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A prospective randomized controlled trial assessing the efficacy of omentopexy during laparoscopic sleeve gastrectomy in reducing postoperative gastrointestinal symptoms

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Abstract
Background Patients undergoing sleeve gastrectomy experience a significant amount of postoperative gastrointestinal (GI) symptoms. The purpose of our study was to assess the efficacy of omentopexy during laparoscopic sleeve gastrectomy (LSG) in reducing postoperative food intolerance and GI symptoms.
Methods Morbidly obese patients undergoing LSG were randomly assigned to have LSG with or without omentopexy from May 2012 to June 2013. A total of 60 patients were recruited with 30 patients in each group. Patients and the symptom scorer were blinded as to the assigned surgery. All procedures were performed by one of two surgeons utilizing the same surgical technique. Patients were administered standardized surveys, including the Rhodes Index survey, gastroesophageal reflux disease (GERD) impact survey, and Eating Assessment Tool (EAT) survey at various time points postoperatively to assess nausea, vomiting, retching, frequency of GI symptoms, and level of distress.
Results There was no significant difference in patient age, percent decrease in BMI at any time point, or length of hospitalization between the two groups ($P > 0.05$). Furthermore, there was no significant difference in Rhodes Index scores, GERD impact scores, or EAT scores at any time point ($P > 0.05$). Patients in the LSG with omentopexy group required significantly more ondansetron perioperatively (16.1 ± 12.9 mg vs. 10.3 ± 10.2 mg, respectively; $P = 0.04$); however, there was no difference in metoclopramide requirement ($P = 0.22$). Surgical morbidity was not significantly different between the two groups ($P > 0.05$). Finally, there was no significant difference in number of postoperative clinic visits, office telephone encounters, total postoperative readmissions, or postoperative readmissions associated with GI symptoms ($P > 0.05$).
Conclusion Omentopexy did not significantly decrease postoperative food intolerance or GI symptoms in morbidly obese patients undergoing LSG. Other methods of mitigating postoperative intolerance to oral intake and GI symptoms should be investigated.

Keywords Gastrointestinal symptoms · Laparoscopic sleeve gastrectomy · Nausea · Omentopexy · Vomiting

Laparoscopic sleeve gastrectomy (LSG), sometimes referred to as vertical gastrectomy, was initially introduced as part of the duodenal switch procedure in super obese patients in 1999 [1], and as a standalone procedure in 2000 [2]. At this time, it is becoming one of the most popular bariatric procedures based on perceived ease of the procedure, with significant improvement in the co-morbidity profile, and evident weight loss. Beginning in 2009 the American Society for Metabolic and Bariatric Surgery (ASMBS) endorsed LSG as a potential first-stage procedure for high-risk morbidly obese patients [3].

Despite the apparent technical simplicity and relatively fewer nutritional complications when compared with the Roux-en-y gastric bypass (RYGB) or the biliopancreatic diversion duodenal switch (BPD/DS), the operation has

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certainly not been standardized [4]. LSG has been associated with a different set of complications, some of which may be associated with the loss of fixation of the gastric wall along the greater curvature. Patients may develop significant postoperative nausea following LSG that may lead to additional clinic telephone encounters, clinic visits, or even readmissions. The most common complications following LSG include exacerbation of pre-existing or new onset gastroesophageal reflux disease (GERD) and food intolerance [5–8]. These complications can have significant impacts on quality of life, which can even require conversion to other procedures such as conversion to a RYGB [8]. Recent studies suggested the loss of intraabdominal ligament fixation of the greater curvature of the stomach may result in malpositioning of the gastric sleeve leading to persistent GERD and food intolerance [9, 10]. Moreover, cases of gastric torsion and even volvulus have been reported following LSG [11].

In an attempt to address these issues given the relatively limited clinical data regarding a solution to this problem, we modified our technique for LSG by performing an omentopexy to the greater gastric curvature. Our hypothesis was that omentopexy would stabilize the greater curvature of the stomach in place of the natural abdominal ligamentous attachments and prevent some of these postoperative issues. The use of omentopexy with LSG has not been previously studied in a randomized comparative fashion. We performed a prospective, randomized, controlled, double-blind study to evaluate the efficacy of omentopexy with LSG in reducing postoperative food intolerance and GERD symptoms.

