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Technical Assessment

Bench test assessment of the new Raumedic Neurovent-P ICP sensor: a technical report by the BrainIT group

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Summary

Background. In clinical practice, fiberberoptic and piezo-electric ICP probes are often used for measuring intracranial pressure (ICP). A number of similar technologies, although performing well in bench test studies, have been shown to exhibit unacceptable zero drift, fragility or both during trials conducted under clinical conditions. Recently, a new technology has become available, the Neurovent-P (Raumedic AG + CO, Raumedic, Germany). As a pre-requisite for a clinical trial, we have conducted and report on bench test studies to confirm the manufacturer's long term zero-drift performance for this technology.

Method. In a test rig static tests (recording of 20 mmHg pressure) and dynamic tests, ranging from 5 to 50 mmHg have been performed.

Findings. 10 ICP probes have been tested for a total of 60 days. All the catheters, after the connection with the ICU monitor displayed a static pressure of 0 ± 1 mmHg and did not required pre-insertion alteration. At five days, mean zero drift was 0.6 ± 0.9 mmHg. Overall, zero drift ranged from 0 to 2 mmHg. At a fixed static pressure of 20 mmHg, the mean recorded value was 20.6 ± 0.8 mmHg, ranging from 19 to 23 mmHg. A regression analysis of the relationship between the applied pressure and the recorded pressure during the dynamic tests of the 10 catheters yielded a correlation coefficient R^2 of 0.997. Applying the Altman and Bland method to assess the bias and confidence limits for the Raumedic catheter responses during the dynamic tests against the applied gold-standard hydrostatic column pressures, the average bias of -0.66 ± 0.85 mmHg, with 95% CLs of -2 mmHg and 1 mmHg.

Conclusions. Mean zero drift, after five days, was very small and long-term continuous recording of a stable pressure was very precise. The response at dynamic tests, i.e. the changes of pressure in a wide range, was excellent. The average bias of the Raumedic catheter compared with the hydrostatic column is very small. After this bench test, the next and most critical step will be to conduct a trial of this promising technology under more demanding clinical environment.

Keywords: Intracranial pressure; evaluation study.

Introduction

Accurate and reliable measurement of ICP in the clinical environment remains a significant challenge. In recent decades, technology of miniaturisation, fiber-optic and piezo-electric ICP measuring devices were introduced. Catheter-tip systems, due to their small diameter, are likely to cause less damage to tissue and are not affected by hydrostatic pressure differences. However, technical complications as well as problems with the accuracy, zero drift, and the robustness of fiberberoptic and piezo-electric ICP probes have been identified in laboratory and clinical studies [1–7, 9, 10]. In-vivo drift is especially important in catheter-tip strain-gauge technology as it is impossible to check if the calibration has altered after being placed in the patient. Catheter tip strain gauge utilizes for pressure transduction a Wheatstone bridge, an electrical bridge circuit used to measure the resistance change in a strain gauge. Recently, a new technology has become available, the Neurovent-P (Raumedic AG + CO, Raumedic, Germany), in which a Wheatstone bridge is fabricated in the probe tip. As a pre-requisite for a clinical trial, we have conducted and report on bench test studies of the Raumedic Neurovent-P catheter to confirm the manufacturer's long term zero-drift performance for this technology.

Methods and materials

The Neurovent-P is a catheter (1.6 mm diameter) for intraparenchymal ICP measurement based on an electronic chip strain gauge coated with a thin silicone membrane and mounted at the distal tip of the probe (Fig. 1). The pressure is transduced by the piezoresistive effect when the silicon membrane is deformed. A Wheatstone bridge is integrated into the chip and ensures the required measuring accuracy and independence from variations in input voltage and environmental temperature. The Neurovent-P1 probe has, as indicated by the manufacturer, a sensitivity of $5\,\mu V/V/mmHg \pm 1\%$. Linearity and hysteresis errors are small in this probe with a combined error of $\pm 0.5\%$.

All the probes are calibrated at the time of manufacture and can be used with any bedside monitoring system without alteration. The probe can be connected to any bedside monitor using a small zero-point simulator specific for the type of patient monitor. Changing the type of bedside monitor during measurement does not cause any problems.

