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The impact of CSF venous fistula embolization on patient's quality of life, a longitudinal clinical-radiological exploration

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Abstract

Background Transvenous Onyx embolization of cerebrospinal fluid-venous fistulas (CSFVF) is an emerging and effective treatment for symptomatic spontaneous intracranial hypotension (SIH). This condition significantly impacts patients' quality of life (QoL) through a variety of debilitating symptoms.

Methods Patients were selected from a prospective database of individuals with CSFVF who underwent transvenous Onyx embolization. All participants were asked to complete 13 questionnaires assessing their QoL, before and three months after treatment. Clinical and radiological data were retrospectively collected from the database, and the impact of embolization was evaluated across multiple variables. Correlations and stepwise regression analyses were used to explore relationships between QoL and specific domains including headache, audio-vestibular and psychological symptoms, and spiritual well-being.

Results The study included 30 patients (mean age: 60.4 ± 14.1; female-to-male ratio: 2:1) diagnosed with SIH and CSFVF, that were treated successfully with Onyx embolization. There was no treatment-related morbidity. All 28 patients with headache reported symptom improvement, with 64% achieving complete resolution. The response rate was 100% for VAS-QoL, HIT-6, MIDAS grade, VAS-HI, and monthly headache days; lower rates were observed for SF-36 (56.6%), MSQ (96.7%), DHI and THI (90%), and psychological questionnaires (80–90%). Global QoL scores (VAS-QoL: $p < 0.001$, SF-36: $p < 0.05$) and QoL scores related to headache significantly improved post-treatment (HIT-6: $p = 0.0119$; MSQ: $p = 0.0004$; MIDAS: $p = 0.0236$). Psychological symptoms like depression and anxiety significantly decreased, while suicidal ideation resolved when present. Significant audio-vestibular QoL improvements were noted for dizziness ($p = 0.002$) and hearing disturbances ($p = 0.021$), but not for tinnitus ($p = 0.101$). MRI findings showed a significant reduction in SIH-related brain abnormalities (mean Bern-score: 6.3 ± 1.9 to 1.7 ± 1.5 post-treatment). However, changes in overall Bern-scores did not correlate with clinical variables, although brain sagging showed a trend toward correlation with headache intensity reduction ($r = 0.37$, $p = 0.06$).

Conclusion CSFVF embolization is associated with significant radiological and clinical improvements, leading to enhanced global quality of life for patients with SIH.

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Keywords Spontaneous intracranial hypotension, Embolization, CSFVF, Quality of life, Headache

Background

Spontaneous intracranial hypotension (SIH) is a debilitating condition primarily caused by cerebrospinal fluid (CSF) leaks at the spinal level. It's hallmark symptom is orthostatic headache [1, 2], although non-orthostatic, thunderclap or chronic daily headaches are equally observed [3]. The headache is frequently accompanied by a constellation of other symptoms, such as dizziness, tinnitus, cognitive impairments and hearing disorders. Since the first description of three cases by Schievink and colleagues in 2014 [4], cerebrospinal fluid veinous fistulas (CSFVF) have become an increasingly recognized cause of SIH. Initially, CSFVF were estimated to account for 2–5% of patients presenting with SIH [5]. With today's improved diagnostic techniques the true incidence of CSFVF might be much higher, as suggested by a study on patients presenting with SIH in Olmsted Country (Minnesota), in which CSFVF accounted for 50% of the leaks [6].

Recent studies have emphasized the significant decline in health-related quality of life among patients with spinal CSF leaks [7, 8]. These patients often experience physical, emotional, and social impairments, highlighting the need for timely and effective therapeutic interventions. Interventional treatments like surgical repair have demonstrated efficacy in improving outcomes, whereas blood patches seem to provide mainly temporary symptomatic relief [9, 10], despite being associated with reduced likelihood of persistent headache at 12 months compared to conservative treatment [11]. Volz et al. demonstrated that the severe impact of mostly type I and II spinal leaks on health-related quality of life improved significantly after closure of the leak [12]. In the case of CSFVF, embolization has been recognized as an effective and safe treatment closing the leak in the majority of patients [13–15]. However, it remains to be evaluated whether successful CSFVF sealing has a comparable positive impact on the patients' quality of life.

This study aims to address this gap by evaluating the impact of CSFVF embolization on patient's quality of life three months after embolization. By focusing on patient-centered outcomes, this research seeks to provide valuable insights into the effectiveness of this intervention in alleviating multilevel symptoms and restoring daily functioning.

Methods

Patient selection

Data of consecutive patients with SIH and a definitive diagnosis of CSFVF, as confirmed by two senior neuroradiologists with experience in SIH, were prospectively added to our database (IRB_MPT_2023_01_202201315). SIH diagnosis was based on clinical symptoms and brain magnetic resonance imaging (MRI) signs [16]. CSFVF were detected using digital subtraction myelography (DSM) performed under local anesthesia, exploring both sides of the spine on separate days for all patients, with either an Azurion 7 B20/15 fluoroscopy unit (Philips Healthcare, Best, The Netherlands) or an Artis Q system with integrated CT scan (Siemens Healthineers, Erlangen, Germany). A dedicated spinal myelography setup, operating at 3–4 frames per second with a tiltable table, was used to position the patient's hips above the shoulders. A 20-gauge spinal needle was utilized to puncture the lumbar thecal sac. The table was tilted between 4° and 7° in the Trendelenburg position, and up to 20 mL of Iopamiron 300 was injected. Initially, a small contrast injection (0.5 mL) was administered to confirm the needle's intrathecal position. Subsequently, 7 mL of Iopamiron 300 was injected over 5 s with the imaging system centered on the cervico-thoracic spine, followed by an additional 5–6 mL injection targeting the thoraco-lumbar spine. In cases of suspected lower lumbar or sacral CSFVF (e.g., presence of perineural cysts in the sacrum), an additional 4 mL of contrast was administered while tilting the table into the anti-Trendelenburg position. During DSM imaging, patients performed resisted inspiration to enhance fistula visualization. This involved having the patient breathe deeply through a 10 cc syringe (without a plunger), held with the right hand if lying right-side down, or the left hand if lying left-side down, with the barrel flange placed in the mouth. The patient was instructed to begin resisted inspiration once the contrast had filled at least three-quarters of the spine of interest. Resisted inspiration was performed twice: once during imaging of the upper cervico-thoracic spine and once during imaging of the lower thoraco-lumbar spine.

