# **Laparoscopic sleeve gastrectomy and simultaneous cholecystectomy:** a choice of optimal tactics

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Obesity has become a worldwide pandemic that has led to an increase in morbidity and mortality in patients, both young and old. Conservative treatments for obesity did not live up to expectations. Bariatric surgery has been proven to be a safe and effective treatment for obesity with weight reduction, resolution of obesity-related comorbidities, improved quality of life and an increased life expectancy.

Laparoscopic sleeve gastrectomy (LSG) has become the most popular bariatric procedure worldwide. Whether to perform simultaneous cholecystectomy (CHE) during bariatric surgery is a subject of debate among bariatric surgeons.

The aim of the study was to form an optimal tactics regarding the expediency of performing simultaneous CHE in LSG in patients

Materials and methods. Between January 2012 and March 2021, 59 morbidly obese patients underwent LSG and were considered for the present study. The patients were subdivided in the first group undergoing LSG (n = 39) and the second group undergoing LSG with simultaneous CHE (n = 20). Demographics of both groups were similar.

Results. The mean BMI in the first group was 51.9 ± 7.6 kg/m<sup>2</sup> with no significant difference compared to the second group values 48.7 ± 7.1 kg/m² (P = 0.117). There was no significant difference in pain syndrome level and postoperative in-patient treatment duration (P = 0.236 and P = 0.983, respectively) in the groups.

Assuming equal intraoperative tactics and approaches to patient management after LSG, the simultaneously performed CHE resulted in significant prolongation of surgical intervention time (P = 0.0001). The postoperative complication rate in the second group was slightly higher than that in the first group, but it did not reach the statistical significance (P = 0.198). No significant difference in the fatality rate was detected in the study groups (P = 0.16).

Conclusions. Simultaneous CHE during LSG is safe and warranted when indicated in gallstone disease. Simultaneous CHE during LSG is still debatable.

### Ключові слова:

ожиріння, жовчнокам'яна хвороба, лапароскопічна рукавна резекція шлунка, холецистектомія.

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# **Лапароскопічна рукавна резекція шлунка та симультанна холецистектомія:** вибір оптимальної тактики

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Ожиріння стало всесвітньою пандемією, яка призвела до збільшення захворюваності, смертності і молодих, і літніх пацієнтів. Консервативні методи лікування ожиріння не виправдали очікувань. Доведено, що баріатрична хірургія – безпечний та ефективний метод лікування ожиріння зі зменшенням ваги, компенсацією супутніх захворювань, пов'язаних з ожирінням, покращенням якості та збільшенням тривалості життя.

Лапароскопічна рукавна резекція шлунка (ЛРРШ) стала найпопулярнішою баріатричної операцією в усьому світі. Питання про те, чи виконувати симультанну холецистектомію (ХЕ) під час баріатричної операції, – предмет наукової дискусії.

Мета роботи – сформувати оптимальну тактику щодо доцільності одночасного виконання ХЕ під час ЛРРШ у пацієнтів з ожирінням.

Матеріали та методи. У дослідження залучили 59 пацієнтів з ожирінням, яким виконали ЛРРШ у період із січня 2012 до березня 2021 року. Пацієнтів поділили на групи: у першу групу включили хворих, яким виконали ЛРРШ (п = 39), у другу – осіб, яким здійснили ЛРРШ і симультанну ХЕ (п = 20). Демографічні показники пацієнтів обох груп зіставні.

Результати. Середній ІМТ у першій групі становив 51,9 ± 7,6 кг/м², без значущої різниці щодо показника другої групи –  $48.7 \pm 7.1$  кг/м² (p = 0,117). Не виявили вірогідну різницю за рівнем больового синдрому та тривалістю післяопераційного стаціонарного лікування між групами (р = 0,236 та р = 0,983 відповідно).

При однаковій інтраопераційній тактиці та підходах до ведення пацієнтів після ЛРРШ одночасне виконання ХЕ призвело до значущого збільшення тривалості хірургічного втручання (р = 0,0001). Частота післяопераційних ускладнень у 2 групі дещо перевищувала показник першої групи, але не досягла рівня статистичної значущості (р = 0,198). Вірогідної різниці за показником летальності у групах дослідження не виявили (р = 0,16).

