Middle Cranial Fossa (MCF) Approach without the use of Lumbar Drain for the Management of Spontaneous Cerebral Spinal Fluid (CSF) Leaks

Running head: MCF CSF Leaks

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- 1 **Objective:** To determine the efficacy and morbidity of repairing spontaneous cerebrospinal
- 2 fluid (CSF) leaks with the middle cranial fossa (MCF) approach without the use of a lumbar
- drain (LD), as perioperative use of LD remains controversial.
- 4
- 5 **Study Design:** Retrospective review from 2003-2015
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- 7 **Setting:** University of Iowa Hospitals and Clinics and Indiana University Health Center
- 8
- 9 Patients: Those with a confirmed lateral skull base spontaneous CSF leaks and/or
- 10 encephaloceles.
- 11
- 12 Intervention: MCF approach for repair of spontaneous CSF leak and/or encephalocele without
- the use of lumbar drain. Assessment of patient age, sex, body mass index (BMI), and medical co-
- 14 morbidities
- 15 Main Outcome Measure: Spontaneous CSF leak patient characteristics (age, sex, BMI,
- obstructive sleep apnea) were collected. Length of stay (LOS), hospital costs, post-operative
- 17 complications, CSF leak rate, and need for LD were calculated.
- 18
- 19 **Results:** 65 operative MCF repairs were performed for spontaneous CSF leaks on 60 patients (5
- 20 had bilateral CSF leaks). CSF diversion with LD was used in 15 of 60 patients, mostly prior to
- 21 2010. After 2010, only 3 of 44 patients (6.7%) had post-operative otorrhea requiring LD. The
- use of LD resulted in significantly longer LOS (3.6 \pm 1.6 vs. 8.7 \pm 2.9 days) and hospital costs
- 23 (\$29,621). There were no postoperative complications in 77% (50 of 65) of cases. Three cases
- required return to the operating room for complications including frontal subdural hematoma (1),
- subdural CSF collection (1) and tension pneumocephalus (1). No patients experienced long-term
- 26 neurologic sequelae or long-term CSF leak recurrence with an average length of follow up of
- 19.5 months (range 3-137 months). The average patient BMI was $37.5 \pm 8.6 \text{ kg/m}^2$. The
- average age was 57.5 ± 11.4 years and 68% were female. Obstructive sleep apnea was present in
- 43.3% (26 of 60) of patients.
- 30

Conclusions: The morbidity of the MCF craniotomy for repair of spontaneous CSF leaks is low and the long-term efficacy of repair is high. Universal use of peri-operative lumbar drain is not indicated and significantly increases length of stay and hospital costs. Obesity and obstructive sleep apnea are highly associated with spontaneous CSF leaks.

INTRODUCTION

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39	Spontaneous cerebrospinal fluid (CSF) leaks of the lateral skull base occur through defects of the
40	dura and the lateral skull base (also known as the tegmen) overlying the pneumatized middle ear
41	and mastoid. In addition, brain tissue can herniate through the bony defect resulting in an
42	encephalocele. CSF leaks are termed spontaneous when there is no preceding trauma, surgery, or
43	inciting cause.
44	
45	The pathologic mechanism of spontaneous CSF leaks is still not well understood. There is a
46	strong association between obesity and spontaneous CSF leaks (1-3). As the obesity epidemic
47	increased between 1980 and 2010, the number of spontaneous CSF leak repairs has nearly
48	doubled in the past decade (4). Though not seen in all obese patients, those with spontaneous
49	CSF leaks have thinning of the skull base in addition to the skull calverium (3). This finding
50	implicates an additional 'obesity-associated' intracranial process leading to skull thinning (3).
51	This process could be due to elevated intracranial pressure. Chronically elevated intracranial
52	pressure (ICP) over many years may lead to erosion of the skull, including the skull base.
53	Spontaneous CSF leaks are associated with idiopathic intracranial hypertension (IIH), also
54	known as benign intracranial hypertension or pseudotumor cerebri (5). Interestingly,
55	measurements of CSF pressures during lumbar puncture in patients undergoing repair of
56	spontaneous CSF leak show that only 10-36% of patients have elevated ICP (6,7). Alternatively,
57	it is possible that there are transient spikes in ICP that may not be detected on routine lumbar
58	puncture. It is known that obstructive sleep apnea (OSA) is highly associated with obesity (8,9)
59	and OSA patients have transient large spikes in ICP during apnea spells (10,11). We have
60	hypothesized that obesity-associated OSA leads to elevated ICP, which leads to skull base
61	thinning and spontaneous CSF leaks (3).
62	
63	Spontaneous CSF leaks have a very low rate of spontaneous closure. Surgical approaches to
64	repair temporal bone spontaneous CSF leaks include middle cranial fossa (MCF) craniotomy
65	(12-17), transmastoid (TM) (2,7,18-20) or a combined (MCF/TM) (1,21,22) approach. The
66	transmastoid approach is appealing as it avoids the risks of a craniotomy. However, the

