

Original Research Article

Prospective interventional study of staple line reinforcement and buttressing in laparoscopic sleeve gastrectomy

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ABSTRACT

Background: Laparoscopic sleeve gastrectomy has gained increasing acceptance among bariatric surgeons and patients. The three main options for staple line reinforcement are over-sewing and buttressing with synthetic polymers or biologic tissue. The purpose of this study was to prospectively analyse the relative efficacy of gastric staple line reinforcement (SLR) by using over sewing as the method of reinforcement and comparing it with non-reinforcement laparoscopic sleeve gastrectomy (LSG) in 60 patients who were admitted in IGGMC Nagpur from May 2017 to November 2019.

Methods: Obese patients with age 18-65 years, BMI 40 and above with-out co-morbidities and 35 and above with co-morbidities, and BMI below 60, with no malignancy, no hiatus hernia, no previous bariatric procedure were included. All patients underwent LSG after thorough evaluation. 30 patients had reinforced staple line, while 30 had simple staple line.

Results: Total 60 patients were studied, 30 in each group. Intraoperative leak was seen in 1 patient each in both study groups. No bleeding was seen in reinforced LSG, while 3 patients had intraop bleeding in simple staple line group. 1 patient each of non-reinforced group had postop leak, postop bleeding and post op morbidity and mortality in 1 patient, while no postop leak or bleeding, morbidity or mortality was seen in reinforced group.

Conclusions: Reinforcement of staple line by over sewing in LSG resulted in significantly fewer surgical complications, lesser morbidity and no mortality compared to simple stapling of the gastric tube.

Keywords: Leak, Sleeve gastrectomy, Staple line reinforcement

INTRODUCTION

Laparoscopic sleeve gastrectomy has gained increasing acceptance among bariatric surgeons and patients because of encouraging excess weight loss and resolution of co-morbidity. Initially established as the first stage of 2-stage bariatric approach it is now used as primary bariatric procedure because of documented excellent weight loss and acceptable risk of complication.^{1,2} It is relatively simple and effective regarding excess weight loss, but it is associated with serious staple line complications such as bleeding, leaks and stenosis, which persists despite advances in the technology of surgical stapling devices.³ Therefore surgeons are

interested in any maneuvers that can minimize the risk of these events. The three main options for staple line reinforcement are over-sewing, and buttressing with synthetic polymers or biologic tissue.⁴ Staple line disruption is the most life threatening complication of after laparoscopic sleeve gastrectomy (LSG), with a mean incidence of 2.7% from 24 studies with 1749 patients.⁵ Leaks after sleeve gastrectomy commonly occur at the proximal aspect of the staple line immediately below the gastro-esophageal junction because of the creation of a high internal pressure. Staple line reinforcement has been advocated by many surgeons but not well studied through prospective or retrospective methodology.⁶ Moreover, surgeons practicing with respect to staple line

reinforcement varies widely. Options for staple line reinforcement include non-reinforcement, over sewing and use of buttressing within stapler load.⁷ The purpose of our study was to prospectively analyze the relative efficacy of gastric staple line reinforcement (SLR) by using over-sewing as the method of reinforcement and comparing it with non-reinforcement LSG with following aims and objectives to analyze the effect of reinforcement and postoperative incidence of staple line leak rate, the incidence of bleeding and to the effect of staple line reinforcement on mortality and overall morbidity of LSG.

METHODS

This was a prospective study was carried out in the department of surgery of tertiary care center over a period of May 2017 to November 2019. It was a prospective interventional study and intervention being LSG or LSG with reinforcement.

Inclusion criteria

Patients above 18 years and with BMI over 40 or greater than 35 with co-morbidities and failed conservative treatment for >2 years.

Exclusion criteria

Patients who had previously undergone a bariatric procedure including adjustable silicon gastric banding or vertical banded gastroplasty, older than 65 years of age, with BMI >60 kg/m², with malignancy 5 years before or operated 5 years before, with uncontrolled diabetes, unable to understand protocol, who were planning to become pregnant, unfit from anesthesia point of view.

