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The effect of the distance from the pyloric sphincter and size of the calibration tube on postoperative outcomes of the laparoscopic sleeve gastrectomy

T.I. Omarov[1,2], N.Yu. Bayramov[1], M.R. Huseynova[2], N.A. Zeynalov[1]

[1]Azerbaijan Medical University, Baku, Azerbaijan;
[2]Modern Hospital, Baku, Azerbaijan

Abstract

Aim. To study of the effect of the diameter of the calibration tube and the distance from the pyloric sphincter on the outcomes of the laparoscopic sleeve gastrectomy.

Methods. The study included 945 (915 women) patients with a body mass index 51.5±9 kg/m^2. The average age of the patients was 53.5±8.5 years. The patients were divided into 2 groups by the type of laparoscopic surgery: in the first group (n=463), a 36 Fr calibration tube was used, the distance from the pyloric sphincter was 4–6 cm; in the second group (n=482), a 32 Fr calibration tube was used, the distance from the pyloric sphincter was 2–3 cm. The main comparison criteria was the percentage of body weight loss in the first 6 and 12 months, and an additional comparison criteria was the of concomitant diseases progress in postoperative and the existence of complications.

Results. A comparative analysis showed that the first group in the first 6 months lost 59±3% of its initial body weight, while in 12 months — 71±4%; in the second group, 73±3 and 87±3% of the initial weight, respectively. Concomitant diseases in the first group decreased by 70–80% by the 6th month after surgery and by 85–96% by the 12th month. In the 2nd group, similar remission with improvement was between 84 and 94% at the 6th month, and remained the same at the 12th month.

Conclusion. The results of the study show that in laparoscopic sleeve gastrectomy with a calibration tube diameter 32 Fr and a distance of 2–3 cm from the pyloric sphincter, compared to a calibration tube diameter 36 Fr or more and a distance of 4–6 cm from the pyloric sphincter, a body weight loss faster and more effective with earlier remission of concomitant diseases, while the number of complications is comparable.

Keywords: calibration tube, pyloric sphincter, longitudinal gastric resection.

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Background. Longitudinal gastric resection (LGR) is accepted as the most effective method of treatment for obesity, causing an effective weight loss and abolition of concomitant diseases. In recent years, the number of such surgeries has increased, accounting for more than half of all bariatric operations [1, 2]. Along with this, some technical aspects of LGR are not standardized, especially the diameter of the calibration probe, the distance from the pyloric sphincter during a resection; the strengthening of the stapler line and other points remain controversial [3–6].

The literature describes the use of a calibration probe with a diameter of 27–50 Fr and a distance from the pyloric sphincter of 2–8 cm [7,8]. Despite the recent consensuses suggesting the use of a calibration probe with a diameter of 32–36 Fr and a distance from the pyloric sphincter of 2–6 cm, these are empirical indicators based on expert reviews [9–11].

Aim. Considering all the above, we aim to study the impact of the calibration probe diameter and the distance from the pyloric sphincter during a surgery on the results of a laparoscopic LGR.

Materials and methods. *Characteristics of patients.* The study included obese patients, who underwent LGR in 2012–2019 for the first time, which was initiated after receiving a written consent from each patient. The patients were examined by a multidisciplinary team of doctors including a bariatric surgeon, endocrinologist, psychiatrist, dietitian, and others. The study also included patients who met the following criteria:

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– Body mass index (BMI) ≥ 40 kg/m^2 or ≥ 35 kg/m^2 and the presence of at least one

concomitant disease (such as diabetes, hypertension, dyslipidemia, apnea syndrome, etc.);

– Inability to reduce body weight using conservative methods (diet and sports) for 2 years;

– Age 18–65 years.

Patients < 18 years old with contraindications to surgery, multiple intra-abdominal adhesions, and repeated bariatric surgeries were excluded in this study.

