Key Points

1. Many different graft materials are available for surgeons to use with a duraplasty
2. Surgeons noted an increase in complications such as aseptic meningitis, pseudomeningocele, and CSF leaks when they were forced to switch to a new type of graft
3. Reviewed records to see if graft used and sealant used had an impact on complication rates
4. Found wide variations in complication and reoperation rates between graft materials and sealant combinations
5. Worst combination had more than 50% complication rate and 33% reoperation rate
6. However, because of the limited number of patients in each group, findings are not statistically significant
7. Some grafts have been pulled from the market in US and Canada
8. Surgeons have reduced their complication rate by switching to autografts

Definitions

aseptic meningitis - condition where the meninges are inflamed, but not due to a bacterial infection; can be caused by a viral infection or immune reaction

autograft - a dural graft which is taken from the patient's own tissue

bovine - from a cow

cadaver - the body of a dead person

collagen - connective tissue

dura - outer layer of the covering of the brain and spine

duraplasty - surgical technique where the dura is expanded by cutting it open and inserting a patch

Complications May Be Related To Graft and Sealant Combination

September 30th, 2011 -- While the primary debate regarding the dura revolves around whether it should be opened during surgery, another dura related surgical factor that varies considerably is what type of graft to use when the dura is opened as part of a Chiari decompression. Historically, many different materials have been tried as dural substitutes and today's surgeon can select a graft ranging from human cadavers, various collagen derived materials, synthetic materials, and tissue from the patient's own body. There have been a couple of studies comparing graft materials, but none have produced convincing arguments and at this time the selection essentially boils down to a surgeon's individual preference and experience.

However, a recent publication in the Journal of Neurosurgery: Pediatrics by surgeons at Duke (some of the authors are now at Texas) shows that, at least in their experience, complication rates may be higher using certain combinations of graft materials and dural sealants. Specifically, the physicians noted an increase in complication rates after they were forced to switch graft materials and decided to investigate. Between 2004 and 2007, the group primarily used the EnDura graft (a collagen derived material), but it was pulled from the market in 2007 and they began to use either cadaver grafts or Durepair (also a collagen derived material). It was after making the switch that they noticed an increase in surgical complications.

To determine if there was a link, the researchers reviewed the records of 114 consecutive pediatric surgical patients they saw between 2004 and 2008. In reviewing the records, they looked for surgical complications such as aseptic meningitis, pseudomeningocele, and CSF leaks. Within the group, most patients had received an EnDura graft (76%) before they were pulled from the market, and the rest were fairly evenly split between cadaver (13%) and Durepair (11%) [Table 1]. In addition, in the majority of cases, the surgeons also used a dural sealant to help close the graft. Tisseal was most commonly used (66%), but DuraSeal was used about 10% of the time (Table 2).

In comparing the graft materials, the surgeons found that the highest complication rate was among patients who had had Durepair grafts, with a frighteningly high complication rate of 42% and a reoperation rate of 25% (Table 3). Next was the cadaver group with a much lower, but still fairly high, complication rate of 27% and a reoperation rate of 13%. Finally, the EnDura group was much lower with a 17% complication rate and 8% reoperation rate. It should be noted that most complications occurred within 3 weeks of surgery, but some patients developed problems months later.

In comparing the tissue sealants, the doctors found that fully half of the patients who received DuraSeal ended up having complications. This compared to the lower rates of 19% for Tisseal and 15% for those who did not receive a sealant. The worst combination, by far, of graft and sealant was the Durepair with DuraSeal, with a staggering 55% complication rate and 33% reoperation rate. The authors point out that Durepair was actually pulled in Canada due to potential reactions when used with other agents, such as sealants.

Finally, the researchers looked at the complication rates based on when the surgery was performed. Perhaps not surprisingly given their motivation to undertake the study, they found that before the EnDura graft was pulled from the market, the overall complication rate 18%. This jumped to 35% after the switch in graft types.

Although the data appears strong, because of the limited number of patients in each group, most of the differences that were found were not statistically significant (meaning it could be due to chance). However, the data was strong enough for the surgeons. Patients who required reoperations because of graft issues were given a graft using tissue from their own body. In addition, for the next 40 patients, autografts were used with a very reasonable (and more in line with other publications) 5% complication rate.

Because one of the grafts in this study was pulled from the US market and a second one from Canada, it may not be worth investigating further. But, studies at additional institutions would be required to validate these findings and ensure they are not due more to the specific surgeons involved than the materials. Either way, it is important for patients who are facing surgery to understand what, if anything, will be placed into their heads, and their specific surgeon's experience in using that type of graft.

Table 1:Type of Dural Graft Used In 114 Pediatric Chiari Surgeries

Material	# of Patients	% of Patients
Cadaver	15	13.2%
Durepair	12	10.5%

meninges - layered covering of the brain and spinal cord

pseudomeningocele - complication from surgery where an abnormal collection of CSF forms and can bulge into the surrounding tissue; some cases require surgical repair

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

Complications following decompression of Chiari malformation Type I in children: dural graft or sealant? Parker SR, Harris P, Cummings TJ, George T, Fuchs H, Grant G. J Neurosurg Pediatr. 2011 Aug;8(2):177-83.

EnDura	87	76.3%

Table 2: Type of Sealant Used In 114 Pediatric Chiari Surgeries

Tisseel	65.8%
DuraSeal	10.5%
None	23.7%

Table 3: Complication and Reoperation Rates by Graft Material (114 Surgeries)

Material	Complication Rate	Reop Rate
Cadaver	26.7%	13%
Durepair	41.7%	25%
EnDura	17.2%	8.1%

Notes: Most variations were not statistically significant due to small number of patients in each group; highest complication and reop rates were for the Durepair-DuraSeal combination (55%, 33%)

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