Case Report

Round window sealing with steroid-soaked sponge in sudden sensorineural hearing loss

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ABSTRACT

Background: A rescue treatment is needed in cases of Sudden Sensorineural Hearing Loss (SSNHL) which fail to obtain complete hearing restoration after conservative steroid therapy. In order to acquire better access of steroid to the cochlea, sealing the round window with a sponge soaked in steroid could be considered as an alternative delivery strategy. **Purpose:** To review the evidence about the impact of round window sealing in SSNHL patients whose hearing failed to recover completely after treated with systemic and/or intratympanic steroid. **Cases:** Seven patients with SSNHL, who had experienced either no or slight response to previous systemic and/or intratympanic steroid administration, underwent transcanal round window sealing with steroid-soaked sponge. Pure Tone Audiometry (PTA) results and symptoms (hearing loss, tinnitus, vertigo) were compared pre- and post-operatively. Five patients reported better hearing and tinnitus symptom. **Method:** A scoping review was made by conducting literature searching at Cochrane, Pubmed, and Google Scholar using keywords "sudden sensorineural hearing loss", AND "round window sealing", and their relevant synonymous terms, employing Boolean operators. **Result:** A total of 8 observational studies with 430 subjects met the inclusion criteria. Time measurement of hearing improvement range from 6 days until 1 year. Most of the studies agreed that the procedure of sealing the round window had a positive impact on hearing improvement. **Conclusion:** This study revealed that round window sealing with steroid-soaked sponged could be considered as an alternative approach for patients with SSNHL who failed in conservative therapy.

Keywords: round window sealing, sudden sensorineural hearing loss, transtympanic steroid

ABSTRAK

Latar belakang: *Tindakan penyelamatan dibutuhkan dalam kasus-kasus tuli mendadak/* Sudden Sensorineural Hearing Loss (SSNHL) *yang gagal mendapatkan pemulihan pendengaran sempurna dari terapi steroid konservatif. Penutupan tingkap bulat dengan spons yang dicelupkan dalam steroid dapat dipertimbangkan menjadi strategi alternatif untuk meningkatkan akses steroid ke koklea.* ***Tujuan:*** *Mendapatkan bukti literatur mengenai pengaruh penutupan tingkap bulat pada pasien tuli mendadak yang gagal mendapatkan perbaikan pendengaran komplit dari terapi steroid sistemik atau intratimpanik.* ***Laporan kasus:*** *Tujuh pasien tuli mendadak, baik yang tidak memberikan respon maupun memberikan sedikit respon terhadap pengobatan steroid sistemik dan/atau intratimpanik sebelumnya, dan menjalani operasi penutupan tingkap bulat dengan spons yang dicelupkan steroid. Hasil audiometri nada murni dan gejala pasien (hilang pendengaran, tinnitus, vertigo) dibandingkan antara sebelum dan sesudah prosedur operasi. Didapatkan 5 pasien mengalami perbaikan pendengaran dan gejala tinitus.* ***Metode:*** *Tinjauan dibuat dengan pencarian literatur di* Cochrane, Pubmed, *dan* Google Scholar *menggunakan*

kata kunci "sudden sensorineural hearing loss"*, DAN* "round window sealing"*, dan kata sinonim yang relevan.* ***Hasil:*** *Delapan studi observasional dengan 430 subyek memenuhi kriteria inklusi. Jangka waktu pengukuran perbaikan pendengaran yaitu antara 6 hari hingga 1 tahun. Sebagian besar studi setuju bahwa tindakan penutupan tingkap bulat memiliki dampak positif pada perbaikan pendengaran.* ***Kesimpulan:*** *Studi ini mengungkapkan bahwa tindakan penutupan tingkap bulat dengan spons yang dicelupkan steroid dapat dipertimbangkan sebagai pendekatan alternatif untuk pasien tuli mendadak yang gagal dengan terapi konservatif.*

Kata kunci: *penutupan tingkap bulat, tuli mendadak, steroid transtimpani*

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INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is categorized as an emergency case in Otolaryngology, though its incidence is relatively low, being 5 to 30 number of cases per 100.000 per year. SSNHL is defined as a hearing loss of ≥ 30 dB at 3 consecutive frequencies in Pure Tone Audiogram (PTA), occurring within a 72-hour period. The degree of hearing loss that is experienced by patients can vary from mild to profound. This condition is usually accompanied by tinnitus and/or vertigo.[1,2]

