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A Study of Factors Affecting Surgical Outcome In Patients of Idiopathic Normal Pressure Hydrocephalus Treated With Programmable Ventriculoperitoneal Shunt

Research Article

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Abstract

Introduction: A triad of symptoms: gait disorder, cognitive impairment, and urinary incontinence with communicating Hydrocephalus and normal CSF pressure define the Normal Pressure Hydrocephalus (NPH). iNPH has reported incidence between 0.5–5.5 cases per 100,000 per year Secondary NPHoccurs after head trauma, subarachnoid hemorrhage, or other brain insults. When no suchpredisposing factors are identified, the syndrome is idiopathic NPH (iNPH).

Aims and Objectives: The aim and objective of the study was1)To assess surgical outcome after programmable ventriculoperitoneal shunt in idiopathic NPH and, 2) To assess relation of opening pressure of ventricle with surgical outcome and functioning of programmable VP shunt in idiopathic NPH.

Methodology: A prospective observational study was done in the Department of Neurosurgery, GIPMER, for one year after obtaining institutional ethical clearance among 15 patient who meet diagnostic criteria for idiopathic NPH according to international guidelines for NPH 2008.The collected data were entered in Microsoft Excel. Data were analyzed and statistically evaluated using the SPSS-PC-25 version.

Results: A total of 15 patients were included in the study. The mean age of the patient was 67.53±3.18 years. There were 13 (86.7 %) males and 2 (13.3%) females. The mean duration of gait abnormalities, urinary incontinence, and dementia were8.80 ±3.55, 7.07 ±2.66, and 5.87 ±2.23 months respectively.

Conclusion: Rapid establishment of optimum programmable pressure valve setting improve patient outcome as well as reduce medical cost by preventing over drainage and shortening hospitalization time

Keywords: INPH; Valve setting; Ventriculoperitoneal shunt

Introduction

In 1964,Doctor Salomon Hakim described a syndrome of symptomatic Hydrocephalus with normal cerebrospinal fluid (CSF) pressure.[1] A triad of symptoms: gait disorder, cognitive impairment, and urinary incontinence with communicating Hydrocephalus and normal CSF pressure define the Normal Pressure Hydrocephalus (NPH).[2] Secondary NPH occurs after head trauma, subarachnoid hemorrhage, or other brain insults.[3]When no such predisposing factors are identified, the syndrome is idiopathic NPH (iNPH). [4]

iNPH has reported incidence between 0.5–5.5 cases per 100,000 per year.[5,6,7]The ventriculoperitoneal shunt is the primary treatment in the management of iNPH.The programmable valve shunt is commonly used for NPH nowadays. The valves in programmable shunt are programmed and reset at the bedside, possibly reducing the need for surgical revision. [3] Theoretically, after shunt, there is reduced strain on ventricle walls, better perfusion, and possibly re-establishment of functions. Hemodynamic assessments have shown that this is better in the case of iNPH. [4, 7] The relation between perfusion and function and the growing complexities of the neural network following shunting is another theorized declaration.[5,6,8] Ventriculoperitoneal Shunt may cause under or over-drainage. If the valve pressure is low, excess drainage may tear subdural veins leading to subdural hematoma or hygroma [9-11] .

Aims and Objectives

1) To assess surgical outcome after programmable ventriculo-peritoneal shunt in idiopathic NPH

2) To assess relation of opening pressure of ventricle with surgical outcome and functioning of programmable VP shunt in idiopathic NPH.

Materials and Methods

The prospective observational study was done in the Department of Neurosurgery, GIPMER, for one year after obtaining institutional ethical clearance.

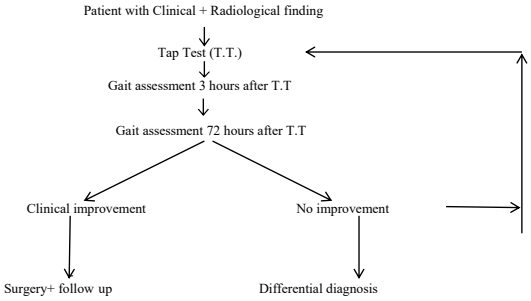
Inclusion criteria: Patient meet diagnostic criteria for idiopathic NPH according to international guidelines for NPH 2008.