Fig. 1. Photograph of the Raumedic Neurovent ICP sensor

We conducted the following bench tests to determine the devices suitability for clinical use:

- Initial zero drift,
- Zero drifts over 5 days,
- Calibration drift during a continuous static pressure of 20 mmHg applied for 5 days,
- Dynamic response of the system to changes of pressure in a stepwise fashion, from 5 to 50 mmHg.

Experimental setting

A total of 10 new catheters were evaluated.

The test rig is shown in Fig. 2. A 100 cm-high Plexiglas graduated column (diameter 3 cm) was connected, with a J-shaped connector, to a 50 cm long tubes (diameter 3 cm) containing three connectors with a side hole. The connectors were used to insert two Neurovent catheters at a time into the test rig and a temperature probe. The system was filled through a side port with 0.9% sodium chloride solution producing different hydrostatic pressure levels. The laboratory temperature was kept stable at 20 °C and was recorded continuously.

The Neurovent catheters were connected to an intensive care monitor (Siemens Sirecust). The monitor was connected by a serial port (RS232) to a Windows-based personal computer in order to store data on a minute-by-minute basis using software developed by the BrainIT research group (www.brainit.org, [8]).

Prior to starting each experimental run, we verified that the recorded pressure value was, as stated in the manufacturer's data sheet, to be in the range 0 ± 1 mmHg.

Catheters were inserted in the system using a Touhy-Borst adaptor to avoid fluid leakage.

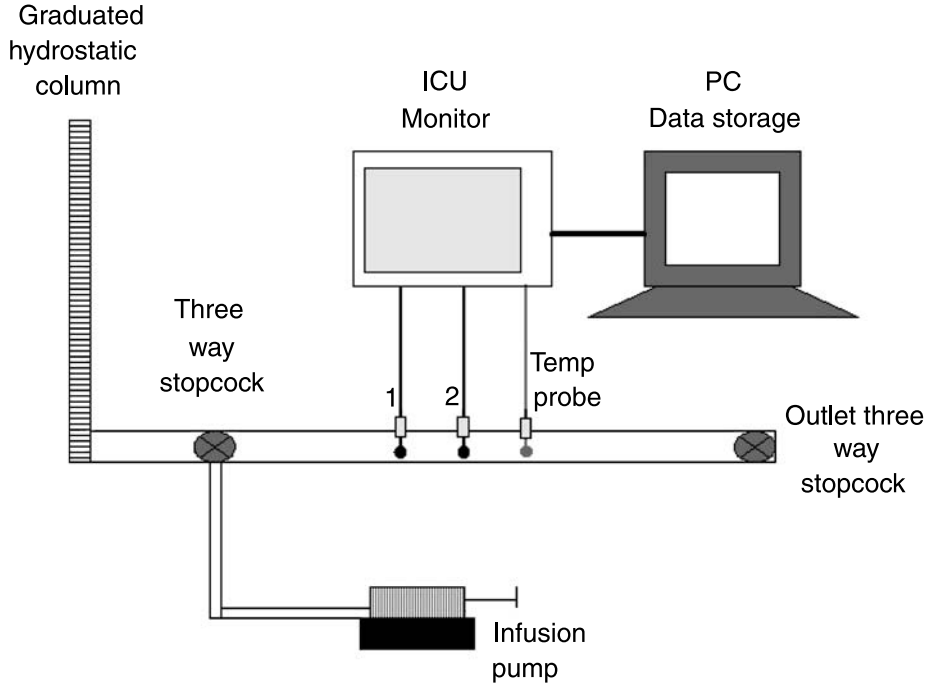

Fig. 2. The bench test apparatus (details are described in the text)

Static tests

The system was filled with saline to produce a hydrostatic pressure of 20 mmHg (column-height 26.6 cm H_2O). After equilibrium of the system, pressure recording from the two catheters was started and continued for 5 days. The water column was checked frequently and covered to prevent evaporation.

At the end of the fifth day, the catheters were removed and the zero drift was recorded.

Dynamic tests

Twice a day, the hydrostatic pressure was altered in a stepwise fashion from 5 to 15, 25 and 50 mmHg. Each pressure level was maintained for 10 minutes.

