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# Venous sinus stenting under conscious sedation

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## ABSTRACT

**Background** Venous sinus stenting (VSS) is an increasingly performed procedure for the treatment of idiopathic intracranial hypertension (IIH) refractory to medical treatment. VSS is typically performed under general anesthesia.

**Objective** To present our experience of VSS in patients with IIH performed under conscious sedation.

**Methods** Retrospective review of a prospectively maintained database of all patients with IIH who underwent VSS in a single center between September 2019 and January 2024. The sedation protocol consisted of a remifentanyl-based target-controlled infusion. Patients' clinical and radiological data, dosage of anesthesia, procedural characteristics, and outcomes were collected.

**Results** Twenty-six patients with IIH underwent venous manometry (VM) and VSS under awake sedation and were included in our study. Patients were predominantly women (24/26) with a median age (IQR) of 33 (13) years. The median (IQR) body mass index was 34 (10) kg/m<sup>2</sup>. There was no need for general anesthesia conversion. Technical success was achieved in all patients. Median (IQR) follow-up after stenting was 7 (2) months. All patients reported resolution of the pulsatile tinnitus; headaches regressed in 20/24 (83.3%) patients and papilloedema improved in 16/20 (80%). Only one non-neurological complication (retroperitoneal hematoma) occurred, without any permanent morbidity or mortality.

**Conclusion** Our study confirms that performing VM and VSS under conscious sedation is safe and feasible. Conscious sedation is a viable alternative to general anesthesia for managing IIH in these patients.

## INTRODUCTION

Venous sinus stenting (VSS) has emerged as a safe and effective treatment for idiopathic intracranial hypertension (IIH) refractory to medical treatment.<sup>1–7</sup> VSS is preceded by venous manometry to measure the venous sinus pressure and to calculate the pressure gradient across the stenosis to assess the patient's candidacy for stenting. The stenting procedure is typically performed under general anesthesia to ensure patient immobilization, pain management, and airway protection, but venous manometry should be performed while patients are awake as pressure measurements and gradients are markedly affected by general anesthesia.<sup>8</sup> The different anesthesia protocols for venous manometry and venous stenting entail consequential

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Venous sinus stenting (VSS) is recognized as an effective treatment for idiopathic intracranial hypertension (IIH). Previous research has demonstrated its efficacy; however, the application of VSS under conscious sedation has not been thoroughly investigated, with a lack of evidence regarding the feasibility, safety, and effectiveness of performing VSS with conscious sedation techniques.

## WHAT THIS STUDY ADDS

⇒ This research provides the first worldwide evidence that remifentanyl-based conscious sedation is feasible, safe, and effective for VSS procedures. The study highlights a new approach to anesthesia in VSS, offering a viable alternative to traditional sedation methods and potentially improving patient comfort and procedural outcomes.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The study's results encourage the initiation of larger and comparative studies to further evaluate the benefits and limitations of conscious sedation for VSS. Practitioners now have a new technique to consider for VSS, which could enhance patient management and procedural efficiency. Findings might lead to updated clinical guidelines and protocols, incorporating conscious sedation options into standard practices for VSS.  
⇒ This study paves the way for further exploration of conscious sedation in VSS, potentially leading to new innovations and improved treatment strategies for IIH.

considerations on the procedural workflow, patient comfort, time efficiency, and cost-effectiveness. For instance, practitioners commonly undertake venogram/manometry with light or no sedation on a separate day from the venous stenting procedure under general anesthesia. Therefore, optimizing procedural integration, potentially enabling completion within a single procedure, as well as exploring alternative sedation modalities for VSS other than general anesthesia, is paramount. Such consolidation offers benefits, including streamlined workflow, reduced healthcare resource utilization,



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**Table 1** Baseline Characteristics of patients undergoing venous sinus stenting

Factors	N or median (IQR)
Age (years)	33 (13.0)
Gender	
Female (N)	24
Male (N)	2
BMI (kg/m <sup>2</sup> )	34 (10.0)
Time from first symptoms to stenting (months)	13 (6.0)
Headache (N)	24
Pulsatile tinnitus (N)	13
Papilledema (N)	20
Carbonic anhydrase inhibitor (N)	23
CSF opening pressure (cm H <sub>2</sub> O)	34 (20.0)

BMI, body mass index; CSF, cerebrospinal fluid.

and mitigated patient discomfort associated with multiple visits and procedures.

There are currently no data available on the use of conscious sedation instead of general anesthesia for the VSS. Our study aimed to investigate the feasibility and safety of venous manometry and VSS under remifentanyl-based conscious sedation in patients with IIH.

