RESEARCH PAPER

A randomised trial of high and low pressure level settings on an adjustable ventriculoperitoneal shunt valve for idiopathic normal pressure hydrocephalus: results of the Dutch evaluation programme Strata shunt (DEPSS) trial

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ABSTRACT

Background In treating idiopathic normal pressure hydrocephalus (INPH) with a shunt there is always a risk of underdrainage or overdrainage. The hypothesis is tested whether patients treated using an adjustable valve preset at the highest opening pressure leads to comparable good clinical results with less subdural effusions than in a control group with an opening pressure preset at a low pressure level.

Methods A multicentre prospective randomised trial was performed on a total of 58 patients suspected of INPH. Thirty patients were assigned to (control) group 1 and received a Strata shunt (Medtronic, Goleta, USA) with the valve preset at a performance level (PL) of 1.0, while 28 patients were assigned to group 2 and received a Strata shunt with the valve preset at PL 2.5. In this group the PL was allowed to be lowered until improvement or radiological signs of overdrainage were met.

Results Significantly more subdural effusions were observed in the improved patients of group 1. There was no statistically significant difference in improvement between both groups overall.

Conclusions On the basis of this multicentre prospective randomised trial it is to be recommended to treat patients with INPH with a shunt with an adjustable valve, preset at the highest opening pressure and lowered until clinical improvement or radiological signs of overdrainage occur although slower improvement and more shunt adjustments might be the consequence.

INTRODUCTION

Idiopathic normal pressure hydrocephalus (INPH) is characterised by a clinical triad of symptoms: gait disturbance, urinary incontinence and cognitive impairment and typically develops among the elderly. In general, 60–70% of patients with the triad and proven hydrocephalus will improve after cerebrospinal fluid shunting.[1] Implantation of a shunt, however, carries complications such as infection, obstruction, underdrainage and overdrainage. The cumulative complication rate and revision rate is estimated to be 35–80% among adults.[2 3] Studies have resulted in incidences of overdrainage between 2% and 21%.[4 5] Børgesen claims 80% of complications of shunting for INPH are related to overdrainage.[6] Overdrainage may lead to low intracranial pressure syndrome and subdural effusion (SDE) or subdural haematoma (SDH). Low intracranial pressure syndrome is characterised by orthostatic headaches and sometimes nausea, vomiting, drowsiness, diplopia, upward gaze palsy and visual defects.[5] Overdrainage can be prevented or treated by implanting an antisiphon device (ASD) or changing the opening pressure of the valve (OPV). Different ASDs have been developed since the first publication in 1973.[7] ASDs have in common that the lumen of the catheter is closed under influence of a negative hydrostatic pressure at the level of the ASD. The optimal valve setting for treating INPH is still the subject of controversy.[8–16]

The hypothesis of the present study is that the use of a ventriculoperitoneal shunt equipped with an ASD and an adjustable valve—initially set at a high OPV—and then fine-tuned to individual clinical demand, will lead to fewer SDEs with good clinical results.

PATIENTS AND METHODS

Subjects were recruited into the study from 1 September 2003 to 31 December 2006. This prospective, multicentre, randomised clinical trial was approved by the local medical ethics committee of the Erasmus MC, Rotterdam (MEC 03.1073). Eight Dutch neurosurgical centres participated: Erasmus University Medical Centre, Rotterdam; Radboud University Medical Centre, Nijmegen; Atrium Medical Centre Parkstad, Heerlen; Isala Clinics, Zwolle; University Medical Centre, Utrecht; Albert Schweitzer Hospital, Dordrecht; University Medical Centre, Maastricht; and Admiraal de Ruyter Hospital, Goes.

Figure 1 shows the inclusion and exclusion criteria for enrolment. The time span for inclusion (40 months) was considered feasible to obtain enough patients for statistically significant results. Randomisation was performed by an independent research secretary using closed envelopes containing a note either ordering to preset the valve at performance level (PL) of 1.0 (group 1) or 2.5 (group 2).

