

COMPARISON OF ROLE OF MOMETASONE VERSUS BECLOMETHASONE IN TREATMENT OF PATIENTS OF OME WITH ADENOIDS – A COMPARATIVE STUDY

MOMETASONE VERSUS BECLOMETHASONE IN OME WITH ADENOIDS

Maryam Zaheer^{*1}, Atif Najam², Saeed Ullah Khan³, Mubashir Iqbal⁴, Umama Tahir⁵

^{1,2,3,4,5} CMH Multan

^{*1}maryamzee5october1995@gmail.com

DOI: <https://doi.org/10.5281/zenodo.19907038>

Keywords

Adenoids, Beclomethasone, Otitis Media with Effusion, Mometasone.

Article History

Received: 10 June 2025

Accepted: 07 July 2025

Published: 13 July 2025

Copyright @Author

Corresponding Author: *

Maryam Zaheer

Abstract

Objectives: To compare the efficacy of mometasone versus beclomethasone in treatment of otitis media with effusion patients with concomitant adenoids hypertrophy.

Study design: Comparative study.

Place and Duration of the study: Combined Military Hospital, Multan, Pakistan from April-2024 to May-2025.

Methodology: A total of 140 patients with concomitant adenoids hypertrophy and otitis media with effusion were included who were divided into Group-M (mometasone) and Group-B (beclomethasone). Therapy was given for eight weeks and at completion of treatment, patients were assessed for efficacy. Measures of efficacy were achievement of either resolution of OME (defined by achievement of type-A tympanogram) and reduction in grade of AH compared to baseline. Intergroup efficacy comparison was done by Chi-square test.

Results: In this study, 140 patients were included divided into two groups. Frequency of OME resolution and reduction in AH grade compared to baseline in Group-M (n = 70) was 62 (88.57%) and 50 (71.43%) while in Group-B (n = 70), it was 36 (51.43%), ($p < 0.001$) and 23 (32.86%), ($p < 0.001$), respectively.

Conclusion: Mometasone is significantly more efficacious as compared to beclomethasone in treatment of otitis media with effusion patients with concomitant adenoids hypertrophy.

INTRODUCTION

Adenoids have an important role in the immune system during early childhood by capturing germs that enter via the mouth and nose and helping the body build adaptive immune responses.¹ Globally, prevalence of adenoid hypertrophy (AH) has been reported at 34%.² In Pakistan, a study found that

the burden of this important condition was 4.31%.³ Persistent antigen exposure, repeated infections and inflammation caused by allergies result in sustained lymphoid proliferation leading to pathological hypertrophy of these lymphoid organs leading to nose blockage, breathing through the mouth, snoring and in severe cases,

obstructive sleep apnoea and even cor-pulmonale.⁴

Another important complication of AH is otitis media with effusion (OME).⁵ This complication is characterized by buildup of sterile fluid within the middle ear cavity with an intact tympanic membrane, resulting from an inflammatory process without any visible sign of inflammation.⁶ Etiopathology of OME is poor function of eustachian tube that causes defective mucociliary drainage and ventilation of middle ear cavity causing fluid production that decreases mobility of tympanic membrane and causes conductive deafness.⁷ Around one-fourth of OME episodes persist for three or more months and is responsible for hearing loss, balance problems, poor school performance, behavioural problems, ear discomfort, recurrent acute otitis media, or poor quality of life.⁸

Steroids play an important therapeutic role in the effective management of these pathologies. Among these mometasone and beclomethasone are commonly prescribed. In this instance, a study reported the efficacy was established in 60% of OME patients treated with mometasone.⁹ In another study, it was reported that among patients treated with beclomethasone, efficacy was established in 34.8% of OME patients.¹⁰ Given the paucity of a study that compares these two agents for managing patients with concomitant OME and AH, present study was conducted.

