

Variation in Patient and Procedural Characteristics by Intervention Selection for Cranial Dural Tears

Barbara H. Johnson¹, Marina Gutierrez², Prinieeth Anand d³, Stephen Johnston¹

¹Johnson & Johnson, New Brunswick, NJ, USA, ²Johnson & Johnson, Raritan, NJ, USA, ³Mu Sigma, Bengaluru, Karnataka, India

Background

- A dural tear can manifest either inadvertently during various surgeries, especially those involving the spine, or deliberately during brain-related procedures like craniotomy.
- When dural tears lead to cerebrospinal fluid (CSF) leakage, they can trigger potentially grave complications, including the development of CSF fistulas, pseudo-meningoceles, and meningitis¹.
- The standard of care for dural tear repair is focused on attaining a watertight closure, but there are a variety of products and techniques used in the attempt to achieve this goal.

Objectives

- The aim of this study was to look across dural tear repair solutions among patients undergoing craniotomy in real world data, comparing clinical and economic outcomes among patients with the use of four different repair techniques: primary closure (PC) only, primary closure plus patch or graft (PC+P/G), primary closure plus sealant (PC+S), and primary closure plus patch or graft and sealant (PC+P/G+S).

Methods

- Retrospective cohort study using the PINC AI™ Healthcare Database.

Methods, continued

- The study included patients aged ≥18 years who had an inpatient hospital encounter for craniotomy/craniectomy between 10/1/2015-03/31/2023 (first=index).
- Patient and procedural characteristics (e.g., age, sex, elective v non-elective, surgical approach [burr hole, endoscopic, open]) were measured at index.
- Operating room (OR) time and 30-day complications (CSF leak, pseudo meningocele, hydrocephalus, meningitis) rates were characterized descriptively for each intervention.

Results

Figure 1. Patient Attrition

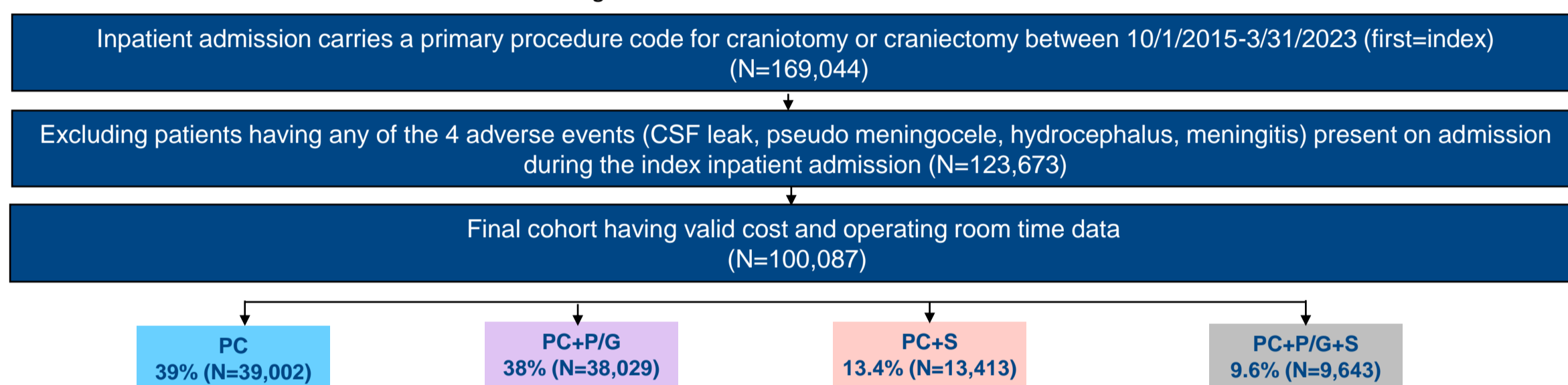
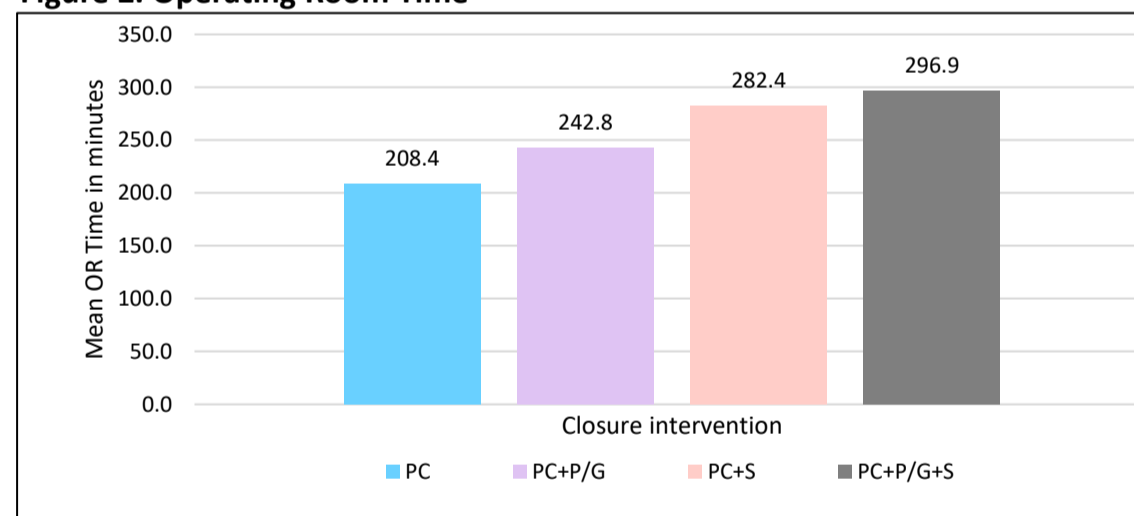