Methods

Patient selection and randomization

The study was conducted after approval from the Institutional Review Board of Weill Cornell Medical College (Protocol No. 1104011630). All patients who qualified for surgery were approached during a surgery clinic visit prior to surgery to participate in the outlined protocol. Any patient who has chosen to undergo LSG from May 2012 to June 2013 was asked to participate in a randomization process, to either LSG with omentopexy or LSG without omentopexy. Exclusion criteria included any patient who had previously been submitted to any type of bariatric surgery, any patient currently taking anti-nausea or GERD medications preoperatively, or any current smokers. All patients undergo preoperative upper gastrointestinal (GI) endoscopy.

A total of 60 patients were enrolled; 30 in each arm. A sample size of 30 in each group will have 80 % power to detect a difference in means of 0.94 (the difference between a control group mean of 1.88 and an experimental group mean of 0.94 [i.e., 50 % reduction]), assuming that the common standard deviation is 1.26, using a two group t test with a 0.05 two-sided significance level.

Patients and the symptom scorer were blinded as to the assigned surgery, and un-blinded at the end of the year study period. After explanation and reviewing the consent, they were asked to sign the consent and complete three GI symptom surveys: a Rhodes Index of nausea, vomiting, and reflux; an Eating Assessment Tool (EAT) score survey for dysphagia; and the GERD impact score survey. The surveys were then completed at day +1, +2, +3, +7, +30, and +365 after surgery. Post-operative days 0, +1, +2, and +3 surveys were administered at the bedside in the hospital. On post-operative day +7, the patients were contacted by telephone for form completion. At day +30, the patients completed the survey evaluation at their routinely scheduled follow-up visit. Patients may have been contacted by phone when necessary for form completion at any research time point, especially at day +365. All our patients are routinely started on maintained on a proton-pump inhibitor on postoperative day 1 and continued for at least 3 months as an outpatient.

Postoperative pathway

All patients were standardized with regard to the postoperative nausea pathway in the immediate perioperative period. The anesthesiologist was prohibited from using nitrous oxide, propofol infusion, and dextrose 5 % infusion. All patients were administered decadron 6 mg intravenously (IV) at the start of the procedure, ondansetron 4 mg IV at the end of the procedure, and a dilaudid patient controlled analgesia pump in the immediate postoperative period. Following the immediate postoperative period, nausea symptoms are controlled with either metoclopramide or ondansetron as needed at the discretion of the surgical team and patient response to medication. When tolerating oral liquids, patients are transitioned to crushed oxycodone tablets.

Analysis parameters

Demographics, preoperative, and postoperative BMI were collected. Pre-op and post-op surveys were analyzed for the type and incidence of postoperative GI symptoms following LSG. Total amounts of antinausea medications administered were collected perioperatively. The number of clinic visits, telephone encounters, total readmissions, and GI-associated readmissions were also recorded. Intraoperative and postoperative complications were also recorded and graded according to the modified Clavien–Dindo classification system [12].

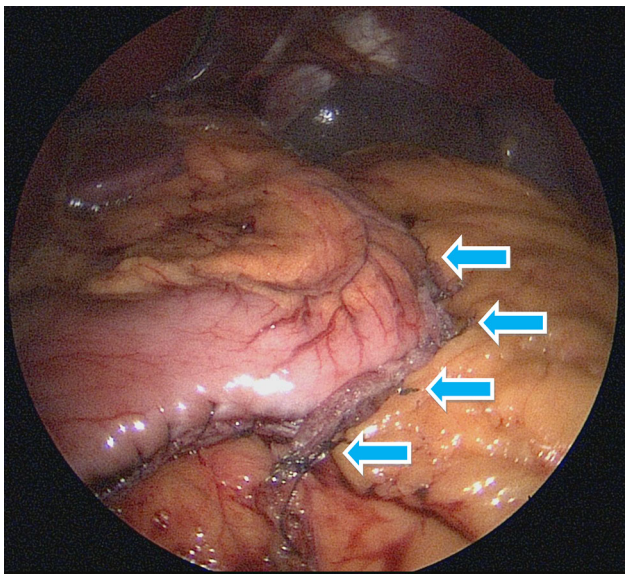

Fig. 1 The image depicts a laparoscopic sleeve gastrectomy with omentopexy. The *blue arrows* point to sites of the omentopexy along the Seamguard® (W. L. Gore & Associates, Newark, DE) staple line

