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ΘΕΜΑ

Comparative efficacy of staple line reinforcement techniques in Laparoscopic Sleeve Gastrectomy. A systematic review.

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Comparative efficacy of staple line reinforcement techniques in Laparoscopic Sleeve Gastrectomy. A Systematic review

Abstract

Objective: To assess the comparative efficacy of staple line reinforcement techniques in Laparoscopic Sleeve Gastrectomy.

Material and methods: A search of the medical literature was undertaken in Pubmed and in the Cochrane Central Register of Controlled Trials until July 2016. All Randomized Controlled Trials (RCTs) were included. The interventions assessed were a) no reinforcement b) buttressing the staple line c) oversewing d) glue application d) thrombin application.

Results: Ten RCT studies met the inclusion criteria. Total sample size was 1511 patients. Leak rates were 1.5 % in glue group, 1.72 % in buttressing group, 2.46 % in non reinforcement group, 2.5 % in oversewing group and 2.5% in thrombin group in ascending order. Hemorrhage rates were 1.87 % in glue group, 4.33 % in oversewing group, 14.9% non reinforcement group. 24.1 % in buttressing group Stenosis rates were greater in oversewing group compared to other groups. There was a significant heterogeneity between the types of cartridges used. Reoperation rates and mortality did not differ between the groups.

Conclusion: Leak rates are not affected by the reinforcement method. Glue and buttressing provide a safety profile regarding hemorrhage. Oversewing might predispose to stenosis. The operative time is doubled prolonged when oversewing compared to buttressing.

Introduction

Laparoscopic Sleeve Gastrectomy (LSG) is the most popular bariatric procedure in USA/Canada and Asia Pacific regions and second to the "gold standard" Roux-en-Y gastric bypass (RNYGBP) in Europe and Latin/South America regions [1]. LSG is positioned between the gastric banding and RNYGBP in terms of morbidity with effectiveness comparable to RYGBP [2, 3]. LSG comprises an 80 % longitudinal resection of stomach creating a long staple line which is potentially in risk of leak or hemorrhage. The technique is still improved. Technical aspects of the technique remain controversial. Several surgical strategies including oversewing, buttressing with absorbable polymer membrane or bovine pericardium, application of fibrin glue have been emerged in order to reduce the leak and haemorrhage rate.

According to Fifth International Consensus Conference for Sleeve Gastrectomy, it seems that there is an increasing trend of buttressing the staple line by the majority of the expert surgeons. Compared to general bariatric surgeons, experts agree to buttress more often especially with absorbable material and both oversew, but they believe that the use of nonabsorbable sutures in oversewing might cause fistulae [4]. The data even from meta analysis are debatable, since it is not clear whether staple line reinforcement may be beneficial for LSG.

Therefore, an up-to-date systematic review was conducted in order to clarify which technique may be beneficial. Such an approach could be useful for clinical practice, improve surgical technique and future research.

Material and Methods

The systematic review was conducted and reported according to The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration [5].

Search strategy

A search of the medical literature was undertaken in pubmed, Cochrane Central Register of Controlled Trials (CENTRAL) until July 2016. The keywords used were "laparoscopic sleeve gastrectomy" AND leak* AND random*, "laparoscopic sleeve gastrectomy AND (haemorrhage OR hemorrhage) AND random*", "laparoscopic sleeve gastrectomy AND reinforc* AND random*)

Eligibility criteria

Types of studies. All the Randomized controlled trials (RCTS) comparing different methods of reinforcement in LSG were potentially eligible for inclusion.

Types of participants. The types of participants were morbidly obese patients (BMI >35) undergoing laparoscopic sleeve gastrectomy.

Types of interventions. The interventions assessed in this study were no reinforcement b) buttressing the staple line with peri strips bovine pericardium or Gore Seamguard c) oversewing the staple line d) application of glue d) application of thrombin.

Types of outcome measures. Outcomes measured were leak, hemorrhage, stenosis, total operative time, time for reinforcing, reoperation, mortality, hospital stay.

Leak was defined according to the United Kingdom Surgical Infection Study Group as "the leak of luminal contents from a surgical join between two hollow viscera". Otherwise, it is an effluent of gastrointestinal content through a suture line, which

may collect near anastomosis, or exit through the wall or the drain. [6]. Stenosis was defined as the narrowing of sleeve. Leak, hemorrhage, stenosis, reoperation, mortality were reported as events. Time for reinforcing was defined as the time to perform the staple line reinforcement. Total operative time was the time from the first incision to the closure of the last incision. Total operative time, time for reinforcing, hospital stay were reported as median.

