CLINICAL EVALUATION OF INTRAPARENCHYMAL SPIEGELBERG PRESSURE SENSOR

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OBJECTIVE: The Spiegelberg 3-PN intraparenchymal pressure sensor was clinically evaluated.

DESCRIPTION OF INSTRUMENTATION: The Spiegelberg intraparenchymal pressure sensor is a low-cost device that uniquely performs regular automatic zeroing in situ throughout the measurement period.

OPERATIVE TECHNIQUE: The Spiegelberg sensor was inserted in 87 patients who required intracranial pressure monitoring as part of their routine management. Complications were assessed by postoperative computed tomographic scanning and clinical investigation. The automated zeroing procedure was assessed after implantation of the sensor and during long-term measurement. In five patients, the "gold standard' of intraventricular pressure was measured simultaneously and compared with the intraparenchymal or subdural Spiegelberg 3-PN pressure.

EXPERIENCE AND RESULTS: No complications associated with the Spiegelberg sensor were observed. The duration of monitoring ranged from 3 to 28 days (mean, 10 d). In 3 patients, technical problems occurred, and in 84 patients, the pressure measurement was successful, including the automatic zeroing procedures performed by the monitor after insertion and hourly thereafter. The absolute difference between the Spiegelberg reading and the intraventricular pressure was less than ± 3 mm Hg in 99.6% and less than ± 2 mm Hg in 91.3% of readings. An Altman-Bland bias plot revealed good agreement between the two methods, with an average bias of 0.5 mm Hg, but revealed a significant trend toward 10% lower Spiegelberg readings with increasing intracranial pressure of >25 mm Hg. There was no difference between intraparenchymal and subdural locations.

CONCLUSION: The Spiegelberg 3-PN sensor was reliable and simple to use. It can be recommended for routine intraparenchymal and subdural pressure measurement at a considerably lower price compared with other tip transducers and has the unique advantage of automated zeroing in vivo.

KEY WORDS: Calibration, Intracranial pressure, Monitoring, Pressure sensor

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The clinical relevance of intracranial pressure (ICP) monitoring in the management of patients with acute intracranial space-occupying lesions is widely accepted. In recent years, a variety of tip transducers have been developed for intraparenchymal pressure measurement, and many reports support the clinical usefulness of these sensors (9, 10, 19, 20, 22). However, compared with the "gold standard" of ventricular pressure measurement that uses a fluid-filled catheter, virtually all of these fiberoptic or strain-gauge sensors are expensive, require a calibration procedure during insertion, and have the potential drawback of silent zero drift. The commercially available Spiegelberg ICP sensor is different from these microsensor tip catheters in terms of measurement technology and can eliminate these drawbacks. The device is unique in performing regular automatic zeroing in situ throughout the measurement period.

In this study, we clinically evaluated the Spiegelberg sensor, which is designed for intraparenchymal and subdural pressure measurement. Our objectives were as follows: 1) to report our clinical experience with this device, 2) to analyze the automatic zeroing of the sensor after implantation and during pressure

recording, 3) to compare the pressure readings with those of the simultaneously recorded gold standard of intraventricular pressure, and 4) to analyze the complication rate with this sensor.

PATIENTS AND METHODS

Patient Population

The study was approved by the local ethics committee of the Johann Wolfgang Goethe University of Frankfurt. Between June 1999 and December 2001, the Spiegelberg sensor was inserted in 87 patients who required ICP monitoring as part of their routine management. The diagnosis was severe head injury in 46 patients, subarachnoid hemorrhage in 26 patients, intracerebral hematoma in 8 patients, brain tumor in 5 patients, and subdural empyema in 1 patient.

ICP Measurement

The Spiegelberg 3-PN sensor (Aesculap, Inc., Center Valley, PA) was approved in 2001 by the United States Food and Drug Administration. In 25 patients, the probe was inserted in the right frontal area at a depth of 2 cm for intraparenchymal measurement. In 62 patients, the probe was placed subdurally at the site of the craniotomy. All patients underwent follow-up computed tomographic scans 1 to 7 days after the insertion of the Spiegelberg sensor. In all cases, we used direct placement of the probe instead of a bolt system.

