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Original Research Article

Success rate of electromagnetic navigation system on ventriculo-peritoneal shunt versus standard shunt placement in patients with hydrocephalus

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ABSTRACT

Background: Accuracy of ventriculoperitoneal shunt with the development of frameless neuronavigation in the field neurosurgery has been validated in different parts of the world. The objective of this study was to compare the success of electromagnetic (EM) navigation system on ventriculoperitoneal (VP) shunt versus standard shunt placement in patients with hydrocephalus.
Methods: This randomized controlled trial was carried out in the Department of Neurosurgery, Multan. This study was approved by the Ethical Review Committee of Nishtar Hospital Multan. Study subjects were selected after an informed consent. Patients were grouped as (A) who received EM and (B) who received routine shunt surgery. Patients with shunts were followed up at the end of 3 months and post-operative CT was performed at the end of 3 months. Both groups were compared in terms of success by using chi-square test.
Results: Among 100 study cases, mean GCS was 12.30±1.85 (with minimum GCS was 9 while maximum was 15) and mean duration of hydrocephalus was noted to be 6.80±2.02 weeks. Forty five (45%) were presented with mild hydrocephalus while 55 (55%) presented with moderate hydrocephalus. Grade outcome (post-operative) was noted in 78 (78%) of our study cases, grade 2 in 18 (18%) while grade 3 (failure) was noted in only 4 (4%).
Conclusions: The usage of electromagnetic (EM) navigation on ventriculoperitoneal (VP) shunt is safe and reliable which is beneficial for optimal positioning and trajectory of ventricular catheters in adult patients with hydrocephalus.

Keywords: Electromagnetic navigation, Hydrocephalus, CSF

INTRODUCTION

A hydrodynamic disorder of cerebrospinal fluid that leads to an increase in the volume of fluid in the central nervous system is known as hydrocephalus. The incidence of hydrocephalus is 3 cases per 1000 live births. Adult hydrocephalus represents approximately 40% of the total cases. Computed tomography (CT) scan, X-ray skull, ultrasonography (USG) and magnetic resonance imaging (MRI) are the various tools for the diagnosis of hydrocephalus. The treatment in most of the cases of hydrocephalus is ventriculoperitoneal (VP) shunt which comes in a variety of forms. The most common of them consists of a valve housing the proximal end of which is inserted into the cranial cavity and the distal end into peritoneal cavity. About 80,000 to 100,000 shunts are implanted each year in the developed countries.

Proximal catheter obstruction is known to be the most common cause of malfunctioning of ventriculoperitoneal (VP) shunt followed by infection and disconnection. Optimal position of the catheter tip was focused to reduce potential occlusion of proximal catheter by ventricular parenchyma or choroidal tissues.[1] Many studies have shown that a ventricular catheter tip surrounded by cerebrospinal fluid (CSF) could decrease the risk of shunt failure.[2]

Accurate placement of ventricular catheter is related with both proper insertion trajectory and proper catheter tip positioning. So recently, many studies have validated accuracy in ventriculoperitoneal shunt (VP shunt) with the development of frameless neuronavigation in the field of neurosurgery.[2] The failure rate of ventricular catheter systems remains as high as 30–40% in the first year, leading to a high incidence of shunt removal or revision.[3] Emergency ultrasound (EUS) is further utilized to diagnose acute life-threatening conditions and treat emergency medical conditions.[4] There was also a recent report on the use of emergency ultrasound (EUS) to evaluate for shunt discontinuity, but the study was limited to confined use in the cervical portion of the distal catheter.[5] Hayhurst et al measured that cost of a shunt revision was ten times greater than the cost of a using navigation in their own country.[6]

A study conducted by Raj et al reported that in conventionally treated study group, 66.66% patients revealed grade 1 placement of ventricular end, 26.66% had grade 2 and 6.66% showed grade 3. Neuronavigation study group had 93.33% patients in grade 1 placement while remaining i.e. 6.66% were in grade 2 while on post-operative CT scan.[7]

The results of this proposed study have generated useful database of our local population as there has not been any study conducted in Pakistan on this topic, which would be compared with existing data in literature from different countries. The results will form the basis to employ better treatment modality and hence improving quality of life for the targeted population and decreasing the burden on health authorities at national level.

