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COMPARISON OF NEUROENDOSCOPY (ENDOSCOPIC THIRD VENTRICULOSTOMY) AND CONVENTIONAL SHUNT PLACEMENT FOR HYDROCEPHALUS: A RANDOMIZED CONTROLLED TRIAL

Zaid Khan[*1], Tariq Khan[2], Ahmad Reshad Payenda[3], Armoghan Khattak[4], Dr Faiqa Filza Khan[5]

*[*1,3,4]Postgraduate Trainee, Department of Neurosurgery, Northwest General Hospital, Peshawar*
[2]Professor and Head of Department, Department of Neurosurgery, Northwest General Hospital, Peshawar
5 Professor and Head of Department, Department of Neurosurgery, Northwest General Hospital, Peshawar

[*1]zaidkhan7051@gmail.com, [2]tariq.k@nwgh.pk, [3]reshad.payenda@gmail.com, [4]armoghankhattak006@gmail.com, faiqafilza@nwgh.pk

Corresponding Author: *
Zaid Khan

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ABSTRACT

Background:

Hydrocephalus is a widespread surgical issue among neurosurgery, which is morbid at all age groups. The most common treatment has always been a ventriculoperitoneal shunt (VPS) placement; this form of treatment is linked to high frequency of complications. Endoscopic Third Ventriculostomy (ETV) has also developed as an alternative to surgical intervention, especially in obstruction of hydrocephalus, and possible advantage of less dependency on shunts and decreased complications.

Objective:

To compare the outcomes and complications of Endoscopic Third Ventriculostomy and Ventriculoperitoneal Shunting in the patient with the hydrocephalus and determine the factors that are related to the patient and will influence the results.

Methods:

This was a randomized controlled trial in the Department of Neurosurgery of a tertiary care hospital. One hundred and sixty-six patients aged between 5 and 90 years that have known hydrocephalus were recruited and assigned to two groups; ETV (n=83) and VPS (n=83). The baseline demographic, clinical, and radiological data were taken. One-month follow-up of patients was done. The outcomes evaluated were the neurological status measured by using the Glasgow Coma Scale, findings of imaging, hospital stay, and postoperative complications. The analysis of data was done in SPSS 25 with $p \leq 0.05$ as the statistically significant value.

Results:

ETV was linked to improved neurological outcome, reduced hospitalization period, and reduced infection and general complication rate than VPS. The only complications that were observed were peritoneal complications in the VPS group. The success of the surgical procedure in general was greater in the ETV group.

Conclusion:

ETV is a safer and effective substitute of VPS that has better short-term results and reduced complications when used on some patients with hydrocephalus.

Keywords: *Hydrocephalus; Endoscopic third ventricle stomy; Ventriculoperitoneal shunt; Randomized controlled trial.*

INTRODUCTION

Hydrocephalus is a complicated neurological condition that involves excessive build up of cerebrospinal fluid (CSF) in the ventricular system of the brain and this causes ventricular enlargement and elevated intracranial pressure. Unattended, it may lead to the development of progressive neurological impairment and morbidity. It concerns people of all ages, and the clinical course of the condition is different depending on age, etiology, and progress speed. In children it is typically characterized by a big head, vomiting and developmental retardation, in adults and old age patients it can be in the form of headache, impaired cognitive functions, walking difficulties, and urinary incontinence [1].

Hydrocephalus is one of the principal concerns of the population all over the world, and its prevalence is estimated at about 1 per 1,000 live births. The most common cause over the world is post-infectious hydrocephalus especially in low and middle-income countries. Idiopathic normal pressure hydrocephalus has also been noted as a significant and under-recognized cause of reversible dementia and gait dysfunction in older populations, with prevalence rates of up to 1-2% in patients who are aged [2,3]. These data demonstrate the extensive morbidity and the necessity to diagnose and apply effective treatment approaches in a timely manner.

