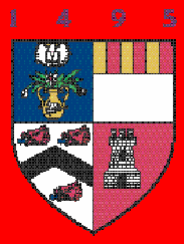

Systematic review of the safety and efficacy of electrosurgery for tonsillectomy

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REVIEW BODY REPORT

Title	Systematic review of the safety and efficacy of electrosurgery for tonsillectomy
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'Home unit' details

The Health Services Research Unit (HSRU), University of Aberdeen is core-funded by the Chief Scientist Office of the Scottish Executive Health Department, and has responsibility for the following general remit:

1. To study or evaluate clinical activities with a view to improving effectiveness and efficiency in health care;
2. To work for the implementation of proven changes in clinical activities;
3. To encourage and support similar work throughout Scotland;
4. To train NHS staff in Scotland, and others, in the principles and practice of health services research in general, and health care evaluation in particular.

In pursuit of this remit, the Unit has established a portfolio of health services research focusing on two main programmes – health care assessment and delivery of care.

Contributions of review team and clinical advisors

Graham Mowatt screened the search results, assessed full text studies for inclusion, undertook data extraction and quality assessment, and drafted the review. Jennifer Burr provided advice on analysis and interpretation of data and commented on drafts of the review. Jonathan Cook provided statistical advice and undertook the Bayesian meta-analyses. Cynthia Fraser developed and ran the search strategies, obtained papers and formatted the references. Bill McKerrow acted as our clinical adviser, provided clinical advice and commented on drafts of the review.

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EXECUTIVE SUMMARY

Background

Tonsillectomy consists of two stages: removal of the tonsil, followed by control of bleeding (haemostasis). It may be performed with or without adenoidectomy (surgical removal of adenoid tissue). In traditional 'cold steel' tonsillectomy, the initial incision in the mucosa is made with scissors, with the subsequent mobilisation of the tonsil usually carried out by some form of blunt dissection using either a specially designed dissector or dissecting forceps to manipulate gauze swabs or cotton wool to separate the tonsil from its bed. Bleeding vessels are initially controlled by pressure on a swab in the tonsil bed and any residual bleeding is controlled with ligatures (ties) once the tonsils have been removed. An alternative approach to dissection and haemostasis is electrosurgery (monopolar or bipolar diathermy). These techniques were introduced around 40 years ago. In the UK, bipolar diathermy dissection and haemostasis is more commonly used than monopolar. Diathermy can also be used for haemostasis following traditional 'cold steel' techniques for dissection, either additional to ties or as the sole technique for control of bleeding, and ties are occasionally used as an adjunct to diathermy for haemostasis. Coblation, a variation of electrosurgery that uses lower temperatures than diathermy, was introduced in the late 1990s. It employs a bipolar probe to generate a radiofrequency current through a solution of sodium chloride.

One of the most important potential complications of tonsillectomy is bleeding. Bleeding may occur during the operation (intraoperative), during the first 24 hours postoperatively (primary or reactionary haemorrhage), or after 24 hours (secondary haemorrhage). Secondary haemorrhage may require readmission to hospital and possibly further surgery to control the bleeding, and is a serious complication that can be life threatening. Diathermy has the potential advantage over cold steel of reduced intraoperative and primary bleeding, but the concern is that the use of diathermy may increase the risk of secondary haemorrhage. The interim report of the England and Northern Ireland National Prospective Tonsillectomy Audit (NPTA) noted an overall postoperative haemorrhage rate at least three times higher with electrosurgery (diathermy or coblation) dissection and haemostasis compared

with cold steel dissection with ties/packs haemostasis, a finding that prompted this systematic review.

Objectives

The objective was to systematically review the evidence for the safety and efficacy of electrosurgery (diathermy or coblation) for tonsillectomy in children and adults, particularly in respect of rates of haemorrhage.

Methods

We searched the following electronic bibliographic databases: Medline, Embase, Medline Extra, Science Citation Index, Web of Science Proceedings, BIOSIS, Cochrane Library, National Research Register, DARE, HTA Database, Clinical Trials, Current Controlled Trials, Conference Papers Index, Zetoc Conference Search. In addition, the reference lists of all included studies were scanned to identify additional potentially relevant reports. Searches were restricted to English language articles and papers published from 1990 onwards and the settings were restricted to the European Union, North America, Australia and New Zealand, in line with the Review Body for Interventional Procedures' (ReBIP) policy.

Crude event rates (and 95% confidence intervals) for each intervention were tabulated by summing across studies for the outcomes of secondary haemorrhage requiring return to theatre, all secondary haemorrhage, primary haemorrhage requiring return to theatre and all primary haemorrhage. Crude event rates by study design were also calculated for each intervention. Additionally, a Bayesian meta-analysis model was used to model the haemorrhage rates for the different interventions, using a cross-design approach to allow randomised controlled trials (RCTs), non-randomised comparative studies, and case-series to be included. Differences between interventions were assessed by odds ratios (ORs) with 95% credible intervals (CrIs). Credible intervals are the Bayesian equivalent of confidence intervals.

In most studies, for each patient the same tonsillectomy technique is applied to both tonsils. In within-patient studies, patients act as their own controls with one tonsil

removed and/or bleeding controlled by one technique and a different technique used on the other tonsil. For this reason within-patient studies were not included in the meta-analysis model.

Study selection and quality assessment

We considered RCTs, prospective/retrospective non-randomised comparative studies, prospective case series containing at least 100 participants and population-based registry reports including prospectively collected UK tonsillectomy audit data. The main safety outcome was secondary haemorrhage, in terms of the need for further surgery to control haemorrhage or blood transfusion as a consequence of haemorrhage. Other safety outcomes were primary haemorrhage, including primary haemorrhage requiring return to theatre and requiring blood transfusion, and intraoperative blood loss. We considered efficacy outcomes that assessed the adequacy of tonsillar tissue removal, and operation time. Where data were available from comparative studies we also considered the time until resumption of normal diet or activity. Two reviewers independently assessed the quality of all included studies, using one of two separate checklists depending on study design.

Results

Out of a total of 1464 reports identified from the literature search 227 items were identified as potentially relevant and full text papers were obtained. Of these, 50 studies met the inclusion criteria for the review, plus population-based registry reports covering England and Northern Ireland, Scotland, and Wales. Of the 50 studies, 11 were within-patient studies, leaving 39 studies for a large number of the subsequent analyses. These 39 studies consisted of 10 RCTs, 15 non-randomised comparative studies and 14 case series. In the majority of the randomised studies and within-patient randomised studies it was unclear whether the treatment allocation sequence generation was truly random or whether the treatment allocation was adequately concealed. The assignment to the treatment groups was judged to be truly random in only one RCT, which used a standard randomisation table to generate the randomisation sequence. Length of follow-up in most studies, irrespective of study design, was less than the three weeks considered an adequate period of time to assess the occurrence of secondary haemorrhage. With regard to

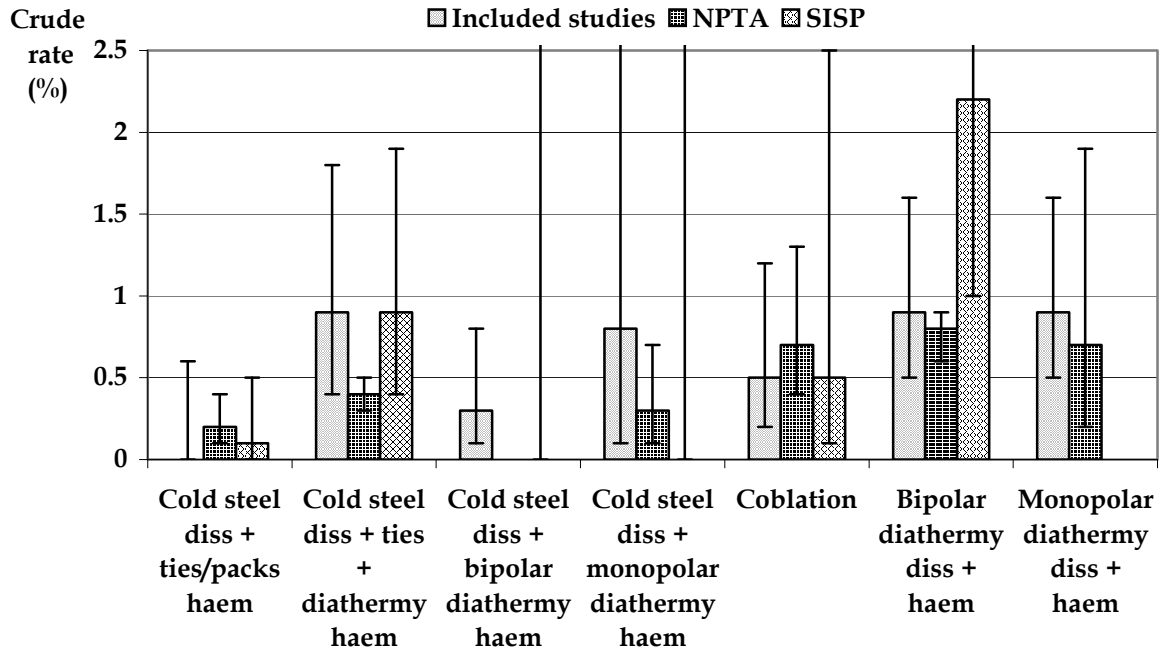
the population-based registry reports, information was reported from the Wales Single-use Instrument Surveillance Programme (SISP) on 3690 patients who underwent tonsillectomy during the period February 2003 to March 2004, from the Scottish Tonsillectomy Audit on 6200 patients who underwent tonsillectomy during the period April 2002 to March 2003, and from the final report of the England and Northern Ireland NPTA on 33,921 patients who underwent tonsillectomy during the period July 2003 to September 2004. It was not possible to provide haemorrhage rates for different tonsillectomy techniques from the Scottish Tonsillectomy Audit, however, as information on the total number of patients who underwent each technique was not available.

Safety

- **Secondary haemorrhage**

Figure 1 shows the crude rates for secondary haemorrhage requiring return to theatre (with 95% confidence intervals), by tonsillectomy technique, for the included studies, England and Northern Ireland NPTA final report and Wales SISP.

Figure 1 Secondary haemorrhage requiring return to theatre



Note:

1. diss = dissection, haem = haemostasis.

Thirty-five studies involving 6417 patients, plus the England and Northern Ireland NPTA involving 33.921 patients and the Wales SISP involving 3690 patients reported secondary haemorrhage requiring return to theatre. The crude overall rate in the included studies was lowest for cold steel dissection with ties/packs haemostasis and highest for cold steel dissection with ties/packs plus diathermy haemostasis, and for bipolar and monopolar diathermy dissection and haemostasis. In the meta-analysis of seven tonsillectomy categories, adjusted for study design, coblation (OR 33.82) was associated with a statistically significant higher rate of secondary haemorrhage requiring return to theatre compared with cold steel dissection with ties/packs haemostasis (reference technique). However there was a large degree of uncertainty surrounding the effect estimates due to low event rates. Data from the Wales SISP showed that rates of secondary haemorrhage requiring return to theatre were lowest for cold steel dissection with either bipolar or monopolar diathermy haemostasis and cold steel dissection with ties/packs haemostasis, and highest for bipolar diathermy dissection and haemostasis. Data from the England and Northern Ireland NPTA final report indicated that the lowest rates were associated with cold steel dissection with ties/packs haemostasis and the highest with bipolar diathermy dissection and haemostasis, monopolar diathermy dissection and haemostasis and coblation. This represented a substantial reduction across all interventional techniques from the rates reported for this outcome in the NPTA interim report. The NPTA final report noted that the lower absolute rates in that report compared with the interim report were because data were included in the interim report from some hospitals that had misinterpreted the way the data sheets should be completed. Consequently, some cases were reclassified and the coding of the complication sheets was revised for the final analysis.

Twenty-five studies involving 3592 patients reported secondary haemorrhage requiring blood transfusion. Two (0.3%) of 719 patients who underwent bipolar diathermy dissection and haemostasis experienced this outcome. The England and Northern Ireland NPTA final report stated that 54 (0.2%) of 33,921 patients experienced a secondary haemorrhage requiring a blood transfusion. Data from the Scottish Tonsillectomy Audit indicated that three (0.05%) of 6200 patients who underwent tonsillectomy, adenotonsillectomy or adenoidectomy experienced a

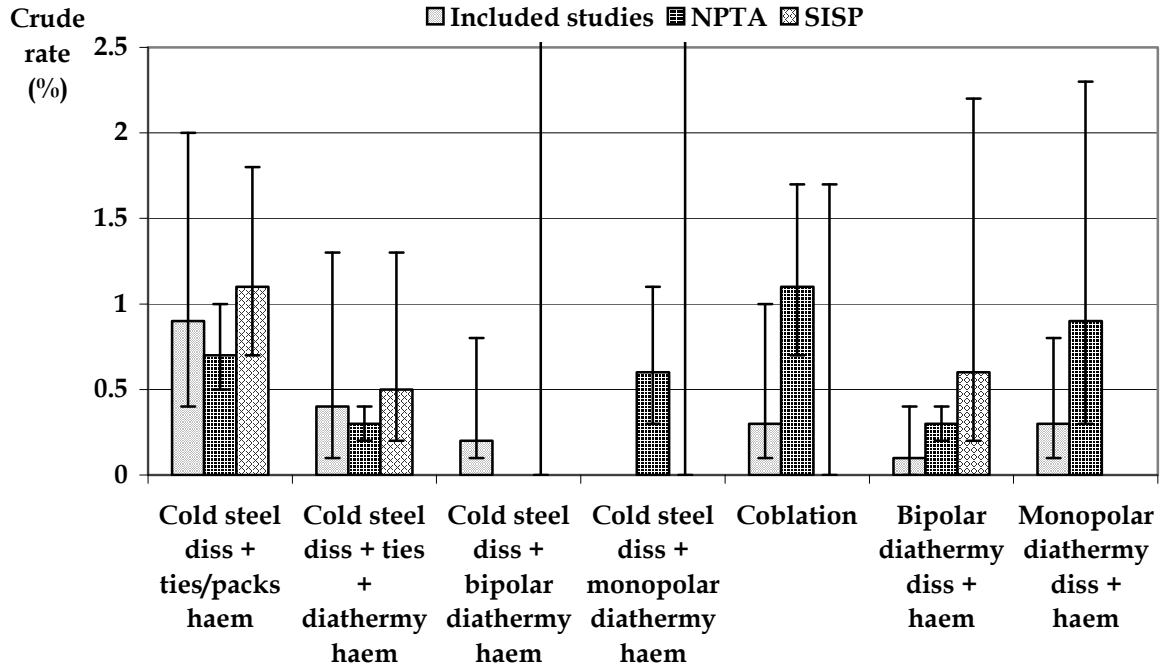
secondary haemorrhage requiring a blood transfusion. Data from the Wales SISP showed that eight (0.2%) of 3690 patients who underwent a tonsillectomy procedure experienced secondary haemorrhage requiring blood transfusion.

Fifty studies involving 11,134 patients plus the England and Northern Ireland NPTA involving 33.921 patients and the Wales SISP involving 3690 patients reported the outcome of all secondary haemorrhage. The crude overall rate in the included studies was lowest for cold steel dissection with ties/packs haemostasis (3.2%, 95% CI 2.6 to 3.9%) and highest for monopolar diathermy dissection and haemostasis (16.2%, 95% CI 14.2 to 18.4%). The overall rate in the within-patient studies was lowest for cold steel dissection with ties/packs plus diathermy haemostasis and coblation (both 0%) and highest for cold steel dissection with bipolar diathermy haemostasis (6.3%). In the meta-analysis, adjusted for study design, the following techniques were associated with a statistically significant higher rate of overall secondary haemorrhage compared with the reference technique of cold steel dissection with ties/packs haemostasis: bipolar diathermy dissection and haemostasis (OR 2.86, 95% CrI 1.12 to 8.02), coblation (OR 3.75, 95% CrI 1.29 to 12.12); monopolar diathermy dissection and haemostasis (OR 4.12, 95% CrI 1.12 to 14.67); and cold steel dissection with bipolar (OR 9.18, 95% CrI 3.09 to 30.53) or monopolar (OR 4.83, 95% CrI 1.56 to 15.95) diathermy haemostasis. Data from the Wales SISP showed that cold steel dissection with monopolar diathermy haemostasis (0%, 95% CI 0 to 9.0%) and cold steel dissection with ties/packs haemostasis (0.6%, 95% CI 0.3 to 1.1%) were associated with the lowest rates of overall secondary haemorrhage, while bipolar diathermy dissection and haemostasis was associated with the highest (8.9%, 95% CI 6.3 to 12.5%). The England and Northern Ireland NPTA final report indicated that cold steel dissection with ties/packs haemostasis was associated with the lowest rate of overall secondary haemorrhage (1.0%, 95% CI 0.7 to 1.3%), while monopolar diathermy dissection and haemostasis was associated with the highest (5.5%, 95% CI 3.8 to 8.0%).

- **Primary haemorrhage**

Figure 2 shows the crude rates for primary haemorrhage requiring return to theatre (with 95% confidence intervals), by tonsillectomy technique, for the included studies, England and Northern Ireland NPTA final report and Wales SISP.

Figure 2 Primary haemorrhage requiring return to theatre



Note:

1. diss = dissection, haem = haemostasis.

Thirty-one studies involving 6157 patients, plus the England and Northern Ireland NPTA involving 33.921 patients and the Wales SISP involving 3690 patients reported primary haemorrhage requiring return to theatre. The crude overall rate in the included studies was lowest for bipolar diathermy dissection and haemostasis and highest for cold steel dissection with ties/packs haemostasis. In the meta-analysis, adjusted for study design, the large degree of uncertainty surrounding the effect estimates due to low event rates was reflected by the wide credible intervals. Bipolar diathermy dissection and haemostasis (OR 0.002) was associated with a statistically significant lower rate of primary haemorrhage requiring return to theatre compared

with cold steel dissection with ties/packs haemostasis (reference technique). Data from the Wales SISP showed that rates of primary haemorrhage requiring return to theatre were lowest for cold steel dissection with bipolar or monopolar diathermy haemostasis, or coblation and highest for cold steel dissection with ties/packs haemostasis. Data from the England and Northern Ireland NPTA final report indicated that the lowest rates were associated with cold steel dissection with bipolar diathermy haemostasis and bipolar diathermy dissection and haemostasis, while the highest rates were associated with coblation and monopolar diathermy dissection and haemostasis.

Twenty-four studies involving 2810 patients reported primary haemorrhage requiring blood transfusion, with no patient experiencing this outcome. The England and Northern Ireland NPTA final report stated that eight (0.02%) of 33,921 patients experienced a primary haemorrhage requiring a blood transfusion. In the Scottish Tonsillectomy Audit one (0.02%) of 6200 patients experienced a primary haemorrhage requiring blood transfusion. Data from the Wales SISP indicated that none of the 3690 patients undergoing a tonsillectomy procedure experienced this event.

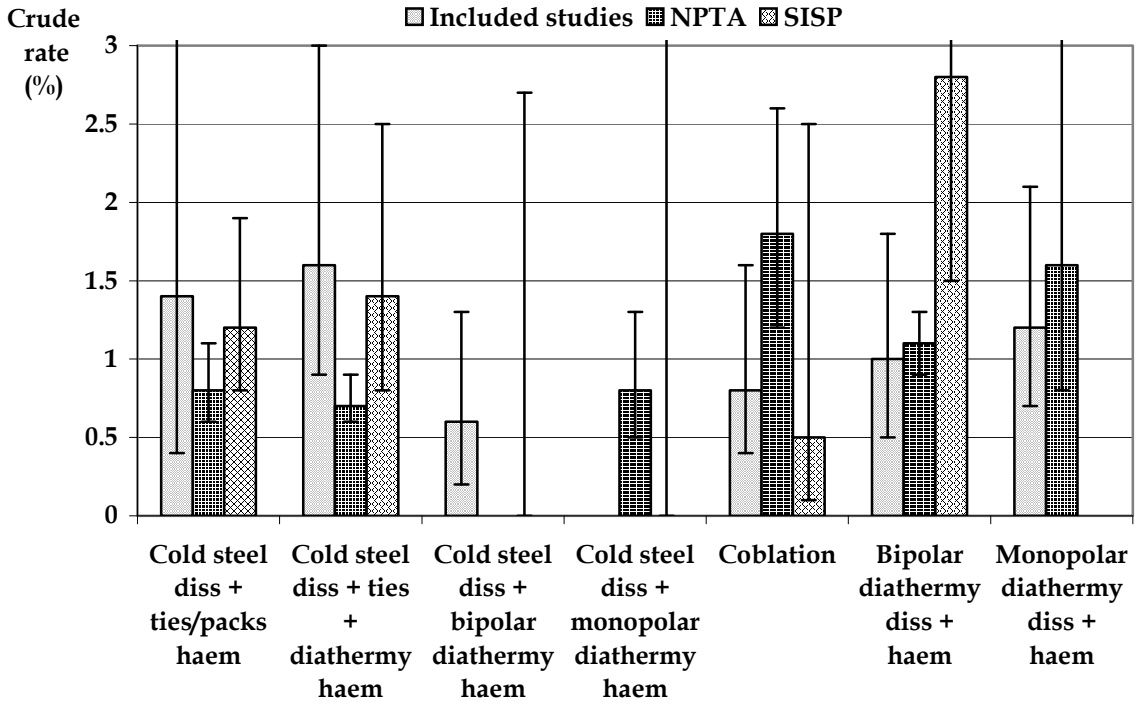
Thirty-nine studies involving 9648 patients plus the England and Northern Ireland NPTA involving 33.921 patients and the Wales SISP involving 3690 patients reported the outcome of all primary haemorrhage. The crude overall rate in the included studies was lowest for cold steel dissection with bipolar diathermy haemostasis (0.3%, 95% CI 0.1 to 0.9%) and bipolar diathermy dissection and haemostasis (0.5%, 95% CI 0.2 to 0.9%) and highest for cold steel dissection with ties/packs haemostasis (2.7%, 95% CI 2.1 to 3.6%). In the meta-analysis, adjusted for study design, bipolar diathermy dissection and haemostasis (OR 0.13, 95% CrI 0.03 to 0.51) was associated with a statistically significant lower rate of all primary haemorrhage compared with cold steel dissection with ties/packs haemostasis (reference technique). Data from the Wales SISP showed that cold steel dissection with either monopolar (0%, 95% CI 0 to 9.0%) or bipolar (0%, 95% CI 0 to 2.7%) diathermy haemostasis was associated with the lowest rate of overall primary haemorrhage while cold steel dissection with ties/packs haemostasis was associated with the highest (1.2%, 95% CI 0.8 to 1.9%). The final report of the England and Northern Ireland NPTA indicated that the lowest

rates of overall primary haemorrhage were associated with bipolar diathermy dissection and haemostasis (0.4%, 95% CI 0.3 to 0.6%), cold steel dissection with bipolar diathermy haemostasis (0.5%, 95% CI 0.4 to 0.6%) and cold steel dissection with monopolar diathermy haemostasis (0.5%, 95% CI 0.3 to 1.0%), while the highest rates were associated with monopolar diathermy dissection and haemostasis (1,1%, 95% CI 0.5 to 2.6%) and coblation (1.0%, 95% CI 0.6 to 1.7%).

- **All postoperative haemorrhage requiring return to theatre**

Figure 3 shows the crude rates for all postoperative haemorrhage requiring return to theatre (with 95% confidence intervals), by tonsillectomy technique, for the included studies, England and Northern Ireland NPTA final report and Wales SISP.

Figure 3 All postoperative haemorrhage requiring return to theatre



Note:
1. diss = dissection, haem = haemostasis.

Twenty-six studies involving 5143 patients, plus the England and Northern Ireland NPTA involving 33.921 patients and the Wales SISP involving 3690 patients reported all postoperative haemorrhage requiring return to theatre. The crude overall rate in

the included studies was lowest for cold steel dissection with bipolar diathermy haemostasis and highest for cold steel dissection with ties/packs plus diathermy haemostasis. Data from the Wales SISP showed that the rates were lowest for cold steel dissection with either bipolar or monopolar diathermy haemostasis and highest for bipolar diathermy dissection and haemostasis. Data from the England and Northern Ireland NPTA final report indicated that the lowest rates were associated with cold steel dissection with bipolar diathermy haemostasis, while the highest rates were associated with coblation. However, when the rates for primary and secondary haemorrhage requiring return to theatre are combined, the differences across the various tonsillectomy techniques become smaller compared with the rates across techniques for these two outcomes when considered separately.

- **Other safety outcomes**

In a meta-analysis of ten studies involving 1593 patients, diathermy dissection and haemostasis was associated with statistically significant less intraoperative blood loss compared with cold steel dissection with ties/packs and/or diathermy haemostasis. In nine studies involving 3180 patients and reporting overall secondary haemorrhage separately for different age categories, there was a tendency across all intervention techniques for older age groups (mainly adults) to experience a higher rate of secondary haemorrhage compared with younger age groups (mainly children). The England and Northern Ireland NPTA final report also reported that adults had higher overall haemorrhage rates than children. Nineteen studies provided some information on power settings used but there was insufficient data to demonstrate an association between different power settings and rates of secondary haemorrhage. The England and Northern Ireland NPTA final report found no association between haemorrhage rate and dissection power setting for bipolar diathermy dissection and haemostasis. However, the NPTA final report noted that there appeared to be a modest increase in the risk of haemorrhage with increasing diathermy power setting if bipolar diathermy was used for haemostasis only.

Sixteen studies provided varying amounts of information as to the experience of the surgeons carrying out the operations but it was not possible to draw conclusions regarding any association between surgeon experience and haemorrhage rates. Two studies involving 570 patients reported that the higher haemorrhage rates amongst

more junior surgeons did not reach statistical significance. The final report of the England and Northern Ireland NPTA stated that although haemorrhage rates were slightly higher in patients operated upon by junior grades of surgeon compared with those operated upon by senior surgeons, these differences were not statistically significant. This was in contrast with the NPTA interim report, which stated that haemorrhage rates were higher in patients operated on by junior surgeons than in those operated on by senior surgeons (4.6% compared with 2.7%, $p < 0.0001$). The NPTA final report suggested that one explanation for the different results between the two reports was that of a change in practice following publication of the National Institute for Health and Clinical Excellence (NICE) interim guidance on the use of electrosurgery in tonsillectomy in March 2004.

Efficacy

Eighteen studies reported the duration of the operation. Excluding the four within-patient studies, the mean duration of the operation was shortest for monopolar diathermy dissection and haemostasis (15.5 minutes) and longest for coblation (24.5 minutes). Operation time tended to be shortest for diathermy dissection and haemostasis techniques, followed by cold steel dissection with ties/packs and/or diathermy haemostasis, then coblation. In four studies the shorter operation time for diathermy compared with cold steel dissection reached statistical significance ($p<0.05$).

In terms of the mean number of days taken to re-establish a normal diet, three of four studies comparing cold steel dissection techniques with diathermy dissection techniques reported a statistically significant difference in favour of the cold steel technique ($p<0.05$), whose patients re-established a normal diet around two days earlier than those undergoing diathermy; the fourth study, however, reported a statistically significant difference in favour of diathermy. In three studies comparing diathermy with coblation, one study reported a statistically significant difference in favour of coblation while the other two reported no significant difference between the techniques.

In terms of the mean number of days taken to return to normal activity, two of three studies comparing cold steel dissection with diathermy dissection reported no statistically significant difference between the two techniques, while the third favoured diathermy ($p<0.05$). Two studies comparing diathermy with coblation reported no statistically significant difference between the two techniques, as did a study comparing cold steel dissection with coblation.

Conclusions

Electrosurgery dissection and haemostasis is associated with higher rates of secondary haemorrhage, including secondary haemorrhage requiring return to theatre, than cold steel dissection with ties/packs haemostasis. A number of potential biases may affect the size of the association, including the selective use of diathermy to control intraoperative bleeding, the age of those undergoing the operation, and for population-based registry studies, a 'centre effect'. Conversely, cold steel dissection with ties/packs haemostasis may be associated with higher rates of primary haemorrhage compared with techniques involving electrosurgery, in particular cold steel dissection with bipolar diathermy haemostasis and bipolar diathermy dissection and haemostasis.

The clinical choice in deciding which technique to employ depends on a number of issues, including the risk of occurrence of primary or secondary haemorrhage, whether secondary haemorrhage is likely to be more or less serious than primary haemorrhage, and whether, for meaningful outcomes such as secondary haemorrhage requiring return to theatre, reported statistically significant differences in haemorrhage rates across different interventional techniques are in fact also clinically significant. Currently, the clinical choice would seem to be between an increased risk of secondary haemorrhage with electrosurgery compared with cold steel techniques or a possible increase in the risk of primary haemorrhage with cold steel techniques compared with electrosurgery.

List of abbreviations

CI	Confidence interval	OR	Odds ratio
CrI	Credible interval	RCT	Randomised controlled trial
DARE	Database of Abstracts of Reviews of Effectivenesss	ReBIP	Review Body for Interventional Procedures
ENT	Ear, Nose and Throat	SHO	Senior House Officer
GATE	Generic Appraisal Tool for Epidemiology	SIGN	Scottish Intercollegiate Guidelines Network
HES	Hospital Episode Statistics	SISP	Single-use Instrument Surveillance Programme
NPTA	National Prospective Tonsillectomy Audit	SPR	Specialist Registrar
NS	Non-significant	vCJD	Variant Creutzfeldt-Jakob Disease
N/S	Not stated	WMD	Weighted means difference

1 AIMS

To systematically review the evidence for safety and efficacy of electrosurgery (diathermy or coblation) for tonsillectomy in children and adults, particularly in respect of rates of haemorrhage.

2 BACKGROUND

2.1 The interventional procedure under review

2.1.1 Description of the interventional procedure

Tonsillectomy is one of the most commonly performed surgical procedures. It generally consists of two stages: removal of the tonsil, followed by control of bleeding (haemostasis). The practice dates back to ancient times, with one of the earliest descriptions given by Celsus in the first century AD.[1] The traditional method of removing the tonsils has been to grasp the tonsil, pull it into the midline, incise the mucous membrane, identify the tonsillar capsule, snare the base of the tonsil, and remove it from the fossa with gentle manipulation. The tonsillar fossae are packed, and haemostasis is achieved by ligatures or sutures.[2] Such 'cold steel' methods date back to the early 1900s.[3] Electrosurgery (diathermy) techniques were introduced around 40 years ago. Coblation, a variation of electrosurgery that uses lower temperatures than diathermy, was introduced in the late 1990s.

Tonsillectomy may be performed with or without adenoidectomy (surgical removal of adenoid tissue). Adenoidectomy is usually performed in children when enlarged adenoids cause symptoms such as blocked nose, mouth breathing or obstructive sleep apnoea.(NPTA 2005) The traditional technique for removing the adenoids is with a specially designed metal curette, with the main alternative being a suction diathermy technique.(NPTA 2005) Haemostasis is generally achieved by packing the wound with swabs for a few minutes after the procedure.(NPTA 2005)

In traditional 'cold steel' tonsillectomy, the initial incision in the mucosa is made with scissors, with the subsequent mobilisation of the tonsil usually carried out by some form of blunt dissection using either a specially designed dissector or dissecting forceps to manipulate gauze swabs or cotton wool to separate the tonsil from its bed. Bleeding vessels are initially controlled by pressure on a swab in the tonsil bed and any residual bleeding is controlled with ligatures (ties), or diathermy, or both, once the tonsils have been removed. Variations on cold steel techniques

include the use of a snare to remove the lower pole of the tonsil, and guillotine tonsillectomy. Guillotine tonsillectomy, no longer widely practiced in the UK, is a rapid procedure involving a crushing blade and a cutting blade, with simultaneous dissection and haemostasis.[4]

Diathermy uses radiofrequency energy applied directly to tissue. The energy is generated in the electromagnetic spectrum between 0.1 and 4.0 MHz, thereby avoiding the risk of electrocution and alterations in nerve or cardiac conductivity. The two main types of diathermy are monopolar and bipolar. In the UK bipolar diathermy is used more commonly than monopolar diathermy. In monopolar diathermy an electrical plate is placed on the patient, usually on the leg, and acts as an indifferent electrode. Current passes between the instrument and indifferent electrode and as the surface area of the instrument is smaller than that of the plate, localised heating is produced at the tip of the instrument. In bipolar diathermy the current passes through the tissue between the tips of a pair of forceps or scissors and not through the patient. The electrical resistance of tissue to the flow of current through the circuit generates heat, which is used to incise the mucosa and divide the strands of tissue that bind the tonsil to the pharyngeal wall. At the same time the vessels that run in these strands can be identified and coagulated. A refinement of the diathermy technique is the use of the operating microscope to facilitate dissection and haemostasis.[5] Diathermy can be used for both dissection and haemostasis, or can be used for haemostasis following traditional 'cold steel' techniques for dissection, either additional to ties or as the sole technique for control of bleeding, Diathermy has the potential advantage over cold steel of reduced perioperative bleeding, but the concern is that the use of diathermy may increase the risk of postoperative secondary haemorrhage following hospital discharge.

