Original Article

Topical Intranasal Corticosteroids Compared to Watchful Waiting Method for the Treatment of Otitis Media with Effusion in Children

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ABSTRACT

Background: Otitis media with effusion (OME) is a leading cause of deafness globally, characterized by middle ear effusion lasting three months or more without infection signs.

Aim and Objectives: To evaluate the effectiveness of topical intranasal corticosteroids in managing OME in children compared to the watchful waiting method.

Patients and Methods: A randomized controlled clinical trial on children with OME from the otorhinolaryngology outpatient clinic of Affiliated Military Hospital in Egypt, 2023.

Result: The otoscopic examination at the third week showed significant differences between groups A and B concerning TM retraction and cone of light ($p < 0.05$). Tympanometry type B after eight weeks and parental smoking in group A showed no statistical significance ($p > 0.05$), with 50% of type B cases having a history of parental smoking compared to 40% with other types. In group B, non-type B cases had a 50% history of parental smoking compared to 25% of type B cases ($p > 0.05$).

Conclusion: In conclusion, the primary data indicate that topical intranasal corticosteroids are probably an effective management for kids with bilateral otitis media with effusion at 8 and 12 weeks, in contrast to watchful waiting. However, these findings require confirmation by larger, more-powered study with larger sample size.

Key Words: Otitis media with effusion (OME), Topical intranasal corticosteroids, watchful waiting method.

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INTRODUCTION

One of the main contributors to deafness worldwide is otitis media with effusion. It is characterized by the existence of middle ear effusion for three months or more without the gross signs of infection[1].

OME can be detected at early childhood as 50% of cases are infants under the age of 1 year and 60% are children under the age of 2 years. The prevalence is specifically high in children with craniofacial anomalies (more commonly trisomy 21 and cleft palate) ranging between 60 and 85%. Chronic OME can cause complications like hearing loss, tympanic membrane diseases (atrophy, retraction pocket and cholesteatoma), delayed speech and behavioural disorder[2].

OME can develop in association with or following infection of upper respiratory tract, due to Eustachian tube dysfunction, or due to acute otitis media. Age is regarded as an important risk factor for OME because of its direct association with the angulation of the eustachian tube. More factors contributing to the incidence of Otitis media with effusion include passive smoking, male gender, and attendance at daycare centers. The prevalence of Otitis media with effusion greatly decreases in breast-fed babies; an extended period of breast-feeding correlates with a diminished risk of OME[3].

The medical management of OME remains a controversial topic. Traditional medical treatments fail to provide adequate and lasting alleviation of otologic symptoms. This includes systemic or topical corticosteroids, antibiotics, antihistaminics, decongestants or mucolytics[4]. Watchful waiting is also used for the management of OME[5].

PATIENTS AND METHODS

Study design

Randomized controlled clinical trial

Study setting

Participants will be enrolled from the otorhinolaryngology outpatient clinic of Affiliated Military Hospital.

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Study population

Population of study

Children with otitis media with effusion confirmed by clinical, otoscopic examination and tympanogram. They will be divided randomly into two groups one will receive topical intranasal corticosteroids spray and the other will follow the watchful waiting method as they will not receive either topical or systemic corticosteroids.

Inclusion criteria

Kids aged from 3 years up to 12 years old with symptoms suggestive of conductive loss of hearing and have otitis media with effusion documented by otoscopic examination and tympanogram at the time of study enrollment.

Exclusion criteria

1. Previous surgery for otitis media with effusion.
2. Sensorineural hearing loss
3. Craniofacial anomalies and cleft palate.

Sampling

Sample type

Convenient sample.

Sample size

Sample size has been determined by utilizing G-Power software, version 3.1.9.4. Based on previous research done by Salmen, Saleh, and Abd Einaeem, in 2021, by considering tympanometry revealed the percent of type A tympanogram (70 %) in the group of children received nasal corticosteroids spray Compared to (20%) in the group of children received seawater nasal spray with 90% power to detect this difference, 95% confidence level and ratio of 1:1, the minimal calculated sample size will be 24 cases in each group, with a total of 48 cases will be required to find this difference. Sample size was inflated by 20% to account for attrition problem in prospective studies.

