REVIEW OF TYPES OF CSF DIVERSION AND THEIR OUTCOME IN PATIENTS WITH POSTERIOR FOSSA TUMOUR AND HYDROCEPHALUS

Submitted for M.ChNeurosurgery By

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DEPARTMENT OF NEUROSURGERY

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The thesis titled, "***REVIEW OF TYPES OF CSF DIVERSION AND THEIR OUTCOME IN PATIENTS WITH POSTERIOR FOSSA TUMOUR AND HYDROCEPHALUS*** " was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

*Clearance was obtained from the Institutional Ethics Committee of this institute(IEC-1787/2021) for carrying out the study.

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APPROVAL OF THE THESIS

The thesis titled

REVIEW OF TYPES OF CSF DIVERSION AND THEIR OUTCOME IN PATIENTS WITH POSTERIOR FOSSA TUMOUR AND HYDROCEPHALUS

Submitted by

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Dr. Darshan H R

REVIEW OF TYPES OF CSF DIVERSION AND THEIR OUTCOME IN PATIENTS WITH POSTERIOR FOSSA TUMOUR AND HYDROCEPHALUS

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DECLARATION

This thesis titled - REVIEW OF TYPES OF CSF DIVERSION AND THEIR OUTCOME IN PATIENTS WITH POSTERIOR FOSSA TUMOUR AND HYDROCEPHALUS is a consolidated report based on a bonafide study of the period from March 2020 to July 2022, done by me under the Department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram.

This thesis is submitted to SCTIMST in partial fulfillment of rules and regulations of the MCh Neurosurgery examination.

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INTRODUCTION

Posterior fossa tumors form a substantial bulk of tumor burden in children. In adults though the incidence is lower to that of the children. In sheer numbers paediatric population has about 54-70% of the tumour burden in posterior fossa whereas in adults its about 15-20%.[1,2] Hydrocephalus in paediatric posterior fossa tumors has an incidence of as high as 70% and most of it is obstructive in nature.[3] In adults though the incidence of hydrocephalus is about 18-42% in patients with Cerebellopontine lesion.[4-7] Debates regarding the need for emergency drainage vs elective drainage, preoperative drainage vs intraoperative drainage and also the need for permanent CSF diversion in these cases is ongoing till date.

Gopalakrishnan et al[8] in their study noted that about less than 1/3rd of the children with posterior fossa tumors required permanent CSF diversion where as Lin et al[9] in their review found a varying incidence of 10-40% of children with persistent hydrocephalus after resection. During early 2000s a routine Endoscopic third ventriculostomy was practised in many centres which was then deemed not completely necessary by many studies including the one by Bognar et al.[10] On the contrary ETV has been mentioned by some studies as a viable option in management of hydrocephalus in adults with Cerebellopontine lesions.[11-14] Due to the high burden of these tumors and the need for surgery for a satisfactory outcome, the factors affecting the outcome especially hydrocephalus needs to be studied in detail in order to provide a better outlook at the treatment

protocol for these tumours. The study will provide a view on the incidence of hydrocephalus in these cases, the different procedures which were employed in treatment of hydrocephalus and predictive factors for evolution of post resection hydrocephalus in patients undergoing the surgery for posterior fossa tumours

REVIEW OF LITERATURE

Hydrocephalus:

Hydrocephalus is essentially a condition in which excess of cerebrospinal fluid is accumulated in the ventricular system.[15] This leads to increase in Intracranial pressure and thus causing various manifestations of pressure dynamics are of utmost importance in the cranial cavity which is essentially a non-pliable black box.[16] Essentially 3 components are found in the skull cavity namely:

1. Brain tissue
2. Blood (Arteries and Veins)
3. CSF (Ventricular system)

Munro Kellie Doctrine[17]:

Named after Alexander Monro, physician and George Kellie, surgeon from Scotland, the Munro- Kellie Doctrine explains the complex volume pressure dynamics in the skull[17]. The relationship between pressure and volume is of utmost importance and is the basis of the Munro-Kellie hypothesis. This relationship essentially strives to achieve a dynamic equilibrium within the skull among important non-compressible components.[18-20]

The average intracranial total volume in an adult skull is around 1700ml. The brain tissue contributes around 1400 ml and CSF and blood of about 150 ml each.[21] Since skull is a rigid space the volume of these 3

components is essentially in a state of constant dynamic equilibrium. The changes in pressure in due to one component will eventually lead to changes in the other two as a compensatory effect. Thus, for example an increase in brain tissue in form of tumour will cause decrease in CSF volume and also Blood volume to maintain the pressure equilibrium[22]. It is also of importance to note that most of the blood volume in cranial cavity is in the low-pressure venous system. Hence compression of venous sinuses can displace substantial amount of blood.

Since the skull is a non-pliable and unyielding structure, any increase in one of these components will increase the pressure and also decrease the other component. Hence when CSF increases in the ventricular system, blood flow reduces to the brain and also herniation of brain tissue ensues. Numerous definitions of hydrocephalus have been proposed through literature[23], most of them are related to the disruption of CSF flow physiology itself.

History:

Hydrocephalus has been defined from ancient times itself. Hippocrates and Claudius Galen talked about fluid accumulation in the cranium.[24] Most of the initial study of hydrocephalus was based on children who had a large head on birth. However the first description of hydrocephalus was given by

Rhazes.[25] The first morphological description as well as the damage of the brain parenchyma was explained by Andreas Vesalius.[26]

It was Thomas Willis[27] who helped us understand In detail about the ventricular system as well as the CSF pathways.He was the one who identified the choroid plexus at the site of CSF production and also introduced the concepts of venous absorption through the arachnoid granulations. With these foundations it was Key and Retzius[28], who established our modern understanding of CSF circulation**.** Further Walter Dandy gave us through his experimental studies the differentiation between obstructive and communicating hydrocephalus.[29-31]

CSF Flow Physiology:

CSF flow Physiology is an intricate balance between its production and absorption. Even though 450 to 500ml of CSF is produced every day only about 150 to 170ml remains in the ventricular system circulation.[32] Thus emphasizing the importance of the absorption system which is responsible for maintaining the amount of CSF in the ventricular system. About 80% of daily CSF production is from the choroid plexus. A small portion however can be produced from the ependyma and the brain parenchyma.[33] This CSF which is largely produced in the lateral ventricles is in the circulation through the lateral ventricles into the third ventricle and exits through the Foramen of Magendie and Foramen of Luschka.

This circulatory CSF is absorbed through various mechanisms. Although direct absorption from brain parenchyma and lymphatic channels has been postulated, the absorption through the arachnoid villae in the superior sagittal sinus is the most important mechanism[34]. Hence any disturbances in either production or absorption of the CSF leads to formation of hydrocephalus.

Classification:

Hydrocephalus has been classified based on their etiology and many other factors but the most useful classification remains that of it being either an obstructive or a communicating. [31]

Obstructive Hydrocephalus as the name suggests is when there is an obstruction to the flow of CSF either in the lateral ventricles, the foreman of Munroe, the third ventricle, the aqueduct of sylvius, the 4th ventricle or the subarachnoid spaces. The obstruction can be internal in the ventricular system or an external which is causing the compression over the ventricular system and hence the flow of the CSF itself.[35,36]

Communicating hydrocephalus is either caused by overproduction of the CSF as in choroid plexus tumors or due to disturbances in the absorption. The blockage of the arachnoid villi can be either caused by blood products

or infective agents or cellular material. Hence in this type of hydrocephalus a surgically remediable cause is usually absent.[35,36]

Posterior Fossa Tumours

Anatomy:

Of the three cranial fossae of the skull, the posterior fossa is the largest and the deepest. Even though it forms approximately 1/8 of the intracranial space, the centers which are regulating, consciousness vital autonomic functions, the pyramidal tracts, the sensory tracts and also the Centers for control of balance and gait are all situated in the posterior cranial fossa. 10 of the 12 cranial nerves either arise in the posterior fossa or have a segment traversing through the posterior cranial fossa.[37-41]

The posterior fossa is also intricately associated with the ventricular system, i.e., 4th ventricle, foramen of magendie, foramen of luschka and the CSF outlet into the spinal cord. It essentially extends from the tentorial surface to the foramen of magnum. Through the tentorial incisura it communicates with the supratentorial space and through the foramen of magum it communicates to the spinal cord. The occipital temporal, parietal and sphenoid bones surround the posterior cranial fossa forming its boundaries. It is bound anteriorly by the dorsum sella, the posterior part of

the sphenoid body and the clivus of the occiput. Posteriorly it is bound by the squamous part of the occipital bone. Laterally the petrous and the mastoid parts of the temporal bone and a small part of the occipital bone which extrudes laterally forms its lateral boundary.

