



Test-Retest Reliability of Outpatient Telemetric Intracranial Pressure Measurements in Shunt-Dependent Patients with Hydrocephalus and Idiopathic Intracranial Hypertension

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■ **BACKGROUND:** Some patients with hydrocephalus and idiopathic intracranial hypertension treated for elevated intracranial pressure (ICP) with a cerebrospinal fluid shunt may continue to experience symptoms or develop new symptoms despite valve adjustments. Use of telemetric ICP measurements may help confirm clinical suspicion of cerebrospinal fluid underdrainage or overdrainage in these patients. However, point in time, duration, and activity during the measurements have never been standardized. We devised a simple, repeatable maneuver for outpatient telemetric ICP recording and evaluated its test-retest reliability.

■ **METHODS:** Data of patients who underwent ventriculoperitoneal or ventriculoatrial shunt placement and subsequent telemetric ICP sensor implantation were retrospectively reviewed. Telemetric ICP recordings in patients were conducted in a standardized manner: The standing-supine-sitting paradigm requires postural changes in 10-minute intervals over 30 minutes. First, the patient is requested to walk; second, to lay down; third, to sit down with a headrest elevation of 60°. ICP data (in mmHg) were reported as mean \pm SD values. Test-retest validity was assessed using Pearson correlation analysis.

■ **RESULTS:** We evaluated 66 ICP datasets obtained repeatedly with a time difference of at least 24 hours. Overall test-retest reliability was excellent (Pearson correlation coefficient 0.99, $P < 0.001$), as were the scores for individual postures: standing (correlation 0.98, $P < 0.001$), supine (correlation 0.98, $P < 0.001$), and sitting (correlation

0.99, $P < 0.001$). The sum of square differences of the test-retest measures reflected a comparable validity of all tested positions.

■ **CONCLUSIONS:** We confirmed high test-retest reliability of the standing-supine-sitting paradigm for telemetric ICP measurements in the outpatient setting. High test-retest reliability should be considered as prerequisite for clinical decision making.

INTRODUCTION

Some patients with hydrocephalus and idiopathic intracranial hypertension treated for elevated intracranial pressure (ICP) by a cerebrospinal fluid shunt may continue to experience symptoms or develop new symptoms related to cerebrospinal fluid overdrainage or underdrainage. Programmable differential pressure valves, a combination of differential pressure valve and a gravitational valve with a fixed opening pressure, and programmable gravitational valves have been developed in recent years to address the problem of overdrainage and underdrainage.¹ However, some patients remain symptomatic despite change of the opening pressure of the valve according to the assumed diagnosis.² In these patients, the use of telemetric ICP measurements may help confirm a clinical suspicion of underdrainage or overdrainage.^{3,5} Point in time, duration, and activity during measurements, which might influence the obtained data, have never been standardized, possibly leading to wrong interpretation of the findings and incorrect therapeutic decision making. Furthermore, owing to lack of external recalibration over

Key words

- Hydrocephalus
- Intracranial pressure
- Shunt failure
- Telemetric measurement

Abbreviations and Acronyms

ICP: Intracranial pressure

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time, implantable long-term sensors are subject to zero shift or drift. This technical limitation leads to an increasing uncertainty in the interpretation of the values obtained by telemetric ICP measurements over time. Therefore, we recently standardized our measurement protocols for better comparability by implementing a 30-minute standing-sitting-supine paradigm. This simple maneuver allowed us to compare telemetric ICP recordings in outpatients and to help in controlling the problem of zero shift. The aim of the present study was to assess the test-retest validity of telemetric ICP measurements.

MATERIALS AND METHODS

Patients and Study Design

Patients included adult outpatients with shunted hydrocephalus or idiopathic intracranial hypertension without acceptable symptom control despite changes of the valve setting, in whom an ICP measurement probe (NEUROVENT-P-tel; RAUMEDIC AG, Helmbrechts, Germany) was implanted. An adjustable differential pressure unit (proGAV; Christoph Miethke GmbH & Co. KG, Potsdam, Germany) was present in all patients. The proGAV was augmented with an additional gravitational unit (with fixed 25 cm H₂O vertical opening pressure) in 4 of 7 cases. An additional programmable shunt assistant (proSA; Christoph Miethke GmbH & Co. KG) was implanted in all patients. The recordings analyzed in this study were performed between January 1, 2015, and May 30, 2017, and were retrospectively and anonymously reviewed in accordance with the Declaration of Helsinki and after approval of the institutional review board of the University Hospital Göttingen, Göttingen, Germany.

