Proceedings of Anticancer Research, 2026, Volume 10, Issue 1
http://ojs.bbwpublisher.com/index.php/PAR
ISSN Online: 2208-3553
ISSN Print: 2208-3545

The Impact of Double-puncture Tympanic Membrane Puncture and Tympanic Cavity Drug Injection on the Complication Rate of Acute Secretory Otitis Media

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Abstract: *Objective*: To explore the therapeutic effect of double-puncture tympanic membrane puncture and tympanic cavity drug injection in patients with acute secretory otitis media. *Methods*: A total of 84 patients with acute secretory otitis media admitted to our hospital from June 2024 to June 2025 were selected and randomly divided into two groups by drawing lots. The control group (42 cases) was treated with the traditional single-puncture tympanic membrane puncture and tympanic cavity drug injection method, while the observation group (42 cases) was treated with the double-puncture tympanic membrane puncture and tympanic cavity drug injection method. The therapeutic effects of the two groups were compared. *Results:* The overall treatment response rate, overall complication rate, time to symptom relief, and improvement in hearing threshold in the observation group were all superior to those in the control group, with statistically significant differences ($P < 0.05$). *Conclusion:* For acute secretory otitis media, the treatment method of double-puncture tympanic membrane puncture and tympanic cavity drug injection demonstrates definite efficacy, significantly reducing the incidence of complications, accelerating symptom relief, and improving hearing function, making it worthy of promotion.

Keywords: Acute secretory otitis media; Double puncture; Tympanic membrane puncture and tympanic cavity drug injection; Complications

Online publication: February 6, 2026

1. Introduction

Acute secretory otitis media is a common acute inflammatory disease in otolaryngology, primarily caused by viral or bacterial infections, eustachian tube dysfunction, and other factors. Symptoms include fluid accumulation in the middle ear cavity, hearing loss, ear fullness, tinnitus, etc. If not effectively treated, it can lead to various

complications such as non-healing tympanic membrane perforation, cholesteatoma, chronic otitis media, and permanent hearing damage, seriously affecting the patient's quality of life. Currently, the focus of clinical treatment for acute secretory otitis media is to remove middle ear fluid, control inflammatory responses, and restore eustachian tube function [1]. Tympanic membrane puncture and injection are widely used due to their simple operation, minimal trauma, and direct drug delivery to the affected area. However, the single-puncture tympanic membrane injection method currently employed in clinical practice has issues such as easy blockage of the puncture, uneven drug distribution, and incomplete removal of fluid, which not only affect efficacy but also increase the incidence of complications. In recent years, the binaural myringotomy with tympanic injection method has begun to garner attention. By creating two perforations in the tympanic cavity, it establishes a flowing pathway within the cavity, effectively clearing inner ear fluid while enabling higher drug concentrations in the body, thereby achieving better therapeutic outcomes and reducing the incidence of complications. This approach can effectively enhance treatment efficacy. Therefore, this study will focus on analyzing the therapeutic effects of the binaural myringotomy with tympanic injection method for acute secretory otitis media, as detailed below.

2. General information and methods

2.1. General information

Eighty-four patients with acute secretory otitis media were selected from our hospital between June 2024 and June 2025. They were randomly assigned to two groups via drawing lots: a control group and an observation group, each consisting of 42 patients. In the control group, the maximum age was 70 years and the minimum was 22 years, with an average age of (45.11 ± 6.02) years and a male-to-female ratio of 22:20. In the observation group, the maximum age was 71 years and the minimum was 23 years, with an average age of (45.19 ± 6.11) years and a male-to-female ratio of 23:19. Comparisons between the two groups revealed no statistically significant differences in their data ($P > 0.05$). This study complies with national laws and regulations and adheres to medical ethical principles.

Inclusion criteria: (1) Completion of clinical diagnosis; (2) Age ≥ 18 years old; (3) Informed consent obtained from both patients and their families, with signed informed consent forms.

Exclusion criteria: (1) Patients with underlying ear conditions such as tympanic membrane perforation, chronic otitis media, or cholesteatoma; (2) Patients with severe dysfunction of vital organs such as the heart, liver, or kidneys; (3) Patients with drug allergies; (4) Women who are pregnant or breastfeeding; (5) Patients with mental illnesses.

2.2. Methods

Before treatment, both groups of patients underwent comprehensive examinations, including otoscopy and pure-tone audiometry to clarify their conditions. They were given conventional basic treatments, including anti-infection therapy, oral mucus-promoting agents, nasal irrigation, and decongestant nasal drops to alleviate symptoms and improve eustachian tube ventilation.

