**ORIGINAL ARTICLE**

# Telemetric Monitoring of Intracranial Pressure

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**Abbreviation List:**
CSF: Cerebrospinal Fluid
ICP: Intracranial Pressure
MAP: Mean Arterial Pressure
CVP: Cerebral Venous Pressure
CPP: Cerebral Perfusion Pressure
CBV: Cerebral Blood Volume
CVR: Cerebrovascular Resistance
CBF: Cerebral Blood Flow
ATP: Adenosine Triphosphate
BIH: Benign Intracranial Hypertension
V-P shunt: Ventriculo-Peritoneal shunt
L-P shunt: Lumbar-Peritoneal shunt
NPH: Normal Pressure Hydrocephalus
MRI: Magnetic Resonance Imaging
CT: Computerised Tomography
BMI: Body Mass Index
VF: Visual Fields
REM: Rapid Eye Movements

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## ABSTRACT

**AIM:** We present the application of a modern telemetric method that records and monitors Intracranial Pressure (ICP) over long periods in patients with possible intracranial hypertension.

**METHODS:** A telemetric device (Raumedic®, Neurovent® P-tel) was surgically implanted in six patients, three with inconclusive diagnosis of benign intracranial hypertension, two with possible diagnosis of aqueduct stenosis and one with Normal Pressure Hydrocephalus. All patients underwent a 3-day ICP recording within the nursing unit. Two more recordings were obtained over a period of 2-6 months at an outpatient basis.

**RESULTS:** All patients had an uncomplicated post-operative course. Analysis of the data excluded the diagnosis of idiopathic intracranial hypertension in two patients, whereas in four patients the data confirmed elevated ICP values. Three of patients underwent shunt implantation, while one patient refused further neurosurgical treatment.

**CONCLUSIONS:** The telemetric device could be safely implanted in selected patients. It could provide long-term ICP recordings, which are necessary to confirm diagnosis and guide the appropriate treatment.

## INTRODUCTION

It is well known that he intracranial cavity contains 3 individual volumes: a) the brain tissue (approximately 1400 ml), b) the cerebrospinal fluid - CSF (100-150 ml) and c) the blood in the cerebral vessels (100-150 ml). The mean pressure exerted by the above masses into the cranial cavity consists the intracranial pressure (ICP). ICP follows the periodic variations of the vascular volume from the pulse wave and the respiratory cycle and can be recorded in a waveform. The final ICP histogram is generated by grouping measurements of the individual pressures. The ICP histogram results from the merging of the normal distributions of the pressures' curves. These distributions follow the Gauze's curve model. These pressures follow the pressures of the heartbeat, since in each heartbeat the brain pulsates. Consequently, the P1 (peak 1) reflects blood brain flow, P2 (peak 2) reflects brain compliance, and P3 (peak 3) reflects the impulse wave of the heartbeat. Correspondingly S1 (spread 1), S2 (spread 2) and S3 (spread 3) are the distribution range of each Gaussian curve. The periodicity of the ICP waveform is similar to that of the heartbeat[1,2] (Figure 1).

The difference in pressure between Mean Arterial Pressure (MAP) and Cerebral Venous Pressure (CVP) is the Cerebral Perfusion Pressure (CPP). Because cerebral venous pressure is close to ICP it implies that **CPP = MAP - ICP**. The Cerebral Blood Volume (CBV) depends on cerebral blood tone and cerebrovascular resistances (CVRs), which are altered to achieve the necessary Cerebral Blood Flow (CBF). The CBF appears as follows: **CBF = CPP / CVR.** There are self-regulating mechanisms that tend to maintain CBF constant regardless of CPP from 50-150mmHg. Most conditions that induce intracranial hypertension are accompanied by a disruption of self-regulating mechanisms and CBF increases according to CPP**.** The ICP in normal conditions ranges between 10-13mmHg when measured in the lumbar region (lateral squat).[1,3,4] Elevated ICP increases cerebral vascular resistance, resulting in a decrease in cerebral blood flow. During prolonged intracranial hypertension a number of metabolic events take place such as an increase in tissue concentrations of lactic and pyruvic acid, a significant degree of lactic acidosis, a decrease in ATP, phosphocreatine tyrosine and bicarbonate due to a disturbance of oxidative metabolism. This leads to damage to cerebrovascular function and tissue hyperemia, particularly following the reversal of intracranial hypertension. In pathological conditions elevated ICP occurs with the **Lundberg type B** and **type C waves**, which represent enhancements in the physiological fluctuations of ICP, resulting from the systolic heart rate and the respiratory cycle. In situations with ICP >60mmHg, the **Type A (plateau waves)** have a height of 50-100mmHg and a duration of 5-20 minutes, indicating immediate treatment and poor prognosis for brain damage (Figure 2). Non-specific clinical manifestations of elevated ICP include headache, nausea, vomiting, diplopia, papillary edema, and reduced level of consciousness.[3,5,6]

