

Evidence-based medicine

Does the use of DuraSeal in head and spinal surgeries reduce the risk of cerebrospinal fluid leaks and complications when compared to conventional methods of dura mater closure?

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INTRODUCTION

Cerebrospinal fluid (CSF) fistula is a common neurosurgical complication, occurring in 1% to 27% of cases. The main clinical manifestations are postural headache, nausea, dizziness, photophobia, and tinnitus. This condition may be associated with inadequate wound healing and infection, meningitis, and pseudomeningocele, factors that increase patient morbidity and mortality.

Despite the limitations, hermetic closure of the dura mater has been recommended for the prevention and treatment of CSF fistula. In recent years, techniques have been developed to reinforce the site of the dura mater closure, such as additional suture, autologous tissue grafts, fibrin sealants, and collagen sponges. DuraSeal is a dura mater sealant consisting of polyethylene glycol hydrogel (PEG hydrogel), to be applied at the site of suture, and has been indicated for head and spinal surgery with opening of the dura mater.

METHODS

A systematic review was performed in MEDLINE, EMBASE, and Scielo/Lilacs databases, recovering a total of 365 articles using the following search strategies: ((duraseal OR dura seal OR polyethylene glycol hydrogel OR dura seal dural sealant system OR dura-seal OR polyethylene glycols OR dura seal xact adhesion barrier and sealant system OR hydrogel) AND (neurosurgical procedures OR neurosurgery OR cranial surgery)) AND random*. The analysis of 365 articles was based on their titles and abstracts. Six articles met the inclusion criteria (randomized clinical trial study design, comparing the use of DuraSeal to suture with or without complementary methods of dura mater closure, and having as outcome the development of CSF fistula and other complications). These articles were critically appraised using the Jadad score¹.

RESULTS

Two studies were selected. Of these, one refers to the use of DuraSeal in head surgeries (Jadad: 1)², and another to the use of DuraSeal in spinal surgeries (Jadad: 3)³.

The study by Kim et al.² evaluated the use of DuraSeal in spinal surgeries. The sample included 158 patients who were randomized (102 patients in the intervention group and 56 in the control group). The primary outcome was CSF fistula; the secondary outcome, other complications. Patient follow-up was performed during the immediate postoperative period, after 30 and 90 days. This study demonstrated that the use of DuraSeal in spinal surgeries is associated with absolute risk reduction (ARR) in 35.6% (95% CI: 23.0%-48.2%) and NNT of 3 for CSF fistula; there was no difference between the control and intervention groups regarding the development of further complications.

The study by Osbun et al.³ analyzed the use of DuraSeal in head surgeries and consisted of 237 randomized patients (120 in the intervention group and 117 in the control group), having CSF fistula as the primary outcome and other complications as the secondary outcome. Patients were followed for 30 days. There was no decrease in the incidence of neurosurgical complications, including CSF leak, as well as incisional complications.

SYNTHESIS OF AVAILABLE EVIDENCE

- Patients undergoing spinal surgery using DuraSeal, when compared to suturing with or without fibrin sealant, showed a decrease in the absolute risk of CSF fistula (ARR: 35.6% and NNT: 3), with no increased risk of complications.
- Patients undergoing head surgery using DuraSeal, when compared to suturing with or without fibrin sealant, showed no reduction in the absolute risk of neurosurgical complications, including CSF leak, and no decrease in the risk of incisional complications.

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