Coblation operates at lower temperatures than diathermy (60-70^{0}C compared with 400^0-600^{0}C). It employs a bipolar probe to generate a radiofrequency current through a solution of sodium chloride. This generates a flow of sodium ions, which destroys surrounding tissue. The probe is used to dissect out the tonsil while cauterising any blood vessels. It has been suggested that, by operating at lower temperatures than diathermy, coblation may result in less surrounding tissue damage, reduce

postoperative pain and improve healing compared with diathermy and also reduce bleeding compared with 'cold steel' techniques.[6,7]

2.1.2 Proposed clinical indications/contraindications and putative impact of the procedure

Indications for tonsillectomy include recurrent acute or chronic tonsillitis, peritonsillar abscess and pharyngeal obstruction/obstructive sleep apnoea.[8]

In 1999 the Scottish Intercollegiate Guidelines Network (SIGN) issued a guideline on management of sore throat and indications for tonsillectomy in which it recommended that people undergoing tonsillectomy should meet all of the following criteria:[9]

- sore throats are due to tonsillitis
- five or more episodes of sore throat per year
- symptoms for at least a year
- the episodes of sore throat are disabling and prevent normal functioning.

Morbidity from tonsillectomy includes bleeding, pain, nausea, vomiting, dehydration, and airway obstruction.[10] The most important potential complications are bleeding and pain. Bleeding may be during the operation (intraoperative), during the first 24 hours postoperatively (primary or reactionary haemorrhage), or after 24 hours (secondary haemorrhage). Primary and secondary haemorrhage may require further surgical intervention. Secondary haemorrhage may require readmission to hospital and possibly further surgery to control the bleeding, and is a serious complication that can be life threatening. Pain may be a significant factor after tonsillectomy, and may be severe enough to delay discharge from hospital, resumption of normal diet and normal activities.[11]

2.1.3 Personnel involved, skill/experience required and setting

Tonsillectomy requires a short admission to hospital (a one or two night stay) and a general anaesthetic. A standard theatre team, consisting of the Surgeon and the Anaesthetist and their respective supporting teams, is required to undertake the

procedure. The Surgeon operates solo and does not require an assistant although one may be present if the operation is being used for training.

Specific training is required to carry out the operation and the duration required for this varies from trainee to trainee and on their previous experience. Training is graduated, starting with the trainee being shown the procedure in detail, to doing parts of the operation with the trainer closely supervising and doing the other parts of the operation, to the trainee doing the whole procedure under the close supervision of the trainer. The next step is for the trainee to do the procedure solo but with the trainer immediately available in the operating room, to eventually the trainer being not present in theatre although available in the hospital.

The support teams required in theatre are, for the Surgeon, a scrub nurse and a floor nurse, and for the Anaesthetist, an operating department assistant. These individuals require training for their tasks and are qualified in these roles. Outwith the operating room itself, although still within theatre, a nurse in the reception area receives the patient into theatre and checks their details and a nurse in the recovery room supervises the patient as they recover from the anaesthetic.

2.1.4 Current use in the UK

In England in 2003/2004 50,531 people had a tonsillectomy, with 57% of procedures carried out in children under the age of 15, 42% on those aged 15 to 59, and 1% on those aged 60 to 74.[12] In Scotland in 2003/2004 5168 tonsillectomies and/or adenoidectomies were performed.[13] Adenoidectomy is performed with tonsillectomy in about one third of patients.[14]

In 1997 the Comparative Audit Service of the Royal College of Surgeons of England undertook an assessment of tonsillectomy. All known Ear, Nose and Throat (ENT) consultants in England and Wales were invited to participate and 132 reported data on 2450 patients.[15] The method of dissection for the vast majority of these patients (77.5%) was 'cold steel'; other techniques included bipolar diathermy (20%), monopolar diathermy (1.5%) and guillotine (1%).[15] Many patients had mixed

haemostasis techniques, the most popular being bipolar diathermy and ties.[15] Since then the popularity of bipolar diathermy dissection and haemostasis has grown.

In the UK in January 2001 routine tonsillectomy and adenoidectomy was halted for six months, pending the availability of single use instruments. This was based on the theoretical risk of variant Creutzfeldt-Jakob Disease (vCJD) being acquired through the use of contaminated equipment. However, following the introduction of single use instruments in June 2001 a possible increased risk of secondary haemorrhage was highlighted associated with some disposable instruments, in particular bipolar diathermy forceps, and standard reusable instruments were reintroduced in England.[16]

In Scotland, the Scottish Otolaryngology Society retrospectively audited 2823 tonsillectomies and adenotonsillectomies performed in 2000 with reusable equipment and there were 16 (0.56%) primary haemorrhages requiring return to theatre, 23 (0.81%) secondary haemorrhages requiring return to theatre, and 115 (4.07%) readmissions to hospital for any cause within 28 days of initial surgery. In 2001 an audit of 2842 tonsillectomies and adenotonsillectomies all performed with disposable equipment, found similar complication rates, 16 (0.56%) primary haemorrhages requiring return to theatre, 27 (0.95%) secondary haemorrhages requiring return to theatre and 144 (5.07%) readmissions to hospital for any cause within 28 days of initial surgery. On this basis the use of disposable instruments was felt not to increase the risk of primary and secondary haemorrhage and the Scottish Executive advised that single use (disposable) instruments should continue to be used for routine tonsillectomy.[17]

In Wales a review of complications associated with the single use instruments that were introduced in 2001 found that serious complication rates had more than doubled, leading the Welsh Assembly Government to terminate the use of these instruments (Alun Tomkinson, University Hospital of Wales, 13 August 2004). The Welsh Assembly Government launched an independent investigation into tonsillectomy instrumentation that led to the creation of a detailed specification for single use instruments. A review following the introduction of these highly specified single use instruments found that the overall complication rates had returned to the

levels experienced in 2000 when reusable instruments were still in use (Alun Tomkinson, University Hospital of Wales, 13 August 2004).[18] Single use equipment for tonsillectomy continues to be used in Scotland[19] and Wales,[20] with ongoing prospective data collection on safety.

Similarly, in 2003, the National Prospective Tonsillectomy Audit (NPTA) was set up in England and Northern Ireland to investigate the occurrence of haemorrhage and other complications after tonsillectomy, the risk factors for these complications, and whether these risk factors explain variation in outcome between centres. The NPTA began to obtain data for all tonsillectomies done in England and Northern Ireland from 7 July 2003, with the exclusion of patients undergoing tonsillectomy for only one tonsil, tonsillar biopsy, tonsillectomy for known carcinoma, and tonsillectomy in conjunction with palatal surgery.[8] The NPTA reported that by February 2004, of 11,796 patients consenting to electronic submission of their tonsillectomy data to a central database, 11.2% had undergone 'cold steel' dissection with ties/packs haemostasis, 32.5% cold steel dissection with bipolar diathermy haemostasis, 5.2% cold steel dissection with monopolar diathermy haemostasis, 39.6% bipolar diathermy dissection and haemostasis, 1.7% monopolar diathermy dissection and haemostasis, 5.8% coblation and 4% other techniques.[8] The preliminary results of their audit found that the overall postoperative haemorrhage rate with electrosurgery (diathermy or coblation) was at least three times as high as cold steel dissection with ties/packs haemostasis.[8] Following these preliminary results, the Chief Medical Officers of England, Scotland and Northern Ireland asked the National Institute for Health and Clinical Excellence (NICE) to review urgently the safety of diathermy in tonsillectomy.

2.1.5 Equipment or devices required

Electrosurgery devices use a radiofrequency generator coupled with application hand pieces such as blades, forceps, scissors and suction devices to generate heat in tissue. Energy transfer can be modulated by physical measures of electrosurgical generators, such as pulse frequency, amplitude and timing. The generators have several waveforms and power settings. Cutting and coagulation modes are created by pulse waveforms with constant, blended, or intermittent duty cycles.[21] Coblation,

a variation of electrosurgery, is a bipolar technique in which a single use wand incorporates a saline layer between the electrodes.

Alternative thermally ablative techniques used in tonsillectomy include the argon beam coagulator, a monopolar electrosurgical device purported to reduce operation time and blood loss,[22] the harmonic scalpel, a dissector and coagulator that uses ultrasonic technology to cut and coagulate tissue[23] and laser ablation technologies.[24] Currently these techniques are not widely used in the UK.

2.2 Description of the underlying health problem

2.2.1 Epidemiology

Recurrent sore throat has an incidence in general practice in the UK of 100 per 1000 population a year.[25] In England in 2002/2003 around 23,300 people were diagnosed with acute tonsillitis, 61% of whom were less than 15 years of age.[12]

2.2.2 Aetiology, pathology and prognosis

Tonsillitis is infection of the parenchyma of the palatine tonsils. Such infection may occur in isolation or as part of a generalised pharyngitis. The clinical distinction between tonsillitis and pharyngitis is unclear in the literature and the condition is often referred to simply as 'acute sore throat'.[26] The diagnosis of acute tonsillitis is primarily clinical, with the main interest of the clinician being in whether the illness is viral or bacterial, which has relevance if the prescription of antibiotics is being considered.[26] The most common complication of acute tonsillitis is peritonsillar abscess.[26] The natural history of tonsillitis is for the episodes to become less frequent with time, but epidemiological data is lacking in all age groups to allow a prediction of this to be made in individual patients.[9]

2.2.3 Burden of disease

Thirty-five million school or work days are lost in the UK per year because of sore throats.[14] The management of sore throat in general practice and the further progress

to tonsillectomy in a number of cases results in significant use of health service resources.[9] GP consultation costs for sore throat alone are approximately £60 million per annum.[14]

2.3 Current management and alternative procedures

The diagnosis of recurrent acute tonsillitis is made by the referring doctor, as patients referred for otolaryngological assessment are rarely seen by a specialist during an acute episode of sore throat.[9] Questioning of the patient by the specialist will help to confirm the diagnosis, the frequency of episodes and provide an assessment of the associated disability.[9] The specialist will discuss the management options with patients meeting the indications for surgery, weighing the benefits of tonsillectomy against the natural history of resolution of the condition and the temporary incapacity associated with procedure.[9] A six-month period of watchful waiting may be recommended prior to tonsillectomy to establish firmly the pattern of symptoms and allow the patient to consider fully the implications of the operation. Once a decision is made to undertake tonsillectomy, the aim is to perform the operation as soon as possible to maximise the period of benefit before natural resolution of symptoms may occur.[9]

The alternative to surgery for recurrent acute tonsillitis is medical management. An overview of tonsillectomy versus antibiotics in children and adults with severe tonsillitis reported that two systematic reviews found insufficient evidence to compare surgical versus medical treatment, but that a subsequent randomised controlled trial (RCT) in less severely affected children found that surgery significantly reduced the frequency of tonsillitis compared with medical treatment.[26] However, a recently published RCT assessing the effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy found that adenotonsillectomy had no major clinical benefits over watchful waiting.[27]

3 SAFETY AND EFFICACY

3.1 Methods for reviewing safety and efficacy

3.1.1 Search strategy

Initial database and website searches were undertaken to identify relevant systematic reviews and other evidence-based reports. Full details of the main sources consulted are listed in Appendix 1.

Electronic searches were conducted to identify both published and unpublished studies evaluating the safety and efficacy of electrosurgery (diathermy or coblation) for tonsillectomy. A list of the databases searched and full details of the searches are documented in Appendix 1. The reference lists of all included studies were scanned to identify additional potentially relevant reports. Authors of included studies were contacted where necessary to provide clarification on aspects of their studies.

3.1.2 Inclusion and exclusion criteria

- **Types of studies**

Types of studies considered were RCTs; prospective/retrospective non-randomised comparative studies; prospective case series with 100 or more participants, and population-based registry reports including the prospectively collected tonsillectomy audit data for England and Northern Ireland, Scotland, and Wales.

In accordance with the methods agreed by NICE for the systematic reviews conducted by the Review Body for Interventional Procedures (ReBIP), we excluded case series reproduced in later publications (where the results related to the same outcomes). We excluded case reports. We excluded non-English language reports, irrespective of whether they contained English language abstracts. However, we included English language abstracts of conference proceedings.

The settings for included studies were restricted to the European Union, North America, Australia and New Zealand.

- **Types of participants**

Participants considered were children or adults undergoing tonsillectomy, including tonsillectomy combined with adenoidectomy, by dissection or electrosurgery in a day case or inpatient setting.

We excluded studies focusing on patients undergoing unilateral tonsillectomy, tonsillar biopsy, tonsillectomy for suspected or known cancer and tonsillectomy in conjunction with palatal surgery or where tonsillectomy was performed as part of a major procedure such as facial reconstructive surgery.

- **Types of intervention**

The interventions considered were tonsillectomy by 'cold steel' or electrosurgical techniques, with control of bleeding by packs, ties, diathermy or coblation. Electrosurgical techniques included bipolar or monopolar diathermy or coblation.

The question of disposable versus reusable instruments was not within the scope of this review. However, if one or more arms of studies comparing disposable versus reusable instruments otherwise met our inclusion criteria, they were included and treated as prospective case series. We excluded studies using the harmonic scalpel, laser ablation technologies, and the argon beam coagulator.

- **Types of outcome**

Safety

The main safety outcome was secondary haemorrhage, in terms of the need for further surgery to control haemorrhage or blood transfusion as a consequence of haemorrhage. Other safety outcomes considered in the review were primary

haemorrhage, including primary haemorrhage requiring return to theatre and primary haemorrhage requiring blood transfusion, and intraoperative blood loss.

Efficacy

We considered efficacy outcomes that assessed the adequacy of tonsillar tissue removal, and operation time.

Where data were available from RCTs and non-randomised comparative studies we examined time until resumption of normal diet or activity.

3.1.3 Quality assessment strategy

Two reviewers independently assessed the quality of all included studies, using one of two separate checklists depending on study design. Any disagreements were resolved by consensus or arbitration by a third party. We considered evidence in order of type of study design, the hierarchy of designs being RCTs, non-randomised comparative studies and prospective case series. A 14-question checklist was used to assess the quality of RCTs and within-patient studies (see Tables 3 and 4). Studies assessed by this checklist in which assignment to the groups was judged to be not really random were subsequently classed as non-randomised studies. A 17-question checklist was used to assess the quality of non-randomised comparative studies (see Table 5), with the same checklist minus four questions used to assess the quality of case series (see Table 6). The checklist for RCTs was adapted from Verhagen and colleagues[28] and the checklist for non-randomised studies and case series was adapted from several sources, including the NHS Centre for Reviews and Dissemination's guidance for those carrying out or commissioning reviews,[29] Verhagen and colleagues,[28] Downs and Black[30] and the Generic Appraisal Tool for Epidemiology (GATE). Both checklists were developed in conjunction with the Review Body for Interventional Procedures (ReBIP).

The methodological quality of reports of the England and Northern Ireland NPTA, Scottish Tonsillectomy Audit and Wales SISP was commented upon in the text without recourse to a specific quality assessment instrument.

3.1.4 Data extraction strategy

One reviewer screened the titles (and abstracts where available) of all papers identified by the search strategy. Full text copies of all reports deemed to be potentially relevant were obtained and one reviewer assessed them for inclusion. Any areas of uncertainty were resolved by consultation with a second reviewer.

We developed and piloted a data extraction form. Two reviewers independently extracted details of study design, methods, participants, interventions and outcomes.

3.1.5 Data analysis

We compared reports in the published literature, including reports of the Scottish Tonsillectomy Audit and Wales SISP, with the results of the England and Northern Ireland NPTA. We divided the tonsillectomy techniques into seven narrow categories (1. monopolar diathermy dissection and haemostasis; 2. bipolar diathermy dissection and haemostasis; 3. coblation dissection and haemostasis; 4. cold steel dissection with monopolar diathermy haemostasis; 5. cold steel dissection with bipolar diathermy haemostasis; 6. cold steel dissection with diathermy haemostasis or ties/packs plus diathermy haemostasis; and, 7. cold steel dissection with ties/packs haemostasis). We also divided the tonsillectomy techniques into four broad categories (1. diathermy dissection and haemostasis; 2. coblation dissection and haemostasis; 3. cold steel dissection with diathermy haemostasis or ties/packs plus diathermy haemostasis, and; 4. cold steel dissection with ties/packs haemostasis). Broad categories were used due to the limited data available and also because in some studies insufficient reporting prevented classification into narrow categories.

Crude event rates (and 95% confidence intervals) for broad and narrow tonsillectomy categories were tabulated by summing across studies for the outcomes of secondary haemorrhage requiring return to theatre, all secondary haemorrhage, primary haemorrhage requiring return to theatre and all primary haemorrhage. The influence of individual studies on these crude events rates was investigated. Where

substantially different, rates excluding one or more outlying studies were reported. Crude event rates by study design were also calculated for each intervention. Ninety-five per cent confidence intervals were calculated for the England and Northern Ireland NPTA and Wales SISP data for these outcomes.

Additionally, meta-analysis models were used to model the haemorrhage rates (both primary and secondary) for the different interventions. A 'cross-design' approach was adopted to allow non-randomised evidence to be included while avoiding the strong assumption of the equivalence of studies implicit in the crude event rates. This approach to evidence synthesis enabled RCTs, non-randomised comparative studies and case-series studies to be included.[31] The specific type of model used was a (Bayesian) binomial random effects model. Differences between interventions were assessed by the corresponding odds ratio and 95% credible interval. Credible intervals are the Bayesian equivalent of confidence intervals. A 95% credible interval for an odds ratio has a 95% probability of containing the population odds ratio. The results from these meta-analysis models are referred to as 'unadjusted' odds ratios. Meta-analysis models that adjusted for study type were also used. The models were extended by including two study type effects to allow for the differences between non-randomised comparative studies and prospective case series, compared with RCTs. The results from these models are referred to as 'adjusted' odds ratios. The WinBUGS software was used to produce the models.[32] A sensitivity analysis explored the impact of individual studies with outlying haemorrhage rates on the global estimates. However, this analysis was problematic and uninformative due to low haemorrhage rates and generally small size of the studies, with a change of one event often leading to a large relative change in the study haemorrhage rate. For this reason details of the sensitivity analysis were not reported.

We used the meta-analysis models to calculate the odds ratios associated with the different tonsillectomy techniques for the outcomes of (i) secondary haemorrhage requiring return to theatre, (ii) all secondary haemorrhage, (iii) primary haemorrhage requiring return to theatre and (iv) all primary haemorrhage. For each outcome, the meta-analysis tables show tonsillectomy technique or category of techniques, the total number of patients (a) analysed by the studies and (b) experiencing the event of

interest, and the unadjusted and adjusted odds ratio and 95% credible interval. The models were applied to both the broad and narrow categories.

The reference technique in each model was cold steel dissection with ties/packs haemostasis. However, in the included studies examining this technique no patient was reported as having experienced the outcome of secondary haemorrhage requiring return to theatre (zero events). Therefore, in order to allow cold steel dissection with ties/packs haemostasis to act as the reference category for this outcome, a single event for this technique was imputed into the model. The event was imputed into the study conducted by Lee and colleagues[33] because it was the biggest study and, therefore, would have least influence.

In most studies, for each patient the same tonsillectomy technique is used for both tonsils. In within-patient studies, however, patients act as their own controls with one tonsil removed and/or bleeding controlled by one technique and a different technique used on the other tonsil. For this reason within-patient studies were not included in the meta-analysis models.

Several factors may confound the relationship between the intervention and the measured outcomes. Potential confounding variables include age, gender, severity of disease, aspirin use, previous surgery, surgeon experience, power settings, and duration of diathermy/coblation application. Although including these variables in the meta-analysis models was considered, this was not feasible due to the fact that they were either inadequately reported or not reported at all.

3.2 Results

3.2.1 Number and type of included studies

A total of 1464 reports were identified from the literature search. Of these, a total of 227 items were identified as potentially relevant from the titles and abstracts (where available) and full text papers were obtained. Fifty studies, reported in 52 papers, met the inclusion criteria for the review, plus population-based registry reports covering England and Northern Ireland,[8](NPTA 2005) Scotland[19] and Wales (SISP,

Alun Tomkinson, University Hospital of Wales, 2005). There were 10 RCTs,[34-45] 15 non-randomised comparative studies[6,46-60] and 14 case series.[5,33,61-72] The remaining 11 studies were within-patient studies.[7,49,73-81] In these studies patients acted as their own controls, in that one tonsil was removed and/or bleeding controlled by one technique, with a different technique used for the other tonsil.

Several studies were reported in more than one paper. There were two reports of the study by Raut and colleagues,[38,39] with the primary reference being Raut 2001.[38] There were two reports of the study by Watson and colleagues[43,44] with the primary reference being Watson 1993.[43] A study by Lee and colleagues (Lee 2004a) involving 337 patients was also reported in two papers by Montague and colleagues,[51,52] with the primary reference being Lee 2004.[49] A report of seven patients who acted as their own controls (Lee 2004b) also contained in Lee 2004[49] was treated as a separate study. Another study by Montague and colleagues, involving 115 patients was also reported in Montague 2003,[51] with the primary reference being Montague 2004.[52]

Excluding the interim and final reports of the England and Northern Ireland NPTA[8] (NPTA 2005) and other population-based registry reports, the 39 studies in which both of the patient's tonsils were removed by the same technique enrolled 10,991 patients, with 10,441 included in the analysis (see Table 1 for demographic details, indication for surgery and tonsillectomy technique for the included studies alongside the England and Northern Ireland NPTA data). The studies took place during the period 1989 – 2003. Eighteen studies took place in the UK (13 in England, four in Scotland and one in Northern Ireland), six in the USA, four in Finland, three in Canada, two each in Spain and Portugal, and one each in Australia, New Zealand, Denmark and Switzerland. Seventeen studies included children and adults, 20 included children only and two adults only. Twenty-eight studies reported follow-up, with a median length of follow-up across studies of 13 days (range one to 178 days). Twenty-four studies provided details of the gender of 4827 patients, 54% of whom were female. Across studies the median age of the patients was 8.1 years (range 0.8 to 72 years). The most common indication for surgery recorded was recurrent acute or chronic tonsillitis. The most frequently used tonsillectomy technique was cold steel dissection with ties/packs haemostasis (2730 patients, 26.1%) with the least common being cold steel dissection with monopolar diathermy

haemostasis (188 patients, 1.8%). With regard to diathermy, 1826 patients (17.5%) received bipolar and 1178 (11.3%) received monopolar diathermy dissection and haemostasis. Cold steel dissection with a combination of ties/packs and diathermy haemostasis was used in 1073 patients (10.3%).

Nine of the 11 studies in which patients acted as their own controls were RCTs[7,73,74,76-81] and two were non-randomised studies.[49,75] One of the studies[76] was reported as a conference abstract. These 11 studies enrolled 706 patients, with 693 (1386 tonsils) included in the analysis. Only three studies gave details of the time period in which they took place. Eight studies took place in the UK (five in England and three in Scotland), two in the USA and one in Sweden. Seven studies included both children and adults, one included children only, one included adults only and two provided no information. Ten studies reported follow-up, with a median length of follow-up across studies of 11 days (range three to 15 days). Seven studies provided details of the gender of 499 patients, 63% of whom were female (see Table 2). Across studies the median age of the patients was 17.9 years (range four to 45 years). The most commonly recorded indication for surgery was recurrent tonsillitis. The most frequently used tonsillectomy technique was cold steel dissection with ties/packs haemostasis (478 tonsils, 34.5%) with the least common being coblation (10 tonsils, 0.7%). Cold steel dissection with a combination of ties/packs and diathermy haemostasis was used in 131 tonsils (9.4%)

The England and Northern Ireland NPTA final report (NPTA 2005) included data on 33,921 children and adults in England and Northern Ireland who had undergone tonsillectomies during the period July 2003 to September 2004 and who, out of a total of 40,514 patients in the audit, had consented to electronic submission of their tonsillectomy data (see Table 1 for details of age, gender, indication for surgery and tonsillectomy technique). Tonsillectomy was combined with adenoidectomy in 27% of patients.

The Scottish Tonsillectomy Audit[19] report included data on 6200 children and adults in Scotland who had undergone tonsillectomies, adenotonsillectomies or adenoidectomies during the period April 2002 to March 2003. However, no

information is available giving details of age, gender, indication for surgery or tonsillectomy technique used.

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported data from the prospective Single-use Instrument Surveillance Programme (SISP) database on 3690 tonsillectomy procedures carried out on children and adults in Wales, with 818 of these patients undergoing simultaneous adenoidectomy. Age and gender information was not reported for this group of patients. Indications for surgery included chronic tonsillitis, quinsy or airway obstruction although patient numbers for each indication were not reported. Nine categories of operative technique were reported: cold steel, monopolar dissection, bipolar dissection, ultrasonic, coblation, KTP laser, CO_2 laser, guillotine or other. Three categories of haemostatic technique were reported: ties alone, diathermy alone, or both. Haemorrhage was defined as primary if it occurred during the same hospital admission period as the initial procedure and categorised as requiring a return to theatre (R1) or minor where conservative measures sufficed (N1). Haemorrhage was defined as secondary if the event was related to a readmission to the ENT department and categorised as either requiring a return to theatre (R2) or was managed conservatively (N2).

Appendix 2 provides details of the characteristics of the included studies.

Table 1 Patient demographic details, indication for surgery and tonsillectomy technique (excluding within-patient studies)

	England and Northern Ireland NPTA final report		Studies (n=39)	
All patients analysed	33921	(100%)	10441	(100%)
Sex				
Male	13523	(39.9%)	2233	(21.2%)
Female	20160	(59.4%)	2594	(24.7%)
Not recorded	238	(0.7%)	5688	(54.1%)
Age group				
< 5 years	5130	(15.1%)	Across studies median	
5-15 years	15933	(47.0%)	8.1 yrs	
≥ 16 years	12620	(37.2%)	(range 0.8 – 72 yrs)	
Not recorded	238	(0.7%)	2095	(20.1%)
Indication for surgery				
Recurrent acute tonsillitis	25691	(75.7%)	1463	(14.0%)
Chronic tonsillitis	2552	(7.5%)		
Peritonsillar abscess	677	(2.0%)	146	(1.4%)
Pharyngeal obstruction/OSA	3217	(9.5%)	63	(0.6%)
Other	594	(1.8%)	179	(1.7%)
Not recorded	1190	(3.5%)	8590	(82.3%)
Tonsillectomy technique				
Cold steel d + ties/packs h	4285	(12.6%)	2730	(26.1%)
Cold steel d + monopolar diathermy h	1772	(5.2%)	188	(1.8%)
Cold steel d + bipolar diathermy h	11956	(35.3%)	1043	(10.0%)
Monopolar diathermy forceps d + h	452	(1.3%)	1178	(11.3%)
Bipolar diathermy forceps d + h	10240	(30.2%)	1826	(17.5%)
Bipolar diathermy scissors d + h	2322	(6.9%)		
Coblation d + h	1565	(4.6%)	976	(9.3%)
Other	1329	(3.9%)		
Cold steel d + ties/packs + diathermy h			1073	(10.3%)
Diathermy technique for dissection and/or haemostasis not specified			1427	(13.7%)

Notes:

1. d=dissection, h= haemostasis.
2. Three studies[41,61,62] provided information on sex for those enrolled rather than those analysed, resulting in this subsection summing to 10,515 rather than 10,441.
3. In 15 studies including 5688 patients the sex of the patients was not reported.
4. In seven studies including 2095 patients no information was provided on the age of the patients.
5. In the section Indication for surgery, the figure of 1463 in the Studies column represents a combined figure for recurrent acute tonsillitis or chronic tonsillitis.
6. In 31 studies including 8590 patients the indication for surgery was not reported.
7. In the section Tonsillectomy technique, in the RCTs, non-randomised comparative studies and case series, 1178 (11.3%) of 10,441 patients underwent monopolar diathermy dissection and haemostasis, a higher proportion than reflects current practice in the UK. Of these 1178 patients, the majority (978, 83%) came from just two case series[61,70] containing 413 and 565 patients respectively.
8. In the section Tonsillectomy technique, the figure of 1826 in the Studies column represents a combined figure for bipolar diathermy forceps dissection and haemostasis or bipolar diathermy scissors dissection and haemostasis.
9. In five studies including 1427 patients the diathermy technique for dissection and/or haemostasis was not specified.

Table 2 Patient demographic details, indications for surgery and tonsillectomy technique for the within-patient studies

Within-patient studies (n=11)		
All patients analysed	693	(100%)
Sex		
Male	186	(26.6%)
Female	313	(44.7%)
Not recorded	201	(28.7%)
Age (years)		
Median (range) age	17.9 (4-45) years	
Not recorded	110	(15.9%)
Indication for surgery		
Recurrent tonsillitis	73	(10.5%)
Other (heavy snorers)	32	(4.6%)
Not recorded	588	(84.9%)
Tonsillectomy technique (tonsils)		
Cold steel d + ties/packs h	478	(34.5%)
Cold steel d + ties/packs + diathermy h	131	(9.4%)
Cold steel d + monopolar diathermy h	255	(18.4%)
Cold steel d + bipolar diathermy h	32	(2.3%)
Monopolar diathermy d + h	42	(3.0%)
Bipolar diathermy d + h	210	(15.2%)
Coblation d + h	10	(0.7%)
Diathermy technique for dissection and haemostasis not specified	228	(16.5%)

Notes:

1. One study[77] provided information on sex for those enrolled rather than those analysed, resulting in this subsection summing to 700 rather than 693.
2. d=dissection, h=haemostasis.
3. In four studies including 201 patients the sex of the patients was not reported.
4. In two studies including 110 patients provided no information on the age of the patients.
5. In seven studies including 588 patients the indication for surgery was not reported.
6. In three studies including 228 patients the diathermy technique for dissection and/or haemostasis was not specified.
7. As these studies are within-patient studies, numbers in the Tonsillectomy technique (tonsils) subsection sum to 1386 rather than 693 as these refer to the number of tonsils, rather than patients, treated.

3.2.2 Number and type of excluded studies; reasons for exclusion

A list of potentially relevant studies identified by the search strategy, for which full text papers were obtained, but which subsequently failed to meet the inclusion criteria given in Section 3.1.2 and hence were excluded, is given in Appendix 3.

3.2.3 Quality of available evidence

The results of the quality assessment of (1) the RCTs (including those studies initially assessed as RCTs but whose assignment was then judged to be not really random), (2) the within-patient studies, (3) the non-randomised comparative studies and (4) the prospective case series are summarised in Tables 3 to 6. In the majority of the randomised studies and within-patient studies it was unclear whether the sequence generation was truly random (computer-generated or derived from a random numbers table) and whether the treatment allocation was adequately concealed. Few studies blinded care providers or outcomes assessors. Around half of the non-randomised comparative studies gave clear inclusion or exclusion criteria but none clearly described the tonsillectomy technique used. Around half of the prospective case series gave clear inclusion or exclusion criteria and clearly described the tonsillectomy technique used. Length of follow-up in most studies, irrespective of study design, was less than the three weeks considered an adequate period of time to assess the occurrence of secondary haemorrhage.

