User Report on Spiegelberg Probe 3

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General

1. Purpose

The Spiegelberg Probe 3 is designed for the recording of the intracranial pressure (ICP) in the ventricular system or in the cerebral parenchyma.

The recording of the ICP is of eminent importance in the medical care of patients with severe injuries of the brain, such as:

- severe head injury
- cerebral infarct
- cerebral hemorrhage
- hydrocephalus
- cerebral swelling as a result of other systemic diseases

2. Innovations

On principle, the intracranial pressure can be measured at different places of the brain. The usual measuring places are:

epidural
subdural
parenchymal
intraventricular

These measuring places each have their specific advantages and disadvantages. Experience has proven, however, that parenchymal and intraventricular measurement provide the most reliable values. The parenchymal and intraventricular position of the probe is prone to a higher rate of complications as compared to the epidural measurement. This risk is accepted with regard to the significance of correct data. All literature, and Anglo-American literature especially, consider this type of ICP measurement to be the „gold standard.“ The ventricular probe can be used both for purely diagnostic reasons and for therapy in the case of increased ICP, by means of CSF drainage.

So far measurement has been done with the water column and external pressure transducers or with pressure transducers in the lumen of the drainage probe. There is a decisive disadvantage to this method, however, because in the case of swelling, faulty measurements occurred in the case of pressed out ventricles, due to the missing water column.

It was just in those phases of excessively increased ICP, when ICP measurement data are crucial to therapy control, that this type of measurement was prone to errors. There was an added danger in that the start of faulty measurement did not set in abruptly to be identified without doubt, but it developed slowly and was often noticed late.

These facts called for the development of probes which could measure the ICP independently of the water column. Therefore, their pressure transducers had to be attached to the exterior of the measuring probe.

The Spiegelberg Probe 3 takes these precise demands into account. Measuring is done independently of CSF, and the measuring diaphragm is mounted at the surface of the measuring probe. In the case of critical ICP values, the measuring probe provides much better patient monitoring and patient safety.

Consequently separating the measuring system from the drainage system allows for implementing trouble-free CSF dynamic examinations as opposed to the former practice of adding a liquid volume through a drainage probe and measuring ICP at the same time. Accordingly, the results of these examinations, which partly decide on the necessity of operations of the brain, are considerably more precise.

System and Application

1. System

Over the length of the first 15 cm, there are two lumina in a drainage tube. One lumen is used for drainage of CSF, the other lumen connects the place of pressure measuring. After this initial portion, the probe is divided into one arm that can be fixed to the scalp where it allows the connection of a CSF drainage bag, and a second arm that is connected to the ICP Monitor.

2. Operating Technique / Postoperative Handling

Application of the probe essentially corresponds to the established operation technique for external drainage. A burr-hole is placed at the typical position. The dura is opened after its coagulation. It is important that the opening be not larger than absolutely necessary so as to avoid unwanted loss of CSF past the probe. After that the pia and the brain surface beneath are coagulated in a punctiform manner, and the pia gets opened.

At this point the method differs slightly from the usual application for external drainage (EVD). EVDs are placed in a subgaleal tunnel and get pushed outside from the skin incision by way of a second incision. In the case of the Spiegelberg Probe 3, this could only be done with great difficulty, because the necessary subgaleal tunnel would have to be rather large.

Ideally, a dissector is used for making the subgaleal tunnel. The probe, which is stiffened through the enclosed stilette, is pushed to the burr-hole through the tunnel. There are several variants to this version, none of which having a special advantage.

It is also possible to bring the probe outside directly via the skin incision of the burr-hole. Although this allows for the direct puncture of the ventricle with the stilette-stiffened probe, literature advises against doing so, because the infection rate appears to be inversely proportional to the length of the subgaleal tunnel.

Our preferred method (as described above) allows only for an indirect puncture of the ventricle with the probe. The drainage arm of the probe would have to be pulled all the way through to the burr-hole in order to insert the stilette. After puncture of the ventricle, it would have to be directed out again at the same spot. This has proved to be impractical and complicated. It is easier to puncture the ventricle by means of a Cushing Needle. Then the probe is pushed forward via the given channel. The probe need not be stiffened with a stilette in this case.

This method usually ensures a safe, quick, and uncomplicated placing of the probe. Swerving of the probe can only occur if the ventriculopuncture presents difficulties that result in repeated probing with the Cushing Needle and a multitude of given channels accordingly. In these cases, safe placing of the probe has to be ensured by stiffening.

