



Superior petrosal vein sacrifice in translabyrinthine approach for resection of vestibule schwannoma

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Abstract

Purpose The aim of this study was to evaluate the safety and surgical outcome of superior petrosal vein (SPV, Dandy's vein) sacrifice in translabyrinthine approach (TLA) for resection of vestibule schwannoma (VS) as compared with SPV preservation, with further investigation of preoperational factors associated with the implement of SPV sacrifice.

Methods The authors prospectively collected data from patients surgically treated for VS through TLA between June 2021 and April 2022 at the Gruppo Otologico.

Results There were 30 and 49 patients in SPV sacrifice and preservation groups, respectively. SPV sacrifice group had significantly larger tumor size (2.46 vs. 1.40 cm), less percentage of solid tumor (26.7% vs. 83.7%), higher incidence of brainstem compression (80% vs. 26.5%), and higher percentage of facial numbness (20.0% vs. 4.1%) than SPV preservation group. Gross total resection (GTR) rates were 73.3% after SPV sacrifice and 87.8% after SPV preservation. Facial nerve preservation rates were similar. No complication related with SPV sacrifice was observed. Logistic regression analysis showed tumor size and complete solid consistency as significant risk factors associated with SPV sacrifice. ROC curve further demonstrated tumor size as a fair predictor (AUC = 0.833), with optimum cutoff value of 1.68 cm.

Conclusion SPV sacrifice via TLA as needed is a safe and effective maneuver for removal of relatively large VS. Tumor size and consistency can be used as a guidance in preoperational decision-making, with cutoff value of 1.68 cm and cystic formation as predictive indicators.

Keywords Vestibular schwannoma · Translabyrinthine approach · Superior petrosal vein · Dandy's vein · Surgical outcome

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Introduction

The surgical resection of vestibular schwannoma (VS) has always been a challenge. Vascular complications have been reported in up to 7% of patients and might result in devastating consequences with significant risks of morbidity and death [1]. The superior petrosal vein (SPV), also termed Dandy's vein, is an important venous structure composed by multiple tributaries and drains into the superior petrosal sinus (SPS) [2, 3]. SPV often obstructs the approach to the upper cerebellopontine angle (CPA), and is sometimes sacrificed to obtain better exposure [2, 4, 5]. However, debate exists about the safety of SPV sacrifice. Advocators reported negligible influence [6–8], while opponents described severe complications after SPV sectioning [9, 10].

The translabyrinthine approach (TLA) was first introduced by Quix for VS resection [11], and has become a safe approach after refinement by neuro-otologists such

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as William House [12] and Mario Sanna [13]. TLA has the advantages of wide surgical exposure, short operative depth, minimal cerebellum retraction and early facial nerve identification, and is mainly applied in VS without servable hearing [14, 15]. Like retrosigmoid and posterior petrosal approaches, SPV can be obstacle during surgery and might be sacrificed to facilitate tumor resection. Hematoma and venous ischemia have been reported [16], but the relationship with SPV interruption is unclear. According to our experience, we have not encountered any surgical complication related to SPV sacrifice in TLA. To resolve the conflicts, we designed a prospective comparative study to compare the surgical outcome and safety between SPV sacrifice and preservation, and investigate the predictive factors associated with SPV sacrifice.

Materials and methods

Study design

This was a prospective study of patients surgically treated for VS between June 2021 and April 2022 at the Gruppo Otorologico, Piacenza-Rome, Italy, a Quaternary referral center for skull base surgery. All the patients with preliminary diagnosis of VS who were scheduled for surgical resection were enrolled. The patients were excluded if the final pathology was not VS. A senior surgeon (MS) completed the tumor resection stage and made the decision of SPV sacrifice. The patients were divided into SPV sacrifice and preservation groups. This study was approved by the ethics committee of Casa Di Cura Hospital, Piacenza, Italy that that no ethical approval was required according to the observational nature. The informed consent requirement was waived.

