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Hemorrhagic Risk in Vestibular Schwannoma Surgeries: Insights and Implications

Authors' Contribution:

Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEF 1 **Alper Tabanlı**
ABCEFG 2 **Hakan Yılmaz** 
ABFG 1 **Emrah Akçay** 
ACEG 2 **Hüseyin Berk Benek** 
BDF 3 **Ibrahim Burak Atci** 
ABDE 4 **Mesut Mete** 

1 Department of Neurosurgery, Izmir Tinaztepe University Faculty of Medicine, Izmir, Türkiye
2 Department of Neurosurgery, Izmir Health Sciences University Faculty of Medicine, Izmir, Türkiye
3 Department of Neurosurgery, Istanbul Health Sciences University Faculty of Medicine, Istanbul, Türkiye
4 Department of Neurosurgery, Celal Bayar University Faculty of Medicine, Manisa, Türkiye

Corresponding Author: Alper Tabanlı, e-mail: dralpertabani@hotmail.com

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Background: Vestibular schwannoma is a slow-growing benign tumor arising from the 8th cranial nerve. It can originate in the cerebellopontine angle (CPA). This retrospective study aimed to investigate the factors associated with outcomes following surgical resection of vestibular schwannoma in the CPA in 30 patients at a single center in Turkey, focusing on postoperative intratumoral hemorrhage.

Material/Methods: Thirty patients (mean age 42.8 years, range 17-81) underwent vestibular schwannoma surgery via a lateral sub-occipital retrosigmoid approach. Patients were categorized as 'less bleeding' (n=15) or 'more bleeding' (n=15) based on the intraoperative nature of the tumor. Demographic characteristics, tumor size, extent of resection, postoperative intratumor bleeding rates, morbidity, and mortality were evaluated.

Results: Mean tumor size was significantly larger in highly hemorrhagic tumors (3.8 cm, range 2.1-5 cm) compared with less hemorrhagic tumors (2.1 cm, range 1.8-3 cm) ($P<0.001$). Total resection was achieved in 60% of patients with highly hemorrhagic tumors >3 cm and chronic diseases, compared with 80% in less hemorrhagic tumors ($P=0.02$). Postoperative intratumoral hemorrhage occurred in 83.3% of subtotal resections in highly hemorrhagic tumors, versus 6.7% in less hemorrhagic tumors ($P<0.001$).

Conclusions: Larger vestibular schwannoma size is associated with increased hemorrhagic nature, complicating total resection. Subtotal resection in hemorrhagic tumors significantly increases the risk of postoperative bleeding and edema. When possible, total removal should be attempted to minimize complications. In cases requiring subtotal excision, careful postoperative management of coagulation and blood pressure is crucial.

Keywords: **Edema • Hemorrhage • Schwann Cells**

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Introduction

Vestibular schwannomas are benign intracranial neoplasms originating from the Schwann cells in the superior and inferior vestibular nerve within the cerebellopontine angle (CPA) area [1]. These tumors cause slowly progressive deafness, tinnitus, vertigo, and balance disorders, profoundly affecting patients' quality of life [2,3].

The CPA can harbor various tumors, including meningiomas, epidermoid cysts, and primary cholesteatomas, alongside vestibular schwannoma [4]. However, vestibular schwannoma accounts for approximately 80-90% of CPA tumors [5]. Management of CPA tumors presents unique challenges due to their proximity to critical neurovascular structures and the risk of postoperative complications [6].

The incidence of vestibular schwannoma is estimated at 1-2 per 100 000 person-years [7]. Patients typically present with unilateral hearing loss, tinnitus, and balance disturbances [8]. Diagnosis relies on magnetic resonance imaging (MRI) with gadolinium enhancement [9]. Management options include observation, surgical resection, or stereotactic radiosurgery, based on tumor size, patient age, and overall health [10].

Surgical resection of vestibular schwannoma, especially large tumors, is complex due to the tumor's proximity to vital structures and potential postoperative complications [11]. Intratumoral hemorrhage and peritumoral edema can significantly increase postoperative morbidity and negatively impact long-term clinical outcomes [12,13]. These complications necessitate meticulous surgical approaches and continuous intraoperative assessment [14].

