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THE EVALUATION OF THE EFFECTIVENESS OF BARIATRIC SURGERY FOR OBESITY IN PATIENTS WITH CONCOMITANT NON-ALCOHOLIC STEATOHEPATITIS

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Relevance

At the end of the 20th and the turn of the 21st centuries, humanity faced a global public health problem: obesity [139]. According to forecasts from the World Obesity Federation (WOF), by the middle of this century, more than half of the planet's population could be overweight or obese [134].

Obesity prevalence affects all regions of the world. Countries with the highest obesity rates include the United States (36.2%), Jordan (35.5%), and Saudi Arabia (35.4%). The continental centers of obesity are considered to be the Americas, Australia, and New Zealand [154]. This also applies to Uzbekistan. According to the results of joint research conducted by the Committee on Sanitary and Epidemiological Welfare and Public Health of the Republic of Uzbekistan and the World Health Organization, half of the country's population aged 18-64 years is overweight, and 20% suffer from obesity [34].

The special attention paid by the leadership of Uzbekistan to this global issue is proven by the Decree of the President of Uzbekistan Sh.M. Mirziyoyev No. UP-6099 “On measures for the widespread introduction of a healthy lifestyle and the further development of mass sports” signed on October 30, 2020 [33].

The danger of obesity to health is due to the development of serious concomitant diseases, which include type 2 diabetes, coronary heart disease, non-alcoholic fatty liver disease, cancer, etc. [70]. Moreover, the costs to society associated with the treatment of these concomitant pathologies today are considered enormous, which further emphasizes the relevance of this problem [179].

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Thus, it has already been proven that the risk of death can double if the patient's BMI is 40 kg/m2 or more [162]. Moreover, the prognostic life expectancy of these patients is reduced by 5-20 years [180]. The search for numerous ways to solve this problem has led to the development of bariatric and metabolic surgery [12, 98].

Today, it is undeniable that bariatric surgery is one of the most popular and successful treatments for both obesity and the associated type 2 diabetes. Furthermore, it has long been proven that intense weight loss after bariatric surgery is the primary postoperative benefit. Acceleration of adipose tissue lipolysis occurs against the background of normalized glycemia and a decrease in glycated hemoglobin [47, 60].

Meanwhile, as noted above, the presence of obesity and the development of insulin resistance leads to a restructuring of metabolic processes due to decreased insulin tolerance and a long-term stable hyperlipidemia [5].

The latter factor, in particular hypercholesterolemia and hypertriglyceridemia, contribute to the development of a chronic inflammatory process in the liver in the form of NAFLD НАЖБП[101, 165]. The negative consequences of NAFLD are the progression of the disease against the background of non-alcoholic steatohepatitis, which leads to the formation and growth of fibrosis in the liver, followed by the development of liver cirrhosis and hepatocellular carcinoma [44, 78].

NAFLD is currently one of the most common chronic diseases, clearly correlated with the level of obesity in the population [80]. Thus, in individuals with overweight and obesity, NAFLD occurs in 74-98% of cases, and non-alcoholic steatohepatitis occurs in up to 25.2%. This prevalence of non-alcoholic steatohepatitis is due to the high frequency of risk factors for this disease, among which the most relevant are obesity, type 2 diabetes mellitus, dyslipoproteinemia, age over 45 years, genetic predisposition, taking certain medications, low-protein diet with high fructose, saturated fats, concomitant bowel diseases, lack of physical activity [86].

Materials and methods

All patients underwent bariatric surgery. Most patients (58.4%) underwent LPR. The proportion of LMG was 41.6%. This distribution of surgical priority was noted among patients in each group (Table 1).

Table 1

Patient distribution depending on the method of bariatric surgery performed

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Distribution of patients by liver condition	METHOD OF OPERATION				TOTAL	
	SRG		LMGP			
	А.ч.	%	А.ч.	%	А.ч.	%
No liver disease	111	21,6	77	15,0	188	36,6
Fatty hepatitis	88	17,1	72	14,0	160	31,1
Fatty hepatosis	101	19,6	65	12,6	166	32,3
TOTAL	300	58,4	214	41,6	514	100,0

A total of 1,110 comorbidities were identified in 514 patients (Table 2). On average, there were 2.16 comorbidities per patient. The most common comorbidities were gastrointestinal pathologies (32%), including НАЖБП. In second place were diseases of the endocrine system (19.3%), mainly in the form of type 2 diabetes mellitus, and diseases of the cardiovascular system (18.8%), which were expressed in the presence of coronary heart disease, arterial hypertension, and varicose veins of the lower extremities.