METHODS

This randomized controlled trial was carried out in the Department of Neurosurgery, Multan, from 15-05-2015 to 15-05-2016. This study was approved by the Ethical Review Committee of Nishtar Hospital Multan. After an informed consent, a total of 100 subjects were recruited and were divided in two groups (50 in each group).

- Group 1: Standard Shunt placement
- Group 2: Neuronavigation

Study subjects were recruited following the inclusion and exclusion criteria.

Inclusion criteria

Inclusion criteria were both genders with hydrocephalus consistent with CT findings as defined in operational definitions; GCS 9 to 15; duration of hydrocephalus more than 2 weeks; age range 20-50 years.

Exclusion criteria

Exclusion criteria were patients with slit ventricles assessed on CT scan brain; previously diagnosed cases of diabetes, hypertension and malignancies (with previous history and medical record); those with revision cases were excluded to minimize selection bias.

Data collection procedure

Patients presenting to the outpatient department of neurosurgery meeting the inclusion and exclusion criteria were enrolled. All patients were divided into 2 groups by using sealed opaque envelope. A third person who was not involved in in study picked one envelope and patients were grouped as (A) who received EM and (B) who received routine shunt surgery. Patients with shunts were followed up at the end of 3 months and post-operative CT was performed at the end of 3 months. Informed consent was taken before surgical procedure. Shunt procedures were performed by neurosurgeons with 5 years of post-fellowship experience. In the standard group, skin incision and trepanation of the cranium was done by using anatomical landmarks like Kocher's point or Frazier's point. Ventricular catheter length was determined based on surgeon's measurement using brain computed tomography (CT) imaging. In the EM group, preoperative data acquisition in 3 planes was obtained by computed tomography (CT) or magnetic resonance imaging. The dynamic reference frame (DRF), a magnetic field detector within the navigational field, was implanted in an area away from the proposed catheter entry site like Kocher's point or Frazier's point. The ventricular catheter was placed over the guiding stylet which the detector coils wrapped around the tip of it. The complex was intended to penetrate the ventricular wall along the planned pathway. A noninvasive dynamic reference frame was applied to the scalp to identify the location of anatomy within the frame of reference. The final outcome or success was measured 3 months post operatively.

Data analysis procedure

Data were entered and analyzed using computer program SPSS-18. Descriptive statistics was employed to determine mean and standard deviation for the age of the patients, duration of hydrocephalus and GCS at presentation. Frequencies and percentages have been calculated for qualitative variables of the study such as (Gender, age groups, severity of hydrocephalus, success and grade system). Both groups were compared in terms of success by using chi-square test. Effect modifiers like age, severity of hydrocephalus, duration of hydrocephalus and genders were controlled by stratification. Post stratification chi-square test was applied to see their effect on outcome. $P \leq 0.05$ was considered as significant.

RESULTS

The current study included a total 100 patients with hydrocephalus meeting inclusion and exclusion criteria. Of these 100 study cases, 53 (53%) were male patients while 47 (47%) were female patients (Table 1).

Table 1: Gender distribution among study cases (n=100).

Gender (n=100)	Group A		Group B	
	Frequency	%	Frequency	%
Male (n=53)	26	52	27	54
Female (n=47)	24	48	23	46
Total	50	100	50	100

Mean age of our study cases was 41.70±5.90 years (with minimum age was 32 years while maximum was 50 years). Mean age of patients in group A was 40.90±6.10 years while mean age in group B was calculated to be 42.50±5.64 years (p=0.177). Our study results have also indicated that majority of our study cases i.e. 85 (85%) belonged to the age group of 36–50 years (Table 2).

Table 2: Age wise distribution of study cases (n=100).

Age groups (n=100)	Group A		Group B	
	Frequency	%	Frequency	%
21-35 years (n=15)	10	20	05	10
36-50 years (n=85)	40	80	45	90
Total	50	100	50	100
Mean (SD)	40.90±6.10		42.50±5.64	
	41.70±5.90			

Table 3: Distribution of study cases by GCS (n=100).

GCS	Group A		Group B	
	Frequency	%	Frequency	%
9-11 (n=40)	20	40	20	40
12-15 (n=60)	30	60	30	60
Total	50	100	50	100
Mean (SD)	12.30±2.02		12.30±1.69	
	12.30±1.85			

Mean GCS was 12.30±1.85 (with minimum GCS was 9 while maximum was 15). Mean GCS in group A was 12.30±2.02 while in group B it was 12.30±1.69 (p=1.00). Mean duration of hydrocephalus was noted to be 6.80±2.02 weeks (with minimum disease duration was 4 weeks and maximum disease duration was 10 weeks). Mean disease duration in group A was 6.60±2.22 weeks while in group B was 7.00±1.80 weeks (p=0.326) (Table 3 and 4).

