The Journal of International Advanced Otology

J Int Adv Otol 2021; 17(6): 514–519 • DOI: 10.5152/iao.2021.21169

Original Article

Combined Amplification and Sound Therapy for Individuals With Tinnitus and Coexisting Hearing Loss: A Retrospective Cohort Study

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Cite this article as: Ganesan P, Rodrigo H, Schmiedge J, Reiter R, Swapna S, Manchaiah V. Combined amplification and sound therapy for individuals with tinnitus and co-existing hearing loss: A retrospective cohort study. *J Int Adv Otol.* 2021;17(6):514-519.

BACKGROUND: The heterogeneity of tinnitus perception and its impact necessitates a tailor-made management approach in everyone. The current study examined the effects of residual inhibition in combined amplification and sound therapy in individuals with tinnitus and coexisting hearing loss.

METHODS: A retrospective analysis was performed on patients with tinnitus and coexisting hearing loss between 2016 and 2019. A total of 72 patients provided with combined amplification and sound therapy were divided into 3 groups based on residual inhibition: (i) complete residual inhibition, (ii) partial residual inhibition, and (iii) negative residual inhibition. Tinnitus severity was measured using the Tinnitus Functional Index before treatment and 1 and 6 months after the intervention. A multilevel mixed-effects model was used to examine the treatment effects including both the main and interaction effects of time and residual inhibition on the tinnitus severity.

RESULTS: Of the 72 participants, 55 (76%) and 61 (85%) had clinically significant changes (13 points in Tinnitus Functional Index) at 1-month and 6-month postintervention, respectively. In the complete, partial, and negative residual inhibition groups, the reduction in tinnitus impact was 100%, 78%, and 74%, respectively. A multilevel mixed model analysis showed that the main effects of time and residual inhibition along with their interaction were significant.

CONCLUSIONS: The study results suggest that combined amplification and sound therapy is beneficial in individuals with tinnitus and coexisting hearing loss in reducing their tinnitus severity, and this benefit was more in individuals with complete residual inhibition. However, these results need to be further confirmed by controlled trials.

KEYWORDS: Hearing aids, hearing loss, residual inhibition, sound therapy, tinnitus

INTRODUCTION

Tinnitus is a heterogeneous condition with different manifestations in different patients.[1] Evidence has shown that tinnitus has possible neurological origins but is triggered by cochlear insults, which causes several types of physiological changes such as increased spontaneous activity, increased neural synchrony, and frequency map reorganization.[2,3] Despite the connection with the auditory system and tinnitus origin, the connection with hearing loss and tinnitus is not simple or straightforward, as some people with troublesome tinnitus have audiometrically normal hearing; conversely, many people with hearing loss do not report tinnitus.[1,4] The tinnitus population in the United States is up to 30 million people or around 10% of the general population. Although tinnitus is correlated with the degree of hearing loss, it is surprising that 13 million Americans with tinnitus report no hearing loss.[5]

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Received: January 15, 2021 • **Accepted:** May 2, 2021
Available online at www.advancedotology.org

There is no known cure for tinnitus, although various treatments exist to manage it.[6] Available treatment options include counseling, wideband sound therapy, and hearing aids when hearing loss is identified.[1] Although some studies have demonstrated the positive effect of amplification and sound therapy on tinnitus patients,[7,8] in general, there is insufficient evidence to support the superiority of sound therapy in tinnitus management.[9,10] Despite the lack of strong evidence, clinicians still recommend amplification and sound therapy for patients with tinnitus and coexisting hearing loss since it has been proven to be beneficial in a lot of patients with tinnitus. The American Academy of Otolaryngology-Head and Neck Surgery Foundation guidelines did recommend sound therapy as a reasonable management option along with counseling for many tinnitus patients although it may not be beneficial in some.[11] However, a recent controlled study demonstrated that many tinnitus patients experienced improved quality of life from sound therapy alone.[12]

The rationale to use amplification and sound therapy for tinnitus management from the perceptual and psychological viewpoint is that this has been seen to impact tinnitus perception as they enable masking by ambient noise, reduce attention to tinnitus, and improve communication and quality of life.[13] Also, an argument can be made from the neurophysiological viewpoint that sound could prevent maladaptive neuroplastic changes resulting from cochlear insults.[14] However, due to the heterogeneous nature of hearing loss as well as tinnitus, it would be ideal to examine what kind of patients, based on their hearing loss and tinnitus characteristics, could benefit from amplification and sound therapy. While little is known in this area, a recent retrospective study that examined the efficacy of hearing aids for tinnitus management suggested that those who achieved complete masking of tinnitus with their hearing aids had a greater reduction in their tinnitus distress.[15] implying that the psychoacoustic properties of tinnitus may be useful in predicting the outcome of the tinnitus intervention.

