcomes were presented with 95% confidence intervals (CI). Subgroup analyses were performed based on hot or cold techniques.

Results: Eleven trials were identified in this review. Five trials (637 patients) contained data that permitted meta-analysis for postoperative pain. Harmonic scalpel tonsillectomy was associated with less postoperative pain compared to other hot techniques on day 1, 4, and 7 (P<0.001). Harmonic tonsillectomy had lower rates of delayed bleeding compared to cold steel (RR 0.44, 95% CI: 0.22–0.89, P=0.02), but no significant difference compared to other hot techniques (RR 1.01, 95% CI: 0.66–1.55, P=0.97).

Conclusions: The harmonic scalpel technique may cause less pain in the postoperative period compared to other techniques, but the difference is small. The harmonic scalpel does demonstrate evidence for superiority compared to blunt dissection, with a 56% reduction in delayed haemorrhage.

Keywords: Tonsillectomy; harmonic; systematic review; ultrasonic scalpel; pain

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Introduction

Tonsillectomy is one of the most common surgical procedures performed. It is a procedure to remove the palatine tonsils by dissection in the peritonsillar space. It is commonly performed for recurrent tonsillitis as well as adenotonsillar hypertrophy causing sleep-disordered breathing, and for other less common indications such as asymmetry or tonsilloliths. The procedure is performed in both adults and children. There are multiple techniques used in current practice. These techniques are variable and have been refined over the years. Some of the common techniques include electrocautery with monopolar or bipolar diathermy, blunt dissection (cold steel dissection), plasma-mediated radiofrequency-based ablation (coblation), and ultrasonic dissection. These techniques are often categorised into hot or cold. Hot techniques utilise instrumentation that employs heat to coagulate and dissect tissues via different methods, such as electrocautery, radiofrequency, or

ultrasonic vibration. The "cold" technique refers to removal of the tonsil using traditional metal surgical instruments (scalpel, scissors, and dissecting forceps). Haemostasis is achieved by applying pressure using a gauze swab to the tonsillar fossa, heat using electrocautery or coblation, or ligatures or vessel ties. Though studies have shown positive results with the use of different surgical techniques, there is limited evidence with regards to controlled trials comparing specific techniques. In addition, there is no consensus in the literature for the recommended technique. Though a commonly-performed procedure, tonsillectomy is also associated with morbidity—mainly postoperative pain and bleeding. Bleeding can occur intraoperatively and during the immediate postoperative period, or more than 24 hours post-procedure (i.e., secondary haemorrhage).

Ultrasonic scalpel tonsillectomy is one of the more recent techniques described in the literature. The harmonic scalpel is a handheld device founded in 1992, which uses ultrasonic energy at the blade tip. The vibrations at the tip allow the blade to cut and coagulate tissue simultaneously. The theoretical advantage is that the harm is reduced with the harmonic scalpel because of lower temperature heat (50–100 degrees Celsius) compared to standard electrocautery (400 to 6,000 degrees Celsius).

Comparison of the different surgical techniques are important as they may hypothetically impact the patient's postoperative recovery. The aim of this systematic review is to identify randomised controlled trials comparing harmonic (ultrasonic) scalpel to alternative standard techniques in both the paediatric and adult population undergoing tonsillectomy looking at postoperative pain, intraoperative blood loss, and rates of secondary haemorrhage. This review will only evaluate studies describing tonsillectomy, where the entire palatine tonsil is removed extra-capsularly leaving bare pharyngeal musculature at the base. This differs from tonsillotomy, where a rim of tonsillar tissue is left behind. We present the following article in accordance with the PRISMA reporting checklist (available at http://dx.doi.org/10.21037/ajo.2019.01.03).

Methods

The protocol for this systematic review was registered with PROSPERO, the international prospective register of systematic reviews (CRD42017081802). PRISMA statement guidelines were followed.

Searching

Randomised controlled trials were identified through Medline, Embase and the Cochrane Central Registry of Randomised Controlled Trials using optimally-sensitive search strategies as per the *Cochrane Handbook for Systematic Reviews of Interventions* (1).

Trials were considered without language restriction. Titles and abstracts from the search results were analysed, and appropriate trials identified according to the inclusion criteria. Medical subject heading terms and text words used were: tonsillectomy, tonsillitis, palatine tonsil, adenotonsillectomy, surgical procedures, harmonic scalpel, ultrasonic scalpel, and bipolar diathermy. Search strategies for major databases are provided in *Table S1*.

Reference lists were also searched and information sought from a clinical expert. Additional trials were searched from the internet.

Selection

Randomised controlled trials (RCTs) where the patient was the unit of randomisation were included. Trials where tonsils were randomised were excluded. Conference abstracts were excluded. The morbidity from concurrent adenoidectomy or ventilation tube insertion was considered to be much less than tonsillectomy alone, and thus trials that described concurrent procedures of this nature were not excluded for analysis. Trials that performed tonsillectomy for retropharyngeal or peritonsillar abscess, or concurrent to other procedures (such as endoscopic sinus surgery or palatoplasty) were excluded. When outcomes were expected to differ due to having a concurrent procedure versus tonsillectomy only, then subgroup analysis was planned.

Intervention & study characteristics

The intervention of interest in this review was harmonic scalpel tonsillectomy (a surgical device that uses ultrasonic vibrations rather than an electric current to cut and cauterise tissues).

The main comparator was electrocautery, specifically bipolar diathermy. Other comparators included other hot techniques (such as coblation and monopolar diathermy) and traditional 'cold' technique ("blunt dissection" or "cold steel") tonsillectomy. The study design for included trials were parallel randomised controlled trials.

Participants were adults or children undergoing elective

tonsillectomy for recurrent tonsillitis or sleep-disordered breathing. Where possible, trials were separated based on participants (paediatric only, adult only, or mixed population).

The primary outcome analysed in this review was postoperative pain as measured using a validated pain scale at 1, 4 and 7 days. Secondary outcomes included measure of intraoperative blood loss (mL) and presence of delayed postoperative bleeding (>24 hours from surgery). Clinical heterogeneity was assessed by comparing differences in trial participant characteristics (sex, age), intervention characteristics (setting of harmonic scalpel and bipolar diathermy where described, level of experience of proceduralist), and timing and method of outcome measurement (i.e., how pain scores were assessed, type of validated pain scale used). Thus, pre-planned subgroup analysis was performed to address heterogeneity, stratifying for similar characteristics of the intervention (i.e., grouped by hot or cold techniques).

Validity assessment

The quality of the trials identified was assessed based on pre-determined criteria, such as risk of bias (allocation concealment, random sequence generation, blinding), loss to follow-up, and intention-to-treat analysis.

Studies were assessed for risk of bias as "low", "high", or "unclear" using the Cochrane Handbook. Bias was assessed in: sequence generation, allocation measurement, blinding, incomplete data, selective reporting, and other sources of bias.

Data extraction

Authors extracted data from each study using a standardised collection form (see *Figures S1-S11*). Data extracted included: study design, study setting, patient inclusion and exclusion criteria, allocation concealment, blinding, number of participants in each group, surgical technique of each group, outcomes collected, and follow-up. The main outcome of interest was pain scores postoperative day 1, 4, and 7 (and where available, day 14 postoperative). These dates were chosen a priori. Day 1 postoperatively was expected to be a consistently collected outcome in terms of time-point from surgery. The assessment of pain at one week postoperatively is a clinically relevant time-point. The authors felt that day 4 postoperative would be a reasonable middle point to assess pain scores between day 1 and day 7. The postoperative pain scale used by the trial was also noted.

Data with respect to secondary outcomes of interest were also collected. This included mean intraoperative blood loss for each group in the trial (including method of assessment), as well as rates of delayed post-operative haemorrhage (i.e., secondary haemorrhage defined as more than 24 hours post operatively). These are consistently collected outcomes collected in tonsillectomy trials.

