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MULTICENTER CLINICAL ASSESSMENT OF THE RAUMEDIC NEUROVENT-P INTRACRANIAL PRESSURE SENSOR: A REPORT BY THE BRAINIT GROUP

OBJECTIVE: The aim of this study was to evaluate the robustness and zero-drift of an intracranial pressure sensor, Neurovent-P (Raumedic AG, Münchberg, Germany), when used in the clinical environment.

METHODS: A prospective multicenter trial, conforming to the International Organization for Standardization 14155 Standard, was conducted in 6 European BrainIT centers between July 2005 and December 2006. Ninety-nine catheters were used. The study was observational, followed by a centralized sensor bench test after catheter removal.

RESULTS: The mean recorded value before probe insertion was 0.17 ± 1.1 mm Hg. Readings outside the range ± 1 mm Hg were recorded in only 3 centers on a total of 15 catheters. Complications were minimal and mainly related to the insertion bolt. The mean recorded pressure value at removal was 0.8 ± 2.2 mm Hg. No relationship was identified between postremoval reading and length of monitoring. The postremoval bench test indicated the probability of a system failure, defined as a drift of more than 3 mm Hg, at a range between 12 and 17%.

CONCLUSION: The Neurovent-P catheter performed well in clinical use in terms of robustness. The majority of technical complications were associated with the bolt fixation technology. Adverse events were rare and clinically nonsignificant. Despite the earlier reported excellent bench test zero-drift rates, under the more demanding clinical conditions, zero-drift rate remains a concern with catheter tip strain gauge technology. This performance is similar, and not superior, to other intracranial pressure devices.

KEY WORDS: Intracranial pressure, Multicenter trials, Physiological monitoring, Technology assessment

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In the 1950s, the first practical method for the clinical monitoring of intracranial pressure (ICP) was developed, and not long after that, its clinical value was demonstrated by Lundberg (8, 10). However, despite nearly 50 years of experience with this technology, the accurate and reliable measurement of ICP in the clinical setting remains a challenge.

Catheter tip pressure sensors, which rely on the technology of miniaturization, are likely to cause less damage to tissue than larger, fluid-filled catheters. As there is no separation between the point of measurement and the pressure sensor, catheter tip sensors are not affected by hydrostatic pressure differences. However, because of the reliance on miniaturization of the sensors and the interconnecting

technology, these devices are more prone to problems of robustness. Also, because the pressure sensor is at the tip of the catheter and its reference zero level cannot be checked after insertion, the technology must exhibit minimal in vivo zero-drift over several days of measurement. There are several catheter tip devices on the market which, although performing well in bench test studies, have exhibited unacceptable zero-drift, robustness, or both, in studies conducted in the clinical environment (3, 5, 13, 15–17, 19–21, 23).

To reduce the physical size of the strain gauge catheter tip, usually only a partial Wheatstone bridge (an electrical bridge circuit used to measure resistance) is used, particularly because of the difficulty of producing robust multiple electrical connections in the miniature catheter tip design. Recently, a new

ABBREVIATION: ICP, intracranial pressure

technology has become available, the Neurovent-P (Raumedic AG, Munchberg, Germany), in which a full Wheatstone bridge is fabricated at the catheter tip together with integral miniature multiwire technology. This solution should, in theory, provide improved zero-drift characteristics. A recent 2-center study conducted in Germany studied the incidence of zero-drift, rate of placement-induced parenchymal hemorrhage, magnetic resonance imaging compatibility, and robustness of this new ICP probe (22).

As a prerequisite for a clinical trial, the BrainIT group conducted and reported on an independent bench test study of the Neurovent-P catheter, which confirmed the manufacturer's long-term zero-drift performance for this technology (4). The results of that study demonstrated that mean zero-drift, after 5 days, was very small, and long-term continuous recording of a stable pressure was very precise. The response in dynamic tests, i.e., the changes of pressure over a wide range, was excellent. The average bias of the Raumedic catheter compared with a known pressure is very small. However, controlled laboratory conditions can be a very different environment from the clinical setting, and although devices may perform satisfactorily in the laboratory, they also need to be evaluated in clinical use. The aim of this study was to evaluate the robustness and zero-drift of this technology when used in the clinical environment in a prospective multicenter trial.