Comparison criteria. The ASMBS/SOARD[1] criteria were used to compare the groups [7]. The main comparison criterion was the percentage of a body weight loss in the first 6 and 12 months, which was calculated using the following formula:

$$\text{Index} = (\text{body weight before a surgery} - \text{body weight after a surgery}) / \text{body weight before a surgery} - \text{ideal body weight corresponding to 25 kg/m}^2 \times 100$$

Additional comparison criteria were the postoperative course of concomitant diseases and the presence of complications, which were determined in accordance with the ASMBS/SOARD standards:

– Arterial hypertension—systolic pressure, ≥ 140 mmHg; diastolic pressure, ≥ 90 mmHg or the use of antihypertensive drugs;

– Diabetes mellitus—fasting blood glucose ≥ 126 mg/dL, 2 hours after meals ≥ 200 mg/dL, or the use of antidiabetic drugs;

– Dyslipidemia—content of triglycerides ≥ 150 mg/dL or low-density lipoproteins ≥ 100 mg/dL;

– Apnea syndrome—snoring during sleep, hypoxia, and a respiratory standstill;

– Arthralgia—the presence of joint and lumbar pain, arthrosis;

– Hyperuricemia—uric acid ≥ 400 mg/dL;

– Depression—diagnosis by a psychiatrist or the use of antidepressant drugs;

– Gastroesophageal reflux disease (GERD)—the presence of esophagitis during endoscopy or abolition of symptoms when using proton pump inhibitors;

– Leakage—extravasation of a contrast material during a radiological examination;

– Stricture—segmental narrowing during the contrast or endoscopic examination as well as dysphagia/regurgitation.

The complete abolition of clinical and laboratory signs of concomitant diseases and the absence of the need for a medical treatment were considered remission, while a 30–50% reduction in the use of medications and laboratory parameters was considered an improvement.

Preoperative research methods. Preoperative and postoperative patient management was based on the protocols of the Association of Anesthetists of Great Britain and Ireland (AAGBI, 2015), the European Association for the Study of Obesity (EASO, 2017), and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO, 2008).

Prior to a surgery, the following were made, clinical examination, endoscopy, routine laboratory tests (general blood test, hepatitis virus tests, lipid spectrum, creatinine, urine analysis), BMI, lung assessment (lung x-ray, spirometry, pulse oximetry, apnea survey, neck circumference), cardiological assessment (electrocardiography, echocardiography, stress test, and others as indicated), liver assessment (activity liver enzymes, ultrasound examination of the abdominal cavity, liver elastography), endocrinological assessment (glucose, glycosylated hemoglobin, thyroxine-binding globulin, cortisol), and dopplerography, to determine thrombosis and assess a surgical risk.

Preoperative preparation. To prevent perioperative complications, the following preoperative measures were taken:

– Spirometry and respiratory gymnastics for the prevention of pulmonary complications and apnea syndrome;

– Smoking cessation 6 months before a surgery;

– Glycemic control;

– A low-carb diet 2–4 weeks before a surgery to reduce the liver size;

– One dose of an antibiotic during an anesthesia;

– Elastic stockings, pneumocompression for patients with a high risk of thrombosis.

Surgical technique. Patients were divided into two groups according to a surgical technique. In the first group (diameter 36 Fr + long distance), after the calibration probe installation, the body and bottom of the stomach were removed at a distance of 4–6 cm from the pyloric sphincter. In the second group (32 Fr + short distance), a resection of the large curvature of the stomach began at a distance of 2–3 cm from the pyloric sphincter.

If there are reflux disease symptoms in the anamnesis, the detection of a diaphragmatic hernia of the first degree, one or two silk sutures are applied to the diaphragmatic legs. In the presence of cholelithiasis, a simultaneous cholecystectomy is performed by the same team of medical workers.

Postoperative management of the patient. On the first postoperative day, patients remained under observation in the intensive care unit and were transferred to the hospital ward the next day. In

[1]ASMBS, American Society for Metabolic and Bariatric Surgery. SOARD, Surgery for Obesity and Related Diseases.

Table. 1. General characteristics of patients

Indicators	Calibration probe 36 Fr, 4–6 cm of the antrum	Calibration probe 32 Fr, 2–3 cm of the antrum	*p*-value
The number, n	463	482	—
Age, years	43.20±20.8	40.40±18.4	0.534
Women, n, (%)	449 (96.9%)	468 (97.1%)	0.712
Men, n, (%)	14 (3.1%)	16 (2.9%)	0.712
Body weight, kg	119.4±37.4	137.0±46.4	0.031
Body mass index, kg/m^2	44.3±10.8	50.8±16.6	0.004
Arterial hypertension, %	188 (40.6%)	194 (41.9%)	0.756
Diabetes mellitus, %	94 (20.3%)	106 (22.9%)	0.325
Dyslipidemia, %	178 (38.4%)	181 (39.1%)	0.851
Apnea syndrome, %	29 (6.3%)	31 (6.7%)	0.152
Arthralgia, %	59 (12.7%)	62 (13.4%)	0.518
Depression, %	17 (3.7%)	19 (4.16%)	0.687
Gastroesophageal reflux disease, %	29 (6.3%)	28 (6%)	0.369

the first 24 hours, patients were allowed to drink water in small amounts and then gradually eat liquid and pureed food, and after 2–4 weeks, they were allowed to switch to solid food. Increased physical activity of patients occurred in 24 postoperative hours. To prevent thrombosis, low-molecular-weight heparins (enoxaparin sodium or dalteparin sodium) were prescribed for 2 weeks.