Where possible, the authors also collected information that may be relevant for subgroup analysis with respect to the outcomes of interest. For example, this would include information regarding the study population (paediatric and adult, paediatric only, or adult only population), whether or not there was a pre-defined perioperative analgesia protocol, and whether patients underwent tonsillectomy alone or with concurrent procedures.

Because surgical indication does not determine the choice of technique used, subgroup analysis based on clinical indication was not performed. Subgroup analysis was performed based on category of technique as hot (coblation, monopolar, bipolar diathermy, ultrasonic scalpel) versus cold (blunt dissection).

Quantitative data synthesis and statistical analysis

Treatment results were pooled across studies where the data was available. Treatment differences for dichotomous outcomes (i.e., secondary haemorrhage) were expressed as risk ratio (RR) with 95% confidence interval. Treatment effects for continuous outcome measures, such as postoperative pain score, were expressed as standardised mean difference (SMD) with 95% confidence intervals to reflect differences in pain scales used. Continuous data was pooled using inverse variance method. Pooled data for dichotomous outcomes was analysed using the Mantel-Haenszel method to calculate RR. Mean difference (MD) was used where the unit of the outcome measure was consistent (i.e., mL for intraoperative blood loss). Random-effects meta-analysis method (DerSimonian and Laird) was used for most outcomes to account for differences in patient populations, institutions, surgical techniques, and surgeon experience. Given that statistical heterogeneity was expected to be high, a random-effects method would provide a more conservative estimate.

In studies where the P value was reported for the comparison of means between intervention and control groups but the standard deviation was not presented in the study, the estimated standard deviations for each group were calculated. The reported P value was converted to

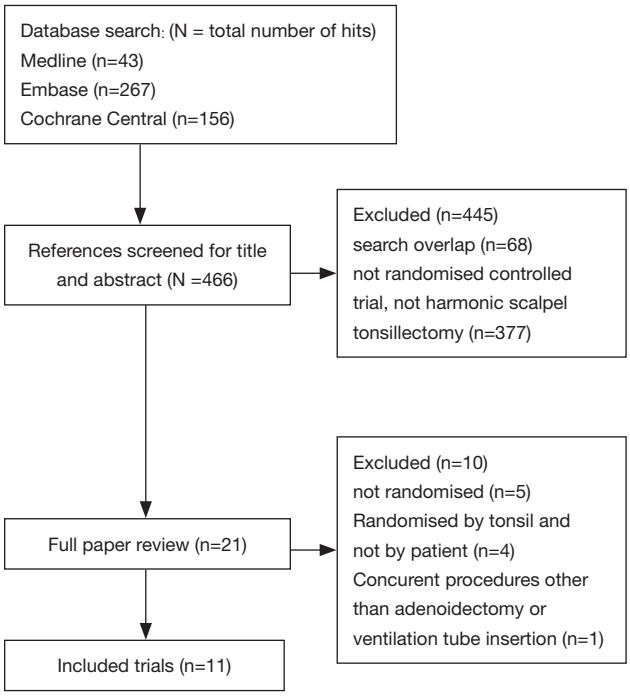

Figure 1 Flow diagram showing number of citations retrieved and number of trials included in this review.

a t-value based on number of participants in each group (i.e., degrees of freedom). The t-value was converted to a standard error by dividing the difference in means by the t-value. The average standard deviations of the groups were calculated using the formula: standard deviation = standard error/square root $[(1/N_{intervention}) + (1/N_{control})]$

Statistical heterogeneity between studies was assessed using I^2 statistic and Chi^2 statistic ($P<0.10$ considered significant). I^2 values greater than 50% suggested substantial percentage of variability secondary to heterogeneity rather than due to chance. Forest plots were also inspected. Clinical heterogeneity was assessed by considering differences in study population, intervention, and outcomes. When heterogeneity was not significant, summary estimates for the intervention were presented with 95% confidence intervals.

It was determined a-priori that causes for differences in the main outcome of interest (postoperative pain) would include: age of the study population (paediatric, adult, or mixed population), presence or absence of a standardised perioperative analgesia protocol, and whether or not a concurrent procedure was performed. Subgroup analysis were planned around these factors. All meta-analyses were performed using Review Manager 5.3 (2).

Results

Trial flow

Of the 466 articles identified, 445 were excluded after review of the abstract and title. Major reasons for exclusion included: non-randomised controlled trial, duplicate publications, or not involving the intervention of interest. After assessing the full text of 21 studies, a total of 11 eligible randomised controlled trials were identified (see *Figure 1* for flow diagram). Four randomised controlled trials were excluded, where the unit of randomisation was by tonsil (3-6).

Study characteristics

Characteristics of the individual trials included for analysis are listed in *Figures S1-S11*. A summary table of the included trials can be found in *Table 1*.

All studies were parallel design, single-blinded randomised controlled trials. Follow-up ranged from 5 to 21 days post-tonsillectomy, with mean of 10 days. Sample sizes ranged from 30 to 300 participants.

Participants

Most of the studies included participants undergoing tonsillectomy for tonsillitis, tonsillar hypertrophy, or both. Trials could be broadly categorised by age of participants as follows:

- Five trials focused on paediatric and adolescent population only (7-11).
- Three trials included mixed population of adult and paediatric patients (12-14).
- Three trials included an adult population only (15-17).

Intervention

All included trials evaluated the effects of the harmonic scalpel. Where specified, the setting used ranged between level 2 and 3. A variety of alternative techniques were used as control. Five studies compared harmonic scalpel to bipolar or monopolar electrocautery. Four studies compared harmonic scalpel to cold steel tonsillectomy. Parsons *et al.* compared harmonic scalpel tonsillectomy to monopolar diathermy and coblation techniques (14). Ragab conducted a multi-arm parallel trial with bipolar diathermy, coblation, and cold steel technique as comparators (16).

Table 1 Summary of trial characteristics

Study characteristics (study, year, country)	Study period	Design	Follow-up (days)	Participants (total number)	Age, years (range)	Intervention (concurrent operation)	Intervention	Control	Perioperative analgesia protocol	Pain scale
Ultrasonic scalpel versus hot techniques										
Arbin 2017, Sweden	–	RCT	7	40	7–40	No	Harmonic scalpel (level 3)	Bipolar diathermy (16 W)	Described	VAS, 0–10
Kemal 2012, Turkey	2008–2011	RCT	14	144	4–18	Adenoidectomy	Harmonic scalpel (level 2)	Bipolar diathermy (25 W)	Not described	WBF, 0–5
Leaper 2006, New Zealand	–	RCT	13	204	6–15	No	Harmonic scalpel (level 2)	Bipolar diathermy (15 W)	Described	VAS, 0–10
Parsons 2006, USA	2002–2004	RCT	10	134	2–42	Adenoidectomy	Harmonic scalpel	Monopolar diathermy, coblation	Not standardized	WBF, 0–10
Ragab 2012, Egypt	2005–2011	RCT	21	300	18–54	No	Harmonic scalpel	Bipolar diathermy (30 W), Coblation, Cold steel	Described	VAS, 0–10
Willging 2003, USA	–	RCT	14	117	3–18	Adenoidectomy, MEVTs	Harmonic scalpel (level 3)	Electrocautery (10–15 W)	Not standardized	WBF, 0–5
Ali 2011, Pakistan	2006–2008	RCT	7	60	18–68	No	Harmonic scalpel	Electrocautery	Described	VAS, 0–10
Ultrasonic scalpel versus cold techniques										
Kamal 2005, UK	2003–2004	RCT	7	280	3–69	Adenoidectomy	Harmonic scalpel (level 2)	Cold steel	Not standardized	Grade 1–6
Oko 2004, UK	–	RCT	9	122	5–13	No	Harmonic scalpel (level 2–3)	Cold steel	Described	WBF, 0–3
Salomone 2007, Brazil	2005–2006	RCT	5	100	3–10	Adenoidectomy	Harmonic scalpel (level 2)	Cold steel	Described	VAS, 1–7
Sugiura 2002, Japan	1999–2001	RCT	6	30	21–40	No	Harmonic scalpel (level 3)	Cold steel	Not described	VAS, 0–10

MEVT, middle ear ventilation tubes; VAS, visual analogue scale; WBF, Wong-Baker faces scale.

