Dural Sealants

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Overview

A complication of neuro and spinal surgery is leakage of cerebrospinal fluid due to tears in the dura. Dural sealants are used to attain a watertight closure of the dura to prevent complications such as meningitis, abscesses, impaired wound healing, cerebellar hemorrhage, and intracranial subdural hematoma.[1,2] Sealants are commonly compromised of either bio- or synthetic polymers and can be used as an adjunct to sutures[1]. Sutures are commonly the first form of closure in treating dura tears, sometimes combined with fat, tissue, or muscle grafts.[2]

Actions for Consideration

Partner: Identify surgeons that have current usage in this category. Determine physicians who could be influential and serve as physician champions for your alignment initiative. Early engagement is key.

Connect: Due to the difference of indications for use of dural sealant products, it is recommended to review current facility usage including procedure type. Collect and review physician data (usage, cost, and waste) to inform management of products.

Communicate: Provide information including available evidence and indications for products to enhance discussions related to efficacy and outcomes, encourage hands on demonstrations to gain familiarity with the products in this category.

Physician Advisor Insight

A panel of orthopedic, spine, and neurosurgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of adhesive sealants[3]:

Important features:

- Ease of use, adhesion ability, creation of a good seal, and not hydrophilic.
- Expansion of the product that does not create compression.

Features unique to DuraSeal**:**

- It was noted that that physicians seemed comfortable with handling and use of the DuraSeal product.
- DuraSeal does have some expansion, and care is needed when using it in confined spaces, some physicians may avoid use in spine.
- Tisseel (hemostatic agent which may be used as a sealant) in comparison was noted to take longer to set up, and had a shorter duration when compared to DuraSeal.

Conversion considerations**:**

- There is limited clinical data comparing sealant products, however knowing adverse reaction comparisons between products would be helpful.
- Hands on demonstrations to handle product to determine ease and method of setup, intraoperative handling.
- Evidence of similar efficacy to the current product would be necessary.
- Share pricing between products.
- Support from supplier representative or respected colleague would be preferred for training.
- Physician champions/advocates for the product can be helpful when having conversion discussions.

Professional Society Statements and Clinical Practice Guidelines

There are currently no clinical practice guidelines or society statements regarding the use of dural sealants.

Clinical Evidence

- A 2021 meta-analysis consisting of 3 controlled, and 3 uncontrolled trials (n = 439) reviewed the use of polyethylene glycol dural (PEG) sealant to determine the efficacy.[4] The controlled studies in this analysis noted that PEG was effective in creating water tight closures $p < 0.001$. The study found that use of polyethylene glycol dural sealant was an effective adjunct treatment for dural closures.[4]
- A 2018 nonrandomized, two-armed, prospective study assessed the safety and effectiveness of use of DuraSeal Exact Spine Sealant as an adjunct therapy dura sealant in spinal surgeries with dural tears.[5] Endpoints in the study were the occurrence of cerebrospinal fluid leak that happened within 90 days of surgery, along with surgical site infection and serious neurological adverse events. There was no significant statistical difference in cerebrospinal fluid leaks ($p = .83$) between the DuraSeal Exact Spine Sealant and the control group, no significant statistical difference in surgical site infection, or adverse neurological events.[5]

Summary

When considering conversion between products, it is important to understand the current usage within your facility. Identify the highest volume users, determine if they can be physician champions in this category. Engage physicians in conversations to understand the clinical differences in what is currently being used, and for what types of procedures. Provide opportunities for physicians to see and possibly trial products to get a better understanding of how the product performs.

References

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