Interpretation of telemetric intracranial pressure recordings in people with Idiopathic Intracranial Hypertension after shunt implantation

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Title: Interpretation of telemetric intracranial pressure recordings in people with Idiopathic Intracranial Hypertension after shunt implantation

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Abstract

Background: The M.scio telesensor (Aesculap-Miethke, Germany) is a device integrated within a ventriculoperitoneal (VP) shunt for non-invasive measurement of the intracranial pressure (ICP). The purpose of this study was to analyse the telemetric recordings with the M.scio system in shunted patients with idiopathic intracranial hypertension (IIH), in order to determine reference values and assist the interpretation of telemetric data.

Methods: This was a cohort study of consecutive patients with fulminant IIH who underwent primary VP shunt insertion between July 2019 and June 2022. The first telemetric measurements after surgery in the sitting and supine position were analysed. Telemetric ICP values, wave morphology and pulse amplitude were determined for functioning and malfunctioning shunts.

Results: Fifty-seven out of 64 patients had available telemetric recordings. The mean ICP was -3.8 mmHg (Standard Deviation (SD) = 5.9) in the sitting and 16.4 mmHg (SD= 6.3) in the supine position. The ICP curve demonstrated pulsatility in 49 (86%) patients. A pulsatile curve with mean ICP in the above ranges indicated a functioning shunt, whereas the lack of pulsatility was challenging to interpret. There was a significant positive correlation between ICP versus amplitude, ICP versus body mass index (BMI) and amplitude versus BMI.

Conclusions: This clinical study defined ICP values and curves in IIH patients with a shunt. The results will assist the interpretation of telemetric ICP recordings in clinical decision making. More research is required to model longitudinal recordings and explore the link between telemetric measurements with clinical outcomes.

Keywords: Cerebrospinal Fluid, Idiopathic Intracranial Hypertension, Intracranial Pressure, M.scio, Pseudotumour Cerebri, Telesensor

Abbreviations and acronyms:

AMP: amplitude; BMI: body mass index; CSF: cerebrospinal fluid; IIH: idiopathic intracranial hypertension; ICP: intracranial pressure; SD: standard deviation; VP: ventriculoperitoneal

Statements and Declarations:

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Authors contributions:

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Fardad Afshari, Mahmoud Samara, Kyaw Zayar Thant, Marian Byrne and Georgios Tsermoulas. The first draft of the manuscript was written by Fardad Afshari and Georgios Tsermoulas, it was reviewed and edited by Alexandra Sinclair and Susan Mollan and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Introduction

Idiopathic intracranial hypertension (IIH) is characterised by raised intracranial pressure (ICP) of unknown cause and is usually treated medically. Less than 10% of patients develop fulminant papilloedema and require intervention to preserve vision [13,17-19]. The commonest intervention is cerebrospinal fluid (CSF) diversion with a shunt to reduce ICP and a ventriculoperitoneal (VP) shunt is the most widely used shunt type in many countries [12,19].

The Birmingham standardized IIH shunt protocol suggests, among others, integration of the M.scio telemetric sensor (Aesculap-Miethke, Germany) to the VP shunt assembly [11, 27]. This is a reservoir with a measuring cell inserted in line with the ventricular catheter proximal to the valve and allows non-invasive measurement of the ICP. The technology has high accuracy and reliability in recording ICP and its purpose is to interrogate the shunt function and guide adjustment of the valve [25]. However, the current literature on interpretation of the data that this system provides is scarce [22]. Clinicians need to be equipped with reference values of the telemetric recordings of a functioning shunt that are disease specific and to know what to expect in case of malfunction.

This study analysed telemetric measurements from the M.scio system in shunted patients with IIH in order to evaluate ICP values and wave morphology of functioning and malfunctioning shunts and explore the relationship between ICP, pulse amplitude (AMP) and body mass index (BMI). For the first time, ICP data from the M.scio system were analysed in a systematic way and the results will enhance the clinical potential of this technology.

