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A Prospective Observational Study Investigating Postoperative Hemorrhage After Laparoscopic Sleeve Gastrectomy Using Bipolar Seal and Cut Caiman (Aesculap AG)

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Objective: This study investigated postoperative hemorrhage after laparoscopic sleeve gastrectomy using the Bipolar Seal and Cut Caiman (Aesculap AG, Tuttlingen, Germany).

Summary of background data: Besides staple line leakage, postoperative hemorrhage (POH) is the most discussed acute complication after laparoscopic sleeve gastrectomy (LSG). POH is the second most important acute complication following LSG, with staple line leakage being the first. POH is reported in up to 5% of cases after LSG. Sufficient vessel sealing is crucial in avoiding later complications of POH during mobilization of the greater curvature. This study investigated bleeding complications after LSG using the Advanced Bipolar Seal and Cut instrument Caiman 5.

Methods: All LSGs were performed in a highly standardized manner according to the standard operating procedure of our Center of Reference for Bariatric Surgery using the Caiman. Primary outcome was the incidence of POH, defined as the need for revisional surgery and/or blood transfusions. Secondary outcomes were hemoglobin levels preoperatively at the day of surgery (POD 0) and at postoperative days (PODs) 1 and 2, volume and duration of drainage at PODs 0 to 2, procedure time, and length of hospital stay.

Results: A total of 100 patients who had undergone LSG from April 2016 to September 2017 were consecutively included in the study. Patients with contraindications to undergo LSG or those who were not able to give consent were excluded. Four patients needed treatment

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because of POH; in 3 of them surgery became necessary. Average operation time was 68.5 minutes and total volume of drainage was 186 mL. The drain stayed *in situ* for 2.2 days (mean). Average hospital stay was 3.6 days.

Conclusion: In our study group of 100 LSG procedures POH was 4%, which is comparable to data reported in the literature. Operation time, volume and duration of drainage, and length of hospital stay were not prolonged. LSG using Caiman is feasible and shows results comparable to those of other vessel-sealing instruments at our center.

Key words: Laparoscopic sleeve gastrectomy – Postoperative hemorrhage – Vessel-sealing instrument

Laparoscopic sleeve gastrectomy (LSG) is the most frequently performed bariatric procedure worldwide.[1] Its popularity is based on having a small learning curve, no enteric anastomosis, and lower risk of internal hernia, dumping syndrome, or marginal ulcer.[2] The rate of mortality (0.19%) is acceptable.[3] Short- and long-term outcomes are comparable to the Roux-en-Y gastric bypass.[2]

The most discussed perioperative complications after LSG are staple line leakage and postoperative hemorrhage (POH). According to the literature, POH after LSG occurs in up to 5% of cases.[4] Bleeding of the staple line, trocar site, organ injury, and sealed vessels of the gastroepiploic arcade or of the short gastric arteries are the most common causes.[5,6]

However, most studies report about staple line bleeding. Preventive measures include oversewing and buttressing, among others.[7]

LSG starts with mobilizing the greater curvature using a vessel-sealing instrument. Especially in obese patients, vessel sealing during the dissection of the adipose tissue of the greater omentum is crucial. Insufficient vessel sealing might lead to bleeding complications, resulting in revisional surgery and/or blood transfusion. Interestingly, in our experience bleeding is often not evident during surgery, although the operating field is controlled for hemostasis carefully while blood pressure is raised above preoperative level by the anesthesiologist. POH becomes mostly evident during surgery or within the first 48 hours postoperatively.[6] Bleeding that occurs after a period of latency can go in line with delayed clinical signs of bleeding.

On the other hand, intraoperatively apparent bleeding might be difficult to detect and stopped laparoscopically due to the bulky visceral and omental fat in particular obese patients.

In our experience, the blood vessels of obese patients are thick. Postoperative bleeding often occurs in patients without intraoperative signs. In summary, reliable vessel sealing during dissection of the adipose tissue is essential to avoid later bleeding complications.

The vessel-sealing instrument is one of the crucial parts during the operation. Several vessel-sealing instruments are available to choose from, including electrothermal monopolar and bipolar as well as ultrasonic devices. Publications on the application of the advanced bipolar sealing instrument Caiman 5 by Aesculap AG (Tuttlingen, Germany) in LSG are limited.