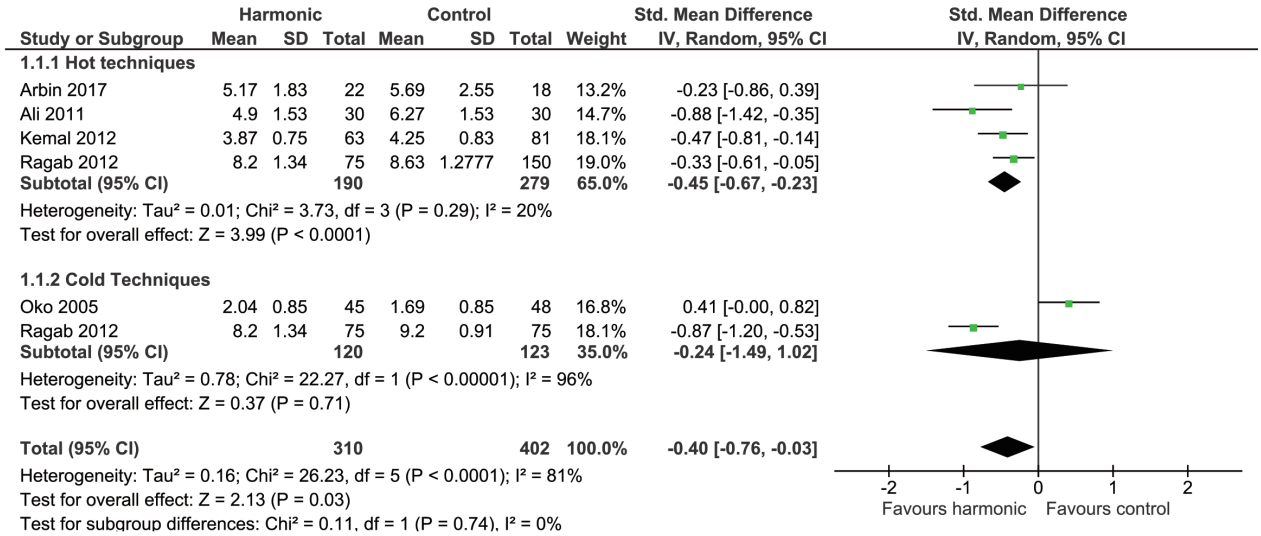

Figure 2 Harmonic scalpel versus other tonsillectomy techniques, pain Day 1.

We classified alternative techniques into either "hot" or "cold". "Cold" comparison techniques included trials that performed tonsillectomy by traditional surgical dissection ("cold steel"), with haemostasis achieved by bipolar diathermy and ties. Adenoidectomy was performed in conjunction with tonsillectomy in at least some patients for five trials (7,10,11,13,14).

Quantitative data synthesis

There was significant heterogeneity among trials in terms of the scale utilised for postoperative pain measurement. Some studies included children undergoing concurrent surgery (i.e., adenoidectomy or myringotomy and ventilation tube insertion) while others did not.

Many studies contained unclear methodology or reported insufficient data. Studies where there was insufficient data to permit calculation of standard deviation were excluded from meta-analysis. Attempt was made to contact study authors where possible to obtain critical data for meta-analysis.

Postoperative pain

Many studies utilised previously validated pain scales, such as the Wong Baker FACES (WBF) scale (7,9,11,14) or the visual analogue scale (VAS) (8,10,12,15-17). However, several studies adapted or abbreviated the scales by changing the numeric reference points. These adapted pain scales may have invalidated them. For example, some studies changed the Wong Baker FACES (WBF) scale to 0 to 5 (7,11) or 0 to 3 (9) rather than 0 to 10. Similarly, one study changed the anchor points of the VAS to 1 to 7 (10). Kamal *et al.* utilised a pain assessment grading system for level of pain, ranging from no pain to very severe, in association with frequency of analgesia intake (grade 1 to 6) (13). Pain scores were compared based on a validated pain scale. It was determined a-priori that pain scores would be compared using validated pain scales only. The decision was made to also include studies that used VAS or WBF scale regardless of the anchor points assigned.

Five trials presented studies on postoperative pain at discrete time points either using VAS or WBF (7,9,12,15,16). Where possible, trial results were pooled to reflect postoperative pain scores at day 1, day 4, and day 7 postoperatively.

Some studies measured postoperative pain scores using a validated scale but presented the data in a way that did not allow for meta-analysis. For example, some trials presented insufficient amount of data (9-11,13,17) or reported an average pain score over several days. Leaper *et al.* (8) calculated the mean pain scores over 6 days postoperatively, rather than presenting mean scores at discrete time points. Similarly, Parsons presented mean pain scores over the 10-day period (14).

Five trials had sufficient data to be pooled for postoperative pain scores (see *Figures 2-4*). In comparison to hot techniques, harmonic scalpel tonsillectomy showed significant reduction in pain scores on day 1 (standard

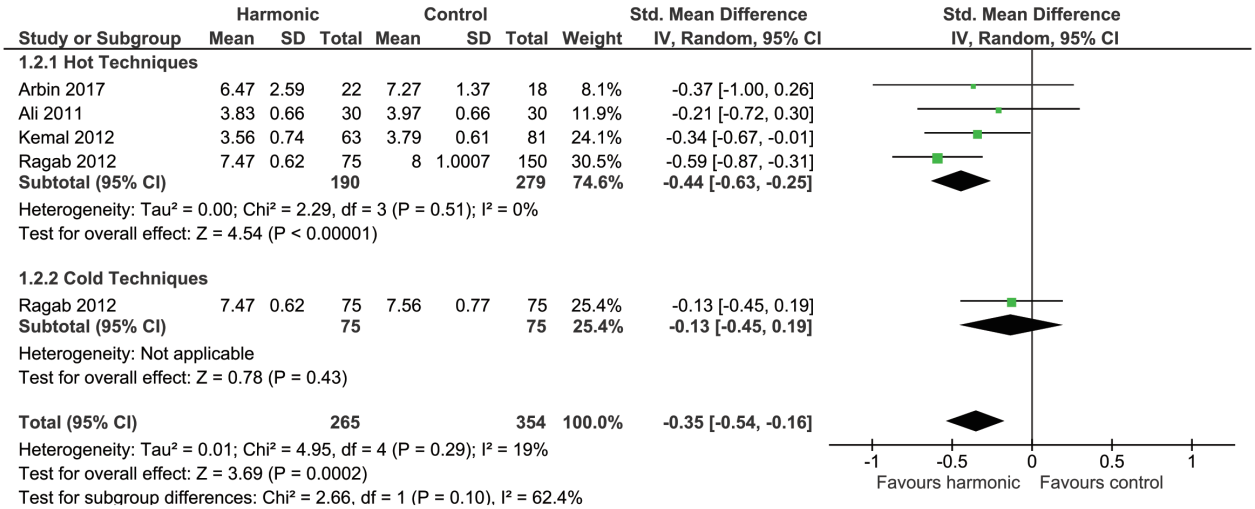

Figure 3 Harmonic scalpel versus other tonsillectomy techniques, pain Day 4.

