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Initial experience with endoscopic sleeve gastroplasty in Poland

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Introduction: Obesity is becoming one of the major public health problems. Bariatric procedures are considered the most effective methods of treating this condition but they are costly and entail a high risk of complications. Thus, there is a need to look for better bariatric treatment solutions. One of the newest, highly promising bariatric methods is endoscopic sleeve gastroplasty (ESG), which is comparably effective to other bariatric procedures in terms of weight loss but at the same time it is much less invasive.

Materials and methods: Eight obese patients underwent ESG. Under general anaesthesia, an endoscope was inserted into the stomach, where a row of 4-5 running stitches was placed (from the pyloric part towards the GE junction). Each of the stitches was cinched tight, which resulted in gastric lumen reduction comparable to that achieved with laparoscopic sleeve gastrectomy.

Results: The procedures were performed without any severe peri-operative complications. The only adverse event was a minor haemorrhage in one of the patients, which did not require any surgical intervention. After the surgery, the patients reported a substantial weight loss. Mean %TBWL was 8.6%, 15.4% and 19.6% at 1, 2 and 3 months, respectively.

Conclusions: Minimally invasive and highly effective in body weight reduction, endoscopic sleeve gastroplasty is a promising method of treating obesity. The procedure requires appropriate tools and equipment. The method guarantees gastric volume reduction comparable to that achieved with sleeve resection. The initial results confirm that the effectiveness of the surgery in terms of body weight loss is similar to that seen in other forms of bariatric treatment.

Discussion: Compared to laparoscopic sleeve gastrectomy, endoscopic sleeve gastroplasty is substantially less invasive. Also, it requires shorter procedure time and shorter hospital stay. Data from other medical centres demonstrate somewhat lower dynamics of total body weight loss but these results need to be verified in a long-term follow-up.

KEYWORDS: endoscopic sleeve gastroplasty, ESG, obesity, bariatric surgery, minimally invasive surgical procedures

INTRODUCTION

With its continuously rising prevalence, obesity is becoming a major public health problem worldwide. As of 2013-2014, 37.9% of Americans were obese (BMI>30) [1], whereas in Poland, the number was 16.8% in 2014 [2]. The health consequences of obesity include cardiovascular diseases, hypertension, diabetes, gallbladder diseases, osteoarthritis, obstructive sleep apnoea syndrome or some cancers [3][4], significantly increasing mortality risk [5][6][7] and generating considerable costs for the public healthcare system [8]. Traditional ways of managing obesity, i.e. nutritional interventions, increased physical activity or pharmacotherapy, very often prove ineffective [9][10][11]. Better results can be achieved with bariatric surgery [12][13]. Currently, the most effective types of bariatric procedures are laparoscopic sleeve gastrectomy and laparoscopic gastric bypass [14][15]. Even though they are relatively safe [16], the procedures are associated with risk of severe peri- and post-operative complications, including haemorrhages, fistulas, infections, and chronic complications such as stomal stenosis, gastroesophageal reflux or nutritional deficiencies [17][18]. The most severe among these complications are anastomotic leak and suture line disruption, which might lead to peritonitis and death of the patient [19][20][21]. Due to the risk of such acute complications, only some of the eligible patients are qualified for bariatric surgery by doctors and nutritionists. Additionally, the prospect of the procedure causes fear in many patients, which prevents them from actually having the surgery. Moreover, the costs of weight-loss procedures limit access to bariatric surgery (studies have shown that only 1% of patients qualified for treatment have access to bariatric surgery [22]). Therefore, despite considerable advancements in bariatric surgery, there is a need to look for less invasive surgical techniques, associated with a lower risk of severe adverse events and high effectiveness in reducing body weight. One of such promising techniques, which is currently gaining popularity, is endoscopic sleeve gastroplasty (ESG) [23][24][25]. The technique has never been used in Poland before. The procedure is performed under general anaesthesia. An endoscope is inserted through the oral cavity into the stomach, where a series of sutures is deployed. Sutures are placed starting from the pyloric part and moving gradually towards the GI junction. Cinched sutures create a line of plications in the wall of the stomach, radically reducing the gastric volume. The procedure is less invasive compared to other bariatric techniques. It allows to avoid stomach resection and intervention in the peritoneal cavity, and requires a shorter procedure time as well as a shorter hospital stay. The aim of the paper is to present the first Polish experiences related to perfor-

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ming eight ESG procedures and to assess treatment outcomes in the patients treated.

METHODS AND CLINICAL MATERIAL

Eight obese patients (3 men and 5 women; mean BMI: 42.6) aged 34-60 years (mean age: 46.8) underwent endoscopic sleeve gastroplasty. All the patients had unsuccessfully attempted to manage obesity by dietary changes. Two of the patients had additionally undergone bariatric procedures other than ESG (intragastric balloon and adjustable gastric band), which did not bring long-term effects.