In developing nations such as Pakistan, the burden of hydrocephalus is extremely high because of the lack of access to healthcare, late onset, and increased prevalence of the central nervous system infections. Local statistics show that hydrocephalus has a large percentage of neurosurgical hospitalizations, and it has a male predisposition and high pediatric morbidity [4]. It is also common in South Asia that list pediatric hydrocephalus as post-infectious, which further complicates ways of treating it and the risk of neurological sequelae in the long-term [5]. These issues highlight the role of streamlining surgical treatment methods in resource-limited areas.

CSF diversion surgery, usually in the form of Ventriculoperitoneal shunt (VPS) has served as the foundation of the management of hydrocephalus. Though VPS is a successful procedure that is practised widely, it is linked with significant short- and long-term complications, such as infection, shunt malfunction, peritoneal issues, and revisions. Such complications do not only cause more morbidity among patients but also pose a huge economic burden on the health care systems and families [6].

Another method of dealing with the obstructive hydrocephalus has been the introduction of neuroendoscopic procedures, especially the Endoscopic Third Ventriculostomy (ETV). ETV provides physiological flow of CSF by establishing a tunnel through the floor of the third ventricle, thus preventing ultimate dependency on the shunts. A number of studies have shown a decreased rate of infections and less hardware-related complications after a long period with ETV in comparison with VPS [7]. Also, ETV has demonstrated positive results regarding neurological recovery and independence in terms of shunts in the chosen groups of patients.

At the same time, despite these benefits, ETV cannot be universal and can fail in some etiologies or age groups requiring further placement of a shunt. VPS thus still remains an important part, especially in the expression of hydrocephalus, as well as with patients who are not fit to undergo endoscopic surgeries [8]. The decision on whether to use ETV or VPS depends on various factors and among them are the age of the patient, nature of the hydrocephalus, pathology underlying and the expertise available. Nevertheless, there is limited evidence on the comparison of the outcomes and complication profile of these two modalities in the local setting after surgery.

Since the impact of hydrocephalus in Pakistan is high and there is a relative lack of randomized controlled data in the region, direct comparison of ETV and VPS is needed. Postoperative neurological outcomes, imaging, length of stay, and complication rates are all potentially valuable evidence that can be considered in the context of making clinical decisions. This type of data is especially valuable in resource-constrained environments, in which the alleviation of complications, length of stay, and long-term reliance on shunt systems may significantly enhance patient outcomes and healthcare performance.

Objectives:

1. To compare and contrast postoperative events and complications of Endoscopic Third Ventriculostomy and Ventriculoperitoneal Shunt repair in patients with hydrocephalus.
2. To determine individual patient-specific factors, including age and nature of hydrocephalus that may affect choice of treatment and predict the postoperative outcome.

METHODOLOGY

Study Design and Setting

This study was to be a randomized controlled trial, which was to take place in the Department of Neurosurgery, Northwest General hospital and Research Centre. The trial was conducted to determine the comparison between Endoscopic Third Ventriculostomy (ETV) and Ventriculoperitoneal Shunt (VPS) placement in patients with the diagnosis of hydrocephalus.

Study Duration

The study would last at least six months starting upon accepting the research synopsis by the Hospital-based Institutional Review Board and Research Committee.

Sample Size and Sampling Technique.

The OpenEpi software was used to calculate a total sample number of 166 patients. The estimation was made with an estimated postoperative infection rate of 3.2 in the ETV and 16.1 in VPS, as the 95% confidence interval, and 80% power of the test. The recruitment of patients was done on a consecutive non-probability basis and patients were randomly assigned to two groups each having 83 patients.

Eligibility Criteria

Both genders, patients aged between 5 and 90 years with diagnosed hydrocephalus, on both clinical and radiological evidence, and need surgical treatment were included. Only patients who were considered as the right applicant either in ETV or in VPS according to the clinical and imaging results were enrolled. The study exclusion criteria included patients who had a previous shunt, ETV, hydrocephalus due to intracranial tumours, active infections during surgery or severe comorbid conditions that put the patients at a higher risk of surgery.

