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Minimizing overdrainage with flow-regulated valves – Initial results of a prospective study on idiopathic normal pressure hydrocephalus

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ABSTRACT

Objective: Overdrainage and frequent reprogramming are common issues with programmable valves after ventriculoperitoneal shunt surgery for idiopathic normal pressure hydrocephalus (iNPH). Flow-regulated valves may address these limitations, but data on their efficacy are sparse. We present our single-center experience with flow-regulated valves focusing on overdrainage and efficiency.

Patients and methods: Thirty-two patients with iNPH treated with the Integra® NPH Low Flow Valve were prospectively enrolled. Clinical evaluation was performed at baseline, postoperatively as well as 3 and 6 months after surgery. The outcome was assessed by employing the iNPH grading scale and the Mini Mental Status Examination (MMSE). Overdrainage was assessed clinically and radiologically by computed tomography.

Results: The mean patient age was 71 years. All patients presented with gait disturbance, 29 had cognitive impairment and 25 had urinary incontinence. The mean duration of symptoms was 22.9 months. At 3-month follow-up, 25/31 patients (80.6%) improved on the total iNPH score by at least 5 points ($p < 0.001$). The mean MMSE score increased from 24.5 to 26.1 points ($p = 0.013$). After 6 months, the improvement rates of the iNPH (82.1%) and the MMSE scores (26.8 points) were stable.

The rate of clinically significant overdrainage was 3.2%. One patient presented with subdural hygromas that necessitated evacuation. In the remaining patients, clinical and radiological signs of overdrainage were absent.

Conclusion: The use of the Integra® NPH Low Flow Valve leads to a good neurological outcome and has low overdrainage rates without the need for reprogramming. These results are encouraging and justify further investigation of this valve.

1. Introduction

Idiopathic normal pressure hydrocephalus (iNPH) is a brain malfunction characterized by an enlargement of the cerebral ventricles with normal or only slightly elevated intracranial pressure. The typical symptom complex of iNPH is known as Hakim`s triad and consists of gradual disturbance of gait, cognitive impairment and urinary incontinence [1].

The treatment of iNPH consists of implantation of a ventriculoperitoneal (VP) shunt. Programmable differential pressure valves are currently recommended for iNPH patients because they allow non-invasive adjustment of the opening pressure by an external magnetic field [2]. To minimize the posture-related changes of the drainage rates, differential pressure valves may be combined with anti-siphon devices or gravitational units that provide a variable outflow resistance dependent on patient position [3–6]. However, over- and underdrainage are still common in practice.

Flow-regulated valves may address these limitations of programmable valves, but data on their efficacy in iNPH are sparse [7].

The Integra® NPH Low Flow Valve (Integra LifeSciences Services, Lyon, France) is a flow-regulated valve that is characterized by a variable resistance to the cerebrospinal fluid (CSF) outflow, which is supposed to maintain constant drainage rates independent of patient position or differential pressure. The aim of this self-regulatory

Abbreviations: CSF, cerebrospinal fluid; CT, computed tomography; ICP, intracranial pressure; iNPH, idiopathic normal pressure hydrocephalus; MMSE, Mini Mental Status Examination; MRI, magnetic resonance imaging; OSV, Orbis-Sigma Valve; postop, postoperative; SD, standard deviation; VP, ventriculoperitoneal

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mechanism is to prevent overdrainage while ensuring a good neurological outcome.

At our institution, we have been treating iNPH patients with the Integra® NPH Low Flow Valve since 2013 with and enrolled them into a prospective observational study.

The objective of this article is to present the treatment results of the first 28 patients treated with flow- regulated valves. We analyzed the short- and midterm neurological outcome and report on overdrainage and complication rates.

2. Patients and methods

The study was approved by the local ethics committee and informed consent was obtained from all patients prior to surgery. The Integra® NPH Low Flow Valve (Integra LifeSciences Services, Lyon, France) was used for all procedures.

2.1. Inclusion and exclusion criteria

Inclusion criteria were as follows:

1 Presence of at least two symptoms of the Hakim's triad (gradual disturbance of gait, cognitive impairment and urinary incontinence).
2 Onset of symptoms after the age of 40 and a gradual worsening of symptoms for at least 3 months.
3 Radiological signs (magnetic resonance imaging, MRI) compatible with iNPH (symmetrical ventriculomegaly and subarachnoid space tightness, Evan's index > 0.3)

Patients with 1) systemic neurological diseases, 2) triventricular hydrocephalus, 3) history of severe concussion or brain bleeding and 4) parenchymal lesions on brain imaging were excluded from analysis.