Their complete clinical details were recorded in the proforma. All patients were selected by convenience sampling method. Every even numbered patient i.e. 2,4,6, 8 etc. was subjected to laparoscopic sleeve gastrectomy without reinforcement and every odd numbered patient i.e. 1, 3, 5, 7 etc. was subjected to laparoscopic sleeve gastrectomy with reinforcement.

LSG with or without reinforcement was performed with a

standard manner in a dedicated Bariatric OT. A gastric calibration tube of 40 Fr was used in all patients. Reinforcement was done in selected cases with 2.0 Stratafix starting from upper most end of staple line and continued by taking continuous sutures distally up to its lower end. Intraoperative methylene blue leak test was performed in all patients and abdominal drain was placed selectively. Postoperatively patients were monitored overnight in the surgical ICU. Ambulation is performed within 4 to 8 hours after surgery and chest physiotherapy is started in the immediate postoperative period. Clear liquids were started after 24 hours. The patient was discharged once oral intake of 1500-2000 ml/24 hours was established. A liquid diet was given for 1 week, a puréed/soft diet for next 3 weeks, and high protein, low sugar, low fat diet for 1 month. Dietary counselling was provided, and a normal consistency, low-calorie, high-protein diet was advised at 1 month after surgery.

Patients were followed up at 3, 6, 12, 18 and 24th post-operative months. Patient will be followed up in surgical OPD during post-operative period and thereafter up to 2 year as per the needs of the patients.

Data was entered in MS Excel, coded and analyzed in statistical software STAT, version 10.1, 2011 and analysis included both Descriptive and inferential statistics. Descriptive statistics were used to summarize quantitative variables with mean and standard deviation while frequency and percentages were used to summarize categorical (qualitative) variables. Inferential statistics included were Chi-square test and Fisher's exact test for assessing significance of difference in proportions in two intervention groups. A p-value <0.05 was considered significant for all comparisons.

RESULTS

This was a prospective and interventional study carried out in 60 cases of obesity with intervention being laparoscopic sleeve gastrectomy with or without reinforcement in department of surgery, IGGMC, Nagpur. There were 30 cases in each study group with the age range being 18-65 years in each group. Maximum patients, i.e. 27 patients (45%) were found in the age group of 30-40 years in both the study groups.

Table 1: General characteristics of patients included in present study and their comparative analysis.

Total (n=60)	Group A with reinforcement (n=30)	Group B without reinforcement (n=30)	P value
Male	13	12	0.013
Female	17	18	0.115
Age (median)	33	35	0.043
BMI (median)	36.5	35.5	0.034
DM	16	25	0.06
Hypertension	21	23	0.05
Sleep apnea	21	21	0.001
Osteoarthritis	11	10	0.002

In the present study there were 13 males (43.33%) and 17 females (56.66%) in LSG with reinforcement group, while 12 males (40%) and 18 females (60%) in LSG without reinforcement group, with overall female preponderance and preference for undergoing LSG for obesity.

In the present study, it has been observed that maximum patients i.e.30 (50%) are obese class 2, followed by 25 patients (41.70%) of obese class 3 and 5 patients (8.30%) were super-obese.

In the present study it has been observed that incidence of hypertension was in 35 patients (58.33%), diabetes mellitus in 41 patients (68.33%), osteoarthritis in 21 patients (35%) and obstructive sleep apnea in 42 patients (70%).

In one patient with simple staple line i.e. non-reinforcement, there was intraoperative leak after methylene blue test which was identified intra operatively and it was managed by taking new sutures and doing partial staple line reinforcement. In another patient with already reinforced staple line there was intraoperative leak, site of which was identified and closed by taking sutures. In both these patients the post-operative period was uneventful. Both these patients were started oral after 72 hours and even their gastrograffin contrast study was done which did not reveal any leak. The p-value is not significant here as all percentages are the same.

Table 2: Comparative analysis of surgical complications in Group A (with reinforcement) and Group B (without reinforcement).