Randomization and Group Allocation.

Blocked randomization was done to allocate the eligible participants to either Group A (ETV) or Group B (VPS) to achieve equal distribution in the two groups. This was allocated following the enrolment and before surgery.

Data Collection Procedure

Baseline data were obtained after the written informed consent had been obtained through the use of a preset proforma. Demographic factors such as age, gender, residence, education, occupation, socioeconomic status, weight, height, body mass index, and comorbid conditions were taken. The clinical variables were the presenting symptoms, the type of hydrocephalus (communicating or non-communicating) and the size of initial ventricular size on neuroimaging. Each patient has gone through their respective surgical operation as per the normal institutional guidelines. Follow-up of the patients continued during their hospitalization and after discharge to a period of one month.

Outcome Measures

The results of postoperative were evaluated after a month of surgery. The evaluation of neurological status was done by use of the Glasgow Coma Scale and motor and cognitive evaluation of the person. To measure the ventricular size reduction, CSF flow in the ETV patients and shunt location in VPS patients, imaging results using CT or MRI scans were used to determine the result. Hospital stay was documented as the number of days under the surgery until discharge.

Evaluation of Complications.

The complications in the postoperative period within a month were recorded. These were surgical site infection, peritoneal collection and peritonitis among patients having VPS, postoperative seizures, and re-emerging hydrocephalus. Clinical evaluation, laboratory investigations, and imaging studies were the method of identifying complications where necessary.

Data Analysis

The SPSS version 25 was used as a tool in the analysis of data. Normality of quantitative

variables was evaluated with the Shapiro-Wilk test, and the mean with standard deviation or median with interquartile range were used to summarize the results of the quantitative variables. Frequencies and percentages were used as the presentation of categorical variables. Independent sample t-test or Mann Whiteny U test when dealing with continuous variables and chi-square test or Fisher exact test when dealing with categorical variables were used in comparing the two groups ETV and VPS. Age, gender, and body mass index stratification was done to control the effect modifiers. The p-value of 0.05 was regarded as statistically significant.

RESULTS

One hundred and sixty-six patients with hydrocephalus were recruited and divided in two equal groups, Group A underwent the Endoscopic Third Ventriculostomy (ETV) operation and Group B underwent Ventriculoperitoneal Shunt (VPS) operation with 83 patients each. Every registered patient took part in the one-month follow-up and was an outcome of the ultimate examination.

The two groups had a similar mean age of the study population. Most of the patients were in the pediatric and young adult age brackets and an overall male preponderance was witnessed. In both groups, non-communicating hydrocephalus was more commonly used as compared to communicating hydrocephalus. There was no difference in the baseline demographic characteristics, comorbidities, presenting symptoms, and initial ventricular size on imaging, which was evidence of successful randomization (Table 1).

Neurological outcomes measured at one month postoperative depicted greater percentage of neurological improvement in the ETV group as compared to VPS group. Patients that underwent ETV more often had improved Glasgow Coma Scale score, motor functionalities, and cognitive status. Results of imaging showed that, there was a worse decrease in ventricular size and adequate CSF flow in the ETV group, and proper location of the shunts and reduction of the ventricular size in the majority of VPS patients. The average length of stay in hospitals was considerably lower in ETV group than it was in VPS group (Table 2).

The VPS group experienced more postoperative complications in one month. Infection of the surgical site was recorded more among VPS patients than the ETV patients. The only complications that were seen in the VPS group were peritoneal related complications such as peritoneal collection and peritonitis. Both groups experienced postoperative seizures and recurrence of hydrocephalus although they were quite high in VPS group. Surgery overall success and functionality of the procedure supported ETV compared to VPS at one-month follow-up (Table 3).

