RESULTS OF SLEEVE GASTRECTOMY IN OBESE PATIENTS WITH TYPE 2 DIABETES MELLITUS AND IMPAIRED GLUCOSE TOLERANCE: RETROSPECTIVE COHORT REGISTRY-BASED STUDY

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ABSTRACT

Background. *In the available literature, the data on the positive effects of sleeve gastrectomy in treatment of type 2 diabetes mellitus (T2DM) and impaired glucose tolerance (IGT) become more common, however, they are heterogeneous and not always unambiguous.*

The aim. *To analyze our own results of treatment of patients with type 2 diabetes mellitus and impaired glucose tolerance, who underwent sleeve gastrectomy.*

Materials and methods. *Retrospective cohort registry-based study was carried out. From 2016 to April 2021, 29 (19 %) and 7 (4.6 %) patients with diagnosed T2DM and IGT respectively underwent surgery. Of these, sleeve gastrectomy was performed in 13 (44.8 %) patients with type 2 diabetes mellitus and in 5 (71.4 %) patients with IGT. The mean duration of follow-up for T2DM and IGT patients was 14.2 ± 12.3 and 11.2 ± 9.0 months respectively.*

Results. *The mean %EWL (% excess weight loss) in patients with T2DM and IGT was 44.1 ± 17.3 and 51.5 ± 16.9 respectively, and the mean %TWL (% total weight loss) was 25.0 ± 8 and 27.8 ± 6.0 respectively. At the moment of observation, all patients had normal level of fasting blood glucose. The level of HbA1c in patients with type 2 diabetes before the surgery was 8.2 ± 1.6, after surgery, at the time of observation – 5.8 ± 0.5 ($U = 4$; $p \leq 0.01$). Target HbA1c values were recorded in all 13 patients with type 2 diabetes.*

Conclusion. *Our study shows the efficiency of sleeve gastrectomy both in terms of weight loss and of the remission for patients with T2DM and IGT.*

Key words: *bariatric surgery, metabolic surgery, sleeve gastrectomy, type 2 diabetes mellitus, obesity*

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РЕЗУЛЬТАТЫ ПРОДОЛЬНОЙ РЕЗЕКЦИИ ЖЕЛУДКА У ПАЦИЕНТОВ С ОЖИРЕНИЕМ В СОЧЕТАНИИ С САХАРНЫМ ДИАБЕТОМ 2-ГО ТИПА И НАРУШЕНИЕМ ТОЛЕРАНТНОСТИ К ГЛЮКОЗЕ: РЕТРОСПЕКТИВНОЕ КОГОРТНОЕ REGISTRY-BASED ИССЛЕДОВАНИЕ

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РЕЗЮМЕ

Обоснование. *В доступной литературе всё чаще встречаются данные о положительных эффектах продольной резекции желудка в отношении сахарного диабета (СД) 2-го типа и нарушения толерантности к глюкозе (НТГ), однако они разнородны и не всегда однозначны.*

Цель исследования. *Анализ собственных результатов лечения пациентов с сахарным диабетом 2-го типа и нарушением толерантности к глюкозе, которым выполнена продольная резекция желудка.*

Методы. *Дизайн – ретроспективное когортное registry-based исследование. За период с 2016 г. по апрель 2022 г. с диагнозом СД 2-го типа и НТГ было прооперировано 29 (19 %) и 7 (4,6 %) пациентов соответственно. Из них продольная резекция желудка выполнена 13 (44,8 %) пациентам с СД 2-го типа и 5 (71,4 %) пациентам с НТГ. Средняя продолжительность наблюдения за пациентами с СД 2-го типа и НТГ составила 14,2 ± 12,3 и 11,2 ± 9,0 мес. соответственно.*

Результаты. *Средний процент потери избыточной массы тела (%EWL, % excess weight loss) у пациентов с СД 2-го типа и НТГ составил 44,1 ± 17,3 и 51,5 ± 16,9 соответственно, а средний процент потери общей массы тела (%TWL, % total weight loss) – 25,0 ± 8,0 и 27,8 ± 6,0 соответственно. У всех пациентов на момент наблюдения достоверно зафиксирована нормализация уровня гликемии натощак. Уровень HbA1c у пациентов с СД 2-го типа перед операцией – 8,2 ± 1,6, после операции на момент наблюдения – 5,8 ± 0,5 ($U = 4$; $p \leq 0,01$). Достижение целевых значений HbA1c установлено у всех 13 пациентов с СД 2-го типа.*