2.2.1. Control group

Patients in the control group were treated using the traditional single-port tympanic membrane puncture and intratympanic injection method. The patients were seated, and the ear was routinely disinfected. The tympanic

membrane was anesthetized with 2% lidocaine. Under the guidance of an otoscope, a No. 7 tympanic membrane puncture needle was used to puncture the lower half of the tympanic cavity, approximately 2 mm from the tympanic annulus. Middle ear effusion was slowly aspirated, and a mixture of 5 mg of dexamethasone sodium phosphate injection (Hubei Jinyao Pharmaceutical Co., Ltd., National Medicine Approval No. H42020019) and 0.5 g of cefuroxime sodium for injection (Shenzhen Lijian Pharmaceutical Co., Ltd., National Medicine Approval No. H20064532) was diluted to 2 mL with 0.9% sodium chloride injection and slowly injected. After the injection, the tube was removed, the ear canal was plugged with a sterile cotton ball, and the patient was instructed to maintain an upward position of the affected ear for 30 minutes. This treatment was administered once a week for a total of two treatments.

2.2.2. Observation group

The treatment method of bilateral myringotomy with intratympanic drug injection was adopted, with the same basic treatment as the control group. Patients were seated, and routine otological disinfection was performed. The tympanic membrane was anesthetized topically with 2% lidocaine. Under the guidance of an otoscope, a No. 7 myringotomy needle was used to puncture the anterior-inferior and posterior-inferior quadrants of the tympanic membrane, respectively, creating two perforations, one approximately 1 mm and the other approximately 3 mm in size. Fluid from the middle ear was slowly aspirated through one perforation, while the aforementioned mixed medication was slowly injected through the other. During the injection, it was important to observe whether the medication flowed out from the first perforation to ensure uniform distribution of the drug within the middle ear cavity. After the injection was completed, the puncture needle was removed, and the ear canal was plugged with a sterile cotton ball. Patients were instructed to maintain an upright position with the affected ear facing upwards for 30 minutes. The treatment was administered once a week for a total of two sessions.

2.3. Observation indicators

(1) Therapeutic efficacy was evaluated after 2 weeks of treatment. Complete recovery was defined as the elimination of clinical manifestations such as tinnitus and hearing loss, no fluid accumulation observed upon otoscopic re-examination, and normalization of auditory thresholds. Significant improvement was characterized by marked alleviation of clinical symptoms, a small amount of fluid observed under the otoscope, and an increase in auditory thresholds of more than 15 decibels. Effective treatment was indicated by noticeable improvement in clinical symptoms, moderate fluid accumulation remaining in the middle ear cavity, and an increase in auditory thresholds of 5-14 decibels. Treatment was considered ineffective if the aforementioned goals were not achieved. The overall effective rate was calculated as the sum of the complete recovery rate, significant improvement rate, and effective rate.

(2) The occurrence of complications in the two groups of patients was recorded, including non-healing tympanic membrane perforation, cholesteatoma formation, aggravated hearing loss, and recurrent otitis media.

(3) The time to symptom relief in the two groups of patients was recorded, including symptoms of ear fullness, tinnitus, and hearing loss.

(4) Before treatment, 2 weeks after treatment, and at the 3-month follow-up, pure-tone audiometry was used to detect and compare the hearing thresholds of patients.

2.4. Statistical analysis

Data were processed using SPSS version 24.0 software. Measurement data were calculated using the "t" test, and count data were tested using the χ^2 test, expressed as mean ± standard deviation (SD) and (%) respectively. A *P*-value < 0.05 was considered statistically significant.

3. Results

3.1. Treatment efficacy rate

The overall treatment efficacy rate in the observation group was higher than that in the control group, with a statistically significant difference ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of postoperative recovery between the two groups (n, %)

Group	n	Recovered	Markedly Effective	Effective	Ineffective	Total Effective Rate
Observation Group	42	25 (59.52)	12 (28.57)	3 (7.14)	2 (4.76)	40 (95.24)
Control Group	42	18 (42.86)	10 (23.81)	6 (14.29)	8 (19.05)	34 (80.95)
χ^2						4.086
P Value						0.043

3.2. Overall incidence of complications

The overall incidence of complications in the observation group was lower than that in the control group, with a statistically significant difference ($P < 0.05$), as shown in **Table 2**.