The tentorial surface of the posterior cranial fossa is by far the one of the most important surfaces. It is formed by the vermis as well as the cerebellar hemispheres laterally. The tentorial surface is in relation to the tentorial incisura which is a non-yielding structure. Further the brainstem passes through this tentorial incisura from the supratentorial fossa to the posterior fossa. The oculomotor nerve, the abducent nerve and various venous structures are related to the tentorial incisura. These relations are of particular importance when studying the herniation syndromes of the brain due to increased intracranial pressure.[42]

The suboccipital surface of the posterior fossa is composed of the cerebellum as well as the cerebellar tonsils. This surface is also in close relationship with the 4th ventricle as well as the Cisterna Magna and the outlet of the posterior cranial fossa into the spinal canal. The medullary cervical junction is present at this outlet and hence the presence of vermis and its relationship with the medulla is important.[37,38]

The petrous or the anterior surface lies in relationship with the posterior surface of the petrous bone the brain stem and the 4th ventricle. It is here

that we find the cerebellopontine angle which is defined by the cerebellopontine fissure. Posterior fossa essentially has three fissures namely the cerebello-mesencephalic fissure which is associated with the upper ventricular roof, the cerebello-medullary fissure associated with the lower roof and the cerebello-pontine fissure associated with the lateral recess.[41]

The posterior fossa also contains important vascular structures such as the vertebral arteries, the basilar artery and its branches to the brainstem as well as the cerebellum.[43,44]

Cerebellopontine Fissure:

As described the cerebellopontine fissure is related to the Petrosal surface of the temporal bone. The floor of the fissure is formed by the middle cerebral peduncle. And the Pons is related closely to its medial surface. The trigeminal nerve, the abducent nerve, the facial nerve, the vestibulocochlear nerve and the lower cranial nerves arise between the superior and the inferior limbs of this cerebellopontine fissure. The internal auditory meatus in the petrous surface of the temporal bone is stable landmark and provides exit for 4 nerves namely the facial the cochlear and the superior and inferior vestibular nerves. The anterior inferior cerebellar artery is in close relationship to the facial and vestibulocochlear nerves. Hence lesions in this area can cause multiple cranial nerve palsies, involvement of the

descending tracts and hydrocephalus due to distortion of the ventricular system.[39,40]

Tumours:

Tumors of the posterior fossa are the most common tumors encountered in the pediatric population. But significant incidence of posterior fossa tumors in adults is also seen. Cerebellopontine angle lesions can also be included in posterior fossa tumors due to their anatomical location. Various tumors have been describing to be occurring in the posterior fossa namely

1. Medulloblastoma
2. Ependymoma
3. Hemangioblastoma
4. Pilocytic astrocytoma
5. Brainstem glioma
6. Vestibular schwanoma
7. Jugular foreman lesions
8. Meningioma
9. Epidermoid cyst
10. Metastisis etc

Clinical presentation:

Apart from causing a myriad of symptoms such as multiple cranial nerve palsies, Symptoms due to involvement of the descending and ascending tracts of the brainstem, balance and gait disturbances due to cerebellar involvement, the most common manifestation of these tumors is hydrocephalus. This is primarily due to the close relationship of the ventricular system with the anatomical structures in the posterior cranial fossa.

- Truncal ataxia and hypotonia are frequently seen symptoms in posterior fossa tumors.[45] The absence of cerebellar inhibitory and modulatory influences the bodily movements and they become inaccurate and poorly controlled.[46] Hypotonia is usually seen in cerebellar lesions whereas increase tone can be seen in tumors involving the brainstem and descending pathways.[47,48]
- Tremor- one of the most major feature of cerebellar disease is a tremor which appears on action, hence called intention or action tremor. These tremors may arise either by a lesion in the cerebellum or an extra axial lesion causing compression on cerebellum. Occasionally truncal tremors can also occur.[49,50]
- Multiple cranial nerve palsies- A tumor in the cerebellopontine angle or the brainstem can cause involvement of multiple cranial nerves. Hearing loss, facial asymmetry, tinnitus, facial paresthesia or

numbness, dysphagia, diplopia etc all are possible symptoms in a tumor in the posterior fossa.[51-55]

- Headache- One of the most common symptoms in patients with posterior fossa be it adults or children. Usually, it is insidious and intermittent in nature, which is severe in the morning because of intracranial pressure increase.[56] In smaller children the headache can be represented by irritability and difficulty to be handled. This headache can be associated with nausea and vomiting.[57,58] Vomiting is due to two mechanisms in posterior fossa. It can either signify an increased intracranial pressure or the irritation of the area postrema in the 4th ventricle due to the mass.[59]
- Nystagmus- Nystagmus in the posterior fossa tumor can either be gaze evoked or spontaneous. Multiple types of nystagmus can occur a patient with posterior fossa tumour. The nystagmus can be either due to involvement of ipsilateral cerebellum due to involvement of the gaze control centres in the brainstem.[60,61,62]

These patients are particularly predisposed to development of the hydrocephalus due to disruption of the CSF flow pathway. About 70 to 80% of children[2] can present with hydrocephalus and its ensuing symptoms due to increased intracranial pressure when having a posterior fossa tumor. Also the incidence of hydrocephalus with cerebellopontine lesions is reported to be around 3.7 to 42%.[5,63,64] Although the main mechanism for

formation of hydrocephalus in a posterior fossa tumor within children or in adults is mainly the obstruction of the CSF pathway, various other mechanism and etiological factors for the formation of the hydrocephalus especially in patients with cerebellopontine lesions has been described.[65] Large tumor size and its midline location can be a predisposing factor for an obstructive hydrocephalus,[66-69] Protein concentration in CSF is also being stated as the etiopathological factor for developmental hydrocephalus especially in cases of vestibular schwannomas.[64,70]

Post resection Hydrocephalus:

Apart from presentation as hydrocephalus in Posterior fossa tumors, post resection hydrocephalus is an important entity for the operating surgeon. Post resection hydrocephalus can either present early in the course of the postoperative period or during the follow up. Late hydrocephalus can also be usually due to tumor recurrence and radiation induced changes.[71]

The incidence of post resection hydrocephalus is not the same between children and adults. It is usually higher in children when compared to adults. Various studies have documented the incidence in adults to as low as 1.6%[72] whereas in children as to 10 to 40%.[3,10,73-76] Most reception hydrocephalus being in itself an emergency condition can also increase risk of wound gaping, CSF leak, pseudomeningocele, prolonged hospital stay

and need for redo surgery.[77] Most of patient with hydrocephalus with posterior fossa tumor are thought to be obstructive.

Hence, it's logical to think that post resection the hydrocephalus is usually relieved, since the obstruction to the CSF flow which was present in form of the tumor has been relieved. But most of the cases, this does not happen. Various studies have been performed to understand the exact reason for the persistence of hydrocephalus after the resection of posterior fossa tumor. It is thought to be multifactorial influence in the persistence.[72,75.76,78] In a study by Kombogiorgas et al[79] the preoperative ventricular volume versus the postoperative ventricular volume was studied. The rate of reduction of this volume was correlated with the need of postoperative ventriculoperitoneal shunt. It was noted that there was no significant difference between the rate of reduction in the ventricular volume between patients who needed post operative ventricular shunt when compared to the ones who did not need a shunt. Thus, giving importance to one of the concepts which has been studied for decades now i.e., a component of communicating hydrocephalus is present in these patients. Cabanes et al[80] demonstrated abnormal CSF flow in basal cisterns using a radioisotope study in these patients and thus suggesting that post resection hydrocephalus maybe a communicating Hydrocephalus. Hence the concept of adaptation period was introduced to identify the interim time period

Between the resection of the tumor and restoration of the CSF flow pathway. To aid this concept the study by Bateman et al[81] demonstrated the relationship between the venous sinus cross sectional area and hydrocephalus. In this study the ventricular volume as well as the cross-sectional area of venous sinus was recorded both preoperatively as well as postoperatively via multiple scans. Following the Kelly Monroe Doctrine preoperatively there was about 70% decrease in the area of the venous sinus, essentially due to the increase CSF as well as the presence of the tumor. Post operative MRI revealed that the normal cross-sectional area of this sinus did not resume up to several weeks after surgery. Thus, suggesting that the ventriculomegaly which occurs post resection is due to the disturbance of absorption rather than and obstruction. Even a study by Nishiyama and colleagues[82] demonstrated that the restoration of Arachnoid granulations and hence the CSF absorption through these granulations take significant amount of time after tumor resection.

Management of Hydrocephalus in patients with Posterior Fossa tumours

Historically patients with posterior fossa tumours used to present with a delayed diagnosis and poor clinical state. In these patients a preoperative shunt was performed to reduce their overall mobility and mortality rates.

Most of these patients were not operated for the tumour. And those patients who were operated, almost 40% of them ended up with the postoperative shunting within a month of surgery.[83,84] With improvements of imaging modalities, Early diagnosis of the posterior fossa tumors ensued. Preoperative CSF diversion in the form of insertion of ventriculoperitoneal shunt remained popular for two reasons. One, to reduce the morbidity and mortality associated with the Acute hydrocephalic attack and secondly as a palliative step in patients whom surgery was not deemed plausible.