Surgical complications (A+B)	Group A (n=30)	Group B (n=30)	P value
Overall			
Leak (postop+intraop)	0	1	0.313
Bleeding (postop+intraop)	1	4	0.0378
Re-operation	0	0	0
Death	0	1	0.313

N=total no of patients having complications (A+B).

Three patients of simple staple line i.e. non-reinforcement, had intraoperative bleeding out of which 1 patient could be managed by applying ligacclips to staple line and 2 patients' partial reinforcement of bleeding staple line with suturing had to be done.

The p-value here is 0.0378 which is significant. Not a single patient of LSG with reinforcement had any postoperative leak. 1 patient with LSG without reinforcement of staple had post-op leak which was identified after 36 hours. A contrast study was done which revealed leak from below GE junction in upper one third of sleeve which was managed by inserting a

megastent endoscopically and this megastent was kept 3 weeks and then removed after confirming no leak on contrast study. Out of total 60 patients in this study, 1 patient (1.66 %) of non-reinforced staple line had post-operative leak. The p-value here is 0.313 which is statistically not significant.

1 patient of simple staple line i.e. non-reinforcement had post-operative bleeding. The patient had drain output of more than 200 ml hemorrhagic in the drain on day 1 and day 2 followed by 150 ml hemorrhagic on day 3, 110 ml on day 4, 60 ml on day 5 and 20 ml on day 6 which became nil on day 7. Patient was monitored closely for hypovolemic shock but eventually patient was stable and recovered. The p-value is 0.313 which is statistically not significant but clinically we can definitely comment this that staple line reinforcement has added benefit to control post-operative bleeding as none of the patient with staple line reinforcement had post-op bleeding.

This was the patient who developed leak from staple line which was not reinforced and megastent has to be inserted. She had prolonged hospital stay of nearly 1 month with severe regurgitation, bile reflux and 1 episode of hematemesis which was managed conservatively which gradually resolved after removal of megastent. Due to prolonged hospital stay the patient got mentally affected and stopped taking oral intake which reduced her immunity and caused wound site infection leading to further hospital stay and further mental deterioration which lead to non-co-operation of the patient. A second leak was developed in this patient which led to sepsis and death of the patient.

1 patient had post-operative mortality because of post-operative leak which led to sepsis. The p-value here is 0.313 which is statistically not significant but clinically it is significant as reinforcing the staple line did not cause any post-operative leak in present study thus no question of mortality.

DISCUSSION

To decrease the morbidity associated with obesity and to improve the quality of life, obese patients frequently opt for bariatric surgery. Laproscopic sleeve gastrectomy is one of the most commonly performed bariatric procedures worldwide. But is fraught with complications like bleeding from staple line and leak from staple line leading to increased morbidity and sometimes mortality. So, with the aim to decrease the complications associated with this procedure surgeons worldwide commonly opt for different measures like using Glue, buttressing or oversewing the staple line. So, this study was performed to systematically review of staple line reinforcement including oversewing and buttressing to analyze the effect of staple line reinforcement on leak rate, post-op bleeding, mortality rate and overall morbidity of LSG.

In the present study it was found that maximum patients of both the groups were found in the age group of 31 to 40 years i.e. 45%. The mean age in the present study was 40 years, which corresponds with the study conducted by Frayer et al, who found out that maximum patients were in the age group of 31-40 years i.e. 49% and mean age in his study was 40 years.⁷ The mean age in the study by Flegal et al, mean age was 33 years and by Jensen et al, mean age was 44 years which does not correspond with the findings of age of above study which may be due to geographical variations.^{8,9}

In the present study female to male sex ratio was 1.4:1 showing that more and more females are prone for obesity and their preference to undergo laparoscopic sleeve gastrectomy. Stroh et al and Livingston et al in their studies found female to male sex ratio to be 2.5:1 and 3.8:1 respectively which shows more incidence of obesity in females.^{10,11}

In present study maximum patients i.e. 50% were found in obese class II category (BMI 35.9-39.9) followed by obese class III category i.e. 41.7% (BMI 40.0-49.9). In the study conducted by Jacob et al, maximum patients were found in obese class II group i.e. 50% followed by obese class III i.e. 12.5%.¹² Nagel et al found that maximum patients were in obese class II category i.e. 60% followed by obese class I i.e. 40%.¹³ Thus findings of this present study are comparable with other studies and maximum patients were in obese class II category (BMI- 35.9-39.9).

