Original Article Could the measurement of pressure in the section of stomach excised during laparoscopic sleeve gastrectomy give an indication of potential leakage in the remnant stomach?

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Abstract: Background: A leak observed after laparoscopic sleeve gastrectomy operations poses a problem that is difficult to treat and follow up and it is the major reason for mortality and morbidity. The staples left in the remnant stomach and the ones in the section excised via sleeve gastrectomy are equal in number and structure. Thus, this study was designed under the consideration that measuring the strength of staples in the excised section could give an indication of the staple line in the remnant stomach. Methods: Two cannulae were inserted in the excised sections of 47 cases. They were inflated in water and their burst pressures were measured. The age, sex, BMI values, number of staples that were used, the first site of leak and burst pressure in mmHg of the cases were recorded. Results: Forty-seven cases were evaluated. Thirty-one of the cases were female and 16 were male. The average BMI value was 46.3 ± 5.5 . The average Staple burst pressure was 30 (17-78) mmHg. The median number of used cartridges was 5 (4-7) and the median number of opened cartridges was 3 (1-5). Conclusion: Performing a pressure measurement on excised section to assess the resistance of the staple line may also give an indication about the remnant stomach. As a matter of fact, the number of staples in the sleeve gastrectomy line is equal to that in the excised section of stomach that corresponds to the first site of leakage in detail during operation and intervention, in case of any problems.

Keywords: Laparoscopic sleeve gastrectomy, staple line, leakage, burst pressure, morbid obesity

Introduction

Today, the development of staple technology along with laparoscopic imaging systems has facilitated the performance of morbid obesity operations [1-3]. Laparoscopic sleeve gastrectomy is one of the most frequently performed morbid obesity operations [4, 5]. The endo-staples used in these operations facilitate the procedure and minimize any technical errors that may develop in manual suturing since they offer fast and safe closure-cutting [4]. The most commonly used endo-staples (EndoGIA Ultra[®], Covidien[®]; Echelon Flex Endopath[®] Staple, Ethicon EndosurgeryTM) function by placing 3 rows of staples on the 2 sides of the closed tissue and cutting the mid-section [6]. Post-operative staple line leaks and hemorrhaging are the most common complications that develop after sleeve gastrectomy. The rate of leak is approximately 1.1-2.5% [7]. Leakage following sleeve gastrectomy poses a problem that is rather difficult to treat and follow up and is the major reason for mortality and morbidity. Generally, it arises out of the deterioration of the staple line due to mechanical and ischemic reasons. The mechanical reasons generally originate from the inappropriate use of staples, uneven staple junction lines, and decreased closure strength due to over-use of the loading unit and ruptures secondary to an excessively thick tissue [7, 8].

The purpose of this study is to focus on the consideration that measuring the staple strength



Figure 1. Preparation of remnant stomach for bursting pressure.



Figure 2. Bursting Area.

in the excised section could give an indication of the staple line in the remnant stomach since the staples in the remnant stomach and those in the excised section are equal in number and structure.

Materials and methods

Patients

After the local ethics committee approval (ethical approval no: ANEAH.EK.2014/141) from September 2015 to December 2015, forty seven consecutive patients who were admitted to our clinic for weight reduction with ≥40 body mass index (BMI), and underwent sleeve gastrectomy, were included the study. All patients were evaluated by a multidisciplinary team for bariatric intervention, and informed of the risks and benefits of the procedure and provided written, informed consent. Only patients who were 18-60 years old were included the study. The exclusion criteria were: active H. pylori infection, active gastric ulcer, previous gastric resection or fundoplication, alcohol or drug abuse, psychiatric disorders, sweet eaters and the patients who were not permitted for surgery by first degree relatives. All operations were performed laparoscopically by two surgeons.

