Vittamed Two Depth Transcranial Doppler for Non-invasive Assessment of Intracranial Pressure
Final Results of Phase 2 study

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Disclosures

- Study was supported by funding from National Space Biomedical Research Institute through NASA NCC 9-58, and Center for Space Medicine.
- Vittamed provided technical support and training on device operation, but had no role in study design, funding, data analysis or interpretation.
Specific Aims

- Compare accuracy of Vittamed device compared to simultaneously invasively measured ICP
- Include patients with normal and elevated ICP, as previous study with Vittamed device was mostly in patients with normal ICP (5 to 15 mmHg)
Vittamed Two Depth Transcranial Doppler uses Ophthalmic Artery as ICP sensor

Baseline Balance point

Ragauskas A et al. Neurology 2012;78;1684
Diagram of Vittamed ICP meter
Headframe and Orbital Cuff
Absolute ICP = 16.38 mmHg
100% completed
Study criteria - Phase 2

- **Inclusion criteria**
  - Age 18 to 70
  - Need lumbar CSF pressure measurement for clinical purposes

- **Exclusion criteria**
  - Focal cerebral mass lesions
  - Eye conditions that would preclude application of pressure to orbital tissues
Procedure Diagram

Step 1: Enrolled 57/61 (93%)

Step 2: Found OA segments 42/57 (74%)

Step 3: ICP obtained 24/42 (57%)
Clinical Validation of a Transcranial Doppler Based Non-Invasive ICP Meter: A Prospective Cross-Sectional Study.

Bershad EM¹, Anand A², DeSantis SM³, Yang M², Tang RA⁴, Calvillo E², Malkin-Gosdin L², Foroozan R⁵, Damani R², Maldonado N², Gupta P², Tan B², Venkatasubba Rao CP⁶, Suarez JI⁶, Clark JB⁶, Sutton JP⁷, Donoviel D⁸.

Author information

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Intracranial pressure; Transcranial Doppler ultrasound; Vittamed; neurocritical care; non-invasive

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Results: Demographics (n=24)

- **Sex:** Women 96%
- **Race:** White 54%, Hispanic 25%, Black 21%
- **Age (mean):** 31 (20-55)
- **Weight:** 98 kg (64-151)
- **Indication for ICP:**
  - Suspect IIH (n=19)
  - Other headache (n=2)
  - Optic neuritis (n=2)
  - Seizure (n=1)

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<th>Height (Inch)</th>
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Summary of ICP data

Mean and range of non-invasive ICP in mmHg

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Mean and range of invasive ICP in mmHg

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<tr>
<th>Min.</th>
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Note: 1 mmHg = 1.34 cmH₂O
Figure 1. Bland-Altman plot of Vittamed intracranial pressure (ICP) meter versus lumbar cerebrospinal fluid (CSF) pressure measurements. The X and Y axes display the mean and difference for each independent paired measure for Vittamed versus lumbar CSF pressure.

Eric M. Bershad, Aashish Anand, Stacia M. DeSantis, Ming Yang, Rosa A. Tang, Eusebia Calvillo, Leslie Malkin-Gosdin, Rod Foroozan, Rahul Damani, Nelson Maldonado, Pramod Gupta, Benedict Tan, Chethan P. Venkatasubba Rao, Jose I. Suarez, Jonathan B. Clark, Jeffrey P. Sutton, Dorit B. Donoviel

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Vittamed Vs Lumbar ICP Scatterplot

Figure 2. Scatterplot of Vittamed intracranial pressure (ICP) versus lumbar cerebrospinal fluid (CSF) pressure measurement. Each point represents an independent paired measurement plotted by lumbar (X-axis) and Vittamed (Y-axis). The solid diagonal line ($y = x + 0$) represents zero difference between measures. The dashed lines mark the limits of an error corridor of $\pm 8$ mmHg.
Subject tolerability - summary

- No major adverse events
- Minor adverse events
  - Vasovagal response during LP (n=1)
  - Backache
  - Head or eye pressure
  - Transient blurry vision (n=2), resolved with saline eye flush
Issues which precluded reliable paired (LP and Vittamed) measurements

- **Headframe issues**
  - Poorly fitting (n=11)
  - Movement of during cuff inflation (n=3)
  - Subject intolerance (n=1)
- Non-reliable result (n=4)
- Software issues (n=2)
- Excessive eye movement (n=2)
- Poor OA signals (n=1)
- Doppler artifact (n=1)
- Lumbar puncture unsuccessful (n=1)
Summary of results

- Overall *fair agreement* between invasive lumbar CSF pressure and Vittamed ICP. Average difference between measures was 4.5 mmHg (SD 3.1)
- Technical factors precluded measurement in some subjects
- Improvements in headframe design, hardware durability, and doppler beam may improve ability to obtain ICP measurements
CE Mark 3rd Generation model
Vittamed operability in SPACE-COT

- Two experienced operators (Eric Bershad and Karina Marshall-Goebel)
- 112 measurements in 6 subjects during 54 sessions (2.1 measures/session)
- Obtained at least 1 reliable ICP measure in 53/54 sessions (98%)
- Completed within allotted time frame in 100% of sessions
Screen display
4th Generation fully integrated model

Picture courtesy of Arminas Ragauskas
Future Plans

- Clinical validation study of the newest (4th generation ICP meter)
- Sites: Baylor College of Medicine, UT Southwestern (Dallas), and UT MD Anderson (Houston).
  - Specific aims
    - Paired measures of ICP (Ommaya reservoir) and Vittamed
    - Paired measures of lumbar CSF pressure and Vittamed (IIH/neurological patients)
    - Assess the change in ICP in the same subject in different body tilt angles (Ommaya) or pre to post CSF drainage (IIH)
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