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RESEARCH PAPER

# Assessment of complications due to intratympanic injections

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**Abstract** *Objective:* The purpose of the study is to report and to analyze the complications following intratympanic injections (ITI) of steroids. The occurrence rate of complications at different ITI sites, four quadrants of eardrum, was also compared.
*Methods:* A retrospective clinical review in a medical center. Each patient received ITI twice in a week for 2–3 consecutive weeks as a salvage therapy for sudden sensorineural hearing loss. Post-injection complications, especially transient dizziness and vertigo, were recorded. Patients with acute or chronic vertigo episodes in 1 month were excluded.
*Results:* A total of 59 patients with sudden sensorineural hearing loss and a total of 278 times of ITI were performed in 1 year. The post-injection complications included pain, tongue numbness, transient dizziness, vertigo, tinnitus, and a small persistent perforation. There was no significant difference in the occurrence of these complications between the injections sites on the 4 quadrants of the tympanic membrane. However, there was statistical significance in the post-injection vertiginous episode after IT injections to posterior-inferior quadrant (Q3) and posterior-superior quadrant (Q4) compared to anterior-superior quadrant (Q1) and anterior-inferior quadrant (Q2) ($P = 0.0113$).

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*Conclusion:* IT injection is recommended to be applied to the Q2 since the Q1 and Q4 injections are more likely to induce the adverse effect of tongue numbness, while the Q3 and Q4 areas are more likely to induce post-injection vertigo.


## Introduction

Corticosteroids are widely used for the treatment of Ménière's disease, sudden sensorineural hearing loss (SSNHL), autoimmune inner ear disease, and tinnitus. Oral treatment with steroid was reported to have 88% adverse effects, such as increasing requirements for insulin or oral hypoglycemic agent (OHA) in patients with diabetes mellitus (DM), increased thirst, and sleep or appetite changes. The intratympanic injection (ITI) was first used by Itoh to treat patients with Ménière's disease in 1991.[1] Silverstein was the first to use intratympanic steroids for the treatment of SSHNL in 1996. This method decreases the side effect of systemic steroid administration and leads to higher concentrations of the injected drug in the inner ear. Recently, many studies have shown the efficacy of corticosteroid use on the cochlear function in both human and animal models.[2] Despite wide-ranging investigations, only minimal information focused on the adverse effects induced by ITI of steroid. The complications of ITI include transient dizziness, injection pain, a burning sensation, increasing tinnitus, post-injection vertigo, tongue numbness, and a small perforation of the eardrum.[3] The most common side effect is transient dizziness, injection site pain, and a burning sensation. The character of post-injection vertigo has not been described in detail. This article will focus on the adverse effects of ITI and a characteristic description of post-injection vertigo. In order to prevent possible annoying side effects,[4,5] previous articles suggested injection of the solution into the posterior-inferior quadrant, via narrow-gauge spinal needle, to fill the middle ear space.[4] However, there is still no consensus to it.

## Materials and methods

### Patient selection

This retrospective clinical study was performed from January 1st, 2013 to December 25th, 2013 in a medical center. It included 59 patients with idiopathic sudden sensorineural hearing loss (ISSHL). Six out of 59 patients had severe vertigo attack along with sudden hearing loss for the initial 2 days, then vertigo subsided and followed by mild to moderate disequilibrium. All intratympanic steroid injected were used as a salvage treatment when primary treatment with oral steroid failed to improve hearing loss and tinnitus completely. The exclusion criteria are patients under active treatment for recurrent vertigo before ITI.

### Intratympanic injection technique

The ITI procedure has been approved by ethic committee of this hospital as a standard procedure to treat sudden deafness. Before the procedure, an informed consent with a clear explanation of the different injection sites, the risks and benefits, and the local anesthesia (although there was evidence that the local anesthesia before ITI is not always necessary[3]), was obtained. Since there are no standard protocol of ITI in this hospital regarding how many injections should be administered to one treatment course, the injection times was determined by the two senior authors. One of them injected 4 times in a 2-week period and the other 6 times in a 3-week period. In total, 38 patients were injected 4 times and 21 were injected for 6 times, which made the total injection times of 278.

Each patient received ITI twice in a week, separated by at least 2 days, for 2 or 3 consecutive weeks. Because this is a retrospective review, the injection sites and criteria were not pre-designed. For both senior authors who did the injection, the sites were mainly dependent on the condition of the eardrum. Most often, the anterior inferior Q will be selected, other alterative sites was chosen under special conditions such as an unhealed perforation by prior injection or blot clot covering the preferred injection sites. We defined Q1 as the anterior-superior quadrant, Q2 as the anterior-inferior quadrant, Q3 as the posterior-inferior quadrant, and Q4 as the posterior-superior quadrant. Injections were administered in the out-patient clinic by the senior authors under operating microscope. Extreme care was taken to slowly inject the steroid into middle ear to avoid injury to the underlying structures despite of different injection sites. We used 20% lidocaine spray as the local anesthetic agent, which is applied and fills the external auditory canal 5 min before injections. In order to prevent a caloric reaction, we asked patients to warm up the injection agent by holding the syringe with drugs in their palm for 5—10 min to warm it to body temperature. The patient was asked to lie in a supine position, with the head turned 45° toward the unaffected ear. Medication was injected through 1 of the 4 different quadrants of the tympanic membrane with a Becton—Dickinson (BD) spinal needle (27 G, 3.50 in., 0.64 mm × 90 mm). Once the IT injection was administered, the patient was asked to keep the same position for 30 min to provide maximal absorption of the medication through the round window. Patients were asked not to speak or swallow to prevent drug leakage through the Eustachian tube. After each injection, patients were asked to report if they perceived intolerable pain, vertigo, or any discomfort immediately. In addition, at the next office hour, patients were requested to describe and