Residual inhibition (RI) is one of the psychoacoustic measures of tinnitus, which is defined as a temporary decrease of tinnitus after a prolonged acoustic stimulation.[16,17] This post-masking effect/forward suppression can be classified as (a) complete (i.e., complete suppression of tinnitus); (b) partial (i.e., reduction in tinnitus loudness), and (c) negative (i.e., no change in tinnitus characteristics).[18,19] The duration and magnitude of tinnitus suppression depend on stimuli intensity, duration, and spectral characteristics. Sound-induced suppression of spontaneous activity has been observed in auditory nerve fibers and dependent on stimuli intensity and duration, much like RI. As the characteristics of RI and neural response suppression are similar, the suppression of hyperactivity at the central auditory neurons likely explains the brief suppression of tinnitus observed in a high percentage of tinnitus sufferers during RI.[3] Even real-world sounds, including human speech, may trigger this suppression, while subsequent sounds help maintain it.

There is very limited research on RI, even though RI is very impactful in many patients with tinnitus. RI is seen to vary from individual to individual; therefore, there may be other factors involved in achieving forward suppression from acoustic signals, which has not been studied yet. However, owing to its short-lived nature and subjective recording, RI is limited as a clinical research tool. RI can still be used to predict the success of tinnitus management with the help of amplification and sound therapy since these triggers forward suppression.

The current study was aimed at examining the benefit of combined amplification and sound therapy for individuals with tinnitus and coexisting hearing loss. Also, we examined if the RI would have any effect on hearing aids and sound therapy in combination. It was hypothesized that individuals with complete RI would demonstrate greater benefit from combined amplification and sound therapy when compared to individuals with partial and negative RI.

METHODS

Study Design and Participants

A retrospective chart review was performed on 98 consecutive patients with tinnitus and coexisting hearing loss who had visited our hearing clinic between January 2016 and December 2019. The inclusion criteria are individuals aged 18 years or over, hearing loss with tinnitus as the primary complaint, significant tinnitus with a Tinnitus Functional Index (TFI) score of 25 and above, and combined amplification and sound therapy as treatment. The following patients were excluded from this study: 7 patients with minimal hearing loss and 19 patients for whom records were inadequate. Eventually, a total of 72 patients were included in the study analysis. Thirty-four of these patients were previous hearing aid users. Ethical approval (IRB-FY21-34) was obtained.

Audiological Assessment

The audiological assessment of participants included detailed case history, assessment of hearing sensitivity, tinnitus psychoacoustic clinical tests, and assessment of tinnitus severity using self-reported outcome measures.

Hearing Sensitivity Assessment

The pure tone thresholds were obtained according to the modified Hughson–Westlake procedure for air conduction at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz and for bone conduction at 250, 500, 1000, 2000, and 4000 Hz (Interacoustics, AC40, Denmark). All subjects underwent tympanometry and acoustic reflexes as part of the audiological test battery approach (Interacoustics, AT235, Denmark).

Tinnitus Psychoacoustic Assessment

Tinnitus psychoacoustic measurements were performed in the ear where the tinnitus was lateralized, and in the better hearing ear if the tinnitus was bilateral or perceived in the head. Tinnitus pitch matching was performed before the tinnitus management paradigm, using a 2-alternative forced-choice (2AFC) method. The frequencies included for pitch matching were between 125 and 8000 Hz with 1/2 octave steps. All the subjects were asked to compare 2 different frequency tones presented at comfortable levels based on their audiometric results and then asked to detect a specific frequency tone, which was similar to their tinnitus pitch. Tinnitus pitch was narrowed down to the frequency tone, which was closest to their tinnitus pitch. Loudness matching was obtained for the tinnitus pitch-matched tone using the 2AFC method. The pitch-matched stimulus was presented at their comfort levels, and loudness was adjusted in small steps until the subjects stated that the loudness was identical to their tinnitus loudness.[16] Narrow-band noise was used as a masking sound

stimulus, and the minimum masking level (MML) was determined based on the level at which subjects indicated that the tinnitus is no longer detectable. RI was determined at the level of MML+10 dB presented for 60 seconds[16,17] and was recorded as complete, partial, and negative based on the post-masking effect.