Висновки. Симультанна ХЕ під час виконання ЛРРШ безпечна і виправдана, коли в пацієнта діагностована жовчнокам'яна хвороба. Відкритим питанням залишається доцільність одночасної ХЕ під час ЛРРШ.

Pandemic character of obesity spreading, among other things, has actualized the matters of a great number of concomitant overweight-related diseases. The problem of cholelithiasis has not become an exception. In fact, some modern studies have shown that the incidence of cholecystolithiasis in obese patients, just based on the ultrasound examination, runs to 45 % and significantly exceeds the general population value. An additional histological examination of specimens after cholecystectomy (CHE) evidences even higher degree of incidence of the above mentioned pathology in the specified patient category [1,2].

It is important that obese patients, compared to subjects with normal body weight, have significantly higher degree of complication incidence related to cholelithiasis, namely, acute cholecystitis, pancreatitis, obstructive jaundice [3]. An intensive increase in cases of metabolic surgery has also made the researchers focus their attention on the matters of gallbladder lithogenesis associated with surgically-induced weight loss [4].

While "symptomatic" cholelithiasis is an unanimously recognized indication to CHE either during a metabolic operation or as a separate intervention, the reasonability of simultaneous extraction of "asymptomatic" calculous gallbladder during the surgical treatment of obesity is nowadays the subject of guite a fierce scientific dispute [5].

The supporters of simultaneous CHE give reasons for their opinion stating that such an expansion of surgical intervention does not increase the postoperative complication rate, and at the same time it relieves the patient of the necessity to be reoperated on and to have additional associated risks in future [6]. In contrast, a number of investigators put in doubt the necessity of combining two surgical operations in such a way, placing the emphasis on further higher increase and actualization of operative and anesthetic risk, being it high any way, in patients with obesity and metabolic syndrome [7].

That is why solving this problem aimed to improvement of metabolic surgery outcomes is definitely important.

## **Aim**

The aim of the study was to explore the impact of simultaneous CHE in asymptomatic cholelithiasis on postoperative course in patients at high operative and anesthetic risk after laparoscopic sleeve gastrectomy (LSG) and to optimize the tactics of surgical treatment for patients with combination of morbid obesity and cholelithiasis.

### **Materials and methods**

A retrospective analysis of surgical treatment outcomes was carried out in 59 patients with morbid obesity who underwent LSG from 2012 to 2021 (39 patients) - the first study group, or LSG with simultaneous CHE due to asymptomatic cholelithiasis (20 patients) – the second group.

The inclusion criteria were as follows:

- morbid obesity (BMI over 40 kg/m<sup>2</sup>);
- concomitant pathology which significantly increases operative and anesthetic risk up to III-IV level according to ASA;
  - no absolute contraindications to LSG.

All the patients enrolled into the study had asymptomatic course of concomitant cholelithiasis.

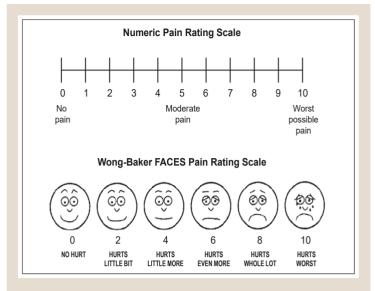


Fig. 1. Visual Analogue rating Scale of pain syndrome intensity.

A comparative analysis of operating time in the patient groups, pain syndrome level, complication rate in early postoperative period (including directly related to CHE), time of postoperative inpatient care was carried out, causes and consequences of refused simultaneous CHE in asymptomatic cholelithiasis were examined.