Invasive neuromonitoring with intracranial intraparenchymal or intraventricular catheters has long been used to monitor ICP waves and detect their increased values. However, its application is usually limited to a few days in order to avoid infectious complications.

Over the years technologies enabling long term ICP monitoring have been demanded. Pathologies with elevated ICP, such as aqueduct stenosis causing obstructive hydrocephalus, benign intracranial hypertension (BIH), ventriculo-peritoneal (V-P) or lumbar-peritoneal (L-P) shunt malfunction and Normal Pressure Hydrocephalus (NPH)[3,7-13] have been the most intended indications for long-term recording and analysis of ICP waveforms. Further on the derived information could be extremely useful for diagnosis and decisions making for further therapeutic action.

Since 1965, many technical proposals had been recommended for "wireless" ICP monitoring. However, no device has been commercially used in routine clinical practice until quite recently. In 2009 Raumedic® Company introduced a new telemetric device called Neurovent® P-tel. Following experimental animal trials confirmed measuring accuracy with long-term stability. Since 2012, many reports for telemetric ICP monitoring in patients have been published[14-20]. Interestingly, in 2016 Ants et all presented their reports with P-tel on a total of 247 patients with suspected or known ICP disorders over a 6 year period[16].

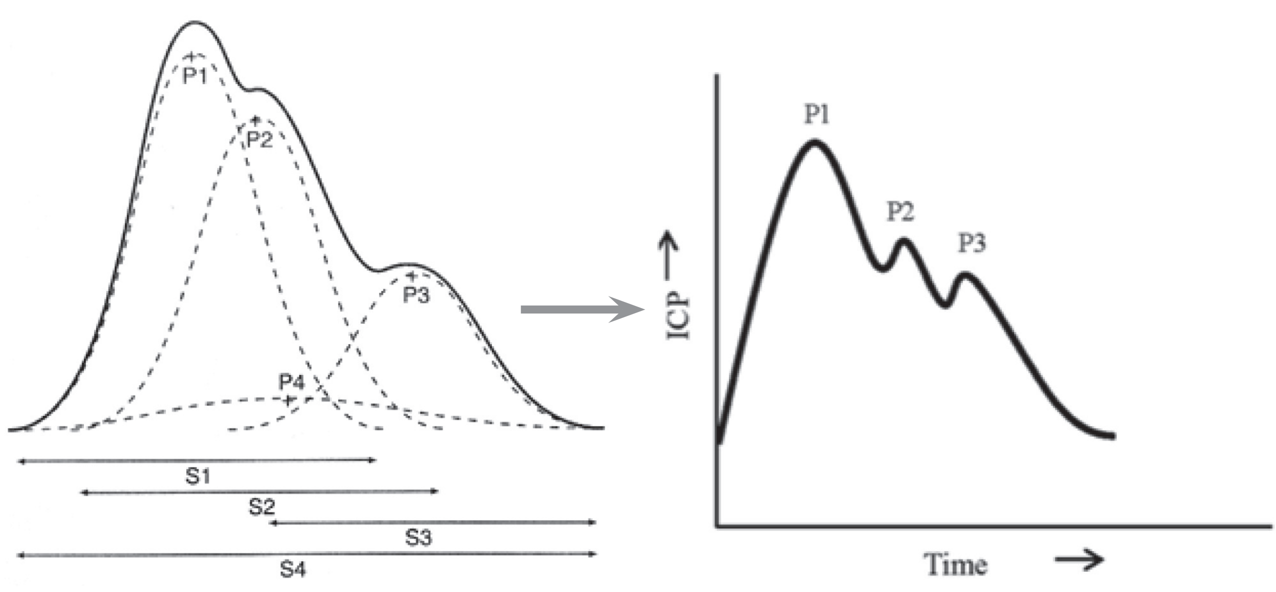


**FIGURE 1.** Normal ICP waveform.

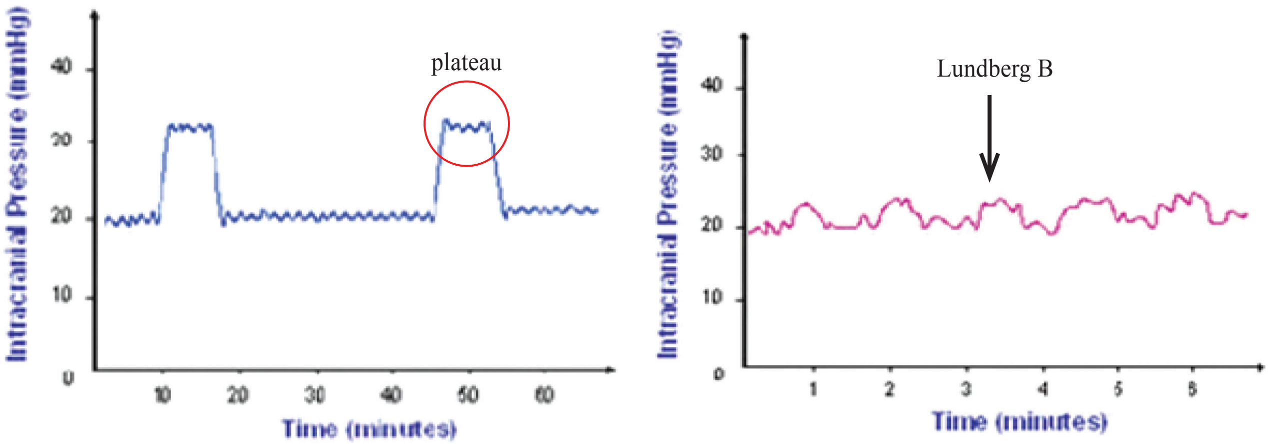


**FIGURE 2.** Lundberg type A (plateau)/Lundberg type B waves.

In this study we present our preliminary results in six patients with suspected intracranial hypertension, who submitted to long-term ICP monitoring with the Neurovent® P-tel Raumedic device. Technical aspects, indications, clinical efficacy, complications and data analysis possibilities are reviewed.

