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Role of topical intranasal steroids in pediatric hearing loss due to otitis media with effusion: the experiences

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ABSTRACT

Background: Otitis media with effusion (OME) is one of the commonest diseases causing hearing impairment in children. Hearing loss in early childhood may lead to risk of speech and language problems and psychosocial abnormalities. Aim of this study is to evaluate the role of topical intranasal steroids (Mometasone furoate) in pediatric hearing loss due to otitis media with adenoid hypertrophy.

Methods: A prospective study carried out at a tertiary care teaching hospital of eastern India where 104 children participated with diagnosis of otitis media with effusion and hearing loss between 2017 to 2019. These participants were divided into study group and control group. The age group of the children was between 5 to 10 years. Detail otoscopic examination, pure tone audiometry, tympanometry and nasopharyngeal endoscopy were done for assessing the hearing loss, fluid in the middle ear and adenoid hypertrophy.

Results: There is improvement of hearing in the study group as compared to control group. A significant improvement in hearing was seen in the study group (p=0.0001). In the study group, 37 (77.08%) out of the 48 children OME resolved over a period of 12 weeks after treatment in comparison to 18 (37.50%) in the control group (p=0.0004).

Conclusions: Intranasal topical steroids can be a treatment option alternative to surgery in OME. As it is short term follow up in this study, long term follow up is required. Intranasal mometasone furoate treatment can be considered as a good treatment option for OME.

Keywords: Adenoid hypertrophy, Hearing loss, Otitis media with effusion, Pediatric patients

INTRODUCTION

Eustachian block is a common etiology for otitis media with effusion in children. Otitis media with effusion is a condition where collection of fluid behind the ear drum without any inflammatory signs, also called "glue ear". Approximately 80% of the children have an episode of OME by the age of 4 years where most of which resolve and only 10% of the episodes lasts for a year or more. OME affects 50-80% of the children by the age of 5 years. Without treatment of OME, it can cause hearing loss which result in linguistic, developmental, behavioral, motor and social impairment of the child. Although most

of OME cases resolve spontaneously, referral rates from primary care remain high with around 1 to 5 per 1000 children in general population undergoing surgery (myringotomy plus grommet insertion) each year. The adenoid tissue of Waldeyer's ring is an important cause for obstructing nasopharyngeal opening of the eustachian tube. Adenoid hypertrophy is the most frequent cause for upper respiratory airway obstruction among pediatric age group. The most common symptoms of adenoid hypertrophy are mouth breathing, snoring, nasal discharge, sleep apnea, hyponasal speech and hearing loss. Traditionally adenoidectomy and grommet insertion are considered as treatment of choice in case of

OME with adenoid hypertrophy. There are different conservative approaches for these clinical conditions are under research. Presently role of corticosteroids in such context has been explored. Topical intranasal steroids may be useful but are under research and require robust evidence.⁶ Mometasone furoate when used as intranasal spray has extensive first metabolism, lower bioavailability and higher binding affinity towards glucocorticosteroids receptors than other topical nasal steroids.⁷ Mometasone furoate nasal sprays does not hamper the function of the hypothalamic-pituitary adrenal axis when used at the clinically relevant doses of 100-200 mcg/day.⁷ This study was done to assess the role of intranasal steroid (mometasone furoate) in pediatric patients of hearing loss by OME with adenoid hypertrophy.

METHODS

This study was conducted during the period between December 2017 to July 2019 at a tertiary care teaching hospital of eastern India. It was approved by the Institutional Ethics committee. One hundred and four children of the age group 5-10 years enrolled in this study. All these cases were diagnosed of otitis media with effusion with hearing loss after otoscopic examination, doing pure tone audiometry and tympanometry. Other than otoscopic examinations, oral cavity, oropharynx, nasal cavity and nasopharyngeal examinations were done. The exclusion criteria for this study were use of intranasal or systemic steroids in last one year, previous adenoidectomy, associated with tonsillar hypertrophy, nasal polyposis, sinusitis, nasal deformity, inferior turbinate hypertrophy, craniofacial anomalies, genetic disease like Down syndrome, acute upper respiratory tract infections within two weeks for enrolling in this study, sensorineural hearing loss and hypersensitivity to mometasone furoate. Out of these, 8 children lost to follow up and were excluded from this study. The exclusion criteria were children with cleft palate and syndromic children. All these children those participated in this study were divided into two groups by odd and even number in equal proportion by a random number table. The even numbers in random number table were represented as control group whereas odd numbers represented as study group. Parents were given steroid sprays with instructions for the child to take steroid spray into each nostril once a day for three months or 12 weeks. The first dose of intranasal steroid was demonstrated by treating doctor. One spray was given in each nostril with technique of neck flexion and the direction of spray is towards posterior nasal cavity. In 48 children of study group were treated with topical nasal steroids for period of 10 weeks with one puff per day and then gradually tapered by next 2 weeks. Mometasone furoate (40 mcg/ day per nostril) intranasal spray was given to them for 3 months. Pure tone audiometry was done at beginning of treatment and after 8 weeks of treatment and after stopping of the treatment. The symptom questionnaires were filled before treatment and 8weeks after treatment. The symptom questionnaire included were hearing loss of the children, nasal obstruction, nasal discharge, mouth breathing and recurrent upper airway infections. The scoring of the symptoms was 0 to 10 as per severity of each. After adding the scores of the patient, compared at the end. Children with control group underwent pure tone audiometry at the time presentation, after 8 weeks and after 12 weeks. The hearing improvements between two groups were compared.

