



Experience with a Novel, Automated, External Cerebrospinal Fluid Drainage Control Device

Christina Duffin; Jan M. Eckermann MD; Susan Schaufelberger NP; Robert E. Lieberson MD, FAANS, FACS; William J. Meyer MD, PhD; Tung T. Trang MD

**Kern NeuroScience Institute, Kern Medical Center Division of Neurosurgery, and Kern Medical Center
Division of Otolaryngology, Bakersfield, California, USA**



Introduction

Most available lumbar drainage systems are functionally identical to the first gravity-fed device described in 1963 (1). Although lumbar drainage is the standard of care for a variety of pathologies, complication rates are high, up to 40% in some series. Additionally, manually controlled lumbar drains are labor intensive and therefore costly. Gravity-independent, pump-regulated systems have been proposed, but adoption was limited by the risks associated with active CSF removal. We propose the use of a new gravity-fed system that is microprocessor controlled, programmable, and prevents over- or under-drainage. It should improve patient safety and lower treatment costs.

Methods

Fourty consecutive patients requiring external lumbar drainage were treated using the FlowSafe™ system (BeckerSmith Medical, Irvine, CA) (2).

Results

Twenty-one men and 19 women, mean age 41.7 years, were drained for a mean of 95.5 hours (range 24 to 168). Drainage rates averaged 8.3 ml/hour (range 5 to 15). A single dose of antibiotics was used in 28 patients. Twelve received antibiotics for 48 to 144 hours. Diagnoses included skull base surgery (22), spontaneous and traumatic CSF fistulas (8), unintentional durotomy (6), normal pressure hydrocephalus (2), intracranial hypertension due to meningitis (1), pseudotumor cerebrii (1). Set up times were minimal. Manual interventions, to regulate flow, were not required. There were no complications related to mechanical failures. There were no major complications. Two patients (5%) reported headaches during treatment. Drainage was temporarily discontinued in one and the rate was decreased in the other. In both, the headaches resolved promptly. One patient, who was drained for six days following a Chiari repair with a dural patch, had persistant leakage of CSF and required a re-operation for repair. There were no other complications.

Discussion

Although now the standard of care for many traumatic and iatrogenic dural tears, after skull base surgery, and following aortic aneurysm operations (3-5), lumbar drains are risk laden and labor intensive to operate. Houle, et al,

developed an early, flow-regulated, electronic system using a device similar to an intravenous fluid pump.(6) It improved safety, eliminated over- and under-drainage, and required less manual oversight. Unfortunately, technical issues limited its widespread adoption. To address some of these issues, Nanidis, et al, recently published his experience with an inexpensive, flow-regulated system, that his group created with readily available components that could be modified at the bedside.(7) FlowSafe was created to address issues related to all currently available systems and is the first system that is fully automated, yet gravity-fed, allowing for complete outflow control without actively pulling CSF.

Conclusions

In our experience, the FlowSafe system was convenient, safe and effective. Our complication rate was lower than in published series for current manual systems. Nursing interventions were not required. Given the ease of use and redundant safety mechanisms, nursing leadership proposed that most patients requiring FlowSafe drainage could be treated outside the ICU. This would open beds for higher acuity patients and would result in significant cost savings. In our institution, ICU beds costs approximately \$4,000.00 per day more than ward beds. For a patient requiring six days of drainage, a savings of \$24,000.00 could be expected. Larger trials are needed and the efficacy of the device should be evaluated in patients with other diagnoses, including those undergoing aortic surgery.

References

- (1) Vourc'H G. Continuous cerebrospinal fluid drainage by indwelling spinal catheter. *British J Anaesth*. Feb 1963;35:118-120.
- (2) J E, Inventor; Beckersmith Medical, Inc. Los Angeles, CA, assignee. Automated Body Fluid Drain Control Apparatus and Method. US patent 8,475,4192013.
- (3) Bell RB, et al. Management of cerebrospinal fluid leak associated with craniomaxillofacial trauma. *Journal of oral and maxillofacial surgery*. Jun 2004;62(6):676-684.
- (4) Bien AG, et al. Utilization of preoperative cerebrospinal fluid drain in skull base surgery. [et al.]. *Skull Base*, Mar 2007;17(2):133-139.
- (5) Keith CJ, Jr., Passman MA, Carignan MJ, et al. Protocol for selective postop lumbar spinal drainage after thoracic endograft. *J Vasc Surg*. Jan 2012;55(1):1-8; disc. 8.

- (6) Houle PJ, et al. Pump-regulated lumbar subarachnoid drainage. *Neurosurgery*. Apr 2000;46(4):929-932.
- (7) Nanidis N, Korfiatis S, Sakas DE. Flow-regulated external lumbar drain: applications and complications. *Acta neurochirurgica*. Nov 2014;156(11):2201-2205; disc. 2205.