On the first postoperative day, all patients underwent a routine contrast gastrography to determine whether there was a leak.

A dietitian, endocrinologist, and surgeon examined patients every month for the first 6 postoperative months and then every 3–6 months. During the examination, along with the body weight, the dynamics in routine laboratory tests and concomitant diseases were also determined.

Statistical processing is conducted using Microsoft Excel and SPSS programs. The Student's t-test was used, and $p < 0.05$ was considered statistically significant.

Results. *Characteristics of patients*. A total of 463 out of 945 patients with BMI = 34.5–69.6 kg/m^2 and 481 patients underwent LGR using a 36 Fr and 32 Fr diameter calibration probe at a distance of 4–6 cm and 2–3 cm from the pyloric sphincter (first group), respectively.

All patients were under medical supervision for 1 year. Table 1 shows the groups differed slightly from each other in terms of age, gender, body weight, BMI, and concomitant diseases. Nine patients from the first group and 7 patients from the second underwent simultaneous cholecystectomy. One patient from each group underwent laparotomy due to bleeding.

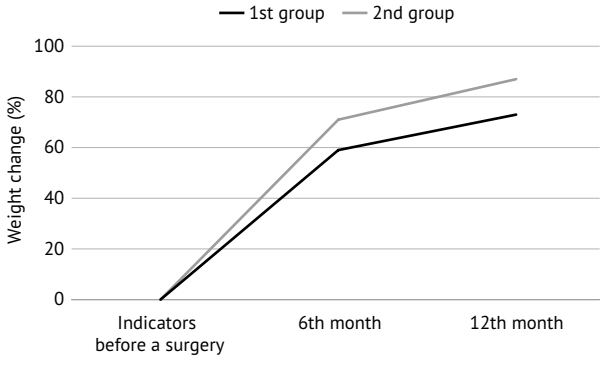

Fig. 1. Dynamics of body weight at the 6th and 12th months

Dynamics of body weight loss. Table 2 shows the dynamics of body weight, its loss, and BMI at the 6th and 12th months in both groups. Figure 1 presents the dynamics of weight loss. The comparative analysis showed that during the 6th and 12th postoperative months, body weight, its loss rate, and BMI were statistically significantly different in both groups. In the second group (32 Fr and a distance of 2–3 cm), body weight loss was registered. The dynamics of excess weight loss shows that the first group lost 59 ± 3% in the first 6 months and 71 ± 4% in the 12th month and the second group 73 ± 3 and 87 ± 3%, accordingly. The difference in the indicators of the 6th and 12th months among the groups was statistically significant ($p < 0.05$). The indicator of body weight loss in the first group was obtained at the 12th month, while in the second group, it was obtained at the 6th month.

The indicators of all patients (n = 945) were analyzed. Table 2 presents the changes in the course of concomitant diseases during the postoperative

Table 2. Dynamics of body weight, its loss index, and BMI for the 6th and 12th months