recurrence rate of CSF leaks after transmastoid approach ranges from 6-20% (7,20). In addition,

the MCF approach allows for a more comprehensive evaluation of the entire tegmen, since up to 68 50% of patients have multiple tegmen defects (15). The reported perioperative risks of MCF 69 70 approach are low, but can include hematomas, stroke and seizures. 71 72 In addition, the use of CSF diversion through the use of a lumbar drain (LD) during the repair of spontaneous CSF leaks is controversial. The use of LDs during endoscopic repair of anterior 73 74 skull base CSF leaks has been studied and found to not reduce the rates of recurrent CSF leaks (23,24). There is currently no consensus on if and when to use a LD for spontaneous CSF leak 75 repairs from the temporal bone. In addition, LD utilization has been associated with increased 76 complication rate of up to 12.3%, including pneumocephalus, persistent headaches, meningitis, 77 78 uncal herniation and lumbar radiculopathy (25). 79 Here we report a large cohort of patients who have undergone MCF repair for spontaneous CSF 80 leaks. We review our perioperative complications of the MCF approach to repair spontaneous 81 CSF leaks. Also, we determine the effectiveness of the MCF repair without the use of lumbar 82 83 drains and the long-term stability of the repair. 84 85 86 87

MATERIALS AND METHODS

88

Retrospective evaluation and data collection of patients were approved by the institutional 89 review boards at the University of Iowa (#201307714) and Indiana University Health 90 (#49109189). Patients were treated by 3 neurotologists (BJG, MRH, RFN) with spontaneous 91 CSF leaks from 2003 to 2015. CSF leaks were considered spontaneous when there was 92 persistent clear otorrhea associated with tegmen defect(s) noted on high resolution CT IAC 93 94 imaging and no previous history of skull base surgery, trauma or skull base fracture. 95 The following patient characteristics were documented from the medical record: (1) body mass 96 index (BMI) calculated as kilograms per square meter (kg/m²), (2) age, (3) sex, (4) obstructive 97 sleep apnea. Long term follow up was calculated from the date of operation to the last recorded 98 99 clinic visit in the medical record. Complications were recorded by review of clinic notes in the medical record. For adults aged 20 years and older, obesity was defined as a BMI of 30.0 or 100 higher (26). Obstructive sleep apnea was confirmed if the patient had (in the chart or per patient 101 report) a positive polysomnogram (apnea-hypopnea index > 5) or was using continuous positive 102 103 airway pressure (CPAP) or bilevel positive airway pressure (BiPAP). Patients without the clinical diagnosis of OSA were not independently tested. However, starting in 2014, all patients 104 105 at Indiana University Health with spontaneous CSF leaks were prospectively tested for OSA 106 with polysomnogram. Differences in means were tested with a 2-tailed T test with significance 107 set to $\alpha \le 0.05$. 108 All patients were treated with an MCF approach. Briefly, a pterional incision was performed 109 110 with harvesting of a large temporalis fascia graft. The temporalis muscle was incised to leave a cuff of muscle and fascia attached to the calvarium and the muscle was reflected anteriorly. A 111 4.5 x 4.5 craniotomy was performed over the middle ear and mastoid. Intraoperative mannitol 112 (0.5 gram per kilogram) was administered and the patient was hyperventilated to end-tidal CO₂ 113 114 <30. The temporal lobe dura was elevated and the dura and skull base defects were identified. 115 The entire floor of the middle fossa was explored including anterior petrous apex. 116 Encephaloceles were amputated and removed with bipolar electrocautry when present. Reconstruction consisted of a multilayer closure with a fascia soft tissue seal on the skull base, 117 split calvarial bone grafts over bone defects and collagen matrix abutting the native dural defects. 118