Exclusion criteria: Patients with pace maker

Outcome variable: Opening pressure of ventricle, Mini mental state examination score (MMSI), Japanese scale score (JSINPH), Evans index, Callosal angle and Final setting of programmable shunt.

Sample size calculation: As per Convenience, sample size was 15.

Patients with typical clinical features: urinary incontinence, gait disturbance and dementia and compatible image findings suggesting iNPHhad a preoperative assessment which consists of Mini-Mental State Examination (MMSE), Japanese Scale for Idiopathic Normal Pressure Hydrocephalus (JSINPH), Evans ratio and Callosal angle. The MMSE is a test introduced by Folstein in order to evaluate the general patterns of dementia disorders. The JSINPH is a tool to access the patients' clinical background. It measures the three main symptoms in different degrees of presentation, and can be easily performed in the preoperative period and as an evaluation questionnaire and in the follow-up of the patients. Patient then underwent Tap Test (TT) in which 40 ml of CSF was drained by lumbar puncture. Gait assessment was done 3 hours and 72 hours after the T.T.



The patient who had improved gait following tap test underwent ventricular peritoneal shunt (CODMAN) through an externally adjustable magnetic radiopaque with anti-siphoning valve a programmed to different drainage pressure.

After making burr hole, dura was cut and coagulated as per standard method of ventricular tap. In order to prevent initial CSF drainage, a three-way connector (TWC) was attached with the proximal end of Ventricular puncture cannula. TWC was attached to cutter line and the pressure recorded as per illustration [Figures 1,2.]

Figure 1: Cutter line attached to the VP needle.

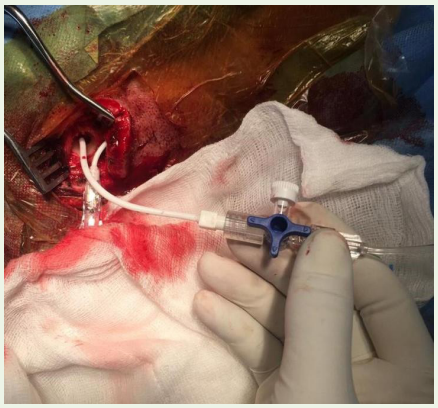


Figure 2: Ventricular end attached to the cutter line.

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The initial valve level was set according to the opening pressure of the ventricle. The MMSE, JSINPH, Evans ratio and Callosal angle were reassessed after 15 days. Patient who had underdrainage or over drainage underwent valve pressure readjustment. Patients were kept in 15 daysfollow up in first three months and then quarterly follow up. The last follow up was done at nine months. The decision of final pressure set point was made based on clinical and radiological outcome variables: MMSE, JSINPH, Evans ratio and Callosal angle.

Data entry and statistical analysis

The collected data were entered in Microsoft Excel. Data were analyzed and statistically evaluated using the SPSS-PC-25 version.

Quantitative data were expressed in mean±standard deviation and depended on normality distribution difference between two comparable groups tested by students' t-test (unpaired) or Mann Whitney'U' test while comparing before and after treatment data Paired t-test or Wilcoxon sign rank test was used. Qualitative data were expressed in percentage. P' value less than 0.05 was considered statistically significant.

Table 1: Opening and final pressure of ventricle in study subjects (N=15)

Ventricle pressure	Opening (N=15)		Final (N=14)	
	No.	%	No.	%
80 mm H_2O	3	20.0	3	20.0
90 mm H_2O	4	26.7	3	20.0
100 mm H_2O	4	26.7	7	46.7
110 mm H_2O	0	0.0	1	6.7
120 mm H_2O	3	20.0	0	0.0
160 mm H_2O	1	6.7	0	0.0

We found that 11 patients had an opening pressure ≤100 mm H_2O and 13 patients had final pressure set at ≤100 mm H_2O. Seven (46.7%) patients had final pressure set at 100 mm H_2O. One patient who had an opening pressure 160 mm H_2Odied during follow up period. So, final pressure could not be set.

Table 2: No. of adjustments done in study subjects after ventriculoperitoneal shunt (N=15).

No. of adjustments	No.	%
No	10	66.7
1	4	26.7
2	1	6.6

In our study, around 33.3% of patients required adjustment. The adjustment was done based on clinico-radiological outcomes.