PATIENTS AND METHODS

The present prospective multicenter trial involved 6 BrainIT (www.brainit.org) centers (Barcelona, Heidelberg, Monza, Newcastle upon Tyne, Uppsala, and Vilnius; see Appendix), where patients in whom ICP monitoring was clinically indicated were enrolled between July 2005 and December 2006.

This study conformed to the International Organization of Standardization 14155 Standard, "Clinical Investigation of Medical Devices for Human Subjects." The model used was one of an investigator-led study design with the BrainIT group coordinating center's host institution (Southern General Hospital, Glasgow, Scotland) acting as the study sponsor. The BrainIT group has a regional language-based coordination, data validation, and study monitoring infrastructure in place to provide the required trial monitoring.

The study hypotheses were that, during typical clinical use, Neurovent-P catheters: 1) maintain accuracy of calibration as measured by postremoval zero-drift and postremoval bench test calibration; 2) are robust, as measured by catheter/cable system failure rate; and 3) are easy to implant and set up, as measured by a structured survey questionnaire of neurosurgeons and bedside nurses involved in the implantation and use of the system.

The inclusion criteria were: 1) clinical indication for ICP monitoring using an intraparenchymal probe, in keeping with the local guidelines; 2) estimated monitoring time longer than 24 hours; and 3) minute-by-minute recording of ICP with a bedside data collection tool.

The exclusion criteria were: 1) age younger than 16 years, 2) no clinical indication for ICP monitoring, 3) coagulopathy, 4) expected monitoring duration less than 24 hours, and 5) no bedside data collection of ICP available.

Patients in whom an increase in ICP was suspected, satisfying the inclusion criteria, were monitored with an intraparenchymal pressure probe. All ICP probes were inserted through a frontal burr hole. The

location was chosen according to local guidelines; in general, this was the right frontal lobe. The Neurovent-P probes were implanted either through the bolt kit or introduced with a twist drill and tunneled subcutaneously. A questionnaire was completed by the neurosurgeon after every implantation to collect information on the procedure. The probe was electrically zeroed to a patient monitor and implanted according to the manufacturer's specifications. The probe placement depth and side of placement were recorded. Minute-by-minute ICP data were collected together with the BrainIT core data as standard.

Recording of Adverse Events

During the course of the study, all adverse events and technical complications were recorded. Adverse events were defined as any undesirable clinical occurrence in a subject, whether it was considered device related or not, such as cerebrospinal fluid infection or cerebral hematoma. Cerebral hematomas were classed into 3 grades: small punctate hemorrhages or localized subarachnoid hemorrhages (I), larger bleeds that did not cause a new neurological deficit or required surgical evacuation but might alter ICP readings (II), and hemorrhages that caused a new deficit or necessitated surgical removal (III). Technical complications were defined as an event or device failure associated with no deviation from a patient's baseline health, such as measuring errors, probe dislocation or unplugging, and probe damage because of cable rupture or pronounced kinking of the sensor. We analyzed whether these complications occurred during nursing maneuvers, during transport of the patient, or for other reasons.

Data collection stopped when a clinical decision was made to remove the ICP monitor from the patient. On removal of the ICP catheter from the patient, the postremoval zero-drift was checked after a stable reading had been achieved.

After removal, all catheters were sent to Monza for bench testing. Using methods and laboratory equipment described previously (14), we tested the zero-drift and dynamic response of the system to changes of pressure in a stepwise fashion, from 5 to 20 mm Hg. Before starting each experimental run, we verified the recorded pressure value, and any sensors that were damaged after removal from the patient were discarded before bench testing. A progressively increased hydrostatic pressure was produced, starting at 0 and rising to 20 mm Hg.