The pathogenesis of SSNHL is mostly idiopathic. As a result, there is no global standard treatment for this disease.[1,3,4] Conservative treatments include systemic steroid (oral or intravenous) and intratympanic steroid.[1,2] However, salvage treatment is proposed for patients who give minimal response to these conservative treatments.[3]

Experts had discussed round window sealing as an alternative surgical treatment for SSNHL, since it offered enhanced accessibility of steroid to the inner ear and sustained delivery of steroid.[5] The procedure has been included by consensus in sudden hearing loss treatment since 2018, especially in patient with history of labyrinthine fistula. Furthermore, other reports also showed hearing improvement in cases without evidence of perilymph leak.[6]

The aim of this study was to assess the impact of round window sealing on SSNHL patients whose hearing failed to recover completely after conservative treatment. To our knowledge, this is the first report of round window sealing in Indonesia.

CASE SERIES

Seven patients with the following criteria, who were presented to ENT departments in Jakarta Islamic Hospital, Jakarta Proklamasi Hospital, and Universitas Indonesia Hospital from January 2023 to May 2023, were included in this study. Patients of all ages fulfilling diagnosis criteria of SSNHL within 1 month, and who had received previous conservative treatment, which was either systemic steroid and/or intratympanic steroid injection, and had no improvement, and/or had slight improvement were entered in the study.

Whereas, exclusion criteria were: patients who showed partial improvement from previous conservative treatment, and patients whose onset of disease was more than 1 month. We use Siegel's criteria to define hearing improvement. Type I (complete recovery) was considered as final PTA better than 25 dB. Type II (partial recovery) was considered as >15 dB gain and final PTA of 25-45 dB. Type III (slight improvement) was considered as >15dB gain and final PTA worse than 45dB. Meanwhile type IV (no

improvement) was considered as <15dB gain and final hearing worse than 75dB.[2,4]

Patient 1 was a 47-year-old man with a time-frame since onset being 7 days. Patient 2 was a 30-year-old man who had been symptomatic for 7 days. Patient 3 was a 16-year-old boy with a 7-day-onset time. Patient 4 was a 43-year-old man who had been experiencing symptoms for 14 days. Patient 5 was an 18-year-old girl with a time-frame since onset being 7 days. Patient 6 was a 56-year-old woman with an 18-day onset time. Meanwhile, patient 7 was a 35-year-old man who had been symptomatic for 30 days. All had previously received either systemic and/or intratympanic steroid, yet showed non-full recovery before receiving round window sealing procedure.

Our surgery protocol followed the technique applied in the Department of Otorhinolaryngology at University Medicine Halle. As outlined in Plontke et al.[7] publication, tympanoscopy and round window false membrane removal were performed to maximize Triamcinolone delivery. In all our cases, surgery was performed under general anesthesia. Firstly, the round window was identified at the postero-inferior of tympanic membrane (TM), followed by an incision made at that precise area. Middle ear cavity was accessed through transcanal tympanotomy with the aid of 0° endoscope. Once the round window niche was recognized and cleared from false membrane, sponge (Spongostan™) was placed to occupy it. Next, sponge was also positioned in front of the round and oval window. Then, a grommet tube was inserted into the tympanic membrane. Subsequently, steroid (1 mL of Flamicort™ Triamcinolone acetonide 40mg/mL) was injected through the tube into the tympanic cavity (Figure 1). Patients were discharged on the same day of the surgery.