Table 3: Association of opening ventricular pressure with the need for adjustment (N=15)

	No readjustment	Adjustment	P-value
Mean Opening ventricular pressure(mmH_2O ± SD)	91.0±8.75	122.0±24.90	0.01

The mean opening pressure was 91.0±8.75 in no readjustment group, while the mean opening pressure in the adjustment group was 122.0±24.90 and was statistically significant (p= 0.01).

Results

A total of 15 patients were included in the study. The mean age of the patient was 67.53±3.18 years. There were 13 (86.7 %) males and 2 (13.3%) females. The mean duration of gait abnormalities, urinary incontinence, and dementia were8.80 ±3.55, 7.07 ±2.66, and 5.87 ±2.23 months respectively.

Discussion

Till date, a lot of research work has been done to calculate the reference set point of PPV, but most of them have not been a reliable option. There is a paucity of research work that has shown an association between PPV set point based on opening pressure and clinical and radiological outcomes. There are no specific criteria or consensus made regarding when to call good outcomes and when to call poor outcomes based on clinical and radiological parameters. In our study, we tried to relate ventricular opening pressure to the clinical and radiological outcome, and attempted to define the reference cut to call good or poor clinical and radiological outcomes.

Duration and severity of symptoms were inversely proportional to the clinical and radiological improvement of the patient. In our study, 33.3% of patients required adjustment in the PPV setting, and most patients (7) had final pressure set at 100 mm H_2O. The mean opening pressure was 91.0±8.75 in no readjustment group, while the

Table 5: Outcome after programmable Ventriculoperitoneal shunt (N=14)

	Baseline	At nine months	P-value
MMSE score	20.80±1.61	24.14±1.29	<0.01
Japanese scale score	6.87±1.50	4.43±0.94	<0.01
EVANS index	0.37±0.02	0.28±0.03	<0.01
Callosal angle	82.33±5.93	91.96±7.38	<0.01

Patient with opening pressure between 80 to 100 mm H_2O, mean preop MMSE was 21. Whereas it was less than 20 when opening pressure was above 120 mm H_2O. Following surgery, mini-mental score improved in all 14 cases with mean increase in MMSE score was 2.65±1.20.The Japanese score has improved in all 14 cases who completed the study. The mean decrease in score was 1.92±0.95. The Evans ratio has decreased in all cases who completed the study. The mean decrease in the EVANS ratio was 0.081±0.05.At nine months, the callosal angle has increased in all cases who completed the study following Programmable VP shunt. The mean increase in the callosal angle at nine months duration was 10.62±2.36.All 14 patients who survived had significant clinical and radiological improvement (P<0.01).

In our study, 13 patients had no complication. One patient developed subdural effusion, which was managed conservatively by increasing PPV pressure by 20 mm H_2O.One patient showed no improvement even after two readjustment of ventricular pressure and died.

Table 4: Association of opening pressure of ventricle with MMSE, JSINPH, EVANS and Pre Callosal angle (N=15)

Opening Ventricular Pressure	Preop MMSE	MMSE Difference (9 months- Baseline)	Preop JSINPH	JSINPH Difference (Baseline- 9 months)	Preop EVANS	EVANS Difference (Baseline- 9 months)	Preop Callosal angle	Callosal angle Difference
80 mm H_2O	21.33±1.52	3.0±2.0	6.0±1.0	2.0±1.0	0.36±0.02	0.096±0.051	80.0±10.0	9.33±2.88
90 mm H_2O	21.25±0.95	3.0±0.81	6.75±1.50	2.0±0.81	0.36±0.02	0.07±0.06	82.5±2.88	11.25±2.50
100 mm H_2O	21.50±1.73	2.75±1.50	6.25±0.95	2.25±0.50	0.38±0.01	0.10±0.04	78.75±4.78	13.75±2.50
120 mm H_2O	20.0±0.0	1.67±1.57	7.67±1.53	1.87±0.45	0.36±0.01	0.066±0.015	86.67±2.88	8.33±2.74
160 mm H_2O	17.0	NA	10.0	NA	0.44	NA	90.0	NA

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mean opening pressure in the adjustment group was 122.0±24.90 (p= 0.01). The improvement in both clinical and radiological outcome variables at 9 months were statistically significant (<0.01).

