Title

Conservative versus Interventional Management of Postsurgical CSF Pseudomeningocoele: A Randomized Controlled Trial

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1. Background and Rationale

Background:
Postsurgical pseudomeningocoele formation is a relatively common complication after intracranial surgery, often associated with fluid collection at the surgical site. Management approaches vary, with options including conservative treatment or interventional strategies such as revision surgery, insertion of lumbar drainage, or simple wound puncture. Current evidence on the most effective treatment is limited, and there is a need for randomized controlled trials to evaluate the outcomes of these approaches.

Rationale:
This trial aims to determine whether an interventional approach offers superior outcomes compared to conservative management in terms of pseudomeningocoele absorption and overall patient recovery.

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2. Objectives and Hypotheses

Primary Objective:

1. New onset of wound CSF leakage necessitating revision surgery

Secondary Objectives:

1. To compare the infection rate between the two treatment groups.
2. To assess functional recovery using the Glasgow Outcome Scale–Extended (GOSE) at 1 year post-surgery.
3. Absorption of pseudomendingocoele at 4 months and 1 year post-surgery assessed by CT or MRI
4. Persistence of headache after the surgery – Pain Scale 0-10 (VAS)

Null Hypothesis:
There is no significant difference in the rate of CSF leakage and pseudomeningocoele absorption at 4 months and 1 year, as measured by CT or MRI, between patients treated ith conservative management and those undergoing interventional procedures (revision surgery, lumbar drainage, or simple puncture). Additionally, there is no significant difference in secondary outcomes, such as infection rates and functional recovery (measured by the Glasgow Outcome Scale–Extended), between the two
groups.

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3. Study Design

This study is a **parallel-group, randomized controlled trial** with two arms:

- **Interventional Group**: Patients undergoing local treatment - lumbar drainage insertion, simple wound puncture, fibrin glue or any combination.
- **Conservative Group**: Patients managed without surgical procedures, except for skin sutures.

Patients will be followed for a total of 1 year with CT or MRI assessments at 4 months and 1 year post-surgery.

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4. Participants / Population

Inclusion Criteria:

- Patients aged 18-80 years who have developed a pseudomeningocoele following elective intracranial surgery.
- Diagnosed fluctuation during clinical examination after the surgery, Pseudomeningocele Palpation Scale (PPS), II-IV

  I No or minimal fluctuation; underlying bone is clearly palpable with light palpation.

  II Definite fluctuation; underlying bone or muscle is palpable with moderate pressure.

  III Marked fluctuation; underlying structures are palpable only with firm pressure.

  IV Tense lesion; painful and/or erythematous; underlying structures are not palpable even with firm pressure.

  Light palpation: minimal pressure without causing discomfort
  Moderate pressure: increased pressure causing awareness but no pain
  Firm pressure: strong pressure causing discomfort or mild pain

- Willing and able to give informed consent.
- No prior history of previous cranial or spinal surgical intervention.

Exclusion Criteria:

- Patients with pseudomeningocoele due to emergency or trauma-related surgeries.
- Known or suspected infection at the pseudomeningocoele site at the time of recruitment.
- Severe comorbid conditions preventing participation (e.g., terminal illness, severe organ failure).
- Patients with conditions that require urgent surgical intervention not related to pseudomeningocoele management.

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5. Interventions

Interventional Arm:

- Patients will undergo one of the following procedures based on clinical judgment:
    1. **Revision surgery**: Surgical intervention to drain the pseudomeningocoele and ensure proper wound closure.
    2. **Lumbar drainage insertion**: Placement of a lumbar drain to facilitate cerebrospinal fluid (CSF) diversion.
    3. **Simple puncture**: Needle aspiration of the pseudomeningocoele under sterile conditions.

Conservative Arm:

- Patients will receive conservative management, with no surgical procedures other than the application of skin sutures if required. Monitoring and wound care will be provided.

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6. Outcomes

Primary Outcome:

- **New onset of wound CSF leakage or tension pseudomeningocele necessitating revision surgery**

Secondary Outcomes:

- **Infection rate**:
  Incidence of infection related to the pseudomeningocoele or any interventions, including signs of local infection, meningitis, or systemic sepsis, within 1 year.

- **Functional recovery (GOSE)**:
  The Glasgow Outcome Scale–Extended (GOSE) will be assessed at 1 year post-surgery to evaluate functional outcomes and quality of life. GOSE scores range from 1 (death) to 8 (upper good recovery).
- **Pseudomeningocoele absorption on CT or MRI**:
  The primary outcome is the resolution or reduction of the pseudomeningocoele, assessed through CT or MRI at **4 months** and **1 year** post-surgery. Scans will be reviewed by blinded radiologists, and pseudomeningocoele size will be measured and recorded.
- **Visual Analogue Scale**

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7. Randomization and Blinding

Randomization:
Participants will be randomized in a 1:1 ratio to the interventional or conservative treatment arms using a computer-generated randomization sequence. Randomization will be stratified by age and body mass index.

Blinding:
Due to the nature of the interventions, patients and surgical teams cannot be blinded to group allocation. However, the radiologists interpreting the CT or MRIs and the independent data assessors evaluating outcomes will be blinded to the treatment arm.

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8. Sample Size Calculation

A sample size of **60 patients** (30 per group) will be required to detect a clinically significant difference in pseudomeningocoele absorption between the two groups, with a power of 80% and an alpha of 0.05.

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9. Statistical Analysis

- **Primary outcome**:
  The proportion of patients requiring revision surgery for CSF leakage or tension pseudomeningocele at 4 months and 1 year will be compared between the two groups using a chi-square test. Time-to-absorption analyses will be conducted using Kaplan-Meier survival curves and log-rank tests.
- **Secondary outcomes**:
  Infection rates will be compared using Fisher's exact test, and GOSE scores will be analyzed using a Mann-Whitney U test to assess differences in functional recovery between groups.
- **Multivariate analysis**:
  Multivariate logistic regression will be used to adjust for potential confounders, such as baseline health status, age, and type of initial surgery.

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10. Ethical Considerations

The study will be conducted following the principles of the Declaration of Helsinki. Informed consent will be obtained from all participants before enrollment. The study protocol has been approved by the institutional review board (IRB). The risks associated with interventional approaches (e.g., infection, procedural complications) will be disclosed to patients during the consent process.

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11. Follow-up and Monitoring

Participants will be followed for a total of 1 year. Follow-up visits will include clinical assessments at **4 months** and **1 year**, as well as CT or MRI scans at these time points. Infection surveillance will occur throughout the study, and any adverse events will be recorded and reported to the IRB.