# TONSILLECTOMY BY HARMONIC SCALPEL: A SYSTEMATIC REVIEW OF EVIDENCE FOR POSTOPERATIVE HEMORRHAGE

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## ABSTRACT

**Objective:** To review the literature systematically on tonsillectomy by harmonic scalpel with a view of comparing its postoperative hemorrhagic rate with the conventional methods for tonsillectomy.

**Data Sources:** Cochrane Library, Medline, Embase, CINAHL, INAHTA, CRD (Centre for Review and Dissemination, York, UK), and related databases. papers were considered irrespective of language of publication.

**Review Methods:** Inclusion and exclusion criteria were applied independently by two reviewers with a third reviewer available for adjudication. The papers were quality assessed using Chalmers' criteria. Eleven randomized controlled trials (RCT) were included in the final review with 5 RCTs comparing harmonic scalpel tonsillectomy with "cold steel" tonsillectomy and 6 RCTs comparing harmonic scalpel with "hot" tonsillectomy techniques.

**Results:** All studies were underpowered to detect a significant difference in the postoperative hemorrhagic complication between harmonic scalpel and the comparator tonsillectomy techniques. The heterogeneity of studies made quantitative combination of results impossible.

**Conclusion:** The evidence reviewed is of low quality and does not support any significant difference in postoperative hemorrhage rates when harmonic scalpel is compared with other tonsillectomy techniques. As studies have numerous methodological flaws and incorporate biases and confounding factors, these results need to be interpreted with caution. Larger and better-conducted studies would be needed in order to compare the safety of harmonic against conventional tonsillectomy methods. The need for a large sample size might make an RCT impractical; therefore a large, well-controlled cohort study could be more suitable.

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## INTRODUCTION.

Tonsillectomy is one of the most common surgical procedures in ENT. The number of tonsillectomies has varied considerably over time, with a drop in numbers possibly being attributed to advances in antimicrobial therapy after the 1950s. Despite the relative decline of tonsillectomy, the numbers of patients undergoing such surgery are still large. In the UK, a national audit between July 2003 and September 2004 enrolled 40,514 patients.[1] In excess of this number of tonsillectomies are performed yearly in the UK (either as a single procedure or in combination with adenoidectomy), at least 5000 in children younger than 5 years and 20,000 in those under 16 years of age. In the United States as many as 259,000 tonsillectomies are performed annually.[2] A range of competing surgical techniques are available for tonsillectomy: cold steel, monopolar or bipolar diathermy (electrocautery), coblation, and harmonic scalpel. Traditionally, "cold steel" tonsillectomy dissection is performed with a combination of scissors and other metal instruments. Bleeding is controlled by applying pressure using temporary packs, then by ligatures; some surgeons use diathermy hemostasis instead of or as well as ligatures. Tonsillectomy by means of diathermy for both dissection and hemostasis is referred to in this paper as "hot" technique. Diathermy uses radiofrequency energy applied directly to the tonsil, and can be bipolar, when the current passes between the tips of the forceps, or monopolar, when the current passes between the tip of the forceps/blade and a plate on the patient's body. The coblator generates a field of plasma or ionized sodium particles that cut the tissue by vaporization. It also acts as a weak bipolar cautery that coagulates small blood vessels. The harmonic scalpel uses ultrasonic energy for both cutting tissue and coagulating the blood vessels.

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The tonsil is cut using a disposable blade, which vibrates at 55 KHz per second. This vibration transfers energy to the tissue and leads to superficial denaturation and coagulation of protein by heating the tissue to temperatures between 55°C and 100°C. The purpose of this study was to systematically review the literature on harmonic scalpel tonsillectomy and rates of postoperative hemorrhage with comparison to conventional tonsillectomy techniques; harmonic scalpel (HS) was compared with cold steel dissection, bipolar forceps and bipolar scissors, monopolar cautery, electrocautery, and coblator

