

Neuroendoscopy in Infants and the International Infant Hydrocephalus Study (IIHS)

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Shlomi Constantini, Spyros Sgouros,
and Abhaya V. Kulkarni

3.1 Introduction: Hydrocephalus, VPS, and ETV

Pediatric hydrocephalus is one of the most common neurosurgical conditions. It is the leading cause of brain surgery for children in the USA. The ventriculoperitoneal shunt (VPS) is the classic treatment for pediatric hydrocephalus since the early 1960s. Shunts are the “bread and butter” of pediatric neurosurgery. Shunts have modified the prognosis of hydrocephalus from a lethal disease to a curable disease with a relatively good prognosis according to etiology [1–4].

Hydrocephalus is a heterogeneous disease. Shunts are able to resolve almost all cases of hydrocephalus, whatever the etiology, with almost no contraindications. Many different types of shunts have been developed and are in use, including pressure-regulated,

volume-regulated, externally regulated, shunt assistants, and dual-switch valves [5–24]. When shunts first appeared in our field, the advantages were clear and far outweighed the disadvantages; they enabled a relatively normal life with a relatively simple procedure.

It took some time to realize and acknowledge that the shunt failure rate is significant, that complications are common, and that children with shunts are dependent upon surgical maintenance throughout their lives [1, 25–34].

Shunt complication rates are unacceptably high. Children with shunts have an increased likelihood of seizures, they can develop *slit ventricle syndrome*, and some of them suffer from under- or over-shunting [35–53].

With all these complications in mind, the arrival of neuroendoscopy on the scene was greeted with great enthusiasm. Neuroendoscopy was seen as a means of solving the challenges of hydrocephalus without the issues of the hardware.

Endoscopic third ventriculostomy (ETV) was designed primarily for hydrocephalus cases in which there is a blockage at the level of the aqueduct of Sylvius. In these cases, the endoscope is guided to the floor of the third ventricle, and an opening is created between the third ventricle and the interpeduncular cistern. This is a straightforward diversion procedure; no hardware is usually left in place, and fluid can egress from the third ventricle to the base of skull and ultimately arrive at the normal absorption sites at the convexity of the brain.

S. Constantini, MD, MSc
Department of Pediatric Neurosurgery,
Dana Children’s Hospital, Tel Aviv Medical Center,
Tel Aviv, Israel

S. Sgouros, MD, FRCS (SN) (✉)
Department of Pediatric Neurosurgery,
Mitera Children’s Hospital,
Athens, Greece

University of Athens Medical School, Athens, Greece
e-mail: sgouros@med.uoa.gr, ssgouros@mitera.gr

A.V. Kulkarni, MD, PhD, FRCSC
Division of Neurosurgery, Hospital for Sick Children,
University of Toronto, Toronto, ON, Canada

3.2 Technical Challenges of ETV

There is no single standardized technique defined for ETV. The same basic procedure is implemented with considerable technical variability in different medical centers. Technical nuances include the use of rinsing fluid, use of navigation, scope types (rigid or flexible), techniques for creating and widening the hole in the base of the third ventricle, and even basic concepts of how to close the skin and open the bone [54–57].

Endoscopic third ventriculostomy and all other neuroendoscopic operations are advanced procedures that are heavily dependent on sophisticated technology. ETVs require a learning curve, substantial experience, and careful coaching of young neurosurgeons. Every case should be carefully discussed between the participating neurosurgeons, analyzing the indications and contraindications, following a close inspection of the specific microanatomical details on the MR. The professional discussions must be accompanied by a discussion with the family of the available alternatives, their advantages, and disadvantages.

Morbidity from endoscopic third ventriculostomy may be underreported. The nightmare of every neuroendoscopist is massive bleeding, mainly arterial, during the procedure. Perforation of the basilar artery has been reported from even the best of medical centers [58–72]. Smaller bleeds, mainly of venous origin, usually stop by themselves with either simple rinsing or a short burst of mono- or bipolar coagulation. Tissue damage during insertion and manipulation of the endoscope, subdural hematomas, endocrinological abnormalities, infections, cranial neuropathies, and other complications are also reported [60, 71, 73–82].

