

## Analysis of Sodium Bicarbonate Injection Ear Bath for Fungal Otitis Externa

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### ABSTRACT

**Objective:** This study aims to systematically evaluate the clinical efficacy of sodium bicarbonate injection ear bath in treating fungal otitis externa, providing scientific evidence and new strategies for managing this condition.

**Methods:** A total of 80 patients diagnosed with fungal otitis externa in the Department of Otorhinolaryngology at our hospital between June 2021 and June 2024 were enrolled as research subjects and randomly divided into an observation group and a control group. The observation group received treatment with sodium bicarbonate injection ear bath, while the control group was treated with traditional antifungal drugs (local application of triamcinolone acetonide econazole cream). Detailed records were maintained for both groups regarding treatment outcomes, symptom/sign improvement times (e.g., ear itching relief time and secretion reduction time), adverse reaction occurrences, and fungal negativity rates.

**Results:** Comparative analysis of the treatment effects between the two groups revealed that the

observation group demonstrated significant advantages in multiple aspects. First, in terms of treatment effectiveness, the cure rate and marked improvement rate were significantly higher in the observation group than in the control group ( $P < 0.05$ ). Second, regarding symptom relief speed, the disappearance time of ear itching was significantly shorter in the observation group compared to the control group ( $P < 0.05$ ), and recovery time was also significantly shorter in the observation group ( $P < 0.05$ ). Additionally, the incidence of adverse reactions was significantly lower in the observation group than in the control group ( $P < 0.05$ ).

**Conclusion:** Sodium bicarbonate injection ear bath represents an effective method for treating fungal otitis externa. By regulating the acid-base balance of the external auditory canal to inhibit fungal growth, it significantly enhances treatment effectiveness, shortens symptom improvement time, and features simple operation and high safety, making it worthy of further promotion and application in clinical practice.

**Key words:** Fungal otitis externa; Sodium bicarbonate injection; Ear bath; Triamcinolone acetonide and econazole cream; Irrigation; Therapeutic effect; Otoscope; Fungal smear

Fungal otitis externa is a skin disease of the external auditory canal caused by fungal infection and exhibits a relatively high incidence rate in clinical practice. It accounts for over 30% of ear diseases in the otolaryngology outpatient department of our hospital. The development of this condition is closely associated with changes in the local environment of the external auditory canal, such as prolonged moisture exposure, elevated temperature, or inadequate ventilation, which may create favorable conditions for fungal growth and reproduction. Furthermore, the misuse of antibiotics represents an important contributing factor to fungal otitis externa. While antibiotics effectively eliminate bacteria, they may also disrupt the balance of normal microbial flora in the human body, thereby promoting the excessive proliferation of fungi.<sup>[1-4]</sup>

In recent years, sodium bicarbonate injection-based ear baths have garnered significant attention in the medical field as a novel treatment approach.<sup>[5-8]</sup> Traditional antifungal treatments primarily involve the use of antifungal drugs, such as oral medications or topical ointments.<sup>[9-11]</sup> However, these methods are subject to certain limitations. For instance, some patients may experience allergic reactions to specific drug components, while incomplete drug absorption may result in suboptimal therapeutic outcomes.<sup>[4]</sup>

Moreover, certain fungi may gradually develop resistance to antifungal agents, further complicating treatment. As a novel therapeutic strategy, sodium bicarbonate injection-based ear baths offer a unique mechanism of action and advantages, warranting further in-depth investigation.

## 1. MATERIALS AND METHODS

### 1.1 General Information

A total of 528 patients diagnosed with fungal otitis externa in the Department of Otorhinolaryngology at our hospital between June 2021 and June 2024 were included in this study. The patients were randomly divided into an observation group and a control group, with 264 cases in each group. In the observation group, there were 35 male patients and 5 female patients, with an age range of 22 to 65 years and an average age of  $(44.93 \pm 14.98)$  years. In the control group, there were 34 male patients and 6 female patients, with an age range of 24 to 65 years and an average age of  $(37.75 \pm 13.94)$  years. There was no statistically significant difference in baseline characteristics such as gender and age between the two groups ( $P > 0.05$ ), indicating that the groups were comparable.