PROCEDURE

The procedures were performed under general anaesthesia with endotracheal intubation. In the first six patients, air insufflation was used, in the other two – carbon dioxide insufflation. A specially designed Overtube (Figure 1) was placed in the oesophagus. The tube enables a streamlined introduction of the endoscope into the stomach and helps to maintain insufflation. Then, a double-channel endoscope equipped with a cap-based Apollo Over-Stitch system was inserted in the oesophagus down to the stomach (Figure 2). Apollo Over-Stitch is an attachment for a dual channel endoscope, which allows for full-thickness suturing of the GI tract wall. The device is operated with a control system mounted to the endoscope handle. The system consists of four basic elements: a curved needle driver, an anchor exchange catheter, a helix device for capturing the stomach wall tissue and a cinch device for knotless stitch fixation. A polypropylene suture (2-0) was used in the procedure. When the endoscope was outfitted with all the elements listed, the suturing procedure began. The helix device was used to capture and hold the stomach tissue prior to needle insertion. The device resembles a corkscrew that is inserted into the stomach wall and allows for pulling the captured tissue towards the endoscope, creating a full-thickness bite for suture placement. The system enables the placement of both interrupted and running stitches. In each of the cases discussed, 4 or 5 running stitches were deployed. The first stitch was placed about 3 cm from the pylorus, and the last one calibrated the cardiac pouch to a capacity of up to 100 ml. Each of the sutures passed through 6 consecutive stomach wall bites. The placement sites were selected in the following order: (1) anterior wall, (2) greater curve, (3) posterior wall, and then back to (4) posterior wall, (5) greater curve and (6) anterior wall. Each of the running stitches was U-shaped, which is one of the variants of intragastric suture placement. After deployment, the stitches were tightened resulting in gastric lumen reduction. Each stitch was cinched with a special cinching device, without the need to tie knots. The secondary row of sutures was placed along the lesser curvature to form a „sleeve" with a desired diameter. It was crucially important to properly select the placement sites as this would allow to obtain the expected plication of the stomach wall. The number of stitches depended on the progress of stomach narrowing, assessed during the procedure, and the need to adequately calibrate the cardiac pouch. In the procedures discussed, 4-5 stitches were placed. The number of stitches and bites varied in individual patients due to the differing initial size of the stomach, placement sites chosen during the suturing procedure and susceptibility of tissue bites to needle insertion, which depended on stomach wall thickness, mucosa condition, stomach size, abdominal adhesions and pressure from the neighbouring organs. The final shape of the stomach was similar to that seen in sleeve gastrectomy. The mean procedure time in the 8 patients treated was 90 minutes (Table 2). The idea of ESG draws on laparoscopic sleeve gastrectomy as the most effective surgical treatment of obesity. The outcome of ESG in terms of gastric volume reduction is similar but the procedure is less invasive and eliminates the risk of fistula formation in the staple line. None of the 8 patients treated experienced severe bleeding or any other peri-operative complications. The post-procedure pain reaction differed depending on the patient – in some cases analgesics were not necessary, whereas other patients were administered different doses of pain medi-

Tab. I. Procedure-related parameters

	1	2	3
A (k)	46	73	a
B (k)	47	65	b
C (m)	51	60	b
D (k)	60	125	a
E (m)	43	95	c
F (k)	39	110	b
G (k)	34	110	b
H (m)	54	80	a
Mean	51	90	–

1 – age (years), 2 – time (min), 3 – intra-operative bleeding (a – none; b – of no significance; c – requiring cell lavage and monitoring; d – requiring injection with sclerosing agents; e – requiring further intervention)

Fig. 1. A specially designed Overtube which enables a streamlined introduction of the endoscope into the stomach and helps to maintain insufflation.

Tab. II. Post-procedure parameters

	1	2	3	4	5		6	7
A (k)	46	none	none	yes	D0 D1 D2 D3	– Py 2.5 g x 2 Py 2.5 g –	no	4
B (k)	47	none	none	yes	D0 D1 D2 D3	Py 2.5 g x 2 Py 2.5 g x 2 – –	yes	4
C (m)	51	none	none	yes	D0 D1 D2 D3	– Py 2.5 g – –	no	4
D (k)	60	none	vomiting, heartburn	yes	D0 D1 D2 D3	Pa 1g, K 100 mg x 2 Pa 1 g, K 100 mg K 100 mg x 2 K 100 mg	no	4
E (m)	43	none	blood clots in vomit contents, loose stools	yes	D0 D1 D2 D3	Pa 1g Pa 1g – –	no	4
F (k)	39	none	vomiting	yes	D0 D1 D2 D3	Pa 1 g Pa 1 g x 2 Pa 1g, I 400 mg, Py 2.5 g Pa 1 g	no	4
G (k)	34	none	none	no	D0 D1 D2 D3	Pa 1g Pa 1g x 3 – –	no	3
H (m)	54	none	none	no	D0 D1 D2 D3	Pa 1g – – –	no	3
Mean	51	–	–	–	–		–	3.75

1 – age (years), 2 – adverse events, 3 – post-operative complaints, 4 – pain, 5 – intravenous administration of analgesics, 6 – fever, 7 – length of hospital stay (days), D – days after surgery, Py – Pyralginum, Pa – Paracetamol, K – Ketonal, I – Ibuprom.

