Endoscopic Insertion of a Self-Expandable Stent Combined with Laparoscopic Rinsing of Peritoneal Cavity as a Method for Staple Line Leaks Treatment in Patients Post Laparoscopic Sleeve Gastrectomy

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Currently, laparoscopic sleeve gastrectomy is one of the most commonly performed bariatric surgeries in the world, and its popularity continuously increases due to very good results in reduction of patient body weight and high rates of resolution in comorbidities. According to the global register data of The International Federation for the Surgery of Obesity and

Metabolic Disorders (IFSO), 16,735 surgeries of this type were performed in the world in 2013 (1). Results of many scientific studies proved that laparoscopic sleeve gastrectomy is effective in body weight reduction. The Effective Excess Weight Loss (EWL) ranges from 50 to 67%. In the first year after the surgery, and 66-72% after three years (2, 3). The most frequent complications of surgeries of this type with the highest mortality rate include bleeding into the GI tract and peritoneal cavity, and sleeve staple line leaks (3). Results of many observational studies report the staple line leak frequency in a range of 0.6 to 7% (4, 5). This is a severe complication prolonging the hospital stay, and frequently leading to patient’s death. So far, no uniform and standard guidelines for management of this group of patients were developed, and attempts at treatment of this complication cover a wide range of methods, starting with radiologically guided percutaneous drainage of fluid reservoirs forming in the leak area, through endoscopic methods (insertion of self-expandable stents into the GI tract, use of tissue glues or special clips), and ending with attempts at sole pharmacological treatment (6, 7, 8).

The aim of this study was to report results on treatment of staple line leaks following laparoscopic sleeve gastrectomy with a laparoscopic procedure and simultaneous endoscopic insertion of a self-expandable stent.

MATERIAL AND METHODS

152 laparoscopic sleeve gastrectomies were performed from April 2009 to December 2014. The surgery was performed in 105 women and 47 men, with BMI ranging from 37.2 to 71.17 and the BMI median of 46.9. Patients’ age ranged from 18 to 66 years, with the age median of 42 years. The comorbidities included type 2 diabetes in 30 (19.73%) patients, impaired fasting glycaemia in 5 (3.28%) patients, hypercholesterolaemia in 90 (59.21%) patients, non-alcoholic fatty liver disease in 97 (63.85%) patients, and hypertension in 97 (63.85%) patients, and 16 (10.52%) patients were diagnosed with the sleep apnoea syndrome on a basis of polysomnography. In the group of operated patients, 26 (17.1%) people smoked. Staple line leaks developed in 3 out of 152 people (1.97%). All patients who developed this complication were included in the study.

All staple line leaks were diagnosed by physical examination, with tachycardia being a predominant symptom present in all patients, and confirmed by an X-ray scan, an upper gastrointestinal series with a watersoluble contrast medium (gastrografin) administered orally. Computed tomography with a contrast medium administered intravenously and secondary reconstruction was also performed in all patients.

The treatment involved laparoscopic revision surgery with simultaneous endoscopic insertion of a self-expandable stent (Boston Scientific, Wallflex Easophageal Stent, 150x23 mm) into the gastric stump during gastroscopy.

Laparoscopy

The treatment involved laparoscopic revision surgery. Patients were placed on an operating table tilted ca. 30 degrees, with upper and lower limbs held away. During the procedure, trocars were inserted in the same locations as during the original operation. The operation was performed using a standard laparoscopic optical system, of 10 cm in diameter and 30 degrees viewing angle. During the procedure, organs in the abdominal cavity were checked, staple line leaks were confirmed, the peritoneal cavity was rinsed, two drains, 20 and 24F, were inserted in the leak area, and one 20F drain was inserted in the vesicorectal space.

Endoscopy

During gastroscopy performed as a part of the laparoscopic procedure described above, the leak area was shown and patency of the gastric stump was confirmed by inserting the endoscope into the duodenum. A guidewire (Boston Scientific, Jagwire, 0.04 mm in diameter, 2300 mm long) was fed through the endoscope channel, with its end placed in the descending duodenum. Then a self-expanding stent (partly covered oesophageal stent Boston Scientific, Wallflex 240x18 mm) was inserted along the guidewire under endoscopic guidance. Also under endoscopic guidance, the stent was expanded so its proximal end was ca. 5-7 cm above the leak location, and the
distal end was as close as possible to the pylorus. After the stent was inserted, the endoscope was fed through its lumen to confirm its patency, and then the endoscope was removed. The stent remained for a period of 4 to 6 weeks, and then was removed endoscopically.

RESULTS

During the follow-up period, 3 patients were treated at our centre for stent leaks following laparoscopic sleeve gastrectomy. Information about patients is presented in tab. 1.