Previous studies have investigated various aspects of vestibular schwannoma surgery. For instance, Khan et al (2022) examined facial nerve outcomes, radiographic analysis, and long-term follow-up in 420 vestibular schwannoma surgeries [15]. However, there is limited data on the impact of intraoperative bleeding and peritumoral edema on surgical outcomes, particularly regarding surgical radicality, facial nerve function, hearing preservation, and postoperative complications [16,17].

This study was planned retrospectively. The factors affecting the results of surgical excision of 30 cases of vestibular schwannomas in the CPA region in a single center in Turkey were examined. This retrospective study investigated the phenomena of intraoperative bleeding and peritumoral edema and their impact on surgical outcome. We purposefully aimed to contribute to the refinement of the surgical techniques involved in excision of vestibular schwannoma, including prevention of complications and postoperative management.

Material and Methods

Ethical Statement

This study was conducted with the approval of the Ethics Committee of Izmir Health Sciences University Bozyaka Training and Research Hospital Faculty of Medicine (Approval date: 03/10/2023, Approval number: 2023/181). The purpose and procedure of the study were explained to all participants, and written informed consent was obtained.

Patient Selection and Diagnosis

The files of patients diagnosed with vestibular schwannoma who underwent surgery using the lateral suboccipital retrosigmoid technique between October 2015 and October 2023, including their pathological results, were assessed. Patients were divided into 2 groups based on intraoperative observations: the group of very hemorrhagic patients (n=15) was designated as "more bleeding" and the group of less hemorrhagic patients (n=15) was designated as "less bleeding". The diagnosis of vestibular schwannoma was made considering the patients' clinical history, neurological examination, imaging studies, and pathological examination of the surgical specimen.

Data Collection

The following variables were collected from the patients' medical records: age, sex, initial symptoms, motor deficit, the preoperative and postoperative Karnofsky performance status, tumor diameter, the length of hospitalization, postoperative complications (bleeding within the operative lobe, diffuse pneumocephalus, cranial nerve palsies, dysphagia due to injury of the lower cranial nerves), Glasgow outcome scale (GOS) scores at discharge, residual tumor, and additional therapies (including postoperative gamma knife surgery).

Surgical Planning and Method

For surgical planning, all patients underwent preoperative brain computed tomography (CT), contrast-enhanced MRI, temporal bone CT, audiometry, and facial nerve electromyogram. Tumor size, lateralization, tumor extension, involvement of surrounding neurovascular structures, and edema were evaluated. The patient was positioned in $\frac{3}{4}$ lateral position (park bench). We prefer to use the park bench position, because we think it is safer for the patient and easier for anesthesia monitoring. The head was fixed with 3 pin fixations and slightly flexed (Mayfield head pin fixation system). The lazy "S" incision was used according to the surgical landmarks (vestibular-facial nerve region, transverse sigmoid junction). A 1.5 inch-wide craniotomy was made in the occipital bone with a drill. After suboccipital craniectomy, the dura was opened with a curvilinear shape,

Table 1. Demographic characteristics and tumor features of patients with vestibular schwannoma.

Characteristic	More-bleeding Group (n=15)	Less-bleeding Group (n=15)	Total (n=30)
Age (mean±SD, range)	45.2±10.5, 18-75	40.3±12.2, 20-68	42.8±11.5, 17-81
Sex (Male/Female)	9/6	8/7	17/13
Tumor size (mean±SD, range)	3.8±0.9, 2.1-5.0	2.1±0.6, 1.8-3.0	3.0±1.2, 1.8-5.0
Presence of chronic diseases [n (%)]	9 (60%)	2 (13%)	11 (37%)
Main clinical symptoms [n (%)]	Hearing loss: 12 (80%), Tinnitus: 10 (66%), Vertigo: 8 (53%)	Hearing loss: 13 (86%), Tinnitus: 11 (73%), Vertigo: 7 (46%)	Hearing loss: 25 (83%), Tinnitus: 21 (70%), Vertigo: 15 (50%)