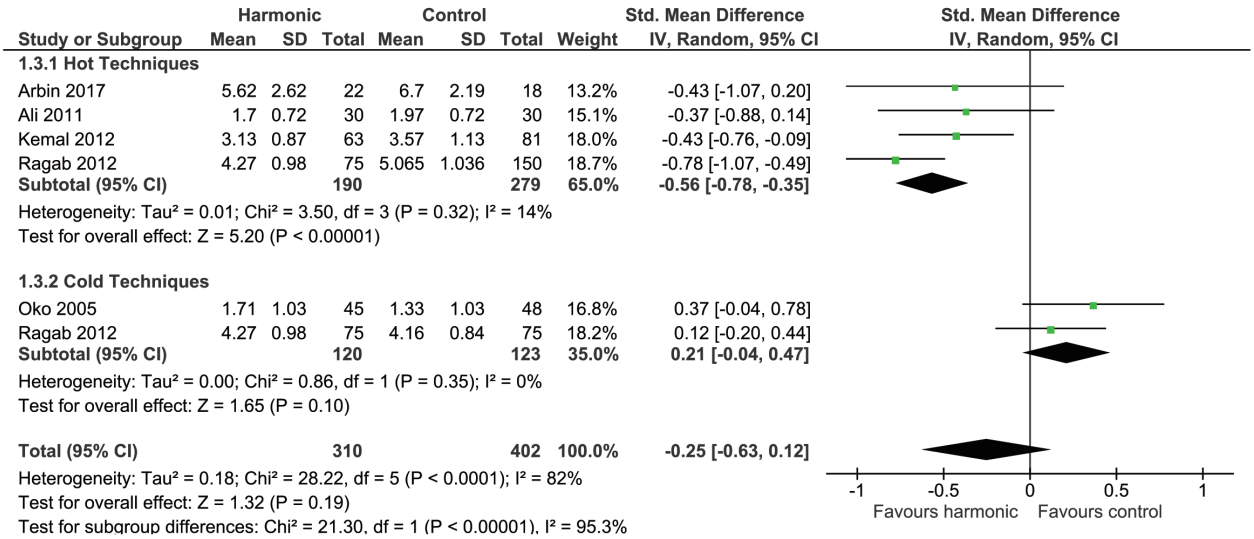

Figure 4 Harmonic scalpel versus other tonsillectomy techniques, pain Day 7.

mean difference –0.45, 95% CI: –0.67 to –0.23, P<0.001), day 4 (SMD –0.44, 95% CI: –0.63 to –0.25, P<0.001), and day 7 (SMD –0.56, 95% CI: –0.78 to –0.35, P<0.001) in comparison to control. There was no statistically significant different in pain scores for harmonic tonsillectomy compared to cold steel, however there were insufficient studies with appropriate methodology in this subgroup to allow for meaningful pooled analysis.

Intraoperative blood loss

A total of 8 studies reported intraoperative blood loss as an outcome (see *Figure 5*). The majority of studies measured intraoperative blood loss either through volume of blood aspirated in the suction bottle or by weight of tonsil swabs (9,10,13,15-17). The method of estimation was not described in two studies (7,14). Importantly, studies that included patients who underwent concurrent adenoidectomy as well as tonsillectomy did not specify the amount of blood loss related to the former procedure, and no information as to whether blood loss was measured separately for tonsillectomy versus adenoidectomy.

Intraoperative blood loss was less in alternative hot

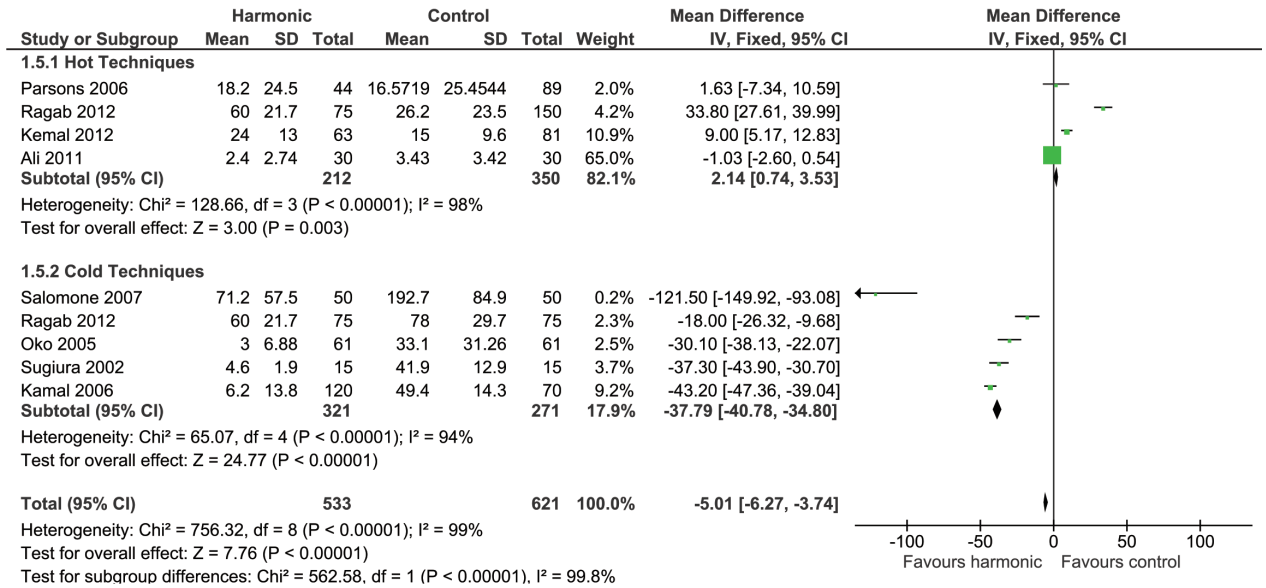

Figure 5 Harmonic scalpel versus other tonsillectomy techniques, intraoperative blood loss (mL).

techniques versus harmonic scalpel (mean difference 2.14 mL, 95% CI: 0.74–3.53, P=0.003). But in comparison to cold steel tonsillectomy, harmonic scalpel was associated with less blood loss (mean difference −37.79, 95% CI: −40.78 to −34.80, P<0.001). Overall, harmonic scalpel was favourable in comparison to all other techniques (mean difference −5.01, 95% CI: −6.27 to −3.74, P<0.001), but there was extreme statistical heterogeneity (I^2 =99%). The quality of the evidence in this outcome is considered to be low quality due to heterogeneity in methodology. None of the studies included separate measurements for blood loss in patients who underwent concurrent adenoidectomy. No comment was made in association with subtraction of saline irrigant from the reported blood loss.

Delayed bleeding

Delayed bleeding was defined as the incidence of bleeding more than 24 hours post-surgery. A total of eleven trials contributed data to this secondary outcome (see *Figure 6*) (7-17).

There was no statistically significant difference in delayed bleeding compared to other hot techniques (RR 1.01, 95% CI: 0.66 to 1.55, P=0.97). Whereas there was a significantly lower risk of delayed bleeding in harmonic scalpel versus cold steel (RR 0.44, 95% CI: 0.22 to 0.89, P=0.02).

Risk of bias

A summary of the risk of bias can be found in *Table 2*. The assessment of each of the trials can be found in the *Characteristics of Included Studies*.

Allocation

Studies that did not adequately describe the method of randomisation were considered to have unclear risk for selection bias.

Blinding

Risk of performance and detection bias for each study was based on this review's primary outcome of postoperative pain. Inability to blind operative personnel for the detection of postoperative pain was not expected to cause significant detection bias, since it is a patient-reported outcome. However, this would be a cause for potential detection bias in assessing intraoperative blood loss and delayed haemorrhage.

Blinding of personnel was not often mentioned in the methodology of the included studies. In some studies, all procedures were performed by a single surgeon. No study described any steps to address possible surgeon bias. Many studies also did not report blinding of the team involved in the postoperative care. As a result, performance bias was considered high for several studies. Detection bias was high for outcomes assessed by surgical personnel such as postoperative haemorrhage and volume of intraoperative blood loss. Given patients were blinded, detection bias was low for patient-reported outcomes (pain).

