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ORIGINAL CONTRIBUTIONS

Minimizing Hemorrhagic Complications in Laparoscopic Sleeve Gastrectomy—a Randomized Controlled Trial

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Abstract
Background Laparoscopic sleeve gastrectomy (LSG) has gained worldwide popularity in recent years. Hemorrhagic complications (HC) are usually the result of stapler line bleeding and are probably underreported. The previous incidence of HC in our department including minor bleeding and late hematomas was 15.0 %. The objective of this study is to assess the impact of stapler line reinforcement (SLR) and intraoperative blood pressure control on HC after LSG.
Methods Between February 2013 and March 2014, patients who were admitted to our department for LSG were randomly assigned to one of three arms: stapler line application of biologic glue—Evicel™ (E), over suture of the stapler line (S) or control (C). Surgical technique in all arms included blood pressure elevation to 140 mmHg before termination of the procedure. Data is presented as mean±SD or median (IQR 25–75).
Results One hundred sixty-five patients were randomized: 49 to E, 49 to S, and 67 to C. There were no demographic differences between arms. Operative time was significantly longer in S than in E and C arms (74±21 vs. 64±23 and 54±19 min, respectively). ΔHb was significantly lower in the S group. Packed cells were used in two from E and one from C arms. Late infected hematoma occurred in three (1.8 %) patients: one from E and two from C arms. Leak rate was 1.2 %: one from S and one from C arms. LOS was the same. No patients were re-operated due to bleeding.
Conclusions In this randomized trial, routine elevation of systolic blood pressure to 140 mmHg and over suture of the staple line in LSG minimized HC, with reasonable prolongation of the procedure.

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Introduction

Laparoscopic sleeve gastrectomy (LSG) was introduced into bariatric surgery in the early 1990s as part of biliopancreatic diversion with duodenal switch [1]. In the early 2000s, patients and surgeons started using it as a stand-alone procedure, with some concerns about its long-term results [2].

Ever since, the procedure has gained in popularity among surgeons and patients alike, due to its main benefits, which include: maintaining gastro-intestinal continuity, absence of foreign body, lack of malabsorption, and a good option of conversion to multiple bariatric procedures. Mid-term results are generally good, with some reports about weight re-gain after 3 years [3].

In Israel alone, the number of bariatric procedures climbed from less than 2000 in 2006, to 8400 in 2012, out of which 6100 (73 %) were LSG (http://www.health.gov.il/UnitsOffice/ICDC/Disease_Registries/Pages/Bariatric.aspx). The Israeli Ministry of Health suspects that there is underreporting of peri-operative complications and therefore has mandated reporting of all bariatric procedure since mid-2013. The most important operative complications of LSG are stapler line leak and bleeding, with reported incidence of up to 4.5 and 13.7 %, respectively [4, 5]. Multiple attempts to reduce the incidence of these complications has been done by stapler line reinforcement (SLR) with synthetic or biologic material or suturing, but the evidence is equivocal; hence, there is no consensus with respect to the best method for SLR or its necessity at all [6–13].

Looking retrospectively at our own prospectively collected database has revealed a disturbing incidence of post-LSG

bleeding during 2012 of 15.0 % (!): 30 out of consecutive 200 patients, of whom 11(5.5 %) were treated conservatively by observation alone (Clavien-Dindo I), 10 (5 %) were treated with packed cells (RBPCs) and FFP alone (Clavien-Dindo II), and six (3 %) underwent a re-laparoscopy for control of bleeding and peritoneal lavage and drainage (Clavien-Dindo III). Five patients were re-admitted due to abdominal pain, with or without fever, and were diagnosed with infected hematomas; two of whom were in the group that received RBPs. We also went back to the videos and anesthesia charts of the patients who had suffered hemorrhagic complications (HC). We learned that at the end of the procedure, the operative field was dry, and systolic blood pressure was 90–100 mmHg, while in the recovery room, blood pressure climbed to 150–160 mmHg.