This practice was further bolstered by various studies who demonstrated the increased risk associated with post resectional hydrocephalus i.e, CSF leak, pseudomeningocele formation, CSF infection due to EVD placement and prolonged hospitalisation.[77] Also several other advantages were documented such as

1. Decrease in mortality- 12.8% versus 3.7% in patients without preoperative shunt versus patients with preoperative shunt.[85]
2. More than 80% reduction in papilledema[86]
3. Decreased rates of CSF leak and pseudomeningocele

But the pre operative insertion of VP shunt did not come without its own drawbacks and disadvantages. Surgery in itself is a risk factor put infections. CSF shunt are known for their failure rates. One study documenting as high as 38% within the first two years of surgery.[87] Since

most of these patients were growing children the shunt failure rates were high. Also, the shunt complications such as hardware malfunction, overdrainage, infection, obstruction, visceral perforation are well documented. A study by Tuli et al[88] where predictors of death in paediatric patients requiring VP shunts was studied, it was found that shunt infections was an independent predictor of death in these patients. Also, the risk of intratumoral haemorrhage and reverse herniation he is well documented in patients who undergo preoperative ventriculoperitoneal shunt.[89] And with time and improvement in the imaging as well as surgical techniques, there was a drastic improvement in the outcome of the patients with posterior fossa tumours. Thus, with significant morbidity which is caused by the ventriculoperitoneal shunt, most surgeons abandoned the essential practice of insertion of ventriculoperitoneal shunt preoperatively in these patients.

External Ventricular drainage:

Since only a fraction of the patients presenting with preoperative hydrocephalus, needed postoperative CSF drainage the practice of placements of external ventricular drain as a temporary method to reduce the pressure became popular.[90] External ventricular drain can be placed preoperatively, intraoperatively or post operatively as the need arises. Preoperative external ventricular drains are mostly reserved as a lifesaving procedure in patients present with increased ICP and altered sensorium.[90]

There are several advantages for an external ventricular drain i.e., it is a temporary measure which can be easily reversed. Controlled drainage of CSF essentially decreases the chances of reverse herniation and intratumoral haemorrhage.[91] Intra operatively it can be used to drain minimum CSF to obtain a lax posterior fossa which will aid in surgery.[92] Also intraoperatively and postoperatively it can be used for removal of blood and tumor debris. Blood and tumor debris can cause block in the CSF flow pathway by interfering in the absorption process. Thus, increasing the risk for post resection hydrocephalus.[93] Hence an EVD can also reduce the incidence of post resection hydrocephalus and thereby the need for ventriculoperitoneal shunt. Further in the postoperative period it can be used for monitoring ICP.[93] But the external ventricular drain is not devoid of any disadvantages or complications. The infection rates are anywhere between 5 to 20% which essentially depends on the duration of the drain in-situ.[10] EVD itself can produce intraventricular haemorrhage as well as Intraparenchymal and extradural haemorrhage.[75] Many studies have also demonstrated the relationship between the risk of post resection hydrocephalus and need for permanent use of diversion with increased duration of EVD.[10,75,94-96] In a study by Habib[97] intraoperative insertion of extra ventricular drainage in posterior fossa tumors with hydrocephalus was studied and it was noted that presence of an intraoperative EVD catheter gives a better control of intracranial pressure.[92] It also helped to resolve the

postoperative hydrocephalus and decrease in immediate postoperative complications such as pseudomeningocele and CSF leak.

Endoscopic Third Ventriculostomy

Endoscopic procedures are becoming popular in the past two decades. And the endoscopy third ventriculostomy as a procedure for CSF diversion is widely accepted and practiced.[3,76] Hence, this procedure was first evaluated in the management of hydrocephalus associated with posterior fossa tumors almost two decades ago. Post which many centres and surgeons started using ETV as a prophylactic measure in these patients to reduce the complications postoperatively as well as the incidence of post resection hydrocephalus. The advantage of an ETV lies essentially in its mechanism of CSF diversion. Instead of an extra-cranial diversion as in a ventriculoperitoneal shunt ETV Is an intracranial CSF diversion and enhances the normal CSF flow physiology. Theoretically many authors have postulated that the prepontine cistern size reduction makes a procedure of ETV difficult in these patients, but this was negated in the study by El Gandar et al.[2,87] There are several advantages for a pre resection ETV, namely:

1. Avoids need of intraoperative EVD placement.[75]

2. Reduction of pre operative morbidity and mortality in patients with hydrocephalus.[59,98]
3. Intraoperative lax posterior fossa for surgery.[3,87]
4. Avoidance of postoperative complications such as CSF leak pseudomeningocele.[3]
5. Avoids the need of external ventricular diversion such as external ventricular drain and ventriculoperitoneal shunt. Thereby avoiding the complications associated with the following.
6. In cases where neoadjuvant chemotherapy can be planned ETV will allow a good control of hydrocephalus in these patients.[99]
7. ETV will also decrease the duration of EVD if it arises intraoperatively or postoperatively.

With all these advantages there are also some disadvantages with performing tumor surgery. Even though about 60 to 80% of the of the children with posterior fossa tumors and 30 to 40% of adults present with hydrocephalus, only about 1/3 of these patients may require permanent CSF diversion post operatively.[8,100,101] Hence subjecting all the patients with hydrocephalus to ETV can be deemed as an unnecessary surgical procedure for the patient. As it is been proven by many studies the stoma closure rates are high with ETV.[59,75] This becomes more prominent since post resection these patients can have tumor debris and blood in the ventricles which can cause the closure of stoma. In a Meta-analysis by

Bouras et al It was noted that ETV was associated with the complication rate of about 8.5%. A permanent morbidity of 2.4% mortality of 0.21%and also a sudden death rate of about 0.07% was also seen in this study.[102]

Materials and Methods

The study is a retrospective collection of data which was carried out in the Department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram. The study period was between January 2015 to December 2019. A total of 143 patients were operated in the study period. After application of the exclusion criteria a total of 116 patients were selected for the evaluation.

Inclusion Criteria

All patients with Posterior fossa tumours who underwent surgical excision of these tumours. CSF diversion procedures and their timing was noted. Further patients with minimum of 12 months of follow up were included in the study

Exclusion Criteria

All patients with recurrent surgeries were excluded but the first surgery of these patients was included if that surgery was performed within the study period. Patient with preoperative CSF diversion were excluded since the evolution of CSF physiology and hydrocephalus in the perioperative period would not be included in them..

Patients with absent preoperative imaging for evaluation of hydrocephalus were also excluded from the study.

Hence after application of all the inclusion and exclusion criteria, a total of 116 patients were included in the study and were subjected to Statistical analysis.

Data collection was done from the Electronic medical records. Following data were recorded:

Clinical Data

Demography data- Age and Sex were recorded. Symptoms and signs of patients were recorded i.e., Headache, Vomiting, Gait steadiness, Nystagmus, Ataxia, Papilledema, hearing loss, cerebellar signs, cranial nerves etc.

Imaging

Imaging data was retrieved from the PACS and reviewed thoroughly. Preoperative imaging was evaluated for presence or absence of hydrocephalus. Evan's index was calculated from the plain CT or MRI images in the records. It was noted to have a mean of 0.3445 and a range of 0.11-0.52. Further these were divided into <0.3, 0.3-0.35, 0.36-0.4 and >0.4 i.e., No hydrocephalus, mild, moderate and severe hydrocephalus respectively. Size of the lesion was also recorded from the MRI images or from the case records in the EMR.

In Hospital course

CSF diversion data were recorded under various headings:

1. Presence of Preoperative EVD insertion
2. EVD insertion intraoperatively. Further it was also recorded that the EVD insertion intraoperatively was either planned or unplanned.
3. Whether EVD was left in-situ postoperatively or not.

4. EVD insertion was inserted postoperatively.
5. EVD drainage postoperatively. If the drainage was continuous, intermittent or only single opening postoperatively.
6. Duration of EVD postoperatively.

In case the shunt was placed in the same in-hospital stay, then the type of shunt was also recorded. CSF lab values i.e., Number of cells, protein and sugar levels at the insertion of EVD and also at shunt placement was recorded.

Postoperative course and Follow-up

Postoperative Shunt complications were recorded i.e.,

1. Obstruction
2. Revision
3. Meningitis
4. Ventriculitis
5. Surgical site infections

Follow up data was recorded to view the timing of insertion of Ventriculoperitoneal shunt and subsequent imaging was also recorded for presence and resolution of hydrocephalus.

Statistical Analysis

Descriptive statistics was used and calculations with frequency and percentages for categorical data were made. Mean and standard deviations using Annova test were calculated for continuous variables. Paired T test and Chi Square test were used to assess statistical significance of associations. SPSS software for windows was used for the analysis.

