NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of tonsillectomy using ultrasonic scalpel

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in August 2005.

Procedure names

- Harmonic scalpel for tonsillectomy.
- Ultrasonic scalpel.
- Ultrasound activated scalpel.

Specialty society

British Association of Otorhinolaryngologists, Head and Neck Surgeons.

Description

Indications

Indications for tonsillectomy include recurrent acute or chronic tonsillitis, peritonsillar abscess and pharyngeal obstruction/obstructive sleep apnoea. Life-threatening complications of these conditions are rare and the main aim of surgery is to relieve symptoms.

Current treatment and alternatives

Surgical removal of the tonsils (tonsillectomy) is one of the most common surgical procedures in the UK. The operation is performed in many different ways but can be broadly divided into two stages: removal (either complete or partial) of the tonsil, followed by control of bleeding (haemostasis).

Traditional ‘cold steel’ tonsillectomy consists of two stages: removal of the tonsil followed by haemostasis. Bleeding is controlled by pressure, then by ligatures. The use of ligatures may be supplemented by diathermy and the use of packs.

Diathermy uses radiofrequency energy applied directly to the tissue, and can be bipolar (current passes between the two tips of the forceps) or monopolar (current passes between the forceps tips and a plate attached to the patient’s skin). The heat

generated may be used in dissection to incise the mucosa and divide the strands of tissue that bind the tonsil to the pharyngeal wall. It may also be used for haemostasis, by coagulating the vessels that run in these strands and any other bleeding vessels.

What the procedure involves

Ultrasonic scalpel tonsillectomy is typically performed under general anaesthetic. This procedure uses ultrasonic energy to simultaneously dissect through tissues and seal blood vessels. Tissues are cut by a disposable blade, which vibrates at an ultrasonic frequency thereby cutting the tissue. This vibration also transfers energy to the tissue, thereby leading to coagulation, and through this achieving haemostasis. The temperature caused by the vibration is around 55–100ºC and is lower than by other hot methods such as diathermy or lasers.

Efficacy

Six studies assessed pain following tonsillectomy using an ultrasonic scalpel, cold steel dissection or diathermy[1, 2, 3, 4, 5, 6]. Similar pain scores up to 7 days were reported following each method of tonsillectomy. Three studies reported on pain at 2 weeks or more[1, 3, 4]. In one study, a randomised trial of 32 patients who had ultrasonic scalpel tonsillectomy on one side and blunt dissection tonsillectomy on the other, pain was found to be significantly worse on the ultrasonic scalpel side during the second week[3]. However, different results were found in two other randomised trials, with one study of 120 patients reporting that on day 14 only three patients reported any pain, and those were all from the diathermy group (n = 59)[1].

Return to normal diet or appetite was assessed in four studies[1, 4, 6, 7]. All four studies reported that ultrasonic scalpel was either similar to or better than cold steel dissection or diathermy. In one study reporting results on 172 patients, return to normal diet at 1 and 3 days respectively was reported by 44.3% and 74.2% of the ultrasonic group compared with 22.7% and 46.7% of the diathermy group[7].

The Specialist Advisers did not have any particular concerns about the efficacy of this procedure but noted that the evidence base for this procedure is still small and a number of the studies have methodological limitations.

Safety

Bleeding is an important complication of tonsillectomy. It can occur intraoperatively, during the first 24 hours after the operation (defined in most studies as primary haemorrhage), or after 24 hours (secondary haemorrhage). Postoperative haemorrhage may require the patient to be readmitted to hospital and possibly undergo further surgery.

In general, primary haemorrhage rates appeared to be lower with the ultrasonic scalpel than with cold steel dissection or diathermy. In a retrospective review of 316 patients, primary haemorrhage occurred in 1 of 70 patients (1.4%) in the ultrasonic scalpel group, 3 out of 109 (2.7%) in the diathermy group, and 4 out of 132 (3%) in the cold dissection group[8].

Similar results were reported in another retrospective review of 407 patients, in which primary haemorrhage rates for patients treated with ultrasonic scalpel, blunt dissection with monopolar diathermy and bipolar diathermy were 1.0%, 7.1% and 2.4% respectively. However, in most studies other techniques (such as ties around blood vessels or diathermy) were needed in addition to the ultrasonic scalpel to achieve haemostasis.

Secondary haemorrhage rates varied among the studies. In a randomised controlled trial of 120 paediatric patients, secondary haemorrhage was observed in 8.2% (5/61) of patients in the ultrasonic group compared with 5.1% (3/59) in the diathermy group, although these differences were not significant[1]. In a small randomised controlled trial of 21 patients undergoing ultrasonic scalpel tonsillectomy on one side and diathermy on the other side (that is, within-patient comparison of the two techniques), there were two cases of delayed bleeding – one for each of the two methods[4]. Another within-patient comparative study of ultrasonic scalpel and cold steel dissection tonsillectomy reported that 3 out of 28.patients had delayed bleeding, all of which occurred on the ultrasonic scalpel side[5]. These data are in general agreement with results from the National Prospective Tonsillectomy Audit [11]. This report notes that the lowest rates of secondary haemorrhage (both those requiring and those not requiring further operation) were associated with cold steel dissection with suture haemostasis, with higher rates reported with the use of other techniques such as coblation and with diathermy for both dissection and haemostasis.