## METHODS – PATIENTS

Between September 2016 and January 2018, six patients aged between 21 and 63 years, with mean age 36.6 years, involved in this study. Four were females and two males and all were categorized according to their possible pathology in three groups:

- Aqueduct Stenosis (Occlusive Hydrocephalus): two patients (Figure 3)
- Benign Intracranial Hypertension (BIH): three patients (Figure 4)
- Normal Pressure Hydrocephalus (NPH): one patient

All had symptoms and signs of suspected intracranial hypertension, such as headaches, nausea, vomiting, and visual disturbances. A full clinical and neuroimaging examination, including a detailed brain CT, MRI scan and visual exam, was performed in each one of them, to exclude other pathologies.

For the purpose of this research study, we used the ICP telemetry system (Neurovent® P-tel Raumedic®). The telemetry hardware has 3 parts:

1. an implantable device made consisting of a) the intraparenchymal portion: a piezoresistive pressure transducer with several electric resistors doped on a flexible membrane, located at the tip of a polyurethane catheter 30mm long and 1.67mm thick, in direct contact with the pulsating brain tissue and b) the portion remaining under the skin: a 31.5mm in diameter and 4.3mm thick round ceramic housing a microchip, which converts transducer's electric modifications into ICP values (Figure 5).
2. a portable device - ICP recording and storage monitor (Raumedic® TDT 1) (Figure 6).
3. a signal transfer antenna (Raumedic® Reader TDT 1) from the implanted device to the monitor based on radiofrequency identification technique[5,6,8,14-20] (Figure 7).