Indicators	Calibration probe 36 Fr, 4–6 cm of the antrum	Calibration probe 32 Fr, 2–3 cm of the antrum	*P*-value
Preoperative body weight, kg	137±5	143±6	—
Body weight—6th month, kg	93±2	85±3	0.003
Body weight—12 months, kg	78±3	70±2	0.032
Weight loss—6th month, kg	29.9±2	38.5±2	0.040
Loss of body weight—12 months, kg	36.2±2	44.8±1	0.001
Preoperative BMI, kg/m^2	47±4	47.5±4	0.000
BMI—6th month, kg/m^2	34.2±1	31.5±0.6	0.002
BMI—12th month, kg/m^2	27.9±1	24.5±0.4	0.023
Preoperative excess body weight, kg	69.9±3	72.1±4	0.002
Excess body weight—6th month, kg	63±3	78±3	0.018
Excess body weight—12 months, kg	75±4	91±3	0.011
Remission of hypertension—6th month	71 (37.8%)	78 (40.2%)	0.026
Remission of hypertension—12th month	83 (44%)	97 (50%)	0.027
Blood pressure improvement—6th month	85 (45.2%)	90 (46.4%)	0.000
Blood pressure improvement—12th month	103 (54.8%)	107 (55.2%)	0.000
Remission of diabetes mellitus—6th month	36 (38.3%)	42 (39.6%)	0.019
Remission of diabetes mellitus—12 months	43 (45%)	52 (50%)	0.019
Improvement of the course of diabetes mellitus—6th month	47 (50%)	54(51%)	0.002
Improvement of the course of diabetes mellitus—12th month	48 (51%)	54 (51%)	0.002
Remission of dyslipidemia—6th month	78 (43.8%)	79 (43.7%)	0.021
Remission of dyslipidemia—12 months	82 (46.1%)	85 (47%)	0.021
Improvement of dyslipidemia—6th month	94 (52.8%)	95 (52.5%)	0.000
Improvement of dyslipidemia—12th month	96 (53.9%)	96 (53%)	0.000
Remission sleep apnea—6 months	9 (31%)	10 (32.3%)	0.000
Apnea remission—12th month	12 (41.4%)	15 (48.4%)	0.000
Improvement of apnea—6th month	16 (55.2%)	19 (61.3%)	0.000
Improvement of apnea—12th month	17 (58.6%)	18 (58.1%)	0.000
Remission of the arthralgia—6 months	24 (40.7%)	27 (43.5%)	0.001
Arthralgia remission—12 months	27 (45.8%)	29 (46.7%)	0.001
Improvement of the course of arthralgia—6th month	29 (49.1%)	31 (50%)	0.001
Improvement of the course of arthralgia—12th month	30 (50%)	30 (50%)	0.001
Remission of depression—6th month	3 (17.6%)	6 (31.5%)	0.012
Remission of depression—12 months	4 (23.5%)	6 (31.5%)	0.012
Improvement in the course of depression—6th month	10 (58.8%)	12 (63.1%)	0.017
Improvement in the course of depression—12th month	11 (70.5%)	12 (63.1%)	0.023
GERD remission—6th month	3 (10.3%)	2 (7.1%)	0.042
Remission of GERD—for 12th month	4 (13.7)	3 (10.7%)	0.042
Improvement of GERD—6th month	8 (27.5%)	7 (25%)	0.048
Improvement of GERD course—12th month	9 (31%)	7 (25%)	0.048
Nausea	3 (4.2%)	12 (16.2%)	0.046

Note: BMI, body mass index; GERD, gastroesophageal reflux disease.

Table 3. Postoperative complications

Indicators	Calibration probe 36 Fr, 4–6 cm of the antrum	Calibration probe 32 Fr, 2–3 cm of the antrum	*p*-value
Leak	1 (0.2%)	1 (0.2%)	0.452
Nausea	8 (1.7%)	19 (3.9%)	0.080
Strictures	1 (0.2%)	1 (0.2%)	0.504
Lack of nutrition	2 (0.4%)	4 (0.8%)	0.478
Newly emerged GERD	14 (3%)	17 (3.5%)	0.653
Adhesive obstruction	1 (0.2%)	1 (0.2%)	0.857
Unsuccessful weight loss	7 (1.5%)	2 (0.4%)	0.992
Bleeding	4 (0.9%)	3 (0.6%)	0.963

Note: GERD, gastroesophageal reflux disease.

period, showing an improvement in the course of hypertension, diabetes, dyslipidemia, apnea, arthralgia, and depression by 70%–80% and 85%–90% at the 6th and 12th months, respectively, in the first group. In the second group, a similar improvement in the course at the 6th month was 84%–94%, and at the 12th month, it remained the same.

Comparative analysis showed no statistically significant difference in remission and improvement of the condition at the 12th month between the two groups, but the remission and improvement at the 12th month in the first group were obtained in the second group already at the 6th postoperative month. In addition, compared to the first group, the second group registered a significant remission of hypertension (44% vs. 50%, $p < 0.05$), diabetes mellitus (43% vs. 52%, $p < 0.05$), and apnea syndrome (41% vs. 48%, $p < 0.05$). Remission and improvement of GERD in the second group were lesser, with no statistically significant difference.