The Specialist Advisers stated that the safety is much the same as for any other method of tonsillectomy; however, it appeared that there was slight increase in post-operative haemorrhage compared with cold steel dissection.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to ultrasonic scalpel for tonsillectomy Searches were conducted via the following databases, covering the period from their from commencement to August 2005 MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Therefore, good quality non-randomised controlled studies may be included in preference to poorly described randomised trials (for example those with poor description in terms of randomisation, blinding or reporting of outcomes). Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Adults or children undergoing tonsillectomy.
Intervention/test	Ultrasonic scalpel.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on nine comparative studies, including three randomised between-patients comparisons[1, 2, 7] and three within-patient comparisons[3, 4, 5].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Existing reviews on this procedure

A Cochrane protocol on harmonic scalpel versus other surgical procedures, published November 2003[10].

Related NICE guidance

NICE has published the following guidance related to this procedure. Appendix B details the recommendations made in the guidance.

Interventional Procedures

- Electrosurgery (diathermy and coblation) for tonsillectomy. *NICE interventional procedure guidance* no.150 (2005). Available from www.nice.org.uk/IPG150

NICE is also in the process of developing interventional procedures guidance on laser-assisted serial tonsillectomy.

Technology appraisals

None applicable

Clinical guidelines

None applicable

Public health

None applicable

Table 2 Summary of key efficacy and safety findings on harmonic scalpel

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Willging and Wiatrak (2003)[1]

USA

Randomised controlled trial

120 paediatric patients (117 assessed, 1 lost to follow-up, 2 patients withdrew)

• 61 ultrasonic scalpel patients mean age 6.3 years

• 59 electrocautery patients mean age 6.9 years

Patients suffered from recurrent tonsillar infection, adenotonsillar hypertrophy with airway obstruction and tonsillar asymmetry

Follow-up: 2 weeks

Disclosure of interest: study was performed with support from Ethicon Endo-Surgery</td>
<td>Outcomes reported: Postoperative pain, otalgia, hydration, operation time, and return to activities of daily living

<table>
<tr><th></th><th>Ultrasonic scalpel</th><th>Electrocautery</th></tr>
<tr><td>Surgical time</td><td>8 min 42 seconds</td><td>4 min 33 seconds</td></tr>
</table>

Assessment of eating, sleeping and activities of daily living (assessed by questionnaire filled out by family)

On postoperative days 1, 2, 3 and 14 significantly more patients in the ultrasonic group slept well

No differences were reported in eating, drinking, swallowing, activities of daily living or in the amount of food consumed at final follow-up

Assessment of pain Wong-Baker FACES pain rating scale (0 no hurt – 5 hurts the most)

<table>
<tr><th></th><th>Ultrasonic</th><th>Electrocautery</th></tr>
<tr><td>Day 1</td><td>2.4</td><td>2.5</td></tr>
<tr><td>Day 2</td><td>2.1</td><td>2.4</td></tr>
<tr><td>Day 3</td><td>1.75</td><td>2.1</td></tr>
<tr><td>Day 4</td><td>1.55</td><td>1.7</td></tr>
<tr><td>Day 5</td><td>1.7</td><td>1.6</td></tr>
<tr><td>Day 6</td><td>1.5</td><td>1.5</td></tr>
<tr><td>Day 7</td><td>1.1</td><td>1.1</td></tr>
</table>

No absolute number given, approximate figures are taken from table

On day 14 only 3 patients reported any pain (all from electrocautery group)</td>
<td>Complications

Intraoperative blood loss > 1 ml
• Ultrasonic 2/61 (3.3%)
• EC 1/59 (1.7%)

Ultrasonic scalpel
▪ 1 (2.8%) patient primary haemorrhage
▪ 5 (8.2%) patients with secondary haemorrhage
▪ 2 (3.3%) patients required surgery to stop bleeding

Electrocautery
▪ 0% patients had primary haemorrhage.
▪ 3 (5.1%) patients with secondary haemorrhage
▪ 1 (1.7%) patients required surgery to stop bleeding

Authors reported no significant differences between groups for adverse events, dehydration or presence of fever</td>
<td>Randomisation allocation unclear: ‘randomisation number was assigned’.

The patient and the patient’s family were blinded to the technique used.

Two surgeons undertook the procedures.

Power setting for electrocautery was 10 W to dissect and 15 W to cauterise.

Pain was assessed using the Wong-Baker FACES pain rating.

Questionnaires were used to assess additional pain and time to return to activities of daily living. No indication given as to how many questionnaires were completed – assumed that all data returned.

No absolute figures given for some outcomes, only percentages.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Walker and Syed (2001)[7]
USA

Randomised controlled trial

April 1999–May 2000

316 paediatric patients
• 155 ultrasonic scalpel patients
• 161 Monopolar electrocautery patients

Patients who underwent monopolar electrocautery received 20 W for cutting 35 W for additional haemostasis. If needed patients in the HS group also had suction cautery at 35W to achieve haemostasis.

Mean age: 7.1 years (range 1–19 years)

Follow-up: 14 days

Disclosure of interest: not specified</td>
<td>Outcomes reported: bleeding and postoperative complications (assessed at follow-up appointment), return to normal diet, resumption of normal activity, medication use (assessed by questionnaire)

Questionnaire response rate
54% patients (172/316): 62.2% (97/155) were ultrasonic scalpel patients, 46.6% (75/161) were electrocautery patients

<table>
<tr><th></th><th>Ultrasonic</th><th>Electrocautery</th><th>p-value</th></tr>
<tr><td>Return to diet (24 hours)</td><td>43 (44.3%)</td><td>17 (22.7%)</td><td>0.003</td></tr>
<tr><td>Return to diet (72 hours)</td><td>72 (74.2%)</td><td>35 (46.7%)</td><td>0.001</td></tr>
<tr><td>Return to activity (24 hours)</td><td>27 (27.8%)</td><td>9 (12.0%)</td><td>0.011</td></tr>
<tr><td>Return to activity (72 hours)</td><td>48 (49.5%)</td><td>17 (22.7%)</td><td>0.001</td></tr>
<tr><td>Medication use</td><td>66 (68%)</td><td>55 (73%)</td><td>NS/NR</td></tr>
</table>
</td>
<td>Complications