## METHODS

### Ethics and data availability

This study was approved by the institutional review board (IRB CRM-2308–368). This study used STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration. De-identified data will be made available on reasonable request to the corresponding author.

### Population and data collection

This is a single-arm retrospective study of consecutive patients diagnosed with IIH and undergoing VSS between September 2019 and January 2024 at a tertiary care center. Patients were eligible for inclusion if they were adults (>18 years old), diagnosed with IIH based on modified Dandy criteria, and optimal medical treatment had failed.

Electronic medical records were queried to extract demographics (sex, age, body mass index), radiological and endovascular details (stenosis type, pre-stenting and post-stenting gradient, stent used, post-stenting angioplasty), anesthetic details, and clinical outcomes (table 1). Anesthetic data encompassed hemodynamic parameters, saturation levels, and the level of conscious sedation evaluated using the Ramsay Sedation Scale.

### Radiographic data

Patients underwent a brain MRI scan and gadolinium-enhanced MR venography. Venous drainage was defined as balanced when the two lateral sinuses were co-dominant, and unbalanced when there was a dominant lateral sinus, defined as at least two times wider than the contralateral sinus. Lateral sinus stenosis was classified as ‘extrinsic’ or ‘intrinsic’ based on images.<sup>9</sup> The type, side (unilateral or bilateral), and location of stenosis were recorded.

### Anesthesia protocol

On admission to the angi suite, patients were continuously monitored by the anesthesia team and the radiology nursing staff with standard ECG, non-invasive blood pressure, and oxygen saturation monitoring. An oxygen face mask with capnography was used in all patients. Remifentanyl was chosen rather than other agents because its dose can be meticulously and rapidly titrated (target-controlled infusion) by the anesthesia care team: the necessary dose is delivered to achieve the desired concentration for a particular patient. This concentration is then titrated to account for variable drug sensitivity to achieve the desired depth of sedation depending on the phase of the procedure.

After securing appropriate intravenous access and conducting the preoperative checklist, remifentanyl-based target-controlled infusion was started with an objective of Ramsay Sedation Scale score of 1–2 (Scale score 1: awake; agitated or restless or both; Scale score 2: awake; cooperative, oriented, and tranquil) for the puncture, venography phase, and venous manometry. Sedation was deepened by the anesthesia team to a Ramsay Sedation Scale score of 3–4 (Scale score 3: awake but responds to commands only; Scale score 4: asleep; brisk response to light glabellar tap or loud auditory stimulus) before the intracranial placement of the guide catheter and the navigation of the microcatheter to ensure patient comfort and reduce the risk of patient movement, especially during the stent’s deployment. Additional drugs (propofol or midazolam) might be occasionally administered to reach our anesthetic goal and are given at the discretion of the attending anesthesiologist.

After the stenting, sedation was stopped and we wait for the patient to regain a mild level of sedation 1–2, then a control manometry procedure is performed. Prophylactic ondansetron was administered to all patients. After the procedure, patients were monitored in the post-anesthesia care unit, followed by transfer to a regular floor for hourly neurological assessments and measurements of vital signs.

### Stenting procedure technique

All patients provided explicit consent before the endovascular intervention. Dual antiplatelet therapy with aspirin (75 mg/day) and ticagrelor (180 mg/day) was initiated 1 day before the procedure and continued for 3 months, followed by 3 months of aspirin alone (75 mg/day). VSS was performed in all cases using a standardized procedure. Femoral artery and vein access were obtained using 5F and 8F sheaths, respectively, with intravenous heparin administered (bolus of 50 IU/kg). Ipsilateral internal carotid artery arteriography was then conducted to obtain venous mapping. A 0.088-inch guide catheter was positioned in the ipsilateral extracranial internal jugular vein before the jugular bulb, and a 0.027-inch microcatheter Excelsior XT-27 (Stryker Neurovascular, Fremont, California, USA) was navigated over a 0.014-inch microwire through the transverse sinus into the superior sagittal sinus then to the contralateral sinus. Manometry was conducted under light sedation as defined by the Ramsay Sedation Scale score of 1–2 to establish pressure measurements and gradients. VSS was confirmed on venous manometry as a stenosis associated with a trans-stenotic venous pressure gradient >5 mm Hg. Stenting was subsequently performed, always under conscious sedation, by deploying a self-expandable Carotid WALLSTENT (Boston Scientific Inc., Marlborough, Massachusetts, USA) based on the length and regions of stenosis. Following the withdrawal of the guide catheter into the internal jugular vein, the same microcatheter was again navigated into the contralateral transverse sinus and then into superior sagittal

sinus, and manometry was repeated in the same way at the end of the procedure.