Tinnitus Severity

The tinnitus severity was assessed using the 25-item self-reported outcome measure—TFI.[20] Each item is rated using a 10-point scale, and the overall score ranges between 0 and 100. TFI indicate high internal consistency ($\alpha = 0.80$) and extremely high reliability (ICC: 0.91). TFI was collected at 0, 1, and 6 months of intervention.

Intervention Amplification With Sound Therapy

All participants were fitted with a binaural open-fit receiver-in-the-canal hearing aid with tinnitus sound support feature and were also given informational counseling with regard to tinnitus management. The hearing aids were programmed based on their respective audiograms, and probe microphone measurements were carried out (Audioscan RM500SL, USA) to verify the hearing instruments' fitting. Amplification options such as speech focus, soft speech booster, and low compression processing strategy were optimized according to their audiometric configuration and lifestyle preferences. The primary amplification was created as program 1 (P1) and amplification plus sound therapy as program 2 (P2), where the therapeutic sound was chosen based on their reaction to various broadband sounds like ocean wave sound, white noise, or pink noise. The therapeutic sound level was set at low, so they do not interfere with speech. Participants were instructed to use programs according to their preferences, as frequently as was necessary.

Data Analysis

Descriptive analysis has been used to explore the data. Bonferroni-adjusted paired *t*-tests were used to assess the effect of hearing aid use in reducing tinnitus distress. A multilevel mixed-effects model was used to examine the treatment effects including both the main and interaction effects of time and RI on the tinnitus severity. Here, time was considered as the first level and subjects were considered as the second level. Statistical assumptions needed for all the above tests, including the normality, were tested and satisfied. Statistical analyses were performed using SAS version 9.4. All statistical tests were 2-sided and were performed using a significance (alpha) level of 0.01.

RESULTS

Study Population

The summary of the participant's demographic information is shown in Table 1. Males were predominant (86%) in this study since our clinic caters to many veterans and workers compensation board (WCB) patients. The average age of the participants was 58.3, which is relatively young due to the inclusion of WCB patients. 87% of them were married, 71% had an education up to high school or more, and 57% were employed. The average duration of tinnitus was 10.25 years. 50% of the participants have experienced ringing in their ears, and 31% of them had static sound. Most of the participants had mild to moderate sensorineural hearing loss with an average better ear pure tone average (PTA) of 35.7 dB hearing loss (HL). The average tinnitus severity using the TFI was 65.8, indicating severe tinnitus. Thirty-eight percent experienced partial RI, 36% had complete RI (36%), and

Table 1. Demographic Characteristics of the Study Participants

Characteristics	Mean ± SD	N (%)
Age (in years)	58.3 ± 9.62	
Sex		
Male		62 (86.1%)
Female		10 (13.9%)
Education		
High school or less		21 (29.2%)
High school or more		51 (70.8%)
Employment		
Employed		41 (56.9%)
Unemployed		31 (43.1%)
Hearing sensitivity		
Right ear PTA	35.8 ± 10.3	
Left ear PTA	36.6 ± 10.7	
Better ear PTA	35.7 ± 10.3	
Configuration of hearing loss		
Flat		15 (20.8%)
High frequency gradually sloping		39 (54.2%)
High frequency precipitously falling		18 (25%)
Tinnitus duration (in years)	10.25 ± 5.09	
Tinnitus severity (pre-intervention)		
Mild (TFI score of 25 or less)		0 (0.0%)
Significant (TFI score from 25 to 50)		7 (9.7%)
Severe (TFI score of 50 or greater)		65 (90.3%)
Tinnitus laterality		
Both		49 (68.1%)
Head		12 (16.7%)
Right		3 (4.1%)
Left		8 (11.1%)
Residual inhibition (RI)		
Complete		26 (36.1%)
Negative		19 (26.4%)
Partial		27 (37.5%)
Hearing aid model and style		
Oticon Alta 2 Pro RIC		4 (5.6%)
Oticon Nera 2 Pro RIC		10 (13.9%)
Oticon OPN 1 RIC		8 (11.1%)
Oticon OPN 2 RIC		7 (9.7%)
Oticon OPN 3 RIC		43 (59.7%)
Average hearing aid use per day (in hours)		
1 month	9:38 hours ± 3:43 hours	
6 months	10:26 hours ± 2:28 hours	
Hearing aid program use (% time)		
Program 1 at 1 month	70.8 ± 21.6	
Program 2 at 1 month	29.2 ± 21.6	
Program 1 at 6 months	79.3 ± 20.5	
Program 2 at 6 months	20.7 ± 20.5	

