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Original Article

Effect of the Combination of Tympanic Paracentesis and Intratympanic Hadocort-D Application on Otitis Media with Effusion in Adults

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ABSTRACT

Background and Aim: The prevalence of otitis media with effusion in adults (OME) is very low, however, if it became chronic otitis media with effusion, it may affect the quality of life due to hearing loss and aural fullness. Therefore, early and proper management is essential. The aim of this study was to evaluate the effect of the combination of tympanic paracentesis and intratympanic Hadocort-D application for otitis media with effusion in adult. **Materials and Methods:** In total, 40 patients with otitis media with effusion that last for less than 2 months and had more than 4 times of tympanic paracentesis were included. They were randomly divided into two groups; the study group and control group. In study group, 20 patients (25 ears) had intratympanic Hadocort-D (Neomycin 75 000IU, Dexamethason mg, Xylometazolin hydroclorid 7.5 mg, Vietnam) application after tympanic paracentesis, and in control group, 20 patients (23 ears) had only tympanic paracentesis. We used tympanometry to confirm the middle ear effusion and pure tone audiometry to determine hearing threshold. **Results:** The intratympanic Hadocort-D application after tympanic paracentesis group produced better outcomes (22 ears, 88.0%) than the simple paracentesis group (11 ears, 47.8%). The recurrent rate was 12% (3 ears) in the study group, which was significantly lower than 39.1% (9 ears) of control group. **Conclusion:** The intratympanic Hadocort-D application after tympanic paracentesis on otitis media with effusion can reduce the number of repetitive procedures of tympanic paracentesis and prevent insertion of the ventilation tube and its short-term and long-term complications. Thus, its use in management of OME is recommended.

Keywords: Otitis Media with Effusion, Tympanic Paracentesis, Hadocort-D.

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INTRODUCTION

Otitis Media with Effusion (OME) is a common disorder in ENT clinics and is found mostly in children.[1] OME refers to an inflammatory effusion behind an intact tympanic membrane and the symptoms are hearing loss, autophonia, aural fullness and so on.[2] In other words, it is the disease that leads to negative pressure in the middle ear resulting in passive transduction of fluid by the Eustachian Tube Dysfunction (ETD). In adults, OME has a low prevalence (approximately 0.55% to 1%), while the symptoms of aural fullness and hearing loss can significantly affect patient quality of life.[1] For patients with Acute OME (AOME) caused by ETD, traditional treatment includes medication such as antibiotics, nasal steroids, and decongestants, physical training such as a Valsalva maneuver, Toynbee maneuver and eustachian tube catheterization.[1-4,5-7] However, if the treatment of AOME is prolonged to the stage of Chronic OME (COME), surgical processes such as myringotomy, Tympanic Paracentesis (TP) and placement of a ventilation tube are recommended.[2,3,5,8-13] The placement of ventilation tube, while, has disadvantages such as otorrhea, persistent perforation of tympanic membrane, occlusion of tube, premature extrusion, granulation tissue and intrusion in the middle ear etc.[3] Thus the traditional treatment has limited success in a portion of patients with intractable otitis media with effusion likely due to ETD.[1]

The aim of this study was to assess the efficacy of the combination of tympanic paracentesis and intratympanic Hadocort-D application on otitis media with effusion in adults in order to prevent the placement of ventilation tube and becoming a chronic disease and lower the recurrent rate.

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MATERIALS AND METHODS

Participants

Forty adult patients (19 males, 47.5% and 21 females, 52.5%) with OME that lasted for less than 2 months and had more than 4 times of tympanic paracentesis were included. They were randomly divided into two groups; the study group and control group.

Diagnostic Assessment

Middle ear effusion was confirmed using tympanometry, and hearing thresholds were evaluated using pure tone audiometry. Patients with type A tympanograms, sensorineural hearing loss, nasopharyngeal tumors, adenoids, purulent tympanic membrane infections, hypertension, or diabetes mellitus were excluded from the study.

Intervention

Study group

Twenty patients (25 ears) received intratympanic Hadocort-D (containing Neomycin 75,000 IU, Dexamethasone 15 mg, and Xylometazoline hydrochloride 7.5 mg; manufactured in Vietnam) following tympanic paracentesis.