Musculoskeletal disorders were diagnosed quite frequently (14.3%), which, to some extent, can also be considered complications of morbid obesity. The least common comorbidities involved the respiratory system (9%) and the urinary and reproductive systems (6.6%).

Table 2

Distribution of comorbidities among obese patients

BODY SYSTEMS	Groups of patients	Groups of patients					
		Without liver pathology		Fatty hepatitis		Fatty hepatosis	
		А.ч.	%	А.ч.	%	А.ч.	%
Cardiovascular system	К	39	28,3	33	15,8	28	15,1
	О	41	27,0	41	18,1	27	13,5
Respiratory system	К	11	8,0	28	13,4	13	7,0
	О	15	9,9	17	7,5	16	8,0
Digestive system	К	16	11,6	79	37,8	82	44,3
	О	13	8,6	81	35,8	84	42,0
	К	9	6,5	13	6,2	7	3,8

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Urinary and reproductive system	O	13	8,6	17	7,5	14	7,0
Musculoskeletal system	K	27	19,6	23	11,0	25	13,5
	O	29	19,1	31	13,7	24	12,0
Endocrine system	K	36	26,1	33	15,8	30	16,2
	O	41	27,0	39	17,3	35	17,5
TOTAL	K	138	25,9	209	39,3	185	34,8
	O	152	26,3	226	39,1	200	34,6
On average per 1 patient	K	1,42		2,65		2,26	
	O	1,67		2,79		2,38	

Thus, the frequency of concomitant diseases among patients with obesity was characterized by predominant damage to the gastrointestinal tract, cardiovascular and endocrine systems.

The operation Laparoscopic longitudinal resection of the stomach was performed using a standard approach and consisted of 10 stages: mobilization of the gastrodiaphragmatic ligament, the Lymer-Bertelli membrane; access to the omental bursa; mobilization of the stomach along its greater curvature; placement of a calibration tube; resection of the stomach; strengthening of the stapler line; Removal of the calibration probe; Stapling line leak testing; Removal of the resected stomach; Abdominal drainage.

Unlike this procedure, LMGP is considered a combined procedure, which was also performed using a standard technique. All research methods were divided into two groups, each based on the purpose of the study. The first group included all mandatory research methods that form the basis of the standards recommended before bariatric surgery in obese patients.

1. The second group included specialized research methods that reflected the solutions to the main scientific objectives of this dissertation.
2. Required (standard) research methods included:
3. Determining the patient's height (in meters) and weight (in kilograms).
4. Calculating the BMI (kg/m²), which is a value that allows for an assessment of how well the patient's weight corresponds to their height. Body mass index is calculated using the formula:

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BMI = patient's weight (kg) / patient's height (m^2)

5. Waist circumference (cm) and hip circumference (cm) were measured, followed by determination of the waist-to-hip ratio as a simple numerical value (units).

6. Blood pressure (mmHg) and pulse rate (every minute) were measured.

7. General clinical laboratory tests included determination of the blood hemoglobin level (g/l), the number of erythrocytes (x1012/l), hematocrit (%), the number of leukocytes (x109/l) with its population (%) to determine the leukocyte formula, the number of platelets (x103/l) and the erythrocyte sedimentation rate (mm/h). All studies were performed on a fully automatic hematology analyzer HumaCount 30TS manufactured by Human (Germany).

8. Coagulometric blood tests: prothrombin index (%), fibrinogen (g/l) and other parameters were determined on a fully automated blood coagulation analyzer HumaClot Pro manufactured by Human (Germany).

9. General blood biochemistry tests: total protein (g/l); albumin (g/l); total bilirubin (mmol/l) and its fractions; urea (mmol/l) and creatinine (μmol/l) levels in blood serum were determined using a semi-automatic biochemical analyzer HUMALYZER 2000 manufactured by Human (Germany).

