Laparoscopic gastric bypass surgery with a single anastomosis: a comparative analysis of the metabolic and bariatric effects

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Abstract

Objective. To compare the results of the effect of long–pouch, distal and mini–gastric bypass surgery with a single anastomosis on the loss of excess body weight, indicators of protein, lipid, carbohydrate metabolism, correction of metabolic syndrome and development of deficiency states after 36 months.

Materials and methods. Patients with morbid obesity were divided into 3 groups: Group 1 – 25 patients who underwent long–pouch gastric bypass with a biliopancreatic loop length of 200 cm; Group 2 – 25 patients who underwent mini–gastric bypass with a biliopancreatic loop length of 200 cm using laparoscopic access; Group 3 – 25 patients who underwent distal gastric bypass with a total loop length of 250 cm.

Results. 36 months after the operation, the loss of excess body weight was (69 ± 1.1)% in group 1, (70.1 ± 1.3)% in group 2 and (72 ± 0.9)% in group 3; remission of dyslipidaemia was observed in 4 (80%) of 5 patients in group 1, 11 (84.6%) of 13 patients in group 2 and 7 (100%) of 7 patients in group 3; remission of type II diabetes mellitus – in 3 (75%) out of 4, 5 (83.3%) out of 6 and 6 (100%) out of 6 patients, respectively; complete remission of arterial hypertension – in 6 (46.2%) out of 13, 7 (50%) out of 14 and 9 (60%) out of 15 patients, respectively.

Conclusions. Laparoscopic long–pouch gastric bypass with a single anastomosis is effective and safe, does not cause severe deficiency states, and can be used as a primary bariatric surgery.

Key words: gastric bypass surgery with a single anastomosis; morbid obesity; general loop; biliopancreatic loop; deficiency states; late postoperative complications.
At present, laparoscopic GB with a single anastomosis is of particular interest. The number of operations for IU is increasing every year, new variants of surgical interventions are emerging, but to date, there is no single methodology, no comprehensive scale for assessing the effectiveness of bariatric operations, no comprehensive approach to choosing a method of surgical correction of IU, little analysis of the causes of unsatisfactory results, no reliable scheme for predicting the outcome of the operation, and no individual approach to each patient. As a rule, the surgeon performs the operation that he or she has chosen as optimal, not the one that would be best for the patient. All of this does not allow us to consider the problems of surgical treatment of patients with MO to be solved today.

More attention needs to be paid to eating behavioural characteristics, including self-assessment before recommending re-operation. The number of re-operations continues to increase in the United States of America every year in the absence of a sufficient understanding of how to optimally select patients who could benefit from re-operation [4].

At present, there are many techniques alternative to biliopancreatic bypass in patients with superobesity – distal Roux–en–Y gastric bypass (D–RYGB) [5]; Gastric bypass with a “very, very long limb Roux–en–Y gastric bypass” (VVLL–RYGB) [6], distal Roux–en–Y gastric bypass with a “very long limb Roux–en–Y gastric bypass” (DVLRYGB) [7], gastroileal bypass with a single anastomosis (Single Anastomosis Gastro–Ileal – SAGI) [8]. In 44% of patients who undergo primary distal gastric bypass surgery, a second intervention is required to lengthen the total loop due to the development of malnutrition [9].

Patients who undergo distal GB have significantly lower levels of calcium, iron, and vitamin D than patients who undergo less aggressive surgery. Therefore, patients should be carefully monitored for nutritional deficiencies after primary distal GB surgery [10]. Such surgeries are indeed characterised by better rates of excess body weight loss (EBWL) and remission of comorbidities, but this is achieved at the expense of persistent vitamin and protein deficiency and exhaustion, which necessitates reconstructive surgery [11].

The choice of primary bariatric surgery in patients with morbid superobesity – long–pouch or distal gastric bypass with a single anastomosis – is particularly widely and heatedly debated. The development and implementation of a “simplified” surgical intervention in combination with a large gastric reservoir and a single anastomosis allow for easier and safer bypass surgery in patients with extreme body weight.

**Materials and methods of the study**

In the period from 2016 to 2022, 75 patients with MO were examined and surgically treated at the Department of Thoracoabdominal Surgery of the Shalimov National Institute of Surgery and Transplantation of the National Academy of Medical Sciences of Ukraine. Long–pouch gastric bypass, distal gastric bypass with a single anastomosis and mini–gastric bypass (mini–GB) were performed.

The study patients were divided into three groups. Group 1 (main) included 25 patients who underwent long–pouch GB from the laparoscopic approach. There were 5 (20%) women and 20 (80%) men aged 28 to 62 years. The average age of patients was (42.9 ± 8.6) years. The 2nd group, which was used for comparison, also included 25 patients who underwent mini–LABA from the laparoscopic approach. There were 16 women (64%) and 9 men (36%) aged 28 to 59 years. The average age of patients was (45 ± 9.4) years. Group 3, which was also used for compar-

<table>
<thead>
<tr>
<th>Diseases</th>
<th>Group of patients</th>
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<tbody>
<tr>
<td></td>
<td>1st (long pouch GB)</td>
</tr>
<tr>
<td></td>
<td>abs.</td>
</tr>
<tr>
<td>Type II diabetes mellitus</td>
<td>4</td>
</tr>
<tr>
<td>AG</td>
<td>13</td>
</tr>
<tr>
<td>Metabolic syndrome</td>
<td>6</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>5</td>
</tr>
<tr>
<td>Chronic lympho-venous insufficiency</td>
<td>4</td>
</tr>
<tr>
<td>Diseases of the musculoskeletal system</td>
<td>3</td>
</tr>
<tr>
<td>Gallstone disease</td>
<td>2</td>
</tr>
<tr>
<td>Hernia of the anterior abdominal wall</td>
<td>1</td>
</tr>
<tr>
<td>Hernia of the esophageal opening of the diaphragm</td>
<td>2</td>
</tr>
<tr>
<td>Erosive gastroduodenitis</td>
<td>3</td>
</tr>
<tr>
<td>Pickwick’s syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Other pathology</td>
<td>3</td>
</tr>
</tbody>
</table>
ison, included 25 patients who underwent distal GB with a single anastomosis from the laparoscopic approach. There were 16 women (64%) and 9 men (36%) aged 22 to 66 years. The average age of patients was 47.9 ± 10.6 years.