After randomisation, baseline primary and secondary outcome measure assessments were

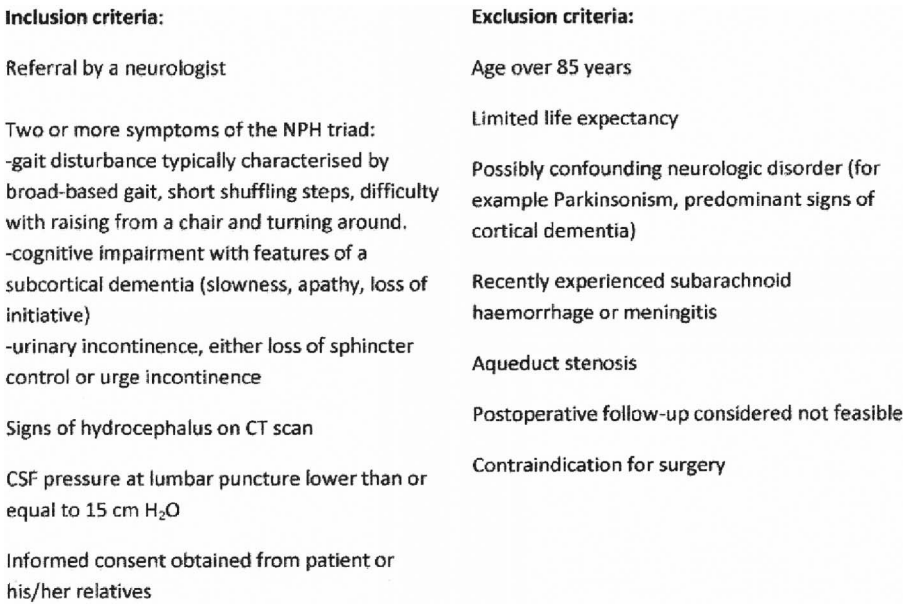

Figure 1 Inclusion and exclusion criteria for enrolment.

conducted. In all patients a ventriculoperitoneal shunt was implanted. The ventricular catheter was placed in the occipital horn except for three patients in which the frontal horn was preferred by one neurosurgeon. Within 24 h of shunting, skull and abdominal x-rays were done to verify device connections and position. Follow-up visits at 1, 3 and 9 months included all primary and secondary outcome assessments. A CT scan of the brain was performed prior to each follow-up visit. All measurements and tests were done by a trained research assistant who visited the participating hospitals to prevent interobserver variation. Study end for each patient was defined as completing the 9-month visit, withdrawal or death, detection of SDE on CT in group 1, or shunt removal or revision due to infection or dysfunction.

When shunt malfunction was suspected, radiological evidence of disconnection or malposition of the shunt components were excluded first and on the new CT scan SDEs or decrease of Evans' ratio had to be excluded. Then, a lumbar infusion test was performed at an infusion rate of 1.5 ml/min, first at PL set at 2.5 several hours before the test and then at PL 0.5. An indication for a check and change operation was a lack of difference in outflow resistance between both measurements. The outflow resistance is calculated by dividing the difference between opening pressure and plateau pressure levels during infusion, by the infusion rate.

In case an SDE was detected in group 1, the patient thereby reached study end, and the treating physician was free to decide how to manage the PL. The 9-month follow-up was still obtained. In practice, only the symptomatic SDEs were treated by upgrading the PL. The PL in group 2 was eventually lowered one step when the modified mini-mental state (3MS)[17] or gait score[18] was not increased ≥15% provided that no SDE was visible on a follow-up CT scan.

Data were collected and stored by the principal investigators (EJD and DAdJ). Digitally stored information was continuously backed-up. Radiological data were stored on CD ROM or as printed copies.