Some cases were repaired with intradural placement of collagen matrix. The craniotomy was replaced and the muscle and galeal layers were sutured in a water-tight fashion. The patient was extubated after the case and ambulation commenced on post-operative day 1.

Lumber drains were placed if there was persistent otorrhea or CSF rhinorrhea on post-operative days 2 or 3. Many patients had an ipsilateral pressure equalizing tube typically placed by an outside otolaryngologist prior to the diagnosis. CSF was drained at 10 ml/hour for 5 days when LD was used. In our cohort of patients, we did not routinely use diuretics or acetazolamide to manage CSF pressure in the post-operative period.

Procedural and hospital costs were estimated based upon previous charges for spontaneous CSF leak patients with lumbar drains using 2016 data. These estimated charges can vary based upon patient comorbidities and hospital location. These amounts are specified as billed charges and do not reflect actual amount reimbursed or paid as these later amounts are variable depending upon insurance coverage. The charges for lumbar drain placed at bedside (CPT 62272) are for the device and facility charges and does not include surgeon fees. The daily hospital charges include progressive care unit facility charges.

RESULTS 137 We examined medical records of 60 patients (65 cases) from 2 academic medical centers who 138 139 underwent MCF repair of spontaneous CSF leaks of the temporal bone from 2007 to 2015. Five (5) patients had bilateral temporal bone CSF leaks. Figure 1 is representative CT image of patient 140 with a dehiscent tegmen mastoidium and fluid filling the mastoid (**Figure 1A**). Many patients 141 have multiple areas of tegmen dehiscence (Figure 1B). 142 143 The average age was 57.5 ± 11.4 years and 68.3% of the patients were female (**Table 1**). Most 144 patients (83.3%) were overweight (BMI >25 kg/m²) and the average BMI was 37.5 ± 8.7 kg/m² 145 (**Table 1**). The rate of obstructive sleep apnea was 43.3% (**Table 1**). Many patients were not 146 prospectively tested for OSA. Starting in 2014, all patients at Indiana University Health with 147 spontaneous CSF leaks underwent polysomnogram and all patients (6 of 6) had OSA. 148 149 There were no perioperateive complications in 77% (50 of 65) of the cases. The most common 150 complication was persistent otorrhea noted on post-operative days 2 or 3 (**Table 2**). In all such 151 152 cases, a LD drain was placed for 5 days and the otorrhea resolved. There were 2 cases of mental status change with temporal lobe edema that resolved with steroid treatment. Three cases 153 required return to the operating room. One patient developed a subdural hematoma that required 154 a burr hole evacuation. Another patient developed a frontal subdural CSF fluid collection after 155 156 hospital discharge that required burr hole evacuation. Lastly, one patient developed tension pneumocephalus that required return to the operating room for evacuation. Intraoperatively it 157 158 was noted that the split calvarial bone grafts had not formed a tight seal on the middle fossa floor resulting in a 'ball valve' effect leading to trapping air intracranially. The temporalis fascia was 159 160 placed over the skull base to form a soft tissue seal, prior to replacement of the bone grafts. All 3 patients recovered fully. Isolated cases of delayed facial paralysis, atrial fibrillation, meningitis 161 162 and seizure were treated medically and patients demonstrated full recovery. There were no cases of ipsilateral CSF leak at last follow up (**Table 2**). 163 164 165 Early in the study, prior to 2010, 21 patients underwent MCF CSF leak repair. Approximately half of the patients had lumber drains placed intra-operatively during MCF repair and the other 166 167 half did not have a lumber drain. There were no post-operative CSF leaks in either group