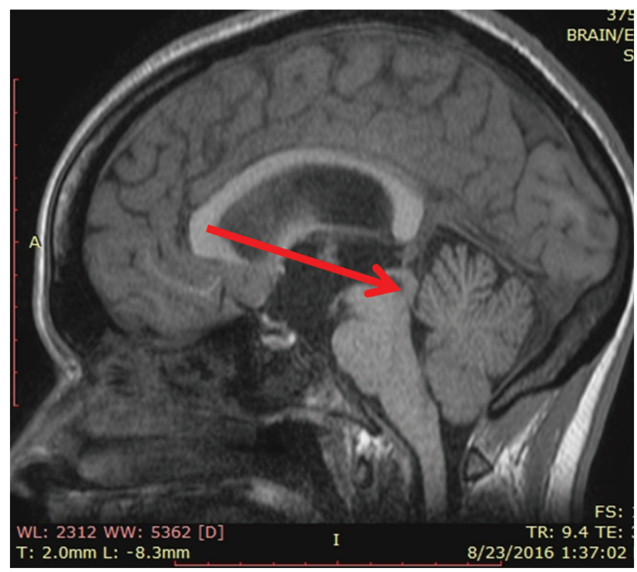


**FIGURE 3.** MRI: Aqueduct stenosis.

The implantation of P-tel can be performed either under general or local anesthesia. The ICP insertion point is the Kocher point: 12 cm from the middle cortical line and 2.5 cm from the midline or 2 cm in front of the coronary suture. After a 4 cm skin incision over the Kocher point, the telemetric device is implanted through a burr hole and opening of the dura, into the right frontal lobe parenchyma (Figures 8, 9). The left frontal lobe (dominant side) could also be used if necessary.

