

Retrospective Study

Are stapler line reinforcement materials necessary in sleeve gastrectomy?

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Abstract

AIM: To investigate the effect of staple line reinforcement materials on decreasing complications related to sleeve gastrectomy.

METHODS: In this retrospective study, we analyzed 84 patients who had sleeve gastrectomy due to obesity between April 2012 and April 2015. Sleeve gastrectomy procedure was performed in patients with a body mass index (BMI) more than 40 kg/m², and the ones with a BMI between 32 and 40 kg/m² in the presence of comorbid diseases. Reinforcement materials were used in 45 patients while they were not used in 39 patients. Materials such as Peristrip, 3/0 prolene, and V-lock were used for reinforcement in the reinforcement group (RG), and the materials used showed variations during the study period. The baseline characteristics, duration of surgery, hospital stay, comorbidities including hypertension, type 2 diabetes mellitus, hypertension, hepatosteatosis, gallstones, osteoarthritis, gastroesophageal reflux, sleep disorders, as well as the complications including leaks and bleeding after surgery were recorded and compared between the reinforcement and non-RGs (NRGs).

RESULTS: There were no differences between the reinforcement and NRGs for baseline characteristics including age ($P = 0.689$), gender ($P = 0.057$), height ($P = 0.483$), weight ($P = 0.889$), BMI ($P = 0.971$), hospital stay ($P = 0.888$), or duration of surgery ($P = 0.229$). The most common comorbidities in the RG were hypertension (24.4%) and hepatosteatosis (24.4%), while type 2 diabetes mellitus (28.2%) and

hepatosteatorosis (28.2%) were the most frequent comorbidities in the NRG. There were no differences between the reinforcement and NRGs for the rates of comorbidities ($P > 0.05$). Leak was observed in one (2.2%) patient in the RG, and there was leak in 2 (5.1%), and bleeding in 2 (5.1%) patients in the NRG. There were no differences between the reinforcement and NRGs for the rate of staple line leaks ($P = 0.446$) or bleeding ($P = 0.213$). One of the patients with leak died in the NRG while there were no deaths in the RG.

CONCLUSION: Although staple line reinforcement materials decreased morbidity and mortality, the differences between the two groups were not statistically significant.

Key words: Obesity; Sleeve gastrectomy; Staple line; Reinforcement

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Core tip: Sleeve gastrectomy is one of the most frequently performed surgical procedures in the treatment of obesity. In this study, we investigated the efficiency of use of staple line reinforcement materials in decreasing these complications. We included 84 patients in our study. Reinforcement materials were used in 45 patients while they were not used in 39 patients. Although we found that staple line reinforcement materials decreased morbidity and mortality, the differences between the two groups were not statistically significant for complications or mortality. There is a need for prospective randomized studies on larger patient populations to further clarify the subject.

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INTRODUCTION

The data published by the World Health Organization in 2014 indicate that 39% of the world population over 18 years of age are overweight and 14% of them are obese, and some problems including hypertension, cardiovascular diseases and gastroesophageal reflux appear due to obesity^[1]. Obesity is a significant health problem in the developed countries, and its prevalence has been increasing in the developing countries. In Turkey, which is a developing country, the prevalence of obesity in adults increased two-fold in the last 15 years, and reached 29.5%.

Laparoscopic sleeve gastrectomy is one of the most frequently performed bariatric procedures with an increasing popularity owing to its efficiency in weight loss, and its ability to improve comorbidities. Sleeve

gastrectomy shows its effect on weight loss by three different mechanisms: (1) Stomach volume is decreased by 80%-85%; (2) The concentration of ghrelin, an ergogenic hormone, decreases; and (3) Gastric emptying rate increases^[2].

The main disadvantages of sleeve gastrectomy are staple line leaks (SLLs) and bleeding. SLLs are seen in 1%-3% of patients after primary procedures^[2]. Leaks subsequently result in abdominal sepsis, chronic gastric fistula, necrotizing fasciitis, multi-organ failure and eventually sepsis, and they are the most important causes of mortality^[3,4]. A number of surgeons use staple line reinforcement materials (SLRMs) to decrease this complication while some others claim that those materials are not necessary, and use of them does not decrease SLLs^[5,6].

