Original Article Clinical effect of endoscopic tympanic membrane catheterization in the treatment of otitis media with effusion

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Abstract: Objective: To analyze the therapeutic effect of endoscopic tympanic membrane catheterization in the treatment of otitis media with effusion (OME). Methods: According to random number table method, 120 patients with subacute OME were divided into a control group (60 cases treated with traditional medicine) and a study group (60 cases treated with endoscopic tympanic membrane catheterization). The clinical therapeutic effect, duration of middle ear effusion resolution, the satisfaction and recurrence rate after treatment, as well as the 36-Item short-form health survey (SF-36) score between the two groups were compared. Results: Compared with the control group, the study group presented a higher total effective rate, a shorter duration of middle ear effusion resolution, a higher satisfaction degree, a lower recurrence rate and a higher SF-36 score. Conclusion: Endoscopic tympanic membrane catheterization can effectively shorten the time required for middle ear effusion resolution in patients with OME, relieve or even cure patients' clinical symptoms, relieve their suffering pains in daily life, and provide a good prognosis for them in the later stage. The therapeutic effect of this technique is significant in the short and long terms application, which can be used as a reference for relevant personnel.

Keywords: Subacute otitis media with effusion, endoscopic tympanic membrane catheterization, duration of middle ear effusion resolution, cure rate

Introduction

Otitis media with effusion (OME) is a clinically common non-suppurative inflammatory disease characterized by progressive hearing loss and fluid accumulation in the middle ear. The symptoms of OME patients often manifested in abnormal tinnitus, aural occlusion and fullness, unbearable otalgia, and gradual hearing loss. In more severe condition, deafness and loss of balance will bring great inconvenience to patients' life [1, 2]. According to the length of onset, OME can be divided into three categories, among which, acute OME refers to symptoms occur within three weeks, subacute OME refers to symptoms occur in more than three weeks but less than three months, while if OME persists for 3 months or more, it is classified as chronic OME [3]. Nowadays, among the recommended treatment for subacute OME, there is still no oriented strategy [4].

Currently, there are two main strategies for treating subacute OME: drug therapy and surgical treatment [5, 6]. On one hand, drug therapy takes advantage of weaker stimulation and small trauma, but the cure rate is not high [7]. On the other hand, although surgical treatment has greater trauma and relatively stronger stimulation, the cure rate after surgical treatment is higher than that of drug therapy [8]. The development of science and technology has driven the wide application of minimally invasive endoscopic technology in clinical diagnosis and treatment, further improving patients' sense of experience and cure rate of the disease [9]. Endoscopic tympanic membrane catheterization is minimally invasive incision performed under the endoscopy to remove the effusion and place the tympanic membrane ventilation tube for drainage, so as to achieve the purpose of minimally invasive lower drainage and prevent the recurrence of effusion [10]. It plays an important part in clinical OME treatment. However, little research has been conducted on comparing the effect of endoscopic tympanic membrane catheterization and drug therapy for subacute OME. Hence, relevant studies need to be carried out urgently.

This study sets out to observe and analyze the effects of the two treatment methods mentioned above on patients' efficacy, duration of middle ear effusion resolution, treatment satisfaction rate and recurrence rate, so as to evaluate the treatment efficacy of endoscopic tympanic membrane catheterization on subacute OME patients.

Materials and methods

General information

Subacute OME patients admitted to Zaozhuang Municipal Hospital from January 2017 to January 2019 were collected and divided into the control group and the study group by random number table method. Patients in the control group received clinical treatment of traditional drugs, while those in the study group were treated with surgical treatment of endoscopic tympanic membrane catheterization. Inclusion criteria: (1) patients diagnosed with subacute OME (those with OME related symptoms for more than three weeks and less than three months); (2) patients with no prior medication or surgical treatment; (3) patients aged 18-80 (included) years old. Exclusion criteria: (1) patients with major organ dysfunction; (2) patients with serious mental illness; (3) patients without compliance to reasonable instructions: (4) patients allergic to the drugs used in this experiment. The experimental plan was successfully approved by the Medical Ethics Committee of Zaozhuang Municipal Hospital.

Test methods

Routine drug therapy: patients in the control group were given 3-day intravenous injection of cefuroxime sodium (GlaxoSmithKline Manufacturing S.P.A., Italy) at 60 mg/kg, and oral administration of dexamethasone at 0.2 mg/kg as an adjuvant. After that, the adjuvant dexamethasone was changed to 0.1 mg/kg for another 3 days. While in the study group, patients undergoing surgical treatment were anesthetized. And an incision of approximately 1 mm to 3 mm was made into the anterior and lower quadrant of the eardrum. With dexamethasone as an anti-inflammatory agent, a microaspirator was used to remove the accumulated fluid until it was rinsed. The silicone tube (Ruixiang Precision Silica Gel Products Co., Ltd., China) was then placed and stuck at the outer edge of the incision. Attention was paid to postoperative anti-infection treatment, and followup was conducted every 3 months for 1 year after surgery.

