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National Institute for Clinical Excellence guidelines on the surgical management of otitis media with effusion: Are they being followed and have they changed practice?

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ABSTRACT

Objective: UK National Institute of Clinical Excellence (NICE) guidelines on surgical management of otitis media with effusion (OME) in children call for an initial 3 month period of observation, with ventilation tube (VT) insertion considered for children with persistent bilateral OME with a hearing level in better ear of 25–30 dB HL or worse ("core criteria"), or for children not meeting those audiologic criteria but when OME has significant impact on developmental, social or educational status (exceptional circumstances). We aimed to establish whether guidelines are followed and whether they have changed clinical practice.

Methods: Retrospective case-notes review in five different centres, analysing practice in accordance with guidelines in all children having first VT insertion before (July–December 06) and after (July–December 08) guidelines introduction.

Results: Records of 319 children were studied, 173 before and 146 after guidelines introduction. There were no significant differences in practice according to guidelines before and after their introduction with respect to having 2 audiograms 3 months apart (57.8 vs. 54.8%), OME persisting at least 3 months (94.8 vs. 92.5%), or fulfilment of the 25 dB audiometric criteria (68.2 vs. 61.0%). Practice in accordance with the core criteria fell significantly from 43.9 to 32.2% (Chi squared $p = 0.032$). However, if the exceptional cases were included there was no significant difference (85.5 vs. 87.0%), as the proportion of exceptional cases rose from 48.3 to 62.2% (Chi squared $p = 0.021$).

Conclusion: This study shows that 87.0% of children have VTs inserted in accordance with NICE guidelines providing exceptional cases are included, but only 32.2% comply with the core criteria. A significant number have surgery due to the invoking of exceptional criteria, suggesting that clinicians are personalising the treatment to each individual child.

1. Introduction

Otitis media with effusion (OME, glue ear) is the commonest cause of hearing impairment in children in the developed world with prevalence in the region of 20% [1,2], and up to 80% of children affected at least temporarily by the age of 10 years. OME is characterised by the presence of a middle ear effusion in the absence of symptoms and signs of acute inflammation [3]. Although it is transient in the majority of children, a proportion develop persistent symptoms that may affect hearing, education, language or behaviour [4,5]. If OME persists after a three month period of watchful waiting, treatment with ventilation tubes (VTs, grommets) or hearing aids may be considered [4,6]. With most UK parents opting for surgery VT insertion is one of the commonest surgical procedures in children [3], with over 30,000 inserted in England each year [7].

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The UK National Institute of Clinical Excellence (NICE) guidelines on surgical management of OME (CG60) [4] provide detailed guidance on the management of children younger than 12 years with suspected OME, covering history-taking, examination, and audiometric testing, and offering a review of the different management options. The guidelines, applied to "newly diagnosed OME of unknown duration", call for an initial 3 month period of observation, with repeat audiological assessment at the end of the three month period. At that stage, VT insertion should be considered for children with persistent bilateral OME with a hearing level in better ear of 25–30 dB NHL or worse (termed core criteria in this paper). VT insertion can also be considered in children not meeting those audiometric criteria but when OME has significant impact on developmental, social or educational status (termed exceptional circumstances in this paper); this flexibility allows the treating clinician to personalise the care offered to each child, focussing on all of the child's symptoms rather than just a hearing level. The guidelines state that surgery is not appropriate for children that have OME only for a short time period or in cases where OME has little effect on child's function and development. Adenoidectomy in uncomplicated OME is not recommended in the absence of co-present history of frequent upper respiratory tract infection.

We carried out a multi-centre comparison to establish if NICE guidelines were being followed, and if they had changed clinical practice.

2. Methods

A multi-centre case-notes review was undertaken in five units: Derbyshire Hospitals NHS Trust, Nottingham University Hospitals NHS Trust, Royal Free Hampstead NHS Trust London, Sherwood Forrest Hospitals NHS Trust, and United Lincolnshire Hospitals NHS Trust (Lincoln County Hospital). The hospitals were anonymised for purposes of data analysis and randomly labelled 1–5. The audit offices in each of the hospitals approved this audit of clinical practice against the national guidelines.