Table 3 presents *postoperative complications* and unsuccessful results. However, no mortality was noted. With the exception of nausea, cases of leakage, bleeding, stricture, nutritional deficiencies, obstruction, recurrent GERD, and unsuccessful weight loss had no significant difference among the groups. Nausea that occurred in the first postoperative months and passed on the 3rd to 6th month was registered more often in the second group. The leak was abolished for one patient by stenting and percutaneous drainage and for another by relaparoscopy, suturing, and stenting. Five of seven patients underwent relaparoscopy and suturing for bleeding. The condition of the remaining two patients was stabilized by conservative methods within 24 hours. To abolish strictures, one patient underwent endoscopic balloon dilation, and another had a Roux-en-y bypass anastomosis. Laparoscopic adhesiolysis abolished the adhesive obstruction of both patients. Due to a lack of nutrition, a conservative treatment was prescribed.

Discussion. In this clinical study, the LGR results were obtained using a calibration probe with a diameter of 36 Fr and 32 Fr at a distance of 4–6 cm (463 patients) and 2–3 cm (482 patients), respectively, and their dynamics were evaluated over 1 year, concluding that the use of a calibration probe with a diameter of 32 Fr at a distance of 2–3 cm leads to faster weight loss and earlier remission of concomitant diseases and does not increase the possibility of complications.

In some randomized and nonrandomized studies, different results were obtained in relation to the diameter of the remaining stomach and the distance from the pyloric sphincter during longitudinal gastric resections [1,2].

In the study by O. Avlanmysh et al. [6], 3-year LGR results for 390 patients were compared using a calibration probe with a diameter of 36 Fr at a distance of less than or more than 3 cm. According to these results, the approach of the resection line to the pyloric sphincter, that is, a large resection of the antrum, led to a sharp increase in the loss of excess body weight in the first months, which in the first year was 82% and in the second 86%. In the group with a distance from the pyloric sphincter of > 3 cm, body weight loss stabilized at the 12th month, amounting to 76%. Based on these results, the authors noted that resection from a short distance from the pyloric sphincter leads to effective and long-term weight loss. In our study, at the 12th month, the excess body weight loss was relatively high (89 ± 3%), which can be attributed to the use of a calibration probe with a small diameter. In two other studies, a greater body weight loss was recorded among patients who underwent gastric resection at a short distance from the pyloric sphincter than those who underwent gastric resection at a greater

distance from the pyloric sphincter; the number of complications were not statistically different [2,4].

Contrary to these studies, there are others in which the distance from the pyloric sphincter does not affect the rate of body weight loss [3]. In one of the randomized studies, the results of LGR were compared at a distance of 2 and 5 cm from the pyloric sphincter, but the result shows no difference between the two groups [5, 7]. In contrast to our study, this study used a calibration probe with a diameter of 42 Fr. Another study compared the results of LGR at a distance of 2 and 6 cm from the pyloric sphincter, but did not find a significant difference [8].

Studies related to the diameter of the calibration probe are known to have controversial results [5–7]. In one of the randomized studies, the results of using calibration probes with a diameter of 27 and 39 Fr were compared, in which the body weight loss indicators had no significant difference [6]. However, unlike our study, in this study, resection was made at a distance of 6–8 cm from the pyloric sphincter. Similarly, in two other studies with a resection made at a distance of 2 and 5–6 cm, no difference in body weight loss was noted, but in one of them, the resection was made at a distance of 5–6 cm, with the other being retrospective [5,7].

There are many studies in which reducing the diameter of the calibration probe increased body weight loss [8,9]. In one study, when using a calibration probe with a diameter of 32 Fr compared to 42 Fr, a large loss of body weight was recorded, but statistical significance was noted only at the 4th year following surgery [9].

The small diameter of the calibration probe and the close distance from the pyloric sphincter during a resection led to earlier and faster remission of comorbidities. In contrast to the results of some studies, our study showed that reducing the diameter of the calibration probe did not increase the frequency of complications.

Our research also has some drawbacks: (1) a relatively small number of patients and (2) the short time of postoperative monitoring and the need for 3- and 5-year monitoring for long-term results.

CONCLUSION

The results of the study show that the use of a 32 Fr calibration probe at a distance of 2–3 cm from the pyloric sphincter during a laparoscopic longitudinal resection of the stomach, compared with the use of a 36 Fr calibration probe and more at a distance of 4–6 cm from the pyloric sphincter, is faster and more effective in body weight loss occurs with an earlier disappearance of concomitant diseases; the number of complications is comparable.

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