Standing-Supine-Sitting Paradigm

The standardized ICP measurement paradigm for outpatients takes 30 minutes. It consists of 10 minutes in the standing position (90°), 10 minutes in the supine position (0°), and 10 minutes in the half-sitting position (60°) (Figure 1). During this maneuver, ICP measurement is performed continuously using the acquisition coil of the data-recording unit (RAUMEDIC MPR 1 DATA-LOGGER; RAUMEDIC AG).

Valve Settings

The valve configuration of the implanted shunts and their respective pressure settings are depicted in Figure 2.

Inclusion and Exclusion Criteria

We included telemetric ICP recordings from patients who underwent 2 consecutive standing-sitting-supine paradigm measurements in outpatient clinics with an intermeasurement interval of >24 hours. We excluded cases in which a surgical intervention or shunt valve adjustment was performed between measurements. Moreover, patients presenting with new symptoms in which a shunt dysfunction was suspected between the 2 measurements were excluded.

Data Processing

After conclusion of the recording, the DATALOGGER was connected to a personal computer using the dedicated software

provided from RAUMEDIC. The CSV file obtained from the proprietary RAUMEDIC program was imported to software programmed by our team. This software (ICP Analyzer) (Figure 3) is available free of charge online (www.icp-analyzer.org). It provides a function to extract 8 minutes of the recording out of 10 minutes by cropping the first and last minute of recording. As a result of later observations, we adjusted it to remove the last 10 seconds and the first 120 seconds before and after each postural change (Figure 4). The software displays separate statistics for sitting, standing, and supine position.

ICP Analyzer

This software tool was programmed using C# and includes statistical features that are not available in commercial products. It reduces the dataset to 12,000 data points for faster computation and provides visualization in a dynamic graph for pressure curves. Three intervals can be selected for further calculations (for each of the 3 positions). The distribution of values is visualized and can be checked for normal distribution using the Shapiro-Wilk test. The tool can also calculate the increase and decrease of the values in the selected intervals using linear and least squares algorithms.