Study device

The PS Medical Strata I valve (Medtronic, Goleta, USA) is an adjustable differential pressure valve with an ASD in which the OPV can be changed non-invasively. The valve has five PLs corresponding to ranges of OPV of 20 mm H_2O to 140 mm H_2O. At 0 mm H_2O hydrostatic pressure (supine position) the valve at PL 1.0 has a pressure range of 35–55 mm H_2O. At PL 2.5 the pressure range is 135–155 mm H_2O.

Outcome measures

As a primary outcome measure the presence of SDE in patients showing clinical improvement, was used. Hence, a clear well-defined group was created with a proven functioning shunt in which the diagnosis of INPH was beyond doubt. SDE was defined as a hypodense film overlying the brain convexity with a maximum thickness >3 mm on CT. The gait score consisted of walking, step and time score as described by Boon *et al*[18] (figure 2). For cognitive function the 3MS examination was used, described by Teng and Chui.[17] It is a brief, objective assessment of cognitive functioning and the score ranges from 0–100. The items tested are date and place of birth, temporal and spatial orientation, mental reversal, repetition, first and second recall, naming objects, explaining similarities, writing, copying a complex figure, and reading and obeying a command.

From an earlier NPH study, the cut-off for cognitive impairment was set at a 3MS of 89.[18] Improvement was defined as an improvement of gait score and/or 3MS of ≥15%. Other assessments used as secondary outcome measures were Sandvik's severity index for urinary incontinence,[19] the modified Rankin scale for functional status,[20] the Evans' ratio and the final PL.

Statistical analysis

Comparison between groups 1 (PL 1.0) and 2 (PL 2.5) was performed using the Mann-Whitney U test for continuous variables. This test was chosen because the continuous variables were not parametrically distributed, owing to the number of included patients. To compare intragroup differences between various time points in follow-up, the Wilcoxon signed rank test was used. Categorical variables were compared using the χ^2 and Fisher's exact tests where appropriate. Outcomes were considered statistically significant when $p<0.05$. SPSS V.15.0 (SPSS Inc., Chicago, Illinois, USA) was used for database management and statistical analysis. Missing values were not imputed.

	Walking score (WS)
Able to walk independently	
Tandem walking disturbed	2
Turning disturbed	2
Trunkbalance disturbed, sway	2
Wide based stride	2
Small steps	2
Reduced foot-floor clearance	2
Start hesitation	2
Tendency toward falling	2
Total	WS = (0–16)
Able to walk with assistance	WS = 18
Not able to walk at all	WS = 20

Number of steps and seconds required for a 10 m walk (average of three attempts) in patients walking independently

Number of steps	Step score (SS)	Number of seconds	Time score (TS)
< 13	1	< 10	1
13–15	2	10–11	2
16–18	3	12–13	3
19–21	4	14–15	4
22–25	5	16–18	5
26–29	6	19–21	6
30–33	7	22–24	7
34–38	8	25–27	8
39–43	9	28–30	9
> 43	10	> 30	10

Gait scale = WS + SS + TS = . . . (2–40)

Figure 2 Gait scale (Boon *et al. Europ J Neurol* 1997;**4**: 39–47). Permission for publication of the Gait scale was obtained by the rights holder.

RESULTS

Overall, 58 patients were included into the study, of whom 30 were randomly assigned to group 1 (PL 1.0) and 28 to group 2 (PL 2.5) (figure 3). Ten patients (five in each group) did not complete the 9-month follow-up. Of these, six patients (four in group 1; two in group 2) died from causes unrelated to shunting. One patient's shunt (group 1) was removed due to infection. Three patients in group 2 were withdrawn from the study, two because of severe disability and one refused further cooperation. No shunt malposition or dysfunction was reported, however, five patients did not improve despite lowering of the PL. None of these patients developed SDE on CT scan or showed a decreased Evans' ratio. In one case a lumbar infusion test was performed that showed patency of the shunt. In the four other cases further analysis was not performed, in two cases because the patients refused, in one case because of bilateral coxarthrosis leading to a severe gait disturbance, and in another case the patient rapidly developed a severe dementia thereby leaving the study. Two of these patients were in group 1, the other two in group 2. Patient sex and age were not significantly different between the groups.

