Prospective Evaluation of Noninvasive HeadSense Intracranial Pressure Monitor in Traumatic Brain Injury Patients Undergoing Invasive Intracranial Pressure Monitoring

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■ BACKGROUND: **Currently, intracranial pressure (ICP) is measured by invasive methods with a significant risk of infectious and hemorrhagic complications. Because of these high risks, there is a need for a noninvasive ICP (nICP) monitor with an accuracy similar to that of an invasive ICP (iICP) monitor.**

■ OBJECTIVE: **We sought to assess prospectively the accuracy and precision of an nICP monitor compared with iICP measurement in severe traumatic brain injury (TBI) patients.**

■ METHODS: **Participants were ICP-monitored patients who had sustained TBI. In parallel with the standard invasive ICP measurements, nICP was measured by the HeadSense HS-1000, which is based on sound propagation. The device generated an acoustic signal using a small transmitter, placed in the patient's ear, and picked up by an acoustic sensor placed in the other ear. The signal is then analyzed using proprietary algorithms, and the ICP value is calculated in millimeter of mercury (mm Hg).**

■ RESULTS: **Analysis of 2911 paired iICP and nICP measurements from 14 severe TBI patients showed a good accuracy of the nICP monitor indicated by a mean difference of 0.5 mm Hg. The precision was also good with a standard deviation of 3.9 mm Hg. The Pearson *r* correlation was 0.604 ($P < 0.001$).**

■ CONCLUSIONS: **The HeadSense HS-1000 nICP monitor seems sufficiently accurate to measure the ICP in severe TBI patients, is patient friendly, and has minimal risk of complications.**

INTRODUCTION

After the primary injury of traumatic brain injury (TBI), one of the main goals is to prevent secondary injury to the brain. Secondary injury is caused by hypoxic-ischemic damage, most commonly due to intracranial hematomas and cerebral edema, followed by raised intracranial pressure (ICP), which prevents an adequate brain perfusion.[1]

ICP is pressure inside the skull and thus in the brain tissue and cerebrospinal fluid (CSF). ICP is measured in millimeter of mercury (mm Hg) and, at rest, is normally 7–15 mm Hg for a supine adult. It becomes negative, averaging −10 mm Hg, in vertical position.[2] Currently, ICP is measured by invasive methods in different intracranial anatomic locations, most commonly intraventricular, with an external ventricular drain (EVD), or intraparenchymal, both placed through a burr hole. Under certain circumstances the ICP can also be measured by lumbar puncture; however, after a TBI this method is often not possible due to increased risk of brain herniation.[3]

Invasive ICP (iICP) monitors are associated with infectious and hemorrhagic complications. After EVD placement, hemorrhagic complications are found in 5.7% of the cases.[4] A positive CSF culture obtained from the EVD is found in up to 27% of the cases.[5] Even if the EVD placement is performed in the sterile environment of an operating room using prophylactic antibiotics, tunneling the catheter subcutaneously at least 10 cm

Key words
- HeadSense
- Intracranial pressure
- Noninvasive ICP
- Traumatic brain injury

Abbreviations and Acronyms
CSF: Cerebrospinal fluid
CT: Computed tomography
EVD: External ventricular drain
ICP: Intracranial pressure
iICP: Invasive intracranial pressure
mm Hg: Millimeter of mercury
nICP: Noninvasive intracranial pressure
TBI: Traumatic brain injury

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from the burr-hole, avoiding routine sampling of CSF, and not changing the catheter, there is still an infection rate of 12%.[6] Also in intraparenchymal monitors, such as the frequently used Camino ICP monitor, a positive culture of the tip is found in 8.5% and hemorrhage in 2.5% of the cases, from which 0.6% is clinically relevant.[7]