The preoperative data including gender, age, symptoms, facial function according to the House–Brackmann (HB) scale [17] and hearing level according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) hearing classification [18] were collected. Preoperative MRI was analyzed: tumor size measured as the largest extrameatal diameter in axial plane, with intrameatal type being 0, and large VS defined as size > 3 cm [19]; solid VS defined as tumor without cystic component; high jugular bulb when the vertical distance between dome and internal auditory canal (IAC) was less than 2 mm on coronal plane [20]; the dominant sigmoid sinus defined as twice larger in diameter than the contralateral side; the laterality, existence of peri-tumor edema, brainstem compression, and hydrocephalus were also recorded. The extend of resection (EOR) was categorized from surgeon's subjective observation: gross total resection (GTR) for complete tumor clearance; near total resection (NTR) when tumor capsule was left behind; subtotal resection (STR) when part of tumor

was left. The preservation of facial nerve was recorded and HB grading of facial function was collected during the hospital stay. Postoperative CT scan was ordered for all the patient and abnormalities were noted. Complications related to SPV sacrifice including massive edema, hematoma, and infarction were emphasized. Other important postoperative complications including cerebral spinal fluid (CSF) leakage, meningitis, lower cranial nerve (LCN) dysfunction, and abdominal hematoma were also evaluated and recorded.

Surgical technique

The surgical details of enlarged TLA were described elsewhere [13]. Briefly, C-shaped postauricular incision was made and an extended mastoidectomy was performed. In case of anterior-lying sigmoid sinus, narrow mastoid space and large tumor, cul-de-sac procedure was performed in two layers along with complete removal of bony external auditory canal. Labyrinthectomy was followed and IAC was exposed by 270°. The fundus was drilled to expose the transverse crest. The superior and inferior vestibular nerves were detached with the tumor and separated from the underlying facial nerve. After dura opening, the tumor was resected with bloodless technique. Internal debulking proceeded before separation from surrounding structures. Transapical drilling became routine practice to control the anterior pole of the tumor. SPV was frequently encountered at the superoposterior margin of the tumor, and sacrificed in case of overstretching, hindering tumor exposure or close adhesion. At the end of the surgery, the cavity was filled with abdominal fat strips.

Statistical analysis

Data were presented as the number of patients with percentage for categorical variables, means \pm standard deviation for parametric continuous variables. One-way ANOVA was used for continuous variables after confirmation of normal distribution. Chi-square test was used for nominally distributed categorical variables. For 2×2 contingency table, Pearson χ^2 test was used when all the cells had expected count greater than 5, otherwise fisher's exact test was used. For $2 \times n$ ($n > 2$) contingency table, Pearson χ^2 test was used when at least 75% of cells had expected count greater than 5, otherwise likelihood ratio test was used. Logistic regression analysis was performed to verify factors that might be associated with SPV sacrifice. A receiver operating characteristic (ROC) curve was constructed to assess the correlation between tumor size and SPV sacrifice and to calculate area under curve (AUC), cutoff value with greatest Youden index, sensitivity and specificity. All statistical analyses were performed using SPSS software (version 25.0, IBM Corp., NY, USA), and a two-sided p value of 0.05 was considered

as statistically significant. The ROC diagram was drawn with GraphPad Prism 8.

Results

Comparison of preoperative characteristics

A total of 79 patients who underwent VS surgery were enrolled, with male–female ratio of 37:42, age from 30

to 75 years, and tumor size from 0 to 4.15 cm. All the patients were divided into SPV sacrifice and preservation groups (30 vs. 49), with illustrative cases presented in Fig. 1. Age and gender distribution were similar between the two groups. However, SPV sacrifice group had significantly larger tumor size (2.46 ± 0.78 vs. 1.40 ± 0.88 , $p < 0.001$), less solid tumor (26.7% vs. 83.7%, $p < 0.001$), and higher incidence of brainstem compression (80% vs. 26.5%, $p < 0.001$) than SPV preservation group. As for symptoms, a significantly higher percentage of facial