An uninterrupted suture at the skin incision precludes CSF leaks. The Luer-Lock connector is designated for CSF drainage sets. It should be placed at the skull so as to avoid contact with the pillows of lying patients, because uncooperative patients may cause the connector to sheer off at the passage to the tube. Placing the connector at about 0.5 cm behind the limit of frontal hair in the median line has proved to be ideal.

Postoperative handling ought to pay strict attention both to asepsis and to padding those connectors that are in direct contact with the skin. The usual disinfectants containing alcohol or iodine can be used without any difficulties. Ether, H_2O_2, and chloroform should not be used.

Clinical Experience

Patient Material, Indication

Since introducing the Spiegelberg Probes 3, more than 200 of these probes have been implanted at our department, the indications being of all conceivable kinds. The following figures refer to the total number.

Indications for implanting a Spiegelberg Probe 3:

Diagnosis	**Number of Patients**
severe head injury	68
subarachnoid hemorrhage	62
intracerebral hemorrhage (with/without damaged ventricle)	16
hydrocephalus	78
occlusive hydrocephalus with mass lesion of the cranial fossa	12
cerebral swelling and cerebral edema from other causes	3
Total	**239**

In most cases, the probes were placed in the ventricle. If the ventricles were narrow, so that no CSF drainage was necessary and the system was only used for ICP monitoring, the probes were placed in the parenchyma.

Initially, the probes were applied other than described. A larger tunneling was necessary, and the uninterrupted suture at the skin incision was done without. The problems resulting therefrom led to an adaptation of the method as described above. Certain described complications are based on these early experiences and will be marked hereinafter.

The probes stayed in situ between 1 and 14 days (an average of 7.8 days). They were treated like external drainages in the clinical routine. On each manipulation of the system, strict importance was attached to asepsis.

Reliability of the Measured Data

Assuming the external measurement of the intraventricular pressure to be the „gold standard“, we analysed the measuring results of the Spiegelberg Monitor and of the external measurement. The data were scanned/read with a frequency of 1 hertz and stored on the PC with a software modul designed for this purpose. After that, the collected data were compared off-line. Measurements were applied with all of the indications specified above. The duration of the measurements was between 1 and 10 days.

Aside from phases of permanently open drainage, slit ventricles, or a clog of the drainage lumen, when the externally measured pressure values were distinctly lower than the data of the Spiegelberg Probe, the pressure values of the two measurement methods differed only marginally. The average deviation of either measurement was at 1.3 mm Hg altogether. The duration of the measurement did not affect this, even after 10 days the Spiegelberg system did not generate a measurable drift. It should be mentioned that various employees, most of whom did not take part in the study, set up the level of reference of the external pressure transducer. Any methodical or biased errors may therefore be excluded. The level of reference cannot be specified exactly, however, but it can only be stated with an accuracy of about 1-2 cm at anatomical landmarks of the patient´s skull. Between the various observers, the level differed within this range. The method described is probably responsible for this difference between the two study procedures, which, however, is of no clinical importance whatsoever. During about 93% of the measuring time, the difference between values was +- 1 mm Hg at the most. Apart from those phases mentioned above, when the value of the external measurement was systematically stated too low, the maximum deviations were at +- 4 mm Hg. It could not be clarified in all of these cases, though, whether these differences were real or caused by a methodical error (e.g. accidental change of the position of the external measuring system relating to the level of reference as a consequence of positioning measures of the nursing staff or an unrecognized occlusion of the drainage catheter). The measured values demonstrated a linear correlation at all ranges of pressure, which is highly significant statistically. Not even when examining the different levels of pressure separately, did the measuring values of the Spiegelberg system tend to deviate to values that would have been either too low or too high.

In the scope of the usual ICP measurements with the system, which were not done with a parallel measurement via an external pressure transducer, we did not notice any measuring data either, that did not correspond to the clinical state of the patient and the brain pressure situation to be expected from that.

Disadvantages, Complications

It can be generally stated that most of the stated complications and side-effects are not specific to this probe, but that they are well-known potential side-effects of any temporary ventricular drainage. The characteristics of the probe are stated expressis verbis hereinafter.