Because of these high risks of iICP monitors, there is a need for a noninvasive ICP (nICP) monitor with an accuracy similar to that of an iICP monitor. The HeadSense HS-1000 (HS-1000, HeadSense Medical Ltd., Netanya, Israel) is such an nICP monitor (Figure 1). This device is based on novel advanced acoustic signal analysis algorithms that analyze an acoustic signal generated by the device. The acoustic signal is transmitted using a small transmitter, placed in the patient's ear, and picked up by an acoustic sensor placed in the other ear. The signal is then analyzed using proprietary algorithms, and the ICP value is calculated in mm Hg. U.S. Food and Drug Administration approval of the device is currently ongoing. We present the results of a prospective comparative clinical study of ICP values measured by the HeadSense HS-1000 nICP monitor and compare it with ICP values measured by invasive ICP monitors, in patients after a severe TBI in need of ICP monitoring. Our main objective is to examine the accuracy and precision of the HeadSense HS-1000 monitor. Our secondary objective is to evaluate the usability and functionality of the device.

PATIENTS AND METHODS

Participants

This prospective comparative study was performed at 2 centers, Elisabeth-Tweesteden Hospital Tilburg, The Netherlands, and Stuttgart Hospital, Germany. The Elisabeth-Tweesteden Hospital is a large level-1 trauma center with >1500 trauma patients treated yearly. The Stuttgart Hospital is one of the largest of its kind in Germany and is also a certified trauma center. Patients were included between June 2014 and October 2015 after admission to the intensive care unit. All patients had sustained TBI and undergone insertion of an iICP monitor. Eligible subjects were at least 18 years old with a survival expectancy >72 hours. Exclusion criteria were blood or cerebrospinal fluid leakage in the ear canal, ear infection, or pregnant/lactating women.

Once the patient was inclined with his upper body 30 degrees to the bed and the invasive ICP monitor displayed the pressure values, the clinical procedure began. The nICP monitor did a loop of measurements in a rate of 3–6 measurements per minute. Following each measurement, the nICP monitor took a photo of the bedside monitor containing the iICP value. Each recording session was 30 minutes long. The measurements were performed in ideal circumstances for the device. So we avoided loud noises around the patient, except the vital ones (e.g., from the ventilator). Therefore we did measurements of 30 minutes each time, not to hinder the standard medical care. Once all recordings were done, the ICP values from the invasive ICP monitor (saved as photos in the monitor's files) together with the nICP were paired. The end point for each patient was to collect 2 hours of nICP measurements, which meant 4 sessions of half an hour. The measurements were done, if possible, within the first 2 days after iICP placement, because of the possible increase in inaccuracy of the iICP monitor over time. The end point of the study was to include a total of 15 patients. With 200 measurements per patient, there were around 3000 paired measurements to compare.

Standard Protocol Approvals, Registrations, and Patient Consents

The study (NCT02773862; https://clinicaltrials.gov/ct2/show/NCT02773862) was approved by the medical ethics committees at Elisabeth-Tweesteden Hospital and Stuttgart Hospital. Informed consent was given by the patients' representatives.

HeadSense HS-1000

The HeadSense HS-1000 operates on the basis of acoustic signals picked up by the microphone placed in the left ear channel. The picked-up signal is composed of an attenuated test signal (68 dB, at a fixed frequency of 621 Hz) generated by the speaker placed in the right ear channel and low frequency signals generated by the

Figure 1. The HeadSense HS-1000 intracranial pressure monitor consists of ear buds connected to a tablet. The intracranial pressure (ICP) is shown in mm Hg on the screen, together with the heart pulse and ICP over time.

Table 1. Baseline Characteristics

Number of patients	14
Male	13 (92.9% of total)
Mean age (years)	47 (range 19–71)
Number of measurements	2911
Number of successful measurements	2782 (95.6%)
Mean invasive ICP (mm Hg)	8.2 (SD 4.8 mm Hg, range −3 to 31)
Mean nICP (mm Hg)	8.7 (SD 4.0 mm Hg, range 0–29)
Mean difference (mm Hg)	0.5 (SD 3.9 mm Hg, range −27.5 to 21.1)
Difference >5 mm Hg (% of total measurements)	18.8
Difference >3 mm Hg (% of total measurements)	38.3

ICP, intracranial pressure; SD, standard deviation; nICP, noninvasive intracranial pressure.