

The use of fibrin sealant to prevent major complications following laparoscopic gastric bypass: results of a multicenter, randomized trial.

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Abstract:

BACKGROUND: Published interim results have shown that fibrin sealant (Tissucol/Tisseel Baxter AG, Vienna, Austria) may be effective in preventing anastomotic leaks and internal hernias following laparoscopic Roux-en-Y gastric bypass (LRYGBP). We report the final results of a multicenter, randomized clinical trial evaluating the use of fibrin sealant in LRYGBP.

METHODS: Between January 2004 and December 2005, 340 patients aged 21-65 years with a body mass index (BMI) of 40-59 kg/m² undergoing LRYGBP were randomized (1:1) to two treatment groups: fibrin sealant group (applied to gastrojejunal and jejunojejunal anastomoses and over mesenteric openings), and control group (no fibrin sealant; suture of the mesenteric openings). Operative time, early and late complications, reinterventions, time to oral diet initiation, and length of stay were assessed.

RESULTS: Overall, 320 patients were included into the study: 160 in the control group and 160 in the fibrin sealant group. All patients completed follow-up assessments at 6 and 12 months, and 60.9% completed assessments at 24 months. There were no significant differences between groups with respect to demographics, operative time, oral diet initiation, hospital stay, and BMI reduction at 6, 12, and 24 months. The incidence of anastomotic leak was numerically, but not significantly,

greater in the control group. The overall reintervention rate for specific early complications (<30 days) was significantly higher in the control group ($p = 0.016$). No deaths or conversions to open laparotomy occurred.

CONCLUSION: The use of fibrin sealant in laparoscopic RYGBP may be beneficial in reducing the reintervention rate for major perioperative (<30 days) complications. Larger studies are needed.