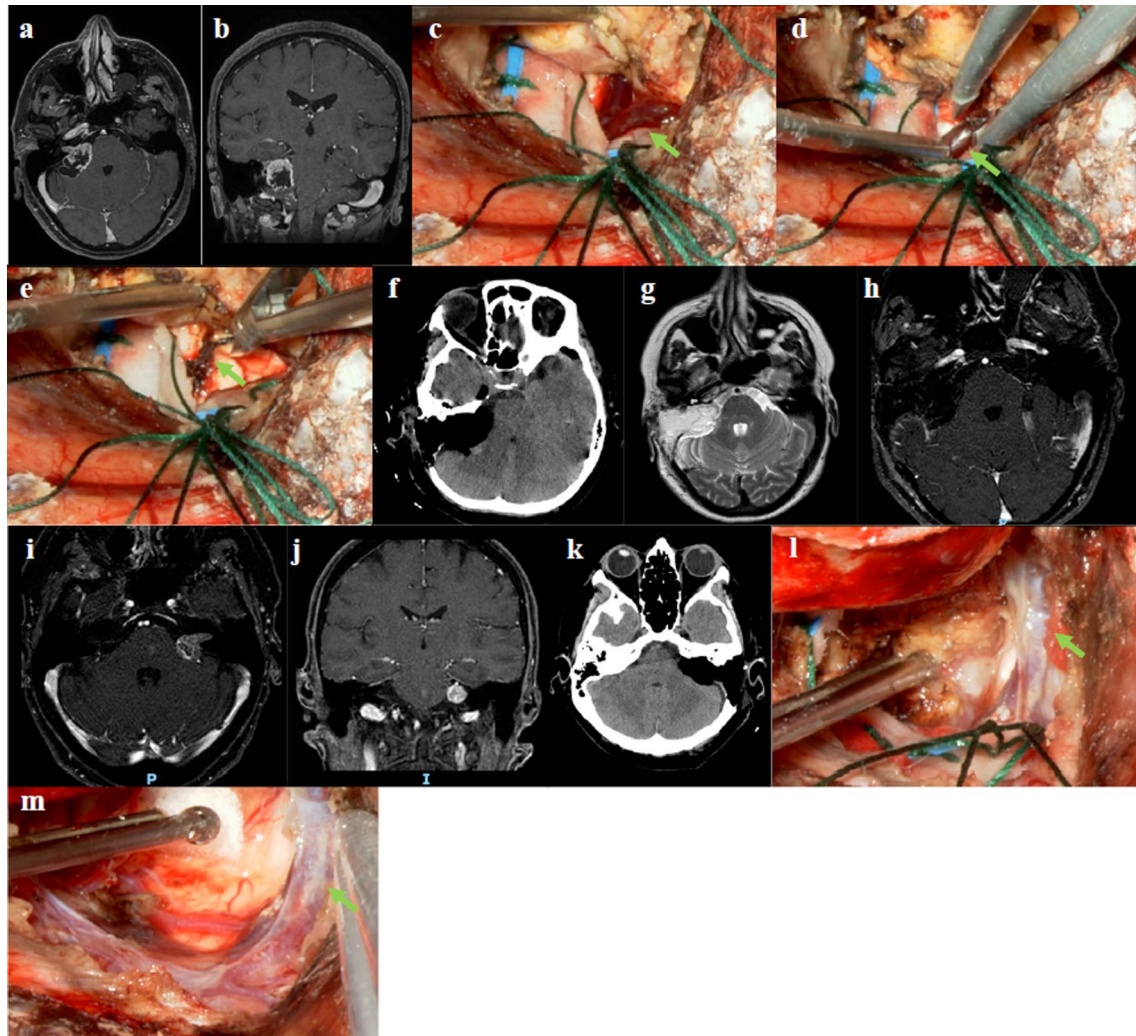


Fig. 1 Case presentations. **a–h** A case of large vestibule schwannoma in a 57-year-old female complaining of tinnitus, facial numbness and dizziness with sacrifice of SPV during tumor resection. **a, b** Gadolinium-enhanced MR images before surgery. Axial (**a**) and coronal (**b**) images displayed a cystic tumor in the right CPA compressing the brainstem. The size of the tumor was measured as 3.51 cm × 1.72 cm × 1.93 cm. **c** Intraoperative visualization of SPV (green arrow) after retraction of the superoposterior pole of the tumor. **d** Coagulation of SPV. **e** Disconnection of SPV to facilitate further tumor dissection. **f** Postoperative CT scan displaying clear surgical cavity. **g, h** MR images 2 months after surgery. T2-weighted

(**g**) and gadolinium-enhanced (**h**) axial images showed complete resection of the tumor with normal appearing surrounding structures and fat graft in the surgical cavity. **i–m** A case of small vestibule schwannoma in a 65-year-old female complaining of tinnitus, hearing loss and vertigo with preservation of SPV during tumor resection. **i, j** Gadolinium-enhanced MR images before surgery. Axial (**i**) and coronal (**j**) images displayed a solid tumor in the left CPA. The size of the tumor was measured as 1.78 cm × 1.26 cm × 1.29 cm. **k** Postoperative CT scan displaying clear surgical cavity. **l** Intraoperative visualization of SPV (green arrow) which could be easily separated from the tumor. **m** SPV remained intact after tumor resection.

numbness was observed in SPV sacrifice group (20.0% vs. 4.1%, $p=0.048$). (Table 1).