Primary outcome

At the patients' study end, 19/26 (73.1%) patients in group 1 and 20/26 (76.9%) in group 2 improved clinically (p=0.606). The valve had to be adjusted in 7/30 (23.3%) of patients in group 1 and 19/28 (67.9%) in group 2 (p=0.001). In group 2, more adjustments were needed towards the patients' study end (table 1).

An improvement of more than 15% in gait score after a follow-up of 9 months was seen in 18/23 (78.3%) and 15/21 (71.4%) patients in groups 1 and 2, respectively (p=0.732). An increase of more than 15% in 3MS was seen in 4/23 (17.4%) and 6/20 (30.0%), respectively (p=0.473). SDE occurred significantly more often in group 1 than in group 2 at 1 month and 9 months (p=0.022 and 0.043, table 2). As a result of

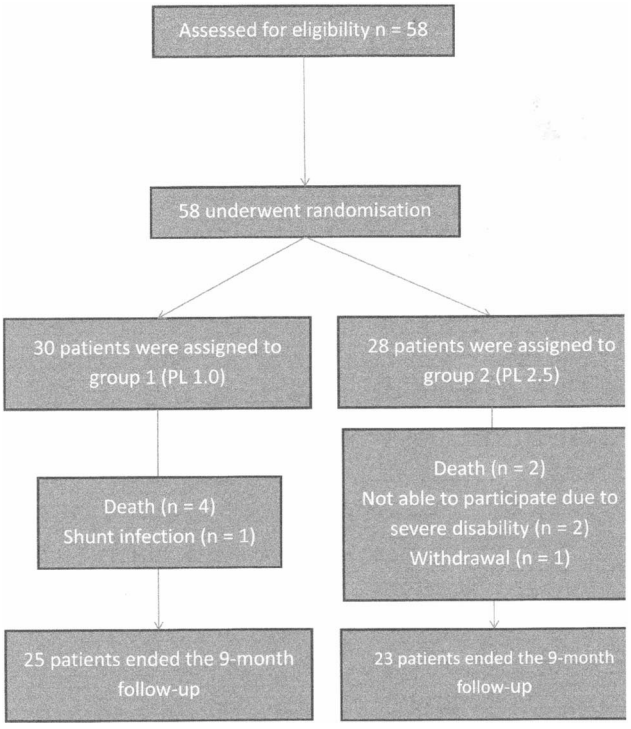

Figure 3 Study participant flow diagram from inclusion to study end.

Table 1 Performance level (PL) of the valve at patients' study end

PL	Group 1 (PL 1.0) no. (%)	Group 2 (PL 0.5) no. (%)	p value
0.5	2/30 (6.7)	0/28 (0)	
1.0	25/30 (83.3)	1/28 (3.6)	<0.001
1.5	2/30 (6.7)	11/28 (39.3)	0.003
2.0	0/30 (0)	7/28 (25.0)	0.003
2.5	1/30 (3.3)	9/28 (32.1)	0.004

Table 2 Incidence of subdural effusion at follow-up

	Baseline	1 month	3 months	9 months
Group 1 (PL 1.0)				
All patients	0/30	6/25	6/21	10/21
Improved patients		4/16	4/13	8/15
Group 2 (PL 2.5)				
All patients	0/28	0/24*	1/21	3/21*
Improved patients		0/19	0/18	2/19

*p<0.05 as compared with Group 1 (PL 1.0). Patients are regarded 'Improved patients' when they have shown an improvement of at least 15% in either gait score or modified mini-mental state examination or both.
PL, performance level.

missing data the denominators of both groups at follow-up are lower than the baseline denominators.