Data collection

Data collection procedures

Children meeting the inclusion criteria will be divided randomly into 2 equal groups:

1. **group A** (treatment arm): Kids will receive topical intranasal corticosteroids spray (fluticasone propionate), one puff in each nostril daily for 3 weeks.
2. **In group B** (control arm): kids will not receive either topical or systemic corticosteroids. as they will follow the watchful waiting method

Randomization: simple randomization

Equal number of pieces of paper with the letters T(treatment) and C(control) written on it, with a total number of papers(T+C) equal the sample size. This will lead eventually to 2 equal groups with randomly selected patients among each group.

Blinding: open labelled.

All patients will be subjected to:

Full medical history

- Personal history : name, age, residence, sex
- Complaint & its duration
- Present history: Analysis of the current patient complaint
- History of allergy to drugs.
- Past Medical history
- Past Surgical history: history of previous operations
- Family history
- History of parental smoking

Full clinical examination

General examination: Full general clinical examination has been performing involving vital signs (pulse, temperature, respiratory rate and blood pressure measurement)

Otoscopic examination: Otoscopy was conducted by inserting the speculum into the case's ear to detect the condition of the EAC and TM. The clinician gently pulled the pinna upward and backward to straighten the ear canal.

Tympanometry

utilizing low-frequency probe tone of 226 hertz for pressure applied to the external canal between + 300 and −300 daPa.

Pure tune audiometry

Pure-tone audiometry is the standard gold method of determining the type, degree, and configuration of hearing loss due to its widespread availability, inter-test reliability, and relative ease of execution.

Otoscope examination, Basic audiological assessment involving pure tune audiometry, and tympanogram will be conducted prior to management and repeated at 3 and 8 weeks following management.

After 8 weeks, management of patients will be determined according to the results of their tympanograms:

1. Type A tympanogram: no further intervention is needed.
2. Type B tympanogram: patient will be scheduled for tympanostomy tube insertion.
3. Type C tympanogram: tympanogram will be repeated after 4 weeks.

The outcome, which is resolution of otitis media with effusion, determined by normal findings on otoscope (mobile tympanic membrane with absence of retraction, fluid level, air bubbles and disturbed cone of light) and type A tympanogram.

Statistical analysis

Pre-coded data was processed and statistically analysed by utilizing the statistical package of the social science software (SPSS), version 21. Data has been summarized using SD and mean for normally distributed quantitative variables or median and IQR for non-normally distributed quantitative variables. Number and percentage were utilized for description of qualitative variables. The Chi-square test was utilized to compare qualitative variables, the independent T-test as been utilized for regularly distributed quantitative variables among groups, and Nonparametric Mann-Whitney tests were applied for non-normally distributed quantitative data. The paired sample t-test and Wilcoxon Signed-Rank test have been utilized for the examination of paired data. Additional statistical tests were utilized if required. *P-values* less than 0.05 were deemed statistically significant.

Ethical considerations

The data acquired from participants are confidential. The research participants will not be recognized by name in any report or publication regarding this research. Prior to the participants' admission to the research, the study's aim, nature, and risk–benefit evaluation has been explained to them. Informed consent was acquired.

RESULTS

Regarding the comparison of Otoscopic examination at 0 week between group A and B, the results were non-statistically significant (*p value* more than 0.05) (Table 1).

As all cases in group A and B had TM retraction at the beginning of the study.

For Fluid level or air bubbles it was present in 20.8% of cases in group A than 8.3% of cases in group B also cone of light was absent in 8.3% of cases in group A than 4,2% of group B.

Regarding loss of luster, it was lost in about three fourth of cases in group A compared to one half of cases in group B.

For TM mobility, about 45.8% of cases in group A had mobile TM compared to 70.8% of cases in group B.

Regarding the comparison of Otoscopic examination at third week between group A and B, the results were statistically significant regarding TM retraction and cone of light (*p value* <0.05)

As only 37.5% of cases in group A had TM retraction after three weeks of follow up than 91.7% of cases in group B, also small percentage of cases in group A (41.7%) had absent cone of light compared to 87.5% of cases in group B

On other hand there is a statistically insignificant variance between group A and B regarding Fluid level or air bubbles, loss of luster and TM mobility (*p value* >0.05)

As the same percentage of cases in group A and group B had Fluid level or air bubbles and loss of luster (8.3% and 33.3% respectively).