Compared with other sensors, the Spiegelberg 3-PN catheter is less expensive (costing approximately 60–75% less than the cost of other tip transducers) and is unique in performing automatic zeroing in situ after connecting the sensor to the monitoring unit. The measurement technology of this sensor involves the use of an air pouch situated at the tip (*Fig. 1*). By maintaining a constant known volume within the air pouch, the system ensures that the pressure within the air pouch is equivalent to the surrounding pressure. The pressure transducer is located in the ICP monitor and is connected to the tip of the catheter. For zeroing, the pressure transducer automatically closes to the sensor and opens to ambient pressure (zero reference). The ambient pressure is then established as zero. The transducer then closes to ambient pressure and opens to the sensor. A total of 0.1 ml of air is then pumped by a piston pump into the air pouch, and continuous measurement is initiated. The procedure of automatic zeroing in situ is repeated every hour. The measurement technology is more extensively described elsewhere (24). The Spiegelberg brain pressure monitor has been tested in vitro (6) and in vivo (4).

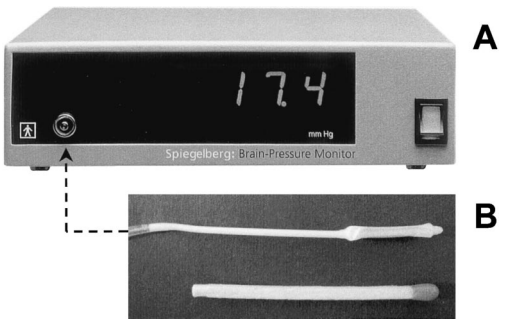

FIGURE 1. *Photograph illustrating the tip of the Spiegelberg 3-PN sensor with the monitor* (A) *and the air pouch mechanism* (B).

In five patients, the intraparenchymal (n = 2) or subdural (n = 3) measurement was simultaneously compared with the gold standard of fluid-coupled ventricular pressure measurement (LogiCal transducer; Medex, Inc., Hilliard, OH). In these five patients, we were afraid of progressive midline shift or compression of the ventricles and failure of fluid-coupled intraventricular pressure measurement. Therefore, we left the ventriculostomy catheter in place to provide an additional treatment modality for increased ICP. Additionally, the Spiegelberg 3-PN sensor was inserted intraparenchymally or subdurally to provide a method of reliable pressure measurement during cerebrospinal fluid drainage or in case of occlusion of the ventriculostomy catheter.

Periods of simultaneous measurement of the two pressures were recorded after zeroing the external transducer and repositioning at the level of the external auditory canal. To avoid potential errors during nursing care procedures, opening of the ventriculostomy catheter, or movements of the patient's head, the data were recorded for analysis only during short periods of direct observation of the patient and the measurement equipment. This method was chosen to eliminate the most common error when comparing external transducer with tip transducer pressures: hydrostatic differences caused by head motions in relation to the external transducer (10).

Data Acquisition and Analysis

All patients were connected to the intensive care data collection system for continuous multimodal signal recording. Analog output was filtered at 25 Hz and processed through an analog-to-digital converter. Digitized data were collected on a personal computer, sampled at 0.5 Hz, and saved for long-term viewing and offline analysis. Linear regression analysis, Altman-Bland plot, and histogram analysis were used to compare the Spiegelberg pressure with the intraventricular pressure.

RESULTS

No complications of intracerebral or subdural hemorrhage were observed. The duration of monitoring ranged from 3 to 28 days (mean, 10 d). There were no clinical infections with symptoms of meningitis. In 3 (3.4%) of 87 patients, erroneous pressure readings caused by air leakage at the monitor connector were recorded. These readings were clearly recognized by the typical decrease in pressure after the automatic zeroing procedures that took place every hour. In the remaining 84 patients, the pressure measurements were technically correct and correlated with the clinical measures and radiological findings.