In the preoperative period, patients in group 1 (long-pouch GB) had a body weight ranging from 95 to 214 kg, the mean body weight was 160.6 ± 35 kg, and the mean BMI was 50.5 ± 8.6 kg/m² (41 – 64.8 kg/m²). Morbid obesity and superfatigue were present in 12 (48%) patients. In patients of group 2 (mini-GB), body weight ranged from 90 to 268 kg and averaged 141.68 ± 37.6 kg. The average BMI in this group was 46.75 ± 37.6 kg/m² (35 – 65 kg/m²). In 7 (28%) patients, extreme forms of obesity were noted, with a BMI of more than 50 kg/m². In patients of group 3 (distal GB with a single anastomosis), body weight varied from 110 to 240 kg, the average BMI was 54.07 ± 8.8 kg/m² (40.5 – 80 kg/m²). In this group, 19 (76%) patients had a BMI of more than 50 kg/m².

There were no statistically significant differences between the body weight and BMI of patients in the main group and patients undergoing mini-GB (U_{em} = 231.0; U_{0.01} = 192.0; U_{0.05} = 227.0). The same was observed for the corresponding indicators of patients undergoing distal GB (U_{em} = 260.0; U_{0.01} = 192.0; U_{0.05} = 227.0). No statistically significant differences were found in the analysis of concomitant pathology (Table 1) between the main group of patients and the group of patients undergoing distal GB (U_{em} = 66.5; U_{0.01} = 31.0; U_{0.05} = 42.0). The same was also observed in relation to the corresponding indicators of patients undergoing distal GB (U_{em} = 60.5; U_{0.01} = 31.0; U_{0.05} = 42.0).

The number of patients under dispensary supervision is sufficient for follow-up for 3 years after surgery and in the longer term (Table 2).

To evaluate the effectiveness of obesity surgery, this study used BMI and WHR to assess the effectiveness of obesity treatment.

The diagnosis of diabetes mellitus was made with a glycated haemoglobin (HbA1c) ≥ 6.5% or a history of a plasma glucose episode of more than 7 mmol/l and/or 11.1 mmol/l within 2 hours of the start of the glucose tolerance test. Depending on the HbA1c level, the degree of compensation for type II diabetes was determined:
- compensated – <7.0%;
- subcompensated – 7.1–7.5%;
- decompensated – >7.5%.

Remission of type II diabetes mellitus in the postoperative period was determined by the following indicators:
- fasting glucose level ≤ 5.6 mmol/l;
- HbA1c level ≤ 6% without adherence to dietary recommendations and taking glucose-lowering drugs.

Partial remission of type II diabetes mellitus in the postoperative period was determined by the following indicators:
- fasting glucose level ≤ 7.0 mmol/l;
- HbA1c level 6.0 – 7.0%.

Improvement in the course of type II diabetes was considered to be a decrease in HbA1c by more than 1% compared with the preoperative level and a decrease in the daily dose of hypoglycaemic drugs.

The diagnosis of metabolic syndrome was established in the presence of 3 or more criteria that meet the generally accepted recommendations of the US National Cholesterol Education Program (NCEP) panel of experts in their guidelines (Adult Treatment Panel III /ATP III), that is Waist circumference ≥ 101.6 cm for men and ≥ 88.9 cm for women and at least two of the following criteria:
- hypertriglyceridaemia – blood triglyceride (TG) levels >1.7 mmol/l or ≥ 150 mg/dl;
- low levels of high-density lipoprotein (HDL), namely < 1.2 mmol/l or < 40 mg/dl for men and < 1.2 mmol/l or ≤ 50 mg/dl for women;
- hypertension (systolic blood pressure – SBP ≥ 130 mm Hg, diastolic blood pressure – DBP ≥ 85 mm Hg);
- hyperglycaemia/insulin resistance (fasting blood glucose ≥ 5.6 mmol/l or ≥ 100 mg/dl).

The effectiveness of surgical treatment on the course of hypertension was assessed on the basis of the following criteria:
- improving the course of the disease – improving the quality of life of patients by reducing the dosage or frequency of antihypertensive drugs or reducing SBP and DBP at constant doses;

Table 2. Number of patients in different follow-up periods

<table>
<thead>
<tr>
<th>Observation period</th>
<th>Group of patients</th>
<th>Group of patients</th>
<th>Group of patients</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1st (long pouch GB)</td>
<td>2nd (mini GB)</td>
<td>3rd (distal GB)</td>
</tr>
<tr>
<td>abs.</td>
<td>%</td>
<td>abs.</td>
<td>%</td>
</tr>
<tr>
<td>Before the operation</td>
<td>25</td>
<td>100</td>
<td>25</td>
</tr>
<tr>
<td>After the operation (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>24</td>
<td>96</td>
<td>23</td>
</tr>
<tr>
<td>2</td>
<td>23</td>
<td>92</td>
<td>22</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>80</td>
<td>20</td>
</tr>
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</table>
achievement of partial remission of hypertension – blood pressure (BP) values within the range of normally elevated values without medication support;

achievement of complete remission of hypertension – blood pressure values within normal limits without the use of drug therapy.

Lipidogram parameters were determined in the preoperative period and at 3, 6, 12, 24 and 36 months after surgery.

According to the recommendations of the American College of Cardiology/American Heart Association (ACC/AHA), if the level of TG and total cholesterol (TC) was >1.7 mmol/l, HDL cholesterol – <1.03 mmol/l in men and <1.29 mmol/l in women, a diagnosis of dyslipidaemia was made.

Compensation of dyslipidaemia in the postoperative period was considered to be the normalisation of the main lipid parameters on the background of discontinuation of antidyslipidaemic drugs. Improvement in the course of dyslipidaemia was considered to be a decrease in the degree of dyslipidaemia compared with preoperative indicators.