METHODOLOGY

This quasi-experimental study was conducted at Combined Military Hospital, Multan, Pakistan from April 2024 to May 2025, once ethical approval was obtained (ERB ref #: 3/Trg 15 April 2024)

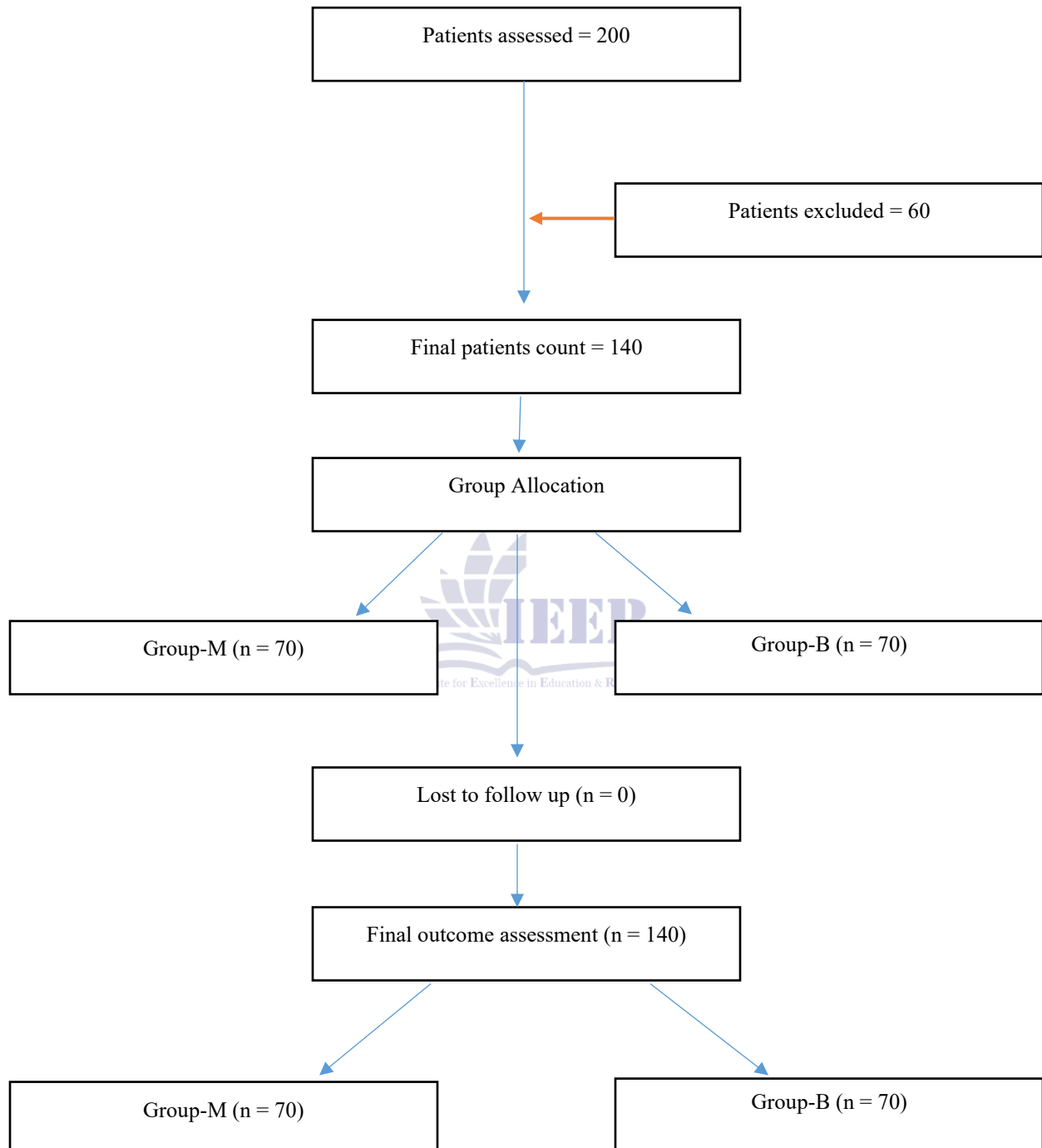
Children aged between 1 and 12 years, of either gender, who were found to have concomitant AH and OME with tympanogram type B & C, and AH grade II & III were included in the study. Patients having cholesteatoma, chronic suppurative otitis media, otosclerosis, sensorineural hearing loss, congenital anomalies, perforation in tympanic membrane and congenital deafness, cerebral palsy and mental retardation were excluded.

