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Initial Experience with Simulation and Deployment of a Self-Calibrating System for Non-Invasive Intracranial Pressure Measurement

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Introduction

Reliable non-invasive intracranial pressure (ICP) monitoring has been a target of considerable translational research for three decades. Problems have centered on a simple sensing system, calibration, drift, accuracy and precision. We report on a CE-marked, image-based, self-calibrating ICP measurement system that uses the ophthalmic artery as natural ICP sensor and Doppler ultrasound and orbital pressure to read out ICP. We also developed a simulator system for bench testing and modeling in conjunction which will be described as well.

Methods

The ophthalmic artery consists of an intracranial segment subject to ICP and an intraorbital segment at ambient atmospheric pressure. Blood velocities (BV) in each segment differ, but can be equilibrated by means of gentle pressure applied to the orbit, and measured using multi-depth Doppler ultrasound. At the point that the velocities equilibrate, the pressure applied equals the ICP. Safety studies were conducted in over 500 patients.

In parallel, a system to simulate this measurement method using rigid two chambers filled with a sonically transparent hydrogel through which is threaded an artificial artery created to simulate the ophthalmic artery was created. Pressures in each chamber can be adjusted separately allowing tests of linearity, precision, accuracy and pressure dynamics along a range of pressures not possible in man or in experimental animals.

Results

Using invasive ICP in TBI and SAH patients for comparison, accuracy (Systematic Bias) was 0.5 mmHg, Standard Deviation less than 2.5 mmHg, and correlation with commercially available was statistically and clinically significant ($R>0.8$). The simulator, not previously described, was used to test for accuracy and precision between 4 mmHg and 120 mmHg to comply with ANSI standards.

Conclusions

Pilot studies support the further development and deployment of a self-calibrating ophthalmic artery-based non-invasive ICP measurement system. The simulation device serves for bench calibration and continued refinement of the Doppler ultrasound imaging system.

Learning Objectives

By the conclusion of this section, participants should be able to
(1) describe and appreciate the deployment of a self-calibrating non-invasive ICP measuring system;
(2) discuss its limitations; and
(3) design studies around the simulator to further expand understanding of ICP dynamics.

References

Fandino J, Kiesler J, et al. Validation of non-invasive absolute intracranial pressure measurements in traumatic brain injury and intracranial hemorrhage. Operative Neurosurgery:in press.