The Journal of Laryngology and Otology
June 1996, Vol. **110**, pp. 527–530

Main Articles

A cost-benefit analysis of the post-operative use of antibiotic ear drops following grommet insertion

C. R. Pearson, M. R. Thomas, H. J. Cox, R. J. N. Garth

Abstract

A prospective randomized controlled study was carried out to investigate the effect of prophylactic antibiotic ear drops used for five days after bilateral grommet insertion. The average improvement in the hearing threshold was significantly better in ears in which there was an effusion (16 dB) compared with no effusion (9 dB). The drops had no significant effect upon grommet function at three months measured by blockage rates, extrusion rates or improvement in pure tone audiometry whether or not there was an effusion. The drops were not therefore cost-effective.

Key words: Middle ear ventilation, drug therapy; Cost-benefit analysis; Audiometry

Introduction

The use of grommets in the treatment of otitis media with effusion is well established but its benefits have been questioned in recent years, not least because of the cost (School of Public Health, University of Leeds, 1992). A significant minority of patients require insertion of a second pair of grommets and up to 15 per cent may require three or more pairs (Curley, 1986).

Otorrhoea is a common problem following grommet insertion. Estimates of its incidence at differing stages have varied widely but the incidence of persistent otorrhoea has been estimated at between 0.6 per cent and five per cent (Pringle, 1993) and in Curley's study (1986) only 14 out of 1011 patients had a problem requiring removal of the grommets.

The use of antibiotic drops has been shown to reduce the incidence of otorrhoea in some studies (Balkany *et al.*, 1983; Baker and Chole, 1988; Salam and Cable, 1993) but not in others (Ramadan *et al.*, 1991; Epstein *et al.*, 1992; Scott and Strunk, 1992; Younis *et al.*, 1992) and had no significant effect upon blockage at two weeks (Salam and Cable, 1993). Although intermittent otorrhoea is a nuisance and may require treatment, blockage renders a grommet ineffective and if an effusion re-accumulates further grommets may be required.

This study examines the effect of prophylactic ear drops on grommet blockage and hearing at three months and compares the cost of routine administration of drops with any likely benefit.

Method

Using an estimated incidence of grommet non-function in untreated ears of 10 per cent, half the incidence in treated ears; power of 0.8; and a significance level of 0.05, 164 patients were required (Machin and Campbell, 1987). Allowing 15 per cent extra for patients lost to follow up, etc., 190 patients undergoing bilateral grommet insertion for eustachian dysfunction or otitis media with effusion were studied.

Pre-operative assessment included otoscopy and tympanometry. When possible, pure tone audiograms were obtained at 0.5, 1, 2 and 4 kHz. Informed consent was obtained from the patients or their parents.

Patients were randomized in groups of ten. In each group, five were asked to use the left ear as the treatment ear and the other five were asked to use the right ear as the treatment ear. The other ear was used as a control. This method of randomization ensured that the number of left and right treatment ears stayed equal as the trial progressed.

At myringotomy any effusion was aspirated and Teflon Shah grommets were inserted bilaterally in all cases. The presence or absence of a mucous effusion was recorded. Sofradex® drops (dexamethasone, framycetin and gramicidin: Roussel Laboratories Ltd) were instilled immediately into the canal of the treatment ear. Patients, or their parents, were asked to instill three drops three times a day into the treatment ear for five days afterwards.

Patients were reviewed after three months and the

From the Department of Otolaryngology, Royal Naval Hospital, Haslar, Gosport, Hants, UK.
Accepted for publication: 16 December 1995.

TABLE I
THRESHOLDS AND NUMBERS WITH EFFUSIONS IN THE WITHDRAWN AND FOLLOWED-UP GROUPS

Thresholds		Presence or absence of effusion*		
		None	Unilateral	Bilateral
Withdrawn	22.5 dB	5	3	16
Followed-up	25.8 dB	42	31	92

*χ^2 = 1.08: p not significant at five per cent level.

function of the grommet was assessed by otoscopy and tympanometry. Pure tone audiometry was repeated over the same range as the pre-operative audiogram. The average over the four frequencies was calculated pre- and post-operatively and hence the average gain (or loss) for each patient.

Patients were withdrawn from the trial at the time of surgery if there was excessive bleeding or infection and it was felt that there was an established indication for antibiotic drops. Patients who failed to attend for follow-up at three months were excluded.

The effect of Sofradex® on grommet function was analyzed using McNemar's test. The difference in hearing thresholds was analyzed using the Kolmogorov-Smirnov test. In either case a probability of 0.05 or less was taken as significant.

Results

Twenty-five patients were withdrawn. The commonest reasons were: four had excessive bleeding, four had signs of acute or chronic suppurative otitis media at time of surgery and 12 patients failed to attend for review at the appropriate time. One hundred and sixty-five results were therefore available. The average pre-operative hearing thresholds and the numbers of patients with and without effusions in the group that was withdrawn were not significantly different from the group that was followed up (Table I).