Intraoperive blood loss

Authors report that there were no early bleeds (primary haemorrhage episodes) in either group

Late bleeds occurring 7–14 days postoperatively: 14/316 (4.4%)

Ultrasonic
5/155 patients (3.2%) had late bleeds (as defined above) of whom 1 patient had to be admitted to the operating room to control bleeding, remaining 4 patients were observed

2 patients (1.3%) had dehydration

Electrocautery
9/161 patients (5.6%) had late bleeds (as defined above) of whom 3 patients need operative intervention, remaining 6 patients were managed conservatively

4 patients (2.5%) had dehydration
1 patient pulmonary oedema (recovered within 24 hours)</td>
<td>Unclear how randomisation was undertaken.

This study is one of the first published studies on this procedure (early experience).

62/161 EC patients had other surgical procedures besides adenoidectomies.

56/166 HS patients had other surgical procedures besides adenoidectomies.

The two broader groups were divided into those 7 years and younger and those 8 years and older.

All patients given same perioperative and postoperative medications.

Outcomes were assessed by questionnaire and follow-up appointment.

Authors decided not to measure pain by scores (pain was not considered a primary outcome).

Response rate to questionnaire was poor – no formal analysis done to see if there were differences between responders and non-responders (however did note that patients from lower socioeconomic group were less likely to respond).</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr>
<td>Sugiura et al (2001)[2]

Tokyo

Randomised controlled trial

November 1999 to January 2001

30 adults patients with recurrent tonsillitis

Patients randomised to:
• ultrasonic tonsillectomy (15)
• blunt dissection (15)

Age range: range 21–40 years (mean not reported)

Follow-up: 6 days

Disclosure of interest: ultrasonic scalpel was donated by Ethicon Endo-Surgery</td>
<td>Outcomes reported: pain and appetite, blood loss

Mean pain scores (VAS; 0 no pain – 10 unbearable pain)

<table>
<tr><th></th><th>Ultrasonic</th><th>Blunt dissection</th></tr>
<tr><td>Day 1</td><td>5.8</td><td>5.5</td></tr>
<tr><td>Day 2</td><td>5.3</td><td>5.5</td></tr>
<tr><td>Day 3</td><td>4.8</td><td>4.3</td></tr>
<tr><td>Day 4</td><td>4.4</td><td>3.7</td></tr>
<tr><td>Day 5</td><td>4.1</td><td>3.4</td></tr>
<tr><td>Day 6</td><td>3.6</td><td>3.0</td></tr>
</table>
This numbers are approximate readings off the graph because no absolute numbers are given

Commentary is made in the text that patients in the ultrasound group had slightly higher VAS scores than those in the blunt dissection group but the differences were not statistically significant

Appetite (VAS; 0 good appetite – 10 no appetite)

<table>
<tr><th></th><th>Ultrasonic</th><th>Blunt dissection</th></tr>
<tr><td>Day 1</td><td>4.3</td><td>4.6</td></tr>
<tr><td>Day 2</td><td>3.3</td><td>4.2</td></tr>
<tr><td>Day 3</td><td>3.2</td><td>3.2</td></tr>
<tr><td>Day 4</td><td>3.1</td><td>2.5</td></tr>
<tr><td>Day 5</td><td>3.2</td><td>3</td></tr>
<tr><td>Day 6</td><td>2.5</td><td>2</td></tr>
</table>
This numbers are approximate readings off the graph because no absolute numbers are given

Commentary is made in the text that there were no statistically significant differences between the groups</td>
<td>Complications

Mean intraoperative blood loss (measured by weighing swabs and measuring the volume of suction aspirate)

Ultrasonic: 4.6 ± 1.9 ml
Blunt dissection: 41.9 ± 12.9 ml

Statistically significant difference
p < 0.0001

Authors note that no postoperative bleeding was observed in any of the patients</td>
<td>Randomisation allocation unclear.

Small number of patients.

Patients were asked to report pain and appetite once a day at the same time each morning before analgesic use.

Outcomes are reported as figures, absolute numbers are not given in the text.

Pain is measured by VAS score, with no analgesic use.

Short follow-up for secondary complications.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr>
<td>Akural et al (2001)[3]

Finland

Randomised trial (within patient)

October 1998–September 1999

32 patients, each had:
• one tonsil removed by ultrasonic scalpel
• one tonsil removed by blunt dissection

Median age: 21 years (range 17–48 years)

Follow-up: 2 weeks

Disclosure of interest: Ethicon Endo-Surgery supplied the ultrasonic scalpel</td>
<td>Outcomes reported: operation time, management bleeding, blood loss, slough and healing, postoperative pain

Mean operation time 25 minutes
The median time was the same for the two procedures (around 7 minutes)

Pain (0 – no pain to 10 worst pain; presented as area under the curve)