Calculation of the appropriate sample size calculation was done by using WHO sample size calculator by assuming 5% level of significance and 80% power. Since no comparative study in this regard have been conducted before, a pilot study was conducted (submitted as an additional/supplementary document) and its statistics for anticipated efficacy of mometasone and beclomethasone of 86.67% and 66.67%, were used. Based on these values a sample size of 140 (70 in each group) was obtained which was selected by using non-probability consecutive sampling technique.

Once a written approval on the consent form was given by the caregiver/guardian/parent of the patient, data collection was performed. In addition, caregiver/guardian/parent were ensured that refusal to take part in this study will not affect treatment of patient. Age and gender of the patients were documented. After this, thorough history and relevant systemic examination was done followed by a detailed examination, performed by a consultant ENT surgeon who had a minimum post-fellowship experience of five years to find out characteristic clinical and otoscopic findings of OME including retraction of tympani membrane with loss of luster and presence of fluid level or air bubbles in the cavity of middle ear.

Pre-intervention grade of AH was assessed and documented to be either Grade-II (26-50% obstruction) or Grade-III (51-75% obstruction). In addition, pure tone audiometry (PTA) was performed to assess type of tympanogram being type-B (flat curve) or type-C (negative pressure). After this, patients were non-randomly assigned either Group-M or Group-B. In Group-M (n = 70), patients were prescribed mometasone furoate nasal spray (50mcg/spray) to be used once daily with one spray in each nostril at night time. In Group-B (n = 70), patients were prescribed beclomethasone dipropionate nasal spray (50mcg/spray) to be used once daily with one spray in each nostril at night time. Total duration of therapy was eight weeks. Patient selection and allocation is given below as CONSORT patient flow diagram for quasi-experimental studies:

Figure-1: CONSORT patient flow diagram (n = 140)



At the completion of eight weeks of therapy, patients were assessed for efficacy. Measures of efficacy were achievement of either resolution of OME (defined by achievement of type-A tympanogram) and reduction in grade of AH compared to baseline.

All the collected data was entered and analysed with SPSS version 22.00. Descriptive statistics was collected for qualitative and quantitative variables. Qualitative variables like gender, AH grade, tympanogram type, resolution of OME and reduction in grade of AH compared to baseline were measured in terms of frequency and percentage and intergroup comparative analysis was done by using Chi-square test. Quantitative variable (age) was measured in median interquartile range (IQR) since analysis by

Shapiro-Wilk test revealed that it was not distributed normally, and intergroup comparative analysis was done by using Mann Whittney U-test. A p-value ≤ 0.05 was considered as significant.

RESULTS

In this study, 140 children were included. Median age was 6.00 (5.00) years. There were 94 (67.10%) male and 46 (32.90%) female patients. Grade-II AH was found in 64 (45.70%) while 76 (54.30%) patients were found to have Grade-III AH. Type-B tympanogram was found in 58 (41.40%) while 82 (58.60%) patients were found to have Type-C tympanogram. Intergroup comparative analysis of pre-treatment patient demographics is given in Table-I:

Table-I: Intergroup pre-treatment patient demographics comparison (n = 140)

Characteristic	Group-M (n = 70)	Group-B (n = 70)	p-value
Median age (years)	6.00 (5.25)	6.00 (6.00)	0.494 ^a
Gender			
Male	49 (70.00%)	45 (64.29%)	0.472 ^b
Female	21 (30.00%)	25 (35.71%)	
AH grade			
II	31 (44.29%)	33 (47.14%)	0.734 ^b
III	39 (55.71%)	37 (52.86%)	
Tympanogram			
B	29 (41.43%)	29 (41.43%)	1.000 ^b
C	41 (58.57%)	41 (58.57%)	