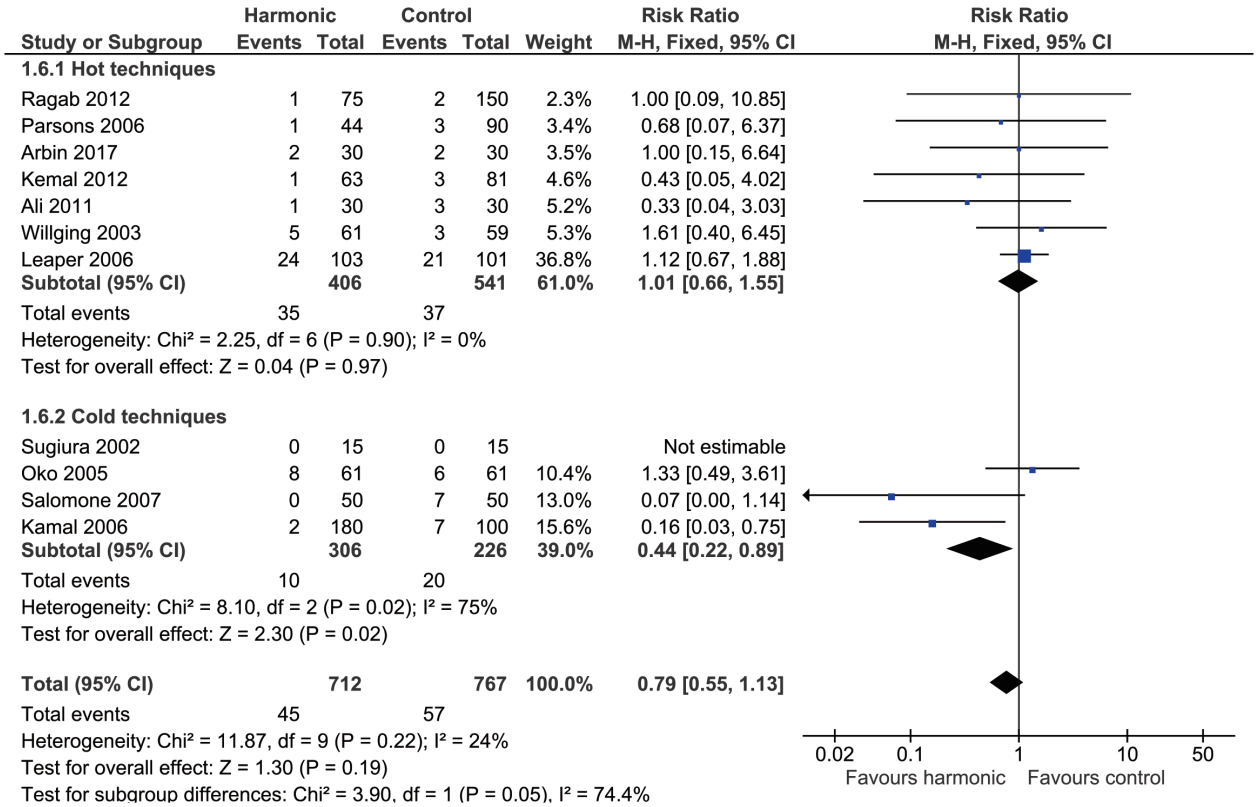

Figure 6 Harmonic scalpel versus other tonsillectomy techniques, delayed bleeding.

Table 2 Summary of methodological assessment

Validity measure	Number of studies (%)
Randomisation method described	
Yes	3 (27.3)
No	8 (72.7)
Allocation concealment	
Adequate	2 (18.2)
Unclear	7 (63.6)
Inadequate	2 (18.2)
Blinding	
Participants	11 (100.0)
Investigators	4 (36.4)
Loss to follow-up (Attrition bias)	
High risk	2 (18.2)
Low risk	4 (36.4)
Unclear	5 (45.5)

Incomplete outcome data

Studies were considered to have high risk of attrition bias with an attrition rate greater than 10%. Studies had an unclear risk if they did not report attrition rates or if there was insufficient information to determine this.

Selective reporting

There were no study protocols available to compare between planned and reported outcomes. Thus, all studies were judged as unclear risk of reporting bias unless studies did not report results for outcomes stated in the methods section.

Discussion

Summary of key findings

This review found low quality evidence that harmonic tonsillectomy may be associated with less pain postoperatively on day 1, day 4 and day 7 in comparison to other hot techniques. The magnitude of this difference was

not clinically significant.

In comparison to other hot techniques harmonic scalpel was associated with higher intraoperative blood loss (mean difference 2.14, 95% CI: 0.74 to 3.53, P=0.003), but less in comparison to cold techniques (mean difference –37.97, 95% CI: –40.78 to –34.80, P<0.001). Results from meta-analysis for intraoperative blood loss was associated with extreme statistical heterogeneity (I^2 =98% for hot techniques, 94% for cold techniques).

There was no statistically significant difference in rates of delayed bleeding compared to other hot techniques (RR 1.01, 95% CI: 0.66 to 1.55, P=0.97). Notably, harmonic scalpel was associated with lower rates of delayed bleeding compared to cold techniques (RR 0.44, 95% CI: 0.22 to 0.89, P=0.02; 4 studies; 532 participants; I^2 =75%).

Clinical interpretation

Theoretically, the use of harmonic scalpel should be associated with decreased levels of pain in comparison to other hot techniques. The use of ultrasound allows for comparatively lower temperatures to coagulate and dissect tissues. Another benefit is that no electrical energy is transferred to the tissue with the harmonic scalpel technique. As a result, lower temperatures should also be associated with less volume of tissue damage intraoperatively. Less thermal damage in the operative field also implicates better postoperative healing. While considering the high level of clinical heterogeneity for the included trials, this review has shown the harmonic scalpel to be marginally associated with lower levels of pain postoperatively.

Intraoperative blood loss is dependent on many factors apart from the instrument used to perform the procedure. For example, the speed of surgery and experience or technique of the operating surgeon are all potential confounding factors that affect interpretability of results.

Strengths and limitations of the study

Although a total of 11 studies were included in this review, most did not report data in a way that allowed for meta-analysis. Where possible, data was pooled for planned subgroup analysis. However, a variety of data-reporting problems limited analysis. For example, some studies did not provide measures of variance (standard deviation) for intraoperative blood loss and postoperative pain scores. Other studies reported only P values for postoperative pain score comparisons, but no mean or standard deviation. Sugiura *et al.* reported pain scores graphically, but exact values could not be derived for meta-analysis (17).

Although subgroup analysis was also planned based on age of participants (children versus adults) and type of surgery (i.e., if concurrent adenoidectomy versus tonsillectomy alone), there was insufficient study data available to conduct these analyses in a meaningful way. The studies also did not report data that allowed separation of outcomes into these subgroups, for example in trials that had mixed patient populations and where concurrent adenoidectomy was performed. Only subgroup analysis based on type of surgical technique (hot versus cold techniques) could be performed. In addition, standard mean difference in pain scores was used because of non-standardised pain outcomes reported in the trials. This has implications for interpretability of results in trials where adult and paediatric populations were combined.

Sensitivity analysis was not performed because the risk of bias was either high or unclear for all outcomes. No meaningful sensitivity analysis could have been conducted because of insufficient studies with low risk of bias.

This review is comprehensive in its inclusion of studies with all types of comparator techniques for tonsillectomy. The studies involved relevant patient populations undergoing tonsillectomy for chronic infection and sleep-disordered breathing. The included studies evaluated clinically important outcomes, such as postoperative pain, intraoperative bleeding, and postoperative bleeding.

The results of this systematic review are limited due to low quality of the studies included. This precludes robust conclusions to be made from the available evidence.

Applicability of findings

Several methodological limitations of the included studies preclude applicability of the findings from this review. Several of the studies failed to describe method of randomisation. Other key methodological issues include: inability to blind the operating surgeon and other personnel in the trial, difficulty blinding outcome assessors reporting intraoperative blood loss and postoperative bleeding. Postoperative pain scores were inconsistently measured on different pain scales. The method for measuring intraoperative blood loss differed between included trials and failed to be mentioned in the methods for others.