Practice was examined over a six month period, 1st July–31st December 2008. The guidelines were published in February 2008, and the study time period chosen therefore allowed over 4 months for guidelines' implementation, and patients included would have been listed since guidelines publication. To establish whether guidelines had changed clinical practice, a six month period (keeping the time of year the same) prior to the introduction of the guidelines was also studied (1st July–31st December 2006), applying the same NICE criteria retrospectively.

All children aged less than 12 years having VT insertion were identified using the Hospital Information Support System data, and their medical records reviewed to identify those that had first VT insertion. Children with Down's syndrome or cleft lip/palate were excluded (NICE guidelines specify a different management pathway), as were those having surgery other than VTs alone or VTs with adenoidectomy, or those with major comorbidities, special educational needs or other sensory impairment that may affect the decision to list for surgery.

The medical records of the included children were studied to determine whether they were listed for surgery in accordance with NICE guidelines. The following variables were studied:

(1) The undertaking of two audiograms at least 3 months apart
(2) Fulfilment of the audiological criteria of a hearing level of 25 dB NHL or worse (averaged at 0.5, 1, 2 and 4 kHz) in the better ear, at time of listing or at the pre-operative audiogram closest to surgery
(3) Fulfilment of both above criteria, which was deemed to indicate that the child fulfilled guideline's core criteria
(4) Duration of OME of at least 3 months on the basis of history, irrespective of whether the child had two audiograms or not
(5) Presence of extenuating reasons justifying surgery when the core criteria were not met. When core criteria were not met, the clinical notes were reviewed to establish whether there was an extenuating reason for surgery, typically concerns over speech or schooling, or recurrent acute otitis media (AOM). The group of children that either met core criteria or had extenuating circumstances leading to surgery were deemed to have complied with guidelines' broad criteria.
(6) The proportion of those children complying with the broad criteria that achieved this status due to invoking of the extenuating circumstances
(7) Number of children having adenoidectomy, and the presence of non-OME reasons justifying adenoidectomy

Statistical analysis was performed using PASW statistics18.

3. Results

A total of 319 patients were included in the study. Notes of a further 41 (12.9%) patients could not be obtained despite multiple searches at different times. The different hospitals (1–5) contributed 41, 90, 107, 30, and 51 patients, respectively.

Pooled data from all 5 units were used to compare practice in accordance with the set criteria before and after guidelines were introduced. During the pre-guidelines period there were 173 cases, and post-guidelines 146. In three units the number of VTs reduced, and in two increased after guidelines introduction. The percentage of boys was 61.4% overall with no significant differences between the two time periods, and the mean age during both time periods was 4.7 years.

Table 1 compares the two time periods. Practice according with the "core criteria" has deteriorated by a significant amount, from 43.9 to 32.2% (Chi squared $p = 0.032$). However, there has been no deterioration in practice in accordance with guidelines if those children listed for extenuating circumstances were included (85.5 and 87.0%, respectively), but this was achieved by a significant rise in the number of such extenuating cases.

Table 1
Practice in accordance with NICE guidelines on OME during the two time periods.

Criterion	Pre-guidelines ($N = 173$)	Post-guidelines ($N = 146$)	Change pre- to post-guidelines
2 audiograms $\geq$ 3 months apart	100/173 (57.8%)	80/146 (54.8%)	↓3.0% ($p = 0.589$)
Duration $\geq$ 3 months	164/173 (94.8%)	135/146 (92.5%)	↓2.3% ($p = 0.392$)
Hearing 25 dB NHL or worse in better ear	118/173 (68.2%)	89/146 (61.0%)	↓7.2% ($p = 0.177$)
Fulfils core criteria	76/173 (43.9%)	47/146 (32.2%)	↓11.7% ($p = 0.032$)
Fulfils core or exceptional criteria	148/173 (85.5%)	127/146 (87.0%)	↑1.5% ($p = 0.711$)
Exceptional cases proportion	72/148 (48.6%)	80/127 (63.0%)	↑14.4% ($p = 0.024$)
Also had Adenoidectomy	37/173 (21.4%)	29/146 (19.9%)	↓1.5% ($p = 0.738$)
Non-OME reason for adenoidectomy	32/37 (86.5%)	21/29 (72.4%)	↓14.1% ($p = 0.154$)