The middle ear fluid was aspirated, and Hadocort-D was sprayed into the external auditory canal. The tragus was pressed several times to facilitate drug entry into the middle ear, Eustachian tube ventilation was verified, and the ear canal was then sealed with dry cotton.

This procedure was performed once daily. Intratympanic application of Hadocort-D was done once or twice weekly starting from the day of paracentesis. If the tympanic membrane healed, the procedure was repeated following another paracentesis.

Control group

20 patients (23 ears) underwent only tympanic paracentesis. Middle ear fluid was aspirated, and the external auditory canal was closed with dry cotton, with no Hadocort-D application.

Outcome Assessment

Therapeutic outcomes were evaluated on the 7th day after treatment initiation and categorized as follows:

Complete recovery: Absence of symptoms, absence of hypomotility of tympanic membrane, complete resolution of air conduction of less than 20 dB on audiometry, type A on tympanic manometry.

Improved: Partial symptom relief, residual tympanic membrane motility, limited tympanic motility, but limited air conduction in audiometry, ranging from 20 to 30 dB, type C on tympanic manometry were considered improved.

Unchanged: No change in subjective or local finding and audiometry was considered unchanged.

Statistical Analysis of Data

The results were analyzed using SPSS 23.0. (Chicago, IL, USA). Comparisons between the groups were assessed by a one-way ANOVA for normally distributed data. An LSD test was used for multiple comparisons. A p value less than 0.05 was considered statistically significant.

RESULTS

Of the 40 patients (48 ears) included, there were 19 (47.5%) males and 21 (52.5%) females (Table 1). Their age ranged from 17 to 65 years. Hearing loss was the main complaint from all patients (100%).

There was no significant difference in age and gender composition between the study group and control group. Pre-treatment tympanogram type B were 14 ears (56.0%) in study group and 11 ears (47.8%) in control group. Type C were 11 ears (44.0%) in study group and 12 ears (52.2%) in control group. There was no tympanogram type A in control group and study group. There were no significant differences in tympanic membrane mobility between groups. The ears with 10~20 dB hearing threshold on pre-treatment Pure Tone Audiometry (PTA) were absent. The threshold of 21~30 dB were 2 ears (8.0%) in study group and 3 ears (13.1%) in control group. The 31~40 dB threshold were 11 (44.0%) in study group and 9 (39.1%) in control group. The 41~50 dB were 12 (48.0%) and 11 (47.8%) respectively. There were no significant differences in PTA between the study and control groups (Table 1).

The ears of type A on post-treatment tympanometry were 17 (68.0%) in study group and 9 (39.1%) in control group, which was significant improvement. The ears of type B were 6 (24.0%) and 9 (39.1%) respectively after treatment. The ears of type C after treatment were 2 (8.0%) and 5 (21.8%) respectively.

The number of ears with hearing threshold of 10~20 dB were 16 (64.0%) in study group and 4 (17.4%) in control group, which was significantly higher in study group compared with control group. The number of ears with 21~30 dB were 4 (16.0%) in study group and 6 (26.1%) in control group. The ears with 31~40 dB were 3 (12.0%) in study group and 8 (34.8%) in control group. The 41~50 dB were 2 (8.0%) and 5 (21.7%) respectively.

The efficacy rate was calculated as sum of recovery rate and improve rate. The efficacy rate after treatment was 88.0% (22 ears) in study group and significantly higher than that of the control group. Thus, hearing improved significantly post-treatment in study group. The recurrence rate was 12% (3 ears) within 3 months after treatment, which was significantly lower than that of the control group (Table 2).

Table 1: **Pre-treatment subjective and objective symptoms**

	Study group (*n*=25)	Control group (*n*=23)	P value
Age			
Max	64y	65y	P=0.299
Min	17y	17y	
Average	37.1±13.4y	35.9±14.3y	
Gender			
Male(n=19)	9	10	P=0.751
Female(n=21)	11	10	
Pre-treatment tympanometry			
Type A(n=0)	-	-	P=0.571
Type B(n=25)	14(56.0)	11(47.8)	P=0.571
Type C(n=23)	11(44.0)	12(52.2)	
Pre-treatment PTA			
10~20dB(n=0)	-	-	
21~30dB(n=5)	2(8.0)	3(13.1)	P=0.567
31~40dB(n=20)	11(44.0)	9(39.1)	P=0.732
41~50dB(n=23)	12(48.0)	11(47.8)	P=0.990

PTA: pure tone audiometry, ():%.