These numbers prompted us to conduct a randomized controlled trial (RCT) with the purpose of evaluating the efficacy of different types of stapler line reinforcement (SLR) materials, on the incidence of HC in LSG, paying particular attention to the systolic blood pressure at the end of the procedure.

The purpose of this study, therefore, is twofold:

1. To examine our hypothesis that staple line bleeding starts in the post anesthesia care unit (PACU) due to a rise in blood pressure and that active elevation of blood pressure while performing hemostasis can reduce the incidence of postoperative bleeding.
2. To assess the added value of fibrin glue, and suturing, on hemostatic control in LSG.

Methods

This is an IRB-approved (0021-11-BNZ) randomized controlled trial ((RCT). Between February 2013 and March 2014, patients who were admitted to our surgery department for LSG were randomly assigned to one of three arms: stapler line application of biologic glue—Evicel™ (E), over suture of the stapler line (S), or control (C). Patients were considered eligible for the trial if they were >18 years old and had clear indication for bariatric surgery. The decision regarding the type of operation was made at the bariatric clinic, prior to admission for surgery. We excluded patients with previous history of coagulopathy, or receiving chronic anticoagulation medication, and patients with an American Society of Anesthesiologists (ASA) risk level above 3. Patients received a clear explanation of the nature of the study and had to sign an informed consent form. Patients were kept blinded with regard to their randomization status until their first postoperative clinic visit—7–10 days following surgery.

Surgical Technique

The operation was performed by three experienced bariatric surgeons, each of whom had performed over 500 LSGs prior to the beginning of the study. We customarily use five trocars—three of 12 mm and two of 5 mm—and a 10-mm 30° scope. For an energy source, we use either Atlas LigaSure (Covidien) or Enseal (J&J) devices. In all procedures, we use long Echelon Flex 60 mm with changing staple height from black to blue loads according to the thickness of the stomach wall. In all groups, the surgeon was able to use hemoclips and surgicel selectively according to individual preference, exactly as we had done in our previous procedures. In the E group, the surgeon dripped 2 cc of Evicel™ on the staple line—through its entire length. In the S group, we used a 3-0 PDS continuous over suture—also along the staple line's entire length. A 10-mm Jackson-Pratt drain was placed in proximity to the staple line in all patients and was left in place for 2 days if there was no bleeding.

In all arms, we performed active blood pressure elevation to at least 140 mm Hg and no more than 150 mmHg at the end of the stomach resection, using either phenylephrine or ephedrine depending on the pulse rate. Only then did the surgeon use the chosen hemostatic material according to the randomization status. We do not perform leak tests of any kind if there is no operative technical problem. Postoperatively, hemodynamic status was assessed at least three times daily in accordance with clinical status. Hemoglobin levels and drain content were assessed at least once daily. The decision whether to administer red blood packed cells or return to the OR was made by the attending surgeon according to our protocol: patients who show clinical signs of bleeding and a decline in their hemoglobin levels towards 9 gr% usually receive two RBPCs, and if they continue bleeding, they are taken to the OR. This protocol in our study did not differ from the one used in our previous 200 cases. Patients resumed clear fluids on postoperative day (POD) 1 and were discharged on POD 2, unless there was a complication. We followed patients for at least 3 months to assess possible postoperative development of infected hematoma.

Statistical Analysis

Statistical analysis was performed with SPSS software version 21. Power analysis was performed according to our hypothesis that HC should occur in no more than 1 % of patients in optimal conditions. Confidence level was set at 95 % and power at 70 %; therefore, 47 patients were needed in each arm. Descriptive statistics demonstrated for all of the parameters in terms of mean, median, SD, and percentiles. Kolmogorov-Smirnov test was used for assessing normal distribution in the quantitative parameters. As some of the quantitative parameters were not normally distributed, non-

parametric tests were used. One-way ANOVA and Kruskal-Wallis with pairwise comparisons was used for differences between groups. Chi-square tests were used for differences in the categorical parameters. $P<0.05$ was considered significant.