SD – standard deviation.

approximately 2 mm medially from the sigmoid sinus and 2 mm inferiorly from the transverse sinus. To relax the brain, the arachnoid that covers the cistern was opened and cerebrospinal fluid (CSF) was taken. An incision was made in the tumor capsule and the center was hollowed out (debulked). Regarding the bleeding tendency during tumor resection, patients were divided into 2 groups; group 1- with more bleeding; group 2- with less bleeding. Tumors for which the bleeding could easily be controlled by hemostasis during tumor dissection and resection were designated as low bleeding. Tumors that were difficult to control with classical bleeding control during tumor dissection and resection were designated as high bleeding. After tumor resection, the dura was closed with a watertight suture. Biologic glue was applied to prevent CSF leakage. The bone flap was replaced and secured with titanium plates and screws. The muscles and skin incisions were sutured back together. Intraoperative neuromonitoring was used, and tumor resection was carried out using microsurgical techniques.

Postoperative Follow-Up and Evaluation

In the early postoperative period, patients were followed up with cranial CT and contrast-enhanced MRI for intralobe hemorrhage, extent of resection, and pneumocephalus. Postoperative complications, facial nerve function (using the House-Brackmann scale), hearing status, and neurological deficits were evaluated. Long-term follow-up included assessment of tumor recurrence and quality of life.

Statistical Analysis

All statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS), version 22.0. Continuous variables were expressed as mean±standard deviation. Categorical variables were presented as numbers and percentages. For comparisons between groups, *t*-test or Mann-Whitney U test was used depending on the normality assumption.

Chi-square test was applied for categorical variables. A *P*-value <0.05 was considered statistically significant.

Results

Patient Demographics and Clinical Presentation

At our clinic, 30 patients operated on by a single surgeon via the lateral suboccipital retrosigmoid approach were assessed. The average age of the patients was 42 years, with a duration of the disease of 8 years (age range: 17-81 years). Among these patients, 12 were women (40%), and 18 were men (60%). All patients were operated on with microsurgery through the retrosigmoid approach, and all surgeries were performed by the same surgical team. The facial nerve and vestibulocochlear nerve were the neural structures in which electrophysiological monitoring was used during the surgeries. The principal clinical manifestations were hearing impairment (83% of the subjects), tinnitus (generally present in 70% of the patients), and gait ataxia (apparent in half of the patients).

Tumor Characteristics and Surgical Outcomes

Patients were divided into 2 groups based on tumor size and bleeding characteristics during surgery: ‘more bleeding’ and ‘less bleeding’. The average size of the tumor in the more-bleeding group (patients with significant bleeding) was 3.8 cm (range 2.1-5 cm), while those in the less-bleeding group (with moderate bleeding) had tumors averaging 2.1 cm (range 1.8-3 cm). We found that chronic diseases were present in 60% of the patients in the more-bleeding group, while chronic diseases were present in 13% of the patients in the less-bleeding group (Table 1).

This means that the extent of resection, which was total, was achieved in 60% of the “more-bleeding” patients (with

Table 2. Surgical outcomes and postoperative complications in vestibular schwannoma resection.

Outcome/complication	More-bleeding Group (n=15)	Less-bleeding Group (n=15)	P-value
Surgical outcomes			
Total resection achieved [n, (%)]	9 (60%)	12 (80%)	0.25
Subtotal resection [n, (%)]	6 (40%)	3 (20%)	0.25
Extent of resection (mean% ±SD)	92.5±5.4	97.3±3.2	0.05
Operative time (mean minutes ±SD)	180±45	120±40	0.02
Estimated blood loss (mean mL ±SD)	800±150	450±120	0.01
Postoperative complications			
Intratumoral hemorrhage [n, (%)]	6 (40%)	1 (6.7%)	0.02
Peritumoral edema [n, (%)]	6 (40%)	1 (6.7%)	0.02
Cranial nerve deficits [n, (%)]	5 (33.3%)	3 (20%)	0.4
CSF leak [n, (%)]	2 (13.3%)	1 (6.7%)	0.5
Wound infection (n,%)	1 (6.7%)	1 (6.7%)	1.0
Other complications (hydrocephalus) [n, (%)]	2 (13.3%)	1 (6.7%)	0.5

CSF – cerebrospinal fluid; SD – standard deviation.

