Counterpoint: Shunts Are Not Going Away So We Need to Do Them Well

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**Hydrocephalus** remains the most common condition treated by most pediatric neurosurgeons (1). **Third ventriculostomy** is an ideal procedure for some patients and the addition of choroid plexus coagulation (CPC) has reenergized the discussion of treating hydrocephalus endoscopically (2). Nevertheless, **ventriculoperitoneal shunts** remain the workhorse for most patients with hydrocephalus. It is therefore important that we look critically at this common procedure in order to optimize patient outcomes. How have we done so far?

Our literature is full of many single-center reports of shunt techniques and outcomes. Recently, some prospective multicenter studies and a few multicenter randomized clinical trials have been reported. In the 1990s, the Shunt Design Trial (SDT) randomized 344 children at 10 centers to one of three valves at the time of their first shunt insertion. No difference in shunt survival was identified. (3). Endoscopic and non-endoscopic ventricular catheter insertion were assessed in the Endoscopic Shunt Insertion Trial (ESIT). There was no improvement in shunt survival with use of the endoscope (4). Adjustable valves and non-adjustable valves were compared in a randomized study in 1995. The Codman Hakim Programmable valve or a differential pressure valve was used at the time of shunt insertion or revision. The shunt survival curves for these two groups were almost identical (5). Recently, the **Management of Myelomeningocele Study (MOMS)** showed that fetal closure of myelomeningocele resulted in a significantly lower incidence of hydrocephalus requiring a shunt (6).

These efforts have been worthwhile. As a pediatric neurosurgery community we have learned a lot about hydrocephalus and shunts. In addition we have demonstrated that we can collaborate on multi-institutional projects in order to address a specific study question and to generate new ideas for further work.

Of course, these studies are not perfect. The SDT demonstrated that the shunt survival was not improved by 50 percent with any of the valves tested. Smaller differences may have been missed. The ESIT was adequately powered for a 10-percent difference in shunt survival and it was negative — and yet endoscopic shunt insertion is still commonly practiced. Why didn’t this study change surgeon behavior? The adjustable valve study mixed insertions with revisions and adults with children. Secondary analysis looked at subgroups but with reduced power. The MOMS trial was methodologically sound and yielded important findings, but took seven years and
more than $22 million to answer a question regarding a condition that is partially preventable and decreasing in incidence.

So where are we today? We are clearly in an era of collaboration and cooperative groups. In pediatric hydrocephalus, the Hydrocephalus Clinical Research Network (HCRN) was founded in 2007. The goals were to create a system for collaborative studies, to monitor and improve quality, and to develop the next generation of clinical scientists in hydrocephalus. The scientific strategy was to create a large prospective database that would characterize the population, identify areas of variation and generate study questions. In the last six years, the HCRN has accumulated detailed information on more than 7,000 hydrocephalus procedures from nine centers. Analyses from this large dataset will answer some questions and pose others. The data allow a first look at new study questions. They also provide accurate information to help plan a new trials and estimate accrual and feasibility. Initial analyses have confirmed the lack of benefit of endoscopic ventricular catheter insertion (endoscope use was actually a risk factor for shunt failure), and confirmed that valve type is not a significant risk factor for failure of the first shunt (7). Shunt survival in the HCRN registry was compared to data from the ESIT and SDT in order to assess trends over time. After adjusting for etiology and age there appeared to be an improved survival of shunts in recent years compared to a decade ago (8). The HCRN established a standardized protocol for shunt surgery, monitored surgeon compliance and demonstrated a significant reduction in shunt infection on the protocol (9). Revisions to the protocol are now being examined. Another HCRN study evaluated the use of ultrasound for shunt placement (10). A series of studies have been conducted on the management of premature children with intraventricular hemorrhage (IVH). Temporizing with a reservoir appeared to be more beneficial than with a subgaleal shunt (11). This apparent difference completely disappeared after a standard protocol was introduced for decision making in these children (12). Studies are also in progress on the role of biomarkers in premature children with IVH and the relationship between ventricle size and neuropsychological outcome.

So where are we headed in the future? What about randomized clinical trials (the gold standard for the assessment of efficacy)? Clearly RCTs will continue to have a key role in answering focused study questions that will impact patient care. In addition, prospective, large detailed datasets will become more and more important sources of information. These will supplement the already available data systems based on discharge coding, which are of limited value for many of our disease-specific questions. Large registries may also provide the infrastructure for RCTs. In a recent NEJM article (13), Michael S. Lauer, MD, and Ralph B. D’Agostino Sr., PhD, discussed “The Randomized Registry Trial – the next disruptive technology in clinical research?” In this model, an RCT is run within an existing registry. There are a number of potential advantages to this methodology. Since the registry is capturing all patients, large numbers can be accrued in a short time and at a lower cost. Generalizability can be assessed since the registry will include patients who are not in the trial. Data entry is on the existing registry system and data monitoring can be done according to the pre-existing registry standard (ref). The impact of dropouts and crossovers will be known
since those patients are in the registry. The outcome events for the RCT are already captured in the registry.

Our future will certainly include quality improvement work. This is being integrated into many hospitals and health-care systems, but our input into QI protocols, risk adjustment models and outcome measures is essential.

Shunts for the management of pediatric hydrocephalus have a long history of saving lives and improving developmental outcomes. Exciting new techniques are emerging that provide alternate treatments for some children, but shunts are not going away. Our continued efforts to evaluate and improve them are essential.

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