In both groups, no SDHs were observed. The three SDEs that occurred in group 2 after the 9 months follow-up period occurred in the patients who did not respond to the shunt and whose Evans' ratio did not decrease in the follow-up period. Three patients had symptomatic SDEs with orthostatic headaches. One patient of group 1 who did not improve had an SDE and headaches at PL 0.5 and the valve was set at 2.5 after which the symptoms subsided. One patient of group 2 who did not improve experienced headaches and had a SDE at PL 1.0, both diminishing after setting the PL at 1.5. One patient of group 2 who showed a late improvement had headaches but no SDE at PL 1.5 which subsided at PL 2.0. In group 2, the PL at 9 months was in most cases 1.5 or more. In nine patients (32.1%) improvement occurred at the highest PL of 2.5.

Secondary outcomes

There was no difference between groups in any of the baseline outcome assessments (table 3).

Patients in both groups experienced significant decreases as compared with baseline in the Evans' ratio and gait score and a significant increase in 3MS. Furthermore, the number of patients who had no urinary incontinence, and the number of patients who were functionally independent increased significantly. No significant delay in improvement was found in patients of group 2 as compared with those in group 1. The 9-month follow-up values were similar between group 1 and group 2 in these secondary outcomes.

DISCUSSION

Summary

After the follow-up period there was no difference in improvement between both groups. Besides, no statistical difference was found in rate of improvement between both groups at 1 month and 3 months respectively. In group 2 there seems to be a non-significant plateau for gait score, 3MS and modified Rankin

Table 3 Secondary outcome measures

	Group 1 (PL 1.0)	Group 2 (PL 2.5)	p value
Evans' ratio, mean±SD			
Baseline	0.38±0.06	0.40±0.05	0.136
1 month	0.35±0.07	0.39±0.05	0.019
3 months	0.35±0.07	0.40±0.05	0.010
9 months	0.34±0.05**	0.37±0.06**	0.093
Gait score, mean±SD			
Baseline	24.9±13.2	21.4±11.1	0.402
1 month	16.9±12.7	17.5±11.3	0.658
3 months	12.8±11.0	16.3±11.6	0.198
9 months	11.8±10.5***	14.2±11.1**	0.416
3MS, mean±SD			
Baseline	76.1±18.4	75.6±18.2	0.962
1 month	85.0±13.6	78.8±17.6	0.130
3 months	86.0±13.7	81.8±13.4	0.194
9 months	86.6±13.5*	85.5±13.1*	0.788
mRS 0–2, no. of patients (%)			
Baseline	14/30 (46.7)	9/28 (32.1)	0.294
1 month	13/28 (46.4)***	11/25 (44.0)***	0.859
3 months	14/24 (58.3)**	11/23 (47.8)***	0.471
9 months	12/23 (52.2)*	12/20 (60.0)*	0.760
SSI, no. of patients (%)			
Baseline			0.336
No incontinence	5 (17.2)	6 (21.4)	
Slight incontinence	2 (6.9)	6 (21.4)	
Moderate incontinence	13 (44.8)	11 (39.3)	
Severe incontinence	9 (31.0)	5 (17.9)	
1 month			0.640
No incontinence	7 (29.2)**	8 (40.0)***	
Slight incontinence	6 (25.0)	5 (25.0)	
Moderate incontinence	7 (29.2)	6 (30.0)	
Severe incontinence	4 (16.7)	1 (5.0)	
3 months			0.580
No incontinence	9 (39.1)**	11 (47.8)**	
Slight incontinence	5 (21.7)	2 (8.7)	
Moderate incontinence	5 (21.7)	7 (30.4)	
Severe incontinence	4 (17.4)	3 (13.0)	
9 months			0.156
No incontinence	7 (31.8)*	13 (59.1)*	
Slight incontinence	5 (22.7)	3 (13.6)	
Moderate incontinence	3 (13.6)	4 (18.2)	
Severe incontinence	7 (31.8)	2 (9.1)	