The England and Northern Ireland NPTA final report (NPTA 2005) provided data on 33,921 patients (84% of the audit's 40,514 patients) who had undergone tonsillectomy during the period July 2003 to September 2004. For different tonsillectomy techniques, information was provided on primary and secondary haemorrhage requiring return to theatre and overall primary and secondary haemorrhage. Information was also provided on the numbers of patients who experienced a primary or secondary haemorrhage requiring blood transfusion, although without detailing the tonsillectomy technique that these patients underwent. Secondary haemorrhage was defined as occurring within 28 days of surgery.

The data for the Scottish Tonsillectomy Audit for April 2002 to March 2003 was reported in a one-page summary table enclosed with a letter issued by the Chief Medical Officer in Scotland on 18 March 2004.[19] This table gave (anonymised) details for each Trust of the numbers of patients for all tonsil and adenoid operations, patients returned to theatre during initial stay, all readmissions, patients returned to theatre during readmission and all problem patients. Data gathered through different sources from ISD Scotland was also provided in the summary table for the number of patients readmitted due to bleeds and for all patient readmissions.

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported data from the Single-use Instrument Surveillance Programme (SISP) for Wales for the period February 2003 to March 2004. For different tonsillectomy techniques involving a total of 3690 tonsillectomy or adenotonsillectomy procedures, information was provided on primary and secondary haemorrhage requiring return to theatre, primary haemorrhage that was managed conservatively and secondary haemorrhage that required a return to hospital but was managed conservatively.

Table 3 Summary of the quality assessment of the RCTs

Criteria	Yes	No	Unclear
1. Was the assignment to the treatment groups really random?	**1**(34)	**5**(46,48,50,58,60)	**9**(35-38,40-43,45)
2. Was the treatment allocation concealed?	**0**	**4**(36,42,58,60)	**11**(34,35,37,38,40,41,43,45,46,48,50)
3. Were the groups similar at baseline in terms of prognostic factors?	**3**(36,43,46)	**0**	**12**(34,35,37,38,40-42,45,48,50,58,60)
4. Were the eligibility criteria specified?	**12**(35-38,40-43,45,46,48,58)	**2**(50,60)	**1**(34)
5. Was the intervention (and comparison) clearly defined?	**7**(36,37,41,46,48,58,60)	**8**(34,35,38,40,42,43,45,50)	**0**
6. Were the groups treated in the same way apart from the intervention received?	**9**(36,38,40-42,45,46,50,58)	**0**	**6**(34,35,37,43,48,60)
7. Was follow-up long enough to detect important effects on outcomes of interest?	**3**(40,41,46)	**9**(34,35,38,42,45,48,50,58,60)	**3**(36,37,43)
8. Was the outcome assessor blinded to the treatment allocation?	**3**(35,36,42)	**5**(41,45,46,58,60)	**7**(34,37,38,40,43,48,50)
9. Was the care provider blinded?	**5**(36,40,45,46,58)	**4**(35,41,42,60)	**6**(34,37,38,43,48,50)
10. Were the patients blinded?	**5**(35,40,41,45,46)	**0**	**10**(34,36-38,42,43,48,50,58,60)
11. Were the point estimates and measures of variability presented for the primary outcome measures?	**9**(36,37,40,41,43,45,46,48,50)	**6**(34,35,38,42,58,60)	**0**
12. Was the withdrawal/drop-out rate likely to cause bias?	**1**(35)	**13**(34,36-38,41-43,45,46,48,50,58,60)	**1**(40)
13. Did the analyses include an intention-to-treat analysis?	**6**(37,40,42,43,48,60)	**8**(35,36,38,41,45,46,50,58)	**1**(34)
14. Was the operation undertaken by somebody experienced in performing the procedure?	**3**(38,43,50)	**1**(35)	**11**(34,36,37,40-42,45,46,48,58,60)

Table 4 Summary of the quality assessment of the within-patient studies

Criteria	Yes	No	Unclear
1. Was the assignment to the treatment groups really random?	**0**	**2**(49,75)	**9**(7,73,74,76-81)
2. Was the treatment allocation concealed?	**2**(79,80)	**4**(7,49,74,75)	**5**(73,76-78,81)
3. Were the groups similar at baseline in terms of prognostic factors?	**11**(7,49,73-81)	**0**	**0**
4. Were the eligibility criteria specified?	**5**(7,73,77,79,80)	**4**(49,75,78,81)	**2**(74,76)
5. Was the intervention (and comparison) clearly defined?	**3**(73,76,80)	**8**(7,49,74,75,77-79,81)	**0**
6. Were the groups treated in the same way apart from the intervention received?	**11**(7,49,73-81)	**0**	**0**
7. Was follow-up long enough to detect important effects on outcomes of interest?	**0**	**10**(7,49,73-75,77-81)	**1**(76)
8. Was the outcome assessor blinded to the treatment allocation?	**4**(7,73,78,81)	**5**(75-77,79,80)	**2**(49,74)
9. Was the care provider blinded?	**1**(74)	**5**(75-77,79,80)	**5**(7,49,73,78,81)
10. Were the patients blinded?	**10**(7,73-81)	**0**	**1**(49)
11. Were the point estimates and measures of variability presented for the primary outcome measures?	**5**(7,73,77,79,80)	**6**(49,74-76,78,81)	**0**
12. Was the withdrawal/drop-out rate likely to cause bias?	**1**(77)	**9**(7,49,73,75,76,78-81)	**1**(74)
13. Did the analyses include an intention-to-treat analysis?	**7**(7,49,74-76,79,80)	**2**(73,81)	**2**(77,78)
14. Was the operation undertaken by somebody experienced in performing the procedure?	**2**(74,81)	**0**	**9**(7,49,73,75-80)

Table 5 Summary of the quality assessment of the non-randomised comparative studies

Criteria	Yes	No	Unclear
1. Were participants a representative sample selected from a relevant patient population?	**7**(6,49,52,54-56,59)	**1**(53)	**2**(47,57)
2. Were the inclusion/exclusion criteria of participants clearly described?	**4**(52,53,56,59)	**6**(6,47,49,54,55,57)	**0**
3. Were participants entering the study at a similar point in their disease progression?	**0**	**0**	**10**(6,47,49,52-57,59)
4. Was selection of patients consecutive?	**4**(49,52,56,59)	**3**(6,53,54)	**3**(47,55,57)
5. Was data collection undertaken prospectively?	**6**(6,47,49,52,55,56)	**4**(53,54,57,59)	**0**
6. Were the groups comparable on demographic characteristics and clinical features?	**1**(56)	**3**(47,53,54)	**6**(6,49,52,55,57,59)
7. Was the intervention (and comparison) clearly defined?	**0**	**10**(6,47,49,52-57,59)	**0**
8. Was the intervention undertaken by someone experienced at performing the procedure?	**1**(57)	**1**(53)	**8**(6,47,49,52,54-56,59)
9. Were the staff, place, and facilities where the patients were treated appropriate for performing the procedure? (e.g. access to back-up facilities)	**7**(49,52-54,56,57,59)	**0**	**3**(6,47,55)
10. Were all the important outcomes considered?	**3**(47,56,57)	**7**(6,49,52-55,59)	**0**
11. Were objective (valid and reliable) outcome measure/s used?	**9**(6,47,49,52-55,57,59)	**0**	**1**(56)
12. Was the assessment of main outcomes blind?	**0**	**10**(6,47,49,52-57,59)	**0**
13. Was follow-up long enough to detect important effects on outcomes of interest?	**0**	**5**(47,49,52,56,57)	**5**(6,53-55,59)
14. Was information provided on non-respondents, dropouts?	**9**(6,47,49,52-56,59)	**1**(57)	**0**
15. Were participants lost to follow-up likely to introduce bias? (e.g. high drop-out rate; differential drop-out; no description of those lost)	**0**	**9**(6,47,49,52-56,59)	**1**(57)
16. Was length of follow-up similar between comparison groups?	**5**(47,49,52,56,57)	**0**	**5**(6,53-55,59)
17. Were the analyses adjusted for confounding factors?	**0**	**9**(6,47,49,52-54,56,57,59)	**1**(55)

Table 6 Summary of the quality assessment of the prospective case series

Criteria	Yes	No	Unclear
1. Were participants a representative sample selected from a relevant patient population?	**6**(61,62,65,67,69,72)	**0**	**8**(5,33,63,64,66,68,70,71)
2. Were the inclusion/exclusion criteria of participants clearly described?	**7**(61-63,65,66,68,69)	**5**(5,67,70-72)	**2**(33,64)
3. Were participants entering the study at a similar point in their disease progression?	**0**	**0**	**14**(5,33,61-72)
4. Was selection of patients consecutive?	**5**(61,62,64,67,70)	**5**(5,33,63,65,68)	**4**(66,69,71,72)
5. Was data collection undertaken prospectively?	**13**(33,61-72)	**0**	**1**(5)
6. Was the intervention (and comparison) clearly defined?	**6**(5,61,68-71)	**7**(62-67,72)	**1**(33)
7. Was the intervention undertaken by someone experienced at performing the procedure?	**0**	**1**(71)	**13**(5,33,61-70,72)
8. Were the staff, place, and facilities where the patients were treated appropriate for performing the procedure? (e.g. access to back-up facilities)	**6**(61,63,65,67,69,71)	**0**	**8**(5,33,62,64,66,68,70,72)
9. Were all the important outcomes considered?	**4**(61,63,71,72)	**10**(5,33,62,64-70)	**0**
10. Were objective (valid and reliable) outcome measure/s used?	**11**(5,61-63,65-71)	**1**(72)	**2**(33,64)
11. Was follow-up long enough to detect important effects on outcomes of interest?	**1**(64)	**9**(33,62,63,65,67-69,71,72)	**4**(5,61,66,70)
12. Was information provided on non-respondents, dropouts?	**9**(5,64,66-72)	**5**(33,61-63,65)	**0**
13. Were participants lost to follow-up likely to introduce bias? (e.g. high drop-out rate; differential drop-out; no description of those lost)	**4**(33,62,65,71)	**9**(5,61,64,66-70,72)	**1**(63)

3.2.4 Summary of safety findings

Secondary haemorrhage

- **Secondary haemorrhage requiring return to theatre**

Overview

Thirty-five studies involving 6417 patients reported secondary haemorrhage requiring return to theatre, including seven RCTs,[35-38,40,42,45] seven within-patient RCTs,[7,73,74,76-79] nine non-randomised comparative studies,[6,46,48-50,53,54,58,60] two within-patient non-randomised studies[49,75] and ten case series.[33,61-63,65-68,70,71]

For each intervention, the crude overall rates of secondary haemorrhage requiring return to theatre across the 35 studies reporting this outcome are shown in Table 7, along with the range of results. For each intervention, the crude rates of secondary haemorrhage requiring return to theatre by study type are shown in Table 8, along with the overall rates and registry data with 95% confidence intervals; blank cells indicate that the data were not reported. Individual study results for this outcome and registry data are given in Appendix 4.

Table 7 Overall rates of secondary haemorrhage requiring return to theatre

	All studies (26) (excluding within-patient studies and registries)		Within-patient studies (9)	
Technique	**N/n**	**Rate (range)**	**N/n**	**Rate (range)**
Cold steel dissection with ties/packs haemostasis	588/0	0%	373/0	0%
Cold steel dissection with diathermy or ties+diathermy haemostasis	780/7	0.9% (0-5.3%)	28/0	0%
Cold steel dissection with bipolar diathermy haemostasis	1043/3	0.3% (0-1.0%)	32/0	0%
Cold steel dissection with monopolar diathermy haemostasis	118/1	0.8% (0-1.1%)	150/0	0%
Coblation	933/5	0.5% (0-6.3%)	10/0	0%
Bipolar diathermy dissection and haemostasis	1298/12	0.9% (0-3.4%)	210/0	0%
Monopolar diathermy dissection and haemostasis	1120/10	0.9% (0-4.0%)	42/0	0%

Note:

1. N = number of participants analysed by the study, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing secondary haemorrhage.

Table 8 Secondary haemorrhage requiring return to theatre, by tonsillectomy technique, overall rates by study type

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties + diathermy haemostasis			Cold steel dissection + ties/packs haemostasis		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
RCTs (7)																					
Total	67	0	0%	271	0	0%	35	1	2.9%	118	1	0.8%	100	1	1.0%	23	0	0%	60	0	0%
Broad groups	338 0 0%						35	1	2.9%	241 2 0.8%									60	0	0%
Non-randomised comparative studies (9)																					
Total				605	10	1.7%	898	4	0.4%				783	2	0.3%	265	2	0.8%	88	0	0%
Broad groups	657 10 1.5%						898	4	0.4%	1048 4 0.4%									88	0	0%
Case series (10)																					
Total	1053	10	0.9%	422	2	0.5%							160	0	0%	492	5	1.0%	440	0	0%
Broad groups	1475 12 0.8%									652 5 0.8%									440	0	0%
Grand total (95% CI)	1120 10 0.9% (0.5% to 1.6%)			1298 12 0.9% (0.5% to 1.6%)			933 5 0.5% (0.2% to 1.2%)			118 1 0.8% (0.1% to 4.6%)			1043 3 0.3% (0.1% to 0.8%)			780 7 0.9% (0.4% to 1.8%)			588 0 0% (0% to 0.6%)		
Broad groups (95% CI)	2470 22 0.9% (0.6% to 1.3%)						933 5 0.5% (0.2% to 1.2%)			1941 11 0.6% (0.3% to 1.0%)									588 0 0% (0% to 0.6%)		
Within-patient studies (9)																					
Total	42	0	0%	210	0	0%	10	0	0%	150	0	0%	32	0	0%	28	0	0%	373	0	0%
Broad groups	377 0 0%						10	0	0%	210 0 0%									373	0	0%
National registries																					
SISP 2005 (95% CI)				325 7 2.2% (1.0% to 4.4%)			221 1 0.5% (0.1% to 2.5%)			39 0 0% (0% to 9.0%)			141 0 0% (0% to 2.7%)			768 7 0.9% (0.4% to 1.9%)			1535 2 0.1% (0% to 0.5%)		
NPTA 2005 (95% CI)	452 3 0.7% (0.2% to 1.9%)			12562 95 0.8% (0.6% to 0.9%)			1565 11 0.7% (0.4% to 1.3%)			1772 5 0.3% (0.1% to 0.7%)			11956 48 0.4% (0.3% to 0.5%)						4285 9 0.2% (0.1% to 0.4%)		

Notes:

1. CI = confidence interval, N = number of participants analysed by the study, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing secondary haemorrhage.
2. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).
3. Total and Broad groups rows exclude England and Northern Ireland NPTA 2005 (final report) and Wales SISP 2005.
4. 95% CIs for Grand total and Broad groups rows are based upon the crude rate estimates.
5. Wales SISP 2005. Numbers do not sum to 3690 as patient numbers for the following operative techniques have not been included in Table 8: cold steel operative technique but haemostasis method unknown (n=73), bipolar diathermy operative technique with ties for haemostasis (n=67), bipolar diathermy operative technique with dissection instruments used for haemostasis (n=62), bipolar diathermy operative technique with ties and instruments used for haemostasis (n=89), coblation operative technique with diathermy used for haemostasis (n=60), coblation operative technique with ties used for haemostasis (n=15), other methods for operative technique with any method for haemostasis (n=42), indeterminate operative technique with any method for haemostasis (n=153).
6. England and Northern Ireland NPTA 2005 (final report). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.
7. England and Northern Ireland NPTA 2005 (final report). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.
8. For the NPTA 2005 (final report), for each technique, the numbers of patients experiencing a secondary haemorrhage requiring return to theatre were calculated from the numbers of patients undergoing each technique and the rate of secondary haemorrhage requiring a return to theatre.

Direct comparisons

a. Cold steel dissection with ties/packs haemostasis versus cold steel dissection with monopolar diathermy haemostasis

One within-patient study[78] involving 150 patients reported that neither technique resulted in any patient suffering a secondary haemorrhage requiring return to theatre.

b. Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis

One RCT,[37] two within-patient studies[74,75] and two non-randomised studies[48,58] involving 416 patients reported this comparison. In the RCT by Pang and colleagues[37] none of the 60 patients in either arm of the study experienced an event. In the two non-randomised studies[48,58] patients undergoing the cold steel technique (n = 88) experienced zero events while, of those undergoing bipolar diathermy (n = 89), one patient (0.7%) required return to theatre. In the two within-patient studies[74,75] none of the 119 patients experienced an event. A within-patient study by Tay and colleagues[79] involving 52 patients and comparing cold steel dissection with ties/packs haemostasis versus diathermy (technique not stated) dissection and haemostasis also reported that no patient experienced an event.

c. Cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis versus diathermy dissection and haemostasis

Four RCTs,[35,36,38,45] three within-patient studies[49,76,77] and four non-randomised studies[49,50,54,60] involving 1367 patients reported this comparison. Excluding the within-patient studies, of 527 patients undergoing the cold steel technique, three (0.6%) experienced secondary haemorrhage requiring return to theatre, compared with nine of 780 patients (1.2%) who underwent diathermy dissection and haemostasis. Of those nine patients, six were from one non-randomised study,[54] which employed bipolar diathermy. In the four RCTs,[35,36,38,45] two (0.8%) of 241

patients undergoing the cold steel technique experienced an event compared with none of 241 who underwent diathermy dissection and haemostasis. In the four non-randomised studies[49,50,54,60] one (0.3%) of 286 patients undergoing the cold steel technique experienced an event compared with nine (1.7%) of 539 who underwent diathermy. In the within-patient studies, none of the 60 patients experienced an event.

d. Cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis versus coblation

Two non-randomised studies[6,46] involving 1624 patients reported this comparison. Of 762 patients undergoing the cold steel technique, three (0.4%) experienced secondary haemorrhage requiring return to theatre, compared with two (0.2%) of 862 undergoing coblation. Of the two studies, most patients came from the study by Belloso and colleagues[6] that compared cold steel dissection with bipolar diathermy haemostasis (n=743) versus coblation (n=844).

e. Diathermy versus coblation

Two RCTs,[40,42] one within-patient study[7] and one non-randomised study[53] involving 147 patients reported this comparison. Excluding the within-patient study, three (4.2%) of 71 patients undergoing coblation experienced secondary haemorrhage requiring return to theatre, while none of the 66 patients undergoing diathermy (49 bipolar, 17 monopolar) required return to theatre because of secondary haemorrhage. In the within-patient study by Timms and colleagues[7] none of the 10 patients experienced a secondary haemorrhage requiring return to theatre.

f. Bipolar versus monopolar diathermy

One within-patient study[73] involving 42 patients reported that no patient experienced a secondary haemorrhage requiring return to theatre.

National prospective tonsillectomy audits

a. England and Northern Ireland National Prospective Tonsillectomy Audit

The England and Northern Ireland NPTA final report (NPTA 2005) provided data for secondary haemorrhage requiring return to theatre for 33,921 patients who underwent tonsillectomy between July 2003 and September 2004. Rates by intervention technique are shown in Table 8. These ranged from 0.2% (cold steel dissection with ties/packs haemostasis) to 0.8% (bipolar diathermy dissection and haemostasis). Monopolar diathermy dissection and haemostasis and coblation were both associated with rates of 0.7%.

b. Scottish Tonsillectomy Audit

According to data provided by the Scottish Otolaryngology Society, of 6200 patients undergoing tonsillectomy and/or adenoidectomy operations in Scotland from April 2002 to March 2003, 137 (2.21%) were readmitted, of whom 17 (0.27%) suffered a secondary haemorrhage requiring return to theatre.[19] No data were available, however, for rates of secondary haemorrhage requiring return to theatre according to intervention technique for all tonsillectomies performed.

c. Wales Single-use Instrument Surveillance Programme

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported secondary haemorrhage requiring return to theatre for 3690 patients who underwent tonsillectomy/ adenotonsillectomy between February 2003 and March 2004. Rates by intervention technique are shown in Table 8. These ranged from 0% (cold steel dissection with either bipolar or monopolar diathermy haemostasis) to 2.2% (bipolar diathermy dissection and haemostasis).

Prospective case series

Ten studies involving 2567 patients reported secondary haemorrhage requiring return to theatre. The overall rates by intervention technique are shown in Table 8.

No case series reported cold steel dissection with monopolar diathermy haemostasis, or coblation.

Meta-analysis

In the meta-analysis of broad tonsillectomy categories (Table 9), adjusted for study design, the reference technique of cold steel dissection with ties/packs haemostasis was associated with the lowest secondary haemorrhage requiring return to theatre, followed by cold steel dissection with ties/packs and/or diathermy haemostasis (OR 9.36), then diathermy dissection and haemostasis (OR 9.59), then coblation (OR 18.10). None of the differences reached statistical significance. The large degree of uncertainty for these results is reflected by the extremely wide credible intervals.

In a meta-analysis of seven narrow categories (Table 10), adjusted for study design, numbers of events were all extremely low and the credible intervals of the effect measures so extreme as to render the results not meaningful. Coblation was associated with a statistically significant higher rate of secondary haemorrhage requiring return to theatre (OR 33.82) compared with cold steel dissection with ties/packs haemostasis (reference technique). In the meta-analysis of both broad and narrow categories the non-randomised comparative studies (OR 2.67 and OR 7.07 respectively) and case series (OR 2.82 and OR 8.00 respectively) suggested a higher event rate than the RCTs (reference study design).

Table 9 Meta-analysis models, secondary haemorrhage requiring return to theatre, broad categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Diathermy dissection and haemostasis	2470	22	8.43	0.72 to 382.80	9.59	0.79 to 365.40
Coblation dissection and haemostasis	933	5	15.35	0.93 to 812.60	18.10	0.98 to 844.90
Cold steel dissection with diathermy haemostasis or ties + diathermy haemostasis	1941	11	8.17	0.63 to 389.90	9.36	0.70 to 385.10
Cold steel dissection with ties/packs haemostasis	588	0	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					2.67	0.31 to 31.86
Prospective case series					2.82	0.31 to 30.44

Notes:

1. N = cumulative number of patients analysed by the studies, n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.
3. Event imputed into meta-analysis models for category cold steel dissection with ties/packs haemostasis (study by Lee and colleagues[33]).

Table 10 Meta-analysis models, secondary haemorrhage requiring return to theatre, narrow categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Monopolar diathermy dissection and haemostasis	1120	10	11.83	0.39 to 721.50	15.78	0.40 to 1859.00
Bipolar diathermy dissection and haemostasis	1298	12	8.87	0.54 to 452.20	12.06	0.61 to 1400.00
Coblation dissection and haemostasis	933	5	20.24	1.01 to 1432.00	33.82	1.25 to 5676.00
Cold steel dissection with monopolar diathermy haemostasis	118	1	16.42	0.20 to 2505.00	95.38	0.65 to 7.44×10^4
Cold steel dissection with bipolar diathermy haemostasis	1043	3	15.49	0.61 to 1569.00	29.41	0.86 to 6829.00
Cold steel dissection with diathermy or ties + diathermy haemostasis	780	7	5.96	0.26 to 318.50	6.86	0.28 to 775.20
Cold steel with ties haemostasis	588	0	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					7.07	0.44 to 172.60
Prospective case series					8.00	0.49 to 266.40

Notes:
1. N = cumulative number of patients analysed by the studies, n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.
3. Event imputed into meta-analysis models for category cold steel dissection with ties/packs haemostasis (study by Lee and colleagues[33]).

Summary

Overall, the crude rate of secondary haemorrhage requiring return to theatre was lowest for cold steel dissection with ties/packs haemostasis (0%, 95% CI 0 to 0.6%) and highest for cold steel dissection with ties/packs plus diathermy haemostasis (0.9%, 95% CI 0.4 to 1.8%) and bipolar and monopolar diathermy dissection and haemostasis (both 0.9%, 95% CI 0.5 to 1.6%). Data from the England and Northern Ireland NPTA final report showed that the rate was lowest for cold steel dissection with ties/packs haemostasis (0.2%, 95% CI 0.1 to 0.4%) while the highest rates were reported for bipolar diathermy dissection and haemostasis (0.8%, 95% CI 0.6 to 0.9%), monopolar diathermy dissection and haemostasis (0.7%, 95% CI 0.2 to 1.9%) and coblation (0.7%, 95% CI 0.4 to 1.3%). Data from the Wales SISP indicated that the lowest rates were for cold steel dissection with either bipolar (0%, 95% CI 0 to 2.7%) or monopolar (0%, 95% CI 0 to 9.0%) diathermy haemostasis and highest for bipolar diathermy dissection and haemostasis (2.2%, 95% CI 1.0 to 4.4%). In the adjusted meta-analysis of narrow tonsillectomy categories coblation (OR 33.82) was associated with a statistically significant higher rate of secondary haemorrhage requiring return to theatre compared with cold steel dissection with ties/packs haemostasis. However there was a large degree of uncertainty surrounding the effect estimates due to low event rates.

- **Secondary haemorrhage requiring blood transfusion**

Overview

Twenty-five studies involving 3592 patients reported this outcome for the intervention techniques used, including four RCTs,[36,37,42,45] ten within patient studies,[7,49,73-80] five non-randomised comparative studies,[48-50,53,60] and six case series.[64-67,69,70] Two (0.3%) of 719 patients undergoing bipolar diathermy dissection and haemostasis experienced a secondary haemorrhage requiring a blood transfusion. In another study[54] comparing cold steel dissection and either bipolar diathermy haemostasis or ties and bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis, one patient experienced a secondary haemorrhage requiring a blood transfusion, but it was unclear to which group this patient belonged. In the remaining studies no patient experienced a secondary haemorrhage requiring a blood transfusion.

Direct comparisons

In the non-randomised comparative study by Lee and colleagues,[49] two (1.0%) of 192 patients undergoing bipolar diathermy dissection and haemostasis experienced a secondary haemorrhage requiring a blood transfusion compared with none of 145 patients undergoing cold steel dissection with ties plus bipolar diathermy haemostasis. In a within-patient study reporting this comparison[49] no patient experienced an event.

National Prospective Tonsillectomy Audits

a. England and Northern Ireland National Prospective Tonsillectomy Audit

The NPTA final report (NPTA 2005) stated that 54 (0.2%) of 33,921 patients experienced a secondary haemorrhage requiring a blood transfusion, 42 of whom were returned to theatre. However, no information was provided on the tonsillectomy technique that the 54 patients had undergone.

b. Scottish Tonsillectomy Audit

The Scottish Tonsillectomy Audit one-page summary table covering the period April 2002 to March 2003 issued by the Chief Medical Officer[19] gave no details of secondary haemorrhage requiring blood transfusion. However, we subsequently obtained additional/updated information on the Scottish Tonsillectomy Audit for this period (personal communication, meeting between and J Burr and B Bingham, Southern General Hospital, Glasgow, 2004) which indicated that of the 6200 patients who underwent tonsillectomy, adenotonsillectomy or adenoidectomy, three (0.05%) patients experienced a secondary haemorrhage requiring a blood transfusion.

c. Wales Single-use Instrument Surveillance Programme

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported that eight (0.2%) of 3690 patients who underwent surgery during the period February 2004 to March 2005 required a blood transfusion. However the operative technique undergone by those patients who required a blood transfusion was not reported.

Prospective case series

In six case series reporting this outcome no patient out of a total of 2046 experienced a secondary haemorrhage requiring blood transfusion. The case series examined cold steel dissection with ties/packs haemostasis,[65,69] cold steel dissection with diathermy or ties plus diathermy haemostasis,[67] cold steel dissection with diathermy (technique not stated) haemostasis,[64] bipolar diathermy dissection and haemostasis[66] and monopolar diathermy dissection and haemostasis.[70]

Meta-analysis

This outcome was not included in a meta-analysis due to the rarity of events.

Summary

In 25 studies involving 3592 patients and reporting this outcome, two (0.3%) of 719 patients undergoing bipolar diathermy dissection and haemostasis experienced a secondary haemorrhage requiring blood transfusion. One other study reported that one patient had experienced this event, but it was unclear which interventional technique this patient had received. In the other studies reporting this outcome no patient experienced a secondary haemorrhage requiring blood transfusion. The England and Northern Ireland NPTA final report stated that 54 (0.2%) of 33,921 patients who underwent tonsillectomy during the period July 2003 to September 2004 experienced a secondary haemorrhage requiring a blood transfusion. Data obtained from the Scottish Tonsillectomy Audit indicated that three (0.05%) of 6200 patients who underwent tonsillectomy, adenotonsillectomy or adenoidectomy during the period April 2002 to March 2003 experienced a secondary haemorrhage requiring a blood transfusion. Data from the Wales SISP indicated that eight (0.2%) of 3690 patients who underwent surgery during the period February 2004 to March 2005 required blood transfusion.

- **All secondary haemorrhage**

Overview

Fifty studies involving 11,134 patients reported all secondary haemorrhage as an outcome, including ten RCTs,[34-38,40-43,45] 11 within-patient studies,[7,49,73-81] 15 non-randomised studies[6,46-50,52-60] and 14 case series.[5,33,61-72]

For each intervention, the crude overall rates of all secondary haemorrhage are shown in Table 11, along with the range of results. For each intervention, the crude rates of all secondary haemorrhage by study type are shown in Table 12, along with the overall rates and registry data with 95% confidence intervals; blank cells indicate that the data were not reported. Individual study results and registry data for this outcome are given in Appendix 5.

Table 11 Overall rates for all secondary haemorrhage

Technique	All studies (39) (excluding within-patient studies and registries)		Within-patient studies (11)	
	N/n	Rate (range)	N/n	Rate (range)
Cold steel dissection with ties/packs haemostasis	2730/86	3.2% (0-12.8%)	478/4	0.8% (0-1.9%)
Cold steel dissection with diathermy or ties+diathermy haemostasis	1073/50	4.7% (0-42.1%)	131/0	0%
Cold steel dissection with bipolar diathermy haemostasis	1043/71	6.8% (0-10.6%)	32/2	6.3%
Cold steel dissection with monopolar diathermy haemostasis	188/25	13.3% (3.8-18.5%)	255/1	0.4% (0-0.7%)
Coblation	976/40	4.1% (0-50.0%)	10/0	0%
Bipolar diathermy dissection and haemostasis	1826/96	5.3% (0-15.4%)	210/4	1.9% (0-6.3%)
Monopolar diathermy dissection and haemostasis	1178/191	16.2% (0-32.9%)	42/1	2.4%

Notes:

1. N = number of participants analysed by the study, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing secondary haemorrhage.