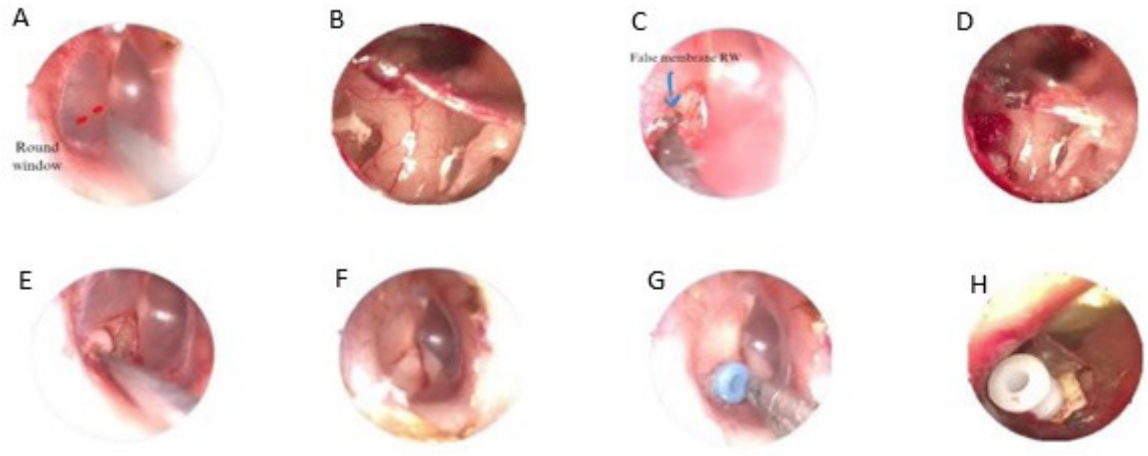

Figure 1. A. Round window identified. B. Round window niche visualized. C. False membrane cleared. D&E. Sponge placed to occupy the niche. F. Sponge placed in front of round and oval window. G&H. Grommet tube inserted.

In order to evaluate the hearing restoration, PTA (at 250, 500, 1000, 2000, 4000, and 8000 Hz) was performed in all patients pre-operatively and post-operatively, one and a half months following the procedure. The degree of hearing improvement was assessed by comparing post-procedure PTA, with initial PTA taken at the patients' first visit to the clinic (Figure 2). The average hearing threshold improvement of each patient was 50, 0, 35, 25, 26.25, 21.25, and 1.25, respectively. Hence, on average, there was a 31.5 dB improvement in 5 patients who responded to the surgery. Meanwhile, the other 2 patients, who started at 120 dB hearing threshold, gave no response to this intervention. Furthermore, clinical symptoms, which include hearing loss, tinnitus and vertigo, were also evaluated (Table 1). After 1.5 months following the surgery, all patients' grommet tube had been extruded and their tympanic membranes had healed completely.

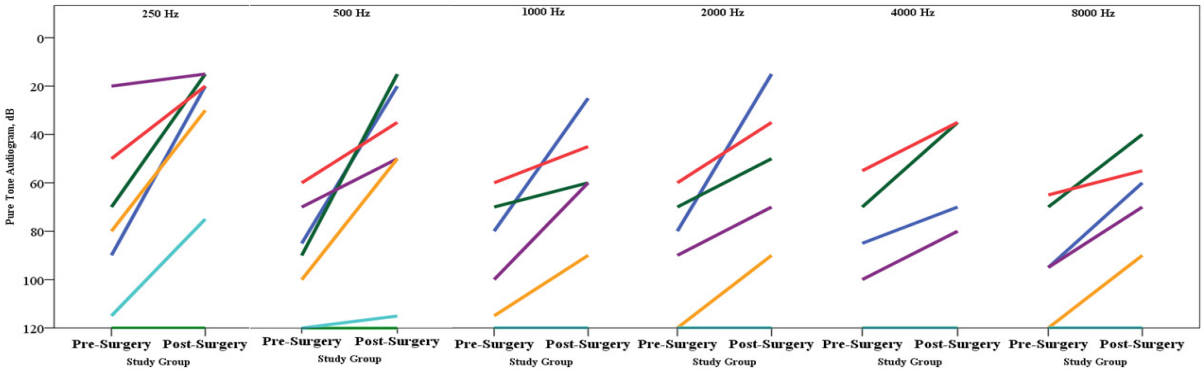

Figure 2. Comparison of pre- and post- Round Window Sealing PTA

Table 1. Comparison of pre- and post- Round Window Sealing clinical symptoms

Patient	Pre-Surgery Hearing Loss	Post-Surgery Hearing Loss	Pre-Surgery Vertigo	Post-Surgery Vertigo	Pre-Surgery Tinnitus	Post-Surgery Tinnitus
Patient 1	Yes	No	Yes	No	Yes	Better
Patient 2	Yes	Yes	Yes	No	Yes	Same
Patient 3	Yes	No	Yes	No	Yes	No
Patient 4	Yes	No	Yes	No	Yes	Better
Patient 5	Yes	No	Yes	No	Yes	No
Patient 6	Yes	No	Yes	No	Yes	No
Patient 7	Yes	Yes	Yes	No	Yes	Same