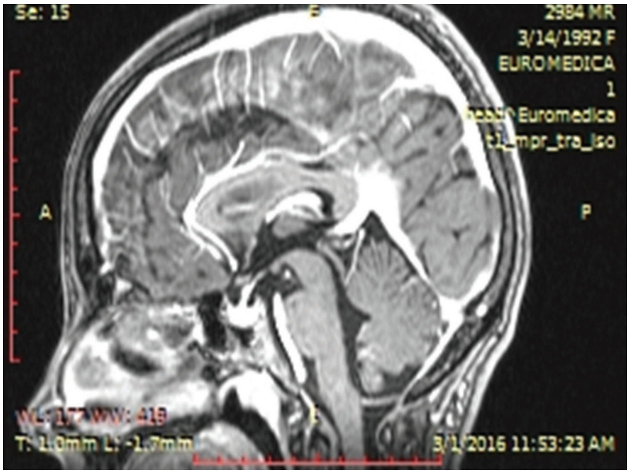


**FIGURE 4.** MRI: Idiopathic Intracranial Hypertension.

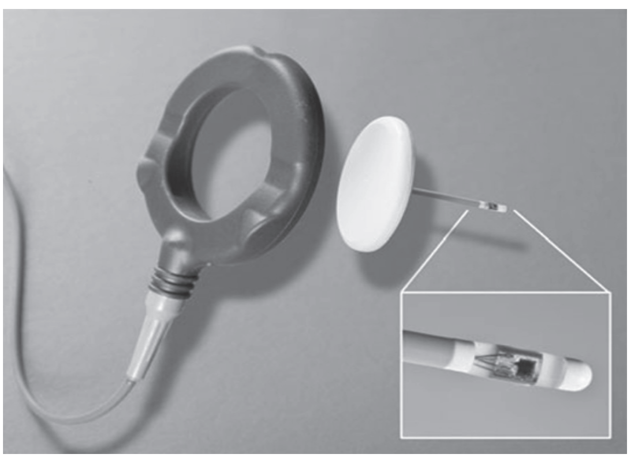

**FIGURE 5.** Neuroment P-tel.

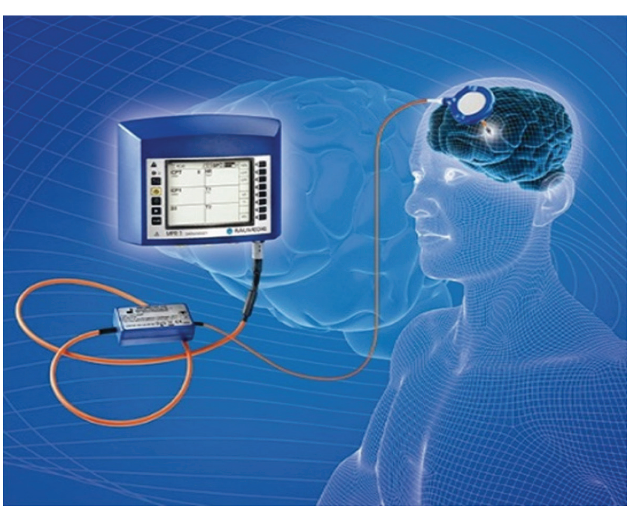

**FIGURE 6.** Raumedic TDT 1.

**FIGURE 7.** Raumedic Reader TDT 1.

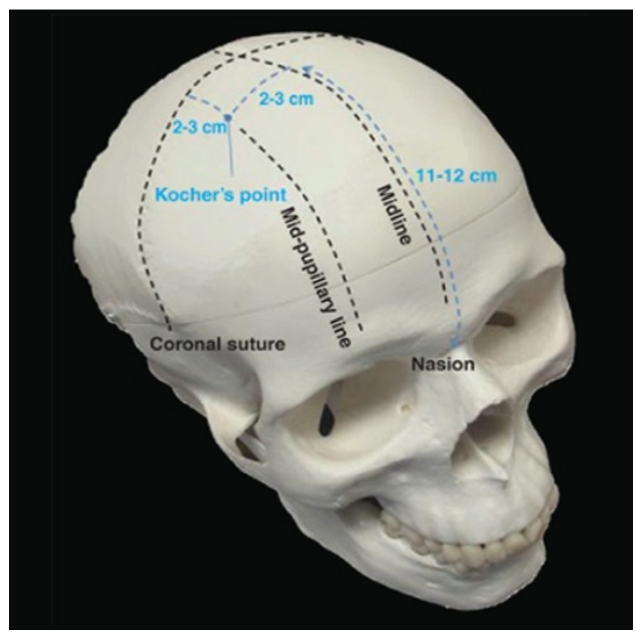


**FIGURE 8.** Kocher's point.

The wound is closed with skin sutures instead of surgical staples to avoid interferences during telemetric data transmission. Surgical removal after 3-6 months requires local anesthesia.

The intracranial device couples with the external antenna placed upon the scalp and measures ICP in real time if connected to the monitor. The acquired data can be analyzed and interpreted with a specialized software in a personal computer and enabling identification of pathologic Lundberg waves. The device has the capacity to store continuous ICP recordings for 72 hours.

