Experimental evaluation of the Spiegelberg intracranial pressure and intracranial compliance monitor

Technical note

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The goal of this study was to compare the Spiegelberg intraventricular intracranial pressure (ICP)/intracranial compliance monitoring device, which features an air-pouch balloon catheter, with existing gold-standard methods of measuring ICP and intracranial compliance.

A Spiegelberg intraventricular catheter, a standard intraventricular catheter, and a Codman intraparenchymal ICP microsensor were placed in five sheep, which previously had been given anesthetic and paralytic agents, to allow comparative measurement of ICP at incremental levels (range 5–50 mm Hg). Intracranial pressure measured using the Spiegelberg intraventricular air-pouch balloon catheter displayed a linear correlation with ICP measured using the standard intraventricular fluid-filled catheter \( (r^2 = 0.9846, p < 0.001; \text{average bias} = 0.74 \text{mm Hg}) \), as well as with ICP measured using the Codman intraparenchymal strain-gauge sensor \( (r^2 = 0.9778, p < 0.001; \text{average bias} 0.01 \text{mm Hg}) \).

Automated measurements of intraventricular compliance obtained using the Spiegelberg compliance device were compared with compliance measurements that were made using the gold-standard manual cerebrospinal fluid bolus injection technique at ICPs ranging from 5 to 50 mm Hg, and a linear correlation was demonstrated between the two methods \( (r^2 = 0.7752, p < 0.001; \text{average bias} = 0.019 \text{ml/mm Hg}) \).

The Spiegelberg air-pouch ICP/compliance monitor provides ICP and compliance data that are very similar to those obtained using both gold-standard methods and an intraparenchymal ICP monitor over a range of pathophysiological ICPs. The automated closed Spiegelberg system offers practical advantages for the measurement of intraventricular compliance. Assessment of the clinical utility and robustness of the Spiegelberg system, together with the development of an intraparenchymal device, would enhance the clinical utility of automated compliance measurement and expand the range of its applications.

**KEY WORDS** • intracranial pressure • intracranial compliance • intracranial pressure monitoring

Methods for the measurement and continuous monitoring of ICP have been in use for more than 20 years. Catheter-tip transducer systems such as the Camino fibersoptics11 (Camino Laboratories, San Diego, CA) and Codman (Johnson & Johnson Professional, Inc., Raynham, MA) strain-gauge intraparenchymal sensors are currently in use at many centers. However, problems with zero drift and the robustness of such systems have been identified in laboratory bench tests and clinical studies;2,10,14–16 in addition, it has been found that these systems cannot be recalibrated in vivo. Camino sensors have an average daily drift of up to 3.2 mm Hg,10 and technical complications resulting in failure of that system occur in 10 to 25% of cases.2,15,16 An average bias of 5 mm Hg or more in 24% of Codman sensors, compared with the Camino system, has also been described.4

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**Abbreviations used in this paper:** CL = confidence limit; CPP = cerebral perfusion pressure; CSF = cerebrospinal fluid; ICP = intracranial pressure.

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A device used in the past for obtaining ICP measurements in the subdural and epidural spaces has recently been adapted to measure ICP in the intraventricular and intraparenchymal compartments. The Spiegelberg system3 (Spiegelberg GmbH & Co. KG, Hamburg, Germany) involves the use of an air-filled balloon catheter to measure ICP and is capable of automatic zero-drift correction in vivo. A newer version of the Spiegelberg monitoring system also has the capacity to measure intracranial compliance. In laboratory bench tests the Spiegelberg ICP system has been found to be accurate and to have the lowest zero-drift characteristics compared with currently adopted catheter-tip systems.3 However, the Spiegelberg system has yet to be tested in vivo against gold-standard methods or devices for measuring ICP in the intraventricular and intraparenchymal compartments. Similarly, experimental validation of the compliance values obtained using this system is required. Validation of the latter feature is particularly pertinent because the Spiegelberg device offers an automated method for measuring intraventricular compli-
ance, whereas the current procedure for measuring intracranial compliance requires manual CSF bolus injections that are both time consuming and labor intensive. When the manual procedure is performed by inexperienced hands, there is also a risk of introducing infection and provoking excessive increases in ICP. 

The current experimental study was designed to assess in vivo variations in ICP measured using a standard fluid-filled intraventricular catheter, an intraparenchymal Codman microsensor, and the Spiegelberg intraventricular air-pouch catheter system. In addition, we compared intraventricular compliance measurements obtained using the gold-standard manual injection method with those obtained using the Spiegelberg method over a range of pathophysiological ICPs. The sheep was chosen as the experimental animal because the sizes of its brain, ventricles, and cranium are ideally suited to accommodate the size and disposition of the ICP catheters and sensors being evaluated.