Observation indicators

The clinical treatment effect was compared between the study group and the control group. The duration of middle ear effusion resolution was recorded from the time of hospitalization to effusion resolution. Recurrence within 3 months after effusion resolution was included in the recurrence rate. SF-36 scoring was measured 4 weeks after discharge and patients' satisfaction rate was collected 1 week after surgery or medication by a self-made satisfaction guestionnaire. The clinical treatment effect was evaluated as: cured: the disappearance of clinical symptoms such as tinnitus and aural occlusion, and the hearing recovery in the 0.5 kHz, 1 kHz and 2 kHz frequency segments; effective: the obvious improvement of tinnitus, aural occlusion and other clinical symptoms, and the hearing improvement in the 0.5 kHz, 1 kHz and 2 kHz frequency bands by 15-20 dB; Ineffective: no obvious improvements in the clinical symptoms, and the hearing improvement in the 0.5 kHz, 1 kHz and 2 kHz frequency bands less than 15 dB [12]. The total effective rate = (cured cases + effective cases)/total cases. As for SF-36 score, it was divided into the following 8 aspects: physical functioning, role-physical, bodily pain, vitality, general health, social functioning, mental health and

Table 1. Comparison of general	information	$(\overline{x} \pm sd,$	n (%)
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	Control group (n=60)	Study group (n=60)	t/χ²	Ρ
Age (year)	44.2±12.7	42.8±11.9	0.623	0.534
Gender (n)			0.304	0.581
Male	32	35		
Female	28	25		
Duration of disease (d)	32.2±7.8	34.6±6.1	-1.877	0.063

 Table 2. Comparison of clinical treatment effect (n, %)

	Control group (n=60)	Study group (n=60)	X ²	Ρ
Cured (n)	29	37		
Effective (n)	13	18		
Ineffective (n)	18	5		
Total effective rate (%)	70.0	91.7	9.090	0.003



Figure 1. Comparison of duration of middle ear effusion resolution. Compared with control group, ***P<0.001.

role-emotional, each scaled 100 points [13]. And the results of patients' satisfaction could be concluded as very satisfied, generally satisfied and dissatisfied. Satisfaction rate = (cases of very satisfied + cases of general satisfied/ total cases.

Statistical analysis

The data were analyzed using SPSS 22.0 statistical software. The measurement data were expressed as mean and standard deviation $(\bar{x} \pm sd)$ and analyzed by independent sample t test. The counting data were expressed as number of cases/percentage (n/%) and tested by Fisher's exact probability or chi-square test. P<0.05 indicated that the difference was statistically significant.

Results

General information

According to relevant requirements, 120 out of 146 patients with subacute OME admitted from January 2017 to January 2019 were selected through layers of screening, and the enrolled 120 patients were randomly divided into the study group (60 cases) and the control group (60 cases) through the random number table method. In this study, no patients suffered from irreversible serious injury, nor were there any halfway

voluntary withdrawals, and all patients with subacute OME successfully passed the test. In addition, there was no significant difference in all general information between the two groups (P>0.05). See **Table 1**.

Total effective rate

The total effective rate of the study group (91.7%) was markedly higher than that of the control group (70.0%), with statistically significant difference (P<0.05). See **Table 2**.

Duration of middle ear effusion resolution

The duration of middle ear effusion resolution in the study group was 7.98 ± 1.12 d after treatment, which was significantly shorter than that in the control group (12.31±2.01 d) (P<0.001). See **Figure 1**.

Satisfaction rate

The satisfaction rate of the study group after treatment was 90.0%, while that of the control group after treatment was 68.3%. It was obvious that the satisfaction rate of the study group was significantly higher (P<0.05). See **Table 3**.