Results

Demographic Data

116 operated patients during the study period were subjected to descriptive analysis. 63 patients were Male (54.3%) and 53 patients were female (45.7%)- Figure:1. Patients were also segregated by decades of their age. (Table 1)

Table 1: Age distribution of the cohort

Age	Frequency	Percentage
<10	35	30.2%
11-20	28	24.1%
21-30	16	13.8%
31-40	11	9.5%
41-50	9	7.8%
51-60	11	9.4%
>60	6	5.1%
Total	116	100%

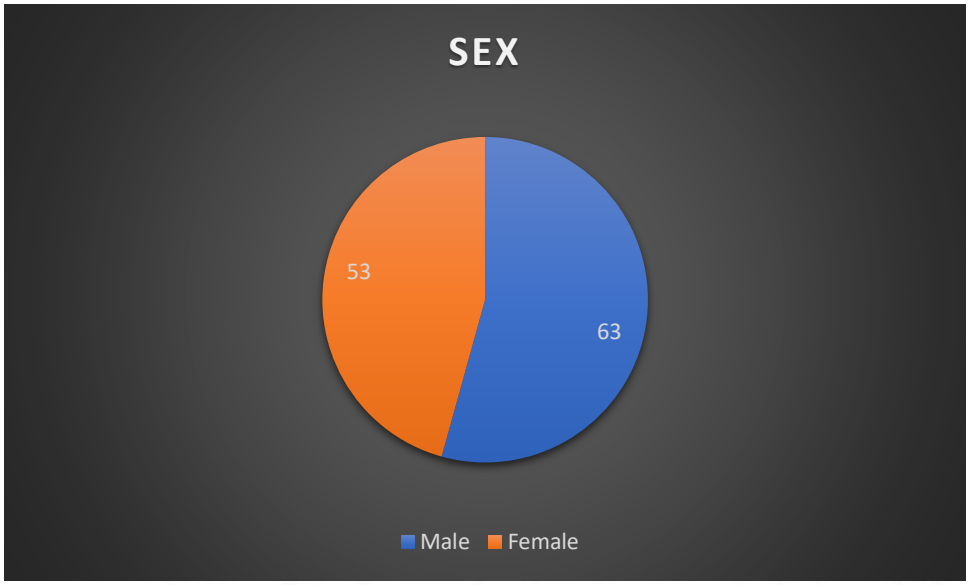

Figure 1

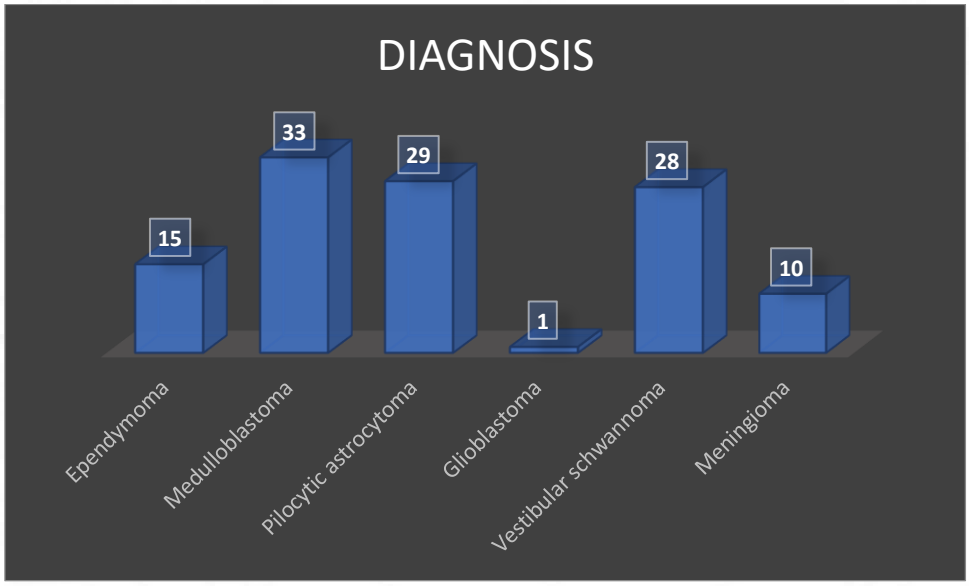

Figure 2

Clinical Presentation

Patient symptomatology and signs were recorded. Headache was the most common symptom seen in 92 patients followed by vomiting in 89 patients.

Gait unsteadiness was seen in 61 patients and hearing loss in 31 patients. Other symptoms such as giddiness, diplopia was seen in 6 patients (Figure 3) (Table 2).

Nystagmus was seen in 48 patients whereas Ataxia was seen in 55 patients. Cerebellar signs such as dysdiadokokinesia, past pointing etc in 53 patients. 78 patients had papilledema which is a significant predictor of increased intracranial pressure. Also, cranial nerve dysfunctions as in 5^{th} nerve, 7^{th} nerve, 8^{th} nerve or lower cranial nerves was seen in 47 patients (Figure 4) (Table 3).

Table 2: Symptoms in patients with posterior fossa tumours

Symptoms	Frequency	
Headache	92	79.3%
Vomiting	89	76.7%
Gait unsteadiness	61	52.6%
Hearing loss	31	26.7%
Others	6	5.2%

Table 3: Signs in patients with Posterior fossa tumours

Signs	Frequency	
Nystagmus	48	41.4%
Ataxia	55	47.4%
Papilledema	78	67.2%
Cerebellar signs	53	45.7%
Cranial nerve Dysfunction	47	40.5%

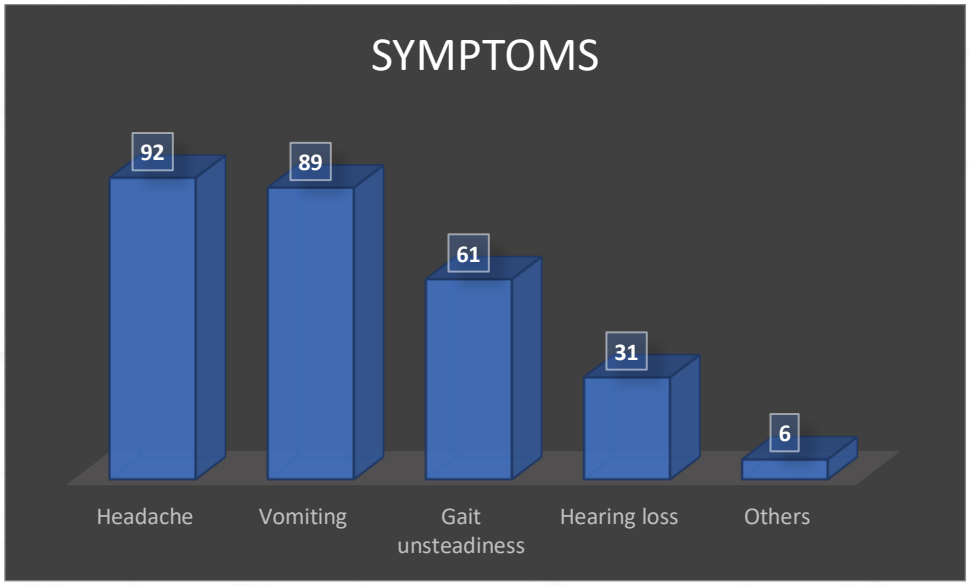

Figure 3

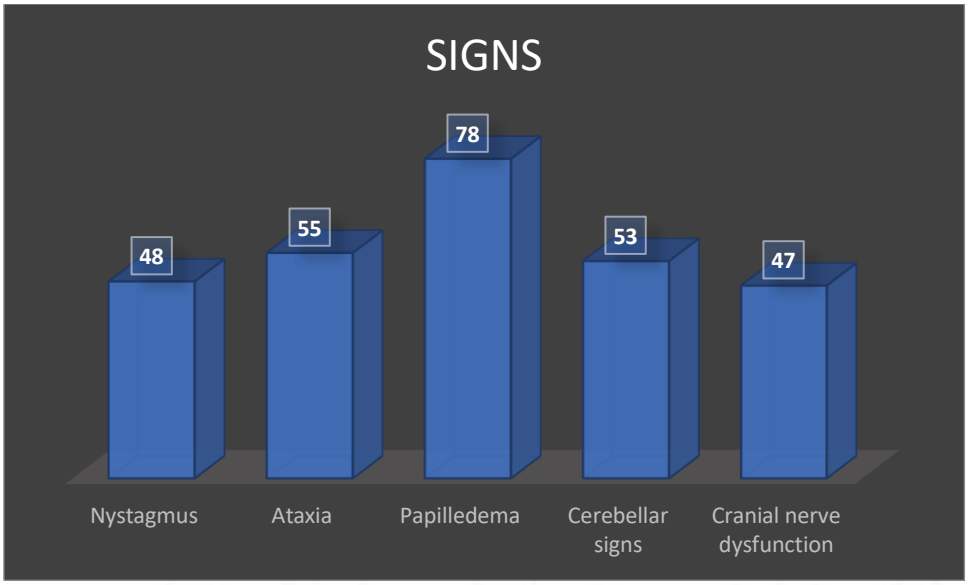

Figure 4

Imaging data

Hydrocephalus was noted in 89 patients preoperatively and 27 patients lacked the presence of it (Figure 5). Size of lesion was also recorded with an average size of 3.8 cm in the largest dimension. Trans ependymal edema was noted in 88 patients and absent in 28 patients (Figure 6).

