First Clinical Results With a New Telemetric Intracranial Pressure-Monitoring System

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BACKGROUND: The knowledge of intracranial pressure (ICP) is the basis of an appropriate neurosurgical treatment. Because clinical, fundoscopic, or radiological data alone are often elusive, a pre- or postoperative long-term monitoring of the ICP itself is desirable.

OBJECTIVE: We describe the first clinical experiences with a new telemetric ICP-monitoring device.

METHODS: The transducer of this telemetric intraparenchymal pressure probe is placed under the galea over the calvaria. ICP can be monitored via a special telemetric reader, placed over the intact skin, and the ICP values are stored in a small portable computer. The system does not require an intensive care environment and can be used in any ward or even at home. The system was successfully applied in 10 patients (age, 3-56 years) in whom raised ICP due to hydrocephalus, shunt dysfunction, endoscopic third ventriculostomy failure, craniostenosis, or pseudotumor cerebri was suspected.

RESULTS: Continuous telemetric monitoring of ICP was performed for 2 to 24 weeks. In 7 patients, increased ICP values could be excluded, and further surgical maneuvers were avoided. In 3 patients, repeated plateaus or continuously raised ICP indicated surgery resulting in a normalization of ICP.

CONCLUSION: This new telemetric system was safe and effective for ICP measurement over a long period, including home monitoring. For the patients, it was easy to handle, and reliable data could be recorded over many weeks. Based on this preliminary experience, the authors consider the new system extremely advantageous in surgical decision making in particularly difficult cases of suspected abnormalities of ICP.

KEY WORDS: Hydrocephalus, Intracranial hypertension, Intracranial pressure, Intracranial pressure monitoring, Telemetry

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Monitoring of intracranial pressure (ICP) is a standard diagnostic procedure in different neurosurgical and neurological diseases.[1,2] In hydrocephalus surgery, there is continuing debate about how to analyze and interpret follow-up results. Traditional neuroimaging techniques have several limitations in assessing the success of a procedure. A decrease in the ventricular size is often minimal, even in normalization of an increased ICP, and the presence of a flow void signal at the floor of the third ventricle has been reported to have a significantly high incidence of false positives.

ABBREVIATIONS: ETV, endoscopic third ventriculostomy; **ICP,** intracranial pressure; **VP,** ventriculoperitoneal

Others favor the direct invasive measurement of ICP by ventricular catheter placement,[3,4] although this harbors the risk of an additional surgical percutaneus implant.

Monitoring of ICP, either by ventricular catheter or by different ICP-monitoring devices, usually implies percutaneus insertion with a certain risk of infection.[2,5-8] Furthermore, percutaneus devices are cumbersome, restrict mobilization of the patient, and are only of short-term value. ICP monitoring in children and noncooperative patients harbors the risk of probe dislocation and therefore requires in-hospital observation.

To improve ICP monitoring, especially in hydrocephalus, first attempts to develop telemetric long-tem implantable ICP systems and other appropriate devices were described 40 years ago.[9-16] However, a broad use did not take place in daily clinical routine because of marked and unpredictable drifts in the measured ICP values over time, making ICP monitoring unreliable over a longer period. Notwithstanding, effective ICP monitoring over a longer period under all-day conditions outside the hospital is highly desirable and would be helpful in surgical decision making.

We present our first results of long-term ICP recording with a new commercially available telemetric ICP-monitoring system. The system was approved for use in neurosurgery by regulatory authorities in Germany, and this is the first report of clinical application in humans.

MATERIALS AND METHODS

Between January 2010 and July 2010, we prospectively studied 10 patients (5 male, 5 female; age, 3-56 years; mean, 21 years). Most of them had previously undergone neurosurgical procedures for hydrocephalus, craniosynostosis, or pseudotumor cerebri and were scheduled for ICP monitoring because of suspected abnormalities in ICP. Details of patients' demographics and clinical course are displayed in Table 1. Informed consent was given either by the patient or by a legal representative in each case.