## MATERIAL & METHODS

Databases systematically searched included Cochrane Library, Medline, Embase, CINAHL, INAHTA, CRD (Centre for Review and Dissemination), and related databases. Conference proceedings were searched on NLM Gateway, medicalconferences.com, and Zetoc. The date of the last search was September 19, 2019; no language restrictions were imposed. The search strategy began with "tonsillectomy, harmonic scalpel, ultrasonic scalpel." Keyword strategies were developed based on terms identified in the scoping search, professional experience, and key words provided by the papers retrieved. Manufacturers of harmonic scalpel technology (Ethicon Endo-Surgery) were contacted for product specifications and information about unpublished trials. Bibliographies of identified studies were manually searched for relevant references. One unpublished trial[3] was identified in the National Research Register in the UK, comparing bipolar diathermy, KTP laser, coblation, and harmonic scalpel. After contacting the authors it became apparent that the trial was stopped before completion. Foreign language publications were scanned using an English abstract where available. In the absence of an English abstract the full text paper was retrieved. Inclusion and Exclusion Criteria While devising inclusion/exclusion criteria, the authors initially proposed the exclusion of studies where patients had adenoidectomy as well as tonsillectomy. It became apparent that by using these stringent criteria a large number of studies, especially those including children, would have to be excluded. In practice, as many as a third of children undergo adenoidectomy and tonsillectomy at the same time;[4] disregarding these studies would bias the review by excluding a large and important patient population. By including these studies the authors believed that the external validity of the review would be enhanced and its results become more applicable to day-to-day clinical practice. The following inclusion/exclusion criteria were applied:

**STUDY DESIGN:** Only randomized controlled studies were included.

**POPULATION:** Adults who underwent bilateral tonsillectomy for indications such as recurrent or chronic tonsillitis, quinsy, or obstructive symptoms were included. Studies where patients underwent harmonic scalpel tonsillectomy as part of an uvulopalatoplasty, tonsillectomy for malignant disease, or unilateral tonsillectomy for histological diagnosis were excluded.

**INTERVENTION:** Harmonic scalpel tonsillectomy (ultrasonic scalpel tonsillectomy).

**COMPARATOR:** Tonsillectomy by cold steel dissection, cold steel dissection with added diathermy for hemostasis, bipolar or monopolar diathermy tonsillectomy, laser tonsillectomy, electrocautery, microdebrider tonsillectomy, coblation. Studies on tonsillotomy or radiofrequency tonsil reduction were excluded.

**OUTCOME:** Postoperative bleeding either primary (first 24 hours) or secondary (day 1 to 14 postoperatively). Studies that did not report any numerical data were excluded from analysis. Decision to include or exclude a study was made independently by two reviewers independent of each other. An inter-observer Kappa score (a measure of chance-corrected agreement) was calculated, indicating excellent agreement at 0.9. Where disagreement existed it was resolved by discussion. A third reviewer was available for consultation if agreement could not be reached but adjudication was not necessary. A quality assessment was performed by two independent reviewers in order to determine a minimum quality threshold for selection of studies; to explore quality difference as an explanation for heterogeneity of results; to guide the interpretation of findings and aid in determining the strength of inferences; and to guide recommendation for future. Data extraction was performed independently by two reviewers. A method described by Chalmers[5] (qualitative instrument) in 1990 was used in order to assist with the interpretation of results. The criteria used are: Is the randomization adequate? Is there potential for selection bias after allocation to study group (ie, losses to follow-up, intention-to-treat analysis)? Were assessors of outcome blinded to patient allocation? What was the quality of outcome assessment? For postoperative hemorrhage a set of criteria were considered important in assessing the quality of measurement: clear definition of primary (occurring within 24 hours of surgery) and secondary bleeding (occurring from day 1 to 14 postoperatively); clear definition of what was recorded as bleeding (ie, any bleeding; primary bleeding that delayed discharge, needed transfusion, needed return to theatres for stopping; secondary bleeding requiring admission for observation after the patient was discharged). Another important aspect is whether follow-up was long enough for outcome to occur, ie, at least 14 days for secondary bleeding. Studies were graded A, B, or C for their overall methodological quality as follows: A: minimization of bias in all categories (1, 2, 3, and 4), ie, adequate randomization, few losses to follow-up, blinding of assessors, high-quality outcome assessment; B: all the above of the criteria partially met; C: one or more of the criteria in A not met. The standard of reporting was poor; results of the quality

assessment are presented in Table 1. Using the Chalmers criteria for quality, two RCTs were awarded a B grade;6,7 the rest of the RCTs included were grade C.8-16