10. The enzyme spectrum of the blood was determined in the following volume: the activity of the enzymes ALT (U/L) and AST (U/L) - by standardized methods using an optimized optical test on a Vitros DT 60 II analyzer (USA). The blood lipid spectrum was determined in the following volume: total cholesterol (mmol/l), HDL (mmol/l), LDL (mmol/l), VLDL (mmol/l) and triglycerides (mmol/l) were determined on a semi-automatic biochemical analyzer HUMALYZER 2000 manufactured by Human (Germany).

11. The study of the carbohydrate spectrum of blood included: determination of the fasting blood glucose level (mmol/l) using a semi-automatic biochemical analyzer HUMALYZER 2000 manufactured by Human (Germany); determination of the level of glycated hemoglobin (HbA1c) using liquid chromatography using a special glycated hemoglobin analyzer H9 manufactured by Lifotronic (China); Blood insulin levels (μU/ml) were determined using chemiluminescence immunoassay (CIIA) on a Beckman Coulter UniCel DxI 800 analyzer (USA). Based on the data obtained, the insulin resistance index (HOMA-IR) was calculated using the formula:

HOMA-IR = fasting glucose (mmol/L) x fasting insulin (μU/ml) / 22.5.

These tests were performed on all patients before surgery and in the postoperative period, based on individual indications.

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The device works in conjunction with a corresponding mobile app, which displays all measured information, determines a lipolysis prognosis for the near future, and provides personalized health advice to the user.

1. The concentration of ketone bodies in the blood and urine was calculated using the calibration curve equation, taking into account the dilution during deproteinization of the corresponding biological material. Optical density was measured using an SF-46 spectrophotometer at a wavelength of 520 nm.

2. The activity of γ-GTP (U/L) and alkaline phosphatase (U/L) in the blood was determined by a standardized enzymatic-kinetic method on a biochemical analyzer FP-901 (Finland).

Specialized research methods were included in our developed protocol, which was reviewed and approved by the Bioethics Committee of the Ministry of Health of the Republic of Uzbekistan. These studies were conducted at baseline and in the postoperative period at 5, 10, 30, 90, 180, and 365 days after surgery.

Among the instrumental research methods used were endoscopic gastrofibroscopy, radiography of the abdominal and chest organs, ultrasound duplex scanning of the veins of the lower extremities, and ultrasound examination of the abdominal organs. According to the indications, other instrumental research methods were used – computed tomography, magnetic resonance imaging, liver fibroscanning on the FibroScan device and liver biopsy.

As noted above, NAFLD was one of the main comorbidities in obese patients. This was due to the presence of varying degrees of insulin resistance in most patients and an imbalance between lipid intake and utilization [184].

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Clinical signs of NAFLD in this pathological process were usually subtle and unpronounced. In most cases, we identified NAFLD during the initial examination of patients during bariatric surgery planning.

In 25.3% of patients, NAFLD was diagnosed by primary care physicians when patients sought treatment for other obesity-related conditions (hypertension, coronary heart disease, peripheral vascular disease, type 2 diabetes, etc.). All of these patients had hepatomegaly and symptoms characteristic of metabolic syndrome, as revealed by ultrasound.

The patients' main complaints included increased fatigue, aching pain, and discomfort in the right hypochondrium, unrelated to the frequency and type of food intake. The medical history was also reviewed, including the frequency and volume of alcohol consumption, the presence of viral hepatitis B or C, and the types and duration of medications used for fatty liver disease.

Special tests in blood analyses determined: activity of the enzymes aspartate aminotransferase (AST) and alanine aminotransferase ALT), γ-glutamyl transpeptidase (γ-GTP), alkaline phosphatase (ALP); fasting glycemia level, glycated hemoglobin (HbAlc), oral glucose tolerance test, fasting insulin level (HOMA-IR); total cholesterol, high-density lipoprotein (HDL), triglycerides, and uric acid levels.

To determine the severity of steatosis (non-alcoholic fatty liver disease), the presence of inflammatory changes (non-alcoholic steatohepatitis), and the stage of liver fibrosis in patients with NAFLD.

In the first block of studies, we used the widely used “HUFA” assessment method proposed by M. Culafic et al. in 2019 [43], while among patients in the second block of studies, we used the “PNASH” software method developed by us (DGU No. 39560 dated 06/05/2024) to calculate the corresponding index.