Table 1 Perioperative data

Parameter	LSG with omentopexy ($N = 30$)	LSG without omentopexy ($N = 30$)	*P* Value
Perioperative data			
Age, years (mean ± SD)	37 ± 9.8	43 ± 12.6	0.07
Preoperative BMI (kg/m^2)	45.1 ± 7.1	49.1 ± 8.3	0.053
Length of stay (h)	71.0 ± 13.7	71.1 ± 16.4	0.72
Morbidity data			
Intraoperative complications	0	0	1.0
No. of patients with postoperative complications	3 (10 %)	3 (10 %)	1.0
Total no. of complications	3	4	–
Minor (I–II)	3	4	–
Major (III–IV)	0	0	
Postoperative antinausea pharmacologic requirement			
Metoclopramide (mg)	12.8 ± 16.2	8.0 ± 11.0	0.22
Ondansetron (mg)	16.1 ± 12.9	10.3 ± 10.2	0.04

BMI body mass index

Surgical technique

Our technique for LSG has been previously reported [2, 13]. All procedures were done by two surgeons for both groups (AP and GD). The omentopexy involves suturing the omentum back to the greater curvature of the stomach in four or five locations, depending on the length of the greater curvature (Fig. 1). The remainder of the procedure was identical for both groups.

Statistical analysis

Statistical analyses were performed using Graphpad Prism software version 5.03 (GraphPad Software, Inc. La Jolla, CA). Categorical variables were compared using χ^2 or Fisher's exact test, whereas continuous variables were compared using Mann–Whitney *U*-test (two-tailed). All results are expressed as mean ± SD, unless specified otherwise. The null hypothesis was rejected when $\alpha < 0.05$.

Results

Perioperative data

The perioperative data is listed in Table 1. There was no significant difference in age, preoperative BMI, length of stay, or percent decrease in BMI at 1 month between the two groups. There was no significant difference in metoclopramide requirement between the two groups ($P = 0.22$); however, the LSG with omentopexy group required significantly more ondansetron than the LSG without omentopexy ($P = 0.04$).

Complications data

There was no significant difference in morbidity between the two groups (Table 1). There were no intraoperative complications and the overall postoperative complication rate was 10 %. All postoperative complications in both groups were considered minor (grade I or II). In the LSG with omentopexy, three postoperative complications, including hyponatremia, pancreatitis, and fever of unknown origin, occurred in three patients. In the LSG without omentopexy group, four postoperative complications, including urinary retention, atrial fibrillation, hematuria, and an ileus, occurred in three patients.

Symptoms surveys

According to the Rhodes Index scores, there was no significant difference in total score, nausea score, vomiting score, retching score, symptom occurrence score, or symptom distress score between the two groups (Fig. 2). Moreover, according to the GERD impact score survey and EAT score survey, there was no significant difference at any of the measured time points (Fig. 3). Overall BMI percentage decreases were not significantly different at any of the measured time points (Fig. 4).