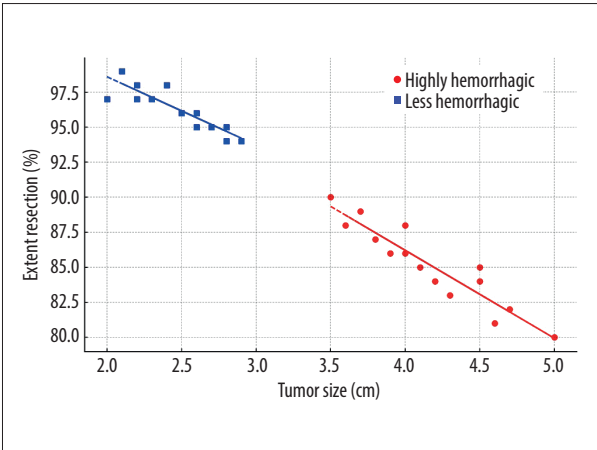


Figure 1. Correlation between tumor size and extent of resection in vestibular schwannomas. This scatter plot demonstrates the relationship between tumor size (cm) and the extent of resection (%) for highly hemorrhagic (“more-bleeding” patients; red circles) and less hemorrhagic (“less-bleeding” patients; blue squares) vestibular schwannomas. The trend lines show a negative correlation between tumor size and extent of resection for both groups, with larger and more hemorrhagic tumors associated with lower resection rates.

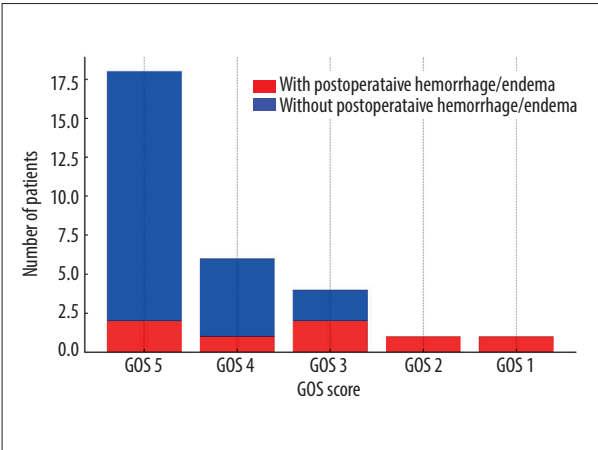


Figure 2. Glasgow Outcome Scale (GOS) scores in relation to postoperative hemorrhage/edema. This stacked bar chart illustrates the distribution of GOS scores among patients with (red) and without (blue) postoperative hemorrhage or edema. GOS scores ranged from 1 (death) to 5 (good recovery), demonstrating the impact of these complications on patient outcomes.

Table 3. Reoperation details, hospital stay, and follow-up for patients with and without postoperative hemorrhage/edema.

Characteristic	Value/hemorrhage/edema Group (n=7)	No hemorrhage/edema Group (n=23)	P-value
Reoperation details			
Patients requiring reoperation [n, (%)]	5 (16.7%)	–	–
Time to reoperation (mean days \pm SD)	12 \pm 4.5	–	–
Reason for reoperation	–	–	–
– Intratumoral hemorrhage	3 (60%)	–	–
– Peritumoral edema	2 (40%)	–	–
Outcomes after reoperation [n, (%) for each GOS score]	–	–	–
– GOS 5 (good recovery)	2 (40%)	–	–
– GOS 4 (moderate disability)	1 (20%)	–	–
– GOS 3 (severe disability)	1 (20%)	–	–
– GOS 1 (death)	1 (20%)	–	–
Hospital stay and follow-up			
Median hospital stay [days (range)]	29 (15-450)	9 (5-47)	0.01
ICU stay required [n, (%)]	5 (71.4%)	3 (13%)	0.003
Median ICU stay (days, range)	10 (3-30)	5 (2-10)	0.02
Patients requiring rehabilitation [n, (%)]	4 (57.1%)	4 (17.4%)	0.04
Median follow-up time [months (range)]	12 (6-24)	18 (12-36)	0.05