Although most failures from endoscopic third ventriculostomy occur in the early period after the procedure, late obstruction of the stoma may lead to increased ICP and even sudden death [83–92]. It is therefore strongly advised that patients who undergo a successful ETV should be clearly told that they are not *cured* from the hydrocephalus and that symptoms can reappear and may have

dangerous consequences [93]. These patients should be followed on an ongoing basis, and the medical center should have an open door policy that encourages the patients to call or come back if any related symptoms are appearing. It is still not known if those patients with no flow void at the third ventricle stoma on postoperative MRI may be at a higher risk to develop a clinical syndrome and should be followed even more closely.

3.3 ETV: Meeting the Standard of Evidence-Based Medicine

Series on the results of ETV in the pediatric age group started to appear in the 1980s, developed during the 1990s, and continue to appear in the literature to this day [56, 60, 91, 94–118].

However, even with all the series that have been published to date, it is hard to extract meaningful research data or operative guidelines. There are too many inconsistencies in the basic “ground rules” used by these researchers [119]. For example, success rates of endoscopic third ventriculostomy are usually defined as one or more of the following factors: the disappearance of hydrocephalus symptoms, no signs of intracranial hypertension evident, and/or a technically successful procedure. Perhaps partially as a result of this wide range of definitions for the term “success,” large disparities are found when looking at the results of ETV in children. Success rate varies widely, ranging from a low 35 % success rate in a series from Toronto [116] up to a high of 83–89 % in other series [106, 108, 120, 121].

Analyzing the differences between successful series and series with less promising results shows that most of the differences can be traced to a gap in the early failure rate. Early ETV failures could be due to wrong technique, different selection criteria in recruiting the patients or in defining failure, and also the multifactorial etiology of the hydrocephalic process itself [122, 123]. It is essential, therefore, to define a uniform set of selection and failure criteria in order to objectively and meaningfully compare results among different centers.

Since the 1990s, ETV has been recognized as a valid alternative to shunt implants, mainly for patients with obstruction at the level of the aqueduct, the tectal plate, and the pineal region. ETV quietly developed into a mainstream, common procedure in pediatric neurosurgery without *any* prospective randomized trials (and certainly no multicenter trials) proving its efficacy compared to shunt procedures. Unfortunately, it seems apparent today that a classic randomized trial is no longer possible, since most of us treating these patients would not agree to expose a classic candidate for ETV to randomization between two alternatives.

As ETV technology continues to evolve and improve, and as we collectively accumulate more experience and confidence with ETV, indications for ETV have broadened, introducing more challenges in understanding the pathophysiology of hydrocephalus and in proving the efficacy of a new procedure (ETV) over the more standard alternative (shunts).

This was one of the reasons that in 2001 we established the International Study Group for Neuroendoscopy (ISGNE). The goal of this organization (more recently transformed into the International Federation for Neuroendoscopy (IFNE)) is to promote neuroendoscopy research and education.

There are many pathologies for which treatment with ETV is debatable. These include hydrocephalus in infants, patients with meningocele and Chiari, Dandy-Walker malformation, fourth ventricular outlet obstruction, during tumor surgery, and patients who have had a hemorrhage or an infection in their past [39, 124–171].

Over the course of 10 years of collaboration within the IFNE, we have learned to appreciate the advantages of cooperative multicenter studies. Our first attempt was with a study on repeat ETV for those patients for whom the original ETV initially succeeded. We pooled our experiences with 20 patients recruited from four centers [114]. Another collaboration involved a multicenter study on the efficacy of ETV in patients who had previously experienced an infection and/or hemorrhage. For this study, we pooled

our experiences with 101 patients from seven medical centers around the world [161]. We are currently analyzing the results of the International Neuroendoscopy Biopsy Study (INEBS) which included 293 patients from 13 medical centers (submitted for publication). In addition to these clinical series, our group has led several major multicenter epidemiological papers that have recently been published. These papers analyzed meta-results obtained by merging data from the very large number of patients recruited through a combination of other series, focusing on specific variables and how they affect success or failure in pediatric ETV [55, 93, 100, 109, 110, 172, 173].