Results

Figure 1 demonstrates patients' flow throughout the trial: In the study period, 214 patients were evaluated for eligibility. Fifteen of them were excluded for reasons that were mentioned above: three were under 18 years old, eight were very high-risk patients with an ASA score of IV, and four were on chronic anticoagulation therapy. Thirty-four patients refused to sign the informed consent. The remaining 165 patients (82 % consent rate) were randomized to E (49), S (49), and control (67). All of these patients were included in the final analysis.

Table 1 demonstrates that there are no differences between groups in terms of demographics and previous medical history.

Table 2 summarizes the outcome measures of the trial: operating time was 10 min longer when we used the Evicel™ and 20 min longer when suture was used. There were no differences between groups in the pre-operative Hg levels, EBL, and the drain-related measures. The change in Hb levels from before the operation to the lowest level reached was defined as ΔHb—this value was the lowest in the S group with significant difference from the other two groups. We also observed those patients that had ΔHb values of more than 2 gr%. The number of these patients in the S group (zero) was significantly lower than that of the control group (with no significant difference from the E group). Only three patients received RBPCs, and two PCs were sufficient. No patient was taken to the OR for re-laparoscopy due to bleeding. Mean length of stay was 3.6±0.4 days with no significant difference between the groups. Three patients were re-admitted due to infected hematoma 2, 3, and 5 weeks postoperatively. Two were treated with antibiotics and CT-guided drainage and one with antibiotics alone.

Table 1 Patients' demographics and past medical history

	Evicel™	Suture	Control	*P* value
Age	39.6±10.15	35.9±11.6	38.5±12.6	0.28
BMI	43.11±5.87	42.13±4.46	43.82±5.32	0.52
Gender (female)	35 (71 %)	34 (70 %)	43 (64 %)	0.72
ASA II	32 (65 %)	34 (70 %)	45 (67 %)	0.61
HTN	10 (29 %)	13 (37 %)	13 (31 %)	0.55
Diabetes	11 (32 %)	8 (23 %)	14 (33 %)	0.73
Aspirin Tx	1 (2 %)	2 (4.1 %)	3 (4.5 %)	0.67

Table 3 looks at all the patients with HC: those who had ΔHb>2 gr%, those who received RBPCs, and those with late infected hematoma. Those who received blood had more than 100 cc bloody fluid in the first 24 h postoperatively.

It is apparent that the group that was randomized to suture is the only group with no HC at all: no patients who had ΔHb>2 gr%, no patients who received blood, and none that were re-admitted with infected hematoma.