For TM mobility, higher percentage of cases in group A (87.5%) had mobile TM than 70.8% of cases in group B, however this difference is non-statistically significant.

Regarding the comparison of Otoscopic examination at eighth week of follow up between group A and B, the results were statistically significant regarding TM retraction and cone of light (*p value* <0.05) .

As only 16.7% of cases in group A had TM retraction after eight weeks of follow up compared to 66.7% of cases in group B, also small percentage of cases in group A (20.8%) had absent cone of light compared to 66.7% of cases in group B

On other hand there is a statistically insignificant variance among group A and B regarding Fluid level or air bubbles, loss of luster and TM mobility (*p value* >0.05)

As no one in group A had Fluid level or air bubbles compared to 2 cases in group B, also only 5 cases in group A had lost of luster compared to 7 cases in group B.

For TM mobility, higher percentage of cases in group A (87.5%) had mobile TM compared to 83.3% of cases in group B, however this difference is non-statistically significant (Figures 1,2).

As regard the comparison between group A and B regarding Tympanometry AT 0 week, 3 weeks and after 8 weeks, the results were statistically significant at third week and eighth week (*p value* <0.05) whereas an insignificant difference was observed at the beginning of study (*p value* 0.05) as all cases in group A and B had Tympanometry type B.

After 3 weeks of follow up there were 33.3% of cases in group A had Tympanometry type A compared to 4.2% of cases in group B, then the percentage increased again after 8 weeks to 75% of cases in group A than 33.3% of cases in group B (Table 2).

Only 2 cases in group A with Tympanometry type C were observed at eighth week of follow up who underwent

another follow up at 12th week, from whom one cases converted into type A and other cases converted into type B

By comparing between group A and B regarding PTA at 0 week, 3 weeks and after 8 weeks, the results were statistically significant at the beginning of study and eighth week (*p value* <0.05) while an insignificant variance has been detected at third week (*p value* >0.05) as mean PTA was significantly higher among cases of group A at 0 week (mean =32.4±3.) than in cases of group B (mean = 29.9±2.6) then in decreased rapidly in group A after 8 weeks to 24±5 to become significantly lower than in group B (26.3±2.1) (Tables 3,4)

While at third week, mean PTA was nearly the same in group A and B (Table 5).

Table 1: comparative analysis among group A and B regarding Otoscopic examination At 0 week

Otoscopic examination At 0 week	Group A (number=48) ears	Group B (number=48) ears	X^2	*P value*
TM retraction				
Retracted	48(100%)	48(100%)	___	___
Not retracted	0(0%)	0(0%)		
Fluid level or air bubbles				
Present	10(20.8%)	4(8.3%)	1.5	0.41
Absent	38(79.2%)	24(91.7%)		
Loss of luster				
Loss	36(75%)	24(50%)	3.2	0.13
Not loss	12(25%)	24(50%)		
Cone of light				
Present	4(8.3%)	2(4.2%)	0.35	0.99
Absent	24(91.7%)	46(95.8%)		
TM mobility				
Mobile	22(45.8%)	34(70.8%)	3.1	0.07
Not mobile	26(54.2%)	14(29.2%)		

* significant at *p value* <0.05

Table 2: comparative analysis among group A and B with regard to Otoscopic examination at 3rd weeks

Otoscopic examination After 3 weeks	Group A (number=48) ears	Group B (number=48) ears	X^2	*P value*
TM retraction				
Retracted	18(37.5%)	44(91.7%)	15.3	<0.001*
Not retracted	30(62.5%)	4(8.3%)		
Fluid level or air bubbles				
Present	4(8.3%)	4(8.3%)	___	__
Absent	44(91.7%)	44(91.7%)		
Loss of luster				
Loss	16(33.3%)	16(33.3%)	__	__
Not loss	32(66.7%)	32(66.7%)		
Cone of light				
Present	28(58.3%)	6(12.5%)	11	0.001*
Absent	20(41.7%)	42(87.5%)		
TM mobility				
Mobile	42(87.5%)	34(70.8%)	2	0.28
Not mobile	6(12.5%)	14(29.2%)		

Table 3: comparatives analysis among group A and B with regard to Otoscopic examination at 8th week