Bone density was determined by performing dual-energy X-ray absorptiometry on a two-photon X-ray absorptiometer "Hologic Discovery" with subsequent determination of the T-score of the lumbar spine and femoral necks 2 years after surgery. According to the obtained densitometry values, the WHO osteoporosis classification was used (Table 3).

The preoperative level of 25-hydroxyvitamin D – D–25(OH) and its dynamics in the postoperative period at 3, 6, 12, 24 and 36 months were studied using laboratory blood parameters. Sufficient levels of this vitamin were indicated by values ≥ 30.0 – 50.0 ng/ml, insufficient – < 30.0 ng/ml, and deficiency – < 10.0 ng/ml. Patients’ quality of life was assessed using outpatient and inpatient questionnaires according to the Moorehead–Ardelt II method before surgery and at 1 to 3 years after surgery.

Laboratory data, data on BMI dynamics, and data from electronic forms were included in a consolidated database using Microsoft Excel. Descriptive statistics methods were used for qualitative indicators and they are presented in the form of an absolute number of observations (n) and their distribution in %. For quantitative indicators, the arithmetic mean in the study groups and the standard deviation were determined. Statistical significance was determined and the results were compared between groups using the non-parametric Mann–Whitney test.

**Methods of performing laparoscopic long-pouch GB**

Positioning of the patient on the operating table: lower limbs are brought in, upper limbs can be brought in or out (Fig. 1).

Trocar placement (Fig. 2). The first optical 10-mm trocar is usually placed 2 cm lateral to the navel on the left along the midclavicular line. The second 13-mm trocar is placed 2 cm lateral to the umbilicus on the right along the midclavicular line, used as a working trocar, and later for insertion of a suturing device during the formation of a gastroentero-anastomosis (GEA). The third 13-mm trocar is placed 2 cm below the edge of the rib arch along the anterior axillary line, and is also used as a working trocar, and later on, for inser-

![Fig. 1. Position of the patient on the operating table.](image1)

![Fig. 2. Scheme of trocar placement.](image2)

<table>
<thead>
<tr>
<th>Classification</th>
<th>T-score indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norma</td>
<td>&gt; -1.0</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>&lt; -1.0 &gt; -2.5</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>&lt; -2.5</td>
</tr>
<tr>
<td>Severe osteoporosis</td>
<td>&lt; -2.5 + concomitant osteoporotic fractures</td>
</tr>
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</table>
tion of a suturing device for horizontal gastric crossing. In patients with hepatomegaly, an additional fourth subxiphoid 5 mm trocar is used.

The first step is the traction of the large cecum, followed by visualisation of the ligament of Treitz. From the ligament of Treitz, the small intestine is measured distally at a distance of 200 cm, in this area a tissue holder is passed through the mesentery of the small intestine, and in this area the driving loop is marked by placing a metal bracket on the peritoneum of the mesentery for easy visualisation in the abdominal cavity.

Long-pouch gastric bypass involves horizontal transection of the stomach at the border of its antrum and body using 2 to 3 non-articulating charges of a 60 mm long linear stapler with a staple height of 3.5 mm. The large curvature of the stomach over a length of 4–5 cm at the border of the body and the antrum is mobilised by cutting the gastroduodenal ligament with an ultrasound scalpel or bipolar energy in a relatively vascular-free area using the perigastric dissection technique. This creates an area of high curvature without the elements of the greater pylorus, and it becomes possible to perform the subsequent stages of mobilisation of the lesser pylorus (Fig. 3).

In patients with morbid superobesity, mobilisation of the stomach along the small curvature is usually technically difficult to perform if the following factors are present: non-alcoholic steatohepatitis with hepatomegaly, adhesion of the abdominal organs after previous operations, large waist circumference and anterior abdominal wall thickness, BMI > 40 kg/m² and abdominal obesity. Therefore, to facilitate the manipulation, it should be divided into two stages: the first – through the cap bag, the second – through the anterior peritoneal leaf of the small cap.

The first stage of mobilisation of the minor curvature is performed in its non-vascular part at the level of the body and the antrum of the stomach by cutting the posterior peritoneum of the jejunum perpendicular to its anterior peritoneum using an ultrasound scalpel or bipolar energy. In particularly technically challenging situations, a preliminary transection of the stomach along the large curvature with a linear stapler can be used to improve visualisation of the stomach wall in the small curvature and elements of the posterior wall of the jejunum (Fig. 4).

After the maximum possible dissection between the stomach wall and peritoneum, a gauze cloth is placed in the formed area, after which the second stage of mobilisation of the small curvature of the stomach is performed. The anterior leaf of the peritoneum of the small cap is dissected (Fig. 5), which is projectively located opposite the mobilised area of the large curvature of the stomach. After preliminary mobilisation of the major and minor curves of the stomach, a proximal gastric reservoir is formed in the area of intersec-
tion of the linear staplers. In case of severe abdominal obesity and significant tension of the mesentery of the small intestine, which complicates the stage of GER formation, dissection of the large cap is performed (Fig. 6).

Features of the GEA formation

The GEA is formed using a single non–articulating charge of a 60 mm long linear stapler with a staple height of 3.5 mm through the angle of the staple suture along the posterior wall of the stomach at an angle of 90° to the line of horizontal transection of the stomach.

To facilitate the passage of the suturing machine cassette branches into the small intestine and stomach cavities, the small intestine is suspended and stretched parallel to the axis of the suturing machine by a pre–arranged holder (Fig. 7). This manipulation makes it easy to guide the suturing machine's arms into the small intestine cavity.

After stapling, the technological hole is sutured on the gastric tube 36 F with a double–row suture in the diversionary loop using V–Loc 3–0 thread.

Methods of performing laparoscopic distal GB

The patient's positioning on the operating table, placement of trocars, and the stages of gastric mobilisation along the major and minor curvatures are the same as in the long–pouch gastric bypass technique. Measurements of the small intestine begin in the proximal direction from the ileocecal angle at a distance of 250 cm (Fig. 8).

In contrast to the long–pouch jejunostomy, in which the small intestine is measured distally from the ligament of Treitz, i.e. the length of the biliopancreatic loop is measured, the distal jejunostomy measures the length of the total loop. The GEA is formed by a similar method.