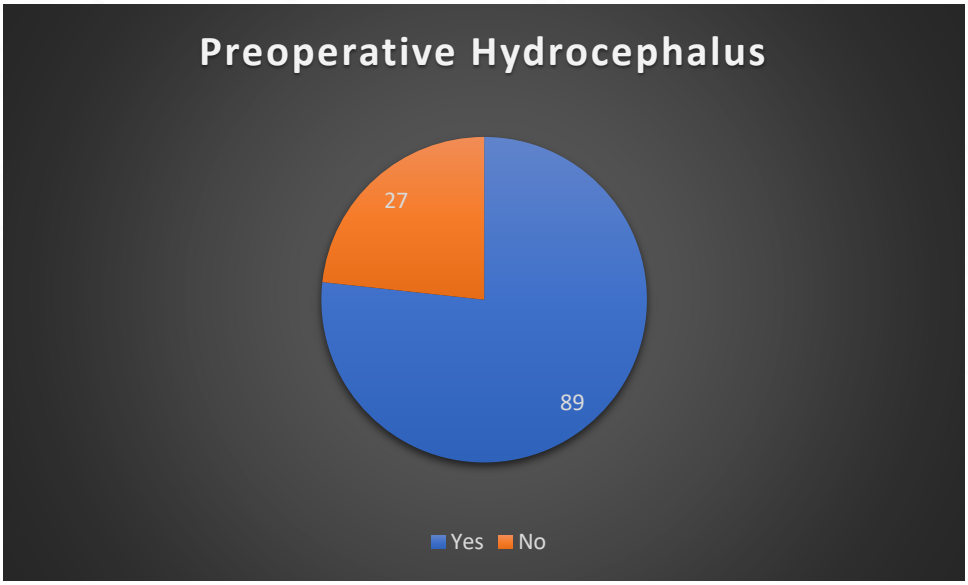

Figure 5

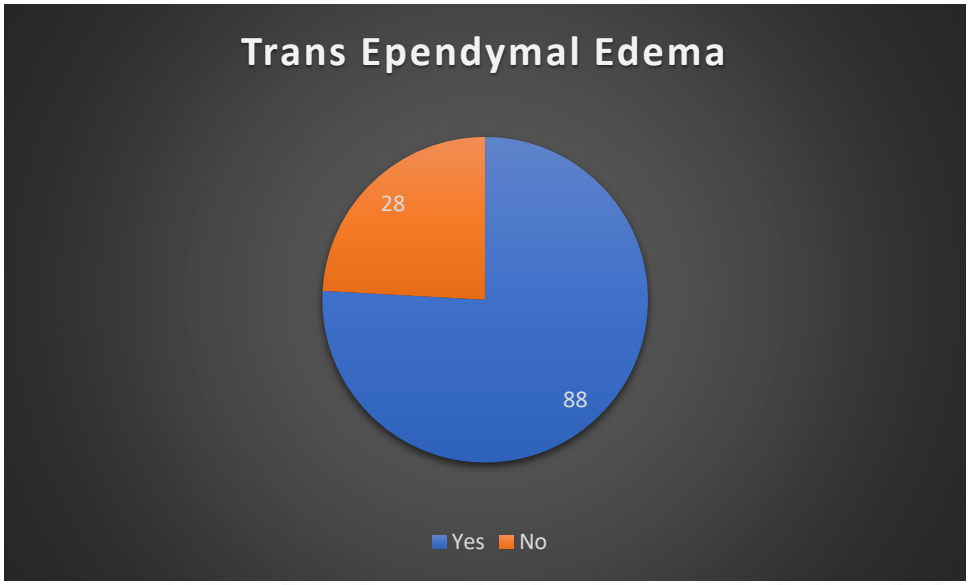

Figure 6

Evan's index calculated from preoperative imaging was recorded. It was noted to have a mean of 0.3445 and a range of 0.11-0.52. Further these were divided into <0.3, 0.3-0.35, 0.36-0.4 and >0.4 i.e., No hydrocephalus, Mild, moderate and severe hydrocephalus respectively. 27 patients had no hydrocephalus whereas 19/116 (16.37%) had mild, 41/116 (35.34%) had moderate and 29/116 (25%) had severe hydrocephalus (Figure 7).

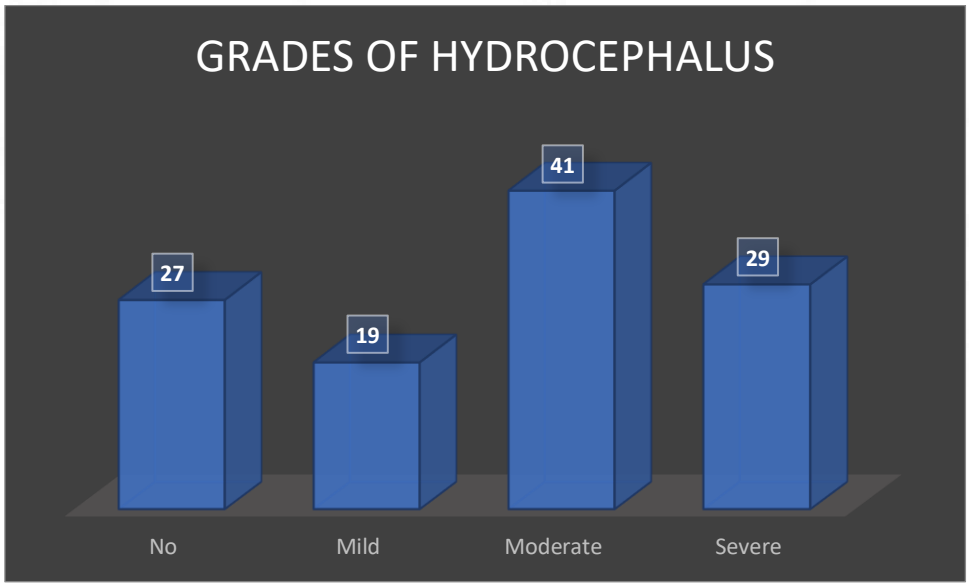

Figure 7

Histopathology and Extent of resection

Final diagnosis was recorded after corelation with histopathology reports. Of the midline lesions 15/116 patients were of Ependymoma, 33/116 of Medulloblastoma, 29/116 of Pilocytic Astrocytoma and one patient of Glioblastoma. Cerebellopontine tumours were of histology of either schwannoma or meningioma i.e., 28/116 of Vestibular schwannoma and 10/116 of meningioma (Figure 8).

Extent of resection was divided as Gross total, near total or subtotal in types. In 92 patients of 116, Gross Total Resection was achieved where as 14/116 Near Total Resection and 10/116 Subtotal Resection was achieved (Figure 9).

