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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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COMPARATIVE ANALYSIS OF EFFECTS INDUCED BY STANDARD AND MODIFIED LAPAROSCOPIC SLEEVE GASTRECTOMY PERFORMANCE ON SHORT TERM AND DISTAL COMPLICATIONS IN PATIENTS WITH 3RD DEGREE OF MORBID OBESITY

Sevak Sanasar Shahbazyan.

Department of General Surgery, Named after M. Heratsi Yerevan State Medical University, Armenia.

Abstract.

Introduction: The effective techniques of surgical intervention that ensure the desired level of weight reduction outcomes (decreased level of obesity) not always improve QOL outcomes, explained by a range of post-surgery complications. There are the specific complications, strongly impacting the QOL of the patients after bariatric surgery and increasing postoperative comorbidity.

Aim: The aim of this retrospective case control study was to evaluate the relative safety of primary LSG performed with standard and modified LSG techniques according to the Clavien–Dindo complication grading system and the rate of long-term complications in patients with BMI>40.

Materials and methods: A total of 497 cases of patients were divided into 2 groups in accordance with the type of LSG performed. The first group (n = 246) were the patients managed with the Standard protocol of LSG and the second group (n = 251) included the patients treated with the modified protocol of the LSG. The prevalence of specific post-bariatric complications and short-term (30-days) complications was calculated and compared in the groups. The long-term complications were assessed after 1-year of post-operation period in both intervention groups. The relative risk ratio, p-value and CI95% were calculated for all complications. The short-term (30-days) complications assessment in both intervention groups was performed in accordance with Clavien-Dindo classification of surgical complications.

Results: The remarkable reduction of relative risks was registered for the minor and major complications rates. Similarly, the total rates for the minor and major complications demonstrated strong difference between group I and group II ($p<0,05$). The intraoperative and early (first 72 hours) complications (acute bleeding, and leakage) rates in patients of group I were reliably lower compared to the patients of group II ($p<0,05$). The RR indicators were 0.123 and 0.121 respectively for acute bleeding and leakage. The indicator of acute obstruction was not essentially different while intergroup comparison was significantly divergent ($p<.05$). However, the RRR was calculated as 80%. The total rate of intraoperative and first 72 hours complications was 7.3% vs 1.2% in group II. The difference was reliable (p-value<.05) in Gall stone disease, GERD, thrombosis malnutrition and anemia. Comparison of the Renal lithiasis and depression didn't reveal any essential difference between clinical groups (p-value>.05).

Conclusion: The results we received are direct confirmation of the comparatively higher effectiveness of the modified LSG evidenced by a significant reduction of the major and minor complications in patients with BMI>40.

Key words. Bariatric complications, laparascopic sleeve gastrectomy (LSG), Clavien–Dindo classification.

Introduction.

Due to the sedentary lifestyle and the high caloric content of the food consumed, the modern living environment is often characterized as "obesogenic" or fattening. The combination of these factors, as a rule, leads to decreased energy expenditure which in turn contributes to obesity [1].

Obesity is a multifactorial pathology, associated with a combination of genetic, environmental and metabolic factors [2,3].

From a public health perspective, obesity is a major risk factor for the multiple comorbid conditions and complications, increasing the cost of medical care and deteriorating the quality of life in patients. Overweight and obesity are among the risk factors for disability and death.

Morbid obesity accounts for 44% of diabetes, 23% of coronary heart disease, 7 to 41% of cancer, and is also associated with hypertension, cardiovascular disease, sleep apnea, and liver failure. 80-90% of alcoholic fatty disease cases occurs in obese individuals, and the high degree of steatosis reflects the degree of fat accumulation in the liver. All these factors, in turn, lead to reduction in life expectancy [1,4].

Laparoscopic sleeve gastrectomy (LSG) with its growing popularity has nowadays become the most performed bariatric procedure worldwide [5,6].

LSG is now widely accepted procedure due to its safety, effectiveness, technical simplicity, short time required for learning, shorter operative time, feasibility, and chances of revision and conversion to minimally invasive surgery [7,8].