GOS – Glasgow Outcome Scale, ICU – Intensive Care Unit.

significant hemorrhage) and 80% of the “less-bleeding” patients (with less hemorrhage). The more-bleeding patients had 40% subtotal resection, while the less-bleeding patients had 20%. The mean resection rate was 92.5% in the more-bleeding group and 97.5% in the less-bleeding group. Anticipated operative times for the 2 groups were 120 \pm 40 minutes for the less-bleeding group and 180 \pm 45 minutes for the more-bleeding group. The operative time and blood loss were greater in the more-bleeding group than in the less-bleeding group (Table 2, Figures 1, 2).

Postoperative Complications and Reoperations

In the postoperative period, 40% of the intratumoral hemorrhage and peritumoral edema were observed in the more-bleeding group, while this rate was 6.7% in the less-bleeding group. Cranial nerve damage was observed in 33.3% of the more-bleeding patients, CSF leakage in 13.3%, and wound infection in 6.7% (Table 2).

Among the patients who required reoperation, the mean reoperation time was 12 days. Reasons for reoperation included

intratumoral bleeding (60%) and peritumoral edema (40%). After reoperation, 40% of the patients recovered well (GOS 5), 20% had severe disability (GOS 3), and 20% died (GOS 1) (Table 3).

Hospital Stay and Follow-Up

The median length of hospital stay was 29 days in the more-bleeding group and 9 days in the less-bleeding group. The length of stay in the intensive care unit was longer in the more-bleeding group and the need for rehabilitation was higher in this group. In addition, the median follow-up period of the patients in the group with multiple hemorrhages was 12 months, while this period was 18 months in the group with fewer hemorrhages (Table 3).

Outcome Assessment

When GOS scores were evaluated in the postoperative period, GOS 5 was seen in 60% of the patients at discharge, while this rate increased to 73.3% at the 6-month follow-up. However, the rate of GOS 1 score (death) remained stable (Table 4, Figure 2).

Table 4. Glasgow outcome scores at discharge and follow-up for vestibular schwannoma patients.

GOS Score	At discharge [n, (%)]	At 3 months [n, (%)]	At 6 months [n, (%)]
GOS 5	18 (60%)	20 (66.7%)	22 (73.3%)
GOS 4	6 (20%)	5 (16.7%)	4 (13.3%)
GOS 3	3 (10%)	2 (6.7%)	2 (6.7%)
GOS 2	2 (6.7%)	1 (3.3%)	1 (3.3%)
GOS 1	1 (3.3%)	1 (3.3%)	1 (3.3%)

GOS – Glasgow Outcome Scale.

Table 5. Risk factors associated with postoperative hemorrhage/edema in vestibular schwannoma surgery.

Factor	Odds ratio	95% CI	P-value
Tumor size >3 cm	4.5	1.8-11.2	0.003
Presence of chronic diseases	3.2	1.2-8.7	0.02
Subtotal resection	5.8	2.1-15.9	0.001
Operative time >120 minutes	2.9	1.1-7.4	0.04
Estimated blood loss >500 mL	4.2	1.6-10.9	0.006
Other relevant factors identified	2.7	0.9-8.1	0.07

CI – confidence interval.

Risk Factors for Postoperative Complications

When the factors associated with postoperative bleeding and edema were examined, tumor size greater than 3 cm, presence of chronic disease, subtotal resection, operation time longer than 300 minutes, and blood loss greater than 500 mL were significantly associated with these complications (**Table 5**). A patient with a mass larger than 3 cm and severe bleeding as an operative observation and with pontocerebellar hemorrhage and residual tumor on postoperative tomography is presented as an example (**Figure 3**).