In this study, we aimed to investigate whether use of SLRM in patients who had sleeve gastrectomy due to obesity decreased complications such as SLLs and bleeding.

MATERIALS AND METHODS

This retrospective study included 84 patients who had sleeve gastrectomy due to obesity at Ankara Numune Education and Research and Medicalpark Ankara Hospitals between April 2012 and April 2015. The patients were divided into two groups as the reinforcement group (RG) in which a reinforcement material was used to reinforce the staple line, and non-RG (NRG) in which a staple line reinforcement material was not used. Selection of the patients into the RG or NRG group was the surgeon's preference. Demographic characteristics, comorbidities, and morbidities of the patients were recorded.

Sleeve gastrectomy procedure was performed in patients with a body mass index (BMI) more than 40 kg/m², and in the ones with a BMI between 32 and 40 kg/m² in the presence of comorbid diseases.

Enoxaparin sodium (Sanofi Winthrop Industrie, Maisons-Alfort/France) 60 mg was injected subcutaneously 12 h before surgery for prophylaxis of venous thromboembolism, and the patients wore anti-embolism socks on the day of surgery. Surgery was performed in the supine position, and the surgeon performed the surgery standing between the legs of the patient. Procedure was performed through 5 trocars: One 15 mm trocar for stapler handle, one 10 mm trocar for the camera, and three 5 mm trocars for instruments and liver retractor. The greater omentum was separated from the greater curvature, starting 2 cm proximal to the pylorus with Harmonic (Ethicon, United States) or Ligasure (Covidien, United States). The stomach was divided approximately 3 cm proximal to pylorus, targeting 1 cm lateral to the esophagogastric junction. Echelon 60 (Ethicon-Mexico) and Covidien 60 (Covidien, United States) staplers were used to divide the stomach.

A thick tissue stapler was used in the antrum, a thin tissue stapler used in the fundus, and a medium-

Table 1 Baseline characteristics of 84 patients that had laparoscopic sleeve gastrectomy

	RG (n = 45)	NRG (n = 39)	P
Age (yr)			
Male, n (%)	9 (20.0)	7 (17.9)	0.811
Female, n (%)	36 (80.0)	32 (82.1)	
Height (cm)	167.1 ± 8.5	166.1 ± 8.1	0.483
Weight (kg)	122.3 ± 23.2	120.9 ± 20.6	0.889
BMI (kg/m ²)	43.1 ± 7.4	43.3 ± 8.2	0.971
Hospital stay (d)	5.0 ± 2.3	4.3 ± 2.3	0.888
Duration of surgery (min)	82.9 ± 33.2	78.2 ± 30.3	0.229

RG: Reinforcement group; NRG: Non-reinforcement group; BMI: Body mass index.

Table 3 Staple-line bleeding and leaks after sleeve gastrectomy n (%)

	RG (n = 45)	NRG (n = 45)	P
Staple-line leaks	1 (2.2)	2 (5.1)	0.446
Staple-line bleeding	0	2 (5.1)	0.213

RG: Reinforcement group; NRG: Non-reinforcement group.

thick tissue stapler in the tissues between. An orogastric tube was inserted during surgery, the stomach contents were aspirated. The tube was then removed, and a 36 F calibration tube was inserted. Diluted methylene blue was given through the calibration tube to test the presence of any leak, and then the tube was removed. Materials such as Peristrip, 3/0 prolene, and V-lock were used for reinforcement in RG. The type of the material showed variations during the study period. Peristrip was used in 27 of 45 patients, 3/0 prolene was used in 12, and V-lock suture was used in 6 patients that had surgery after October 2014. The stomach tissue was removed through the 15-mm trocar incision. A Jackson-Pratt drain was placed, and it was removed when the drainage was less than 30 mL. The patient drank 100 mL methylene blue on postoperative day 1, and the drain was checked for the presence of methylene blue. The patient was given oral liquids after making sure that there was no leak.

Statistical analysis

SPSS version 22.0 (SPSS Inc, Chicago, IL) was used for statistical analyses. The categorical variables were compared by Fisher exact χ^2 test. Numerical data are presented as mean ± SD, and one sample *t*-test was used to determine whether they were parametric or not. Since the numerical data were determined to be non-parametric, Mann Whitney-U test was used to compare the two groups.