Surgical technique of LSG. Using electrosurgical instruments LigaSure on a 12 mm diameter calibrating tube (36 Fr), mobilization of the greater curvature and the gastric fundus was performed with electrical ligation of gastric branches of the right and left gastro-epiploic vessels, short vessels and posterior gastric artery with obligatory dissection of diaphragmatic ligament and visualization of the left crus of the diaphragm. The latter is a criterion for the mobilization adequacy in the area of the gastric fundus. The initial level of greater curvature mobilization was at the distance of 4 cm from the pylorus. Then, the calibration tube was inserted into the duodenum and its location along a lesser curvature was preserved. With the help of endoscopic linear stapler Echelon Flex of Ethicon company or Endo GIA of Medtronic company, a step-by-step vertical gastrectomy was performed on the 12 mm (36 Fr) calibrating tube at the 4 cm level from the pylorus (initial mobilization point) to the angle of Hiss providing the width of the gastric tube up to 2 cm and controlled deviation of the staple stitch line at 1 cm from the esophageal gastric junction. The resection stage of the operation was performed under the condition of moderate lateral traction of the stomach greater curvature by an assistant strictly beyond the line of its mobilization. The staple suture line was peritonized on the calibration tube with a continuous sero-serous suture. During the operation, each patient underwent a test for the tightness of the gastric tube with a solution of methylene blue through a nasogastric tube, and the operation was completed by drainage of the abdominal cavity.

The Visual Analogue Scale (VAS) is intended for evaluation of pain syndrome intensity. It represents a continuous scale with a 10 cm long horizontal line and points located on it: "No hurt", "Hurts a little bit", "Hurts a little more", "Hurts even more", "Hurts a whole lot" and "Hurts worst" (Fig. 1).

Table 1. Nature and incidence of concomitant pathology for obesity in the study groups

Concomitant disease	_	First group (n = 39)		Second group (n = 20)	
	abs.	%	abs.	%	
Arterial hypertension	25	64.1	13	65	
Ischemic heart disease	8	20.5	5	25	
Type 2 diabetes mellitus	12	30.8	5	25	
Chronic lymphovenous insufficiency of the lower extremities	9	23.1	6	30	
Sleep apnea syndrome	5	12.8	3	15	
Chronic obstructive pulmonary disease	7	17.9	4	20	
Total number of patients with concomitant diseases#	35	89.7	18	90	

<sup>#:</sup> one patient may have one or several concomitant diseases

Table 2. Comparative patient clinical characteristic

Parameters, units of measure	Study groups		Р	
	First group (n = 39)	Second group (n = 20)		
Age, years	43.6 ± 10.6	47.3 ± 8.1	0.173*	
Weight, kg	154.5 ± 25.8	142.0 ± 23.5	0.075*	
BMI, kg/m <sup>2</sup>	$51.9 \pm 7.6$	48.7 ± 7.1	0.117*	
Sex: M/F	18/21	8/12	0.653**	
Test for gastric tube leakproofness	100 %	100 %		
Complications:	2/37	3/17	0.198**	
<ul> <li>intra-abdominal bleeding</li> </ul>	1	1		
– failure	1	1		
- rhabdomyolysis	0	1		
Drain	100 %	100 %		
Antibiotic prophylaxis	100 %	100 %		
Prevention of venous thromboembolism	100 %	100 %		
Operation duration, min	127.2 ± 22.7	190.3 ± 43.9	0.0001*	
Pain level by the VAS 48 hours after operation	1.19 ± 0.60	1.32 ± 0.40	0.236*	
Postoperative hospitalization duration	7.6 ± 2.5	7.7 ± 2.8	0.983*	
Treatment outcome: recovered/fatality rate	39/0	19/1	0.16**	

<sup>\*:</sup> Student's t-test; \*\*: Pearson's chi-squared test.

The procedure of pain syndrome intensity evaluation according to the VAS was the following. Patients were asked to mark a point on the line that best corresponded to the severity of their pain intensity. The higher point meant the pain syndrome intensity value.

The statistical data processing has been carried out by the methods of descriptive statistics with the use of statistical analysis packet SPSS, version 23. The descriptive statistics was applied in order to obtain demographic data. Statistical ratios of mean values (M), as well as the mean square deviation (SD) were used in the work. In order to evaluate statistically significant difference in qualitative values of variables subjected to normal distribution law, parametric methods of evaluation in independent groups were used (Student's t-test). The comparison of frequency characteristics of the examined parameters in different groups of patients was carried out in accordance with Pearson's chi-squared test. The difference was considered statistically significant at a level of P < 0.05.