The studied group included two women and one man, age 34 to 38 years, with mean BMI of 56.6 kg/m² (from 44 to 65 kg/m²). In all patients, obesity was accompanied by other diseases: hypertension in 3 people, and non-alcoholic fatty liver disease and hypercholesterolaemia in 1 person. One patient, shown in the table as patient No 2, had a history of numerous surgeries within the peritoneal cavity.

Laparoscopic sleeve gastrectomy and its characteristics in each patient are shown in tab. 2.

The first of three laparoscopic sleeve gastrectomies in which staple line leaks developed in the postoperative period was performed in a patient with super obesity and significantly limited working space within the peritoneal cavity. No intraoperative complications occurred during the operation; however, due to significant technical problems this was the only surgery without continuous suturing of the staple line (PDS 3-0). The second operation was conducted in a patient with a history of numerous surgeries within the peritoneum, and this patient was initially qualified for laparoscopic gastric bypass. As numerous peritoneal adhesions were found intraoperatively, the operating team changed its decision during the procedure and performed laparoscopic sleeve gastrectomy. The third operation was without intraoperative problems and complications. This was the only case in which a 34F nasogastric tube was used for calibration.

Each surgery ended with a tightness test using methyl blue administered through the nasogastric tube, which did not penetrate outside the gastric lumen in any case, thus excluding the staple line leak.

Table 1. Details in patients who developed staple line leaks

<table>
<thead>
<tr>
<th>Successive number</th>
<th>Sex</th>
<th>Age</th>
<th>BMI during the procedure</th>
<th>Comorbidities</th>
<th>Time from diagnosis to treatment</th>
<th>Time to the leak healing (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>K</td>
<td>34</td>
<td>61</td>
<td>HL, NAFLD, HT</td>
<td>1</td>
<td>60</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>36</td>
<td>65</td>
<td>HT, condition post numerous laparotomies</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>3</td>
<td>K</td>
<td>38</td>
<td>44</td>
<td>HT</td>
<td>5</td>
<td>240</td>
</tr>
</tbody>
</table>

Table 2. Analysis of laparoscopic sleeve gastrectomies

<table>
<thead>
<tr>
<th>Successive number</th>
<th>Diameter of a nasogastric tube used for calibration</th>
<th>Staple type and information about additional strengthening of mechanical sutures</th>
<th>Result of an intraoperative tightness test with methyl blue</th>
<th>Leak symptoms</th>
<th>X-ray scan results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>36F</td>
<td>4 loads of 4.2 mm + 1 load of 4.6 mm</td>
<td>no leak</td>
<td>peritonitis symptoms, tachycardia</td>
<td>leak signs in a series with oral gastrografin administration, fluid reservoir in CT</td>
</tr>
<tr>
<td>2</td>
<td>36F</td>
<td>4 loads of 4.2 mm + suturing the staple line with the PDS 3-0 suture</td>
<td>no leak</td>
<td>fever, stomach ache, tachycardia</td>
<td>leak signs in a series with oral gastrografin administration, fluid reservoir in CT</td>
</tr>
<tr>
<td>3</td>
<td>34F</td>
<td>4 loads of 4.2 mm + suturing the staple line with the PDS 3-0 suture</td>
<td>no leak</td>
<td>peritonitis symptoms, tachycardia, fever</td>
<td>leak signs in a series with oral gastrografin administration, fluid reservoir in CT</td>
</tr>
</tbody>
</table>
Leaks following laparoscopic sleeve gastrectomy were diagnosed on day 5 (1-10 days) after the procedure, on average. Thus all leaks had signs of so-called early leaks. The predominant leak symptoms included symptoms of peritonitis, tachycardia and fever. An upper gastrointestinal series with a water-soluble contrast medium (Gastrografin™) administered orally confirmed presence of leaks in all examined patients, and in each case showed a leak in the cardia area. The CT scan of the abdominal cavity with intravenous administration of a contrast medium showed pathological fluid reservoirs in the leak region.

Intervention consisting of laparoscopy and endoscopic insertion of a self-expandable stent was initiated within 14 hours (4–23 hours) of diagnosing the leak, on average. Treatment described in the study method was applied to all patients. All leaks showed during the endoscopic examination were found in the upper third of the gastric stump, near the gastro-oesophageal junction.

Following the surgery and endoscopic stent insertion, nutritional intervention was initiated in all patients, by including complete parenteral nutrition of caloric value and composition selected accordingly to patient anthropometric parameters.