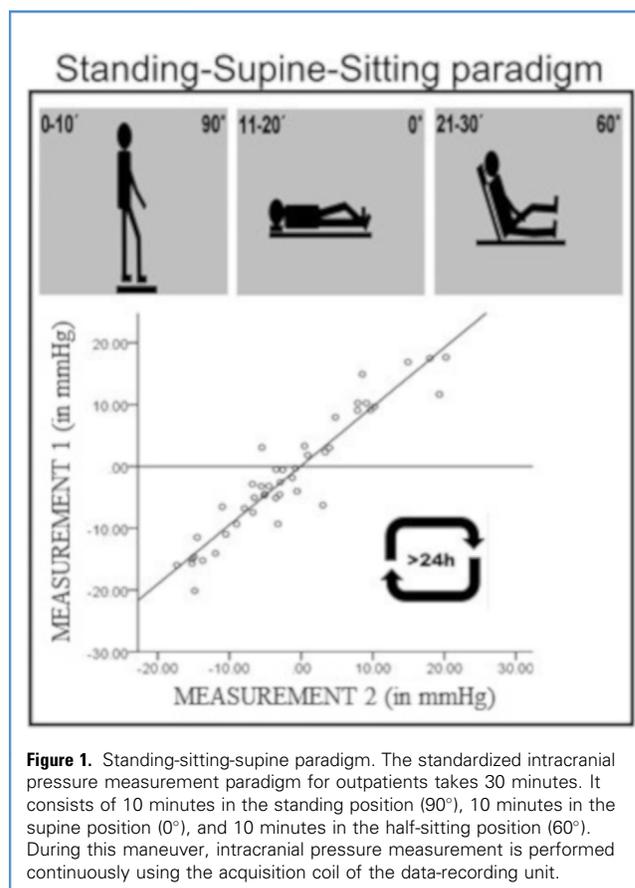
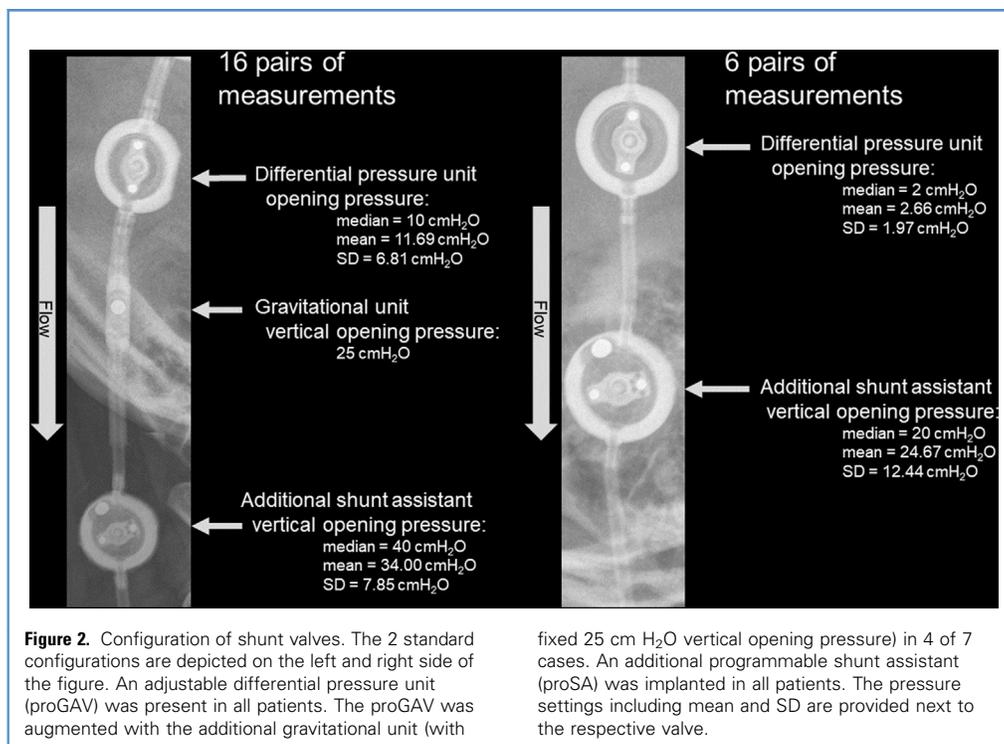


Figure 1. Standing-sitting-supine paradigm. The standardized intracranial pressure measurement paradigm for outpatients takes 30 minutes. It consists of 10 minutes in the standing position (90°), 10 minutes in the supine position (0°), and 10 minutes in the half-sitting position (60°). During this maneuver, intracranial pressure measurement is performed continuously using the acquisition coil of the data-recording unit.



fixed 25 cm H₂O vertical opening pressure) in 4 of 7 cases. An additional programmable shunt assistant (proSA) was implanted in all patients. The pressure settings including mean and SD are provided next to the respective valve.

Generating Measurement Pairs for Correlation Analysis

Only directly consecutive pairs of measurements were included. If a patient underwent 4 separate recordings spaced >24 hours apart, we generated only pairs of adjacent measurements—that is, we paired measurement 1 with measurement 2, measurement 2 with measurement 3, and measurement 3 with measurement 4.

Statistical Analysis

SPSS Version 18.0 software (SPSS, Inc., Chicago, IL, USA) was used for analysis. Pearson correlation and Cronbach α were calculated for correlation and reliability testing. *P* values < 0.05 were considered significant.