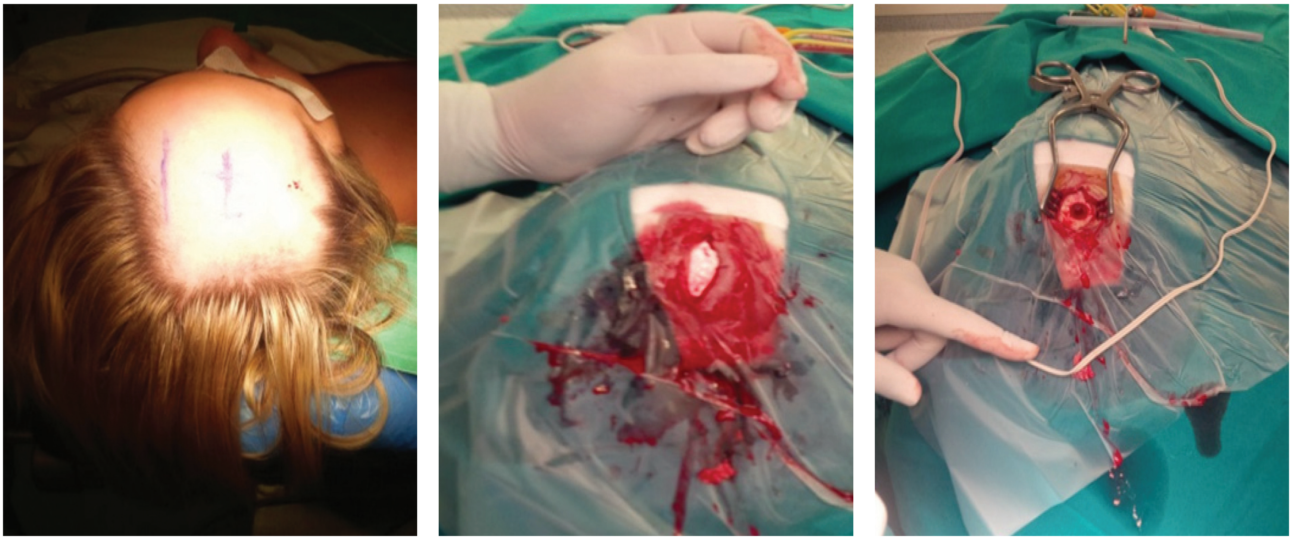

**FIGURE 9.** Surgical implantation procedure: Steps: 1. skin preparation, 2. skin incision, 3. burr hole opening**.**

The choice of the above system was made for the following reasons:

- No calibration needed.
- It is placed under the skin under aseptic conditions, having the advantage of "non-open" trauma and infections' avoidance.
- It allows for long-term follow-up, without affecting the quality of patients' lives, also reducing significantly their hospitalization time.
- It enables direct recording, storage and data transfer by enabling the analysis of these via a computer, using special software.
- It is not compromised by magnetic fields of up to 3 Tesla, giving the patient the ability to undergo MRI after surgery, if necessary.[8,15,16]

All six involved patients underwent telemetric ICP monitoring and recording for 72 hours, starting immediately after implantation in the nursing unit. Three further recordings followed at two, four and six months post-implantation at home for 48-72 hours each time. The ICP recordings were examined during daytime and nighttime, for episodes of raised ICP and evaluation of ICP waves' morphology such as presence of pathologic Lundberg B-waves or A-waves.

## RESULTS

After analysis of the recording data, intracranial hypertension was not confirmed in two patients. In contrast, four patients recorded with increased intracranial pressure and eventually two of them underwent V-P shunt implantation and one L-P shunt implantation. One patient refused further neurosurgical intervention. Two of the patients are still under medical attendance (Table 1).

The above patients underwent a total of 890 hours of ICP recording and monitoring as follows:

- The 23-year-old female patient (No 1) had normal brain MRI scan and with ICP telemetry she recorded negative ICP values, up to -18mmHg. A local cerebral oedema around the intracranial catheter position was observed in a brain CT scan, one month following ICP probe implantation. Eventually, no further neurosurgical action suggested.
- The 33-year-old female patient (No 2) experienced severe headache in association with progressively deteriorating gait instability. The patient had a brain MRI scan which showed possible stenosis of the aqueduct. She was initially treated with acetazolamide, without any improvement in symptoms. ICP Telemetry proved high ICP values. After the V-P shunt insertion, the values initially measured near the upper normal limits. Subsequently, during a six-month follow-up period, with appropriate regulation of the valve mechanism, ICP values measured within normal range. At the same time, both headaches and walking instability disappeared.
- Similarly, the 63-year-old male patient (No 3) had a brain MRI with possible aqueduct stenosis. ICP telemetry recorded elevated ICP values, particularly at night. After implantation of a V-P shunt the ICP restored to normal values.
- The 22-year-old female patient (No 4), with the empty sella syndrome presented with very high ICP values (> 28mmHg) throughout the telemetry study. However, she refused any further neurosurgical treatment.
- The 21-year-old male patient (No 5) found with brain

