

Why there is No Standardization in Laparoscopic Sleeve Gastrectomy?

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INTRODUCTION

Obesity has become a worldwide epidemic and it is related with many chronic diseases such as hypertension, type 2 diabetes, dyslipidemia, cardiovascular diseases, sleep apne etc. [1]. The obese population has different kinds of eating behaviours. They try lots of ways for losing weight (diet, exercise, medical treatment etc.) but usually it results with regaining weight [2]. Nowadays it seems that bariatric surgery is the most effective therapy in struggling with obesity even if there are some contradictory results [3].

There are few kinds of techniques in bariatric surgery and sleeve gastrectomy is one of the most popular ones. Sleeve gastrectomy is a restrictive type operation for morbid obesity. Open sleeve gastrectomy was first performed by Almqvist et al. in 1993 [4]. It was firstly described as the first step of Duodenal Switch (**DS**) and Biliopancreatic Diversion (**BPD**) [5-6]. Nowadays Laparoscopic Sleeve Gastrectomy (**LSG**) is a more popular operation than other procedures, with low rate of postoperative morbidity and mortality [7-8]. It was first performed laparoscopically as a part of a DS by Gagner et al. in 1999 [9]. After then Regan used this procedure as the first step of gastric bypass [10]. With the notice of marked weight loss with less morbidity and

mortality rate, LSG has replaced other surgical procedures' in the bariatric surgery world [11-12]. There are some advantages and disadvantages about LSG. Even though LSG has replaced laparoscopic Roux-an-Y gastric bypass within past decade [13-14], recent years; it has shown less success in resolution of type 2 diabetes, gastroesophageal reflux disease and 1 year Excess Weight Loss (**EWL**) [15-17]. On the other hand, its convertibility to other surgical procedures and low complication rate is satisfactory [18]. LSG, which is based on reducing gastric capacity, provides food restriction, early satiety, decreasing level of ghrelin (which is appetite stimulating hormone) and increasing level of GLP-1 and PYY-36 [19,20]. Up until today many surgeons performed this technique and cumulatively numbers are increasing [21]. Although it is seen as an easy operation by some surgeons, there is controversy about technical details which needs to be resolved. It is being performed in various ways and still there is no consensus on the topic; such as the size of bougie, the distance of from the pylorus to the first line of section, the section shape at the gastroesophageal junction, the staple line reinforcement and use of intraoperative seal testing. All of these issues continue being argued by authors [22]. The only consensual aspect is that the sleeve gastrectomy should be done by laparoscopy because the dissection of the greater curvature near the spleen is greatly facilitated by direct vision hence it helps to avoid iatrogenic injury [23,24].

After all, for achieving similar results in different serials for it to be considered safe by the public, it is important for the LSG procedure to become standardized [25]. Below we will discuss this topic.

SURGICAL TECHNIQUE

The operation begins from the dissection of great curvature to the gastroesophageal junction. Fundus is separated from spleen with opening the gastrosplenic ligament. Then dissection continues to the pylorus. After inserting the calibration tube called bougie, stomach is stapled from pylorus to gastroesophageal junction. We see the contradictions appearing here. The first question arises from determination of the size of the bougie. After stapling the stomach second question comes up; is stapler reinforcement necessary or not? Then the third question is determining the distance to the gastroesophageal junction and pylorus. Many surgeons use intraoperative seal test with methylene blue and place a drain.

SIZE OF BOUGIE

Bougie is used to calibrate the stomach. Despite the large numbers of sleeve gastrectomy cases, there is still no consensus on the size of bougie to be used. There are especially two aspects about the size of bougie; that it can affect Excess weight loss (**EWL**) rate and cause leaks. Especially staple line leaks are rare but very important. On the other hand, EWL rate is seemed as a success of the operation by people.

We know that 1 French (**F**) is equal to 0.33 cm and there are lots of discussions on what size the bougie should be. But actually small enlargement of the bougie size does not change noticeably the bougie diameter.