Therefore, we conducted a prospective observational study including 100 patients undergoing LSG using the bipolar seal-and-cut instrument Caiman. The aim of the study was to investigate bleeding complications after LSG using the Caiman instrument.

Methods

The study was approved by the local ethics committee (No. 3004-2016; Hannover Medical School, Hannover, Germany). The principles of the Declaration of Helsinki for biomedical research were followed. From April 2016 until September 2017 a total of 100 patients, aged 18 to 73 years, who were scheduled for LSG at our Reference Center for Bariatric Surgery were included consecutively and gave their informed consent to participate in the study. Patients with anesthetic or psychologic contraindications, without ability to participate in follow-up appointments, or without informed consent were excluded from the study. All procedures met the criteria of the German guidelines for the treatment of obesity and bariatric surgery (Prävention und Therapie der Adipositas [Deutsche Adipositas-Gesellschaft (DAG)], Chirurgie der Adipositas [Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie–Chirurgische Arbeitsgemein-

schaft für Adipositastherapie (CA-ADIP)].[8] All patients had to undergo psychologic, nutritional, endocrinologic, and endoscopic workup.

Surgical technique

All procedures were performed according to local standard operating procedures. The procedures started with the mobilization of the stomach along the greater curvature using Caiman Seal & Cut (Aesculap AG), a bipolar vessel-sealing instrument. Gastric fundus was mobilized completely until the angle of HIS, adhesions of the dorsal part of the stomach, were dissected carefully to avoid torsion of the sleeve. A linear cutter was used to dissect the stomach over a 40 Charriére bougie starting 4 to 6 cm orally of the pylorus. Following completion of the resection of the stomach, the patient's blood pressure was raised intraoperatively above preoperative level to detect local bleeding. Bleedings of the staple line were clipped using a clip applicator, and bleeding in the adipose tissue was sealed with the Caiman Seal & Cut. Additionally, the proximal staple line was oversewn. The resected stomach was removed at the median incision. A drain was placed along the staple line.

Enoxaparin was given subcutaneously for prophylactic anticoagulation beginning the evening after the operation. Dose was 1 mg per 1 kg body weight, maximal 100 mg once a day. In case of therapeutic anticoagulation an individualized dosage was chosen.

Caiman energy device

The Caiman advanced energy device (5-mm shaft diameter, 44-cm working length, nonarticulating jaw, PL742SU; Aesculap) was used in all cases, according to the instructions for use. The Caiman Seal & Cut system was introduced in European Union market in 2013. Caiman Seal & Cut is a bipolar radio frequency sealing system, which consists of the bipolar Lektrafuse RF Generator and Caiman instruments. This system can be used for grasping, dissection, sealing, and cutting of tissue during open and minimally invasive surgery. It can be used on vessels and vessel bundles with diameters up to 7 mm as well as for soft tissue in general surgery. Other surgical disciplines, such as gynecology, urology and bariatric surgery, and colorectal and thoracic surgery, also use this device. Sealed blood vessels are divided by a mechanical blade. Caiman Seal & Cut instruments differ from other commercially available products by a patented novel jaw closure mechanism. This allows tip-first closure, avoiding tissue slippage leading to uniform pressure distribution. The uniform tissue compression in the jaw leads to consistent sealing quality from distal to proximal tip. Because of the special closing mechanism and the even compression, the jaw can be designed longer compared with other energy devices, resulting in an extended sealing length of 26.5 mm.

Postoperative follow-up

Intravenous hemoglobin and volume of drainage were documented postoperatively (postoperative day [POD] 0) the evening after surgery, and at PODs 1 and 2. The drain was removed at POD 2 in case secretion did not indicate adverse events, for example staple line leakage or bleeding. Patients were usually discharged at POD 3. Patients were seen as outpatients 8 weeks postoperatively.

Statistical analysis

Demographic and clinical data were documented and analyzed descriptively.

Primary outcome was the rate of postoperative bleeding defined as the need for revisional surgery and/or blood transfusions. Secondary outcome was operation time, duration and volume of drainage, and hospital stay, as well as hemoglobin at POD 0-2.