Otoscopic examination After 8 weeks	Group A (number=48) ears	Group B (number=48) ears	X^2	*P value*
TM retraction				
Retracted	8(16.7%)	32(66.7%)	12.3	<0.001*
Not retracted	40(83.3%)	16(33.3%)		
Fluid level or air bubbles				
Present	0(0%)	4(8.3%)	2	0.14
Absent	48(100%)	44(91.7%)		
Loss of luster				
Loss	10(20.8%)	14(29.2%)	0.44	0.50
Not loss	38(79.2%)	34(70.8%)		
Cone of light				
Present	38(79.2%)	16(33.3%)	10.2	0.001*
Absent	10(20.8%)	32(66.7%)		
TM mobility				
Mobile	42(87.5%)	40(83.3%)	0.16	0.68
Not mobile	6(12.5%)	8(16.7%)		

Table 4: comparative analysis among group A and B regarding Tympanometry AT 0 week, 3 weeks and after 8 weeks

Tympanometry	Group A (number=48) ears	Group B (number=48)ears	X^2	*P value*
At 0 week				
Type A	0(0%)	0(0%)		
Type B	48(100%)	48(100%)	—	—
Type C	0(0%)	0(0%)		
At 3th weeks				
Type A	16(33.3%)	2(4.2%)	14.6	0.001*
Type B	22(45.8%)	46(95.8%)		
Type C	10(20.8%)	0(0%)		
At 8th weeks				
Type A	36(75%)	16(33.3%)	12.3	0.002*
Type B	8(16.7%)	32(66.7%)		
Type C	4(8.3%)	0(0%)		
At 12th weeks	(n=4)			
Type A	2(50%)			
Type B	2(50%)			
Type C				

_* significant at *p value* <0.05

Table 5: comparative analysis between group A and B regarding PTA AT 0 week, 3 weeks and after 8 weeks

PTA	Group A (number=24)	Group B (number=24)	T/U	*P value*
At 0 week				
Mean ± SD	32.4±3.3	29.9±2.6	2.8	0.006*
Range	28:38	25:35		
At 3 week				
Mean ± SD	27.3±4.2	27.5±2.1	-0.08	0.93
Range	20:35	24:31		
At 8 week				
Mean ± SD	24±5	26.3±2.1	-1.9	0.05*
Range	17:35	24:30		
At 12 week (n=2)				
Mean ± SD	29±5.6	—	—	—
Range	25:33			

_* significant at *p value* <0.05

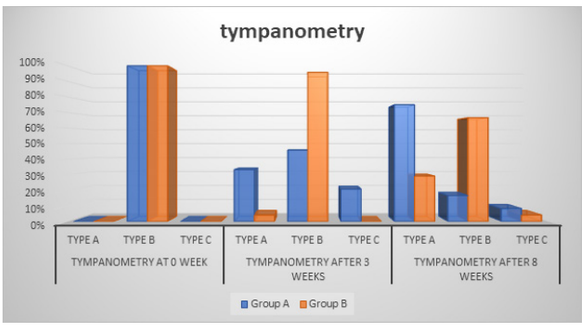

Fig. 1: bar chart represent comparison among group A and B with regard to tympanometry type.

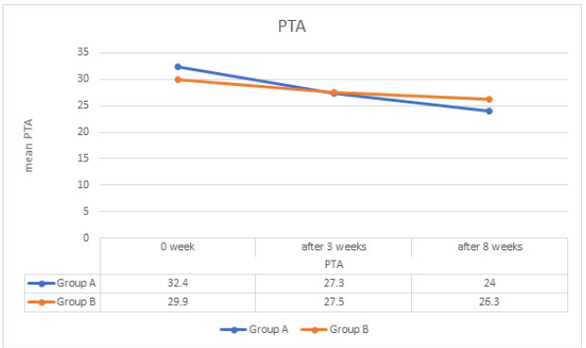

Fig. 2: line graph represent comparison between group A and B regarding PTA AT 0 week, 3 weeks and after 8 weeks.

DISCUSSION

A randomized controlled clinical trial was conducted on 48 children with otitis media with effusion confirmed by clinical, otoscopic examination and tympanogram.

