COMPLICATIONS OF SPINAL FLUID DRAINAGE, PREVENTIVE MEASURES & STRATEGIES TO MINIMIZE SPINAL CORD INJURY

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SPINAL DRAIN COMPLICATIONS
Spinal fluid drainage used in 4,717/6,593 procedures (72%) in 34 studies

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any complications</td>
<td>167</td>
<td>10</td>
</tr>
<tr>
<td>Headache</td>
<td>155</td>
<td>10</td>
</tr>
<tr>
<td>Intravascular hemorrhage</td>
<td>73</td>
<td>1.5</td>
</tr>
<tr>
<td>Spinal fluid leakage</td>
<td>44</td>
<td>1</td>
</tr>
<tr>
<td>Spinal hematoma</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>Meningitis</td>
<td>6</td>
<td>0.1</td>
</tr>
<tr>
<td>Drain fracture requiring surgical removal</td>
<td>3</td>
<td>0.1</td>
</tr>
<tr>
<td>Deaths</td>
<td>15</td>
<td>0.3</td>
</tr>
</tbody>
</table>


DISCLOSURE
- Consulting fees (All paid to Mayo)
  - Cook Medical Inc., WL Gore, GE Healthcare
- Research grants (All paid to Mayo)
  - Cook Medical Inc., WL Gore, GE Healthcare
- Off label technique
  - Up and over IBD deployment

Update on the first 250 patients enrolled in a prospective, non-randomized study to evaluate F-BEVAR for complex aortic aneurysms


30-DAY RESULTS
No in-hospital mortality
One (0.4%) 30-day mortality from spinal drain complication

293 IDE trial patients
Nov 2013 – Oct 2018

No drain
n=106 (36%)

Drain in 1st stage TEVAR or F-BEVAR n=187 (64%)

TASP completion (n=5)

1st stage TEVAR (n=51)

187 pts with 240 endo procedures with drain
**SPINAL DRAIN COMPLICATIONS**

- 19/187 patients (10%) had moderate to severe spinal drain complications in 21240 procedures (9%)
  - F-BEVAR 15/184 (8%)
  - 1st stage TEVAR 6/55 (10%)
- Other 20 patients (11%) had minor complications (blood tinged drainage or bleeding at puncture site)

**Complications**

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any complication</td>
<td>19</td>
<td>10</td>
</tr>
<tr>
<td>Intracranial hypotension</td>
<td>12</td>
<td>6%</td>
</tr>
<tr>
<td>Intracranial hemorrhage</td>
<td>3</td>
<td>2%</td>
</tr>
<tr>
<td>Headache</td>
<td>9</td>
<td>5%</td>
</tr>
<tr>
<td>Spinal hematoma</td>
<td>6</td>
<td>3%</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Transient paraparesis</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Puncture hemorrhage resulting in procedure cancellation</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Spinal fluid leakage</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Retained spinal drain fragment</td>
<td>1</td>
<td>0.5%</td>
</tr>
<tr>
<td>Interventions for spinal drain complications</td>
<td>1</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

**Interventions**

- Blood patch: 6 patients (3%)
- Emergent spinal decompression: 1 patient (0.5%)
- Death: 1 patient (0.5%)

**INTRACRANIAL HYPOTENSION**

- 12 patients (6%) had evidence of intracranial hypotension
  - Headache without bleeding in 9 patients (5%)
    - Median duration: 4 days (2-9 days)
    - Required narcotics in 7 patients
    - Required blood patch in 5 patients (multiple in 3)
  - Intracranial hemorrhage in 3 patients (2%)
    - Patient 1: Subarachnoid and intraventricular hemorrhage, multiple complications, no neurological improvements, dismissal to palliative care, death on POD 21
      - Patient 2: Severe hemorrhagic stroke, feeding problems, death from aspiration pneumonia on POD 103
      - Patient 3: Transient hemiparesis and seizure

**INTRACRANIAL HEMORRHAGE**

- Subarachnoid and intraventricular hemorrhage: 12 patients (6%)
- Intracerebellar hemorrhage: 3 patients (2%)
- Intracerebral hemorrhage: 6 patients (3%)

**SPINAL HEMATOMA**

- 6 patients (3%) had spinal hematoma
- 2 patients (1%) developed paraplegia
  - Patient 1: Emergency surgical decompression (Permanent Grade 3c)
  - Patient 2: Conservative treatment (Grade 3a > Grade 2)
- 2 patients (1%) had paraparesis
- 1 patient had severe radicular back pain
- 1 patient was asymptomatic and diagnosed by MRI after attempted drain placement with frank bleeding

**CHANGES IN PRACTICE**

- Eliminated spinal drainage:
  - Extent IV TAAAs
  - First stage procedures
  - Most Extent III TAAA repairs
- Changed protocol from routine pressure controlled drainage (10cm H2O, max 20 ml/hr) to selective drainage guided by decline in near infrared Spectroscopy (NIRS) or symptoms
SPINAL CORD INJURY PREVENTION PROTOCOL

• Staged repair for Extent III TAAAs
• Spinal drainage for Extent I and II and selected patients with Extent III TAAAs
• Permissive hypertension
• Early limb reperfusion

Neuromonitoring and near infrared spectroscopy (NIRS)
Selecte temporary aneurysm sac perfusion (TASP) with delayed closure

Severe pancreatitis
Fluid/pressors
Dialysis
Full recovery

CONCLUSION

• Spinal drainage is potentially dangerous and its should be carefully weighted against potential benefits
• Our current protocol uses:
  - Routine spinal drainage for Extent I and II TAAAs, selective for Extent III and no drainage for Extent IV and pararenal AAAs
  - Intraoperative neuromonitoring and NiRS
  - Selective temporary aneurysm sac perfusion guided by changes in neuromonitoring

No other major complications
Intraoperative maneuvers:

- CSF 0-5 cm H2O
- MAP >90-100 mm Hg
- No change or deterioration
- Restore pelvic & lower extremity flow
- Temporary sac perfusion

No change in MEP/SSEP amp

Improvement

Complete the repair

No changes in MEP/SSEP amp

Improvement

Temporary sac perfusion

Complete the repair

No change or deterioration

Complete the repair