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Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Microdebrider intracapsular tonsillectomy

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**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID S000069

NAME OF TECHNOLOGY MICRODEBRIDER INTRACAPSULAR
TONSILLECTOMY

PURPOSE AND TARGET GROUP PAEDIATRIC PATIENTS SUFFERING FROM
TONSILLITIS OR OBSTRUCTIVE SLEEP DISORDERS

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input checked="" type="checkbox"/> Established <i>but</i> changed indication
or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|--|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input type="checkbox"/> No | | |
| <input checked="" type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States		✓	

IMPACT SUMMARY

Intracapsular tonsillectomy utilising a microdebrider is an alternative technique to conventional tonsillectomy with the aim of treating tonsillitis and obstructive sleep disorders within the paediatric population.

BACKGROUND

Tonsillectomy is one of the most frequent procedures performed in the paediatric population, and was first described by Fowler in 1930 primarily for the treatment of chronic infections/tonsillitis (Fowler 1930). Over time, obstructive sleep disorders have surpassed chronic infections/tonsillitis as the primary indication for tonsillectomy in

children (Derkay et al. 2006). The basic technique of tonsillectomy, dissection of all tonsillar tissue free from the underlying pharyngeal constrictor muscle, has not changed substantially in over 60 years. Tonsillectomy can be performed utilising a variety of technical means, such as cold dissection, electrocautery, bipolar cautery and coblation (Solares et al. 2005). However, despite the widespread utilisation of new tonsillectomy techniques, patients are often affected by two common complications; prolonged pain and delayed bleeding (Sorin et al. 2004, Schmidt et al. 2007).

The pain experienced post-tonsillectomy occurs due to the exposure of the pharyngeal musculature to injury, bacterial colonisation and inflammation. This pain typically persists for 7 to 10 days post-surgery, ranging from moderate to severe in intensity. Chronic pain can occur in some patients, and it is not unusual for some patients to be readmitted for the control of severe pain and the management of dehydration as a result of poor fluid intake secondary to this pain (Schmidt et al. 2007). Bleeding remains a risk until the primary tonsillar feeding vessels have healed (Solares et al. 2005), and delayed bleeding have been documented in 2% to 4% of all patients (Schmidt et al. 2007).

In recent literature, intracapsular tonsillectomy had garnered interest within the medical community as a potential alternative technique with the promise of reducing or even eliminating the risk of pain and delayed bleeding. Intracapsular tonsillectomy is in fact *not* an entirely new procedure, it can be considered a “re-introduction” of an older procedure utilising a modern medical device, the microdebrider.

Intracapsular tonsillectomy is essentially a purposeful reduction in tonsil size (~90%) utilising an endoscopic microdebrider, eliminating the infected/obstructive portion of the tonsil while preserving the tonsillar capsule. The tonsillar capsule acts as a protective cover to the pharyngeal musculature; which should theoretically reduce pain and the risk of bleeding while improving the healing process (Vaughan and Derkay 2007).

CLINICAL NEED AND BURDEN OF DISEASE

Obstructive sleep apnoea (OSA) is one of the most referred conditions to paediatric otolaryngologists (Tamay et al. 2006) with estimated prevalence rates of 0.5% to 3% in the literature (Kuppersmith 1996). The epidemiology of paediatric OSA is poorly understood due to the absence of extensive epidemiologic studies and the lack of consensus with regards to the criteria utilised to diagnosed OSA in children. This is worrying considering the fact that OSA, if left untreated, can result in growth retardation, cor pulmonale and neurocognitive deficits (Tamay et al. 2006).

Prior to the increasing use of tonsillectomy to treat OSA, tonsillitis was the main indication for the procedure. Tonsillitis has an incidence of 100 per 1000 population a year in general practice in the UK, with acute tonsillitis occurring more frequently in children (Georgalas et al. 2007). Recurrent severe tonsillitis can result in considerable morbidity, with the most common complication being peritonsillar abscess. If the infection is associated with group A beta haemolytic streptococci, rheumatic fever and

acute glomerulonephritis may develop, but this is relatively rare in resource rich countries.