**TABLE 1.** Patients' demographic, clinical, radiology & ICP monitoring data

| A/A | sex | Age yrs | BMI | V.F. | MRI/ suspected diagnosis | ICP...mmHg post ICP implantation | V-P shunt | L-P shunt | ICP post-op | ICP 2 months | ICP 4 months | ICP 6 months | comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | F | 23 | 3 | + | without findings/BIH | <15 | - | - | - | <15 | <15 | <15 | |
| 2 | F | 33 | 2 | + | Aqueduct stenosis/ Occlusive Hydrocephalus | >40 | + | | <20 | <15 | <15 | <15 | |
| 3 | M | 63 | 3 | - | Aqueduct stenosis/cclusive Hydrocephalus | >30 | + | | <20 | <15 | <15 | <15 | |
| 4 | F | 22 | 4 | - | Empty sella/BIH | >40 | - | - | - | >40 | - | - | Refusal |
| 5 | M | 21 | 2 | - | NPH | <20 | - | - | - | <15 | <15 | - | In study |
| 6 | F | 58 | 4 | - | without findings/BIH | >40 | - | + | <25 | <20 | - | - | In study |

**Body Mass Index -** BMI 1: <18,5: underweight
BMI 2: 18,5-24,9: normal weight
BMI 3: 25-29,9: overweight
BMI 4: >30: obesity

**Visual Fields**: V.F. + : with deficit
- : without deficit

ventricular dilatation in a random brain CT imaging for a mild traumatic head injury, without history of any neurological symptoms or signs. The ICP telemetric recordings were within normal limits. He presented with a generalised epileptic seizure one week after removal of the ICP bolt due to a small intracerebral haemorrhage. He received conservative treatment for 3 months.

- The 58-year-old female patient (No 6) presented with one year history of spontaneous rhinorrhea, without known trauma mechanism. She had a brain MRI scan, in which a CSF leak was detected through the ethmoid bone and subsequently she was treated with an endoscopic procedure. The ICP telemetry proved very high ICP values. She underwent a L-P shunt insertion and the ICP returned to normal values. She remains in study.

It is interesting to mention that all patients with increased intracranial pressure, independently of their pathology, experienced elevated ICP values during night time sleep, particularly between 3:00 am and 6:00 am, with increase of ICP >25mmHg (Lundberg B waves) for maximum duration of 2 minutes (Figure 10).

In our series the overall clinical complication rate after Neurovent® P-tel Raumedic® implantation was limited. None technical problems occurred. One female patient (No 1) presented with a radiological finding of a small brain oedema around the ICP bolt one month following the implantation, without clinical consequences. In addition one male patient (No 5) presented with a generalised epileptic seizure one week after removal of the ICP bolt. The post-op brain CT scan, showed a small 2 cm intraparenchymal clot into the right frontal lobe around the bolt position. No surgical action required and he was treated with antiepileptics for 3 months, without further consequences.

More patients are scheduled to be included in our study, in order ICP telemetry efficacy and complication rate to be further clarified.

## DISCUSSION

For more than 50 years techniques enabling wireless ICP measurement and monitoring were demanded by several investigators in the literature.[8,16] Monitoring of the ICP under non-hospital conditions and the possibility of performing long-term measurement without increased risk of infection or delivering of imprecise ICP data, were the main anticipated advantages.[8,16]

Eventually, in 2009 the Neurovent® P-tel Raumedic® telemetric device was introduced promising reliability on ICP recorded values.[16] Thereafter, handling of the system proved


**FIGURE 10.** B-waves (P1<P2).

simple for the doctors / nursing staff as well as for the patients during their hospital stay or even at home, while lying, sleeping or walking. Implantation and removal procedure proved easy to perform and there is no cable connection between the brain and ICP monitor. The system could be remained implanted for long periods and not only for 5-10 days as happens with the conventional ICP recording systems. However, a second operation under local anaesthesia to remove the probe, is required.