Table 4: Distribution of study cases by disease duration (n=100).

Disease duration (in weeks)	Group A		Group B	
	Frequency	%	Frequency	%
3–6 weeks (n=45)	25	50	20	40
More than 6 weeks (n=55)	25	50	30	60
Total	50	100	50	100
Mean (SD)	6.60±2.22		7.00±1.80	
	6.80±2.02			

Table 5: Distribution of study cases by severity of hydrocephalus (n=100).

Severity	Group A		Group B	
	Frequency	%	Frequency	%
Mild (n=45)	20	40	25	50
Moderate (n=55)	30	60	25	50
Total	50	100	50	100

Table 6: Distribution of study cases by outcome (n=100).

Outcome	Group A		Group B	
	Frequency	%	Frequency	%
Grade 1 (n=78)	46	92	32	64
Grade 2 (n=18)	04	08	14	28
Grade 3 (n=04)	Nil	NA	04	08
Total	50	100	50	100

*Grade 1 and 2 has been taken as successful outcome.

Table 7: Stratification of gender with regards to outcome in both groups (n=100).

Gender	Outcome	Groups		P value
		Group A	Group B	
Male (n=53)	Grade 1 (n=41)	26	15	0.000
	Grade 2 (n=12)	00	12	
Female (n=47)	Grade 1 (n=37)	20	17	0.087
	Grade 2 (n=06)	04	02	
	Grade 3 (n=04)	00	04	

Forty five (45%) presented with mild hydrocephalus while 55 (55%) presented with moderate hydrocephalus

(Table 5). Grade outcome (post-operative) was noted in 78 (78%) of our study cases, grade 2 in 18 (18%) while grade 3 (failure) was noted in only 4 (4%) of our study cases (Table 6).

Outcome (grading) was stratified with regards to gender (p=0.000 and p=0.087), age (p=0.095 and p=0.018), GCS (p=0.007 and p=0.125), disease duration (p=0.001 and p=0.341) and severity of hydrocephalus (p=0.003 and p=0.208) (Table 7–11).

Table 8: Stratification of age with regards to outcome in both groups (n=100).

Age groups	Outcome	Groups		P value
		Group A	Group B	
20-35 years (n=15)	Grade 1 (n=13)	10	03	0.095
	Grade 3 (n=02)	00	02	
36-50 years (n=85)	Grade 1 (n=65)	36	29	0.018
	Grade 2 (n=18)	04	14	
	Grade 3 (n=2)	00	02	

Table 9: Stratification of GCS with regards to outcome in both groups (n=100).

GCS	Outcome	Groups		P value
		Group A	Group B	
9-11 (n=40)	Grade 1 (n=32)	20	12	0.007
	Grade 2 (n=04)	00	04	
	Grade 3 (n=04)	00	04	
12-15 (n=60)	Grade 1 (n=46)	26	20	0.125
	Grade 2 (n=14)	04	10	

Table 10: Stratification of disease duration with regards to outcome in both groups (n=100).

Disease duration	Outcome	Groups		P value
		Group A	Group B	
3-6 weeks (n=45)	Grade 1 (n=36)	25	11	0.001
	Grade 2 (n=5)	00	05	
	Grade 3 (n=4)	00	04	
More than 6 weeks (n=55)	Grade 1 (n=42)	21	21	0.341
	Grade 2 (n=13)	04	09	

Table 11: Stratification of severity of hydrocephalus with regards to outcome in both groups (n=100).