Заключение. *Наше исследование показывает эффективность продольной резекции желудка как в отношении снижения массы тела, так и в части компенсации СД 2-го типа и НТГ.*

Ключевые слова: *бариатрическая хирургия, метаболическая хирургия, продольная резекция желудка, сахарный диабет 2-го типа, ожирение*

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OBJECTIVES

Bariatric and metabolic surgery is increasingly becoming the method of choice in the treatment of obesity and type 2 diabetes mellitus (T2DM). Numerous studies show statistically significant effectiveness of surgical methods for the treatment of T2DM compared with traditional medical methods [1–3].

The results in complete or partial remission of T2DM between operations are ambiguous. It is believed that the best results of surgical treatment of T2DM are demonstrated by gastric bypass interventions [4, 5].

However, there is increasing evidence on the effectiveness of sleeve gastrectomy in terms of remission of T2DM due to the metabolic effects identified in this procedure [6–9]. Meta-analysis by Y. Han et al. (2020) confirms the similar effectiveness of sleeve gastrectomy in comparison with standard gastric bypass in terms of reducing excess weight and controlling T2DM, separately focusing on the lower frequency of complications and repeated operations after sleeve gastrectomy [10].

Attempts are also being made to stratify the choice of surgery depending on the patient's body mass index (BMI) and the duration of T2DM. For example, Roux-en-Y gastric bypass was the optimal choice for patients with a duration of T2DM > 5 years in terms of achieving complete remission of diabetes 1 year after surgery. Nevertheless, sleeve gastrectomy proved to be a cost-effective choice for patients with a duration of T2DM ≤ 5 years and BMI ≥ 35.5 kg/m^2 [11].

Sleeve gastrectomy is a surgery whose effects are still being actively studied. It can become an option of choice in the case when there is no technical possibility to perform a bypass operation (multiple operations on the abdominal cavity with a massive adhesion), and it is safer to perform sleeve gastrectomy if the patient has a high prevalence of comorbidities. In patients who smoke and do not plan to give up nicotine, a bypass surgery is a risk of ulceration in the gastroenteroanastomosis area. SADIs surgery (single anastomosis duodenal-ileal bypass with sleeve) can solve this problem, but technically it is much more difficult to perform and requires a serious level of compliance from the patient. Here, the patient's unwillingness to constantly take vitamin and mineral complexes can also tip the scales in favor of sleeve gastrectomy.

In this article we analyzed our own results of treatment of patients with type 2 diabetes mellitus and impaired glucose tolerance (IGT), who underwent sleeve gastrectomy.

METHODS

Study design. To achieve this goal, a retrospective cohort registry-based study was carried out. During the study, the National Bariatric Register collected and stored patient observation data.

Compliance criteria. Inclusion criteria: 1) sleeve gastrectomy; 2) type 2 diabetes mellitus or IGT. Exclusion criteria: 1) any other bariatric procedures; 2) no T2DM or IGT at the time of surgery.

Procedure situation. The study was conducted in the elective surgery unit of the Nizhnevartovsk District Clinical Hospital.

Duration of the study. This article presents intermediate data (from 2016 to April 2022), allowing to assess the feasibility of conducting the study in the future.

Description of the medical intervention. The study is based on the experience of surgical treatment of 153 obese patients admitted to the Nizhnevartovsk District Clinical Hospital from 2016 to April 2022. Sleeve gastrectomy was performed in 125 (81 %) patients; MGB-OAGB surgery (mini gastric bypass – one anastomosis gastric bypass) – 20 (13 %); standard bypass surgery – 2 (1 %); SASi bypass surgery (single anastomosis sleeve ileal bypass) – 3 (2 %); gastroplication – 1 (1 %); bariatric revision surgery – 4 (3 %). The treatment of obese patients was carried out in accordance with the National Clinical Recommendations for Morbid Obesity Treatment in Adults (3rd revision) [12].

A total of 29 (19 %) and 7 (4.6 %) patients with T2DM and IGT respectively were operated. Sleeve gastrectomy was performed in 13 (44.8 %) patients with type 2 diabetes mellitus and 5 (71.4 %) patients with impaired glucose tolerance. Demographic data are presented in Table 1.