Methods

Study design and Data Collection

The study included consecutive patients with IIH who underwent VP shunt insertion at the Queen Elizabeth Hospital Birmingham from 1st July 2019 to 30th June 2022. Indication for shunting was severe papilloedema posing a risk of permanent visual loss, which is in keeping with consensus guidelines for surgical intervention in IIH [11,13,17]. The operation was performed based on the Birmingham standardized IIH shunt protocol [27]. Two of the six components of the protocol include the use of the valve proGAV 2.0 with Gravitational Unit and integration of the M.scio telemetric sensor in the shunt assembly (Aesculap-Miethke, Germany). The opening pressure of the Gravitational Unit is fixed at 25 cmH_2O (18.4 Hg) and initially the proGAV 2.0 was set at 15 cmH_2O (11 mmHg), but later the protocol was amended and the initial setting was reduced to 10 cmH_2O (7.4 mmHg), as it resulted in more expeditious resolution of the papilloedema [27]. Following surgery, baseline telemetric measurements were obtained routinely in sitting and supine positions for 1-2 minutes in each position. The reader unit of the system was set in the mode for sampling at the highest rate of up to 44 measurements per second.

The data for analysis included demographics, BMI and the first telemetric recordings after surgery. In case of shunt malfunction, the recordings following revision surgery were included for analysis, in order to determine the baseline recordings of functioning shunts. The position and integrity of the shunt system was assessed by post-operative radiological imaging (CT brain, shunt X-rays) and its function by neuro-ophthalmic examination. The ICP recordings alone did not guide clinical decision making.

Telemetric intracranial pressure analysis

Telemetric recordings were retrospectively analysed with the online software ICPicture (Christoph Miethke GmbH & Co, Potsdam, Germany). The software displayed sequential pressure readings as a curve on a graph with ICP in the x axis and time in the y axis. The ICP curves were categorized as pulsatile if they depicted regular pulses with morphology and frequency of traditional ICP waveforms and as irregular if they did not depict a recognizable pattern.

The software was then used to compute the mean pressure of each curve, which corresponded to the mean ICP. Pulse AMP is defined as the difference between the peak and trough of the pulse and the software computed the pressure difference. The mean AMP was calculated for pulsatile curves only, because AMP is not clinically relevant for irregular curves. The average of those means provided the mean ICP and mean AMP in the sitting and supine position. Telemetric recordings of shunts that were non-functioning were also described in order to demonstrate the difference with "normal" measurements of a functioning shunt.

Statistical Analysis and Ethics Approval

Descriptive statistics were used to summarise the data set. Continuous variables were compared with the independent t-test. To explore whether there was a relationship between ICP, BMI and AMP linear correlations between each factor were assessed with the Pearson correlation coefficient. Statistical significance was accepted with a p value ≤ 0.05.

All data included in the cohort were obtained as part of routine clinical practice. This study was approved as service evaluation by University Hospitals Birmingham NHS Foundation Trust (Clinical Audit Registration & Management System number: 18463; date: 14th

September 2022) and ethics approval by a research ethics committee was not required. All data were anonymized for analysis so that individual patients could not be identified, and patient consent was not required.

Results

Sixty-four consecutive patients with IIH underwent insertion of VP shunt in a 3-year period. Seven patients were excluded from the study, 3 who did not have an M.scio inserted and 4 who did not have ICP measurement. Fifty-seven patients had available baseline telemetric recordings and were analysed. The lumbar puncture opening pressure at initial diagnosis was available in 53 out of the 57 patients (lumbar puncture failed in 2 patients and not attempted in 2 patients due to cerebellar tonsillar descend) and the mean value was 40 cmH_2O (29.4 mmHg). In the first 37 patients the proGAV 2.0 was set at 15 cmH_2O and in the later 20 cases at 10 cmH_2O. In 26 cases the recording took place within two days following surgery and the median interval between surgery and recording was 22 days. Most of the patients were females with a sex ratio 10:1. At the time of surgery, mean age was 27 years (Standard Deviation (SD) = 7.2, range 16 - 50) and mean BMI was 37 kg/m^2 (SD= 9.7, range 20 - 59). Table 1 summarizes the baseline characteristics and the main results.