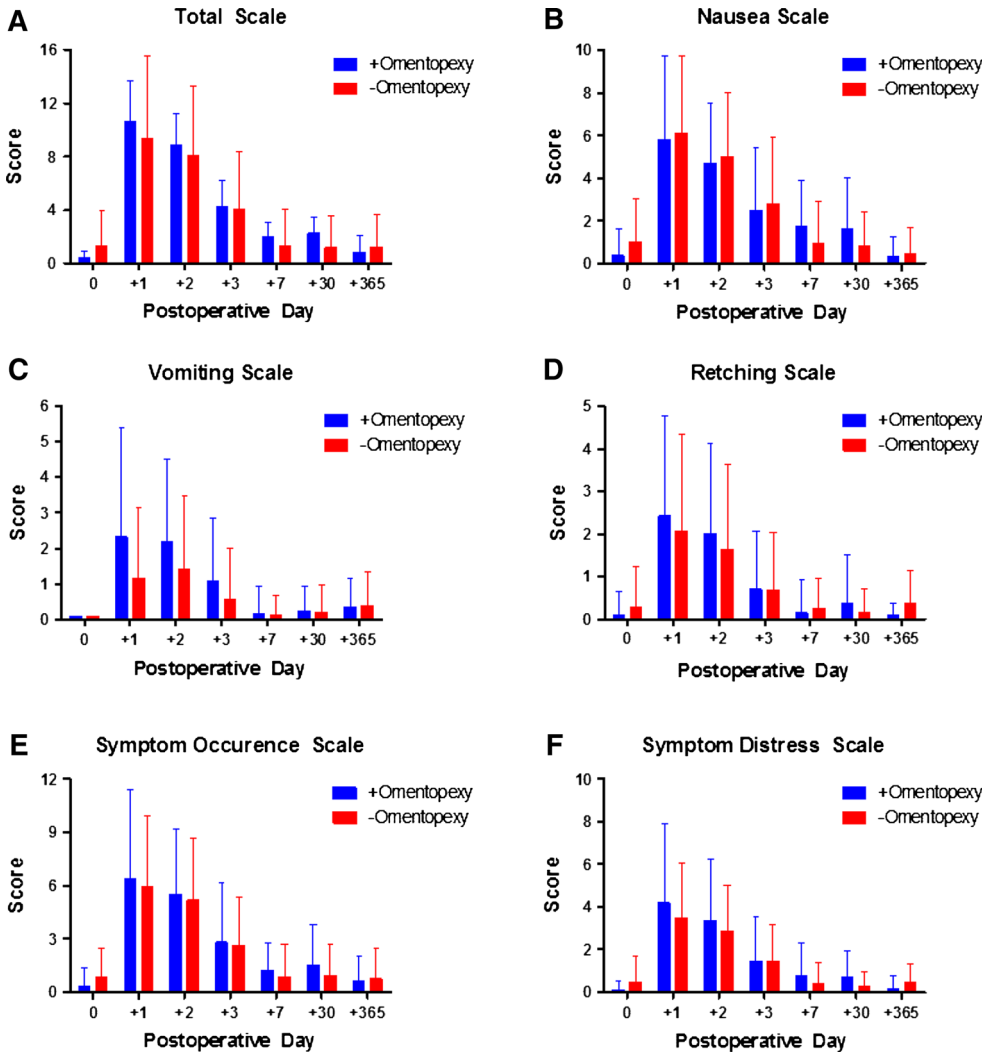

Fig. 2 The *bar* graphs show the mean and the *error bars* illustrate the standard deviation. The *x*-axis represents the postoperative day and the *y*-axis represents the scores. There was no significant difference ($P > 0.05$) in any of the categories listed (panels **A**–**F**)

Follow-up data

The follow-up data was similar between the two groups (Table 2). There was no significant difference in number of clinic visits, telephone encounters, overall readmissions, and GI-associated readmissions. The mean follow-ups were 7.4 months in the LSG with omentopexy and 9.8 months in the LSG without omentopexy.

Discussion

Our data demonstrated that omentopexy did not significantly improve food intolerance and GERD profiles in morbidly obese patients undergoing LSG. The lack of improvement was evident in the immediate postoperative period as well as up to 1 year postoperatively. In fact, those patients undergoing omentopexy had a slightly, but significantly higher postoperative antiemetic medication requirement in the perioperative period than those patients without omentopexy following LSG.

The LSG procedure is associated with changes in gastric emptying. The incidence of delayed gastric emptying and persistent food intolerance is reported as high as 30 % [14–16]. Goitein et al. studied the early postoperative emptying patterns on upper GI swallow studies of 55 patients undergoing LSG using a uniform surgical technique and bougie size [17]. In this study, patients were divided into two groups: those with passage of contrast into the duodenum in <30 s (type 1) and those >30 s (type 2). Patients in the type 1 groups experienced better tolerance of liquids in the immediate postoperative period with shorter lengths of stay. Thus, according to this study, irrespective of the variable gastric sleeve size, food tolerability was associated with swift gastric emptying than "twisting" or "torsion" of the gastric sleeve. The effect of omentopexy on gastric emptying has not been studied at this time.

The LSG has been linked to the promotion and/or aggravation of GERD in morbidly obese patients [18–20].