Inclusion and exclusion criteria

Two independently reviewers (D.C. and N.S) screened abstracts, reviewed full text versions of all studies classified, and extracted data. Any trial considered relevant was retrieved for further review. The fulltext was independently assessed by two reviewers. Disagreements were resolved with a third reviewer. Only published articles in the English language were included. Meta analysis, systematic reviews, letters to the editor, case studies, non-English language publications, duplicate studies, experimental studies, conference papers were excluded.

Data extraction, quality assessment, risk of bias in individual studies

One reviewer (E.S.) extracted data from selected trials and a second reviewer (E.E.) checked for accuracy. The data were standardized extracted from each study and data were recorded into a database. Variables collected were: First author, year of publication, country, interventions, number of arms, number of participants randomized in each arm, demographics (age, gender, BMI), parameters potential relevant to leak such as bougie size, distance from pylorus and types of cartridges. We also recorded events of leak, hemorrhage and stenosis, as well as total operative time, time for reinforcing, reoperation, mortality, hospital stay.

The methodological quality of each study was evaluated using the Critical Appraisal Skills Programme (CASP) Randomised Controlled Trial Checklist. [7].We assessed the risk of study bias using the following evidence-based criteria: method of allocation concealment, randomization technique, blocking, double-blinding and description of withdrawals/dropouts. Two reviewers independently assessed each study.

Summary measures

All the above variables were summarized as median per arm, a) no reinforcement b) buttressing the staple line with Peri Strips bovine pericardium or Gore Seamguard c) oversewing the staple line d) application of glue d) application of thrombin.

Results

Study selection

One hundred thirty one studies were screened for eligibility and sixteen studies assessed in full text. Six studies were excluded due to various reasons. One study was best evidence topic, two studies assessed different technique of reinforcement, one study had lower BMI, one study was experimental and one study had no randomization. Finally ten studies were eligible to be included in the systematic review (Figure 1). There was complete agreement among the authors as to the inclusion of these studies.