Both harm (rates of postoperative bleeding, intraoperative blood loss) as well as benefits (decreased postoperative pain) were evaluated in this review for

harmonic tonsillectomy. Variations in treatment effect could only be investigated through subgroup analysis for surgical technique. The results of this review reveal that the harmonic scalpel is comparable in terms of risk of delayed bleeding in comparison to other hot techniques and does show benefit over cold techniques. The number needed to treat with harmonic tonsillectomy to prevent one case of delayed bleeding from cold steel tonsillectomy is 18 (absolute risk reduction 0.06).

Comparison to previous works & future research directions

No systematic review has been conducted previously comparing harmonic scalpel tonsillectomy to alternative techniques. One protocol was found on the Cochrane Library for harmonic scalpel versus other surgical procedures for tonsillectomy (18). A similar systematic review was conducted for coblation versus other techniques for tonsillectomy (19). Thus, the results of this review have provided a comprehensive summary for the current body of evidence, where previous non-randomised prospective and retrospective studies have shown varying results comparing harmonic tonsillectomy to alternative techniques.

Given that the quality of current trials are low, further randomised control trials are required. Future studies should report outcomes using CONSORT guidelines for more consistent reporting of outcomes. This would also allow adequate data extraction to update this review. Bias must also be minimised in future trials by standardising outcome measures. A significant reason for clinical heterogeneity was the lack of consensus in reporting outcomes, especially with regards to timing and methodology. As demonstrated in this review, there were major limitations in the measurement of postoperative pain—future trials should have standardised and specific, relevant time points for this outcome measure (either as an average over time or on certain postoperative days).

Conclusions

The harmonic scalpel technique may cause less pain in the postoperative period compared to other techniques, but the difference is small and clinically irrelevant. This statistically significant difference in pain scores compared to standard techniques was observed on day 1 and day 4 postoperatively. This technique may be associated with less intraoperative blood loss, however there was significant statistical heterogeneity among included studies pooled for meta-analysis (I^2 =99%). The harmonic scalpel does demonstrate evidence for superiority compared to blunt dissection ("cold steel" technique), with a 56% in reduction in delayed haemorrhage. However, there is insufficient evidence to recommend the use of harmonic scalpel over other hot techniques.

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Supplementary

Table S1 Search strategies

Central

1. Tonsillectomy/
2. tonsillectom*.mp.
3. tonsilectom*.mp.
4. adenotonsillectom*.mp.
5. adenotonsilectom*.mp.
6. exp Palatine Tonsil/
7. exp Tonsillitis/
8. tonsil*.mp.
9. adenotonsil*.mp.
10. 1 or 2 or 3 or 4 or 5
11. 6 or 7 or 8 or 9
12. exp Surgical Procedures, Operative/
13. (surg* or excis* or extract* or re- mov* or dissect*).mp.
14. 12 or 13
15. 11 and 14
16. 10 or 15
17. (bipolar or harmonic).mp.
18. ultraso*.mp.
19. harmonic scalpel.mp.
20. 17 or 18 or 19
21. 16 and 20

Medline

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. randomly.ab.
5. trial.ab.
6. groups.ab.
7. 1 or 2 or 3 or 4 or 5 or 6
8. (tonsillectom$ or tonsilectom$ or adenotonsillectom$ or adenotonsilectom$).tw.
9. exp Tonsillectomy/
10. exp Palatine Tonsil/
11. exp Tonsillitis/
12. (tonsil$ or adenotonsil$).tw.
13. 10 or 11 or 12
14. (surg$ or excis$ or extract$ or remov$).tw.
15. exp General Surgery/
16. 14 or 15
17. 13 and 16
18. 8 or 9 or 17
19. (harmonic adj3 scalpel).mp.
20. (ultrason$ adj3 scalpel).mp.
21. (ultrason$ adj3 tonsil$).mp.
22. (harmonic adj6 tonsil$).mp.
23. 19 or 20 or 21 or 22
24. 18 and 23
25. 7 and 24

Embase

1. tonsillectomy/
2. (tonsillectom* or tonsilectom* or adeno- tonsillectom* or adenotonsilectom* or tonsillotom* or tonsilotom*).tw.
3. tonsil/
4. tonsillitis/
5. (tonsil* or adenotonsil*).tw.
6. surgery/
7. (surg* or excis* or extract* or remov*).tw.
8. 3 or 4 or 5
9. 6 or 7
10. 8 and 9
11. 1 or 2 or 10
12. ("harmonic" or "ultrasonic scalpel").tw.
13. "ultraso*".tw.
14. 12 or 13
15. 11 and 14

Methods		Parallel randomized controlled trial with 7-day follow-up
Participants		Setting: Aga Khan University Hospital, Pakistan from June 2006 to August 2008 Sample size ❖ Number randomized: 60 Inclusion criteria: Age >18, recurrent tonsillitis, obstructive sleep apnea, history of quinsy, suspected malignancy between June 2006 to August 2008 Exclusion criteria: bleeding disorders, significant chronic illness that would interfere with recovery Patient demographic ❖ Age (mean, SD) • Harmonic: 20±7.35 years • Electrocautery: 29.43±1.22 ❖ Sex • Harmonic: 16 male, 14 female • Electrocautery: 17 male, 13 female
Interventions		Ultrasonic Scalpel N=30 Electrocautery N=30
Outcomes		Postoperative pain (VAS, 0–10 daily from postoperative day 1–7), intraoperative blood loss (mL), operative time, secondary hemorrhage *No SD for pain scores, and could not be included in meta-analysis
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Low	"Patients were divided in two groups by using random numbers table"
Allocation concealment (selection bias)	Unclear	Not described
Blinding of participants and personnel (performance bias)	High	Personnel: High Patient: Unclear "All cases were performed by a single surgeon (MI)"
Blinding of outcome assessment (detection bias)	Low	Insufficient. Intra-operative blood loss assessed by weighing standard tonsil swabs pre and post-operatively. Each swab weighing more than 1 g was considered 5 mL of blood when fully soaked
Incomplete outcome data (attrition bias)	Unclear	Not described
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias		None identified

Figure S1 Characteristics (Ali 2011).

Methods	Parallel randomized controlled trial with 10-day follow-up (tonsillectomy only)	
Participants	Setting: Vasteras Central Hospital, Sweden Sample size ❖ Number randomized: 60 ❖ Number completed: 40 Inclusion criteria: Aged 7–40, tonsillectomy for recurrent tonsillitis or upper airway obstruction due to tonsillar hypertrophy Exclusion criteria: Concurrent surgical procedure, acute tonsillitis, previous peritonsillar abscess, inability to understand instructions, bleeding disorder, hypersensitivity / allergy to paracetamol or ibuprofen	
Interventions	Harmonic group (level 3): N=22 Bipolar diathermy N=18	
Outcomes	Postoperative pain—at awakening and worst pain level of the day (Day 1, 4, 7) using VAS (0–10)	
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	Theatre nurse performed the randomization. No information regarding method of random sequence generation
Allocation concealment (selection bias)	Low	"opening a non-transparent envelope with the lowest remaining randomization number"
Blinding of participants and personnel (performance bias)	Low	Surgical method blinded from staff of the postoperative unit "The surgical method that had been used was kept blinded to the patient (and the caregiver in the case of children) as well as for the staff of the postoperative unit to keep the study double-blinded."
Blinding of outcome assessment (detection bias)	Low	Surgical method was blinded to the patient (and caregiver)
Incomplete outcome data (attrition bias)	Low	None lost to follow-up.
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias	Unclear	Nil identified Standardized perioperative analgesia protocol provided

Figure S2 Characteristics (Arbin 2017).