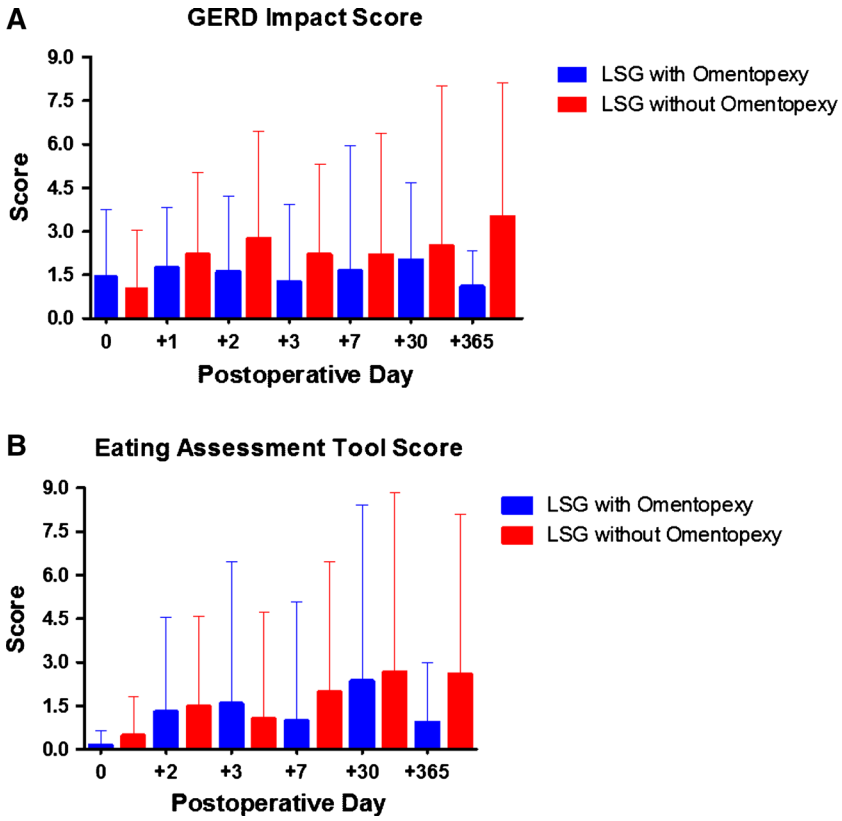

Fig. 3 The *bar* graphs show the mean and the *error bars* illustrate the standard deviation. The *x*-axis represents the postoperative day and the *y*-axis represents the scores. There was no significant difference ($P > 0.05$) in any of the categories listed (panels **A** and **B**)

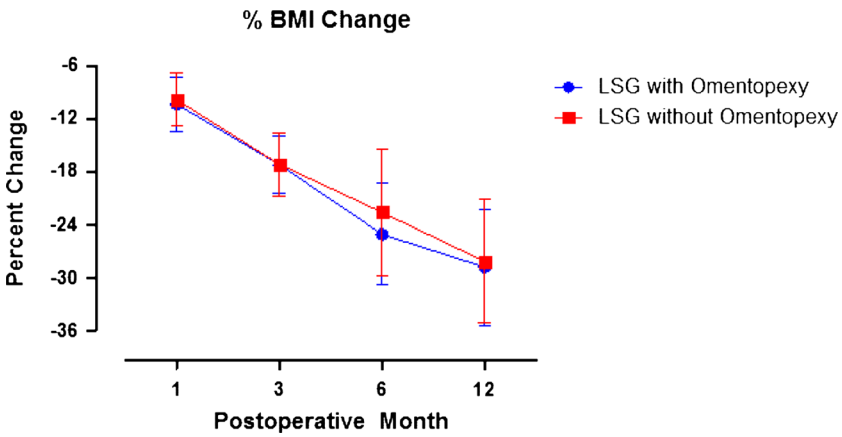

Fig. 4 The *x*-axis represents the postoperative month, while the *y*-axis represents the percent change in BMI. There was no significant difference ($P > 0.05$) at any time point postoperatively

The incidence has been reported as high as 22 % in the early postoperative period, although this percentage decreases after several years [20]. The postulated mechanism for increase GERD symptoms results from dissection of the angle of His and associated sling fibers with subsequent lower esophageal sphincter (LES) impairment [5, 15, 20]. Although some patients improve with medical therapy, others are very refractory to maximal medical therapy and may require revision of the LSG to a RYGB [21, 22]. In our study, omentopexy did not reduce the incidence of GERD symptoms or GI-associated readmissions; however, it is important to note that the GERD impact scores were very low at all the measured time points with or without an omentopexy. This may be related to our standard practice of maintaining all patients undergoing a LSG on a proton-pump inhibitor for at least 3 months.