Results

A total of 100 patients undergoing LSG between ages 18 and 73 years were consecutively included in the study; according to the study protocol, no patient was excluded. Complete data from 83 consecutive patients were available for analysis of secondary outcomes. The data of 17 patients were incomplete with respect to hemoglobin levels and volume of drainage. These were excluded for the analysis of secondary outcomes. There were 33 male patients. Mean age was 41.4 years. The average body mass index was 49.4 kg/m^2. Comorbidities were as follows: 28 patients experienced diabetes mellitus, 57 hypertension, and 26 obstructive sleep apnea (OSA; Table 1).

Four patients showed POH (Table 2). Three patients had to undergo relaparoscopy or relaparotomy; 1 patient died. This patient was a 54-year-old man suffering from hypertension, coronary heart disease, chronic obstructive pulmonary disorder,

Table 1 Demographic data

	Value
Sex, n	
Male	33
Female	67
Age, y	41.4
BMI, kg/m^2	49.4
Diabetes mellitus, n	28
Hypertension, n	57
OSA, n	26

BMI, body mass index.

Table 2 Outcomes using Caiman

	Value
POH, %	4
Operation time, min	68.5
Duration of drainage, days*	2.2
Total volume of drainage, mL*	186
POD 0	56.2
POD 1	65.4
POD 2	64.4
Duration of hospital stay, days*	3.6

*Patients who had POH are not included.

OSA, diabetes mellitus, hyperuricemia, and steatosis hepatis. After primary LSG he needed to undergo laparotomy after a drop in hemoglobin from 12 to 7.6 g/dL. He developed multiorgan failure and septicemia. There were no signs of a staple line leak. One patient recovered after blood transfusion. None of these patients had platelet aggregation inhibition. Two patients were female, 2 were male. Two experienced OSA, 3 experienced hypertension.

Average operation time was 68.5 minutes. Operation time for patients showing POH postoperatively took 50, 40, 67, and 80 minutes.

Data of 83 patients were available to describe volume and duration of drainage and levels of hemoglobin. None of the 17 excluded patients had POH. The drain stayed *in situ* for 2.2 days (mean) and showed an average secretion of 186 mL in total, and 56.2, 65.4, and 64.4 mL at PODs 0,1, and 2, respectively. Patients who had POH were extracted from this analysis because drainage was not representative because of reoperation or other treatment.

Average hospital stay was 3.6 days (Table 2).

Preoperative hemoglobin was 14.2 g/dL on average, hemoglobin at POD 0 was 13.4 g/dL, and it was 13.0 and 14.4 g/dL at PODs 1 and 2, respectively. On average, hemoglobin dropped by 0.8 g/dL during the first hours after surgery (POD 0), and by another 0.4 g/dL at POD 1. At POD 2 there was a rise of hemoglobin by 1.4 g/dL.

Patients who had undergone revisional surgery or needed blood transfusions because of POH showed an average hemoglobin of 15 g/dL preoperatively, and 12.7, 10.5, and 9.4 g/dL at PODs 0, 1, and 2, respectively (Table 3 and Fig. 1).

Another 10 patients showed a drop of hemoglobin $\geq$3 g/dL without the need of revisional surgery or blood transfusion. The cause of the hemoglobin drop remained unclear; patients were discharged in good condition.

Discussion/Conclusion

In our study POH after LSG occurred in 4 patients, 3 of them had to undergo revisional surgery. One patient recovered after blood transfusion without surgery. One of these patients died at POD 31 following septicemia.

As described in the literature postoperative bleeding occurs in up to 5% of cases.[4] In 2018 POH following LSG occurred in 5% of all patients undergoing LSG at our center when the Ligasure Atlas clamp was used for vessel sealing (data not shown). POH after LSG using Caiman (4%) was comparable to LSG when other vessel-sealing instruments were used at our department.

As described in the literature, risk factors predisposing for POH include hypertension, OSA, renal insufficiency, and preoperative use of therapeutic anticoagulation.[4,9] The use of platelet inhibition did not influence postoperative bleeding in our study group. In addition, diabetes mellitus had no impact on postoperative bleeding in our patients. A total of 3 of 4 patients of the bleeding group did not experience diabetes mellitus. Hypertension and OSA are discussed to cause a higher peripheral resistance and atherosclerosis, which might influence vessel sealing by advanced energy instruments.[4] In our study group 57% experienced hypertension, 26% experienced OSA. Three patients who had to undergo revisional surgery for POH

Table 3 Postoperative hemoglobin in patients with and without POH

Hemoglobin	POH−, mean, g/dL	Δ POH−, g/dL	POH+, mean, g/dL	Δ POH+, g/dL
Preoperative	14.2		15.0	
POD 0	13.4	−0.8	12.7	−2.3
POD 1	13.0	−0.4	10.5	−2.2
POD 2	14.4	+1.4	9.4	−1.1

Δ, difference from the previous measurement.