Statistical analysis

Summary statistics reported include mean, median, maximum, minimum, standard deviation and the 25th and 75th percentiles. Regression analysis was used to compare gold standard (hydrostatic water column) against measured pressure for the dynamic tests and to assess correlation. Bland and Altman analysis was performed to assess bias and limits of agreement between methods. *Splus* was used to perform statistical analysis (MathSoft Inc., Wisconsin, USA).

Results

From the 10 catheters tested, a total of 87622 minutes (1460 hours, i.e. 60 days) of readings were obtained and stored on a personal computer.

Initial zero drift

As stated by the manufacturer, if the initial zero reading was in the range 0 ± 2 mmHg, the catheter did not require pre-insertion alteration. All the catheters, after the connection with the ICU monitor (Siemens Sirecust), displayed a static pressure of 0 ± 1 mmHg.

Mean initial difference at the starting point of each experimental run for all catheters was 0.05 ± 0.22 mmHg. For this reason, none of the probes required manual re-zeroing.

Long term zero drift

Long term zero drift monitoring ranged from 3.2 to 8.0 days. 8/10 of the catheters were monitored for at least 5 days. In fact, due to a computer hardware fault, two catheters were tested continuously only for 3.2 days (mean zero drift at the end of the test was 0.04 ± 1.4 mmHg).

At five days, mean zero drift of the 8 remaining catheters was 0.6 ± 0.96 mmHg. Overall, zero drift ranged from 0 to 2 mmHg.

Continuous static readings at 20 mmHg for 5 days

For the 10 catheters, a total of 87426 minutes of data were recorded at a fixed static pressure of 20 mmHg. A summary of the results is found in Table 1. For each catheter the length of monitoring, the mean ($\pm$SD) pressure difference between the hydrostatic column and the recorded value, the median, 25th and 75th percentile and the minimum and maximal differences between the hydrostatic column and the recorded value are indicated.

The mean recorded value was 20.66 ± 0.85 mmHg. The distribution of all the recorded points is presented in Fig. 3, which showed a range of values from 19 to 23 mmHg. For each catheter, the mean bias between actual and recorded pressure ranged between -1.9 and 0.0001 mmHg.

Table 1. *Results of the continuous static readings at 20 mmHg. For each catheter the length of monitoring, in minutes and days, the mean ($\pm$SD) pressure difference between the hydrostatic column and the recorded value, the median, 25th and 75th percentile and the minimum and maximal differences difference between the hydrostatic column and the recorded value are shown*

Catheter	Recorded minutes	Mean pressure difference	StdDev	Median	Lower 25th %tile	Upper 75th %tile	Minimum	Maximum
1	4740*	*−0.94*	0.30	−1	−1	−1	0	1
2	4740*	*1.014*	0.21	1	1	1	−1	0
3	8059	*0.00*	0.01	0	0	0	−1	1
4	8059	*−0.74*	0.44	−1	−1	0	0	2
5	11567	*−0.35*	0.49	0	−1	0	−1	1
6	11567	*−0.99*	0.016	−1	−1	−1	−1	0
7	11486	*−1.77*	0.42	−2	−2	−2	−2	0
8	11486	*0.077*	0.26	0	0	0	0	1
9	7959	*−0.23*	0.42	0	0	0	−1	0
10	7959	*−1.95*	0.22	−2	−2	−2	−3	0

* Recording length for catheter 1 and 2 was lower than 5 days due to a computer failure on day 3.

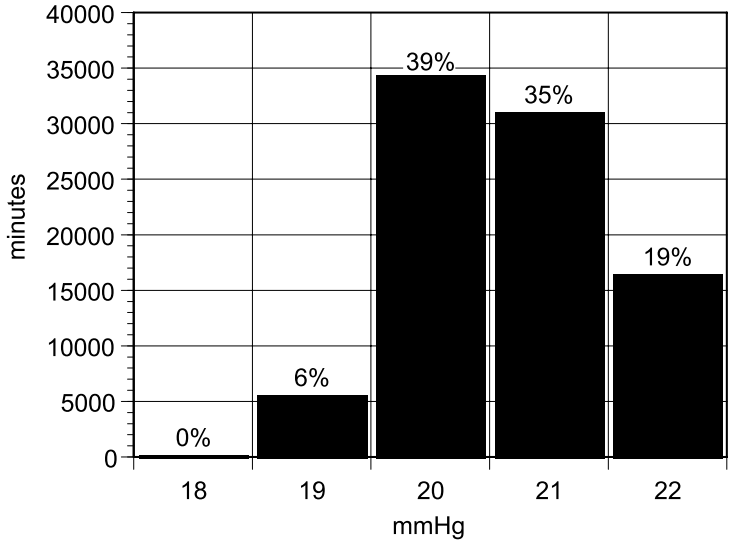

Fig. 3. A histogram showing the distribution of the data points during the continuous static readings at 20 mmHg for 5 days