Following the final injection, CBCT was performed to further assist in CSFVF detection, with patients instructed to hold their breath to minimize motion artifacts. Immediately afterward, patients underwent a full-spine post-DSM dual-energy CT scan in the lateral decubitus position.

All patients with a definite diagnosis of SIH related to a CFSVF underwent transvenous Onyx embolization by the same experienced interventionalist (FC) and were screened for participation. Further inclusion criteria included patient's consent and cognitive capacity to complete clinical evaluation questionnaires and non-opposition to the scientific use of their imaging data. Patients with a spinal longitudinal extradural CSF collection were excluded from this study. Decision for endovascular

treatment was always confirmed by a multidisciplinary team including neuroradiologists, neurologists and neurosurgeons with expertise in CSF dynamics disorders.

Study design

All patients underwent brain MRI and completed clinical questionnaires within two weeks before embolization and at three months after intervention. Patients meeting the inclusion criteria were first contacted by phone to complete an initial set of questionnaires, after which a second set was sent by either email or post. The same procedure was repeated three months after embolization. Endovascular embolization was performed under general anesthesia by an experienced interventional neuroradiologist.

Endovascular procedure

Transvenous access was obtained by a femoral approach, as first described by the Mayo Clinic group in a technical report [13]. A detailed description of our institution's endovascular CSFVF treatment procedures is provided in a previous publication [14]. The procedure was carried out under general anesthesia. Following venous system catheterization, intravenous heparin was administered, resulting in activated clotting times measured between 200 and 250 s. Vascular access was achieved via the right or left common femoral vein. A 7 French Rist catheter was navigated into the azygos vein, ascending lumbar vein, or vertebral veins, depending on the fistula's location, using a 5 French Merit vertebral catheter as a guide. Microcatheterization of the paraspinal vein was performed with either a Headway Duo or a Scepter XC microcatheter, supported by a 0.14-inch microguidewire. Onyx 18 was employed to embolize the target veins. In certain cases, coils were placed to block high-risk connections to the azygos vein, minimizing the risk of Onyx migration.

Data collection

Clinical data and questionnaires were prospectively collected up to April 2024. Radiological data necessary for calculating the Bern score were gathered retrospectively from MRIs performed at baseline (Day 0) and at 3 months post-procedure. CSFVF location and characteristics were retrieved from the lateral decubitus dynamic DSM and dual-energy CT myelography.

Brain MRI

All patients underwent a brain and spine MRI (3T MAGNETOM Vida, Siemens Healthcare). This included 3DT1 weighted imaging, 3D FLAIR (fluid-attenuated inversion recovery), T2 GRE (gradient echo), axial DWI (diffusion weighted imaging) and SWI (susceptibility weighted imaging). The whole spine MRI was composed of heavy weighted 3D high-resolution SPACE (sampling perfection with application optimized contrast using different flip angle evolutions) with and without fat suppression. Images were used to estimate the MRI SIH score [9], composed of six criteria: venous sinus distention, pachymeningeal enhancement, subdural fluid collections, effacement of suprasellar cistern, of pre-pontine cistern and reduced mamillopontine distance. The latter two items were used to evaluate the presence of brain sagging [17]. Brain MRI was repeated at 3, 6, 12, and 24 months to assess the SIH score and its stability over the follow-up period.

Clinical evaluation

All patients underwent comprehensive neurological evaluation prior to treatment and at 3 months. Evaluations were conducted by the neuroradiologist that performed embolization and by a neurologist specialized in headaches. Clinical evaluations were continued at 6, 12, and 24 months to assess the stability of clinical improvement. All patients underwent thorough clinical evaluation by completing 13 standardized tests, addressing five domains (Table 1): 1) global quality of life, 2) headache related quality of Life, 3) audio-vestibular symptoms, 4) psychological symptoms and 5) spiritual well-being. In addition, we evaluated the frequency (number of days per month) and the intensity (0-100 visual analogue pain scale) of patient' headaches as potential covariates of interest. The global quality of life was evaluated through the 36-item Short Form Survey (SF-36) [18], and a Visual Analog Scale evaluating the subjective quality of life on a scale from 0 to 100 (VAS-QoL). The SF-36 is composed of eight subscales, corresponding either to the physical (physical functioning, role limitations due to physical healthy, bodily pain and general health) or to the mental component summary (vitality, social functioning, role limitations due to emotional health and mental health) [19]. Headache related quality of life was evaluated with the headache impact test (HIT-6) [20], the Migraine Specific Quality of Life Questionnaire (MSQ) [21] and the Migraine Disability Assessment (MIDAS) [22]. Audio-vestibular well-being was addressed with the Dizziness Handicap Inventory (DHI) [23], the Tinnitus Handicap Inventory (THI) [24] and the Speech, Spatial & Quality of Hearing Scale (15iSSQ) [25, 26]. The latter is a short form of Gatehouse and Nobles' (2004) Speech, Spatial and Qualities of hearing scale. The items are grouped in three subscales. The mean score of each subscale was calculated. Psychological well-being focused on anxiety, depression and suicide ideation using the Patient Health Questionnaire-9 (PHQ-9) [27], the General Anxiety Disorder-7 (GAD-7) [28], the Hospital Anxiety and Depression Scale (HAD) [29], and the Suicidal Ideation Attributes Scale (SIDAS) [30, 31]. Finally, spiritual well-being was evaluated with the Functional Assessment

