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LETTER TO THE EDITOR

Comparison of tranexamic acid and stapling line reinforcement in laparoscopic sleeve gastrectomy in postoperative bleeding outcomes

Dear Editor,

Laparoscopic Sleeve Gastrectomy (LSG) is a type of bariatric surgery considered safe and technically simpler to perform than gastric bypass. One risk of this technique is bleeding in the staple line, with an incidence of up to 10%.[1,2]

The option of using Tranexamic Acid (TXA) as an auxiliary method to reduce bleeding is a possibility and has the advantages of low cost and fast execution.[1] A dose of 1g has been suggested to produce a reduction in bleeding that is not improved by giving higher doses and is likely to be sufficient for most adults.[3,4]

Due to the small number of studies on the use of TXA and the controversial results in Staple line Reinforcement (SR) techniques in bariatric surgeries, the authors decided to compare the efficacy of SR and the use of TXA in the reduction of complications of the LSG technique.

The study was a prospective, comparative, double-blind, non-randomized clinical trial, approved by the institutional Research Ethics Committee (CAAE 95198518.9.0000.5085/ Number 4.058.659) and registered in the Brazilian Registry of Clinical Trials (REBEC RBR-4w39gz). Patients aged 18 to 65 years, American Society of Anesthesiologists (ASA) physical status II or III, who underwent LSG from January 2019 to June 2020 were included in the study.

The selected patients either received venous tranexamic acid (1g) at anesthesia induction (TXA Group), no intervention (Control Group — CG), or received Staple line Reinforcement (SR group) without TXA. Perioperative care protocols were the same for all groups.

To help minimize potential bias induced due to non-randomization, the researchers who collected the data and measured the outcomes did not know which group each patient belonged to. The sample size calculation was an estimated n of 90, with a confidence level of 95% and a margin of error of 5%.

Clinical and surgical data were collected. Data from laboratory tests were also collected at the time anesthesia was administered and 24 h postoperatively. Intraoperative bleeding was evaluated by the number of hemostatic interventions performed to control the bleeding points in the staple line. Estimated intraoperative bleeding was assessed by weighing the gauze and the volume of blood found in the suction pump reservoir at the end of the operation. Postoperative bleeding was evaluated in patients who underwent reoperations, and a comparative quantitative evaluation was performed of the hematological data obtained by laboratory tests at the time anesthesia was administered and 24 h postoperatively (Table 1).

The following were used: chi-square test for categorical variables, ANOVA for parametrical numerical variables, and Kruskal-Wallis for nonparametric variables. Post hoc analysis was performed with the Bonferroni test. Statistical significance was set at $p < 0.05$.

A total of 89 patients were included: 31 in the Control Group (CG), 30 in the Tranexamic Acid Group (GTXA), and 28 in the Staple line Reinforcement Group (GSR). The clinical characteristics of the patients were similar among the groups. Moreover, there was no difference in the duration of surgery and anesthesia (Table 1).

Although a significant reduction in the surgical time was observed in another study for patients who used TXA,[1] in this clinical trial, this factor was not statistically relevant. In a retrospective review,[5] a significant increase in the surgical time of patients who received SR intervention was verified, as well as the necessity of having this method performed by trained professionals to avoid complications resulting from this procedure[5] (Table 1).

The hemodynamic variables and hematological data were similar among the groups before surgery. Regarding the parameters for bleeding assessment, bleeding volume was greater in the CG (median 80 mL; 30—300) than in the GTXA (median 50 mL; 20—110) $p = 0.013$, but there was no difference concerning the weight of the gauze and the number of interventions applied to control bleeding (sutures and clips) among the three groups. In the postoperative period, GTXA patients were observed to have a higher hemoglobin value ($p = 0.023$), higher hematocrit ($p < 0.001$), greater prothrombin activity ($p = 0.004$), and lower INR value ($p = 0.013$) than the control group. The GSR also had a higher hematocrit value ($p < 0.001$) and prothrombin activity ($p = 0.004$) than the CG. A similar result was shown in the study performed by Chakravartty et al.,[3] which also applied this approach for bariatric surgeries (Table 1).

