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Original Article

Tinnitus and Health-Related Quality of Life After Gamma Knife Radiosurgery for Vestibular Schwannoma

Chai Yoon Kim, Won Jae Lee, Jung-Won Choi, Doo-Sik Kong, Ho Jun Seol, Do-Hyun Nam, Jung-Il Lee

Department of Neurosurgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea

ORCID iDs of the authors: C.Y.K. 0000-0002-9781-2691, W.J.L. 0000-0003-0653-8568, J-W.C. 0000-0002-7425-6784, D-S.K. 0000-0002-7519-3594, H.J.S. 0000-0003-4187-054X, D-H.N. 0000-0002-8477-6791, J-I.L. 0000-0001-8143-5513.

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BACKGROUND: Tinnitus is a common symptom in patients with vestibular schwannoma (VS). The impact of Gamma Knife radiosurgery (GKRS) on tinnitus and the health-related quality of life (HRQoL) of patients with VS remains unclear. This study evaluated the effect of GKRS on HRQoL affected by tinnitus.

METHODS: From December 2020 to April 2022, spontaneous VS patients who had no prior history of treatment and underwent their first GKRS in this period were analyzed. Subjective distress from tinnitus was measured by the Tinnitus Handicap Inventory (THI) and their HRQoL by 36-Item Short Form Survey Version 2 (SF-36v2). Pre-GKRS THI and SF-36v2 were obtained, and after GKRS, consecutive THI and SF-36v2 were obtained during the follow-up period. Bowker's test, paired Student's *t*-test, and Spearman's correlation were used to analyze the changes in THI grade, SF-36v2 score, and the correlation between THI grade and SF-36v2 score. Factors affecting the THI grade change and SF-36v2 score were evaluated through univariate and multivariate models.

RESULTS: Twenty of 34 patients showed serviceable hearing before GKRS. The median radiation dose of GKRS was 12.75 Gy (range, 12-21 Gy). Twenty-two of 33 patients demonstrated no change or worse THI grade after GKRS, but the change was not statistically significant ($P = .34$). However, with age, the odds ratio of THI improvement is 0.905 (95% CI 0.83-0.98, $P = .02$). Patients with serviceable hearing before GKRS displayed THI grade improvement (OR = 6.721; $P = .03$). Compared to those with pre-GKRS THI grade 1, grades 3 and 4 exhibited lower odds of THI improvement (OR = 0.095; $P = .0449$). No significant change was noted in SF-36v2 scores after GKRS. A high THI grade was correlated with a low physical component score ($P = .03$) and mental component score ($P = .0002$) of SF-36v2.

CONCLUSION: Although THI grade and SF-36v2 change before and after GKRS did not show statistical significance, several factors affected THI grade change. Moreover, the THI grade and SF-36v2 score had a significant negative correlation. Factors that may aggravate tinnitus and further impact HRQoL of VS patients should be taken into account when planning treatment and providing counseling to VS patients.

KEYWORDS: 36-Item Short-Form Health Survey, Gamma Knife radiosurgery, health-related quality of life, tinnitus, Tinnitus Handicap Inventory

INTRODUCTION

Tinnitus is a subjective perception of sound without an external acoustic stimulus. It presents in approximately 45%-75% of patients with vestibular schwannoma (VS). In 10%-12% of VS patients, tinnitus is a primary presenting symptom[1] causing considerable distress. A prospective study demonstrated that the severity of distress in VS patients, measured by the 36-Item Short-Form Health Survey (SF-36), was mostly impacted by the Tinnitus Handicap Inventory (THI) grade than by the Dizziness Handicap Inventory grade or visual analog scale (VAS) score for hearing impairment. Moreover, tinnitus significantly affects subjective hearing impairment and the degree of anxiety and depression.[2] However, due to its subjective and innocuous nature, the influence of tinnitus on patients is frequently overlooked during both the preoperative and postoperative stages. As the primary goal for the intervention of VS is focused on the preservation of facial nerve function, hearing, and health-related quality of life (HRQoL), changes in tinnitus after treatment should also be further examined.[3] Previous studies have assessed changes in tinnitus after the surgical

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removal of VS. Although the results have varied, several studies have demonstrated that tinnitus improves after surgery, regardless of the approach.[4] Some studies have identified that preserving the cochlear nerve without useful hearing aggravates tinnitus[5] and increases the THI score.[6] One study displayed that the THI and VAS scores significantly increased following Gamma Knife radiosurgery (GKRS), in contrast to the decreased scores in the surgery group.[7] However, no published studies are available regarding the impact of GKRS on tinnitus and its further impact on HRQoL. Thus, this retrospective study was designed to investigate changes in tinnitus and HRQoL after GKRS in patients with VS at our institution.