<table>
<tr><th></th><th>Ultrasonic</th><th>Dissection</th><th>p-value</th></tr>
<tr><td>At rest</td><td></td><td></td><td></td></tr>
<tr><td>0–10 hours</td><td>12.3 (6.3–17.5)</td><td>24.87 (12.1–44.4)</td><td>0.002</td></tr>
<tr><td>1st week</td><td>22.8 (19.8–29.3)</td><td>21.3 (16.2–31)</td><td>0.802</td></tr>
<tr><td>2nd week</td><td>11.5 (4.9–18.4)</td><td>6.8 (3.3–10.8)</td><td>0.002</td></tr>
<tr><td>On swallowing</td><td></td><td></td><td></td></tr>
<tr><td>0–10 hours</td><td>32.5 (17.9–42)</td><td>50.5 (38.9–61)</td><td>0.001</td></tr>
<tr><td>1st week</td><td>30.9 (25.3–38.3)</td><td>29.8 (24.3–39.3)</td><td>0.665</td></tr>
<tr><td>2nd week</td><td>16.8 (8.5–22.6)</td><td>9.8 (4.8–15.3)</td><td>0.003</td></tr>
<tr><td>Otalgia</td><td></td><td></td><td></td></tr>
<tr><td>1st week</td><td>27.3 (10.5–37.1)</td><td>22.3 (7.3–34.8)</td><td>0.469</td></tr>
<tr><td>2nd week</td><td>10 (6–24.5)</td><td>7 (1.5–12)</td><td>0.002</td></tr>
</table>
</td>
<td>Complications

Median perioperative blood loss
Ultrasonic scalpel 0 ml (range 0–65 ml)
Blunt dissection 21 ml (range 5–128 ml)

Wound healing and slough were similar on both sides on the first day and at 2 weeks after tonsillectomy

Authors do not report upon postoperative haemorrhage rates.

Note: management of bleeding
Ultrasonic scalpel: electrocoagulation was used in half of the patients (median number of sequences 0, range 0–3)

Blunt dissection: electrocoagulation was used in all patients (median number of sequences 45, range 15–121)</td>
<td>Tonsils were randomised rather than patients.

Tonsil to be removed by ultrasonic scalpel was chosen randomly by using a sealed envelope.

Four patients were not included in the analysis (two protocol violations and two patients re-operation due to bleeding: one HS and one blunt dissection). An intent to treat analysis was not undertaken.

Authors calculated that at least 30 subjects were needed to detect at 10% in pain scores with a 90% power.

Patient and outcomes assessor were blind to the procedure.

Three of the authors familiar with ultrasonic scalpel performed the procedure.

If bleeding could not be managed by ultrasonic scalpel, then electrocoagulation was used.

Electrocoagulation was used to manage bleeding with blunt dissection.

Secondary bleeds were not discussed.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr>
<td>Sheahan et al (2004)[4]

UK

Randomised trial (within patient)

11 October 2002–30 June 2003

21 patients (originally 24 patients), each had:
• one tonsil removed by ultrasonic scalpel
• one tonsil removed by bipolar diathermy

16 women, 5 men

Age 16–31 years

Selection criteria: elective tonsillectomy

Exclusion: age less than 16 years, known bleeding diathesis, acute infection or contraindication to general anaesthesia

Follow-up: 3 weeks

Disclosure of interest: Ultrasonic scalpel was donated by Ethicon Endo-Surgery</td>
<td>Outcomes reported: pain (VAS)

Pain: Number of patients stating more painful side

<table>
<tr><th></th><th>Ultrasonic</th><th>Bipolar</th><th>No difference/ don’t know</th></tr>
<tr><td>Day 1</td><td>7</td><td>7</td><td>7</td></tr>
<tr><td>Day 2</td><td>7</td><td>9</td><td>5</td></tr>
<tr><td>Day 7</td><td>7</td><td>7</td><td>3 (4 lost to follow-up)</td></tr>
<tr><td>Week 3</td><td>5</td><td>6</td><td>3 (6 lost to follow-up)</td></tr>
</table>

Mean pain scores on each side

<table>
<tr><th></th><th>Ultrasonic</th><th>Bipolar</th></tr>
<tr><td>Day 1</td><td>5.2</td><td>2.0</td></tr>
<tr><td>Day 2</td><td>3.9</td><td>3.9</td></tr>
<tr><td>Day 7</td><td>2.9</td><td>3.6</td></tr>
<tr><td>Week 3</td><td>1.4</td><td>1.2</td></tr>
</table>

Note: operating time was not assessed because this was likely to be confounded by which side was operated on first</td>
<td>Complications

Haemostasis: in 18/21 sides randomised to HS, an alternative technique of haemostasis was required (14 bipolar, 4 ties)

In 2/21 sides randomised to bipolar, an alternative technique of haemostasis was required (ties).

Secondary haemorrhage:
• one patient from the HS side
• one patient from the bipolar side
Both cases settled conservatively without having to return to theatre. No patient suffered from reactionary haemorrhage

Note: Significant blood loss was not anticipated with either technique, so this was not assessed</td>
<td>Tonsils were randomised rather than patients.

Tonsil to be removed by ultrasonic scalpel was chosen by using a table of random numbers/sealed envelopes.

Three patients had to be withdrawn from study (n = 21) because of problems with the equipment.

Operations were performed by five different surgeons.

For ultrasonic scalpel, haemostasis was achieved using the blunt end of the hook. In cases where this was not easily achieved alternative techniques (such as ties or bipolar diathermy) were used.

Power calculations were undertaken – sample of 23 would be required to detect a 0.75 difference in pain at a probability of 80%.