After implantation of the sensor and the first connection to the monitoring devices, the zeroing procedure was performed successfully in all cases. Likewise, automatic zeroing procedures performed

hourly by the monitor were successful in all patients. There was no single period of a discrepancy between the last seconds of ICP monitoring before zeroing and the first seconds after zeroing. After removing the sensor and exposing it to atmospheric pressure levels, the maximum zero drift was less than ±2 mm Hg.

The total number of simultaneous recordings of intraventricular pressure and the Spiegelberg 3-PN pressure obtained under direct observation of the patient and the measurement equipment was 15,104 (251 min). A significant correlation was found between the intraventricular pressure and the Spiegelberg 3-PN pressure, regardless of the subdural or intraparenchymal location (n = 15,104; r^2 = 0.97) (*Fig. 2*). The absolute difference between the two readings was less than ±3 mm Hg in 99.6% and less than ±2 mm Hg in 91.3% of readings (*Fig. 3*). An Altman-Bland bias plot revealed good agreement between the two methods with an average bias of 0.5 mm Hg, but it also revealed a significant trend toward 10% lower Spiegelberg readings with increasing ICP (r^2 = 0.27) (*Fig. 4*). However, this trend was statistically significant only when ICP exceeded 25 mm Hg.

DISCUSSION

Intraventricular pressure is considered to be the gold standard in ICP monitoring: it is the standard by which all other systems are compared (13, 15). However, standard ventriculostomy catheters measuring intraventricular pressure by fluid-coupled external transducers have certain limitations in both clinical practice and experimental work. They may fail in the context of progressive mass lesions and compressed ventricles, in situations of catheter blockage, or when the catheter is dislodged and placed within the brain parenchyma. Technological improvements have led to development of various fiberoptic, strain-gauge, or silicon-microchip tip transducers with direct pressure measurement. These techniques were developed primarily for intraparenchymal pressure measurement, in which fluid coupling is not possible or does not give correct results. Unfortunately, these sensors are expensive and require a zeroing procedure of varying sophistication at the time of sensor insertion. Most of these sensors cannot be rezeroed during the pressure measurement in patients. Some exceptions exist, such as the Gaeltec (Gaeltec, Ltd., Dunvegan, Isle of Skye, Scotland) and Ladd (Ladd Research Industries, Burlington, VT) sensors, which were designed primarily for extradural pressure measurement (1, 11, 12, 16, 23).

The clinical relevance of zero drift with modern transducers has been emphasized recently (2, 8). Although, with most tip transducers, the measurement accuracy is acceptable in the majority of patients, problems with zero drift and robustness have been identified in laboratory bench tests and clinical studies (3,

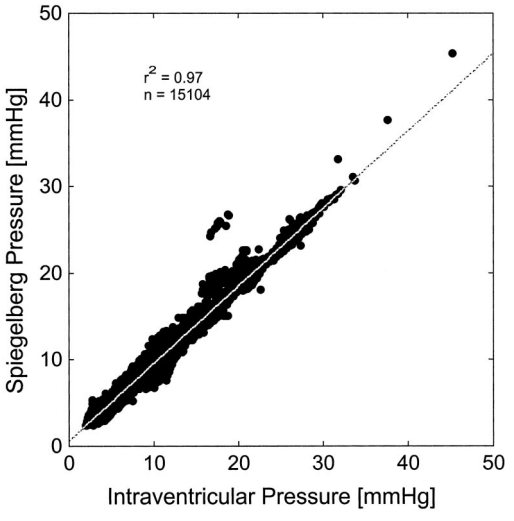

FIGURE 2. *Scatterplot illustrating the relationship between intraventricular pressure and Spiegelberg 3-PN pressure readings.*

