

# **Clinical evaluation of fibrin glue in the prevention of anastomotic leak and internal hernia after laparoscopic gastric bypass: preliminary results of a prospective, randomized multicenter trial.**

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## **Abstract:**

**BACKGROUND:** Gastro-jejunal anastomotic leak and internal hernia can be life-threatening complications of laparoscopic Roux-en-Y gastric bypass (LRYGBP), ranging from 0.1-4.3% and from 0.8-4.5% respectively. The safety and efficacy of a fibrin glue (Tissucol) was assessed when placed around the anastomoses and over the mesenteric openings for prevention of anastomotic leaks and internal hernias after LRYGBP.

**METHODS:** A prospective, randomized, multicenter, clinical trial commenced in January 2004. Patients with BMI 40-59 kg/m<sup>2</sup>, aged 21-60 years, undergoing LRYGBP, were randomized into: 1) study group (fibrin glue applied on the gastro-jejunal and jejuno-jejunal anastomoses and the mesenteric openings); 2) control group (no fibrin glue, but suture of the mesenteric openings). 322 patients, 161 for each arm, will be enrolled for an estimated period of 24 months. Sex, age, operative time, time to postoperative oral diet and hospital stay, early and late complications rates are evaluated. An interim evaluation was conducted after 15 months.

**RESULTS:** To April 2005, 204 patients were randomized: 111 in the control group (mean age 39.0+/-11.6 years, BMI 46.4 +/- 8.2) and 93 in the fibrin glue group (mean age 42.9+/-11.7 years, BMI 46.9+/-6.4). There was no mortality or conversion in both groups; no differences in operative

time and postoperative hospital stay were recorded. Time to postoperative oral diet was shorter for the fibrin glue group ( $P = 0.0044$ ). Neither leaks nor internal hernias have occurred in the fibrin glue group. The incidence of leaks (2 cases, 1.8%) and the overall reoperation rate were higher in the control group ( $P=0.0165$ ).

**CONCLUSION:** The preliminary results suggest that Tissucol application has no adverse effects, is not time-consuming, and may be effective in preventing leaks and internal hernias in morbidly obese patients undergoing LRYGBP.