Sample Size Calculation and Statistical Analysis

Evidence from previous work with the Raumedic ICP probe showed that zero-drift had been recorded as 0.2 ± 0.41 mm Hg initially, as 1.7 ± 1.36 mm Hg after monitoring was completed, and 0.6 ± 0.9 mm Hg after 5 days on bench testing (4, 22). To be able to calculate the failure rate, clinically defined as a zero-drift of ± 3 mm Hg or more, it was necessary to observe at least 1 failure (1). The probability of observing a drift of ± 3 mm Hg or more for different values of mean pressure and standard deviation were calculated. A sample size of 100 catheters would yield a 95% chance of including at least 1 failure if the standard deviation was 1.5, whatever the size of the mean drift, and a 95% chance of including at least 1 failure if the standard deviation was 1.0 and the mean drift was 1.3 mm Hg or more. Using this approach, we designed the study to collect data from 100 catheters. For the bench test studies, summary statistics reported include mean, median, maximum, minimum, standard deviation, and the 25th and 75th percentiles. The measured pressure for the dynamic tests was compared with the "gold standard" (hydrostatic water column). Splus 2000 software (Mathsoft, Inc., Seattle, WA) and SPSS software (Version 14; SPSS, Inc., Chicago, IL), were used to perform statistical analyses.

TABLE 1. Patient distribution among centers, percentage of bolt use, depth of introduction, site of introduction, and percentage of traumatic brain injury^a

Center	Patients		Bolt use (%)	Depth of introduction (mm)	Right frontal position (%)	Traumatic brain injury (%)
	No.	%				
Monza	28	28.3%	0	39.2 ± 8	24 (86%)	23 (82%)
Uppsala	25	25.3%	0	28.1 ± 1.3	20 (80%)	19 (76%)
Barcelona	23	23.2%	16 (76%)	46.8 ± 8	18 (78%)	19 (82%)
Vilnius	14	14.1%	0	20.7 ± 2	12 (85%)	14 (100%)
Newcastle	5	5.1%	5 (24%)	54 ± 1.1	5 (100%)	0
Heidelberg	4	4.0%	0	37.5 ± 1.6	2 (50%)	3 (75%)
Total cases	99	100%	21 (21%)	36.9 ± 1.3	81 (81%)	78 (78%)
P value			≤0.0001	≤0.0001	NS	≤0.0001

^a NS, not significant.

RESULTS

Clinical Results

Population

Ninety-nine catheters were placed in patients, with a variable distribution between centers ranging from 4 to 28 cases/center (Table 1). Two catheters were not implanted because of technical problems (2 sensors were damaged by the surgeon during the procedure).

The main pathology was traumatic brain injury (78 patients, 78.8%), followed by miscellaneous pathologies (12 patients, 12.1%), subarachnoid hemorrhage (5 patients, 5%), and hydrocephalus (4 patients, 4%). The fixation bolt was used in 21% of the cases, with significant differences between centers. In 81% of the patients, the sensor was introduced in the right frontal lobe. The mean depth of placement into the parenchyma was 36.9 ± 13.6 mm, with significant intercenter differences. The mean duration of monitoring was 138.7 ± 118 hours (25th percentile, 50 hours; 75th percentile, 192 hours).

Preinsertion Zero-drift

Data were available from 76 catheters. The distribution of the values is presented in Figure 1. The mean recorded value before the probe insertion was 0.17 ± 1.1 mm Hg (median, 0 mm Hg; 25th and 75th percentile, 0 mm Hg).

Readings outside the range -1 to +1 mm Hg were recorded in only 3 centers on a total of 15 catheters (2 in Newcastle upon Tyne, 10 in Vilnius, and 3 in Uppsala; analysis of variance, not significant).

