

SPIDER Study Protocol

Study Title

SPIDER – *Spinal Dural Arteriovenous Fistula International Data and Outcomes Registry*

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Study Version and Date

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Background and Rationale

Spinal dural arteriovenous fistulas (SDAVFs, type I spinal vascular malformations) are the most common spinal vascular malformation but remain frequently underdiagnosed due to their insidious onset and nonspecific clinical presentation. Delayed diagnosis is common and often results in progressive, and sometimes irreversible, myelopathy. Despite advances in imaging and treatment, there remains significant variability in diagnostic timelines, treatment strategies (endovascular, surgical, or combined), and reported outcomes across institutions.

Existing literature is largely limited to single-center retrospective series or small cohorts, often underpowered to evaluate predictors of outcome, recurrence, and the impact of diagnostic delay. Furthermore, direct comparisons between treatment modalities and long-term functional outcomes using standardized clinical scales are limited.

The SPIDER registry is designed to address these gaps by creating the largest international, multicenter dataset of patients with spinal dural AVFs. By pooling de-identified data from high-volume centers worldwide, this study aims to provide robust, generalizable evidence to inform clinical decision-making and optimize patient outcomes.

Study Objectives

Primary Objectives

1. To characterize the clinical, radiological, and angiographic presentation of spinal dural AVFs.
2. To compare treatment strategies (endovascular, surgical, combined, or conservative management) and their angiographic and clinical outcomes.
3. To evaluate long-term neurological and functional outcomes following treatment.
4. To assess the impact of diagnostic delay on neurological status and long-term outcomes.

Secondary Objectives

- To identify factors associated with treatment failure or recurrence.
- To evaluate complication rates associated with different treatment modalities.
- To explore predictors of functional recovery using standardized outcome measures.

Study Design

This is an **international, multicenter, retrospective observational cohort study**.

Participating centers will contribute de-identified data on patients diagnosed with spinal dural arteriovenous fistulas who were evaluated and/or treated at their institution.

No interventions will be performed as part of this study. All data are derived from existing medical records, imaging, and procedural reports.

Study Population

Inclusion Criteria

- Patients of any age diagnosed with **spinal dural arteriovenous fistula (Type I)**.
- Diagnosis confirmed by spinal angiography, MRI findings consistent with SDAVF, and/or operative findings.
- Patients managed with endovascular treatment, open surgery, combined approaches, or conservative management.
- Both symptomatic and incidental/asymptomatic cases.

Exclusion Criteria

- Intramedullary spinal vascular malformations (e.g., glomus AVMs, juvenile AVMs).
- Perimedullary AVFs or other non-dural spinal vascular lesions.
- Cases lacking sufficient data to confirm diagnosis or treatment details.

Data Collection and Variables

Each participating center will extract data using a standardized spreadsheet with predefined categorical options to ensure consistency across sites. All data will be fully de-identified prior to submission.

Demographics and Center Information

- Country

- Study center (institution name)
- Patient study number
- Age at diagnosis
- Sex

Clinical History and Presentation

- Months from symptom onset to diagnosis
- Misdiagnoses prior to SDAVF diagnosis
- History of spinal trauma
- Incidental/asymptomatic presentation
- Presentation with rupture (spinal, intracranial, both, or none)
- Presence of myelopathy at diagnosis
- Presenting symptoms: back pain, radicular pain, sensory symptoms, motor weakness, spasticity

Functional Status at Diagnosis

- Modified Aminoff–Logue Scale (Gait)
- Modified Aminoff–Logue Scale (Bladder)
- Modified Rankin Scale (mRS)

Radiological and Angiographic Characteristics

- Laterality of fistula
- Spinal level of fistula (highest level if multilevel)
- Number of arterial feeders
- Highest and lowest arterial feeder levels (if multiple)
- Involvement of the artery of Adamkiewicz
- MRI findings (myelomalacia, cord edema, or T2 hyperintensity)

Treatment Details

- Year of treatment
- Time from diagnosis to first treatment
- Initial treatment modality:
 - Endovascular embolization alone
 - Open surgery alone
 - Combined approaches
 - Conservative management
- Endovascular details:

- Number of embolization attempts
- Embolic agent used
- Angiographic outcome
- Intra- or postprocedural complications
- Surgical details:
 - Intraoperative visualization modality
 - Indication for visualization
 - Surgical outcome (successful or unsuccessful disconnection)
 - Intra- or postoperative complications

Recurrence and Re-treatment

- Occurrence of recurrence
- Time to recurrence
- Treatment modality for recurrence
- Angiographic outcome after re-treatment

Follow-Up and Outcomes

- Duration of follow-up
- Symptom evolution at last follow-up (pain, sensory, motor)
- Modified Aminoff–Logue Scale (Gait and Bladder) at last follow-up
- Modified Rankin Scale at last follow-up
- Overall clinical status at last follow-up (improved, unchanged, worsened)
- Death, if applicable

Notes

- Additional relevant clinical or radiological comments

Outcomes

Primary Outcomes

- Functional outcome at last follow-up as measured by mRS and Modified Aminoff–Logue scales.
- Angiographic success (complete vs partial vs unsuccessful occlusion).

Secondary Outcomes

- Rate and predictors of recurrence.
- Complication rates by treatment modality.
- Association between diagnostic delay and neurological outcome.

Statistical Analysis Plan

Descriptive statistics will be used to summarize demographic, clinical, radiological, and treatment characteristics. Continuous variables will be reported as means with standard deviations or medians with interquartile ranges, as appropriate. Categorical variables will be reported as frequencies and percentages.

Comparative analyses will be performed to evaluate outcomes across treatment modalities using appropriate statistical tests (e.g., chi-square, t-test, ANOVA, or non-parametric equivalents). Multivariable regression models may be used to identify independent predictors of outcomes and recurrence.

Missing data will be handled using appropriate statistical methods depending on the extent and pattern of missingness.

Ethical Considerations

This study involves retrospective collection of **fully de-identified data** and poses minimal risk to participants. No direct patient contact will occur, and no protected health information will be shared.

Each participating institution is responsible for obtaining local Institutional Review Board (IRB) or Ethics Committee approval or exemption, as required by local regulations.

Data will be securely stored and accessed only by authorized study investigators.

Data Sharing and Publication Policy

Contributing centers will retain ownership of their local data. Aggregated data will be used for pooled analyses, conducted at the main study center. All participating centers will have

the opportunity to submit project proposals to conduct analyses using the study database, subject to review and approval at the discretion of the main study center.

Authorship on resulting manuscripts will follow ICMJE guidelines and will include contributors from participating centers based on data contribution and intellectual involvement.

If enrollment targets are met, the SPIDER registry is expected to support multiple high-impact publications addressing clinical presentation, treatment strategies, radiological predictors, and outcomes.

Timeline

- Center enrollment and IRB approvals: Ongoing
- Data collection deadline: **End of February 2026**
- Data cleaning and analysis: 2026
- Manuscripts preparation and submission: 2026

Funding and Conflicts of Interest

This study is investigator-initiated and currently unfunded. Any potential conflicts of interest will be disclosed in resulting publications.

Conclusion

The SPIDER registry aims to establish the most comprehensive international dataset on spinal dural AVFs to date. By leveraging multicenter collaboration, this study seeks to generate high-quality evidence to improve diagnosis, treatment selection, and long-term outcomes for patients with this rare but debilitating condition.