Telemetric ICP Probe

This comercially available system consists of an implantable telemetric ICP probe (Neurovent-P-tel), a reading device (RAUMEDIC TDT 1 readP), a portable recording device including Universal Serial Bus port (RAUMEDIC Datalogger MPR1; Figure 1), and a PC software for storing and analyzing data (RAUMEDIC Datalogger Vers. 1.7; Figure 2). All devices were manufactured by Raumedic AG, Helmbrechts, Germany.

The implanted telemetry ICP probe has a length of 25 mm and a thickness of 1.76 mm; it consists of an intraparenchymatous pressure sensor at the end of the tip and a subgaleal transducer with a width of 31.5 mm in diameter and 4.3 mm thickness (Figure 3).

Calibration is not necessary. According to the manufacturer's specification, the system is compatible with MRI scanners up to 3 Tesla. Technical specifications of Neurovent-P-tel are given in Table 2. The system and implantable intraparenchymal ICP probe are approved by German authorities for an implantation period of 29 days. If measurement was requested by the patients beyond this time, additional informed consent was given by the patients or parents.

The reading device consists of a radiofrequency transmission coil (TDT 1 readP) and a mobile rechargeable, battery-driven recording and monitoring device (Datalogger MPR1; Figure 1).

ICP recording is immediately possible by placing the telemetric reading device either on the wound dressing or the skin itself and can be easily fixed by adhesive strips. The implanted telemetric ICP probe records data only when it is in proximity to the radiofrequency transmission coil. If necessary, up to 4 additional numeric vital parameters can be monitored simultaneously. These additional parameters can be directly measured or imported from other systems such as intensive-care monitors or brain tissue oxygenation systems.

The recording device gives off an acoustic signal if ICP exceeds critical values. This acoustic alarm and the ICP threshold can be adjusted or switched off.

ICP recording can be done in a short- and a long-play mode. The short-play mode allows the storage of 5 ICP values per second, the storage of the pulsatile curve for b-wave analysis, and calculation of compliance. The long-play mode allows the storage of 1 ICP value per second. In this mode,

TABLE 1. Patient Demographics and Results[a]

Patient	Age, y	Sex	Diagnosis	Indication for ICP Monitoring	Implantation Period, d	Implantation Time, min	Explantation Time, min	Drift, mm Hg	Clinical Consequences of ICP Monitoring
1	14	m	Late-onset posthemorrhagic hydrocephalus	Active hydrocephalus, sufficient ETV?	>180	35	–	–	ETV failure, VP-shunt implantation
2	14	f	Hydrocephalus, suspected shunt dysfunction	Persistent hydrocephalus, shunt closure	28	27	20	0	No persistent hydrocephalus, shunt not necessary
3	35	f	Obstructive hydrocephalus	Sufficient ETV?	> 60	15	–	–	Sufficient ETV
4	56	m	Obstructive hydrocephalus VP-shunt infection	Sufficient ETV?	15	11	12	0	Sufficient ETV
5	3	m	Scaphocephaly	Craniostenosis? Resurgery?	> 30	25	–	–	No raised ICP after re-decompression
6	33	f	Tectal glioma, obstructive hydrocephalus	Sufficient ETV?	16	12	14	0	Sufficient ETV
7	9	m	Obstructive hydrocephalus	Sufficient ETV?	14	17	14	0	Sufficient ETV
8	5	m	Intracranial hemorrhage, hydrocephalus	Sufficient ETV?	>25	18	–	–	Normal ICP, none
9	11	f	Obstructive hydrocephalus	Sufficient ETV? Shunt closure	>19	17	–	–	Normal ICP, VP-shunt explantation planned
10	31	f	Pseudotumor cerebri	Shunt dysfunction?	>14	21	–	–	Shunt revision

[a]m, male; f, female; ETV, endoscopic third ventriculostomy; ICP, intracranial pressure; VP, ventriculoperitoneal.