Comparison of postoperative outcomes

GTR, NTR and STR were achieved in 22 (73.3%), 6 (20.0%) and 2 (6.7%) patients in SPV sacrifice group, respectively, comparable with 43 (87.8%), 4 (8.2%) and 2 (4.1%) in SPV preservation group. Although the facial nerve preservation rates were not significantly different (73.3% vs. 85.7%, $p=0.173$), immediate postoperative HB grading showed significantly different distributions ($p<0.001$), with 16.7% of grades I–III and 83.3% of grades IV–VI in SPV sacrifice group, and 42.9% of grades I–III and 57.1% of grades IV–VI in SPV preservation group. According to our experience, the majority of patients with unfavorable HB grade immediately after surgery would gradually recovered (Table 2).

Comparison of complications

Postoperative CT scan did not show massive edema, temporal lobe hematoma/infarction and cerebellum hematoma,

nor did the patients present any related symptoms. In one patient with cystic VS and SPV sacrificed, anterior inferior cerebellum artery (AICA) was encased by the tumor and could not be separated. Therefore, a piece of tumor was left. Postoperative CT demonstrated cerebellum infarction possibly due to vasospasm, and a small piece of subdural hematoma in the surgical cavity. Hydrocephalus developed and the patient gradually fell into drowsiness. Ventricular drainage was immediately performed and the patient recovered without major morbidity. Another patient in SPV preservation group developed asymptomatic cerebellum infarction due to injury of a small branch of AICA. Two patients (4.1%) in SPV preservation group had CSF leakage, one with subcutaneous CSF accumulation and the other with rhinoliquorrhea. Both were successfully treated with revision surgery. No patient developed meningitis. Three patients in SPV preservation group displayed mild LCN dysfunction and recovered within 1 week. Two patients in SPV preservation group with subcutaneous abdomen hematoma received evacuations surgery. No mortality was observed (Table 2).

Table 1 Summary of preoperative characteristics

Variables	SPV sacrifice ($n=30$)	SPV preservation ($n=49$)	Statistical test	p Value
Age (years)	56.3 ± 9.1	55.0 ± 10.2	One-way ANOVA	0.575
Gender (M:F)	15:15	22:27	Pearson χ^2	0.659
Size/cm	2.46 ± 0.78	1.40 ± 0.88	One-way ANOVA	<0.001
Intrameatal	0 (0%)	6 (12.2%)	Fisher's exact	0.078
Large (> 3 cm)	7 (23.3%)	4 (8.2%)	Fisher's exact	0.092
Solid tumor	8 (26.7%)	41 (83.7%)	Pearson χ^2	<0.001
Laterality (L:R)	14:16	24:25	Pearson χ^2	0.842
Peri-tumor edema	1 (3.3%)	0 (0%)	Fisher's exact	0.380
Brainstem compression	24 (80%)	13 (26.5%)	Pearson χ^2	<0.001
Hydrocephalus	2 (6.7%)	0 (0%)	Fisher's exact	0.141
Dominant sigmoid sinus	4 (13.3%)	6 (13.9%)	Fisher's exact	1
High jugular bulb	7 (23.3%)	4 (8%)	Fisher's exact	0.092
Symptoms				
Tinnitus	18 (60.0%)	38 (77.6%)	Pearson χ^2	0.096
Hearing loss	26 (86.7%)	43 (87.8%)	Fisher's exact	1
Facial numbness	6 (20.0%)	2 (4.1%)	Fisher's exact	0.048
Facial paralysis	4 (13.3%)	3 (6.1%)	Fisher's exact	0.417
Dizziness/vertigo	20 (66.7%)	28 (57.1%)	Pearson χ^2	0.400
Hearing class (AAO-HNS)				
A	4 (13.3%)	5 (10.2%)	Pearson χ^2	0.797
B	12 (40.4%)	21 (42.9%)		
C	10 (33.3%)	13 (26.5%)		
D	4 (13.3%)	10 (20.4%)		
House–Brackmann grade				
I	26 (86.7%)	46 (93.9%)	Fisher's exact	0.417
II	4 (13.3%)	3 (6.1%)		