Mean intracranial pressure

The average value of mean ICP was -3.8 mmHg (SD= 5.9, range -19.2 – 9.3) in the sitting position and 16.4 mmHg (SD= 6.3, range -0.7 – 31.2) in the supine position for the entire cohort. The mean difference in ICP between the two positions was 20.2 mmHg (Figure 1). The mean time interval between recordings in the two positions was 4 minutes (range 1 - 10 min). When evaluating the difference between valve settings, the average value of mean sitting ICP was -2.7 mmHg versus -5.6 mmHg (p= 0.08) and mean supine ICP was 18.4 mmHg versus 12.9 mmHg (p= 0.001) at the valve settings of 15 cmH_2O versus 10 cmH_2O respectively. There was a significant positive correlation between ICP and BMI both in sitting (r= 0.3, p= 0.02) and supine position (r= 0.3 p= 0.01) (Figure 2a-b). The mean ICP at diagnosis, measured by lumbar puncture opening pressure, dropped from 29.4mmHg to a mean -3.8 mmHg in the sitting and 16.4 mmHg in the supine position. However, there was not any significant correlation between lumbar puncture opening pressure at diagnosis and telemetric ICP in the sitting (r= -0.16, p= 0.25) and supine position (r= -0.05, p= 0.73).

ICP pulsatility

The ICP curves demonstrated pulsatility generated by arterial pulsations in 49 (86%) out of the 57 patients (Figure 3a). Pulsatility was present in both positions in all 49 cases but one, where it was absent in the supine position (Figure 3b). The average value of mean sitting ICP in pulsatile curves was -3.2 mmHg versus -7 mmHg in irregular curves ($p= 0.09$) and the average of mean supine ICP in pulsatile curves was 16.8 mmHg versus 14.2 mmHg in non-pulsatile ones ($p= 0.26$).

The 8 irregular curves were non-specific composite waves of random small spikes that typically had high frequency. Some curves had large periodic waves (Figure 3c), whereas others depicted less fluctuation (Figure 3b). There was confirmed CSF drainage through the shunts with irregular ICP curves, based on corroborating radiological and neuro-ophthalmic evidence.

Lack of pulsatility is expected in shunt obstruction proximal to the telemetric sensor, because the transmission of waves is interrupted. Figure 3d represented such a case. This patient from the cohort underwent VP shunt insertion with the post-operative imaging being satisfactory. However, the papilloedema as evidenced by the clinical examination and with optical coherence tomography imaging measures, did not improve and subsequent downward adjustment of the valve did not resolve the clinical findings. The baseline telemetric recordings showed an irregular curve, similar in appearance to that of a functioning shunt, with ICP -11.8 mmHg in sitting and 11 mmHg in supine position. Shunt exploration revealed proximal catheter blockage and following revision the papilloedema resolved.

<u>Pulse amplitude</u>

In the 49 patients with pulsatile curves, the average value of mean AMP was 6.3 mmHg (SD= 2.2, range 3.7 – 14.7) in the sitting and 5.7 mmHg (SD= 2.1, range 1.8 - 11) in the supine position. Mean AMP was higher at valve setting 15 compared to 10, in both sitting (6.6 versus 5.7, $p= 0.22$) and supine position (6 versus 4.9, $p= 0.12$). There was a significant positive correlation between ICP and AMP in both positions (sitting: $r= 0.61$, $p< 0.001$; supine: $r= 0.33$, $p= 0.02$) (Figure 2c-d). Similarly, there was a positive correlation between AMP and BMI (sitting: $r= 0.36$, $p= 0.01$; supine: $r=0.34$, $p= 0.02$) (Figure 2e-f).