suggesting that lumber drain placement may not be necessary for a successful repair. Thus, starting in 2010, we performed 44 MCF repairs of spontaneous CSF leaks with the intention of not using a perioperative LD. After 2010, only 3 of 44 patients (6.7%) has post-operative otorrhea requiring LD. The average length of stay for patients without LD was significantly shorter than those who had a LD placed preoperatively $(3.6 \pm 1.6 \text{ vs. } 8.7 \pm 2.9 \text{ days; P} < 0.01;$ **Table 3**). In addition, the use of lumbar drains increases cost. We estimated the cost (in 2016 dollars) to be \$13,316 for placement of the LD and \$3,261 per day for hospital room and nursing care. Thus, for 5 additional hospital days and LD, the added cost is approximately \$29,621 (**Table 3**).

DISCUSSION 179 Here we show that the MCF approach to repair temporal bone spontaneous CSF leaks is highly 180 181 effective and is safe. The use of a LD is not required for successful repair in most cases. 182 Preemptive use of LDs increases length of stay and cost. 183 Consistent with other previous reports (1,2,4), we find a strong association between spontaneous 184 CSF leaks and obesity. The obesity epidemic developed in the United States starting in the 1990s 185 (27). The percentage of American that are obese (BMI ≥30) has risen from 12% in 1991 to 186 19.8% in 2000 to 29% in 2010 (28). The mechanism of how obesity could lead to skull thinning 187 188 remains unknown. Previously, we showed that patients with spontaneous CSF leaks were obese and had thinning of the calvarium in addition to the skull base, while a control group of obese 189 190 patients without spontaneous CSF leaks did not have thinning of the calvarium. Because obesity is highly associated with spontaneous CSF leaks, these data suggest that there is another obesity-191 192 associated factor which contributes to skull thinning and spontaneous CSF leaks. This obesityassociated factor likely leads to elevated intracranial pressure either chronically or on an 193 194 intermittent basis. 195 Spontaneous CSF leaks are associated with IIH (5), and some patients (~36%) have elevated ICP 196 during lumbar puncture (6). This shows that not all patients with spontaneous CSF leaks have 197 198 elevated baseline ICP, and other factors may contribute to transient elevations in ICP. Patients 199 with spontaneous CSF leaks have a high rate of OSA and patients with OSA have been found to 200 have elevations in ICP and arterial blood pressure during apnea events (10). It is postulated that apneas lead to hypercarbia, which in turn leads to cerebral vasodilation and elevated ICP. Our 201 data show that patients with spontaneous CSF leaks have a much higher prevalence of OSA 202 203 (~43%) than the national average. In addition, these patients presented with the diagnosis of 204 OSA and many had not had a polysomnogram. Thus, this rate may underestimate the true rate of OSA in patients with spontaneous CSF leaks. Since 2014, we have tested all patients with 205 206 spontaneous CSF leaks for sleep apnea with a polysomnogram. 207 Superior semicircular canal dehiscence (SSCD) has been associated with tegmen erosion (29,30) 208 and the surgeon should be alerted to the possibility of SSCD as the dura is elevated from the 209