Complications at Insertion and during Use

Some centers pointed out difficulties in using the fixation probe at insertion and/or removal. Most of these incidents were recorded in the early patients: 1 probe was damaged by the surgeon before insertion, 1 defective cable was suspected, 3 probes were difficult to remove, 3 probes provided unreliable

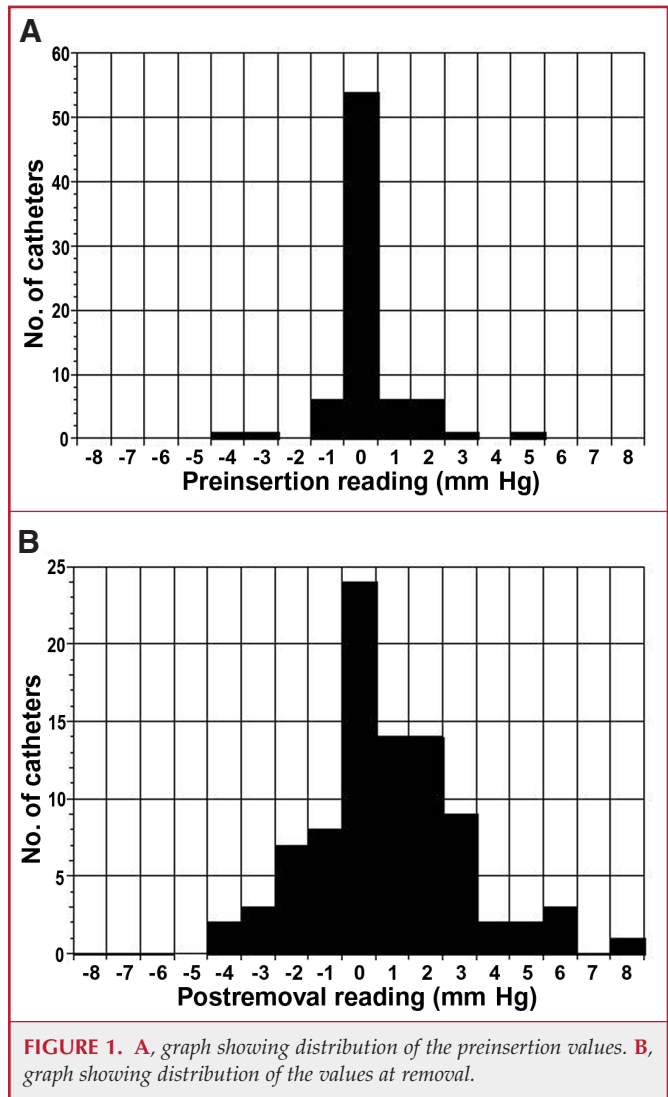


FIGURE 1. A, graph showing distribution of the preinsertion values. B, graph showing distribution of the values at removal.

readings (checked with other systems), 5 probes had problems with the bolt, 2 probes were defective, 0 probes broke, 4 probes were dislocated (2 during surgery, 1 during nursing, 1 during radiology), 0 patients had central nervous system infection, and 2 patients had Grade I hematomas.

Postremoval Zero-drift

Data were available for 89 catheters, mainly because of damage during the removal phase that prevented the adequate recording of the postremoval zero reading. Distribution of the values is presented in Figure 1. The mean recorded value at removal was 0.8 ± 2.2 mm Hg (median, 1 mm Hg; range, -4 to 8 mm Hg; 25th percentile, 0 mm Hg; 75th percentile, 2 mm Hg). Statistically, but not clinically, significant differences were recorded between centers: Barcelona, 0.7 ± 1.7 mm Hg; Heidelberg, 2 ± 0 mm Hg; Monza, 0.7 ± 2.2 mm Hg; Newcastle upon Tyne, 1.2 ± 3.9 mm Hg; Uppsala, 1.7 ± 2.6 mm Hg; Vilnius, -0.3 ± 1.2 mmHg (analysis of variance, $P = 0.006$). Failures, defined as a recorded zero-drift of ± 3 mm Hg or more, were identified in 22 cases. No relationship between failure and length of monitoring was identified (Fig. 2).