Statistical analysis

Statistical analysis was done by using SPSS 20.0 (IBM, Chicago, USA). This study was assessed by using descriptive statistical methods (frequency) besides using χ^2 tests to compare qualitative data. Results were assessed at 95% confidence interval with significance level at p<0.05.

RESULTS

There are 104 children diagnosed as OME in this study. The age range of the children was 5 to 10 years with a mean age of 6.43±2.32 years. The clinical examinations of the children were done along with flexible endoscopy for examining the nose, nasopharynx and oropharynx. Adenoid hypertrophy, eustachian opening at the nasopharynx, both sides nasal cavity and palatine tonsils were examined (Table 1).

Pure tone audiometry done in all children those participated in this study average hearing loss of 32.40 decibel in audiogram (500-4000Hz) before treatment. All the children with OME had type B tympanogram. Eight children lost follow up so excluded from the study. Fortyeight children (odd number/Group A) of the study group received topical nasal steroids. Rests of the children (even number/Group B) of the control group were received normal saline nasal spray. Children with topical nasal steroids showed improvement in hearing in pure tone audiogram done after three months of treatment. In group A, 37 (77.08%) out of the 48 children OME resolved over a period of 12 weeks after treatment in comparison to 18 (37.50%) in the control group (p=0.0004) (Table 2).

Table 1: Clinical conditions associated with OME patients.

Patients of OME	Study group (n=48)	Percentage (%)	Control group (n=48)	Percentage (%)
Adenoid hypertrophy	41	85.41	39	81.25
Chronic tonsillitis	32	66.66	31	64.58
Tubal tonsillar hypertrophy	37	77.08	35	72.91
Allergic rhinitis	26	54.16	27	56.25
Hearing loss	48	100	48	100

Table 2: Patient output after 12 weeks of treatment with intranasal steroids.

Parameters	Group-A (Study group)	Group-B (Control group)	P value
Decreased adenoid size	38	7	0.0001
Improved hearing in audiogram	37	5	0.0001
Improved tympanogram	37 (Type-A in 21 cases and Type-C in 16 cases)	8	0.0002
Resolved OME	37	18	0.0004

After 12 weeks of treatment in group A statistically significant reduction in symptom score was seen (p=0.0001). Pure tone audiogram showed improvement in 37 cases whereas only 5 cases hearing improvement in control group (p=0.0001). When the pure tone audiogram of the study group was compared of pre- and posttreatment, a mean improvement of 10.61 decibel in the AB gap was observed (p=0.003). Among 48 children of study group, 21 (43.75%) became type-A and 16 (33.33%) became type-C tympanogram. Tympanic membrane appears normal with presence of cone of light at antero-inferior quadrant of the tympanic membrane in 21 children of the study group whereas 8 children in control group. After treatment of 12 weeks, adenoid size decreased its size to grade-I in 38 cases in study group whereas only 7 cases in control group. As size of the adenoid is decreased with treatment, obstructive symptoms improve in 38 cases of study group whereas size of the adenoid reduced only in few cases (n=7) so no significant the obstructive symptoms improved in the control group (p=0.0001). After 3 months of treatment with intranasal mometasone spray, all the children of the study group were examined to check crusting in the nasal cavity or dryness in the nose and enquired for any nasal bleeding. Three children showed dryness in 5 children, crusting in the nasal cavity in 3 children in the group A (study group). Two children presented minor nasal bleeding during treatment in the study group (Table 3). There were no such findings like nasal crusts and history bleeding during treatment happened in the control group those treated with only normal saline nasal spray. The children of the study group those developed nasal crusting and nasal bleeding were treated with only normal saline nasal drops for three weeks.

Table 3: Complications due to topical intranasal spray of Mometasone furoate and normal saline.

Complications	Group A (Study group)	Group B (Control group)
Dryness	5	0
Nasal crusting	2	0
Epistaxis	2	0