Technical stenting success was defined as both angiographic resolution of the stenosis and an appropriate reduction in the trans-stenosis gradient below 5. After stenting, repeat ipsilateral internal carotid artery arteriography was performed, with meticulous attention to the venous phase, to evaluate any procedural complications, especially the permeability of the venous system or in-stent or juxta stent stenosis. A closure device was then used for arterial hemostasis, and manual compression was applied at the venous access site for at least 10 min.

### Clinical and radiological follow-up

Patients included in this study were systematically followed up, with the first imaging control at 1 month with a CT scan and a CT-venography examination. Subsequent follow-up assessments included an MRI-venography scan at 6 months, along with neurological and ophthalmologic examinations at 6 and 12 months.

### Complication definition

Inpatient complications were defined as those identified during the procedure (intraprocedural), in the post-anesthesia care unit, or while admitted to the postprocedural ward before discharge. Early outpatient complications were defined as those identified within the initial 48 hours after hospital discharge. Late outpatient complications were defined as those occurring between 48 hours and 7 days after discharge. Complications were defined as (1) any type of intracranial hemorrhage; (2) acute ischemic stroke; (3) acute or worsening neurological deficit or visual loss; (4) acute stent thrombosis; (5) access site or other bleeding complication; (6) seizure; (7) conscious sedation-related complications (conversion to general anesthesia, dyspnea, desaturation, introduction of norepinephrine, agitation); (7) worsening of previous symptoms; (8) otherwise unspecified complications requiring the need of a higher level of care. Acute headache and nausea were not included as they are commonly associated with stent implantation.

### Statistical analysis

Statistical analysis of data was performed using SPSS software (version 25.0; IBM, Armonk, New York, USA). Qualitative variables were reported as numbers and percentages, whereas quantitative variables were reported as medians with IQR.

## RESULTS

### Clinical and radiological data

The baseline characteristics of this cohort are reported in [table 1](#). Twenty-six patients were included in our study. The median (IQR) age was 33 (13) years and 24 (92.3%) patients were female. The median (IQR) body mass index was 34 (10). The median (IQR) duration of symptoms up to stent placement was 13 (6) months. Of the 26 patients, 20 (76.9%) had papilledema, 24 (92.3%) daily headaches, and 13 (50%) had pulsatile tinnitus. In 23/26 (88.5%) patients, stenting was performed after failure of medical treatment. One patient had acute fulminant IHH and one patient was treated after cerebrospinal fluid diversion failure. Fifteen patients (57.7%) had extrinsic stenoses. The stenoses were bilateral in 13 cases (50%). The venous drainage was balanced in 8 cases and unbalanced 18 cases. The median (IQR) cerebrospinal fluid opening pressure was 34 (10) cm H<sub>2</sub>O.

**Table 2** Procedural, hospitalization and follow-up data of patients undergoing venous sinus stenting

Factors	N or median (IQR)
Stenosis	
Unilateral (N)	13
Bilateral (N)	13
Patients with extrinsic stenosis (N)	15
Bilateral stenting	3
Preprocedural trans-stenosis gradient (mm Hg)	14 (11.0)
Postprocedural trans-stenosis gradient (mm Hg)	3 (2.0)
Median arterial pressure (mm Hg)	95 (5.0)
Saturation O <sub>2</sub> (%)	100 (2.0)
NPRS (0–10)	2 (1)
Complications	1
Patients admitted to ICU	0
Follow-up (months)	7 (2.0)
Patients with regression or resolution of	
Headaches (N)	22
Papilledema (N)	16
Tinnitus (N)	13
Any stroke, permanent morbidity, or mortality (N)	0

ICU, intensive care unit; NPRS, Numeric Pain Rating Scale.

### Procedural data

All patients underwent VSS under conscious sedation. Three patients (3/26, 11.5%) patients needed the addition of propofol and two patients (2/26, 7.7%) needed midazolam, but none were converted to general anesthesia. A Carotid WALLSTENT (Boston Scientific, Marlborough, Massachusetts, USA) was used in all patients. The median preprocedural trans-stenosis pressure gradient was 14 (11) mm Hg. The median (IQR) arterial pressure was 95 (5.0) mm Hg and there was no case of hypoxemia. Twenty-three patients underwent unilateral stenting. No patient required two or more ipsilateral stents. Only one patient required post-stenting angioplasty during the procedure. In 3/13 (23.1%) patients with a bilateral stenosis, a bilateral stenting was done in the same session to lower the trans-stenotic gradient that persisted after the deployment of the first stent. Technical success was achieved in all included patients. The Numeric Pain Rating Scale was evaluated (within 1 hour) with 25/26 (96.2) patients reporting pain  $\leq$ 2 and only one patient reporting 3. None of the patients were admitted to the intensive care unit following VSS. All patients were discharged after an overnight stay. During the 48 hours after discharge, no patient returned to any emergency room for evaluation. The procedural and hospitalization data are reported in [table 2](#).