Table 2: **Pos-treatment results.**

	Study group (n=25)	Control group (n=23)	P value
Post-treatment tympanometry			
Type A(n=26)	17(68.0)	9(39.1)	0.045
Type B(n=15)	6(24.0)	9(39.1)	0.259
Type C(n=6)	2(8.0)	5(21.8)	0.178
Post-treatment PTA			
10~20 dB(n=20)	16(64.0)	4(17.4)	0.001
21~30 dB(n=11)	4(16.0)	6(26.1)	0.390
31~40 dB(n=11)	3(12.0)	8(34.8)	0.060
41~50 dB(n=23)	2(8.0)	5(21.7)	0.178
Efficacy rate			
Recovery(n=27)	19(76.0)	8(34.8)	0.004
Improved(n=6)	3(12.0)	3(13.0)	0.913
Unchanged(n=15)	3(12.0)	12(52.2)	0.003
Recurrence rate			
Month 1	-	2(8.7)	0.129
Month 2	1(4.0)	4(17.4)	0.568
Month 3	2(8.0)	3(13.0)	0.030
Total	3(12.0)	9(39.1)	

PTA: pure tone audiometry, ():%.

DISCUSSION

OME is defined as middle ear effusion without signs and symptoms of an acute infection, and it can occur as a primary disorder or as a sequel of acute otitis media.[6] There have been reports of treating otitis media with effusion in children with the adjuvant intratympanic steroid treatment, but there was whereas no data have been reported on treating on intratympanic drug application after tympanic paracentesis on otitis media with effusion in adults.[5] OME has long been recognized that Eustachian Tube (ET) dysfunction or obstruction predisposes to OME. Myringotomy and fluid aspiration alone are ineffective due to the short duration of the perforation healing time (usually only 1 to 2 days).[6,8] On the other hand, the ventilation tube has several short-term and long-term complications such as middle ear infection and otorrhea, persistent perforation of tympanic membrane, occlusion of tube, premature extrusion, granulation tissue and intrusion in the middle ear etc.[3,4]

According to our results, tympanometry of post-treatment was significantly higher in the study group (17 ears, 68.0%) than in the control group (9 ears, 39.1%), and post-treatment pure tone audiometry showed that the 10-20 dB ear group had 16 ears (64.0%), significantly more than the control group (4 ears, 17.4%). The efficacy rate after treatment was also 88% (22 ears) and significantly higher than that of the control group. The recurrence rate was 12% (3 ears) within 3 months of treatment, which was significantly higher than that of the control group.

We believe that the intratympanic Hadocort application after tympanic paracentesis in OME may reduce inflammatory changes including swelling of the tympanic mucosa and the ET, preventing continued filling of the exudates. Thus, the intratympanic Hadocort-D application (once or twice) after tympanic paracentesis for otitis media with effusion in adults prevents chronicity, reduces the number of repetitive tympanic paracentesis, effecting recovery without grommet insert. The recurrence rate is lowered, the cost of treatment is reduced and the side effects of medications are decreased compared to previous treatments.

CONCLUSION

We believe that intratympanic Hadocort application after tympanic paracentesis for otitis media with effusion is effective treatment to reduce the number of repetitive tympanic paracentesis, prevent the placement of the ventilation tube, and prevent short and long-term complications that result from the tympanic paracentesis. Thus, its use in management of OME is recommended.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

ABBREVIATIONS

OME: Otitis Media with Effusion; **AOME:** Acute Otitis Media with Effusion; **COME:** Chronic Otitis Media with Effusion; **TP:** Tympanic Paracentesis; **ETD:** Eustachian Tube Dysfunction; **PTA:** Pure Tone Audiometry; **IU:** International Units; **mg:** Milligrams; **SPSS:** Statistical Package for the Social Sciences; **dB:** Decibel.

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