ORIGINAL ARTICLE

Polyester sutures for pancreaticojejunostomy protect against postoperative pancreatic fistula: a case-control, risk-adjusted analysis

Stefano Andrianello¹, Giovanni Marchegiani¹, Giuseppe Malleo¹, Valentina Allegrini¹, Alessandra Pulvirenti¹, Alessandro Giardino², Giovanni Butturini², Roberto Girelli², Roberto Salvia¹ & Claudio Bassi¹

¹Department of Surgery and Oncology, General and Pancreatic Surgery – The Pancreas Institute, University of Verona Hospital, and ²Department of Hepato-Pancreatico-Biliary Surgery – Casa di Cura Pederzoli, Peschiera del Garda, Italy

Abstract

Background: There is wide variability in the use of suture material for pancreatic anastomosis after pancreaticoduodenectomy (PD). This study evaluates the role of suture material on clinically relevant postoperative pancreatic fistula (CR-POPF) after pancreaticojejunostomy (PJ) in a risk-adjusted setting. **Methods:** A retrospective study comparing (polyester) PE with polydioxanone (PDO) in 520 PDs. Patients were matched for risk for CR-POPF according to the fistula risk score (FRS) with the propensity score.

Results: The matched PE and PDO groups consisted of 232 patients. The incidence of CR-POPF was lower for PE group (11.6 vs. 22%, p<0.01), with a lower rate of grade B (10.3 vs. 15.5%, p<0.01) and C (1.3 vs. 6.5%, p<0.01). After stratifying by fistula risk zone, PE suture remained associated with a reduced incidence of CR-POPF (9.4 vs. 15.6% low-, p = 0.04; 15.6 vs. 28.1% intermediate-, p = 0.02; 16.7 vs. 83.3% high-risk zone, p<0.01, respectively). Multivariable analysis demonstrated that pancreatic texture, preoperative diagnosis, FRS and the use of PE sutures were independent predictors of CR-POPF.

Conclusions: In the setting of a case-control matched for risk analysis, the use of PE suture for PJ is associated with a significant reduction of CR-POPF.

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Correspondence

Roberto Salvia, Associate Professor of Surgery, University of Verona, P.le Scuro 10 37134 Verona, Italy. E-mail: roberto.salvia@univr.it

Introduction

Postoperative pancreatic fistula (POPF) is the major determinant of outcome after pancreaticoduodenectomy (PD) because it is associated with further complications, including abdominal abscesses, surgical site infection, sepsis, delayed gastric emptying (DGE), and post-pancreatectomy hemorrhage (PPH).^{1–3} In recent decades, the incidence of clinically relevant POPF (CR-POPF) has remained stable at 5–26%.^{4,5} Risk factors for POPF have been extensively investigated, and composite scores have been formulated to predict the occurrence of fistula in a reproducible manner. The fistula risk score (FRS), a ten-point scale based on four variables assessed at the time of anastomotic construction, namely, pancreatic stump texture, main pancreatic

duct (MPD) size, estimated blood loss (EBL) and presumptive diagnosis, has been internally and externally validated^{6,7} and has been used to evaluate surgical performance in a risk-adjusted fashion.⁸ In an attempt to decrease or mitigate the burden of POPF, different strategies have been evaluated, including modification of the anastomotic techniques, ^{9–12} the use of biologic glues or sealants, ¹³ the use of external or internal stents, ^{14–16} the use of prophylactic somatostatin analogues or other drugs, ^{17,18} and selective drain management. ^{19–21} Despite its intuitive role, the effect of suture material on the rate of CR-POPF has not been thoroughly explored, and it is unclear whether any specific material impacts anastomotic failure. In this regard, a study showed that polydioxanone (PDO) was the strongest suture material when incubated in pancreatic juice and bile.²² In addition, it was

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suggested in a retrospective analysis that polyester suture (PE) was independently associated with a reduced rate of POPF after PJ when compared to other suture materials.²³ A recent survey exploring the practice of PD around the world indicated a substantial variability in operative techniques and fistula mitigation strategies. In particular, the type of suture material employed for the pancreatic capsule-to bowel layer differed significantly among surgeons and geographical areas.²⁴

The aim of the present study was to investigate if the suture material impacts the development of CR-POPF after PJ in a riskadjusted fashion.