From a technical point of view, all surgeries were performed in accordance with the clinical practical guidelines of the European Association of Endoscopic Surgery (EAES) for bariatric surgery [13] and included the use of disposable suturing instruments and cartridges, modern surgical energy for tissue separation and ligation. All surgeries are performed using a calibration tube (38 Fr).

All patients were operated under general anesthesia with the use of inhalation anesthetic gas. All patients underwent preoperative antibiotic prevention with cephalosporins of the I generation 30 minutes before surgery. Prevention of venous thromboembolic complications was carried out according to clinical recommendations and included early activation of the patient, which began 6 hours after surgery, compression garment of the lower extremities, the appointment of low molecular heparins in preventive dosages.

In the postoperative period, all patients underwent standardized fluid therapy and analgesia.

Only 2 patients with IGT and 6 patients with T2DM received single-drug preoperative oral antidiabetic therapy. Four patients with T2DM took 2 or more oral antidiabetic drugs. Oral antidiabetic drugs (OAD) in combination with prolonged forms of insulin were received by 2 patients with T2DM. In 1 case, T2DM was corrected for the first time by preoperative diet therapy.

The main outcome of the study: achievement of normoglycemia and target values of HbA1c in patients after surgery at the moment of observation; achievement of target values of weight loss (percentage of excess weight loss (%EWL) ≥ 50; percentage of total weight loss (%TWL) ≥ 25).

Additional outcomes of the study: postoperative bed-day, the number and nature of complications.

Methods of statistical data processing. The data were retrospectively collected in the database of the National Bariatric Register of the Russian Federation and included the period from 2016 to April 2022. Descriptive

TABLE 1
DEMOGRAPHICS INFORMATION OF THE PATIENTS

Parameters	Patients with T2DM (*n* = 13)	Patients with IGT (*n* = 5)
Female	9	2
Mean follow-up duration, months	14.2 ± 12.3 (1–36)	11.2 ± 9.0 (4–21)
Mean age, years	51.1 ± 12.3 (31–71)	42.8 ± 7.1 (37–55)
Mean weight before surgery, kg	127.3 ± 22.3 (86–169)	129.8 ± 21.6 (107–156)
Mean BMI, kg/m^2	45.5 ± 8.3 (32.4–62.9)	43.6 ± 8.2 (32.3–51.4)
History of T2DM and IGT, months	52.8 ± 72.2 (1–240)	10.0 ± 9.6 (1–24)
Mean risk according to ASA	2.6 ± 0.5	2.4 ± 0.5
Micro- and macroangiopathies, *n*	2	0
High-risk AH	9	3
CAD	2	1
OSA	1	1
Hyperlipidemia/dyslipidemia	8	3
NAFLD	8	3
CHF	8	2
Atherosclerosis	3	1
Smoking	7	3

Note. ASA – American Society of Anesthesiologists; AH – arterial hypertension; CAD – coronary artery disease; OSA – obstructive sleep apnea; NAFLD – non-alcoholic fatty liver disease; CHF – chronic heart failure.

analysis included the calculation of mean values, standard deviations and proportions. During the analysis, a non-parametric test (Mann – Whitney U test for numerical data and Pearson Chi-Square test with Yates' continuity correction for relative indicators) was used to evaluate differences in subgroups when calculating *p*-values. The value of $p < 0.05$ was considered a statistically significant difference. All calculations were carried out using a licensed Statistica 13.0 software package for statistical analysis (StatSoft Inc., USA).

RESULTS

The duration of the surgery in patients with T2DM and IGT did not differ statistically significantly (118.1 ± 39.1 and 102.0 ± 26.1 min, respectively; $U = 27$; $p > 0.05$).

The main results of the study. All patients had sustained weight loss after the surgery. The results of weight loss are shown in Table 2.

The variability of values is associated with different duration of patient follow-up: from 1 to 36 months in patients with T2DM and from 4 to 21 months in patients with IGT.

The distribution of patients by blood glucose level before and after the surgery at the moment of observation is shown in Table 3.

As indicated in the table, at the moment of observation all patients had normal level of fasting blood glucose. The blood glucose level in patients with IGT returned to normal after 1.4 ± 0.4 months.

The level of HbA1c in patients with T2DM before surgery was 8.2 ± 1.6, after surgery, at the moment of observation – 5.8 ± 0.5 ($U = 4$; $p \leq 0.01$). Target HbA1c values were recorded in all 13 patients with type 2 diabetes. Complete withdrawal of OAD was achieved in 9 patients, OAD dosage reduction – in 2 patients, reduction of dosages of OAD and prolonged forms of insulin – in 1 patient. Complete withdrawal of insulin therapy with reduced dosages of OAD was registered in 1 patient. Target HbA1c values in patients with T2DM noted within 4.0 ± 1.7 months.