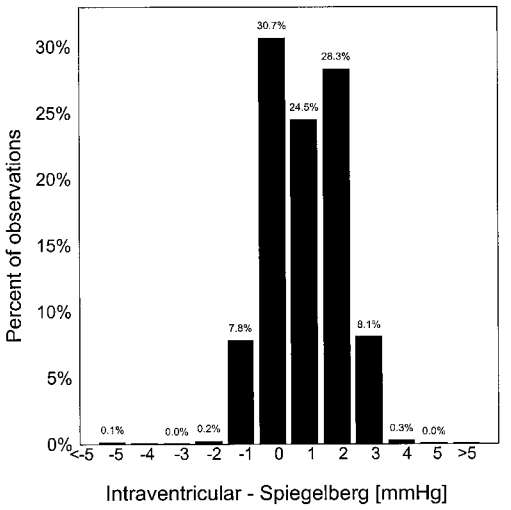

FIGURE 3. *Frequency distribution of the difference between the intraventricular pressure and the pressure measured by the Spiegelberg 3-PN sensor.*

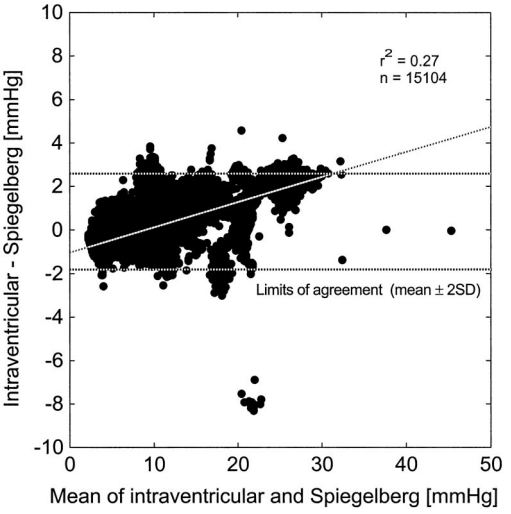

FIGURE 4. *Altman-Bland plot illustrating the limits of agreement between the intraventricular pressure and the pressure measured by the Spiegelberg 3-PN sensor.* SD, *standard deviation.*

18, 21, 23). There are reports of zero drift as high as 1.5 mm Hg per day during bench testing (17), a range of zero drift from −13 to 22 mm Hg with the Camino device (21) (Camino Laboratories, San Diego, CA) or from −20 to 30 mm Hg with the Codman microsensor (Codman/Johnson & Johnson, Raynham, MA), or an average bias of 10 mm Hg or more in 9% of measurements with the Codman sensors (7). Although rare, these erroneous pressure readings that are caused by zero drift indicate normal pulsations and cannot be distinguished from correct readings, except by exposing the transducer to ambient pressure. Therefore, they may lead to inadequate treatment decisions and may result in severe complications from aggressive (but unnecessary) or missed (but necessary) ICP therapy.

The technological principle of the Spiegelberg ICP system offers the unique clinical advantage of automated zeroing after insertion of the probe and every hour thereafter. The reliability of this principle has been demonstrated in rigorous bench testing with the ventricular Spiegelberg probe (6) and in experimental (24) and clinical studies (4), and the sensor was recommended by the United Kingdom Shunt Evaluation Laboratory (6).

Our study was the first clinical analysis of a large cohort of patients. In this study of 87 patients, we found no complication associated with the Spiegelberg device, as demonstrated by postoperative computed tomographic scanning and a reliable pressure measurement in 84 patients.

We are aware of the small numbers of patients in whom the Spiegelberg 3-PN pressure and the intraventricular pressure readings were directly compared. We included only patients in whom both intraventricular catheter and the Spiegelberg sensor had been inserted for clinical reasons. The acquisition of more comparative measurements between the intraventricular pressure and the intraparenchymal and subdural Spiegelberg pressure should be the subject of further investigation.