Sleeve gastrectomy technique

The procedures were performed by one surgical team. The standard surgical technique was used. Dissection of the greater curvature of the stomach was performed with Ligasure, beginning in the area located half way across the stomach body. After opening of the omental sac, the stomach was dissected towards the His angle, sealing the short gastric vessels and revealing the left portion of the diaphragm. Then the greater curvature was dissected towards the pylorus, terminating the dissection about 4-5 cm from it. A 39 French gastric tube was introduced into the patient's duodenum through the oral cavity. It was used as a calibration tube for the "new" stomach formation. Ethicon linear staplers with 60 mm long green cartridges were used during stomach resection in all cases. Staples from the last cartridge were applied leaving a margin of about 5-10 mm from the His angle. A latex drain was placed in the His angle region and brought out through one of the trocar insertion sites. The 15 mm trocar site was widened about 2 cm in order to avoid damage to the staple line on the removed stomach part. A leak test was performed using methylene blue administered under pressure through a gastric tube placed in the region of the gastroesophageal junction.

Study design

This research was an experimental study investigating the bursting pressure of resected stomach in patients undergoing sleeve gastrectomy for morbid obesity. The experimental method consisted of measuring the bursting pressure with Cem DT-8890[®] digital barometer during the time of staple line bursting. To fill the resected stomach and to measure the bursting pressure, two catheters were introduced to the fundus (**Figure 1**). The resected stomach was filled with air under water. The site of the first air bubble appearing in the staple line as well as the pressure at the time of bursting were recorded (**Figures 2, 3**).



Figure 3. Area showing bubble.

The number of used cartridges (UC), the number of opened cartridges (OC) which created the bursting site of the staple line (beginning from antrum to fundus), staple line bursting site (BS) (in the middle of one cartridge created staple line or in junction), staple line bursting pressure (BP) and the number of firings (NoF) with a staple gun in opened cartridge which created the staple line in bursting site were recorded. For further interpretation of staple gun usage, the number of staple gun firings was defined as the number of operations that were performed with one staple gun (according to our results; a staple gun was accepted as used in one operation when it fired five cartridges).

Limitations

Although we excluded patients who had ulcers and/or infected with H. pylori, we did not separately evaluate the patients who had mild or moderate antral gastritis.

The measurements of pressure and resistance of the staple lines were performed in extracted dead tissues but not on live tissues, therefore, in theory, the results might not be comparable between both situations. On the other hand, this work might be useful in testing stapler malfunction which is known to be the main cause of early leaks. The late leaks are generally attributed to ischemic events instead of the closing capacity of the staple.

Statistical analysis

Continuous data were presented as median and range or mean ± standard deviation (SD). Dichotomous and categorical data were presented as numbers with percentages. Normally distributed continuous data was assessed with Student's t-Test or ANOVA test. If the data was not normally distributed, continuous data was assessed with Mann-Whitney *U* test or Kruskal-Wallis test. The Chi square test was used for categorical data. A two-tailed *p* value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS, version 16.00 (Chicago, IL, USA).

Results

Forty seven consecutive patients (31 women and 16 men; mean age, 32.7 ± 8.8 years) who underwent laparoscopic sleeve gastrectomy were evaluated. The mean BMI was 46.3 ± 5.5 . The median number of UC was 5 (4-7): 4 cartridges in 14 patients, 5 cartridges in 16 patients, 6 cartridges in 16 patients, and 7 cartridges in one patient.

The median number of OC was 3 (1-5) (in the middle of one cartridge created staple line in 24 patients, and in junction in 23 patients). The median staple line bursting pressure in the time of staple line bursting was found to be 30 (17-78) mmHg. The median number of firings with a staple gun in opened cartridge that created the staple line in bursting site was 7 (3-19). Also, the median number of the operations performed with one staple gun that created the bursting staple line was 2 (1-4).

UC, OC, BS, BP and NoF were evaluated according to patients' sex, age groups (20-29; 30-39; 40-49; and \geq 50 years), and BMI groups (40-49; 50-59; and \geq 60) (**Table 1**). Briefly, the mean number of UC was significantly reduced in young patients (4.6 ± 0.7 in 20-29 years vs. 5.2 ± 0.8 and 5.7 ± 0.6 years in 30-39 years and 40-49 years old patients) (P=0.008). Also the percentage of staple line BS in the junction was found to be significantly elevated in young age group (20-29 years), while the percentage of staple line BS in the middle was found to be elevated in 30-39 years group (P=0.030).