Fibroscanning of the liver with the FibroScan device was also used as a non-invasive diagnostic method for non-alcoholic fatty liver disease. This diagnostic method allowed differentiation of the liver disease process only when liver fibrosis developed. However, if liver fibrosis was detected, a definitive diagnosis was established by liver biopsy. This method, unfortunately, remains the only “gold standard” for diagnosing not only NAFLD, but also the stages of its development, allowing for the differentiation of non-alcoholic fatty liver disease and non-alcoholic fatty steatohepatitis with up to 100% accuracy. A liver biopsy also helps rule out other causes of liver damage and predict the course of this pathological process.

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Anesthesiological risk stratification was performed using the American Society of Anesthesiologists (ASA) scale [https://www.asahq.org/].

The stages of development of ketonemic syndrome were assessed using the method developed by O.B. Ospanov et al. [20] as improved by K.U. Sultanov et al. [30]. We also improved this method by introducing quantitative indicators of ketonuria and expanding the dispersion of values. This allowed us not only to increase the accuracy of diagnosis, but also to eliminate the need to determine blood pH, since its significance remained only at the level of development of the last (severe) stage of ketonemic syndrome, which we did not observe in any of the patients in the postoperative period.

Our revised gradation of ketonemic syndrome occurring during bariatric surgery was as follows:

Normal parameters (reference values) – ketone levels in exhaled breath condensate ranged from 0.1 to 0.4 ppm, urine ketone levels were up to 0.5 mmol/L, and serum ketone levels were up to 0.43 mmol/L.

Blood γ-GTP activity was up to 70 U/L. ALP activity was up to 124 U/L. However, patients did not present with any complaints typical of ketonemic syndrome.

Stage One (Mild Physiological Bariatric Ketosis). This stage was also characterized by the absence of complaints typical of ketosis, or they could be minor.

The level of ketones in exhaled air condensate varied within the range from 0.41 ppm to 24.9 ppm; ketonuria was detected at the level of 0.51-0.84 mmol/l; ketonemia was 0.44-1.49 mmol/l. The activity of the enzyme γ-GTP in the blood was 71-100 U/l. The activity of the enzyme alkaline phosphatase in the blood was 125-150 U/l.

Stage two (stage of pronounced physiological bariatric ketosis). This stage was characterized by patients experiencing "keto flu"-like symptoms, including mild poisoning accompanied by decreased appetite and increased thirst. Ketone levels in exhaled breath condensate ranged from 25.0 ppm to 49.9 ppm. Ketonuria was characterized by levels of 0.85–1.64 mmol/L. Ketonemia was characterized by blood ketone levels fluctuating between 1.5 mmol/L and 2.99 mmol/L. Blood γ-GTP enzyme activity was 101–120 U/L. Blood alkaline phosphatase activity was 151–175 U/L.

Stage three (pathological bariatric ketosis). This stage was characterized by patients complaining of moderate poisoning symptoms and a sharp loss of appetite. Patients also experienced a fruity odor from their mouth or urine. Patients also experienced elevated insulin levels. Ketone levels in exhaled breath condensate ranged from 50.0 to 60.0 ppm. Ketonuria, indicating excess toxins, ranged from 1.65 to 2.24 mmol/L. Ketonemia ranged

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from 3 mmol/L to 7.9 mmol/L. Blood γ-GTP enzyme activity ranged from 121 to 150 U/L. Blood alkaline phosphatase activity ranged from 176 to 200 U/L.

Stage IV (ketoacidosis stage). This stage was characterized by severe poisoning symptoms and a "rotten apple smell" in the mouth, nausea, and vomiting. Ketone levels in exhaled breath condensate were greater than 61 ppm. Ketonuria was characterized by significantly elevated ketone body concentrations in urine, reaching 2.25 mmol/L or higher. Ketonemia was characterized by elevated serum ketone body levels of 8 mmol/L and above. Blood γ-GTP activity was greater than 151 U/L. Blood alkaline phosphatase activity was greater than 200 U/L.

The results obtained were systematized as they were received in a unified summary table in Microsoft Excel and processed using Statistica for Windows (version 5.12). Basic statistical indicators were calculated in accordance with the goals and objectives of the study (mean values, standard errors of the means, standard deviations, and range of data dispersion), construction, and visual analysis of data scatter diagrams. Indicators were compared using the signs of nonparametric tests.