Weight loss after LSG is multifactorial. Initially, when Regan et al. performed sleeve gastrectomy with a 60-F bougie, they reported the percentage EWL rate as a 33% in 11 months [10]. Since then, surgeons used smaller-sized bougies and the rates of EWL reached 62% [25]. Breathauer et al. found this rate as 82% [26]. Some reports have shown that decreasing the size of the bougie can lead to greater percentage in EWL rate [27]. In addition, there is continuous disagreement as to whether LSG is only a restrictive procedure or combination of restrictive and hormonal procedure [28]. Many investigations have shown the effects of LSG on ghrelin levels and hunger feeling as well as on additional metabolic hormones [29,30]. LSG is resulted with restriction of gastric volume, decreasing in ghrelin levels which are released from fundic gland, rapid gastric emptying and faster intestinal transit [30-34]. Procedure is resulted with less eating, decrease in hunger feeling and early satiety. Reducing gastric capacity and decreasing levels of ghrelin, limits the amount of food consumption and causes a feeling early satiety. In this procedure we must bear in mind that the part of the stomach, that is most easily distended, is the gastric fundus. Ghrelin is released from the fundus as well. We must remove this part of the stomach because of ghrelin effect and possibility of the creation of a new fundus or dilatation. Some authors think that the more narrow the tube, the more successful the surgery. But leakage should never be underestimated. Yehoshua et al. investigated the relation between volume and pressure. They showed that narrower diameter can cause gastric stenosis, leaks and Gastroesophageal Reflux Disease (**GERD**) due to increased intraluminal pressure [35]. Similar to Yehoshua some other authors found that using larger diametered bougie decreases the leakage rates in relation to lower gastric pressure. For example Gagner et al. revealed that there is a decrease in the rate of leakage when larger bougie is used but also showed that there were no differences in weight loss between using 50F and 60 F bougie [36,37].

Weiner et al. investigated, in 120 patients, influence of sleeve size and gastric volume with comparing different size of bougie (32F-44F) and no calibration. They found similar results in the entire group on the rate of EWL. The non calibrated group showed a slight weight regain. However the best results in the rate of EWL, after 2 years, were observed in the most restrictive group (32F). In their practice they didn't see any stenosis in all the groups and only one leak in a patient who had had prior surgery [27]. Parikh et al, following meta-analysis on 9991 LSG patients, recommended the use of >40 F size bougie due to decreased leak rate without impacting EWL rate. In their own practice, on 135 patients, in 2008, they compared 40F and 60F bougie. They did not find any difference in terms of EWL rate (47.3%). They also pointed out that distance from pylorus did not have any influence on leak and EWL rate [37-38]. Yuval et al. analyzed 32 publications consisting of 4999 patients. They found that in groups where larger bougie was used, the rate of leak was lower but there was no difference in weight loss [39]. Spivak et al. used 32F and 42F bougie for calibrating. As regards to bougie size there was no influence on EWL rate in the first year. In both of the groups no leak was observed [40]. Jammu et al. who compared 1107 bariatric surgery cases, made 339 LSG surgeries. They used 36F-48F bougie, started from the 3-5 cm proximal to the pylorus. In terms of weight loss, there was no difference between two

different bougie groups. On the other hand, the higher incidence of leaks was in the LSG group which was related to the high intraluminal pressure which occurred in the 36F group [41]. Cal et al. compared the results of 27F and 39F bougie in 126 patients. They firstly stapled approximately 6-8 cm away from pylorus, constantly reinforced by suturing. The difference between groups' EWL rate was not statistically significant. They also found that narrower tube did not increase the risk of leakage [42] (Table 1).

Table 1: There is no difference in %EWL according to bougie size.

	Case (n)	Bougie size	% EWL
Wieren et al. (2007)	120	32-44	62
Parikh et al.* (2013)	9991	40 F-	70.1
Yuval et al.* (2013)	4999	40 F-	60.7-69.2
Spivak et al. (2014)	120	32-42	65-67
Jammu et al. (2016)	339	39-48	53.6
Cal et al. (2016)	126	27-39	75.6-71.3

*: meta-analysis

Sanchez-Santos et al. analyzed 540 patients proving that smaller bougie size is important in achieving higher EWL rates [43]. Bellanger et al. who have large series in literature, pointed out that it is of high importance not to staple near the esophagus at the angle of His and not to cause a strictures at the incusura angularis. They started the resection 3-4 cm from the pylorus and used 34F bougie. Despite of not using any reinforcement techniques, they did not observe any leakage. Their EWL rate was 65.92% after 1 year [44]. Atkins et al compared 40F and 50F bougie and found better results in smaller bougie size groups [45]. Ellatif et al. performed LSG to 1395 patients with 36F-44F bougie from the distance of 2-7 cm from pylorus. After 3 years of follow up, they found that the size of bougie did not affect EWL rate. But weight regain rate was greater in 44F than 34F bougie and reinforcement of staple line was not of value in terms of leak [46]. Szewczyk et al. performed LSG to 565 patients. They calibrated the stomach with 34F bougie and reinforced staple line with continuous sutures. In their series, the leak rate was 1.59% and the EWL rate was significantly high at 72.9% [47]. Alvarenga et al. published 1020 LSG cases. In their practice they found EWL rate as 86% using 32F bougie. They reported the leak rate as 0.1% and stricture as 0.59 % [48]. Lemaitre et al. performed LSG to 510 patients using 33F bougie and found average EWL rate as 64.3% after 1 year [49] (Table 2).