Nature of complication	number	specific to this probe/more frequent than average
CSF leak	8 (3.3%)	no
Infection	12 (5%)	no
Dislocation	3 (1.25%)	yes
Hemorrhages	1 (0.4%)	no
Material fatigue	5 (2%)	yes
Pressure sore	8 (3.3%)	yes
Occlusion of drainage lumen	see text	no

1. CSF Leak
The percentage of CSF leaks, i.e. the outflow of CSF next to the drainage at its outlet point in the skin, equals that of other CSF drainages. Whenever such CSF leaks occurred, they had been caused by slight errors in the placement of the probes. These errors can result in CSF leak.with any other CSF drainage just as well, however. They are neither specific to the Spiegelberg probe nor do certain characteristics of this probe provoke them. Small dura openings, a careful subgaleal tunneling as described above, inserting gelatin sponges into the burr-hole as well as a tobacco pouch suture at the passage of the probe through the skin, all serve to preclude these complications in most cases.

2. Infections
Of all those patients treated with the system, two developed a severe ventriculitis and meningitis. For several days, the drainage arm of the pressure probes had to be irrigated several times a day because clots and brain detritus resp. obstructed the CSF drainage. One of the infections healed without consequences, whereas the other could not be controlled sufficiently and resulted in an encephalitis with permanent injuries. In 4.4% of the cases, the daily routine checks of CSF showed increased intrathecal cell counts, the extent of which could not be ascribed to the underlying disease. Irrespective of possible germinal findings in the CSF, either an intrathecal or a systemic antibiosis treatment or both were immediately initiated for these patients. In each case, the intrathecal signs of inflammation vanished without consequences within a few days. Usually, these infections occurred on the 6th day after implantation of the probe.

3. Dislocations
In 3 cases of disoriented, uncooperative patients, who were not fixed, the probes were removed by manipulation. In each of these cases, the probe was pulled outward through the flap, i.e. out of the ventricle, in spite of correct suturing at the head and correct fixing of the probe at the suturing flap. Any attempts at reinforcing the connection between the suturing flap and the probe by fastening the fixing thread more tightly, inevitably resulted in a compression of the drainage lumen and could not be maintained for that reason.

Tensile stress of the probe, which can easily occur when the patient gets treated inattentively, did not result in dislocation in any one case.

4. Hemorrhages

In one case, a hemorrhage of the channel in the parenchyma was evident in the CAT scan. It went along almost the entire length of the channel and distended about 1 cm around it. This complication, however, was the coincidance of several unfortunate factors: the patient´s proneness to hemorrhage, inexperienced operator, bad position of the catheter with exceeding of the median line. Under these circumstances, this complication could have occurred in connection with any other CSF drainage. Any special constructional characteristics of the Spiegelberg Probe do not appear to have been its cause.

5. Material fatigue

When suturing the flap to the skin, the thread must not be fastened too tightly in order to avoid cutting into the soft material of the flap.

In two cases after a longer measuring period (> 10 days), the material got torn at the connection of the drainage arm and the measuring. Both cases resulted in CSF leak at the point of defect. Under these circumstances, „repair work“ is not possible so that the probes had to be removed immediately. The material of the probes made the impression of being externally soaked by chemicals. It has not been possible so far to trace the causal chemical. It is certain, however, that the usual alcoholic and iodic disinfectants do not corrode the probe.

In 3 cases, an accidental, high mechanical stress caused the plastic tube of the drainage arm to tear, brought about by shearing forces at the passage to the metal connector. One of these cases had been induced by an incorrect placement of the corresponding Luer-Lock connector in the passage between the parietal and the occipital region of the skull. After placement of the drainage bag, the patient was practically lying on the Luer-Lock connector, and each movement of the head resulted in shearing forces at the connector. The other two cases had been caused by accidental rough handling. The damage was mended in all of the cases by removing the defective part, thus shortening the catheter, and partly, too, by additional correction of the suturing point.

6. Pressure sores/ulcerations

Another problem of the Luer-Lock connector with the suturing flap is the material, which is solid plastic. The component´s lever arm is long as compared to the fixing, and the contact surface on the skin is so narrow that the back part and especially the front part can be pressed onto the skin, e.g. by head dressings with prominent edges. If such a condition goes unnoticed for several days, it can result in pressure sores/ulcerations of the skin underneath. We had one case of this kind. The ulceration was shallow, however, so it healed after pressure relief of the skin and without any further help. Eight other cases of skin lesions were discovered in statu nascendi and could be prevented easily.