**MATERIALS AND METHODS**

All study procedures were regulated according to the United Kingdom Animals Scientific Procedures Act 1986. Valid British Home Office Project (PPL 60/2513) and personal licenses covered the experimental work.

The Spiegelberg system for measuring ICP involves the use of an intraventricular catheter with an air-pouch balloon situated at the tip. The air-pouch method is based on the technique described by Marey and Chauveau (as mentioned by Geddes). By maintaining a constant known volume within the air pouch, the pressure within the air-pouch balloon is equivalent to the surrounding pressure; when the catheter tip is placed within the intraventricular compartment, ICP can thus be measured at the intraventricular site (Fig. 1).

Two sets of ICP measurement comparisons were undertaken: 1) the Spiegelberg device with the intraventricular air-pouch balloon catheter was compared with the fluid-filled intraventricular catheter connected to an external strain-gauge transducer; and 2) the Spiegelberg device was compared with the Codman intraparenchymal catheter-tip strain-gauge sensor.

Automated measurement of intracranial compliance made using the Spiegelberg device requires insertion of a double-lumen intraventricular catheter (Probe 3; Spiegelberg KG). One lumen is filled with fluid and connects directly with the CSF space, whereas the other connects the monitoring system to an air-pouch balloon mounted on the tip of the catheter (this balloon is the same one used solely for measuring ICP). Through the latter lumen of the catheter, automated injections and withdrawals of air can be made to and from the balloon while it is positioned within the ventricular CSF space. Added volumes are small (≤ 0.1 ml) and the exact volumes added are calculated after derivation of algorithms based on the gas law equation:

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P V = nRT
\]

in which \(P\) = pressure, \(V\) = volume, \(n\) = number of moles of gas, \(R\) = universal gas constant, and \(T\) = temperature in Kelvin. The resultant perturbations in ICP are detected through the fluid-filled lumen, which is connected to an external strain-gauge pressure transducer (Baxter Truwave; Baxter b.v., Uden, The Netherlands).

For this study the filter setting was set for up to 120 injection–withdrawal sequences over a period of approximately 10 minutes to allow time-averaged compliance values to be calculated. These values were compared with those obtained using the manual-injection procedure in which boluses of 0.9% saline are injected into the ventricular CSF space over a period of approximately 1 second. The mean injected volume was 0.8 ml (change in volume).

Surgical Preparation

Five Suffolk cross-bred ewes were used in this study. A state of anesthesia was induced in each sheep by intravenous injection of etomidate (0.5 mg/kg) and midazolam (0.5 mg/kg). After tracheal intubation, anesthesia was maintained by administration of halothane delivered in a
1:2 O/N/O mixture, and neuromuscular blockade was achieved by addition of cis-atracurium (0.1 mg/kg). The animals’ lungs were mechanically ventilated to maintain PaCO2 within a range of 35 to 45 mm Hg. Arterial and venous access was obtained, and mean arterial blood pressure was maintained at approximately 90 mm Hg. The electrocardiogram of each animal was monitored continuously. The animal was placed in sternal recumbency throughout the experiment, with its head secured in a Mayfield pin headholder. The cranium was exposed by a midline incision and burr holes were drilled 5 mm posterior and lateral to the junction of the coronal and sagittal sutures. An intraventricular catheter (Cordis, Brentford, UK) was inserted on the right side for infusion of mock CSF. A Spiegelberg double-lumen catheter was inserted into the left ventricle for measurements of ICP/intracranial compliance. Influx and backflow of fluid from an attached column of saline were used to aid confirmation of intraventricular placement. A Codman ICP sensor was inserted into the right frontal brain parenchyma through a separate, anteriorly placed burr hole. Catheters were secured in position and all burr holes were sealed with bone wax. Anesthesia was maintained in the animals throughout the experiment. At the conclusion of data collection, each sheep was killed by an intravenous injection of pentobarbital, after which the brain was removed, fixed in 10% formaldehyde solution, and serially sectioned. These brain specimens were later examined for gross pathological evidence of tissue damage resulting from catheter placement.