Results were calculation on an intent to treat basis.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr>
<td>Collison and Weiner (2004)[5]

USA

Controlled trial (unclear if randomised)

28 patients with recurrent tonsillitis and/or adenotonsillar hypertrophy, each had:
• one tonsil out with ultrasonic scalpel
• one tonsil out with cold dissection tonsillectomy with electrocautery suction

Mean age: 17 years (range 6–40 years)

Follow-up: 1 week

Disclosure of interest: Ultrasonic scalpel was donated by Ethicon Endo-Surgery</td>
<td>Outcomes reported: pain (VAS 10 point scale), blood loss, operating time

Pain
<table><tr><th></th><th>3 hours</th><th>1 week</th></tr><tr><td>Ultrasonic</td><td>3.5 (range 1–10)</td><td>2.7 (range 0–9)</td></tr><tr><td>Dissection-cautery</td><td>4.4 (0–10)</td><td>2.6 (range 1–10)</td></tr></table>
Operating time
<table><tr><th></th><th>Operating time</th></tr><tr><td>Ultrasonic</td><td>5–25 minutes (mean 10.9)</td></tr><tr><td>Dissection-cautery</td><td>5–16 minutes (mean 7.7)</td></tr></table></td>
<td>Complications

Intraoperative blood loss
<table><tr><th></th><th>Blood loss</th></tr><tr><td>Ultrasonic</td><td>Estimates 0–50 ml (mean 6.2 ml)</td></tr><tr><td>Dissection-cautery</td><td>Estimates 7–125 ml (mean 58.8 ml)</td></tr></table>
In 7/28 patients (25%) cautery was required on the ultrasonic side to coagulate one or two larger vessels

Delayed bleeding (after more than 24 hours)

Three patients had delayed bleeding (10.7%) all of which occurred on the ultrasonic scalpel side

Bleeding stopped spontaneously in two patients, and one patient needed a blood transfusion</td>
<td>Tonsils have been randomly allocated rather than patients.

Those performing outcome assessment were blinded. The decision as to which procedure would be performed on each tonsil was made randomly by the surgeon.

Unclear about experience of surgeons with the ultrasonic scalpel procedure.

Authors stated in the discussion section that they terminated study when the trend in delayed bleeding became apparent.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Morgenstein et al (2002)[6]

USA

Non-randomised controlled study

159 paediatric patients

Patients presented for tonsillectomy alone or tonsillectomy plus adenoidectomy

Ultrasonic scalpel (95 patients)
Mean age: 8.3 years

Electrocautery (61 patients)
Mean age: 8 years

Age range: 3–18 years

Follow-up: 6 days (unclear)

Follow-up data was complete for 110 (71%) patients

In hospital data was complete for all patients

Disclosure of interest: study funded by Central DuPage Hospital</td>
<td>Outcomes reported: surgical time, estimated blood loss ≥ 30 ml, recovery room and phase 2 nurses' perception of pain, pain medications, postoperative pain, time to first soft foods, time to a regular diet

<table>
<tr><th></th><th>Ultrasonic</th><th>Electrocautery</th></tr>
<tr><td>Pain in recovery</td><td>0.43 ± 0.82</td><td>0.29 ± 0.64</td></tr>
<tr><td>No of patients receiving medication in recovery</td><td>59/95 (62%)</td><td>37/61 (60.7%)</td></tr>
<tr><td>Pain in phase 2</td><td>0.59 ± 0.68</td><td>0.53 ± 0.60</td></tr>
<tr><td>No of patients receiving medication in phase 2</td><td>38/95 (40%)</td><td>25/61 (41%)</td></tr>
<tr><td>Surgical time (minutes)</td><td>25.4 ± 9.5</td><td>25.3 ± 9.3</td></tr>
<tr><td colspan="3">Food intake (assessed by parents)
Follow-up n = 110, unclear how many in each group</td></tr>
<tr><td>Days until soft food taken</td><td>2.02 ± 1.97</td><td>1.45 ± 1.62</td></tr>
<tr><td>Days until regular diet</td><td>4.24 ± 2.10</td><td>3.71 ± 2.33</td></tr>
</table>

There were no significant differences between the two groups

Postoperative pain (assessed by parents)
Follow-up n = 110, unclear how many in each group)

<table>
<tr><th></th><th>Ultrasonic</th><th>Electrocautery</th></tr>
<tr><td>Day 1</td><td>2.45 ± 1.21</td><td>2.07 ± 1.18</td></tr>
<tr><td>Day 3</td><td>2.20 ± 1.22</td><td>1.76 ± 1.09</td></tr>
<tr><td>Day 6</td><td>1.68 ± 1.33</td><td>1.18 ± 1.39</td></tr>
</table>

Subgroup analysis was undertaken of patients who received ultrasonic scalpel and electrocautery n = 14</td>
<td>Complications

Intraoperative blood loss ≥ 30 ml
Ultrasonic 21/95 (22%)
EC 8/61 (13%)

Ultrasonic scalpel
▪ 7 (7.4%) patients with nausea/vomiting in recovery
▪ 23 (24.2%) patients with nausea/vomiting in phase 2
▪ 14 (14.7%) patients required significant use of electrocautery for control of bleeding

Electrocautery
▪ 2 (3.3%) patients with nausea/vomiting in recovery
▪ 10 (16.4%) patients with nausea/vomiting in phase 2
▪ 2 (3.3%) required repeat intervention to control late onset bleeding (within 30 days)</td>
<td>Allocation to group was determined by the surgeon.

Study involved four group practices, six individual surgeons, different techniques and different nurses.

Some ultrasonic scalpel patients also received electrocautery for bleeding.

Surgeons experience with the ultrasonic procedure was not recorded.

Pain assessment in the recovery period/phase 2 was based on nurses' perception.

Pain postoperatively was recorded by patients.