The significance of differences between samples with distributions close to normal was determined using the parametric Student's t-test with a 95% confidence interval. The generally accepted medical value of $p < 0.05$ was used as the criterion for statistical significance of the obtained conclusions.

The prognostic value of the developed diagnostic program was determined using the method described by R. Fletcher [13] based on the calculation of the frequency of occurrence of false negative, false positive, true positive and true negative results; specificity and sensitivity of the test, as well as the positivity of reliability or expected value.

The conditions for interpreting the corresponding calculations of clinical and laboratory evidence and the effectiveness of the method we developed for predicting the development of ketonemic syndrome after various bariatric surgeries in patients with non-alcoholic steatohepatitis were based on the results of the conducted biochemical studies of the ketone content in exhaled air condensate, the level of ketonemia and ketonuria, as well as the activity of alkaline phosphatase and γ-GTP in the blood according to the following criteria: true positive results are the number of patients with a positive probability of developing ketonemic syndrome after bariatric surgery, which were correctly classified using the test used; false positive results are the number of patients with a positive probability of developing ketonemic syndrome after bariatric surgery who were erroneously classified as patients meeting this criterion based on the test results;

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True negatives are the number of patients with a negative probability of developing ketonemic syndrome after bariatric surgery who were correctly classified by the test used; False negatives are the number of patients with a negative probability of developing ketonemic syndrome after bariatric surgery who were incorrectly classified by the test used.

Thus, our proposed criteria for assessing the degree of active manifestation and prognosis of non-alcoholic steatohepatitis in patients with obesity "PNASH", based on a combination of instrumental (ultrasound and fibroscanning of the liver) and laboratory assessment of lipolysis activity (activity of γ-GTP and alkaline phosphatase), as well as the formation of ketone bodies in the liver (the level of ketones in the condensate of exhaled air, in the blood and in the urine) in the preoperative period and after various types of bariatric surgery, make it possible to predict with a probability of up to 96.2% the severity of the development of ketonemic syndrome in the postoperative period.

All of the above criteria served as the basis for developing the corresponding prognostic program "PNASH."

A comparative assessment of the effectiveness and reliability of criteria for predicting the severity of nonalcoholic steatohepatitis activity in the form of ketonemic syndrome in patients after bariatric surgery showed that the true-positive results in patients in the control group were 54.5%, while among patients using our method it was 68.7%. True-negative results in the control group of patients were noted in 24.1% of cases, and among patients in the main group in 26.5% of cases.

False positive and false negative rates were higher among patients in the control group (10.9% and 10.5%, respectively, in patients in the control group, and 2.7% and 1.9%, respectively, among patients in the main group). Overall, the predictive sensitivity of the analog test among patients in the control group was 83.9%. and among patients in the main group – 97.2%. Moreover, the specificity of the analog test was 69.7%, and among patients with the method we developed – 93.2%. The expected predictive value between different diagnostic methods was 83.4% and 96.2% in favor of the method we developed.

CONCLUSION.

1. In the absence of a risk of active non-alcoholic steatohepatitis and the development of ketonemic syndrome in the postoperative period in obese patients with a BMI greater than 40 kg/m2 and concomitant type 2 diabetes mellitus, it is recommended to use LMGP
2. In the absence of the likelihood of active manifestation of non-alcoholic steatohepatitis and the development of ketonemic syndrome in the postoperative

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period in obese patients with a BMI of more than 35 kg/m2, but provided that there is no concomitant type 2 diabetes mellitus, it is recommended to use LPR

3. in case of low probability of active manifestation of non-alcoholic steatohepatitis and development of ketonemic syndrome in the postoperative period in obese patients with BMI over 40 kg/m2 and in the presence of concomitant type 2 diabetes mellitus, it is recommended to use LMGSP after preliminary hepatoprotective therapy (Thiazolidinediones, ursodeoxycholic acid, vitamin E, statins, etc.).

4. In case of a high probability of active manifestation of non-alcoholic steatohepatitis and development of ketonemic syndrome in the postoperative period in obese patients, it is recommended to use LMGP even if concomitant type 2 diabetes mellitus is not detected

Moreover, this type of bariatric surgery is recommended to be performed after a thorough examination of the patient, including a liver biopsy and other markers of the activity of the inflammatory process in the liver and conducting conservative treatment in a specialized institution with subsequent re-decision on the possibility of performing bariatric surgery.

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