Also, BS and BP were found to be similar regarding the number of UC and the number of the operation performed with one staple gun that created the bursting staple line (**Tables 2** and **3**, respectively).

None of our cases were observed to have staple leaks or hemorrhaging in the presented study.

	Sex			Age groups				BMI groups				
	Male	Vale Female		20-29	20-29 30-39	40-49	≥50	p values	40-49	50-59	≥60	P values
	(n=16)	(n=31)	p values	(n=19)	(n=17)	(n=10)	(n=1)		(n=38)	(n=8)	(n=1)	
UC	5.3 ± 0.8	4.9 ± 0.8	0.095	4.6 ± 0.7	5.2 ± 0.8	5.7 ± 0.6	5	0.008	5 ± 0.8	5.3 ± 0.7	6	0.302
OC												
1st	2 (12.5)	3 (9.7)		1 (5.3)	3 (17.6)	1 (10)	-		4 (10.5)	1 (12.5)	-	
2nd	2 (12.5)	9 (29)		2 (10.5)	2 (11.8)	2 (20)	-		10 (26.3)	1 (12.5)	-	
3rd	4 (25)	4 (12.9)		2 (10.5)	3 (17.6)	2 (20)	1 (100)		7 (18.4)	1 (12.5)	-	
4th	3 (18.8)	9 (29)		8 (42.1)	4 (23.5)	2 (20)	-		10 (26.3)	4 (50)	-	
5th	3 (18.8)	6 (19.4)		1 (5.3)	5 (29.4)	3 (30)	-		7 (18.4)	1 (12.5)	1 (100)	
BS												
Middle	8 (50)	16 (51.6)	0.917	5 (26.3)	12 (70.6)	6 (60)	1 (100)	0.030	21 (55.3)	3 (37.5)	-	0.351
Junc.	8 (50)	15 (48.4)		14 (73.7)	5 (29.4)	4 (40)	-		17 (44.7)	5 (62.5)	1 (100)	
BP	28 (20-57)	33 (17-78)	0.425	28 (17-56)	32 (19-78)	29.5 (22-57)	24	0.537	30 (17-78)	30 (20-56)	54	0.360
NoF	9 (3-15)	7 (3-19)	0.179	7 (4-19)	9 (3-15)	9 (3-15)	3	0.342	7 (3-19)	8 (4-14)	10	0.773

Table 1. Used Cartridges (UC), Opened Cartridges (OC), Bursting Site (BS), Bursting Pressure (BP) and Number of Firings (NoF) according to patients' sex, age and BMI groups

BMI: Body mass index, UC: The number of used cartridge, OC: The number of opened cartridge which created the bursting site of the stapler line (beginning from antrum to fundus), BS: Stapler line bursting site (in the middle of one cartridge created stapler line or in junction), BP: Stapler line bursting pressure, NoF: The number of firings with a stapler gun in opened cartridge which created the stapler line in bursting site.

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	The number of used Cartridges (UC)						
	4 cartridges	5 cartridges	6 cartridges	7 cartridges	Р		
	(n=14)	(n=16)	(n=16)	(n=1)	value		
00							
1st	2 (14.3)	1 (6.2)	2 (12.5)	-			
2nd	4 (28.6)	4 (25)	3 (18.8)	-			
3rd	6 (42.9)	5 (31.2)	1 (6.2)	-			
4th	6 (42.9)	3 (18.8)	4 (25)	1 (100)			
5th	-	3 (18.8)	6 (37.5)	-			
BS							
Middle	7 (50)	8 (50)	8 (50)	1 (100)	0.806		
Junc.	7 (50)	8 (50)	8 (50)	-			
BP	32.5 (17-41)	27.5 (19-56)	30.5 (20-78)	57	0.322		

 Table 2. Opened Cartridges (OC), Bursting Site (BS) and Bursting

 Pressure (BP) regarding the number of UC

UC: The number of used Cartridges, OC: The number of opened cartridge which created the bursting site of the stapler line (beginning from antrum to fundus), BS: Stapler line bursting site (in the middle of one cartridge created stapler line or in junction), BP: Stapler line bursting pressure.