Pain was assessed on a 0 (none) to 5 (worst pain) scale in face formats. Unclear how blood loss measured.

Follow-up was undertaken by an outcomes nurse. Families were contacted by telephone after surgery.

No breakdown given of number of patients in each group who returned follow-up data. This may result in significant differences.

Both telephone survey and follow-up letter were used for follow-up data. These different methods could introduce bias.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Schrey et al (2004)[9]

Finland

January 1998–30 August 2000

407 patients who underwent tonsillectomy
• 143 children (< 16 years)
• 264 adults

84 (21%) patients underwent operation on the basis of acute peritonsillar abscess

Group 1: 102 patients, blunt dissection – haemostasis with monopolar diathermy

Mean age 22.4 years

Group 2: 140 patients, haemostasis with bipolar diathermy

Mean age 22 years

Group 3: 165 patients, ultrasonic scalpel – haemostasis with scalpel or monopolar cautery

Mean age 20.9 years

Follow-up: not specified

Disclosure of interest: study funded by Medical Research Fund of Vassa Hospital District</td>
<td>Outcomes reported: blood loss, operation time.

<table>
<tr><th></th><th>Operating time (minutes)</th></tr>
<tr><td>Dissection and Monopolar</td><td>18.4 (95% CI 16.8–20.0 minutes)</td></tr>
<tr><td>Bipolar</td><td>22.1 (95% CI 19.6–24.6 minutes)</td></tr>
<tr><td>Ultrasonic</td><td>32.3 (95% CI 30.2–34.4 minutes)</td></tr>
<tr><td>Overall</td><td>23.3 (95% CI 21.9–24 minutes)</td></tr>
</table>
</td>
<td>Complications

56 (13.8%) patients had postoperative bleeding – 20 of these cases did not need a re-operation

14 patients had 15 primary haemorrhages and 44 patients had 53 secondary haemorrhages

Postoperative bleeding rate
• 13.6% for dissection/monopolar patients
• 17.0% for bipolar patients
• 20.6% for ultrasonic patients

Primary haemorrhage
• 7.1% for dissection/monopolar patients
• 2.4% for bipolar patients
• 1.0% for ultrasonic patients

Secondary haemorrhage
• 6.4% for dissection/monopolar patients
• 14.5% for bipolar patients
• 19.6% for ultrasonic patients (significantly higher)
•
<table>
<tr><th></th><th>Blood loss</th></tr>
<tr><td>Monopolar</td><td>58.7 ml (95% CI 45.9–71.5 ml)</td></tr>
<tr><td>Bipolar</td><td>43.8 ml (95% CI 34.8–52.8 ml)</td></tr>
<tr><td>Ultrasonic</td><td>24.8 ml (95% CI 17.2–32.4 ml) significantly lower</td></tr>
<tr><td>Overall</td><td>43.6 ml (CI 37.5–49.7 ml)</td></tr>
</table>
</td>
<td>Retrospective review.

Postoperative bleeding was defined as any bleeding that required any type of medical intervention.

Primary bleeding was defined as occurring within 24 hours of surgery, secondary as occurring between 1–14 days after surgery.

Limited information reported on patient demographics.</td>
</tr>
</table>

Abbreviations used: CI – confidence interval; EC – electrocautery; HS – harmonic scalpel; NS – non-significant; NR – not reported; VAS – Visual Analogue Scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr>
<td>Shinhar et al (2004)[8]

USA

September 2000–August 2001

316 patients who had undergone adenotonsillectomy (n = 268) or tonsillectomy alone (n = 48)
• 175 male
• 141 female

Mean age: 7.3 years (1–23 years)

70 patients underwent ultrasonic scalpel tonsillectomy

109 patients electrocautery (not specified)

132 by cold surgical dissection

Follow-up: not specified

Disclosure of interest: not specified</td>
<td>Outcomes reported: operating time, blood loss, dehydration

<table>
<tr><th></th><th>Ultrasonic scalpel</th><th>EC</th><th>Surgical dissection</th></tr>
<tr><td>Mean operating time (tonsillectomy)</td><td>23.6 min</td><td>30.2 min</td><td>35.3 min</td></tr>
<tr><td>Postoperative bleeding (%)</td><td>1 (1.3%)</td><td>3 (2.8%)</td><td>4 (3.0%)</td></tr>
<tr><td>Dehydration (%)</td><td>1 (1.3)</td><td>3 (2.8%)</td><td>4 (3.0%)</td></tr>
<tr><td>Mean hospital stay, bleeding</td><td>2 days</td><td>1 day</td><td>0.7 days</td></tr>
<tr><td>Mean hospital stay, dehydration</td><td>1 day</td><td>1.3 days</td><td>1.5 days</td></tr>
</table>
</td>
<td>Complications

Complications were seen in 16 patients (5.1%)

Eight patients experienced primary haemorrhage (within 24 hours)
• 1 in ultrasonic scalpel group
• 3 in electrocautery group
• 4 in cold dissection group

Overall complications rates (taking into account dehydration)
• 2.7% ultrasonic scalpel group
• 5.5% electrocautery group
• 6.1% cold dissection group</td>
<td>Retrospective review.

Only a proportion of patients (15.2%) underwent tonsillectomy alone.

Pain was not assessed.

Secondary haemorrhage rates were not discussed.

All procedures were performed by one of three experienced surgeons.

Time period covered by the review is unclear.</td>
</tr>
</table>

Validity and generalisability of the studies

- In general outcomes were poorly assessed and poorly reported. For example in many of the studies it was unclear how blood loss was measured, what proportion of treated patients were evaluated for pain and who (for example nurse or patient) was assessing pain. Some studies also did not report absolute figures but instead presented graphs.