In present study maximum patient had Hypertension, DM and OSA as a co-morbidity associated with obesity i.e. 58.33%, 68.33 and 70% respectively followed by osteoarthritis i.e. 35%. In a study conducted by Capopglalia et al, maximum patients in the study were hypertensive i.e. 35%, diabetic i.e. 40% and had OSA i.e. 60% while in the study conducted by Numain et al, maximum patients were hypertensive i.e. 30% and diabetic i.e. 36%.^{14,15} Thus it can be seen that obesity is associated with other diseases like HT, DM, OSA and osteoarthritis in a majority of patients.

In this present study intraoperative methylene blue leak test was done in all the patients and the incidence of intraoperative leak was seen in 2 patients i.e. 3.3%, which was managed by taking additional sutures or reinforcement of staple line. Postoperative period of these 2 patients was uneventful. In a study conducted by Melissas et al, 1 patient had intra-operative leak i.e. 5.3% and in the study of Roa et al, 2 patients had intraoperative leak after methylene blue test i.e. 6.6%.^{16,17} In both studies the leak which was identified intraoperatively was managed by taking sutures. And anyways it is always better to detect leak intraoperatively than postoperatively and the findings of this study in relation to intraoperative leak correspond with the studies of above 2 authors.

In the present study intra-operative bleeding was seen in 5% patients and these were patients who had a non-reinforced staple line, which had to partially reinforce with sutures to control the bleeding. In the study conducted by Gill et al, 189 patients were included in study out of which 26 patients had intra-operative bleeding from staple line i.e. 13.7% and in the study conducted by Casella et al, 76 patients were included in study out of which 6 patients had intra-operative bleeding from staple line i.e. 7.8%.^{18,19} The incidence of intra-operative bleeding of present study is nearly comparable with the above mentioned studies and it is a complication which needs to be managed on table.

In the present study postoperative leak was seen in 1 patient out of 60 patients i.e. 1.6%. In a study conducted by Burgos et al, 7 patients out of 214 i.e. 3.2% developed post op leak, while in study conducted by Dapri et al, 75 patients were included out of which 4 patients (i.e. 5.3%) developed post op leak, and study by Daskalakis et al, 230 patients were included, out of which 10 patients (i.e. 4.3%) patients developed post op leak.²⁰⁻²² Thus it can be concluded that post-operative leak in present study can be compared with other studies and incidence of post op leak after laparoscopic sleeve gastrectomy without reinforcement is nearly the same.

In the present study, post-operative bleeding was seen in 1 patient out of 60 i.e. 1.6% and it settled in few days with conservative management. However in 2 studies conducted by Cottam et al and Serra et al the incidence of post op bleed was 0.9% (2 patients of 126) and 0.6% (6 patients of 993) respectively.^{23,24} The incidence of post-operative bleeding is slightly more in the present study because the sample size of above mentioned studies are more than the present study and as the experience of the operating team increases, the incidence of such post-operative complications decreases.

In the present study 1 patient of 60 i.e. 1.6% developed a post-operative leak which was managed by inserting a megastent under endoscopic guidance and this patient already had an abdominal drain placed during primary LSG. In study conducted by Burgos et al, 7 patients of 214 i.e. 3.2% developed post op leaks which was managed with percutaneous image guided drainage, total parenteral nutrition and antibiotics while in study conducted by Dapri et al, 4 patients of 75 i.e. 5.3% had post op leak which was managed surgically by conversion of sleeve to gastric bypass while in study conducted by Daskalakis et al, 10 patients of 230 i.e. 4.3% had post-operative leak, out of which 2 patients were managed with endoscopic drainage, 4 patients were managed by percutaneous image guided drainage, 2 patients were managed by fibrin glue insertion to the fistulous tract and 2 patients were managed surgically by gastric bypass procedure.^{21,22,25} Thus it can be seen that there are different methods to manage post-operative leak in the form of endoscopic stent insertion, image guided drainage of collection, total parenteral nutrition, fibrin

glue insertion and even conversion of gastric sleeve procedure to bypass procedure.