## RESULTS

After the described quality assessment,[11] RCTs were included in the review; As cold steel dissection and "hot" tonsillectomy techniques have a different rate of postoperative hemorrhage,[4] studies were analyzed separately for the two types of surgical techniques. A sample size calculation for each study was undertaken in the review in order to detect the role chance might have played in the results. The sample size needed in each arm of study to detect the reported differences in bleeding rates with a power of 80% and a significance of 0.05 is presented in Tables 1 and 2. All studies were underpowered. Studies included in the review were extremely heterogeneous not only in terms of population (different ages and indications for tonsillectomy), but also in terms of comparator techniques, added hemostatic procedures (see Tables 1 and 2), definitions of postoperative hemorrhage (see Tables 1 and 2), and surgical expertise of the operator (see Tables 1 and 2). The clinical heterogeneity of studies precluded any quantitative combination of results with a view to improve power. Numerous confounding factors were identified. In the selection of patients eligible to participate, some studies have excluded patients who have a history of peritonsillar abscess.[6] Previous peritonsillar abscess is a likely risk factor for postoperative hemorrhage and conversely patients with a history of obstructive sleep apnea are probably at lowest risk of postoperative hemorrhage.[4] It is likely that fibrosis and scarring that may result from severe or repeated infection contributes to difficulty of tonsillar dissection and potentially higher risk of subsequent hemorrhage. Age of patients is also likely to substantially influence the rate of postoperative hemorrhage as this has been reported more frequently in adults when compared to children.[4] Three of the studies included adults only,[8,11,14] Four RCTs included children and adolescents [6,7,15,16] and [4] RCTs included both children and adults.[9,10,12,13] No separate analysis of results was undertaken for different age groups in any of the studies. A number of studies reported the use of "hot" hemostatic techniques such as bipolar diathermy, monopolar diathermy, or suction diathermy added to either the harmonic scalpel or the comparator technique or both (see Table 1). If the effect of using such techniques (including the dose administered) is not adjusted for in the analysis of results.

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polar diathermy. In the majority of studies an added hemostatic procedure was needed with the harmonic scalpel. The results for harmonic scalpel vs "hot" techniques where patients are the unit of randomization are summarized in Table 2. Bipolar Scissors Leaper6 did not find any difference between harmonic scalpel (at 40% power) and bipolar scissors (at 15 W) in the rate of secondary hemorrhage (23% vs 21% respectively). For the purposes of the study, bleeding of any quantity was noted, which could explain the relatively high rate recorded. The authors did not encounter any primary bleeding. Monopolar Cautery and Coblator In comparing harmonic scalpel with monopolar cautery and coblator, Parsons[13] did not record any difference in postoperative bleeding. The authors fail to

**Table 1: Harmonic scalpel vs cold steel postoperative hemorrhage.**

| S.No | Study Year Chalmers grade Country | Randomization unit Number of patients | Postoperative bleeding | Comments Sample size needed |
|---|---|---|---|---|
| 1 | Haegner 2002 Chalmers C Germany | Patients 25HS/25CS Adults | No primary hemorrhage Secondary hemorrhage HS-7 patients 28% CS-3 cases 12% No return to theatres P 0.28 | Any bleeding taken into account Bipolar diathermy added to both techniques Surgeons experience not stated |
| 2 | Kamal 2006 Chalmers C UK | Patients 180HS/100CS Adults and children | No primary hemorrhage Secondary hemorrhage HS-2 patients 1.7% CS-7 patients 7% P 0.01 | Bleeding recorded only if needed admission Bipolar added to both techniques Surgeon experience variable |
| 3 | Oko 2005 Chalmers B UK | Patients 61HS/61CS Children | No primary hemorrhage Secondary hemorrhage HS-8 patients 13% CS-6 patients 10% P 0.77 | Haemorrhage not defined bipolar Diathermy used in both groups Two surgeons, year 3-4 Senior Specialist |
| 4 | Akural 2001 Chalmers C Finland | Tonsil side 28 patients Adults | Primary hemorrhage HS-1 patients Secondary hemorrhage CS-1 patients | Hemorrhage not defined.Electrocautry used in both groups.Three surgeons familiar with HS. |
| | Collison 2004 Chalmers C USA | Tonsil side 28 patients Adults and children | No primary hemorrhage Secondary hemorrhage HS-3 patients, 1 return to theatre.CS-0 patients | Hemorrhage not defined Suction cautery used in both groups Surgeons' experience not stated |