RESULTS

Clinical Data

Of 18 patients and 85 pairs of measurements (255 total measurements) in the examination period, 7 patients (1 men, 6 women; 48.6 ± 12.2 years) and 22 pairs of measurements (66 total measurements) met our inclusion criteria. The majority of patients were excluded because of change of the opening pressure of the valve after the first measurement. Implantation diagnoses were idiopathic intracranial hypertension (*n* = 2), congenital hydrocephalus (*n* = 2), normal-pressure hydrocephalus (*n* = 1), and malresorptive hydrocephalus (*n* = 2). The mean interval between 2 paired measurements was 38.6 days (SD 81.5 days; range, 1–385 days). One ventriculoatrial shunt and 6 ventriculoperitoneal shunts were included. The mean body mass

index was 27.66 ± 9.31 kg/m² (mean height 1.64 ± 0.11 m; mean weight 74.4 ± 23.75 kg).

Measurements

We identified 34 pairs of measurements under the same valve settings and conditions, 22 of which were directly consecutive recordings. As mentioned earlier, every measurement consists of 3 separate measurements in each position. Mean and median ICP measurements for standing, supine, and sitting positions are listed in **Table 1**. As these measurements were almost normally distributed and the standard deviation of every measurement was very low (average overall SD 1.61 mm Hg, average standing SD 2.26 mm Hg, average supine SD 1.19 mm Hg, average sitting SD 1.37 mm Hg), an analysis of the median values was sufficient for our purposes.

Reliability Analysis of Directly Consecutive Pairs

The correlation between measurements was excellent for the overall measurements as well as for the individual positions (**Table 2**). Pearson correlation was 0.98 for the overall data pool, 0.97 in the sitting position, 0.97 in the lying position, and 0.98 in the standing position, with *P* < 0.001 in all cases. Cronbach α showed very good reliability in all cases: 0.99 for all measurements, 0.98 for measurements in the standing position, 0.98 for measurements in the supine position, and 0.99 for measurements in the sitting position (**Figure 5**).

DISCUSSION

Before beginning our analysis, we were uncertain about the optimal way to read data from telemetric ICP sensors. Some in our