Table 1 Clinical symptoms & quality of life evaluations

Global Quality of Life				
Test (Abbreviation)	**Short-Form Health survey (SF-36)**			**Visual-Analog-Scale on Quality of Life (VAS-QoL)**
Purpose	Global QoL assessment on the physiological and mental domain			Subjective global quality of life assessment in relation to the intracranial hypotension symptoms
No. Of questions	36			1
Recall period	Current and past four weeks			Current
Scoring system	0-100 (higher score better QoL)			0-100 (higher score better QoL)
Headache related Quality of Life				
Test (Abbreviation)	**Headache Impact Test (HIT-6)**	**Migraine specific Quality of Life Questionnaire (MSQ)**		**Migraine disability assessment (MIDAS)**
Purpose	Impact headache on ability to function (job, school, home, social)	How migraines affect and/or limit daily function across three domains		Functional impact of migraine and headache on working life
No. Of questions	6	14		5
Recall period	Lifetime & past 4 weeks	Past 4 weeks		Past three months
Scoring system	36–78 (higher score lower QoL)	0-100 mean score of: RR – perceived limitations, PR – activities prevented by migraine, EF – migraine associated emotions), with higher score, better QoL		Grade I-IV (higher grade, lower QoL)
Headache frequency and intensity				
Test (Abbreviation)	**Visual-Analog-Scale of headache intensity (VAS-HI)**			**The amount of monthly headache days (MHD)**
Purpose	Subjective perception of the headache's intensity			Objective count of the amount of headache days per month
No. Of questions	1			1
Recall period	current			1 month
Scoring system	0-100 (higher score, more severe pain)			0–30 (higher score, more days)
Audio-vestibular symptoms				
Test (Abbreviation)	**Dizziness Handicap Inventory (DHI)**		**Tinnitus Handicap Inventory (THI)**	**Speech Spatial & Qualities of hearing Scale (15iSSQ)**
Purpose	Evaluation of self-perceived handicap through dizziness.		Identification, quantification and evaluation of difficulties following tinnitus	Screening of spatial hearing and speech understanding ability in adults
No. Of questions	25		25	15
Recall period	Current		Current	Current
Scoring system	0-100 (higher score, more dizziness)		0-100 (higher score, stronger tinnitus)	0–10 (higher score, less hearing disability)
Psychological symptoms				
Test (Abbreviation)	**Patient Health Questionnaire-9 (PHQ9)**	**General Anxiety Disorder (GAD-7)**	**Hospital Anxiety and Depression Scale (HAD)**	**Suicidal Ideation attributes scale (SIDAS)**
Purpose	Evaluation of depression symptoms	Assessment of General Anxiety Disorder	Presence and severity of anxiety and depression symptoms in medical settings	Quantification of frequency and severity of suicidal ideation
No. Of questions	9	7	0–21 per condition	5

Table 1 (continued)

Recall period	Past two weeks	Past two weeks	Past week	Past Months
Scoring system	0–27 (higher score less favorable)	0–21 (higher score less favorable)	0–21 (higher score less favorable)	0–50 (higher score less favorable)
Spiritual well-being				
Test (Abbreviation)	**Functional Assessment of Chronic Illness Therapy on Spiritual Well-Being (FACITsp12)**			
Purpose	Evaluation of spiritual well-being in patients receiving treatment for chronic conditions			
No. Of questions	12			
Recall period	Past week			
Scoring system	0–48 (higher score more favorable)			

of Chronic Illness Therapy-spiritual Well-being test (FACIT-sp12) [32].

The response rate was 100% for VAS-QoL, HIT-6, MIDAS grade, VAS-HI, and monthly headache days. Response rates were lower for the SF-36 (56.6%), MSQ (96.7%), DHI and THI (90%), and psychological questionnaires (ranging between 80% and 90%).

Previous history of primary headache was recorded, as well as the presence of anxiety and depression before the beginning of SIH symptoms.

Patients were also asked to report their symptoms and specify whether they had improved, completely resolved, remained unchanged, or worsened. Symptom improvement was defined as the resolution or partial improvement of any symptom (e.g., resolution of orthostatic headache while dizziness persisted).

Post-treatment rebound headache was assessed through clinical evaluation and characterized by a shift in headache patterns, such as the development of non-orthostatic headaches or worsening of symptoms while lying down [33]. These headaches were commonly localized to the frontal or peri-orbital regions.

Statistical analysis

All analyses were performed with Medcalc 19.8 (MedCalc Software Ltd, Ostend, Belgium). The impact of CSFVF embolization was first evaluated for each collected variable, using a paired-T-test if normality was accepted and a Wilcoxon signed-rank test for non-parametric paired variables. Second, we evaluated the concordance between the two global quality of life measures, before evaluating potential relations between the global quality of life and headache, audio-vestibular, psychological, and spiritual related estimations of well-being and/or quality of life through correlation and stepwise regression analyses. Transformation was performed when the normality or the heterogeneity of variance assumptions for linear regression were violated.

Radiological sign resolution was compared using a repeated measures MANCOVA analysis, to evaluate potential interactions between radiological signs and quality of life, headache, audio-vestibular, psychological, and spiritual factors.

Results were expressed with the median [interquartile range] for continuous variables and as a percentage for categorical variables. The statistical threshold was set at $p < 0.05$. Because of the exploratory nature of the project, p-values were not adjusted for multiple testing. However, given the increased likelihood of Type-1 errors, significant results were interpreted with caution when near the threshold. Missing data were not imputed and were excluded from analysis.

Results

A total of 30 patients (20 female) were included in our study (mean age of 60.4 ± 14.1 years; mean body mass index of 23.5 ± 3.6). The mean symptom duration before embolization was 33 months ± 44. The most common symptom was headache (28 patients, 93%), with exertion (22 patients, 78%), cough (20 patients, 71%), orthostatic headache (19 patients, 68%), being present in most of patients, followed by non-orthostatic headache reported by four patients (14%). No patients except one had a previous history of primary headache. This was a 50-year-old female patient with a diagnosis of migraine for more than 10 years, under treatment with triptans. She developed orthostatic and cough headaches secondary to SIH in the last year, which had not been present before. No one had a previous history of depression or anxiety.

Ten patients had multiple CSFVF, with a maximum of three in one case. Successful embolization was achieved in all patients, without any morbidity related to the treatment (Table 2). Seven patients (23%) developed transient local back pain at the site of Onyx injection. There was one case of Onyx migration into the Azygos vein and two cases of epidural plexus perforation without any clinical symptoms. All patients reported improvement of headache symptoms at three months after embolization, with 64% of subjects feeling complete headache resolution. In addition, the