Kids who meeting the inclusion criteria was separated randomly into 2 equal groups:

Group A: 24 kids received topical intranasal corticosteroids spray, one puff in each nostril daily for 3 weeks.

Group B: 24 kids didn't receive neither topical nor systemic corticosteroids.

Regarding the comparison of demographic data between group A and B, there is non-statistically significant variance as regard age, sex and house hold parental smoker (p value above 0.05) as mean age of group A was 7.13±2.1 years compared to 6.2±2.3 years in group B, as regard sex, 45.8% of group A were males compared to 54.2% of group B. for house hold parental smoker, it was positive in 41.7% in both group A and B separately.

According to Rasheed[6], the purpose of this research was to determine whether or not the application of topical nasal steroids is beneficial for the management of otitis media with effusion. The research involved a total of 40 kids (80 ears), aged between 6 and 10 years (mean age = 7.45 years ± SD 1.32). Of the 40 cases, 23 (57.5%) were male and 17 (42.5%) were female, resulting in a male-to-female ratio of 1.4:1. No significant distinction observed among the two groups for age and gender (*P-value* above 0.05).

Similar to the previous study Hussein *et al*[7], the purpose of this study was to compare the effects of intranasal steroids and watchful waiting on the resolution of otitis media with effusion among kids aged 2–11 years old. A total of 290 kids who had bilateral otitis media with effusion were divided into three groups: group A received oral steroids followed by intranasal steroids; group B received oral steroids only; and group C underwent watchful waiting. Patients underwent evaluation by audiometry and tympanometry. No significant distinction was seen among the three groups in demographic data (*p-value* above 0.05).

A recent study of Mulvaney *et al*[8] encompassed randomized controlled trials (RCTs) and quasi-randomized trials including kids aged six months to twelve years with unilateral or bilateral OME. They incorporated investigations that contrasted topical or oral steroids with either a placebo or a strategy of careful waiting (no intervention). Most of the included trials indicated no significant differences among the tested groups for demographic characteristics (*p-value* above 0.05).

Regarding the comparison of Otoscopic examination at 0 week among group A and B, the outcomes were a statistically insignificant (*p value* above 0.05). As all cases in group A and B had TM retraction at the beginning of the study. For Fluid level or air bubbles it was present in 20.8% of cases in group A than 8.3% of cases in group B also cone of light was absent in 8.3% of cases in group A than 4,2% of group B. Regarding loss of luster, it was lost in about three fourth of cases in group A compared to one half of cases in group B. For TM mobility, about 45.8% of cases in group A had mobile TM compared to 70.8% of cases in group B.

The outcomes of Rasheed[6] corroborate our results, indicating there is an insignificant distinction among group A and group B for pre-treatment otoscopic results and the average pure tone hearing thresholds at 0.5, 1, 2, and 4 kHz. All cases in group A 40 (100%) and B 40 (100%) had TM retraction at the beginning of the study. Air Fluid level was present in 4 (10%) of cases in group A than 2 (5%) of cases in group B. Air bubbles were present in 2 (5%) of cases in group A than 2 (5%) cases in group B (*p* >0.05).

Regarding the comparison of Otoscopic examination at third week between group A and B, the results were statistically significant regarding TM retraction and cone of light (*p value* less than 0.05). On other hand there is a statistically insignificant variance among group A and B regarding Fluid level or air bubbles, loss of luster and TM mobility (*p value* >0.05) For TM mobility, higher percentage of cases in group A (87.5%) had mobile TM

compared to 70.8% of cases in group B , however this difference is non-statistically significant.

In the research by Rasheed[6], statistical analysis indicated no statistically significant distinction among cases in group A and group B at the conclusion of the second post-treatment week for otoscopic and tympanometric .Where, 32 (80%) of cases in group A had TM retraction after three weeks of follow up compared to 34 (85%) of cases in group B. there was an insignificant variance among group A and B with regard to Fluid level it was found in 3 (7.5%) cases in group A and 2 (5%) of cases in group B (all *p-values* were >0.05).

In the current study only 2 cases in group A with tympanometry type C underwent another follow up at 12th week, of whom one cases had TM retraction, loss of luster, absent cone of light, mobile TM and both cases had no Fluid level or air bubbles. While for group B, there were no one with tympanometry type C at 8th week who need another follow up after 4 weeks.