METHODS

Of the patients with VS who came to our clinic between December 2020 and April 2022, those who underwent their first GKRS in this period were selected for this retrospective study. The study excluded patients with bilateral VS, those who underwent any prior treatment, or those who received no treatment. Subjective discomfort due to tinnitus was measured using the grades of THI and scores of SF-36 version 2 (SF-36v2). This study was approved by Samsung Medical Center Institutional Review Board (no. 2020-10-152, date: 04.11.2020). Written informed consent was obtained from the patients for the collection, analysis, and publication of their anonymized data for this non-interventional study.

The THI is a 25-item self-reported questionnaire that evaluates functional, emotional, and catastrophic subscales affected by tinnitus. The questionnaire demonstrates high convergent validity, construct validity, and retest reliability.[8] Grading for the THI was based on the guidelines suggested in *Clinical Otolaryngology*.[8] The change in THI grade was analyzed, with a high grade implicating higher subjective distress due to tinnitus. A questionnaire was filled out incompletely, thus excluded from the analysis.

SF-36 version 2 is a self-reported, general health status measure with the following 8 subscales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH).[9] The physical component summary (PCS) score is the average score of the PF, RP, BP, and GH subscales, and the mental component summary (MCS) score is the average score of the VT, SF, RE, and MH subscales. High PCS and MCS scores indicate better subjective HRQoL. Three PCS scores and 1 MCS score were excluded from the analysis due to incompletely filled out questionnaires.

Tinnitus Handicap Inventory grades and SF-36v2 scores were obtained before and after GKRS, with consecutive assessments performed during regular follow-up. The follow-up interval and the number of follow-up evaluations were not consistent due to variable compliance of the patients. However, the final follow-up period was November 2022, with the median interval between the final and initial assessments being 273 days (range, 74-703 days) for the THI grade, 231 days (59-599 days) for the PCS score, and 234 days (74-599 days) for the MCS score.

SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for statistical analysis. Changes in the THI grade before and after GKRS were statistically evaluated using Bowker's test. Changes in the MCS and PCS scores were analyzed using paired Student's *t*-tests. The correlations between the THI grade and the PCS and MCS scores were assessed using Spearman's correlation. Finally, factors affecting the changes in THI grade and PCS and MCS scores were investigated using univariate and multivariate models. Throughout these analyses, *P*-values less than .05 were considered statistically significant.

RESULTS

Between December 2020 and April 2022, 34 patients underwent GKRS for VS and completed the THI and SF-36v2 surveys before and after GKRS. The median age of the patients was 57.5 years (range, 34-80 years) with 9 males and 25 females. Pure-tone audiometry and speech audiometry were performed at the time of diagnosis. Twenty patients had serviceable hearing, whereas 14 patients had non-serviceable hearing. Twenty five of the 34 patients underwent single GKRS, and 9 patients underwent 3-fraction GKRS. The median radiation dose was 12.75 Gy (range, 12-21 Gy), with a median prescription isodose volume of 2265.50 cm^3 (range, 254.00-12 835.00 cm^3). The median tumor volume was 1847.50 cm^3, with 41.2% of patients displaying Koos grade 3. After GKRS, several consecutive THI and SF-36v2 questionnaires were implemented. As the follow-up time interval varied due to variable compliance, the pre-GKRS and final post-GKRS THI grades and PCS and MCS scores were evaluated. The median time between the pre-GKRS and final post-GKRS THI grade and SF-36v2 score was 9.1 and 7.7 months, respectively. The patient characteristics are summarized in Table 1.