**1.2 Inclusion Criteria:** Patients who met the following criteria were included: (1) Diagnosis of fungal otitis externa confirmed by clinical symptoms (e.g., ear itching, a sensation of moisture in the ear, hearing loss, etc.) and laboratory tests (fungal hyphae or spores detected in ear canal secretion smears); (2) Age range of 18 to 65 years; (3) Simple fungal otitis externa without severe complications such as external auditory canal stenosis or tympanic membrane perforation with middle ear inflammation; (4) Good compliance, including the ability to cooperate with ear bath treatment and subsequent follow-up observations, such as regular hospital re-examinations and correct use of sodium bicarbonate injection for ear bath procedures.

**1.3 Exclusion Criteria:** Patients meeting any of the following criteria were excluded: (1) Concurrent bacterial mixed infection otitis externa; (2) Other middle ear diseases, such as chronic suppurative otitis media or cholesteatoma otitis media; (3) Severe systemic diseases, including immunodeficiency diseases (e.g., AIDS, severe immunosuppression due to radiotherapy or chemotherapy for malignant tumors); (4) History of sodium bicarbonate allergy; (5) Recent (within 1-2 weeks) use of other local

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antifungal drugs for the ear or recent ear surgery.

This study was approved by the Ethics Committee of Shanghai Medical University Hospital (Number: 20210601). All patients provided voluntary informed consent prior to participation.

#### 1.4 Observation Indicators

##### 1.4.1 Time to Itch Relief and Complete Resolution

Record the specific time points at which the patient's external auditory canal itching begins to alleviate and achieves full resolution. The cure criteria are specified in Table 1.

**Table 1:** Criteria for Fungal Otitis Externa Treatment Outcome (n, %)

Outcome	Ear Itching	Fungal Infection	Fungal Smear
Cured	Itching Resolved	Fungus Absent	Fungus Absent
Improved	Itching Reduced	Fungus Reduced by 60%	Obvious Hyphae or Spores
No Effect	Symptoms Unchanged	Fungus Persists	Fungus Detected

##### 1.4.2 Treatment Effectiveness Rate

The treatment response rate was assessed at Weeks 1, 2, 3, and 4 post-treatment. The formula for calculating the treatment response rate is:  $[(\text{number of cured cases} + \text{number of markedly effective cases}) / \text{total number of cases}] \times 100\%$ .

##### 1.4.3 Adverse Reaction Incidence

The adverse reaction incidence in both groups during treatment was recorded and compared. For example, sodium bicarbonate injection and triamcinolone acetonide econazole cream may cause local irritation (e.g., mild stinging or burning), improper operation may lead to tympanic membrane issues (e.g., transient tinnitus or hearing loss), and the drugs may trigger skin allergies (e.g., erythema, itching, rash, or blisters, especially in patients with allergies). Long-term hormone use may result in adverse effects (e.g., skin atrophy, telangiectasia), increasing the risk of damage, secondary infection, and impacting normal physiological function.

1.5 Statistical Methods: All patients' basic information, treatment conditions, and observation indicator

data were meticulously recorded to establish a database. Statistical analyses were conducted using SPSS 27.0 software. Measurement data were expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ), and intergroup comparisons were performed using t-tests. Count data were expressed as percentages (%), and intergroup comparisons were conducted using  $\chi^2$  tests. A P-value  $< 0.05$  was considered statistically significant.

## 2 RESULTS

### 2.1 Comparison of cure time

Study group has obvious advantages in shortening the recovery time than those of the control group, and the differences were statistically significant (Table2) ( $P < 0.05$ ).

**Table 2:** Comparison of recovery times between the two treatment groups (d)

Group	Recovery time
Control group (n=40)	20.23 $\pm$ 3.75
Study group (n=40)	7.33 $\pm$ 2.38
t value	18.39
P value	$< 0.05$

### 2.2 Comparison of Itch Relief Time

The study group exhibited obvious advantages in itch relief time compared to the control group, and the differences were statistically significant (Table 3) ( $P < 0.05$ ).