Results

The impact of surgery on body weight dynamics

In the preoperative period in group 1 (main), the mean BMI (Table 4) was (50.5 ± 8.6) kg/m² (41 – 64.8 kg/m²).

Morbid superobesity and superfatigue were present in 12 (48 %) patients. In group 2 (mini–GB), the mean BMI was (46.75 ± 37.6) kg/m² (35 – 65 kg/m²). Morbid superobesity and superfatigue were present in 7 (28%) patients. In group 3 (distal GB), the mean BMI was (54.07 ± 8.8) kg/m² (40.5 – 80 kg/m²). Morbid superobesity and superfatigue were present in 19 (76%) patients. The preoperative BMI values of patients in the 1st (main) and 2nd (mini–GBA) groups did not differ statistically according to the Mann–Whitney test ($U_{\text{em}} = 114.0; U_{0.01} = 59.0; U_{0.05} = 75.0$). They also did not differ from the corresponding indicators of patients in group 3 (distal GB): $U_{\text{em}} = 28.0; U_{0.01} = 12.0; U_{0.05} = 19.0$. 

Fig. 6.
Dissection of the greater cecum with tension of the mesentery of the small intestine.

Fig. 7.
«Вивішування» тонкої кишки паралельно вісі зшивального апарату.

Fig. 8.
Scheme of distal GB with a single anastomosis.
The studied operations had a good effect on the LVEF rate. At 36 months after long–pouch GB surgery, the LVEF rate was (69 ± 1.1)%, and after mini–GB – (70.1 ± 1.3)%. The highest rate of LVEF was in group 3 (distal GB) – (72 ± 0.9)%. The dynamics of body weight in the main group and both other groups used for comparison, did not differ significantly at 36 months after surgery, the lowest BMI (Fig. 9) and the highest WHR were observed after distal GB.

Statistical analysis of postoperative body weight using the Mann–Whitney test showed that there were no statistically significant differences between BMI and WHR in the main group and group 2 (mini–GB) (U_{emp} = 78.5; U_{0.01} = 36.0; U_{0.05} = 48.0). There were also no statistically significant differences between these indices and BMI and WHR of patients undergoing distal GB (U_{emp} = 32.0; U_{0.01} = 13.0; U_{0.05} = 20.0). Therefore, it can be assumed that BMI and WHR in all groups are comparable.

The impact of surgery on lipid metabolism

Dyslipidaemia in the preoperative period in the main group was diagnosed in 5 (20%) patients of the main group (long–pouch GB), in 13 (52%) patients of the 2nd group (mini–GB) and in 7 (28%) patients of the 3rd group (distal GB). At 12 months postoperative follow–up in the main group, dyslipidaemia remission was recorded in 3 (60%) of 5 patients, and at 36 months – in 4 (80%) of 5 patients; in group 2 (mini–GB) – in 8 (61.5%) of 13 patients and in 11 (84.6%) of 13 patients, respectively. In group 3 (distal GB), during the follow–up period of 12 months after surgery, dys-

### Table 4. Dynamics of preoperative body weight in 36 months after surgery

<table>
<thead>
<tr>
<th>Indicators.</th>
<th>Bariatric surgeries</th>
<th>long pouch GB</th>
<th>mini GB</th>
<th>distal GB</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI, kg/m²</td>
<td>before the operation (n=25)</td>
<td>50.5 ± 8,6</td>
<td>46.75 ± 37,6</td>
<td>54 ± 8,8</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>31,1 ± 2,1</td>
<td>30,5 ± 1,9</td>
<td>29 ± 1,1</td>
</tr>
<tr>
<td>GROSS MARGIN, %</td>
<td>before the operation (n=25)</td>
<td>-</td>
<td>70,1 ± 1,3</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>69 ± 1,1</td>
<td>72 ± 0,9</td>
<td>-</td>
</tr>
</tbody>
</table>

### Table 5. Dynamics of preoperative lipid metabolism in 36 months after surgery

<table>
<thead>
<tr>
<th>Indicators.</th>
<th>Bariatric surgeries</th>
<th>long pouch GB</th>
<th>mini GB</th>
<th>distal GB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol, mmol/l</td>
<td>before the operation (n=25)</td>
<td>5,8 ± 1,4</td>
<td>5,7 ± 1,04</td>
<td>5,5 ± 1,04</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>4,1 ± 0,3</td>
<td>3,9 ± 0,65</td>
<td>3,1 ± 0,60</td>
</tr>
<tr>
<td>TG, mmol/l</td>
<td>before the operation (n=25)</td>
<td>2,12 ± 1,3</td>
<td>1,97 ± 0,23</td>
<td>1,37 ± 0,7</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>1,16 ± 0,6</td>
<td>1,48 ± 0,20</td>
<td>1,45 ± 0,23</td>
</tr>
<tr>
<td>HDL, mmol/l</td>
<td>before the operation (n=25)</td>
<td>1,22 ± 0,2</td>
<td>1,07 ± 0,23</td>
<td>1,01 ± 0,21</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>1,47 ± 0,3</td>
<td>1,48 ± 0,20</td>
<td>1,45 ± 0,20</td>
</tr>
<tr>
<td>LDL, mmol/l</td>
<td>before the operation (n=25)</td>
<td>3,5 ± 1,2</td>
<td>4,1 ± 0,78</td>
<td>3,54 ± 0,85</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>2,55 ± 0,7</td>
<td>2,38 ± 0,65</td>
<td>1,37 ± 0,7</td>
</tr>
<tr>
<td>VLDL, mmol/l</td>
<td>before the operation (n=25)</td>
<td>1,2 ± 0,2</td>
<td>1,1 ± 0,19</td>
<td>1,3 ± 0,17</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>0,63 ± 0,2</td>
<td>0,48 ± 0,14</td>
<td>0,34 ± 0,14</td>
</tr>
<tr>
<td>CA, Od</td>
<td>before the operation (n=25)</td>
<td>3,67 ± 0,6</td>
<td>3,57 ± 1,1</td>
<td>4,0 ± 0,44</td>
</tr>
<tr>
<td></td>
<td>after 36 months (n=20)</td>
<td>2,3 ± 0,45</td>
<td>2,5 ± 0,9</td>
<td>1,9 ± 0,50</td>
</tr>
</tbody>
</table>

**Note.** LDL indicates low-density lipoprotein; VLDL, very low-density lipoprotein; CA, atherogenicity coefficient.
lipidaemia remission was achieved in 7 (100%) of 7 patients, and it was maintained at 36 months after surgery (Table 5).