Bench Test Results

Continuous Readings at 0 to 20 mm Hg

Testing the recorded value after the application of a variable pressure, ranging from 0 to 20 mm Hg, the probability of a system failure, defined as a drift of more than 3 mm Hg, was estimated to range between 12 and 17% (Table 2).

Differences between Observed and Applied Hydrostatic Pressure

The box-and-whisker plot (Fig. 3) demonstrates the distribution of the differences between the observed and applied pressures at each of the applied pressure values and illustrates the

many observations of more than 3 mm Hg (i.e., 2 standard deviations) from the applied pressure. To confirm whether this was because of a consistent drift across the applied pressure values in individual catheters, e.g., whether a catheter consistently recorded a value 4 mm Hg above the applied level, we investigated the difference between the observed readings of individual catheters at an applied pressure of 5 mm Hg and an applied pressure of 0 mm Hg, and so on. For each individual catheter, we would expect the difference in observed pressures to remain at 5 for each 5-mm Hg increase in pressure. Table 3 shows that this was not the case; for instance, a catheter might have an observed pressure of 11 mm Hg when the applied pressure was 10 mm Hg and an observed pressure of 19 mm Hg when the applied pressure was 15 mm Hg.

DISCUSSION

The accuracy and reliability of different methods of measurement for ICP remains a critical problem during management of acutely brain-injured patients, particularly of patients with severe head injuries in whom ICP monitoring is an accepted standard of care.

To guide therapy decisions, accurate measurement of ICP is essential. As the treatment threshold for increased ICP is low (20 mm Hg), relative to the physiological range of pressure that can be monitored with this technology (typically, 100 mm Hg), a measurement accuracy of 1 to 2% is required (16). For this reason, we predefined a failure as a reading of more than ± 3 mm Hg. Use of systems with poor accuracy or unacceptably high zero-drift could lead to inappropriate treatment or, worse still, failure to treat when treatment is warranted.

The gold standard for ICP measurement remains the fluid-coupled ventricular catheter attached to an external pressure transducer. The advantage of this approach is that by using an externally mounted transducer, zero-drift and calibration can be checked and corrected, if necessary. This approach, however, is not without difficulties, especially in comatose head-injured patients, in whom the ventricle can be difficult to puncture; an additional risk of infection is reported with this type of catheter. For these reasons, catheter tip-mounted pressure sensor technology offers advantages. With this technology, pressure is measured at the tip of the probe, and consequently, ICP is measured directly in the parenchyma. Furthermore, this technology allows monitoring of patients in whom it is difficult to puncture the cerebral ventricles, and it avoids the problem of hydrostatic pressure differences. The main disadvantage of such catheter tip technology is that once placed into the patient, any zero-drift cannot be checked for or corrected. For this reason, it is critical that catheter tip devices are stable and robust and that their zero-drift characteristics remain within the known manufacturer's specifications.

The catheter tip systems most frequently used in the management of head-injured patients (Camino and Codman) do not allow pressure calibration to be performed *in vivo*, and so they cannot be corrected for inherent zero-drift after catheter placement. One of the potential advantages of the system we

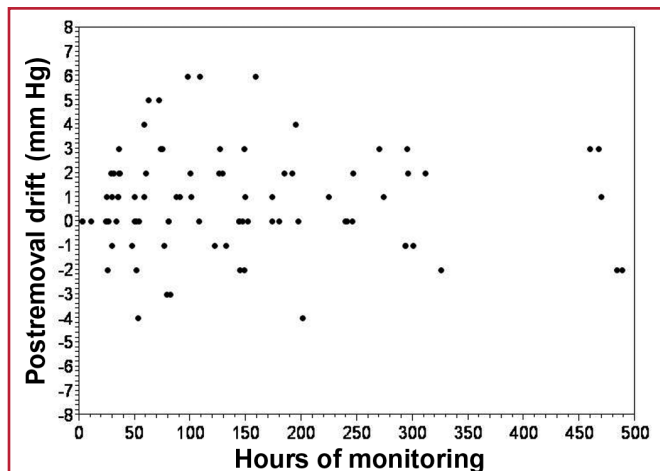


FIGURE 2. Scatter plot of the recorded postremoval reading (mm Hg) and duration of monitoring (h).