Figure 4 shows a high magnification histopathologic image of a vestibular schwannoma (H&E staining, 60× magnification). Typical spindle cells, wavy nucleus structure, and palisading are seen. Antoni A (dense cellular) and Antoni B (loose, myxoid) areas were observed.

Discussion

Peritumoral edema and postoperative hemorrhage are the life-threatening complications seen following vestibular schwannoma surgery, because it can mainly cause obstruction of the fourth ventricle which would result in intracranial hypertension. In previous studies, factors such as tumor size >3 cm, presence of chronic disease, and subtotal resection were significantly

associated with postoperative hemorrhage [17,18]. In our study with 30 patients, tumors larger than 3 cm were associated with increased intraoperative bleeding and higher rates of postoperative complications. Also, total resection was achieved at a higher rate in tumors with less bleeding.

Surgical management of vestibular schwannoma is among the routine surgeries performed in neurosurgical practice and carries a high mortality and morbidity profile. Other findings presented in the literature also show that the greater the tumor size, the higher the possibility of intraoperative complications. For instance, Guo et al published that a tumor size above 30 mm was significantly related to postoperative bleeding and reoperation requirements [18]. Moreover, Kunert et al showed that tumors larger than 3 cm posed a considerable threat to intra-operative hemorrhage and also had deleterious impacts on the facial nerve [19]. In addition, Zhao et al found that larger tumors increased intraoperative bleeding and that the size of the tumor was directly proportional to surgical complications [20]. It was observed in our study that tumors greater than 3 cm were hemorrhagic in nature, making total excision difficult, and the incidence of complications like postoperative bleeding and edema was higher if total excision was not possible.

This has been found to be particularly true in cases of vestibular schwannoma, whereby the authors have noted that, where total resection is possible, the level of complications is