PTA, Pure Tone Average; TFI, Tinnitus Functional Index; RIC, Receiver in canal.

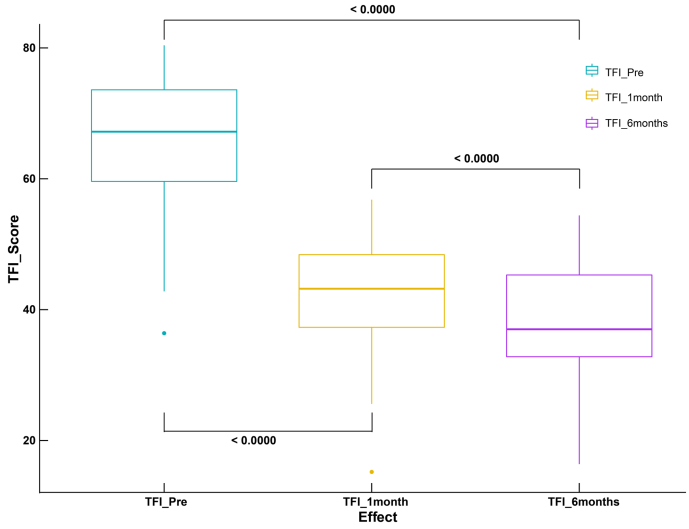

Figure 1. Tinnitus severity before and after hearing aid sound therapy. Bonferroni-adjusted paired *t*-tests were performed between each intervention and corresponding *P* values indicate significant reduction from pre- to 1-month postintervention, pre- to 6-month postintervention, and 1-month to 6-month postintervention.

26% had negative RI. The average hearing aid use was 10 hours per day. The average hearing aid usage with program 1 after 1 month and 6 months was 71% and 80%, respectively.

Hearing Aid Sound Therapy Treatment Effects

The average TFI score at 0, 1, and 6 months of the intervention was 65.8 (SD = 9.89), 42.4 (SD = 7.82), and 38.2 (SD = 7.92), respectively (Figure 1). Of the 72 participants, 76% and 85% had clinically significant change (13-point change in TFI) at 1-month and 6-month postintervention, respectively, with the average change in TFI from baseline to 1 month being 23.4 (SD = 13) and from baseline to 6 months being 27.5 (SD = 14). The average tinnitus severity score differences were tested using Bonferroni-adjusted *t*-tests, and effect sizes were measured using Cohen's *D*. All 3 comparisons from baseline to 1 month (effect size:1.8, Bonferroni-adjusted *P* value < .00001), baseline to 6 months (effect size: 2.1, Bonferroni-adjusted *P* value < .00001) and 1 month to 6 months (effect size: 1.4, Bonferroni-adjusted *P* value < .00001) show significant reductions in the scores (Figure 1).

The multilevel mixed-effects model analysis was used to assess the effect of RI, and the intervention over time on the TFI score (Table 2). Out of several competing mixed models, we have selected the one with the lowest Akaike information criteria (AIC) and Bayesian information criteria (BIC) along with statistically/clinically significant variables. The model suggested that the main effects of time (*P* value < .0001) and RI (*P* value .0015) along with their interaction (*P* value:<.0001) were significant. Participants had significant benefits from amplification and sound therapy irrespective of the RI, although the RI affected the level of benefit (Figure 2).