Methods	Parallel randomized controlled trial with 7-day follow-up, single-blinded, dual-center
Participants	Setting: United Kingdom Feb 2004 – Oct 2004, Whipps Cross University Hospital July 2003 – Aug 2004, Royal Hants County Hospital, Winchester Sample size ❖ Number randomized: 280 Inclusion criteria: Recurrent acute tonsillitis (4-6 episodes per year for 2 years), Single episode of quinsy in patients < 30 years of age, obstructive sleep apnea Exclusion criteria: Nil specified Patient demographic ❖ Age (mean, SD) • Ultrasonic scalpel: Age 3–69 • Cold steel: Age 3–66 ❖ Sex • Male-female ratio not provided
Interventions	Ultrasonic Scalpel N=180 (Tonsillectomy only n=120; adenotonsillectomy n=60) Blunt dissection N=100 (Tonsillectomy only n=70; adenotonsillectomy n=30) Preoperative analgesics described. Not standardized between groups. Non-harmonic scalpel group received paracetamol, ibuprofen and codeine phosphate. Harmonic scalpel group received paracetamol and ibuprofen Intraoperative analgesics including morphine were not given to harmonic scalpel group of patients whereas the cold steel group received morphine intraoperatively Postoperative analgesia: paracetamol and ibuprofen to both groups. Codeine sulfate routinely prescribed to the cold steel group
Outcomes	Postoperative pain, graded from 1-6. Results could not be pooled as pain was not assessed at pre-specified time points. Surgical duration, intraoperative blood loss, postoperative bleeding

Risk of Bias

Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	No information provided regarding method of randomization
Allocation concealment (selection bias)	Unclear	Not described
Blinding of participants and personnel (performance bias)	High	Patients: Low Personnel: High Single-blinded
Blinding of outcome assessment (detection bias)	Low	Standard tonsil swabs were used. Each swab weighing more than 1 g contained approximately 5 mL of blood when fully soaked
Incomplete outcome data (attrition bias)	Unclear	Not described
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias		None identified

Figure S3 Characteristics (Kamal 2006).

Methods	Parallel randomized controlled trial	
Participants	Setting: Diyarbakir Government Hospital between July 2008 and December 2010, Turkey Sample size ❖ Number randomized: 144 ❖ Number completed: 144 Inclusion criteria: Obstructive sleep apnea or chronic tonsillitis Exclusion criteria: Bleeding disorders, chronic diseases, craniofacial anomalies, acute infection, past history of peritonsillar abscess Patient Demographics ❖ Age • Bipolar: 8.98±4.22 years • Harmonic: 9±4.02 years ❖ Sex • Total 144 patients: 83 male, 61 female	
Interventions	Harmonic group: N = 63 Bipolar diathermy N = 81 *Same surgeon	
Outcomes	Intraoperative bleeding Postoperative pain scores at 1, 4, 7, 14 days (Wong-Baker Faces 0–5) Primary hemorrhage, Secondary hemorrhage	
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	Not described
Allocation concealment (selection bias)	Unclear	Not described
Blinding of participants and personnel (performance bias)	High	Personnel: High All patients were operated by the same surgeon
Blinding of outcome assessment (detection bias)	Low	Method of measurement of intraoperative blood loss not specified
Incomplete outcome data (attrition bias)	Unclear	Not described
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias	Unclear	None identified

Figure S4 Characteristics (Kemal 2012).

Methods	Parallel randomized controlled trial with 13 days follow-up
Participants	Setting: Auckland, New Zealand Sample size ❖ Number randomized: 204 Inclusion criteria: History of recurrent tonsillitis or upper airway resistance from adenotonsillar hypertrophy, age >6 and <15 Exclusion criteria: Previous history of peritonsillar abscess, bleeding tendency, intolerance to any post-operative analgesics (acetaminophen, ibuprofen). Other concurrent operative procedure apart from adenoidectomy or myringotomy with ventilation tube insertion Patient demographic ❖ Age (mean, SD) • Ultrasonic: 10 (2.8) • Bipolar: 9 (2.6) ❖ Sex • Ultrasonic: 40/103 (39%) male • Bipolar: 45/101 (45%) male No reported difference in analgesic use intraoperative and post-anesthetic recovery
Interventions	Harmonic group: N=103 Bipolar diathermy N=101
Outcomes	Postoperative pain (VAS 0–10) within 30 min of surgery, 4 hours post Daily pain scores for 7 days postop Second-daily pain scores from day 8–13 Intraoperative blood loss (mL), postoperative bleeding, readmission to hospital for bleeding, return to theatre for bleeding

Risk of Bias

Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Low	"Randomly allocated using a preformed sheet containing a list of group allocations"
Allocation concealment (selection bias)	Low	"…drawing it out of an envelope one case at a time" Inadequate
Blinding of participants and personnel (performance bias)	High	Participants: low Personnel: high Surgeries were performed by one of four surgeons. Unclear if research nurse blinded. Surgeon not blinded No other description provided
Blinding of outcome assessment (detection bias)	Low	Participants: low Personnel: high Method of assessing intraoperative blood loss not described
Incomplete outcome data (attrition bias)	Unclear	No loss to follow-up described
Selective reporting (reporting bias)	Unclear risk	None identified
Other sources of bias		None identified

Figure S5 Characteristics (Leaper 2006).

Methods		Parallel single-blinded randomized controlled trial with 9-day follow-up
Participants		Setting: Royal Hospital for Sick Children, Yorkhill, Glasgow Sample size ❖ Number randomized: 122 ❖ Number completed: 93 Inclusion criteria: Aged 5-13 undergoing tonsillectomy for recurrent tonsillitis Exclusion criteria: Personal or family history of bleeding diathesis, inability to provide informed consent, unable to communicate pain levels, major illness or medical problems, any history of obstructive sleep apnea Patient demographic ❖ Age (mean, SD) • Ultrasonic scalpel: 8 (2.5) • Blunt dissection: 8.4 (2.6) ❖ Sex • Not mentioned
Interventions		Ultrasonic Scalpel N=61 (45 completed pain and dietary cards) Blunt dissection N=61 (48 completed pain and dietary cards) Two operators (senior registrars) performed all tonsillectomies All children discharged on one-week course of weight-calculated dose of acetaminophen
Outcomes		Postoperative pain (abbreviated "faces" pain scale, 0-3) on days 1, 3, 5, 7, 9 Dietary intake scores Intraoperative blood loss (mL), secondary hemorrhage
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	Method of randomization not described. "A theatre nurse performed randomization immediately preoperatively"
Allocation concealment (selection bias)	Low	"…using a closed envelope system" Inadequate
Blinding of participants and personnel (performance bias)	Low	Personnel: Low Patients: Low "A blinded team member (specialist pain nurse) reviewed the patients on postoperative day 1…"
Blinding of outcome assessment (detection bias)	Low	Blood loss measured to the nearest 0.5 mL in suction bottles and weight of swabs *Two senior registrars performed all tonsillectomies
Incomplete outcome data (attrition bias)	High	"Results for intraoperative blood loss, operative time, reactive and secondary hemorrhage rates, and use of bipolar diathermy were available for all children enrolled…" Pain scores - % loss to follow-up • Blunt: 13/61 (21%) • Ultrasonic: 16/61 (26%)
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias		None identified

Figure S6 Characteristics (Oko 2005).

Methods	Parallel randomized controlled trial with 10 days postop	
Participants	Setting: Indiana University, USA from Dec 2002 – Dec 2004 Sample size ❖ Number randomized: 134 ❖ Number completed: 61 Inclusion criteria: Tonsillectomy or adenotonsillectomy between Dec 2002 – Dec 2004 Exclusion criteria: None stated Patient demographic ❖ Age: • Coblation (2.0 to 32.0, mean 9.5, SD 7.3) • Monopolar (1.9 to 42.0, mean 10.1, SD 9.0) • Ultrasonic (1.9 to 33.0, mean 10.9, SD 8.8) ❖ Sex: • Coblation: 19/47 (40%) male • Monopolar: 23/43 (53%) male • Ultrasonic: 23/44 (52%) male	
Interventions	Coblation group: N=47 Monopolar electrocautery N=43 Ultrasonic harmonic scalpel N=44	
Outcomes	Duration of surgery, intraoperative blood loss, postoperative pain (Wong Baker FACES 0–10)—expressed as mean score over 10 days, adverse events (postoperative complications), return to normal diet and activity, primary bleeding, secondary bleeding, need for postoperative analgesia	
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	Patients were randomly assigned but method of randomization not described
Allocation concealment (selection bias)	Unclear	Not described
Blinding of participants and personnel (performance bias)	High	"Patients were blinded" Operations were performed by trainees
Blinding of outcome assessment (detection bias)	Low	"Patients were blinded" No descriptions provided. Method of estimating intraoperative blood loss was not described
Incomplete outcome data (attrition bias)	High	Patients lost to follow-up: Total: 73/134 (55%) Coblation: 22/47 (47%) Monopolar: 24/43 (56%) Harmonic: 27/44 (61%)
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias		None identified

Figure S7 Characteristics (Parsons 2006).