At the same time, its implementation does not always provide the expected results. The effectiveness of surgery is determined not only by weight loss indicators, but also by changes in the course of obesity associated diseases, the quality of life of patients and correlated with the type of surgery, the technique of performance, and postoperative management strategy. Besides, there are the specific complications, strongly impacting the QOL of the patients after bariatric surgery and increasing postoperative comorbidity. The effective techniques of surgical intervention that ensure the desired level of weight reduction outcomes (decreased level of obesity) not always improve QOL outcomes, explained by a range of post-surgery complications.

There is a lack of unity in reporting the complications following bariatric surgery. Therefore, there may be a misperception about the general level of safety associated with bariatric surgery methods applied worldwide [9,10].

Analysis of above-mentioned issues requires new approaches in the management of postoperative complications following the LSG and improving the overall bariatric outcomes.

Aim.

The aim of this retrospective case control study was to evaluate the relative safety of primary LSG performed with standard

and modified LSG techniques according to the Clavien–Dindo complication grading system and the rate of long-term complications in patients with BMI>40.

Materials and Methods.

Study design:

This retrospective case control, descriptive study was carried out between August 2019 and March of 2024 in a sample of 20+ years old bariatric patients of "Shengavit" Medical Center.

The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in the approval by human research committee. The study protocol was approved by the Ethics Committee of Yerevan State Medical University.

Patient selection criteria were as follows: age >20 and identified BMI>40. The exclusion criteria of the study were as follows: active Helicobacter pylori infection, non-scared gastric ulcer, previous gastric resection or fundoplication, drug or alcohol abuse and mental health disorders, age <20 and BMI<40.

Operations were performed by the same surgical team via laparascopy.

Study participants:

A total of 497 cases of patients, admitted to the surgical department of the "Shengavit" Medical Center for bariatric surgery within the mentioned period, corresponding to the inclusion criteria, were included in the study. The selected participants were divided into 2 groups in accordance with the type of LSG performed. The first group (n = 246) were the patients managed with the Standard protocol of LSG and the second group (n = 251) included the patients treated with the modified protocol of the LSG.

Clinical research methods.

Body mass index (BMI) data of patients:

BMI was calculated according to the standard formula [11].

Comrbidity burden Index (CBI) is calculated in accordance with the BMI at baseline, presence and degree of severity of comorbid pathologies, smoking heaviness, patient's age etc. [12].

Complications:

The prevalence of specific post-bariatric complications and short-term (30-days) complications was calculated and compared in the groups. The long-term complications were assessed after 1-year of post-operation period in both intervention groups. The relative risk ratio, p-value and CI95% were calculated for all complications [9,13-16].

The short-term (30-days) complications assessment in both intervention groups was performed in accordance with Clavien-Dindo classification of surgical complications (see table 1) [13,17].

In accordance with the Clavien-Dindo classification, the results assessed by 1-2 scores were considered minor complications while the results assessed by 3 and higher scores were included in major complications.

Treatment protocols.

The preoperative Management was performed by multidisciplinary team. Medical, nutritional, endocrinological, and psychiatric standard preoperative assessment included, abdominal ultrasound investigation (USI), barium X-ray of the upper gastrointestinal tract, esophagogastro -duodenoscopy, blood analysis, cardiologic evaluation, and chest X-ray.

Table 1. *30-day complication rates using the Clavien-Dindo classification [17].*

Grade	Clavien-Dindo classification of surgical complications
1.	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological intervention.
	Acceptable therapeutic regimens are drugs as antiemetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy.
	This grade also includes wound infections opened at the bedside.
2.	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions, antibiotics and total parenteral nutrition are also included.
3.	Requiring surgical, endoscopic or radiological intervention.
3a.	Intervention under regional/local anesthesia
3b.	Intervention under general anesthesia
4.	Life-threatening complication requiring intensive care/ intensive care unit management
4a.	Single-organ dysfunction
4b.	Multi-organ dysfunction
5.	Patient demise

Group 1. SLSG: Under general anesthesia, a carboxyperitoneum up to 15 mm Hg is created in the left upper abdominal quadrant. The trocars and optical devices were placed. An initial laparoscopy was performed, followed by the mobilization of the greater curvature of the stomach from the pyloric region 2.5 cm proximal to the cardiac region. An orogastric calibrating probe 32-34 Fr was fixed. Longitudinal dissection of the stomach was performed using a linear cutting "Eshelon" 60mm device (4-6 cartridges are used). Haemostasis was assessed and a nasogastric tube was placed. One drain was placed along the length of the stomach edge. The part of the stomach to be removed was taken out from the right-side incision, the wound was sutured layer by layer with an interrupted absorbable thread suture. The residual volume of the stomach was 150 ml. Desufflation was performed, trocars and instruments were removed. Wounds were sutured [18].