Tab. III. Patients' body weight before and after surgery

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
A	1,66	98	35,6	2,9	6,2	8	7,6	17,2	22,4	7,7	17,5	22,4	26,5	59,5	78
B	1,7	150	51,9	3,5	6,9	9,3	10	20	27	6,7	13,3	18	12,9	25,9	34,9
C	1,75	152	49,6	3,6	6,5	9,1	11	20	28	7,2	13,2	18,4	14,7	26,8	37,5
D	1,7	134	46,4	5,2	7	–	15	20,1	–	11,2	15	–	24,5	32,8	–
E	1,84	126	37,2	4,7	6,2	–	16,4	20,6	–	13	16,3	–	40,2	50,5	–
F	1,74	108	35,7	3,7	6,3	–	11	18,6	–	10,2	17,2	–	34,5	58,3	–
G	1,7	114	39,4	2	–	–	6	–	–	5,3	–	–	14,5	–	–
H	1,7	130	45	3,5	–	–	10	–	–	7,7	–	–	17,4	–	–
Śrd.	1,72	126	42,6	3,6	6,5	8,8	10,9	19,4	25,8	8,6	15,4	19,6	23,2	42,3	50,1

1 – height (m), 2 – initial body weight (kg), 3 – initial BMI, 4 – reduction in BMI after 1 month, 5 – reduction in BMI after 2 months, 6 – reduction in BMI after 3 months, 7 – total body weight loss after 1 month (TBWL), 8 – total body weight loss after 2 months (TBWL), 9 – total body weight loss after 3 months (TBWL), 10 – percentage initial body weight loss after 1 month (%TBWL), 11 – percentage total body weight loss after 2 months (%TBWL), 12 – percentage total body weight loss after 3 months (%TBWL), 13 – percentage excess weight loss after 1 month (%EWL) (percentage body weight loss compared to excess body weight defined as body weight minus body weight corresponding to BMI of 25 kg/m2), 14 – percentage excess weight loss after 2 months (%EWL), 15 – percentage excess weight loss after 3 months (%EWL)

cations up to 3 days after surgery (post-procedure parameters – Table 2). In the evening post-procedure, the patients drank water. The following day, after abdominal examination and general health assessment, they were recommended a liquid diet. In 3 patients, the observation was extended and the liquid diet started on the second and third day post-procedure. In one of the patients, post--operative pain was so strong that abdominal and GI tract X-ray examinations were performed to exclude the possibility of other adverse events (Figure 3). None of the examinations showed any irregularities and when the pain gradually subsided, the patient began a liquid diet on the third day post-procedure. The patients were discharged after 3-4 days (Table 2) and instructed to follow a liquid diet for the subsequent 7 days.

DIETARY RECOMMENDATIONS FOLLOWING ENDOSCOPIC SLEEVE GASTROPLASTY

7 out of 8 of the patients received nutritionist care from a specialist cooperating with the hospital. The patients were asked to continue the liquid diet started at the ward for the first 2 weeks after discharge. The recommended food comprised liquid fat-free dairy products and barley groat and rice gruel. Sugar, juices, fizzy drinks or solid products were not allowed. Through the subsequent 2 weeks, the patients were allowed to eat a puréed diet based on easily digestible vegetables. A liquid diet was also recommended by Lopez-Nava et al. throughout the first month post-procedure [24]. Through the next 4 weeks, solids were gradually introduced – after 8 weeks post-procedure, the patients could eat solids without any restrictions. At first, it was recommended that the patients had 7 meals a day (the suggested meal volume was 70-100 ml), and in the subsequent months, this number was to be limited to 5 meals a day. There were no restrictions as to the calorie intake at any of the stages. The patients would naturally consume fewer calories due to the decreased stomach volume and the resulting faster occurrence of the feeling of satiety. In order for this mechanism to work, the patients were not allowed to eat products containing monosaccharides. Since in the first weeks after surgery, even the smallest amount of food promoted the feeling of fullness, the patients were at risk of malnourishment. Thus, they were asked to follow a diet delivering 70 g of protein a day, based to a large extent on whey protein products with a small volume

Fig. 2. A double-channel endoscope equipped with an Apollo Over-Stitch system.

and complete amino acid composition. The female patient who reported cow's milk protein allergy was advised to use a replacement based on pea protein. Moreover, it was recommended that the patients take oral vitamin D and B group vitamin supplements through the first 2 weeks post-procedure (due to a low intake of grain products). As proper hydration is very important in the entire process, the patients were required to drink about 2,000 ml of still water with low mineral content per day. They were to drink water at least 45 minutes before and 45 minutes after a meal, so that water consumption would not increase the food volume in the stomach. After 8 weeks, the patients began a regular healthy diet comprising 5 meals a day, consumed every 3 hours.