TABLE 2. Pressure recorded during the bench test after the application of a variable pressure ranging from 0 to 20 mm Hg and estimate of the probability of a system failure^a

Pressure (mm Hg)	Mean	SD	U	Min	Max	Percentile			Drift	Probability of system failure ^b
						25	Med	75		
0	0.55	2.33	± 4.7	-7	6	0.0	1.0	2.0	0.55 ± 2.3	13%
5	4.83	2.44	± 4.9	-4	9	4.0	5.0	6.0	-0.17 ± 2.4	12%
10	10.04	2.56	± 5.1	1	15	9.0	11.0	12.0	0.04 ± 2.6	13%
15	15.07	2.65	± 5.3	6	19	14.0	16.0	17.0	0.07 ± 2.6	13%
20	20.28	2.94	± 5.9	7	25	20.0	21.0	22.0	0.28 ± 2.9	17%

^a SD, standard deviation; U, uncertainty; Min, minimum value; Max, maximum value; Med, median.

^b System failure is defined as a drift of more than 3 mm Hg.

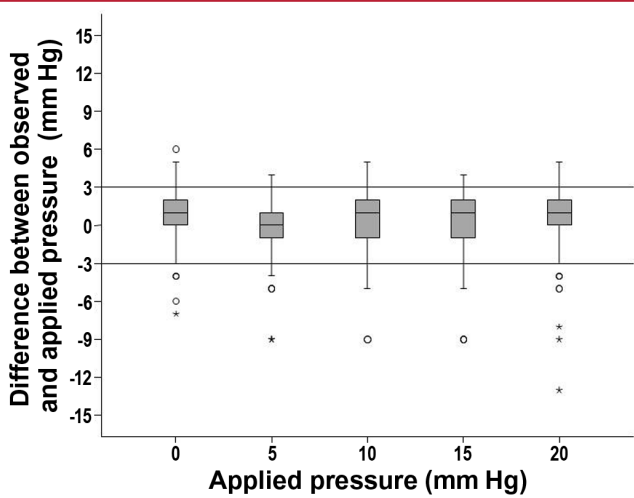


FIGURE 3. Box-and-whisker plot (representing the 25th and 75th percentiles) showing the distribution of the differences between the observed and applied pressures at each of the applied pressure values, and the number of observations more than 3 mm Hg from the applied pressure.

TABLE 3. Bias data at different levels of pressure^a

Difference (mm Hg)	Mean ± SD (mm Hg)	No. >8 or <2
0-5	4.28 ± 1.63	6
5-10	5.20 ± 0.68	0
10-15	5.04 ± 1.18	3
15-20	5.20 ± 1.12	3

^a SD, standard deviation.

Issues Raised during the Multicenter Study

As in many multicenter trials, enrollment was slower than expected, and, because of local difficulties, some centers were not able to enroll the expected 15 cases. The cases are predominantly but not exclusively traumatic brain injuries, representing the use of ICP devices in other clinical conditions.

In this trial, there was no period of specific training or specific recommendations regarding insertion depth or whether to use the bolt or not. This could have an important influence on some of the problems detected in this study. In fact, a wide intercenter variability in the depth of probe placement was recorded across centers, ranging from 20 to 54 mm, with an average of 37 mm. These depths refer to distance from the end of the bolt or from the inner cranium. One of the helpful features of the Neurovent-P catheter is that number markings are recorded on its surface, thus making it easier to verify the actual placement depth. Unlike some bolts that have a physical stop, limiting depth of placement, this is not the case with the Raumedic bolt. It is surprising to find such a large intercenter variation, and perhaps this is in part a result of a lack of consensus or manufacturer guidelines for the depth of placement.

