Cardiac-gated intracranial balloon pump

Augmenting brain perfusion or reducing intracranial pressure (ICP) dose is the end target of many therapies in the neurocritical care unit. Many present therapies rely on aggressive systemic interventions that may lead to untoward effects. Previous studies have used a cardiac-gated intracranial balloon pump (ICBP) to model hydrocephalus or to flatten the intracranial pressure waveform.

Dorn et al., sought to sought to optimize ICBP activation parameters to improve cerebral physiological parameters in a swine model of raised ICP.

They developed a cardiac-gated ICBP in which the volume, timing, and duty cycle (time relative to a single cardiac cycle) of balloon inflation could be altered. They studied the ICBP in a swine model of elevated ICP attained by continuous intracranial fluid infusion with continuous monitoring of systemic and cerebral physiological parameters, and defined two specific protocols of ICBP activation.

Eleven swine were studied, 3 of which were studied to define the optimal timing, volume, and duty cycle of balloon inflation. Eight swine were studied with two defined protocols at baseline and with ICP gradually raised to a mean of 30.5 mm Hg. ICBP activation caused a consistent modification of the ICP waveform. Two ICBP activation protocols were used. Balloon activation protocol A led to a consistent elevation in cerebral blood flow (8%-25% above baseline, $p < 0.00001$). Protocol B resulted in a modest reduction of ICP over time (8%-11%, $p < 0.0001$) at all ICP levels. Neither protocol significantly affected systemic physiological parameters.

The preliminary results indicate that optimized protocols of ICBP activation may have beneficial effects on cerebral physiological parameters, with minimal effect on systemic parameters. Further studies are warranted to explore whether ICBP protocols may be of clinical benefit in patients with brain injuries with increased ICP [1)].

Luciano et al., presented in 2017 a novel method and device for altering the ICP waveform via cardiac-gated volume changes.

The novel device used in this experiment (named Cadence) consists of a small air-filled inelastic balloon (approximately 1.0 ml) implanted into the intracranial space and connected to an external programmable pump, triggered by an R-wave detector. Balloons were implanted into the epidural space above 1 of the hemispheres of 19 canines for up to 10 hours. When activated, the balloons were programed to cyclically inflate with the cardiac cycle with variable delay, phase, and volume. The ICP response was measured in both hemispheres. Additionally, cerebral blood flow (heat diffusion and laser Doppler) was studied in 16 canines. RESULTS This system, depending on the inflation pattern of the balloon, allowed a flattening of the ICP waveform, increase in the ICP waveform amplitude, or phase shift of the wave. This occurred with small mean ICP changes, typically around ± 2 mm Hg (15%). Bilateral ICP effects were observed with activation of the device: balloon inflation at each systole increased the systolic ICP pulse (up to 16 mm Hg, 1200%) and deflation at systole decreased or even inverted the systolic ICP pulse (-0.5 to -19 mm Hg, -5% to -1600%) in a dose-(balloon volume) dependent fashion. No aphysiological or deleterious effects on systemic pressure (≤ ±10 mm Hg; 13% change in mean pressure) or cardiac rate (≤ ± 17 beats per minute; 16% change) were observed during up to 4 hours of balloon activity.

The results of these initial studies using an intracranially implanted, cardiac-gated, volume-oscillating balloon suggest the Cadence device can be used to modify ICP pulsations, without physiologically deleterious effects on mean ICP, systemic vascular effects, or brain injury. This device and technique may be used to study the role of ICP pulsatility in intracranial hemo- and hydrodynamic processes and introduces the creation of a potential platform of a cardiac-gated system for treatment of acute and chronic low blood flow states, and diseases requiring augmentation of CSF substance clearance or delivery. [2)]

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Doron O, Or T, Battino L, Rosenthal G, Barnea O. Cerebral blood flow augmentation using a cardiac-gated intracranial pulsating balloon pump in a swine model of elevated ICP. J Neurosurg. 2019 Apr 12:1-10. doi: 10.3171/2019.1.JNS182864. [Epub ahead of print] PubMed PMID: 30978692.
2)
Luciano MG, Dombrowski SM, Qvarlander S, El-Khoury S, Yang J, Thyagaraj S, Loth F. Novel method for dynamic control of intracranial pressure. J Neurosurg. 2017 May;126(5):1629-1640. doi: 10.3171/2016.4.JNS152457. Epub 2016 Jul 15. PubMed PMID: 27419825.