Late Failure of Endoscopic Third Ventriculostomy(LFETV): A multicenter international study

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Introduction

Hydrocephalus is characterized by an excessive accumulation of Cerebro-Spinal Fluid (CSF) in the ventricular system, leading to an increase in intracranial pressure[1]. ETV is an effective treatment for *obstructive hydrocephalus* (HCP). It works,by bypassing the obstruction and creating an alternative pathway between the ventricular compartment and the subarachnoid space (SAS). Careful patient selection is critical. Factors such as patient age, etiology of hydrocephalus and individual anatomy, and previous shunting, have been shown to influence ETV success rates[2]. ETV may fail. Early failures occur due to either technical issues, or, when there is an absorptive component or an obstruction distal to the interpeduncular cistern. Late failure occurs mainly when the ETV stoma occludes[3]. Redo ETV, have been shown to have success rates of 65-70%[4]. Higher rates of redo ETV success can be achieved if the interval to failure is more than 6 months since the original ETV, associated with 90% success[5]. Another way to treat failing ETV it by placing a shunt[6].

ETV failure can be a life-threatening event, with a risk of rapid deterioration[7–9]. The time between ETV and death due to stoma closure ranged from 1 month to 7 years in some series[7,9], although faster declines have been reported. [7,10]

Midline sagittal T2-weighted MR imaging (MRI) sequences as well as other MRI flow sequences provide a relatively reliable tool for ascertaining the patency of the stoma during follow-up evaluation[10]. However, even when imaging shows flow through the stoma, patients may still experience clinical failure, increase intracranial pressure and a treat to life. Therefore, the demonstration of a flow void is not a guarantee over time. The reason is that a flow void may represent an up-down movement of the 3rd ventricular floor and not necessarily a flow of CSF through a patent stoma. Vice versa, the absence of a flow-void does not necessarily indicate clinical failure[11,12]. Currently, there are no substantiated follow up protocols following an ETV. Furthermore, it is debatable how long we should continue to follow asymptomatic patients. There is no clear consensus on the most appropriate imaging method to use during follow-up, how often to perform it, and what is the significance of a close stoma. Also, there is no consensus on what to do with those who have no flow void but are asymptomatic.

In this study, we will collect experience with those who experience LFETV (>5 years following an ETV). We will evaluate the imaging preceding the clinical failure, seeking for potential risk factors, hoping to improve our surveillance protocols, and avoiding acute ETV failure which may be life threatening.

Objective

To Collect, on an international level experience cases with LFETV to better define clinical and radiological risk factors.

Hypothesis

A long-term follow-up protocol, including routine patient education, and screening imaging may help prevent life-threatening events resulting from LFETV.

Methods

This is a retrospective study. Data will be obtained from the database of the Department of Pediatric Neurosurgery at the Dana Children's Hospital. This data will be obtained from the electronic database (located on the department's server-PNS-server and Chameleon).

This study is performed in collaboration with pediatric neurosurgery departments in Israel and in other countries. We will send each participating center an excel database sheet with the relevant variables of interest, as well as a copy of this IRB template.

The Collected data: Demographics, etiology of hydrocephalus, history of previous shunt or ETV, age at which ETV was performed, imaging results along the years, ETV surgery procedure details, and time from diagnosis of ETV to failure.

Clinical and surgical outcomes will be expressed by clinical assessment in the review clinic, radiological follow-up, and the need for further surgery thereafter.

Anonymization Procedure

Data from the TLVMC will be collected regarding cases operated between 1.1.2005 - 31.12.25. The study will be based on anonimyzed data, collected from patients' files (department's server-pns-server and chamilion) located on the hospital's sever or software. Data will be extracted by the investigators which are employed by the TLVMC and have approved access to patient's files. The file will not be distributed via e-mail and will not be sent outside the hospital without signing a data-transferring contract with the Research & Development Division. The participants' names or ID will not be recorded. Any personal identifiers will be coded, and the file will be kept in the password-protected clinic's computer, behind the institutional fire wall, and, accessible to the research team members only. The chart containing the given numbers and the

participant's details will be kept in a hospital's computer protected by login name and password, and will be erased once data processing ends. Separation of the identified data from the file will only be done by the principal investigator a member from the medical institution, who is permitted to open patient's files, where the study is conducted

Inclusion criteria
-Children and adults who have undergone ETV for all indications

-ETV patients who failed after more than 5 years after the procedure

-Complete follow up of at least 5 years including clinical and radiological variables

Exclusion criteria
-Insufficient Follow up less than 5 years from last ETV surgery

Discontinuation from study

As this is a retrospective study, no patients (which fulfil the inclusion criteria) will be expelled from the database.

Number of patients to participate in the study
From Tel Aviv medical Center, Tel Aviv - up to 20 patients

Special populations:
Children (under 18) and adults (including pregnant women) will be included

Impact on study participants
This study is retrospective, this study will not affect the participants

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