AH = Adenoid hypertrophy, a = Mann Whittney U-test, b = Chi-square test

Frequency of OME resolution (by achievement of type-A tympanogram) and reduction in AH grade compared to baseline in Group-M (n = 70) was 62 (88.57%) and 50 (71.43%) while in Group-B (n =

70), it was 36 (51.43%), (p < 0.001) and 23 (32.86%), (p < 0.001), respectively. Intergroup comparative analysis of efficacy measures is given in Table-II:

Table-II: Intergroup efficacy measures comparison (n = 140)

Characteristic	Group-M (n = 70)	Group-B (n = 70)	p-value
OME resolution			
Yes	62 (88.57%)	36 (51.43%)	< 0.001 ^b
No	8 (11.43%)	34 (48.57%)	
Reduction of AH grade			
Yes	50 (71.43%)	23 (32.86%)	< 0.001 ^b
No	20 (28.57%)	47 (67.14%)	

OME = Otitis media with effusion, AH = Adenoid hypertrophy, b = Chi-square test

DISCUSSION

Locally administered steroids have been considered the cornerstone in managing AH as well as OME.^{11, 12} Present study focused on comparison of effectiveness of two different types of locally administered steroids (mometasone and beclomethasone) in management of OME with concomitant AH. In present study, diagnosis as well as grading of AH and OME was made with combined utilisation of clinical evaluation, otoscopy and PTA. In this instance, PTA does play a crucial role, particularly in diagnosis of OME since it is associated with some degree of deafness in approximately 50% of the suffering children resulting in abnormal tympanogram.^{13, 14} Similarly,

Upon assessment of patient demographics, it was observed that average age of the patients who had both AH and OME was six years. Compared to this, a study found that patients who suffered from OME had an average age of seven years which is almost similar to present study.¹⁵ Similarly, in another study in which clinical characteristic of patients with AH were studied, it was found that most number of patients (40%) were aged between 6-8 years.¹⁶ This young age could be attributed to higher chances of children in this age group to develop recurrent infection of upper airways leading to development of these conditions.¹⁷

In present study, most sufferers of AH and OME were males constituting 67.1% of the patients. One study in this regard analysed the clinical characteristics of the children who were suffering from AH and reported this similar male predominance with males making up 58% of the children.¹⁸ Similarly, in another study, this male predominance was reported among OME cases, with males making up 52.2% of the patients.¹⁹ This predominance of male children could not be determined but previous research shows the possibility of higher chances of to get exposed to allergens and difference in propensity of certain infections between genders.²⁰

Upon comparative analysis of efficacy, it was observed that mometasone performed significantly better in terms of OME resolution ($p < 0.001$) as well as improvement in AH grade ($p < 0.001$), in comparison to beclomethasone. These

findings correlate with the results of pilot study attached as the supplementary material which was conducted at the institutional level in which efficacy of mometasone was 86.67% while for beclomethasone it was 66.67%.

In present study, efficacy parameters revealed that the mometasone efficacy was as high as 88.57%. In one study conducted to determine the efficacy of nasal mometasone in treatment of OME with AH in which it was reported that this medication was found efficacious in 60% of the cases when given alone while it increased to 80% when it was added to patients who were also taking montelukast.²¹ Similarly, in another study this efficacy of mometasone was 60%.⁹ Regarding beclomethasone, analysis of efficacy parameters revealed that OME resolution occurred in 51.43% while reduction in AH grade was observed in only 32.86% of the patients. Compared to this, a study found that when nasal beclomethasone was used for managing OME, efficacy was only observed in 34.8% of the patients.¹⁰ In another study, it was observed that when nasal beclomethasone was used for treating concomitant OME and AH, frequency of OME resolution was 41.6% while AH size reduction was also significant ($p < 0.001$).²²

These findings are different as compared to the efficacy of mometasone and beclomethasone reported in present study. The exact reason could not be determined for this difference but could be attributed to differences in sample sizes, patient demographics, pre-treatment patient condition, duration of therapy and difference in the parameters selection that were used to establish efficacy.