Table 2 Technical and clinical outcomes after CSFVF embolization

EMBOLIZATION			
		Number of patients	**%**
Successful embolization (number of CSFVF)		30 (48)	100%
Overall Complications		10	33%
Permanent complications		0	0%
Transient complications		10	33%
Type of complication			
- Transient local pain		7	23%
- Perforation of the epidural plexus		1	3%
- Onyx migration into the Azygos vein		2	6%
Overall rate of recurrent symptoms		3	10%
Overall rate of patients requiring repeated CSFVF embolization		3	10%
Patients developing post-treatment rebound headache		12	40%
Patients receiving medical treatment for rebound headache		6	20%
CLINICAL SYMPTOM EVOLUTION AFTER EMBOLIZATION			
	Number of patients	**Recovery after CSFVF embolization**	
		Complete	**Partial**	**No recovery**
Global			
Self-evaluated improvement after treatment	30 (100%)	19 (63%)	11 (37%)	0
Headaches			
Headache	28 (93%)	18 (64%)	10 (35%)	0 (0%)
Orthostatic	19 (68%)	15 (79%)	4 (21%)	0 (0%)
Non-Orthostatic	3 (10%)	2 (67%)	0 (0%)	1 (33%)
Exertion	22 (78%)	19 (86%)	3 (13,6%)	0 (0%)
Cough	20 (71%)	18 (90%)	2 (10%)	0 (0%)
Audio-vestibular			
Dizziness/Vertigo	19 (63%)	8 (42%)	7 (37%)	5 (26%) *
Tinnitus	13 (43%)	5 (38%)	3 (23%)	7 (54%) **
Hearing disturbance	12 (40%)	3(25%)	4 (33%)	5 (42%)
Psychological			
Depression	15 (50%)	9 (60%)	5 (33%)	1 (7%)
Anxiety	19 (63%)	8 (42%)	6 (32%)	5 (26%)
Suicide ideation	3 (10%)	3 (100%)	0 (0%)	0 (0%)

Psychological symptoms were considered positive when above the clinical threshold on any relevant clinical scale. *One patient developed dizziness symptomatology after embolization. **Two patients developed tinnitus after embolization

mean number of headache days per month significantly decreased at follow-up, with headache being present about 25 (± 9.2) days a month before treatment, and 2.8 (± 7.4) a month at follow-up ($p < 0.0001$). Patients rated their headache severity on a visual analogue scale (VAS-HI 0-100) with an intensity of 74.3 ± 27.6 before treatment, and 9.0 ± 15.6 after treatment ($p < 0.0001$). The rate of rebound post-treatment headache was 40% (12 patients) with a mean duration of one week (ranging from 24 h to 15 days).

All patients underwent brain MRI and clinical follow-up for a mean duration of 10 months (range, 6–24 months). Clinical symptoms and the Bern score remained stable during follow-up for all patients except three (10%). These three patients, who had initially experienced complete clinical and radiological recovery, developed recurrent symptoms approximately one year later. DSM revealed a de-novo CSFVF, which required a second embolization that led to complete symptom resolution.

Global & headache related quality of life

Before embolization 82.3% of patients rated their global quality of life as evaluated with the SF-36 on the physical domain as poor (< 50/100). Three months after embolization this improved to good or excellent physical health (60>/100) in the majority of patients (70.6%) underlining better physical health, reduced limitations, and enhanced ability to perform daily activities (Table 3). Similarly, the mental component showed a significant improvement from poor (76.4%) to good-excellent (100%) underlining a change from a negative stressful state to a generally positive mood, low stress, and good coping mechanisms. The VAS-QoL significantly increased after treatment from 23.5 (±25.8) to 88.7 (±15.5) ($p < 0.001$). Interestingly, both components of the SF-36 correlated with the VAS-QoL

Table 3 Overview of Radio-clinical symptoms before and after CSFVF embolization

	Respondents (% (nr)) **Pre-embolization**		**Respondents (%, (nr))** **Post-embolization**			
Radiological MRI-SIH						
	Mean ± std	Median[IQR]	Mean ± std	Median[IQR]	n	p
Overall Bern-score	6.2 ± 1.9	6.0 [5–8]	1.7 ± 1.5	2 [0–3]	30	< 0.001
Brain sagging	76.9% (20)		38.5% (10)			
Global quality of life						
SF-36 mental	38.7 ± 25.7	37.3 [20–57]	73.1 ± 21.6	79.0 [65–87]	17	< 0.0001
Poor (0–50)	76.4% (13)		5.9% (1)			
Fair (51–60)	5.9% (1)		5.9% (1)			
Good (61–75)	11.8% (2)		47.1% (8)			
Excellent (76–100)	5.9% (1)		52.9% (9)			
SF36-Physical	37.3 ± 23.3	32.8 [20–50]	71.0 ± 24.4	75.8 [59–91]	17	0.0001
Poor (0–50)	82.3% (14)		17.6% (3)			
Fair (51–60)	0% (0)		11.8% (2)			
Good (61–75)	17.6% (3)		11.8% (2)			
Excellent (76–100)	5.9% (1)		58.8% (10)			
VAS-QoL (0-100)	23.5 ± 25.8	15.0 [0–40]	88.7 ± 15.5	100 [80–100]	30	< 0.0001
Headache related quality of life						
HIT-6	65.7 ± 14.1	71.5 [62–75]	39.9 ± 7.1	36.0 [36–40]	30	< 0.0001
Minimal (36–49)	16.7% (5)		83.3% (25)			
Moderate (50–55)	6.7% (2)		13.3% (4)			
Substantial (56–59)	0% (0)		3.3% (1)			
Severe (60–78)	76.7% (23)		0% (0%)			
MSQ	47.7 ± 33.8	44.8 [22–77]	93.3 ± 14.6	100 [97–100]	29	< 0.0001
Severe (0–50)	51.7% (15)		3.4% (1)			
Moderate (51–70)	17.2 (5%)		6.9% (2)			
Mild (71–85)	10.3% (3)		6.9% (2)			
Minimal (86–100)	20.7% (6)		82.7% (24)			
MIDAS grade	3.4 ± 1.1	4.0 [4–4]	1.1 ± 0.6	1.0 [1–1]	30	< 0.0001
Mild (I) (0–5)	13.3% (4)		83.3% (25)			
Moderate (II) (6–10)	10% (3)		3.3% (1)			
Severe (III) (11–20)	0% (0)		0% (0)			
Very severe (IV) (≥ 21)	76.7% (23)		13.3% (4)			
Headache frequency and severity						
VAS-HI (0-100)	74.3 ± 27.6	80 [70–100]	9.0 ± 15.6	0.0 [0–10]	30	< 0.0001
MHD (days/month)	25.0 ± 9.2	30 [20–33]	2.8 ± 7.4	0.0 [0–0]	30	< 0.0001
Audio-vestibular symptoms						
DHI	35.8 ± 30.0	32.0 [0–54]	13.8 ± 20.5	0 [0–23]	27	0.002
No (< 16)	29.6% (8)		55.6% (15)			
Mild (16–34)	22.2% (6)		22.2% (6)			
Moderate (36–52)	22.2% (6)		18.5% (5)			
Severe (54–100)	25.9% (7)		3.7% (1)			
THI	23.5 ± 31.5	0.0 [0–50]	14.2 ± 25.5	0.0 [0–14]	27	0.102
No (0)	48.1% (13)		63.0% (17)			
Very mild (1–16)	11.1% (3)		14.8% (4)			
Mild (18–36)	7.4% (2)		0% (0)			
Moderate (38–56)	22.2% (6)		14.8% (4)			
Severe (58–76)	3.7% (1)		3.7% (1)			
*Catastrophic (78–100)_*	7.4% (2)		3.7% (1)			
15iSSQ	8.7 ± 2.1	10.0 [8.7–10]	9.4 ± 1.1	10 [8.9–10]	25	0.021
Little-no (8–10)	80.0% (20)		84.0% (21)			
Mild-moderate (6–8)	0% (0)		12.0% (3)			
Moderate-severe (< 6)	20.0% (5)		4.0% (1)			

