Safety and Efficacy of TachoSil (Absorbable Fibrin Sealant Patch) Compared With Current Practice for the Prevention of Cerebrospinal Fluid Leaks in Patients Undergoing Skull Base Surgery: A Randomized Controlled Trial.

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Abstract:

Background:Cerebrospinal fluid (CSF) leakage associated with incomplete sealing of the dura mater is a major complication of intradural procedures. Objective:To compare the efficacy and safety of adjunctive TachoSil (Takeda Pharma A/S, Roskilde, Denmark) with current practice for the prevention of postoperative CSF leaks in patients undergoing elective skull base surgery involving dura mater closure. Methods:Patients were intraoperatively randomized to TachoSil or current practice immediately before primary dura closure by suturing ± duraplasty. Choice of adjunctive treatment in the current practice group was at the surgeon's discretion. Primary efficacy endpoint was occurrence of clinically evident verified postoperative CSF leak or clinically evident pseudomeningocele within 7 weeks after surgery or treatment failure (third application of trial treatment or use of other treatment). Results:A total of 726 patients were randomized to TachoSil (n = 361) or current practice (n = 365). More current practice patients had sutures plus duraplasty for primary dura closure compared with TachoSil (49.6% vs 35.7%) and fewer had sutures only (45.5% vs 63.2%). The primary endpoint of estimated leak rate favored TachoSil with events in 25 (6.9%) patients vs 30 (8.2%) current practice patients; however, this was not statistically significant (odds ratio: 0.82; 95% confidence interval: 0.47, 1.43; P = .485). Both treatments were well tolerated with similar frequency of adverse events. Conclusion:Very low rates of postoperative CSF leaks can be achieved in patients undergoing skull base surgery of various indications. Although the study did not

meet its primary endpoint, TachoSil appears to be safe and effective for the prevention of CSF leaks and associated complications.