The age range was 1.5 years to 41.5 years, mean age 6.3 years, and 109 patients (66 per cent) were male. The right ear was the treatment ear in 76 cases (46 per cent).

The incidence of functioning and non-functioning grommets is shown in Table II. Only cases in which the outcome in treated and control ears was different are of significance in McNemar's test. The difference between the treatment ears alone functioning *vs* control ears alone functioning (14 and 9, respectively) was not significant. A similar analysis for blocked grommets and extruded grommets taken separately also failed to show any significant difference—Tables III and IV. In no case was one grommet blocked and the other extruded. Neither was there any significant difference when the patients with bilateral effusions or no effusion were taken separately—Tables V and VI. Note that the totals in Tables III and IV exclude extrusion and blockage respectively, because only one or the other could occur. The totals in Tables V and VI do not add up to 165 because there was a unilateral effusion in some cases.

Persistent otorrhoea was noted in only two cases at three months. In both cases it occurred in the control ear alone.

Table VII shows the average pre- and post-operative hearing loss over 0.5, 1, 2 and 4 kHz in all cases in which audiometry was possible and in the groups with or without effusions. There was no appreciable difference in the hearing gain overall between the treated ears and the control ears (13.6 dB and 12.9 dB respectively). The hearing gain was greater in patients in whom there were bilateral effusions (16.0 dB, treated and 16.0 dB, control) than no effusion (9.7 dB, treated and 8.0 dB, control) but there was no appreciable effect of the drops in either group taken separately.

The average improvement in hearing when there were bilateral effusions was significantly greater than when there was no effusion (16.0 dB and 8.8 dB respectively, Kolmogorov-Smirnov test $p<0.01$). This was due to the worse average pre-operative threshold in the effusion group than the no effusion group (28.7 dB and 21.8 dB respectively, $p<0.01$) rather than any difference in the post-operative thresholds in which there was no significant difference (12.7 dB and 13.0 dB respectively, $p>0.05$).

Discussion

Prior to this study, it was the custom of one of the authors (RJNG) to prescribe Sofradex® drops following routine grommet insertion. The aim of the study was to discover whether the expense was justified.

TABLE II
THE EFFECT OF SOFRADEX® ON GROMMET FUNCTION (N = 165)

		Sofradex®	
		Non-functioning	Functioning
Untreated	Non-functioning	3	14
	Functioning	9	139

χ^2 1.09: p not significant at five per cent level.

TABLE III
THE EFFECT OF SOFRADEX® ON GROMMET BLOCKAGE (N = 155)

		Sofradex®	
		Blocked	Functioning
Untreated	Blocked	1	10
	Functioning	5	139

χ^2 = 1.67: p not significant at five per cent level.

TABLE IV
THE EFFECT OF SOFRADEX® ON GROMMET EXTRUSION (N = 149)

		Sofradex®	
		Extruded	Functioning
Untreated	Extruded	2	4
	Functioning	4	139

χ^2 = 0: p not significant at five per cent level.

https://doi.org/10.1017/S0022215100134176 Published online by Cambridge University Press

TABLE V
THE EFFECT OF SOFRADEX® ON GROMMET FUNCTION—BILATERAL EFFUSIONS (N = 92)

		Sofradex®	
		Non-functioning	Functioning
Untreated	Non-functioning	2	8
	Functioning	3	79

$\chi^2 = 2.27$: p not significant at five per cent level.

TABLE VI
THE EFFECT OF SOFRADEX® ON GROMMET FUNCTION—NO EFFUSION (N = 42)

		Sofradex®	
		Non-functioning	Functioning
Untreated	Non-functioning	0	4
	Functioning	4	34

$\chi^2 = 0$: p not significant at five per cent level.

Three-month review is our usual policy because it is administratively convenient and allows the ears to recover from surgery and this is supported by our low incidence of otorrhoea. We also feel that a shorter interval would tend to miss some cases of early extrusion or blockage. The low incidence of otorrhoea does not allow us to form any conclusion as to the effect of prophylactic drops on otorrhoea, notwithstanding the fact that both instances occurred in the control ears.

We made no attempt to assess patients' compliance with the drops because there is no reason to believe that it would be any better under normal circumstances.

Our study confirms the conclusion of Salam and Cable (1993) that drops have no significant effect upon grommet blockage although our review period was later than their two weeks. Neither did we find any significant effect on extrusion rates. Although it might be difficult to envisage a mechanism whereby drops might prevent early extrusion it might be that blocked grommets are more likely to extrude. This hypothesis is unproven.

Two studies, one *in vitro* (Mills *et al.*, 1990) and one in chinchillas (Meyerhoff *et al.*, 1983) have suggested that eustachian function is necessary for drops to penetrate grommets. If this is so *in vivo*, it is not surprising that drops have no effect on blockage because presumably they would have to enter the grommet to wash away any blood or mucus.

Scott and Strunk (1992) and Epstein *et al.* (1992) suggested that drops had a greater effect upon ears in which there was a mucoid effusion. We found no difference in the effect of drops on grommet function between the groups with, or without, an effusion.

