EP-172

Effect of flowable thrombin-containing collagen-based hemostatic matrix for preventing pancreatic fistula after pancreatectomy: A randomized clinical trial

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Introduction: The aim of this study was to evaluate the safety and efficacy of a flowable hemostatic matrix, and their effect for post-operative pancreatic fistula (POPF) after pancreatectomy.

Methods: This was a randomized, clinical, single-center, single-blind (participant), non-inferiority, phase IV, and parallel-group trial. The primary endpoint was the incidence of POPF. The secondary endpoints were risk factors for POPF, drain removal days, incidence of complication, 90-day mortality, and length of hospital stay.

Results: This study evaluated a total of 54 patients, with 26 patients in the intervention group (flowable hemostatic matrix) and 27 patients in the control group (thrombin-coated collagen patch). POPF was more common in the control group than in the intervention group (59.3% vs. 30.8%, $p = 0.037$). Among participants who underwent distal pancreatectomy (DP), POPF (33.3% vs. 92.3%, $p = 0.004$) and clinically relevant POPF (8.3% vs. 46.2%, $p = 0.027$) were more common in the control group. A multivariate logistic regression model identified flowable hemostatic matrix use ($p = 0.029$) as an independent negative risk factor for POPF.

Conclusions: Flowable hemostatic matrix application is a simple, feasible, and effective method of preventing POPF after pancreatectomy, especially for patients with DP.

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