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The Swedish grommet register – Hearing results and adherence to guidelines

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ABSTRACT

Objectives: The insertion of grommets is one of the most commonly performed surgical procedures in children. The underlying reason might be otitis media with effusion (OME) with concomitant hearing loss, recurrent acute otitis media (rAOM) or a combination of the two. Sweden has a national quality register for children receiving grommets with the purpose of evaluating how treatment guidelines are followed, and if surgery confers good quality health care. The purpose of this study was to investigate the circumstances during which Swedish children receive grommets and to examine how doctors follow the guidelines for grommet surgery.

Methods: Quality register data was extracted from 2010 to 2016, and information on reasons for surgery, audiometry, number of AOM episodes, type of grommet etc was analysed.

Results: The dominating reason for surgery was OME (71%). A large proportion (27%) of children with OME had not undergone a preoperative audiometry, despite national guidelines stating that it is hearing impairment that calls for surgery. Furthermore, among those who had done audiometry, 47% did not have a hearing impairment as measured by pure tone average. Nevertheless, a significant hearing improvement (11 dB, $p < 0.001$) was seen on post-operative follow-ups in those children who underwent audiometry. Forty-four percent of children operated due to rAOM had had fewer episodes of AOM than recommended as an indication for surgery, though this figure should be interpreted with caution as GP diagnosed episodes are not entered in the register.

Conclusion: Even though grommet insertions are quick and confer a low per-operative risk, it seems many children undergo surgery without a clear indication. This puts them at an unnecessary risk of per-operative as well as long-term complications. Since the procedure is so common, it also means large sums of money are spent on operations that might not be necessary.

1. Introduction

The insertion of grommets, or ventilation tubes, is one of the most commonly performed surgical procedures in children. There are two principally different reasons to insert grommets: persistent otitis media with effusion (OME) and subsequent hearing loss; and recurrent acute otitis media (rAOM), however, some children display a combination of these two diagnoses. The effect of ventilation tubes on OME is well established. A Cochrane review from 2010 showed that hearing was improved at 6–9 months after surgery, however, the effect abated at 12 and 18 months [1]. Another systematic review from 2011 showed strong evidence for a beneficial effect of ventilation tubes on hearing for at least 9 months after surgery. This study also showed moderately strong evidence for an improved quality of life for up to 9 months [2]. The effect of grommets on rAOM, however, is less clear. Few high quality studies on the matter exist, and Cochrane reviews as well as other systematic reviews have concluded that further research is needed regarding this question [3].

The Swedish Association of Otorhinolaryngology, Head and Neck Surgery runs several quality registers for various ENT interventions, including one for grommets. Otherwise healthy children below the age of 15 years who are referred for grommets are eligible for the grommet register. The main purpose of the register is to evaluate how treatment guidelines are followed, and if they confer good quality health care. Not all ENT clinics have chosen to participate, but coverage has increased, and at those clinics that do participate, reporting is relatively high.

The national recommendations state that children who fulfill the criteria for rAOM (at least 3 AOM episodes during the last 6 months, or 4 during the last year) or children with OME persistent for at least 3 months with concomitant conductive hearing loss (pure tone average – PTA - of 25 dB or worse on the best ear) are eligible for grommets [4,5]. An alternative indication for children with OME is to have a disease duration of 6 months in combination with a subjective hearing loss that affects the child socially. Thus, a preoperative hearing test is required for children with OME unless the history is very long.

Knowledge about compliance with guidelines for surgery is essential

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Table 1
Details of the four questionnaires.

Questionnaire number	Timing	Type of information
1	At time of decision of grommet surgery	Age Gender Reason for surgery (OME/rAOM/OME + rAOM/other) Pure tone average (500, 1000, 2000 and 4000 Hz) on the best ear Other type of audiometry Previous grommet treatment Number of AOM episodes diagnosed by an ENT surgeon during the last 6 months Number of episodes with ear discharge in last 6 months Presence and duration of subjective hearing loss Ear disease affecting the child's wellbeing and behaviour
2	At time of surgery	Date Type of grommet
3	At first post-operative check-up, about 3 months postop	Date Re-operation planned Grommet still in place Pure tone average (500, 1000, 2000 and 4000 Hz) on the best ear Other type of audiometry
4	6 months postop	Satisfactory preoperative information Subjective hearing impairment Ear disease affecting the child's wellbeing and behaviour

when evaluating the results of the intervention, and the quality registers can play an important role in this context.