3.4 Uncertainty Regarding ETV in Infants

For infants, the potential benefit of ETV is substantial, due to the admittedly high complication rate of shunting. Common complications include a high rate of mechanical failure, high rate of infection, slit ventricle syndrome, and seizures. Shunt complication rate (both mechanical and infectious) is age-dependent. Infants usually have more complications compared to older patients. Shunted infants generally require many surgical revisions. Twenty to forty percent of infants require revisions in the first year following insertion and, in subsequent years, generally add another 10–15 % per year [28].

There are other concerns regarding ETV in infants. Is ETV more dangerous for infants? Safety concerns fall into three areas: *short term* (during the surgery itself), *intermediate term* (e.g., postoperative leaks or infections), and *long term* (e.g., perhaps due to unforeseen risks to development or stoma closure leading to a sudden hydrocephalus emergency). Another unresolved concern is whether the CSF absorption mechanism in infants with aqueductal stenosis is mature enough to handle the CSF after the obstruction is bypassed.

Even if all the technical/physiological issues were resolved, another major concern is that some of the infants considered to have been successfully treated with ETV may actually have

been transformed from *active* hydrocephalus to an *arrested* type. We might be paying a neurological price for such “successes” by adversely affecting their long-term development. This theory is based on the observation that children who have had their hydrocephalus treated with ETV almost always have ventricles considerably larger than children who were treated with VPS [174]. At least one study has shown a direct correlation between decreased ventricular volume and clinical improvement [175]. Unfortunately, nobody, so far, has been reviewing systematically the relevant developmental variables in children following ETV. No study has attempted to correlate the size of the ventricles to any neurodevelopmental measurement. So this belief has not been scientifically proven or refuted.

Conversely, other surgeons advocating ETV are concerned with the long-term complications of *shunting* on the developing brain, especially the cumulative risk of shunt infections due to multiple operations. The theory for this correlation is based on the observed link between shunt infection and reduction of IQ, as well as measured memory deficits among shunted children [94, 169, 176–186]. Advocates for ETV also claim that it is a more “physiological solution” and therefore is better for the infant brain.

Having reviewed the papers that appeared on this subject over the last 10 years, 32 papers reported an average success rate from 50 to 55 %. However, this “average” success rate does not really reflect the wide range of results found when analyzing the studies to date.

Results from around the world ranged from 25 % shunt independence [108, 126, 187–190] up to 89 % shunt independence [59, 191–197].

Two-thirds of the studies reviewed concluded that age is a significant predictor of success, suggesting that for infants up to 1 year of age, the ETV success rate is strongly age-dependent [27, 55, 79, 80, 99, 100, 106, 108, 113, 116, 149, 167, 191, 198–203]. On the other hand, one-third of the studies found no correlation between age and success rates [97, 132, 134, 150, 168, 192, 197, 204].

There is also a very wide range of failure definition after ETV in this age group. Some would

shunt every post-ETV infant who still has a full fontanel, while others would wait for more overt signs of high ICP before declaring a failure [22, 55, 59, 60, 78–80, 82, 93, 94, 96, 97, 100, 102, 106–113, 116–118, 126, 132, 134, 141, 149, 150, 152, 156, 161, 166–169, 172, 173, 177, 185, 187–256].

With all these very plausible theories and beliefs, *there has never been a direct controlled comparison of the two types of treatment, studying their impact on the intellectual development of children*, and certainly not of infants.