The present study shows the ability of using telemetric ICP measurements for long-term evaluation of ICP in patients with inconclusive diagnosis of diseases such as benign intracranial hypertension (BIH), aqueduct stenosis and normal pressure hydrocephalus (NPH). Particularly, in patients with suspected BIH, opening pressure at lumbar punctures as well as clinical, ophthalmologic and radiologic criteria are not sometimes sufficient to confirm BIH. Similarly, the suspected NPH patients could avoid unnecessary shunting since, according to the literature, clinical and radiological findings have only limited prognostic value. Increased activity of Lundberg B waves, especially at night, could be associated with NPH, despite their disputed predictive value. Moreover, literature shows that in shunted patients, imaging studies (CT, MRI), shunt radiography series, clinical and ophthalmologic data are not always reliable in indicating shunt malfunction (under-drainage or over-drainage). Telemetric ICP records could guide to valve readjustment for optimization of programmable shunt's settings, surgical exploration and revision of shunt if necessary and direct documentation of the post-adjustment or post-operative ICP normalization. On the other hand, Lundberg A waves in patients with suspected aqueduct stenosis must always be considered as abnormal findings indicating further neurosurgical action.

Moreover, as we mentioned in Results section, all patients with increased intracranial pressure, independently of their pathology, experienced elevated ICP values during night time sleep, particularly between 3:00 am and 6:00 am, with increase of ICP >25mmHg (Lundberg B waves) for a maximum duration of 2 minutes. This effect was observed even after the implantation of a shunt mechanism, although with lower ICP values. Whether the sleeping state of REM or any other sleeping state affects the waveform of ICP (B-waves), is a question that needs to be further clarified.[8-20]

In larger series of patients the overall clinical complication rate after P-tel implantation was 7.3% including temporary hemiparesis, small intracerebral haemorrhage, new-onset seizures and infections (brain abscesses or superficial wound infections). Moreover, the technical problems due to defects or damages of the device occurred in a rate of less than 3%. These incidences were comparable with the complication rate after insertion of conventional ICP recording systems. In our small series of 6 patients, one patient presented with a local cerebral oedema around the intracranial catheter position in a brain CT scan, without neurological symptoms, one month following ICP probe implantation and a second patient presented with an epileptic seizure one week post removal of the ICP bolt due to a very small intraparenchymal hematoma. Both patients were treated conservatively without further problems. It's interesting to mention that the perifocal small oedematous reactions surrounding inserted telemetric catheters could be observed up to 46.9 % in literature. Presumably long term fixed implants may induce some damage to the surrounding tissue resulting from pulsation of the brain. Additionally, the initial local tissue trauma during P-tel insertion may contribute to the oedema development. This oedema has the tendency of complete resolution over time.[8,16]

It is obvious that even using the P-tel telemetric device, limitations still exist. The Reader TDT antenna must be positioned and fixed over the implant on the head skin for continuous ICP measurements and thus the patients are limited with regard to their out-hospital activities. It would be more desirable if the antenna receives data from the implanted probe, without direct patient contact. Moreover, further improvements in system hardware and software need to be considered. Finally, the disadvantage of a second operation to remove the probe, remains.[18-20]

Lastly, we need to clarify that insertion of a telemetric device should not be generally recommended for all patients with BIH, NPH, shunt or aqueduct stenosis. Quite often clinical and radiologic signs are sufficient to confirm diagnosis and consequently it is proposed that the decision whether ICP telemetric measurement should be performed needs to be considered on a case by case basis.[18-20]

## CONCLUSIONS

ICP telemetry, despite its limitations, allows long-term ICP recordings in patients with suspected intracranial hypertension and clinical and imaging inconclusive data, even outside the nursing unit.

ICP telemetry could be safely implanted via a rather simple procedure and allows significant reduction of hospitalization time and overall cost. Patients with normal recordings avoid unnecessary shunt implantations, making them "shunt-dependents" for the rest of their lives, under the shadow of long-term shunt-related complications. In addition shunted patients could be benefited by telemetric confirmation of CSF over- or under-drainage.

In selected patients telemetric ICP recording has sufficient potential to become established in clinical routine, in order to confirm diagnoses and guide to the appropriate treatments.

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