A Dual-Institution Randomized Controlled Trial of Remnant Closure after Distal Pancreatectomy: Does the Addition of a Falciform Patch and Fibrin Glue Improve Outcomes?.

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Abstract:

Objective: The objective of the study was to assess the efficacy of two pancreatic remnant closure techniques following distal pancreatectomy: (1) stapled or sutured closure versus (2) stapled or sutured closure plus falciform patch and fibrin glue reinforcement in the setting of a prospective randomized trial, with the primary endpoint being pancreatic fistula. Summary and Background Data: Pancreatic stump leak following left-sided pancreatic resection (distal pancreatectomy) remains common. Despite multiple and varied techniques for closure, the reported leak rate varies up to 30 %. A retrospective analysis by Iannitti et al. (J Am Coll Surg 203(6):857-864, 2006) detected a decreased leak rate in patients receiving a traditional closure buttressed with an autologous falciform ligament patch and fibrin glue. Methods: Between April 2008 and October 2011, all willing patients scheduled to undergo distal pancreatectomy at the authors' institutions were consented and enrolled at the preoperative office visit. Patients were intraoperatively stratified as having hard or soft glands and randomized to one of two groups: (1) closure utilizing stapling or suturing (SS) versus (2) stapled or sutured plus falciform ligament patch and fibrin glue (FF). The trial design and power analysis (alpha = 0. 05, beta = 0. 2, power 80 %, chi-square test) hypothesized that the FF intervention would reduce the primary endpoint (pancreatic fistula) from 30 % to 15 % and targeted an accrual goal of 190 patients. Secondary endpoints included length of postoperative hospital stay, 30-day mortality, hospital readmission, and ISGPF fistula grade (A, B, and C). Results: The trial

accrued 109 patients, 55 in the SS group and 54 in the FF group. Enrollment was closed prior to the target accrual, following an interim analysis and futility calculation. Due to insufficient enrollment, patients stratified as having a hard gland were excluded (n = 8) from analysis, leaving 101 patients in the soft stratum. The overall pancreatic leak rate was 19. 8 % (20 patients) for patients with soft glands. Patients randomized to the FF group had a leak rate of 20 %, as compared with 19. 6 % in the SS group (p = 1. 000). Fistula grades in both groups were identical: 1A, 8B, and 1C in the FF group as compared to 1A, 8B, and 1C in the SS group. Complication rates were comparable between the two groups. The median length of postoperative hospital stay was 5 days in both groups. There was a trend towards a higher 30-day readmission rate in the FF group (28 % vs. 17. 6 %, p = 0. 243). Conclusion: The addition of a falciform ligament patch and fibrin glue to standard stapled or sutured remnant closure did not reduce the rate or severity of pancreatic fistula in patients undergoing distal pancreatectomy (ClinicalTrials. gov NCT00889213).