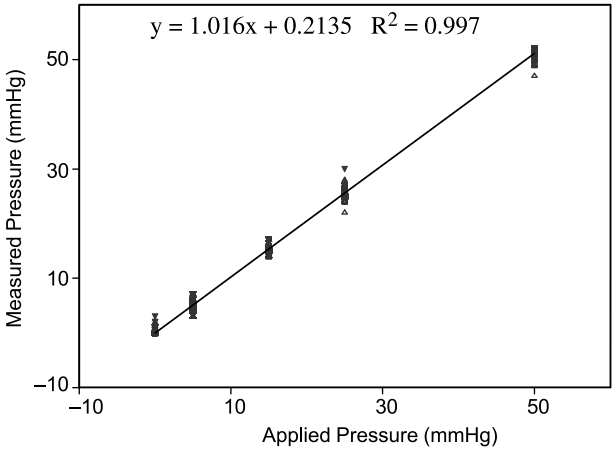

Fig. 4. A regression plot of the measured and applied pressure at each pressure level during the dynamic pressure tests at 5, 15, 25 and 50 mmHg

Dynamic tests

The pressure in the system was raised in a stepwise fashion from 5 to 15 to 25 and then to 50 mmHg. The test was done daily and repeated in both directions, increasing from 5 to 50 mmHg and decreasing from 50 to 5 mmHg. The recorded values, for each pressure level, are shown in Table 2 are indicated, at each pressure level, the mean recorded value (±SD), the median value, the 25th and 75th percentile and the minimum and maximum value.

A regression analysis of the relationship between the applied pressure and the recorded pressure during the dynamic tests of the 10 catheters yielded a linear equation: $y = 1.016x + 0.2135$ with a correlation coefficient (R^2) of 0.997 (Fig. 4).

Bland and Altman test

The use of correlation when comparing two clinical measurement systems can be misleading due to the high number of readings and their repetitive nature. We used the Altman and Bland method to assess the bias and confidence limits for the Raumedic catheter responses during the dynamic tests against the applied gold-standard hydrostatic column pressures. Results, shown graphically in Fig. 5, yielded an average bias

Table 2. *Dynamic test results*

Pressure level (mmHg)	Mean	StdDev	Median	Lower 25th %tile	Upper 75th %tile	Minimum	Maximum
0	0.39	0.67	0	0	1	0	3
5	5.21	0.84	5	5	6	3	7
15	15.48	0.86	15	15	16	14	17
25	25.71	0.88	26	25	26	22	30
50	50.99	0.89	51	50	52	47	52