REVIEW METHOD

Based on these reported cases, the background question for review was formulated by utilizing the elements of Population, Concept, and Context (PCC). The population was patients with SSNHL who had experienced no or slight response upon conservative treatments, which were either systemic or intratympanic steroid. The concept was hearing improvement, which was measured objectively by PTA, and clinical symptoms, which was assessed subjectively by direct interview, after the procedure of Round Window sealing. Here, the context was hospital setting. Therefore, the question was "What is the impact of

Round Window sealing procedure for patients with SSNHL who had experienced no or slight response to previous administration of systemic and/or intratympanic steroid?"

A systematic literature searching was conducted through Cochrane, Pubmed, and Google Scholar on May 25th 2023 with the following keywords: "sudden sensorineural hearing loss" OR "sudden deafness" OR "idiopathic sensorineural hearing loss", coupled with (AND) "round window sealing" OR "round window packing" OR "transtympanic steroid". This study included English articles with all study design without restriction of publishing year.

Authors did not retrieve 102 studies for the interchangeable terminology between "transtympanic steroid" and "intratympanic steroid". Authors who performed round window sealing, use the term "transtympany" when applying steroid directly to round and oval window. Meanwhile, "intratympany" was used when steroid was injected through the tympanic membrane into the tympanic cavity. Hand searching was also performed.

Patients who underwent round window sealing using either sponge or fascia or connective tissue were included in this study. Whereas, patients who received transtympanic steroid only, by tympanotomy or grommet tube or microcatheter, were excluded from this study. Hence, we included 8 articles in total.

In the final review, the following details were obtained: last name of the first author; year of publication; country of study; sample size; study design; patients recruited; type of intervention; and the outcome. A summary of the data was created and extracted into a table (Table 2) to describe the impact of round window sealing in SSNHL patients in their studies.