The diagnosis of iNPH and indication for shunt surgery was made based on clinical and radiological findings. Patients with questionable diagnosis of iNPH received a supplementary diagnostic testing by placement of lumbar drain for 3 days. In case of positive response to extended lumbar drainage, shunt surgery was indicated and the patients were enrolled into this study.

2.2. Patient evaluation

At study entry, patient demographics, symptoms and risk factors for cerebrovascular disease (hypertension, diabetes mellitus, peripheral artery disease, coronary heart disease, myocardial infarction and nicotine abuse) were registered.

All study subjects underwent standardized clinical evaluation at study entry (baseline), two days after surgery and at the follow-up visits after 3 and 6 months, respectively.

The severity of iNPH before surgery and the neurological outcome after shunt placement was assessed by the iNPH grading scale as described previously [8]. This scale consists of the four subdomains gait, neuropsychology, balance and continence.

The gait was rated by an ordinal scale and the numbers of steps and the time frame needed to walk a distance of 10 m were measured.

Neuropsychological function was studied with the Grooved Pegboard test. Hereby, a total of 25 pegs needed to be placed into holes with randomly positioned slots as fast as possible. This test analyzes fine motor skills and requires visual motor coordination.

Balance was rated by an ordinal scale based on one and two legs stand.

Urinary continence was rated by an ordinal scale according to information given by the patient.

Each domain score ranges from 0 (poor) to 100 (excellent).The total iNPH score represents the mean value of the domain scores, whereby the gait domain was counted twice. Neurological improvement was defined as an increase of at least 5 points on the total iNPH score or its domain scores at follow-up visits.

For further evaluation of cognitive function, the Mini Mental Status Examination (MMSE) was administered at baseline and each follow-up visit.

Cranial computed tomography (CT) scans were routinely performed on the first postoperative day to verify proper ventricular catheter position and three months after surgery to rule out radiological signs of overdrainage, e.g. subdural hygromas.

All procedure-related complications and the necessity for revision surgery were recorded prospectively.

The primary outcome measures of this study were the differences between the iNPH score determined before surgery and at follow-up visits. Secondary outcome measures were overdrainage and complication rates.

2.3. Statistical analysis

Numerical variables were presented as means ± standard deviation (SD). Changes between baseline and follow-up were evaluated using the Wilcoxon signed-rank test. Categorical variables were presented as numbers and percentages. All statistic tests were performed using SPSS Version 25.0 for Windows (IBM, Armonk, NY, USA). A p-value < 0.05 was considered as statistically significant.

3. Results

3.1. Patient characteristics

From July 2013 to December 2017, a total of 32 patients were treated with the Integra® NPH Low Flow Valve, including 11 females and 21 males. The mean patient age was 71.2 ± 7.7 years (range: 55–84 years). All patients presented with gait disturbance. Additionally, 29/32 patients (90.6%) experienced cognitive impairment and 25/32 (78.1%) presented with urinary incontinence. The mean duration of symptoms before surgery was 22.9 ± 13.5 months (range: 6–60 months). The mean Evan's index before surgery was 0.41 ± 0.05. Patient demographics and comorbidities are listed in Table 1.

The distribution of the total and domain scores on the iNPH scale at baseline is detailed in Fig. 1.

Placement of the VP shunt was technically successful in all patients. Two days after surgery, an improvement on the iNPH scale of at least 5 points was observed in 24/28 patients (85.7%) with a median change of 11 points. Four patients were not available for complete evaluation of

Table 1
Patient characteristics.

Number of patients	32
Patient age (years)	71.2 ± 7.7
Sex	
Female	11
Male	21
Duration of symptoms (months)	
Gait disturbance (N = 32)	22.9 ± 13.5
Cognitive impairment (N = 29)	19.4 ± 9.3
Incontinence (N = 25)	19.2 ± 12.9
Comorbidities	
Hypertension	22 (68.8%)
Diabetes mellitus	11 (34.4%)
Peripheral artery disease	0 (0%)
Coronary heart disease	8 (25.0%)
Myocardial infarction	3 (9.4%)
Nicotine abuse	3 (9.4%)
Alcohol abuse	7 (21.9%)
Length of hospital stay (days)	4.8 ± 1.6
Evan's Index	0.41 ± 0.05