Table 3 (continued)

	Respondents (% (nr)) Pre-embolization		Respondents (%, (nr)) Post-embolization			
Psychological symptoms						
HAD-Anxiety	9.0 ± 4.2	9.0 [6–12]	3.6 ± 4.0	3.0 [0–5]	27	< 0.001
No (0–7)	44.4% (12)		81.5% (22)			
Borderline (8–10)	22.2% (6)		11.1% (3)			
Likely clinical (≥ 11)	33.3% (9)		7.4% (2)			
HAD-Depression	7.9 ± 5.1	7.0 [4–11]	1.7 ± 1.9	1.0 [0–3]	27	< 0.001
No (0–7)	55.6% (15)		89.7% (26)			
Borderline (8–10)	14.8% (4)		3.7% (1)			
Likely clinical (≥ 11)	29.6% (8)		0% (0)			
GAD	6.0 ± 7.1	3.0 [0–10]	2.7 ± 3.9	1.0 [0–6]	27	0.001
Minimal (0–4)	59.3% (16)		70.4% (19)			
Mild (5–9)	14.8% (4)		18.5% (5)			
Moderate (10–14)	7.4% (2)		11.1% (3)			
Severe (15–21)	18.5% (5)		0% (0)			
PHQ-9	8.8 ± 8.2	6.5 [3–12]	3.7 ± 4.3	2.0 [0–6]	24	0.003
None (0–4)	45.8% (11)		66.6% (16)			
Mild (5–9)	20.8% (5)		16.7% (4)			
Moderate (10–14)	12.5% (3)		12.5% (3)			
Moderately severe (15–19)	0% (0)		4.2% (1)			
Severe (20–27)	20.8% (5)		0% (0)			
SIDAS	1.3 ± 4.8	0.0 [0–0]	0.1 ± 0.4	0.0 [0.0]	27	0.250
No (0–4)	92.6% (25)		100% (27)			
Mild (5–9)	3.7% (1)		0% (0)			
Moderate (10–14)	0% (0)		0% (0)			
Severe (15–20)	3.7% (1)		0% (0)			
Spiritual well-being						
FACIT-sp-12	24.8 ± 9.1	24.0 [20–32]	29.4 ± 10.1	26.5 [23–34]	24	0.002
High (40–48)	4.2% (1)		16.7% (4)			
Moderate (20–39)	75% (18)		79.2% (19)			
Low well-being (0–19)	20.8% (5)		4.2% (1)			

before embolization (SF36-mental: $p = 0.01$, $r = 0.586$; SF36-physical: $p = 0.000$, $r = 0.754$), but not after (VAS-QOL vs. SF36-mental: $p = 0.581$, $r = 0.135$; VAS-QoL vs. SF36-physical: $p = 0.529$, $r = 0.154$). Still, the changes in both subscales also correlated with the change in VAS-QoL (dVAS-QoL vs. dSF36-mental: $p = 0.008$, $r = 0.59$; dVAS-QoL vs. dSF36-physical: $p = 0.003$, $r = 0.64$).

All questionnaires evaluating the impact of headaches on the quality of life showed significant improvements after embolization (Table 3). Interestingly, the change in global QoL as assessed by the SF36 was uncorrelated to any of the headache related questionnaires (HIT-6, MSQ, and MIDAS) or headache frequency and severity (VAS-HI and amount of monthly headache days), whereas the self-esteemed quality of life as assessed by the VAS-QoL significantly correlated with all of them (Table 4). This suggested that the patients' subjective analysis of their quality of life was directly influenced by their primary symptom, whereas specifically constructed questions about mental and physical quality of life provide information on global factors impacting quality of life. In addition, the VAS-QoL before treatment was correlated with the time to treatment ($r = 0.387$, $p = 0.046$), and headache related questionnaires showed a higher negative impact of headaches on QoL for patients treated after the first year after symptom onset, compared to those treated within the first year (MIDAS: $p = 0.035$; HIT-6: $p = 0.034$). Thus, patients who waited longer for the correct diagnosis and treatment showed lower levels of health-related quality of life before intervention. This finding highlights the importance of treating patients as early as possible, as the impact on quality of life is directly proportional to the duration of symptoms. However, after intervention, no such effect was observed, underscoring the positive impact of embolization on patients' quality of life, even in cases of delayed diagnosis.

Psychological symptoms

Psychological well-being focused on three components known to be elevated in patients with confirmed SIH: depression, anxiety, and suicidal ideation [7]. These symptoms were described in 50% (15 patients) 63% (19

Table 4 Change in global quality of life as a function of headaches, psychological, audio-vestibular, and spiritual factors, using a ranked-spearman correlation