There were more technical complications reported than expected, with nearly 10% attributable to difficulties with the bolt fixation either on placement or removal. The bolt was difficult to remove in a number of patients, which could be an important problem in clinical use in countries where this is the preferred method of placement. However, bolts are not required by this device, and it can be easily implanted with a twist drill and safely tunneled.

tested is the incorporation of a full Wheatstone bridge into the catheter tip electronics. This technological improvement should enhance the zero-drift characteristics by reducing temperature sensitivity and the effects of non-pressure-related external strains. Until recently, this approach was only possible in the physically much larger external strain gauge systems. Through advances in miniaturization technology, it is now feasible to incorporate this technology into small catheter tip systems. Despite our promising bench test study results, further work was required to determine the performance of this measurement device in the clinical environment.

After these bench tests were performed, the next and most critical step was to conduct a trial of this technology in the more demanding clinical environment. The BrainIT group, as a multicenter collaborative group of neurointensive care scientists and clinicians, were well placed to design and conduct such a trial. All participating centers had great clinical experience with various ICP monitoring devices.

Adverse events were rare, with no infections and only 2 clinically nonrelevant hematomas. A higher-than-expected postremoval zero-drift was recorded and confirmed by postremoval bench test results. The probability of a catheter exhibiting a zero-drift rate of greater than ± 3 mm Hg (failure) was pressure-dependent, with a 13% probability for low-pressure testing, which increased to 17% at a test pressure of 20 mm Hg. We consider this to be unacceptably high. We are unsure as to the root cause of the drift values outside this range, as they did not appear to be related to the center, physiological monitor, or any visible defect. A much larger study would be required to explore this aspect.

In general, the result of ICP measurement is only an approximation of the ICP value, and thus the ICP measurement result is complete only when accompanied by a quantitative statement of its uncertainty (6, 7, 12). We found that the postremoval uncertainty of the Neurovent-P catheter (Table 2) was within the limits ± 4.7 to ± 5.9 mm Hg (95% confidence interval). That uncertainty propagates to the uncertainty of clinical treatment decisions and to the uncertainty of the conclusions of ICP pathophysiology scientific studies. The challenge for ICP sensor manufacturers is to decrease that absolute ICP value measurement uncertainty to the clinically acceptable level of ± 3.0 mm Hg or less.

CONCLUSIONS

The Raumedic Neurovent-P catheter performed well in clinical use in terms of robustness, with only a 2% complete catheter failure rate. The majority of other technical complications were associated with the bolt fixation technology. Adverse events in terms of infection or hematoma were rare and clinically nonsignificant.

At 13%, zero-drift rates of failure (defined as > 3 mm Hg drift) remain unacceptably high for this catheter. This is a particular issue with the Neurovent-P catheter, which provides no electrical means for adjusting any zero-drift identified before or during use. Despite the earlier reported excellent bench test zero-drift rates, under the more demanding clinical conditions, the zero-drift rate remains a concern with catheter tip strain gauge technology.

This performance is similar, but not superior, to that previously described in other articles on the clinical use of other solid-state and fiberoptic ICP devices (9, 11, 13, 15, 18–21). Nevertheless, in our opinion, this sensor has some clinical advantages over existing ones: its robustness is superior to traditional fiberoptic sensors, and it can be attached to any bedside monitor in the intensive care unit with a very simple interface.

APPENDIX

Investigators and Participating Centers

Barcelona, Spain: Juan Sahuquillo, M.D., Jorge Alberto de los Rios, M.D.; Heidelberg, Germany: Karl Keining, M.D., Janet Mattern, M.D.; Monza, Italy: Giuseppe Citerio, M.D., Davide Galli, M.D.; Newcastle upon Tyne, England: Iain R. Chambers,

Ph.D.; Uppsala, Sweden: Per Enblad, M.D.; Vilnius, Lithuania: Saulius Ročka, M.D.