Group 2. MLSG: The operation is performed according to the standard procedure with our modification [12,18]. Under general anesthesia, a carboxyperitoneum up to 15 mm Hg is created in the left upper quadrant. The trocars and optical devices are placed. An initial laparoscopy was performed, then the greater curvature of the stomach is mobilized from the pyloric region 2.5 cm proximal to the cardiac region. MLSG was performed with 26-28-F bougie, and the gastric resection was carried out with a reinforced linear stapler. Longitudinal dissection (with simultaneous suturing) of the stomach was performed using a linear cutting "Eshelon" 60mm device (4-6 cartridges were used). The antral part was sewn with staplers with a height of 2.0-4.1 mm (the first two pieces), and the remaining part - with staples of 1.5-3.5 mm height, the number of which is determined

by the length of stomach residual part. One drain is placed along the length of the stomach edge. The part of the stomach to be removed was taken out from the right-side incision, the wound is sutured layer by layer with an interrupted absorbable thread suture. The residual volume of the stomach was 110-120 ml. Desufflation was performed, trocars and instruments are removed. Wounds were sutured [12,18].

Postoperative Management.

All patients underwent early mobilization in postoperative 8-12h. The postoperative management was conducted according to the recommended conventional care guidelines.

Group 1:

Early mobilization, 8-12 hours after surgery, was performed in all patients. Dietary guidelines comprised a 15-day liquid and pureed meal diet followed by a 15-day semisolid diet. After a month, the patients progressively began to incorporate a substantial meal that was rich in protein, low in fat, and low in carbohydrates into their nutritional regimen. The prescriptions are not associated with the patients' age, primary BMI and comorbidity.

Group 2: Early mobilization, 8-12 hours after surgery, was performed in all patients. Physical activity should be moderated taking into consideration the patient's age, degree of obesity and associated diseases.

After 1 month, the patients gradually started to include in their nutritional plan a low-fat, low-carbohydrate and high-protein solid diet. The diet is prescribed according to the guidelines but is subject to modification in subgroups of patients depending on their age, degree of obesity and comorbidity.

Intake of liquids was performed according to the schedule and to the patient's age, degree of obesity and severity of related diseases. The modified postoperative management drug prescriptions list contains the medicines, directed to prevention of complications [12,18].

Data Analysis.

Clinical and functional parameters of participants in each group were assessed. The assessment and intergroup comparison (standard vs modified LSG) were performed based on the Clavien-Dindo classification of complications including intraoperative, early postoperative (first 72 hours), short term (30-days) and long-term complications.

Statistical analysis.

To determine any significant difference in post-operative rates of complications between the groups the Statistical data processing was performed using the statistical software package SPSS 23 (Statistical Package for Social Science 23). Categorical variables are described using frequencies and percentages. For a comparative analysis of the group results obtained after intervention the prevalence rates (PR), relative risk (RR) and relative risk reduction (RRR) were calculated in CI95%. The p-value=.05 was considered the statistical significance of differences in the variance of the compared groups.

Results.

Baseline characteristics of the patients:

We included patients aged 20–65 years with a BMI ≥ 40. The male patients were 134 (54.5 %) and 129 (51.4 %) (correspondingly in group I and group II). The Preoperative BMI was 47.2 ± 5.4 kg/m2 in group I and 48.9± 6.2 kg/m2 in group II. The family history of Obesity was stated in 44.3% and 50.2 % in patients of group I and group II respectively. The average Comorbidity Burden Index was calculated 14.3 ± 4.34 for group I and 15.1 ± 4.98 for group II. The strong difference was not observed in the preliminary parameters between the interventional groups at the study baseline (p>0.05).

The data regarding 30-days complication rates in accordance with Clavien Dindo classification in patients of standard and modified LSG groups are represented in the table 3. Associations are reported as relative risks (RRs), and relative risk reduction (RRR) with 95% CI.