7. Occlusion of the probe

Tissue particles or clots occluding the drainage holes or the catheter lumen are a problem that can arise on the first day of ventricular CSF drainage. Despite several different approaches at solving this problem, none has succeeded so far. Therefore it is not surprising that the drainage lumen of the Spiegelberg Probe can clog as well. In most cases however, restitution of the CSF drainage can be done by strictly aseptic irrigation, so the new installation of a CSF drainage is not necessary.

The state of the CSF to be drained is mainly responsible for this complication, so our observations can only be compared to figures given in the references up to a certain point, because the two samples cannot be expected to be homogenous with regard to the frequency and the quality of a CSF that can result in occlusion of the probes. Concrete figures should not be given here for that reason. Due to the aforementioned demands on the homogeneity of the study collectives, they are not available anyway.

According to our own observations, the drainage arm of the probe does not get clogged sooner or more often than one would expect from other external drainages under the same circumstances, i.e. untoward CSF conditions. We even get the impression that the Spiegelberg Probe is rather less prone to this complication than other external ventricular drainages. This is probably due to the fact that the lumen of the drainage holes and the inner lumen of the probe´s drainage tube have the same diameter so that those particles that could clog the lumen do not get there on principle.

Discussion of Experiences and Impressions

The Spiegelberg Probe 3 has several advantages over the formerly applied mode of external ICP measurement:

It used to be crucial to pay attention to the fact that the pressure transducer had to be zero-adjusted (For. Monroi level). Faulty measured values used to be the result if this step was neglected. The Spiegelberg system does not call for such precautions within this method of ICP measurement because it does not require any patient-oriented zero-adjustment. This has very much contributed to simplify the handling of ICP measurement and to avoid mistakes that occurred among the nursing staff.

The robustness of the probe is of essential importance in the hospital routine. Whereas some of the other manufacturers´ measuring systems have to be applied with the utmost caution so the probe does not get exposed to tensile or any other mechanical stress, the Spiegelberg Probe has proved to be most resistant to such forces. The staff accepted it to a much higher degree because the usual performances on the patient need not be modified with respect to the probe. The „single-button-operation“ has proved to be another asset because it leaves out certain sources of mistake, such as calibration before implantation and calibration of interfaces. Other measurement systems demand certain facilities for manual after-calibration at the least. The Spiegelberg system has already integrated these automatically.

CSF drainage and pressure measurement are completely independent, so it is possible to measure the pressure when the drainage is open. With external measurements, the ICP is regularly shown to be too low in such cases, because the compliance of the craniospinal space gets enlarged by the volume of the external drainage. On the other hand, ICP monitoring can be continued independently of the passage of CSF through the drainage system, despite a possibly clogged drainage lumen, which can occur regularly with external drainages, depending on the clinical situation. Again this means a significant improvement of monitoring safety.

Certain clinical situations necessitate the determination of the CSF-dynamic parameters. The determination of these parameters proceeds as follows: A given volume of „artificial CSF“ is inserted into the ventricular system over a given time (a few sec. or more than about 30 min.). The change of ICP is determined under these circumstances. The Spiegelberg Probe 3 renders this procedure thoroughly unproblematic, because the measuring arm of the system is completely independent of the drainage arm through which the liquid is supplied. The simultaneously necessary ICP measuring does not get influenced hereby. When using drainage systems with only one lumen, it used to be sometimes necessary to use a three way tap in order to supply the liquid and measure the ICP at the same time. Depending on the rate of flow of the liquid to be supplied and on the inner diameter of the drainage tube, it sometimes happened that an additional pressure gradient built up in the measuring tube. If applied uncritically, this resulted in misinterpretations. The set-up of the Spiegelberg Probe 3 solves this problem.

The development of slit ventricles used to be a much-dreaded problem when measuring the intracranial pressure by way of the water column in external drainages via an external pressure transducer. Due to brain swelling, e.g. after craniocerebral injuries or other mass lesions, the ventricular system gets so compressed that the ventricular septums tightly enclose the catheter. The CSF is no longer in free contact with the liquid inside the drainage tube because the holes of the drainage tube are closed with the ventricular septum. Such processes do not develop rapidly but over a period of several hours. As the drainage openings keeps clogging up, the measurement gets increasingly inaccurate. Though rather damped, the pulsations of the brain keep effecting on the water column in the drainage by way of the wall of the drainage tube. For that reason, the pulsatile elements in the course of pressure of the ICP curve do not get completely lost, which often results in misinterpretations. Typically, the measured pressure is below the actual one. This is the more alarming as it is just in those situations of the patient´s ICP being in a critical stage, and the intracranial reserve supplies are largely exhausted, when the surgeon must have an exact idea of the intracranial pressure conditions. Besides the fact that this situation develops slowly, so a lot of experience is needed to detect it, it used to be just those situations when exact ICP figures are crucial, that no measuring method whatsoever could supply these figures. The Spiegelberg system of separating the pressure measurement from the water column has put an end to such problems. When comparing measurements of the Spiegelberg system´s course of pressure to an external measurement via the water column, we repeatedly observed this phenomenon in connection with the development of slit ventricles.