Methods

Study design

After Institutional Review Board approval, data from all PD consecutively performed from 2012 to 2016 were retrieved from a prospectively maintained database. The present study was designed as a before-after, risk-adjusted analysis and was consistent with the STROBE recommendations (STrengthening the Reporting of Observational studies in Epidemiology). All surgical procedures were carried out in the Pancreatic Surgery Network - University of Verona Hospital Trust and Peschiera del Garda Pancreas Centers. Data regarding the suture material used for the capsule-to bowel layer of both dunking and duct-tomucosa PJ were captured and analyzed. PDO, which was widely used in our institutional practice, was no longer available from 2014 and onwards because the hospital contract with the producing company expired. Accordingly, PE became the most widely employed suture material for pancreatic anastomosis. Patients undergoing either pancreaticogastrostomy or PJ with external transanastomotic stent were excluded from the current analysis. Patients with a PJ fashioned with other suture materials (i.e. silk or polybutester) and patients with missing data regarding the suture material were also excluded.

The risk assessment for Postoperative pancreatic fistula (POPF) development was intraoperatively performed using the FRS.⁶ As previously mentioned, this 10-point score is based on the assessment of pancreatic stump texture, MPD size, EBL and preoperative diagnosis, identifying a group at low risk (pancreatic ductal adenocarcinoma and chronic pancreatitis) and a group at high risk for CR-POPF (duodenal or ampullary cancer, cystic disease and neuroendocrine tumors). The pancreatic stump texture was defined as "hard" or "soft" by subjective evaluation through manual palpation of the remnant performed by an expert pancreatic surgeon with at least 100 PDs performed during his/ her career. The FRS was calculated through the summation of all items, and the final score identified as one of the following four CR-POPF risk categories: negligible-risk zone (0 points), low-risk zone (1-2 points), intermediate-risk zone (3-6 points) or highrisk zone (7-10 points). For patients treated before the publication of the FRS, the score was calculated retrospectively. A propensity score was applied to match patients according to the FRS

risk categories, obtaining two populations, one with PJ fashioned with PDO and the other with PJ carried out with PE. POPF, DGE³ and PPH¹ were defined according to the International Study Group for Pancreatic Surgery (ISGPS) definitions. CR-POPF was defined as POPF grade B and C. This paper employed the 2005 definition of POPF since data collection was concluded before the publication of the 2016 version. Abdominal abscess was defined as the presence of a fluid collection containing gas bubbles and determining systemic signs of infection such as fever, elevated white blood cells count and elevated C-reactive protein. Mortality was defined as 90-day mortality.

Operative technique

The anastomotic technique was uniform across the two participating centers and was performed by senior pancreatic surgeons that completed their learning curve before the beginning of the study period in the setting of a high-volume Institution. A dunking PJ or a duct-to-mucosa PJ were fashioned according to the MPD size. When MPD measuring less than 3 mm, duct-to-mucosa PJ was preferred. The dunking PJ was carried out through an anterior and a posterior layer of interrupted capsule-to-bowel stitches either with 3.0 PDO or 3.0 PE. Duct-to-mucosa was fashioned using 5.0 polypropylene interrupted stitches for the MPD layer and either 3.0 PDO or 3.0 PE for the anterior and posterior capsule-to-bowel layers.

Statistical analysis

Propensity score matching was set with a caliper of 0.1. For univariate comparisons, Chi-square or Fisher's exact tests were used to evaluate categorical variables. Continuous variables were analyzed using Student's t-test or the Mann—Whitney test when appropriate. Stepwise backward logistic regression analyses identified covariates associated with the incidence of CR-POPF. Variables were assessed for multicollinearity and removed from the model if necessary. All tests were 2-tailed. P values <0.05 were considered statistically significant. Statistical analysis was performed with SPSS software (SPSS Inc., version 20 for Macintosh, IBM, Chicago, Il).

Results

During the study period, 816 patients who consecutively underwent PD were assessed for eligibility. As shown in Fig. 1, 296 patients who did not meet the inclusion criteria were excluded. Their characteristics (fistula risk zone and incidence of CRPOPF) are summarized in supplementary Table 1. Eventually, 520 patients were included in the study and matched according to the CR-POPF risk zones. Table 1 shows the main features of the unmatched and matched populations. The unmatched population consisted of 238 (45.8%) patients for the PDO group and 282 (54.2%) patients for the PE group. According to the FRS risk zones, patients in the PE group were at a significantly higher risk of CR-POPF having more cases classified as intermediate

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