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The use of antibiotic/steroid ear drops to reduce post-operative otorrhoea and blockage of ventilation tubes. A prospective study

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Abstract

This prospective randomized study investigates whether the use of antibiotic/steroid ear drops (Betnesol-N) is effective in reducing early post-operative otorrhoea and blockage of ventilation tubes (VTs). The study included 162 children who had bilateral VT insertion and used Betnesol-N ear drops in one ear only for three days after surgery, the other ear was left as control. These children were reviewed two weeks later and their ears were examined for VT patency, presence of blood or of mucopus. Statistical analysis of our results showed that the use of Betnesol-N ear drops has significantly reduced the incidence of post-operative otorrhoea within two weeks of VTs insertion ($p<0.01$). However, these drops did not have a significant effect on the blockage rates of VTs with dried blood ($p>0.05$).

Key words: Otitis media with effusion; Middle ear ventilation, drug therapy

Introduction

Otitis media with effusion (OME) is the commonest cause of childhood hearing impairment in the United Kingdom (Ramsden *et al.*, 1977). Since Armstrong (1954) initiated the treatment of OME with polyethylene VTs, a large number of children have been treated in this way following myringotomy and aspiration of effusion.

In the first few days after insertion of VTs, some may become blocked by dried blood while others may have otorrhoea with or without infection. In both cases, middle ear ventilation is impaired and the effusion may recur. This prospective randomized study investigates whether the use of antibiotic/steroid ear drops (Betnesol-N) can reduce the incidence of post-operative blockage and otorrhoea of VTs.

Patients and methods

Informed consent was obtained from the parents on behalf of 176 children with bilateral OME, who were admitted for bilateral VT insertion. They were asked to use Betnesol-N in one ear only immediately after surgery and then three times a day (t.d.s) for three days. Fourteen children were excluded from the study because of failure to use the drops regularly (five patients) or to attend the follow-up (nine patients). The rest (n = 162) were included and each child satisfied the following criteria:

(1) No previous history of ear surgery.
(2) Middle ear fluid was found in both ears at surgery.
(3) One type of VTs was inserted in all patients (Sheehy collar button).
(4) Betnesol-N eardrops were used regularly in one ear only for three days after surgery.

All surgery was performed under general anaesthesia by one surgeon (MAS) to eliminate operator variability. The side treated with drops was allocated randomly by one of the nurses choosing blindly a card from a pack of cards in two colours and the other ear was left as control. All children were instructed to avoid getting water into their ears and they were reviewed two weeks later in the clinic. Both ears were examined for VT patency or presence of otorrhoea and all data was recorded by the examiner. The results were analysed statistically using McNemars test for paired data to see whether the use of Betnesol-N drops had made a significant difference in the incidence of otorrhoea and blockage of VTs between treated and untreated ears. The χ^2 was calculated and a p value <0.05 was taken as significant.

Results

This study included 162 children between the ages of three and 12 years (mean age = 4.6 years). They were 95 girls (58.6 per cent) and 67 boys (41.4 per cent). Table I shows the incidence of post-operative otorrhoea through VTs in treated and untreated ears with Betnesol-N ear drops. Fourteen VTs (8.64 per cent) were seen with otorrhoea in the untreated ears compared to three VTs (1.85 per cent) in ears treated with the drops.

Statistical analysis using McNemars test showed a significant difference in the incidence of otorrhoea after VT insertion between untreated and treated ears with Betnesol-N ear drops ($\chi^2 = 9.3, p<0.01$).

Table II shows the incidence of blocked VTs with dried blood in untreated and treated ears with Betnesol-N ear

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TABLE I

THE EFFECT OF BETNESOL-N EAR DROPS ON THE INCIDENCE OF POST-OPERATIVE OTORRHOEA OF VTs (N = 162)

		Treated ears	
		Otorrhoea	No Otorrhoea
Untreated ears	Otorrhoea	2	12
	No Otorrhoea	1	147

χ^2 = 9.3; p is significant at 1 per cent level.

TABLE II

THE EFFECT OF BETNESOL-N EAR DROPS ON THE INCIDENCE OF POST-OPERATIVE BLOCKAGE OF VTs (N = 162)

		Treated ears	
		Blocked VT	Patent VT
Untreated ears	Blocked VT	2	5
	Patent VT	1	154

χ^2 = 2.66; p is not significant at 5 per cent level.

drops. Seven VTs (4.32 per cent) were blocked in the untreated ears compared to three VTs (1.85 per cent) in ears treated with the drops.

Statistical analysis using McNemars test as above showed no significant difference in the incidence of blocked VTs between treated and untreated ears with Betnesol-N ear drops ($\chi^2 = 2.66, p>0.05$).

Discussion

This prospective randomized study investigates whether antibiotic/steroid ear drops (Betnesol-N) are effective in reducing post-operative otorrhoea and blockage of VTs. Betnesol-N was chosen because of its low cost compared to other ear drops with the same effect. In 162 children, the use of these drops t.d.s for three days after VTs insertion resulted in a significant reduction in post-operative otorrhoea. Three VTs (1.85 per cent) were seen with otorrhoea in ears treated with the drops compared to 14 VTs (8.64 per cent) in the untreated ears. Previous studies have shown that disinfection of the external ear canal using povidone-iodine before VTs insertion had no effect on post-operative otorrhoea (Aland and Baldwin, 1988; Giebink *et al.*, 1992). Two studies have reported that prophylactic ototopical corticosporin treatment initiated at surgery did not significantly reduce the post-operative otorrhoea rate. The first, a randomized controlled study by Balkany *et al.* (1983), was small yielding a large probability that a real difference might have gone undetected. In the second study by Giebink *et al.* (1992), treatment with corticosporin was neither blinded nor randomized. Ampicillin treatment initiated one day before and continued for three days after surgery (Balkany *et al.*, 1983) or the use of trimethoprimsulfamethoxazole and prednisone for two weeks after surgery (Giebink *et al.*, 1992) did not significantly reduce the otorrhoea rate after VTs insertion.

In our study, Sheehy collar button tubes were used in all patients to eliminate the variability in design and extrusion rate of different types of VTs. Sheehy collar button VTs were reported to be the longest retained pattern (in situ 15 to 24 months) when compared with eight other types of VTs (Gibb and Mackenzie, 1985). Large bore VTs are better retained, but are associated with significant complication rates (Hampal *et al.*, 1991). Brockbank *et al.* (1988) noted otorrhoea in 28 per cent of ears treated with Goode T-tubes and concluded that they should be reserved for refractory cases of OME or patients with cleft palate.

In our study, there was no statistical significant reduction in blockage rates of VTs after using Betnesol-N drops. The blockage of VTs with dried blood usually occurs within a few hours after surgery due to intraoperative bleeding. Parker *et al.* (1990) reported that observed intratympanic haemorrhage was associated with higher incidence of tympanosclerosis. This bleeding may occur due to increased vascularity of the tympanic membrane, or poor surgical technique during myringotomy incision suction of when inserting the VT. It seems unlikely that the drops will dissolve the blood clot once it is formed in the narrow VT lumen.

Conclusion

This prospective randomized study demonstrates that the use of Betnesol-N ear drops for three days after insertion of VTs is effective in reducing otorrhoea rates significantly within two weeks post-operatively ($p<0.01$). However, these drops do not have a significant effect on the blockage rates of VTs with dried blood ($p>0.05$).

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