2. In the within-patient studies column, for the outcome of all secondary haemorrhage, one study reported cold steel dissection with bipolar diathermy haemostasis[76] and one study reported monopolar diathermy dissection and haemostasis.[73]

Table 12 All secondary haemorrhage (irrespective of severity), by tonsillectomy technique, overall rates by study type

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties + diathermy haemostasis			Cold steel dissection + ties/packs haemostasis		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
RCTs (10)																					
Total	109	4	3.7%	330	19	5.8%	78	4	5.1%	188	25	13.3%	100	8	8.0%	23	0	0%	573	8	1.4%
Broad groups	439 23 5.2%						78	4	5.1%	834 41 4.9%									573	8	1.4%
Non-randomised comparative studies (15)																					
Total	16	1	6.3%	809	70	8.7%	898	36	4.0%				783	46	5.9%	558	35	6.3%	907	24	2.6%
Broad groups	1047 87 8.3%						898	36	4.0%	1831 94 5.1%									907	24	2.6%
Case series (14)																					
Total	1053	186	17.7%	687	7	1.0%							160	17	10.6%	492	15	3.0%	1250	54	4.3%
Broad groups	1740 193 11.1%									844 44 5.2%									1250	54	4.3%
Grand total (95% CI)	1178 191 16.2% (14.2% to 18.4%)			1826 96 5.3% (4.3% to 6.4%)			976 40 4.1% (3.0% to 5.5%)			188 25 13.3% (9.2% to 18.9%)			1043 71 6.8% (5.4% to 8.5%)			1073 50 4.7% (3.6% to 6.1%)			2730 86 3.2% (2.6% to 3.9%)		
Broad groups (95% CI)	3226 303 9.4% (8.4% to 10.4%)						976 40 4.1% (3.0% to 5.5%)			3509 179 5.1% (4.4% to 5.9%)									2730 86 3.2% (2.6% to 3.9%)		
Within-patient studies (11)																					
Total	42	1	2.4%	210	4	1.9%	10	0	0%	255	1	0.4%	32	2	6.3%	131	0	0%	478	4	0.8%
Broad groups	480 9 1.9%						10	0	0%	418 3 0.7%									478	4	0.8%
National registries																					
SISP 2005 (95% CI)				325 29 8.9% (6.3% to 12.5%)			221 6 2.7% (1.3% to 5.8%)			39 0 0% (0% to 9.0%)			141 3 2.1% (0.7% to 6.1%)			768 23 3.0% (2.0% to 4.5%)			1535 9 0.6% (0.3% to 1.1%)		
NPTA 2005 (95% CI)	452 25 5.5% (3.8% to 8.0%)			12562 547 4.4% (4.0% to 4.7%)			1565 56 3.6% (2.8% to 4.6%)			1772 43 2.4% (1.8% to 3.3%)			11956 275 2.3% (2.0% to 2.6%)						4285 43 1.0% (0.7% to 1.3%)		

Notes:

1. CI = confidence interval, N = number of participants analysed by the study, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing secondary haemorrhage.
2. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).
3. Total and Broad groups rows are excluding England and Northern Ireland NPTA 2005 (final report) and Wales SISP 2005.
4. 95% CIs for Grand total and Broad groups rows are based upon the crude rate estimates.
5. 95% CIs for Grand total and Broad Groups rows. Sensitivity analysis showed that two studies (Blomgren 2001, case series, monopolar diathermy; Raut 2001, RCT, cold steel dissection with monopolar diathermy haemostasis compared with bipolar diathermy dissection and haemostasis) had an extreme impact on the confidence intervals. If these studies had been excluded from the calculations for all secondary haemorrhage then the crude overall rates for the narrow groups would have been 7.2% (95% CI 5.6 to 9.2%) for monopolar diathermy dissection and haemostasis, 4.7% (95% CI 3.8 to 5.8%) for bipolar diathermy dissection and haemostasis, and 8.3% (95% CI 4.3 to 15.6%) for cold steel dissection with monopolar diathermy haemostasis; the crude overall rates for the broad groups would have been 5.6% (95% CI 4.8 to 6.6%) for diathermy and 4.7% (95% CI 4.1 to 5.5%) for cold steel dissection with diathermy or ties plus diathermy haemostasis.
6. Wales SISP 2005. Patient numbers do not sum to 3690 as some categories of operative technique have not been included. See Table 8, note 5.
7. England and Northern Ireland NPTA 2005 (final report). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.
8. England and Northern Ireland NPTA 2005 (final report). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.
9. For the NPTA 2005 (final report), for each technique, the numbers of patients experiencing a secondary haemorrhage were calculated from the numbers of patients undergoing each technique and the secondary haemorrhage rate for each technique.

Direct comparisons

a. Cold steel dissection with ties/packs haemostasis versus cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis

One RCT,[43] two within-patient studies[78,80] and two non-randomised comparative studies[55,56] involving 2375 patients reported overall secondary haemorrhage for cold steel dissection with ties/packs haemostasis compared with cold steel dissection with diathermy or ties plus diathermy haemostasis. In the RCT by Watson and colleagues[43] seven (1.4%) of 513 patients undergoing cold steel dissection with ties experienced a secondary haemorrhage compared with eight (1.5%) of 523 patients undergoing cold steel dissection with diathermy (technique not stated) haemostasis. In the two within-patient studies[78,80] two (0.8%) of 255 patients experienced a secondary haemorrhage on the side undergoing cold steel dissection with ties haemostasis compared with one (0.4%) of 255 patients on the side undergoing cold steel dissection with monopolar diathermy haemostasis. In the two non-randomised studies[55,56] nine (1.7%) of 537 patients undergoing cold steel dissection with ties haemostasis experienced a secondary haemorrhage compared with 16 (2.9%) of 547 patients undergoing cold steel dissection with diathermy or ties plus diathermy haemostasis.

b. Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis

One RCT,[37] two within-patient studies[74,75] and two non-randomised comparative studies[48,58] involving 296 patients reported this comparison. In the RCT by Pang and colleagues[37] one (1.7%) of 60 patients in each arm of the study experienced a secondary haemorrhage. In the two non-randomised studies[48,58] none of the 88 patients undergoing the cold steel technique experienced a secondary haemorrhage compared with one (1.1%) of 89 patients undergoing bipolar diathermy. In the two within-patient studies[74,75] none of the 119 patients experienced a secondary haemorrhage.

One within-patient study[79] and one non-randomised study[59] compared cold steel dissection with ties/packs haemostasis versus diathermy (technique not stated) dissection and haemostasis. The within-patient study by Tay and colleagues[79] reported that two (1.9%) of 104 patients experienced a secondary haemorrhage on the side undergoing the cold steel technique and two patients also experienced a secondary haemorrhage on the side undergoing diathermy. In the study by Tan and colleagues[59] 15 (5.3%) of 282 patients undergoing the cold steel technique experienced a secondary haemorrhage compared with eight (4.7%) of 170 undergoing diathermy.

c. Cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis versus diathermy dissection and haemostasis

Sixteen studies involving 2055 patients compared cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis versus diathermy dissection and haemostasis, including five RCTs[34-36,38,45] four within-patient studies[49,76,77,81] and seven non-randomised comparative studies.[47,49,50,52,54,57,60] One RCT,[35] one within-patient study[76] and one non-randomised comparative study[50] involving 308 patients compared cold steel dissection with bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis. The secondary haemorrhage rates for those undergoing the cold steel technique were 8%,[35] 6%[76] 0%[50] compared with 3%, 6% and 3% respectively for those undergoing bipolar diathermy. In three non-randomised studies[49,52,54] comparing cold steel dissection with ties plus bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis 11 (4.0%) of 273 patients undergoing cold steel dissection experienced a secondary haemorrhage compared with 43 (8.8%) of 490 patients undergoing bipolar diathermy. In a within-patient study examining this comparison[49] no patient experienced a haemorrhage.

In two RCTs[34,38] involving 312 patients, 24 (14.8%) of 162 patients undergoing cold steel dissection with monopolar diathermy haemostasis experienced a secondary haemorrhage compared with 15 (10%) of 150 undergoing bipolar diathermy dissection and haemostasis. A non-randomised study by Schrey and colleagues[57] reported that six (4.3%) of 140 patients undergoing cold steel dissection with packs

plus monopolar diathermy haemostasis experienced a secondary haemorrhage compared with 24 (14.5%) of 165 patients undergoing bipolar diathermy dissection and haemostasis. In the RCT by Nunez and colleagues[36] one (3.8%) of 26 patients undergoing cold steel dissection with monopolar diathermy haemostasis experienced a secondary haemorrhage compared with two (8.3%) of 24 patients undergoing monopolar diathermy dissection and haemostasis. One RCT[45] and one non-randomised study[47] reported cold steel dissection with ties plus monopolar diathermy haemostasis versus monopolar diathermy dissection and haemostasis, with secondary haemorrhage rates of 0%[45] and 5%[47] for the cold steel technique and 0% and 6% respectively for monopolar diathermy.

Two within-patient studies[77,81] and one non-randomised study[60] involving 225 patients compared cold steel dissection with diathermy or ties plus diathermy haemostasis versus diathermy dissection and haemostasis (diathermy technique not stated). In the within-patient studies none of the 124 patients experienced a secondary haemorrhage on the side undertaken by the cold steel technique compared with two (1.6%) of 124 patients on the diathermy dissection side. In the non-randomised study by Wexler and colleagues six (12.2%) of 49 patients who underwent the cold steel technique experienced a secondary haemorrhage compared with eight (15.4%) of 52 who underwent diathermy.

d. Coblation versus diathermy

Three RCTs,[40-42] one within-patient study[7] and one non-randomised study[53] involving 232 patients reported this comparison. In the three RCTs four (5.1%) of 78 patients undergoing coblation experienced a secondary haemorrhage compared with none of 20 undergoing bipolar diathermy and two (3.4%) of 59 undergoing monopolar diathermy. In the within-patient study comparing coblation with bipolar diathermy none of the 10 patients experienced a secondary haemorrhage. In the non-randomised comparative study by Noon and colleagues[53] eight (22.2%) of 36 patients undergoing coblation experienced a secondary haemorrhage compared with one (3.4%) of 29 patients undergoing bipolar diathermy.

e. Coblation versus cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis

Two non-randomised studies involving 1624 patients[6,46] compared coblation with cold steel dissection and bipolar diathermy haemostasis[6] or ties plus bipolar diathermy haemostasis.[46] Most patients (n = 1587) were from the study by Belloso and colleagues,[6] which reported that 46 (6.2%) of 743 patients undergoing the cold steel technique experienced a secondary haemorrhage compared with 19 (2.3%) of 844 undergoing coblation. In the study by Back and colleagues[46] eight (42.1%) of 19 patients undergoing the cold steel technique experienced a secondary haemorrhage compared with nine (50%) of 18 undergoing coblation.

National prospective tonsillectomy audits

a. England and Northern Ireland National Prospective Tonsillectomy Audit

The England and Northern Ireland NPTA final report (NPTA 2005) provided data on all secondary haemorrhage for 33,921 patients who underwent tonsillectomy between July 2003 and September 2004. Rates by intervention technique are shown in Table 12. These ranged from 1.0% (cold steel dissection with ties/packs haemostasis) to 5.5% (monopolar diathermy dissection and haemostasis).

b. Scottish Tonsillectomy Audit

The one page summary table covering April 2002 to March 2003[19] gave no figures for overall secondary haemorrhage. ISD Scotland data included with the table, however, indicated that during this period 337 (5.4%) of the 6200 patients who underwent tonsillectomy, adenotonsillectomy or adenoidectomy were readmitted due to bleeding.

We subsequently obtained additional/updated information on the Scottish Tonsillectomy Audit for the period April 2002 – March 2003 (personal communication, meeting between J Burr and B Bingham, Southern General Hospital, Glasgow, 2004). This information indicated that a total of 166 patients experienced

problems, of whom 140 experienced a secondary haemorrhage requiring readmission. In 138 of the patients who were readmitted, the method of dissection was cold steel (92 patients), ultrasonic (15 patients), bipolar diathermy (12 patients), coblation (eight patients) and was not recorded in 11 patients. Although information from the Scottish Tonsillectomy Audit was available on the type of tonsillectomy technique employed for those patients who experienced problems, this information was not available for all of the patients who underwent tonsillectomy. Therefore it was not possible to calculate the primary and secondary haemorrhage rates according to intervention technique.

c. Wales Single-use Instrument Surveillance Programme

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported secondary haemorrhage requiring return to theatre, and secondary haemorrhage requiring a return to hospital but was managed conservatively, for 3690 patients who underwent tonsillectomy/adenotonsillectomy between February 2003 and March 2004. These figures were combined in Table 12 to provide an indication of overall secondary haemorrhage rates across different tonsillectomy techniques. The rate was lowest for cold steel dissection with monopolar diathermy haemostasis (0%) and highest for bipolar diathermy dissection and haemostasis (8.9%).

Prospective case series

Fourteen case series involving 3834 patients reported all secondary haemorrhage. The overall rates by intervention technique are shown in Table 12. No case series reported cold steel dissection with monopolar diathermy haemostasis or coblation.

Meta-analysis

In the meta-analysis of broad tonsillectomy categories for all secondary haemorrhage (Table 13), adjusted for study design, none of the differences between the techniques reached statistical significance. In the meta-analysis of narrow tonsillectomy categories (Table 14), adjusted for study design, bipolar diathermy dissection and haemostasis (OR 2.86, 95% CrI 1.12 to 8.02), coblation (OR 3.75, 95% CrI 1.29 to 12.12),

monopolar diathermy dissection and haemostasis (OR 4.12, 95% CrI 1.12 to 14.67), cold steel dissection with monopolar diathermy haemostasis (OR 4.83, 95% CrI 1.56 to 15.95) and cold steel dissection with bipolar diathermy haemostasis (OR 9.18, 95% CrI 3.09 to 30.53) were all associated with statistically significant more overall secondary haemorrhage compared with cold steel dissection with ties/packs haemostasis (reference technique). In the meta-analysis of both broad and narrow categories, the non-randomised comparative studies (OR 1.75, 95% CrI 0.50 to 6.49, and OR 2.69, 95% CrI 0.75 to 9.62 respectively) and case series (OR 1.24, 95% CrI 0.35 to 4.48, and OR 1.92, 95% CrI 0.52 to 7.01 respectively) suggested a higher event rate than the RCTs (reference study design).

Table 13 Meta-analysis models, all secondary haemorrhage, broad categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Diathermy	3226	303	1.50	0.93 to 2.45	1.47	0.90 to 2.43
Coblation	976	40	0.85	0.45 to 1.56	0.82	0.43 to 1.56
Cold steel with diathermy and/or ties haemostasis	3509	179	1.34	0.84 to 2.14	1.30	0.81 to 2.10
Cold steel with ties haemostasis	2730	86	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					1.75	0.50 to 6.49
Prospective case series					1.24	0.35 to 4.48

Notes:

1. N = cumulative number of patients analysed by the studies; n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.

Table 14 Meta-analysis models, all secondary haemorrhage, narrow categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Monopolar diathermy dissection and haemostasis	1178	191	3.31	0.98 to 13.00	4.12	1.12 to 14.67
Bipolar diathermy dissection and haemostasis	1826	96	2.63	1.06 to 7.89	2.86	1.12 to 8.02
Coblation dissection and haemostasis	976	40	3.35	1.16 to 11.56	3.75	1.29 to 12.12
Cold steel dissection with monopolar diathermy haemostasis	188	25	4.10	1.39 to 14.74	4.83	1.56 to 15.95
Cold steel dissection with bipolar diathermy haemostasis	1043	71	8.20	2.75 to 29.37	9.18	3.09 to 30.53
Cold steel dissection with diathermy or ties + diathermy haemostasis	1073	50	1.18	0.46 to 3.51	1.24	0.47 to 3.52
Cold steel dissection with ties/packs haemostasis	2730	86	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					2.69	0.75 to 9.62
Prospective case series					1.92	0.52 to 7.01

Notes:

1. N = cumulative number of patients analysed by the studies, n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.

Summary

Overall (excluding within-patient studies), the crude rate for all secondary haemorrhage was lowest for cold steel dissection with ties/packs haemostasis (3.2%, 95% CI 2.6 to 3.9%) and highest for monopolar diathermy dissection and haemostasis (16.2%, 95% CI 14.2 to 18.4%). In the within-patient studies, the rate for all secondary haemorrhage was lowest for cold steel dissection with ties/packs plus diathermy haemostasis (0%) and for coblation (0%), with the highest rate associated with cold steel dissection with bipolar diathermy haemostasis (6.3%). In the England and Northern Ireland NPTA final report the rate was lowest for cold steel dissection with ties/packs haemostasis (1.0%, 95% CI 0.7 to 1.3%) and highest for monopolar diathermy dissection and haemostasis (5.5%, 95% CI 3.8 to 8.0%). Data from the Wales SISP indicated that the rate was lowest for cold steel dissection with monopolar diathermy haemostasis (0%, 95% CI 0 to 9.0%) and highest for bipolar diathermy dissection and haemostasis (8.9%, 95% CI 6.3 to 12.5%). In the meta-analysis of narrow tonsillectomy categories, adjusted for study design, the reference technique of cold steel dissection with ties/packs haemostasis was associated with the lowest overall secondary haemorrhage. Bipolar diathermy dissection and haemostasis (OR 2.86, 95% CrI 1.12 to 8.02), coblation (OR 3.75, 95% CrI 1.29 to 12.12), monopolar diathermy dissection and haemostasis (OR 4.12, 95% CrI 1.12 to 14.67), cold steel dissection with monopolar diathermy haemostasis (OR 4.83, 95% CrI 1.56 to 15.95) and cold steel dissection with bipolar diathermy haemostasis (OR 9.18, 95% CrI 3.09 to 30.53) were all associated with statistically significant higher overall secondary haemorrhage.

Primary haemorrhage

- **Primary haemorrhage requiring return to theatre**

Overview

Thirty-one studies involving 6157 patients reported primary haemorrhage requiring return to theatre, including three RCTs,[35,37,42] ten within-patient studies,[7,49,73-76,78-81] nine non-randomised comparative studies,[6,46,48,50,52-54,58,60] and nine case series.[5,61,63,66-71]

For each intervention, the crude overall rates of primary haemorrhage requiring return to theatre across the 21 studies reporting this outcome (excluding within-patient studies) are shown in Table 15, along with the range of results. No study involving cold steel dissection with monopolar diathermy haemostasis reported the outcome of primary haemorrhage requiring return to theatre. For each intervention, the crude rates of primary haemorrhage requiring return to theatre by study type are shown in Table 16, along with the overall rates and registry data with 95% confidence intervals; blank cells indicate that the data were not reported. Individual study results for this outcome along with registry data are given in Appendix 6.

Table 15 Overall rates of primary haemorrhage requiring return to theatre

	All studies (21) (excluding within-patient studies and registries)		Within-patient studies (10)	
Technique	**N/n**	**Rate (range)**	**N/n**	**Rate (range)**
Cold steel dissection with ties/packs haemostasis	574/5	0.9% (0-3.6%)	478/0	0%
Cold steel dissection with diathermy or ties+diathermy haemostasis	688/3	0.4% (0-0.8%)	110/1	0.9% (0-1.0%)
Cold steel dissection with bipolar diathermy haemostasis	883/2	0.2% (0-0.3%)	32/0	0%
Cold steel dissection with monopolar diathermy haemostasis	Outcome not reported		255/1	0.4% (0-1.0%)
Coblation	916/3	0.3% (0-5.6%)	10/0	0%
Bipolar diathermy dissection and haemostasis	1319/1	0.1% (0-0.3%)	210/0	0%
Monopolar diathermy dissection and haemostasis	1053/3	0.3% (0-0.4%)	42/0	0%

Note:

1. N = number of participants analysed by the study, n = number of participants experiencing primary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing primary haemorrhage.

Table 16 Primary haemorrhage requiring return to theatre, by tonsillectomy technique, overall rates by study type

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties + diathermy haemostasis			Cold steel dissection + ties/packs haemostasis		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
RCTs (3)																					
Total				180	0	0%	18	0	0%				100	0	0%				60	1	1.7%
Broad groups	180 0 0%						18	0	0%	100 0 0%									60	1	1.7%
Non-randomised comparative studies (9)																					
Total				452	0	0%	898	3	0.3%				783	2	0.3%	196	0	0%	88	1	1.1%
Broad groups	504 0 0%						898	3	0.3%	979 2 0.2%									88	1	1.1%
Case series (9)																					
Total	1053	3	0.3%	687	1	0.1%										492	3	0.6%	426	3	0.7%
Broad groups	1740 4 0.2%									492 3 0.6%									426	3	0.7%
Grand total (95% CI)	1053 3 0.3% (0.1% to 0.8%)			1319 1 0.1% (0% to 0.4%)			916 3 0.3% (0.1% to 1.0%)						883 2 0.2% (0.1% to 0.8%)			688 3 0.4% (0.1% to 1.3%)			574 5 0.9% (0.4% to 2.0%)		
Broad groups (95% CI)	2424 4 0.2% (0.1% to 0.4%)						916 3 0.3% (0.1% to 1.0%)			1571 5 0.3% (0.1% to 0.7%)									574 5 0.9% (0.4% to 2.0%)		
Within-patient studies (10)																					
Total	42	0	0%	210	0	0%	10	0	0%	255	1	0.4%	32	0	0%	110	1	0.9%	478	0	0%
Broad groups	459 0 0%						10	0	0%	397 2 0.5%									478	0	0%
National registries																					
SISP 2005 (95% CI)				325 2 0.6% (0.2% to 2.2%)			221 0 0% (0% to 1.7%)			39 0 0% (0% to 9.0%)			141 0 0% (0% to 2.7%)			768 4 0.5% (0.2% to 1.3%)			1535 17 1.1% (0.7% to 1.8%)		
NPTA 2005 (95% CI)	452 4 0.9% (0.3% to 2.3%)			12562 40 0.3% (0.2% to 0.4%)			1565 17 1.1% (0.7% to 1.7%)			1772 11 0.6% (0.3% to 1.1%)			11956 36 0.3% (0.2% to 0.4%)						4285 30 0.7% (0.5% to 1.0%)		

Notes:

1. CI = confidence interval, N = number of participants analysed by the study, n = number of participants experiencing primary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing primary haemorrhage.
2. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).
3. Total and Broad groups rows are excluding England and Northern Ireland NPTA 2005 (final report) and Wales SISP 2005.
4. 95% CIs for Grand total and Broad groups rows are based upon the crude rate estimates.
5. Wales SISP 2005. Patient numbers do not sum to 3690 as some categories of operative technique have not been included. See Table 8, note 5.
6. England and Northern Ireland NPTA 2005 (final report). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.
7. England and Northern Ireland NPTA 2005 (final report). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.
8. For the NPTA 2005 (final report), for each technique, the numbers of patients experiencing a primary haemorrhage requiring return to theatre were calculated from the numbers of patients undergoing each technique and the primary haemorrhage requiring a return to theatre rate for each technique.

Direct comparisons

a. Cold steel dissection with ties/packs haemostasis versus cold steel dissection with monopolar diathermy haemostasis

Two within-patient studies[78,80] involving 255 patients reported this comparison, with one (0.4%) patient experiencing a primary haemorrhage on the side treated by monopolar diathermy haemostasis requiring return to theatre compared with none of the patients on the side treated by ties/packs haemostasis.

b. Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis

One RCT,[37] two within-patient studies,[74,75] and two non-randomised studies[48,58] involving 416 patients reported this comparison. In the RCT by Pang and colleagues[37] one (1.7%) of 60 patients undergoing the cold steel technique experienced a primary haemorrhage requiring return to theatre compared with none of the 60 patients undergoing bipolar diathermy. In the two non-randomised studies[48,58] one (1.1%) of 88 patients undergoing the cold steel technique experienced an event compared with none of the 89 patients undergoing bipolar diathermy. In the two within-patient studies[74,75] involving 119 patients no patient experienced an event.

One within-patient study[79] involving 104 patients compared cold steel dissection with ties/packs haemostasis versus diathermy (technique not stated) dissection and haemostasis, with no patient experiencing an event.

c. Cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis versus diathermy dissection and haemostasis

One RCT,[35] three within-patient studies[49,76,81] and four non-randomised comparative studies[50,52,54,60] involving 945 patients reported this comparison. The studies compared cold steel dissection with bipolar diathermy haemostasis versus bipolar

diathermy dissection and haemostasis,[35,50,76] cold steel dissection with bipolar diathermy haemostasis or ties plus bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis[49,52,54] and cold steel dissection with diathermy or ties plus diathermy haemostasis versus diathermy (technique not stated) dissection and haemostasis.[60,81] In the within-patient study by Weimert and colleagues[81] one (1.0%) of 103 patients experienced a primary haemorrhage on the side receiving cold steel dissection that required a return to theatre while no patient experienced an event on the side receiving diathermy dissection. No patient in any of the other studies experienced a primary haemorrhage requiring return to theatre.

d. Bipolar versus monopolar diathermy dissection and haemostasis

In the within-patient study by Akkielah and colleagues[73] none of the 42 patients experienced a primary haemorrhage requiring return to theatre.

e. Coblation versus bipolar diathermy

One RCT,[42] one within-patient study[7] and one non-randomised study[53] involving 113 patients compared coblation with bipolar diathermy. In the RCT by Temple and colleagues[42] none of the 18 patients undergoing coblation or of the 20 patients undergoing bipolar diathermy experienced an event and in the within-patient study by Timms and colleagues[7] none of the 10 patients experienced an event. In the non-randomised study by Noon and colleagues[53] two (6%) of 36 patients undergoing coblation experienced a primary haemorrhage requiring return to theatre while none of the 29 patients undergoing bipolar diathermy experienced an event.

f. Coblation versus cold steel dissection with bipolar diathermy haemostasis or ties plus bipolar diathermy haemostasis

Two non-randomised studies[6,46] involving 1624 patients compared coblation versus cold steel dissection with bipolar diathermy or ties plus bipolar diathermy haemostasis[46] or versus cold steel dissection with bipolar diathermy haemostasis.[6] In the study by Back and colleagues[46] none of the 18 patients undergoing coblation or of the 19 patients undergoing the cold steel technique experienced a primary

haemorrhage requiring return to theatre. In the study by Belloso and colleagues[6] one (0.1%) of 844 patients undergoing coblation experienced an event compared with two (0.3%) of 743 patients undergoing the cold steel technique.

National prospective tonsillectomy audits

a. England and Northern Ireland National Prospective Tonsillectomy Audit

The England and Northern Ireland NPTA final report (NPTA 2005) provided data for primary haemorrhage requiring return to theatre for 33,921 patients who underwent tonsillectomy between July 2003 and September 2004. Rates by intervention technique are shown in Table 16. These ranged from 0.3% for both cold steel dissection with bipolar diathermy haemostasis, and bipolar diathermy dissection and haemostasis, to 1.1% for coblation.

b. Scottish Tonsillectomy Audit

According to the Scottish Otolaryngology Society, of 6200 patients undergoing tonsillectomy and/or adenoidectomy operations in Scotland from April 2002 to March 2003, 22 (0.4%) experienced a primary haemorrhage requiring return to theatre.[19] No data were available, however, for rates of primary haemorrhage requiring return to theatre according to intervention technique.

We subsequently obtained additional/updated information on the Scottish Tonsillectomy Audit for the period April 2002 to March 2003 (personal communication, meeting between J Burr and B Bingham, Southern General Hospital, Glasgow, 2004) which indicated that of the 22 patients who experienced a primary haemorrhage requiring returned to theatre, the method of haemostasis had been diathermy (eight patients), ties (four patients), both diathermy and ties (five patients) and was not recorded in five patients. However as information on tonsillectomy technique was not available for all patients who underwent tonsillectomy, it was not possible to calculate the rate of primary haemorrhage requiring return to theatre by intervention technique.

c. Wales Single-use Instrument Surveillance Programme

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported primary haemorrhage requiring return to theatre for 3690 patients who underwent tonsillectomy/adenotonsillectomy between February 2003 and March 2004. Rates by intervention technique are shown in Table 16. These ranged from 0% (cold steel dissection with either bipolar or monopolar diathermy haemostasis, or coblation) to 1.1% (cold steel dissection with ties/packs haemostasis).

Prospective case series

Nine case series involving 2658 patients reported primary haemorrhage requiring return to theatre. The overall rates by intervention technique are shown in Table 16. No case series involving cold steel dissection with monopolar diathermy haemostasis, or of coblation, reported primary haemorrhage requiring return to theatre.

Meta-analysis

In the meta-analysis of broad categories (Table 17), adjusted for study design, diathermy dissection and haemostasis (OR 0.06) was associated with statistically less primary haemorrhage requiring return to theatre than cold steel dissection with ties/packs haemostasis (reference technique). Cold steel dissection with ties/packs and/or diathermy haemostasis (OR 0.27) and coblation (OR 0.42) were also associated with less primary haemorrhage requiring return to theatre than cold steel dissection with ties/packs haemostasis, but without reaching statistical significance. In the meta-analysis of narrow categories (Table 18), adjusted for study design, bipolar diathermy dissection and haemostasis (OR 0.002) was associated with statistically less primary haemorrhage requiring return to theatre than cold steel dissection with ties/packs haemostasis. All of the other techniques were also associated with less primary haemorrhage requiring return to theatre than the reference technique, but without reaching statistical significance. The extremely wide credible intervals reflect the large degree of uncertainty surrounding these

results. No studies of cold steel dissection with monopolar diathermy haemostasis reported the outcome of primary haemorrhage requiring return to theatre. In the meta-analysis of both broad and narrow categories the non-randomised comparative studies (OR 1.45 and OR 2.40 respectively) and case series (OR 3.92 and OR 45.77 respectively) suggested a higher event rate than the RCTs (reference study design).

Table 17 Meta-analysis models, primary haemorrhage requiring return to theatre, broad categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Diathermy	2424	4	0.13	0.008 to 0.70	0.06	<0.001 to 0.60
Coblation	916	3	0.40	0.03 to 3.17	0.42	0.004 to 6.83
Cold steel with diathermy and/or ties haemostasis	1571	5	0.32	0.03 to 2.05	0.27	0.004 to 3.44
Cold steel with ties haemostasis	574	5	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					1.45	0.018 to 200.20
Prospective case series					3.92	0.15 to 1093.00

Notes:

1. N = cumulative number of patients analysed by the studies, n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.

Table 18 Meta-analysis models, primary haemorrhage requiring return to theatre, narrow categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Monopolar diathermy dissection and haemostasis	1053	3	0.25	0.005 to 6.20	0.03	<0.001 to 14.60
Bipolar diathermy dissection and haemostasis	1319	1	0.03	<0.001 to 0.48	0.002	<0.001 to 0.26
Coblation dissection and haemostasis	916	3	0.39	0.01 to 6.30	0.45	<0.001 to 216.30
Cold steel dissection with monopolar diathermy haemostasis	No studies					
Cold steel dissection with bipolar diathermy haemostasis	883	2	0.32	0.01 to 8.90	0.54	<0.001 to 520.00
Cold steel dissection with ties + diathermy haemostasis	688	3	0.23	0.001 to 2.64	0.02	<0.001 to 2.46
Cold steel dissection with ties/packs haemostasis	574	5	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					2.40	0.001 to 10,870.00
Prospective case series					45.77	0.09 to >10,000.00

Notes:

1. N = cumulative number of patients analysed by the studies, n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.

Summary

Across studies the crude overall rate of primary haemorrhage requiring return to theatre was lowest for bipolar diathermy dissection and haemostasis (0.1%, 95% CI 0 to 0.4%) and highest for cold steel dissection with ties/packs haemostasis (0.9%, 95% CI 0.4 to 2.0%). In the England and Northern Ireland NPTA final report the lowest rates were associated with cold steel dissection with bipolar diathermy haemostasis (0.3%, 95% CI 0.2 to 0.4%) and bipolar diathermy dissection and haemostasis (0.3%, 95% CI 0.2 to 0.4%), while the highest rates were associated with coblation (1.1%, 95% CI 0.7 to 1.7%) and monopolar diathermy dissection and haemostasis (0.9%, 95% CI 0.3 to 2.3%). Data from the Wales SISP indicated that rates were lowest for cold steel dissection with either bipolar (0%, 95% CI 0 to 2.7%) or monopolar (0%, 95% CI 0 to 9.0%) diathermy haemostasis, or coblation (0%, 95% CI 0 to 1.7%) and highest for cold steel dissection with ties/packs haemostasis (1.1%, 95% CI 0.7 to 1.8%). In the meta-analysis of narrow tonsillectomy categories, adjusted for study design, bipolar diathermy dissection and haemostasis (OR 0.002) was associated with statistically significant less primary haemorrhage requiring return to theatre than cold steel dissection with ties/packs haemostasis (reference technique). All other techniques were also associated with less primary haemorrhage requiring return to theatre compared with the reference technique, but without reaching statistical significance. However the extremely wide credible intervals reflected the rarity of primary haemorrhage requiring return to theatre and the associated large degree of uncertainty surrounding the meta-analysis results for this outcome.