Severity	Outcome	Groups		P value
		Group A	Group B	
Mild (n=45)	Grade 1 (n=34)	20	14	0.003
	Grade 2 (n=09)	00	09	
	Grade 3 (n=02)	00	02	
Moderate (n=55)	Grade 1 (n=44)	26	18	0.208
	Grade 2 (n=09)	04	05	
	Grade 3 (n=02)	00	02	

DISCUSSION

Historically, the outcome of hydrocephalus used to be appalling: Laurence reported in 1962 a 20% survival rate into adulthood, the surviving patients having generally severe sequels.[8,9] The outcome of hydrocephalic patients has undergone a sea change when shunts were introduced in the 1960s, with most patients surviving the initial phase and growing into adulthood.[10] However, the long-term outcome of children treated for hydrocephalus is poorly documented because most studies available were based on surveys, and thus subject to important selection biases, and involving limited numbers of patients, or very detailed studies with a short follow-up.[11,12]

Shunt malfunction is a permanent risk in patients treated with shunts, carrying risks of both morbidity and mortality. All studies of shunt outcome show similar biphasic survival curves; however, the incidence of very late obstruction is poorly documented in the literature. Late shunt infection is a risk inherent in harboring a shunt, and although surgery is the most common source of infection, contamination sometimes comes from other sources.

Evidence of shunt dependence is provided by the occurrence of symptomatic shunt failure. When a patient who has never been revised before presents with an asymptomatic shunt rupture, the question arises of either a ruptured but still functional shunt or an obstructed shunt in a patient who has become at some point shunt-independent. In any case, a broken shunt in an asymptomatic patient should not be taken as a proof of shunt independence, even with a wide gap between the shunt fragments.[13] Electromagnetic image guidance has been used and studied as a technical adjuvant for assisting placement of ventricular catheters. In a case series by Clark et al published in 2008, prospectively collected data confirmed the feasibility of using EM image guidance, specifically in 23 patients with anatomy that was difficult to navigate, including those with small and slit ventricles or complex loculated hydrocephalus.[14]

Our study included a total 100 patients with hydrocephalus meeting inclusion and exclusion criteria of our study. Of these 100 study cases, 53 (53%) were male patients while 47 (47%) were female patients. A study conducted by Wilson et al reported 54% male patients and 46% female patients with hydrocephalus, these findings are close to that of our study results.[15]

Mean age of our study cases was 41.70±5.90 years (with minimum age was 32 years while maximum was 50 years). Mean age of patients in group A was 40.90±6.10 years while mean age in group B was calculated to be 42.50±5.64 years (p=0.177). Our study results have also indicated that majority of our study cases i.e. 85 (85%) belonged to the age group of 36–50 years. A study conducted by Sampath et al in USA reported mean age of the hydrocephalus patients to be 44.6 years which is close to that of our study results.[16] Another study by Wilson et al also reported 44±20 years mean age of these patients, this mean age is close to our study results.[15]

Mean GCS was 12.30±1.85 (with minimum GCS was 9 while maximum was 15). Mean GCS in group A was 12.30±2.02 while in group B it was 12.30±1.69 (p=1.00). Mean duration of hydrocephalus was noted to be 6.80±2.02 weeks (with minimum disease duration was 4 weeks and maximum disease duration was 10 weeks). Mean disease duration in group A was 6.60±2.22 weeks while in group B was 7.00±1.80 weeks (p=0.326). Forty five (45%) presented with mild hydrocephalus while 55 (55%) presented with moderate hydrocephalus. Grade outcome (post-operative) was noted in 78 (78%) of our study cases, grade 2 in 18 (18%) while grade 3 (failure) was noted in only 4 (4%) of our study cases. A study conducted by Raj et al reported that in conventionally treated study group, 66.66% patients revealed grade 1 placement of ventricular end, 26.66% had grade 2 and 6.66% showed grade 3. Neuronavigation study group had 93.33% patients in grade 1 placement while remaining i.e. 6.66% were in grade 2 while on post-operative CT scan.[7] Sampath et al from USA reported only 1.4% failure rate with electromagnetic (EM) navigation on VP shunt. The findings of Raj et al and Sampath et al are close to our study results which demonstrate EM navigation on VP shunt is associated with significant successful outcome compared with that of standard shunt placement.[16]

CONCLUSION

The usage of electromagnetic (EM) navigation on ventriculoperitoneal (VP) shunt is safe and reliable which is beneficial for optimal positioning and trajectory of ventricular catheters in adult patients with hydrocephalus. The usage of electromagnetic (EM) navigation in routine shunt surgeries can help to eradicate poor shunt placement which may result in a significant reduction in failure rates which will ultimately lead to decrease the proportion of revision. This will help to improve quality of life of our targeted population and also be beneficial for health authorities to decrease prolonged hospital stays and more economic investments. No complications were noted among targeted population.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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