2. Materials and methods

The register underwent a major reconstruction in 2010. For this study, comprehensive data was extracted from the new, updated register from its start until October 2016. The register report cards are made up of four different questionnaires; the preoperative questionnaire is filled in jointly by the doctor and parent when a decision about surgery is made, the second is filled in by the doctor at the time of surgery, the third by the doctor when the child comes for the first postoperative check-up after about 3 months, and the fourth is filled in by the parents 6 months after surgery.

Details about the type of information obtained in the various questionnaires are shown in Table 1.

The number of clinics contributing data to the register was compared to the total number of clinics who perform grommet surgery. The number of reported procedures from each participating clinic was then compared to mandatory diagnosis data from the respective hospitals. To get an idea of the proportion of grommet surgeries represented in the register on a national level, data from the register was also compared to the National Board of Health and Welfare statistics database.

The number of procedures reported to the register was analysed and compared with respect to age, gender, diagnosis, type of grommet and presence of grommets at the 3 month follow-up. In order to check how well national guidelines were followed, data on hearing tests and the number of AOM episodes was evaluated. For those children who had undergone pre-as well as postoperative audiometry, PTA4 before and after surgery was compared. PTA4 was defined as the average hearing threshold at 500, 1000, 2000 and 4000 Hz on the best ear.

Statistical analysis was done using Stata 13 (Stata Corp, College Station, Texas, USA). Logistic regression was used to estimate differences in proportions between groups. The improvement in hearing pre- and postoperatively was estimated evaluated using a paired *t*-test.

The study was approved by the Ethical Committee at Lund University.

3. Results

3.1. General results

During the study period, a total of 8846 children were reported to the register, reporting increasing for each year after the reconstruction of the register in 2010. In 2016 alone, 1752 grommet insertions were reported to the register. This corresponds to 33% of the total number of grommet insertions (n = 5286) in children < 15 years in Sweden that year. At participating clinics, 78% of eligible cases were included in the register in 2016. The average age of the children was 4 years, and 60% of the children were boys (Table 2). The reason for surgery was OME in the majority of cases (71%), and the distribution of the various indications was the same in boys and girls (Table 2). Information about the type of grommet used was available in 2599 cases (Table 3). Long, single-flanged tubes were the most common. The type of tube did not vary much with age group or reason for surgery. The proportion of extruded tubes after 3 months was greater with fluoroplastic than with silicone tubes (Table 3). On the whole, 87% of grommets were still in place and functioning after 3 months.

Table 2
Number of registrations in relation to various indications for surgery.

	OME	rAOM	OME + rAOM	Other indication	Total
No of operations in the register	6026	1516	704	200	8446
Mean age in years (SD)[a]	4.8 (2.6)	2.6 (2.1)	3.4 (2.3)	6.5 (3.2)	4.3 (2.7)
Male gender (%)	3633 (60)	916 (60)	417 (59)	127 (63.5)	5093 (60)
Preoperative PTA 4 available (% of registered operations)	3101 (51)	199 (13)	189 (27)	92 (46)	3581 (42)
Mean no of confirmed AOM episodes[b] (SD)	0.4 (1.3)	3.5 (3.3)	1.9 (2.9)	0.6 (1.4)	1.1 (2.3)
No of registered postoperative visits after 3 months (% of registered operations)	4304 (71)	878 (58)	390 (55)	136 (68)	5708 (68)
Postoperative PTA 4 available (% of registered operations)	2592 (43)	330 (22)	174 (25)	84 (42)	3180 (38)
Pre- and postoperative PTA 4 from the same individual (% of registered operations)	1658 (28)	78 (5)	96 (14)	42 (21)	1874 (22)

[a] Age range in all groups 0–14 years.
[b] Ear discharge and ENT-diagnosed AOM combined during the 6 months prior to decision of surgery.