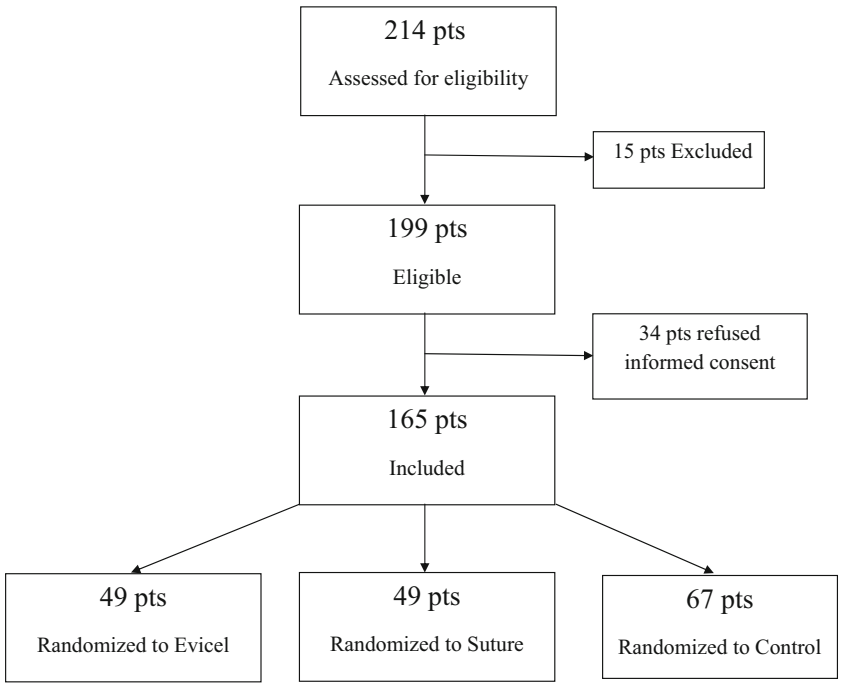

Fig. 1 Flow of patients in the trial

Table 2 Main outcome measures for the three groups

	Evicel™	Suture	Control	*P* value
Operating time (min)	64±23	74±21	54±19	$P=0.017^a$
				$P<0.001^b$
				$P=0.087^c$
EBL (median, 25–75 %)	5 (0–10)	2.5 (0–10)	2.5 (0–10)	0.86
Pre-Hb (gr%)	13.5±1.5	13.2±1.4	13.8±1.4	0.11
ΔHb (pre-post, median, 25–75 %)	0.60 (0.1–0.9)	0.31 (0.025–0.7)	0.80 (0.35–1.4)	$P=0.28^a$
				$P=0.008^b$
				$P=0.67^c$
ΔHb>2	2 (4 %)	0	7 (10 %)	$P=0.29^a$
patients				$P=0.02^b$
				$P=0.49^c$
Drain – amount (cc)	67±43	61±48	63±41	0.73
In first 24 h				
Patients with bloody drain	8 (16.3 %)	4 (8.2 %)	8 (11.9 %)	0.58
Patients receiving PC	2 (4 %)	0	1 (1.5 %)	0.57
Late infected hematoma	1 (2 %)	0	2 (3 %)	0.63

[a] Between E and C
[b] Between S and C
[c] Between E and S

Table 4 summarizes the differences between our previous cohort and the different groups of the current trial—the difference from the control group can be attributed to the blood pressure policy alone. We looked specifically at significant complications—Clavien-Dindo class II–III—since those have the most meaningful clinical impact on patient outcomes.

Leak rate in our study was 1.2 %: one patient from the S group and one from the control. They were both discharged on POD 2 and were re-admitted on POD 8 and 10 due to fever and abdominal pain. Both were treated with CT-guided drainage and long-term antibiotics.

Discussion

This study suggests that blood pressure elevation to 140 mmHg at the end of stomach resection may play a role in reducing HC in LSG. Little benefit was derived from the use of Evicel™ to reduce HC. Over suture of the staple line had, in our experience, the best outcomes with regard to HC with the price of prolongation of the procedure.

Fibrin Glue

Researchers have recently been trying to assess the effectiveness of different types of fibrin glue in reduction of complications in LSG. Gentileschi et al. conducted a randomized trial and used gelatin fibrin matrix (Floseal®) in one of the arms with no benefit compared to the other two arms. In their study, there were very few bleeding complications; however, it is not clear how these were defined [11]. Others used Tisseel®: Bulbuller et al., for example, conducted a four-arm randomized trial with a total of 65 patients. They too had very few complications, but raised some concerns about the use of V-

Table 3 All patients with bleeding complications

Patient no.	13	24	44	47	85	97	104	144	154	162	181
Randomization group	C	E	E	C	C	C	C	C	C	C	E
Pre-Hb (gr%)	15.4	11.0	11.5	10.8	16.5	16.2	14.6	13.7	13.7	12.5	12.5
ΔHb (gr%)	4.6	0.4	0.6	0.6	6	2.4	2.1	5	2.1	2.3	3.7
Drain – amount (cc)	10	100	100	30	150	75	80	185	125	80	150
Drain quality	SA	B	B	S	B	B	S	B	S	SA	B
Received PC	–	2	–	–	–	–	–	2	–	–	2
Late hematoma + CT drainage	-	-	33 day post op	23 days post op +	–	–	–	16 days post op +	–	–	–