In present study postoperative mortality was 1.6% i.e. out of 60 patients, 1 patient expired. While in study conducted by Morino et al with a sample size of 215, 2 patients died due staple line leak leading sepsis i.e. 4.3% and in a study conducted by Omalu et al, 16,638 patients underwent sleeve gastrectomy out of which 440 patient died i.e. 2.6.^{26,27} So overall the mortality in patients in the study is less than other studies as half of the patients has re-reinforcement of staple line which definitely reduces the chances of post-operative leak, morbidity and mortality.^{28,29}

CONCLUSION

Therefore from this present study “prospective interventional study of staple line reinforcement and buttressing in laparoscopic sleeve gastrectomy” it can be concluded that, reinforcement of staple line by over sewing in LSG resulted in significantly fewer surgical complications compared to standard stapling of the gastric tube, was beneficial when compared to doing nothing but its efficacy needed to be compared with other technique by means of more prospective studies with better evidence and over sewing reinforcement of staple line is safe and less expensive but time consuming due to which it may increase the overall costs of the procedure and also learning curve in another concern.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Brethauer SA, Hammel JP, Schauer PR. Systematic review of sleeve gastrectomy as staging and primary bariatric procedure. *Surg Obes Relat Dis.* 2009;4:469-75.
- Casella G, Soricelli E, Rizzello M, Trentino P, Fiocca F, Fantini A, et al. Nonsurgical treatment of staple line leaks after laparoscopic sleeve gastrectomy. *Obes Surg.* 2009;19(7):821-6.
- Armstrong J, O'Malley SP. Outcomes of sleeve gastrectomy for morbid obesity: a safe and effective procedure? *Int J Surg.* 2010;8(1):69-71.
- Bellanger DE, Greenway FL. Laparoscopic sleeve gastrectomy, 529 cases without a leak: short-term results and technical considerations. *Obes Surg.* 2011;21:146-50
- Ravitch MM, Steichen FM. Staple suturing in the gastrointestinal tract. *Ann Surg.* 1972;175:815-36.
- Aurora AR, Khaitan L, Saber AA. Sleeve gastrectomy and the risk of leak: a systematic analysis of 4,888 patients. *Surg endosc.* 2012;26(6):1509-15.
- Fryar CD, Carroll MD, Ogden CL. Prevalence of overweight, obesity, and extreme obesity among adults aged 20 and over: United States, 1960-1962 through 2011-2014. National Center for Health Statistics Data, Health E-Stats, July 2016. Available at: https://www.cdc.gov/nchs/data/hestat/obesity_adult_13_14/obesity_adult_13_14.htm. Accessed on July 25, 2017.
- Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in obesity among adults in the United States, 2005 to 2014. *J Am Med Assoc.* 2016;315(21):2284-91.
- Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *J Am Coll Cardiol.* 2014;63(25):2985-3023.
- Stroh C, Köckerling F, Weiner R, Horbach T, Ludwig K, Dressler M, et al. Are there gender-specific aspects of sleeve gastrectomy-data analysis from the quality assurance study of surgical treatment of obesity in Germany. *Obes Surg.* 2012;22:1214-9.
- Livingston EH, Huerta S, Arthur D, Lee S, De Shields S, Heber D. Male gender is a predictor of morbidity and age a predictor of mortality for patients undergoing gastric bypass surgery. *Ann Surg.* 2002;236:576-82.
- Jacobs EJ, Newton CC, Wang Y, Patel AV, McCullough ML, Campbell PT, et al. Waist circumference and all-cause mortality in a large US cohort. *Arch Intern Med.* 2010;170(15):1293-301.
- Klenk J, Nagel G, Ulmer H, Strasak A, Concin H, Diem G, Rapp K, VHM&PP Study Group. Body mass index and mortality: results of a cohort of 184,697 adults in Austria. *Eur J Epidemiol.* 2009;24(2):83-91.
- Sahakyan KR, Somers VK, Rodriguez-Escudero JP, Hodge DO, Carter RE, Sochor O, et al. Normal-weight central obesity: implications for total and cardiovascular mortality. *Ann Intern Med.* 2015;163(11):827-35.
- Al-Nuaim AR, Al-Rubeaan K, Al-Mazrou Y, Al-Daghari N, Khoja T. High prevalence of overweight and obesity in Saudi Arabia. *Int J Obes Relat Metab Disord.* 1996;20:547-52.
- Melissas J, Koukouraki S, Askoxylakis J. Sleeve gastrectomy- a restrictive procedure? *Obes Surg.* 2007;17:57-62
- Roa PE, Kaidar-Person O, Pinto D. Laparoscopic sleeve gastrectomy as treatment for morbid obesity: technique and shortterm outcome. *Obes Surg.* 2006;16:1323-6.
- Gill RS, Switzer N, Driedger M, Shi X, Vizhul A, Sharma AM, et al. Laparoscopic sleeve gastrectomy with staple line buttress reinforcement in 116

