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LITERATURE REVIEW

Harmonic scalpel tonsillectomy: A systematic review of evidence for postoperative hemorrhage

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OBJECTIVE: To systematically review the literature on harmonic scalpel tonsillectomy 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. The date of the last search was September 19, 2006; 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 five RCTs comparing harmonic scalpel tonsillectomy with "cold steel" tonsillectomy and six 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.

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. 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.

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, 2006; 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, profes-

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sional experience, and key words provided by the papers retrieved.

Manufacturers of harmonic scalpel technology (Ethicon Endo-Surgery, USA) 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 or children 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. 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:

1. Is the randomization adequate?
2. Is there potential for selection bias after allocation to study group (ie, losses to follow-up, intention-to-treat analysis)?
3. Were assessors of outcome blinded to patient allocation?
4. 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 of the above 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; Figure 1 details the selection process. 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