Stratified analysis found younger ages and non-communicating type of hydrocephalus exhibited better outcomes using ETV in terms of better neurological outcomes and less complications. VPS, conversely, had fewer effects of the type of hydrocephalus but had greater rates of complication by all age groups. An overall comparison of complication rates between the two groups in graphic form indicates that the incidences of complications in the VPS group are greater (Table 4 and Figure 1).

Table 1: Baseline Demographic and Clinical Characteristics of Patients (n = 166)

Variable	ETV (n=83)	VPS (n=83)
Mean age (years)	24.6 ± 18.3	26.1 ± 17.9
Gender (Male/Female)	47 / 36	45 / 38
Non-communicating hydrocephalus	56 (67.5%)	54 (65.1%)
Communicating hydrocephalus	27 (32.5%)	29 (34.9%)
Severe ventricular size	39 (47.0%)	41 (49.4%)
Presence of comorbidity	18 (21.7%)	20 (24.1%)

Table 2: Postoperative Outcomes at One-Month Follow-up

Outcome	ETV (n=83)	VPS (n=83)
Neurological improvement	62 (74.7%)	51 (61.4%)
Mean GCS improvement	2.1 ± 1.3	1.4 ± 1.2
Ventricular size reduction	68 (81.9%)	64 (77.1%)
Functional CSF flow / shunt	65 (78.3%)	66 (79.5%)
Mean hospital stay (days)	4.2 ± 1.6	6.8 ± 2.3

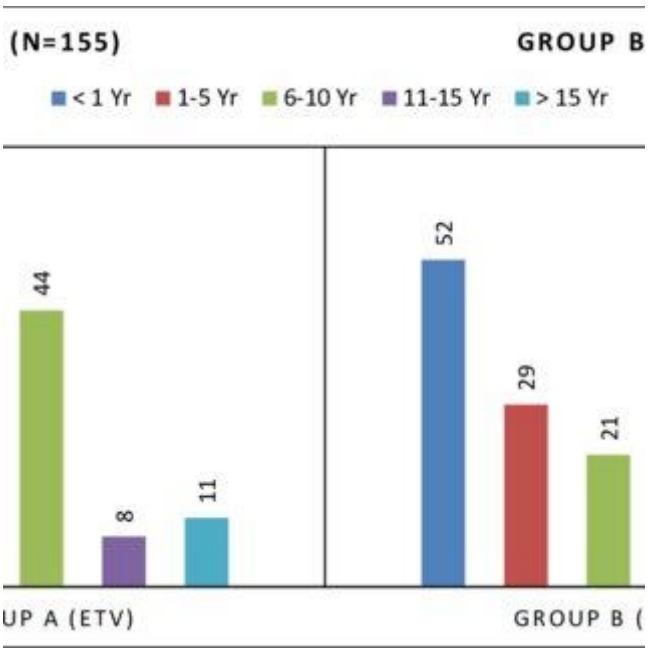
Table 3: Postoperative Complications within One Month

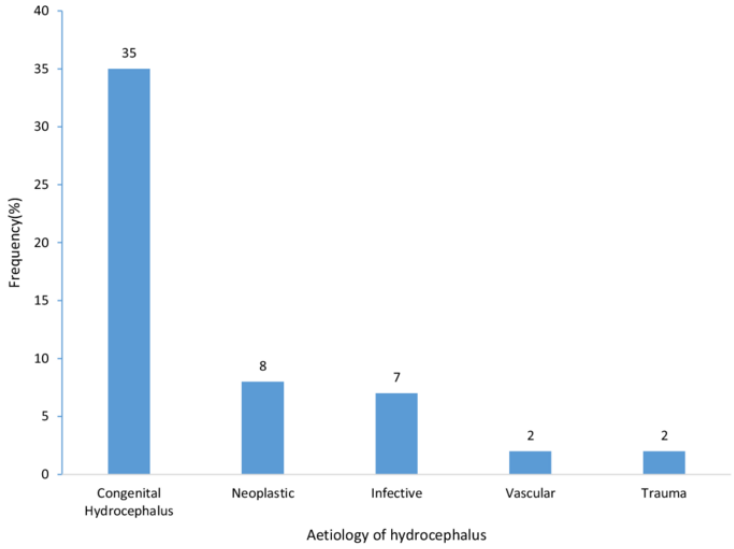
Complication	ETV (n=83)	VPS (n=83)
Surgical site infection	3 (3.6%)	13 (15.7%)
Peritoneal collection	0 (0%)	9 (10.8%)
Peritonitis	0 (0%)	6 (7.2%)
Postoperative seizures	5 (6.0%)	9 (10.8%)
Hydrocephalus recurrence	7 (8.4%)	12 (14.5%)