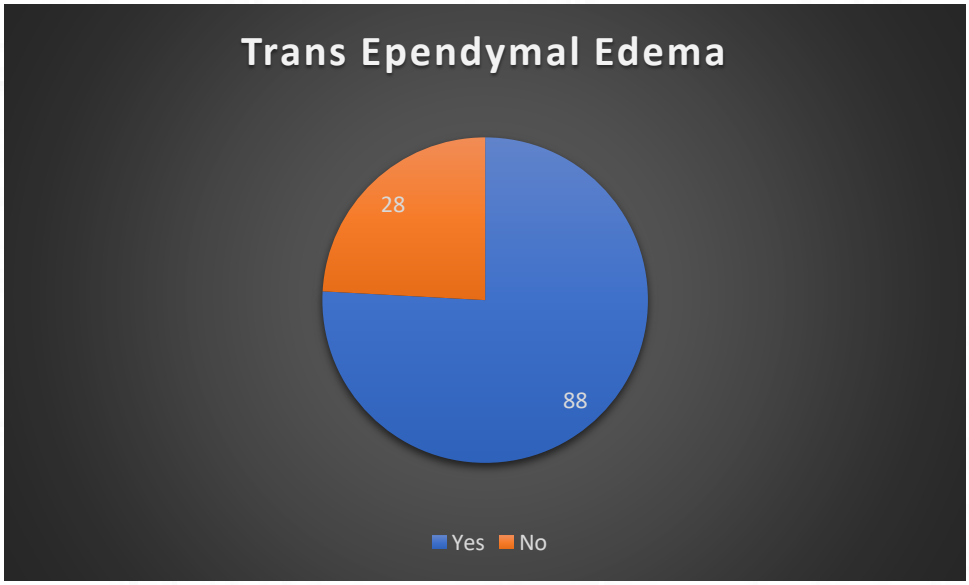

Figure 8

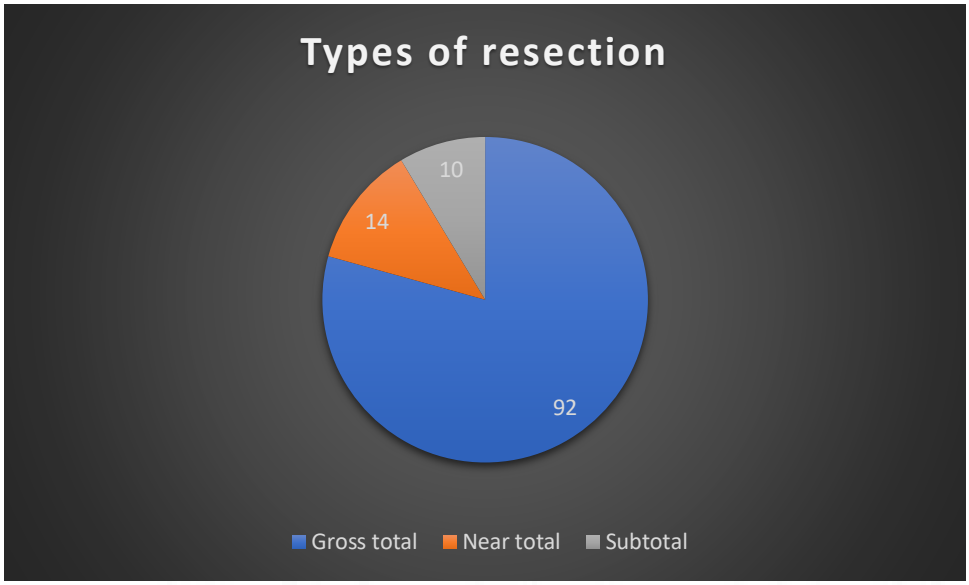

Figure 9

EVD insertion and Shunt placement

66 patients had intraoperative CSF tapping. 58 of these patients had a planned burr placement and 9 patients had an emergency burr placement. 65 of these 66 patients had EVD retained in the postoperative period (Figure 10) (Table 5).

4 more patients had EVD insertion in the post operative period. In the total of 69 patients who had postoperative EVD in-situ, 50 had intermittent opening, 13 had single opening and 6 had continuous open state of EVD (Figure 11) (Table 6). Duration of EVD In-situ was noted and had a mean value of 3.75 days with standard deviation of 4.118 days.

34 patients underwent permanent CSF diversion either during the same in-hospital stay or in the follow up period. 16 of these 34 patients had programmable VP shunt placement whereas 18 patients had non-programmable VP shunt insertion.

Table 5: Data on EVD insertion

	Frequency
Intra-operative EVD insertion	66/116
Planned insertion	58/66
Emergency insertion	9/66

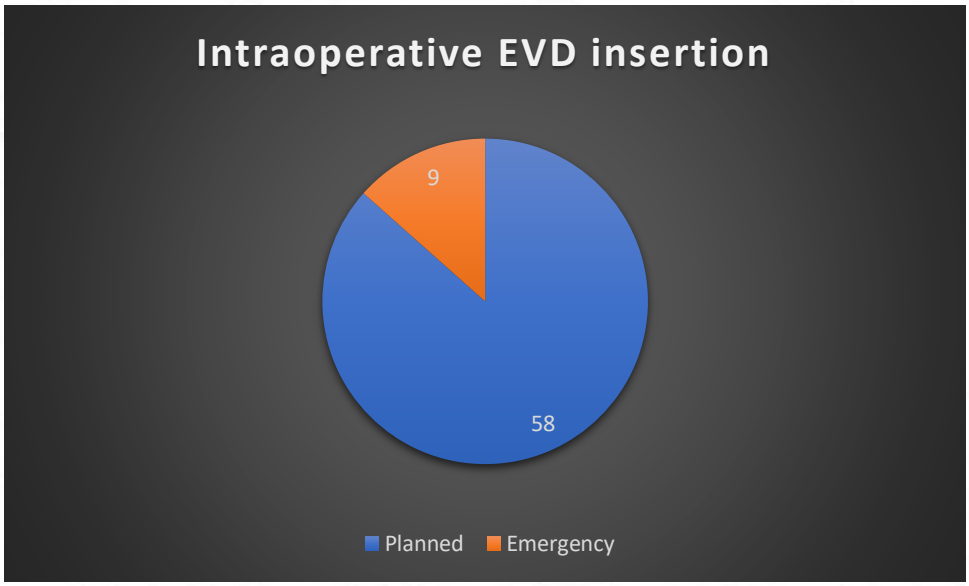

Figure 10

Table 6: Postoperative EVD drainage

Postoperative EVD Drainage	Frequency
Intermittent	50
Single	13
Continuous	6

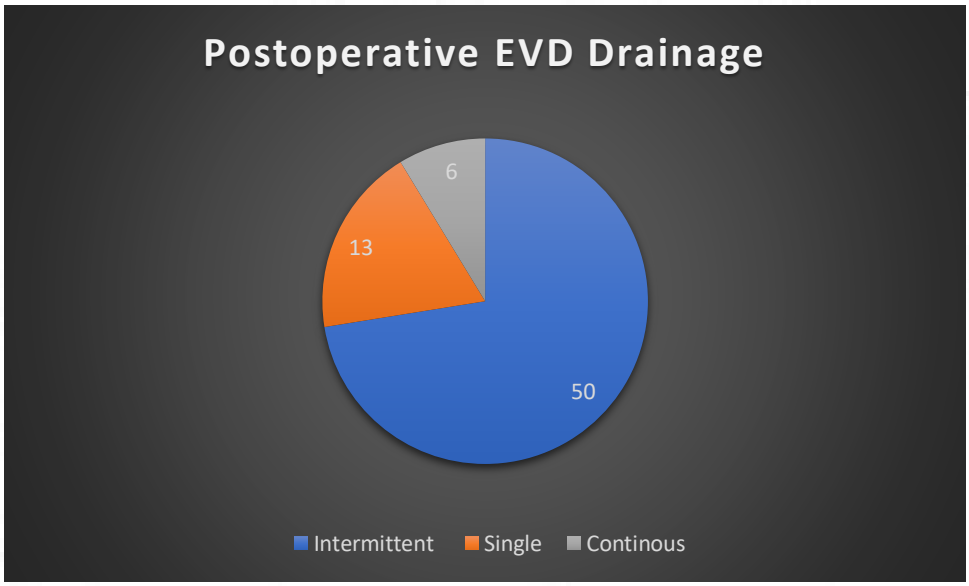

Figure 11

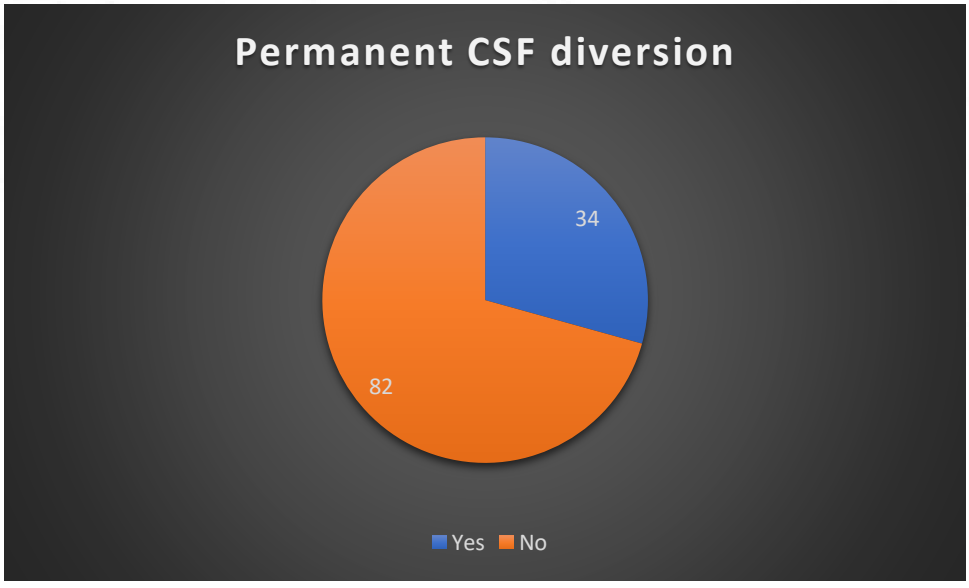

Figure 12

CSF Lab values

Biochemical values of CSF at insertion were as follows: Cells with a mean of 6.89 with a standard deviation of 25.437. Sugars and proteins with a mean value of 41.94 and 18.06 respectively.

Biochemical evaluation of CSF was also recorded. Cells, sugars and proteins at shunt placement had mean values of 4.14, 19.16 and 8.41 respectively. These values were also analysed with permanent CSF diversion for statistical correlation.

Demographics and Need for CSF diversion

Age and Sex were analysed for correlation with Need for permanent CSF diversion. Both were statistically insignificant with p value of 0.987 and 0.063 respectively (Table 7 and 8).

Table 7: Analysis of Age with Permanent CSF diversion

Age in years	Permanent CSF Diversion		Total	p- value
	No	Yes		
	Numbers	Numbers	Numbers	
≤10	25	10	35	
11-20	21	7	28	
21 – 30	11	5	16	
31 – 40	7	4	11	
41 – 50	6	3	9	
51-60	8	3	11	
>60	4	2	6	0.987
Total	82	34	116	

Table 8: Analysis of Sex and Permanent CSF diversion

Sex	Permanent CSF Diversion		Total	p-value
	No	Yes		
	Numbers	Numbers	Numbers	
Male	40	23	63	0.063
Female	42	11	53	
Total	82	34	116	

Clinical features and Need for CSF diversion

Symptoms and signs of the patients were analysed and its association with shunt placement was studied. None of them reached statistical significance except for papilledema (p- value- 0.007) (Table 9).