Table 2 Surgical results and postoperative complications

Variables	SPV sacrifice (<i>n</i> = 30)	SPV preservation (<i>n</i> = 49)	Statistical test	<i>p</i> Value
EOR			Likelihood ratio	0.26
GTR	22 (73.3%)	43 (87.8%)		
NTR	6 (20.0%)	4 (8.2%)		
STR	2 (6.7%)	2 (4.1%)		
Facial nerve preservation	22 (73.3%)	42 (85.7%)	Pearson χ^2	0.173
House–Brackmann grade			Likelihood ratio	0.001
I	0 (0%)	12 (24.5%)		
II	0 (0%)	4 (8.2%)		
III	5 (16.7%)	5 (10.2%)		
IV	3 (10.0%)	7 (14.3%)		
V	2 (6.7%)	0 (0%)		
VI	20 (66.7%)	21 (42.9%)		
CT abnormality				
Massive edema	0 (0%)	0 (0%)		
Temporal lobe hematoma	0 (0%)	0 (0%)		
Cerebellum hematoma	0 (0%)	0 (0%)		
Subdural hematoma	2 (6.7%)	0 (0%)	Fisher's exact	0.141
Hydrocephalus	1 (3.3%)	0 (0%)	Fisher's exact	0.380
Cerebellum infarction	1 (3.3%)	1 (2.0%)	Fisher's exact	1
CSF leakage	0 (0%)	2 (4.1%)	Fisher's exact	0.523
Meningitis	0 (0%)	0 (0%)		
LCN dysfunction	3 (10%)	0 (0%)	Fisher's exact	0.051
Abdominal hematoma	2 (6.7%)	0 (0%)	Fisher's exact	0.141

Factors related to SPV sacrifice

Logistic regression analysis was applied to analyze factors associated with SPV sacrifice. All the factors with $p < 0.10$ were included except “Intrameatal” and “Large (> 3 cm)”, which were already incorporated into the size information. After application of backward likelihood ratio test, model with best predictive accuracy (SPV sacrifice 76.7%, SPV preservation 87.8%, overall 83.5%) was selected. Only tumor size ($p = 0.01$) and not complete solid consistency ($p = 0.001$) were significant risk factors associated with SPV sacrifice (Table 3). We further plotted ROC curve, which demonstrated tumor size as a fair predictor of SPV sacrifice, with area under curve (AUC) of 0.833, cutoff value of 1.68 cm, sensitivity of 90% and specificity of 75.5% (Fig. 2).

Table 3 Multiple logistic regression analysis for factors related to SPV sacrifice during surgery

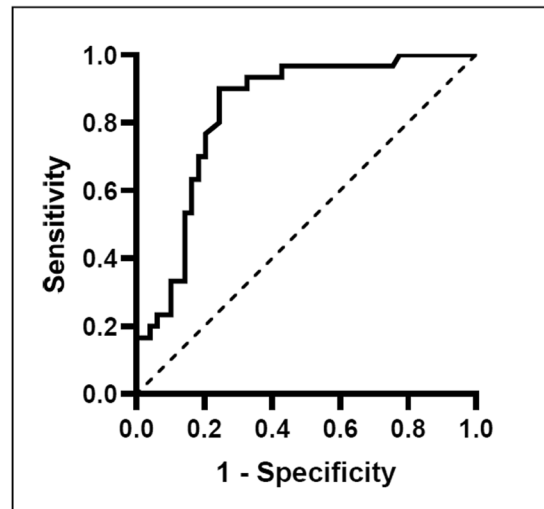
Variables	Regression coefficient	Standard error	Odds ratio	95% CI	<i>p</i> Value
Size	0.998	0.388	2.714	1.268–5.808	0.010
Solid tumor	− 2.102	0.648	0.122	0.034–0.435	0.001
High jugular bulb	1.176	0.861	3.241	0.600–17.504	0.172
Tinnitus	− 0.748	0.662	0.473	0.129–1.730	0.258