Of the participants with negative RI, 63% and 74% had a clinically significant change at 1-month and 6-month postintervention, similarly, 70% and 78% in the partial RI group, and 92% and 100% in the complete RI group, respectively. Thereby, those with complete RI had the highest benefit from amplification and sound therapy when compared to those with partial and negative RI. A post hoc power analysis for mixed models was conducted using simr package in R. According to that, with the current sample size and alpha 0.05, the model has a power of 100% (95% CI, 96.38%, 100%) in detecting effect from the amplification and sound therapy intervention effect.

Table 2. Multilevel Mixed-Effects Model Exploring the Effect of Sound Therapy (Level 1, Time; Level 2, Residual Inhibition [RI])

Fixed Effect	Category	Parameter Estimate (SE, *P*)
Intercept		63.85 (2.22, <.0001)
Time	Pre	Ref
	Post_1month	−15.22 (2.66, <.0001)
	Post_6month	−18.27 (2.56, <.0001)
RI	Negative	Ref
	Partial	0.01 (2.90, .9962)
	Complete	5.32 (2.92, .0734)
Time*RI	Post_1month*Negative	Ref
	Post_1month*Partial	−6.9 (3.48, .0512)
	Post_1month*Complete	−15.36 (3.50, <.0001)
	Post_6month*Negative	Ref
	Post_6month*Partial	−6.69 (3.35, .0495)
	Post_6month*Complete	−18.7 (3.37, <.0001)
Model fit	Akaike information criterion	1320.9
	Bayesian information criterion	1334.6

RI, Residual Inhibition.

DISCUSSION

The study examined the benefit of amplification and sound therapy in individuals with hearing loss and tinnitus as the primary complaint and the effect of RI on amplification and sound therapy. The study results suggest that amplification and sound therapy are beneficial

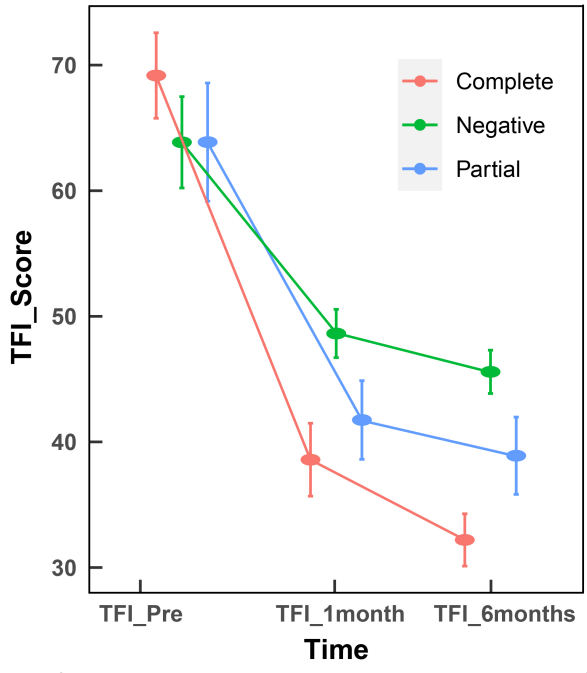

Figure 2. The variation in tinnitus severity among participant groups based on their residual inhibition. The error bar represents the 95% CI associated with each time interval.

for individuals with tinnitus and coexisting hearing loss. Also, these benefits are higher in people with complete RI than those with partial and negative RI.

Effect of Amplification and Sound Therapy

Hearing aid amplification is recommended as a treatment option for individuals with hearing loss who also report bothersome tinnitus.[21,22] McNeill et al[15] based on observational study results recommended that the hearing aid fitting can reduce the tinnitus impact in patients with tinnitus and hearing loss, with better low-frequency hearing and a strong reaction to tinnitus yielding better prognosis. The current study participants also had better low-frequency hearing and had severe tinnitus, similar to the abovementioned study, hence yielding a better prognosis. Hearing aids are reported to bring perceptual changes to tinnitus, and these changes in tinnitus perception may arise from either the extent of hearing deficits or the duration and robustness of the neuroplastic changes that originally give rise to tinnitus.[23]