210 middle fossa floor. In this study, we did not specifically evaluate or repair SSCD unless the 211 patient had vestibular symptoms consistent with SSCD (i.e. Tullio's phenomena). However, 212 during the repair we resurface the SSC as we resurface the skull base with soft tissue and bone grafts. 213 214 Several previous reports have used LDs during MCF repair of temporal bone spontaneous CSF 215 216 leaks (15,17,21,22) with postoperative CSF leaks rates of 4-9%. Since 2010 we have not used LD during our MCF CSF leak repairs and our post-operative leak rate in 44 patients was 6.7%. 217 In addition, we estimated that the added cost of a LD and 5 days in the hospital to be close to 218 219 \$60,000. Given that it is not necessary in the vast majority of cases, we advocate against the preemptive use of LDs for spontaneous CSF leaks. A review study using LD for anterior skull 220 base CSF leaks also failed to show significant benefit in CSF leak repair (24). 221 222 The vast majority of patients who underwent MCF CSF leak repair had no postoperative 223 224 complications. The most common complication was a postoperative CSF leak that was managed 225 effectively with a LD. We placed the LD relatively early in the postoperative period (day 2-3) if there was persistent otorrhea. While it is possible that some of these cases may have gone on to 226 227 resolve without the need for a LD if they had been observed longer, we favored early intervention in these cases. There were no long term sequela from using the MCF approach. 228 229 There are inherent limitations to this study. By design the study is retrospective and non-230 231 randomized. In addition, increased surgeon experience over time could account for a decreased post-operative CSF leak rate. Finally, the generalizability of the results to all centers irrespective 232 233 of surgical experience with MCF approach may not be possible. 234 235 Thus, we find the morbidity of the MCF craniotomy for repair of spontaneous CSF leaks is low and the long-term efficacy of repair is high. The universal preoperative placement of LD does 236 237 not appear to be indicated. We advocate for LD only in the infrequent case of post-operative 238 otorrhea. Use of LD significantly increases length of stay and hospital costs. Finally, we also advocate for all patients with spontaneous CSF leaks to be tested for OSA. 239