Recurrence rate

After 12 months follow-up after treatment, there were 3 cases of recurrence and 57 cases of non-recurrence in the study group, with the recurrence rate of 5.0%. While in the control

Table 5. Companson of Satisfaction rate (II, %	Table 3.	Comparison	of satisfaction	rate (n,	%)
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	Control group (n=60)	Study group (n=60)	X ²	Р
Very satisfied (n)	30	38		
General satisfied (n)	11	16		
Dissatisfied (n)	19	6		
Total satisfaction rate (%)	68.3	90.0	8.539	0.004

Table 4. Comparison of recurrence rate (n, %)

	Control group (n=60)	Study group (n=60)	X ²	Р
Recurrence (n)	18	3		
No recurrence (n)	42	57		
Recurrence rate (%)	30.0	5.0	12.987	0.000

Table 5. Comparison of SF-36 scores ($\overline{x} \pm sd$)

	Control group (n=60)	Study group (n=60)	t	Ρ
Physical functioning	66.45±12.34	85.65±14.71	-7.746	0.000
Role physical	68.93±13.21	84.23±16.47	-5.613	0.000
Bodily pain	77.98±13.99	85.78±16.14	-2.829	0.005
Vitality	68.54±14.11	83.77±15.01	-5.727	0.000
General health	66.23±14.32	84.43±16.73	-6.402	0.000
Social functioning	80.87±15.43	89.34±17.32	-2.828	0.005
Mental health	79.39±13.49	88.73±16.91	-3.345	0.001
Role-emotional	78.45±16.44	85.21±17.25	-2.197	0.030

group, there were 18 cases of recurrence, 42 cases of non-recurrence, and the recurrence rate was 30.0%. The recurrence rate in the study group was significantly lower than that in the control group (P<0.001). See **Table 4**.

SF-36 score after treatment

The SF-36 score was followed up one month after discharge. The scores of physical functioning, role-physical, bodily pain, vitality, general health, social functioning, mental health, and role-emotional were significantly higher in the research group than those in the control group (all P<0.05). See **Table 5**.

Discussion

There are many factors to be blamed for developing subacute OME, a common clinical disease. (1) Eustachian tube dysfunction: eustachian tube obstruction can be caused by pharyngeal tonsillitis enlargement, chronic sinusitis, benign and malignant occupying of nasopharynx, giant nasal polyp, nasal septum distortion, etc. [14, 15]; (2) Infection: remaining bacteria in the body are to cause infection: (3) Immune response: immune responses are associated with type I and type III allergies [16]. (4) Long-term adhesion of eustachian tube and oropharynx as well as nasal obstruction will bring bad effect [17]; (5) Damage caused by changes in air pressure: air pressure difference inside and outside the ear can be caused by various reasons [18]: (6) Special infections: special infections like DTT, TP, TB, AIDS also contribute to the disease [19]. With various causes mentioned above and the unclear underlying mechanism of subacute OME, there are still some difficulties in clinical treatment.

Glucocorticoid therapy is a conventional medical treatment of subacute OME, whose effect is often limited as subacute OME is mainly manifested in surgery

[20]. This study found that endoscopic tympanic membrane catheterization, taking the advantages of technique itself, can significantly increase the treatment efficiency and reduce the recurrence rate of patients [10, 21]. During the process, drainage of effusion should be maximized; meanwhile, strategies such as antiinfection and local hormone use were applied to minimize the adverse reactions caused by the operation to ensure the safety and effectiveness of subacute OME treatment [22-24]. These remarks provide strong evidence for the significant shortening duration of middle ear effusion resolution under endoscopic tympanic membrane catheterization.

At the same time, the current study confirmed that the satisfaction of patients with endoscopic surgery increased significantly after treatment. The possible reason can be that the symptoms caused by subacute OME were better improved after surgical treatment when compared with conventional drug treatment. In this way, patients' daily life was greatly influenced, making their quality of life improved and further welfare achieved. However, the total sample size of this study was relatively small and the follow-up time was short, which may result in relatively large errors of the results, so it is necessary to carry out related randomized controlled trials more precisely.

In conclusion, endoscopic tympanic membrane catheterization can not only effectively shorten the time to resolve middle ear effusion for subacute OME patients, but also significantly reduce the clinical symptoms of patients and further improve their satisfaction with treatment. In addition, compared with traditional drugs, patients underwent surgical treatment showed a lower recurrence rate, and less influenced on life and learning. In a word, endoscopic tympanic membrane catheterization has a significant effect and is worthy of reference.

Disclosure of conflict of interest

None.

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References

- [1] Li ZH, Fu QY, Li ZY, Wang KX, Xu YC and Xue JP. The role of Th1/Th2 cells imbalance in the pathogenesis of secretory otitis media. Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi 2018; 32: 206-208.
- [2] Zhu Z, Zheng GX, Li Q, Shi QL, Zhou HG and Fang RP. Analysis of related factors of recurrent otitis media with effusion in children. Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi 2017; 31: 1168-1173.
- [3] Emami A, Pirbonyeh N, Moattari A, Bazargani A and Motamedifar M. Risk of otitis media with effusion (OME) in children by Pseudomonas aeruginosa. Int J Pediatr Otorhinolaryngol 2019; 125: 6-10.
- [4] Vanneste P and Page C. Otitis media with effusion in children: pathophysiology, diagnosis, and treatment. A review. J Otol 2019; 14: 33-39.
- [5] Hao J, Chen M, Liu B, Yang Y, Liu W, Ma N, Han Y, Liu Q, Ni X and Zhang J. Correction to: com-

pare two surgical interventions for otitis media with effusion in young children. Eur Arch Otorhinolaryngol 2019; 276: 2133-2134.