The classic triad of iNPH was present in all our patients while literature showed triad to be in only 33%. [12] We observed gait abnormalities to be the first symptoms to occur, followed by urinary incontinence and then dementia, consistent with the literature data. While there is no level I evidence on shunt surgery, several studies have reported a beneficial outcome after shunt surgery in most selected patients. We performed programmable VP shunt in all our patients after calculating the risk-benefit ratio and PPV setting was done based on ventricular opening pressure.

There are various techniques available in the literature for programmable pressure valve setting. Preoperative CSF dynamics test used by O Tsuji and K Sato in 1998.[13] In 2000, Miyaki et al gave a new concept for the pressure setting of a programmable pressure valve by measuring vivo shunt flow performed using a micro flow meter. [14]A study by Zemack et al in 2002used adjustable valves in normal-pressure Hydrocephalus. In their study, the opening pressure setting was decided based on the patient's age, the duration of the underlying disease, the size of the ventricles, and the curve profile, amplitude, and opening pressure findings derived from a constant manometric lumbar infusion test. In their study, the high (140–180 mm H_2O) opening pressure level was selected to avoid subdural hematomas in elderly patients. [15] In 2008, Miyaki et al concluded QRT which was reliable for reducing over-drainage complications and medical costs. The readjustment rate was 40%. [16] In contrary, the readjustment rate was 33.3% in our study. Kim et alkept initial valve-opening pressures from 30 to180 mm H_2O (mean, 102 ± 27.5 mm H_2O) while we set valve opening pressure based on ventricular opening pressure. There were 154 adjustments in 81 operations (mean, 1.9 times) while only five patients in our study needed readjustment, among which 4 improved after a single adjustment and one patient expired after two adjustments. In Kim's study, around 84% of patients improved completely. There were 18 (22%) major complications: 7 subdural hygroma, six shunt obstructions, and five shunt infections.[17] We had 2 patients who developed complications among whom one patient improved by increasing pressure setting by 20 mm H_2O and one patient died. In 120 patients, Ma and Sharma et al set Medtronic Strata Adjustable Pressure valve set at 1.5.[18] Patients had an adjustment rate of 0.5 per follow-up visit to achieve the best clinical outcome and avoid complications. Out of the improved 71 patients, only 24% improved in all three symptoms while in our study all three symptoms improved in all 14 survived patients. They needed valve pressure adjustment at least once in 85 patients (mean number of 1.68 adjustments). In contrast, only 5 of our patients needed adjustment, among whom four patients improved after a single adjustment. The complications rate was 40% in Ma and Sharma's study, while only 2 of our patients developed a complication. They followed up the patients for up to 19 months while we followed up only for nine months

Our study showed opening valve pressure based on opening ventricular pressure provides a better clue about the final pressure setting in iNPH. Various studies have considered the improvement in MMSE by 4 points, JSI by two scores, final callosal angle (>90 degrees) and Evans index <0.3 to be good outcomes, but none of those literature has compiled all four above mentioned clinical and radiological tools to define the criteria of good outcome in post-operatively. We considered the improvement in MMSE by 3 points, JSI by two scores with final callosal angle (>90 degree)and Evans index <0.3 to a good outcome. Nearly all our patients showed good outcomes. Surprisingly, only 5 out of 15 patients required to readjust the valve pressure.

We followed our patient up to 9 months, unlike other studies that followed their patient for more than a year. The literature has shown that over time these improvements start to regress. Larger studies with longer follow up needed to support our evidence that PPV setting based on ventricular opening pressure is more reliable and effective technique while considering programmable VP shunt in iNPH.

Limitations: Our Study was a single centre study. The sample size was relatively small. The follow -up period of our study was 9 months.

Conclusion

The readjustment rate after setting the initial programmable pressure valve according to opening ventricular pressure is 33%. The factors affecting good outcome in patients of NPH are younger age group, less duration and severity of symptoms, good preop MMSE, less degree of ventricular dilatation. We also concluded that improvement in MMSE by 3 points, improvement in JSINPH score by 2 score, final callosal angle >90 degree and final Evans ratio <0.3 could be considered as good outcome and all these combined reference level could give us idea when to stop readjustment. Rapid establishment of optimum programmable pressure valve setting improve patient outcome as well as reduce medical cost by preventing over drainage and shortening hospitalization time. Larger studies with longer follow up needed to support our evidence that PPV setting based on ventricular opening pressure is more reliable and effective technique while considering programmable VP shunt in iNPH.

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