**Table 3:** Comparison of Itch Relief Time Between the Two Treatment Groups (d)

Group	Itch Relief Time
Control group (n=40)	9.60 $\pm$ 2.85
Study group (n=40)	3.00 $\pm$ 1.11
t value	13.63
P value	$< 0.05$

### 2.3 Comparison of Cure Rates

At Weeks 1, 2, and 3, a statistically significant difference was observed in the cure rates between the observation group and the control group, with the observation group demonstrating higher cure rates

(Table 4) ( $P < 0.05$ ).

**Table 4:** Cure Rates in Two Groups (n, %)

Group	1 week	2 week	3 week	4 week
Control group (n=40)	0	2	24	40
Study group (n=40)	30	40	40	40
$\chi^2$ value	44.85	68.62	17.58	
P value	<0.05	<0.05	<0.05	

## 2.4 Complication Rates in Two Groups

The research group exhibited a significantly lower adverse reaction rate compared to the control group, with statistically significant differences (Table 5) ( $P < 0.05$ ).

**Table 5:** Complication Rates in Two Groups (n, %)

Group	local irritation (n)	skin allergy (n)	eardrum irritation (n)	adverse hormone reactions (n)	total (%)
Control group (n=40)	12	15	6	5	95%
Study group (n=40)	12	2	2	0	40%
$\chi^2$ value					25.13
P value					<0.05

## 3. DISCUSSION

### 3.1 Mechanism of Action of Sodium Bicarbonate Injection Ear Bath

3.1.1 Altering the pH of the External Auditory Canal: Fungi generally thrive in acidic environments, whereas sodium bicarbonate injection is an alkaline solution. After ear bathing, it can significantly elevate the pH level of the external auditory canal, creating an unfavorable environment for fungal growth and effectively inhibiting fungal proliferation.<sup>[12,13]</sup>

3.1.2 Cleaning the External Auditory Canal: During the ear bath process, sodium bicarbonate injection softens and dissolves substances such as cerumen, fungal hyphae, and spores in the external auditory canal, thereby performing a cleaning function and reducing the substrates required for fungal growth.

<sup>[14]</sup>

### 3.2 Advantages Compared to Traditional Antifungal Drug Treatment

3.2.1 Reduced Drug Side Effects: Traditional antifungal drugs may cause adverse reactions, such as

local irritation or allergic responses, while sodium bicarbonate injection is relatively safe and rarely induces adverse effects, making it particularly suitable for patients with sensitive skin in the external auditory canal.

**3.2.2 Simple Operation:** The sodium bicarbonate injection ear bath is easy to perform, allowing patients to conduct the treatment at home without professional assistance. This method is convenient and efficient, significantly enhancing patient compliance.

### 3.3 Existing Issues and Future Prospects

Although sodium bicarbonate injection ear bath has demonstrated good therapeutic effects in the treatment of fungal otitis externa, certain limitations remain. For example, in cases of severe conditions with deep fungal invasion, using sodium bicarbonate injection ear bath alone may not be sufficient for complete cure, necessitating combination with other antifungal drugs for treatment. In the future, further research could explore the optimal combination of sodium bicarbonate injection with other drugs for ear bath, as well as its role in preventing recurrence of fungal otitis externa, aiming to provide enhanced treatment strategies for clinical practice.

## 4. CONCLUSION

Sodium bicarbonate injection ear bath exhibits favorable therapeutic effects in the treatment of fungal otitis externa, significantly improving treatment efficacy and shortening the time required for symptom relief. It offers advantages such as simple operation and high safety. In clinical practice, it can serve as an important method for treating fungal otitis externa, especially for patients with mild or initial conditions, and can also be used as part of combined therapy. Meanwhile, further research is necessary to continuously optimize the treatment plan and enhance its clinical application value.

**Author contributions:** Yan Li performed the experiments and wrote the article. Shugang Wang performed the experiments. Yan Li and Yonggang Jin revised the article. Yan Li and Shugang Wang designed the study and reviewed the article. All authors read and approved the final manuscript as submitted.

**Conflict of interest:** The authors declare no conflict of interest.

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