In the CG group, one patient developed a large hematoma of the abdominal wall that did not require intervention, and

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Table 1 Comparation between groups.

Variables	Group			*p*-value
	Group Control	Group TXA	Group SR	
Clinical characteristics of patients				
Age				
Med (Min–Max)	37 (24–59)	36 (19–62)	36 (19–64)	0.672[a]
Gender				
Female	26 (83.9%)	19 (63.3%)	22 (78.6%)	0.158[b]
Male	5 (16.1%)	11 (36.7%)	6 (21.4%)	
Diabetes Mellitus				
Yes	7 (22.6%)	7 (23.3%)	7 (25%)	0.976[b]
No	24 (77.4%)	23 (76.7%)	21 (75%)	
Hypertension				
Yes	10 (32.3%)	10 (33.3%)	8 (28.6%)	0.920[b]
No	21 (67.7%)	20 (66.7%)	20 (71.4%)	
Previous Surgeries				
Yes	19 (61.3%)	18 (60%)	12 (42.9%)	0.291[b]
No	12 (38.7%)	12 (40%)	16 (57.1%)	
Weight (kg)	96.5 ± 10.9	103.9 ± 15.1	99.4 ± 9.4	0.062[c]
Height (cm)	160.5 ± 8.6	164.4 ± 7.9	161.7 ± 5.8	0.116[c]
BMI	37.3 (33.6–41.9)	38.1 (32.4-50.3)	38 (33.5-43.4)	0.475[a]
Length of surgery (minutes)	92 ± 18	85 ± 17	86 ± 19	0.329[c]
Length of anesthesia (minutes)	140 ± 22	128 ± 23	133 ± 28	0.197[c]
Comparison of hemodynamic variables and hematological data in the preoperative period between the groups evaluated				
Heart rate (bpm)	76 (52–92)	73 (54–95)	72 (55–114)	0.792[a]
Systolic BP (mmHg)	120 (80–158)	108 (90–160)	113 (84–160)	0.097[a]
Diastolic BP (mmHg)	74 (40–99)	70 (43–100)	80 (50–94)	0.577[a]
Mean BP (mmHg)	88 ± 16	85 ± 13	87 ± 11	0.550[c]
Hemoglobin ($g.dL^{-1}$)	12.3 ± 1.3	12.65 ± 1.2	12.20 ± 1.0	0.076[c]
Hematocrit (V/V) %	36.7 ± 3.7	38.1 ± 3.5	37.3 ± 2.8	0.263[c]
Platelets	252 ± 43	251 ± 55	236 ± 37	0.327[c]
Prothrombin Time (s)	14.4 (13.3–15.4)	14.3 (13.4–16.5)	14.2 (13–15.2)	0.134[a]
Prothrombin Activity (%)	84 ± 5	84 ± 8	85 ± 5	0.690[c]
TTPa (s)	31.1 (21.3–39.2)	31.6 (21.5–39.9)	31.4 (24.5–39.1)	0.567[a]
RTTPa	1.05 (0.72–1.33)	1.06 (0–1.22)	1.05 (0.83–1.33)	0.088[a]
INR	1.12 (1–1.21)	1.11 (1–1.32)	1.11 (1.04–1.22)	0.615[a]
Fibrinogen ($mg.dL^{-1}$)	289 ± 59	298 ± 41	310 ± 46	0.244[c]
Comparison of interventions to control bleeding and intraoperative bleeding between the groups evaluated				
N° of interventions for bleeding control (Suture or Clips)	8 (4–24)	11 (6–18)	9 (6–16)	0.469[a]
N° Clips for hemostasis	2 (0–18)	5 (0–12)	3 (0–10)	0.483[a]
Gauze Weight (g)	15 (10–50)	20 (10–50)	20 (10–65)	0.580[a]
N° Staples	6 (5–8)[a]	6 (6–7)[a]	6 (5–7)	0.005[a]
Vol. of blood on pump (mL)	80 (30–300)[a,b]	50 (20–110)[a]	100 (50–120)[b]	0.013[a]
Comparison of hematological data in the postoperative period between the groups evaluated				
Hemoglobin ($g.dL^{-1}$)	12.3 ± 1.4[a]	13.2 ± 1.4[a]	12.8 ± 0.9	0.023[c]
Hematocrit (V/V) %	36.4 ± 4.2[a,b]	38.7 ± 3.6[a]	38.8 ± 2.8[b]	0.000[c]
Platelets	266 (196–408)	251 (116–382)	274 (173–378)	0.463[a]
Prothrombin Time (s)	14.6 (11.9–15.7)	14.6 (13.4–29.2)	14.6 (13.5–15.7)	0.905[a]
Prothrombin Activity (%)	80 (71–96)[a,b]	82.5 (62–99)[a]	85 (69–93)[b]	0.004[a]
TTPa(s)	29.1 ± 1.8[a]	30.3 ± 2.7	30.7 ± 2.3[a]	0.032[c]
RTTPa	1.02 ± 0.11	1.04 ± 0.07	1.04 ± 0.08	0.547[c]
INR	1.16 (1.06–1.9) [a]	1.11 (1–1.35) [a]	1.13 (1.05–1.27)	0.013[a]
Fibrinogen ($mg.dL^{-1}$)	309 (205–481)	329 (234–477)	341 (252–492)	0.208[a]