- **Primary haemorrhage requiring blood transfusion**

Overview

Twenty-four studies involving 2810 patients reported this outcome, including two RCTs,[35,42] nine within-patient studies,[7,49,73-76,78-80] seven non-randomised studies[48,50,52-54,58,60] and six case series.[5,63,64,68,69,71] In these studies no patient experienced a primary haemorrhage requiring blood transfusion. Information from the Scottish Tonsillectomy Audit indicated that one (0.02%) of 6200 patients experienced a primary haemorrhage requiring blood transfusion.

Direct comparisons

In 18 comparative studies reporting this outcome no patient out of 1158 experienced a primary haemorrhage requiring blood transfusion. The studies compared: cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis;[48,58,74,75] cold steel dissection with ties/packs haemostasis versus cold steel dissection with monopolar diathermy haemostasis;[78,80] cold steel dissection with ties/packs haemostasis versus diathermy (technique not stated) dissection and haemostasis;[79] cold steel dissection with diathermy or ties plus diathermy haemostasis versus bipolar diathermy dissection and haemostasis;[49,52,54] cold steel dissection with diathermy or ties plus diathermy haemostasis versus diathermy (technique not stated) dissection and haemostasis;[60] cold steel dissection with bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis;[35,50,76] bipolar diathermy dissection and haemostasis versus coblation;[7,42,53] and bipolar versus monopolar diathermy dissection and haemostasis.[73]

National prospective tonsillectomy audits

a. England and Northern Ireland National Prospective Tonsillectomy Audit

The NPTA final report (NPTA 2005) stated that eight (0.02%) of 33,921 patients experienced a primary haemorrhage requiring a blood transfusion, six of whom were

returned to theatre. However, no information was provided on the tonsillectomy technique that the eight patients had undergone.

b. Scottish Tonsillectomy Audit

The Scottish Tonsillectomy Audit one-page summary table covering the period April 2002 to March 2003 issued by the Chief Medical Officer in Scotland[19] gave no details of primary haemorrhage requiring blood transfusion. However, we subsequently obtained additional/updated information on the Scottish Tonsillectomy Audit for this period (personal communication, meeting between J Burr and B Bingham, Southern General Hospital, Glasgow, 2004), which indicated that of the 6200 patients who underwent tonsillectomy, adenotonsillectomy or adenoidectomy, one (0.02%) experienced a primary haemorrhage requiring a blood transfusion.

c. Wales Single-use Instrument Surveillance Programme

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported that none of the 3690 tonsillectomy procedures undertaken between February 2003 and March 2004 resulted in any patient experiencing a primary haemorrhage that required blood transfusion.

Prospective case series

In six case series reporting this outcome no patient out of a total of 1158 experienced a primary haemorrhage requiring blood transfusion. The case series reported: cold steel dissection with ties/packs haemostasis;[69] cold steel dissection with packs plus bipolar diathermy haemostasis;[63] cold steel dissection with diathermy (technique not stated) haemostasis;[64] bipolar diathermy dissection and haemostasis;[5,68] and monopolar diathermy dissection and haemostasis.[71]

Meta-analysis

This outcome was not considered in a meta-analysis due to the rarity of events.

Summary

In 24 studies involving 2810 patients no patient experienced a primary haemorrhage requiring blood transfusion. The England and Northern Ireland NPTA final report stated that eight (0.02%) of 33,921 patients experienced a primary haemorrhage requiring a blood transfusion. Data obtained from the Scottish Tonsillectomy Audit indicated that one (0.02%) of 6200 patients who underwent tonsillectomy, adenotonsillectomy or adenoidectomy experienced a primary haemorrhage requiring a blood transfusion. Data from the Wales SISP indicated that, of 3690 tonsillectomy procedures undertaken, none resulted in primary haemorrhage requiring blood transfusion.

- **All primary haemorrhage**

Overview

Thirty-nine studies involving 9648 patients reported all primary haemorrhage as an outcome, including five RCTs,[35,37,41-43] ten within-patient studies,[7,49,73-76,78-81] 14 non-randomised comparative studies[6,46,48-50,52-60] and 10 case series.[5,61,63,64,66-71]

For each intervention, the crude overall rates of all primary haemorrhage are shown in Table 19, along with the range of results. For each intervention, the crude rates for all primary haemorrhage by study type are shown in Table 20, along with the overall rates and registry data with 95% confidence intervals; blank cells indicate that the data were not reported. Individual study results for this outcome along with registry data are given in Appendix 7.

Table 19 Overall rates for all primary haemorrhage

Technique	All studies (29) (excluding within-patient studies and registries)		Within-patient studies (10)	
	N/n	Rate (range)	N/n	Rate (range)
Cold steel dissection with ties/packs haemostasis	1906/52	2.7% (0.9-5.1%)	478/0	0%
Cold steel dissection with diathermy or ties+diathermy haemostasis	1030/21	2.0% (0-15.8%)	110/1	0.9% (0-1.0%)
Cold steel dissection with bipolar diathermy haemostasis	883/3	0.3% (0-0.4%)	32/0	0%
Cold steel dissection with monopolar diathermy haemostasis	Outcome not reported		255/1	0.4% (0-1.0%)
Coblation	959/14	1.5% (0-27.8%)	10/0	0%
Bipolar diathermy dissection and haemostasis	1676/8	0.5% (0-2.4%)	210/0	0%
Monopolar diathermy dissection and haemostasis	1095/12	1.1% (0-2.4%)	42/0	0%

Note:

1. N = number of participants analysed by the study, n = number of participants experiencing primary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing primary haemorrhage.

Table 20 All primary haemorrhage (irrespective of severity), by tonsillectomy technique, overall rates by study type

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties + diathermy haemostasis			Cold steel dissection + ties/packs haemostasis		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
RCTs (5)																					
Total	42	0	0%	180	0	0%	61	1	1.6%				100	0	0%				573	13	2.3%
Broad groups	222 0 0%						61	1	1.6%	623 15 2.4%									573	13	2.3%
Non-randomised comparative studies (14)																					
Total				809	5	0.6%	898	13	1.4%				783	3	0.4%	538	15	2.8%	907	35	3.9%
Broad groups	1031 7 0.7%						898	13	1.4%	1811 27 1.5%									907	35	3.9%
Case series (10)																					
Total	1053	12	1.1%	687	3	0.4%										492	6	1.2%	426	4	0.9%
Broad groups	1740 15 0.9%									684 10 1.5%									426	4	0.9%
Grand total (95% CI)	1095 12 1.1% (0.6% to 1.9%)			1676 8 0.5% (0.2% to 0.9%)			959 14 1.5% (0.9% to 2.4%)						883 3 0.3% (0.1% to 0.9%)			1030 21 2.0% (1.5% to 3.4%)			1906 52 2.7% (2.1% to 3.6%)		
Broad groups (95% CI)	2993 22 0.7% (0.5% to 1.1%)						959 14 1.5% (0.9% to 2.4%)			3118 52 1.7% (1.3% to 2.2%)									1906 52 2.7% (2.1% to 3.6%)		
Within-patient studies (10)																					
Total	42	0	0%	210	0	0%	10	0	0%	255	1	0.4%	32	0	0%	110	1	0.9%	478	0	0%
Broad groups	459 0 0%						10	0	0%	397 2 0.5%									478	0	0%
National registries																					
SISP 2005 (95% CI)				325 3 0.9% (0.3% to 2.7%)			221 1 0.5% (0.1% to 2.5%)			39 0 0% (0% to 9.0%)			141 0 0% (0% to 2.7%)			768 6 0.8% (0.4% to 1.7%)			1535 19 1.2% (0.8% to 1.9%)		
NPTA 2005 (95% CI)	452 5 1.1% (0.5% to 2.6%)			12562 55 0.4% (0.3% to 0.6%)			1565 16 1.0% (0.6% to 1.7%)			1772 9 0.5% (0.3% to 1.0%)			11956 60 0.5% (0.4% to 0.6%)						4285 34 0.8% (0.6% to 1.1%)		

Notes:

1. CI = confidence interval, N = number of participants analysed by the study, n = number of participants experiencing primary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing primary haemorrhage.
2. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).
3. Total and Broad groups rows are excluding England and Northern Ireland NPTA 2005 (final report) and Wales SISP 2005.
4. 95% CIs for Grand total and Broad groups rows are based upon the crude rate estimates.
5. Wales SISP 2005. Patient numbers do not sum to 3690 as some categories of operative technique have not been included. See Table 8, note 5.
6. England and Northern Ireland NPTA 2005 (final report). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.
7. England and Northern Ireland NPTA 2005 (final report). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.
8. For the NPTA 2005 (final report), for each technique, the numbers of patients experiencing a primary haemorrhage were calculated from the numbers of patients undergoing each technique and the primary haemorrhage rate for each technique.

Direct comparisons

a. Cold steel dissection with ties/packs haemostasis versus cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis

One RCT,[43] two within-patient studies[78,80] and two non-randomised comparative studies[55,56] involving 2375 patients reported this comparison. In the RCT by Watson and colleagues[43] 12 (2.3%) of 513 patients undergoing cold steel dissection with ties/packs haemostasis experienced a primary haemorrhage compared with 15 (2.9%) of 523 patients who underwent diathermy (technique not stated) haemostasis. In the two within-patient studies[78,80] comparing cold steel dissection with ties haemostasis versus cold steel dissection with monopolar diathermy haemostasis, none of the 255 patients experienced a primary haemorrhage on the side receiving ties/packs haemostasis compared with one (0.4%) patient who experienced an event on the side treated by monopolar diathermy haemostasis. In the two non-randomised studies[55,56] 19 (3.5%) of 537 patients who underwent cold steel dissection with ties/packs haemostasis experienced a primary haemorrhage compared with 12 (2.2%) of 547 patients who underwent diathermy (technique not stated) haemostasis or ties plus bipolar diathermy haemostasis.

b. Cold steel dissection with ties/packs haemostasis versus diathermy dissection and haemostasis

One RCT,[37] two within-patient studies[74,75] and two non-randomised comparative studies[48,58] involving 416 patients compared cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis. In the RCT by Pang and colleagues[37] one (1.7%) of 60 patients who underwent the cold steel technique experienced a primary haemorrhage compared with none of the 60 patients who received bipolar diathermy. In the two within-patient studies[74,75] none of the 119 patients experienced a primary haemorrhage. In the two non-randomised studies[48,58] two (2.3%) of 88 patients who underwent the cold steel technique experienced a primary haemorrhage compared with none of 89 patients who underwent bipolar diathermy.[48,58] In a non-randomised study by Tan and

colleagues[59] 14 (5.0%) of 282 patients who underwent cold steel dissection with ties/packs haemostasis experienced a primary haemorrhage compared with two (1.2%) of 170 who underwent diathermy (technique not stated) dissection and haemostasis. A within-patient study by Tay and colleagues[79] comparing cold steel dissection with ties/packs haemostasis versus diathermy (technique not stated) dissection and haemostasis reported that none of the 104 patients experienced a primary haemorrhage.

c. Cold steel dissection with diathermy haemostasis or ties/packs plus diathermy haemostasis versus diathermy dissection and haemostasis

One RCT,[35] three within-patient studies[49,76,81] and six non-randomised studies[49,50,52,54,57,60] involving 1587 patients reported this comparison. In the RCT by Kujawski and colleagues[35] none of the 100 patients in either the cold steel dissection with bipolar diathermy haemostasis group or bipolar diathermy dissection and haemostasis group experienced a primary haemorrhage. In the within-patient study by Haraldsson and colleagues[76] comparing cold steel dissection with bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis none of the 32 patients experienced a primary haemorrhage. The non-randomised study by MacGregor and colleagues[50] also reported that none of the 40 patients undergoing cold steel dissection with bipolar diathermy haemostasis or of the 36 patients undergoing bipolar diathermy dissection and haemostasis experienced a primary haemorrhage. In four non-randomised studies[49,52,54,57] nine (1.4%) of 644 patients receiving cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis experienced a primary haemorrhage compared with five (0.8%) of 655 patients undergoing bipolar diathermy dissection and haemostasis. The study by Schrey and colleagues[57] accounted for most of these, with nine (6.4%) of 140 patients who underwent cold steel dissection with packs plus monopolar diathermy haemostasis and four (2.4%) of 165 patients who underwent bipolar diathermy dissection and haemostasis experiencing a primary haemorrhage. In the within-patient study by Lee and colleagues[49] none of the seven patients undergoing cold steel dissection with ties plus bipolar diathermy haemostasis or bipolar diathermy dissection and haemostasis experienced an event. In the within-patient study by Weimert and colleagues[81] one (1.0%) of 103 patients experienced a primary

haemorrhage on the side treated by cold steel dissection with diathermy or ties plus diathermy haemostasis while no patient experienced a primary haemorrhage on the side treated by diathermy (technique not stated) dissection and haemostasis. In the non-randomised study by Wexler and colleagues[60] none of the 49 patients who underwent cold steel dissection with diathermy or ties plus diathermy haemostasis or of the 52 who underwent diathermy (technique not stated) dissection and haemostasis experienced a primary haemorrhage.

d. Bipolar versus monopolar diathermy

One within-patient study[73] reported that none of the 42 patients experienced a primary haemorrhage.

e. Coblation versus diathermy

One RCT,[42] one within-patient study[7] and one non-randomised study[53] involving 113 patients compared coblation with bipolar diathermy, with event rates of 0%, 0% and 8% respectively for coblation while no patient undergoing bipolar diathermy experienced an event. In an RCT by Stoker and colleagues[41] one (2.3%) of 43 patients undergoing coblation experienced a primary haemorrhage compared with none of 42 patients who underwent monopolar diathermy.

f. Coblation versus cold steel dissection with diathermy haemostasis or ties plus diathermy haemostasis

Two non-randomised studies involving 1624 patients[6,46] compared coblation versus cold steel dissection with bipolar diathermy haemostasis[6] or ties plus bipolar diathermy haemostasis;[46] most patients (n = 1587) were from the study by Belloso and colleagues.[6] Ten (1.2%) of 862 patients undergoing coblation experienced a primary haemorrhage compared with six (0.8%) of 762 patients who underwent the cold steel technique.

National prospective tonsillectomy audits

a. England and Northern Ireland National Prospective Tonsillectomy Audit

The NPTA final report (NPTA 2005) provided data for all primary haemorrhage for 33,921 patients who underwent tonsillectomy between July 2003 and September 2004. Rates by intervention technique are shown in Table 20. These ranged from 0.4% (bipolar diathermy dissection and haemostasis) to 1.1% (monopolar diathermy dissection and haemostasis). Cold steel dissection with bipolar or monopolar diathermy haemostasis were both associated with rates of 0.5% while coblation was associated with a rate of 1.0%.(NPTA 2005)

b. Scottish Tonsillectomy Audit

The Scottish Tonsillectomy Audit one page summary table covering the period April 2002 to March 2003 issued by the Chief Medical Officer in Scotland[19] gave no figures for overall primary haemorrhage. Subsequently obtained additional/updated information on the Scottish Tonsillectomy Audit for this period (personal communication, meeting between J Burr and B Bingham, Southern General Hospital, Glasgow, 2004) gave no indication of the overall number of patients who experienced a primary haemorrhage. However, this number would have been at least 22, as this was the number of patients who were returned to theatre during their initial stay because of a primary bleed.

c. Wales Single-use Instrument Surveillance Programme

Tomkinson and colleagues (SISP, University Hospital of Wales, 2005) reported primary haemorrhage that occurred during the initial admission and either required a return to theatre or was managed conservatively, for 3690 patients who underwent tonsillectomy/adenotonsillectomy between February 2003 and March 2004. These figures were combined in Table 20 to provide an indication of overall primary haemorrhage rates for different tonsillectomy techniques. The lowest rates were for cold steel dissection with either bipolar or monopolar diathermy haemostasis (0%) and the highest were for cold steel dissection with ties/packs haemostasis (1.2%).

Prospective case series

Ten case series involving 2850 patients reported all primary haemorrhage. The overall rates by intervention technique are shown in Table 20. No case series reported cold steel dissection with monopolar diathermy haemostasis, or coblation.

Meta-analysis

In the meta-analysis of broad categories (Table 21), adjusted for study design, diathermy (OR 0.22, 95% CrI 0.09 to 0.48) was associated with statistically significant less overall primary haemorrhage compared with the reference technique of cold steel dissection with ties/packs haemostasis. Cold steel dissection with ties/packs and/or diathermy haemostasis (OR 0.77) was associated with less, and coblation (OR 1.68) more, overall primary haemorrhage compared with the reference technique, but without reaching statistical significance. In the meta-analysis of narrow categories (Table 22), adjusted for study design, bipolar diathermy dissection and haemostasis (OR 0.13, 95% CrI 0.03 to 0.51) was associated with statistically significant less overall primary haemorrhage compared with cold steel dissection with ties/packs haemostasis (reference technique). Monopolar diathermy dissection and haemostasis (OR 0.36), cold steel dissection with bipolar diathermy haemostasis (OR 0.42) and cold steel dissection with ties/packs plus diathermy haemostasis (OR 0.48) were all associated with less overall primary haemorrhage than the reference technique, but without reaching statistical significance. No studies of cold steel dissection with monopolar diathermy haemostasis reported the outcome of overall primary haemorrhage. In the meta-analysis of both broad and narrow categories, the non-randomised comparative studies (OR 2.39, 95% CrI 0.41 to 16.25, and OR 2.96, 95% CrI 0.53 to 25.02 respectively) and case series (OR 1.87, 95% CrI 0.28 to 14.63, and OR 1.58, 95% CrI 0.22 to 18.45 respectively) suggested a higher event rate than the RCTs (reference study design).

Table 21 Meta-analysis models, all primary haemorrhage, broad categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Diathermy	2993	22	0.22	0.09 to 0.47	0.22	0.09 to 0.48
Coblation	959	14	1.68	0.60 to 4.75	1.68	0.60 to 4.84
Cold steel with diathermy and/or ties haemostasis	3118	52	0.77	0.47 to 1.25	0.77	0.47 to 1.25
Cold steel with ties haemostasis	1906	52	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					2.39	0.41 to 16.25
Prospective case series					1.87	0.28 to 14.63

Notes:

1. N = cumulative number of patients analysed by the studies; n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.

Table 22 Meta-analysis models, all primary haemorrhage, narrow categories

Categories	N	n	OR (unadjusted)	95% CrI	OR (adjusted for study design)	95% CrI
Monopolar diathermy dissection and haemostasis	1095	12	0.28	0.03 to 1.92	0.36	0.03 to 3.04
Bipolar diathermy dissection and haemostasis	1676	8	0.14	0.03 to 0.49	0.13	0.03 to 0.51
Coblation dissection and haemostasis	959	14	1.18	0.26 to 4.91	1.14	0.26 to 5.02
Cold steel dissection with monopolar diathermy haemostasis	No studies					
Cold steel dissection with bipolar diathermy haemostasis	883	3	0.42	0.06 to 2.71	0.42	0.06 to 2.78
Cold steel dissection with ties + diathermy haemostasis	1030	21	0.51	0.14 to 1.55	0.48	0.14 to 1.55
Cold steel dissection with ties/packs haemostasis	1906	52	Reference technique		Reference technique	
RCTs					Reference study design	
Non-randomised comparative studies					2.96	0.53 to 25.02
Prospective case series					1.58	0.22 to 18.45

Notes:

1. N = cumulative number of patients analysed by the studies, n = cumulative number of patients experiencing the event.
2. CrI. Credible interval with 95% probability of containing the true OR.

Summary

The crude overall rate for all primary haemorrhage in the included studies was lowest for cold steel dissection with bipolar diathermy haemostasis (0.3%, 95% CI 0.1 to 0.9%) and highest for cold steel dissection with ties/packs haemostasis (2.7%, 95% CI 2.1 to 3.6%). In the within-patient studies most of the intervention techniques were associated with a zero event rate, other than cold steel dissection with ties plus diathermy haemostasis (0.9% event rate) and cold steel dissection with monopolar diathermy haemostasis (0.4% event rate). In the England and Northern Ireland NPTA final report the rates were lowest for bipolar diathermy dissection and haemostasis (0.4%, 95% CI 0.3 to 0.6%) and cold steel dissection with either bipolar (0.5%, 95% CI 0.4 to 0.6%) or monopolar (0.5%, 95% CI 0.3 to 1.0%) diathermy haemostasis, while the highest rates were associated with monopolar diathermy dissection and haemostasis (1.1%, 95% CI 0.5 to 2.6%), and coblation (1.0%, 95% CI 0.6 to 1.7%). Data from the Wales SISP indicated that the lowest rates were for cold steel dissection with either bipolar (0%, 95% CI 0 to 2.7%) or monopolar (0%, 95% CI 0 to 9.0%) diathermy haemostasis, with the highest being for cold steel dissection with ties/packs haemostasis (1.2%, 95% CI 0.8 to 1.9%). In the meta-analysis of narrow categories, adjusted for study design, bipolar diathermy dissection and haemostasis was associated with statistically significant less overall primary haemorrhage (OR 0.13, 95% CrI 0.03 to 0.51) than cold steel dissection with ties/packs haemostasis (reference technique).

Other safety outcomes

- **Intraoperative blood loss**

Twenty studies involving 3107 patients reported intraoperative blood loss, including six RCTs,[35-38,40,45] three within-patient studies,[76,77,81] seven non-randomised comparative studies[46,50,56-60] and four case series.[61,68,70,71]

Figure 4 shows a meta-analysis of ten studies involving 1593 patients that compared cold steel dissection with ties and/or diathermy haemostasis versus diathermy dissection and haemostasis, using a random effects model (weighted means difference). There was a statistically significant lower intraoperative blood loss with diathermy dissection and haemostasis compared with cold steel dissection with ties and/or diathermy for haemostasis. The five studies in the meta-analysis where data were not estimable because no standard deviations were provided[38,57-60] also reported consistently less intraoperative blood loss with diathermy dissection and haemostasis.

Three other comparative studies excluded from the meta-analysis because of insufficient data compared different techniques. Rungby and colleagues[56] reported a median intraoperative blood loss of 100 mls for both cold steel dissection with ties and/or packs for haemostasis (range 25 to 600), and also for cold steel dissection with a combination of ties and bipolar diathermy haemostasis (range 0 to 1000). Back and colleagues[46] reported a median intraoperative blood loss of 20 mls (range 5 to 100) for cold steel dissection with a combination of ties and bipolar diathermy haemostasis compared with 80 mls (range 5 to 300) for coblation dissection and haemostasis. Shah and colleagues[40] reported a mean intraoperative blood loss of 90.9 mls (SD 35.3) for coblation dissection and haemostasis compared with 83.8 mls (SD 46.4) for monopolar diathermy dissection and haemostasis.

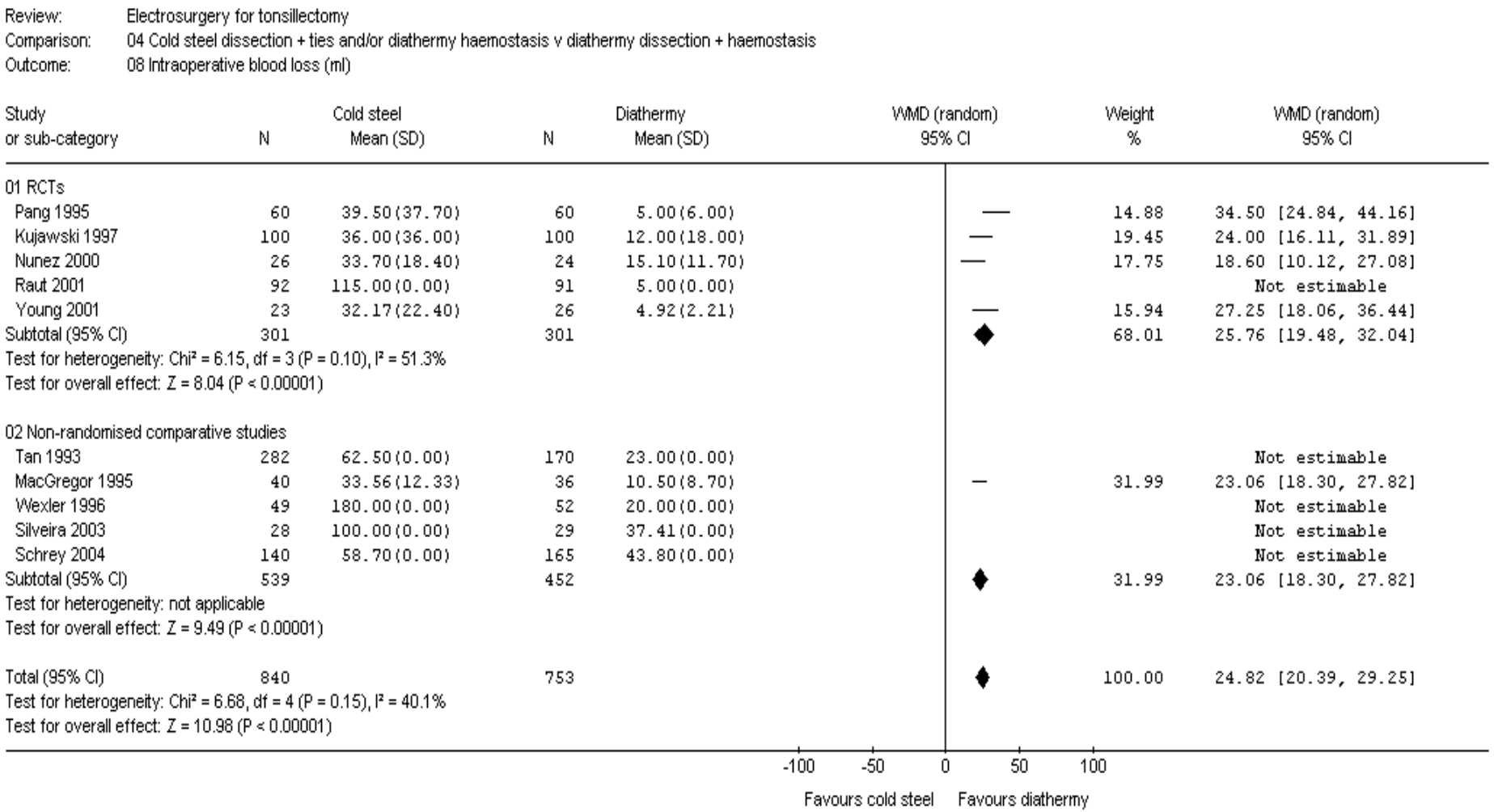
The three within-patient studies[76,77,81] all reported a greater mean blood loss for cold steel techniques compared with diathermy. In the study by Haraldsson and colleagues[76] mean blood loss was 47.0 mls for cold steel dissection with bipolar diathermy haemostasis compared with 2.4 mls for bipolar diathermy dissection and

haemostasis. In the studies by Leach and colleagues[77] and Weimert and colleagues[81] mean blood loss was 78.4 and 65.0 mls respectively for cold steel dissection with a combination of ties plus diathermy haemostasis compared with 26.6 and less than 5 mls for diathermy dissection and haemostasis.

Four case series reported diathermy for dissection and haemostasis. Three studies of monopolar diathermy[61,70,71] reported a mean intraoperative blood loss of 29.1 mls (range 0-500), 3.0 mls (range 0 to 70) and less than 25 mls respectively. Pang and colleagues[68] reported a mean intraoperative blood loss of 4.0 mls (range 0 to <25) for bipolar diathermy.

In summary, diathermy dissection and haemostasis was associated with a statistically significant lower rate of intraoperative blood loss compared with cold steel techniques.

Figure 4 **Intraoperative blood loss – cold steel dissection with ties and/or diathermy haemostasis compared with diathermy dissection and haemostasis**



- **Age and secondary haemorrhage**

The England and Northern Ireland NPTA final report (NPTA 2005) stated that adults had higher haemorrhage rates (primary and secondary combined) than children. Haemorrhage rates were: up to 5 years, 1.9%; 5 to 15 years, 3.0%; 16 years or older, 4.9%, although measures of statistical significance for these groups were not reported.(NPTA 2005) Nine studies involving 3180 patients reported the outcome of all secondary haemorrhage by age group, including two RCTs,[35,38] three within-patient studies,[78-80] three non-randomised comparative studies[6,49,60] and one case series[61] (see Table 23). The studies mostly compared different intervention techniques and reported secondary haemorrhage for a variety of different age categories. There was a tendency for older age groups to experience more secondary haemorrhage than younger age groups receiving the same interventional technique within the same study. None of the studies gave any indication whether the tonsillectomy technique used was in any way influenced by the age of the patient.

Only three studies[35,49,61] reported p values for secondary haemorrhage rates between different age groups who received the same interventional technique. Kujawski and colleagues[35] reported that the differences between patients less than seven years old and those aged seven years or more who received bipolar diathermy dissection and haemostasis, and who received cold steel dissection with bipolar diathermy haemostasis, were not statistically significant. Lee and colleagues[49] reported that adults who received bipolar diathermy dissection and haemostasis experienced a statistically significant higher rate of secondary haemorrhage than children ($p < 0.05$), while the differences between adults and children receiving cold steel dissection with ties plus diathermy haemostasis were not statistically significant. Blomgren and colleagues[61] reported that secondary haemorrhages were significantly more common in older patient groups, especially in patients 30 years of age or older ($p = 0.009$).

Table 23 Studies reporting secondary haemorrhage by age category

Study design and study id	Age categories	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
		N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
RCTs																						
Kujawski 1997[35]	**<7 years**				40	1	3%							40	2	5%						
	≥7 years				60	2	3%							60	6	10%						
Raut 2001[38]	**>10, <16 yrs**				18	3	17%				31	4	13%									
	≥16 years				73	11	15%				61`	13	21%									
Non-randomised comparative studies																						
Belloso 2003[6]	**≤16 years**							526	5	1%				482	23	5%						
	>16 years							318	14	4%				261	23	9%						
Lee 2004[49]	**Children**				94	6	6%										62	2	3%			
	Adults				98	17	17%										83	6	7%			
Wexler 1996[60]	**2-12 years**	26 1 4%															25	1	4%			
	≥13 years	26 7 27%															24	5	21%			
Case series																						
Blomgren 2001[61]	**<10 years**	106	7	7%																		
	10-19 years	164	26	16%																		
	20-29 years	86	17	20%																		
	≥30 years	57	16	28%																		
Within-patient studies																						
Salam 1992[78]	**4-12 years**										80	0	0%							80	0	0%
	13-45 years										70	1	1%							70	1	1%
Tay 1995[79]	**>7, <14 yrs**	31 0 0%																		31	0	0%
	≥14 years	73 2 3%																		73	2	3%
Tay 1996[80]	**>7, <14 yrs**										18	0	0%							18	0	0%
	≥14 years										87	0	0%							87	1	1%

Notes:

1. N = number of participants, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils operated on, n = number of fossae experiencing secondary haemorrhage.
2. Wexler 1996, Tay 1995, Tay 1996. Diathermy technique not specified.
3. Blomgren 2001. n = number of participants experiencing secondary haemorrhage who saw a doctor.

- **Power settings**

Nineteen studies provided information on power settings used, including five RCTs,[34,36,37,41,45] four within-patient studies,[7,73,76,80] six non-randomised comparative studies[46,48,50,53,58,60] and four case series.[61,68,70,71] Appendix 8 shows the tonsillectomy techniques and power settings used in the studies, along with the rates for all secondary haemorrhage and secondary haemorrhage requiring return to theatre. The wattage used ranged from 6 W for monopolar diathermy haemostasis following cold steel dissection in the RCT by Brodsky and colleagues[34] to 70 W for incision during monopolar diathermy dissection and haemostasis in the RCT by Nunez and colleagues.[36]

Given the relatively small number of studies reporting power settings and the limited information provided, it was not possible to draw conclusions regarding any possible association between different power settings and rates of secondary haemorrhage.