- Many of the randomised controlled trials were small and were possibly under-powered to detect some differences between groups.

- Very few of the randomised controlled trials adequately described the method of allocation or randomisation. This is despite the CONSORT statement highlighting the importance of undertaking (and reporting) proper randomisation in order to eliminate selection bias.

- Ultrasonic scalpel was compared to both cold steel dissection and diathermy (monopolar and bipolar), in different studies. These comparator techniques have slightly different safety profiles, as highlighted in the 'National Prospective Tonsillectomy Audit'[11] .

- In most studies, when using ultrasonic scalpel additional subsequent techniques (such as diathermy) were used to achieve intraoperative haemostasis (control of primary haemorrhage). Theoretically this may be responsible for comparatively high pain scores observed in some studies for the ultrasonic scalpel group [4]

- Questionnaires were frequently used to assess pain, and in many cases response rate was poor or unclear. Few studies looked at whether there were any differences between responders and non-responders.

- Follow-up in the studies ranged from 6 to 21 days. Secondary haemorrhage is frequently defined as bleeding occurring up to 10 days[10] after the operation. Therefore studies with shorter-term follow-up may not capture all secondary haemorrhages.

- Studies also varied in terms of the age of study participants, with the majority of studies reported being on child patients. A number of studies did assess ultrasonic scalpel tonsillectomy in adults.

- Very few studies reported on the previous experience (workload volume) of the surgeons undertaking ultrasonic scalpel tonsillectomy.

Specialist Advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College: Mr Peter Brown, Professor Richard Ramsden, Mr Michael Timms, Mr Liam Flood, Mr N Marks.

- Ultrasonic scalpel is a minor variation on an existing procedure.

- Only a small number of surgeons are using this technique.

- Skill and training of the surgeon is important.

- As with all new tonsillectomy techniques, supervised training is necessary.
- The evidence in the literature is contradictory and generally of a low level.

Issues for consideration by IPAC

The title 'Ultrasonic scalpel' may be more appropriate.

Although the National Prospective Tonsillectomy Audit collects data on ultrasonic scalpel tonsillectomy, this data cannot be provided for review because only a few surgeons are currently performing this procedure; hence the numbers are too small to be analysed in a meaningful way and could potentially be traced back to the individual surgeon.

References

1 Willging JP, Wiatrak BJ (2003) Harmonic scalpel tonsillectomy in children: a randomized prospective study. *Otolaryngology – Head and Neck Surgery* 128: 318–25.

2 Sugiura N, Ochi K, Komatsuzaki Y et al. (2002) Postoperative pain in tonsillectomy: comparison of ultrasonic tonsillectomy versus blunt dissection tonsillectomy. *ORL; Journal of Oto-Rhino-Laryngology and its Related Specialties* 64: 339–42.

3 Akural EI, Koivunen PT, Teppo H et al. (2001) Post-tonsillectomy pain: a prospective, randomised and double-blinded study to compare an ultrasonically activated scalpel technique with the blunt dissection technique. *Anaesthesia* 56: 1045–50.

4 Sheahan P, Miller I, Colreavy M et al. (2004) The ultrasonically activated scalpel versus bipolar diathermy for tonsillectomy: a prospective, randomized trial. *Clinical Otolaryngology and Allied Sciences* 29: 530–4.

5 Collison PJ and Weiner R (2004) Harmonic scalpel versus conventional tonsillectomy: a double-blind clinical trial. *Ear, Nose and Throat Journal* 83: 707–10.

6 Morgenstein SA, Jacobs HK, Brusca PA et al. (2002) A comparison of tonsillectomy with the harmonic scalpel versus electrocautery. *Otolaryngology – Head and Neck Surgery* 127: 333–8.

7 Walker RA, Syed ZA (2001) Harmonic scalpel tonsillectomy versus electrocautery tonsillectomy: a comparative pilot study. *Otolaryngology – Head and Neck Surgery* 125: 449–55.

8 Shinhar S, Scotch BM, Belenky W et al. (2004) Harmonic scalpel tonsillectomy versus hot electrocautery and cold dissection: an objective comparison. *Ear, Nose and Throat Journal* 83: 712–5.

9 Schrey A, Pulkkinen J, Fremling C et al. (2004) Ultrasonically activated scalpel compared with electrocautery in tonsillectomy. *ORL; Journal of Oto-Rhino-Laryngology and its Related Specialties* 66: 136–40.

10 Doree CJ, Burton MJ (2004) Harmonic scalpel versus other surgical procedures for tonsillectomy.*The Cochrane Database of Systematic Reviews: Protocols.* Issue 1.

11 British Association of Otorhinolaryngologists – Head and Neck Surgeons Comparative Audit Group and the Clinical Effectiveness Unit, The Royal College of Surgeons of England (2005) *National Prospective Tonsillectomy Audit FINAL REPORT of an audit carried out in England and Northern Ireland between July 2003 and September 2004.* London: Royal College of Surgeons. Available from www.tonsil-audit.org

Appendix A: Additional papers on harmonic scalpel for tonsillectomy not included in the summary tables