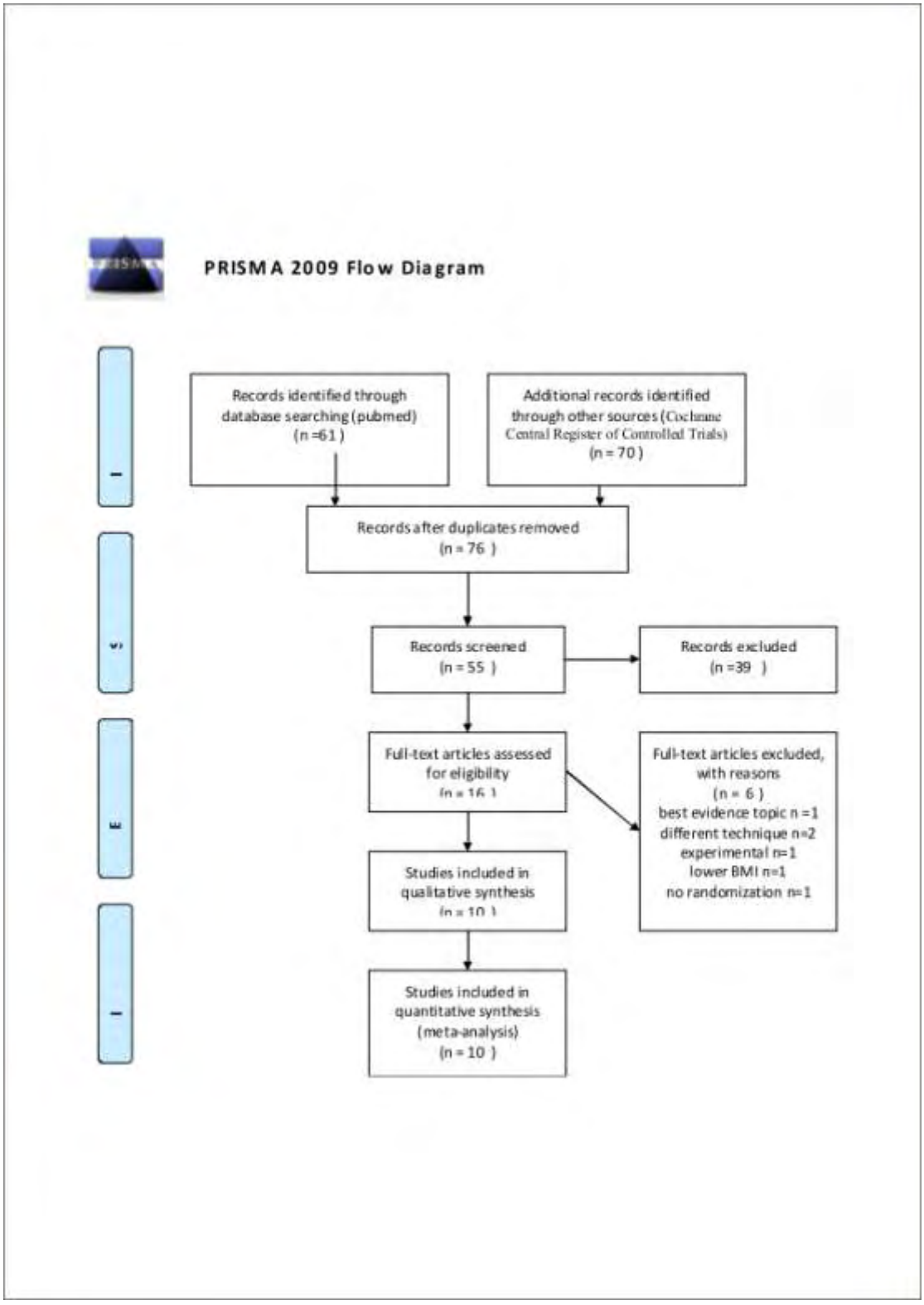

Figure 1.PRISMA flow diagram of clinical trials included in the systematic review.

Study characteristics

Six studies were conducted in Europe (Italy [n=3], France, Greece and Belgium, whereas two studies were performed in India, one in Turkey and one in Israel. Three studies compared no reinforcement with oversewing [8,9,10], one study compared no reinforcement with Peri strips[11], Carandina and Bullbuller et al compared no reinforcement with evicel glue and two different types of oversewing [12,13], Sroka et al. compared no reinforcement with evicel glue and oversewing [14], Musella et al compared no reinforcement with fibrin sealant[15], Gentilesshi et al. compared oversewing with buttressing Gore Seamguard and Floseal thrombin[16], Dapri et al. compared no reinforcement with buttressing Gore Seamguard and oversewing [17]. Three studies used buttressing material. Gore Seamguard was used in two studies, while Peristrips was used in one study. There was a great heterogeneity in method of suture oversewing and suture material. The various described methods could be divided in oversewing methods and continuous seroserosal sutures. Furthermore different suture materials such as monocryl, V- loc, PDS 0,1-0, 2-0 or 3-0, prolene 3-0

were used in these suturing types(Table 1).

A/A	First author's name	Year of publication	Country	Type of study	Total Sample size	Arms	Description
1	Carandina et al	2016	France	RCT	600	1	no reinforcement
						2	evicel fibrin glue
						3	oversewn SL with imbricating absorbable (Monocryl™; Ethilon Cincinati, USA) running suture
						4	oversewn SL with non-imbricating running suture using Vloc V suture
2	Albanopoulos et al	2015	Greece	RCT	146	1	no suture
						2	running absorbable suture full thickness PDS II
3	Sroka et al	2015	Israel	RCT	165	1	Evicel
						2	Suture over suture PDS 3-0 continuous
						3	Control
4	Shah et al	2014	India	RCT	100	1	Buttressing Peri-Strips Dry®
						2	No
5	Musella et al	2014	Italy	RCT	160	1	fibrin sealant
						2	no
6	Bulbuller et al	2013	Turkey	RCT	65	1	no reinforcement
						2	continuous serosal 3-0 prolene sutures
						3	v-loc suture serosal
						4	tissel fibrin sealant
7	Aggarwal et al	2013	India	RCT	60	1	continuous suture 2-0 polydiaxonone
						2	no
8	Gentileschi et al	2012	Italy	RCT	120	1	Oversewing seroserosal running sutures
						2	buttressing Gore Seamguard
						3	Floseal thrombin
9	Musella et al	2011	Italy	RCT	160	1	polypropylene3 suture oversewn
						2	no
10	Dapri et al	2010	Belgium	RCT	75	1	no
						2	Buttressing Gore Seamguard
						3	suturing non sero-serosal running sutures using absorbable material (polydiaxone, 1 PDS)

Table 1. Study characteristics

In total, 1511 patients underwent laparoscopic sleeve gastrectomy and were randomized in various intervention and control arms. Mean sample size was 151.1 patients (range 60-600). 468 were male and 1043 were female. The demographics characteristics per intervention group are presented in table 2.

Table 2

	No reinforcement group	Glue group	Buttressing group	Oversewing group	Thrombin group
Sample size	488	267	116	600	40
Sex male	163	84	47	167	7
Sex female	325	183	69	433	33
age	37.03±12.16	36.32±10.38	40.9±10.66	37.98±11.45	44.1±10.3
BMI	45.98±6.38	44.6±5.32	47.6±7.4	46.96±7.92	47.4±6.5

Table 2. Demographic data per intervention group.

