

A dual-institution randomized controlled trial of remnant closure after distal pancreatectomy: Does the addition of 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-stapled/sutured closure versus stapled/sutured closure plus falciform patch and fibrin glue reinforcement-in the setting of a prospective randomized, controlled trial, with the primary endpoint being pancreatic fistula. **Summary and Background Data:** Pancreatic stump leak following left sided resection remains common. Despite multiple and varied techniques for closure, the leak rate averages 30%. A retrospective review by Ferrone et al. 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 undergoing distal pancreatectomy at the authors' institutions, were consented and enrolled at the preoperative office visit. Patients were intraoperatively stratified as "hard" or "soft" glands and randomized to one of two groups: (1) closure utilizing standard stapling, suturing, or both (SS) versus (2) stapled, sutured, or both plus fibrin glue and falciform ligament patch (FF). The trial design and power analysis ($\alpha=0.05$, $\beta=0.2$, power 80%, chi-square test) assumed the FF intervention would reduce the endpoint (pancreatic fistula) from 30% to 15% and yielded an accrual goal of 190 patients. Secondary endpoints included length of stay, mortality, readmission, and ISGPF fistula grade. **Results:** The trial accrued 109 patients, 55 in the control group and 54 in the experimental group. Enrollment was closed early, 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 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 similar: 1A, 8B, and 1C compared to 1A, 8B and 1C in the FF and SS groups respectively. 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). Based on conditional probability calculations with 52.5% of enrollment, the probability of success of the trial given the current trend fell below 50%, and the trial was ended. 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. (Table Presented).