Subdural pressure measurement via fluid-filled catheter is usually regarded as less reliable because of underestimating ICP compared with intraventricular pressure (1, 14). In studies in which direct pressure measurements were obtained by tip transducers, there was much less difference between subdural and intraventricular pressure, and the authors of these studies have recommended it as a satisfactory alternative to intraventricular pressure recording (1, 5, 10). By comparing our measurements, and by using Altman-Bland bias plot, there was a trend toward 10% lower Spiegelberg readings with increasing ICP ($r^2 = 0.27$). This bias was statistically significant only when ICP exceeded 25 mm Hg. This bias is not clinically relevant, considering a 3 mm Hg error at 30 mm Hg, or a 5 mm Hg error at 50 mm Hg. Overall, the accuracy was higher compared with other reports (4, 10). In summary, our data confirm that subdural tip transducers provide reliable pressure measurement. Although the intraventricular or intraparenchymal placement of pressure sensors remains the method of choice when a burr hole is used, subdural placement of a tip transducer may be a useful alternative after a craniotomy and removal of a hematoma, contusion, or tumor, or after other neurosurgical procedures.

CONCLUSION

The Spiegelberg 3-PN sensor was reliable and simple to use. It can be recommended for routine clinical intraparenchymal and subdural pressure measurement at a considerably lower price compared with other tip transducers, and it may eliminate the problem of silent zero drift.

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COMMENTS

The authors report their experience with the Spiegelberg "self-zeroing" intraparenchymal (or subdural) intracranial pressure (ICP) catheter. In this study of 87 patients, only three catheters failed mechanically. In a subcohort of five patients, ICP measurements from a concurrent ventriculostomy catheter demonstrated excellent correlations, with the exception of a small underestimation bias at higher ICPs. The zero-drift measurement error with micro-strain-gauge and fiberoptic ICP transducers can result in undertreatment or unnecessarily prolonged overtreatment of up to 10% of critically ill patients with ICP disorders. The Spiegelberg system appears to have solved this problem. For clinical scenarios in which cerebrospinal fluid drainage is not necessary, the use of this catheter would appear to make practical and economic sense.

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Marvin Bergsneider
Los Angeles, California

The good correspondence found between intraventricular pressure measured with a catheter and pressure within the brain parenchyma measured with this system and the self-zeroing feature make this system attractive for ICP monitoring.

Robert G. Grossman
Houston, Texas

The ability to accurately measure ICP facilitates the management of a wide range of central nervous system disorders. In this article, the authors report their experience with 87 patients undergoing ICP monitoring with the new Spiegelberg 3-PN sensor. Monitoring was successful in 84 patients (96%), and there were no complications. In 5 patients, sensor-generated measurements of intraparenchymal and subdural pressure were found to be in close agreement with simultaneous measurements of intraventricular pressure. A not insignificant feature of the technology was its popularity with the nursing staff. Putative advantages of the sensor include its low cost and unique feature of automatic zeroing in vivo.

This is an interesting report of a potentially important technology for monitoring ICP. More work will be necessary to compare the Spiegelberg sensor with currently available tip transducers. The report would have been stronger if it had included more comparative measurements of sensor-generated intraparenchymal and/or subdural pressure with simultaneous measurements of intraventricular pressure. The acquisition of such data should be the subject of future investigations.

Thomas H. Milhorat
Manhasset, New York

Modern technology continuously influences clinical practice. Evaluation studies are of extreme importance, because they produce landmarks in future trends in the monitoring of patients with head injury. I read the article by Lang et al. with great interest. Let me offer, with all due respect, some possible conclusions that I can draw from this study and also from my own experience:

1. The Spiegelberg transducer performed as accurately as the "gold standard" cerebrospinal fluid measurement in only five cases. This means that we have a chance (but not a certainty) to measure a good ICP value in 84% of our patients. I think that a much larger group should be studied to reach stronger conclusions about its accuracy.
2. There is no question that self-zeroing is a great virtue of this transducer. A 10% underestimation of ICP is not a big problem.
3. The poor frequency response of this transducer makes many methods of ICP waveform analysis impossible.
4. I am really sorry to hear that it is so expensive. Up to 75% of the cost of the microchip transducer that we need to pay for the sterilized balloon seems to me a little bit "over the top." In addition, this transducer does not work without an expensive (probably several thousand dollars) monitoring unit.

Marek Czosnyka
Cambridge, England