RESULT

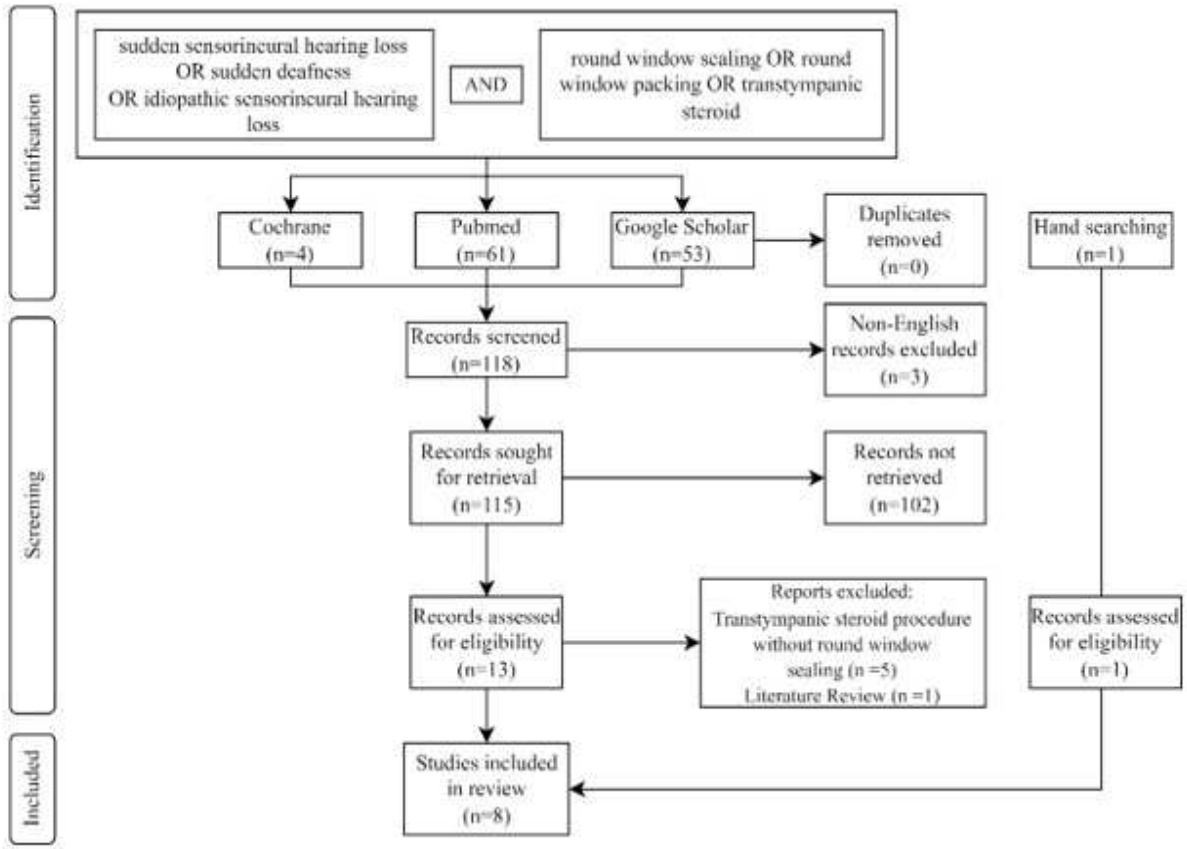

Figure 3. PRISMA flow diagram of the literature searching

Based on our literature search, 118 articles were relevant to our terms. Three non-English articles were excluded. Out of 115 titles and abstracts that were screened, 102 articles did not meet the inclusion criteria. Finally, the eligibility of 13 full-text articles were checked and found 8 articles in total, which were summarised in the tables below (Table 2,3). The study selection process was shown in Figure 3.

Table 2. Summary of studies

Author	Year	Country	Sample Size	Study design	Patient	Intervention	Outcome
Gedlicka et al.[10]	2009	Austria	60	Retrospective cohort	Patients with unilateral SSNHL, acoustic, and barotrauma who failed intravenous steroid + oral glutamate-receptor antagonist therapy	Round window sealing using connective tissue	Improvement in hearing levels measured by PTA (10 SSNHL patients recovered <10dB, 9 SSNHL patients recovered 10-30dB, 15 SSNHL patients recovered >30dB)
Ul-Mulk et al.[11]	2011	Denmark	22	Case series	Patients with SSNHL who had not experienced spontaneous recovery in 1-month period	Round window sealing using fat, connective tissue, and spongostan	Improvement in hearing levels measured by PTA (mean improvement:12 dB), and associated symptoms including vertigo and tinnitus
Haubner et al.[12]	2012	Germany	69	Retrospective cohort	Patients with unilateral SSNHL with ≥50 dB hearing loss over 3 frequencies who failed high-dose steroid therapy	Round window sealing using fat, soft tissue, and combinations of soft tissue and fat as well as combinations with fibrous glue + intravenous prednisone for 12 days	Improvement in hearing levels measured by PTA (43% of patients improved >20dB, 31% of patients improved between 5 and 20 dB) with only 18.8% of patients found to have definite perilymphatic fistula. As much as 26% (18) patients had no improvement.

Loader et al.[3]	2013	Austria	25	Retrospective cohort	Patients with SSNHL who failed intravenous and oral steroid therapy	Round window sealing using triamcinolone-soaked fascia	An average improvement of 37.2 dB in hearing levels in responding patients especially at lower to middle frequencies measured by PTA
Kampfner et al.[4]	2013	Germany	101	Retrospective cohort	Patients with severe to profound unilateral SSNHL who failed cortisone and/ pentoxifyllin and/or intravenous hydroxyethylated starch	Round window sealing using connective tissue + prednisolone administration for 12 days	21.7-dB-average-improvement in hearing levels measured by PTA
Hoch et al.[13]	2015	Germany	51	Retrospective cohort	Patients with unilateral SSNHL with ≥60 dB hearing loss over 5 frequencies without previous therapy occurring within 3 days	Round window sealing using connective tissue + prednisolone administration for 10 days + intravenous hydroxy-ethylated starch	Improvement in hearing levels measured by PTA (mean improvement: 33.3 dB) and associated symptoms including vertigo, tinnitus, ear fullness or periauricular dysaethesia
Prenzler et al.[8]	2017	Israel	82	Retrospective cohort	Patients with severe to profound SSNHL who failed intravenous steroid therapy	Round and oval window sealing using temporal fascia	Significant increase of hearing levels at 250-4000 Hz generally measured by PTA. Mean increase of 10.0 ± 15.0 % in patients without PLF. As much as 28% (23) patients were diagnosed with PLF. There is greater decrease of hearing loss in patients with PLF compared to patients without PLF