3.5 The International Infant Hydrocephalus Study (IIHS)

Because ETV in infants is so controversial, with strong, plausible arguments on both sides of the divide, we concluded that a randomized prospective study in this group would be morally justified and well accepted by our community. This was why more than 4 years ago we initiated the International Infant Hydrocephalus Study (IIHS).

IIHS is a multicenter prospective randomized study on infants up to 2 years of age with no flow at the level of the aqueduct. IIHS represents a major departure from most published works on the value of neuroendoscopy in the treatment of hydrocephalus. Whereas most studies focus on the survival of the created stoma or implanted shunt and surgical complications, this study focuses primarily on the effect of treatment on the neurodevelopmental outcome at 5 years, including a comprehensive assessment of relevant risks and benefits [257].

IIHS is the first randomized study of the long-term outcome for patients with infantile hydrocephalus due to aqueductal stenosis. Due to the lack of clear superiority of either surgical technique, it became obvious that randomization to shunt or ETV groups, in the clearly defined population of infants under 2 years of age with obstructive hydrocephalus due to pure aqueductal stenosis, is not only ethical but also a duty for all medical personnel involved in the management of such patients. Nevertheless, families who are presented with both options in a non-biased way and elect to choose one, possibly on the basis of

information that they have already gathered on their own, are also included in the study. This option (termed “parental preference”) does not violate the statistical validity of the study and is built into the study design, based on a comprehensive cohort design model [257, 258].

Given the complexity of the study outcomes, it is possible that there might not be a single, clear, unambiguous set of findings. For example, it may well prove that one type of treatment enjoys a considerably better neurodevelopmental outcome but possibly at the “cost” of a higher complication rate. Ultimately, we may decide that in the future, it may be up to the parents, together with the treating neurosurgeon, to choose one or the other treatment, with full awareness and understanding of the facts and details. With this in mind, IIHS is also analyzing other factors as secondary outcome measures, such as complication rates, hospitalization time, the need for repeat surgeries, and imaging use. This dual-level approach will ultimately provide a unique opportunity to directly compare, under controlled circumstances, the management consequences of ETV and VPS.

Until now, such a comparison has not been possible. Currently, when neurosurgeons counsel patients and their families before surgery, we quote complication rates from different studies. Unfortunately, the studies available to date are not even directly comparable because, at the very least, they are not based on comparable patient populations. And of course, the reality is that with all the uncertainty surrounding the question of ETV vs. VPS, we all have our own personal beliefs and biases. It is only human nature for the neurosurgeon to choose, perhaps subconsciously, the statistics most supportive of a preferred choice. Hopefully, one of the outcomes of the IIHS will be to provide a more objectively balanced set of data to discuss with the families.

3.6 How Does the IIHS Work?

Information about the IIHS administrative and organizational details, (steering committee, study coordinator, etc.), as well as the study principles, is provided on the study web site www.IIHStudy.org.

IIHS principles are also presented in a paper by Sgouros, Kulkarni, and Constantini [257].

Participating medical centers must meet a stiff set of inclusion criteria. IIHS participation requires medical centers have strong neuroendoscopic orientations with at least five infant ETV operations per surgeon annually and a philosophical acceptance of the underlying principles of the study. IIHS demands a strong commitment to timely patient follow-up and data submissions, combined with the ability to follow patients for at least 5 years. Research ethics requirements are per institutional rules.

Recruited infants must meet their own set of inclusion criteria. Children must be under 2 years of age, the product of a full-term pregnancy, and newly diagnosed with untreated obstructive hydrocephalus. Ventricular enlargement and no flow at the aqueductal level must be clearly visible on the MR. Local logistics and social complexities must be considered – it must be possible for the medical center to follow the child and schedule follow-up exams for at least 5 years. Exclusion criteria include children who are either prematurely born or have other major structural neurological and brain abnormalities.