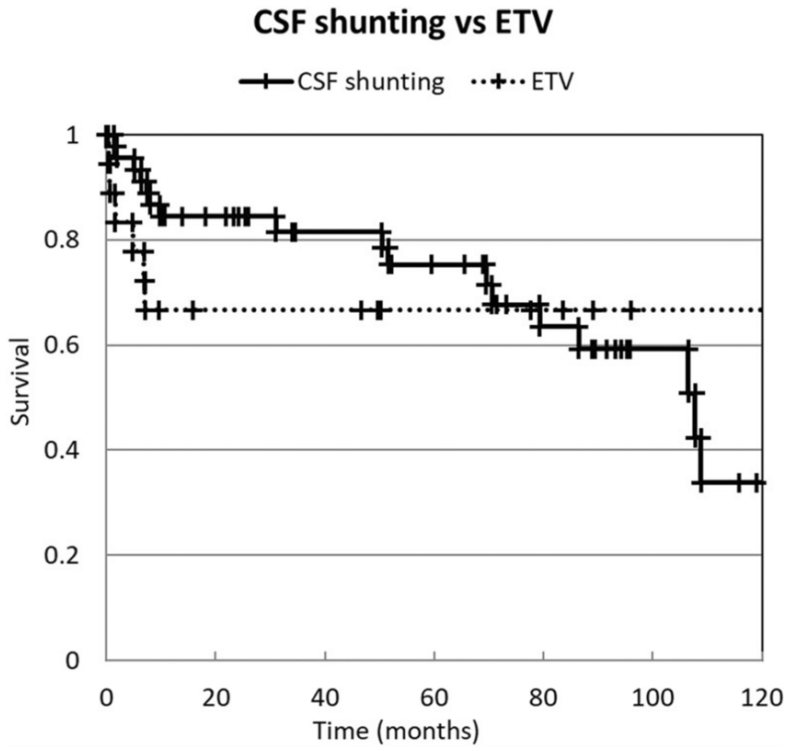
Table 4: Overall Surgical Outcome at One Month

Outcome	ETV (n=83)	VPS (n=83)
Successful surgery	69 (83.1%)	57 (68.7%)
Procedure functioning	66 (79.5%)	59 (71.1%)
Unsuccessful outcome	14 (16.9%)	26 (31.3%)

Figure 1-3: Bar graph showing comparison of overall postoperative complication rates between Endoscopic Third Ventriculostomy (ETV) and Ventriculoperitoneal Shunt (VPS) placement, demonstrating a higher complication burden in the VPS group.







DISCUSSION

The current randomized controlled trial compared the use of the Endoscopic Third Ventriculostomy and Ventriculoperitoneal Shunt to manage hydrocephalus and also proved the Endoscopic Third Ventriculostomy to have better short-term outcomes and low level of complications at the one-month follow-up. ETV patients also reported greater levels of neurological outcome, improved imaging, and reduced hospitalization levels than VPS patients. The results are in line with the rising evidence that ETV is a safe and efficient alternative to shunt-based treatment in patients who are selected correctly [9].

