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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 postoperative 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 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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