241	FIGURE LEDGENDS
242	
243	Figure 1: A. Representative coronal temporal bone CT scan image demonstrating a right tegmen
244	mastoideum defect with fluid in the mastoid. B . Intraoperative view of a left middle fossa floor
245	showing multiple tegmen defects (arrows). AE = arcuate eminence, L = Lateral, M = Medial, A
246	= Anterior, P = Posterior.
247	
248	Table 1: Patient characteristic; BMI = Body Mass Index; kg = kilograms; m = meter
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250	Table 2: Post-operative Complications (65 cases). * = required return to the operating room
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252	Table 3: Lumbar Drain Use and Estimated Cost
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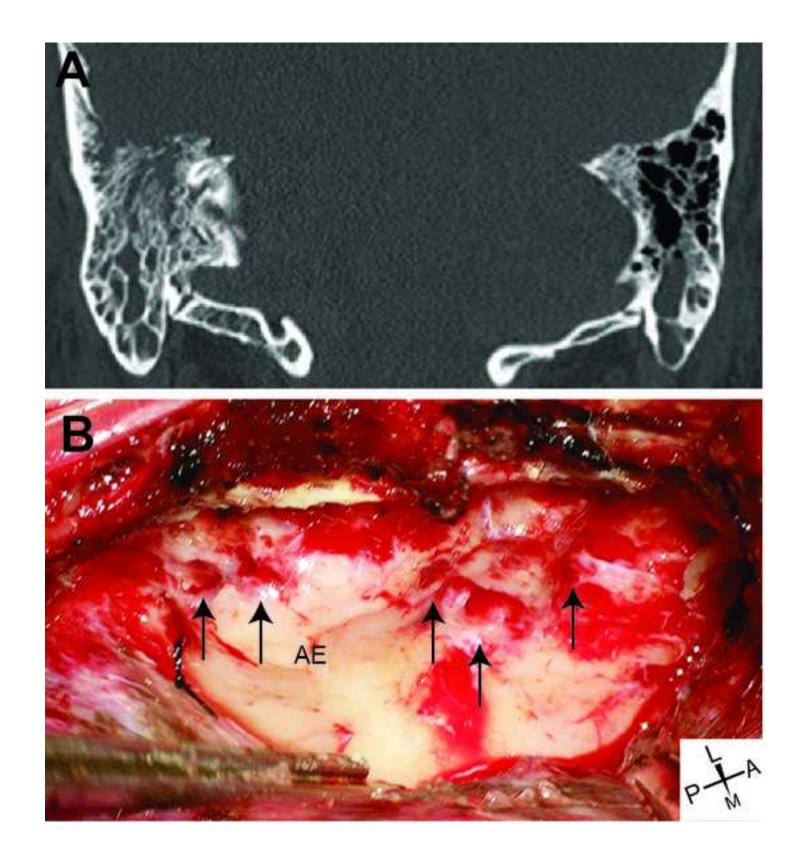
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Gender	Number (%)
Male	19 (31.7%)
Female	41 (68.3%)
	Total = 60
Age (Years)	Number (%)
21-30	1 (1.7%)
31-40	6 (10.0%)
41-50	6 (10.0%)
51-60	18 (30.0%)
61-70	23 (38.3%)
71-80	5 (8.3%)
81-90	1 (1.7%)
Average = 57.5 ± 11.4	
BMI (kg/m²)	Number (%)
BMI (kg/m²) ≤24.99	Number (%) 2 (3.3%)
	` ,
≤24.99	2 (3.3%)
≤24.99 25.00-29.99	2 (3.3%) 8 (13.3%)
≤24.99 25.00-29.99 30.00-34.99	2 (3.3%) 8 (13.3%) 15 (25.0%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99 45.00-49.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%) 5 (8.3%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99 45.00-49.99 50.00-54.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%) 5 (8.3%) 2 (3.3%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99 45.00-49.99 50.00-54.99 55.00-59.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%) 5 (8.3%) 2 (3.3%) 0 (0%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99 45.00-49.99 50.00-54.99 55.00-59.99 60.00-64.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%) 5 (8.3%) 2 (3.3%) 0 (0%) 2 (3.3%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99 45.00-49.99 50.00-54.99 55.00-59.99 60.00-64.99 65.00-69.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%) 5 (8.3%) 2 (3.3%) 0 (0%) 2 (3.3%)
≤24.99 25.00-29.99 30.00-34.99 35.00-39.99 40.00-44.99 45.00-49.99 50.00-54.99 55.00-59.99 60.00-64.99 65.00-69.99	2 (3.3%) 8 (13.3%) 15 (25.0%) 13 (21.7%) 13 (21.7%) 5 (8.3%) 2 (3.3%) 0 (0%) 2 (3.3%)

Complication (<30 days post-op)	Number (%)
Persistent otorrhea requiring LD	5 (7.7%)
Confusion with Temporal Lobe Edema	2 (3.1%)
Frontal Subdural Hematoma*	1 (1.5%)
Subdural CSF Collection*	1 (1.5%)
Tension Pneumocephalus*	1 (1.5%)
Delayed Facial Paralysis	1 (1.5%)
Meningitis	1 (1.5%)
Seizure	1 (1.5%)
Atrial Fibrillation	1 (1.5%)
Complication (>30 days post-op)	Number (%)
Wound drainage	1 (1.5%)
Complex partial seizure	1 (1.5%)
Word finding difficulty	1 (1.5%)
Ipsilateral CSF leak	0 (0%)

Perioperative Lumbar Drain (# cases)	Length of stay (days)
No (50)	3.6 +/- 1.6
Yes (15)	8.7 +/- 2.9
Type of Charge	Cost (estimated)
Lumbar drain	\$ 13,316
Hospital Room + Nursing	\$ 3,261 (per day)
5 day total charge	\$ 29,621