

7<sup>th</sup> December 2009

Address mailmerge

Dear SHA Directors of Commissioning

**ENTUK Position Papers 2009  
Tonsillectomy  
OME (Glue Ear) / Adenoids and Grommet Insertion**

Please find enclosed the two position papers we have generated on these topics because of recent speculation on the future of elective surgery. The publication of the McKinsey Report questioned the efficiency of these operations and proposed reductions in activity to reduce costs in the NHS. However, this is not the first time these reductions have been proposed.

These documents are based on existing evidence which is referenced in them. I am pleased to inform you that more evidence has been accumulated from randomised trials and this will be published in 2010. This will confirm the patient benefit of these interventions and we will make it widely available following publication.

Existing evidence indicates that severe reductions in the numbers of these commonly performed procedures will deny useful treatment to a large number of patients, particularly children.

With this in mind, I would be grateful if you would arrange for this letter and the enclosed papers to be circulated to relevant Directors of Commissioning and to Chairs and Medical Directors of the Primary Care Trusts in your Strategic Health Authority.

Yours sincerely,



Alan P Johnson FRCS  
President



at The Royal College of Surgeons of England  
35-43 Lincoln's Inn Fields  
London WC2A 3PE

Tel: 020 7404 8373 Fax: 020 7404 4200

Email: [admin@entuk.org](mailto:admin@entuk.org) Web: [www.entuk.org](http://www.entuk.org)

# **OME (Glue Ear)/ Adenoid and Grommet Position Paper ENT UK 2009**

ENT UK trading as  
British Academic Conference in Otolaryngology (BACO) and British Association of Otorhinolaryngology –  
Head & Neck Surgery (BAO-HNS)

*Registered as a Company limited by Guarantee in England and Wales under Company No 06452601  
Registered with the Charity Commission in England and Wales under Charity No 1125524*

# **OME (Glue Ear)/ Adenoid and Grommet Position Paper ENT UK 2009**

## **Role of surgery in treating glue ear**

The only effective intervention for treating childhood hearing loss caused by glue ear (otitis media with effusion; OME) is the insertion of grommets, (ventilation tubes). In selected cases removal of the adenoid from the back of the nose, adjacent to the Eustachian tube opening (which allows air pressure equilibration) is also recommended. Grommet insertion and adenoidectomy work by reducing low grade infective biofilm<sup>1</sup> load in the back of the nose, and causing a massive increase in oxygen tension in the middle ear; this in turn, further inhibits inflammation mucin gene activity and hence the formation of middle ear fluid (glue)<sup>2</sup>. Most grommet and adenoid procedures are carried out as day cases with very little systemic morbidity or risk.

## **Intervention criteria**

In 2008, the National Institute for Health and Clinical Excellence (NICE) published guidance following expert statistical and health economic review of the optimum international scientific evidence (CG60, Surgical management of OME). NICE states that children who will benefit from surgical intervention are those with persistent bilateral glue ear, documented for a period of 3 months or more, and a hearing level in the better ear of 25–30 decibels hearing loss or worse, averaged at 0.5, 1, 2 and 4 kHz. (For reference, a 16 to 25 dB hearing loss may be mimicked by plugging the ears with the index fingers). At even 16dB, a child can miss 10% of the speech signal even when the listener is 4 feet away. Thus, in a classroom environment, a 25 - 30dB loss presents an appreciable educational difficulty.

The rate of UK surgical intervention for childhood glue ear has fallen steadily over the past 15 years. Adenoidectomy rates fell dramatically in the late 1990's from over 16,000 procedures per annum, and in 2008-09 there were 5529 adenoidectomy operations in children <15 years<sup>3</sup>. Childhood grommet insertion has also fallen from over 43,300 operations in 1994-95 to under 25300 in 2008-09 – a 42% reduction, largely due to the better understanding of the natural history of glue ear and the role of 'watchful waiting'.

## **Watchful waiting or 'active monitoring'**

Watchful waiting<sup>4</sup> is now recognised as an essential, preliminary period of observation with monitoring of hearing loss, since research by ENTUK surgeons, funded by the MRC (the TARGET multicentre trial<sup>5</sup>) has shown that 50% of children with a bilateral hearing loss of at least 20dB are likely to recover to normal with no treatment in the first three months after diagnosis. The remaining 50% with persistent hearing loss, concerns about speech, language or other associated problems are those potentially eligible for surgical intervention. In the persistent cases, of course, surgical intervention is inevitably delayed by this watchful waiting policy, leading to concerns that the UK surgical cut backs imposed over the last decade might have been excessive<sup>6</sup>, driven by cost-cutting rather than clinical evidence. This was the finding in Australia, where an independent medical investigation concluded that there was now actually an under-utilisation of ear nose and throat surgery in children - i.e. children requiring surgery were going untreated.