Disclosure

The BrainIT coordinating center (Southern General Hospital, Glasgow, Scotland) received a grant from Raumedic AG (Münchberg, Germany) to run the trial. Raumedic also donated all the disposables and catheters that were used in the study. None of the participants in the study received payment for the trial or for consultancy and/or advisory work, or honoraria for educational or other purposes, including for travel or other expenses. None of the participants hold stocks or shares in Raumedic.

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COMMENTS

Citerio et al. conducted careful postmarketing testing of the Craumedic Neurovent-P intracranial pressure (ICP) sensor. Novel design features had promised significant theoretical advantages of this technology, and laboratory testing had demonstrated lesser tendency toward zero-drift than other commonly used ICP devices. In practice, the device was quite robust, although superiority of performance could not be easily proven. With rigorous surveillance, problems were encountered in relation to bolt placement technique. And relevant zero-drift remained a frequent occurrence that was unrelated to duration of insertion. This affected the validity of ICP measurements in a significant fraction of cases.

Unfortunately, such careful studies are all too rarely undertaken after successful marketing of new devices, with diminished manufacturers' or champions' incentives to document real performance. And all too often, "equivalent performance" is sought "up front," which easily could reflect small sample size and type 2 error, whereas the advantages of new technology are accepted at face value on the basis of theoretical arguments. This study reminds me of Henri Poincaré's admonition in *La Science et l'Hypothèse*, more than 100 years ago, that "All generalization is a hypothesis. It ought always, as soon as possible, as often as possible, to be subjected to verification. If it does not stand this test, it ought to be abandoned without reserve. We do so with an ill humor. This ill humor is not justified" (1).

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1. Poincaré H: *Science and Hypothesis* [in French], 1906.

The authors have put together a very well-constructed, thorough, and transparent study of this promising ICP technology. Neurovent-P has the theoretical advantage of being a full Wheatstone bridge in the catheter tip, promising minimal to zero-drift, no adjustments after placement, ability to withstand a broad range of conditions, and thus improved accuracy for the patient and simplicity for the surgeons and nurses. In this study, the catheter seemed to be able to withstand the usually trying conditions of an ICU, provided real-time bedside recording, and demonstrated excellent preinsertion reliability. However, after removal, there were 22 cases in which the catheters displayed a 3 mm Hg or greater drift.

I am unclear on why there were significant differences in centers for the postremoval zero-drift measurement unless the bench test was flawed or the test was difficult to standardize owing to interobserver variability. There appeared to be few defects in the catheters. I agree with the authors, who stated that this technology is both accurate and robust, but, thus far, it is arguably no more reliable than our current fiberoptic standard. The aim should be to decrease the ICP measurement uncertainty below its current level.

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This is an excellent contribution from the BrainIT group, a serious scientific multicenter neurointensive care study group from Europe that evaluated a commercial ICP monitor with due diligence. The authors found that the catheter performed well in clinical use with few adverse events, but zero-drift rate remained a concern. Overall, the authors felt that the performance was similar to that of other ICP monitors available. From the large number of detailed evaluations that were performed, we ought to be persuaded to believe them, although it is questionable whether we will switch from using current ICP monitoring devices, which are all fairly similar.

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The BrainIT group describes a well-conducted clinical evaluation of a new parenchymal ICP monitor. As one might perhaps expect, results during actual clinical testing were not as favorable as the previously reported results during bench testing. In particular, the zero-drift rate remains problematic. In future studies of this type, it might be interesting to compare different manufacturers' devices in a randomized (but, obviously, unblinded) fashion. Such a study design might allow determination of whether problems with a monitor are unique to that particular device, or whether all monitors at a particular institution have a high rate of problems (thus suggesting that difficulties are institution-specific). In the case of trials of ICP monitors, a comparison to ventriculostomy catheters should also be considered by study planners.

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