FIGURE 1. *Telemetric reading and monitoring device for ICP measurement. ICP, intracranial pressure.*

the device can operate for several weeks without clearing the storage; therefore, this mode was used for ICP monitoring outside the hospital.

Implantation

The tip of the intraparenchymateous telemetric ICP probe was inserted either through an existing or a new frontal burr hole in the brain parenchyma. The telemetric transducer was placed between the calvaria and the galea. Skin incision was curved in 1 patient; in all other cases, the system was placed via a straight skin incision.

Explantation

Explantation was done under general anesthesia. After explantation of the telemetric probe, a possible drift was assessed by additional measurement against the atmosphere immediately after the operation.

An overview of the patient's data is given in Table 1.

RESULTS

The time for surgical implantation of this device ranged from 11 to 35 minutes (mean, 20 minutes). Up to now, we have not observed any complications, especially no infections.

We found no differences in ICP values if monitoring was done by placing the telemetric reading device either on the wound dressing or the skin itself. ICP recording could be performed easily by placing the telemetric reading device either on the wound dressing or the skin itself. Because of the battery-driven reading device, the patients were fully mobilized during ICP recording. If ICP monitoring was not necessary for several hours, the system was disconnected by taking the reading and recording device off the patient. Placement and handling of this device was very easy. Eight patients were discharged from the hospital, and ICP was measured and monitored by the patient or family members at home. In 5 patients, cranial MRI using a 3-Tesla scanner was done with the

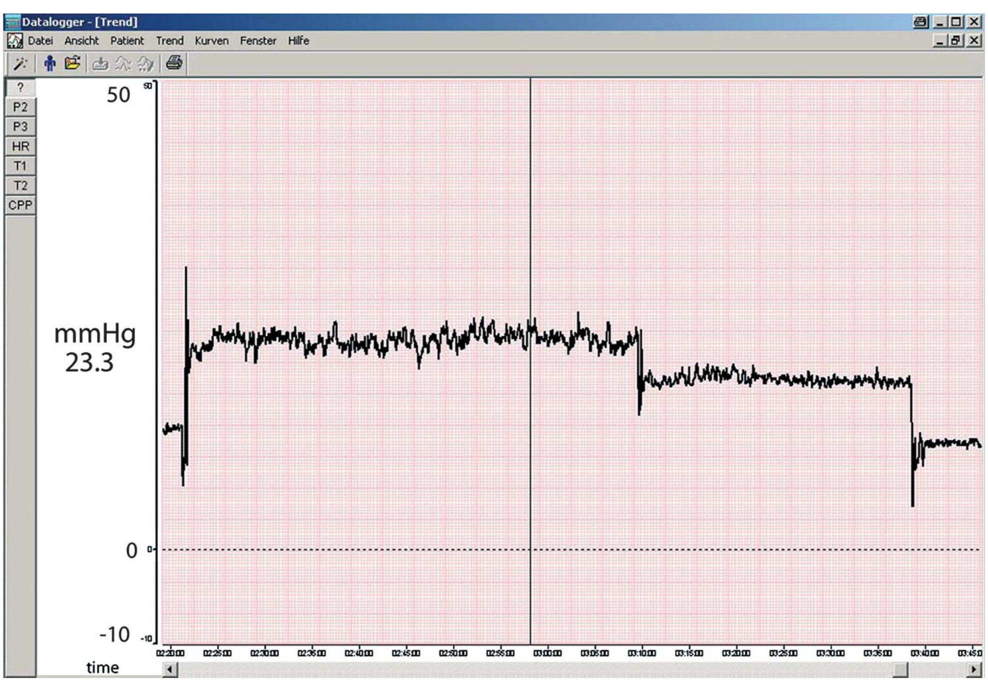

FIGURE 2. *Storage and analyzing software. Display of elevated ICP lasting longer than 30 minutes at night after ETV. This patient is scheduled for VP shunt (patient 1). ICP, intracranial pressure; ETV, endoscopic third ventriculostomy; VP, ventriculoperitoneal.*