Table 2: Smaller bougie size increases % EWL.

	Case (n)	Bougie size (F)	% EWL
Sanchez-Santos et al. (2009)	540	32-34	68
Bellanger et al. (2011)	529	34	68
Atkins et al. (2012)	294	40-50	60.2-45.4
Ellatif et al. (2014)	1395	36-44	56-51
Szewczyk et al. (2014)	565	34	72.9
Alvarenga et al. (2015)	1020	38	86
Lemaître et al.(2016)	510	33	64

Roa et al. found 52.8 % EWL rate with 52F bougie [50] contrary to Serra et al. [19]. Dapri et al pointed out the importance of bougie size, placement and over sewing the staple line. Smaller bougie size, wrong placement and suturing the staple line can cause narrowing of the gastric tube. In their 9 patients they performed seromyotomy for stenosis after failed endoscopic dilatation [51]. Brethauer et al. analysed 36 studies, with a diversity of 32F to 60 F bougie size, and reported EWL rate at 33% and 85% similar to Gagner et al's report [26]. Boza et al. published their 3 years experience in 2012 with 1000 patients as EWL rate at 86.6%. They used 60F bougie and resected 6 cm from pylorus with suturing the staple line [52]. Ramos et al. performed LSG to 120 patients, using 32F bougie, resecting from 2 cm distance of pylorus and oversewing with absorbable suture. They emphasized that usage of bougie less than 36F in size increases significantly the risk of complications, like leakage, and does have any positive effect on the rate of weight loss [23] (Table 3).

Table 3: Larger bougie size increases rate of % EWL.

	Case (n)	Bougie size (F)	% EWL
Roa et al. (2006)	62	52	52.8
Breathour et al. (2009)	2570	32-60	33-85
Boza et al. (2012)	1000	60	86.6

The another topic about results of bougie size is stenosis. Some reports say that using larger sized bougie could cause high stenosis rate, some of them the controversial. These contradictory reports opened the discussion of other technical details. Some surgeons used suturing of staple line to avoid leakage although Bellanger et al. not using any reinforcement, did not report any leakage [44]. Some surgeons changed their techniques by giving up suturing. (Cottom et al. [5]) This brings up the fact that surgeons must be careful when suturing the staple line especially at the incusura. Plenty of tissue must be taken and bougie must be moved back and forward. In larger bougie size, due to over-retraction of the greater curvature, surgeon has the risk of cutting the corner and cause narrowing incusura angularis [53].

After all, there is a diversity of bougie size being used in LSG. A recent International Sleeve Gastrectomy Consensus (**ISGEPSCS**) published a set of guidelines. The panel included experienced surgeons, with a minimum of 500 LSG surgeries performed, from 11 countries representing 6

continents and compromised 24 surgical centers with a collective total of 12,799 LSG surgeries. R. Baker presented 828 patients using 34F sized bougie. Their results were 0.5% leakage rate, 0.12% stricture rate. A. Aceves presented 1127 patients with results of leakage rate as 0.62% and stricture rate as 0.35%. In the Consensus it was declared the optimal bougie size should be 32F-36F, due to greater weight loss and prevention of dilatation [7].

REINFORCEMENT

The most common major postoperative complications are bleeding and staple-line leakage. Leakage can be fatal if it is not managed quickly. In literature, mean leak rate is 2-3%. Leaks commonly occur in the proximal part of stomach, especially in the gastroesophageal junction. Although the pathophysiology of staple-line leaks after LSG is unclear, the most important reason is high pressure in gastric tube. Several studies compared different reinforcement techniques. Unlike others some surgeons do not use any reinforcement techniques. It is thought that reinforcing the staple line will increase its strength and decrease leaks. On the other hand, a definitive, joint decision has not been accepted yet. Reinforcement techniques and materials are various. It can be made with some sutures, absorbable polymer membrane, bovine pericardium or fibrin sealant.