Tinnitus Handicap Inventory Grade

The pre-GKRS THI assessment was performed before GKRS treatment and the final post-GKRS THI assessment was performed after a median interval of 9.1 months. The first THI assessment demonstrated a median score of 35 (range, 0-86), corresponding to a THI grade of 2 according to *Clinical Otolaryngology*.[8] Eleven of the 33 patients displayed pre-GKRS THI grade 1, 7 patients demonstrated grade 3 or 4, and 6 patients displayed grade 2. The final post-GKRS THI assessment displayed a median score of 40 (range, 0-88), corresponding to a THI grade of 3. Fourteen of the 33 patients displayed THI grade 3, with 12 patients demonstrating THI grade 2. Table 2 displays the change in THI grade from first to the last THI assessment and its proportion. Eleven of the 33 patients exhibited lower THI grade after GKRS, indicating less discomfort caused by tinnitus, whereas 22 patients exhibited no change or a worse THI grade. However, no statistically significant change was observed in THI grade ($P = .34$). Furthermore, considering the minimal clinically important differences (MCIDs) of THI score suggested by Zeman et al,[10] median score between pre-GKRS and final post-GKRS THI score demonstrates no change.

To determine the factors affecting the decrease in the THI score, indicating an improvement in subjective distress caused by tinnitus, age, sex, hearing at the time of diagnosis, Koos grade, tumor volume, radiation dose, prescription isodose volume, time between the pre-GKRS and the final post-GKRS THI assessment, and the pre-GKRS THI grade were evaluated (Table 3). Among these factors, age, hearing at the time of diagnosis, and a pre-GKRS THI grade of 3 and 4 demonstrated statistical significance. As the age increased, the odds of a THI score improvement decreased (odds ratio [OR] = 0.905, $P = .02$). Compared to patients with non-serviceable hearing at the time of diagnosis, those with serviceable hearing displayed a significant decrease in the THI score (OR = 6.721, $P = .03$). Patients with an initial THI grade of 3 or 4 demonstrated a significant difference in THI score improvement

Table 1. Patient Characteristics

	N (%)	Mean ± SD or Median (Q1, Q3) (min, max)
Age	34	57.50 (47.00, 63.00) (34.00, 80.00)
Sex		
Male	9 (26.5)	
Female	25 (73.5)	
Hearing at the time of diagnosis		
Nonserviceable	14 (41.2)	
Serviceable	20 (58.8)	
GKRS Fraction		
Single GKRS	25 (73.5)	
Fractionated GKRS	9 (26.5)	
Radiation dose (Gy)		12.75 (12.00, 19.50) (12.00, 21.00)
Prescription isodose volume		2265.50 (702.00, 4294.00) (254.00, 12835.00)
Tumor volume (cm^3)		1847.50 (412.00, 3222.00) (171.00, 12404.00)
Koos grade		
1	6 (17.6)	
2	9 (26.5)	
3	14 (41.2)	
4	5 (14.7)	
Interval time between pre-GKRS and last post-GKRS THI (days)		273.00 (217.00, 410.00) (74.00, 703.00)
First THI score		37.294 ± 26.067, 35.00 (14.00, 58.00) (0.00, 86.00)
Last THI score		38.242 ± 20.444, 40.00 (24.00, 52.00) (0.00, 88.00)
Interval time between pre-GKRS and last post-GKRS PCS (days)		231.00 (196.00, 382.00) (59.00, 599.00)
Interval time between pre-GKRS and last post-GKRS MCS (days)		234.00 (214.00, 382.00) (74.00, 599.00)

GKRS, Gamma Knife radiosurgery, THI, Tinnitus Handicap Inventory, PCS, physical component score, MCS, mental component score.

compared to those with a THI grade of 1 (OR = 0.095, $P = .04$). In the multivariate model incorporating age and hearing at diagnosis, age (OR = 0.913, $P = .04$) retained a significant influence on the THI score improvement, while serviceable hearing did not.