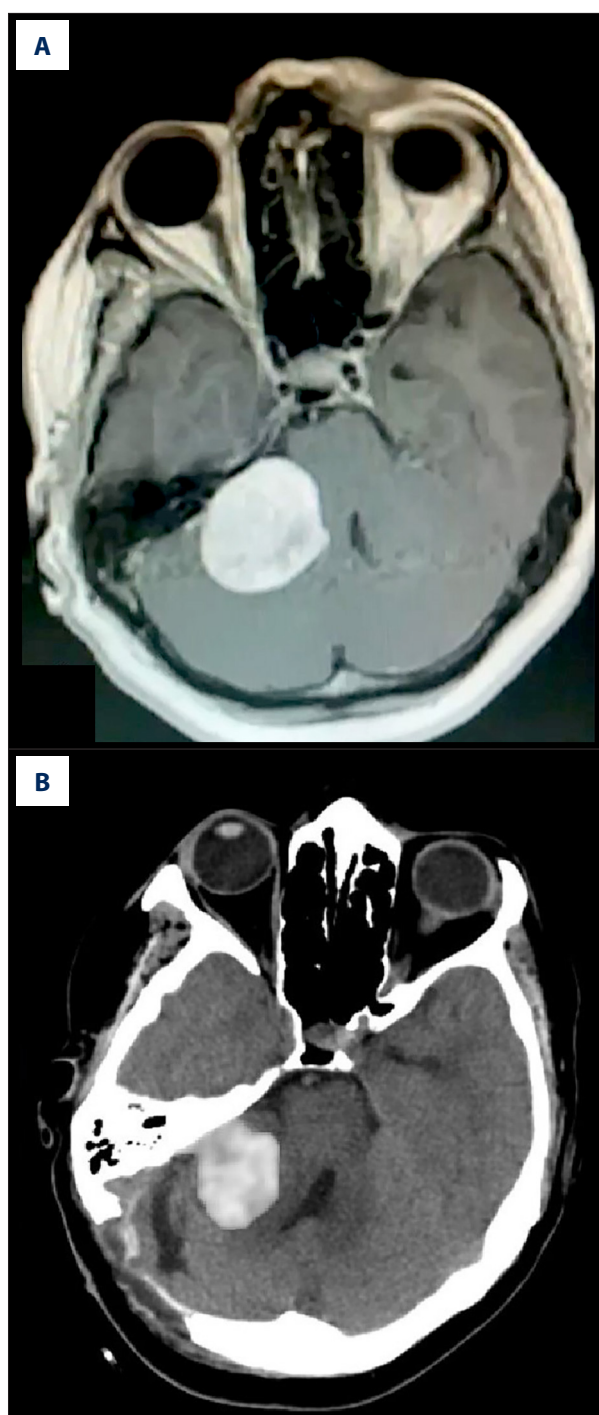


Figure 3. Preoperative and postoperative imaging of a large vestibular schwannoma with hemorrhagic complications. **(A)** Preoperative cranial MRI showing a large vestibular schwannoma on the right side. **(B)** Postoperative CT scan revealing hemorrhage within the surgical site. **(C)** Follow-up CT scan after evacuation of the hemorrhage, demonstrating residual tumor (black arrow) without evidence of further bleeding. MRI – magnetic resonance imaging; CT – computed tomography.

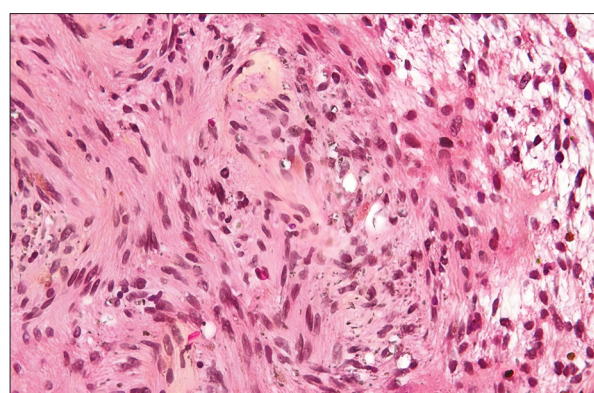


Figure 4. Histopathological features of vestibular schwannoma. This high-power microscopic image (H&E stain, 400× magnification) shows the characteristic histological appearance of a vestibular schwannoma. The image demonstrates spindle-shaped Schwann cells arranged in interlacing fascicles with alternating hypercellular (Antoni A) and hypocellular (Antoni B) areas, typical of this tumor type. H&E: Hematoxylin and Eosin.

significantly lower. These findings are also supported in the literature. Moreover, Monfared et al stated that although enucleation in thalassemia decreased the risk of tumor recurrence when compared with subtotal resection, there was a 3-fold increased risk of tumor growth compared with total resection, leading to postoperative complications [21]. Like them, Radwan et al stressed that further treatment using radiosurgery is frequently required after a subtotal resection of the

tumor, and that this might have negative implications on the facial nerve [22]. However, Daniel et al have documented that planned subtotal resection followed by gamma knife radiosurgery could afford good facial nerve function despite large tumor sizes, although follow-up and intervention are needed more than with total resection [23]. It was also noticed in the present study that total resection led to a reduction in cases of postoperative intratumoral hemorrhage and edema, with reduced mortality and morbidity.

Another surgical challenge in vestibular schwannoma surgery is when the surgery must be performed in patients with chronic disease. It has been observed that total resection rates are low and the risk of postoperative complications is increased in patients with chronic disease. These findings are also supported in the literature. For example, Alkins et al reported that chronic diseases such as diabetes mellitus significantly increased the risk of serious postoperative complications such as myocardial infarction, pneumonia, and meningitis after vestibular schwannoma surgery [24]. Similarly, Hatch et al showed that complication rates were higher in patients with chronic diseases who underwent surgery in low-volume hospitals and that these patients stayed in the hospital longer [25]. In our study, subtotal resection was usually performed in patients with chronic disease and this was associated with postoperative bleeding and edema.