Table 3. Opened Cartridges (OC), Bursting Site (BS) and BurstingPressure (BP) regarding the number of the operation performedwith one stapler gun which created the bursting stapler line

	The number of the operation performed with one stapler gun which created the bursting stapler line (with an estimation of 5 firings in one case)						
	1-5 firings (n=12)	6-10 firings (n=23)	11-15 firings (n=11)	≥16 firings (n=1)	P value		
OC							
1st	-	3 (13)	2 (18.2)	-			
2nd	-	9 (39.1)	2 (18.2)	-			
3rd	3 (25)	2 (8.7)	3 (27.3)	-			
4th	7 (58.3)	5 (21.7)	1 (9.1)	1 (100)			
5th	2 (16.7)	4 (17.4)	3 (27.3)	-			
BS							
Middle	6 (50)	12 (52.2)	6 (54.5)	-	0.774		
Junc.	6 (50)	11 (47.8)	5 (45.5)	1 (100)			
BP	34.5 (20-57)	30 (17-78)	28 (22-52)	40	0.718		

OC: The number of opened cartridge which created the bursting site of the stapler line (beginning from antrum to fundus), BS: Stapler line bursting site (in the middle of one cartridge created stapler line or in junction), BP: Stapler line bursting pressure.

Discussion

The fact that increasing staple strength is one of the most commonly discussed subjects among bariatric surgeons is due to the consideration that staples constitute the most important reason for leaks [1, 5, 9, 10]. While several authors suggest over-sewing sutures or strengthening materials on the staple line (GORE®, (10) SEAMGUARD[®], Peri-Strips Dry[®] etc.) [11-13], Ivan J. Arteaga-Gonzalez (6) states that 5 lines of staples has to remain in the remnant stomach in order to strengthen the staple line and 1 line of staples have to remain in the section of the stomach that would be excised. Similarly, Santoro [14] states that 4 lines of staples has to remain in the remnant stomach while 2 lines of staples has to remain in the section to be excised. The staples that are currently used provide stapling on both sides of the tissue in 3 rows followed by cutting the mid-section. The advantage of this feature for our study is that the staples in the excised section and the remnant stomach are equal in number and quality; therefore, the pressure and endurance test conducted in the residue tissue is able to provide information on the staple line in the remnant stomach.

There are relatively few experimental studies measuring the staple line strength available via literature. A study similar in nature to the one we performed is the study conducted by Karakoyun et al. [13]. This study compared the supportive methods for the staple line with the normal staple resistance and concluded that staple resis-

tance was higher in cases where staple line supporting material was utilized (106 ± 10.5 mmHg) as compared to cases where staple line supporting material was not utilized (30.5 ± 3.06 mmHg). In our study, the average burst pressure was measured as 30 (17-78) mmHg and the results we obtained were similar to the studies conducted. The main point of discus-



Figure 4. Bursting pressure and bursting site values.

sion in our study is the exact pressure that poses the risk for causing leaks. In order to determine this, it is recommended that one should check the burst pressure value in cases that developed leaks observed in the clinical follow-up. For example, in a case with 25 mmHg burst pressure that was identified to have a leak in the post-operative period in a leak site that corresponds to the site in the specimen, precautions for this particular site may be considered. Assuming that the pressure measurement value was recorded for all cases observed to have leaks, the cut-off value that indicates a leak risk may be calculated with the consequent cases. This depends on whether this technique will be widely adopted and introduced in practice on the basis of long-term clinical studies.

