

Accurate consent for insertion and later removal of grommets

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Dear Sirs,

We write in response to the above article by Sood and Waddell.

It is commonly agreed that the rate of complications of simple grommet insertion (e.g. infectious discharge, further procedure) is significant. However, these authors' suggestion of advising patients undergoing grommet insertion that there is a one in 13 (7.6%) chance of it needing removal does not seem to fit with routine clinical practice.

Sood and Waddell's depiction of summary Hospital Episode Statistics data, although easily accessible, needs more in-depth analysis to support such conclusions. The indications for ventilation tube insertion and for long or short term ventilation tube usage, the grommet's construction material, shape and design, and the operative procedure of grommet insertion all remain unknown variables. Long term tubes are designed to remain in place for two years or more, and we generally expect higher rates of retained tubes in such cases. With such a profound lack of knowledge of such variables, it is meaningless to attempt to draw conclusions from these data.

The authors, having rightly identified many fundamental weaknesses in their study, omit any comparison with their own clinical practice and do not attempt to find other sources of data to support their conclusions. In fact, more accurate information is already readily available and was found easily by a casual search of Pubmed. A three-year follow up of 1096 ventilation tubes by Lindstrom *et al.* (2004) found that only 1.32 per cent of the short term ventilation tubes required removal.¹ The study demonstrates a clear picture of this and other complication rates, which is in keeping with the rest of the literature and is indeed reflected in at least our routine clinical practice.

Unfortunately, it is not sufficient for Sood and Waddell merely to comment on the seemingly similar data pattern in order to validate their findings, especially when the conclusion derived is at odds with other cohort studies in the literature.²

Perhaps of more importance to the patient or parent is the need for further surgery to reinsert an expelled grommet; this was required in as many as 50 per cent of a cohort of 185 children followed up over five years.³ This risk of further surgery does not seem to have been addressed by Sood and Waddell when obtaining consent from their patients.

Sood and Waddell rely solely on a summary of data which does not comply with their use in clinical research. Their study design is intrinsically flawed, and there is a clear lack of effort to corroborate the unexpected findings with other, more robust literature available. We are concerned that these authors still chose to publish this study,

which has the potential to mislead both clinicians and patients, without further exploration of the data.

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References

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- 3 Maw AR. Development of tympanosclerosis in children with otitis media with effusion and ventilation tubes. *J Laryngol Otol* 1991;**105**:614–17

Authors' reply

We appreciate the comments raised by Messrs Sithampanathan and Warrington.

Our motivation to undertake this study was based on our experiences in the Great Western Hospital, Swindon. Between August 2004 and January 2007, 584 patients underwent grommet insertion, with or without additional procedures such as adenoidectomy. Over the same period, 74 patients had one or both grommets removed. We accept that this is a different cohort of patients, which may overlap. Of those 74 patients, nine (12 per cent) also underwent insertion of grommets under the same anaesthetic as that for the grommet removal.

Sixty-five patients (88 per cent) had removal of one or two grommets as a sole procedure, presumably for infection or obstruction.

In Swindon, for every eight patients in whom we insert grommets, we would expect to see one patient for removal of grommets.

In our paper,¹ we stated that, nationally, the ratio was one in 13, so we believe that our local results and the national figures offered some mutual validation.

Following our study, within our department we now follow routinely a protocol of advising patients undergoing grommet insertion regarding the risk of requiring further surgery, in the form of grommet removal or reinsertion.

We agree that we made no attempt to differentiate between different types of ventilation tube and different age cohorts.

However, we reject the concerns of Messrs Sithampanathan and Warrington that we chose to submit this study without further exploration of the data.

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Reference

- 1 Sood S, Waddell A. Accurate consent for insertion and later removal of grommets. *J Laryngol Otol* 2007;**121**:338–40

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