TABLE 2

RESULTS OF WEIGHT LOSS IN PATIENTS WITH TYPE 2 DIABETES AND IMPAIRED GLUCOSE TOLERANCE

Parameters	Patients with T2DM (*n* = 13)	Patients with IGT (*n* = 5)
Mean weight before surgery, kg	127.3 ± 22.3 (86–169)	129.8 ± 21.6 (107–156)
Mean BMI before surgery, kg/m^2	45.5 ± 8.3 (32.4–62.9)	43.6 ± 8.2 (32.3–51.4)
Mean weight after surgery, kg	95.2 ± 17.7 (59–121)	93.8 ± 18.8 (76–117)
Mean %EWL	44.1 ± 17.3 (12.0–79.4)	51.5 ± 16.9 (37.2–73.7)
Mean %TWL	25.0 ± 8.7 (6.6–39.6)	27.8 ± 6.0 (22.4–36.9)
Mean TWL, kg	32.1 ± 14.4 (8–67)	36.0 ± 8.7 (24–48)
Mean TBMIL, kg/m^2	11.5 ± 5.0 (3.0–21.1)	12.3 ± 4.2 (7.2–19.0)

Note. TBMIL – total body mass index loss

TABLE 3

DISPOSITION OF PATIENTS BY THE BLOOD GLUCOSE LEVEL

Patients	Blood glucose level before the surgery, mmol/L	Blood glucose level at the moment of observation, mmol/L	U	*p*
Patients with T2DM (*n* = 13)	10.4 ± 4.2	5.4 ± 0.7	5	$p \leq 0.01$
Patients with IGT (*n* = 5)	7.1 ± 1.5	4.7 ± 0.7	0.5	$p \leq 0.01$

Additional results of the study. There were no surgical, general or therapeutic complications. Mean bed-day of all patients was 4.4 ± 2.4 days.

Adverse events. No adverse events were noted.

In one case, a patient with T2DM underwent revision bariatric surgery – MGB-OAGB after sleeve gastrectomy due to obesity relapse. Before the first surgery, the patient's weight was 110 kg, BMI 36.8 kg/m^2; the patient took three OAD in combination with long-acting insulin (Levemir, 25 Uday). The level of fasting blood glucose was 12.3 mmol/L, HbA1c – 10.2 %, target HbA1c < 7 %. Preoperative preparation with short forms of insulin was performed in the hospital in order to normalize the blood glucose level. 10 months after sleeve gastrectomy the maximum %EWL is 78.8, %TWL is 24.5; the fasting blood glucose level is 6.0 mmol/L, HbA1c is 5.9 %. There was a withdrawal of one of the three OADs, the withdrawal of prolonged insulin. Target HbA1c values were noted within 6 months after surgery. Weight regain of up to 103 kg was recorded 47 months after sleeve gastrectomy, BMI – 34.4 kg /m^2, HbA1c – 6.3 %. A bariatric revision surgery was performed: sleeve gastrectomy in MGB-OAGB. At the moment of observation, the patient's weight was 90 kg, BMI – 30.1 kg/m^2, %EWL – 25.5, %TWL – 12.6 of the values before the second surgery; fasting blood glucose level – 5.9 mmol/L, HbA1c – 6.0 %.

DISCUSSION

This is a pilot study and is intended to assess the feasibility of conducting more solid studies in the future, which would include a larger number of patients, a longer follow-up period and a control group (patients with gastric bypass surgery).

Summary of the main result of the study. Sleeve gastrectomy demonstrates solid results in weight loss in obese patients. Moreover, the available metabolic effects of this operation allow to recommend it as the surgery of choice for patients with T2DM and IGT with a thorough clinical assessment of the patient.

CONCLUSION

The obtained results of the study indicate the undoubted advantage of sleeve gastrectomy both in terms of weight loss and compensation for type 2 diabetes mellitus and IGT. Improvement of the results of surgical treatment of this group of patients is possible by rational choice of the type of surgery. The performed study shows the expediency of further study of this problem and conducting more solid studies.

Conflict of interest

The authors of this article declare the absence of a conflict of interest.

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