- consecutive morbidly obese patients. *Obes Surg.* 2012;22(4):560-4.
19. Casella G, Soricelli E, Rizzello M, Trentino P, Fiocca F, Fantini A, et al. Nonsurgical treatment of staple line leaks after laparoscopic sleeve gastrectomy. *Obes Surg.* 2009;19(7):821-6.
 20. Burgos AM, Braghetto I, Csendes A, Maluenda F, Korn O, Yarmuch J, et al. Gastric leak after laparoscopic-sleeve gastrectomy for obesity. *Obes Surg.* 2009;19(12):1672-7.
 21. Dapri G, Cadiere GB, Himpens J. Reinforcing the staple line during laparoscopic sleeve gastrectomy: prospective randomized clinical study comparing three different techniques. *Obes Surg.* 2009;20:462-7.
 22. Daskalakis M, Berdan Y, Theodoridou S. Impact of surgeon experience and buttress material on postoperative complications after laparoscopic sleeve gastrectomy. *Surg Endosc.* 2011;25:88-97.
 23. Cottam D, Qureshi FG, Mattar SG, Sharma S, Holover S, Bonanomi G, et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. *Surg Endosc.* 2006;20(6):859-63.
 24. Serra C, Baltasar A, Andreo L. Treatment of gastric leaks with coated self-expanding stents after sleeve gastrectomy. *Obes Surg.* 2007;17:866-72.
 25. Burgos AM, Braghetto I, Csendes A, Maluenda F, Korn O, Yarmuch J, et al. Gastric leak after laparoscopic-sleeve gastrectomy for obesity. *Obes Surg.* 2009;19(12):1672-7.
 26. Morino M, Toppino M, Forestieri P, Angrisani L, Allaix ME, Scopinaro N. Mortality after bariatric surgery: analysis of 13,871 morbidly obese patients from a national registry. *Ann Surg.* 2007;246(6):1002-9.
 27. Omalu BI, Ives DG, Buhari AM, Lindner JL, Schauer PR, Wecht CH, et al. Death rates and causes of death after bariatric surgery for Pennsylvania residents, 1995 to 2004. *Arch Surg.* 2007;142(10):923-8.
 28. Iossa A, Abdelgawad M, Watkins BM, Silecchia G. Leaks after laparoscopic sleeve gastrectomy: overview of pathogenesis and risk factors. *Langenbecks Arch Surg.* 2016;401:757-66.
 29. Baker RS, Foote J, Kemmeter P, Brady R, Vroegop T, Serveld M. The science of stapling and leaks. *Obes Surg.* 2004;14:1290-8.

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