Eligible patients and their families must have a long discussion with the treating neurosurgeon. After an explanation of the study and the different arms, they may be either randomized or categorized according to “parental preference.” All children are subject to continuous follow-up until they reach the age of 5 years. The 5-year outcome measurements are based on a complete test battery, including three questionnaires completed by the parents and two questionnaires completed by professionals. These tests have been translated and validated in eight different languages. A number of secondary variables reflecting more standard secondary outcome measures will also be documented.

3.7 What Has the IIHS Achieved So Far?

IIHS patient recruitment began about 4 years ago, following a major design process. Forty-three international centers have joined the IIHS. The majority (27) are from Europe, with other participants from

North America, Latin America, and other continents. Twenty-five centers have already contributed over 150 patients. Most of our patients were recruited at under 1 year of age. An interim analysis showed a similar rate of adverse surgical effects between the two arms. Our monitoring committee therefore authorized continuing the recruitment process. Outcome results will be analyzed only after study recruitment is completed. Patient recruitment will probably continue for another 3 years and follow-up for another 5 years after that.

Four years into the IIHS, we can conclude the following: We are dealing with a rare disease. Even very busy centers usually recruit no more than two to four patients yearly. So maintaining a high recruitment rate is an ongoing challenge. Randomization of a surgical procedure is a difficult challenge as well. This is a culture change and requires time and effort from the participating centers. Since our study is only modestly funded, a strong determination and certain “idealism” is part of the participation motivation.

One more point is as follows: While it is important to try to provide informative, objective, prospective data, the significance of the IIHS is much more than that of a single important study. The fact that we have the commitment of so many colleagues around the world, who are all equally passionate about treating and hydrocephalus, is very encouraging. This group of centers and investigators can be used for other collaborative hydrocephalus studies in the future. IIHS is, therefore, laying the groundwork for a future of global collaborative studies that may just change the way medical research is conducted.

3.8 Other Challenges in Infant Neuroendoscopy

ETV in infants with aqueductal stenosis is only one of the scientific and clinical dilemmas facing us today. Several other controversial indications exist.

ETV combined with Choroid Plexus Coagulation (ETV/CPC) has been rejuvenated by Benjamin Warf, who has contributed enormously to the body of research through his Uganda experience. He and others have reported on the use

of CPC, mainly in post-meningitis hydrocephalus and in those with MMC [22, 141, 166, 168, 169, 200, 253, 254, 259–261]. In the coming years, the challenge will be to see if the huge African experience can be extrapolated to developed nations. It has been proposed that ETV/CPC can play an important role in post-hemorrhagic hydrocephalus, for example. This condition is rarely seen in sub-Saharan Africa, but very common in developed nations. A prospective study designed to advance our knowledge in this direction is about to start soon.

ETV for Dandy-Walker syndrome is a valid option, but only small series are available in the literature [124, 126, 146, 148, 150, 164, 262–268].

ETV for obstruction of the outlet of the fourth ventricle is another clinical front. Theoretically, ETV should work to bypass such an obstruction. Nevertheless, several obstacles in defining this entity and the role of ETV exist. First, the MR criteria to differentiate those who have a combined obstruction of the Luschka and the Magendie vs. those with “communicating” hydrocephalus are not clear. Most clinicians will not expose their patients to invasive preparatory imaging such as a dynamic ventriculography. When performing this study on several candidates, we realized the low predictive ability of MR in selecting the right candidates for this procedure. While initial results are promising [39, 53, 128, 129, 131, 133, 136, 138–140, 143, 147, 149, 153, 155], the jury is out on the indication for ETV in this situation.

ETV for hydrocephalus in dysraphic patients is also an option. Although it makes sense in selected patients, it has not yet become too popular as a first measure to control hydrocephalus in infants following closure of their MMC [127, 132, 134, 137, 141, 142, 145, 154, 163, 166–170, 269].

Conclusion

Neuroendoscopy in infants poses a special clinical research challenge. Available data is accumulating rather slowly. The IIHS offers some hope of providing more reliable data in infants with aqueductal stenosis. Other indications for endoscopy in this age group need to be better studied to expand our understanding of the indications, dangers, and benefits.

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