Table 2. Overall incidence of complications (n, %)

Group	n	Non-healing of Tympanic Membrane Perforation	Cholesteatoma	Hearing Loss Aggravation	Recurrent Otitis Media	Total Incidence Rate
Observation	42	1 (2.38)	0 (0.00)	0 (0.00)	1 (2.38)	2 (4.76)
Control	42	3 (7.14)	1 (2.38)	2 (4.76)	2 (4.76)	8 (19.05)
X^2						4.086
P						0.043

3.3. Time to symptom relief

The time to symptom relief in the observation group was shorter than that in the control group, with a statistically significant difference ($P < 0.05$), as shown in **Table 3**.

Table 3. Time to symptom relief (n, mean ± SD, d)

Group	n	Ear Fullness Relief Time (days)	Tinnitus Relief Time (days)	Hearing Loss Relief Time (days)
Observation	42	3.25 ± 1.02	4.12 ± 1.23	5.36 ± 1.45
Control	42	4.86 ± 1.35	5.78 ± 1.56	7.28 ± 1.67
t		6.167	5.145	5.626
P		0.000	0.000	0.000

3.4. Changes in hearing threshold

After treatment, the hearing thresholds at various time points in the observation group were lower than those in the control group, with a statistically significant difference ($P < 0.05$), as shown in **Table 4**.

Table 4. Changes in Hearing Threshold (n, mean ± SD, dBHL)

Group	n	Before Treatment	2 Weeks After Treatment	3-Month Follow-up
Observation	42	38.62 ± 5.34	27.15 ± 3.26	24.38 ± 2.85
Control	42	39.15 ± 5.12	32.46 ± 3.58	29.64 ± 3.12
t		0.464	7.107	8.067
P		0.644	0.000	0.000

4. Discussion

The ear is a crucial organ for hearing and balance, and its functional integrity is closely related to an individual's quality of life and social abilities. Acute secretory otitis media is a common inflammatory condition in otolaryngology that poses significant harm to patients, their families, and society. Exploring effective and safe treatment methods to thoroughly eliminate middle ear effusion, rapidly suppress inflammatory responses, and optimize their effects is an urgent challenge in otolaryngology both domestically and internationally [2]. Currently, intratympanic drug injection is widely used clinically due to its advantages of simple operation, minimal trauma, and direct drug delivery to the lesion site. However, the current single-hole tympanic membrane puncture method is prone to blockage of the puncture hole by secretions, failing to completely eliminate the effusion. Additionally, uneven drug distribution in the middle ear cavity affects treatment efficacy, and multiple punctures increase the risk of eardrum damage, thereby limiting the improvement of therapeutic outcomes. Against this backdrop, the binaural myringotomy with tympanic injection technique emerged, which achieves the synergistic effects of effusion removal and drug infusion by establishing a bidirectional pathway, thereby providing a new approach to optimizing the treatment outcomes for acute secretory otitis media.

The results of this study indicate that the overall treatment effectiveness in the observation group was higher than that in the control group, with a statistically significant difference ($P < 0.05$). The analysis suggests that conventional single-puncture needle insertion can only perform a single fluid aspiration or drug administration. After fluid extraction, the puncture site is prone to blockage by residual secretions, hindering subsequent drug delivery. Moreover, drugs are difficult to evenly distribute across all lesion sites, and inflammatory reactions at hidden spots may not be effectively suppressed. In contrast, binaural puncture involves creating two puncture sites in the upper and lower directions, which not only prevents blockage caused by single puncture but also ensures complete drug effusion. Additionally, it allows for the uniform distribution of drugs under pressure to areas such as the tympanic sinus and the pharyngeal opening of the Eustachian tube. By establishing dual channels, drug reflux is reduced, and drug retention in the middle ear cavity is enhanced, enabling full contact between the lesion site and the drug, thereby better suppressing inflammatory reactions, promoting the recovery of Eustachian tube function, and improving overall treatment efficacy. Furthermore, the puncture sites for the binaural puncture method are located around the middle ear, where blood supply is abundant and the tympanic membrane tissue is not damaged, providing a better environment for postoperative reconstruction of the middle ear mucosa and thus improving treatment outcomes [3].