Total leak rate was 34/1511 (2.25%), whereas total bleeding was 124/1511 (8.2%). Total stenosis was observed in 12/1511 (0.79%) and 3 deaths (0.19%) were recorded. Reoperation was 8/1511 (0.53%).

Leak

Leak rates were 2.46 % (12/488) in non reinforcement group, 1.5 % (4/267) in glue group, 1.72 % (2/116) in buttressing group, 2.5 % (15/600) in oversewing group and 2.5% (1/40) in thrombin group (Table 3). Interestingly, out of the 10 studies, none reported significant differences in rates of leak between the assessed interventions.

Table 3

	No reinforcement group	Glue group	Buttressing group	Oversewing group	Thrombin group
leak	2.46 % (12/488)	1.5 % (4/267)	1.72 % (2/116)	2.5 % (15/600)	2.5 % (1/40)
bleeding	14.9% (69/463)	1.87% (5/267)	24.1 % (28/116)	4.33 % (26/600)	0
stenosis	0.9% (3/332)	0.91% (2/218)	NR	1.54% (7/454)	NR

Table 3. Summary data for leak, hemorrhage, stenosis per intervention group.

Hemorrhage

Hemorrhage rates were 14.9% (69/463) in non reinforcement group, 1.87 % (5/267) in glue group, 24.1 % (28/116) in buttressing group, 4.33 % (26/600) in oversewing group and 0 in thrombin group (Table 3). Out of the 10 studies, three reported significant differences in rates of hemorrhage between the assessed interventions. Shah et al. observed fewer staple-line bleeds in the Peri strips group (PSD-V) group than the control group (23/51 [45.1%] vs 39/49 [79.6%] patients; p=0.0005), with lower severity of bleeding (p=0.0002)[11]. Dapri et al, reported that buttressing of the staple line with absorbable material as Gore Seamguard was superior to no staple line reinforcement or oversewing the staple line. Mean total blood loss was statistically significantly different too (p=0.03), smaller for buttressing group, 32.5±46.5 mL

versus 48.9±67.1 mL for no reinforcement group and 61.9±69.4 mL for oversewing group[17]. Musella 2014 et al, reported also that hemorrhage in glue group were significantly lower than in control group (7/50 vs. 1/50, p = 0.03)[15].

Stenosis

Stenosis were 0.9 % (3/332) in non reinforcement group, (0.91%) 2/218 in glue group, 1.54 % (7/454) in oversewing group and was not reported in buttressing and thrombin group (Table 3). Out of the ten studies, only one study showed statistical significance in terms of stenosis between the oversewing group and the no oversewing group (4/40 vs. 0/40, p=0.000).

Total operative time

Mean total operative time was 85.86±15.77 minutes in no reinforcement group, 97.37±16.76 minutes in glue group, 57.23±13.83 minutes in buttressing group and 116.02±14.61 minutes in oversewing group. Out of the 10 studies, five reported significant differences in rates of total operative time between the groups. Carandina et al. showed that mean total operative time was statistically significantly different, lower for the glue group, 104.4±22.1 min, versus 126.2±18.9 min and 124.6±22.8 (for oversewing groups) ($p<0.0001$) [12]. Aggarwal et al. reported that the mean operative time in oversewing group (139± 10 minutes) was significantly greater than in no reinforcement group. (117± 19 minutes) (P = .02) [9]. Dapri et. also found statistical significance between the three groups, smaller for no reinforcement group, 47.4±10.7 min versus 48.9±18.4 min (buttressing group with Gore Seamguard) and 59.9±19.6 min (oversewing group). (p=0.02)[17]. Musella et al, found statistical difference between the oversewing group and the no reinforcement group (89± 4 minutes vs. 80± 4, respectively ($p<0.001$) [10]. Shah et al. reported shorter surgical

time was shorter in patients who received Peri strips PSD-V compared to no reinforcement group (58.8 vs 72.8 min; p=0.0153) [11].

Time for oversewing

Only few studies assessed time for reinforcing. Carandina et al reported that time for reinforcing was 3.4±1.3 minutes for the glue group, 26.8±8.5 minutes for imbricating absorbable (Monocryl™; Ethilon Cinccinati,USA) running suture, 21.1±8.4 minutes for non-imbricating running suture using V loc suture[12]. Gentileshi et al reported that time for reinforcing was 2.4±1.8 minutes for buttressing group and 14.2±4.2 minutes for seroserosal running suture [16].