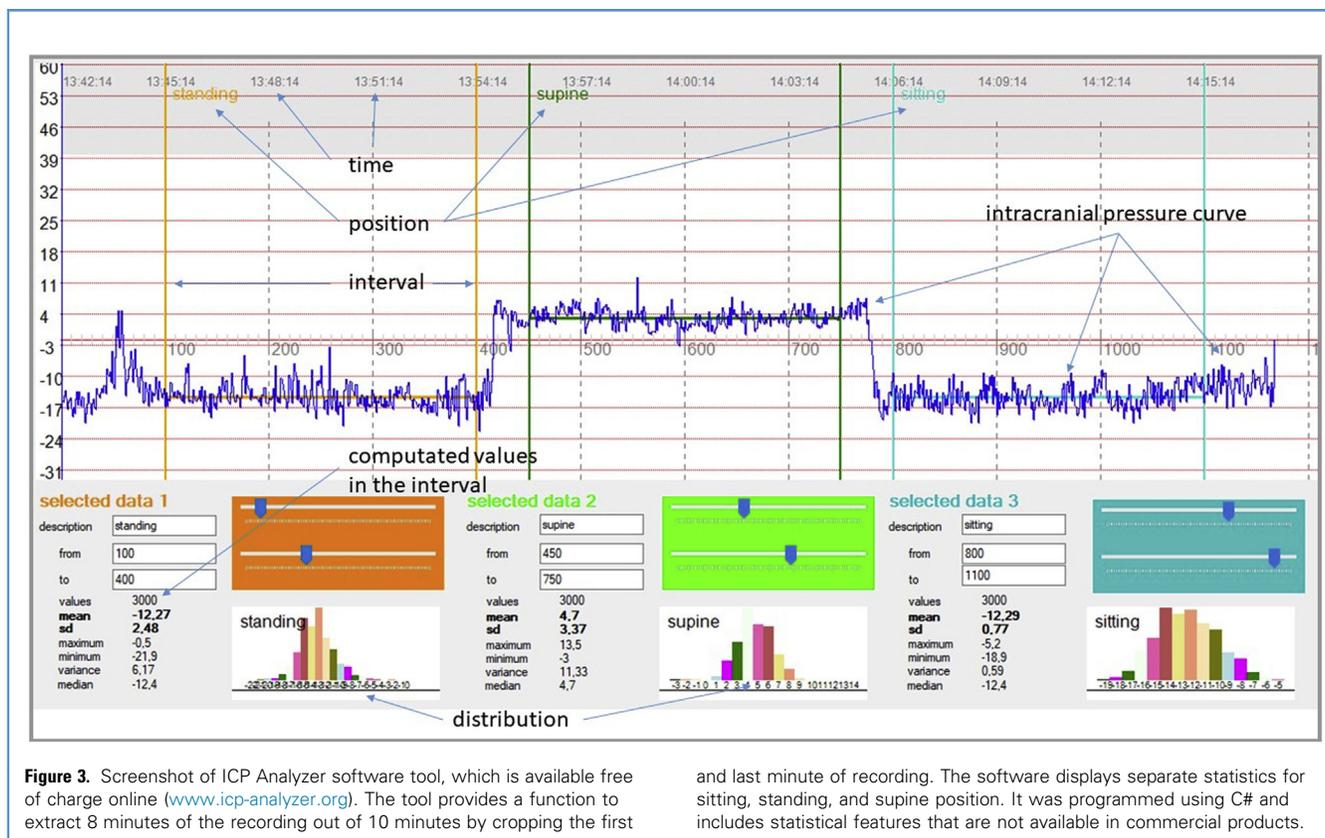


Figure 3. Screenshot of ICP Analyzer software tool, which is available free of charge online (www.icp-analyzer.org). The tool provides a function to extract 8 minutes of the recording out of 10 minutes by cropping the first

and last minute of recording. The software displays separate statistics for sitting, standing, and supine position. It was programmed using C# and includes statistical features that are not available in commercial products.

group cautioned against outpatient visits and put forth the argument that long-term measurements were needed. Others argued that without standardization, comparisons and informed treatment were difficult. However, the longer the observation period would be, the more values were likely to vary because of postural and activity changes. Therefore, we devised a 30-minute paradigm with standardized body positions that enabled us to compare the patients' readings at each visit. As our post hoc analysis revealed, the postural change induces a phase of high ICP fluctuation that lasts for a maximum of 120 seconds. Therefore, measuring the ICP for an arbitrary duration after that initial fluctuation period should provide reproducible results. Hence, our data support the notion that an interval of 12–15 minutes should be acceptable without harming the stability of the results, essentially halving the recording time in the current study. Good reliability was observed in all our measurements. The expected position-dependent pressure differences were shown as well, as previously reported by Frim and Lathrop⁶ and Petersen et al.⁷ Therefore, the 30-minute measurement can be reproduced and may be sufficient to reflect ICP changes in a given patient and to adjust the opening pressure of the valve accordingly.^{8,9} Valve adjustments are especially complex in patients with a combination of adjustable valves, normally a combination of a programmable differential pressure valve with a programmable gravitational valve. Using the telemetric ICP data, the effect of the change of the opening pressure of a single valve can be tested.^{2,8}

Zero Drift

We did not observe any zero shift or drift. Our average measurement interval was only 38 days. The zero shift usually occurs in a larger time corridor, as demonstrated by Citerio et al.,^{10,11} Kiefer et al.,^{12,13} and Eide and Bakken.¹⁴ The probability for a shift of >3 mm Hg lies is 12%–17%. Eide and Bakken¹⁴ showed in a physiologic experiment that a small electrostatic discharge can alter the baseline of a telemetric sensor. Changes of >2 mm Hg were shown in 53% of all RAUMEDIC probes and 96% of Codman (Integra LifeSciences, Plainsboro, New Jersey, USA) sensors.¹⁴ A separate study compared RAUMEDIC NEUROVENT-S-tel and NEUROVENT-P-tel sensors (both with device specification of ± 2 mm Hg drift per year), showing a good reliability for the first 6 months after implantation. Whereas average values were similar, standard deviations were high for both NEUROVENT-S-tel, -1.7 ± 7.6 mm Hg (limits of agreement 4.4 ± 1.9 mm Hg), and NEUROVENT-P-tel, -3.0 ± 6.0 mm Hg (limits of agreement 3.6 ± 2.6 mm Hg).¹³