### **Limitations of RCTs of surgical intervention due to parental choice**

The UK TARGET study was a randomised trial design of surgical treatments for glue ear versus non-intervention, and final results reporting is imminent. The delay in the MRC team's publishing the overall trial outcome is partly because almost 60% of children with glue ear who were randomly selected into the 'no-surgical treatment' limb were switched out of the nonsurgical group by their parents, who decided their children should undergo surgery rather than suffer continuing hearing loss for the purposes of the research study. In other studies of similar high quality, up to 85% of parents of children allocated to the 'no treatment' group requested a move to the treatment group.

The fact that parents tend to switch children out of no treatment into surgery for glue ear has two important implications. Firstly, of course it underlines the level of concern and the recognition of the effectiveness of surgical intervention on the part of parents. Less obvious, but equally important is the fact that not all studies properly report the results according to who switched from no surgery to have surgery. The statistical impact of this habit is to underestimate the difference between the surgery and no surgery groups, as those gaining surgical benefit continue to be analysed as part of the no treatment group.

### **Implications for children of severe rationing of surgery for glue ear**

ENTUK is therefore alarmed to learn that non-medical 'consultants' on Health Service resource allocation have recently stated that the treatment of children's hearing impairment is largely 'unnecessary'. One problem for commissioners scrutinising the results of surgery is that sound is measured by the decibel scale which is logarithmic; the 2005 Cochrane review showed about 9dB improvement from grommets in the first six months after operation, 6dB in the next.. The raw numbers look unimpressive – but due to the logarithmic decibel scale, even a 3dB increase in sound equates to a doubling of intensity and hearing sensitivity. After 12 months there is, predictably little residual difference, in some series, between treated and control groups, as the hearing in both groups is now normal. Most parents (and teachers) do not want a child to spend a year in a school classroom with subnormal hearing.

Many other quoted studies include no hearing test data, as the children recruited were too young to perform the test. In this context, early, active management is supported by the testament of adults with glue ear<sup>7</sup>, who regularly present for treatment and well articulate the daily functional impact of a middle ear effusion. Any specific rationing of children's glue ear treatment, imposed by public health policy, would appear to represent a form of age discrimination favouring adults at the expense of children.

Earlier this year, McKinsey submitted a vision of wholesale withdrawal of 90% of NHS funded surgical treatment for hearing-impaired children (Table 1).

Table 1

Extract from Table “**Up to £700m could be saved if PCT’s decommissioned some procedures**”: 2009 report by McKinsey management consultants commissioned by the DH, as published in the *Health Service Journal*, 10 Sept 2009

<b>“Relatively ineffective”</b>	<b>Max potential reduction in procedures (%)</b>	<b>Max potential savings (£m)</b>
Tonsillectomy	90	45
Back pain injections and infusions	90	24
Grommets (glue ear)	90	21

ENTUK is concerned that there is no scientific basis for selection of the 10% of English children still in future to be judged ‘worthy’ in the eyes of the management consultants to receive definitive therapy. Parents, paediatricians, audiologists and otolaryngologists do not want children to be disadvantaged. The surgical alternative - to provide all children with glue ear with NHS digital hearing aids is neither cheap for providers nor acceptable to the vast majority of service users. Health economic modelling by NICE is fanciful in its speculative and evidence-free cost estimation of this alternative. At the end of the day, most of us, given the choice, would prefer not to have to wear a hearing aid when a safe and effective day case surgical treatment fixes the problem as a day case procedure.

### References

1. Fergie N et al. Is otitis media a biofilm infection? *Clin Otolaryngol* 2004; 29: 38-46.
2. Ubell ML et al Mucin gene polymorphisms in otitis media patients *Laryngoscope* 2009, epub ahead of print
3. [www.hesonline.nhs.uk](http://www.hesonline.nhs.uk)
4. Browning GG. Watchful waiting in childhood otitis media with effusion. Editorial. *Clin Otolaryngol* 2001; 26: 263-264.
5. MRC Multi-Centre Otitis Media Study Group Surgery for persistent otitis media with effusion: generalizability of results from the UK trial (TARGET). *Trial of Alternative Regimens in Glue Ear Treatment*. *Clin Otolaryngol* 2001;26: 417-424.
6. Hall AJ et al Developmental outcomes in early compared with delayed surgery for glue ear up to age 7 years: a randomised controlled trial. *Clin Otolaryngol* 2009, 34: 12-20
7. McCluney NA et al The assessment of hearing test results following surgery for otitis media with effusion in adults using the Glasgow Benefit Plot: how we do it. *Clin Otolaryngol* 2009, 34: 377-80



