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PROSAIKA: A prospective multicenter registry with the first programmable gravitational device for hydrocephalus shunting

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ABSTRACT

Objective: Cerebrospinal fluid (CSF) overdrainage is a major problem in shunt therapy for hydrocephalus. The adjustable gravitational valve proSA allows for the first time a targeted compensation for overdrainage in the upright position without interfering with the differential pressure valve. To evaluate benefit, safety and reliability, the multicenter prospective registry PROSAIKA was conducted in 10 German neurosurgical centers.

Methods: Between March 2009 and July 2010, 120 hydrocephalic patients undergoing first time shunt implantation or shunt revision using proSA entered the study. 93 patients completed the 12 months follow-up.

Results: Hydrocephalus symptoms were improved in 86%, unchanged in 9% and deteriorated in 3%. In 51%, the proSA opening pressure was readjusted one or several times to treat suspected suboptimal shunt function, this resulted in clinical improvement in 55%, no change in 25%, and deterioration in 20% of these patients. The 1 year censored proSA shunt survival rate was 89%. Device related shunt failure was seen in two cases.

Conclusions: This is the first clinical report on the implantation of the adjustable gravitational valve proSA with a follow-up of 12 months in a substantial number of patients. Irrespective of different hydrocephalus etiologies and indications for shunt surgery, the overall results after 12 months were very satisfying. The high frequency of valve readjustments underlines the fact that preoperative selection of the appropriate valve opening pressure is difficult. The low number of revisions and complications compared to other valves proves that proSA implantation adds no further risk; this valve is reliable, helpful and safe.

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1. Introduction

The phenomenon of cerebrospinal fluid (CSF) overdrainage in the therapy of hydrocephalus with shunts is known since many years and several technical devices have been developed to overcome this problem [1–3].

Gravitational devices with fixed opening pressures have proved their role in the prevention of CSF overdrainage in ventriculoperitoneal (vp) shunts [4–7]. However, the selection of the optimal opening pressure of the gravitational device for the individual patient remains difficult and patient-valve mismatch does occur [12]. One reason is that the effective hydrostatic pressure difference between the ventricular system and the abdominal cavity, which is the major driving force of overdrainage, is difficult to estimate. Another reason may be the intra-abdominal pressure, which is difficult to predict and may change over time. A third reason may be the eventual development of an at least partially functioning CSF absorption that reduces the need for CSF derivation by the shunt and cannot be quantified or predicted. An adjustment possibility in gravitational valves could attenuate or even overcome problems of inappropriate preoperative opening pressure selection. Effective hydrostatic pressure difference and intra-abdominal pressure both change during the lifetime, likewise requiring opening pressure adjustment for optimal shunt performance. Therefore, an adjustable gravitational valve (programmable ShuntAssistant – proSA, Braun/Aesculap/Miethke, Germany) was developed and made commercially available since December 2008. The theoretical advantages are evident, but the clinical experience is limited so far to a few single cases. For this reason, the prospective safety and reliability registry (PROSAIKA: **proSA** in **i**nitial **c**linical **a**pplication – in German: **proSA** in **i**nitialer **k**linischer **A**nwendung) was conducted in 10 German neurosurgical centers.

2. Methods

2.1. The programmable gravitational valve (proSA)

The valve with its inside construction is shown in Fig. 1. According to the information provided by the manufacturer the mechanism of the novel device is as follows: in the upright position a sapphire ball is pressed by a weight towards the device inlet, blocking the CSF inflow. When CSF pressure is higher than the weight, CSF may flow into and through the device. The weight is connected to a spring. The tension of the spring determines the effective weight. The tension can be modified by adjusting the rotor, which can be performed transcutaneously with a magnetic pen. The construction allows setting an effective opening pressure between 0 and 40 cm H_2O. In the horizontal position, there is no gravitational force in the effective direction of the weight with the consequence that the ball will not occlude any more the inlet of the device. Because gravitation steers this valve it is also called gravitational device.