Hospital stay

Mean hospital stay was 4.48±1.32 days in no reinforcement group, 5.6±3.6 days in glue group, 3.9±1.5 days in buttressing group (it was reported only in one study), 4.64±2.81 minutes in oversewing group. Hospital stay was not reported in three studies[10,11,14]. Out of the ten studies, there was statistical significance between no reinforcement, buttressing and oversewing groups in one study. [3.6±1.4 days vs. 3.9±1.5 days vs. 2.8±0.8 days (p=0.01))[17]

Bouzie size, Distance from pylorus, Type of cartridges

The bouzie size ranged from 32-42F. 36 F bougie was used in three studies. Distance from pylorus ranged from 3 to 7 cm. The distance was not reported in two studies. There was a significant heterogeneity between the types of cartridges used. (Table 4)

Table 4.

A/A	First author's name	Bougie size	Distance from pylorus	Type of cartridges
1	Carandina et al	36	6	sequential firings of linear green and blue GIA reloads
2	Albanopoulos et al	34	3-4	two firings of a laparoscopic linear stapler with thick tissue loads (4.1mm) and subsequently firings with regular tissue loads (3.5mm).
3	Sroka et al	42	NR	changing staple height from black to blue loads according to the thickness of the stomach wall.
4	Shah et al	34 or 36	NR	Arm1 Peristrips Dry: green staple cartridges 2.0mm
				Arm2 control : lower part of the stomach green (2.0 mm); staples in the upper part of the stomach blue (1.5 mm)
5	Musella et al	36	5-6	a "green" cartridge (4.1 mm staple height) for the first firing followed by two "gold" cartridges (3.8 mm staple height)/. The last two firings performed by a couple of "blue" cartridges (3.5 mm staple height).
6	Bullbuller et al	32	4	First ignition was started with green cartridge then proceeded with blue cartridge
7	Aggarwal et a l	36	5	NR
8	Gentileschi et al	40	3	green cartridge for the first firing and blue cartridges for the remaining ones in all cases
9	Musella et al	38	7	gold cartidge was used three times followed by a blue one until the gastroesophageal juction was reached
10	Dapri et al	34	3	First two firings of linear stapler 4 80/60-mm green load. Further firings (3 5 60 mm blue cartridges)

NR: not reported

Table 4. Distance from pylorus, bouzie size, types of cartridges used in studies.

Reoperation

Reoperation was 0.81% (4/246) in no reinforcement group, 0.8% (2/251) in oversewing group, 0% in glue group, 0.86 % (1/116) in buttressing group and 2.5% (1/40) in thrombin group. This case came from the subgroup of Gore Seamguard. Reoperation was not reported in one study [14], and was not reported by group in another study [12]. None of the 10 studies reported significant differences in rates of reoperation between the assessed interventions.

Mortality

No deaths were observed in the 'no reinforcement group, one death (1/218-0.46%) in glue group 0% in buttressing group, 0% in thrombin group and 0.2% (1/495) in oversewing group. This case was present when v-loc suture material was used. Mortality was not reported in two studies [14,17]. None of the 10 studies reported significant differences in rates of mortality between the assessed groups.

Risk of bias within studies

The studies were of adequate quality based on the assessment using the CASP Randomised Controlled Trial checklist. (Appendix). All studies reported adequate randomisation, blinding, allocation concealment. No selective reporting of data was reported. Only one study had to stop early due to the fact that preliminary statistical analysis showed that running suture produced more hemorrhage and hematomas intraoperatively, but the sample size was sufficient to prove the results [8].

Discussion

We performed a systematic review comparing the different methods of reinforcements in LSG aiming to assess morbidity and mortality. In this systematic review, 10 randomized controlled trials with a population sample of 1511 were included. The patients were categorized in 4 study arms. Most of the studies did not show any significant results, however inferences are based in a small number of events.

The data in the literature regarding the use of staple line reinforcement techniques in LSG are debatable. Wang et al. reported that staple line reinforcement was associated with statistical significant lower risk of hemorrhage but not of leak and operative time prolongation[18]. Shikora et al. reported that buttressing with bovine pericardium (Peri strips) was more effective in terms of leak and hemorrhage followed by oversewing, buttressing with biocompatible glycolide copolymer (Gore Seamguard) and no oversewing [19]. Gagner et al reported that staple line reinforcement with absorbable polymer membrane was superior for reducing leak compared to staple line reinforcement with nonabsorbable bovine pericardial strips, oversewing or no reinforcement [20]. Knapps et al. found no statistical difference for leak and haemorrhage with or without staple line reinforcement [21]. Parikh et al found that buttressing had no impact on leak [22]. Choi et al. found decreased incidence of leak when reinforcing [23]. Chen et al. reported that reinforcement reduced hemorrhage, but was questionable for the leak [24].