RESULTS

The baseline characteristics of 84 patients are presented in Table 1. There were no significant differences between

Table 2 Comorbidities of the patients n (%)

	RG (n = 45)	NRG (n = 39)	P
Hypertension	11 (24.4)	10 (25.6)	0.899
Hyperlipidemia	9 (20.0)	10 (25.6)	0.926
Type 2 diabetes mellitus	9 (20.0)	11 (28.2)	0.883
Sleep disorders	7 (15.6)	6 (15.4)	0.560
GERD	10 (22.2)	10 (25.6)	0.714
Depression	7 (15.6)	6 (15.4)	0.560
Hepatosteatorsis	11 (24.4)	11 (28.2)	0.696
Gallstone	8 (17.8)	8 (20.5)	0.750
Osteoarthritis	4 (8.9)	4 (10.3)	0.560

RG: Reinforcement group; NRG: Non-reinforcement group; GERD: Gastroesophageal reflux disease.

Table 4 Comparison of the groups for the complications other than staple line leaks and bleeding n (%)

	RG (n = 45)	NRG (n = 45)	P
Venous thromboembolism	0	1 (2.6)	0.464
Surgical field infection	3 (6.7)	2 (5.1)	0.568
Pulmonary complications	0	1 (2.6)	0.464

RG: Reinforcement group; NRG: Non-reinforcement group.

the two groups.

There were 9 different comorbidities in the two groups. The most common comorbidities in RG were hypertension and hepatosteatorsis (24.4%), while type 2 diabetes mellitus and hepatosteatorsis were the most frequent comorbidities (28.2%) in NRG (Table 2).

Leak, which is the most distressing complication in sleeve gastrectomy, was seen in one patient in RG (2.2%), and in 2 (5.1%) patients in NRG ($P = 0.446$). Leaks were recognized within three days after surgery, and the patients were followed conservatively first. However, none of the patients responded to conservative treatment. The leak orifice was closed endoscopically with over-the-scope clips at postoperative 2nd-4th wk. All patients recovered with this intervention. There were no bleeding in RG, however, it developed in 2 (5.1%) patients in NRG. The difference between the groups was not statistically significant ($P = 0.213$) (Table 3).

Comparison of the groups for the complications other than SLLs and staple line bleeding is presented in Table 4. Infection of the surgical field was seen in 3 patients in RG. Venous thromboembolism was seen in 1, surgical field infection was seen in 2, and pulmonary complications were seen in 1 patient in NRG. One patient in RG and 2 patients in NRG also had SLLs. Antibiotics and conservative treatment were administered to those patients. One patient in NRG died despite all those treatments, and other patients recovered.

DISCUSSION

SLL is the most important cause of mortality and morbidity after sleeve gastrectomy. Stapler line is reinforced

in order to minimize this distressing complication^[7]. Various SLRMs are used for this purpose, and the staple line is sutured. The primary SLRM used is a synthetic bioabsorbable material composed of the copolymer polyglycolic acid/trimethylene carbonate (GORE SEAM-GUARD Bioabsorbable Staple Line R, W.L. Gore and Associates, Elkton, MD, United States) put into the stapler cartridge, and Peri-Strips Dry with veritas. A recent meta-analysis including 56 studies and 6578 patients reported that SLRMs were used in 56% of the patients that had laparoscopic sleeve gastrectomy^[8]. The results of this meta-analysis indicated that use of SLRMs decreased the leak rate from 3.2% to 2%, without any statistically significant difference in between. Knapps *et al*^[4] reviewed 30 papers including 4881 patients, and did not find any statistically significant difference for leaks or bleeding with use of SLRM. Albanopoulos *et al*^[9] performed a randomized study on 40 patients, and reported that use of SLRMs did not decrease the leak rate. On the other hand, some surgeons claimed that use of those materials decreased SLLs. Ser *et al*^[10] performed a study on 118 patients, and reported the SLL rate as 10% without use of SLRMs, and as 0% with use of SLRMs. The results of that study reported a great difference between the two groups. However, it must be noted that the study of Ser *et al*^[10] included smaller number of patients when compared to other meta-analyses and reviews. In our study, SLL was seen in 1 (2.2%) patient in RG, and in 2 (5.1%) patients in NRG, and bleeding was seen in 2 (5.1%) patients in NRG.

