

Endoscopic sclerotherapy for the treatment of weight regain after Roux-en-Y gastric bypass: outcomes, complications, and predictors of response in 575 procedures

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Background: Weight regain after Roux-en-Y gastric bypass (RYGB) is common. Endoscopic sclerotherapy is increasingly used to treat this weight regain.

Objectives: To report safety, outcomes, durability, and predictors of response to sclerotherapy in a large prospective cohort.

Design: Retrospective analysis of a prospective cohort study of patients with weight regain after RYGB.

Patients: A total of 231 consecutive patients undergoing 575 sclerotherapy procedures between September 2008 and March 2011.

Interventions: Single or multiple sclerotherapy procedures to inject sodium morrhuate into the rim of the gastrojejunal anastomosis.

Main Outcome Measurements: We report weight loss, complications, and predictors of response. We also used Kaplan-Meier survival analysis and log-rank test to compare time to continuation of weight regain after sclerotherapy in patients undergoing a single versus multiple sclerotherapy procedures.

Results: At 6 and 12 months from the last sclerotherapy procedure, weight regain stabilized in 92% and 78% of the cohort, respectively. Those who underwent 2 or 3 sclerotherapy sessions had significantly higher rates of weight regain stabilization than those who underwent a single session (90% vs 60% at 12 months; $P = .003$). The average weight loss at 6 months from the last sclerotherapy session for the entire cohort was 10 lb (standard deviation 16), representing 18% of the weight regained after RYGB. A subset of 73 patients (32% of the cohort) had greater weight loss at 6 months (26 lb, standard deviation 12), representing 61% of the weight regained. Predictors of a favorable outcome included greater weight regain and the number of sclerotherapy procedures. Bleeding was reported in 2.4% of procedures and transient diastolic blood pressure increases in 15%, without adverse health outcomes. No GI perforations were reported.

Conclusions: Endoscopic sclerotherapy appears to be a safe and effective tool for the management of weight regain after RYGB. (*Gastrointest Endosc* 2012;76:275-82.)

Abbreviations: GIWLS, GI weight loss surgery; GJ, gastrojejunal; RYGB, Roux-en-Y gastric bypass; SD, standard deviation.

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Obesity and its associated conditions, including type 2 diabetes and cardiovascular disease, have reached epidemic proportions. The burden of this disease is particularly evident in the developed world, where the consequences include substantially increased morbidity, mortality, and cost to the health care system.¹⁻³ Of the many therapeutic approaches to the treatment of obesity and its complications, GI weight loss surgery (GIWLS) shows the most promise in achieving significant and sustained weight loss and diabetes resolution compared with medications or dietary and behavioral modifications.⁴

The proven efficacy of GIWLS, coupled with an improved surgical safety profile afforded by the introduction of laparoscopic techniques, has led to a surge in the number of bariatric procedures performed in the United States and worldwide, with an estimated 220,000 bariatric operations performed in the United States and Canada in 2008.^{5,6} Despite this increase, a large mismatch exists between the magnitude of the obesity epidemic and the number of GIWLSs performed, promising further increase in the number of bariatric surgery procedures.

Even after a common and effective procedure such as Roux-en-Y gastric bypass (RYGB) surgery, weight regain in the long term is typical and associated with a negative impact on patient quality of life and health status.^{7,8} This, coupled with a prohibitive rate of morbidity and mortality associated with surgical revision,⁹⁻¹¹ has presented the field of interventional endoscopy with the challenge of preventing and treating this unfavorable post-RYGB surgery outcome.

Much of the focus on endoscopic revision of the RYGB has been on the gastrojejunal (GJ) anastomosis and gastric pouch because dilation of the anastomosis and/or enlargement of the gastric pouch are thought to be risk factors for suboptimal weight loss and weight regain after surgery.^{12,13} Although postsurgical physiology and the exact mechanisms of weight regain remain unclear, a variety of less-invasive endoscopic techniques have been developed that focus on the reduction of the GJ stomal aperture and gastric pouch volume.¹⁴ Of these techniques, endoscopic sclerotherapy (Fig. 1) has started to gain acceptance for a variety of reasons, including widespread availability, ease of administration, short procedure time, relatively low cost, and short-term effectiveness demonstrated in small uncontrolled studies.¹⁵⁻¹⁹

Here we report the short- and mid-term outcomes, complications, and predictors of response to sclerotherapy as a treatment for weight regain after RYGB surgery in a consecutive cohort of 231 subjects undergoing 575 procedures. We also compare outcomes after a single sclerotherapy session compared with multiple sclerotherapy sessions to demonstrate a dose-response effect.

Take-home Message

- Weight regain after gastric bypass is a common problem that leads to worsening health status.
- Sclerotherapy is an effective and minimally invasive treatment alternative for this common problem.

METHODS

This is a retrospective analysis of prospectively collected data on 231 consecutive patients undergoing 575 sclerotherapy sessions for weight regain after RYGB surgery between September 2008 and March 2011. All patients had reached their nadir weight after RYGB surgery and were actively gaining weight at the time of inclusion to the study. Weight regain was defined from the weight loss nadir, and subjects with a gastrogastric fistula on a baseline upper endoscopy or barium study were excluded. Dietary counseling and conservative measures in a weight management program had failed in all patients. Patients were also seen in a clinic before their first sclerotherapy session to discuss the risks, benefits, and alternatives to this procedure. The available literature and our limited experience with the procedure were discussed with patients at this visit.

Our primary outcome was time to continuation of weight regain after the last sclerotherapy procedure. Continuation of weight regain was defined as a 5-lb or greater increase from presclerotherapy weight. Our secondary outcome was absolute weight change in pounds at an average follow-up of 6 months from the last sclerotherapy procedure.

All subjects were interviewed before each sclerotherapy procedure to gather baseline demographics, weight trends after RYGB surgery, and information about potential confounders. This information was recorded on standardized data entry forms. Subjects' height and weight were measured before each sclerotherapy procedure, and their weight changes from the last sclerotherapy procedure were recorded at each follow-up endoscopy and clinic appointment. The gastric pouch length and GJ stoma diameter were measured before sclerotherapy by using a consistent protocol. Calibrations on the upper endoscope shaft were used to measure the gastric pouch length, and a direct reading calibrated endoscopic measuring instrument (Olympus America, Center Valley, Pa) was positioned across the GJ stoma to measure maximal diameter (Fig. 1).

Sclerotherapy was performed by injecting sodium morrhuate (50 mg/mL) (Luitpold Pharmaceuticals, Shirley, NY) into the rim of the GJ anastomosis by using an endoscopic sclerotherapy needle. A 2-mL test dose was administered first, followed by a pause of 3 minutes to assess for sensitivity and acute adverse reactions. After the test dose, 2-mL aliquots were injected circumferentially surrounding the GJ anastomosis. The total volume of sodium morrhuate injected per session depended on the GJ stoma diameter and tissue re-

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