- [6] Fortanier AC, Venekamp RP, Boonacker CW, Hak E, Schilder AG, Sanders EA and Damoiseaux RA. Pneumococcal conjugate vaccines for preventing acute otitis media in children. Cochrane Database Syst Rev 2019; 5: CD001480.
- [7] Venekamp RP, Damoiseaux RA and Schilder AG. Acute otitis media in children. Am Fam Physician 2017; 95: 109-110.
- [8] Li ZF, Yi SJ, Wang WH, He XS and Liu QH. The efficacy comparation of adenoidectomy with acupuncture and tympanonstomy in children secretory otitis media. Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi 2018; 32: 383-385.
- [9] Li H, Xu W, Xing G and Bu X. Effect of nasal endoscopy-assisted adenoidectomy on the development of pediatric chronic sinusitis and otitis media with effusion. Lin Chuang Er Bi Yan Hou Ke Za Zhi 2005; 19: 596-597.
- [10] Capaccio P, Torretta S, Marciante GA, Marchisio P, Forti S and Pignataro L. Endoscopic adenoidectomy in children with otitis media with effusion and mild hearing loss. Clin Exp Otorhinolaryngol 2016; 9: 33-38.
- [11] Cioffi L, Gallo P, D'Avino A, Carlomagno F, Aloi G, D'Onofrio A, Del Gaizo D, Giuliano M, De Franchis R, Sandomenico ML and Pecoraro A. Clinical improvement of subacute and chronic otitis media with effusion treated with hyaluronic acid plus hypertonic solution via nasal lavage: a randomized controlled trial. Glob Pediatr Health 2017; 4: 2333794X17725983.
- [12] Swedish Council on Health Technology Assessment. Tympanostomy tube insertion for otitis media in children: a systematic review. Stockholm: Swedish Council on Health Technology Assessment (SBU) 2008.
- [13] Ware JE Jr. SF-36 health survey update. Spine (Phila Pa 1976) 2000; 25: 3130-3139.
- [14] Christov F and Gluth MB. Histopathology of the mucosa of eustachian tube orifice at the middle ear in chronic otitis media with effusion: possible insight into tuboplasty failure. Ann Otol Rhinol Laryngol 2018; 127: 817-822.
- [15] Yildirim N, Sahan M and Karslioglu Y. Adenoid hypertrophy in adults: clinical and morphological characteristics. J Int Med Res 2008; 36: 157-162.
- [16] Daval M, Picard H, Bequignon E, Bedbeder P, Coste A, Ayache D and Escabasse V. Chronic otitis media with effusion in chronic sinusitis with polyps. Ear Nose Throat J 2018; 97: E13-E18.
- [17] American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery and American Academy of

Pediatrics Subcommittee on Otitis Media With Effusion. Otitis media with effusion. Pediatrics 2004; 113: 1412-1429.

- [18] Mills R and Hathorn I. Aetiology and pathology of otitis media with effusion in adult life. J Laryngol Otol 2016; 130: 418-424.
- [19] Hurst DS. The role of allergy in otitis media with effusion. Otolaryngol Clin North Am 2011; 44: 637-654.
- [20] Dunne AA and Werner JA. Status of the controversial discussion of the pathogenesis and treatment of chronic otitis media with effusion in childhood. Laryngorhinootologie 2001; 80: 1-10.
- [21] Torretta S, Marchisio P, Rinaldi V, Carioli D, Nazzari E and Pignataro L. Endoscopic and clinical benefits of hyaluronic acid in children with chronic adenoiditis and middle ear disease. Eur Arch Otorhinolaryngol 2017; 274: 1423-1429.

- [22] Martellucci S, Pagliuca G, de Vincentiis M, De Virgilio A, Fusconi M, Gallipoli C, Rosato C and Gallo A. Myringotomy and ventilation tube insertion with endoscopic or microscopic technique in adults: a pilot study. Otolaryngol Head Neck Surg 2015; 152: 927-930.
- [23] Han JJ, Park JM, Kim DK, Park SY and Park SN. A pilot study to investigate the therapeutic effect of Valsalva maneuver on otitis media with effusion in adults. Auris Nasus Larynx 2019; 46: 34-37.
- [24] Dang PT and Gubbels SP. Is nasopharyngoscopy necessary in adult-onset otitis media with effusion? Laryngoscope 2013; 123: 2081-2082.