Impact of operations on carbohydrate metabolism

Before surgery, type II diabetes mellitus was diagnosed in 16 (21.3%) patients: 4 (16%) patients in group 1 (main), 6 (24%) patients in group 2 (mini–GB) and 6 (24%) patients in group 3 (distal GB). None of the patients in all three groups received insulin preparations in the preoperative period. The preoperative blood glucose and HbA1c levels in the main and two other groups used for comparison were statistically comparable. As a rule, blood glucose levels normalised on the 3rd day after long–pouch GB and mini–GB operations. In patients who underwent distal GB, normalisation of blood glucose levels was already noticeable on the 1st to 2nd day after surgery (Fig. 10).

Hypoglycaemia was not observed in patients of groups 1 (main) and 2 in the early and long–term periods after surgery. In group 3 (distal GB), hypoglycaemia was recorded in 4 patients at 8, 9 and 13 months after surgery, and these patients had type II diabetes.

Based on the data in Table 6, it can be concluded that after distal GB, remission of type II diabetes mellitus was observed in all 6 patients at month 3, and it was maintained at all subsequent follow–ups.

Remission of type II diabetes mellitus was achieved in 3 (75%) of 4 patients in the main group (long–pouch GB) and in 5 (83.3%) of 6 patients who underwent mini–GB. The most pronounced metabolic effect on the course of type II diabetes mellitus was observed in group 3 (distal GB), as remission of the disease was noted in 6 (100%) of 6 patients.

The HbA1c values of patients in groups 1 (long–pouch GB) and 2 (mini–GB) were not statistically significantly different (U_{exp} = 9.5; U_{0.01} = 1.0; U_{0.05} = 4.0). Therefore, it can be concluded that the results of the effect of long–pouch GB and mini–GB on the course of type II diabetes mellitus are comparable.

Impact of operations on the course of the AG

In the preoperative period, hypertension was diagnosed in 42 patients: 13 (52%) patients in group 1 (long–pouch GB), 14 (56%) patients in group 2 (mini–GB) and 15 (60%) patients in group 3 (distal GB). Patients were divided according to the degree of hypertension: in group 1 (main), grade I hypertension was diagnosed in 6 patients, grade II hypertension – in 5, grade III hypertension – in 2; in group 2 (mini–GB) – in 6, 5 and 3 patients, respectively; in group 3 (distal GB) – in 7, 5 and 3 patients, respectively.

In order to compensate, all patients with hypertension of II and III degrees were prescribed antihypertensive therapy.

In group 1 (main), the mean preoperative values of SBP were (146.05 ± 19.43) mm Hg, and DBP – (95.06 ± 11.88) mm Hg, in group 2 (mini–GB) – respectively (147.08 ± 17.44) and (96.09 ± 12.76) mm Hg, in group 3 (distal GB) – respectively (149.03 ± 16.48) and (98.04 ± 10.55) mm Hg.

At 12 months postoperative follow–up in the main and both other groups used for comparison, a decrease in mean SBP and DBP was observed. In the main group (long–pouch GB), the mean values of SBP were (134.5 ± 10.44) mm Hg, DBP – (83.32 ± 4.32) mm Hg.

During the follow–up period of 36 months after surgery in the 1st (main) group, the mean values of SBP were (134.5 ± 10.44) mm Hg, DBP – (83.32 ± 4.32) mm Hg.

After 36 months of follow–up, the number of patients in group 1 (main) with hypertension decreased from 13 (52%) to 7 (28%), as 6 (46.1%) patients had complete remission of grade I hypertension. In 4 (30.8%) of patients with grade II hypertension, there was a partial remission of the disease, and in 1 (7.7%) patient there was an improvement in the course of grade II hypertension. In 2 (15.4%) patients with grade III hypertension, the course of the disease also improved.

After 36 months of follow–up, the number of patients in group 2 (mini–GB) with hypertension decreased from 14 (56%) to 7 (28%), as 6 (42.9%) patients had complete remission of grade I hypertension and 1 (7.1%) patient had grade

Table 6. Dynamics of HbA1c (%) in patients with type II diabetes mellitus at different follow–up periods

<table>
<thead>
<tr>
<th>Observation periods</th>
<th>Bariatric surgeries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>long pouch GB (n=4)</td>
</tr>
<tr>
<td>Before the operation</td>
<td>10.3 ± 3.3</td>
</tr>
<tr>
<td>After the operation, months</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>6.2 ± 0.7</td>
</tr>
<tr>
<td>6</td>
<td>6.1 ± 0.6</td>
</tr>
<tr>
<td>12</td>
<td>5.9 ± 0.4</td>
</tr>
<tr>
<td>36</td>
<td>6.1 ± 0.8</td>
</tr>
</tbody>
</table>
II hypertension. In 4 (28.6%) out of 5 patients with grade II hypertension, there was a partial remission of the disease. In 3 (21.4%) patients with grade III hypertension, the course of the disease improved.

At 36 months after surgery in group 3 (distal GB), the number of patients with hypertension decreased from 15 (60%) to 6 (24%), as 7 (46.7%) patients had complete remission of grade I hypertension and 2 (13.3%) had complete remission of grade II hypertension. Of the 5 patients with grade II hypertension, 3 (20%) had a partial remission of its course. All 3 (20%) patients with grade III hypertension had partial remission of its course.

According to SBP and DBP before and 36 months after surgery, patients in the main group and both groups used for comparison were divided according to the classification of hypertension (Table 7).

Achieving compensation of hypertension made it possible to completely stop the use of conservative therapy in patients to control this pathological condition. In 6 (46.2%) patients of the 1st (main) group, 7 (50%) patients of the 2nd group (mini–GB) and 9 (60%) patients of the 3rd group (distal GB), complete remission of hypertension occurred – blood pressure values normalised. Partial remission of hypertension was noted in 5 (38.4%) patients of the 1st (main) group (long–pouch bypass), in 4 (28.6%) patients of the 2nd group (mini–GB) and in 5 (33.3%) patients of the 3rd group (distal GB).