Based on the results of present study, it is evident that when a choice is to be made between these two steroid formulations, mometasone furoate is a better choice of local therapy for managing concomitant OME and AH as compared to beclomethasone dipropionate. Therefore, preferential use of mometasone furoate for managing concomitant OME and AH is strongly recommended. One major limitation of present study was lack of comparison of the results of present study with previous study that compared these two drugs head to head, however, this was inevitable since no such study had been found

despite extensive search in PubMed, MedLine, Google Scholar, CrossRef and Cochrane library data base.

CONCLUSION

In conclusion, mometasone furoate is more efficacious as compared to beclomethasone furoate in management of patients with concomitant otitis media with effusion and adenoid hyperplasia.

PATIENTS' CONSENT

Informed consent in writing was taken from all participants.

COMPETING INTEREST

None.

REFERENCES

- Niedzielski A, Chmielik LP, Mielnik-Niedzielska G, Kasprzyk A, Bogusławska J. Adenoid hypertrophy in children: a narrative review of pathogenesis and clinical relevance. *BMJ Paediatr Open*. 2023;7(1):e001710. <https://doi.org/10.1136/bmjpo-2022-001710>.
- Tse KL, Savoldi F, Li KY, McGrath CP, Yang Y, Gu M. Prevalence of adenoid hypertrophy among 12-year-old children and its association with craniofacial characteristics: a cross-sectional study. *Prog Orthod*. 2023;24(1):31. <https://doi.org/10.1186/s40510-023-00481-4>.
- Khan MA, Nawaz FUH, Hakim A, Khan M. Frequency of adenoid hypertrophy among adult patients with nasal obstruction. *J Postgrad Med Inst*. 2018;32(3):262-265. URL: <https://jpmi.org.pk/index.php/jpmi/article/view/2200>.
- Ahmad Z, Krüger K, Lautermann J, Lippert B, Tenenbaum T, Tigges M, et al. Adenoid hypertrophy-diagnosis and treatment: the new S2k guideline. *HNO*. 2023;71(Suppl 1):67-72. <https://doi.org/10.1007/s00106-023-01299-6>.
- Alzahrani HA, Alkhaldi RO, Alsufyani DH, Alghamdi SA, Althobity TA, Fageeh YA. Adenoid hypertrophy and orthodontic complications: an assessment of parental knowledge in Saudi Arabia. *Cureus*. 2023;15(7):e41692. <https://doi.org/10.7759/cureus.41692>.
- Mills RP. Management of otitis media with effusion in adults. *J Laryngol Otol*. 2025;139(5):383-8. <https://doi.org/10.1017/S002221512500012X>.
- Mulvaney CA, Galbraith K, Webster KE, Rana M, Connolly R, Marom T, et al. Antibiotics for otitis media with effusion (OME) in children. *Cochrane Database Syst Rev*. 2023;10(10):CD015254. <https://doi.org/10.1002/14651858.CD015254.pub2>.
- Seamus B, Michael I, Ivan K. Disease-specific quality of life in Irish children with otitis media with effusion. *Saudi J Otorhinolaryngol Head Neck Surg*. 2024;26(2):79-82. https://doi.org/10.4103/sjoh.sjoh_29_23.
- Ahmed MR, Eldeeb WE. Effectiveness of mometasone furoate nasal spray on tympanometric results and hearing loss in children with otitis media with effusion. *Egypt J Otolaryngol*. 2022;38:32. <https://doi.org/10.1186/s43163-022-00225-x>.
- Barati B, Omrani MR, Okhovat AR, Kelishadi R, Hashemi M, Hassanzadeh A, et al. Effect of nasal beclomethasone spray in the treatment of otitis media with effusion. *J Res Med Sci*. 2011;16(4):509-515. URL: <https://pmc.ncbi.nlm.nih.gov/articles/PMC3214356/pdf/JRMS-16-509.pdf>