The overall complication rate in the observation group was lower than that in the control group, with a statistically significant difference ($P < 0.05$). Analyzing the reasons, repeated punctures using the conventional single-port method can easily cause irreversible damage to the fibrous tissue of the eardrum, leading to difficulties in perforation. Bacteria proliferating in residual secretions can readily trigger chronic inflammation, continuously stimulating the eardrum and the mucosa of the middle ear, thereby increasing the likelihood of cholesteatoma development. If prolonged, it can also cause greater harm to the auditory ossicles and auditory nerves, resulting in hearing loss. The double-port puncture method features evenly distributed puncture points, effectively preventing concentrated damage at a single location and reducing harm to the fibrous layer of the eardrum, thus achieving better therapeutic outcomes. Moreover, the dual channels ensure complete evacuation, eliminating the possibility of bacterial proliferation, controlling inflammatory residues at the source, and reducing the chances of chronicity and recurrence. Additionally, during the double-port puncture process, medications can be evenly dispersed within the middle ear cavity, effectively suppressing inflammatory responses and reducing inflammatory damage to the middle ear mucosa and auditory ossicles, thereby decreasing the risk of hearing impairment. Furthermore, during double-port puncture, the presence or absence of medication discharge from other puncture ports can be precisely determined, effectively preventing tympanic cavity hypertension caused by excessive infusion, reducing excessive stimulation of the eardrum, and decreasing the risk of non-union of eardrum perforations, thereby significantly lowering the incidence of complications [4].

The symptom relief time in the observation group was shorter than that in the control group, with a statistically significant difference ($P < 0.05$). The reasons for this are as follows: Conventional single-port puncture often fails to completely remove the accumulated fluid in the body, making it difficult to rapidly restore it to its original level. Moreover, uneven drug distribution within the body can hinder the elimination of chronic inflammatory reactions, thereby prolonging the treatment duration for patients. In contrast, dual-port puncture can quickly and thoroughly eliminate the accumulated fluid. During the process of fluid extraction, it promptly relieves the pressure within the middle ear cavity, allowing for rapid alleviation of ear discomfort symptoms. Once the fluid is completely drained, the obstacles to auditory conduction are eliminated, temporarily alleviating the patient's hearing impairment. Simultaneously, through dual-port puncture, inflammatory mediators can be rapidly and effectively controlled, reducing congestion and edema of the middle ear mucosa, minimizing inflammatory stimulation to the auditory nerve, and improving tinnitus. In addition, double-lumen puncture can also promote the rapid recovery of eustachian tube function. When the ventilation function of the eustachian tube is restored, it can effectively balance the pressure between the middle ear cavity and the external environment, prevent the reaccumulation of effusion, improve the condition, and thus prevent recurrence.

After treatment, the average hearing threshold values at various time points in the observation group were lower than those in the control group, with statistically significant differences ($P < 0.05$). The analysis suggests that conventional single-lumen puncture fails to completely remove the fluid in the body, causing obstacles to sound transmission. The long-term impact of residual inflammatory reactions on the auditory ossicles and auditory nerves makes it difficult for patients to recover rapidly and may even lead to deterioration. However, binaural myringotomy completely eliminates middle ear effusion, promptly removing the obstacle of fluid to sound transmission and allowing sound to be correctly transmitted to the auditory ossicles, thereby achieving early auditory effects. On this basis, the binaural perforation technique enables the uniform dispersion of medication within the body, swiftly and effectively suppressing inflammatory responses, reducing the damage caused by inflammatory factors to the auditory ossicles, tympanic membrane, and auditory nerve, and preventing

the occurrence of auditory impairment. Additionally, the binaural approach causes less damage to the tympanic membrane, with the perforations closing rapidly, effectively preventing hearing damage caused by the perforations. The swift elimination of inflammatory responses accelerates the repair of the middle ear mucosa, thereby improving the acoustic environment of the middle ear and enhancing auditory effects. The results show that the binaural approach not only rapidly improves hearing but also completely eliminates inflammation, promotes tissue repair, and achieves a long-lasting and stable level of hearing. Meanwhile, due to the limitations of unilateral myringotomy, including its constraints and residual inflammatory responses, the control group experienced a slow repair rate of the middle ear mucosa and insufficient recovery of auditory ossicle function, resulting in poor improvement in hearing thresholds and inadequate long-term stability [5].

5. Conclusion

In summary, for acute secretory otitis media, the treatment method of binaural tympanic membrane puncture and intratympanic drug injection demonstrates definite efficacy, significantly reducing the incidence of complications, accelerating symptom relief, and improving hearing function, making it worthy of promotion.

Disclosure statement

The author declares no conflict of interest.

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