The data from RCTs provide the strongest level of evidence to assess a surgical intervention. In this systematic review, total leak rate was 2.25 %. Leak rates were lower in glue and buttressing groups followed by no reinforcement and oversewing groups. The leak rates did not differ significant between the assessed groups. Our

results are similar to other studies [20]. More specifically, leak was reported only in one study of the glue group. In the buttressing group, leak was present in one study where the bougie size was 34 F and the distance from pylorus was 3 cm. [17]. It seems that the created sleeve was narrow enough and the use of buttressing material in these cases made a tighter sleeve predisponding to increased intraluminal pressure and leak development. Focusing at the oversewing group, no leak was reported in two studies. The suture materials used was continuous seroserosal prolene 3-0 running suture and continuous seromuscular PDS 2-0 continuous suture. The bouzie size used were 32 F and the distance for pylorus was 4 cm in one case and 36 F and 5 cm from the pylorus in the other study [9,13].

Hemorrhage rates differ between the assessed groups. The highest rates were in the buttressing group followed by non reinforcement group, oversewing group and glue group in descending order. It seems that glue and oversewing provide a safety profile regarding hemorrhage. Concerning oversewing, a lot of cases were present in one study, where full thickness PDS 0 suture material was used [8]. No cases of hemorrhage were reported when continuous serosal prolene 3-0, over suture 3-0 PDS continuous, continuous seromuscular suture using 2-0 polydiaxonone, non sero-serosal running sutures using absorbable material (polydiaxone, 1 PDS) were used [14, 13,9,17]

Stenosis rates were similar in non reinforcement group and in glue group (0.9, 0.91% respectively) and greater in oversewing group (1.54 %). This can be explained that oversewing might reduce the diameter of sleeve providing stenosis. No data are available concerning stenosis in buttressing and thrombin group. Further studies are needed to clarify this.

Mean total operative time was 57.23±13.83 minutes in buttressing group, 85.86±15.77 minutes in no reinforcement group, 97.37±16.76 minutes in glue group, and 116.02±14.61 minutes in oversewing group in ascending order. It seems that the operative time is almost doubled when oversewing compared to buttressing material. This result should taken into account when to choose between methods of reinforcement.

Time for reinforcing was also assessed in few studies. It seems reasonable that the use of buttressing material or glue is faster compared to oversewing. Among the different types of oversuturing, seroserosal suture is faster followed by non-imbricating running suture V loc and imbricating absorbable (Monocryl™; Ethilon Cinccinati,USA) running suture.

Hospital stay was shorter in buttressing group, followed by similar values in the oversewing and no reinforcement group and the hospital stay was prolonged in the glue group. Technical parameters are predisposing factors for leak. So, it is recommended the use of bougie size >40 F, the beginning of the transaction 5-6 cm from the pylorus and the use of appropriate cartridge colors from antrum to fundus to avoid leak [25]. In this systematic review, only two studies reported bougie > 40 [14, 16]. The most frequent used bougie size was 36F. As far as distance from pylorus three studies reported the beginning according to the above recommendations. The significant heterogeneity between the types of cartridges used found does not allow us to interpret the results. Further randomized controlled studies are needed in order to clarify which is the best type or even combination of cartridges.Reoperation rates were similar either you reinforce or not or use buttressing material. No reoperation was reported when glue was used, while the greater percentage reported for the

thrombin group is supported only by one study. As far as mortality, it was reported in the glue group and in the oversewing group when v-loc suture was used.

Several limitations of the study should be taken into account. The sample size and the size of the events was small. Furthermore, the unblinding from the surgeons' view was difficult. We also observed heterogeneity in surgical techniques between the suturing methods and the types of cartridges used which might influence the results. Due to these reasons, we did not attempt to synthesize the results.

Conclusion

Leak rates seem not to be affected by the reinforcement method. Glue and buttressing provide a safety profile regarding hemorrhage. Oversewing might predispose to stenosis. The operative time is almost doubled prolonged when oversewing compared to buttressing material. Further well designed randomized controlled trials including presidsposing parameters to leak would be useful to clarify the safest technique regarding LSG. The standardization of the technique is still mandatory. The use of buttressing material needs further evaluation before included in decision making algorithm.

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Appendix

CASP Randomized Controlled Trials Checklists of the studies.

Aggarwal et al

11 questions to help you make sense of a trial How to use this appraisal tool

Three broad issues need to be considered when appraising the report of a randomised controlled trial:

- **Are the results of the trial valid? (Section A)**
- **What are the results? (Section B)**
- **Will the results help locally? (Section C)**

The 11 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is ***yes***, it is worth proceeding with the remaining questions.