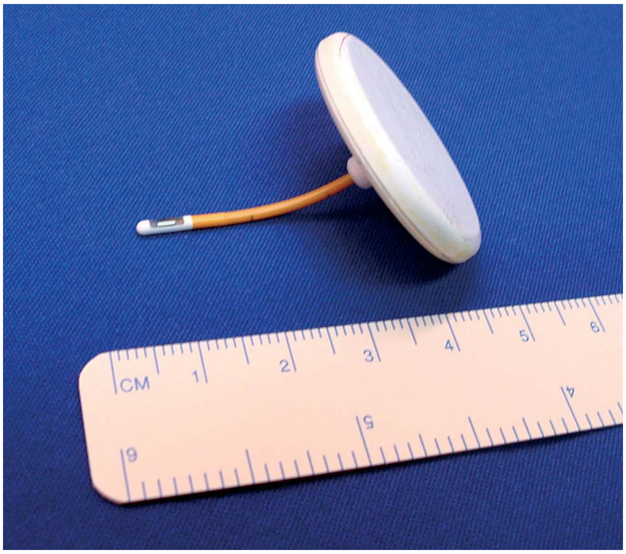

FIGURE 3. *Telemetric ICP probe, consisting of a ceramic body and a silicone-coated catheter tip. ICP, intracranial pressure.*

implanted ICP probe. No complications occurred, and the subsequent measurements were as reliable as before.

After a recording time of 3 weeks, the data had to be transferred to a computer to clear storage on the reading device. This transfer was completed by Universal Serial Bus port in several minutes. The retrospective analysis of ICP was performed by displaying the ICP curve on a computer (Figure 2).

In several patients, we observed impressive ICP changes during patient position changes, especially from recumbent to upright with a sudden drop of ICP up to negative values. We also observed elevated IPC values during physical exercise or crying of children at night. These events were documented by the patients or parents in a diary, and the elevated ICP during these events was not rated as pathological.

In all patients, we observed no technical problems with ICP monitoring. In 7 cases, long-term measurement of ICP did not reveal elevated ICP (patients 2, 3, 4, 6, 7, 8, and 9), so further surgery was not indicated and we decided to explant the telemetric ICP probe (patients 2, 4, 6, and 7; patients 3, 8, and 9 planned for explantation). In no case did we observe any complications during explantation, especially no bony ingrowth or adhesion of the probe to the brain parenchyma.

TABLE 2. **Technical Specification of Neurovent-P-tel**

Items	Description
Pressure range	−20 to +400 mm Hg
Drift	±2 mm Hg per 29 days
Limit of atmospheric pressure	1500 mm Hg
Accuracy	±2 mm Hg
Sensitivity	1 mm Hg
Limit of temperature	15°C to 45°C
Sampling frequency	5 Hz

Clinical Relevance of Long-term ICP Monitoring

In one patient (patient 1), long-term ICP monitoring detected elevated ICP due to hydrocephalus, which was insufficiently treated by endoscopic third ventriculostomy (ETV). In this case, ICP monitoring demonstrated raised ICP, correlated to clinical signs but not corresponding to neuroimaging. After ventriculo-peritoneal (VP) shunt implantation, the valve opening pressure was adjusted under ICP control. In another patient (patient 5), ICP monitoring revealed elevated ICP due to craniostenosis after correction for scaphocephaly. In patient 10, with pseudotumor cerebri, the ICP monitoring revealed dysfunction of the VP shunt. In these 3 cases, ICP monitoring contributed substantially to surgical decision-making.

In patients 2 and 9, ICP monitoring demonstrated normal ICP values despite a closed VP shunt, so that further surgical procedures could be avoided. In all other patients, ICP monitoring revealed normal ICP and, therefore, sufficient ETV. In addition, long-term ICP monitoring could reduce the number of follow-up CT scans.

In 3 patients, ongoing ICP measurement demonstrated stable, normal ICP values in appropriate correlation with clinical status and MRI findings.