Justification of performance of an omentopexy with LSG to prevent food intolerance is based on recreating the normal anatomic position of the stomach. In its normal anatomic position the stomach is anchored in place by the gastrohepatic, gastrocolic, and gastrosplenic ligaments. Gastric volvulus and organaxial torsion have been reported in the absence of one of the ligamentous attachment of the stomach upon distension of the stomach, particularly in the

Table 2 Follow-up data

Parameter	LSG with omentopexy ($N = 30$)	LSG without omentopexy ($N = 30$)	P value
Follow-up data (median, range)			
Clinic visits	2 (1–7)	2 (0–6)	0.41
Telephone encounters	1 (0–9)	2 (0–5)	0.18
All readmissions	0 (0–2)	0 (0–1)	0.82
GI-associated readmissions	0 (0–2)	0 (0–1)	0.24
Overall follow-up (months)	7.5 (1–17)	10.7 (1–19)	0.13

GI gastrointestinal

presence of food [11, 23, 24]. Omentopexy may potentially attenuate the incidence of intermittent gastric torsion that may contribute to food intolerance following LSG. Bauman et al. described a study quantitatively analyzing the detailed anatomy of the stomach following LSG [9]. In this study, they examined 32 multislice computed tomography datasets from 27 patients. Forty percent (40 %) of patients with intrathoracic migration of the staple line developed persistent postoperative nausea compared to only 12 % with correctly positioned staple lines. Omentopexy maintains the stomach in the abdominal cavity and prevents intrathoracic migration. Thus, loss of proper positioning of the stomach may significantly contribute to the development of food intolerance. Our technique pays particular attention to balancing the anterior and posterior retraction on the stomach during stapling to achieve a well-centered staple line, which may minimize the probability of torque during gastric peristalsis. We believe this technique may minimize any potential efficacy, if any, achieved by omentopexy.

Omentopexy has been described in the past by several groups for various reasons. Greenbaum et al. described a series of 41 patients undergoing revisional bariatric surgery with conversion from a variety of procedures to a BPD/DS with omentopexy and feeding jejunostomy [25]. The purpose of the omentopexy along the gastrogastrostomy and lateral gastric staple line in this study was to attenuate the leak rate. Although the suspected or potential leak rate was 20 %, none of the cases required surgical or radiographic intervention. The authors concluded that a randomized controlled trial was necessary to assess the efficacy of omentopexy when converting a RYGB to a duodenal switch. In another study, de Godoy and colleagues describe their technique of gastric fixation of the greater curvature of the stomach following LSG. The authors report the technique to potentially attenuate the incidence of GERD and food intolerance. Nevertheless, the authors only speculate about the efficacy without demonstrating any data to support the technique [26].

Our study has several limitations. First, the study is powered to detect at least a 50 % reduction in food intolerance symptoms, thus any reduction in symptoms <50 % may not be detected. Second, a power analysis was not performed to detect a difference in the incidence of torsion, and thus, is probably underpowered for this outcome. Moreover, the selection of anti-nausea medication following any LSG was not uniform and at the discretion of the housestaff physicians caring for a given patient at that time. In addition, the anti-nausea medication could not be standardized with a single agent as some patients responded better to specific medications. Nevertheless, this is the first and only prospective randomized controlled trial evaluating the efficacy of omentopexy with LSG with respect to postoperative food intolerance and GERD symptoms.

In conclusion, while surgical morbidity was not increased with this technical modification, omentopexy did not decrease postoperative food intolerance and GERD symptoms in morbidly obese patients undergoing LSG. Any potential benefit of omentopexy on preventing gastric torsion remains unclear at this time, perhaps due to other aspects of surgical technique and the infrequent nature of this complication. Nevertheless, other methods of mitigating postoperative GI symptoms should be investigated.

Disclosures Dr. Afaneh, Mr. Costa, Dr. Pomp, and Dr. Dakin have no financial ties to disclose.

Conflict of interest Dr. Afaneh, Mr. Costa, Dr. Pomp, and Dr. Dakin have no conflicts of interest.

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