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There will not be time in the small groups to answer them all in detail!

These checklists were designed to be used as educational tools as part of a workshop

(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

Sixty consecutive
patients who underwent LSG for morbid obesity

- The intervention given

Group A (control group), patients underwent LSG with oversewing of the entire staple line with a continuous suture;

- The comparator given

or Group B (test group), patients underwent LSG without oversewing of the staple line

- The outcomes considered

Postoperative complications,including gastric leak (diagnosed on clinical features and imaging) and bleeding (as ascertained by need for re-exploration or need for blood transfusion in the postoperative period). Stricture, which is a late complication, was ascertained by requirement of endoscopic dilatation or any other surgical intervention for narrowing.

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

- Was the allocation concealed from researchers?

randomized into the following two groups using computer generated random numbers, which were then sealed in envelopes and opened by the floor nurse before the start of each case:

Detailed questions

Albanopoulos et al

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

146 patients were subjected to LSG

- The intervention given
- The comparator given

In the first group (Group A) patients underwent LSG without any reinforcement of the staple line. In the second group (Group B) patients underwent LSG with oversewing of the entire staple line with a continuous suture.

- The outcomes considered

Preoperative and intraoperative data were gender, age, weight, height, body mass index, previous operations, demographic data, operative time, and numbers of trocars and cartridges. Intraoperative complications, hospital stay, 30-day postoperative complications, and treatment of complications were also recorded and analyzed

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

These patients were randomized into two groups using computer-generated random numbers. The randomization of the patients was performed after their first visit at the clinic.

- Was the allocation concealed from researchers?

Bullbuller et al

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

65 patients between 18-60 years of age that underwent Classical Laparoscopic Sleeve Gastrectomy (LSG) in the General Surgery Department of Antalya Training and Research Hospital between January 2012 and May 2013 were included in the study

- The intervention given

compared four different techniques to evaluate staple line reinforcement in LSG.

- The comparator given

During LSG, support to stapler line was not reinforced in 15 patients (group 1), individual sutures with 3-0 propylene were used to reinforce stapler line in 16 patients (group 2), stapler line was strengthened by v-loc suture in 16 patients (group 3), and Tisseel 4 ml fibrin sealant (Two component Fibrin Sealant; 2 ml fibrinogen and 2 ml thrombin - Eczacıbaşı Baxter Drugs) was applied in 18 patients throughout stapler line (group 4).

- The outcomes considered

Patients were followed-up on for postoperative complications such as, duration of hospital stay, bleeding, anastomosis leakage, wound site infection, and abscess formation.

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

- Was the allocation concealed from researchers?

Carandina et al

11 questions to help you make sense of a trial How to use this appraisal tool

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

morbidly obese patients who
underwent LSG between April 2012 and December 2014 at
our University Hospital.

- The intervention given

- The comparator given

The 600 patients were randomly assigned to no staple line reinforcement (group A; n=150), Evicel ® fibrin glue (Ethicon, Sommerville, USA) cover (group B; n=150), oversewn SL with imbricating absorbable (Monocryl™; Ethicon, Cincinnati, USA) running suture (group C; n=100), or oversewn SL with non-imbricating running suture using VLoc ™ V suture (Covidien, New Haven, USA) (group D; n=100)

- The outcomes considered

Main outcome measures were post-operative complications such as post-operative leaks, bleeding, and stenosis, while as secondary outcomes we considered the time to perform the staple line reinforcement (SLR) and total operative time. Bleeding was recorded as a surgical complication when hemoglobin dropped to more than 3 g/dl in post-operative period. Patients with symptoms consistent with stenosis underwent further workup to confirm the diagnosis. Stenosis was defined as focal narrowing of sleeve seen on upper gastrointestinal contrast study and/or endoscopy. Time for SLR was calculated as the time between the end of the last fired GIA reload and the end of the roofing of the entire SL in group B, and the time between the end of the last fired GIA reload and the end of the oversewing of the SL in groups C and D. Total operative time was recorded as the time between the first skin incision and the end of skin closure.

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

11 questions to help you make sense of a trial **How to use this appraisal tool**

Three broad issues need to be considered when appraising the report of a randomised controlled trial:

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied
- The intervention given

Randomly compare three techniques in LSG: no staple line reinforcement (group 1), buttressing of the staple line with Gore Seamguard® (group 2), and staple line suturing (group 3).

- The comparator given

Randomly compare three techniques in LSG: no staple line reinforcement (group 1), buttressing of the staple line with Gore Seamguard® (group 2), and staple line suturing (group 3).

