Dynamic Intracranial Pressure (ICP) Monitoring Using a Smart External Drain (SED); Initial Bench Prototype Validation

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Introduction

Monitoring intracranial pressure (ICP) typically requires daily intensive care unit (ICU) monitoring and nursing oversight for titration of external ventricular drain (EVD) relative to patient position. Few alternative options exist for automatically regulating ICP and CSF output flow-rate in a dynamic model.

Methods

We describe the "Smart External Drain" (SED) device and report its initial testing and validation in an artificial model of CSF production with varying head position.

Results

The SED device consists of an SED console and a disposable SED cartridge, intended for 28 days of use (Figure 1). Four SEDs were tested continuously over 29 days, in an artificial system that proved a constant infusion of water to mimic a physiologic rate of CSF production (19.7 mL/hr). Measured pressure recordings were maintained at 15 cm H20 (representing targeted ICP) for the duration of testing, accuracy was within 4 cm H20, drift was less than 2 cm H20 during days 10 – 28. Height of the drain input (e.g. symbolizing the patient's head position) ranged from 80 to 177 cm above the floor. SED cartridges were temporarily removed and reinserted 20 times during the 29 days to test the ability to resume regulation (representing removal for magnetic resonance imaging, etc.). The system tolerated 5 "high pressure" boluses of 30 psi in order to simulate flushing the drain system in the event of particle occlusion.

Conclusions

The SED device represents a novel approach to automate CSF diversion management, with a validated efficacy in maintaining a set ICP via regulating flow rate in various patient positions without the need for nursing intervention. Potential implications of such a system in clinical practice include safer, less expensive management and improved outcomes via earlier patient mobilization and reduced nursing burden and oversight.

Learning Objectives

- To overview the process of early prototype testing and validation
- To demonstrate efficacy of the Smart External Drain (SED) device

FDA disclosure 501(K) Number: K161605

Figure 1

Smart EVD Device