Headache related Quality of Life						
		dHIT-6	*dMSQ*	*dMIDAS*		
dSF-36 mental	r	-0.436	0.432	-0.024		
	p	0.0619	0.0648	0.9210		
dSF-36 physical	r	-0.321	0.288	0.104		
	p	0.1809	0.2320	0.6732		
dVAS-QoL	r	-0.453	0.617	-0.412		
	p	0.0119	0.0004	0.0236		
Psychological symptoms						
		dHAD-A	*dHAD-D*	*dGAD*	*dPHQ9*	*dSIDAS*
dSF-36 mental	r	-0.635	-0.512	-0.411	-0.387	-0.308
	p	0.0046	0.0299	0.0900	0.1013	0.1992
dSF-36 physical	r	-0.424	-0.166	-0.256	-0.114	0.010
	p	0.0793	0.5103	0.3049	0.6408	0.9674
dVAS-QoL	r	-0.461	-0.450	-0.248	-0.351	0.008
	p	0.0155	0.0186	0.2117	0.0927	0.9688
Audio-vestibular & physical headache symptoms						
		dDHI	*dTHI*	*d15iSSQ*	*dVAS-HI*	*dMHD*
dSF-36 mental	r	-0.210	-0.329	0.353	-0.341	-0.384
	p	0.3891	0.1685	0.1802	0.1537	0.1045
dSF-36 physical	r	-0.023	-0.117	0.098	-0.291	-0.320
	p	0.9254	0.6337	0.7183	0.2267	0.1812
dVAS-QoL	r	-0.271	-0.308	-0.121	-0.550	-0.424
	p	0.1723	0.1177	0.5829	0.0017	0.0194
Spiritual well-being						
		dFACIT				
dSF-36 mental	r	0.496				
	p	0.0308				
dSF-36 physical	r	0.387				
	p	0.1013				
dVAS-QoL	r	0.185				
	p	0.3857				

d = delta, signifying the change in score on each of the related questionnaires, r = spearman's ranked r; p-threshold < 0.05

patients) and 10% (3 patients) of the cases, respectively. Associated rates of complete regression were 60% (9 patients), 42% (8 patients), and 100% (3 patients).

HAD scores on both the anxiety and the depression component reached the clinical threshold in about 30% of the patients. This is both concordant with the GAD-7 on which 25% of the patients had a score above the clinically significant anxiety threshold of 10 points and the PHQ-9, which indicated the potential presence of severe depressive traits in ~20% of the patients. All scores dropped significantly after embolization with over 66% of patients having no complaints at all. Only three patients scored positive of suicidal ideation, of which one clinical. All suicidal thoughts disappeared after embolization (Table 3).

Interestingly, the changes in mental quality of life (SF36-mental) correlated negatively with the change in anxiety and depression in clinical settings as evaluated by the HAD. The lower the patients QoL, the higher the experienced anxiety and depression. Spiritual well-being, being correlated with both, might thereby function as a protective factor: the higher the spiritual well-being, the better the global quality of life of patients ($r = 0.549$, $p = 0.001$); whereby an increase in spiritual well-being correlated with the decrease in experienced anxiety (HAD-A: r=-0.640, $p = 0.001$) and depression (PQH-9: r=-0.558, $p = 0.005$). In addition, the intensity of psychological symptoms differed between patients that were treated within the first year of symptom onset ($n = 18$) and those treated after the first year ($n = 9$). Not only showed the late-treatment group higher levels of anxiety (HAD-A: $p = 0.0306$), depression (PSQ-9: $p = 0.033$) and suicidal ideation ($p = 0.043$), but also their resilience was lower (FACIT-sp12: $p = 0.012$). No effect of time-to-treatment was found after invention on psychological symptoms, demonstrating the efficiency of embolization in symptom resolution.

Audio-vestibular symptoms

Dizziness and vertigo were reported in 63% of patients (19 patients), non-pulsatile tinnitus in 43% (13 patients), and hearing disturbance (subjective feeling of hearing loss) in 40% (12 patients) with complete resolution

achieved in 42% (8 patients), 38% (5 patients), and 25% (3 patients) of the cases, respectively.

A significant change in audio-vestibular symptoms was observed for dizziness ($p = 0.002$) and hearing disturbance ($p = 0.021$), but not for tinnitus ($p = 0.101$). Dizziness symptoms remained unchanged in 21% of the patients (4 cases). For tinnitus and hearing disturbances no change was observed in 38% (5 cases), and 42% of the patients (5 cases), respectively. Furthermore, after CSFVF one patient experienced dizziness, and two patients reported non-pulsatile tinnitus, despite normalization of the brain MRI. Although, dizziness significantly decreased by the embolization, the presences of tinnitus did not (Table 3). None of the audio-vestibular symptoms correlated with QoL and none were impacted by the time between symptom onset and treatment. However, the change in intensity of audio-vestibular symptoms did correlate with the change in anxiety (dHAD-A, d15iSSQ r=-0.547, $p = 0.008$; dHAD-A, dTHI: $r = 0.713$, $p = 0.000$; dGAD-7, dDHI: 0.583, $p = 0.002$) and depression (dPHQ-9, d15iSSQ: r=-0.616, $p = 0.003$, dHAD-D, dTHI: $r = 0.704$, $p = 0.000$; dPHQ-9, dDHI: $p = 0.575$, $p = 0.003$).

Stepwise regression

The potential link between the change in global quality of life and psychological and physiological questions was addressed by a stepwise regression. As a limited amount patients completed the SF-36 at both time-points (19/30) in addition to missing data on the other clinical scales, no valid regression could be performed with the SF-36. The change in global quality of life as estimated by the VAS-QoL was predicted by the intensity of headaches on the one hand (reg. 1), and by the hospital related anxiety on the other (reg.2).

Reg.1: All physical symptoms: DHI, THI, 15iSSQ, MHD, VAS-HI

$$dVAS\text{-}QoL = -27.43 - 5.93 * dVAS\text{-}HI,\ (F\text{-}ratio: 18.9,\ p < 0.001,\ r = -0.680,\ r^2_{adj} = 0.437).$$

Reg 2: All psychological symptoms: HAD-A, HAD-D, GAD, PHQ9, SIDAS

$$dVAS\text{-}QoL = -45.89 - 3.09 * dHAD\text{-}A,\ (F\text{-}ratio: 7.17,\ p = 0.01,\ r = -0.52,\ r^2_{adj} = 0.236)$$

MRI-SIH brain signs

Radiological follow-up confirmed a significant drop in MRI-SIH brain signs following the Bern-score from 6.3(± 1.9) to 1.7(± 1.5) after CSFVF embolization. However, the changes in the Bern-score did not correlate with any of the clinical variables. Instead, when focusing on brain sagging only, it was found that the amount of change in brain sagging following embolization tended to correlate with the amount of change in headache intensity ($r = 0.37$, $p = 0.06$). Moreover, when dividing our patients in two groups 'with any change in brain-sagging' (15 cases) and 'without any change in brain sagging' (11 cases) it was found that the former showed stronger improvements in hearing disabilities ($p = 0.05$). Unfortunately, subsequent sub-group analyses (MANCOVA) between those with and without brain sagging did not show any between-group interactions with headache, psychological, or audio-vestibular related symptoms, although this might be caused by the relatively small sample size.