It has been observed that patients with higher complication rates need to be reoperated on after pontocerebellar angle tumor surgery, and that this has adverse effects on long-term outcomes. These findings are also supported elsewhere in the literature. For example, Guo et al reported that peritumoral edema after vestibular schwannoma surgery increased the risk of postoperative bleeding and thereby directly influenced reoperation requirements [18]. Similarly, Samii et al emphasized that peritumoral edema did not affect surgical radicality in vestibular schwannoma surgery but increased the risk of postoperative bleeding and therefore the need for reoperation [26]. Bartek Jr et al showed that hematomas and other complications occurring after vestibular schwannoma surgery had to be reoperated on and were among the outcomes which were negative for healing [27]. In our study, a poor prognosis was noted among those patients who were reoperated because of postoperative hemorrhage and edema.

We observed that morbidity and mortality rates are high and low, respectively, after vestibular schwannoma surgery. These findings have also been supported in the literature. For example, Gelfand et al [28] reported a 0.4% mortality rate at 30 days after vestibular schwannoma surgery but a complication rate of 7%. Similarly, Nuno et al [29] reported that there were treatment-related complications in 28.5% of patients after surgery and morbidity was higher in the scalpel-based surgical vs the radiosurgical group. Hatch et al [25] reported that elderly patients

had higher complication rates and that higher age was associated with increased mortality for vestibular schwannoma surgery.

The careful utilization of surgical techniques is important to prevent complications such as intratumoral bleeding and peritumoral edema in vestibular schwannoma surgery. The risk of postoperative hemorrhage is increased by peritumoral edema and larger tumor size; this directly affects reoperation necessity according to Guo et al [18]. Therefore, high-risk individuals should be subjected to hemostatic measures and carefully performed surgeries instead of endovascular interventions alone. According to Samii et al, however, peritumoral edema around vestibular schwannoma does not affect its radicality but elevates postoperative bleeding risk; hence, caution is needed towards effective hemostasis during operation [26].

The strong points of this study are that patients who had surgery via the retrosigmoid approach were meticulously chosen and all surgeries were performed by the same surgeon, which means that surgical techniques' consistency and outcome comparability were increased. However, there were limitations in terms of the small sample size and a lack of generalizability since the results are based on data collected from a single surgeon's experience only. Broadly speaking, major tumors and those with a hemorrhagic nature should be totally resected, while for subtotal excision, bleeding control as well as management of postoperative edema are critical. Reducing postoperative complications could involve optimization of surgery techniques. The researchers recommend further studies comprising larger populations with diversification as well as focusing on the development of new surgical methods to reduce the risk of bleeding. Furthermore, advanced imaging and biomarkers would be useful in determining what factors predispose patients to bleeding or edema.

This study has a number of limitations that should be taken into account while drawing conclusions about the findings. First of all, the small sample size of 30 patients may affect how general our findings are. Second, all operations were done by a single surgeon in a single center which may create bias and limit the generalizability of our work to other surgical settings. As mentioned earlier, a retrospective design of research may in some instances risk improper data collection. Further larger multi-center prospective studies are needed to verify our results, and are necessary to develop better evidence-based modifications of surgical methods for vestibular schwannoma resection.

Conclusions

The current research demonstrates that the tumor volume and the bleeding context of the vestibular schwannoma are

important factors for the results of surgical interventions. Larger tumors (>3 cm) and those with hemorrhagic characteristics are associated with increased surgical difficulties and higher rates of postoperative complications. Complete resection, when feasible, reduces the risk of postoperative bleeding and edema, whereas subtotal resection is associated with increased complication rates. Factors such as chronic disease, prolonged operation time, and substantial blood loss also contribute to adverse outcomes. These results call for a very selective approach regarding the patient prior to the surgery and optimal management of the vestibular schwannoma during the

excision process, to lower the incidence of complications after the operation. Future studies should be directed towards achieving adequate control of such cases and enhancement of outcomes in patients with prolonged treatment or bleeding vestibular schwannomas.

Declaration of Figures Authenticity

All figures submitted were created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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