

National Institute for Health and Clinical Excellence

242 – Tonsillectomy using the ultrasonic scalpel

Comments table

IPAC date: 13 April 2006

Consultee name and organisation	Section no.	Comment no.	Comments	Response
Spartanburg ENT	1	1	post op bleed is no more prevalent than conventional methods	Please respond to all comments Recommendation as per electrosurgery for tonsillectomy. The safety section clearly states that primary haemorrhage rates appear to be lower but secondary haemorrhage rates varied – and in one study comparing ultrasonic scalpel to cold steel haemorrhage rates were higher. A finding of the National Audit was that higher rates of haemorrhage occurred with thermal methods, although harmonic scalpel was not included in this analysis. In addition, specialist advisors (2.4.5) also commented that secondary haemorrhage rates appear to be higher.

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Individual respondent – Clinician	1	2	Having extensive experience in the use of ultrasonic shears in laparoscopic colorectal surgery, haemorrhage is REDUCED with this method, ultrasound is much more efficient in coagulation than diathermy. It is also less damaging as the depth of tissue affected is 2cm rather than 7cm with diathermy. lower temperatures are also generated so the reduction in toxic smoke produced is much less both to the patient and the theatre staff. The plume produced with ultrasound is not smoke but water vapour, steam. I have experience using ultrasound in laparoscopic surgery for the last 5 years. Vessels of up to 2mm can be ligated safely with ultrasound.	Noted but no change in guidance, as per above comment.

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Johnson and Johnson medical Ltd	1	3	<p>Thank you for the opportunity to comment on the above interventional procedures consultation document. The review summarises the available evidence in a balanced and fair manner.</p> <p>We broadly agree with the recommendations as they currently stand. However, we would contend that the clinical evidence base available today for this indication is insufficient to infer that the incidence rates of haemorrhage associated with the harmonic scalpel, are higher than those seen with conventional techniques used for tonsillectomy.</p>	<p>See above comment.</p> <p>1.2 States that the use of ultrasonic scalpel for tonsillectomy may result in higher rates of secondary haemorrhage rates.</p> <p>The comment about the evidence base is acknowledged in 2.3.3 which states that the evidence base is still small and that a number of the studies had methodological limitations.</p>
Johnson and Johnson medical Ltd	1.2	4	<p>We suggest that the wording of the guidance should reflect this uncertainty and be changed to “the rate of haemorrhage associated with the use of harmonic scalpel in tonsillectomy has yet to be conclusively demonstrated to be different to the rates seen with existing techniques.”</p> <p>The guidance should reflect the current level of evidence for this procedure, and we hope that as the level of evidence supporting the safety and efficacy of the use of the harmonic scalpel in tonsillectomy increases, that this recommendation may be revised in the near future.</p>	<p>Adopting the consultee’s comment would disregard both the evidence presented in section 2.4 (safety) and specialist advisors comments. No change required.</p>
Spartanburg ENT	2.1	5	<p>indications are the same for any tonsillectomy-- method is not complicated and easy to master</p>	<p>No change in the guidance is required.</p>

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Spartanburg ENT	2.3	6	pain is the same or less than traditional methods	This is already addressed in 2.3.1 (states that similar pain scores were reported following each method of tonsillectomy).
Spartanburg ENT	2.4	7	Bleeding is no more than other methods and probably less	See comments above