Methods		Parallel randomized controlled trial with 21-day follow-up
Participants		Setting: Tanta University Hospital, Egypt from January 2005 and March 2011 Sample size ❖ Number randomized: 300 ❖ Number completed: 300 Inclusion criteria: history of recurrent tonsillitis Exclusion criteria: Less than 18 years, history of quinsy, bleeding disorders, any major illness of medical problems, contraindication to general anesthetic, contraindication to paracetamol or diclofenac, craniofacial abnormalities, any other concurrent surgery Patient demographic ❖ Age (mean, SD) • Overall: age 18–54 years • Mean ± SD: 29±10 years ❖ Sex • 173 male: 127 female
Interventions		Ultrasonic Scalpel N=75 Cold dissection N=75 Bipolar Radiofrequency N=75 Bipolar Electrocautery N=75
Outcomes		Operative time, intraoperative blood loss (mL), pain score (VAS, 0–10 on postoperative days 1, 4, 7, 10, 14, and 21), time to return to full diet and work (days), tonsillar fossa healing (0 per cent slough, 1–25 per cent slough, 26–50 per cent slough, 51–75 per cent slough and 76–100 per cent slough), post-operative bleeding
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Low	"Randomization was done using random blocks"
Allocation concealment (selection bias)	Low	"The group assignment was placed in consecutively numbered envelopes, which were allocated to successive cases in chronological order. Each patient's envelope was opened in the operating theatre after induction of general anesthesia."
Blinding of participants and personnel (performance bias)	Low	Personnel: Low Patient: Low "Neither the patient nor the investigator was aware of the group assignment, either at the time of randomization or during the follow-up…During the follow-up period, the operative data was not disclosed to either the patient or the investigator"
Blinding of outcome assessment (detection bias)	Low	Intraoperative blood loss—measurement of blood volume in suction bottles, and weight of swabs
Incomplete outcome data (attrition bias)	Low	"All patients completed the 21-day follow-up period"
Selective reporting (reporting bias)	Unclear	None identified.
Other sources of bias	Unclear	None identified

Figure S8 Characteristics (Ragab 2012).

Methods		Parallel randomized controlled trial with 5-day follow-up
Participants		Setting: Hospital CEMA, Sao Paulo, Brazil from 2005 to 2006 Sample size ❖ Number randomized: 100 Inclusion criteria: Tonsillar hypertrophy Exclusion criteria: Peritonsillar abscess, coagulopathies, chronic illnesses, and acute infection Patient demographic ❖ Age (mean, SD) • Ultrasonic: 6.2±2.0 • Cold steel: 5.6±2.2 ❖ Sex • Ultrasonic: 30 male, 20 female • Cold steel: 33 male, 17 female
Interventions		Ultrasonic Scalpel N=50 Blunt dissection N=50
Outcomes		Postoperative pain scores (VAS 1-7), at discharge and day 5 postop, intraoperative blood loss (mL), tonsillar fossa assessment (dry, edema, edema and fibrin, or coagulum); Bleeding 5 days after the surgery
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	Children were divided randomly into two groups, but method of randomization not described
Allocation concealment (selection bias)	Unclear	Not described
Blinding of participants and personnel (performance bias)	High	Personnel: High Patients: Low "The surgeries have all been performed by the same surgeon…"
Blinding of outcome assessment (detection bias)	Low	"Evaluation at the first outpatient return, after 5 days, was performed by another researcher who was not aware of to which group the child belonged ("blind" examiner)" "The bleeding during surgery was evaluated through the volume measured in the collector of the aspirator …in mL"
Incomplete outcome data (attrition bias)	Low	All patients attended outpatient appointments at 5 days postop
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias		Translated study. Translation errors

Figure S9 Characteristics (Salomone 2007).

Methods		Parallel randomized controlled trial with 6-day follow-up
Participants		Setting: St Marianna University Tokyo Hospital, Japan from Nov 1999 – January 2001 Sample size ❖ Number randomized: 30 ❖ Number completed: 30 Inclusion criteria: Recurrent tonsillitis Exclusion criteria: "Severe mental or physical disorders", incompatible with anesthetic and postoperative visual analogue scale (VAS) protocols Patient demographic ❖ Age: 21–40 ❖ Male: female ratio not described
Interventions		Ultrasonic Scalpel N=15 Blunt dissection N=15
Outcomes		Intraoperative blood loss (mL) Postoperative pain (VAS 0–10), appetite (VAS 0–10) from day 1 to day 6
Risk of Bias		
Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	Patients were randomly assigned but method of randomization not specified
Allocation concealment (selection bias)	Unclear	Not described
Blinding of participants and personnel (performance bias)	High	Personnel: High Patients: Low
Blinding of outcome assessment (detection bias)	Low	"Intraoperative blood loss was measured by weighing swabs and measuring the volume of suction aspirate"
Incomplete outcome data (attrition bias)	Unclear	No lost to follow-up described
Selective reporting (reporting bias)	High	Only p-values comparing two groups for postoperative pain and appetite. VAS scores (mean and SD) are not presented for both groups Baseline characteristics of participants in intervention and control arms are not presented
Other sources of bias		None identified

Figure S10 Characteristics (Sugiura 2002).

Methods	Parallel single-blinded dual-center randomized controlled trial with 14 days follow-up
Participants	Setting: Cincinnati Children's Hospital and Children's Hospital of Alabama, USA Sample size ❖ Number randomized: 120 ❖ Number completed: 117 Inclusion criteria: Pediatric and adolescent patients with recurrent tonsillar infection, adenotonsillar hypertrophy with airway obstruction, tonsillar asymmetry Exclusion criteria: Malignancy, acute peritonsillar abscess, immunocompromise, HIV infection, acute mononucleosis, receiving chemotherapy, chronic steroid use, pregnant or lactating Patient demographic ❖ Age (mean, SD) • Ultrasonic: 6.3 (5.6–7.0) • Electrocautery: 6.9 (6.1–7.8) ❖ Sex • Ultrasonic: 24/61 (39%) male • Electrocautery: 29/59 (49%) male Demographics reportedly similar between groups
Interventions	Ultrasonic N=61 Electrocautery N=59
Outcomes	Intraoperative blood loss, Postoperative pain scores for days 1–7 and day 14 (WBF 0–5) Time to return to activities of daily living (questionnaires)

Risk of Bias

Bias	Author's Judgment	Support
Random sequence generation (selection bias)	Unclear	"Once the subject was enrolled, a subject number and randomization number were assigned". No information how the sequence was generated.
Allocation concealment (selection bias)	Unclear	"The randomization number …was known only to the surgeon"
Blinding of participants and personnel (performance bias)	High	Personnel: High Patient: Low "The technique used was not disclosed to the patient or the patient's family"
Blinding of outcome assessment (detection bias)	Low	Patients: Low
Incomplete outcome data (attrition bias)	Low	Follow-up complete for 117/120. "...2 subjects discontinued the study before surgery, 1 was lost to follow-up after the surgery"
Selective reporting (reporting bias)	Unclear	None identified
Other sources of bias		Trial supported by Ethicon Endosurgery, Incorporated

Figure S11 Characteristics (Willging 2003).