Consten et al. compared non-reinforcing with buttressing material in 20 patients. They found that absorbable polymer membranes reduced leakage and bleeding [54]. Choi et al. analyzed the literature until August 2011, involving 1345 patients, about reinforcing the staple line. In that analysis, it was observed that reinforcing decreased leaks but statistically was not significant. They also realized that, except buttress, all reinforcing methods did not have any effect in terms of hemorrhage and even saw that over sewing might increase the risk of hemorrhage [55]. Gentileschi et al. studied the effect of trombin matrix and realized that it could be used safely to avoid leakage [56]. Aggrwal and Sroka et al. indicated that over sewing reduced bleeding and leakage, but it is also related with the efficiency and learning curve of the surgeon [57-58]. Gagner et al. analyzed 88 reviewed articles with 8920 patients in connection with reinforcement options. There observed 191 leaks (2.1%). Even though smaller bougie sizes were used and patients had lower BMI, the group which absorbable polymer membrane was used, was found to have much lower leakage rate compared to others [59]. Durmush et al. compared their 518 patients. Even though the stomach resection begun close to the pylorus and bougie smaller than 40F was used, they did not observe any leakage and even bleeding in absorbable membrane used group [60]. Carandina et al. analyzed 600 patients with or without used staple line reinforcement. They divided patients to 4 groups. No staple line reinforcement, reinforcement with absorbable suture, v-loc or fibrin glue. All reinforcement techniques were evaluated as decreasing the leakage but prolonging the time of surgery. Though it was not statistically significant, they also saw stenosis in reinforced group's similar to non-reinforced groups [61] (Table 4).

Table 4: Reinforcement decreases leakage.

	Year	Cases (n)	Reinforcement type
Consten et al.	2004	20	APM ^{**}
Choi et al. [*]	2012	1345	APM(butressing)
Gentileschi et al.	2012	1345	thrombin matrix
Agrawal et al.	2013	60	oversewing
Gagner et al. [*]	2014	8920	APM
Durmush et al.	2014	518	APM
Carandina et al.	2016	600	all type ^{***}

^{*}: meta-analysis,

^{**}: Absorbable polymer membrane

^{***}: v-loc, fibrin sealant, APM

Dapri et al. compared 3 techniques; non-reinforcement, absorbable membrane and staple line suture. There was no difference in leakage but absorbable membrane decreased bleeding [62]. Knapps et al. published a systematic review of staple line reinforcement in almost 4881 patients. Their analysis showed no difference in leakage rate with or without staple-line reinforcement [63]. Bülbüller et al. compared 4 methods in 65 LSG patients which was performed 3 cm proximal from pylorus with 32F bougie size. They did not use any reinforcement in 15 patients and used v-loc or 3.0 prolon for suturing and fibrin sealant. Although some reports say that reinforcement with v-loc reduces leakage, they found increased risk of leakage in this group and no difference in other groups. In light of this result, they advised that it must be sought with more number of cases because their cases were limited in number [64]. Kasalicky et al. experienced no problem in LSG cases without an over sewing of the staple line, likewise Bülbüller and Bellanger et al. They also recommended longer compression time after application of the stapler before firing to avoid from bleeding [65]. Shah et al. published their experience in 2014. When comparing 100 patients with 34F or 36F bougie and reinforcement or not, they found no difference in two groups in terms of leakage. No leakage was observed any of the groups. They realized that bougie size influenced bleeding and reinforcement reduced the severity of leakage rate [66]. Wang et al. evaluated 8 published randomized controlled studies, involving 791 patients. They suggested that reinforcement techniques could reduce postoperative hemorrhage but there was no significant reduction in leakage [67]. In 2015 Barreto et al. published their own center experience. 1502 patients who underwent LSG surgery were evaluated for three types of staple line reinforcement. Although they didn't find statistically significant differences, they saw that was a higher leakage rate in Bovine Pericardial Strips (**BPS**) groups compared to imbrications and absorbable polymer membrane. There was no difference between all groups in terms of bleeding [68] (Table 5).

Table 5: Reinforcement doesn't effect leakage.

	Year	Cases (n)	Reinforcement type
Dapri et al.	2010	75	APM**
Knapps et al.	2013	4881	all***
Bülbüller et al.	2013	65	all
Kasalicky et al.	2014	60	oversewing
Shah et al.	2014	100	all
Barretto et al.	2015	1502	all (except buttressing)
Wang et al.	2016	791	all

*: meta-analysis

** : Absorbable polymer membrane

***all: over sewing, APM, fibrin glue

Aurora et al. purposed to manifest the risk of sleeve gastrectomy leak analyzing in 29 publications, on 4888 patients. They realized that using larger than 40F bougie size may decrease the risk of leakage and accomplishing better EWL rate [69].