DIFFUSION

Intracapsular tonsillectomy is not standard practice in any country. Its implementation lies solely on the decision of the patient/parents and the clinician. At the time of writing, there is no clear indication of the extent of its utilisation within the Australian and New Zealand healthcare system.

COMPARATORS

- Conventional tonsillectomy
- Coblation tonsillectomy
- Laser-based tonsillectomy
- Radiofrequency-based tonsillectomy
- Electrocautery
- All other variations of tonsillectomy

SAFETY AND EFFECTIVENESS ISSUES

Large retrospective studies comparing intracapsular tonsillectomy utilising the microdebrider to other techniques (e.g. electrocautery) have been published (Schmidt et al. 2007, Solares et al. 2005, Koltai et al. 2003). However, considering the potential scientific bias and inaccuracies that are associated with the use of retrospective data, only results from randomised controlled trials (RCT) will be presented in this summary.

In all three RCTs, children were treated for obstructive adenotonsillar hypertrophy, with primary outcomes being the intensity of pain, cessation of pain medication, blood loss, resumption of normal activity/normal diet and patient/parent satisfaction. All RCTs compared microdebrider intracapsular tonsillectomy to total electrocautery tonsillectomy.

a) Safety

A randomised controlled trial comparing microdebrider intracapsular tonsillectomy to electrocautery (Derkey et al. 2006) highlighted that both paediatric patient groups had similar rates of blood loss during the tonsillectomy portion of the procedure. However, 15% of microdebrider patients experienced blood loss greater than 25 cc during the entire procedure, significantly higher in comparison to the 4% in electrocautery patients ($p < 0.01$). Nevertheless this data includes the blood loss experienced during the adenoidectomy part of the procedure, and is therefore of little significance for the purposes of this comparison. Nearly all patients (in both groups) had less than 25 cc blood loss during the tonsillectomy portion of the procedure, indicating that microdebrider intracapsular tonsillectomy does not result in greater blood loss relative to electrocautery. Contrary to this, the RCT by Sobol et al. (2006) reported a significant difference in blood loss between intracapsular microdebrider patients (45 ml) and monopolar electrocautery patients (30 ml) ($p = 0.01$). However, the upper bound of the confidence interval for blood loss did not exceed the clinically important difference of

~30 ml. Therefore these results, although statistically significant, are not likely to be clinically significant (Sobol et al. 2006).

Delayed bleeding for microdebrider intracapsular tonsillectomy patients were virtually similar in all the three RCTs relative to electrocautery. Derkay et al. (2006) noted that only one microdebrider patient and two electrocautery patients required control of postoperative bleeding. Meanwhile, no postoperative bleeding was observed for microdebrider intracapsular patients by Sobol et al. (2006) and Lister et al. (2006). It appears therefore that delayed bleeding is at least comparable to electrocautery within this limited pool of RCTs.

Derkay et al. (2006) also noted that no differences were observed with respect to readmission for dehydration or bleeding between microdebrider and electrocautery patients.

Pain levels at discharge were comparable to electrocautery in one RCT (Derkay et al. 2006). Sobol et al. (2006) observed no difference with regards to the number of days to near complete resolution of pain, but the intensity of pain immediately post-treatment/at discharge was not reported. The paired control RCT¹ by Lister et al. (2006) had more supportive results, with microdebrider tonsillectomy sides experiencing significantly less pain (Faces Pain Scale-Revised [FPS-R]) compared to the electrocautery side from days one to nine post-treatment. FPS-R scores for microdebrider patients levelled off to a mean of 1 at day 9, compared to day 12 for electrocautery, indicating a faster rate of pain resolution (Lister et al. 2006). It should be noted that following bilateral tonsillar procedures, there is a tendency for the sensation of pain to be generalised to the entire oropharynx. Therefore the differences in pain reported for paired control studies such as this one may be understated. Conversely, this may also distort the results if the child focuses more on the side with greater pain, thus overstating the difference between the procedures.