Study Protocol

Each catheter and sensor under comparison was connected to the monitoring units via the appropriate inter-
face. The Codman intraparenchymal ICP sensor was calibrated to zero according to the manufacturer's instructions prior to placement. After the external pressure transducer connected to the intraventricular fluid-filled catheter was calibrated to zero and a satisfactory ICP waveform was obtained, the data collection sequence was commenced. Raw data were fed directly into a microcomputer via a standard RS232 interface and stored. Data were analyzed with the aid of specially written in-house analysis software. Ten-minute-long datasets were collected at 5–mm Hg ICP bands, starting at baseline (approximately 3–8 mm Hg) and increasing by 10-mm Hg increments, with measurements made up to 50 mm Hg. Mock ICP increases were achieved through regulated continuous infusion of normal saline through the right-sided intraventricular catheter. At each ICP bandwidth, ICP levels recorded with the Spiegelberg catheter, the fluid-filled intraventricular catheter, and the Codman sensor were noted for comparison.

Minute-by-minute compliance data were fed into the computer by using a specially written data collection program. Collected raw data included all values for the added volume (ΔV) and the ICP values before and after each volume addition, which occurred approximately once every 5 seconds. Each run for measurement at a particular ICP band lasted approximately 10 minutes, with as many as 120 individual sets of volume-pressure values. Steady maintenance of the requisite ICP within the proposed ICP band was achieved by continual adjustment of the saline infusion rate. The individual sets of compliance data were processed, and measurements that were made while the ICP level was outside the study ICP band were rejected. Compliance calculated on the basis of data processing was recorded.

For each compliance run at a given ICP band, the manual-injection method (previously described) was used at the beginning and end of each run. The two compliance values were averaged to provide one measure for compliance using the manual-injection method. Automated compliance measurements were obtained during the 10-minute interval between the two manual-injection measurements at that ICP band. Once the ICP had stabilized after the final manual injection, a set of ICP recordings were recorded from all three ICP devices under comparison.

Statistical Analysis

Pairs of calculated compliance data obtained by using the automated and manual methods were plotted and a linear trend line was fitted according to the least-squares method. The sets of ICP measurements made using the different systems were similarly plotted. Calculations were made for Pearson's product-moment correlation and results were examined using the Bland–Altman procedure for comparing two methods of clinical measurement.

RESULTS

Data were collected from all five animals, yielding a total of 15 sets of ICP measurements made with the Spiegelberg system, the intraventricular fluid-filled catheter with an external strain gauge, and the Codman sensor. Nineteen pairs of compliance values that were measured using the automated compliance device and by using the manual-injection technique were also obtained. Technical problems encountered during placement of the ICP catheter in the first sheep prevented us from recording a complete set of ICP measurements with all three ICP devices under comparison. The ICP values for the comparative study ranged from 3.3 to 44.6 mm Hg (Spiegelberg system), 3.7 to 44.3 mm Hg (fluid-filled catheter with external strain gauge), and 2.2 to 45.6 mm Hg (Codman sensor). Compliance ranged from 0.0587 to 0.2688 ml/mm Hg measured using the automated system and from 0.0525 to 0.425 ml/mm Hg measured using the manual-injection method. The ICP levels at which measurements of compliance were made ranged from 5 to 48.8 mm Hg.

A comparison of ICP levels measured using the Spiegelberg system with those measured using the intraventricular fluid-filled external strain-gauge catheter revealed...
linear correlation ($R^2 = 0.9778$). The average bias was lower than the manual technique (Fig. 4). A comparison of ICP levels measure using the Spiegelberg system with those measured using the Codman sensor again yielded a statistically significant ($p < 0.001$) linear correlation ($R = 0.9778$). The average bias was 0.01 mm Hg, with 95% CLs of agreement for bias being $-0.972$ and 0.972 (Fig. 3).

Measurements of compliance obtained using the automated system showed the typical relationship of decreasing compliance with rising ICP (Fig. 4 upper). There was a statistically significant ($p < 0.001$) linear correlation between the results obtained using the two methods for measuring compliance ($r = 0.7752$). The average bias was $-0.019$ ml/mm Hg (95% CLs of agreement for bias $-0.031$ and $-0.0073$). The automated system for measuring compliance yielded lower compliance values compared with the manual technique (Fig. 4 lower).

Macroscopic examination of the fixed brains revealed fine hemorrhagic tracks associated with insertion of the double-lumen intraventricular catheters used for automated measurements of ICP and compliance. In one case, initial incorrect placement of the intraventricular catheter resulted in thalamic hemorrhage before the catheter was drawn back into the ventricle. There was no evidence of significant subarachnoid, ventricular, or focal parenchymal hemorrhage in any of the other brains. Insertion of the Codman intraparenchymal catheter and straight intraventricular catheter for ventricular saline infusion resulted in minimal macroscopic tissue damage.