Eighteen of 39 patients had been followed-up with pure-tone audiometry and speech audiometry after GKRS. As demonstrated in Table 4, among those who maintained serviceable hearing after GKRS, 5 patients present increased THI grade, whereas 2 patients show decreased THI grade. In patients who had serviceable hearing but their last follow-up test showing non-serviceable hearing, 1 shows alleviation and aggravation of THI grade, with 3 patients showing no difference in THI grade. Lastly, among patients who had non-serviceable hearing before and after GKRS, 2 patients presented decreased, increased, and no difference in THI grade change.

36-Item Short Form Survey Version 2 Score

The SF-36v2 score was also assessed along with the separate analysis of pre-GKRS and final post-GKRS PCS and MCS scores. As summarized in Table 5, the mean pre-GKRS and final post-GKRS PCS scores were 67.693 ± 17.298 and 63.914 ± 17.215, respectively. The mean pre-GKRS and final post-GKRS MCS scores were 68.521 ± 16.514 and 66.570 ± 19.824, respectively. Both PCS and MCS scores did not exhibit significant *P*-values in change between pre-GKRS and final post-GKRS state. Also considering MCID in PCS and MCS score suggested in Carlson et al,[11] mean score between pre-GKRS and final post-GKRS does not show significant change. According to Han et al,[9] the norm-based PCS and MCS scores in healthy individuals in Korea are 70.6 and 72.64, and for individuals with chronic disease, the scores are 43.81 and 48.47, respectively. This demonstrates that the PCS and MCS scores for patients with VS with tinnitus are higher than the scores for individuals with chronic disease but lower than the scores for healthy individuals in Korea.

Factors affecting the changes in PCS and MCS scores were evaluated using a univariate model, similar to the THI grade. As summarized in Table 6, as the pre-GKRS PCS score increased, the difference between the final post-GKRS score and the pre-GKRS PCS score significantly decreased by 0.404 ($P = .01$). For the MCS score, as the radiation dose increased, the difference between the final post-GKRS score and the pre-GKRS MCS score decreased significantly by 1.441 ($P = .03$).

Table 2. Change in Tinnitus Handicap Inventory Grade

Pre-GKRS THI Grade	Last Post-GKRS THI Grade						
	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	Total (%)	*P*
1	3 (8.82)	7 (20.59)	1 (2.94)	0 (0.00)	0 (0.00)	11 (33.33)	.3447
2	1 (2.94)	2 (5.88)	2 (5.88)	1 (2.94)	0 (0.00)	6 (18.18)	
3	0 (0.00)	2 (5.88)	4 (11.76)	1 (2.94)	0 (0.00)	7 (21.21)	
4	0 (0.00)	1 (2.94)	5 (14.71)	0 (0.00)	1 (2.94)	7 (21.21)	
5	0 (0.00)	0 (0.00)	2 (5.88)	0 (0.00)	0 (0.00)	2 (6.06)	
Total	4 (12.12)	12 (36.36)	14 (42.42)	2 (6.06)	1 (3.03)	33 (100.0)	

GKRS, Gamma Knife radiosurgery, THI, Tinnitus Handicap Inventory.

Table 3. Factors Affecting Decrease in Tinnitus Handicap Inventory Score

Univariable Model		
	OR (95% CI)	***P***
Age	0.905 (0.833-0.983)	.0177
Sex		
M	Reference	
F	1.429 (0.287-7.118)	.6634
Hearing at the time of diagnosis		
Nonserviceable	Reference	
Serviceable	6.721 (1.174-38.492)	.0324
Koos grade		
1	Reference	
2	1.200 (0.130-11.052)	.8721
3	1.125 (0.141-8.995)	.9116
4	0.375 (0.022-6.348)	.4968
Tumor volume	1.000 (1.000-1.000)	.9075
Radiation dose	1.116 (0.924-1.348)	.2555
Prescription isodose volume	1.000 (1.000-1.000)	.9859
Interval time between pre-GKRS and last post-GKRS THI	0.995 (0.990-1.001)	.104
First THI grade		
1	Reference	
2	0.412 (0.052-3.237)	.399
3	0.095 (0.010-0.948)	.0449
4	0.095 (0.010-0.948)	.0449
5	0.082 (0.002-4.233)	.2142
Multivariable Model		
	OR (95% CI)	*P*
Age	0.913 (0.835-0.999)	.0487
Hearing at the time of diagnosis		
Nonserviceable	Reference	
Serviceable	4.522 (0.666-30.685)	.1224

GKRS, Gamma Knife radiosurgery, THI, Tinnitus Handicap Inventory.