Table 1. Demographic and Procedural Characteristics

Variables	Overall		Closure intervention							
			PC		PC+P/G		PC+S		PC+P/G+S	
	N	%	N	%	N	%	N	%	N	%
All	100,087	100.0%	39,002	100.0%	38,029	100.0%	13,413	100.0%	9,643	100.0%
Age (Mean, SD)	58.6	16.9	60.3	17.3	59.3	16.3	54.0	16.8	56.1	16.2
Female Gender	48,864	48.8%	17,340	44.5%	18,720	49.2%	7,485	55.8%	5,319	55.2%
Race										
Asian	3,002	3.0%	1,419	3.6%	1,035	2.7%	317	2.4%	231	2.4%
Black	13,199	13.2%	4,959	12.7%	4,962	13.0%	1,994	14.9%	1,284	13.3%
Other	9,151	9.1%	3,024	7.8%	3,627	9.5%	1,572	11.7%	928	9.6%
Unknown	3,010	3.0%	1,324	3.4%	1,035	2.7%	381	2.8%	270	2.8%
White	71,725	71.7%	28,276	72.5%	27,370	72.0%	9,149	68.2%	6,930	71.9%
Ethnicity										
Hispanic	9,793	9.8%	3,729	9.6%	3,810	10.0%	1,303	9.7%	951	9.9%
Non-Hispanic	72,838	72.8%	27,259	69.9%	28,231	74.2%	10,012	74.6%	7,336	76.1%
Unknown	17,456	17.4%	8,014	20.5%	5,988	15.7%	2,098	15.6%	1,356	14.1%
Payor category										
Commercial	35,757	35.7%	12,512	32.1%	13,115	34.5%	6,121	45.6%	4,009	41.6%
Medicaid	13,650	13.6%	5,241	13.4%	5,130	13.5%	1,906	14.2%	1,373	14.2%
Medicare	42,627	42.6%	18,066	46.3%	16,592	43.6%	4,457	33.2%	3,512	36.4%
Other	8,053	8.0%	3,183	8.2%	3,192	8.4%	929	6.9%	749	7.8%
Surgical Indication										
Benign neoplasm	25,635	25.6%	7,376	18.9%	9,014	23.7%	5,833	43.5%	3,412	35.4%
Malignant neoplasm/metastatic disease	25,864	25.8%	9,158	23.5%	11,257	29.6%	2,684	20.0%	2,765	28.7%
Nervous system disease	8,574	8.6%	2,664	6.8%	2,229	5.9%	2,411	18.0%	1,270	13.2%
Non-traumatic intracranial hemorrhage	10,583	10.6%	5,670	14.5%	4,003	10.5%	432	3.2%	478	5.0%
Traumatic intracranial injury	17,793	17.8%	9,445	24.2%	7,217	19.0%	591	4.4%	540	5.6%
Other	11,638	11.6%	4,689	12.0%	4,309	11.3%	1,462	10.9%	1,178	12.2%
Surgical Status										
Elective	45,482	45.4%	14,573	37.4%	15,652	41.2%	9,390	70.0%	5,867	60.8%
Non-elective	49,909	49.9%	22,385	57.4%	20,087	52.8%	3,824	28.5%	3,613	37.5%
Trauma	4,696	4.7%	2,044	5.2%	2,290	6.0%	199	1.5%	163	1.7%
Surgical Approach										
Open	87,898	87.8%	33,033	84.7%	36,235	95.3%	10,153	75.7%	8,477	87.9%
Endoscopic	8,391	8.4%	2,931	7.5%	1,339	3.5%	3,057	22.8%	1,064	11.0%
Burr hole	3,798	3.8%	3,038	7.8%	455	1.2%	203	1.5%	102	1.1%
Region of Brain										
Infratentorial	8,134	8.1%	1,766	4.5%	2,365	6.2%	2,353	17.5%	1,650	17.1%
Supratentorial	37,384	37.4%	13,343	34.2%	13,820	36.3%	6,510	48.5%	3,711	38.5%
Unspecified	54,569	54.5%	23,893	61.3%	21,844	57.4%	4,550	33.9%	4,282	44.4%

Figure 2. Operating Room Time



- Observed mean OR time (Figure 2) and incidence proportions of 30-day complications (Table 3) increased with more resource intensive closure technique.

Table 3. Incidence Proportions of 30-day Complications

Variables	Overall		Closure solution							
			PC		PC+P/G		PC+S		PC+P/G+S	
	N	%	N	%	N	%	N	%	N	%
All	100,087	100.0%	39,002	100.0%	38,029	100.0%	13,413	100.0%	9,643	100.0%
Any Complication	3,128	3.1%	810	2.1%	1,110	2.9%	628	4.7%	580	6.0%
CSF leak	1,212	1.2%	270	0.7%	375	1.0%	315	2.3%	252	2.6%
Pseudo meningocele	262	0.3%	44	0.1%	91	0.2%	54	0.4%	73	0.8%
Hydrocephalus	1,259	1.3%	374	1.0%	496	1.3%	182	1.4%	207	2.1%
Meningitis	792	0.8%	203	0.5%	271	0.7%	168	1.3%	150	1.6%

Conclusions

- In this study of patients undergoing cranial dural repair, there was substantial variation in patient and procedural characteristics across the different closure techniques.
- Varying case complexity in craniotomy will always exist, however, a more effective and less complex dural tear repair solution may help improve resource utilization and outcomes.

1. Ha B-J, Cheong JH, Yi H-J. Risk factors for cerebrospinal fluid leakage after craniotomy and the efficacy of dural sealants application versus dural suturing alone. The Nerve. 2016;2(2):22-5.