Discussion

This longitudinal radiological-clinical study provides valuable insights into the impact of transvenous Onyx embolization in patients with SIH associated to CSFVF. We aimed to unravel the complex interactions between patients' perceived quality of life, their time-to-treatment, radiological, physiological, and psychological symptoms before and three months after treatment. First, we confirmed the efficiency of embolization in resolving radiological, headache, audio-vestibular and psychological symptoms. Secondly, we highlighted how alleviating the debilitating symptoms significantly improved patients' quality of life. The main physical factor explaining perceived quality of life was the intensity of the headaches, whereas, psychologically, the patients' anxiety had the strongest impact on their quality of life. Interestingly, the quality of life before embolization correlated with the time-to-treatment, the longer the time to treatment, the lower the perceived quality of life. In addition, those patients treated over one year after symptom onset showed significantly higher levels of anxiety, depression and suicidal thoughts, with lower levels of quality of life, independently of their actual physical symptom intensity.

Quality of life improvements

Our findings underscore the substantial burden of SIH caused by CSFVF on patients' QoL. Pre-treatment, the majority of patients reported severe impairments: 76% and 82% fell into the "Poor" category for SF-36 mental and physical health, respectively, with a median VAS-QoL scores of 15.0 out of 100. These results align with the global literature on quality of life in patients with SIH, highlighting that people with confirmed or suspected SIH face severe impairments in basic daily living activities, resulting in considerable QoL reduction [7, 8, 12, 34, 35]. Subsequently, we demonstrated that successful embolization of a CSFVF leak induced a dramatic shift in QoL. That is, only 6% of patients remained in the "Poor" mental health category, while 53% achieved "Excellent" outcomes. Similarly, for physical health, the proportion in the "Poor" category dropped to 17%, with 59% reaching

"Excellent" scores. VAS-QoL mirrored these improvements, with a post-treatment mean of 88.7 and a median of 100. These findings highlight a remarkable transition from impaired QoL to near-to-optimal health and functionality for the majority of our patients. Comparably, targeted surgical treatment of mainly type I-II leaks also demonstrated substantial improvements in specifically health-related quality of life (HRQOL), as evidenced by significant increases in health state index and the visual analog scale of the EuroQoL questionnaire [12]. Moreover, surgical or endovascular interventions have recently been shown to not only restore (health-related) QoL, but also the socioeconomic status of patients [36].

Headache relief

Headache was the most prevalent and debilitating symptom among patients with SIH caused by CSFVF. Notably, the 64% complete headache resolution rate and the dramatic reduction in headache frequency—from 25 to 2.8 days per month—demonstrates the profound efficacy of transvenous Onyx embolization in addressing this primary symptom. These results align with the broader literature on SIH. In a comprehensive study by Brinjikji et al., involving 100 patients with CSFVF treated via transvenous embolization, demonstrating that 72% of patients presenting with headache experienced complete resolution and an additional 19% reporting significant improvement [37]. Additionally, we observed a substantial decrease in headache intensity, that underscored the intervention's ability to alleviate pain severity, further reinforcing the therapeutic potential of targeted embolization. This is important, as the change in headache intensity was the physical symptom that contributed most to the improvements in quality of life. The substantial changes in MIDAS and HIT-6 scores confirm the efficacy of embolization in reducing the functional limitations imposed by headaches. The MSQ results underscore the broader impact of treatment on restoring patients' ability to engage in daily activities. All of which are indicators of improved health-related QoL (HRQoL). Interestingly, while the global QoL as assessed by the SF-36 showed no correlation with headache-specific metrics such as the HIT-6, MSQ, MIDAS, or headache severity and frequency (VAS-HI and monthly headache days), the self-reported QoL demonstrated a strong correlation with all of these parameters. This dichotomy underscores the multifaceted nature of QoL assessments. Standardized tools like the SF-36 are constructed to evaluate broad physical and mental health dimensions providing an estimation of well-being beyond medical conditions [38]. In contrast, the VAS-QoL reflects patients' subjective perception of their global QoL, which appears to be directly influenced by the disease-related dominant symptom, in our case headache. These findings emphasize the importance of incorporating both subjective and standardized QoL assessments to comprehensively evaluate treatment outcomes, as they provide complementary insights into the physical, psychological, and symptom-specific impacts of CSFVF.

Psychological symptoms

Depression and anxiety are among the most prevalent psychological comorbidities associated with SIH, as evidenced in both this study and prior literature. Approximately 30% of patients in our cohort were classified as having moderate-to-severe or clinically relevant depression based on PHQ-9 and HAD scores before intervention. These findings align with the work of Liaw et al., [7] who reported even higher rates of depression (approximately 50%) among patients with confirmed or clinically suspected SIH. Our results demonstrate significant improvements in depression metrics following embolization. In contrast, health related anxiety levels remained elevated for a portion of the patients. That is, even though the proportion of patients in the "no-anxiety" category (HAD-A score 0–7) increased, the proportion of patients classified as having likely clinical anxiety (HAD score > 11) decreased only from 33 to 7% post-treatment. In line, any anxiety on the GAD-7 (> 4) dropped from 61.3 to 29.6% and the proportion of patients with moderate to severe anxiety (GAD-7 10–21) dropped from 26 to 11%. Thus, although embolization is very efficient in alleviating depressive symptoms, anxiety-related symptoms might take more time. This is important as the level of health-related anxiety was the main psychological predictor of patients' QoL. Nevertheless, a direct link seems again to be confirmed between symptom relief and improved psychological stress and mental health, whether for depression [7] or anxiety [7, 12]. The fact that both anxiety and depressive levels were higher in the group of patients that were treated later underscores the critical need for timely targeted diagnosis and treatment, such as embolization, to seal the leak and alleviating not only physical complaints but also avoiding long-lasting psychological distressed associated to SIH. It might be hypothesized that patients' anxiety levels rise with every medical visit with unsuccessful explanation for the triad of debilitating physical complaints increasing feelings of helplessness, loneliness and isolation [39, 40].

