Key Points

1. Evidence based medicine assesses the strength of available published studies to make recommendations on treatment and prevention
2. Studies are graded based on scientific rigor
3. Factors include randomization, control groups, multiple institutions, and more
4. Researchers performed an evidence based review of posterior fossa decompression with and without duraplasty in children
5. No Level I or Level II-1 studies
6. Most available evidence is the lowest level, Level III
7. Difficult to draw any conclusions based on weak evidence
8. May not be a right answer as to which procedure is better; may depend on individual patient

Definitions

blinded - research technique, intended to reduce bias, where researchers who perform tasks during the study are not aware of what group individual subjects are in; also may not be aware of the hypotheses of the study

dura - outer covering of the brain and spinal cord

duraplasty - surgical technique where the dura is opened and a patch is sewn in, in order to create more room underneath

PFD - posterior fossa decompression

PFDD - posterior fossa decompression with duraplasty

prospective - type of research where subjects participate in the study after the study is set up

randomized - scientific technique, intended to reduce bias, where subjects are randomly assigned to

A Question of Opening The Dura

March 31st, 2011 -- Evidence based medicine is an approach to medicine that makes treatment and prevention recommendations based on all the available scientific evidence. In order to evaluate the available evidence, different grading systems have been developed to rate how rigorous the scientific publications on a given topic are, based on the design of the studies in question.

While different types of research questions can be answered by different types of study designs, in general, a prospective, randomized, controlled trial is considered the gold standard for medical research. This means that the study participants are randomly assigned to a group (for example treatment or placebo), the study has a control group to compare against, and the data is obtained prospectively rather than looking back at events that have already happened. According to a commonly accepted evidence grading scale, this type of study is considered to produce Level 1 evidence (Figure 1).

At the other end of the spectrum are descriptions of results with a series of patients, or the opinions of experts. These types of studies are considered to be Level III, which is not as strong. In the middle are studies which have some scientific rigor, but also have drawbacks, such as the data is only from one institution.

Figure 1: Levels of Evidence from Scientific Studies

- Level I: Evidence obtained from at least one properly designed randomized controlled trial.
- Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

When a panel of experts tries to address a medical issue with public policy implications, they will base the strength of their recommendations in part on the level of evidence that is available.

While evidence based medicine makes a great deal of logical sense at first glance, there are significant criticisms against it. Specifically, its detractors believe it is simply a tool for health and insurance managers to decide what tests and procedures can be done from a cost point of view and that an individual doctor knows better what is best for his or her specific patients.

Recently, there have been research articles highlighting the limitations of this approach and the fundamental limitations inherent in all medical research, no matter how well it is designed. For example, given the number of genetic variations between two individuals, there is no realistic way to control for it with randomization (because it would take too many people). Criticisms have also emerged that making decisions based on average benefits may ignore subsets of patients for who may respond differently to a treatment. Finally, some studies have shown that most (if not virtually all) medical research publications use statistics in a flawed way.

The answer to these issues may lie in a combination of evidence based medicine and a growing recognition that personalized medicine, which takes into account a patient's unique genetics and background, is the best approach.

Given that rather lengthy background, an evidence based research study from Alabama (Hankinson) on opening the dura during pediatric surgery, found that the level of available evidence is not sufficient to draw any strong conclusions.

The ongoing debate over whether to open the dura during surgery (especially for children) has begin to coalesce around the idea that not opening the dura significantly reduces complication rates, but that opening the dura reduces the percentage of patients who require additional surgery.

Hankinson decided to assess the issue using an evidence based medicine approach. To do this, he and his colleagues performed a literature search with the terms Chiari Malformation, syringomyelia, syrinx, syringohydromelia, child, and pediatric. The resulting studies were grouped into three categories: those that contained both PFD (no duraplasty) and PFDD (duraplasty) surgeries in the same report, those that only had PFD, and those that only had PFDD. The Alabama team reviewed the results of the studies for three outcomes:

different groups

retrospective - type of research which looks back in time at things that have already happened, such as using MRIs and medical records

cerebellar tonsils - portion of the cerebellum located at the bottom, so named because of their shape

cerebellum - part of the brain located at the bottom of the skull, near the opening to the spinal area; important for muscle control, movement, and balance

cerebrospinal fluid (CSF) - clear liquid in the brain and spinal cord, acts as a shock absorber

Chiari malformation I - condition where the cerebellar tonsils are displaced out of the skull area into the spinal area, causing compression of brain tissue and disruption of CSF flow

decompression surgery - general term used for any of several surgical techniques employed to create more space around a Chiari malformation and to relieve compression

syringomyelia - condition where a fluid filled cyst forms in the spinal cord

Source

Duraplasty or not? An evidence-based review of the pediatric Chiari I malformation. Hankinson T, Tubbs RS, Wellons JC. Childs Nerv Syst. 2011 Jan;27(1):35-40.

clinical improvement, syrinx improvement, and scoliosis improvement.

In the studies which directly compared the techniques - 6 such studies - the strength of the comparison was weakened by the fact that the surgeons would make the decision on whether to open the dura or not during the procedure itself based on what they saw. In these studies the range of clinical symptom improvement was 33%-90% for PFD surgeries and 61%-100% for PFDD surgeries. For syrinx improvement, the PFD improvement was 40%-67%, while it was 63%-100% for PFDD (Table 1). Similarly, in the studies that had separate PFD and PFDD results, the PFDD range of improvement was slightly higher, but the complication rate also went as high as 16.7% for this technique (Table 2). In terms of scoliosis, there were so few patients who had had PFD surgery that it was impossible to compare the techniques.

In general, the limited number of patients in these studies remains a major problem. In the 6 comparison studies, the total of all subjects involved was less than 400. For a surgery that is performed more than 10,000 times a year, this is not a large number.

In fact, this combined with the fact that patients were never randomized to a treatment and most of the studies were single institution and retrospective, meant that from an evidence grade point of view, the available evidence to address this issue is very weak. Specifically, there are no Level I or Level II-1 studies and the majority are Level III.

It is not clear if it would be ethical to randomize patients to one surgical technique versus another, especially if a surgeon can see during surgery that one technique may not be sufficient. It is also not clear that there is a definitive answer to this question that would apply to all patients (highlighting the limitations of the evidence based approach in that it assumes that one technique is better than another). Rather, patient outcomes may improve by finding better ways to identify patients who can benefit from surgery without opening the dura, and thus reducing complications, time in the hospital, and the overall trauma of the surgery.

Table 1: Results From Studies Which Directly Compared PFD to PFDD (6 Total)

	Total Patients	Range of Clinical Improvement	Range of Syrinx Improve.
PFD	145	33%-90%	40%-67%
PFDD	221	61%-100%	63%-100%

Table 2: Results From Separate Studies of PFD and PFDD

	Range of Clinical Improvement	Range of Syrinx Improvement
PFD	81%-93%	50%-80%
PFDD	83%-100%	55%-100%

Note: Complication rate for PFDD studies referenced in Table 2 were as high as 16.7%

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