Table 9: Analysis of Signs and symptoms with Permanent CSF diversion

Symptoms and Signs	Sex	Permanent CSF Diversion		Total	p value
		No	Yes		
		Number	Number	Number	
Headache	No	15	9	24	
	Yes	67	25	92	0.322
Vomiting	No	24	3	27	
	Yes	58	31	89	0.068
Gait unsteadiness	No	39	16	55	
	Yes	43	18	61	0.961
Hearing loss	No	62	23	85	
	Yes	20	11	31	0.378
Others	No	57	21	78	
	Yes	4	2	6	0.734
Nystagmus	No	50	18	68	

	Yes	32	16	48	0.424
Ataxia	No	43	18	61	
	Yes	39	16	55	0.961
Papilledema	No	31	7	38	
	Yes	51	27	78	0.007
Cerebellar signs	No	44	19	63	
	Yes	38	15	53	0.827
Cranial nerve dysfunction	No	51	18	69	
	Yes	31	16	47	0.355

Diagnosis and Need for CSF diversion

Final diagnosis of the patient was found to be not statistically significant with p value of 0.819 for Need for permanent CSF diversion. (Table 10)

Table 10: Histology of tumours and Need for Permanent CSF diversion

Diagnosis	Permanent CSF Diversion		Total	p-value
	No	Yes		
	Numbers	Numbers	Numbers	
Medulloblastoma	21	12	33	
Ependymoma	11	4	15	
Pilocytic Astrocytoma	21	8	29	
Vestibular Schwannoma	20	8	28	
Meningioma	8	2	10	
Glioblastoma	1	0	1	0.819
Total	82	34	116	

Extent of Resection and Need for CSF diversion

Extent of resection was found to be statistically significant with p value of 0.021 for Need for permanent CSF diversion. (Table 11)

Table 11: Analysis of Extent of Resection and Need for Permanent CSF diversion

Extent of Resection	Permanent CSF Diversion		Total	p-value
	No	Yes		
	Numbers	Numbers	Numbers	
Gross Total Resection	68	24	92	0.021
Near Total Resection	6	8	14	
Sub Total Resection	8	2	10	
Total	82	34	116	

Evan's Index and Need for CSF diversion

Evans index was classified as <0.3, 0.3-0.35, 0.36-0.4 and >0.4 as No, mild, moderate and severe hydrocephalus respectively. Evans index and thereby degrees of hydrocephalus had statistical significance with need for VP shunt insertion with p value of 0.002 (Table 12)

Table 12: Analysis of severity of hydrocephalus and Need for permanent CSF diversion

Evans Index	Permanent CSF Diversion		Total	p-value
	No	Yes		
	Numbers	Numbers	Numbers	
<0.3	27	0	27	0.002
0.3-0.35	16	3	19	
0.36-0.4	31	10	41	
>0.4	8	21	29	
Total	82	34	116	

Trans Ependymal Edema and Need for CSF diversion

Trans Ependymal Edema in preoperative imaging was seen in 88 patients and it was significantly associated with need for permanent CSF Diversion with p value of 0.022. (Table 13)

Table 13: Analysis of Transependymal edema and need for Permanent CSF diversion

Trans Ependymal Edema	Permanent CSF Diversion		Total	p-value
	No	Yes		
	Numbers	Numbers	Numbers	
Yes	56	32	88	0.022
No	26	2	28	
Total	82	34	116	

Duration of EVD in-situ and Need for CSF diversion

Postoperative EVD Duration was noted and had a mean of 3.09 days in the group with patients not needing Permanent CSF diversion while a mean of 5.16 days in patients needing Permanent CSF diversion. Longer duration of EVD was statistically significant with need for VP shunt in these patients. (p value- 0.011) (Table 14)

Table 14: Analysis of EVD duration and Need for Permanent CSF diversion

	Permanent CSF Diversion	Number	Mean (days)	Standard Deviation	p Value
Duration of EVD	No	82	3.09	3.047	0.011
	Yes	34	5.16	5.570	

Type of EVD drainage and Need for CSF diversion

Postoperatively EVD was either opened once or intermittently or in continuous drainage. Continuous drainage was significantly associated with postoperative VP shunt insertion. (p value: 0.001) (Table 15)

Table 15: Analysis of Type of EVD drainage and Permanent CSF diversion

Type of EVD drainage	Permanent CSF Diversion		Total	p-value
	No	Yes		
	Numbers	Numbers	Numbers	
Single	9	1	10	0.068
Intermittent	24	26	50	0.41
Continuous	1	5	6	0.001
Total	34	32	66	

CSF Values and Need for CSF diversion

Cells, proteins and as well sugars at insertion had no significance in the outcome of the need for permanent CSF diversion

DISCUSSION

Hydrocephalus is one of the most common presenting features of posterior fossa tumours in children and a frequent feature in adults also. Hence it is responsible for significant morbidity and also mortality in the patients. The incidence of hydrocephalus in children has been estimated about 60-70% while in adults it has been reported to about 3.7-15%.[1-4] The post resection hydrocephalus in children remains about 10-62% patients.[3,10] But it has been seen in various studies that only about 1/3rd of these patient will require permanent CSF diversion.[8,100,101] It was also noticed that the incidence and need for CSF diversion in children under 3 years of age.

Symptoms in children due to hydrocephalus are more dramatic than in adults. Children can present with headache, vomiting, papilledema, altered sensorium and even death, while adults have typical signs such as papilledema maybe rare but head ache and vomiting form still a significant portion of symptoms and signs.[46-50] Many adults though can present with features which are similar to Normal pressure hydrocephalus. Large tumours can cause significant compression on structures of posterior fossa and thus closure of 4th ventricle, hence hydrocephalus. But there have been

instances with presence of hydrocephalus with no evidence of compression of 4th ventricle.[66-69] High protein levels have been attributed to the development of hydrocephalus. It is postulated that these proteins can clog the arachnoid granulations and thus causing reduced absorption and resultant hydrocephalus.[64,70]

Post resection hydrocephalus is a cause of significant morbidity and mortality in postoperative period. Complications such as CSF leak, Pseudomeningocoele, increased hospital stay, infections are more evident in the patients with post resection hydrocephalus.[77] Post resection hydrocephalus is not essentially an obstructive type as preoperatively, but can be a communicating type due dysfunction of absorption mechanism.[72,75,76]

Several predictive factors for hydrocephalus postoperatively as well as need for shunt placement have been documented and studied.[8,10, 96, 100-106] With these factors, scores have been devised for the prediction of the same. The management of hydrocephalus in patients with posterior fossa tumours has evolved through decades. With insertion of preoperative VP shunt in most patients previously, the management evolved towards ETV preoperatively.

With emergence of endoscopy, Endoscopic Third Ventriculostomy preoperatively was practiced as a remedy for preoperative and prevention of incidence of post-resection hydrocephalus. But this method was met with much criticism since many patients underwent unnecessary procedure of ETV since not all with preoperative hydrocephalus needed postoperative permanent CSF drainage.[8,10,11,14,98-106]

Selective EVD placement intraoperatively can also be a effective method of managing peri-operative hydrocephalus with overcoming certain disadvantages associated with Preoperative ventriculoperitoneal shunt or Endoscopic Third Ventriculostomy. Thus, the factors associated with evolution of hydrocephalus in patients with posterior fossa tumours and their subsequent management of the same remains a matter of debate and study.

Predictors for post-resection hydrocephalus

AGE and SEX

Younger age with posterior fossa tumours has shown to be of higher risk for pre-resection hydrocephalus. Lee et al[107] documented a mean age of 5.4 years for patients who required shunt rather than those not requiring shunt with mean age of 10 years. Bognar et al[10] demonstrated age at diagnosis as a factor prediction of need for permanent CSF diversion. Age was not statistically significant for incidence of pre-resection hydrocephalus.

Males were almost twice in the group who needed permanent CSF diversion when compared to women. (M:F- 23:11- 2.1:1). This is in concordance with literature which shows male preponderance.

CLINICAL FEATURES

Headache was the most common symptom with occurrence in almost 80% of patients followed by vomiting and gait unsteadiness. Hearing loss was seen more in adults than in children. Papilledema was seen in 67% patients

and other signs such as nystagmus, ataxia and cerebellar signs were seen after that. Cranial nerve dysfunction was seen in about 40% patients with cranial nerve 8 and lower cranial nerve dysfunction being dominant.

None of the symptoms and signs showed statistical significance with need for permanent CSF diversion except for papilledema (p value- 0.007). Presence of papilledema was present in the original Modified Canadian preoperative Prediction model for Hydrocephalus but was subsequently replaced by presence of Transependymal edema in the subsequent validation and modification study in 2013.[104] But many studies including the study by Pitsika et al[74] has demonstrated, papilledema as a significant prediction of post resection hydrocephalus.

