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Title **A Double-Blind Randomized Placebo Controlled Trial of Topical Intranasal Corticosteroids in 4- to 11-Year-Old Children with Persistent Bilateral Otitis Media with Effusion in Primary Care**

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Aim

To determine the effectiveness of topical intranasal corticosteroid in children with bilateral otitis media with effusion.

Conclusions and results

Of the topical steroid group, 40.6% (39/96) demonstrated tympanometric clearance (C1 or A type) in one or both ears at 1 month. The figure in the placebo group was 44.9% (44/98). The risk difference favoring placebo was 4.3% (95% CI -9.26% to 18.05%), making the number needed to treat (NNT) at least 11.The odds ratio (OR) was 0.84 (95% CI 0.48 to 1.48). Four covariates were prespecified for inclusion in logistic regression analysis: age as a continuous variable (p=0.94), season (p=0.70), atopy (p=0.61), and clinical severity (p=0.006). The adjusted odds ratio (AOR) at 1 month for the main outcome was 0.93 (95% CI 0.50 to 1.75). Secondary analysis at 3 months showed 58.1% of the steroid group had resolved and 52.3%of the placebo group, AOR 1.45 (95% CI 0.74 to 2.84). At 9 months, 55.6% of the treated group remained clear in at least one ear, but was higher at 65.3% of the placebo group, AOR 0.82 (95% CI 0.39 to 1.75). Adverse events were relatively minor and included nasal stinging, epistaxis, dry throat, and cough. Differences between groups were not significant. The OM8-30 scores reported hearing difficulty and days with otalgia were not significantly different between groups at 3 months (p=0.55, 0.08, 0.46 respectively). Cost effectiveness and health utilities analyses were not significant, but identified a trend toward increased benefits and lower costs in those aged 6.5 years or over, were male, and had milder disease (severity score>0.63) and a trend towards harm (reduced QALYs) in those under 6.5 years, female, and with more severe disease.

Recommendations

Topical nasal steroids are not likely to be an effective or worthwhile treatment for glue ear in primary care. Active monitoring in primary care for children with suspected glue ear is acceptable and satisfactory to children and families, but the current methods used to monitor children may require adaptation. Relatively few children with histories of ear problems attending the GP surgery have glue ear actually confirmed on both sides and need treatment. Children over 6.5 years have milder glue ear in primary care and while not actually showing significant benefit of topical steroids are an important group to consider regarding potential treatment benefits.

Methods

See Executive Summary link at www.hta.ac.uk/project/1352.asp.

Further research/reviews required

This large study of topical nasal steroids in a primary care population with null effect suggests that further studies, particularly in primary care populations, would not be worthwhile. However, a potential effect in children aged ≥ 6.5 years may be further evaluated. Other interventions feasible in the primary care setting, eg, autoinflation, need to be evaluated, but interventions for younger children in primary care remain problematic.

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