- Alqutub A, Mozahim SF, Mozahim NF, Alsulami OA, AlSharif SM, Malebari AZ, et al. Effectiveness and safety of intranasal corticosteroids for adenoid Hypertrophy: A systematic review and meta-analysis. *Int J Pediatr Otorhinolaryngol*. 2025;195:112450. <https://doi.org/10.1016/j.ijporl.2025.112450>.
- Ikeda R, Hidaka H, Ito M, Kamide Y, Kuroki H, Nakano A, et al. Pharmacotherapy focusing on for the management of otitis media with effusion in children: Systematic review and meta-analysis. *Auris Nasus Larynx*. 2022;49(5):748-754. <https://doi.org/10.1016/j.anl.2022.03.017>.
- Şentürk M, Ardiç FN, Tümkaya F, Kara CO. Wideband tympanometry and absorbance for diagnosing middle ear fluids in otitis media with effusion. *J Int Adv Otol*. 2023;19(2):140-148. <https://doi.org/10.5152/iao.2023.22697>.
- Arif M, Noor A, Nawaz H. Accuracy of tympanometry in the diagnosis of otitis media with effusion in children's at myringotomies: tympanometry in otitis media. *Pak J Health Sci*. 2025;6(4):243-247. <https://doi.org/10.54393/pjhs.v6i4.3003>.
- Anwar K, Yar MA, Khan S. Spontaneous resolution of 'glue ear' in children- An experience at a tertiary care teaching hospital of Khyber Pakhtunkhwa. *Pak J Health Sci*. 2023;4(3):157-161. <https://doi.org/10.54393/pjhs.v4i03.605>.
- Mathur M, Kumar VB, Gattani VN, Mathur S. Clinical characteristics of chronic adenoiditis in children aged 0 to 12 years: a study. *Int J Life Sci Biotech Pharm Res*. 2025;14(6):976-979. https://doi.org/10.69605/ijlbpr_14.6.2025.166.
- Corsetto A, Milani GP, Picca M, Buzzetti R, Carrozzo R, Gambino M, et al. Recurrent upper respiratory tract infections in early childhood: a newly defined clinical condition. *Ital J Pediatr*. 2024;50(1):30. <https://doi.org/10.1186/s13052-024-01600-5>.
- Jyothirmai ASL, Sadhana O, Chandra TS, Murthy P. Assessment of adenoid hypertrophy with clinical grading versus radiology and endoscopy- A cross-sectional study. *J Otorhinolaryngol Allied Sci*. 2020;3(4):130-135. <https://doi.org/10.18231/j.ijoas.2020.028>.
- Restuti RD, Tamin S, Nugroho DA, Hutauruk SM, Mansyur M. Factors affecting the occurrence of otitis media with effusion in preschool and elementary school children: a comparative cross-sectional study. *BMJ Open*. 2022;12:e065291. <https://doi.org/10.1136/bmjopen-2022-065291>.
- Bhise S, Hippargekar P, Kothule S, Dhanwe M, Ngullie O. A clinical study of persistent adenoid and its secondary effect. *Indian J Otolaryngol Head Neck Surg*. 2023;75(4):3507-3513. <https://doi.org/10.1007/s12070-023-03841-y>.
- Khanam A, Akhtar G, Rahman MA, Chowdhury NN. Efficacy of mometasone furoate nasal spray with oral montelukast in the treatment of otitis media with effusion with or without adenoid hypertrophy and atopic diseases. *Bangladesh J Med Sci*. 2022;21(4):836-841. <https://doi.org/10.3329/bjms.v21i4.60282>.
- Abdul Aema FB, Abbas Al-Timimi HM. Efficacy of intranasal beclomethasone in the treatment of children with otitis media with effusion and/or adenoid hypertrophy. *Iraqi Postgrad Med J*. 2017;16(2):176-183. URL: <https://iasj.rdd.edu.iq/journals/uploads/2024/12/15/020c5cb514393ff09d790288f20cdabc.pdf>.