The England and Northern Ireland NPTA final report (NPTA 2005) noted that in multilevel multiple regression analysis, no association was found between haemorrhage rate and dissection power setting for bipolar diathermy dissection and haemostasis (adjusted OR 1.01 per increase of 1 watt, 95% CI 0.99 to 1.03, p = 0.3). When bipolar diathermy was used for haemostasis only, the overall risk of haemorrhage was estimated to increase by around 2% for every additional watt in power used for haemostasis (adjusted OR 1.02, 95% CI 1.0 to 1.4, p = 0.04).(NPTA 2005) The report concluded that there appeared to be a modest increase in the risk of haemorrhage with the diathermy power setting if diathermy was used for haemostasis only.(NPTA 2005)

- **Surgeon experience**

The England and Northern Ireland NPTA final report (NPTA 2005) stated that although haemorrhage rates were slightly higher in patients operated upon by junior grades of surgeon (specialist registrar and senior house officer) compared with those operated upon by senior surgeons, there was no statistically significant association between haemorrhage rates and grade of operating surgeon (see Table 24). The NPTA final report also stated that there was evidence that the risks associated with grades of surgeon might have changed between the period before and after the NICE interim guidance on the use of electrosurgery in tonsillectomy was issued in March 2004. The results of a comparison of two models of risk factors in the period before and after publication of the NICE guidance suggested that the risk of haemorrhage from senior house officers fell after the guidance was issued.(NPTA 2005)

Sixteen studies provided varying degrees of information about the experience of the surgeons carrying out the operations, including three RCTs[35,38,43] three within-patient studies,[49,75,77] seven non-randomised comparative studies[47,49,50,52,54,56,57] and three case series.[33,64,70] Of the RCTs, in the study by Kujawski and colleagues,[35] most of the procedures were performed by residents (non-consultants) in their early head and neck surgery training under the supervision of an experienced surgeon familiar with the techniques used. In the study by Raut and colleagues[38] tonsillectomy was carried out by three grades of surgeons (consultants, staff surgeons and senior specialist registrars) who were all familiar with the methods of tonsillectomy being used. Watson and colleagues[43] reported that the operating surgeon had been performing tonsillectomy regularly for at least six months. The within-patient study by Leach and colleagues[77] suggested that one possibility for more pain being noted on the cauterised side might have been the use of electrosurgery by inexperienced residents (non-consultants) leading to greater removal of the tonsillar pillar mucosa.

Of the non-randomised comparative studies, Carr and colleagues[47] reported that residents (non-consultants) performed tonsillectomies in the attending surgeon's usual manner and that in the cold steel group residents (non-consultants) performed surgery more often than other grades. In the study by MacGregor and colleagues[50]

one surgeon who was skilled in the bipolar diathermy dissection technique carried out this procedure on one list while another surgeon carried out blunt dissection tonsillectomies with bipolar diathermy haemostasis on the other list. Rungby and colleagues[56] reported that in their study all grades of surgeons performed tonsillectomy, while in the study by Schrey and colleagues[57] all operations were performed by senior surgeons. In the study by Oluwasanmi and colleagues,[54] senior house officers (19.9% of operations), specialist registrars (31.5%), staff grades (38%) and consultants (10.6%) performed the tonsillectomies. Lee and colleagues[49] and Montague and colleagues[52] gave details of the various grades of staff performing tonsillectomies along with the associated overall (primary and secondary) haemorrhage rates (see Table 24). Although the highest haemorrhage rates were from operations carried out by specialist registrars, they also undertook the majority of the operations. However, both studies reported that the difference between haemorrhage rates for surgeons with different levels of experience was not statistically significant ($p > 0.1$). Of the techniques being assessed, neither study reported whether these differed amongst different grades of surgeon; both studies reported that in each case the operating surgeon was free to choose which technique to use according to their preference. The setting for both of these studies was Ninewells Hospital, Dundee. The within-patient study by Choy and colleagues[75] reported that bipolar diathermy was easier to use for junior doctors and, compared with ligation, took less time for haemostasis in less experienced hands, resulting in a shorter operating time. Some or all of the seven patients included in the within-patient study by Lee and colleagues[49] may also be included in the patient numbers given for Lee 2004a in Table 24.

Of the case series, Kennedy and colleagues[64] reported that in their study the operating surgeons were residents (non-consultants) at the same chronological level of training. In the study by Lee and colleagues[33] tonsillectomies were performed by all grades of surgeons, while Walker and colleagues[70] reported that only children personally operated upon by the operating surgeon were included in the study.

Table 24 Grades of staff performing tonsillectomies

Study identifier	Grade	No (%) of operations	No (%) of haemorrhages
NPTA 2005	Consultant	8649 (29.2%)	337 (3.9%)
	Non-training/ associate specialist	9699 (32.7%)	330 (3.4%)
	SPR	6753 (22.8%)	270 (4.0%)
	SHO	4435 (15.0%)	191 (4.3%)
	Not specified	92 (0.3%)	5 (5.4%)
	Total	29,628 (100%)	1133 (3.8%)
Lee 2004a[49]	Consultant	59 (17.2%)	4 (6.8%)
	SPR	234 (68.0%)	24 (10.2%)
	SHO	51 (14.8%)	3 (5.9%)
	Total	344 (100%)	31 (9.0%)
Montague 2004[52]	Consultant	54 (23.9%)	3 (5.6%)
	SPR	151 (66.8%)	19 (12.6%)
	SPR and SHO	7 (3.1%)	0 (0%)
	SHO	14 (6.2%)	1 (7.1%)
	Total	226 (100%)	23 (10.2%)

Notes:

1. SPR = Specialist Registrar, SHO = Senior House Officer.
2. NPTA 2005. The data are for NHS hospitals. For each grade of surgeon, the number of haemorrhages was calculated from the number of operations and the haemorrhage rate.

3.2.5 Summary of efficacy findings

The following three aspects of efficacy are covered in this section: operation time; return to normal diet; and return to normal activity.

- **Operation time**

Eighteen studies reported the time taken for the operation (see Table 25), including seven RCTs,[35,37,38,40,41,43,45] four within-patient studies,[74,76,77,81] five non-randomised studies[46,48,50,57,58] and two case series.[61,69]

Excluding the within-patient studies, across studies the overall mean duration of the operation in minutes for each of the techniques was: monopolar diathermy dissection and haemostasis 15.5, bipolar diathermy dissection and haemostasis 17.3, cold steel dissection with diathermy or ties plus diathermy haemostasis 17.5, cold steel dissection with ties/packs haemostasis 18.3, cold steel dissection with monopolar diathermy haemostasis 20.0, cold steel dissection with bipolar diathermy haemostasis 23.1 and coblation 24.5. The shortest duration of operation was for the diathermy dissection and haemostasis techniques, followed by cold steel dissection with ties/packs or diathermy haemostasis or a combination of both, with the duration of the operation longest for coblation. However, these results are based on a relatively small number of studies reporting this outcome.

In three of the four within-patient studies[74,76,81] cold steel dissection resulted in a longer operating time compared with diathermy. In the study by Atallah and colleagues[74] the mean time for the cold steel dissection with ties/packs haemostasis side was 10.3 minutes compared with 4.3 minutes for bipolar diathermy dissection and haemostasis side ($p<0.0005$). Haraldsson and colleagues[76] reported a mean time of 10.1 minutes (range 2-23 minutes) for the cold steel dissection with bipolar diathermy haemostasis side compared with 2.4 minutes (range 1-5 minutes) for the bipolar diathermy dissection and haemostasis side ($p<0.001$). Leach and colleagues[77] reported a mean time of 9.9 minutes (range 4-27 minutes) for the cold steel dissection with diathermy or ties plus diathermy haemostasis side compared with 13.5 minutes (range 5-25 minutes) for the diathermy dissection and haemostasis side ($p<0.01$,

diathermy technique not stated). In the study by Weimert and colleagues[81] the mean time taken for the cold steel dissection with diathermy or ties plus diathermy haemostasis side was 6.0 minutes compared with 2.5 minutes for the diathermy side (diathermy technique not stated).

Table 25 Mean duration of operation (minutes)

	Monopolar diathermy dissection and haemostasis	Bipolar diathermy dissection and haemostasis	Coblation dissection and haemostasis	Cold steel dissection + monopolar haemostasis	Cold steel dissection + bipolar haemostasis	Cold steel dissection + ties + diathermy haemostasis	Cold steel dissection + ties/ packs haemostasis
RCTs							
Kujawski 1997[35]		36.9			35.9 p=0.67		
Pang 1995[37]		11.2 (5-20) SD 2.7					19.9 (10-55) SD 9.9 P<0.0001
Raut 2001[38]		13.0 (3-55)		20.0 (6-50) p<0.001			
Shah 2002[40]	16.2 SD 3.2		23.8 SD 7.9 p=0.002				
Stoker 2004[41]	23.0 SE? 11.7		22.7 SE? 13.5 p=0.919				
Watson 1993[43]				9.2 SD 4.0 diathermy technique for haemostasis not stated			11.5 SD 4.8 p<0.0001
Young 2001[45]	7.2 (4-14) SD 2.88					16.0 (11-25) SD 3.98 p<0.05	
Non-randomised comparative studies							
Back 2001[46]			27.0			18.0 p<0.001	
Lassaletta 1997[48]		15.3 (8-27) SD 4.68					16.3 (6-39) SD 7.21
MacGregor 1995[50]		9.1 SE 0.56			10.2 SE 0.45 p=NS		
Schrey 2004[57]		22.1				18.4	
Silveira 2003[58]		13.3 (9-23)					21.0 (13-30) p<0.05
Case series							
Blomgren 2001[61]	15.4 (3-80) SE 0.5						
Rivas Lacarte 1999[69]							23.0 (13-48)

	Monopolar diathermy dissection and haemostasis	Bipolar diathermy dissection and haemostasis	Coblation dissection and haemostasis	Cold steel dissection + monopolar haemostasis	Cold steel dissection + bipolar haemostasis	Cold steel dissection + ties + diathermy haemostasis	Cold steel dissection + ties/ packs haemostasis
RCT mean	15.5	20.4	23.3	20.0	35.9	16.0	15.7
Non-RCT mean	-	15.0	27.0	-	10.2	18.2	18.7
Case series mean	15.4	-		-		-	23.0
Overall mean	15.5	17.3	24.5	20.0	23.1	17.5	18.3
Broad groups	16.6		24.5	18.2			18.3

Notes:

1. Duration of operation is given in minutes mean (range) apart from Raut 2001,[38] where duration is given as median (range).
2. NS=not significant.

- **Return to normal diet**

Seven comparative studies reported the time taken to return to a normal diet, including five RCTs[34,36,40-42] and two non-randomised studies[50,60] (see Table 26). In the study by Brodsky and colleagues,[34] patients in the bipolar diathermy dissection and haemostasis group returned to a normal diet significantly sooner ($p<0.01$) than those in the cold steel dissection and monopolar diathermy haemostasis group. Nunez and colleagues[36] reported a median time taken to re-establish a normal diet of five days (95% CI 3 to 7 days) for the cold steel dissection with monopolar diathermy haemostasis group compared with 7.5 days (95% CI 5 to 8 days) for the monopolar diathermy dissection and haemostasis group ($p<0.05$). The study by Shah and colleagues[40] reported no statistically significant difference in recovery of diet, based on the return of 47% of questionnaires from each of the monopolar diathermy dissection and haemostasis and coblation groups. Likewise, Stoker and colleagues[41] reported a non-statistically significant difference ($p=0.4$) in the mean number of days (6.7 versus 7.4) taken by the monopolar diathermy and coblation groups respectively to return to a normal diet. However Temple and colleagues[42] reported that the number of days taken to return to a normal diet was 2.4 for the coblation group compared with 7.6 days for the bipolar diathermy dissection and haemostasis group ($p<0.0001$).

The study by MacGregor and colleagues[50] reported a mean time taken to re-establish a normal diet of 5.15 days (SD 0.36) for the cold steel dissection with bipolar diathermy haemostasis group compared with 7.07 days (SD 0.44) for the bipolar diathermy dissection and haemostasis group ($p=0.001$). In the study by Wexler and colleagues[60] the mean time taken to re-establish a normal diet was 9 days for the cold steel dissection with diathermy or ties plus diathermy haemostasis group compared with 11 days for the diathermy dissection and haemostasis group ($p<0.05$). For children, return to a normal diet required an average of 1.5 days longer in the diathermy group compared with the cold steel group but this difference did not reach statistical significance.[60]

Table 26 Mean number of days taken to re-establish a normal diet

Study id	Study type	Cold steel	Diathermy	Coblation	P-value
Brodsky 1996[34]	RCT	Favours diathermy			<0.01
Nunez 2000[36]	RCT	5	7.5		<0.05
Shah 2002[40]	RCT	No statistically significant difference			
Stoker 2004[41]	RCT		6.7	7.4	=0.4
Temple 2001[42]	RCT		7.6	2.4	<0.0001
MacGregor 1995[50]	NRCS	5.15	7.07		=0.001
Wexler 1996[60]	NRCS	9	11		<0.05 (adults)
		No statistically significant difference in children			

Notes:

1. For Nunez 2000, time taken to re-establish a normal diet was reported as median number of days.
2. NRCS = non-randomised comparative study.

- **Return to normal activity**

Six comparative studies reported the time taken to return to normal activity, including four RCTs[34,36,40,41] and two non-randomised studies[46,60] (see Table 27). Brodsky and colleagues[34] reported that return to normal activity was on average 2.3 days sooner in the bipolar diathermy dissection and haemostasis group compared with the cold steel dissection with monopolar diathermy haemostasis group ($p<0.03$). In the study by Nunez and colleagues[36] the median number of days until resumption of normal activity was 5 days (95% CI 3 to 8 days) for the cold steel dissection with monopolar diathermy haemostasis group compared with 7 days (95% CI 5 to 8 days) for the monopolar diathermy dissection and haemostasis group (p=NS). The studies by Shah and colleagues[40] and Stoker and colleagues[41] reported no statistically significant difference in return to normal activity for the monopolar diathermy dissection and haemostasis, and coblation, groups.

Back and colleagues[46] reported a median time taken to return to work of 14 days (range 14 to 27 days) for the cold steel dissection with diathermy or ties plus diathermy haemostasis group compared with 14 (range 14 to 21 days) for the coblation group (p=0.92). The mean number of days taken to return to regular activity by the adults in the study by Wexler and colleagues[60] was 8 days for the cold steel dissection with diathermy or ties plus diathermy haemostasis group compared with 9.5 days for the diathermy dissection and haemostasis group (p=NS). Reported return to regular activity by the children also showed approximately a one-day delay in the diathermy group (p=NS).

Table 27 Mean number of days taken to re-establish normal activity

Study id	Study type	Cold steel	Diathermy	Coblation	P-value
Brodsky 1996[34]	RCT	2.3 days sooner in diathermy group			<0.03
Nunez 2000[36]	RCT	5	7		NS
Shah 2002[40]	RCT	No statistically significant difference			
Stoker 2004[41]	RCT		6.9	7.0	=0.951
Back 2001[46]	NRCS	14		14	NS
Wexler 1996[60]	NRCS	8	9.5		NS

Notes:

1. For Nunez 2000, time taken to re-establish normal activity was reported as median number of days.
2. For Back 2001, time taken to return to work was reported as median number of days.
3. NRCS = non-randomised comparative study.

4 DISCUSSION

4.1 Safety results

Table 28 shows the results of the England and Northern Ireland NPTA interim report[8] and final report (NPTA 2005) for the outcomes of secondary haemorrhage requiring return to theatre, all secondary haemorrhage, primary haemorrhage requiring return to theatre and all primary haemorrhage. In the interim report,[8] the lowest rate of secondary haemorrhage requiring return to theatre was associated with cold steel dissection with ties/packs haemostasis (0.5%), while higher rates were associated with cold steel dissection with monopolar (1.3%) or bipolar (1.5%) diathermy haemostasis, with the highest rates associated with coblation (2.0%), bipolar (2.0%) and monopolar (3.5%) diathermy dissection and haemostasis. These findings prompted this review. In the NPTA final report (NPTA 2005) there were substantially lower (about four-fold) rates of secondary haemorrhage requiring return to theatre across all interventional techniques. The lowest rate remained associated with cold steel dissection with ties/packs haemostasis (0.2%), with higher rates associated with cold steel dissection with monopolar (0.3%) and bipolar (0.4%) diathermy haemostasis, with the highest rates associated with coblation (0.7%) and monopolar (0.7%) and bipolar (0.8%) diathermy dissection and haemostasis. The data in the final report were broadly consistent with those in the interim report in indicating increasing rates of secondary haemorrhage requiring return to theatre when moving from cold steel dissection with ties/packs haemostasis through to electrosurgery for dissection and haemostasis. The NPTA final report noted that the lower absolute rates in that report compared with the interim report were because data were included in the interim report from some hospitals that had misinterpreted the way the data sheets should be completed. Consequently, some cases were reclassified and the coding of the complication sheets was revised for the final analysis.(NPTA 2005) The reduction in rates did not appear to be due to a change in practice following the publication in March 2004 of the NICE interim guidance on the use of electrosurgery in tonsillectomy, as the overall rate of return to theatre due to secondary haemorrhage did not change greatly between the period before and after the interim guidance (0.6 versus 0.4%, $p = 0.07$).(NPTA 2005)

Table 28 Secondary and primary haemorrhage, NPTA interim report[8] and NPTA final report (NPTA 2005)

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar diathermy haemostasis			Cold steel dissection + bipolar diathermy haemostasis			Cold steel dissection + ties + bipolar diathermy haemostasis			Cold steel dissection + ties/packs haemostasis		
	N	N	%	N	n	%	N	N	%	N	n	%	N	n	%	N	n	%	N	n	%
Secondary haemorrhage requiring return to theatre																					
NPTA 2004[8] (95% CI)	198	7	3.5% (1.7% to 7.1%)	4666	95	2.0% (1.7% to 2.5%)	684	14	2.0% (1.2% to 3.4%)	613	8	1.3% (0.7% to 2.6%)	3831	56	1.5% (1.1% to 1.9%)				1327	7	0.5% (0.3% to 1.1%)
NPTA 2005 (95% CI)	452	3	0.7% (0.2% to 1.9%)	12562	95	0.8% (0.6% to 0.9%)	1565	11	0.7% (0.4% to 1.3%)	1772	5	0.3% (0.1% to 0.7%)	11956	48	0.4% (0.3% to 0.5%)				4285	9	0.2% (0.1% to 0.4%)
All secondary haemorrhage																					
NPTA 2004[8] (95% CI)	198	11	5.6% (3.1% to 9.7%)	4666	167	3.6% (3.1% to 4.2%)	684	23	3.4% (2.3% to 5.0%)	613	13	2.1% (1.2% to 3.6%)	3831	95	2.5% (2.0% to 3.0%)				1327	10	0.8% (0.4% to 1.4%)
NPTA 2005 (95% CI)	452	25	5.5% (3.8% to 8.0%)	12562	547	4.4% (4.0% to 4.7%)	1565	56	3.6% (2.8% to 4.6%)	1772	43	2.4% (1.8% to 3.3%)	11956	275	2.3% (2.0% to 2.6%)				4285	43	1.0% (0.7% to 1.3%)
Primary haemorrhage requiring return to theatre																					
NPTA 2004[8] (95% CI)	198	1	0.5% (0.1% to 2.8%)	4666	17	0.4% (0.2% to 0.6%)	684	7	1.0% (0.5% to 2.1%)	613	5	0.8% (0.3% to 1.9%)	3831	8	0.2% (0.1% to 0.4%)				1327	7	0.5% (0.3% to 1.1%)
NPTA 2005 (95% CI)	452	4	0.9% (0.3% to 2.3%)	12562	40	0.3% (0.2% to 0.4%)	1565	17	1.1% (0.7% to 1.7%)	1772	11	0.6% (0.3% to 1.1%)	11956	36	0.3% (0.2% to 0.4%)				4285	30	0.7% (0.5% to 1.0%)
All primary haemorrhage																					
NPTA 2004[8] (95% CI)	198	1	0.5% (0.1% to 2.8%)	4666	21	0.5% (0.3% to 0.7%)	684	7	1.0% (0.5% to 2.1%)	613	5	0.8% (0.3% to 1.9%)	3831	14	0.4% (0.2% to 0.6%)				1327	8	0.6% (0.3% to 1.2%)
NPTA 2005 (95% CI)	452	5	1.1% (0.5% to 2.6%)	12562	55	0.4% (0.3% to 0.6%)	1565	16	1.0% (0.6% to 1.7%)	1772	9	0.5% (0.3% to 1.0%)	11956	60	0.5% (0.4% to 0.6%)				4285	34	0.8% (0.6% to 1.1%)

Notes:

1. CI = confidence interval, N = number of participants analysed by the study, n = number of participants experiencing haemorrhage.
2. England and Northern Ireland NPTA 2004 (interim report) and NPTA 2005 (final report). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.
3. England and Northern Ireland NPTA 2004 (interim report). Numbers of patients experiencing primary and secondary haemorrhage requiring return to theatre were provided from personal communication between D Cromwell and J Burr, February 2005.
4. England and Northern Ireland NPTA 2005 (final report). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.
5. For the NPTA 2005 (final report), for each technique, for the outcomes of secondary haemorrhage requiring return to theatre, all secondary haemorrhage, primary haemorrhage requiring return to theatre and all primary haemorrhage, the numbers of patients experiencing a haemorrhage were calculated from the numbers of patients undergoing each technique and the haemorrhage rate for each technique.

Data from the Wales SISP and crude overall data from the included studies were broadly consistent with the England and Northern Ireland NPTA final report data in indicating that cold steel dissection with ties/packs haemostasis was associated with the lowest rates for secondary haemorrhage requiring return to theatre (0.1% and 0% respectively) while diathermy dissection and haemostasis was associated with the highest rates (Wales SISP: bipolar diathermy, 2.2%; crude overall data from included studies: bipolar and monopolar diathermy, both 0.9%). The technique of monopolar diathermy dissection and haemostasis was not reported by the Wales SISP. In the meta-analysis, adjusted for study design, coblation was associated with a statistically significant higher rate of secondary haemorrhage requiring return to theatre compared with cold steel dissection with ties/packs haemostasis (reference technique), while all of the other techniques were associated with increased odds of an event, without reaching statistical significance. In summary, in the meta-analysis for this outcome, low event rates resulted in a large degree of uncertainty surrounding the effect estimates, and hence wide credible intervals.

A range of estimates for the number of patients per 1000 treated who might be expected to experience primary and secondary haemorrhage requiring return to theatre was

calculated for coblation, bipolar and monopolar diathermy for both dissection and haemostasis and cold steel dissection with ties/packs haemostasis. While acknowledging the lack of certainty, the 95% CIs for the England and Northern Ireland NPTA (final report) and Wales SISP population-based registries and for the crude overall event rates from the included studies were used to generate a lower and upper range. The lowest rates of the three lower bounds of the 95% CIs were converted into a number of patients per 1000 treated, the 'best case' estimate. Correspondingly, the highest rates of the three upper bounds of the 95% CIs were used to generate the 'worst case' estimate. If the lowest rate of the three lower bounds indicated that less than a single case per thousand might expect to experience primary or secondary haemorrhage requiring return to theatre, the lower case bound was set at one patient per 1000. A plausible range per 1000 patients for secondary haemorrhage requiring return to theatre was therefore calculated as between 1 to 6 patients for cold steel dissection with ties/packs haemostasis, between 2 to 19 patients for monopolar diathermy dissection and haemostasis, between 5 to 44 patients for bipolar diathermy dissection and haemostasis and between 1 to 25 patients for coblation.

Rates for the outcome of all secondary haemorrhage followed a similar pattern to those for secondary haemorrhage requiring return to theatre. The England and Northern Ireland NPTA interim report[8] indicated that the lowest rate was associated with cold steel dissection with ties/packs haemostasis (0.8%), increasing with cold steel dissection with monopolar (2.1%) and bipolar (2.5%) haemostasis, with the highest rates associated with coblation (3.4%), bipolar (3.6%) and monopolar (5.6%) diathermy dissection and haemostasis. The rates in the NPTA final report (NPTA 2005) were similar to those in the interim report, apart from bipolar diathermy dissection and haemostasis, whose rates of all secondary haemorrhage increased from 3.6% to 4.4% (see Table 28). In the final report the lowest rate remained associated with cold steel dissection with ties/packs haemostasis (1.0%) and the highest with monopolar diathermy dissection and haemostasis (5.5%).

Data from the Wales SISP and the crude overall data from the included studies were again broadly consistent with the England and Northern Ireland NPTA data in indicating that cold steel dissection with ties/packs haemostasis was associated with the lowest rates for this outcome (0.6% and 3.2% respectively) while diathermy dissection

and haemostasis was associated with the highest rates (Wales SISP: bipolar diathermy, 8.9%; crude overall data from included studies: monopolar diathermy, 16.2%). Compared with cold steel dissection with ties/packs haemostasis, relatively high rates were also reported both by the Wales SISP and the included studies for cold steel dissection with ties plus diathermy haemostasis (3.0% and 4.7% respectively). In the meta-analysis, cold steel dissection with monopolar or bipolar diathermy haemostasis, coblation and bipolar and monopolar diathermy dissection and haemostasis were all associated with a statistically significant higher event rate compared with the reference technique of cold steel dissection with ties/packs haemostasis. In the meta-analysis for this outcome more events resulted in less uncertainty surrounding the effect estimates.

Data from the England and Northern Ireland NPTA interim report[8] indicated that the lowest rate of primary haemorrhage requiring return to theatre was associated with cold steel dissection with bipolar diathermy haemostasis (0.2%); higher rates were associated with bipolar diathermy dissection and haemostasis (0.4%), cold steel dissection with ties/packs haemostasis and monopolar diathermy dissection and haemostasis (both 0.5%), with the highest rates associated with cold steel dissection with monopolar diathermy haemostasis (0.8%) and coblation (1.0%). The rates in the NPTA final report (NPTA 2005) were broadly similar to those in the interim report, apart from monopolar diathermy dissection and haemostasis, whose rates of primary haemorrhage requiring return to theatre increased from 0.5% to 0.9% (see Table 28). In the NPTA final report the lowest rates were associated with cold steel dissection with bipolar diathermy haemostasis, and bipolar diathermy dissection and haemostasis (both 0.3%), while the highest rates were associated with coblation (1.1%) and monopolar diathermy dissection and haemostasis (0.9%).

Data from the Wales SISP and the crude overall data from the included studies, on the other hand, were consistent in indicating that the highest event rates were associated with cold steel dissection with ties/packs haemostasis (1.1% and 0.9% respectively). The Wales SISP reported that the lowest rates were associated with coblation, and cold steel dissection with either bipolar or monopolar diathermy haemostasis (all 0%). While the crude overall data from the included studies showed bipolar diathermy dissection and haemostasis to be associated with the lowest rate of primary haemorrhage requiring return to theatre (0.1%), the Wales SISP, on the other hand, reported a higher rate for this

technique (0.6%). Relatively high rates were also shown both by the Wales SISP and the crude overall data for cold steel dissection with ties plus diathermy haemostasis (0.5% and 0.4% respectively). In the meta-analysis, adjusted for study design, bipolar diathermy dissection and haemostasis was associated with a statistically significant lower rate of primary haemorrhage requiring return to theatre compared with cold steel dissection with ties/packs haemostasis (reference technique), while all of the other techniques were associated with lower odds of an event, without reaching statistical significance. As with secondary haemorrhage requiring return to theatre, low event rates resulted in a large degree of uncertainty surrounding the effect estimates in the meta-analysis.

In terms of the 'best case' and 'worst case' scenarios referred to above, the estimated numbers of patients per 1000 who might be expected to experience a primary haemorrhage requiring return to theatre were: cold steel dissection with ties/packs haemostasis, 4 to 20 patients; monopolar diathermy dissection and haemostasis, 1 to 23 patients; bipolar diathermy dissection and haemostasis, 1 to 22 patients; and coblation, 1 to 17 patients.

However, when the outcome of all postoperative haemorrhage requiring return to theatre is considered, the differences across the various tonsillectomy techniques become smaller compared with the differences across techniques when primary and secondary haemorrhage requiring return to theatre are considered separately (see Figure 3). In the included studies, the crude overall rate was lowest for cold steel dissection with bipolar diathermy haemostasis (0.6%) and highest for cold steel dissection with ties/packs plus diathermy haemostasis (1.6%). Data from the Wales SISP showed that the rates were lowest for cold steel dissection with either bipolar or monopolar diathermy haemostasis (both 0%) and highest for bipolar diathermy dissection and haemostasis (2.8%). Data from the England and Northern Ireland NPTA final report indicated that the lowest rates were associated with cold steel dissection with bipolar diathermy haemostasis (0.7%), while the highest rates were associated with coblation (1.8%).

In terms of all primary haemorrhage, the England and Northern Ireland NPTA interim report[8] indicated that the lowest rate was associated with cold steel dissection with bipolar diathermy haemostasis (0.4%) while the highest was associated with coblation

(1.0%), following a similar pattern to the rates in the interim report for primary haemorrhage requiring return to theatre. The rates in the NPTA final report (NPTA 2005) were again broadly similar to those in the interim report, apart from monopolar diathermy dissection and haemostasis, whose rates of overall primary haemorrhage increased from 0.5% to 1.1% (see Table 28). In the NPTA final report the lowest rates were associated with bipolar diathermy dissection and haemostasis (0.4%) and cold steel dissection with bipolar or monopolar diathermy haemostasis (both 0.5%), while the highest rates were associated with monopolar diathermy dissection and haemostasis (1.1%) and coblation (1.0%).

Data from the Wales SISP and the crude overall data from the included studies also followed the same broad pattern as for primary haemorrhage requiring return to theatre, with the lowest rates associated with cold steel dissection with bipolar diathermy haemostasis (Wales SISP: 0%; crude overall data from included studies: 0.3%) and the highest associated with cold steel dissection with ties/packs haemostasis (Wales SISP: 1.2%; crude overall data from included studies: 2.7%). As with the outcome of primary haemorrhage requiring return to theatre, the Wales SISP also reported a higher event rate for all primary haemorrhage for bipolar diathermy dissection and haemostasis (0.9%) compared with the crude overall data from the included studies (0.5%). In contrast, in the meta-analysis, bipolar diathermy dissection and haemostasis remained the only technique to be associated with a statistically significant lower rate of events compared with cold steel dissection with ties/packs haemostasis, although all of the other techniques were associated with reduced odds of an event compared with the reference technique. In the meta-analysis for this outcome, as for the outcome of all secondary haemorrhage, more events resulted in less uncertainty surrounding the effect estimates.

The broad trend towards increasing secondary haemorrhage rates when moving from cold steel dissection with ties/packs haemostasis, to cold steel dissection with diathermy haemostasis, to diathermy/coblation dissection and haemostasis suggests electrosurgery is associated with increased rates of secondary haemorrhage compared with cold steel dissection with ties/packs haemostasis. Conversely, the crude overall data from the included studies, data from the Wales SISP and the meta-analysis suggest that cold steel dissection with ties/packs haemostasis is associated with increased rates of primary

haemorrhage compared with electrosurgery, in particular cold steel dissection with bipolar diathermy haemostasis and bipolar diathermy dissection and haemostasis, although data from the NPTA final report suggest that both monopolar diathermy dissection and haemostasis and coblation are associated with even higher rates of overall primary haemorrhage than cold steel dissection with ties/packs haemostasis.

4.2 Efficacy results

In terms of efficacy results, across the 18 studies reporting operation time this tended to be shortest for diathermy dissection and haemostasis (mean 16.6 minutes), followed by cold steel dissection with ties/packs and/or diathermy haemostasis (mean 18.2 minutes), with the longest operation time for coblation (mean 24.5 minutes). However an accurate comparison of operation time across techniques was difficult because of differences between studies in their definition of the start and end points of the operation. Of four studies comparing cold steel dissection with diathermy and reporting time taken to return to normal diet, three favoured the cold steel technique by around two days, while a fourth favoured diathermy. In six studies reporting time taken to return to normal activity there was generally little difference between cold steel, diathermy and coblation.