RESULTS

Table 1. Procedure-related parameters
Table 2. Post-procedure parameters
Table 3. Patients' body weight before and after surgery

DISCUSSION

Endoscopic sleeve gastroplasty is not a widely used bariatric procedure. Attempts to perform gastroplasty with the use of endoscopic suturing to treat obesity have already been made 10 years ago [27], and from that time, the procedure has undergone a series of modifications [28][29][30]. However, these early techniques did not allow for an effective reduction in stomach volume, comparable to that achieved with sleeve gastrectomy. This was only possible with the Apollo OverStitch system, the use of which in a gastric volume reduction procedure was first described by Kumar et al. (2014) [31]. To date, several studies on large groups of patients have demonstrated the effectiveness of this procedure in reducing body weight [23][32][33]. Lopez-Nava et al. assessed 248 patients treated with ESG using the Apollo OverStitch system (2017). Severe adverse events occurred in 2% of cases (5 patients) but none of them required surgical intervention [34]. Perigastric fluid collections were observed in 2 patients. One patient suffered a haemorrhage into the abdominal cavity, which was managed conservatively. In one patient, pulmonary embolism occurred post-operatively, and one patient developed pneumothorax and pneumoperitoneum that required drainage. The mean percentage total body weight loss at 24 months was 18.6% (data for 92 patients). In another study, including 154 patients with the use of the Apollo system, Lopez-Nava et al. (2017) did not observe any severe adverse events [35]. The mean percentage total body weight loss at 24 months was 19.5% (data for 28 patients). In 2017, Novikov et al. compared ESG and laparoscopic sleeve gastrectomy in terms of effectiveness and safety. The authors reported that compared to laparoscopic sleeve gastrectomy, ESG is slightly less effective in terms of body weight reduction (%TBWL in 12 months: 29.28% and 17.57%, respectively; $p<0.001$). However, they demonstrated that ESG is associated with a substantially lower risk of complications (9.17% and 2.20%, respectively; $p<0.05$). The length of hospital stay is also noticeably shorter 3.09 ± 1.47 days vs. 0.34 ± 0.73 days, respectively; $p<0.01$) [36]. Post-operative care of a psychologist and nutritionist is an important part of any type of bariatric treatment, including ESG. As suggested by Lopez et al. [37], such care significantly increases the chance of effective and long-lasting weight loss. The 8 procedures we performed are in line with the above-mentioned findings: the mean %TBWL in the patients (data for 3 patients) was 19.6% at 3 months post-surgery (Table 3), and none of the patients experienced any severe complications. The mean length of hospital stay was 3.75 days. Based on the procedures performed thus far, another two substantial advantages of ESG should be emphasised. In case of unsatisfactory gastric volume reduction and lack of expected body weight loss, another surgery can be performed, with additional 1-2 narrowing sutures placed in the stomach wall. Theoretically, ESG is a reversible procedure. Namely, if the stomach is too narrow, it is possible to cut out one or several stitches

Fig. 3. An abdominal and GI tract X-ray performed postoperatively in one patient to exclude the possibility of adverse events.

or even restore the pre-operative gastric volume. This is impossible with sleeve gastrectomy. Even though further observations may prove ESG less effective in body weight reduction compared to laparoscopic sleeve gastrectomy, the advantages of the former seem far more significant. The fact that ESG is minimally invasive and thus associated with fewer severe adverse events may be helpful in popularizing the method. More patients will be qualified for the procedure and more will decide on having the surgery. As a result, ESG may contribute to the improvement in the health and quality of life of a much greater number of people compared to other types of bariatric surgery.

CONCLUSIONS

Endoscopic sleeve gastroplasty is a minimally invasive and safe procedure, which seems to be a promising alternative to the most effective method of treating obesity to date, i.e. laparoscopic sleeve gastrectomy. Technical principles of the procedure are well established. Mastering the method requires experience in surgical endoscopy. The devices used comprise another stage in the development of minimally invasive endoscopic methods for treating gastrointestinal diseases. They offer the possibility of surgical management not only of obesity but also other conditions. However, assessment of long-term effects and of the role of ESG in treating obesity in comparison with other bariatric procedures requires further research.

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