The graphic art is provided by the manufacturer of the device with permission to publish.

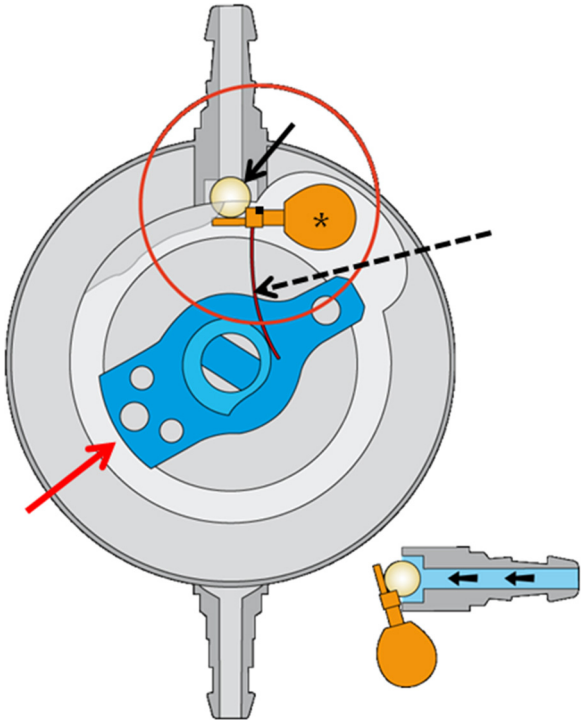

Fig. 1. The mechanism of the proSA: due to gravity, the ball (black arrow) is pressed upwards by the weight (*) and occludes the inlet. The weight itself is connected to a spring (dotted arrow). The tension of the spring can be changed by rotating the ax (red/left arrow) from outside with a magnetic pen. In this way the effective weight occluding the device can be changed – at the proSA with a range from 0 to 40 cm H_2O. In the horizontal position there is no gravity on the weight and no consecutive occlusion of the device occurs (see little figure at the right bottom). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

2.2. Data acquisition

Ten German neurosurgical centers participated in the prospective data acquisition. After obtaining informed consent, all patients undergoing proSA implantation were included in the PROSAIKA registry. After a 1-year follow-up period, the rate of shunt/device failure, clinical outcome, frequency and effect of proSA adjustments with their clinical influence, re-operations, and complications (infections, CSF over- and underdrainage) were recorded. The only exclusion criteria were lacking consent and not available 12 months follow-up. The flow chart in Fig. 2 specifies the different diagnostic and therapeutic steps during the follow-up period.

At the time of surgery, the indication (first shunt implantation or revision surgery, cause of hydrocephalus), the proSA implantation site (retroauricular or thoracic), distal catheter placement (vp or ventriculoatrial [va]), opening pressure setting of the proSA and other valve components integrated in the shunt were documented.

The position of the proSA was controlled postoperatively by X-ray or palpation, as a correct vertical orientation of this device is a condition for its proper function. A deviation of up to 20 degrees from the vertical line was accepted as correct implantation. However, if the vertical orientation was improper, no failure of the study device was registered as long as the clinical outcome did not resulted in a revision.

In every instance of proSA readjustment, the reason, performance of readjustment (technically successful? easy or difficult to perform?), and possible alternatives to readjustment (wait-and-see with further follow-up or surgical revision) were documented. A clinical evaluation 4 (2–6) weeks after valve readjustment either by outpatient examination or telephone interview to classify the outcome into “improved“, “unchanged” or “deteriorated” was performed.

At 12 months follow up, a clinical examination was performed with an additional documentation of the patients and/or relatives assessment of the outcome. Again, the outcome classification into “improved”, “unchanged”, or “deteriorated” compared to the presurgical condition was used.

As requested by the ethical committee, no routine CT at 12 months follow-up was performed for ventricular size assessment. Therefore, CT or MRI were only made in patients with