4.3 Potential biases

A number of potential biases may affect the results of attempts to provide a comparison of haemorrhage rates between cold steel and electrosurgery techniques. The addition of diathermy as a method of haemostasis to cold steel dissection with ties/packs may be associated with a form of clinical indication bias in reflecting more difficult cases and therefore a higher secondary haemorrhage rate might be expected compared with ties/packs haemostasis alone. In the included studies, for cold steel dissection with ties/packs plus diathermy haemostasis compared with ties/packs haemostasis alone, the crude overall rate for secondary haemorrhage requiring return to theatre was 0.9% and 0% respectively, and for all secondary haemorrhage 4.7% and 3.2% respectively. The Wales SISP also reported higher rates of secondary haemorrhage requiring return to theatre (0.9% v 0.1%), and overall secondary haemorrhage (3.0% v 0.6%), associated with cold steel dissection with ties/packs plus diathermy haemostasis compared with

ties/packs haemostasis alone. This suggests that the patients who underwent cold steel dissection with ties/packs plus diathermy haemostasis may have presented more problems in controlling bleeding during the operation than those who underwent cold steel dissection with ties/packs haemostasis alone. The England and Northern Ireland NPTA final report (NPTA 2005) stated that ties were used with diathermy in 46% of cases in the cold steel dissection and bipolar diathermy haemostasis group and in 37% of cases in the cold steel dissection and monopolar diathermy haemostasis group. However, the NPTA final report suggested that it was unlikely that the use of diathermy was in response to excessive intraoperative bleeding after ties had been used, as the overall haemorrhage rate (primary and secondary combined) was less for the group of patients for whom ties as well as diathermy haemostasis was reported (2.3%) compared with the group of patients for whom only bipolar diathermy haemostasis was reported (3.0%).(NPTA 2005) Secondary and primary haemorrhage rates were not reported separately for these two groups of patients.

The method of cold steel dissection with ties/packs plus diathermy haemostasis differed to some extent across studies in the way that it was applied. Some studies used bipolar diathermy for haemostasis[46,49,52,54,56,63] while others used monopolar diathermy[45,47,57] and some did not specify the type of diathermy used.[60,67] In some studies diathermy was used additional to ties/packs to control persistent bleeding,[46,47] while in others[49,52] ties were used additional to diathermy to control bleeding.

Another potential source of bias may be the age of those undergoing tonsillectomy. In those studies providing a breakdown of secondary haemorrhage for different age categories, older age groups (mainly adults) experienced more secondary haemorrhage than younger age groups (mainly children) across all intervention techniques. This remained the case even with different cut offs (7, 12, 14, or 16 years) between age categories being used by studies. The England and Northern Ireland NPTA final report (NPTA 2005) also reported that adults had higher overall haemorrhage rates than children.

Occasionally, exact details of the tonsillectomy technique employed may be inaccurately recorded, resulting in a form of reporting bias. Thus, for a technique reported as consisting of cold steel dissection with bipolar diathermy haemostasis, it may be the case

that some patients recorded within this tonsillectomy category may actually have received a combination of diathermy plus ties haemostasis, or some patients recorded as receiving cold steel dissection with ties/packs haemostasis may actually also have received diathermy as part of the haemostasis. The Wales SISP report described the operative technique in 153 (4.1%) of 3690 tonsillectomy procedures carried out between February 2003 and March 2004 as indeterminate.

There may be some blurring in the distinction between primary and secondary haemorrhage if a haemorrhage occurs towards the end of the 24 hour period following the operation but for whatever reason is not reported until following hospital discharge when the patient is back in the community. This could result in some haemorrhages that were actually primary in nature being misclassified as secondary, leading to higher secondary haemorrhage rates being reported than would otherwise be the case.

Another potential bias in attempting to compare secondary haemorrhage rates across different tonsillectomy techniques may be the different ways in which the same type of diathermy equipment is applied by different surgeons/in different settings. In a letter issued in March 2004 regarding tonsillectomy audit, surgical techniques and bleeding, the Chief Medical Officer for Scotland stated that at present there was no reliable measure of the quantity or amount of diathermy used in an individual tonsil bed and that laboratory experiments with diathermy equipment were required to advance this area.[19] Some of the variables contributing to the amount of diathermy used (and potentially to the likelihood of secondary haemorrhage occurring) include forceps tip size and space between the tips (bipolar diathermy), resistance to the diathermy cable, application time, the depth to which the instrument is pressed, the quantity of blood present and the power setting on the diathermy machine (personal communication, meeting between J Burr and B Bingham, Southern General Hospital, Glasgow, 2004). Maini and colleagues[82] carried out an animal tissue experiment using bipolar diathermy to see whether there were differences in the area and depth of tissue coagulated with different power settings (15, 20, 25 W) over different time periods (one to four seconds). They reported that at one second on the different power settings there was no difference in the maximum diameter of visible tissue damage (2mm). At four seconds duration visible tissue damage increased from 5mm (15 W) to 7mm (25 W) for single-use bipolar diathermy and from 4mm (15 W) to 5mm (25 W) for reusable bipolar diathermy. Thus

the power settings used and other factors associated with how the equipment is applied to some extent may potentially have an effect on secondary haemorrhage rates. Fifteen comparative studies provided varying amounts of information on the power settings used but it was not possible to draw conclusions from the information provided on whether differences in power settings contributed to secondary haemorrhage rates.

Surgeon experience may also potentially bias the results of comparisons of haemorrhage rates across different tonsillectomy techniques. The England and Northern Ireland NPTA interim report[8] stated that haemorrhage rates were higher in patients operated upon by junior surgeons (specialist registrar and senior house officer grades) than in those operated upon by senior surgeons (4.6% compared with 2.7%, $p < 0.0001$). It may be the case that some junior, less experienced surgeons prefer electrosurgery to cold steel methods. However, the England and Northern Ireland NPTA final report (NPTA 2005) stated that although haemorrhage rates were slightly higher in patients operated upon by junior grades of surgeon (specialist registrar and senior house officer) compared with those operated upon by senior surgeons, these differences were no longer statistically significant. One possible explanation for the difference in results between the interim and final NPTA reports may be a change in practice following the NICE interim guidance on the use of electrosurgery in tonsillectomy that was issued in March 2004. The NPTA final report stated that there was evidence that the risks associated with grades of surgeon might have changed between the period before and after the NICE interim guidance was issued. The results of a comparison of two models of risk factors in the period before and after publication of the NICE interim guidance suggested that the risk of haemorrhage from senior house officers fell in the latter period.(NPTA 2005)

Sixteen studies gave some information on the experience of the surgeons carrying out the operation, but as they mostly did not provide a breakdown of haemorrhage rates for different levels of experience it was not possible to draw conclusions as to whether this affected the occurrence of secondary haemorrhage. However, two studies that did provide a breakdown of haemorrhage rates by grades of surgeon[49,52] suggesting higher rates for specialist registrars compared with consultants both reported that the differences in haemorrhage rates for surgeons of different grades did not reach statistical significance.

The pattern of usage and availability of different tonsillectomy techniques in centres providing registry data may potentially result in a 'centre effect' bias in reports of population-based registry data, if certain centres have a significantly higher usage of electrosurgery compared with others and/or higher secondary haemorrhage rates. Prior to the NICE interim guidance on electrosurgery for tonsillectomy issued in March 2004, the English NHS Trusts submitted information on approximately 70% of the 23,574 patients identified in the Hospital Episode Statistics (HES) data.(NPTA 2005) In the period after the guidance was issued the information received by the NPTA dropped to about 66% of the patients in HES.(NPTA 2005) The NPTA final report (NPTA 2005) also indicated that when haemorrhage rates were adjusted for patient factors and the clustering of patients within hospitals, of 130 English NHS Trusts providing data, there were 20 whose adjusted haemorrhage rates differed from the overall rate by an amount greater than expected.(NPTA 2005) However, the NPTA final report argued that poor agreement between the outliers identified by the NPTA data and outliers identified by Trust-level haemorrhage rates calculated from HES data meant that differences in haemorrhage rates between NHS Trusts needed to be treated with caution.(NPTA 2005)

All of the above may, to a greater or lesser extent, potentially bias the results of attempts to compare haemorrhage rates across different tonsillectomy techniques. The ideal study design to overcome at least some of these potential biases would be large RCTs. However, all 16 of the RCTs and within-patient studies reporting secondary haemorrhage requiring return to theatre contained fairly small sample sizes of 200 or fewer patients, with nine studies containing fewer than 50 patients.[7,40,42,45,49,73,75-77] While the studies tended to suggest no difference between techniques the confidence intervals were all very wide. Furthermore, in only one[34] of the RCTs was the assignment to the treatment groups judged to be really random. This study used a standard randomisation table to generate the randomisation sequence but did not report secondary haemorrhage requiring return to theatre.

Two systematic reviews[10,11] comparing cold steel dissection with diathermy and including secondary haemorrhage as an outcome reported that very few patients had postoperative bleeding and there were no meaningful differences between the techniques[10] and that the rate of secondary haemorrhage was low and there were insufficient data to show that one method of tonsillectomy was superior.[11] Leinbach

and colleagues[10] compared monopolar diathermy with cold steel dissection; they included prospective clinical trials (including within-patient studies) published in English. Their review included six studies, five of which are included in the present review.[36,60,77,79,81] The sixth study[83] was published prior to 1990 and therefore outwith our inclusion criteria. Pinder and Hilton[11] compared cold steel dissection with diathermy; they excluded within-patient studies and also studies where concealment of treatment allocation schedule and generation of allocation sequence was deemed inadequate, studies where all those randomised were not included in the analysis, and studies in which the patients or outcome assessors were not blinded. Their review included two studies,[35,36] both of which are included in the present review.

4.4 Nature of the association between electrosurgery and haemorrhage rates

One possible explanation for the association between higher secondary haemorrhage rates for electrosurgery compared with cold steel dissection with ties/packs haemostasis is that it could be entirely due to chance. However, the fact that the broad pattern of higher rates associated with electrosurgery for the outcome of all secondary haemorrhage generally follows that for secondary haemorrhage requiring return to theatre but with less uncertainty surrounding the effect estimates suggests the existence of a causal relationship. This is supported by the broad consistency of findings between the England and Northern Ireland NPTA final report, the Wales SISP data, the crude overall data from the included studies and the results of the meta-analysis. Also, higher rates of secondary haemorrhage, including secondary haemorrhage requiring return to theatre, for cold steel dissection with ties/packs plus diathermy haemostasis compared with ties/packs haemostasis alone suggests a possible causal relationship. It seems plausible that more electrosurgery generates more eschar (scarring), increasing the risk of secondary haemorrhage. Nevertheless, even assuming a causal relationship between electrosurgery and higher secondary haemorrhage rates, chance could still impact on the magnitude of the association.

In the meta-analysis, coblation was associated with a statistically significant higher rate of secondary haemorrhage requiring return to theatre compared with cold steel dissection with ties/packs haemostasis. Differences in event rates between techniques that are statistically significant, however, may or may not also be clinically significant.

Given that cold steel dissection with ties/packs haemostasis is associated with less secondary haemorrhage than electrosurgery, but may be associated with more primary haemorrhage, an issue requiring clinical judgement is whether secondary haemorrhage is potentially more serious than primary haemorrhage, occurring as it does following hospital discharge when the patient is back in the community, or whether primary haemorrhage is a potentially more serious event, occurring sooner after the operation although when the patient is still in hospital.

4.5 Summary

The data from the included studies, Wales SISP and England and Northern Ireland NPTA final report suggest that electrosurgery is associated with higher rates of secondary haemorrhage, including secondary haemorrhage requiring return to theatre, compared with cold steel dissection with ties/packs haemostasis. Conversely, the crude overall data from the included studies, data from the Wales SISP and the meta-analysis suggest that cold steel dissection with ties/packs haemostasis is associated with higher rates of primary haemorrhage compared with electrosurgery, in particular cold steel dissection with bipolar diathermy haemostasis and bipolar diathermy dissection and haemostasis, although data from the NPTA final report suggest that both monopolar diathermy dissection and haemostasis and coblation are associated with even higher rates of overall primary haemorrhage compared with cold steel dissection with ties/packs haemostasis. A number of potential biases, including patient age and centre effect, may confound the results of reports of haemorrhage rates across different tonsillectomy techniques. Also, the effect size of any causal link between diathermy and secondary haemorrhage may be exaggerated by the selective use of diathermy for haemostasis additional to ties in patients whose bleeding is more difficult to control.

5 CONCLUSIONS

Electrosurgery dissection and haemostasis is associated with higher rates of secondary haemorrhage, including secondary haemorrhage requiring return to theatre, than cold steel dissection with ties/packs haemostasis. These higher rates generally follow the same pattern for all secondary haemorrhage as they do for secondary haemorrhage requiring return to theatre, but with more events, suggesting a causal relationship. A number of potential biases may affect the size of the association, including the age of those undergoing the operation, the selective use of diathermy to control intraoperative bleeding, and for registry studies, a 'centre effect'. Conversely, cold steel dissection with ties/packs haemostasis may be associated with a higher rate of primary haemorrhage, including primary haemorrhage requiring return to theatre, compared with some techniques involving electrosurgery, in particular cold steel dissection with bipolar diathermy haemostasis and bipolar diathermy dissection and haemostasis.

The clinical choice in deciding which technique to employ depends on a number of issues, including the risk of occurrence of primary or secondary haemorrhage, whether secondary haemorrhage is likely to be more or less serious than primary haemorrhage, and whether, for meaningful outcomes such as secondary haemorrhage requiring return to theatre, reported statistically significant differences in haemorrhage rates across different interventional techniques are in fact also clinically important. Currently, the clinical choice would seem to be between an increased risk of secondary haemorrhage with electrosurgery compared with cold steel techniques or a possible increase in the risk of primary haemorrhage with cold steel techniques compared with electrosurgery.

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Appendix 1. Search strategy

1. Sources searched for systematic reviews, other evidence-based reports and background information.

Databases
Cochrane Database of Systematic Reviews (CDSR). The Cochrane Library (Issue 2, 2004).
Database of Abstracts of Reviews of Effects (NHS Centre for Reviews & Dissemination) April 2004
HTA Database (NHS Centre for Reviews & Dissemination) April 2004
Trip database. Available from: http://www.tripdatabase.com/ [accessed May 2004]

Websites
American Academy of Otolarynology – Head & Neck Surgery Available from: http://www.entnet.org/[accessed June 2004]
Chief Medical Officer Wales. Available from: http://www.cmo.wales.gov.uk/content/index.htm [accessed June 2004]
NHS Scotland: Scotland's Health on the Web (SHOW). Available from: http://www.show.scot.nhs.uk/ [accessed June 2004]
ISD Scotland. Scottish Health Statistics. Available from: http://www.isdscotland.org/isd/index2.jsp;jsessionid=EDA7C4AAE95857B928E6176798D1F411?p_applic=CCC&p_service=Content.show&pContentID=1& [accessed September 2004]
UK Department of Health Available from: http://www.dh.gov.uk/Home/fs/en [accessed September 2004]

2. Search strategies used to identify reports assessing safety and efficacy of electrosurgery

MEDLINE (1966 – November Week 3 2004) EMBASE (1988 – Week 50 2004) (Medline Extra 10th December 2004)
Ovid Multifile Search URL: http://gateway.ovid.com/athens

1 tonsillectomy/ use mesz
2 exp tonsillectomy/ use emed
3 tonsil/su use mesz
4 tonsil/ use emed
5 tonsillectomy.tw.
6 tonsil?.tw.
7 tonsillar.tw.
8 or/1-7
9 electrosurgery/
10 exp diathermy/
11 electrosurg$.tw.
12 electro surg$.tw.
13 electrodissection.tw.
14 electro dissection.tw.
15 hot.tw.

16 bipolar.tw.
17 (monopolar or unipolar).tw.
18 or/9-17
19 (coblation or ablation).tw.
20 cold.tw.
21 blunt.tw.
22 sharp.tw.
23 snare?.tw.
24 dissection.tw.
25 (traditional or conventional or standard).tw.
26 or/20-25
27 8 and (18 or 19 or 26)
28 tonsillectomy/mt use mesz
29 tonsil/su use mesz
30 or/27-29
31 exp electrocoagulation/
32 electrocoagulat$.tw.
33 electr$ coagulat$.tw.
34 electrocauter$.tw.
35 electr$ cauter$.tw.
36 or/31-35
37 ligation/
38 (ligation or ligatur$).tw.
39 (ties or sutures or pack$).tw.
40 or/37-39
41 Hemostasis, Surgical/
42 (hemostasis or haemostasis).tw.
43 or/41-42
44 8 and (36 or 40 or 43)
45 Tonsillectomy/ae, mo use mesz
46 blood loss,surgical/
47 postoperative hemorrhage/
48 hemorrhage/
49 postoperative complications/
50 (haemorrhage or hemorrhage).tw.
51 posttonsillectomy.tw.
52 Pain, Postoperative/
53 or/46-52
54 8 and 53
55 45 or 54
56 30 or 44 or 55
57 case report/
58 case reports.pt.
59 56 not (57 or 58)
60 animal/ or nonhuman/
61 human/
62 60 not 61
63 59 not 62
64 limit 63 to english language
65 limit 64 to yr=1990-2004
66 remove duplicates from 65

Science Citation Index 1981 – 16th May 2004
Web of Science Proceedings 1990 – 15th May 2004
Web of Knowledge URL: http://wok.mimas.ac.uk/
#1 TS=tonsillectomy
#2 TS=(tonsil or tonsils or tonsillar)
#3 #1 or #2
#4 TS=(electrosurg* or electro surg*)
#5 TS=(electrodissection or electro dissection)
#6 TS=diathermy
#7 TS=(hot or bipolar or monopolar or unipolar)
#8 #4 or #5 or #6 or #7
#9 #3 and #8
#10 TS=(coblation or ablation)
#11 #3 and #10
#12 TS=(cold or blunt or sharp or snare*)
#13 TS=(dissection or conventional or standard or traditional)
#14 #12 or #13
#15 #3 and #14
#16 #9 or #11 or #15
#17 TS=(electrocoagulat* or electr* coagulat*)
#18 TS=(electrocauter* or electr* cauter*)
#19 TS=(liagtion or ligatur* or ties or sutures or pack*)
#20 TS=(hemostasis or haemostasis)
#21 #17 or #18 or #19 or #20
#22 #3 and #21
#23 TS=(postoperative or posttonsillectomy)
#24 TS=(hemorrhage or haemorrhage)
#25 #23 or #24
#26 #3 and #25
#28 TS=random*
#29 TS=trial*
#30 TS=control*
#31 TS=compar*
#32 #28 or #29 or #30 or #31
#33 #26 and #32
#34 #16 or #22 or #33

BIOSIS (1985 - 12th May 2004)
Edina URL: http://edina.ac.uk/biosis/
((((((((((al: (traditional) or al: (standard) or al: (conventional)) or (al: (snare*) or al: (dissection))) or (al: (cold) or al: (blunt) or al: (sharp)))) and (al: (tonsil*)))) and (((al: (coblation) or al: (ablation)) and (al: (tonsil*)))))) or ((((((((al: (traditional) or al: (standard) or al: (conventional)) or (al: (snare*) or al: (dissection))) or (al: (cold) or al: (blunt) or al: (sharp)))) and (al: (tonsil*)))) and (((((((al: (monopolar) or al: (unipolar)) or (al: (bipolar) or al: (scissor*) or al: (forcep*))) or (al: (electrodissect*) or al: (electro* dissect*) or al: (hot))) or (al: (electrocauter*) or al: (electro* cauter*) or al: (diathermy)))) and (al: (tonsil*)))))))) or (((((al: (coblation) or al: (ablation)) and (al: (tonsil*)))) and (((((((al: (monopolar) or al: (unipolar)) or (al: (bipolar) or al: (scissor*)

or al: (forcep*))) or (al: (electrodissect*) or al: (electro* dissect*) or al: (hot))) or (al: (electrocauter*) or al: (electro* cauter*) or al: (diathermy)))) and (al: (tonsil*))))))) or ((((((al: (ties) or al: (sutures) or al: (pack*)) or (al: (ligation) or al: (ligatur*)))) and (al: (tonsil*)))) and (((((al: (electrocauter*) or al: (electr* cauter*)) or (al: (electrocoagulat*) or al: (electr* coagulat*)))) and (al: (tonsil*)))))) or
((((al: (hemorrhage) or al: (haemorrhage)) or (al: (hemostasis) or al: (haemostasis)))) and (al: (tonsil*)))

Cochrane Library Issue 2, 2004
URL: http://www.update-software.com/clibng/cliblogon.htm

National Research Register (Issue 2, 2004)
URL: http://www.update-software.com/National/

#1. TONSILLECTOMY single term (MeSH)
#2. TONSIL [su] single term (MeSH)
#3. tonsil*
#4. (#1 or #2 or #3)
#5. ELECTROSURGERY single term (MeSH)
#6. DIATHERMY explode all trees (MeSH)
#7. (electrosurg* or (electro next surg*))
#8. (electrodissection or (electro next dissection))
#9. (hot or bipolar or monopolar or unipolar)
#10. (#5 or #6 or #7 or #8 or #9)
#11. (#4 and #10)
#12. (coblation or ablation)
#13. (#4 and #12)
#14. (cold or blunt or sharp or snare* or dissection)
#15. (traditional or conventional or standard)
#16. (#14 or #15)
#17. (#4 and #16)
#18. TONSILLECTOMY [mt] single term (MeSH)
#19. (#11 or #13 or #17 or #18)
#20. ELECTROCOAGULATION explode tree 1 (MeSH)
#21. (electrocoagulat* or (electr* next coagulat*))
#22. (electrocauter* or (electr* next cauter*))
#23. LIGATION single term (MeSH)
#24. (ligation or ligatur* or ties or sutures or pack*)
#25. HEMOSTASIS SURGICAL single term (MeSH)
#26. (hemostasis or haemostasis) 3
#27. (#20 or #21 or #22 or #23 or #24 or #25 or #26)
#28. (#4 and #27)
#29. BLOOD LOSS SURGICAL single term (MeSH)
#30. POSTOPERATIVE HEMORRHAGE single term (MeSH)
#31. POSTOPERATIVE COMPLICATIONS single term (MeSH)
#32. PAIN POSTOPERATIVE single term (MeSH)
#33. posttonsillectomy
#34. (haemorrhage or hemorrhage)
#35. (#29 or #30 or #31 or #32 or #33 or #34)
#36. (#4 and #35)
#37. TONSILLECTOMY [ae] single term (MeSH)

#38. (#36 or #37)
#39. (#19 or #28 or #38)

DARE and HTA Databases(April 2004)
NHS Centre for Reviews & Dissemination
URL:http://nhscrd.york.ac.uk/welcome.htm

Clinical Trials (June 2004)
URL: http://clinicaltrials.gov/ct/gui/c/r

Current Controlled Trials (June 2004)
URL: **http://www.controlled-trials.com/**

Conference Papers Index (1982-May 2002)
Cambridge Scientific Abstracts URL:http://www.csa1.co.uk/

Zetoc Conference Search (1993 –June 2004)
MIMAS URL:http://zetoc.mimas.ac.uk/
Tonsillectomy or tonsil*

Appendix 2. Characteristics of the included studies

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
RCTs									
Brodsky 1996[34]	129	129	10 days	13 months	USA	Children	N/S	N/S	Cold steel dissection with monopolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Kujawski 1997[35]	200	200	10 days	November 1993- March 1995	Switzerland	Both	N/S	N/S	Cold steel dissection with bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Nunez 2000[36]	54	50	14 days	N/S	UK (Scotland)	Children	6.4	M: 23; F: 27	Cold steel dissection with monopolar diathermy haemostasis versus monopolar diathermy dissection and haemostasis
Pang 1995[37]	120	120	N/S	February 1993-March 1994	UK (England)	Children	10.3 (4-15)	M: 53; F: 67	Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis
Raut 2001[38]	200	183	15-17 days	March-September 2000	UK (NI)	Both	22 (10-54)	M: 51; F: 132	Cold steel dissection with monopolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Shah 2002[40]	34	34	178 days mean	August 1999-April 2000	USA	Children	5.3	M: 19; F: 15	Coblation versus monopolar diathermy dissection and haemostasis
Stoker 2004[41]	89	85	30 days	N/S	USA	Children	6 (3-12)	M: 46; F: 43	Coblation versus monopolar diathermy dissection and haemostasis

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
Temple 2001[42]	38	38	9 days	N/S	UK (England)	Children	5.6 (4-12)	M: 19; F: 19	Coblation versus bipolar diathermy dissection and haemostasis
Watson 1993[43]	1036	1036	N/S	N/S	UK (England)	Both	9 median (1-64)	M: 436; F: 600	Cold steel dissection with ties/packs haemostasis versus cold steel dissection with diathermy haemostasis (diathermy technique not stated)
Young 2001[45]	50	49	14 days	September 2000-January 2001	Canada	Children	6.6 (2-15)	M: 26; F: 23	Cold steel dissection with ties plus monopolar diathermy haemostasis versus monopolar diathermy dissection and haemostasis
Non-randomised comparative studies									
Back 2001[46]	40	37	3 weeks	N/S	Finland	Adults	30 (19-63)	M: 15; F: 22	Cold steel dissection with ties/packs plus bipolar diathermy haemostasis versus coblation
Belloso 2003[6]	1587	1587	N/S	July 2001-January 2003	UK (England)	Both	16	N/S	Cold steel dissection with bipolar diathermy haemostasis versus coblation
Carr 2001[47]	36	36	10 days	October 1996-April 1998	Canada	Children	9.6 (5.3-15.4)	M: 14; F: 22	Cold steel dissection with ties/packs plus monopolar diathermy haemostasis versus monopolar diathermy dissection and haemostasis
Lassaletta 1997[48]	120	120	10 days	N/S	Spain	Children	5.3 (2-14)	M: 58; F: 62	Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
Lee 2004a[49]	337	337	10 days	November 1999 – November 2000	UK (Scotland)	Both	16.7	M: 134; F: 203	Cold steel dissection with haemostasis by bipolar diathermy, ligatures or a combination of both versus bipolar diathermy dissection and haemostasis
MacGregor 1995[50]	81	76	10 days	N/S	UK (England)	Children	5 (18 months – 13 yrs)	N/S	Cold steel dissection with bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Montague 2004[52]	115	115	10 days	August-December 2001	UK (Scotland)	Children	N/S	N/S	Cold steel dissection with ties/packs plus bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Noon 2003[53]	65	65	N/S	August 2001– November 2002	UK (England)	Adults	23.5 (16-50)	M: 17; F: 48	Coblation versus bipolar diathermy dissection and haemostasis
Oluwasanmi 2003[54]	311	311	N/S	April-October 2000 and April - October 2001	UK (England)	Both	(2-72)	N/S	Cold steel dissection with ties/packs plus bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Roberts 1992[55]	950	950	N/S	12 months	UK (England)	Both	N/S	N/S	Cold steel dissection with ties/packs haemostasis versus cold steel/guillotine dissection with diathermy haemostasis (diathermy technique not stated)

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
Rungby 2000[56]	207	134	12 days	January-August 1997	Denmark	Both	20 (3-66)	M: 45; F: 89	Cold steel dissection with ties/packs haemostasis versus cold steel dissection with ties plus bipolar diathermy haemostasis
Schrey 2004[57]	305	305	N/S	January 1998 – August 2000	Finland	Both	22.4 (cold steel) 22.0 (bipolar diathermy)	M:132; F:173	Cold steel dissection with haemostasis by gauze packs followed by monopolar diathermy versus bipolar diathermy dissection and haemostasis
Silveira 2003[58]	60	57	10 days	September 2000-March 2001	Portugal (Azores)	Children	6.75 (3-13)	M: 32; F: 25	Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis
Tan 1993[59]	555	452	N/S	January 1990-March 1991	Canada	Children	6.5 (6-8)	N/S	Cold steel dissection with ties/packs haemostasis versus diathermy dissection and haemostasis (diathermy technique not stated)
Wexler 1996[60]	101	101	14 days	N/S	USA	Both	14.5 (2-54)	M: 43; F: 58	Cold steel dissection with ties/packs plus diathermy haemostasis versus diathermy dissection and haemostasis (diathermy technique not stated)
Case series									
Andrea 1993[5]	265	265	N/S	1989-March 1992	Portugal	Both	<5yrs: 50 5-10 yrs: 54 11-17 yrs: 16 18+: 14 (of author's 134 patients)	N/S	Bipolar diathermy dissection and haemostasis

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
Blomgren 2001[61]	440	413	N/S	1997	Finland	Both	17.9 (2.4-58.2)	M: 208; F: 232	Monopolar diathermy dissection and haemostasis
Ghufoor 2000[62]	203	160	14 days	October 1996-April 1997	UK (England)	Both	N/S	M: 84; F: 119	Cold steel dissection with bipolar diathermy haemostasis
Kanerva 2003[63]	100	100	14 days	September – November 2000	Finland	Children	7.7 (2.7-16.7)	M: 54; F: 46	Cold steel dissection with packs plus bipolar diathermy haemostasis
Kennedy 1990[64]	192	192	30 days	N/S	USA	Both	18 (2-56)	M: 116; F: 76	Cold steel dissection with diathermy haemostasis (diathermy technique not stated)
Kuo 1995[65]	183	149	14 days	October 1991-March 1992	UK (England)	Both	N/S	N/S	Cold steel dissection with ties/packs haemostasis
Lee 1996[33]	419	291	5 days	N/S	UK (England)	Children	6.8 (3-14)	M: 158; F: 133	Cold steel dissection with ties/packs haemostasis
Mahadevan 1995[66]	322	322	9 days minimum	January 1992-February 1994	New Zealand	Children	(2-12)	N/S	Bipolar diathermy dissection and haemostasis
Panarese 1999[67]	392	392	1 day	N/S	UK (England)	Children	N/S	N/S	Cold steel dissection with ties/packs plus diathermy haemostasis
Pang 1994[68]	100	100	7 days	February-October 1993	UK (England)	Both	(2-52)	N/S	Bipolar diathermy dissection and haemostasis
Rivas Lacarte 1999[69]	445	426	14 days	January 1991-January 1998	Spain	Children	5.8 (3-15)	M: 248; F: 178	Cold steel dissection with ties/packs haemostasis
Walker 1999[70]	565	565	N/S	January 1994-December 1998	Australia	Children	6.4 (0.8-17)	N/S	Monopolar diathermy dissection and haemostasis
Walker 2001[71]	161	75	14 days	April 1999-May 2000	USA	Both	7.1 (1-19)	N/S	Monopolar diathermy dissection and haemostasis
Wilson 2001[72]	384	384	14 days	N/S	UK (Scotland)	Children	8.4 (4-12)	M: 202; F: 182	Cold steel dissection with ties/packs haemostasis

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
Within-patient studies									
Akkielah 1997[73]	45	42	Up to 6 days	N/S	UK (England)	Both	15 (5-29)	N/S	Bipolar diathermy dissection and haemostasis versus monopolar diathermy dissection and haemostasis
Atallah 2000[74]	70	70	15 days	August 1997-July 1998	UK (England)	Both	22 (10-37)	M: 21; F: 49	Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis
Choy 1992[75]	49	49	N/S	N/S	UK (England)	Children	(4-12)	N/S	Cold steel dissection with ties/packs haemostasis versus bipolar diathermy dissection and haemostasis
Haraldsson 2003[76]	32	32	12 days minimum	N/S	Sweden	Both	9.7 (4-24)	M: 12; F: 20	Cold steel dissection with bipolar diathermy haemostasis versus bipolar diathermy dissection and haemostasis
Leach 1993[77]	28	21	7 days	January 1990-April 1991	USA	Both	17.9 (13-32)	M: 20; F: 8	Cold steel dissection with ties/packs plus diathermy haemostasis versus diathermy dissection and haemostasis (diathermy technique not stated)
Lee 2004b[49]	7	7	10 days	November 1999 – November 2000	UK (Scotland)	N/S	N/S	N/S	Cold steel dissection with haemostasis by bipolar diathermy, ligatures or a combination of both versus bipolar diathermy dissection and haemostasis

Study design and study id	Enrolled	Analysed	Follow-up	Study period	Setting	Adults/ children	Age mean (range)	Gender	Intervention(s)
Salam 1992[78]	150	150	3 days	N/S	UK (England)	Both	13 (4-45)	M: 60; F: 90	Cold steel dissection with ties/packs haemostasis versus cold steel dissection with monopolar diathermy haemostasis
Tay 1995[79]	104	104	14 days	N/S	UK (Scotland)	Both	18.4	M: 36; F: 68	Cold steel dissection with ties/packs haemostasis versus diathermy dissection and haemostasis (diathermy technique not stated)
Tay 1996[80]	105	105	14 days	N/S	UK (Scotland)	Both	17.9	M: 34; F: 71	Cold steel dissection with ties/packs haemostasis versus cold steel dissection with monopolar diathermy haemostasis
Timms 2002[7]	10	10	9 days	N/S	UK (England)	Adults	25.3 (18-36)	M: 3; F: 7	Coblation versus bipolar diathermy dissection and haemostasis
Weimert 1990[81]	106	103	14 days	October 1987-April 1988	USA	N/S	N/S	N/S	Cold steel dissection with ties/packs plus diathermy haemostasis versus diathermy dissection and haemostasis (diathermy technique not stated)

Notes:

1. N/S = not stated, M=male, F=female.
2. Age is mean years unless otherwise stated.
3. For the within-patient studies, for each patient the tonsil was removed on one side by one intervention technique and on the other side by the comparator technique.