High AMP associated with high ICP is expected in shunt blockage distal to the M.scio, in which case the transmission of waves to the sensor is unobstructed, but CSF drainage does not occur. Figure 3e represented such an example. This patient from our cohort underwent VP shunt insertion, but post-operative X-ray revealed kinking of the distal catheter and the papilloedema did not improve. Telemetric recordings showed a pulsatile curve with mean

ICP 14 mmHg and AMP 14.7 in the sitting, and mean ICP 27.2 mmHg and AMP 15.4 in the supine position. Following revision, ICP and AMP "normalized" and the papilloedema resolved.

Discussion

Telemetric ICP measurements with the M.scio system, as presented in this large cohort of patients with IIH who had a VP shunt, were clinically meaningful. The derived ICP values and curves can be used as a reference to assist in the diagnosis of shunt malfunction and valve setting optimization. This is the first study that defined disease specific ICP measurements with a non-invasive method in shunted patients with IIH.

Telemetric ICP technology has been available in clinical practice for many years with benefits in management of patients with CSF disorders [2, 4, 15, 23, 24, 27, 28]. There is no reported standardised procedure of measuring telemetric ICP and our method of 1-2 min recording in sitting and supine position was based on accepted conventions regarding ICP measurement and on a pragmatic approach that suited local clinical practice. This study was the first systematic analysis of M.scio recordings to provide real world measurements and address the main limitation of interpreting telemetric data in a single disease cohort with no prior reference values to guide management.

Mean intracranial pressure

The ICP was the pressure difference between the ventricular CSF and a reference pressure value that was set when the M.scio was calibrated during production. The average value of mean sitting ICP -3.8 mmHg and mean supine ICP 16.4 mmHg represented the values of functioning shunts that were implanted to prevent visual loss. A study in patients with a variety of CSF disorders who had VP shunts with a fixed pressure valve and antisiphon device showed that the ICP, measured with a different telemetric system, ranged from -5.1 to 2.2 mmHg in the upright and above 18.4 mmHg in the supine position [5]. Other studies in patients with VP shunt for hydrocephalus or raised ICP concluded that the difference in ICP between the supine and the upright position was about 10 – 20 mmHg, which was similar to our IIH cohort [8, 16]. This difference is higher compared to the reported decrease by 10.4 mmHg from the supine to the upright position in patients with IIH without a shunt [1]. In general, postural fluctuations in ICP are more pronounced in people with shunts [1, 8].

The valve setting 10 resulted in better resolution of papilloedema compared to the setting 15 and the mean ICP -5.6 mmHg in the sitting and 12.9 mmHg in the supine position with the valve at 10, was considered optimal in our practice [27]. A similar valve setting was suggested for patients with IIH, where the NEUROVENT-P-tel telemetric sensor (Raumedic, Germany) was used for optimization of shunt function [28]. In that study, the ideal setting was considered 6 cmH_2O for the differential valve and 30 cmH_2O for the gravitational unit, which had almost the same opening pressure in the vertical (36 versus 35 cmH_2O) and slightly lower opening pressure in the horizontal position (6 versus 10 cmH_2O) to our recommended setting.

There is a positive correlation between BMI and ICP in healthy people and in those with IIH [29]. Our results showed that this correlation persists in patients with shunts, which supports the importance of counselling regarding weight management options after shunt insertion. As CSF shunting does not modify the underlying disease process in IIH, it has been recommended that all people with IIH and a BMI >30 kg/m^2 should be counselled about weight loss to induce remission. This could potentially negate the need for revision surgery, should the shunt fail [17]. Indeed, a recent randomized controlled trial comparing bariatric surgery and a dietary intervention found that there was a direct correlation between weight loss and reduction in ICP, both at 12 and 24 months [20, 21]. Twenty-four percentage of weight loss, equating to a mean weight loss of 13.3 kg, was associated with disease remission defined as an ICP $\leq$ 25 cmH_2O [21].