C control, *E* Evicel™, *B* bloody, *S* serous, *SA* serous-anginous

Table 4 Comparison of HC between the previous cohort and the present study groups

	Previous cohort (1)	Control group (2)	Evicel™ group (3)	Suture group (4)	*P* value
Total	30/200	8/67	3/49	0/49	1 vs. 2=0.68
HC	15 %	11.9 %	6.1 %	0 %	1 vs. 3=0.15
					1 vs. 4=0.0012
Meaningful	19/200	2/67	3/49	0/49	1 vs. 2=0.11
HC	9.5 %	3 %	6.1 %	0 %	1 vs. 3=0.58
Clavien-Dindo					1 vs. 4=0.03
II–III					

Loc suture since they had two patients out of 16 with leak in this group [14]. Musella et al. also conducted an RCT with two groups—Tisseel® or control. Each arm had 50 patients. They had seven patients (14 %) with significant bleeding (defined as more than 300 cc during the first postoperative day) in the control group, compared to only one in the Tisseel® group [13]. We found no previous trials that used Evicel™ in LSG. Our results do not support the use of Evicel™ to reduce bleeding from the staple line.

Suturing

Dapri et al. conducted a three-arm RCT with either Seamguard® or suture as the reinforcement methods [15]. Their outcome measures included bleeding from the operation itself (bleeding during stomach resection) and not from the first postoperative days. They concluded that suturing is inferior to Seamguard® in terms of bleeding prevention. Musella et al. also questioned the necessity of suturing, by conducting another RCT with two arms: over suture with 3-0 Prolene or control [8]. There was no difference in early complications but sleeve stenosis was significantly greater in the suture group. On the other hand, Albanopoulos et al. compared Seamguard® and suturing in a RCT and had early complications only in the group that used Seamguard®. They defined bleeding as blood in the drain or drop of hemoglobin of >2 gr%. They concluded therefore that suturing is useful [9]. Al Hajj and Haddad presented their experience with suturing 160 LSGs and then started using bovine pericardium (BPS) in 84 patients. While the leak rate for the suture group was 5 %, it was only 1.2 % in the BPS group. One should raise the question of whether these differences might be related to learning curve effect [16]. D'ugo et al. conducted a multi-center retrospective trial to address the same issue: out of 1162 patients, 476 went through oversewing of the staple line. Their findings were that leak rate was relatively high (2.2–7.8 %) in all groups except for the group that used Peri-Strips-Dry. Bleeding rate was 13.7 % in the group with no reinforcement and dropped to 0–1.6 % with all other reinforcement methods [4].

Buttressed Material

As early as 2004, Consten et al. reported reduced bleeding after LSG with or without duodenal switch using Seamguard® [17]. The same group reported intraluminal migration of BPS and raised concerns with regard to the use of reinforcement materials [18]. These concerns prompted a comparative study in pigs; the results of which were that the group that was operated on with BPS had more complications (one vs. no leaks, six vs. three ulcers), but the differences were not significant [19]. Stamou et al. also explored the use of Peri-Strips-Dry compared to control in a RCT with more than 90 patients in each group. Their results showed significantly less HC in the reinforcement group but no statistical difference in terms of leaks [6].

Learning Curve

Very few studies have addressed the issue of surgeon's experience and the learning curve: Ser et al. compared their first 40 cases without any SLR to the next 78 patients that received over suture with 3-0 Vicryl. They had four leaks in the first 40 cases and none in the rest of the patients and came to the conclusion that reinforcement is strongly recommended [20]. One should remember, though, that bias might exist from the surgical experience point of view. Daskalakis et al. challenged this notion when they compared three surgeons with different levels of experience retrospectively and found no differences in the incidence of complications [21]. They did recommend the use of Peri-Strips-Dry; however, they had no control group to compare with. Durmush et al. also compared retrospectively 186 patients with no SLR and the next 332 patients who were treated with Seamguard®. They concluded cautiously that SLR may reduce leaks and bleeding [22], but did not discuss the optional bias of the learning curve.