SEVERITY of HYDROCEPHALUS

The extent of hydrocephalus preoperatively was measured and evaluated by Evan's Index. Moderate to severe hydrocephalus was included as predictive factor in mCPPRH by Cambarin et al.[9] Morello et al[100] also demonstrated the presence of severe preoperative hydrocephalus as a factor for relation with need for permanent CSF diversion. This was also strengthened by studies by Oliveira et al[103] and Gopalakrishnan et al.[8] Won et al[96] had statistically significant association of preoperative hydrocephalus with postoperative CSF drainage. In our study Preoperative

Evan's Index of more than 0.35 was significantly associated with need for postoperative Shunt insertion. But not all studies have a similar finding regarding preoperative hydrocephalus as a factor for need for CSF drainage in postoperative period. Bognar et al[10] and Culley et al[75] showed that preoperative hydrocephalus did not significantly predict postoperative CSF drainage.

PRESENCE of TRANSEPENDYMAL EDEMA

Also known as periventricular edema and periventricular capping is a well-known marker of increased intracranial pressure seen in CT and MRI. It can also serve as a marker of severity of increase intracranial pressure. It was significantly associated with post-resection hydrocephalus and also its easier way of identification on imaging led to the replacement of papilledema in the mCPPRH score by Camabrin et al.[9]

Transependymal edema was noted in 88 patients with 32 of these patients underwent permanent CSF diversion. With a p value of 0.022 this was noted to have statistically significant.

HISTOLOGY

Even though numerous tumour types have been seen in posterior fossa tumours, Medulloblastoma, ependymoma and astrocytoma dominate in

children whereas Schwannoma and meningiomas are frequently seen in adults. Bognar et al[10], Kumar et al[78], Tonnessean et al[71] and Gopalakrishnan et al[8] noted that medulloblastoma and ependymoma had higher rates of Shunt insertion postoperatively. However, Culley et al[75] noted that no significant relation was noted between tumour histology and subsequent need for shunt in the postoperative period. Even study with Won et al[96] it was noted that histology i.e., Schwannoma, Meningioma had no significant association with postoperative shunt placement. In our study the tumour histology was also found to have no significant correlation with need for shunt. An explanation for the difference of significance with tumour histology with need for shunt was given has the incidence of astrocytomas and schwannomas laterally while others in midline. But this was contraindicated by the study by Won et al[96] in which both lateral placed tumours and midline placed tumours were significantly associated with need for permanent CSF diversion.

PLACEMENT of EXTERNAL VENTRICULAR DRAINAGE

It has been documented that Cushing placed several and separate burr holes in the surgery for posterior fossa tumours in order to drain the ventricles. EVD placement has shown to be useful in emergency as well as elective setting. Kumar et al[78], Culley et al[75] and Dias et al[92] in their study did not find any difference between the insertion of EVD and requirement of

Postoperative Shunt. Won et al[96] demonstrated 71% patients in their study group of 197 had EVD placement while 31/197 patients underwent prophylactic burrhole placement. Although these observations were contraindicated by study by Gopalakrishnan et al[8]. It was noted that patients with intraoperative EVD placement had a significance with need for postoperative shunt placement. Bognar et al[10] also noted the need for EVD and postoperative shunt placement were significantly correlated.

Majority of our patients underwent EVD insertion intraoperatively and many of them continued to have EVD insitu postoperatively. Only small proportion of patients had prophylactic burr hole placement, while most had EVD drainage. Postoperatively CSF drainage was either continuous, Single or intermittent i.e., once in 24/48 hours.

The Duration of EVD also was noted to be significantly associated with need for permanent CSF diversion. We noted that in the group requiring Permanent CSF diversion, the average duration of EVD in-situ was longer and was statistically significant. The other group the duration was significantly lower. Also, noteworthy was the type of EVD drainage postoperatively and its relation to need for postoperative shunt placement. Patients with continuous CSF drainage postoperatively was significantly

associated with need for permanent Shunt placement while patients with single or intermittent had lower incidence of Permanent CSF diversion.

Management of hydrocephalus either intraoperatively or postoperatively i.e., Post-resection Hydrocephalus can be efficiently managed by an EVD in-situ. Hence Insertion of EVD at intraoperative period is essentially useful but also act as a predictor for persistence of post-resection hydrocephalus and the subsequent VP shunt placement.

EXTENT of TUMOUR RESECTION

The extent of tumour resection is important for patient prognosis and also for prediction of Post-resection Hydrocephalus. Since the hydrocephalus in these patients is mostly obstructive type, relief in obstruction via total resection theoretically should decrease the incidence of Post-resection Hydrocephalus. But this was not the observation in many studies. Stein et al[108] reported a higher rate of post-resection hydrocephalus even after Total resection of tumours in comparison to subtotal resection. Authors explained that total resection leads to a larger raw tumour bed, which in turn leads to CSF reaction and hence hydrocephalus. But Kumar et al[78] and Dias et al[92] observed the significance between subtotal tumour resection and postoperative shunt placement. Won et al[96] also noted significant difference between subtotal resection and need for shunt placement.

However, Bognar et al[10], Culley et al[75], Oliveria et al[103] and Gopalakrishnan et al[8] noted no difference between extent of resection and prediction of post-resection hydrocephalus. Gopalakrishnan et al[8] also noted that tumours with brainstem infiltration underwent subtotal resection and hence all those patients underwent postoperative shunt placement.

In our study it was noted as in various previous studies, anything other than gross total resection was associated with need for permanent CSF drainage. Patients with near total and subtotal resection in our study had statistically significant association with postoperative shunt placement. Hence, extent of resection is a significant predictor for the need for permanent shunt placement.

CONCLUSION

Post resection hydrocephalus is a serious clinical problem faced in patients with posterior fossa tumours. Ventriculoperitoneal shunt and Endoscopic Third Ventriculostomy have their own disadvantages and hence their usage in all the patients with hydrocephalus and posterior fossa tumours is not advisable. External Ventricular Drain insertion is an important emergency procedure and also is important in evolution of Hydrocephalus in the perioperative period of these patients. Longer postoperative EVD and also continuous EVD drainage are associated with need for permanent CSF diversion. Hence early removal and also clamping of EVD, for establishment of normal CSF pathways, are important for reduction in need for Permanent CSF diversion. Prophylactic ETV based on existing predictive tools is still not a feasible option and hence other predictive factors should be explored. We reiterate the importance of clinical decision for EVD insertion and emphasise the need for better predictive system for risk stratification of these patients.

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Patient Proforma

Date of admission:

Clinical presentation

- Headache-
- Vomiting-
- Gait unsteadiness-
- Hearing loss-
- Any others-

Signs

- Ataxia-
- Nystagmus-
- Papilledema-
- Cerebellar signs-

Hydrocephalus: Yes or No

Preoperative CSF diversion: Yes or No

EVD insertion

- Continuous drainage

- Intermittent drainage
- Single drainage

Intraoperative CSF tapping: Yes or No

- Planned Burr placement:
- Emergency burr placement:

Postoperative CSF diversion: Yes or No

Need for Permanent CSF Diversion: Yes or No

CSF Values:

- At insertion
  - Cells:
  - Sugars:
  - Protein:
- At Shunt placement
  - Cells:
  - Sugars:
  - Protein:

Complications:

- Meningitis
- Ventriculitis
- Obstruction
- Shunt revision
- SSI

- Postoperative hematoma formation

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1787/DECEMBER/ 2021

30.03.2022

Dr. Darshan HR
Senior Resident
Department of Neurosurgery
SCTIMST, Thiruvananthapuram

Dear Dr. Darshan,

The Institutional Ethics Committee held on 18th December, 2021, reviewed and discussed your application to conduct the study titled "**ANALYSIS OF TYPES OF CSF DIVERSION AND THEIR OUTCOME IN PATIENTS WITH POSTERIOR FOSSA TUMOUR AND HYDROCEPHALUS**" (IEC/1787).

The following members of the Ethics Committee were present at the meeting held on 18th December, 2021

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Prof. C.C. Kartha	MBBS,MD	Male	Basic Medical Scientist (Chairman)	No
2.	Dr. Kala Kesavan P	MBBS,MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
5.	Dr. Rejnish Kumar	MBBS,MD ,DNB	Male	Clinician	No
6.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
7.	Dr. Narayanan Namboodiri. K.K	MBBS,MD,DM	Male	Clinician	Yes
8.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
9.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
10.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Checklist Form
2. Dean's signature form
3. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 20.07.2021
4. IEC Application Form
5. Project Proposal
6. CV of PI and Co-PIs
7. Proforma
8. TAC Approval Letter
9. Declaration Form

Revised submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 28.03.2022
2. Checklist Form
3. Dean's signature form
4. Covering letter addressed to the Technical Advisory Committee, SCTIMST dated 10.01.2022
5. IEC Application Form
6. Project Proposal
7. CV of PI and Co-PIs
8. Proforma
9. TAC Approval Letter
10. Declaration Form

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:
The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY • INSTITUTIONAL ETHICS COMMITTEE (IEC) SCTIMST THIRUVANANTHAPURAM