Improvement in the course of hypertension, which allowed to reduce the frequency of antihypertensive drugs and dosage, was noted in 2 (15.4%) patients of the 1st (main) group, 3 (21.4%) – in the 2nd group (mini–GB) and 1 (6.7%) patient of the 3rd group (distal GB). According to the Mann–Whitney test, there were no statistically significant differences between the SBP values of patients in the main (long–pouch GB) and 2nd (mini–GB) groups ($U_{\text{em}} = 11.5; U_{0.01} = 1.0; U_{0.05} = 4.0$). Comparison of SBP values in the main group and group 3 (distal GB) showed statistically significant differences – $U_{\text{em}} = 0; U_{0.01} = 1.0; U_{0.05} = 4.0$ ($p < 0.01$).

**Early postoperative complications**

Complications were divided into “major” and “minor” according to the recommendations of the American Society for Metabolic and Bariatric Surgery (ASMBS). The incidence of various postoperative complications in patients with MO ranged from 2 to 25%. None of the patients died in the early postoperative period.

After long–pouch GB, 2 (8%) patients had complications in the immediate period (hospital stay). A "major" postoperative complication occurred in 1 (4%) patient. It was caused by intra--abdominal bleeding that developed 2 hours after the operation and required relaparoscopy to stop it. A "minor" postoperative complication occurred in 1 (4%) patient – intraluminal bleeding, which was stopped by endoscopic clipping of the staple suture of the gastric stump.

There were also 2 (8%) complications after distal gastric bypass in the early period. In 1 (4%) patient, a "minor" complication was noted – intraluminal bleeding from the stapler suture line of the gastric stump, which was stopped by endoscopic clipping, and in 1 (4%) patient, a "major" complication occurred – intra--abdominal bleeding, which required relaxation surgery to stop it.

"Major“ early complications after mini–LABS included twisted pouch in 1 (4%) patient, which required repeat laparoscopy on the 2nd day after surgery, and intra--abdominal bleeding in 1 (4%) patient, which required laparotomy and subsequent stoppage.

Taking into account the above complications, it can be concluded that there are more "major" early complications after mini–GB than after long–pouch and distal GB.

---

**Table 7.** Distribution of patients according to blood pressure before surgery and within 36 months after the operation

<table>
<thead>
<tr>
<th>Blood pressure indicators</th>
<th>Number of patients before the operation</th>
<th>Number of patients 36 months after surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>long pouch GB</td>
<td>mini GB</td>
</tr>
<tr>
<td></td>
<td>abs.</td>
<td>%</td>
</tr>
<tr>
<td>Norma</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Elevated normal blood pressure</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>AG, degree</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I</td>
<td>6</td>
<td>46.1</td>
</tr>
<tr>
<td>II</td>
<td>5</td>
<td>38.5</td>
</tr>
<tr>
<td>III</td>
<td>2</td>
<td>15.4</td>
</tr>
<tr>
<td>In total ...</td>
<td>13</td>
<td>100</td>
</tr>
</tbody>
</table>
Table 8. **Average levels of vitamins B9, B12 and iron preoperatively and at different times after surgery**

<table>
<thead>
<tr>
<th>Elements</th>
<th>Norma</th>
<th>Bariatric surgeries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>long pouch GB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>before the operation (n=25)</td>
</tr>
<tr>
<td>Iron, µmol/l</td>
<td>10.6-28.3</td>
<td>18.3</td>
</tr>
<tr>
<td>B9, ng/ml</td>
<td>3.1-19.9</td>
<td>15.5</td>
</tr>
<tr>
<td>B12, pkg/ml</td>
<td>191-663</td>
<td>250</td>
</tr>
</tbody>
</table>

Table 9. **The required dosage of constant daily intake of vitamins B12, B9 and iron at different times after surgery (months)**

<table>
<thead>
<tr>
<th>Elements and their required dosage</th>
<th>Bariatric surgeries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>long pouch GB (n=1)</td>
</tr>
<tr>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Iron, mg, daily</td>
<td>-</td>
</tr>
<tr>
<td>B9, mg, daily</td>
<td>-</td>
</tr>
<tr>
<td>B12, mg, 7-day course, once every 6 months</td>
<td>-</td>
</tr>
</tbody>
</table>

**Long-term postoperative complications. Deficiency conditions**

**Deficiency of vitamins B9, B12 and iron**

In the 1st (main) group, 1 (5%) patient was observed 36 months after surgery with iron deficiency and vitamins B9 and B12, which required correction of supplementary therapy.

In group 2 (mini–GB), 1 (5%) patient with a bilopancreatic loop length of 300 cm had a proportional decrease in iron and the above vitamins. He is currently taking oral iron supplements at a dose of 200 mg daily in combination with folic acid at a dose of 5 mg daily. As a rule, in patients in the long term (more than 1 year after surgery), a combination of iron and vitamins B9 and B12 deficiency was found (Table 8).

In group 3 (distal GB), vitamin B9, B12 and iron deficiency was more common. In 21 (87.5%) patients, 1 year after surgery, symptoms of anaemia gradually developed due to the deficiency of these vitamins, which were confirmed by laboratory tests. The required average doses of iron and vitamins B9 and B12 replacement therapy to achieve optimal levels were calculated (Table 9).

**Magnesium deficiency**

In groups 1 (main) and 2 (mini–LAD), no hypomagnesaemia was observed during the follow-up period of 36 months. Hypomagnesaemia was noted in 10 (40%) patients in group 3 (distal GB). As a rule, these patients had persistent steatorrhoea for 3 weeks or more, and hypomagnesaemia was recorded at 12, 18, and 30 months after surgery. These patients had the following clinical manifestations: transient muscle spasm of the hands and twitching of the calf muscles, insomnia and fatigue. Hypomagnesaemia was corrected by taking magnesium lactate dihydrate tablets in combination with pyridoxine.