Appendix 3. List of excluded studies

Secondary haemorrhage not reported

Chaplin J, Stevenson S, Stewart I. Paediatric day surgery adenotonsillectomy in New Zealand: A prospective study. Aust J Otolaryngol 1995;2(1):11-15.

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Appendix 4 Study results, secondary haemorrhage requiring return to theatre

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
RCTs																					
Kujawski 1997[35]				100	0	0%							100	1	1%						
Nunez 2000[36]	24	0	0%							26	0	0%									
Pang 1995[37]				60	0	0%													60	0	0%
Raut 2001[38]				91	0	0%				92	1	1%									
Shah 2002[40]	17	0	0%				17	1	6%												
Temple 2001[42]				20	0	0%	18	0	0%												
Young 2001[45]	26	0	0%													23	0	0%M			
National registries																					
SISP 2005				325	7	2.2%	221	1	0.5%	39	0	0%	141	0	0%	768	7	0.9%	1535	2	0.1%
NPTA 2005	452	3	0.7%	12562	95	0.8%	1565	11	0.7%	1772	5	0.3%	11956 48 0.4%						4285	9	0.2%
Non-randomised comparative studies																					
Back 2001[46]							18	1	6%							19	1	5%B			
Belloso 2003[6]							844	1	0.1%				743	2	0.3%						
Lassaletta 1997[48]				60	0	0%													60	0	0%
Lee 2004a[49]				192	3	2%										145	0	0%B			
MacGregor 1995[50]				36	0	0%							40	0	0%						
Noon 2003[53]				29	0	0%	36	2	6%												
Oluwasanmi 2003[54]				259	6	2%										52	1	2%B			
Silveira 2003[58]				29	1	3%													28	0	0%
Wexler 1996[60]	52 0 0% electrocautery technique not stated															49	0	0%			
Case series																					
Blomgren 2001[61]	413	5	1%																		

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
Ghufoor 2000[62]													160	0	0%						
Kanerva 2003[63]																100	5	5%B			
Kuo 1995[65]																			149	0	0%
Lee 1996[33]																			291	0	0%
Mahadevan 1995[66]				322	0	0%															
Panarese 1999[67]																392	0	0%			
Pang 1994[68]				100	2	2%															
Walker 1999[70]	565	2	0.4%																		
Walker 2001[71]	75	3	4%																		
Total	1120	10	0.9%	1298	12	0.9%	933	5	0.5%	118	1	0.8%	1043	3	0.3%	780	7	0.9%	588	0	0%
Broad groups	2470 22 0.9%						933	5	0.5%	1941 11 0.6%									588	0	0%
Within-patient studies																					
Akkielah 1997[73]	42	0	0%	42	0	0%															
Atallah 2000[74]				70	0	0%													70	0	0%
Choy 1992[75]				49	0	0%													49	0	0%
Haraldsson 2003[76]				32	0	0%							32	0	0%						
Leach 1993[77]	21 0 0% Method of diathermy not stated															21	0	0%			
Lee 2004b[49]				7	0	0%										7	0	0%B			
Salam 1992[78]										150	0	0%							150	0	0%
Tay 1995[79]	104 0 0% Method of electrodissection not stated																		104	0	0%
Timms 2002[7]				10	0	0%	10	0	0%												
Total	42	0	0%	210	0	0%	10	0	0%	150	0	0%	32	0	0%	28	0	0%	373	0	0%
Broad groups	377 0 0%						10	0	0%	210 0 0%									373	0	0%

Notes:

1. N = number of participants analysed by the study, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing secondary haemorrhage, B = bipolar diathermy, M = monopolar diathermy.

2. England and Northern Ireland NPTA final report (NPTA 2005). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.

3. England and Northern Ireland NPTA final report (NPTA 2005). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.

4. For the NPTA final report (NPTA 2005), for each technique, the numbers of patients experiencing a secondary haemorrhage requiring return to theatre were calculated from the numbers of patients undergoing each technique and the rate of secondary haemorrhage requiring a return to theatre.

5. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).

6. Total and Broad groups rows are excluding the England and Northern Ireland NPTA final report (NPTA 2005) and Wales SISP 2005.

7. Cold steel dissection with ties/packs plus diathermy haemostasis column – additional information on the haemostasis technique:

   Back 2001. Haemostasis was achieved by the application of pressure with packs, and persistent bleeding was controlled by a bipolar diathermy coagulation of vessels.

   Kanerva 2003. Tonsillectomy was done with a cold dissection method, and haemostasis with packing and bipolar diathermy.

   Oluwasanmi 2003. Methods of haemostasis included: (1) bipolar diathermy, and (2) bipolar diathermy and ties. (Two patients also had pillars oversown.)

   Panarese 1999. Tonsillectomy was performed using blunt dissection with the snare or tie technique to the lower pole and haemostasis was achieved by electrocautery or ligation of the vessels.

   Wexler 1996. Gauze packs were placed followed by selective cauterisation at bleeding sites with suction electrocautery.

   Young 2001. Haemostasis was achieved by packing the tonsil bed with a Bismuth Subgallate and topical adrenaline paste mixture. Cautery with a monopolar bayonet forcep set at 20 coag. on a Valleylab Force 2 machine was used to cauterise point bleeders.

8. Tan 1993. This study compared cold steel dissection (haemostasis technique not stated, assume ties/packs) with diathermy for dissection and haemostasis (diathermy technique not stated). The study gave results for inpatient and outpatient, but the numbers in the table are only for outpatient as secondary haemorrhage results for inpatients were not presented separately for cold steel and diathermy.

9. Oluwasanmi 2003. The cold steel dissection + bipolar diathermy haemostasis group includes some with just bipolar diathermy haemostasis (n=22) and some with bipolar diathermy + ties haemostasis (n=28).

10. Leach 1993. Postoperative bleeding was rated subjectively on a scale of 0 to 10. On the cautery excision side, bleeding was rated an average of 1.3; on the dissection/snare side, it was rated an average 1.7. The number of patients with any bleeding was not large enough to allow significant statistical comparison. One patient presented at postoperative day 6 complaining of bleeding from the cautery excision side. On presentation, the bleeding had ceased, and the patient was haemodynamically stable. No further intervention was rendered, and the bleeding did not recur.

Appendix 5. Study results, all secondary haemorrhage

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
RCTs																					
Brodsky 1996[34]				59	1	2%				70	7	10%									
Kujawski 1997[35]				100	3	3%							100	8	8%						
Nunez 2000[36]	24	2	8%							26	1	4%									
Pang 1995[37]				60	1	2%													60	1	2%
Raut 2001[38]				91	14	15%				92	17	18%									
Shah 2002[40]	17	0	0%				17	1	6%												
Stoker 2004[41]	42	2	5%				43	3	7%												
Temple 2001[42]				20	0	0%	18	0	0%												
Watson 1993[43]										523 8 2% diathermy technique for haemostasis not stated									513	7	1%
Young 2001[45]	26	0	0%													23	0	0%M			
National registries																					
SISP 2005				325	29	8.9%	221	6	2.7%	39	0	0%	141	3	2.1%	768	23	3.0%	1535	9	0.6%
NPTA 2005	452	25	5.5%	12562	547	4.4%	1565	56	3.6%	1772	43	2.4%	11956 275 2.3%						4285	43	1.0%
Non-randomised comparative studies																					
Back 2001[46]							18	9	50%							19	8	42%B			
Belloso 2003[6]							844	19	2%				743	46	6%						
Carr 2001[47]	16	1	6%													20	1	5%M			
Lassaletta 1997[48]				60	0	0%													60	0	0%
Lee 2004a[49]				192	23	12%										145	8	6%B			
MacGregor 1995[50]				36	1	3%							40	0	0%						
Montague 2004[52]				39	5	13%										76	2	3%B			

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
Noon 2003[53]				29	1	3%	36	8	22%												
Oluwasanmi 2003[54]				259	15	6%										52	1	2%B			
Roberts 1992[55]										490 13 3% diathermy technique for haemostasis not stated									460	8	2%
Rungby 2000[56]																57	3	5%B	77	1	1%
Schrey 2004[57]				165	24	15%										140	6	4%M			
Silveira 2003[58]				29	1	3%													28	0	0%
Tan 1993[59]	170 8 5% method of diathermy not stated																		282	15	5%
Wexler 1996[60]	52 8 15% electrocautery technique not stated															49	6	12%			
Case series																					
Andrea 1993[5]				265	1	0.4%															
Blomgren 2001[61]	413	136	33%																		
Ghufoor 2000[62]													160	17	11%						
Kanerva 2003[63]																100	15	15%B			
Kennedy 1990[64]										192 12 6% electrocautery technique for haemostasis not stated											
Kuo 1995[65]																			149	19	13%
Lee 1996[33]																			291	26	9%
Mahadevan 1995[66]				322	3	0.9%															
Panarese 1999[67]																392	0	0%			
Pang 1994[68]				100	3	3%															
Rivas Lacarte 1999[69]																			426	1	0.2%
Walker 1999[70]	565	41	7%																		
Walker 2001[71]	75	9	12%																		
Wilson 2001[72]																			384	8	2%

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection + ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
Total	1178	191	16%	1826	96	5%	976	40	4%	188	25	13%	1043	71	7%	1073	50	5%	2730	86	3%
Broad groups	3226 303 9%						976	40	4%	3509 179 5%									2730	86	3%
Within-patient studies																					
Akkielah 1997[73]	42	1	2%	42	2	5%															
Atallah 2000[74]				70	0	0%													70	0	0%
Choy 1992[75]				49	0	0%													49	0	0%
Haraldsson 2003[76]				32	2	6%							32	2	6%						
Leach 1993[77]	21 1 5% Method of diathermy not stated															21	0	0%			
Lee 2004b[49]				7	0	0%										7	0	0%B			
Salam 1992[78]										150	1	0.7%							150	1	0.7%
Tay 1995[79]	104 2 2% Method of diathermy not stated																		104	2	2%
Tay 1996[80]										105	0	0%							105	1	1%
Timms 2002[7]				10	0	0%	10	0	0%												
Weimert 1990[81]	103 1 1% Method of diathermy not stated															103	0	0%			
Total	42	1	2%	210	4	2%	10	0	0%	255	1	0.4%	32	2	6%	131	0	0%	478	4	0.8%
Broad groups	480 9 2%						10	0	0%	418 3 0.7%									478	4	0.8%

Notes:

1. N = number of participants analysed by the study, n = number of participants experiencing secondary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing secondary haemorrhage, B = bipolar diathermy, M = monopolar diathermy.

2. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).

3. Wales SISP 2005. Patient numbers do not sum to 3690 as some categories of operative technique have not been included. See Table 8, note 5.

4. Total and Broad groups rows are excluding the England and Northern Ireland NPTA final report (NPTA 2005) and Wales SISP 2005.

5. Cold steel dissection with ties/packs plus diathermy haemostasis column – additional information on the haemostasis technique:

Back 2001. Haemostasis was achieved by the application of pressure with packs, and persistent bleeding was controlled by a bipolar diathermy coagulation of vessels.

Carr 2001. In the cold steel group tonsils were removed with a curette and snare. Suction cautery was used sparingly for persistent bleeding points.

Kanerva 2003. Tonsillectomy was done with a cold dissection method, and haemostasis with packing and bipolar diathermy.

Lee 2004a. The haemostasis technique comprised bipolar diathermy with or without ties during cold dissection tonsillectomy.

Montague 2004. The haemostasis technique comprised bipolar diathermy with or without ties during cold dissection tonsillectomy.

Oluwasanmi 2003. Methods of haemostasis included: (1) bipolar diathermy, and (2) bipolar diathermy and ties. (Two patients also had pillars oversown.)

Panarese 1999. Tonsillectomy was performed using blunt dissection with the snare or tie technique to the lower pole and haemostasis was achieved by electrocautery or ligation of the vessels.

Rungby 2000. Methods of haemostasis were: (1) sole compression of the tonsillar fossae by packing with gauze tampons, (2) ligation, (3) bipolar diathermy, and (4) both ligation and bipolar diathermy.

Wexler 1996. Gauze packs were placed followed by selective cauterisation at bleeding sites with suction electrocautery.

Young 2001. Haemostasis was achieved by packing the tonsil bed with a Bismuth Subgallate and topical adrenaline paste mixture. Cautery with a monopolar bayonet forcep set at 20 coag. on a Valleylab Force 2 machine was used to cauterise point bleeders.

6. Brodsky 1996. The numbers in each group were not reported and were calculated from the secondary haemorrhage rate given.

7. Rungby 2000. This study contained 4 comparisons: (a) cold steel dissection with packs for haemostasis, (b) cold steel dissection with ligatures for haemostasis, (c) cold steel dissection with bipolar diathermy for haemostasis, (d) cold steel dissection with ligatures and bipolar diathermy for haemostasis. In the table (a) and (b) have been combined, and (c) and (d) have been combined. The 1 secondary haemorrhage in combined (a) and (b) came from (b). The 3 secondary haemorrhages in combined (c) and (d) came from (d).

8. Tan 1993. This study compared cold steel dissection (haemostasis technique not stated, assume ties/packs) with diathermy for dissection and haemostasis (diathermy technique not stated). The study gave results for inpatient and outpatient, but the numbers in the table are only for outpatient as secondary haemorrhage results for inpatients were not presented separately for cold steel and diathermy.

9. England and Northern Ireland NPTA final report (NPTA 2005). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.

10. England and Northern Ireland NPTA final report (NPTA 2005). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.

11. For the NPTA final report (NPTA 2005), for each technique, the numbers of patients experiencing a secondary haemorrhage were calculated from the numbers of patients undergoing each technique and the secondary haemorrhage rate for each technique.

12. Oluwasanmi 2003. The cold steel dissection + bipolar diathermy haemostasis group includes some patients with just bipolar diathermy haemostasis (n=22) and some with bipolar diathermy + ties haemostasis (n=28).

13. Schrey 2004. The numbers in each group were not reported and were calculated from the secondary haemorrhage rate given.

14. Leach 1993. For the cold steel technique, for haemostasis pressure packs were applied to the fossa and persistent bleeding was controlled by point coagulation of vessels. Postoperative bleeding was rated subjectively on a scale of 0 to 10. On the cautery excision side, bleeding was rated an average of 1.3; on the dissection/snare side, it was rated an average 1.7. The number of patients with any bleeding was not large enough to allow significant statistical comparison. One patient presented at postoperative day 6 complaining of bleeding from the cautery excision side. On presentation, the bleeding had ceased, and the patient was haemodynamically stable. No further intervention was rendered, and the bleeding did not recur.

Appendix 6. Study results, primary haemorrhage requiring return to theatre

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	n	%	N	N	%	N	n	%	N	N	%	N	n	%	N	n	%	N	n	%
RCTs																					
Kujawski 1997[35]				100	0	0%							100	0	0%						
Pang 1995[37]				60	0	0%													60	1	2%
Temple 2001[42]				20	0	0%	18	0	0%												
National registries																					
SISP 2005				325	2	0.6%	221	0	0%	39	0	0%	141	0	0%	768	4	0.5%	1535	17	1.1%
NPTA 2005	452	4	0.9%	12562	40	0.3%	1565	17	1.1%	1772	11	0.6%	11956 36 0.3%						4285	30	0.7%
Non-randomised comparative studies																					
Back 2001[46]							18	0	0%							19	0	0%B			
Belloso 2003[6]							844	1	0.1%				743	2	0.3%						
Lassaletta 1997[48]				60	0	0%													60	0	0%
MacGregor 1995[50]				36	0	0%							40	0	0%						
Montague 2004[52]				39	0	0%										76	0	0%B			
Noon 2003[53]				29	0	0%	36	2	6%												
Oluwasanmi 2003[54]				259	0	0%										52	0	0%B			
Silveira 2003[58]				29	0	0%													28	1	4%
Wexler 1996[60]	52 0 0% electrocautery technique not stated															49	0	0%			
Case series																					
Andrea 1993[5]				265	0	0%															
Blomgren 2001[61]	413	1	0.2%																		
Kanerva 2003[63]																100	0	0%B			

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	n	%	N	N	%	N	n	%	N	N	%	N	n	%	N	n	%	N	n	%
Mahadevan 1995[66]				322	1	0.3%															
Panarese 1999[67]																392	3	0.8%			
Pang 1994[68]				100	0	0%															
Rivas Lacarte 1999[69]																			426	3	0.7%
Walker 1999[70]	565	2	0.4%																		
Walker 2001[71]	75	0	0%																		
Total	1053	3	0.3%	1319	1	0.1%	916	3	0.3%				883	2	0.2%	688	3	0.4%	574	5	0.9%
Broad groups	2424 4 0.2%						916	3	0.3%	1571 5 0.3%									574	5	0.9%
Within-patient studies																					
Akkielah 1997[73]	42	0	0%	42	0	0%															
Atallah 2000[74]				70	0	0%													70	0	0%
Choy 1992[75]				49	0	0%													49	0	0%
Haraldsson 2003[76]				32	0	0%							32	0	0%						
Lee 2004b[49]				7	0	0%										7	0	0%			
Salam 1992[78]										150	0	0%							150	0	0%
Tay 1995[79]	104 0 0% Method of electrodissection not stated																		104	0	0%
Tay 1996[80]										105	1	1%							105	0	0%
Timms 2002[7]				10	0	0%	10	0	0%												
Weimert 1990[81]	103 0 0% Method of electrodissection not stated															103	1	1%			
Total	42	0	0%	210	0	0%	10	0	0%	255	1	0.4%	32	0	0%	110	1	0.9%	478	0	0%
Broad groups	459 0 0%						10	0	0%	397 2 0.5%									478	0	0%

Notes:

1. N = number of participants analysed by the study, n = number of participants experiencing primary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing primary haemorrhage, B = bipolar diathermy, M = monopolar diathermy.

2. Wales SISP 2005. Patient numbers do not sum to 3690 as some categories of operative technique have not been included. See Table 8, note 5.

3. England and Northern Ireland final report (NPTA 2005). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.

4. England and Northern Ireland NPTA final report (NPTA 2005). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.

5. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).

6. Total and Broad groups rows are excluding the England and Northern Ireland NPTA final report (NPTA 2005) and Wales SISP 2005.

7. For the NPTA final report (NPTA 2005), for each technique, the numbers of patients experiencing a primary haemorrhage requiring return to theatre were calculated from the numbers of patients undergoing each technique and the primary haemorrhage requiring a return to theatre rate for each technique.

8. Cold steel dissection with ties/packs plus diathermy haemostasis column – additional information on the haemostasis technique:

   Back 2001. Haemostasis was achieved by the application of pressure with packs, and persistent bleeding was controlled by a bipolar diathermy coagulation of vessels.

   Kanerva 2003. Tonsillectomy was done with a cold dissection method, and haemostasis with packing and bipolar diathermy.

   Montague 2004. The haemostasis technique comprised bipolar diathermy with or without ties during cold dissection tonsillectomy.

   Oluwasanmi 2003. Methods of haemostasis included: (1) bipolar diathermy (n=22), and (2) bipolar diathermy and ties (n=28). (Two patients also had pillars oversown.)

   Panarese 1999. Tonsillectomy was performed using blunt dissection with the snare or tie technique to the lower pole and haemostasis was achieved by electrocautery or ligation of the vessels.

   Wexler 1996. Gauze packs were placed followed by selective cauterisation at bleeding sites with suction electrocautery.

Appendix 7 Study results, all primary haemorrhage

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
RCTs																					
Kujawski 1997[35]				100	0	0%							100	0	0%						
Pang 1995[37]				60	0	0%													60	1	2%
Stoker 2004[41]	42	0	0%				43	1	2%												
Temple 2001[42]				20	0	0%	18	0	0%												
Watson 1993[43]										523 15 3% diathermy technique for haemostasis not stated									513	12	2%
National registries																					
SISP 2005				325	3	0.9%	221	1	0.5%	39	0	0%	141	0	0%	768	6	0.8%	1535	19	1.2%
NPTA 2005	452	5	1.1%	12562	55	0.4%	1565	16	1.0%	1772	9	0.5%	11956 60 0.5%						4285	34	0.8%
Non-randomised comparative studies																					
Back 2001[46]							18	5	28%							19	3	16%B			
Belloso 2003[6]							844	5	0.6%				743	3	0.4%						
Lassaletta 1997[48]				60	0	0%													60	1	2%
Lee 2004a[49]				192	1	0.5%										145	0	0%B			
MacGregor 1995[50]				36	0	0%							40	0	0%						
Montague 2004[52]				39	0	0%										76	0	0%B			
Noon 2003[53]				29	0	0%	36	3	8%												
Oluwasanmi 2003[54]				259	0	0%										52	0	0%B			

Study design and study id	Monopolar diathermy dissection and haemostasis			Biopolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection + bipolar haemostasis			Cold steel dissection+ties plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Roberts 1992[55]										490 9 2% specific diathermy technique for haemostasis not stated									460	16	4%
Rungby 2000[56]																57	3	5%B	77	3	4%
Schrey 2004[57]				165	4	2%										140	9	6%M			
Silveira 2003[58]				29	0	0%													28	1	4%
Tan 1993[59]	170 2 1% method of diathermy not stated																		282	14	5%
Wexler 1996[60]	52 0 0% electrocautery technique not stated															49	0	0%			
Case series																					
Andrea 1993[5]				265	0	0%															
Blomgren 2001[61]	413	10	2%																		
Kanerva 2003[63]																100	0	0%B			
Kennedy 1990[64]										192 4 2% electrocautery technique for haemostasis not stated											
Mahadevan 1995[66]				322	3	0.9%															
Panarese 1999[67]																392	6	2%			
Pang 1994[68]				100	0	0%															
Rivas Lacarte 1999[69]																			426	4	0.9%
Walker 1999[70]	565	2	0.4 %																		
Walker 2001[71]	75	0	0%																		
Total	1095	12	1%	1676	8	0.5%	959	14	1%				883	3	0.3%	1030	21	2%	1906	52	3%
Broad groups	2993 22 0.7%						959	14	1%	3118 52 2%									1906	52	3%
Within-patient studies																					
Akkielah 1997[73]	42	0	0%	42	0	0%															
Atallah 2000[74]				70	0	0%													70	0	0%
Choy 1992[75]				49	0	0%													49	0	0%

Study design and study id	Monopolar diathermy dissection and haemostasis			Bipolar diathermy dissection and haemostasis			Coblation dissection and haemostasis			Cold steel dissection + monopolar haemostasis			Cold steel dissection +bipolar haemostasis			Cold steel dissection +ties Plus diathermy haemostasis			Cold steel dissection + ligatures/packs haemostasis		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Haraldsson 2003[76]				32	0	0%							32	0	0%						
Lee 2004b[49]				7	0	0%										7	0	0%			
Salam 1992[78]										150	0	0%							150	0	0%
Tay 1995[79]	104 0 0% Method of electrodissection not stated																		104	0	0%
Tay 1996[80]										105	1	1%							105	0	0%
Timms 2002[7]				10	0	0%	10	0	0%												
Weimert 1990[81]	103 0 0% Method of electrodissection not stated															103	1	1%			
Total	42	0	0%	210	0	0%	10	0	0%	255	1	0.4%	32	0	0%	110	1	0.9%	478	0	0%
Broad groups	459 0 0%						10	0	0%	397 2 0.5%									478	0	0%

Notes:

1. N = number of participants analysed by the study, n = number of participants experiencing primary haemorrhage, except for within-patient studies, where N = number of tonsils, n = number of fossae experiencing primary haemorrhage, B = bipolar diathermy, M = monopolar diathermy.

2. The numbers in the Total row may not sum to the number in the equivalent Broad groups row. This is because in some studies although diathermy was used it was unclear whether this was monopolar or bipolar and therefore these studies could not be included in the Total row giving numbers for specific techniques (e.g. monopolar diathermy, bipolar diathermy) but they could be included in the equivalent Broad groups row (e.g. diathermy).

3. Total and Broad groups rows are excluding the England and Northern Ireland NPTA final report (NPTA 2005) and Wales SISP 2005.

4. Wales SISP 2005. Patient numbers do not sum to 3690 as some categories of operative technique have not been included. See Table 8, note 5.

5. Cold steel dissection with ties/packs plus diathermy haemostasis column – additional information on the haemostasis technique:

   Back 2001. Haemostasis was achieved by the application of pressure with packs, and persistent bleeding was controlled by a bipolar diathermy coagulation of vessels.

   Kanerva 2003. Tonsillectomy was done with a cold dissection method, and haemostasis with packing.

   Lee 2004a. The haemostasis technique comprised bipolar diathermy with or without ties during cold dissection tonsillectomy.

Montague 2004. The haemostasis technique comprised bipolar diathermy with or without ties during cold dissection tonsillectomy.

Oluwasanmi 2003. Methods of haemostasis included: (1) bipolar diathermy (n=22), and (2) bipolar diathermy and ties (n=28). (Two patients also had pillars oversown.)

Panarese 1999. Tonsillectomy was performed using blunt dissection with the snare or tie technique to the lower pole and haemostasis was achieved by electrocautery or ligation of the vessels.

Rungby 2000. Methods of haemostasis were: (a) sole compression of the tonsillar fossae by packing with gauze tampons, (b) ligation, (c) bipolar diathermy, and (d) both ligation and bipolar diathermy. In the table (a) and (b) have been combined, and (c) and (d) have been combined.

Wexler 1996. Gauze packs were placed followed by selective cauterisation at bleeding sites with suction electrocautery.

6. Schrey 2004. The numbers in each group were not reported and were calculated from the primary haemorrhage rate given.

7. Tan 1993. The study gave results for inpatient and outpatient, but the numbers in the table are only for outpatient as secondary haemorrhage results for inpatients were not presented separately for cold steel and diathermy.

8. England and Northern Ireland NPTA final report (NPTA 2005). In the table, the numbers for (i) bipolar diathermy scissors for dissection and haemostasis and (ii) for bipolar diathermy forceps for dissection and haemostasis have been combined.

9. England and Northern Ireland NPTA final report (NPTA 2005). Ties were used with diathermy in 5508 (46%) cases in the cold steel dissection and bipolar diathermy haemostasis group and in 649 (37%) cases in the cold steel dissection and monopolar diathermy haemostasis group.

10. For the NPTA final report (NPTA 2005), for each technique, the numbers of patients experiencing a primary haemorrhage were calculated from the numbers of patients undergoing each technique and the primary haemorrhage rate for each technique.

Appendix 8 Power settings and secondary haemorrhage rates

Study id	Technique	Power setting	All secondary haemorrhage; secondary haemorrhage requiring return to theatre	Technique	Power setting	All secondary haemorrhage; secondary haemorrhage requiring return to theatre
RCTs						
Brodsky 1996[34]	Cold steel dissection with monopolar diathermy haemostasis	20 W for haemostasis	10%; not reported	Bipolar diathermy	10 W, soft, for haemostasis	2%; not reported
Nunez 2000[36]	Cold steel dissection with monopolar diathermy haemostasis	30 W for haemostasis	4%; 0%	Monopolar diathermy	70 W cutting mode for incision 40 W coagulation mode for dissection 30 W for haemostasis	8%; 0%
Pang 1995[37]	Cold steel dissection with ties/packs haemostasis		2%; 0%	Bipolar diathermy	30 W for dissection 30 W for haemostasis	2%; 0%
Stoker 2004[41]	Monopolar diathermy dissection and haemostasis	Set point 17±3 for dissection Set point 25±3 for haemostasis	5%; not reported	Coblation	Set point between 6 and 9 for excision	7%; not reported
Young 2001[45]	Cold steel dissection with diathermy or ties plus diathermy haemostasis	30 W for dissection 55 W coagulation for haemostasis	0%; 0%	Monopolar diathermy	20 W coagulation for haemostasis	0%; 0%
Non-randomised comparative studies						
Back 2001[46]	Cold steel dissection with diathermy or ties plus diathermy haemostasis	Not reported	42%; 5%	Coblation	Power set to levels 5–7 (192-260 Vrms during ablation. In case of bleeding coagulation mode applied	50%; 6%
Lassaletta 1997[48]	Cold steel dissection with ties/packs haemostasis		0%; 0%	Bipolar diathermy	30 W for haemostasis	0%; 0%

Study id	Technique	Power setting	All secondary haemorrhage; secondary haemorrhage requiring return to theatre	Technique	Power setting	All secondary haemorrhage; secondary haemorrhage requiring return to theatre
MacGregor 1995[50]	Cold steel dissection with bipolar diathermy haemostasis	Not reported	0%; 0%	Bipolar diathermy	8 W dissection, increased if necessary	3%; 0%
Noon 2003[53]	Bipolar diathermy	50 W and set at 4/10 for haemostasis	3%; 0%	Coblation	Not reported	22%; 6%
Silveira 2003[58]	Cold steel dissection with ties/packs haemostasis		0%; 0%	Bipolar diathermy	40 W dissection 40 W haemostasis	3%; 3%
Wexler 1996[60]	Cold steel dissection with diathermy or ties plus diathermy haemostasis	Not reported	12%; 0%	Diathermy (technique not stated)	20 W in coagulation mode for dissection and haemostasis	15%; 0%
Case series						
Blomgren 2001[61]	Monopolar diathermy	17.5 W coagulation for dissection and haemostasis	33%; 1%			
Pang 1994[68]	Bipolar diathermy	30 W dissection 30 W haemostasis	3%; 2%			
Walker 1999[70]	Monopolar diathermy	15-20 W cut/coagulation blend for dissection and haemostasis	7%; 0.4%			
Walker 2001[71]	Monopolar diathermy	20 W for dissection 35 W for additional haemostasis	12%; 4%			

Study id	Technique	Power setting	All secondary haemorrhage; secondary haemorrhage requiring return to theatre	Technique	Power setting	All secondary haemorrhage; secondary haemorrhage requiring return to theatre
Within-patient studies						
Akkielah 1997[73]	Bipolar diathermy	6 W	5%; 0%	Monopolar diathermy	4 W cutting 8 W coagulation in blend mode	2%; 0%
Haraldsson 2003[76]	Cold steel dissection with bipolar diathermy haemostasis	Not reported	6%; 0%	Bipolar diathermy	20 W dissection	6%; 0%
Tay 1996[80]	Cold steel dissection with ties/packs haemostasis		1%; not reported	Cold steel dissection with monopolar diathermy haemostasis	25 W for children 30 W for adults	0%; 0%
Timms 2002[7]	Bipolar diathermy	50 W and set at 4/10 for dissection	0%; 0%	Coblation	Not reported	0%; 0%