**HS**:Harmonic Scalpel, **CS**:Cold Steel, **BD**:Bipolar diathermy.

**Table 2: Harmonic scalpel vs"hot" tonsillectomy postoperative hemorrhage—patient randomized.**

| Author Year Country Chalmers grade | Unit of randomization Patient characteristics Surgery | Number of patients Age | Intervention /comparator | Bleeding postoperatively | Comments |
|---|---|---|---|---|---|
| AlBeeka 2003 Australia Grade C | Patient randomized Adults and children | 25/25 No baseline data | HS/MD HSand-MCsettingsnot started | No primary bleeds. 1 in each group secondary bleeding | Randomized on the base of surgery day Sample size not calculated |
| Parsons 2006 USA Grade C | Patient randomized Adults and children | | HS+MC coblator Settings not stated | 1 patient in each group had primary bleeding | secondary bleeding Surgeons year 3-4 residents Sample size needed 3379 |
| Walker 2001 USA Grade C | Patient randomized Children | Age mean and SD | HS/EC HS setting not stated EC setting 20W to dissect and 30 W to cauterize | No primary bleeds. 14 delayed bleeds. 1 HS returned to theatre | bleeding apart from return to theatre Sample size needed 1601 |
| Willging 2001 USA Grade C | Patient randomized Childrenand adolescent | Age mean 95% CI) HS6.3(5.6-7.0) EC6.9(6.1-7.8 | HS/EC HS setting3 EC setting10W to dissect and15 W to cauterize | 1 primary bleeding 3 returns to theatre No significant difference of quantity of bleeding noted | Patients with previous peritonsillar abscess, bleeding tendency,or NSAID intolerance excluded |
| Leaper 2006 New-Zeeland Grade B | Patient randomized Children | 103/101 mean age SD 102.8/92.6 | HS=silk ties/bipolar scissors BS HS setting 40% power Bipolar scissors setting 15W Silk ties needed for 48% of HS group | No primary bleeds Secondary bleeds HS 24 cases 23% BS 21 patients 21% P0.8 | Two surgeons experince not stated No separate group reporting for bleeding |

define bleeding and both the harmonic scalpel group had monopolar cautery added for hemostasis. Electrocautery Walker[15] and Willging[16] compared harmonic scalpel with electrocautery in children. Both studies fail to report the rate of bleeding separately for each group randomized but report no difference in the rate of return to theatre for secondary hemorrhage between groups. Bipolar Diathermy No primary hemorrhages were recorded by Sheahan[14] when comparing tonsil sides operated with either harmonic scalpel or bipolar diathermy in 21 patients. In the harmonic scalpel group hemostasis was achieved by bipolar diathermy and ties with 18 patients needing rescue hemostasis on HS side. One secondary tonsillar bleed was recorded in each group.