Table 4. Change in Hearing and Tinnitus Handicap Inventory Grade

		THI Grade Change (Last Post-GKRS THI – Pre-GKRS THI)		
Pre-GKRS Hearing	**Post-GKRS Hearing**	**Decreased (n)**	**No difference (n)**	**Increased (n)**
Serviceable	Serviceable	2	0	5
Serviceable	Non-serviceable	1	3	1
Non-serviceable	Non-serviceable	2	2	2

GKRS, Gamma Knife radiosurgery, THI, Tinnitus Handicap Inventory.

Correlation Between Tinnitus Handicap Inventory Grade and 36-Item Short Form Survey Version 2 Score

Data were analyzed to identify correlations between MCS and PCS scores and THI grade (Table 7). As the pre-GKRS THI grade increased, the pre-GKRS PCS and MCS scores significantly decreased ($P = .01$ for both). The final post-GKRS THI grade and post-GKRS PCS and MCS scores also demonstrated a significant negative correlation ($P = .03$ and $P < .01$, respectively).

Table 5. Change in Mental Component Summary and Physical Component Summary Score

	Pre-GKRS Score	**Last Post-GKRS Score**	**Change (95% CI)**	***P***
PCS (n = 31)	67.693 ± 17.298	63.914 ± 17.215	−3.779 (−9.446 to −1.887)	.1833
MCS (n = 33)	68.521 ± 16.514	66.570 ± 19.824	−1.951 (−7.139 to −3.237)	.4493

GKRS, Gamma Knife radiosurgery.

Table 6. Factors Affecting Change in Physical Component Score and Mental Component Score

Univariable Model				
	PCS		**MCS**	
	Beta (SE)	***P***	**Beta (SE)**	***P***
Age	−0.062 (0.263)	0.8155	0.404 (0.218)	.0734
Sex				
M	Reference		Reference	
F	−9.148 (6.532)	0.172	−8.901 (5.823)	.1365
Hearing at the time of diagnosis				
Nonserviceable	Reference		Reference	
Serviceable	0.042 (5.898)	0.9944	−2.134 (5.282)	.689
Koos Grade				
1	Reference		Reference	
2	−1.125 (9.271)	0.9043	3.305 (8.197)	.6897
3	−1.081 (8.472)	0.8994	4.518 (7.406)	.5466
4	−2.921 (10.909)	0.7909	−1.246 (9.190)	.8931
Tumor volume	−0.001 (0.001)	0.2227	−0.001 (0.001)	.3637
Radiation dose	−1.296 (0.707)	0.0771	−1.441 (0.650)	.0341
Prescription isodose volume	−0.001 (0.001)	0.2503	−0.001 (0.001)	.4184
Interval time between pre-GKRS and last post-GKRS score	0.005 (0.020)	0.8121	−0.015 (0.020)	.4639
Pre-GKRS score	−0.404 (0.148)	0.0107	−0.172 (0.156)	.2793

GKRS, Gamma Knife radiosurgery, PCS, physical component score, MCS, mental component score.

DISCUSSION

Overall, no significant changes were observed in the THI grade or SF-36v2 score after GKRS. No significant changes were observed in the median THI score and mean PCS and MCS scores in light of MCIDs of THI and SF-36v2. However, 67% of patients displayed no change or a worsening of THI grade, with an increasing trend in the median THI grade after GKRS. Although a large study population and a standardized follow-up period should yield accurate results, these findings indicate the worsening of subjective discomfort post-GKRS, as reported in other studies. Park et al[7] discovered that, compared to the surgical group, the GKRS group displayed a higher rate of worsening

Table 7. Correlation Between Tinnitus Handicap Inventory Grade and 36-Item Short Form Survey Version 2 Score