Audio-vestibular symptoms

Audio-vestibular symptoms were unrelated to the global or health related quality of life. Still, they did correlate with anxiety and depression levels. Among the cohort of patients, dizziness and vertigo were reported in 63% of patients, while non-pulsatile tinnitus subjective hearing disturbances were described in 43% and 40% of patients, respectively. Interestingly, the resolution rates

for these symptoms varied. When patients were asked to describe symptom rate improvement, dizziness and vertigo showed complete resolution in 42% of patients, while non-pulsatile tinnitus and hearing disturbances resolved in 38%, and 25%, respectively. However, the change in tinnitus, as evaluated by the THI, did not significantly decrease for the overall patient group. This seems to be caused by the fact that little changes were observed among patients with severe and catastrophic tinnitus (from 11 to 7%). It suggests that while the treatment may provide some relief for mild tinnitus symptoms, it is less effective for patients with more severe tinnitus. This aligns with previous large studies on CSFVF embolization. Brinjikji et al. [37] highlighted significant prevalence of auditory and vestibular symptoms—tinnitus (55%), dizziness/vertigo (29%), and hearing loss (35%)—in patients with CSFVF, reporting that tinnitus tends to persist despite effective embolization, especially in very chronic SIH patients. It is likely that tinnitus may arise from the transmission of abnormal CSF pressure to the cochlear perilymph or from brain sagging, which can stretch and irritate the vestibulocochlear nerve, leading to auditory symptoms such as tinnitus that may persist despite de resolution of the cause [41]. Tinnitus management may thus require more specialized approaches, such as cognitive-behavioral therapy, sound therapy, or tinnitus retraining therapy [42, 43]. Future studies should investigate adjunctive treatments that specifically target tinnitus to enhance outcomes in SIH patients.

Symptom duration & clinical manifestations

In our study, the mean symptom duration prior to embolization was 33 months, with 40% of patients suffering for more than five years. These patients' higher levels of anxiety and lower levels of quality of life and spiritual resilience emphasized both the chronic and debilitating nature of SIH and the challenges in diagnosing CSFVF. Previous studies have confirmed that extended symptom duration not only amplifies the physical and psychological burden of SIH but also reduces the likelihood of achieving complete clinical remission in both type I-II and type III leaks [35, 37, 44], although we could not confirm this finding, either as a function of the high embolization success rates or as a function of our limited sample-size.

Closer interdisciplinary collaboration — involving neurologists, neuroradiologists, ENT specialists, psychiatrists, and pain specialists — could greatly enhance the early recognition and management of SIH. Raising awareness across different disciplines about the varied clinical manifestations is crucial to increase sensitivity to the importance of early and targeted closure of the leak.

Limitations

Our study has some limitations. First, the results of the questionnaires were collected at three months, which is a relatively short follow-up period, although all patients were clinically and radiologically followed for a longer time. Second, some of the headache-specific tests, such as HIT-6, MIDAS, and MSQ, are not formally validated for secondary headaches, although there is a growing body of literature supporting their use in headaches secondary to SIH.

Another important limitation is the lower complete response rate for some quality of life assessments, such as the SF-36, which had a 56.6% complete response rate, and for some of the psychological test batteries, which had a complete response rate ranging between 80% and 90%. Completion of the psychological test battery was dependent on the available time of both the interventionists and the patients. Nevertheless, we believe that our findings are valuable, as they demonstrate the significant impact of CSFVF embolization on patients' well-being and quality of life.

In addition, they highlight the importance of integrating psychological evaluations before and after the intervention with a dedicated neuropsychologist, who could provide counseling when needed and ensure higher response rates. Following the results of this study, we have routinely integrated dedicated neuropsychological counseling for all SIH patients in our department, both before and during follow-up.

Another limitation of our study is the absence of an objective assessment of drug consumption. Patients often tend to minimize or inaccurately recall medication use during interviews, and this information was inconsistently reported in the headache diaries. Therefore, we chose not to analyze drug consumption data for the purposes of this study.

The generalizability of our findings is limited by the small sample size, the mid-term longitudinal follow-up, and the monocentric nature of the results.

Accordingly, future studies should consider longer follow-up periods beyond three months to evaluate the long-term persistence of treatment effects and the impact on working life and social reintegration. Finally, it would be interesting to evaluate targeted treatment of CSFVF through multicenter studies, in order to more robustly demonstrate the impact of fistula closure in a larger population.

Conclusion

This study underscores the substantial impact of SIH caused by CSFVF on patient well-being and highlights the clinical efficacy of transvenous Onyx embolization as a transformative intervention. The results demonstrate significant improvements across multiple domains,

including quality of life, headache severity, psychological health, and certain audio-vestibular symptoms. Quality of life was best predicted by the intensity of the headaches and the level of health-related anxiety, whereby longer treatment times was associated with a lower quality of life. The strong correlation between physical and psychological symptoms emphasizes the importance to decrease treatment times. Our findings highlight thus again the critical need for early recognition and targeted treatment of the leak to mitigate the long-term impact of CSFVF on peoples' lives.

Abbreviations

15iSSQ	15 item short form of the speech, spatial and qualities of hearing scale
CSF	Cerebral spinal fluid
CSFVF	Cerebral spinal fluid venous fistula
CT	Computed tomography
DHI	Dizziness handicap inventory
DSM	Digital subtraction myelography
FACIT-sp12	Functional assessment of chronic illness therapy on spiritual well-being
GAD-7	General anxiety disorder scale-7
HAD	Hospital anxiety (A) and depression (D) scale
HIT-6	Headache impact test-6
MHD	Monthly headache days
MIDAS	Migraine disability assessment
MRI	Magnetic resonance imaging
MSQ	Migraine specific quality of life questionnaire
PHQ-9	Patient health questionnarire-9
QoL	Quality of life
SF-36	Short-form health survey
SIDAS	Suicidal ideation attributes scale
SIH	Spontaneous intracranial hypotension
THI	Tinnitus handicap inventory
VAS-HI	Visual analogue scale of perceived headache intensity
VAS-QoL	Visual analogue scale of perceive global quality of life

Author contributions

MG: data collection, data analysis, interpretation and manuscript writing. LVD: data analysis, interpretation, manuscript writing and project coordination. VC: project coordination and interpretation. GR: data acquisition and data analysis. LC: data acquisition and interpretation. OP: neuropsychological data interpretation. NL: data acquisition and interpretation. ELB: MRI data acquisition and analysis. AD: data acquisition and interpretation. FC: project conception, project coordination, interpretation and manuscript writing. All authors reviewed and approved the final manuscript.

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Data availability

The dataset supporting the findings of this study is available upon reasonable request from any qualified investigator.

Declarations

Ethics approval and consent to participate

This study was approved by the local ethical committee (IRB_MPT_2023_01_202201315). All procedures were in line with the declaration of Helsinki. All participant received an information letter and gave consent by non-opposition.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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