The use of right staples suitable for the tissue is a topic that is frequently emphasized in the case related literature [8]. It is stated that the tissue becomes thinner on the path from antrum to proximal stomach and staple thickness also needs to decrease towards the proximal stomach [15]. We use Echelon Flex Endopath Green Staples in all our cases. Based on a comparison of the burst pressures in our study, it was demonstrated that the differences among the burst pressures in the antrum or fundus sites were not statistically significant. Furthermore, the burst pressure in our study increased on the path from antrum to fundus even though no statistically significant differences were observed (**Figure 4**). Naturally, this situation does not refute the thesis that staples in different sizes need to be used in different tissue thicknesses; however, it can be interpreted as a finding in favor of the malnutrition hypothesis considering that leaks originate mostly in the staple line close to the gastroesophageal junction. This situation can be clarified as a result of studies designed in parallel with our study involving use of cartridges in different sizes and pressure measurements.

It is considered that the majority of leaks observed in the staple line originate in the staple junction sites [16, 17]. In our study, no statistically significant differences were detected in terms of burst pressures among the staple junction sites and other sites. It may be considered that the leaks in this section may also stem from technical problems.

Male sex is an independent risk factor for anastomosis leaks in bariatric surgery as in gastrointestinal system surgery and it is even used in scoring systems [18-20]. Although no statistical significance was identified in our study, the median burst pressure in males was 28 mmHg while it was found to be 33 mmHg in females. There were also differences among the maximum burst pressures. Similarly, elderly age poses a risk for anastomotic leaks while no statistical significance was identified in our study based on a comparison of burst pressures (20-29 years); however, the median staple pressure that was identified (28 mmHg) was lower as compared to the other age groups (32 mmHg for 30-39 years, 29.5 mmHg for 40-49 years). Considering this situation in combination with the staple line dehiscence site by age, which was found statistically significant, the fact that staple line dehiscence has a higher incidence among young patients (20-29 years) as compared to the junction site (73.7%) may account for the development of burst at lower pressures. Taking precautions for the staple junction site in younger patients will most likely produce better results (8 sutures or clips etc.).

There are no specific distinctions in the literature between BMI values and leak. In our study, no significant differences were observed among the BMI values and burst pressures. The fact that it has not reached a statistical significance level may be attributed to the low number of specimens.

There is also discussion as to whether the closure and cutting quality is decreased in parallel with an increase in the number of staple loading units used. In our study, the burst pressures for the first 5 firings and the burst pressures after 11-15 firings were comparable. As stated, no differences of statistical significance in terms of staple closure and firing strength were identified for the first 20 firings. The staple line dehiscence site is similar even after the 3rd surgery is performed with the same loading unit, which may suggest that frequent use of the staple loading unit may not actually disturb the integrity in the staple line contrary to common knowledge because dehiscence in the middle section of the staple line would be expected to be higher if the common knowledge had been correct.

Conclusion

The differences in staple line pressure with respect to male sex and younger age were found slightly lower, although not statistically significant. Bursting at the cartridge junction in the younger age (20-29) group was observed more often and it was considered that taking precautions for the junction sites in this group of patients might be more beneficial. It was observed that frequent use of the staple gun did not cause weakness in the middle of the staple line; however, the burst pressure decreased in inverse proportion to the frequency of use; however, no statistical differences were recorded for this situation. Performing firings at the recommended number and considering taking precautions for the junction site in younger patients may constitute a better approach aimed at avoiding leaks, which may cause catastrophic clinical results.

Pressure test with methylene blue or air test is conducted to assess whether there are leaks following resection in order to assess the staple closure strength in sleeve gastrectomy operations. We conduct this test for all cases. In our opinion, performing a pressure measurement in the excised section to assess the staple line strength may also give an indication for the remnant stomach. As a matter of fact, the number of staples in the sleeve gastrectomy line is equal in the excised section and this procedure is a rather easy, short and non-invasive test. The part of the stomach that corresponds to the first site of leakage observed following the test should be examined in detail and intervention is necessary in case of any problems. The limitation of our study is that we were only able to take the measurements mechanically in non-living tissue. It should also be noted that leaks may possibly arise due to ischemia.

Disclosure of conflict of interest

None.

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