

A multicentre, prospective, randomized, controlled study to evaluate the use of a fibrin sealant as an adjunct to sutured dural repair.

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Abstract:

Background. Obtaining intra-operative watertight closure of the dura is considered important in reducing post-operative cerebrospinal fluid (CSF) leak. The purpose of this study was to evaluate a fibrin sealant as an adjunct to sutured dural repair to obtain intra-operative watertight closure in cranial neurosurgery. Methods. This randomized, controlled multicenter study compared a fibrin sealant (EVICELFibrin Sealant [Human]) to sutured dural closure (Control). Subjects underwent supratentorial or posterior fossa procedures. Following primary dural repair by sutures, the closure was evaluated for intra-operative CSF leak by moderately increasing the intracranial pressure. If present, subjects were randomized to EVICELor additional sutures (2:1 ratio), stratified by surgical approach. Following treatment, subjects were successful if no CSF leaks were present during provocative challenge. Safety was assessed to 30 days post-surgery, including incidence of CSF leakage. Results. One hundred and thirty-nine subjects were randomized: 89 to EVICELand 50 to Control. Intra-operative watertight closure was achieved in 92.1% EVICEL-treated subjects versus 38.0% controls; a treatment difference of 54.1% ($p < 0.001$). The treatment differences in the supratentorial and posterior fossa strata were 49.1% and 75.7%, respectively ($p < 0.001$). The incidence of adverse events was similar between treatment groups. No deaths or unexpected serious adverse drug reactions were reported. CSF leakage within 30 days post-operatively was 2.2% and 2.0% in EVICELand control groups, respectively. In addition, 2 cases of CSF rhinorrhoea were observed in the

EVICELgroup. Although not associated with the suture line where EVICELwas applied, when combined with the other CSF leaks, the observed leak rate in the EVICELgroup was 4.5%. Conclusions. These results indicate that EVICELis effective as an adjunct to dural sutures to provide watertight closure of the dura mater in cranial surgery. The study confirmed the safety profile of EVICEL.

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