### Follow-up

Median (IQR) follow-up after stenting was 7 (2) months. Of 24 patients, 22 (91.7%) had improvements in headaches. All the 13 patients presenting with pulsatile tinnitus had resolution of symptoms immediately after stenting, without recurrence during the follow-up. Of the 20 patients with papilledema pre-stenting, 16 (80%) had improvement on follow-up fundoscopic and optical coherence tomography examination. No patient was re-treated by stenting or required surgical treatment. All stents were patent on the control CT venography at 1 month. The follow-up data are reported in [table 2](#).

## Complications

One complication was detected (retroperitoneal hematoma requiring endovascular embolization with a good recovery). No complications were identified after the stay in the post-anesthesia care unit and no additional patients required transfer to a higher level of care.

## DISCUSSION

In the present study, remifentanyl-based awake sedation was a safe and effective alternative to general anesthesia for VSS. To our knowledge, this is the first study reporting the use of conscious sedation for VSS. Conscious or awake sedation offers several advantages for VSS procedures. First, it allows the evaluation of trans-stenotic gradients pre-stenting and post-stenting in a nearly physiological state.<sup>10</sup> It also offers adequate control of the potentially painful and anxiety-inducing VSS while avoiding the inherent risks of general anesthesia, such as the need for invasive monitoring, endotracheal intubation, and the systemic effects of inhalational and intravenous agents.<sup>11</sup> Additional benefits of conscious sedation include shorter procedural time, reduced care unit stay, and accelerated recovery with fast hospital discharge. Performing the angiography, venography, manometry, and stenting in the same session without interruption has several advantages for workflow, patient comfort, and cost-effectiveness. Furthermore, remifentanyl-based conscious sedation is very effective in providing patient comfort and offers fast and predictable time to assessment of neurological function. This allows the interventionalist to monitor neurological status during the procedure and allows patients to respond appropriately to verbal commands or tactile stimulation in case relevant patient movement occurs during the procedure. In addition to the clinical assessment of the patient, awake sedation with remifentanyl in VSS has also the potential to reduce the need for future procedures by permitting accurate measurement of the gradient after stenting under the same sedation conditions. This would allow the interventionalist to make earlier decisions about additional stenting or angioplasty in cases of persistent symptoms or high-pressure gradient after the first stenting.

In view of the unique pharmacokinetic properties of remifentanyl (onset of action of about 1 min and an elimination half-life of less than 10 min),<sup>12</sup> it has been used extensively for a wide variety of surgical procedures and in a wide age range of patients, from neonates to geriatric patients. The usefulness of remifentanyl in patients undergoing awake neurosurgical procedures has also been demonstrated.<sup>13</sup> The cerebral hemodynamic effects of remifentanyl are similar to those of fentanyl.<sup>14</sup> Particularly, when ventilation is controlled, remifentanyl did not increase the intracranial pressure in patients undergoing craniotomy.<sup>15</sup>

Conscious sedation with opioids has its potential risks, including emesis, apnea, and dose-dependent difficult ventilation (opioid-induced glottic spasm, usually attenuated by pretreatment with midazolam), making it a delicate procedure.<sup>16</sup> In our series, no serious adverse effects were observed. In particular, obesity, which is often associated with IIIH,<sup>17</sup> is thought to be associated with an increased risk of difficult intubation in cases of general anesthesia, whereas conscious sedation allows reduction of the risk of failed airway management as the patient maintains spontaneous breathing.<sup>18 19</sup> It is also known that remifentanyl synergistically interacts with sedative agents. Therefore, the recommended starting dose of propofol is much lower than that used for hypnotic-based sedation when using remifentanyl-based sedation.<sup>14</sup>

The rate of procedure-related complications and mortality in our cohort was in line with previous studies evaluating VSS

under general anesthesia.<sup>20</sup> Nicholson *et al*<sup>3</sup> reported the overall rate of major complications as 1.9% while Satti *et al*<sup>21</sup> reported a major complication rate of 2.9%.

The limitations of this study were: (1) its retrospective nature and non-controlled design, making it prone to a selection bias; (2) the relatively small number of treated patients; (3) the absence of a matched comparison group receiving VSS under general anesthesia.

## CONCLUSION

Venous sinus stenting with remifentanyl-based conscious sedation was feasible, safe, and effective in patients with idiopathic intracranial hypertension and should be considered as an alternative for general anesthesia in patients undergoing venous sinus stenting. Larger and comparative studies are needed to further evaluate the safety and effectiveness of venous sinus stenting under conscious sedation.

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