In the explanted devices, the testing for a possible drift demonstrated no changes over time (Table 1).

CASE DESCRIPTIONS

Patient 1

This 14-year-old boy experienced a perinatal intracranial hemorrhage and presented with concentration disorders, cephalgia, deterioration of school performance, and increased fatigue. Cranial CT scan and MRI scans demonstrated no significant changes in serial controls. Diagnostic telemetric ICP monitoring at home revealed raised ICP at night and in the early morning, with ICP plateaus >25 mm Hg for more than 30 minutes. ETV was performed, and postoperatively his condition ameliorated. Initial ICP monitoring after ETV demonstrated no elevated ICP values for 3 days. His clinical condition showed no cephalgia in the morning for 8 days. Three days postoperative, the monitoring showed raised ICP values again with plateaus >20 mm Hg at night and in the early morning. Recurrence of cephalgia was reported by the patient 2 weeks after the ETV. The long-term ICP monitoring at home, over a period of 3 months, revealed ongoing raised ICP plateaus.

In consequence, implantation of a ventriculoperitoneal shunt was done, and the opening pressure of the valve was adjusted ongoing according to the ICP measuring. Eventually, the patient was symptom-free with normalized ICP values.

Patient 2

This 14-year-old girl underwent implantation of a ventriculoperitoneal shunt in infancy because of hydrocephalus. The girl was sent to our hospital with clinical signs of overdrainage despite a high valve pressure level and shunt assistant. Shunt closure and implantation of the telemetric ICP-monitoring system was performed. The long-term ICP monitoring over 4 weeks revealed no increasing ICP after shunt closure, and the telemetric system could be removed.

Patients 3, 4, 6, 7, and 9

In these 5 patients, obstructive hydrocephalus was diagnosed by clinical signs of intracranial hypertension and by MRI scan. ETV was performed in all 5 cases with additional implantation of the telemetric ICP-monitoring system. In patients 3 and 6, ICP values were normal. In patient 4, in the first postoperative days, the ICP monitoring showed increasing ICP, and an additional lumbar drainage was necessary for 1 week. In patient 9, ETV was combined with closure of the VP shunt. The ICP monitoring thereafter no longer revealed an increased ICP. None of these 5 patients needed a ventriculoperitoneal shunt or shunt revision.

Patient 5

This 3-year-old boy had scaphocephaly, and surgical correction was performed in the first year of life. In the beginning, there were no signs of raised ICP and the skull showed normal growth. At the age of 3 years, however, he developed mental retardation, cephalgia, and papilledema. MR showed no major abnormalities. ICP monitoring over 3 weeks revealed substantially raised ICP values, with an ICP baseline of >20 mm g; at night, ICP plateaus up to 40 mm Hg for 30 to 60 minutes were repeatedly present. Decompressive recraniotomy was performed, and the postoperative ICP monitoring demonstrated normalized pressure.

Patient 8

This 5-year-old boy was prematurely born and experienced intracranial bleeding. In follow-up after ETV, no clinical signs of hydrocephalus occurred, but there were enlarged ventricles in the MRI scan. Because of increasing frequency of headache, concentration disturbances, and suspected papilledema, the telemetric ICP monitoring was performed under daily life conditions. After 7 weeks of ICP home monitoring, no increased ICP was found.

Patient 10

This 31-year-old woman had undergone VP shunt implantation in pseudotumor cerebri several years before. The new onset of daily headaches was suspected to be a symptom of overdrainage or shunt dysfunction. Radiological imaging showed slitlike ventricles and no signs of shunt dysfunction. The telemetric ICP monitoring revealed raised ICP, especially in the overnight measurement. The operative consequence was revision of the shunt and an incomplete obstruction of the ventricular catheter was found. Because of a history of overdrainage, an adjustable shunt assistant was additionally implanted to the existing differential pressure valve.

DISCUSSION

In several neurosurgical diseases, the course of ICP cannot be reliably assessed on the basis of clinical or radiological data alone.[10] Abnormal ICP may occur as an early or late phenomenon after surgery or otherwise in the course of the disease.