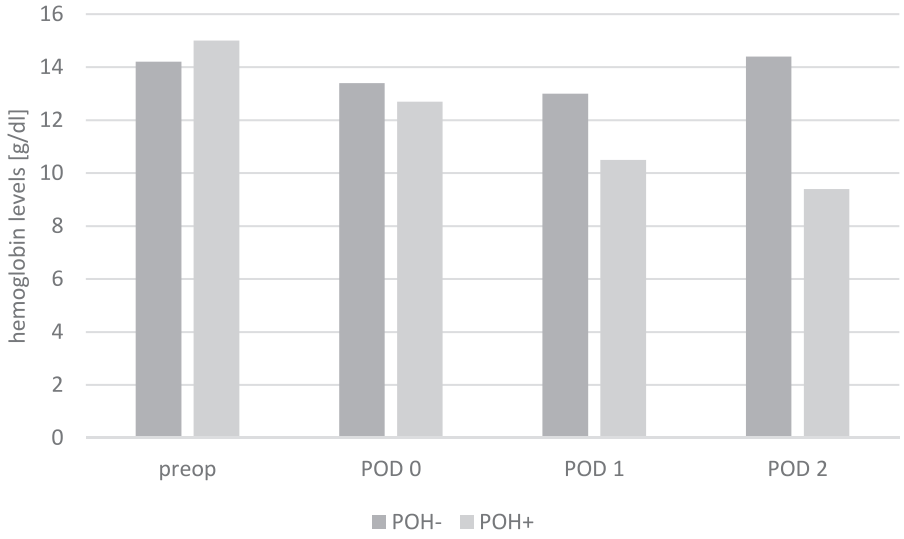

Fig. 1 Hemoglobin levels preoperative and at postoperative days (PODs) 0 to 2.

experienced hypertension and 2 patients experienced OSA.

Patients are usually discharged at POD 3, 1 day after the drain is removed. Mean hospital stay (3.6 days) was not prolonged in our study group.

Preparation using the Caiman device did not decelerate the procedure. Caiman jaws are long and small compared with sealing instruments from other manufacturers. Still, mean operation time (68.5 minutes) did not differ from procedures performed with instruments from other manufacturers. Average operation time of LSG in our department was 68 minutes in 2018, when a different instrument was used. In the literature, a procedure time of 78 minutes (SD, 37.4 minutes) has been described.[10]

We did not differentiate between bleeding of the staple line or parenchymal organs or the omentum.

In fact, most studies report about staple line bleeding, a lot do not differentiate between the causes of bleeding. During relaparoscopy the cause of bleeding cannot be identified in most cases. POH in patients in our cohort did not show staple line bleeding during reoperation. One of our 4 patients with POH showed hematoma in the left upper quadrant, probably originating from the greater omentum, without signs of active bleeding during revisional surgery. Reoperation of another patient in the POH group indicated bleeding from venous gastroepiploic vessels or trocar site. One patient with POH showed bleeding of the short gastric vessels. The fourth patient did not require reoperation.

It is well known that laparoscopic surgery causes less trauma and therefore allows a faster patient recovery. Nowadays, surgeons intend to make smaller incisions in order to limit the patient's trauma as much as possible. One advantage of the Caiman device is the use of a 5-mm trocar leading to smaller incisions compared with other vessel-sealing instruments. The novel design of the Caiman 5 jaws is longer than those scissorlike jaws of other instruments on the market. The pressure along the jaws is distributed equally so that the sealing process is reliable throughout the full length of the grabbed tissue.[11]

Our data show that LSG using the Caiman device is feasible and safe. LSG performed with the Caiman shows comparable rates of POH compared with instruments from other manufacturers. Trauma of the smaller 5-mm trocar seems advantageous, since operation time is not different.

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The authors declare that there is no conflict of interest.

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