**ENT UK**

at The Royal College of Surgeons of England  
35-43 Lincoln's Inn Fields  
London WC2A 3PE

Tel: 020 7404 8373 Fax: 020 7404 4200

Email: [admin@entuk.org](mailto:admin@entuk.org) Web: [www.entuk.org](http://www.entuk.org)

# **Indications for Tonsillectomy Position Paper ENT UK 2009**

ENT UK trading as  
British Academic Conference in Otolaryngology (BACO) and British Association of  
Otorhinolaryngology – Head & Neck Surgery (BAO-HNS)

*Registered as a Company limited by Guarantee in England and Wales under Company No 06452601  
Registered with the Charity Commission in England and Wales under Charity No 1125524*

# **Indications for Tonsillectomy Position Paper ENT UK 2009**

## **Introduction**

This is a short paper produced by ENTUK to define the current position of tonsillectomy as a surgical procedure in terms of the indications, predicted outcomes and benefits of surgery. This document is based on the available evidence and references are available to support its conclusions.

## **Description of Tonsillitis**

Tonsillitis is an acute infection of the palatine tonsils. Episodes last for 5 to 14 days, during which the patient experiences some or all of the following: fever, malaise, nausea, severe throat pain, white spots on the tonsils, enlarged lymph glands in the neck (and sometimes abdomen). The attacks are common in children and their frequency may reduce with age, but the loss of time at school – usually 3 to 5 days per attack, several times per annum – can impact significantly on education. Tonsillitis is not as common in adults, but attacks can be as frequent and even more severe than in children and may cause significant loss of work due to illness. A severe complication of tonsillitis arising mainly in adults is peritonsillar abscess or **quinsy**, and this condition often requires hospital admission for treatment and pain control.

## **The cost of tonsillitis**

The economic impact of tonsillitis is considerable. Annually, 35 million days are lost from school or work due to sore throats in the UK. GP consultations for sore throat cost around £60 million annually.

## **Indications for surgery**

Tonsillectomy, the removal of the palatine tonsils, has three principal indications.

1. Recurrent attacks of tonsillitis (typically Streptococcal).
2. Enlarged tonsils causing obstruction of the airway, which may be the cause of Obstructive Sleep Apnoea – recurrent airway obstruction at night – and this has serious effects on health and wellbeing.
3. Possible malignant disease in the tonsils – typically squamous carcinoma or lymphoma.

For many years the UK guidance on tonsillectomy for tonsillitis has been only to consider surgery in those with attacks of at least moderate severity (several days' duration) per annum, for > 1 year – the SIGN guidance summarises the current consensus <sup>1</sup>:

Patients should meet all of the following criteria:

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

Those with very frequent infection (>8 per annum) or who are hospitalised with extremely severe tonsillitis or peritonsillar abscess (quinsy) may seek intervention within a year of symptom onset. Very similar guidance has evolved independently in the USA and Australia.

### **Changing practice**

In the 1950s there were about 200,000 tonsillectomies performed a year. In the last 15 years the rate of tonsillectomy has fallen in all age groups from 77,604 in 1994-95 to 49,187 in 2008-09<sup>2</sup>, a 37% reduction. In children, the Department of Health identified almost 56,000 childhood tonsillectomies in 1994-95. By 2008 – 09 HES data show under 27,400 tonsillectomies in those aged ≤ 15 years. Of these, an estimated 25% were for enlarged, obstructive tonsils, the remainder for infection. In adults there were just under 22,000 tonsillectomy procedures in 2008-09, the majority for persistent tonsillitis. The reason for the reduction in the rate of surgery is because surgeons have used the data available to refine the indications for surgery so that the operation is now only offered to patients most likely to benefit.