As can be seen from the data presented in the table, the differences in rates of 30-days post-operative complications (in accordance with Clavien-Dindo classification) between the patients of the first and second clinical groups were significant.

The between group comparison for the rates of minor and major complications demonstrated reliable difference (RR =0.412, p= .0316, CI95% [0.1891-0.9250] and RR= 0.196, p= .0092, CI95% [0.057 - 0.669] correspondingly for the minor and major complication rates). The remarkable reduction of relative risks was registered for the minor and major complications rates (58,8% & 80.4% respectively). The total rates for the minor and major complications demonstrated strong difference between group I and group II (RR= 0.317, RRR= 68.3%, p= .0006, CI 95% [0.164 to 0.612].

The data concerning most specific intraoperative, early postoperative (first 72 hours) and long-term complications after bariatric operations in patients of standard and modified LSG are represented in the Table 4.

The intraoperative and early (first 72 hours) complications (acute bleeding, and leakage) rates in patients of group I were reliably lower compared to the patients of group II (P<0,05). The RR indicators were 0.123 and 0.121 respectively for acute bleeding and leakage.

The indicator of acute obstruction was not essentially different while intergroup comparison was significantly divergent (p<.05). However, the RRR was calculated as 80%.

The total rate of intraoperative and first 72 hours complications was 7.3% vs 1.2% in group II.

The long-term complications (Gall stone disease, GERD, thrombosis (inclusive non-obstructive), nutrition disorders and anemia) rates as well were characterized by comparatively low levels in the patients of group II vs group I. The difference was reliable (p-value<.05) in mentioned complications with RR= 0.381, RR=0.374, RR=0.123, RR=0.220 and RR=0.358 respectively for Gall stone disease, GERD, thrombosis malnutrition and anemia.

Comparison of the Renal lithiasis and depression didn't reveal any essential difference between clinical groups (p-value>.05 for both prevalence indicators) with RR=0.392 and RR=0.844 correspondingly for renal lithiasis and depression.

Discussion.

While planning our research we investigated the identical data of those of other studies that used the CD classification [9,13-16].

Table 2. *Descriptive data of the Study Participants' Baseline Characteristics.*

Baseline Characteristics	**Group I N=246**	**Group II N=251**	**p-value**
Age	48.4 ±11.6	49.7 ±10.4	>.05
Male Gender, n (%)	134 (54.5)	129 (51.4)	>.05
Preoperative BMI, kg/m2	47.2 ± 5.4	48.9± 6.2	>.05
Family history of Obesity, n (%)	109 (44.3)	126 (50.2)	>.05
Comorbidity burden Index (CBI)	14.3 ± 4.34	15.1±4.98	>.05

Table 3. *Statistics data of 30-days complication rates in accordance with Clavien Dindo classification in patients of standard and modified LSG groups.*

Clavien Dindo Grade	**Sleeve Gastrectomy (standard technique) N =246**	**Sleeve Gastrectomy (modified technique) N = 251**	**Relative risk/ Relative risk reduction, P, CI95%**	
Minor Complications rate, n (%)	19 (7.7)	8 (3.2)	RR*	0.412
			RRR, % **	58,8
			p-value	.0316
			CI 95%***	[0.189-0.925]
Major Complications rate, n (%)	15 (6.1)	3 (1.2)	RR	0.196
			RRR, %	80,4%
			p-value	.0092
			CI 95%	[0.057 - 0.669]
Total Complications rate, n (%)	34 (13.8)	11 (4.4)	RR	0.317
			RRR, %	68,3
			p-value	.0006
			CI 95%	[0.164 - 0.612]

**RR - relative risk.*
***RRR – Relative Risk Reduction.*
**** 95% CI – 95% Confidence Interval.*

In the study by Vidal and colleagues,14 minor complications were reported in 5 (4.4%) patients: urinary tract infection (n = 2), pseudomembranous colitis (n = 1), hypertensive crisis (n = 1) and subphrenic abscess (n = 1). Major complications were reported in 5 (4.4%) patients: gastric leak (n = 2), bleeding from the port site (n = 2) and acute myocardial infarction resulting in death (n = 1) [16].

Three nonsurgical, one surgical, and three dysphagia-related minor complications were among the fifteen recorded in 7.5% of patients in the study by Peterli & colleagues. Major problems were determined to be obstruction and infection, representing a 0.9% rate [15].