**Vitamin D–25(OH) and calcium deficiency. Secondary hyperparathyroidism and osteoporosis**

**Vitamin D–25(OH) insufficiency and deficiency before surgery**

In group 1 (main), only 1 patient had a sufficient level of vitamin D before surgery, which was also observed in both groups used for comparison. No vitamin D deficiency was recorded in the study patients at the prehospital stage. In 72 (96%) patients, vitamin D insufficiency was recorded, which required its additional intake in prophylactic doses at the prehospital stage. No deficiency of ionised or total calcium was observed in the prehospital stage.

**Insufficiency and deficiency of vitamin D–25(OH), increased levels of parathyroid hormone, hypocalcaemia after surgery**

Vitamin D–25(OH) deficiency was recorded 6 months after surgery in all patients of groups 1 (long–pouch GB) and 3 (distal GB). In group 2 (mini–GB), vitamin D–25(OH) deficiency was recorded in 23 (92%) patients, 1 (4%) patient developed a deficiency of this vitamin, and 1 (4%) patient had a sufficient level.

After 12 months, in the main group (long–pouch GB), vitamin D–25(OH) deficiency developed in 1 (4.2%) patient with an increase in parathyroid hormone levels. Vitamin D–25(OH) deficiency was recorded in 20 (83.3%) patients, and only 3 (12.5%) patients had sufficient levels.
In group 2 (mini–GB), none of the patients had vitamin D–25(OH) deficiency after 12 months. Only 2 (8.7%) patients had insufficient levels without an increase in parathyroid hormone levels. Twenty–one (91.3%) patients had sufficient vitamin D–25(OH) levels.

In group 3 (distal GB), changes in the level of this vitamin were more pronounced: 13 (54.2%) patients had its deficiency, 10 (41.7%) – insufficiency, and 1 (4.1%) patient had a sufficient level of vitamin D–25(OH). In patients with vitamin D–25(OH) insufficiency and deficiency, the level of parathyroid hormone also increased in parallel (Table 10).

No hypocalcaemia events were observed during the 36–month follow–up period in groups 1 (long–pouch BMS) and 2 (mini–BMS). As a rule, in group 3 (distal GB), mild hypocalcaemia was observed already 12 months after surgery. The average "low" calcium level in 23 (95.8%) patients was (1.95 ± 0.5) mmol/l. Hypocalcaemia is associated not only with the development of secondary hyperparathyroidism and gradual depletion of bone calcium stores, but also with an increase in the monthly dose of vitamin D, so it is especially important to monitor this indicator when increasing the daily dose of cholecalciferol. At 36 months after surgery, none of the patients in the 1st (main) group had vitamin D–25(OH) deficiency or insufficiency. In group 2 (mini–GB), only 1 (5%) patient had a deficiency of this vitamin without any increase in parathyroid hormone levels.

In group 3 (distal GB), 1 (5%) patient had a deficiency of vitamin D–25(OH), 4 (20%) patients had insufficient levels. Sufficient levels of vitamin D–25(OH) were in 15 (75%) patients. Patients with insufficient levels and deficiency of this vitamin had secondary hyperparathyroidism. Considering the persistent deficiency of vitamin D–25(OH) and the development of secondary hyperparathyroidism, especially in group 3 (distal GB), its daily dose was increased and the required average doses were calculated (Table 11).

According to bone densitometry performed 24 months after surgery, no bone disorders were detected in any patient of the main group (long–pouch GB). At the same time, in 1 patient with a biliopancreatic loop length of 300 cm, osteopenia of the lumbar spine without femoral neck lesions was detected after mini–GB. For 2 years after the operation, he had neglected to take supplementary therapy and control tests. At the time of the examination, the patient's calcium, parathyroid hormone, and vitamin D–25(OH) levels were normal.

In 24 months after distal GB, 1 patient was diagnosed with osteopenia of the lumbar spine and femoral necks, 3 patients with osteoporosis of the lumbar spine, and 2 patients with severe osteoporosis, as they had osteoporotic compression fractures of the lumbar vertebral bodies LI – LIV.

**The impact of surgery on the quality of life of patients**

The quality of life of patients was assessed using outpatient and inpatient questionnaires according to the Moore
The questionnaire included 6 main indicators: self-esteem, physical, social and sexual activity; work capacity; and eating behaviour. A scale with 10 items for each question was used for the assessment. After reading the questionnaire, patients filled it out independently. After the scores were calculated, the quality of life score was determined. In the 1st (main) group, before the operation, patients rated their quality of life at (−1.5 ± 0.4) points, which corresponded to the indicator “poor”. In group 2 (mini–GB), patients rated their quality of life at (−1.6 ± 0.5) points, which also corresponded to the “poor” indicator. In group 3 (distal GB), the quality of life score was also poor – (−1.4 ± 0.5) points. The lowest scores were given to self-esteem, physical and sexual activity, and ability to work (Fig. 11).

Patients’ quality of life scores improved significantly after surgery and corresponded to “very good”. After 12 months of follow-up, patients in the main group (long–pouch GB) rated the quality of life at (2.4 ± 0.3) points, in group 2 (mini–GB) – at (2.6 ± 0.4) points, in group 3 (distal GB) – at (2.8 ± 0.2) points. After 36 months of observation, the quality of life scores remained virtually unchanged in the main (long–pouch GB) and 2nd (mini–GBD) groups – respectively (2.5 ± 0.4) and (2.7 ± 0.3) points, which corresponded to the “very good” score.

Due to the development of deficiency states and the appearance of “bone” complications in 4 patients in group 3 (distal GB), the average quality of life score decreased from (2.8 ± 0.2) to (1 ± 0.3) points, which corresponded to the “satisfactory” score.

Discussion

In patients with MO, the performance of conventional bariatric surgery is associated with great technical difficulties. To date, there are no uniform criteria or indications for performing a particular bariatric surgery in these patients. However, it is still believed that an increase in the length of the biliopancreatic loop leads to better metabolic correction and an increase in the BMD. Newer approaches consist of total measurement of the patient’s small intestine during surgery with subsequent adaptation of the length of the biliopancreatic loop depending on the total length of the small intestine, which is also variable [12].