The improvement in the average hearing threshold of 13 dB overall confirms the benefit of grommet insertion, particularly when there was an effusion when the average improvement was 16 dB. The significant difference in the gain between the groups with, and without, an effusion (16 dB *vs* 9 dB, respectively) is explained by the greater pre-operative hearing loss in the former and not by any post-operative difference.

The cost of a bottle of Sofradex® is £3.90 (British National Formulary) and compares with an estimated cost of £307 for grommet insertion (School of Public Health, University of Leeds, 1992). The cost is, however, only justified if the use of drops decreases the need for early reinsertion or improves the effect of grommets on hearing threshold. Although rather more grommets were non-functioning in the control ears, this finding was probably by chance. The rate of bilateral early blockage or extrusion was three in 165 cases (1.8 per cent) so £214.50 would be spent on Sofradex® for each patient with early grommet blockage or extrusion. This would only be cost-effective if virtually all the cases required early grommet reinsertion (ours did not) and the drops prevented blockage or extrusion in a clear majority of cases. Our data clearly indicate that this is not the case.

The negligible difference in improvement in hearing thresholds between the treated and control ears confirms the absence of benefit in the use of prophylactic ear drops.

Conclusion

This prospective randomized controlled trial has shown no benefit from the use of prophylactic antibiotic ear drops after grommet insertion whether assessed by grommet function or improvement in hearing threshold at three months, independent of the presence or absence of an effusion and its cost cannot therefore be justified.

Acknowledgement

The authors would like to thank Dr R. Pethybridge, Institute of Naval Medicine for his statistical advice.

TABLE VII
AVERAGE HEARING LOSS PRE- AND POST-OPERATIVELY IN TREATED AND CONTROL EARS

	All ears n = 165		Bilateral effusions n = 92		No effusion n = 42	
	Treated	Control	Treated	Control	Treated	Control
Pre-op	25.8 dB	25.7 dB	28.2 dB	29.2 dB	22.6 dB	21.0 dB
Post-op	12.2 dB	12.8 dB	12.2 dB	13.2 dB	12.9 dB	13.0 dB
Difference	13.6 dB	12.9 dB	16.0 dB	16.0 dB	9.7 dB	8.0 dB

References

Baker, R. S., Chole, R. A. (1988) A randomized clinical trial of topical gentamicin after tympanostomy tube placement. *Archives of Otolaryngology, Head and Neck Surgery* **114:** 755–757.

Balkany, T. J., Barkin, R. M., Suzuki, B.H., Watson, W. J. (1983) A prospective study of infection following tympanostomy and tube insertion. *American Journal of Otology* **4:** 288–291.

British National Formulary Number 28 (1994) London: British Medical Association and Royal Pharmaceutical Society of Great Britain.

Curley, J. W. A. (1986) Grommet insertion: some basic questions answered. *Clinical Otolaryngology* **11:** 1–4.

Epstein, J. S., Beane, J., Hubbell, R. (1992) Prevention of early otorrhea in ventilation tubes. *Otolaryngology – Head and Neck Surgery* **107:** 758–762.

Machin, D., Campbell, M. J. (1987) *Statistical Tables for the Design of Clinical Trials.* Blackwell Scientific Publications, Oxford. pp 13, 192.

Meyerhoff, W. L., Morizono, T., Wright, C. G., Shaddock, L. C., Shea, D. A., Sikora, M. A. (1983) Tympanostomy tubes and otic drops. *Laryngoscope* **93:** 1022–1027.

Mills, R. P., Albizzati, C., Todd, A. S. (1990) Ear drops and grommets. *Clinical Otolaryngology* **15:** 315–319.

Pringle, M. B. (1993) Grommets, swimming and otorrhoea - a review. *Journal of Laryngology and Otology* **107:** 190–194.

Ramadan, H. H., Tarazi, T., Zaytoun, G. M. (1991) Use of prophylactic otic drops after tympanostomy tube insertion. *Archives of Otolaryngology, Head and Neck Surgery* **117:** 537.

Salam, M. A., Cable, H. R. (1993) The use of antibiotic/steroid ear drops to reduce post-operative otorrhoea and blockage of ventilation tubes. A prospective study. *Journal of Laryngology and Otology* **107:** 188–189.

School of Public Health, University of Leeds; Centre for Health Economics, University of York; Research Unit, Royal College of Physicians (1992) The treatment of persistent glue ear in children. *Effective Health Care, Number 4.* Leeds: University of Leeds. p 9.

Scott, B. A., Strunk, C. L. (1992) Post-tympanostomy otorrhea: a randomized clinical trial of topical prophylaxis. *Otolaryngology – Head and Neck Surgery* **106:** 34–41.

Younis, R. T., Lazar, R. H., Long, T. E. (1992) Ventilation tubes and prophylactic antibiotic ear drops. *Otolaryngology – Head and Neck Surgery* **106:** 193–195.

Address for correspondence:
C. R. Pearson, M.A., F.R.C.S.,
Department of Otolaryngology,
Royal Naval Hospital,
Haslar,
Gosport,
Hants PO12 2AA.