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Efficacy of Intranasal Mometasone Furoate in the Management of Pediatric Otitis Media with Effusion: A Prospective Study.

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Abstract

Background: To evaluate the clinical and audiological efficacy of mometasone furoate monohydrate topical nasal spray as a non-surgical treatment for otitis media with effusion (OME) in pediatric patients. Methods: A prospective clinical study was conducted involving 22 children (aged 4 to 15 years) diagnosed with OME. Patients were treated with intranasal mometasone furoate (100 mcg/day) for 6 weeks. Pre- and post-treatment evaluations included pneumatic otoscopy, tympanometry, pure-tone audiometry, tuning fork tests, and parental symptom severity scoring. Results: Following 6 weeks of treatment, 52.7% of ears initially presenting with a Type B tympanogram demonstrated clearance of middle ear fluid. The mean air-bone (A-B) gap improved significantly by 29.4 dB. Additionally, overall symptom scores improved by 30.9%. Conclusion: Intranasal mometasone furoate spray demonstrated significant efficacy in resolving middle ear effusion, improving hearing thresholds, and alleviating associated clinical symptoms, positioning it as a viable medical alternative to early surgical intervention.

INTRODUCTION

Otitis media with effusion (OME), frequently referred to as secretory otitis media or glue ear, is characterized by the presence of fluid in the middle ear cleft without acute signs of infection. It remains one of the most prevalent chronic otological conditions in childhood, affecting up to 90% of children before school age. The persistence of middle ear effusion is the leading cause of acquired conductive hearing loss in the pediatric population, which can significantly impair speech, language acquisition, and cognitive development.

Historically, the medical management of OME—including antihistamines, decongestants, and systemic antibiotics—has demonstrated limited efficacy in achieving long-term resolution. Consequently, the surgical insertion of tympanostomy tubes is widely regarded as the gold standard of treatment, despite the inherent risks and costs associated with general anesthesia.

Recently, the role of local inflammation and Eustachian tube dysfunction in the pathogenesis of OME has prompted investigations into topical targeted therapies. Intranasal corticosteroids, such as mometasone furoate, offer potent local anti-inflammatory effects with minimal systemic bioavailability. This study aims to evaluate the clinical and audiological efficacy of mometasone furoate monohydrate nasal spray in treating pediatric OME, assessing its viability as a primary non-surgical alternative.

MATERIALS AND METHODS

Study Design and Population

A prospective clinical study was conducted at the Department of E.N.T and Head and Neck Surgery at Kasturba Medical College, Manipal. The study enrolled 22 children, aged 4 to 15 years, presenting with a confirmed diagnosis of OME.

Inclusion Criteria: Otoscopic evidence of middle ear effusion, Type B flat curve on tympanometry, conductive hearing loss documented on pure-tone audiometry, and associated clinical symptoms.

Exclusion Criteria: History of prior middle ear surgery, recent systemic or topical corticosteroid use, active upper respiratory tract infections, sensorineural hearing loss, or craniofacial anomalies.

Intervention and Clinical Evaluation
All participants were prescribed mometasone furoate monohydrate topical nasal spray, administered as one spray (50 mcg) in each nostril daily, totaling a daily dose of 100 mcg for 6 weeks. Efficacy was measured at baseline (Week 0) and post-treatment (Week 6) using pure-tone audiometry, tympanometry, tuning fork tests, and parental symptom severity questionnaires.

RESULTS

Baseline Demographics and Clinical Presentation
The study cohort consisted of 22 pediatric patients (44 ears), comprising 45% males and 55% females. The majority of the cohort (68%) was between 4 and 8 years of age. Baseline clinical symptoms were distributed as snoring (21%), mouth breathing (17%), decreased hearing (16%), recurrent upper respiratory infections (14%), and nasal discharge (12%).

Clinical Tuning Fork Outcomes
After 6 weeks of targeted intranasal therapy, tuning fork evaluations demonstrated substantial functional recovery:

Rinne Test: Out of 18 initially Rinne-negative ears (40.9% of the 44 total ears), 11 became positive, reflecting a 61.1% improvement. (A minor deterioration of 3.85% was noted as 1 out of 26 initially positive ears became negative).

Weber Test: Out of 22 patients, 8 showed lateralization (36.36%) at baseline. Of these, 5 became central after treatment, showing a 62.5% improvement. (A 21.4% deterioration was observed in 3 out of 14 initially central patients who lateralized at 6 weeks).

Pure-Tone Audiometry (PTA) Outcomes
At baseline, 30 out of 44 ears (68.18%) presented with an air-bone (A-B) gap greater than 20 dB. After 6 weeks of treatment, 17 ears showed significant closure (>10 dB) in the A-B gap, representing a 56.67% improvement. The mean A-B gap across all 44 ears improved from 54.6 dB at baseline to 25.2 dB post-treatment, yielding a mean improvement of 29.4 dB.

Tympanometric Changes
Impedance audiometry demonstrated clearance of middle ear effusion:

Baseline (Week 0): Type A curves in 5 ears (11.36%), Type B curves in 36 ears (81.81%), and Type C curves in 3 ears (6.81%).
Post-Treatment (Week 6): Type A curves in 18 ears (40.9%), Type B curves in 18 ears (40.9%), and Type C curves in 8 ears (18.18%).

Out of the 36 baseline Type B ears, 12 transitioned to Type A and 7 transitioned to Type C, resulting in a 52.7% clearance of middle ear fluid. Total parental symptom scores showed an overall improvement of 30.9%.

DISCUSSION

The primary objective in managing OME is to re-establish middle ear aeration, restore normal hearing thresholds, and prevent long-term sequelae without subjecting pediatric patients to unnecessary surgical risks. The findings of this prospective study indicate that a 6-week course of intranasal mometasone furoate spray (100 mcg/day) serves as an effective modality for achieving these goals.

The therapeutic benefit was objectively validated by tympanometry and audiometry. The conversion of 52.7% of Type B tympanograms to aerated states signifies a high rate of middle ear effusion clearance. This physiological improvement directly correlated with a marked audiological recovery, highlighted by a mean A-B gap closure of 29.4 dB. These audiological gains are critical for the 4-to-8-year age demographic (constituting 68% of the cohort) to prevent language and cognitive delays.

The mechanism of action likely involves the localized reduction of mucosal inflammation at the nasopharyngeal orifice of the Eustachian tube and a reduction in adenoidal tissue bulk. This aligns with prior literature emphasizing the link between topical nasal steroids, adenoid reduction, and improved Eustachian tube function.

CONCLUSION

The efficacy of mometasone furoate monohydrate topical nasal spray in the resolution of middle ear fluid in children between 4 and 15 years of age with otitis media with effusion was observed to be significant (52.7%). Alongside the clearance of effusion, significant improvements were seen in overall clinical symptoms (30.9%) and audiological status (mean A-B gap improvement of 29.4 dB). Thus, topical steroids can serve as a powerful alternative to surgery in controlling OME. Nasal administration of this steroid is safe, reproducible, easily performed, and well-tolerated by pediatric patients. However, because these results represent short-term outcomes, long-term follow-up studies remain necessary.

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