Previous research Williamson *et al*.[9] indicated that a three-month regimen of topical intranasal corticosteroids in kids aged four to eleven years appears to be no more effective than a placebo in enhancing the clearance of otitis media effusions at one, three, and nine months, or in enhancing essential symptom-related results.

Regarding the comparison of otoscopic examination at 0 weeks, after 3 weeks and after 8 weeks among cases of group A, the outcomes were statistically significant (*p value* under 0.05). As there were significant decline in percentage of cases with TM retraction after 3 weeks, another decline was observed after 8 weeks of follow up and significant decline in percentage of cases with Fluid level or air bubbles after 3 weeks then to 0% after 8 weeks.

Along with our study the 2ry analysis at three months in study of Williamson *et al*.[9] illustrated that fifty-eight percent of the topical steroid group had TM retraction decreased to 32% at nine weeks, and all of the topical steroid group remained clear in at least one ear.

As regard the comparison between group A and B regarding Tympanometry AT 0 week, 3 weeks and after 8 weeks, the results were statistically significant at third week and eighth week (*p value* under 0.05) whereas an insignificant variance was observed at the beginning of study (*p value* above 0.05) as all cases in group A and B had Tympanometry type B.

Tympanometry is an objective assessment that provides information about the dynamic characteristics of the middle ear and the tympano-ossicular complex. It estimates the acoustic admittance of the middle ear concerning the pressure variations of the outer ear (Nozza *et al*., 1992).

In a recent research titled " Is Topical Nasal Steroid Useful for Treatment of Otitis Media with Effusion in Children?" Rasheed[6] found that Tympanograms were flat (type B) in all patient's groups involved in the research. As regards Tympanometric outcomes at the end of second post-treatment week. Type A were found in 6% cases in group A and 4% cases in group B, Type B were found in 26% cases in group A and 32% cases in group B and Type C were found in 8% cases in group A and 4% cases in group B and (*p value* above 0.05).

Regarding the comparison of Tympanometry at 0 weeks, after 3 weeks and after 8 weeks among cases of group A, it was observed that percentage of cases with type B was significantly decreased from 100% at the beginning of study to 45.8% after 4 weeks and then to 16.7% after 8 weeks, with significant *p value* <0.05.

In comparative research examining oral steroids versus topical nasal steroids for the management of OME, El-Anwar *et al*[10] found no significant enhancement in tympanic membrane appearance at any therapy stage for kids with OME receiving topical nasal steroids (group A) following two and four weeks. In each group individually, there was a highly significant enhancement in tympanometric outcomes at all stages of the investigation, except for the first stage (following two weeks), when significant enhancement was observed just in group A.

The research conducted by Williamson *et al*[9] aimed to evaluate the clinical effectiveness of topical intranasal corticosteroids in children diagnosed with bilateral OME, utilizing tympanometric criteria at one month (the proportion of kids exhibiting at least one ear with an A or C type recording), as kids with this condition are considered to be at an elevated risk of disability compared to those with normal hearing in one ear. We utilized kids instead of ears for the result, as ears aren't independent variables. Tympanometry provided a more objective assessment than parental reports.

Regarding the comparison of Tympanometry at 0 weeks, after 3 weeks and after 8 weeks among cases of group B, it was observed that percentage of cases with type B was significantly decreased from 100% at the beginning of study to 95.8% after 4 weeks and then to 66.7% after 8 weeks and the remaining 33.3% of cases had type A as no one had type C after 8 weeks of follow up with significant *p value* <0.05.

In a previous research Williamson *et al*.[9] noted that, regarding tympanometric cure from the beginning of study to three weeks and nine weeks after baseline significantly decreased was noted in type B cases.

Little *et al*.[11] utilized diary-based symptom and severity scores, recorded weekly over three weeks, for determining either the number of influenced days (e.g., days with earache) or severity on Likert-type scales. They observed a significant reduction in type B tympanometry cases from baseline to eight weeks (*p -value* less than 0.05).

By comparing among group A and B regarding pure tone audiometric (PTA) at 0 week, 3 weeks and after 8 weeks, the results were statistically significant at the beginning of study and eighth week (*p value* <0.05) while an insignificant variance has been observed at third week (*p value* >0.05) as mean PTA was significantly higher among cases of group A at 0 week (mean =32.4±3.) than in cases of group B (mean = 29.9±2.6) then in decreased rapidly in group A after 8 weeks to 24±5 to become significantly lower than in group B (26.3±2.1). While at third week, mean PTA was nearly the same in group A and B.