For this purpose, several authors recommend ICP monitoring by ventricular or lumbar drainage, intraparenchymatous or epidural/subdural ICP sensors.[4,7,17-19] In our institution, we regularly inserted a ventricular drain or a conventional ICP probe, but the handling of these systems is not comfortable and carries the risk of infection. Up to now, ICP monitoring has been time-limited and confined to the hospital or even to the intensive care unit.

The main advantage of this new telemetric ICP-monitoring system is the possibility of long-term measurement under daily life conditions. Especially in patients with intermittent clinical signs of raised ICP, the long-term ICP monitoring at home under daily life conditions offers the possibility to detect raised ICP values, which may be hidden in short-term monitoring. Therefore, telemetric long-term ICP monitoring could detect elevated ICP values, which may be overlooked in short-term in-hospital monitoring. Even in these circumstances, neuroimaging or ophthalmologic methods may correlate incompletely with ICP. In childhood, noninvasive transcutaneus ICP monitoring seems to be well tolerated and more comfortable. We observed a high acceptance for this kind of measurement by the patients as well as by their relatives.

The measurement results are highly reliable and the hardware and software are well engineered. Our small collective showed a high acceptance of this new system, especially in cases of home monitoring. The possibility of continuous monitoring and acoustic alarm signal gives additional safety and allows early discharge from, as well as early admission to, the hospital.

The knowledge of long-term ICP values will give us further information about operative outcome and pathogenesis of several neurosurgical diseases and it helps in surgical decision making.[10,15,18]

Long-term telemetric monitoring can be reliably performed through a bulky wound dressing. To prevent skin lesions, the authors recommend padding between the skin and telemetric coil. The implanted probe does not have its own power source that allows recording and storage of ICP data of the implanted probe itself at all times. Therefore, a complete wireless measurement is not possible with this system.

This is the first clinical report of a new implantable telemetric intraparenchymatous ICP device that allows the measurement of positive and negative ICP values. In our small series, we were able to demonstrate the safety of the system and the comfortable handling even by patients themselves or by family members. Telemetric ICP monitoring appears to be a promising technique that offers the possibility of detection of early ICP changes, is minimally invasive, allows long-term ICP measurements, and may lead to a reduction in the frequency of CT scans or invasive ICP testing such as lumbar puncture or puncture of shunting systems. The application of this new technique may be helpful as an adjunct in the postoperative care of patients who are at risk for developing complications related to intracranial hypertension. The telemetric ICP monitoring could be helpful for any shunt-weaning procedure and for patients experiencing a severe head injury to exclude late complications. In all patients with an indication for long-term ICP monitoring, this new method allows the detection of raised ICP or overdrainage. The authors suggest that this new system will take an especially important role in ICP diagnostics and the monitoring of children. Further studies have to evaluate a possible improvement of this technique in relation to alternative well-established ICP-monitoring techniques.

Disclosure

The authors state that they have no relationships to the manufacturing company and no financial interest in the technology presented in this article.

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COMMENT

The manuscript by Welschehold et al describes the authors' initial experience with a remote implantable telemetric intracranial pressure (ICP) monitoring device in 10 patients, most of whom were assessed because of hydrocephalus. Continuous monitoring was performed for 2 to 12 weeks. The authors describe how long-term measurement of ICP was used in clinical decision making in this small series. This is a new and interesting technological innovation that has the potential to influence clinical care. Long-term monitoring of ICP with an implanted telemetric device has the potential to greatly enhance our knowledge of cerebral physiology beyond the current boundaries of the acute-care setting in the intensive care unit. Although the authors present a small series, the potential usefulness of this technology is intriguing. The authors demonstrate the feasibility of using this device in the nonacute setting and at home. A significant limitation of the technology that warrants mentioning is that the implanted monitor itself has no integral power source, so that recording of ICP can only take place when the patient is in close proximity to the transmission coil.

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