	Pre-GKRS THI Grade		Last Post-GKRS THI Grade	
	r (95% CI)	*P*	*r* (95% CI)	*P*
PCS	−0.438 (−0.675 to −0.104)	0.0102	−0.388 (−0.649 to −0.033)	.0302
MCS	−0.434 (−0.670 to −0.106)	0.0097	−0.592 (−0.776 to −0.298)	.0002

GKRS, Gamma Knife radiosurgery, THI, Tinnitus Handicap Inventory., PCS, physical component score, MCS, mental component score.

of tinnitus and an increase in THI and VAS scores. The aggravation of tinnitus following GKRS may be caused by direct radiotoxicity affecting the cochlear nerve. However, the pathophysiology of tinnitus is still controversial and multifactorial. Some studies have reported that, although the cochlear nerve is resected during microsurgery, tinnitus remained in 73% of patients and was unchanged in 37% of patients.[5] Moreover, 91% of patients without preoperative tinnitus did not develop postoperative tinnitus.[5] This may be explained by the fact that not only could tinnitus arise from the continuous firing of auditory nerve fibers, but cochlear nuclear dysfunction caused by brainstem compression or cortical reorganization after severe sensorineural hearing loss might trigger tinnitus. This may cause persistent tinnitus, regardless of cochlear nerve resection.[12] The findings of this study support this hypothesis. Increasing age, a moderate THI grade of 3 or 4, and non-serviceable hearing before GKRS were significant factors predicting the odds of no improvement or worsening of THI grade after GKRS. Long-lasting brainstem compression or extended tumor presence, allowing for cortical reorganization of the hearing pathway, might play a significant role in initiating tinnitus than direct stimulation of the cochlear nerve.

Investigating the correlation between changes in hearing and THI score would aid in predicting the effect of GKRS on tinnitus. In this study, the period when pure tone audiometry and speech audiometry were obtained after GKRS did not correspond with the last THI follow-up period nor obtained after regular time interval. However, it is interesting that patients showing deterioration of hearing from serviceable to non-serviceable hearing did not all present with aggravation, but majority showed no difference in THI grade. Moreover, those maintaining serviceable hearing after GKRS showed more patients with aggravation of THI grade rather than alleviation. Changes in hearing might be a confounding factor affecting THI grade and thus should be further studied with a larger study population and objective measurement of hearing change.

Regarding the PCS and MCS subscores of the SF-36v2, it was identified that when the pre-GKRS PCS score was high, the difference between the final post-GKRS score and the pre-GKRS PCS score decreased. This implied that the difference in PCS score before and after GKRS was significant when the physical HRQoL was low beforehand. However, the difference between the final post-GKRS and pre-GKRS MCS scores tended to decrease as the radiation dose increased. This may indicate that a radiation dose above a specific threshold does not cause a significant change in tinnitus. Although no statistically significant changes were observed in the PCS and MCS scores, the decreasing trend in both the PCS and MCS scores after GKRS is noteworthy. Additionally, the THI grade and PCS and MCS scores demonstrated significant negative correlations. This indicates that subjective distress caused by tinnitus impacts the HRQoL of patients. Therefore, further investigation of the pathophysiology and course of tinnitus after GKRS in patients with VS is warranted and should be considered when planning treatment for such patients.

CONCLUSION

This study evaluates the effect of tinnitus on the HRQoL QOL of patients with VS and its change after GKRS. Although the THI grade and SF-36v2 score before and after GKRS did not display significant differences, age, a THI grade of 3 or 4**,** and non-serviceable hearing exhibited low odds of THI grade improvement. Furthermore, the correlation between THI grade and SF-36v2 score implied a significant impact on the patient's HRQoL due to tinnitus than is commonly anticipated. Long-term follow-up data from a large study population, coupled with assessments of objective measurements of tinnitus and high patient compliance, could provide insights into the impact of GKRS on tinnitus and the HRQoL for patients with VS. This would further aid in planning treatment and providing counseling to patients with VS.

Data Availability Statement: All relevant data are available in the article and no additional source data are required. Raw data of this study are available from the corresponding author upon reasonable request.

Ethics Committee Approval: This study was approved by the Ethics Committee of Samsung Medical Center (Approval no: 2020-10-152; Date: 04.11.2020).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

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