The positive impression of the Spiegelberg Probe 3 has been confirmed by in vitro studies, which were done under both static and dynamic aspects. A static long-term test over a course of 3 weeks led to only minimal differences of pressure (0,4 mm Hg after 3 weeks) of the Spiegelberg Probe as compared to a high-precision pressure transducer for industrial and scientific purposes. This is largely due to the fact that the Spiegelberg system carries out zeroing regularly. A high resolution recording of the course of pressure showed the Spiegelberg measuring system to deviate by 1-2 mm Hg towards the end (about 5-7 min. before a renewed calibration) of a calibration cycle (length: 60 min.). However, this deviation was always corrected by the zeroing. The probe reacted in the same stable and practically drift-free manner under dynamic conditions.

The determination of the dynamic response showed the only obvious drawback of the Spiegelberg system. Transmitting the pressure in the probe to the actual measuring instrument, i.e. the place where informations on pressure are transduced into concrete data, is done by way of an air column. This means that high-frequency oscillations of the measuring medium can only be reproduced undamped up to a cut-off frequency of 3 Hz. This drawback, which is inherent in the system, does not affect the routine ICP measurement, however. The mean pressure is displayed correctly, and the registration of pathologic intracranial ICP waves is unaffected as well. The shortcoming only has an effect, when scientific research requires an exact diagram of the single ICP wave form and an absolutely exact amplitude of the ICP wave form. The ICP wave form is a bit subdued on the monitor, and the exact amplitude gets slightly underrated systematically.

As to their characteristics and their frequency, most of the observed complications are well known from other ventricular CSF drainages. Possible complications are inherent in the system, and they mainly result from the component which both allows the fixing of the drainage arm to the scalp and holds the Luer-Lock connector for fastening the CSF drainage bag. They are of minor significance, and they can either be prevented by appropriate measures, or they can be corrected effortlessly.

To sum up, our clinical experiences and examinations as well as our laboratory tests have shown that the Spiegelberg Probe 3 is outstandingly well suited for parenchymal and intraventricular ICP measurement, because it produces correct values practically drift-free, even over a longer period of time. The relatively low cut-off frequency is of no immediate clinical significance. The construction of the probe is instrumental in significantly improving the patient´s safety, especially under those critical conditions, when the intracranial reserve supplies are exhausted. The automatic zeroing and the measuring system´s independence from anatomical landmarks greatly simplify the continuous ICP monitoring, and they are instrumental in avoiding mistakes. The separation of pressure measurement and CSF drainage is a definite safety factor.

The easy practicability and the higher precision of CSF dynamic tests can be rated as another positive characteristic of the measuring system.

The system has proved to be highly suitable for the sometimes „rough“ routine applications of the intensive care unit. The material is very robust, and handling is not different from other external drainages, well-known to the staff. The exterior control of the measuring system is reduced to an on/off switch, which reduces accidental mismeasurements.

In our experience, the Spiegelberg Probe 3 significantly extends the possibilities of monitoring intracranial pressure. It contributes greatly to improve the patient´s safety. It facilitates diagnostic examinations of the CSF dynamics. To my knowledge, there is only one other ICP measurement probe with similar constructional features on the international market. This probe, however, has one serious constructional defect, which raises grave doubts concerning its suitability for routine use. Although the manufacturer has been informed about this problem for more than a year, the defect has not been eliminated yet.

The method of implantation differs only negligibly from the method of external CSF drainage that has been known for decades and is proven world-wide. The characteristics and the frequency of complications are equivalent to those known from other external CSF drainages.

When CSF drainage or exact ICP measurement are indicated, and the potential complications are accepted, the Spiegelberg Probe 3 has considerable advantages for patient monitoring. It can be recommended for measurement in the clinical routine without a doubt. Specific scientific applications, however, call for other probes.