In agreements with our results were the results of Cai *et al*.,[12] who showed that, all kids with otitis media with effusion had the same pure tone audiometric value at the end of three and four weeks of management with intranasal steroids and in control group (*p -value* above 0.05).

In a comparative study titled "The Efficacy of Nasal Steroids in Treatment of Otitis Media with Effusion" Salmen *et al*.,[13] found that mean PTA was significantly higher among children cases treated with nasal Steroids at baseline when compared with control group.

Regarding the comparison of PTA at 0 weeks, after 3 weeks and after 8 weeks among cases of each group A and B separately there were statistically significant decline in mean PTA after 3 weeks compared to baseline also after 8 weeks compared to baseline with significant *p value* <0.05.

In agreement was a previous study titled " Topical intranasal corticosteroids in 4–11-year-old children with persistent bilateral otitis media with effusion in primary care" where the results of Williamson *et al*.,[9] showed significant decrease in PTA value after 1, 3, and 9 weeks compared to baseline among all children received topical intranasal corticosteroids.

This was in line with several studies Chow *et al*.,[14]; Chavan and Nagpure,[15] Swain *et al*.,[16] which sported the findings of our study.

Regarding association between cases with tympanometry type B after 8 weeks of follow up and Parental smoking among cases of group A, the outcomes were a statistically insignificant (*p value* above 0.05) nevertheless higher percentage of cases with type B had positive history of parental smoking (50%) compared to 40% in cases with other tympanometry type.

Also, the results were non-statistically significant among cases of group B, however higher percentage of cases with non-type B had positive history of parental smoking (50%) compared to 25% in cases with type B.

In prior research by Saad *et al*.[17], the incidence of passive smoking among kids with OME was unexpectedly low at 15.5%. No significant correlation was found between OME and exposure to passive smoking (*P* = 0.73, OR = 1.71, 95% CI = 0.48-3.19).

Identical results were previously observed by Martines *et al*.[18] and Straetemans *et al*.[19]. Conversely, Kırıs *et al*.[20] observed a statistically significant association among passive smoke exposure and OME.

El-Houfey *et al*.[21] recognized the universally recognized benefits of breastfeeding, with prior research demonstrating its efficacy to decrease respiratory and GIT infection.

A comparative investigation of the related variables in kids with OME across various age groups. Tong *et al*.[22] stated that exposure to passive smoking at home is a previously identified risk factor for kids with OME.

In a previous study Zernotti *et al*.,[23] reported that, atopy, Passive smoking, day-care nursery ,bottle-feeding are detectible risk factors for OME.

LIMITATIONS OF THE STUDY

Lack of compliance of some cases regarding the treatment instructions and follow up visits.

RECOMMENDATIONS

- We suggest for the utilization of intranasal corticosteroids as a treatment strategy for OME.
- Future research should include rigorously planned randomized controlled trials or extensive comparative observational investigation.
- Inclusion a representative sample of cases with comparable age, gender, and illness severity.
- The sample size of future research must be large enough to yield significant findings and to mitigate confounding variables.
- To accurately evaluate long-term results, researches should have a longer monitoring period.
- We recommend that further investigations use multicenter investigations to confirm our results.

CONCLUSION

In conclusion, the main findings provide proof that topical intranasal corticosteroids are possibly to be an effective means of manging kids with bilateral otitis media with effusion at 8 and 12 weeks when compared to watchful waiting. While, at third week, it was nearly the same results in group A and B. However, these findings require confirmation by larger, more-powered study with larger sample size.

ABBREVIATIONS

EAC: external auditory canal, **OME:** Otitis media with effusion, **PTA:** pure tone audiometry, **TM:** tympanic membrane.

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AUTHORS' CONTRIBUTIONS

MB: conception and design of the study. WR: design of the data collection tool, data collection, and revising the manuscript AA: design the data collection tool, data collection, analysis and interpretation, and writing the original draft. MA: design of the study and analysis and interpretation of data. All authors have read and approved the manuscript.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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