- The outcomes considered

Main outcome measures were defined as the operative time to perform the stomach sectioning, the total operative time, blood loss during stomach sectioning, total blood loss, and the number of stapler cartridges used. Time to perform the stomach sectioning was calculated as the time between the introduction in the abdomen of the first linear stapler and the end of the last firing of stapler for group 1 and group 2, and the time between the introduction of the first linear stapler and the end of the oversewing the staple line for group 3. Total operative time was calculated in all groups as the time between the introduction of the trocars in the abdomen and the placement of the drain along the staple line. Blood loss was calculated by measuring the volume of blood in suction pump at the end of sectioning and at the end of the procedure. Secondary outcome measures were preoperative complications, hospital stay, early complications, and late complications. Since leak is a seldom event, our study had no possibility to detect between the groups a statistically significant difference in terms of this event. Hence, this complication has not been considered as a main outcome of this study

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

Gentileshi et al

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

patients submitted to LSG

- The intervention given

Compare prospectively and randomly three different techniques of SLR during LSG

- The comparator given

Forty patients were allocated to the arm of oversewing (group A), 40 patients to the buttressing of the staple line with Gore Seamguard_ (group B) and 40 patients to the staple line roofing with Floseal_ (group C).

- The outcomes considered

Primary endpoints were reinforcement operative time, incidence of postoperative staple-line bleeding, and leaks. Operative time was calculated as follows: oversewing time in group A; positioning of polyglycolide acid and trimethylene carbonate over the stapler in group B; and roofing of the entire staple line in group C Moreover, mean additional costs were calculated using hospital current fees for each material but not for operating room occupancy

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

Randomization was performed by using a shuffling method with Excel_

- Was the allocation concealed from researchers?

Detailed questions

Musella et al.

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

100 consecutive patients who underwent laparoscopic sleeve gastrectomy

- The intervention given
- The comparator given

Patients were randomized to receive (Group A) a polypropylene 3-0 running oversewing suture and in Gropu B no oversewing of the staple line.

- The outcomes considered

Compare the material effectiveness of oversewing the staple line.

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

- Was the allocation concealed from researchers?

The patients were randomized into 2 groups according to the admission protocol number

Detailed questions

3. Were patients, health workers and study ❒Yes ❒Can't tell ❒No

Musella et al.

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied

one hundred morbidly obese patients,
scheduled to LSG, were recruited from our outpatient
obesity unit

- The intervention given
- The comparator given

randomized (1:1) to two treatment groups: fibrin sealant (group A) and control (no fibrin sealant, group B)

- The outcomes considered

Data collected were demographics, surgery (technique, time, conversion, methylene-blue test, fibrin sealant usage, and time to oral diet initiation), hospital stay, and complications.
The primary endpoint was the occurrence of complications (suture line leak, significant bleeding, stenosis) occurring during the first 30 days from surgery. By a significant bleeding, a blood loss originating from the staple line, higher than 300 ml during the first postoperative day, is meant. Secondary endpoints were the operative time in minutes, the length of hospital stay (LOS) in days, the time to oral diet initiation in days and the adverse effects directly related to fibrin sealant application. A staff surgeon not participating in surgery, and blinded to the procedure used, was responsible to record the endpoints.

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

- Was the allocation concealed from researchers?

Shah et al.

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied patients undergoing standard sleeve gastrectomy with a 34 or 36 French bougie
- The intervention given
- The comparator given
- The outcomes considered

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment

randomization performed using sealed envelopes that were opened immediately prior to surgery. The randomization block size was 6 and no randomization errors occurred.

- Was the allocation concealed from researchers?

Detailed questions

3. Were patients, health workers and study ❒Yes ❒Can't tell ❒No personnel blinded?

Consider:

- Health workers could be; clinicians, nurses etc

Sroka et al.

11 questions to help you make sense of a trial **How to use this appraisal tool**

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ❒Yes ❒Can't tell ❒No

Consider: An issue can be 'focused' In terms of

- The population studied patients who were admitted to our surgery department for LSG were randomly assigned to one of three arms
- The intervention given
- The comparator given

Stapler line application of biologic glue—Evicel™(E), over suture of the stapler line (S), or control (C).

- The outcomes considered

2. Was the assignment of patients to treatments ❒Yes ❒Can't tell ❒No randomised?

Consider:

- How was this carried out, some methods

may produce broken allocation concealment
randomization method was based on the personal identification number and not on computer programs.

- Was the allocation concealed from researchers?

Detailed questions

3. Were patients, health workers and study ❒Yes ❒Can't tell ❒No personnel blinded?

Consider:

- Health workers could be; clinicians, nurses etc
- Study personnel – especially outcome assessors