Article title	Study design/Number of patients	Main outcomes	Reasons for non-inclusion
Al Bekaa S (2003) Harmonic scalpel tonsillectomy vs diathermy tonsillectomy: A comparative study. *Australian Journal of Otolaryngology* 6: 80.	50 patients 25 ultrasonic scalpel 25 monopolar	Pain HS MD Day 10 2 3.8 Return to diet 76% 63% Blood loss 10.5 42.6 Secondary 1 1	Randomised controlled trial. Patients were randomly selected based on days presenting to surgery.
Arena-S C (2000) The use of the harmonic scalpel and postoperative pain following tonsillectomy: a prospective randomised clinical trial. *Australian Journal of Otolaryngology* 3: 495–7.	26 patients Patients had standard dissection on one side and ultrasonic scalpel on the other	Mean pain scores over the 2 weeks for both techniques. There were no primary or second haemorrhages	Randomised controlled trial – very limited information given on results. No absolute numbers given in the text.
Potts KL, Augenstein A, Goldman JL (2005) A parallel group analysis of tonsillectomy using the harmonic scalpel vs electrocautery. *Archives of Otolaryngology – Head & Neck Surgery* 131: 49–51.	605 patients 313 patients electrocautery 292 HS group	No significant difference in operative time **Secondary haemorrhage** Younger patients (< 7 years) 4/174 in the EC group 1/252 in the HS group Older patients (> 7 years) 9/139 in the EC group 1/40 HS group	Retrospective review includes those with adenotonsillectomy. Limited information.
Sood S, Corbridge R, Powles J et al. (2001) Effectiveness of the ultrasonic harmonic scalpel for tonsillectomy. *Ear, Nose and Throat Journal* 80: 514–6.	59 patients UK paper Follow-up: 2 weeks	**Outcome** **Median** Operating time 7 min 50 sec Blood loss 0.5 ml Time to first food 4 hours Return to diet 7 days Analgesia 6 doses First post-op pain 4.0 Return to function 11 days 3 patients had postoperative haemorrhage	Case series. Small number of patients.
Weingarten C (1997) Ultrasonic tonsillectomy: rationale and technique. *Otolaryngology – Head and Neck Surgery* 116: 193–6.	23 patients	Authors report that all patients tolerated the operation without significant complications, including immediate or delayed bleeding or infection	Case series, small number of cases.
Fenton RS, Long J (2000) Ultrasonic tonsillectomy. *Journal of Otolaryngology* 29: 348–50.	25 patients	Authors report that there was no undue primary bleeding in either group and no immediate or late postoperative bleeding.	Case-series (although refers to historical controls). No comparative data given. Limited information.

Article title	Study design/Number of patients	Main outcomes	Reasons for non-inclusion
Ochi K, Ohashi T, Sugiura N et al. (2000) Tonsillectomy using an ultrasonically activated scalpel. *Laryngoscope* 110: 1237–8.	14 patients (8 adults, 6 children)	Not applicable	Case series. Limited information. Not relevant.
Metternich FU, Sagowski C, Wenzel S et al. (2001) [Tonsillectomy with the ultrasound activated scalpel. Initial results of technique with Ultracision Harmonic Scalpel]. [German]. *HNO* 49: 465–70.	60 patients	Not applicable	Non-English paper. Limited information provided in abstract.
Hamada M (2002) Ultrasonic tonsillectomy. *Otolaryngology – Head and Neck Surgery (Tokyo)* 74: 724–7.	Not reported in abstract	Not applicable	Non-English paper. Limited information provided. Appears as though controlled study.

Appendix B: Related NICE guidance for harmonic scalpel for tonsillectomy

Guidance	Recommendation
Interventional procedures guidance **no. 150**	1.1 Current evidence on the safety and efficacy of electrosurgery (diathermy and coblation) for tonsillectomy appears adequate to support the use of these techniques, provided that normal arrangements are in place for consent, audit and clinical governance. 1.2 Surgeons should avoid excessive use of diathermy during tonsillectomy. Surgeons using diathermy in tonsillectomy for dissection and/or haemostasis should be fully trained in its use and should understand the potential complications. 1.3 Use of coblation for tonsillectomy can result in higher rates of haemorrhage than other techniques and clinicians wishing to use coblation should be specifically trained. The British Association of Otorhinolaryngologists – Head and Neck Surgeons has agreed to produce standards for training. 1.4 Surgeons should ensure that patients or their parents/carers understand the risk of haemorrhage after tonsillectomy using these techniques. In addition, use of the Institute's *Information for the public* is recommended. 1.5 Surgeons should audit and review the rates of haemorrhage complicating tonsillectomy in their own practices and in the context of the techniques they use. Publication of further information about the influence of different techniques and other factors (such as age) on the incidence of haemorrhage after tonsillectomy would be useful in guiding future practice.
Technology appraisals	None relevant
Clinical guidelines	None relevant

Public health	None relevant

Appendix C: Literature search for harmonic scalpel for tonsillectomy

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

Databases	Version searched (if applicable)	Date searched
The Cochrane Library	2005 Issue 3	22/08/2005
CRD		22/08/2005
Embase	1980 to 2005 Week 33	18/08/2005
Medline	1966 to August Week 2 2005	18/08/2005
PreMedline	August 17, 2005	18/08/2005
CINAHL	1982 to August Week 2 2005	18/08/2005
British Library Inside Conferences (limited to current year only)		22/08/2005
National Research Register	2005 Issue 3	22/08/2005
Controlled Trials Registry		22/08/2005

Search strategy used in Medline

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1. tonsil$.tw.
2. *tonsillitis/
3. *tonsil/
4. *tonsillectomy/
5. or/1-4
6. ultrasonics/
7. ultrasonic therapy/
8. (harmonic adj3 scalpel$).tw.
9. ((ultrasonic$ or ultrasound) adj3 (scalpel$ or therap$)).tw.
10. or/6-9
11. 10 and 5
12. animal/ not human/
13. 11 not 12
```