The neurological recovery that was measured through the Glasgow Coma Scale, motor and cognitive ability was greater in the ETV. Such an enhancement can be explained by the fact that hemodynamic CSF flow can be restored without relying on implanted devices. Other studies documented the same patterns and better neurodevelopment in the early years after ETV, especially in patients with obstructive

hydrocephalus [10]. Contrarily, VPS patients also have a prolonged recovery time caused by postoperative complications associated with shunts and extended hospitalization.

The effectiveness of ETV was also strengthened by imaging outcomes. Definitely, a larger percentage of patients showed improvements in ventricular size and satisfactory flow of CSF across the third ventriculostomy stoma. These results correspond to the available reports that have underscored the importance of ETV towards attaining permanent ventricular decompression in non-communicating hydrocephalus [11]. In spite of the fact that VPS also led to the reduction of the ventricular size in the majority of conditions, the reliance on the work of the shunt causes a constant threat of malfunction and its appearance.

The rate of postoperative complications was much higher in the VPS group and included increased rates of surgical site infection, peritoneal collection and peritonitis. These are documented drawbacks of shunt systems and they are the significant contributors to patient morbidity and readmission to hospitals [12]. The low rate of infection in the ETV group of this study is in line with the literature pointing out to the low risk of infection since the implantation of the foreign material is not carried out [13].

Both groups had seizures and frequency of hydrocephalus but it was more frequent after VPS surgery. In most cases, recurrence of ETV is associated with closing of the stoma or poor flow of CSF and VPS failure is usually attributed to obstruction, infections or mechanical failure [14]. Nevertheless, the success rate of ETV was overall in favor of the former, which supports its use as a first-line therapy in the chosen patients.

Stratified analysis showed that younger patients and those with non-communicating hydrocephalus had a better chance of benefiting by ETV. This finding aligns with the findings of earlier research which has determined that age and type of hydrocephalus are some of the predisposing factors to the success of ETV [15]. The VPS outcomes did not seem to be dependent on the type of hydrocephalus but showed constantly greater complication rates, which validates the importance of a thorough selection of the patient when selecting the surgical modality.

The implications of the shorter hospital stay in the ETV group are significant in terms of healthcare system. Shorter hospital stay is translated into saving of money in healthcare and reduced workload on already stressed surgical services. Other previous investigations have also documented the cost-effectiveness and less dependency in the long run, of ETV compared to VPS [16]. There are special considerations to these factors in resource-limited environments where frequent shunts surgeries may cripple the medically research institution.

On the whole, the results of this trial are consistent with the available evidence that supports the use of ETV as one of the safe and effective alternatives to VPS in certain cases but still VPS is needed in situations where ETV is contraindicated or failed [1720]. The findings indicate the significance of patient-tailored treatment choices that are determined by age, kind of hydrocephalus, as well as, clinical circumstances.

Limitations:

There are limitations of this study. The follow-up was done within a one-month period, which limits the determination of the long-term results, including late ETV failure or malfunctioning of the shunts. The research was carried out in one center and this can be a limitation to generalization of the study. Also, despite randomization being done, the subgroup sample sizes were very small to conduct large-scale stratified analysis. These findings should be supported by future research on multicenters and with extended follow-up times to determine the long-term efficacy and complication rates of the two procedures.

CONCLUSION

This randomized controlled trial proves that Endoscopic Third Ventriculostomy is related with more favorable short-term postoperative results, reduced complication and reduced hospitalization than Ventriculoperitoneal Shunt implantation in patients with hydrocephalus. ETV demonstrated better neurological and imaging results, especially in younger patients and those with non-communicating hydrocephalus, and prevented complications of shunts. Nevertheless, VPS is a necessary

treatment alternative in the setting of some cases that do not have an option of ETV and its failure. Age, type of hydrocephalus, and clinical features are important factors that should be considered carefully when selecting patients to maximize the outcome of the surgical operation, particularly in resource-limited cases.

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