Differences Between Positions and Measured Data

Assessment of reliability and reproducibility of data was the main concern of this study. We found that measurements in the standing position showed the largest standard deviation. Also, the correlation coefficient was lowest in the standing position. Blood pressure adaptation with a constant secondary adaptive autor-regulation response of cerebral vasculature and concomitant ICP

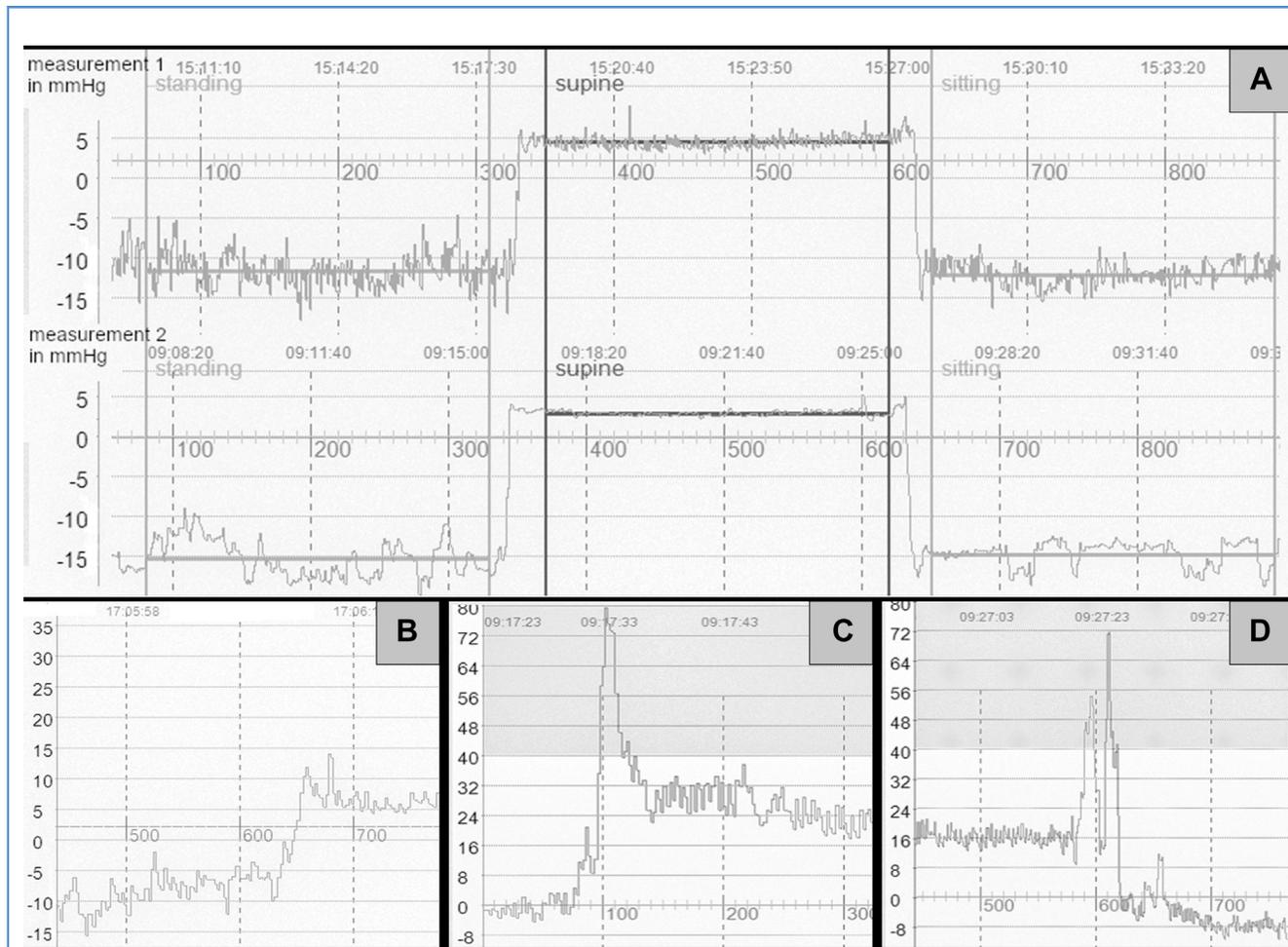


Figure 4. Sample waveforms. **(A)** Standard recording (standing, supine, sitting). **(B)** Sample waveform of postural change from standing to supine in a patient with normal-pressure hydrocephalus. **(C)** Sample waveform of

postural change from standing to supine in a patient with idiopathic intracranial hypertension. **(D)** Sample waveform of postural change from supine to sitting in a patient with idiopathic intracranial hypertension.

fluctuations are the likely explanation. During our measurements, the patients were allowed to walk slowly if they could not stand still, introducing the potential for movement artifacts. This is the most variable factor in our standardized protocol, albeit one that we deem negligible in light of the high reproducibility. Furthermore, patients with a cerebrospinal fluid shunt have limited ICP