<u>ICP pulsatility</u>

A pulsatile curve was displayed in the majority of recordings in both positions and in one case it was present only in one position. It indicated patency of the shunt between the ventricular catheter and the sensor. The results suggest that the presence of pulsatility and ICP values in sitting and supine position within the above reference ranges confirm that the shunt is working. Higher ICP especially associated with high AMP is in keeping with underdrainage or blockage distal to the sensor. Lower ICP may indicate over-drainage (Table 2).

An irregular curve without arterial pulses was displayed in a small group of patients and the mean ICP was lower compared to curves with pulsatility. These observations were challenging to interpret, and we could not differentiate these telemetric recordings with those of proximal shunt blockage, as both cases depicted irregular curves with similar pressures. A possible explanation for lack of pulsatility in functioning shunts was partial collapse of the ventricular wall on the catheter that impeded transmission of pressure waves. In some patients, subsequent recordings displayed pulsatility and vice versa, which suggested a dynamic rather than fixed obstacle in the transmission, without causing lasting underdrainage. Our experience suggests that ICP curve analysis had a high diagnostic value when pulsatility was present, which occurred in the majority of cases. Further research is required to examine if irregular ICP curves depict specific patterns for the different scenarios.

Pulse amplitude

The AMP in this cohort was slightly higher in the sitting position and within a range previously reported for patients who had intracranial monitoring for a variety of conditions [6, 26]. Slight increase of the AMP in sitting compared to supine position was also noted in previous studies, but the interpretation of this observation is not well established [8]. AMP has been reported through lumbar monitoring in IIH, but the values were lower, because while mean ICP is uniformly distributed within CSF spaces, AMP is higher in the intracranial compartment and somewhat dampens as the pulsatile wave is transmitting along the spinal subarachnoid space [3, 9, 10]. A valve setting of 10 in this cohort was associated with a lower AMP compared to setting of 15 and resulted in a better therapeutic response to shunting. AMP is a measure of intracranial compliance, and it is small when compliance is high, hence the setting of 10 resulted in better compliance [7, 14]. AMP above the aforementioned range associated with high ICP should raise the suspicion of blockage distal to the sensor (Table 2). Positive correlation between ICP and AMP has been observed in patients with IIH without a shunt and our results showed that this correlation persists after shunting [6]. The positive correlation between AMP and BMI indicates that increasing BMI is associated with reducing intracranial compliance in IIH patients with a shunt and further supports the consideration of weight management.

Limitations

This study was disease and valve-setting specific, but the principles of telemetric data interpretation can apply to other disorders and the values can be extrapolated to different valve configurations. The measurements represented only a screenshot at baseline following shunt insertion and future research on longitudinal telemetric recordings could provide a better understanding on long term shunt function. Waveform morphology was not analysed and this would be interesting to study in the future, as it may yield useful diagnostic information. Correlation with other clinical measures such as optical coherence tomography imaging and visual fields would be beneficial.

Conclusion

This study documents a range of ICP recordings in patients with IIH and a functioning shunt using the M.scio system. The results will assist the interpretation of telemetric ICP monitoring in the diagnosis of shunt malfunction and optimization of valve setting in IIH. A high BMI is associated with reduced intracranial compliance in IIH patients with shunts. Telemetric ICP measurements can inform clinical decision making and more research is required to evaluate longitudinal recordings and explore the link between telemetric data, clinical data and patient outcomes.

Compliance with Ethical Standards

Funding: No funding was received for this research.

Competing interests: The authors have no relevant financial or non-financial interests to disclose. The authors have no competing interests to declare that are relevant to the content of this article.