BMI, Body Mass Index; TXA, Tranexamic Acid; SR, Staple Line Reinforcement; BP, Blood Pressure; TTPa, Activated partial thromboplastin time; RTTPa, Activated partial thromboplastin time ratio; INR, International normalized ratio.

[a] Kruskal-Wallis;

[b] Chi-Square;

[c] ANOVA; For statistical significance the value of $p < 0.05$ was considered; Equal over-written letters indicate statistical difference in the inter-group post hoc analysis.

another patient required surgical intervention for intra-abdominal bleeding on the first postoperative day, with 300 mL of blood being aspirated.

Four patients in the CG group had to remain hospitalized for 3 days. Thus, the time of hospitalization was longer in the CG (median 2; 2—3) than in the GTXA (median 2; 2—2), and in the GSR (median 2; 2—2) ($p = 0.019$).

The length of hospital stay of patients undergoing bariatric surgeries may vary among institutions using different discharge protocols. Although there already are strategies and protocols to reduce the length of hospital stay, such as ERAS, additional methods for avoiding complications that increase the length of hospital stay are continuously being investigated. Considering that bleeding is a complication commonly reported by studies that investigated the surgical complications of bariatric surgery and had the largest impact on hospital stay, the possibility of improving patient outcomes by intervening in this problem becomes even greater.

Despite the risk of thromboembolic events, the safety of this approach was demonstrated by the absence of thromboembolic events and adverse events in this study, and the patients were monitored for at least 6 months after surgery. This result was similar to the few studies that used TXA in the context of bariatric surgeries, including Chakravartty et al.,[1] who used tranexamic acid in the preoperative period of LSG.

Despite the limitations, the use of tranexamic acid was statistically relevant in reducing intraoperative bleeding volume, presenting less postoperative complications, which led to a reduction in the length of hospital stay. Thus, tranexamic acid can be an important alternative for preventing bleeding in the stapling line of patients undergoing LSG.

Ethical approval statement

Institutional Research Ethics Committee (CAAE 95198518. 9.0000.5085/Number 4.058.659) and registered in the Brazilian Registry of Clinical Trials (REBEC RBR-4w39gz).

All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent statement

Informed consent was obtained from all individual participants included in the study.

Conflicts of interest

The authors declare no conflicts of interest.

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