There were 29 serious problems, and 38 minor complications described by Lemanu and colleagues (2016). There were 23 grade III, 5 grade IV, and 1 grade V among the 28 significant problems. The authors documented one mortality (0.3%), staple line hemorrhage (2.5%), and staple line leakage (2%) [14].

Goitein et al. (2015) observed an overall complication rate of 4.1% using the CD classification as well. 1.8% of patients had significant problems and 2.3% of patients had minor ones. The following 30-day absolute complication rates were given: 2.5% (n = 66) for bleeding, 0.8% (n = 22) for leakage, 0.2% (n = 4) for venous thromboembolism, and 0.1% (n = 3) for blockage [9].

As it is following from data, mentioned above, the various complications rates were reported by researchers from different countries. This controversy triggered us to perform the analysis of the national data. At the same time the efficacy of modified LSG and modified (individual) schedule of postoperative management in terms of complications was another attractive subject to be assessed.

To increase the accuracy of the judgement regarding the efficacy of the modification, the RR and RRR indicators were calculated. The performed processing of statistical data has revealed the significant difference for 30-days major and minor complications rates in accordance with Clavien Dindo classification in patients from standard and modified LSG groups (p-value <.05). On another hand, while comparing intraoperative, early postoperative (72 hours after operation) and late complications' prevalence rates, the mosaic pattern has been revealed.

So, some early postoperative complications (acute obstruction) has not demonstrated significant difference in between group comparison at the same time providing fellable reduction of Relative risk (RR=80.4%).

In spite of the fact of low relative risk of some late complications (renal lithiasis (RR = 0.392) and depression (RR = 0.844)) and significant reduction of the relative risk complications (RRR = 60.8% for renal lithiasis and (RRR =15.6% for depression), in patients treated with MLSG, the difference was not reliable (p-value>.05 for both complications).

Table 4. *The most specific intraoperative, early postoperative and longtime complications in bariatric patients of standard and modified LSG groups.*

Complications	**Sleeve Gastrectomy (standard technique) N =-246/98**	**Sleeve Gastrectomy (modified technique) N= 251/108**	**Statistical indicator**	**Relative risk/ Relative risk reduction, P, CI95%**
INTRAOPERATIVE AND EARLY POSTOPERATIVE COMPLICATIONS				
Acute bleeding, n (%)	8 (3.25)	1 (0.39)	RR*	0.123
			RRR, %**	87.7
			p-value	.047
			95% CI***	[0.015 - 0.972]
Acute obstruction, n (%)	2 (0.8)	-	RR	0.196
			RRR, %	80.4
			p-value	.292
			95% CI	[0.009 - 4.063]
Leakage, n (%)	8(3.25)	1(0.4)	RR	0.123
			RRR, %	87.7
			p-value	.047
			95% CI	[0.015 - 0.972]
LONG-TERM COMPLICATIONS				
Gall-stones disease, n (%)	54 (21.95)	21 (8.36)	RR	0.381
			RRR, %	61.9
			p-value	.0001
			95% CI	[0.237 - 0.611]
GERD, n (%)	89 (36.18)	34 (13.55)	RR	0.374
			RRR, %	62.6
			p-value	.0001
			95% CI	[1.875 - 3.805]
Thrombosis (inclusive non-obstructive), n (%)	8 (3.25)	1 (0.4)	RR	0.123
			RRR, %	87.7
			p-value	.047
			95% CI	[0.015 - 0.972]
Nutrition Disorders (malnutrition), n (%)	49 (19.92)	11 (4.3)	RR	0.220
			RRR, %	78.0
			p-value	.0001
			95% CI	[0.117 - 0.413]
Anemia, n (%)	127 (51.6)	47 (18.7)	RR	0.358
			RRR, %	64.2
			p-value	.0001
			95% CI	[0.269 - 0.476]
Renal lithiasis, n (%)	10 (4.1)	4 (1.6)	RR	0.392
			RRR, %	60.8
			p-value	.109
			95% CI	[0.125 - 1.233]
Depression, n (%)	65 (26.4)	56 (22.3)	RR	0.844
			RRR, %	15.6
			p-value	.287
			95% CI	[0.619 - 1.153]

**RR - relative risk.*
***RRR – Relative Risk Reduction.*
**** 95% CI – 95% Confidence Interval.*

Conclusion.