Fibrin sealants are also used to prevent fistulas. It is believed that it prevents leakage by binding tissue surfaces. Several studies have reported a decrease in the rate of leakage [70-71]. Omentopexy is another technique that uses by some surgeons to avoid leakage. There is no adequate data. Baltasar et al. used omentopexy together with inverting continue subserosal sutures [25,72]. Noel et al. published their 10 years experience. They emphasized some technical details. All connective tissue and vascular attachments of the stomach, especially posterior wall, must be divided to create a symmetric sleeve. Appropriate staple must be used and thermal injury must be avoided when using instruments. They insistently emphasized that surgeons experience will influence the leakage rate together with reinforcement [73]. Huang et al. emphasized the importance of using suitable staple height due to the various ranges of gastric wall [74]. Guetta et al. evaluated 308 LSG patients and pointed that if there is a secondary surgical procedure the rate of complications will raise [75].

In 2012 International Sleeve Gastrectomy Consensus; it was pointed out that staple line reinforcement would reduce staple line bleeding. The mechanism is unclear it is thought to arise from compression on tissue. Even if there are many studies about v-loc that it can be used safely at the staple line, more investigation is needed. When using it the surgeon must be careful due to the risk of serosal defect during the traction of stomach [7].

BEGINNING OF THE DISTAL SECTION

Another controversial point is the distance from the pylorus. Some of surgeons prefer long distance and some of close. Some surgeons believe that going further from the pylorus decreases intraluminal pressure and promotes gastric emptying by preserving its contractile function. It

would be safer if the integrity of vagal nerve can be preserved. According to other surgeons, the narrower the tube the better results in terms of weight loss. Until today, no clear consensus has been reached on weight regain. In long term case series, weight regain incidences were reported as 19.2% [76]. Recently it has been guessed that this figure is approximately 5-10% [77].

Fahmy et al. reported that there is a positive correlation with distance of pylorus and weight loss [78]. Ellatif et al. reported in 1395 patients, operated with different bougie size and distance from pylorus, that smaller bougie size and closer distance to the pylorus when resecting the stomach would bring better the results of EWL rate [11]. Elgeidie et al. searched the effect of gastric antrum size on the outcome of LSG surgeries. In their practice they applied two techniques. They started the resection from 6 cm proximal and 4cm proximal from pylorus. They saw that weight loss was greater in the group operated 4 cm proximal from pylorus, but did not find it statistically significant [79]. Abdallah and Obeidat et al. also discussed the same topic. They found that the bigger the resected antrum the better the result [80-81].

Lauti et al. searched the literatures to find out weight regain rate after LSG surgery. They highlighted the possible mechanism of weight regain, initial sleeve size, sleeve dilatation, increased ghrelin levels, follow-up support, lifestyle behaviours [82] Sanchez-Santos et al. obtained the data of 17 centers. They believed that initial narrow tube might decrease the incidence of gastric dilatation. They also found that closing to pylorus would bring better EWL rates [43]. On the other hand, some authors begun resection 6-7 cm proximal from pylorus and found greater results. Their hypothesis was preserving antrum would redound to gastric emptying and better results [5,83,84]. Bellanger et al. begun the transection from 3-4 cm proximal pylorus and they believed that this reduced the risk of stenosis and relating leakage [44]. Robert et al. prospectively evaluated 67 patients who underwent LSG surgery. They suggested that using small size bougie and making radical antrum resection did not improve weight loss and caused digestive intolerance on top of it [85].

In our practice we use 28F calibrating tube, illuminated with led lamp to lead for placement. After all gastric attachments were opened with thermal equipment, we begin transecting the stomach, 2 cm distance from pylorus and ended 1 cm far from angle of His. We pay attention not to stretch the gastric wall too much when positioning the staple due to the risk of rotation of the staple line. We chose the staple-height type according to tissue thickness. After resecting the stomach, we use 3.0 v-loc sutures with continuous suturing. In GE junction we imbricate the top of the fundus and in the other parts we use only over sewing. After the resected stomach is extracted, we performed a methylene blue test and place a drain near the staple line.

It can be clearly observed that most of the previous published studies have focused on this topic but as a result of the lack of standardization some issues were accepted in ISGEPCS. Some issues are accepted from most of surgeons (Table 6) [7].

Table 6: Surgical technique: consensus points.

Consensus statement
<i>Sizing bougie size:</i> Optimal bougie size is 32-36 F Imbricating staple line causes narrowing in the tube Always bougie must be used
<i>Staple heights:</i> Don't use less than that of blue load in any part of the stomach Never use less than that of green load in antrum If it is a revision surgery the last firing must be green or greater
<i>Resecting:</i> Transection should begin 2-6 cm from pylorus Stay away from GE junction on the last firing
<i>Mobilization:</i> Fundus must be completely mobilize before transection (also short gastric vessel)
<i>Reinforcement:</i> Reinforcement is acceptable procedures They can reduce bleeding, but have no effect on leak

GE: Gastroesophageal

LSG is a succesful operation. If it is provided a consensus on techniques, success will improve more.

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