The pathophysiological basis of stapler line reinforcement is not clear. Poor blood flow at staple line, insufficient closure of stapler cartridge, postoperative gastroparesis and pyloric dysfunction have been accused for SLLs^[11]. In addition, a staple line closure which is not straight is one of the most important causes for leaks.

Some stapler-related and tissue-related factors affect the morbidity of surgery. The stomach has the most variable wall thickness among the gastrointestinal system organs. Its wall is the thickest in prepyloric antrum, and the thinnest in the fundus. The thickness of the stomach wall decreases as one gets closer to the greater curvature, along the axis of the stomach^[7]. The tissue thickness must be taken into consideration when performing sleeve gastrectomy. The most important features of staplers are their leg lengths, closing characteristics, and the type of metal. Tissue-related characteristics are viscosity and thickness. The risk for leaks and bleeding increases with a long leg length, on the other hand, the leak risk also increases with a short leg length due to tissue ischemia and necrosis^[12]. Staplers with a long leg length must be used in the antrum, and those with a short leg length must be used in fundus. If a stapler with a short leg length is used in the antrum, this may cause dehiscence at the staple line^[13]. We preferred staplers with a long leg length in the antrum, staplers with a medium leg length in the corpus, and staplers with a short leg length in the fundus.

The likelihood of leak through the cut edge of the

stomach differs after sleeve gastrectomy. Of all leaks, 6.8%-14.3% were seen in distal 1/3 of the stomach while 75%-100% of them occurred in the proximal 1/3 of the stomach, particularly at the level of the esophagogastric junction^[14]. The leaks occurring in 3 patients in our series were at the level of the esophagogastric junction, in other words, in the proximal 1/3 of the stomach. Thin walls and poor vascularity in this part of stomach may be responsible for the leaks.

Leaks usually occur due to mechanical and ischemic factors. Wrong firing of stapler, and cutting in irregular zig-zags are among the mechanical factors, and they usually cause leak in the first postoperative 2 d. Ischemic factors are dissection of the tissues excessively with energy devices (Harmonic, Ligasure) and disturbance of the vasculature^[3]. Therefore, the tissues must be held carefully while using energy devices, and their use must be avoided in distal narrowings. Some surgeons wait for a while after squeezing the tissue with stapler in order to prevent leaks and bleeding, and they think that the fluid content of the tissue decreases and the vessels collapse in this way^[15]. Our team also practices this method, and we think that it is effective.

The thickness of the bougies used in sleeve gastrectomy for calibration and standardization is still debated. Bariatric surgeons usually use bougies with a diameter of 32-40 F^[16]. Some studies suggest that use of small-diameter bougies accelerates weight loss, however, increases the frequency of SLLs. The reference point here is higher intraluminal pressure in the stomach in case of a smaller diameter. Usually 34 and 36 F bougies have been recommended. Larger bougies may make reaching the ideal weight difficult^[17]. We used 36 F bougies in our series.

The mechanism of leak and bleed prevention by SLRMs is not known. However, it is sure that the materials used show a compressive effect. It is not known how effective this compression is. Some argue that compressive materials shorten operation time more than oversewing sutures^[18]. Durmush *et al*^[19] studied 518 patients retrospectively, and reported that materials that were implanted to stapler cartridge shortened operation time by 13 min when compared to oversewing. Kasalicky *et al*^[20] reported their experience on 207 patients, and stated that they did not use any reinforcement materials at the staple line or sutured it, the duration of operation shortened by 10 min, and the risk of bleeding did not increase. On the other hand, in their series with 100 patients, Shah *et al*^[21] reported that SLRM shortened operation time by 14 min on average (58.8 ± 19.7 min vs 72.8 ± 25.8 min, $P = 0.0153$). In our series, the operation time was approximately 5 min longer in RG, however, the difference between the two groups was not statistically significant.