regulation capacity compared with individuals with normal ICP shown by Andresen et al.¹⁵ The supine and sitting positions showed both a similar excellent reliability and a lower standard deviation. Overall, reproducibility was satisfactory and will allow us to pursue using this positional change paradigm as a standard reference for outpatient ICP measurements.

Table 1. Mean and Median Values of Intracranial Pressure Readings

Position	Number	Mean ± SD		Median (Range)	
		Measurement 1 (mm Hg)	Measurement 2 (mm Hg)	Measurement 1 (mm Hg)	Measurement 2 (mm Hg)
All	66	-5.68 ± 15.22	-6.04 ± 16.1	-3.63 (-42.1 to 17.7)	-3.97 (-44.1 to 23.4)
Standing	22	-10.22 ± 14.07	-10.89 ± 14.27	-5.67 (-42.1 to 4.9)	-5.99 (-44.1 to 3.1)
Supine	22	4.86 ± 14.14	4.79 ± 15.61	9.67 (-29.3 to 17.7)	8.8 (-34.4 to 23.4)
Sitting	22	-11.69 ± 11.95	-12.03 ± 13.02	-9.32 (-41.0 to 2.9)	-8.4 (-43.7 to 2.8)

Table 2. Correlation of Directly Consecutive Measurements

Position	Number	Correlation Coefficient <i>R</i>	Significance	Cronbach α
All	66	0.98	<0.001	0.99
Standing	22	0.97	<0.001	0.98
Supine	22	0.97	<0.001	0.98
Sitting	22	0.98	<0.001	0.99