Ethical approval: All procedures performed in this study were in accordance with the ethical standards of University Hospitals Birmingham NHS Foundation Trust and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All data included in the cohort were obtained as part of routine clinical practice and this study was approved as service evaluation (Clinical Audit Registration & Management System number: 18463). Ethics approval by a research ethics committee was not required. All data were anonymized for analysis so that individual patients could not be identified, and patient consent was not required.

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Table 1. A) Baseline characteristics, mean intracranial pressure (ICP), ICP pulsatility and mean amplitude (AMP) for patients with Idiopathic Intracranial Hypertension and a functioning shunt. **B)** Mean intracranial pressure and amplitude with valve setting at 15 and 10.

A	N=57	
Mean Age (years)	27	
Male: Female	1:10	
Mean BMI (kg/m^2)	37	
Mean sitting ICP (mmHg)	-3.8 (SD=5.9)	
Mean supine ICP (mmHg)	16.4 (SD=6.3)	
Pulsatile curve	49 (86%)	
Mean sitting AMP (mmHg)[a]	6.3 (SD=2.2)	
Mean supine AMP (mmHg)[a]	5.7 (SD=2.1)	
B	Valve setting 15 (N=37)	Valve setting 10 (N=20)
Mean sitting ICP (mmHg)	-2.7 (SD=5.1)	-5.6 (SD=6.9)
Mean supine ICP (mmHg)	18.4 (SD=4.2)	12.9 (SD=8)
Mean sitting AMP (mmHg)[a]	6.6 (SD=2.3)	5.7 (SD=2)
Mean supine AMP (mmHg)[a]	6 (SD=2.1)	4.9 (SD=1.8)

[a] Amplitude was calculated only in pulsatile curves

Table 2. Interpretation of intracranial pressure (ICP) values coupled with curve morphology in patients with Idiopathic Intracranial Hypertension and an integrated M.scio in the shunt.

Mean ICP / ICP curve	Within range[a]	Above range	Below range
Pulsatile	Functioning shunt	Distal blockage[b]	Over-drainage
Irregular	Non-diagnostic	Uncertain[c]	Uncertain[c]

[a] ICP range depends on valve opening pressure
[b] High amplitude is expected as well
[c] No or limited experience with these scenarios

Figure Captions:

Fig.1 Mean ICP in supine (dotted red line) and sitting (solid blue line) position in all 57 patients of the cohort with a functioning shunt. The graph demonstrates a proportional postural change in ICP in the two positions. The average value of mean ICP was -3.8 mmHg in sitting position and 16.6 mmHg in the supine position for the entire cohort

Fig.2 Graphs demonstrating Pearson correlation line fit plot between different variables in the cohort of patients with Idiopathic Intracranial Hypertension and functioning shunts. ICP and AMP values are in mmHg and BMI in kg/m^2. There was positive correlation for: **a)** sitting ICP versus BMI and **b)** supine ICP versus BMI in the whole cohort of 57 patients; **c)** sitting AMP versus ICP and **d**) supine AMP versus ICP in 49 patients with pulsatily; and **e**) sitting AMP versus BMI and **f)** supine AMP versus BMI in 49 patients with pulsatily

Fig.3 Representative ICP curves (30 seconds recordings) in 5 different patients. Pressure on Y axis is in mmHg and time on X axis is in hh:min:sec (cropped screenshots from the ICPicture software, version: 0.5.5-Beta Last update: 25th July 2022). **a**) Pulsatile curve of functioning shunt in sitting position (mean ICP 19 mmHg, AMP 8.8). **b**) Irregular curve of functioning shunt in supine position (mean ICP 18.7 mmHg). This was the only case in the cohort that the pulsatility was present in the other position. **c**) Irregular curve of functioning shunt in sitting position (mean ICP -4.6 mmHg). **d)** Irregular curve and lack of pulsatility in shunt obstruction proximal to the telemetric sensor. **e**) Pulsatile curve with high AMP and high ICP in shunt blockage distal to the M.scio