DISCUSSION

Otitis media with effusion is an inflammatory response of the middle ear cleft which is defined by effusion in the middle ear cavity and does not show acute infection symptoms.⁸ This is often due to blockage of eustachian tube at nasopharynx by adenoid. The adenoids are pyramid shaped lymphoid tissue at the nasopharynx present since birth. Adenoids are aggregation of lymphoid tissue when enlarged block the nasopharyngeal airway and cause nasal block, mouth breathing, rhinorrhea, snoring and rhinolalia clausa. OME is the commonest etiology for hearing loss in pediatric age group which can impair cognitive language, speech and psychosocial development in affected children. Adenoid hypertrophy blocks the nasopharyngeal airway in children which leads to several clinical manifestations like hearing loss, enuresis, retardation in cognitive growth and delayed physical development and cardiorespiratory diseases. OME may cause chronic middle ear sequel like retraction of the tympanic membrane, cholesteatoma formation and permanent hearing loss. ¹⁰ In this study, hearing impairment in OME is typically conductive type of hearing loss and often mild to moderate grade. Pure tone audiogram was done in all cases of the study and control group. Intra-nasal mometasone spray brought statistically improvement in hearing on study group in comparison to control group. When the pure tone audiogram of the study group was compared of pre- and post-treatment by intranasal steroids, a mean improvement of 10.61 decibel in the AB gap was observed (p=0.003). In case of adenoid hypertrophy with OME, the non-surgical treatment options are limited to the treatment of upper respiratory infections. The mechanism of actions in adenoid hypertrophy with OME is still unclear. Mometasone furoate has been shown to help improve the transport function of ciliary epithelium which enhances the clinical effects.¹¹ There is high level of expression of human glucocorticoids receptor alpha at the adenoids and tonsils of the children who have obstructive sleep apnea versus chronic throat infections suggested a possible chance to respond to intra-nasal steroid therapy. 12 Statistically significant reduction of adenoid size in nasopharynx was found with use of intra-nasal mometasone nasal spray. In this study, adenoid size was decreased to grade-I in 38 patients out of 48 cases whereas it was decreased in 7cases out of 48 cases of control group. Similar findings of objective reduction of size of adenoid hypertrophy with pre- and post-treatment was documented. Mometasone furoate nasal spray was selected because of its favorable benefit-risk ratio. Adenoid hypertrophy and OME with hearing loss is a common indication for surgery in a pediatric patient. The present treatment for OME includes eradication of the risk factors, use of antibiotics, decongestant and maneuvers for opening of

the eustachian tube like nasal balloons. If medical treatment fails to resolve, placement of grommet with or without adenoidectomy is done.¹⁶ Recently in few centers, use of nasal endoscopy along with eustachian tube dilation become a new treatment option in OME. A balloon/catheter is inserted into cartilaginous part of the esustachian tube through nasopharyngeal opening and made dilated the tube. It may be safe, easy and effective method for OME but in some cases, it cause injury the eustachian tube lumen. It is often not considered as physiological for eustachian tube dilation.¹⁷ It is thought that intranasal steroids spray may clear the effusion from the middle ear by stabilizing membrane phospholipids breakdown so that preventing formation of arachidonic acid and related inflammatory mediators. 18 It also shrinks peritubal lymphoid tissue, increase secretion of eustachian tube surfactant and decrease middle ear fluid viscosity.¹⁸ As OME fluctuates, initial management is audiometric confirmation and quantification of the hearing loss, counseling to the parents or care givers and watchful waiting with audiometric monitoring. There is statistically significant improvement of the relieve of OME with intra-nasal mometasone spray in comparison to control group. In study group, 37 (77.08%) out of the 48 children OME resolved over a period of 12 weeks of treatment in comparison to 18 (37.50%) in the control group. Similar outcomes have been documented by other studies. 19,20 The non-responsive children were treated with myringotomy and grommet insertion. One of the important problems of nasal steroid therapy is duration and doses as there are no consensus in the medical literature. The dose used in study for OME and adenoid hypertrophy is equal to that used in allergic rhinitis. The safety of the intranasal steroid is at least one year long use for children with allergic rhinitis described in literature. Topical nasal steroids have less side effects in comparison to systemic steroids.²¹ Similarly there are minor complications in this study such as 3 children showed dryness in 5 children, crusting in the nasal cavity in 3 children. Two children presented minor nasal bleeding during treatment in the study group so we can adopt long term nasal steroids in routine dose for adenoid hypertrophy and OME. Medical use of intranasal steroids such as mometasone furoate in adenoid hypertrophy is successful for controlling nasal obstructive symptoms.² The mechanism for reduction of adenoid size by mometasone furoate is not yet clear but may occur due to lympholytic cause; anti-inflammatory properties of corticosteroids. 24,25 Adenoid tissues have many receptors for glucocorticosteroids and messenger RNA which strengthens the mechanism for reduction of adenoid size. 26 There is significant reduction of the size of adenoid hypertrophy after intranasal mometasone furoate in study group in comparison to control group.

CONCLUSION

Intranasal steroid sprays are likely to be effective treatment for otitis media with effusion and prevent hearing loss in pediatric age group. The efficacy of mometasone furoate nasal spray for resolution of the middle ear fluid in OME in children is observed to be significant. There is good improvement of hearing in children after use of topical intranasal steroids. So, topical nasal steroid can be considered as a viable option other than surgery controlling OME. A long term follows up is required to evaluate the whether the effects are temporary or permanent. Intranasal mometasone furoate treatment can be considered as good treatment option in OME. Administration of this topical steroid in children is safe, reproduced easily and well tolerated among pediatric patients with OME.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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