Lei et al.[9]	2023	China	20	Case series	Patients with unilateral SSNHL with PTA improvement <10 dB after systemic steroid	Round window sealing using dexamethasone-soaked sponge gelatin	11.9-dB-mean-improvement in hearing levels especially at lower to middle frequencies measured by PTA

This scoping review found 8 retrospective studies with a total subject of 430 subjects that shared the same aim generally, which was to analyse the effectiveness of round window sealing in SSNHL patients who failed conservative treatment. All of these studies, published between 2009 and 2023, reported improvement in post-operative hearing levels, as measured by PTA. The duration of follow-up across the studies varied from as short as 6 days to a longer period of 1 year. In addition, Loader et al.[3], Prenzler et al.[8], and Lei et al.[9] mentioned that the most significant recovery of hearing levels was in lower and middle-frequency range. However, it was worth noting that Prenzler et al.[8] also performed an additional procedure of oval window sealing to the subjects.

The various materials that were used in the studies ranged from fat, connective tissue, fascia, to spongostan.[3,4,8–13]. Among the included studies, Haubner et al.[12], Kampfner et al.[4] and Hoch et al.[13] conducted studies in which systemic steroid was administered concurrently. Therefore, Hoch et al.[13] stated in his study, whether the role of round window sealing is beneficial in SSNHL cases remains unclear despite the increase in hearing levels.

As the pathogenesis was still speculative, Haubner et al.[12] and Prenzler et al.[8] observed the presence of round window rupture/ perilymphatic fistula as a potential factor causing SSNHL. Haubner et al[12] discovered that although only 18.8% of the patients had that condition, all of them experienced hearing remission following the procedure of round window sealing. Meanwhile, Prenzler et al.[8] showed that round window sealing could make a greater decrease of hearing loss in patients with perilymphatic fistula compared to patients without perilymphatic fistula.

Hoch et al.[13] and Ul-Mulk.[11] et al reported that clinical symptoms including vertigo and tinnitus were reduced after the procedure. Not all studies documented the procedure's adverse effects. However, Ul-Mulk et al.[11] and Haubner et al.[12] explicitly confirmed that round window sealing is a safe procedure without any observed complications. Meanwhile, two complications were mentioned in studies by Hoch et al.[13] and Lei et al.[9], which were chorda tympani injury without any residual symptom in 2 of 51 studied subjects and persistent eardrum perforation in 1 of 20 studied subjects, respectively.

Table 3. Characteristics of studies

Parameter	Total
Publication year	
2019-2023	1
2014-2018	2
2009-2013	5
n	**8**
Country	
Austria	2
Denmark	1
Germany	3
Israel	1
China	1
n	**8**
Study Design	
Retrospective cohort	6
Case series	2
n	**8**

Round Window Seal Type	
Connective tissue	3
Fascia	2
Fat	1
Fat, connective tissue, and spongostan	1
Absorbable gelatin sponge	1
n	8
Time Interval between surgery and hearing evaluation	
≤7 days	1
≤14 days	2
≤21 days	1
≤28 days	1
≤2 months	1
≥3 months	2
n	**8**

DISCUSSION

In our analysis of all the studies, it became evident that hearing levels showed improvement following round window sealing. It was important to consider the varying timeframes for the studies in conducting post-procedure PTA assessments.

In these case series, hearing levels were also generally improved. However, the improvement did not occur in two patients who both had experienced profound hearing loss, with average hearing thresholds at 0.5, 1, 2, and 4 kHz measuring 120 dB. This might be due to the fact that profound hearing loss was a negative prognostic factor that affect hearing result.[14]

Amidst the global diversity in the standard management of SSNHL, steroid has been commonly used to treat the condition because of its ability to reduce inflammation cascade in the inner ear. It acted on either inhibiting or reversing the apoptotic pathway of the injured cochlear hair cells. As a result, hearing improvement was supposed to be achieved.[1,2] Even though the use of systemic steroid was favourable as an initial therapeutic choice for SSNHL, local administration of drugs was beneficial considering the adverse effects of systemic steroid, and the anatomy of blood-labyrinth barrier (BLB) of the cochlea that restricted the passage of systemic steroid therapy.[2,15]