### **Increasing hospital admissions for tonsillitis and quinsy**

There is now a risk that too few tonsillectomies are being carried out. An increasing number of adults and children are being hospitalised annually for throat infections. In 2000-01, there were 30,942 tonsil-related admissions for medical treatments. By 2008-09, the figure had risen to 43,641 medical admissions for throat symptoms, an increase of over 41% (12,700 admissions in England) in 8 years. The incidence of admissions for quinsy is also rising - 6,352 admissions in 2000-01, rising to 7,683 in 2008-09, an increase of 1,331 admissions (over 20%), with a total of 11,865 bed days<sup>2</sup>. Quinsy is an extremely painful and debilitating complication of acute tonsillitis, which requires intraoral drainage in the fully conscious patient, followed by admission for intravenous antibiotic therapy. These conditions are cured by tonsillectomy and as tonsillectomy rates fall it is predictable that hospital admissions for severe tonsillitis and its complications will rise, and this is borne out by the data available. Any further reduction in the rate of tonsillectomy is likely to be associated with increases in hospital admissions for tonsillitis.

### **Alternative Treatment**

Antibiotic treatment is the standard treatment for acute bacterial tonsillitis, but the evidence is that increasing this treatment is likely to be neither good medical practice nor cost effective. Recent UK analysis of a million cases of sore throat treated in the 1990's showed a significant reduction in quinsy by the use of antibiotics – odds ratio 0.84<sup>3</sup> - but due to the relative incidence of sore throat and quinsy, the number needed to treat was 4,300, and the use of antibiotics for all sore throats remains hard to justify. For recurrent sore throat, indiscriminate use of antibiotics by GPs is well documented as serving mostly to increase reattendance rates<sup>4</sup>.

### **Benefits of Tonsillectomy**

Published data using generic and disease specific patient reported outcome measures on both sides of the Atlantic confirm the marked health status benefits in children<sup>5-8</sup>. These include both significant benefits in the general health perceptions, parental impact and family activities reported by over 90% of parents. The quality of life benefits in adults are likewise unequivocal (large effect size improvements in health care utilisation, swallowing, and breathing, as well as general health related quality of life physical functioning).



About one in five tonsillectomies in England are performed for tonsillar enlargement, which is associated with Obstructive Sleep Apnoea (OSA). OSA is a potentially life threatening condition and is the main indication for tonsillectomy in approximately 25% of UK children. - Adenotonsillectomy is curative in 75 to 80% of cases of OSA. In the USA, the performance of adenotonsillectomy for obstruction has increased markedly in the past 30 years from 12% in the early 1970's to 77% in 2000-2005<sup>9</sup>. It is to be hoped that national drives to promote healthy lifestyle in children will prevent the UK ever experiencing such an epidemic, as Obstructive Sleep Apnoea has a well documented, huge impact on childhood quality of life. The proportion of adults undergoing tonsillectomy for obstructive symptoms (2171 in England in 2007-08) is under 10%, possibly due to lower levels of morbid obesity than in the USA.

### **Conclusion**

Tonsillectomy remains a highly effective intervention in appropriate patients, not only in elimination of severe sore throats or upper airway obstruction, but also in terms of patient and parent reported quality of life. There are no data to suggest that the procedure is overused or abused in the UK. Tonsillectomy rates are lower in the UK than in any other country in Europe. In fact the trends of increasing hospitalisation for quinsy and severe forms of tonsillitis might indicate that rather than performing too many tonsillectomies in the UK, we are now performing too few.

### **References**

1. SIGN guideline No. 34 Management of sore throat and indications for tonsillectomy 1999
2. [www.hesonline.nhs.uk](http://www.hesonline.nhs.uk)
3. Petersen I et al Protective effect of antibiotics against serious complications of common respiratory tract infections; retrospective cohort study with the General Practice Research Database. *BMJ* 2007, 335: 982-4
4. Little P et al Open randomised trial of prescribing strategies in managing sore throat. *BMJ* 1997, 314: 722-7
5. Goldstein NA et al Quality of life after tonsillectomy in children with recurrent tonsillitis. *Otolaryngol Head Neck Surg* 2008, 138: S9-S16
6. Witsell DL et al Quality of life after tonsillectomy in adults with recurrent or chronic tonsillitis. *Otolaryngol Head Neck Surg* 2008 138: S1-S8
7. Kubba H et al Measuring quality of life in preschool children with sore throats and otitis media using the TAPQOL questionnaire. *Otolaryngol Head Neck Surg* 2005, 132: 647-652
8. Robb PJ et al Paediatric tonsillectomy: parental experience and outcomes. *J Laryngol Otol*. 2009, 123: 103-7
9. Erikson BK et al Changes in incidence and indications of tonsillectomy and adenotonsillectomy, 1970-2005. *Otolaryngol Head Neck Surg* 2009, 140: 894-901