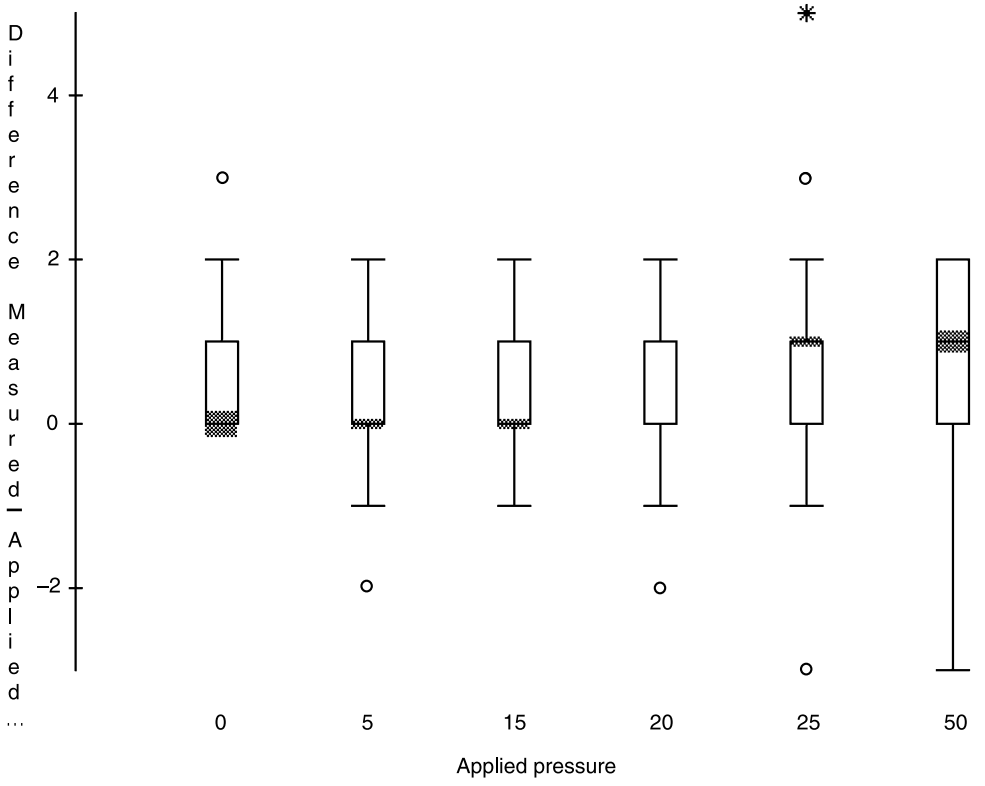

Fig. 5. A Bland–Altman plot showing the difference between the pressure readings obtained using the hydrostatic column plotted against the ICP as the average of the two methods (Raumedic catheters and hydrostatic column). Average bias is -0.66 ± 0.85 mmHg, with 95% CLs of -2 mmHg and 1 mmHg

of -0.66 ± 0.85 mmHg, with 95% CLs of -2 mmHg and 1 mmHg.

Discussion

In order to guide treatment decisions, accurate measurement of intracranial pressure is essential. Due to clinical reasons, a technical accuracy of 1–2% is required. Catheter-tip mounted pressure sensor technology offers advantages, compared to classical ventriculostomy, such as the ability to measure intracranial pressure in the parenchyma without access to the ventricles and a better frequency response of the system. Their main disadvantage is that, once placed into the patient, there is no means to check for, or correct, zero-drift.

One potential plus of the Raumedic NeuroVent system we tested is the incorporation of a Wheatstone bridge into the catheter-tip electronics. This Wheatstone technological improvement should enhance the zero drift characteristics by reducing temperature sensitivity and the effects of non-pressure related external strains. During this bench study each catheter was tested for days, from a minimum of three to more than eight days. This timeframe is almost comparable to the period for which intracranial pressure transducers are used in the clinical setting. The results from this bench test study confirm the manufacture's claim that pre-insertion adjustments are not required as the drift was within manufacture's specifications (± 1 mmHg). Both long term zero drift and the dynamic pressure test results also confirm that this system performs well in bench test studies and meets the manufactures specifications. Mean zero drift, after five days, was very small and long-term continuous recording of a stable pressure was very precise. The response at dynamic tests, i.e. the changes of pressure in a wide range, was excellent. The average bias of the Raumedic catheter compared with the hydrostatic column is very small. After this bench test, the next and most critical step will be to conduct a trial of this promising technology under the more demanding clinical environment. The Brain-IT group (www.brainit.org, [8]) as a multi-centre collaborative group of neuro-intensive care scientists and clinicians are well placed to design and conduct such a trial.

Disclaimer

Funding

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Competing interests

Dr. Citerio has been lecturer for Codman Italia since 2000.

Ethical approval

Not required.

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Comment

Citerio and colleagues describe the results of an *in vitro* analysis of a new cerebral parenchymal pressure monitor. The major advantage of this new device is that it does not require calibration prior to insertion, at least in most cases. The data in this article confirm that the monitor exhibits minimal zero drift after five days. The accuracy of the recorded pressures seems to be acceptable within the tested range of 5–50 mm Hg.

As the authors state, the next step is to assess the accuracy and drift of this catheter in the clinical arena. These data will permit comparison of this monitor's performance to that of ventriculostomy catheters and other commercially available parenchymal monitors.

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