Although dexamethasone was the most common choice of steroid, triamcinolone acetonide was used for its advanced local efficacy. Based on perilymph analysis, triamcinolone, which is metabolized as triamcinolone in the inner ear, is eliminated slower compared to dexamethasone. Therefore, the use of triamcinolone allows more wide distribution to apical cochlear regions. Furthermore, the pharmacokinetic analysis of triamcinolone-acetonide shows that it readily enters the round window and stapes.[16]

Round window was discussed by experts as a natural entrance that could be targeted to give better access of steroid into the perilymphatic space of cochlea. The opening of round window is covered by a semipermeable round window membrane (RWM), which is a continuation of the middle ear's mucous membrane in the outer, followed by a connective tissue layer in the middle, and cellular layer facing the scala tympani (ST) in the inner. RWM is permeable to low molecular weight molecules, such as steroid.[5,15]

The anatomy of round window niche presents a range of possibilities, from easily accessible to being obstructed by structures such as false membranes, mucosa, fat deposits, or soft tissue plugs. These obstructions could reduce the contact between drug and the RWM, potentially causing therapeutic failure.[17]

The diversity of RWM thickness, the presence of round window pseudomembrane, and the variability of round window niche across patients are thought to be factors that affect how effective steroid can be delivered via intratympanic route. Moreover, because drugs in the middle ear are eliminated through the Eustachian tube, the contact time between the drug and RWM is reduced. As consequence,

the percentage of drug entering the inner ear could be relatively low. Due to this limitation of intratympanic steroid injection, there have been efforts to maximize drug delivery to the inner ear, and minimize drug clearance through the Eustachian tube.[5,15,17] One of them is by performing round window sealing.

The sealing procedure is accomplished by clearing any obstruction at the round window niche and utilizing the niche structure to contain the seal, thus facilitating direct application of steroid. These steps allow greater contact between the drug and the RWM.

There are various types of seals that are available for sealing the round window, such as absorbable sponge/hydrogel, fat plugs, and fascia. In this study, sponge (Spongostan™) that was soaked with steroid, was used. Because the material degrades slowly, high concentration of steroid could be firmly held in position. The drug is supposed to diffuse slowly and stay in the middle ear in a longer period. As a result, drug delivery to the inner ear is enhanced. Moreover, the increase in residence time of the steroid on RWM leads to more uniform drug distribution in the cochlea. The structure of round window niche supports the retention of substances, particularly solid gel-like matrices. Subsequently, steroid clearance through the Eustachian tube can be delayed.[3,5]

However, due to the fact that 28-68% patients with SSNHL can recover spontaneously, it is generally advised that tympanotomy with round window sealing is not carried out in the early days. Additional trauma could be caused by premature surgical intervention, resulting smaller possibility of spontaneous remission.[3,10]

In this case series, round window sealing procedure generally could be seen giving improvement in hearing levels, particularly at low to middle frequencies. The PTA improvement was in line with the studies that we reviewed. However, the improvement did not occur in two patients who both had experienced profound hearing loss, with average hearing thresholds at 0.5, 1, 2, and 4 kHz measuring 120 dB at their first visit to our clinic. This might be due to the fact that profound hearing loss has different pathogenesis, that is a negative prognostic factor that affect hearing result.[14]

According to the symptoms observed during the one-and-a-half-month period after the procedure, patients generally reported improved hearing, reduced vertigo/dizziness, and better tinnitus outcomes. However, in 30% (2 out of 7) of our patients who did not experience improvements in PTA, tinnitus persisted at the same level as pre-surgery. These specific patients had an average hearing threshold of 120 dB during their initial visit and had no response after initial treatment. The same pattern of this result was found in a report by Lei et al.[9], in which a patient with a 110 dB initial hearing threshold did not get post-procedure PTA improvement

Our study was the first case series and scoping review of this particular intervention technique in Indonesia, employing systematic evidence-based literature searching. However, some limitations that exist were the various criteria used for assessing hearing improvement between the reviewed studies and the various time-frames for outcome evaluation. Persistent TM perforation was reported as a possible long-term adverse effect caused by this surgery, as reported by Lei et al.[9]

In conclusion, round window sealing with steroid-soaked sponge is a potential rescue treatment for SSNHL patients whose hearing was not restored completely in response to conventional steroid treatment. A long-term adverse effect that is probable to happen is persistent TM perforation.

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