All patients received intravenous antibiotics, initially selected empirically, including second generation cephalosporins, followed by antibiotic selected on a basis of microbiological tests results and antibiograms. The mean duration of treatment with intravenous antibiotics was 18 days (14-21 days). In one patient (presented in the tables as case No 3), intravenous administration of antifungal medicines was necessary due to symptoms of infection with Candida albicans strain.

The patient, presented in the tables as case No 3 and operated after the longest time since the diagnosis, required 16 days stay at an intensive care unit, and use of artificial ventilation and haemodiafiltration.

The median for the time of maintaining drainage installed during the surgery was 32 days (21-52 days). The drain inserted into the vesicorectal space was removed as first, followed by one of the drains in the leak area, which was less effective in removing liquid matter from the leak area. Feeding by the oral route was stopped completely for 14 days on average (11-23 days). After a radiological scan documenting good flow of the contrast medium to the duodenum and further sections of the gastrointestinal tract, with no or minimum well-drained leaks at the leak location, administration of liquids was initiated, usually on day 14 (11-23 days), and oral administration of mashed food was usually initiated on day 35 (28-42 days).

Stents were not well tolerated by the patients. All patients complained of heartburn and burning feeling, with recurrent gastro-oesophageal reflux occurring in two patients, who were forced to sleep in a semi-recumbent position. These symptoms were eliminated by intravenous administration of proton pump inhibitors, and when oral administration of liquids was initiated, by oral administration of alkalisng medicines in form of dihydroxialumini sodium carbonate suspension.

The mean time for which the stent was kept was 5 weeks (4–6 weeks). There was no case of the stent migration. In each case the stent

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Table 3. List of publications on use of endoscopically inserted self-expandable stents in patients with staple line leaks after laparoscopic sleeve gastrectomy

<table>
<thead>
<tr>
<th>Author</th>
<th>Year of publication</th>
<th>Number of patients</th>
<th>Effectiveness rate (%)</th>
<th>Stent type</th>
<th>Mean time for leak healing (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serra</td>
<td>2007</td>
<td>3</td>
<td>66</td>
<td>Hanarostent</td>
<td>120</td>
</tr>
<tr>
<td>Deviere</td>
<td>2007</td>
<td>4</td>
<td>75</td>
<td>partly covered SEMS sent</td>
<td>no data</td>
</tr>
<tr>
<td>Oshiro</td>
<td>2009</td>
<td>2</td>
<td>100</td>
<td>Hanarostent</td>
<td>90</td>
</tr>
<tr>
<td>Casella</td>
<td>2009</td>
<td>3</td>
<td>100</td>
<td>Ultraflex</td>
<td>55</td>
</tr>
<tr>
<td>Nguyen</td>
<td>2010</td>
<td>3</td>
<td>100</td>
<td>Alimaxx-E</td>
<td>63</td>
</tr>
<tr>
<td>Blackmon</td>
<td>2010</td>
<td>4</td>
<td>100</td>
<td>Alimax-E, Ultraflex</td>
<td>27.7</td>
</tr>
<tr>
<td>Tan</td>
<td>2010</td>
<td>4</td>
<td>50</td>
<td>no data</td>
<td>no data</td>
</tr>
<tr>
<td>Sakran</td>
<td>2012</td>
<td>11</td>
<td>55</td>
<td>no data</td>
<td>40</td>
</tr>
<tr>
<td>Simon</td>
<td>2013</td>
<td>9</td>
<td>78</td>
<td>Hanarostent</td>
<td>45</td>
</tr>
<tr>
<td>Alazmi</td>
<td>2014</td>
<td>17</td>
<td>76</td>
<td>Ultraflex+Polyflex</td>
<td>42</td>
</tr>
</tbody>
</table>
was removed without a need to install a new one. The leak closing was confirmed with endoscopic examination and a series with oral administration of a contrast medium. Stenting proved to be fully effective in all patients, where a cutaneous fistul periodically (every 2–3 weeks) discharging several millilitres of chyme persisted in one patient after discharging home. It was not accompanied by any other symptoms. Currently, after 5 months the fistula is completely closed, and no discharge has been noted for 4 months.

The mean time for the leak healing in 2 patients, in whom the described method was successful in treatment of this complication, was 37 days. In these patients the mean follow-up time after the end of treatment was 10.5 months (3–12 months), and during that time no leak recurrence was observed. No patient died in the perioperative or follow-up period.

**DISCUSSION**

The described method for staple line leak treatment combining endoscopic insertion of a covered self-expandable stent into the stomach with simultaneous laparoscopic rinsing of the peritoneal cavity and drain insertion is a good and effective procedure facilitating primary healing of the leak.