With the advancement of technology, hearing aids have inbuilt sound therapy features, which allows for the usage of amplification and sound therapy, either separately or as combination therapy, to reduce the impact of tinnitus.[24] In the current study, combined amplification and sound therapy resulted in a clinically significant change in 76% and 85% at 1-month and 6-month postintervention, respectively, which is in accordance with other studies.[7,8] However, there is some controversy on the benefit of combined amplification and sound therapy over amplification alone in tinnitus management. For example, a study by Santos et al[25] showed combined amplification and sound therapy to be effective in reducing the tinnitus impact compared to amplification alone. However, these results were not replicated in a controlled trial, where the difference in the reduction of tinnitus annoyance between the combined fitting group and amplification alone group was not statistically significant.[26] Sound therapy can still be recommended as a practical management option for individuals with tinnitus, since a recent controlled study demonstrated tinnitus relief from sound therapy alone, using partial masking.[12]

Effect of Residual Inhibition

Although the combined amplification and sound therapy is reported to benefit individuals with tinnitus and coexisting hearing loss, there is limited research on which type of patient groups would be more suitable for this treatment approach based on the characteristics of the tinnitus. McNeill et al[15] suggested that participants who achieved tinnitus masking with their hearing aids had a greater reduction in tinnitus severity. A clinically significant change was achieved by 51% of its participants. However, on examining the results more closely, it was noted that clinically significant change was noted in 100% of the total masking group, 36% in the partial masking group, and none in the no masking group. In the current study, the treatment effect differed between tinnitus patient groups based on their RI. 100%, 78%, and 74% of patients from complete, partial, and negative RI groups were found to have a clinically significant change at 6-month postintervention, respectively. Moreover, participants with complete RI had a higher reduction in tinnitus severity when compared to the other 2 groups, which is similar to the above study. Although all 3 RI groups had significant improvement with intervention, the complete RI group showed better improvement in TFI subscales such as relaxation, quality of life, and emotional distress. This may be explained by the fact that hearing difficulties in this group may be more due to hearing loss rather than tinnitus, whereas the reverse may be true in the other 2 groups. It may also be due to individual personalities whereby sound responsiveness or sensitivity may differ from individual to individual.[27] This may be the reason why partial and negative RI groups have used program 2 more than the complete RI group.

Therapeutic sounds used for sound therapy may vary depending on their temporal, spectral, and emotion-evoking characteristics.[27] With the flexibility of hearing aid technology, clinicians can offer true sound therapy personalization. Individuals with hearing difficulties due to tinnitus may require both amplification and sound therapy. Psychosocial factors such as stress, anxiety, lifestyle preferences, sleep disturbances, and age play a major role in influencing management strategies. A recent study demonstrated tinnitus benefits with sound therapy alone especially in the areas of sleep, thoughts, emotions, and concentrations,[12] so clinicians can encourage tinnitus patients to use sound therapy programs whenever psychosocial parameters are compromised.

This study has a few limitations. First, the study is likely to have some sampling bias as the study included individuals with severe tinnitus and who had it on an average for over 10 years. Second, as an observational study, there was no control group and no blinding, which is likely to have resulted in some placebo effect. Third, this is a retrospective analysis, which may present limitations on the interpretation of the study.

CONCLUSION

The current study provides some preliminary evidence for the benefit of amplification and sound therapy in individuals with tinnitus and hearing loss. 85% had significant benefits from amplification and sound therapy, and this benefit was more in individuals with complete RI. Clinicians may encourage the use of sound therapy whenever psychosocial parameters are compromised. Finally, the results need to be treated as tentative until they are further confirmed via experimental studies.

Ethics Committee Approval: Ethical approval (IRB-FY21-34) was obtained from Lamar University's Institutional Review Board (IRB).

Informed Consent: Informed consent is not necessary due to retrospective nature of the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – P.G; V.M.; S.S.; Design - V.M.; S.S; Supervision - V.M.; R.R.; Resource - J.S.; P.G.; V.M.; Materials - P.G.; S.S.; J.S.; R.R.; Data Collection and/or Processing - P.G; J.S.; R.R.; H.R; Analysis and/or Interpretation - H.R.; V.M.; Literature Search - P.G.; V.M.; J.S.; Writing - P.G.; S.S.; J.S. R.R.; Critical Reviews - V.M.; H.R.; R.R.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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