**DISCUSSION**

The results of this study demonstrate that the Spiegelberg intraventricular air-pouch balloon catheter compares well with both the intraventricular fluid-filled external strain-gauge catheter and the Codman intraparenchymal catheter-tip strain-gauge catheter over a wide range of ICPs in a model of diffusely raised ICP in sheep. The automated compliance measurements obtained using the Spiegelberg system demonstrated the expected changes in compliance with increasing ICP, and the method compared very favorably with the manual-injection method in obtaining data. Bias and limits of agreement between the two techniques were similar to those recorded in a clinical validation study. We noted some tissue damage resulting from insertion of the intraventricular catheters used with the Spiegelberg ICP/intracranial compliance device, but this was limited to fine hemorrhage along the track of catheter passage and was comparable with the level of damage expected from placement of an intraventricular catheter.

When comparing the measurements of ICP obtained using the three devices, there was one outlier result, with a bias of $-4.4$ mm Hg between the Spiegelberg intraventricular balloon catheter and the intraventricular fluid-filled strain-gauge catheter and a bias of $-6.2$ mm Hg between the Spiegelberg catheter and the Codman sensor. These outliers can be explained by the difficulties inherent in maintaining a steady state of ICP by using the intraventricular infusion of saline at higher ICP bands, before all three values were recorded.

Problems with zero drift and robustness continue to be reported in clinical and experimental studies of the devices currently used for measuring and monitoring ICP. Ours is the first study to demonstrate that the Spiegelberg intraventricular ICP method is accurate when compared with both the standard intraventricular method and the currently widely adopted intraparenchymal system. This new system with its inherent automatic zero function in vivo is worth assessing in larger clinical studies to evaluate its longer-term zero drift and robustness.

Although there is a theoretical advantage in measuring volume and pressure parameters such as the pressure-volume index and the volume-pressure response, these measurements have previously depended on manual-injection methods. Their use in clinical practice has been limited because of the labor-intensive process of obtaining repeated measurements, which requires an accurately calibrated rate and volume of injection, and because of the inherent risks of infection. In addition to providing automated measurements of compliance that are comparable in accuracy with those obtained using the manual-injection method, the Spiegelberg system has the capacity for continuous measurement and monitoring of intracranial compliance. There remains, however, the task of identifying critical thresholds in compliance values in patients with brain injury, and their utility as a means of predicting rises in ICP. Toward this end, an international multicenter study has been undertaken to collect patient data that will help validate the predictive relationship between falling intracranial compliance and increases in ICP, as well as to determine the thresholds of poor compliance (for information, consult the “Brain-IT” website at http://www.brainit.gla.ac.uk/brainit).

There are some limitations to the current automated system for measurement of intracranial compliance. Above all, intraventricular placement of the air-pouch bal-
loon is required for volume additions. At many centers in the United States and the United Kingdom it is standard policy to use intraparenchymal—but rarely intraventricular—catheters in the care of patients with acute brain injury. Additionally, in some patients it is difficult to cannulate the small ventricles. If the Spiegelberg method of monitoring both ICP and intracranial compliance is to find widespread clinical application, the system needs to be modified to enable measurement of compliance in the intraparenchymal compartment.

Figure 5 provides a summary of pilot data on intraparenchymal compliance measurements obtained in a sheep model of raised ICP using a modified air-pouch balloon catheter with a catheter tip–mounted transducer. It can be seen from this that, unlike intraventricular CSF compliance, intraparenchymal compliance exhibits a complex and possibly biphasic relationship with increased ICP in association with reduced CPP. This may correlate with earlier findings that the pressure–volume index varies directly with CPP within limits of autoregulation, and indirectly with CPP below the autoregulatory range.6 Measurement variability is high and further observations are required; however, intraparenchymal compliance monitored using this method may act as a measure of a more complex function of brain perfusion and of physiological, rather than physical, compliance. Additional studies of this phenomenon are currently in progress.

Despite its limitations, the current double-lumen catheter system used for continuous intraventricular compliance measurement in this study retains potential clinical advantages, including its automatic zero drift–corrected measurement of ICP and the fact that it permits CSF drainage as a treatment option.

Disclosure

None of the authors has a financial interest in Spiegelberg (GmbH & Co.) KG as a consultant, shareholder, or in any other capacity.

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