Values are displayed as means with SD or percentages.
*p<0.05 as compared with preoperative values; **p<0.01 as compared with preoperative values; and ***p<0.001 as compared with preoperative values.
PL, performance level; 3MS, modified mini-mental state examination; SSI, Sandvik's severity index for urinary incontinence (no incontinence (SSI=0), slight (SSI=1–2), moderate (SSI=3–5), and severe (SSI>5) incontinence); mRS, modified Rankin scale (0–2=functionally independent).

scale between 1 and 3 months follow-up, while in group 1 further improvement is observed in this time interval. This finding indicates that starting with a high PL might lead to a slower improvement than when starting with a lower PL. Furthermore, during this period the patient with the valve preset at the highest PL may be more at risk of complications such as falling accidents. Towards the end of the patients' study more adjustments were performed in group 2 because of failure of improvement or correction of SDE. Significantly more SDEs were observed in the control group (PL 1.0). Surprisingly, most patients with PL settings of 1.5 or more improved significantly. In more than 30% of cases improvement occurred at the

highest PL (2.5), corresponding to an opening pressure of 140 mm H_2O. The limitations of the present study are several. Defining improvement after shunting is difficult.[16] The cut-off point of improvement at 15% was chosen, based on the study of Boon *et al*.[9] The lack of reliable parameters to calculate the statistical power of the study resulted in choosing a rather arbitrary time span of 40 months for inclusion. Also, the number of patients not reaching the complete follow-up (10/58) resulted in a limited study size. Four patients with possible shunt malfunction could not be further analysed by lumbar infusion test and finally, the present study had missing data that however appeared to be evenly distributed over both study groups.

Review of the literature

Samuelson *et al*[21] were the first to report on the relatively high incidence of subdural fluid collections as a complication of a shunting procedure for INPH patients. They describe five out of a series of 24 patients who developed a SDH, all necessitating burr-hole evacuation. Larsson *et al*[22] found a significant increase of subdural haematomas in shunted patients older than 60 years. Weiner *et al*[2] state that SDHs occur in 20–40% of cases, shunted for NPH while Bergsneider *et al*[23] state that reported values of SDH range widely, from 2% to 17% and that a primary SDE might convert in the more serious SDH. According to Bloch and McDermott[24] even with use of adjustable valves, modern INPH series have reported SDH rates as high as 10% with up to 7% requiring evacuation.

In the prospective randomised Dutch NPH study the low pressure valve caused significantly more radiological signs and symptoms of overdrainage than the medium pressure valve.[9] In 8.3% of cases (8/96) an SDE or SDH had to be surgically evacuated for clinical reasons. Black[25] advises to use an adjustable valve and to titrate the valve setting down until the ventricles start to shrink on CT or MRI scan. However, no specific advice on initial valve setting for INPH is given. The use of an Orbis Sigma valve is controversial.[2]

CONCLUSION

This study shows that it is worthwhile and safe to treat INPH patients with a shunt with an adjustable Strata valve and start with the highest setting, and if necessary, titrating down until signs of improvement or overdrainage are observed. Using this protocol leads to significantly fewer SDEs compared with starting at a low setting. However, it should be noted that starting with a high setting might delay clinical improvement and lead to more valve adjustments than starting at a low pressure setting.

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Contributors EJD and DAdJ produced the idea for the manuscript. EJD was involved in acquisition of the data and drafted, revised the manuscript and provided overall supervision for the study. DAdJ was involved in acquisition and storage of the data and revised the manuscript. RD undertook the statistical analysis and interpretation of the data and revised the manuscript. EK and WvdB were involved in acquisition of the data and interpretation and revision of the manuscript. CMFD was involved in interpretation of the data, and revised and approved the manuscript.

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Competing interests None.

Ethics approval Medical Ethics Committee Erasmus Medical Centre.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement All data derived from the study are kept by the principal investigator (EJD) and all the data are used and/or included in the present manuscript. All data are available for members of the editorial board.

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