Discussion

The anatomy and function of SPV

Dandy first described the anatomical course of SPV in CPA [21]. Ever since, numerous studies have been undertaken to understand this complex venous structure. The SPV may be formed as a common stem composed by up to five branches or as separated terminal segments [2, 22]. The most common tributaries of SPV include cerebellopontine fissure vein, middle cerebellar peduncle vein, transverse pontine vein, pontotrigeminal vein, and the veins of lateral cerebellar hemisphere [2, 22]. Anatomical studies failed to show direct connection between bilateral SPVs, but demonstrated anastomosis between the ipsilateral infratentorial and supratentorial

Fig. 2 ROC curve and the predictive value of tumor size associated with SPV sacrifice



AUC	95% CI	p value	Youden index	cutoff	sensitivity	specificity
0.833	0.742-0.924	<0.0001	0.6551	1.68cm	90.0%	75.5%

compartments [23]: (1) the pontine/ponto-mesencephalic vein connecting SPV with basal vein; (2) anterolateral multiple tiny branches connecting the supra- and infratentorial venous system; (3) the lateral mesencephalic vein; and (4) the galenopetrosal vein. SPV is considered as an important drainage system for the anterolateral cerebellum and anterior brainstem. However, SPV can also become obstacle during tumor dissection in CPA, especially when it is large in diameter [2, 4, 5]. As a result, the manipulation of SPV during surgery has always been the center of debate.

The consequence of SPV sacrifice

Samii concluded that SPV could be safely transected during petroclival meningioma resection because SPV has frequently been markedly compressed by the tumor and collateral veins have developed [8]. Mizutani analyzed 39 patients with petroclival meningioma via anterior transpetrosal approach, among whom 10 patients had SPV sacrifice and no venous complications were observed [24]. Ghara-baghi also reported obliteration of SPV in almost half of the petrous apex meningiomas and only unrelated complication of hearing loss was observed [6]. However, complications after SPV sacrifice have been stressed which raised the question against SPV interruption [25]. In 30 cases of petrous apex meningioma with SPV sacrifice, Koerbel reported a minor venous-congestion complication rate of 23% and a major complication rate of 7% including severe cerebellar edema and infarction [10]. Inamasu presented a case of VS surgery via posterior petrosal approach complicated by massive cerebral hematoma after co-transection of SPV and SPS [9]. A Chinese study of 149 VS patients treated by retrosigmoid approach reported SPV sacrifice in 8 patients. The

postoperative complications included 3 cases of cerebellum hematoma, which showed significant difference from SPV preservation, and 5 cases of cerebellum edema [26]. The results from these studies strongly advocate preservation of SPV whenever possible.

Besides retrosigmoid approach, TLA provides a safe, retractorless, and effective approach for the removal of VS [13]. The safety of SPV sacrifice in TLA has rarely been stressed in literature. Horowitz applied CT scan after VS resection via TLA to analyze postoperative abnormalities. Radiologic presentation of temporal lobe venous ischemia (22%), cerebral/cerebellar infarction (11%), and cerebellar hematoma (12%) was demonstrated. The authors only mentioned two cases of temporal lobe infarction after SPV sacrifice without surgical details and attributed these complications to the involvement of SPV, SPS, and/or cavernous sinus [16]. As a matter of fact, a properly performed TLA should spare SPS and cavernous sinus. Moreover, SPV only drains infratentorial structures, and SPV compromise alone should not interfere supratentorial drainage. Therefore, we suspected that the temporal lobe venous complications were not related with SPV, but with the surgical techniques. In our series, we performed enlarged TLA and had relatively low complication rates, none of them being related to SPV sacrifice. During routine practice, we also kept a low profile to SPV sacrifice and did not encounter any related complications. We believed SPV sacrifice in properly selected cases as a safe technique.

Rationale of SPV sacrifice in TLA

Factors related to the complications after SPV sacrifice include anatomy and diameter of the SPV complex,

collateral compensation, preservation of arachnoid membrane, surgical approach, cerebellar retraction, pathology, and sectioning of the main stem versus tributaries [10, 25, 27]. Following VS resection, the median volume of cerebellar edema was significantly smaller in TLA group than that in retrosigmoid group (1.7 cm^3 vs. 7.8 cm^3 , $p < 0.001$) [28]. The sustained retraction of cerebellum in retrosigmoid approach will impair the parenchymal venous system and lead to cerebellar edema. As a result, the addition of SPV sacrifice will cause severe complication. The retractorless nature of TLA, however, helps to avoid cerebellar damage, especially for large VS [13, 14], and contributes to better preserved parenchymal venous system. As mentioned above, various anastomoses with SPV, together with the lateral medullary vein, provide alternative drainage pathways [23]. Moreover, diffusive anastomosis lies within the terminal cerebellar veins and a collateral arrangement is formed by the tentorial venous channels [29, 30]. These preserved venous webs after TLA provide powerful reservoir to compensate the extra blood flow of SPV after its ligation.