b) Effectiveness

Children treated with microdebrider intracapsular tonsillectomy resumed normal activity faster compared to those treated with electrocautery (Median: 2.5 days vs 4 days). Meanwhile, median time to normal diet was similar between treatment groups. Cessation of pain medication was significantly quicker for microdebrider patients compared to electrocautery ($p < 0.0001$), indicating faster recovery although pain intensity at discharge was similar between treatment groups (Derkay et al. 2006). In addition, patients who underwent microdebrider intracapsular tonsillectomy were able to return to a normal diet 1.5 days sooner. Meanwhile, Sobol et al. (2006) noted no difference in time to normal activity and cessation of pain medication. However, microdebrider patients experienced significantly quicker recovery of near-normal diet relative to electrocautery (4.4 days vs. 2.7 days; $p = 0.04$) (Sobol et al. 2006).

¹ The paired control RCT by Lister et al. (2006) treated one side with microdebrider intracapsular tonsillectomy, while the remaining side received electrocautery tonsillectomy.

Quality of life surveys did not reveal any significant differences between microdebrider tonsillectomy and electrocautery with regards to pre- and post-treatment changes in physical suffering, sleep disturbance, speech/swallowing problems and caregiver concern. Both patient groups experienced comparable and equivalent improvements in all these parameters and all were satisfied with their treatment (Derkay et al. 2006). However, children treated with microdebrider tonsillectomy appeared to be more satisfied. Parent's of the microdebrider group noted that there was a significantly larger decrease in emotional distress ($p = 0.01$) and activity limitation ($p < 0.01$) relative to parents of children who underwent electrocautery (Derkay et al. 2006).

Derkay and colleagues (2006) noted that patients who underwent microdebrider tonsillectomy were almost 5 times more likely (23%) to have some visible lymphoid tissue in their tonsillar fossa at 4 weeks post-treatment compared to total tonsillectomy electrocautery patients (6%). Nevertheless, no patient demonstrated the presence of clinically significant residual tissue and relief of snoring was evident in all patients.

COST IMPACT

The cost of each disposable blade for the use of the microdebrider is approximately US\$100 (Derkay et al. 2006). Sobol et al. (2006) reported that adenotonsillectomy took an average 4.3 minutes longer when a microdebrider was utilised. When the authors took into account the fact that an average of 2300 adenotonsillectomy procedures are performed per annum, the increased time with the microdebrider may account for 165 hours of operative time per annum. With a cost per minute of operating time of US\$86.71, the estimated increased cost was greater than US\$370 per patient compared to electrocautery (Sobol et al. 2006). Considering that no cost effectiveness studies have been undertaken, it is difficult to predict if the potential benefits of microdebrider intracapsular tonsillectomy justifies its increased ongoing cost.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

None of the studies included evaluated the relief of tonsillar hypertrophy symptoms in sufficient detail. Furthermore the risk of recurrent tonsillitis, evident from the nature of intracapsular tonsillectomy, was not investigated in the included RCTs.

SUMMARY OF FINDINGS

The included evidence indicates that microdebrider intracapsular tonsillectomy *may* result in less pain (Lister et al. 2006), but two of the three included RCTs did not observe a significant improvement in pain intensity at discharge relative to electrocautery (Derkay et al. 2006, Sobol et al. 2006). There is some evidence that indicated a faster rate of recovery (time to normal activity/diet, cessation of pain medication etc.) (Derkay et al.

2006); or at least comparable recovery rates (Sobol et al. 2006) relative to electrocautery patients. The residual tonsil tissue from intracapsular tonsillectomy could theoretically result in future bouts of tonsillitis; however this was not investigated in the included studies.

HEALTHPACT ACTION

Based on the available evidence, microdebrider intracapsular tonsillectomy will be archived.

NUMBER OF STUDIES INCLUDED

Total number of studies 3
Level II intervention evidence

REFERENCES

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SEARCH CRITERIA TO BE USED

Tonsillectomy

Intracapsular tonsil*

Tonsillotomy