The results we received are direct confirmation of the comparatively higher effectiveness of the modified LSG evidenced by a significant reduction of the major and minor complications in patients with BMI>40.

REFERENCES

1. Bhandari M, Fobi MAL, Buchwald JN. Bariatric Metabolic Surgery Standardization (BMSS) Working Group. Standardization of Bariatric Metabolic Procedures. World Consensus Meeting Statement. Obes Surg. 2019;29:309-345.
2. Flores-Dorantes MT, Díaz-López YE, Gutiérrez-Aguilar R. Environment and Gene Association With Obesity and Their Impact on Neurodegenerative and Neurodevelopmental Diseases. Front Neurosci. 2020;14:863.
3. Qasim A, Turcotte M, de Souza RJ, et al. On the origin of obesity: identifying the biological, environmental and cultural drivers of genetic risk among human populations. Obes Rev. 2018;19:121-149.
4. Kitahara CM, FlintAJ, Berrington deGonzalez A, et al. Association between class III obesity (BMI of 40-59 kg/m2) and mortality: a pooled analysis of 20 prospective studies. PLoS Med. 2014;11:e1001673.
5. Mocian F, Coroş M. Laparoscopic sleeve gastrectomy as a primary bariatric procedure: postoperative outcomes. Med Pharm Rep. 2021;94:208-213.
6. Varela JE, Nguyen NT. Laparoscopic sleeve gastrectomy leads the U.S. utilization of bariatric surgery at academic medical centers. Surgery for Obesity and Related Diseases. 2015;11:987-990.
7. Angrisani L, Santonicola A, Iovino P, et al. Bariatric surgery worldwide 2013. Obesity Surgery. 2015;25:1822-1832.
8. Gentileschi P, Bianciardi E, Siragusa L, et al. Banded Sleeve Gastrectomy Improves Weight Loss Compared to Nonbanded Sleeve: Midterm Results from a Prospective Randomized Study. J Obes. 2020;2020:9792518.
9. Goiten G, Razeil A, Szold A, et al. Assessment of perioperative complications following primary bariatric surgery according to the Clavien–Dindo classification. Surg Endosc. 2016;30:273-8.
10. Goitein D, Raziel A, Szold A, et al. Assessment of perioperative complications following primary bariatric surgery according to the Clavien-Dindo classification: comparison of sleeve gastrectomy and Roux-Y gastric bypass. Surg Endosc. 2016;30:273-8.
11. https://www.nhlbi.nih.gov/health/educational/lose_wt/bmitools.htm
12. Official Bulletin of the Intellectual Property Agency of RA, 2024. No 05/1, page 5, https://aipo.am/public/uploads/files/file-aptjrI1Fn1.pdf (in Armenian).
13. Falk V, Twells L, Gregory D, et al. Laparoscopic sleeve gastrectomy at a new bariatric surgery centre in Canada: 30-day complication rates using the Clavien-Dindo classification. Can J Surg. 2016;59:93-97.
14. Lemanu DP, Srinivasa S, Singh PP, et al. Single-stage laparoscopic sleeve gastrectomy: safety and efficacy in the super-obese. J Surg Res. 2012;177:49-54.
15. Peterli R, Borbély Y, Keran B, et al. Early results of the Swiss Multicentre Bypass or Sleeve Study (SM-BOSS): a prospective randomized trial comparing laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass. Ann Surg. 2013;258:690-694.
16. Vidal P, Ramón JM, Goday A, et al. Laparoscopic gastric bypass versus laparoscopic sleeve gastrectomy as a definitive surgical procedure for morbid obesity. Mid-term results. Obes Surg. 2013;23:292-9.
17. Vartanian ED, Lynn JV, Perrault DP, et al. Risk Factors Associated with Reconstructive Complications Following Sacrectomy. Plast Reconstr Surg Glob Open. 2018;6:e2002.
18. Shahbazyan S.S, Badalova Z.E. Comparative analysis of the effect of longitudinal gastrectomy on comorbidity indicators in different groups of patients with 3rd degree obesity Armenian Medical Science, 2024, n.2 (in Armenian).