One of the reasons for increased SLLs is revision surgery. Revision surgery is usually performed in patients who had laparoscopic adjustable gastric band surgery, and later had band removal due to band-related problems. The risk of leak is higher than 10% in those

patients^[22]. This high risk is due to insufficient stapler closure resulting from increased fibrosis and edema. Staged surgery was recommended to reduce this risk. Gastric band is removed in the first operation, and one week later, sleeve gastrectomy is performed^[23]. Four of our patients had had laparoscopic gastric band before, and our team had removed the band. We performed staged surgery in all those patients, and no leaks were observed.

Early diagnosis and treatment of SLLs are important to decrease morbidity and mortality. Therefore, an appropriate method must be used to identify leaks. Methylene blue, air-liquid test, and observation of the staple line with endoscopes are used for this purpose^[24,25]. In our study, leak test was performed by administration of diluted methylene blue both during surgery, and on postoperative day 1. A positive methylene blue test was confirmed in all of our patients by whole abdomen computerized tomography obtained after the patient was given an oral contrast material.

We could not have a final judgment on the use of SLRMs. The reasons for this is a small number of patients included in our study, retrospective and non-standardized study design, and no standardization of the materials used for reinforcement, which are limitations of our study. There is a need for further studies on a larger patient population with use of standard reinforcement materials.

In conclusion, sleeve gastrectomy is one of the most frequently performed bariatric procedures. Leak and bleeding are the most worrisome complications of this surgical technique. Various materials are used to reinforce the staple line to prevent those complications. However, there is no consensus in the literature on whether use of reinforcement materials decreased the complications or not. Although we could not have a final judgment in our study on use of SLRMs, we will go on using those materials in some patients depending on patient factors and course of surgery.

COMMENTS

Background

Sleeve gastrectomy is one of the most frequently performed surgical procedures in the treatment of obesity. However, it may result in some complications such as staple line leaks and bleeding, and even death.

Research frontiers

Reducing morbidities, particularly staple line leaks and bleeding, will increase the safety of the procedure. A number of surgeons use staple line reinforcement materials to decrease this complication while some others claim that those materials are not necessary, and use of them does not decrease staple line leak. There is still a need for research in this area.

Innovations and breakthroughs

In the authors' study, staple line leak was seen in 1 (2.2%) patient in the reinforcement group (RG), and in 2 (5.1%) patients in the non-RG (NRG), and bleeding was seen in 2 (5.1%) patients in the NRG, without any significant differences between the groups. The leaks occurred in 3 patients in their series were at the level of the esophagogastric junction, in other words, in the proximal 1/3 of the stomach. They preferred staplers with a long leg length in the antrum,

staplers with a medium leg length in the corpus, and staplers with a short leg length in the fundus since the stomach wall is the thickest in the prepyloric antrum, and the thinnest in the fundus. They waited for a while after squeezing the tissue with stapler in order to prevent leaks and bleeding, and they think that the fluid content of the tissue decreases and the vessels collapse in this way. They performed staged surgery in gastric band patients, and no leaks were observed.

Applications

The authors could not have a final judgment on the use of staple line reinforcement materials. The reasons for this is a small number of patients included in their study, retrospective and non-standardized study design, and no standardization of the materials used for reinforcement. There is a need for further studies on a larger patient population with use of standard reinforcement materials.

Terminology

Laparoscopic sleeve gastrectomy was performed through 5 trocars: One 15 mm trocar for stapler handle, one 10 mm trocar for the camera, and three 5 mm trocars for instruments and liver retractor. The greater omentum was separated from the greater curvature, starting 2 cm proximal to the pylorus with Harmonic (Ethicon, United States) or Ligasure (Covidien, United States). The stomach was divided approximately 3 cm proximal to the pylorus, targeting 1 cm lateral to the esophagogastric junction. Echelon 60 stapler (Ethicon-Mexico) and Covidien 60 (Covidien, United States) stapler were used to divide the stomach, and a thick tissue stapler was used in the antrum, a thin tissue stapler was used in the fundus, and a medium-thick tissue stapler was used in the tissues between. A 36 F calibration tube was used to determine the width of the remaining stomach.

Peer-review

The manuscript on staple line reinforcement is well-written and thus, of interest for the readers of the journal.

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