Recently, several papers were published describing use of self-expandable stents in treatment of staple line leaks following laparoscopic sleeve gastrectomy (9, 10, 11). These reports are scarce, and described groups of patients are small (tab. 3). The largest available meta-analysis covers a group of 67 patients, in whom self-expandable stents were used in treatment of leaks after bariatric procedures, with 87.7% effectiveness (12). In his report Simon described seven patients treated for leaks following laparoscopic sleeve gastrectomy with 78% effectiveness, and he used self-expandable stents combined with percutaneous drainage (13). In Pequignot’s et al. report describing 6 patients after laparoscopic sleeve gastrectomy, the leak was successfully treated in 84% of patients (14). The results reported in this paper are consistent with those obtained by other surgeons. However, it is worth to consider here a longer healing time in one of our patients. With appropriately selected drain location, treatment by endoscopic stent insertion and laparoscopically installed drainage facilitates achieving sufficient improvement and stabilisation in patient’s status, so they can function well and leave the hospital, and achieve complete healing of the fistula in time.

In publications concerning use of endoscopically inserted self-expandable stents used in treatment of leaks after laparoscopic sleeve gastrectomy, a correlation between treatment outcome and the time between the leak diagnosis and stent insertion is frequently noted. In the analysed group of patients, in each case the stent was inserted during the first undertaken reoperation, and the mean time between the leak diagnosis and stent insertion was 14 hours (4-23 hours). This is one of the shortest described intervention times. Tan describes a group of 4 patients in whom he inserted the self-expandable stent after 7 days of the leak diagnosis. De Aretxabela et al. describes treatment of 4 patients (15). Some of them had self-expandable stents inserted after 15 days of the leak diagnosis, with the treatment time of 41 days, and some after 4 weeks of the leak diagnosis, and then the mean treatment time was 110 days. Oshiro et al. also describes 2 patients who had the stent inserted after 3 months from the leak diagnosis, and the treatment time in such case was 160 days (16).

The main noted disadvantages of self-expandable stents include poor tolerance of treatment involving their use, related to recurring heartburn and feeling of burning behind the sternum. Also at our centre these problems affected all treated patients. They can be temporarily alleviated by administering proton pump inhibitors and alkalisising medicines; however, the symptoms are fully resolved only with removal of the stent. Recent reports include information concerning use of a new type of self-expanding stents from the company Hanaro, provided with a silicone anti-reflux valve. According to authors of those reports, heartburn symptoms appear in less than half of patients treated with them (17).

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Obviously, the authors will be interested in including this solution into the armamentarium of methods available at our centre for treatment of leaks after gastrointestinal tract resection procedures, as bibliographic data is very encouraging.

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Self-expandable stent and laparoscopic rinsing in staple line leaks post sleeve gastrectomy

gastrectomies proposed by the authors, endoscopic insertion of a self-expandable stent was performed at the same time as a laparoscopic operation with a drain insertion in the leak area. In the authors opinion, with this combination of two methods it is possible to use principles for treatment of peritonitis based on elimination of the peritonitis trigger and thorough rinsing and draining of the peritoneal cavity, known and successfully used by generations of surgeons. According to this concept, laparoscopic access to peritoneal cavity allows its effective rinsing and drain insertion, and endoscopic insertion of a self-expandable stent into a gastric stump helps to eliminate the infection trigger. It should be noted here that self-expandable stents are mainly used not to seal the leak area, but to ensure an efficient flow from the area above the leak towards the pylorus, which is much more important. This elimination of overpressure leading to leak development is a key mechanism in treatment of the resultant leak. Drainage inserted into the peritoneal cavity on one hand helps to remove remains of fibrin and liquid matter from this body cavity, while on the other, when inserted precisely in the leak area, it effectively evacuates residual chyme leaking through a defect in the gastric wall, thus preventing peritonitis recurrence. In favourable circumstances such drain can help in determining a direction of a forming gastrocutaneous fistula; and although its formation may result in longer treatment, yet it sufficiently protects against chyme spreading within the peritoneal cavity.

At the end, limitations of this publication should be mentioned. Certainly, the most important one is a small group of described patients, and the observational nature of the study. A randomised clinical study would certainly be a useful tool for verification of the method proposed by the authors. However, considering the continuously increasing number of centres performing laparoscopic sleeve gastrectomy in our country, and thus the increasing likelihood for these complications to occur in daily surgical practice, the authors deemed appropriate to share their initial results and observations with the readers, believing they may prove useful in daily work of surgeons performing bariatric operations.

CONCLUSIONS

The proposed method for treatment of staple line leaks following laparoscopic sleeve gastrectomy by combined laparoscopic rinsing and draining of the peritoneal cavity and endoscopic insertion of a self-expandable stent is an interesting and worth recommending method for treatment of this complication.

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