During the surgery, we prefer to transect SPV rather than running the risk of tearing by overstretching. Otherwise, massive package with hemostatic materials or blind coagulation may take place and result in extra damage to SPV tributaries and further compromise venous compensation. Moreover, SPV was often sacrificed in case of relatively large tumor or close adhesion. We agree with Samii that collateral veins have developed after long-term compression [8]. The last issue to be stressed is the surgical angle. TLA provides an anterolateral surgical trajectory with direct visualization of the brainstem and nerves [31]. Therefore, sometimes sacrifice of SPV branch such as pontotrigeminal vein overlying the trigeminal nerve will provide sufficient space.

Tumor size and SPV sacrifice

Commonly the larger the tumor is, the more difficult it will be to preserve the SPV [26]. In a series of 1006 VSs, Sampath reported SPV sacrifice rate of 1% in tumor $< 2.5 \text{ cm}$, 13% in tumor between 2.5 and 4 cm, 54% in tumor $> 4 \text{ cm}$, and concluded sacrifice of bridging petrosal veins as a safe technique in large-sized tumors [32]. In our study, we also proved tumor size being positively associated with SPV sacrifice (odd ratio 2.714). ROC analysis further confirmed tumor size as a positive indicator. Large VS requires more space for resection, while SPV prevents sufficient dynamic or static retraction on cerebellum and hinders exposure of superior CPA. In addition, it is usually more difficult to separate SPV from the capsule of large VS.

Tumor consistency and SPV sacrifice

The formation of cystic component in VS is not completely understood. Anyway, it has been widely accepted that cystic VS has more aggressive behavior and worse surgical outcomes [33]. According to our experience, VS with cystic formation adheres more tightly with the surrounding structures and increases the difficulty of separation. As a result, the venous structures such as bridging veins are more prone to be torn and may be responsible for insidious postoperative hemorrhage [1]. It has been proved that cystic tumor is a risk factor of postoperative hematoma [34]. Therefore, a gentle and careful dissection maneuver should be encouraged. The result from our study revealed complete solid tumor consistency as a protective factor of SPV preservation (odd ratio 0.122, 95%CI 0.034–0.435, $p = 0.001$). In other words, VS with cystic component has a higher tendency towards SPV sacrifice.

Other factors associated with SPV sacrifice

Although significant difference was not reached, high jugular bulb was also included in the logistic regression model as an adverse factor of SPV sacrifice (odd ratio 3.241, 95% CI 0.600–17.504, $p = 0.172$). High jugular bulb will obstruct exposure of posterior fossa and limit surgical freedom during TLA [20], which might lead to surgeon's decision on SPV sacrifice to increase surgical applicability. Univariate analysis also found a significantly higher proportion of facial numbness in SPV sacrifice group (20.0% vs. 4.1%, $p = 0.048$), which denoted involvement of trigeminal nerve by the tumor. It is reasonable to have a higher chance of SPV sacrifice due to intimate relationship of SPV and its pontotrigeminal branch with trigeminal nerve.

Limitations

There are some limitations. First, although the sample size of our study is comparable with others [16, 28], a larger population can decrease sampling bias and lead to a more solid conclusion. Second, using CT scan for postoperative evaluation might result in underestimation of minor postoperative abnormalities. Third, the long-term consequence after SPV sacrifice is still not known due to lack of follow-up data. Larger sample size and implement of postoperative MRI are required in future studies.

Conclusion

Our comparative study demonstrated SPV sacrifice in VS operated through TLA was safe, with surgical results comparable with SPV preservation. Anyway, SPV sacrifice should

not be interpreted as a non-selective surgical maneuver, and is only recommended when necessary. We have shown tumor size and consistency as potential indicators associated with SPV sacrifice. Future studies are needed to generate a more consolidated predictive model, and guide preoperative decision-making.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00405-023-08208-1>.

Data availability The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest The authors declare that no funds, grants, or other support were received during the preparation of this manuscript. The authors have no relevant conflicts of interests to disclose.

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