## DISCUSSION

The included studies were found to be heterogeneous in terms of population, comparator, outcome, and quality and this unfortunately precluded any quantitative combination. Quality issues center on poor reporting in the studies and small study size. In a particularly small study, postoperative hemorrhage, the main outcome of interest may not have been reported in either of the groups. Any potential difference in hemorrhage rates between tonsillectomy techniques then remains unidentified and the low sample size introduces bias, as results in this case could be due to chance alone rather than the techniques being of equivalent safety. This review includes both studies randomizing patients (both tonsils operated with the same technique) and studies randomizing tonsil side (each tonsil operated with different technique). In a study with patient randomization the chances of postoperative hemorrhage are theoretically doubled in comparison with a study where tonsils are randomized. While the RCT is regarded as “gold standard” in study design, it may still produce results that are not representative of the population. Some studies included either children [15,16,17,18] or adults;[19-21] others had a mixture of patients,[22,23.13] without separately reporting results for the different ages. Indications for tonsillectomy may easily vary from country to country as the clinician’s threshold for offering surgery. We incorporated studies from several countries and some where more than one surgeon operated. Some surgeons excluded patients with recurrent tonsillitis, chronic tonsillitis, and quinsy, which results in a selected population that has a smaller risk of postoperative bleeding.[24-28] Other surgeons operated on patients with acute peritonsillar abscess, which can account for higher postoperative bleeding rate in their sample.[29-34] The intervention of interest, harmonic scalpel tonsillectomy, was uniformly applied, with very small variations in settings of the generator, but the studies varied widely in the choice of added hemostatic technique. Some studies used ties while others used bipolar diathermy, monopolar diathermy, or suction diathermy to stop the bleeding when the harmonic scalpel may have failed to do so.[35-37] Cold steel tonsillectomy required additional hemostatic technique in all studies reviewed; the choices for hemostasis were similar to the ones in the harmonic scalpel group. The addition of supplementary hemostatic measures to both the harmonic scalpel and comparator technique introduces an element of confounding that was not accounted for in analysis in any of the studies reviewed. An additional problem was that of failure to separately analyze cases where adjunctive surgery took place.

## UNCORRECTED PROOF

Additional surgical procedures may easily impact on pain, return to normal diet or activity, bleeding, and operative time. Follow-up rates were reported in a minority of studies and some authors failed to report it separately for each of the groups considered. Most studies failed to give a clear definition of what was considered a primary and secondary hemorrhage. This may explain to a large extent observed differences in hemorrhage rates reported. Many studies failed to report the rate of hemorrhage separately for primary and secondary hemorrhage. Methodological Limitations As detailed, this systematic review is based upon evidence that incorporates biases and many confounding factors. The populations in the studies included are heterogeneous in terms of patient age and indication for tonsillectomy. Our application of inclusion/exclusion criteria and data extraction in the review was not blinded to the author and institution affiliation. Conference proceedings reporting on harmonic scalpel vs other tonsillectomy techniques, although identified in the search, were not included in the final review. The authors have decided to exclude these studies as the information presented was insufficient in order to assess the quality of the studies. No attempt to contact authors of studies with missing data was possible due to time and resource limitations. Implications for Future Practice and Research As revealed by the sample size calculations, large randomized studies will be needed in order to assess with confidence the rate of postoperative hemorrhage in harmonic scalpel tonsillectomy. This could make an RCT impractical and too expensive to run; therefore a large, well-controlled cohort study might be more appropriate and of greater power in providing data on relatively rare hemorrhagic complications. Cold steel dissection with ties for hemostasis and no use of hot techniques remains the comparator of choice and appears to have the lowest overall hemorrhage rate. The follow-up period should be at least 14 days to ensure that late post-tonsillectomy bleeds are captured. A clear definition of what is considered primary and secondary hemorrhage would need to be established to ensure accurate reporting. The experience of the surgeons performing tonsillectomy with both harmonic scalpel and comparator should be stated, irrespective of the outcome of interest in the study. A study design that incorporates economic endpoints would ease the burden of collecting cost-effectiveness data at a later date and could assist decision makers

in adopting or refuting harmonic scalpel as an alternative to conventional tonsillectomy.

## CONCLUSIONS

Data reviewed is of low quality and does not support any significant difference in postoperative hemorrhage rates, either primary or secondary, when harmonic scalpel is compared with other tonsillectomy techniques. The studies were underpowered and have methodological flaws; therefore these results need to be interpreted with caution. As no obvious reduction in hemorrhagic complications associated with the use of harmonic scalpel could be demonstrated in comparison with conventional tonsillectomy, at present the additional costs involved may not be justified without further research. Other patient-related outcomes such as postoperative pain and return to normal diet and normal activity, along

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Following authors have made substantial contributions to the manuscript as under

**Khan AR:** Main Idea, Critical review

**Hafeez M:** Data Interpretation, Data analysis

**Arif AU:** Data Collection,Bibliography.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.