Drains

In this trial, we used drains in all patients in order to assess their impact. Their possible advantage would be to reduce the

amount of blood in the abdominal cavity in patients who bled and were not re-operated on. Albanopoulos et al. compared retrospectively patients who had LSG with or without drains. There was no difference in complications between the groups, even for late hematomas and abscess formation [23]. A review by Lemanu et al. argues that the evidence is very limited and the use of drains may be unnecessary [24]. Our results do not support the need to use drains routinely in LSG, but our study was not designed for that purpose.

Source of Bleeding

One should remember that complications can occur in LSG due to bleeding from sources other than the staple line: the omentum, the short gastric vessels, and the abdominal wall. Jossart thoroughly explains these sources and how to avoid getting into trouble [25]. Our assumption was that most bleeding complications in LSG occur from the long staple line, which is very rich in blood supply. We routinely close the left abdominal incision through which the stomach is pulled out, but other incisions can bleed as well. We believe that the nature of bleeding from the short gastric vessels would send most patients suffering from it back to the OR. In our study, only three patients were in need of RBPCs and we cannot be sure of their source of bleeding.

Different reviews and one meta-analysis were not able to show any clear benefit in the routine use of SLR in LSG [10, 12, 26, 27]. One of the reasons for this is that the outcome measures related to LSG complications are not standardized and uniformly reported. Another reason is that numerous studies are industry driven; therefore, their level of evidence is not high. There is clearly a need for more RCTs in order to answer questions of this sort.

Blood pressure elevation at the end of stomach resection was reported orally in staff meetings, but we could find no study that compared results with or without this policy. The logic behind this policy is very simple: a dry staple line turns red immediately when blood pressure rises from 100 to 140 mmHg, and the surgeon can address the bleeding and control it. No medication was used when blood pressure was 130 mmHg and higher, but this occurred only in four patients in our study population. Comparison of our previous cohort with the control group in the prospective trial examines, retrospectively, the effect of the blood pressure policy alone on HC: Looking specifically at meaningful complications—Clavien-Dindo class II–III—there is a clinically significant drop in HC rate from 9.5 to 3 %, which did not reach statistical significance due to a lack of sufficient power of the study. The suture group showed statistically significant difference compared to the cohort, with no patients at all who had HC.

Leak Rate

There are ongoing attempts to identify factors influencing leak rate after LSG. A recent important review and meta-analysis of approximately 10,000 patients has revealed that buttressing did not affect leak rate. Bougie size of <40 Fr was found to increase leak rates [28]. We had two patients with a leak in the second week after the operation: one from the S group and one from the C group. This 1.2 % leak rate is quite acceptable and no different from the previous cohort where we had three leaks (1.5 %). We use routinely a 42-Fr bougie. Our study was not powered to show differences between groups in that respect. We believe that other factors might influence leak rate after LSG: tissue ischemia and the shape and functionality of the sleeve, and those are yet to be studied. It is the experience of other researchers as well that different factors influence HC and leaks after LSG.

Limitations

Our study has certain limitations: one is that the comparison of the results, with or without the blood pressure elevation policy, is not part of the randomized trial, but rather a comparison to our previous cohort of patients. We assumed that learning curve is not an issue here because the surgeons had a great deal of experience during the cohort as well, and we did not change any other surgical techniques in between. The second limitation is that we did not use buttress materials due to budget issues; therefore, we cannot compare those to the use of suture. Another limitation regards the randomization method which was based on the personal identification number and not on computer programs. Nevertheless, as can be seen from Table 1, the groups were equal in most of the parameters that could have influenced bleeding rate.

Conclusion

In this randomized trial, routine elevation of systolic blood pressure to 140 mmHg and over suture of the staple line in LSG minimized HC, with negligible cost and reasonable prolongation of the procedure.

Conflict of Interest Drs. Sroka, Milevsky, Shteinberg, Mady, and Mattar have no financial conflicts of interest to declare.

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