

P087

The effect of application of Fibrinogen/Thrombin-coated Collagen Patch (TachoSil®) in pancreaticojejunostomy for prevention of pancreatic fistula after pancreatoduodenectomy : a randomized clinical trial

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Introduction : For reducing of postoperative pancreatic fistula (POPF) after pancreatico-enteric anastomosis, fibrin sealants and topical glue were studied previously, but there has been no definite conclusion to reduce POPF innovatively. The purpose of this study was to evaluate effectiveness of applying fibrin sealant patch to pancreatico-enteric anastomosis to reduce postoperative complications including POPF.

Methods : It was designed as a single center, prospective, randomized, parallel-group, phase IV, single blind (participant) with three pancreas-biliary surgeons. The primary outcome was POPF. Secondary outcome included complication, removal of drainage, hospital stay, readmission rate and cost. Risk factors for POPF were identified by logistic regression analysis.

Results : A total 124 patients were enrolled. Biochemical leakage or POPF occurred 16 patients (25.8%) in intervention group, 23 patients (37.1%) in control group. Occurrence rate was different, but there was no statistically significant difference. Clinical relevant POPF occurred in 4 patients (6.5%) in intervention group, same as control group ($p=1.000$). Hospital stay (11.6 days vs 12.1 days, $p=0.585$) and drain removal days (5.7 days vs 5.3 days, $p=0.281$) were not different between two groups. Complication rate was not different between two group ($p=0.506$). Readmission rate (12.9 % vs 11.3 %, $p=1.000$) and cost (13549 \$ vs 15038 \$, $p=0.103$) were not different between two group. A multivariable logistic regression model identified age, pancreas texture, fibrin sealant patch as independent risk factors for biochemical leakage or POPF.

Conclusions : Fibrin sealant patch after pancreaticojejunostomy did not reduce the incidence of POPF and postoperative complications. This study was registered at clinicaltrials.gov (NCT03269955).

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