The evolution of changes in the length of the biliopancreatic loop in a single–anastomosis gastric bypass reflects the desire of surgeons to achieve an optimal balance between the LBM and minimising the risk of nutritional complications.

An increase in the volume of the proximal gastric reservoir in the long term after gastric bypass surgery does not generally affect the development of unsatisfactory results and is usually primarily associated with unsatisfactory results of the operation as a whole [13]. After repeated operations aimed at reducing the gastric reservoir, as a rule, the rates of LOS and correction of the metabolic syndrome are insignificant [14]. Unfortunately, no prospective studies have been published on the study of isolated gastric restriction after gastric bypass surgery. Therefore, the issue of choosing the volume of the gastric reservoir during primary bariatric surgery remains unresolved.

The results of the study indicate the possibility of using long–pouch gastric bypass in the treatment of patients with MO and concomitant metabolic disorders as a primary bariatric surgery. After the studied bariatric surgeries, the course of comorbidities associated with MO, such as type II diabetes, dyslipidaemia and hypertension, improved, but the difference between the values of BMD was insignificant. The most pronounced metabolic effect on the course of comorbidities was observed in distal GB, but it was accompanied

<table>
<thead>
<tr>
<th>Drugs and their required dosage</th>
<th>Bariatric surgeries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>long pouch GB</td>
</tr>
<tr>
<td></td>
<td>(n=25)</td>
</tr>
<tr>
<td>Cholecalciferol, thousand IU</td>
<td>100</td>
</tr>
<tr>
<td>Calcium carbonate, mg daily</td>
<td>500</td>
</tr>
</tbody>
</table>
Laparoscopic long–pouch GB does not lead to severe defi-
tients of the main (long–pouch GB) and group 2 (mini–GB).
period, 37.5% of patients in group 3 (distal GB) developed
the 3rd group (distal GB). In the long–term postoperative
tients of the 2nd group (mini–GB) and 9 (60%) patients of
patients of the main group (long–pouch GB), 7 (50%) pa-
Complete remission of hypertension occurred in 6 (46.2%)
of groups 1, 2 and 3 improved the course of hypertension.
and in group 3 (distal GB) – in 100% of patients. All patients
betes mellitus was achieved in 75% of patients in the main
teriority and laboratory monitoring.

The safety and efficacy of the long–pouch gastric bypass
technique allow us to recommend its use in clinical prac-
by more severe nutritional disorders that required constant
correction and laboratory monitoring and significantly higher
doses of adjunctive therapy in the long term after surgery.
The long–pouch GB operation is technically simpler and
does not require specific positioning of the patient on the
operating table, which is essentially technically difficult in
patients with morbid obesity.
From an economic point of view, a laparoscopic long–pouch
GB operation requires 3 non–articulating linear stapler cassettes, while a mini–GB operation uses 5–6 cassettes, one of which is articulating, which is more expensive.
The introduction of this method has significantly simplified the operation technique, reduced its duration, the frequency of intraoperative complications and economic costs, especially in patients with morbid superobesity. In the long–term follow–up after this operation, there are no severe nu-
tritional disorders and deficiency states, i.e. there is no need for constant dynamic laboratory monitoring.

The Conclusions

Laparoscopic long–pouch GB with a single anastomosis
provides a stable LVEF rate of (69 ± 1.1)% after 36 months
and is not accompanied by a high incidence of complica-
tions. "Minor" complications occurred in 1 (4%) patient, and
"major" complications – also in 1 (4%) patient. After mini–
GB, the LIMA rate was (70.1 ± 1.3)%, there were no "minor"
complications, and "major" complications occurred in 2 (8%)
patients. After distal GB with a single anastomosis, the LOS
rate was (72 ± 0.9)%; "minor" complications occurred in 1
(4%), and "major" complications – in 1 (4%) patient. Long–
patch, distal GB and mini–GB operations with a single anas-
tomosis lead to reliable compensation of the main compo-
nents of the metabolic syndrome. Remission of type II dia-
betes mellitus was achieved in 75% of patients in the main
group (long–pouch GB), 83.3% of patients in group 2 (mini–
and 100% of patients in group 3 (distal GB). Remission of
dyslipidaemia was observed in 80% of patients in the main
group (long–pouch GB), in group 2 (mini–GB) – in 84.6%,
and in group 3 (distal GB) – in 100% of patients. All patients
of groups 1, 2 and 3 improved the course of hypertension.
Complete remission of hypertension occurred in 6 (46.2%)
patients of the main group (long–pouch GB), 7 (50%) pa-
tients of the 2nd group (mini–GB) and 9 (60%) patients of
the 3rd group (distal GB). In the long–term postoperative
period, 37.5% of patients in group 3 (distal GB) developed
persistent hypoproteinaemia, which was not the case in pa-
tients of the main (long–pouch GB) and group 2 (mini–GB).
Laparoscopic long–pouch GB does not lead to severe defi-
ciency states. An increase in the length of the biliopancre-
atic loop is more often accompanied by deficiency states. In
the long–term postoperative period, the need for constant
intake of iron, vitamins B9, B12 arose in 1 (5%) patient af-
ter long–pouch LS, in 1 (5%) patient after mini–LS and in all
patients after distal LS. All patients in the main group (long–
pouch GB) and group 2 (mini–GB) had sufficient levels of
vitamin D–25(OH) in the long–term postoperative period.
Persistent deficiency and insufficiency of vitamin D–25(OH)
was observed in 5 (25%) patients of group 3 (distal GB). In
the long–term postoperative period, the dynamics of the
quality of life index was stable in patients of the main group
(long–pouch GB) and group 2 (mini–GB): 12 months – 2.4
and 2.6; 24 months – 2.4 and 2.5; 36 months – 2.5 and 2.7,
respectively. In group 3 (distal GB), a decrease in the level of
the quality of life index after surgery was noted: 12 months
– 2.8; 24 months – 2; 36 months – 1.

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Authors’ contributions. All authors contributed equa-
ly to this paper.

Conflict of interest. The authors declare that they have
no conflicts of interest.

Consent to publication. All authors have read and ap-
proved the final version of the manuscript and agreed to its
publication.

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