Rationing based on 'procedures of limited clinical effectiveness': what are the risks?

Ear, nose and throat surgery originally arose with the primary purpose of draining pus from the ears, sinuses and various spaces of the head and neck. It became a specialty in its own right in the early 20th century after the fields of otology and laryngology combined. Since then it has come a long way but, in the main, finds itself focused on conditions that affect the quality of an individual's life rather than its quantity.

Defining clinical effectiveness

As is often the case with procedures and interventions that affect quality of life, the measurement of end points and outcomes is notoriously difficult. Historically, such assessment was done as part of a post-operative follow-up consultation. Generations of surgeons have been brought up on such practice and have been used to seeing patients, and their parents, report the benefits of their efforts, or lack of it. Criticism has been levelled at such evidence as necessarily biased by observer error and inaccurate recall, not to mention the patient's desire to please the surgeon.

Archie Cochrane is widely attributed as the founding father of evidence-based medicine – a system designed to review the best available evidence against prescribed standards and to make a quantitative decision about a treatment's efficacy and value. Such an approach undoubtedly provides a useful guide for the clinician and has helped to standardize care for patients. A worrying recent development, however, is that political masters and commissioners are using 'evidence-based medicine' as a cost-cutting tool.

In a drive to make financial savings, certain interventions are being labelled as 'procedures of limited clinical effectiveness'. For such procedures, funding from primary care trusts has either been completely lost or will only be provided if strict criteria are adhered to. However, it is important to remember that evidence-based medicine has its own limitations (Cohen and Hersh, 2004). Cochrane himself said: 'Lack of evidence of benefit does not mean evidence of lack of benefit'.

There are many procedures that do not have a sound evidence base to support their use. Perhaps the most illustrative is incision and drainage of an abscess. There are likely to be few doctors who would not feel that this is one of the oldest and most valuable procedures undertaken by physicians, and yet there is no level I evidence to support this intervention. Treatment for the individual cannot be based on evidence alone; clinical judgment is required to take into account the specific disease process and the patient's values and individual circumstances.

Ear, nose and throat surgery and procedures of limited clinical effectiveness

In ear, nose and throat surgery, two of the 'bread and butter' procedures, tonsillectomy and grommet insertion, have been labelled as procedures of limited clinical effectiveness. The authors believe that such a label is false and is, in fact, fraught with danger; this will be illustrated by taking a closer look at both of these interventions.

Grommets are placed for the management of otitis media with effusion – so-called 'glue ear'. Their placement allows the middle ear to ventilate and drain the accumulated fluid which returns the hearing thresholds to normal. Indications are a persisting hearing loss, particularly with speech delay or other educational issues. The UK TARGET study (Trial of Alternative Regimens in Glue Ear Treatment) examined 3831 children between the ages of 3 and 7 years and found significant benefit from grommet insertion compared to conservative management (Rollin and Narula, 2011). Of note, at 12-month follow up there is little difference between treatment groups in terms of audiological thresholds, as glue ear resolves spontaneously and grommets fall out. However, in children with grommets, parents continued to report improvement in hearing disability in the second year of observation.

It is noteworthy that 60% of children who were assigned to conservative treatment were switched into the surgical treatment arm by their parents. Parents do not want their children to have a year of early development affected by suboptimal hearing. And of course there are a small percentage of children in whom glue ear will not resolve spontaneously by 12 months. A long-term birth-cohort study showed that glue ear-related deficit in IQ testing remains significant at 13 years and deficit in reading ability is significant up to 18 years of age (Bennett et al, 2001). Can anyone really say that surgical intervention is of 'limited clinical effectiveness' in these children?

Tonsillectomy is undertaken mainly for recurrent tonsillitis in adults and children or obstructive sleep apnoea in children. The North of England and Scotland Study of Tonsillectomy and Adenotonsillectomy in Children (NESSTAC) enrolled 729 children and compared surgical to medical therapy (Wilson et al, 2012). This showed that tonsillectomy resulted in an average reduction of more than eight sore throats over 2 years. This was associated with reduced levels of GP consultation and antibiotic prescribing. Once again this study showed that the majority of parents and children prefer surgical intervention. In another study of children undergoing tonsillectomy, there was a 100% parental satisfaction rate and 90% of parents reported an improvement in their child's general health (Conlon et al, 1997).

So what would the effect be of abandoning tonsillectomy altogether – would it be 'just a bit more tonsillitis'? The answer to this question can perhaps be found in Hospital Episodes Statistics data. In the last 10 years, in parallel with a reduction in tonsillectomy rate, there has been a 40% rise in the rate of hospital admissions for complications associated with tonsillitis, such as dehydration, dysphagia and quinsy.

Historically, ear, nose and throat surgeons may have been over-zealous with surgical intervention but this is no longer the case. Childhood grommet insertion has fallen by 43% from 43 300 operations in 1994–5 to 24 700 in 2009–10 (Hospital Episodes Statistics online, 2012). The number of tonsillectomies performed was around 200 000 in the mid 1950s and this too has fallen to 49 400 in 2009–10. Furthermore, the surgical variation rate between regions has reduced from over 50-fold in 1958 to less than 7-fold in 2010 (Illingworth, 1961; Suleman et al, 2010). Ear, nose and throat surgeons have long been refining their indications for surgery, culminating in the publication of national guidance by the National Institute for Health and Clinical Excellence and the Scottish Intercollegiate Guidance Network for grommet insertion and tonsillectomy respectively.

Conclusions

Perhaps both TARGET and NESSTAC are examples of too little too late? Certainly it is in the commissioning conscience that in austere times these procedures are of questionable benefit. Current commissioning arrangements aim to raise the threshold in terms of severity of disease before the procedure can be provided on the NHS, but there is a danger that they might be abandoned altogether.

The debate on tonsillectomy and grommets has been going on for over 50 years and is not over, but basing this discussion on 'clinical effectiveness' rather than health economics is flawed. In selected patients, these procedures are hugely beneficial and arguably necessary. Rationing based on limited clinical effectiveness will lead to a misinformed public, rising complications from untreated pathology and a group of children who start their lives at a handicap. It is, sadly, the most socially disadvantaged who are likely to suffer most from these restrictions (Watt, 2002). It is these very individuals who need every decibel of hearing and every possible day of school attendance to maximize their future opportunities. As always, the vocal middle classes will find ways of accessing and affording appropriate services. The real discussion should surely be around trying to quantify the benefit available from any given intervention, and its real and relative cost? But perhaps this debate is just too hard to have and to inform? BJHM

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KEY POINTS

- 'Procedures of limited clinical effectiveness' is a misnomer.
- Both grommet insertion and tonsillectomy have been shown to have significant benefit.
- The number of tonsillectomies and grommet insertions being performed has dropped rapidly over the last few decades.
- Inpatient admissions for complications of tonsillitis have increased significantly over the last 15 years.
- If these procedures are restricted it is the lower social classes who are most likely to suffer the greatest restriction of access.
- What is not clear is the relative cost/benefit ratio, in other words how much medical 'bang' you get for your 'buck'.

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