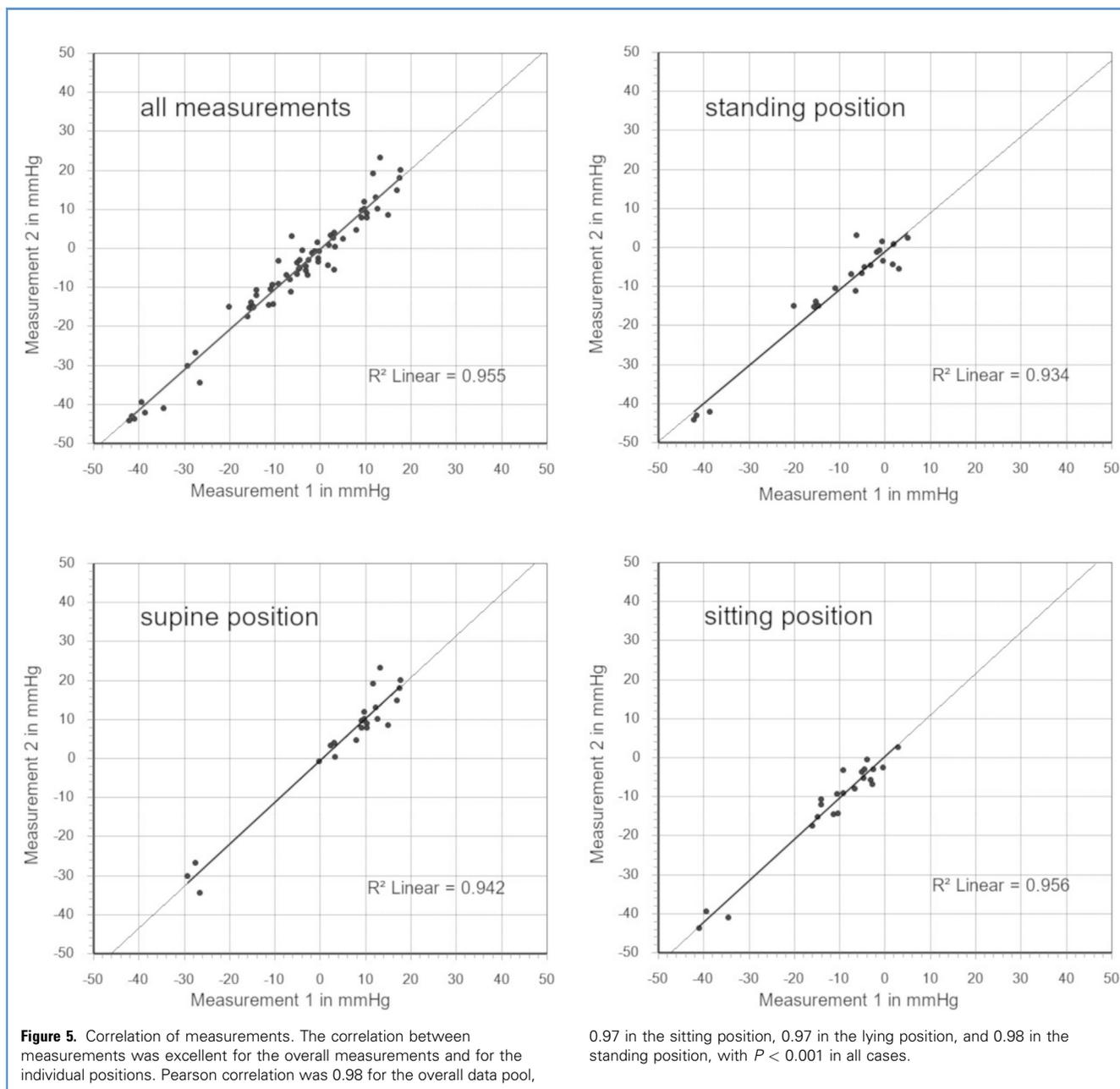


Figure 5. Correlation of measurements. The correlation between measurements was excellent for the overall measurements and for the individual positions. Pearson correlation was 0.98 for the overall data pool,

0.97 in the sitting position, 0.97 in the lying position, and 0.98 in the standing position, with $P < 0.001$ in all cases.

Telemedicine

The next step in personalized shunt therapy may be the transfer of ICP data via the Internet to the hospital. Technically it would be feasible. Hospitalization time may be reduced, as important diagnostic information could be available before admission. A shunt dysfunction could probably be detectable with this home-based approach. With the right patient selection, telemedicine can be useful for collecting and evaluating ICP recordings in the future.

Limitations

Although encouraging, we are aware that short-term measurements of 30 minutes cannot capture the whole set of symptoms that patients often experience. ICP spikes can be missed by virtue of the short temporal catchment window. One of the issues in performing repeated measurements is the temptation of more permissive change of the opening pressure of the valve in patients with telemetric devices. Whereas the number of patients ($N = 7$) is

small, data on repeat measurements in similar conditions, especially with comparable shunt settings, have remained elusive to date, rendering this analysis unique and valuable.

CONCLUSIONS

We confirmed the test-retest reliability of the standing-supine-sitting paradigm for telemetric ICP measurements in the outpatient setting. All body positions produced similar correlation coefficients. Therefore, a 30-minute recording can be reproduced, may be sufficient to reflect ICP changes in a given patient, and may help in correct therapeutic decision making. We advocate the implementation and further testing of this method to validate its utility in guiding treatment decisions.

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