# Results

There were 33 (55.9 %) men and 26 (44.1 %) women among 59 patients enrolled into the study, the mean age of the patients enrolled into the study was 44.8 ± 9.9 years (from 21 to 68 years), the mean body mass index was  $50.9 \pm 7.5 \text{ kg/m}^2 \text{ (from } 40.0 \text{ to } 76.3 \text{ kg/m}^2\text{)}.$ 

The mean age in the first group was 43.6 ± 10.6 years (from 21 to 68 years) and it was less statistically significant than in the second study group: 47.3 ± 8.1 years (from 32 to 62 years) (t = 1.381; P = 0.173). The mean body mass value and body mass index in the first group was fixed at the level of 154.5 ± 25.8 kg (from 115 kg to 249 kg) and 51.9 ± 7.6 kg/m² (from 40.0 kg/m² to 76.3 kg/m²) respectively, with no significant difference compared to that values in the second group: 142.0 ± 23.5 kg (from 102 kg to 189 kg) and  $48.7 \pm 7.1 \text{ kg/m}^2$  (from  $40.0 \text{ kg/m}^2$  to  $61.7 \text{ kg/m}^2$ ) (P > 0.05).

No significant difference in the incidence of concomitant diseases and metabolic disturbances for obesity was detected either in the study groups (Table 1).

The level of operative and anesthetic risk according to ASA was comparable in patients from the first and the second group.

Comparative data related to patient clinical characteristics, properties of surgical intervention and postoperative period management are represented in Table 2.

The above-mentioned data evidence that under condition of similar intraoperative tactics and approaches to patient management after sleeve gastrectomy, the simultaneous CHE resulted in significant prolongation of surgical intervention time (t = 7.3; P = 0.0001). In this case, no significant difference in pain syndrome level, postoperative in-patient treatment duration was detected (t = 0.87; P = 0.236 and t = 0.021; P = 0.983) in the groups.

The postoperative complication rate in the second group was slightly higher than that in the first group, but it did not reach the statistical significance ( $\chi^2 = 1.661$ ; P = 0.198). The complications in both groups were also comparable by their nature and severity. However, an additional analysis of the obtained data evidenced that in the second study group, 2 of 3 cases of complicated postoperative course were directly related to the simultaneous CHE.

The first case of intra-abdominal bleeding occurred due to an unnoticed intraoperative marginal wounding the hepatic segment 3, probably, while changing the trocar position in the epigastrium for CHE.

The second case (rhabdomyolysis syndrome) was caused by a significant prolongation of surgical intervention time (from 160 minutes of sleeve gastrectomy to total 315 minutes) due to simultaneous intervention in a patient with morbid superobesity in the conditions of high operative and anesthetic risk.

Other complications in patients enrolled in the study (1 case of gastric tube stapler suture line failure in each group and 1 case of intra-abdominal bleeding from the stapler suture line in the second study group) were not related to CHE.

All the patients who had a complicated postoperative course were reoperated on. In the first study group, no fatal cases were registered. In the second study group, one patient died due to rhabdomyolysis syndrome with the development of acute renal failure. No significant difference in the fatality rate was detected in the study groups  $(\chi^2 = 1.984; P = 0.16).$ 

It is important to emphasize that among the first study group patients, 4 individuals had asymptomatic cholelithiasis, the simultaneous CHE was not performed to them for tactic considerations. In 2 patients – due to hepatic cirrhosis and a high risk of uncontrolled bleeding from the gallbladder bed, in 2 patients – due to a high operative and anesthetic risk (ASA IV), time prolongation of technically complex sleeve gastrectomy and predicted critical total surgical intervention time prolongation. The early postoperative period was without complications in the above-mentioned patients. During the further postoperative follow-up from one to two years, no cholelithiasis symptoms or complications were detected in any of the patients.

#### **Discussion**

With regard to a high incidence of cholelithiasis in the population of obese patients (according to modern literature data, it is from 19 % to 45 %), the issue of surgical treatment tactics in patients with such a variant of combined pathology is undoubtedly relevant.

Special attention should be paid to the patients with high operative and anesthetic risk and asymptomatic course of cholelithiasis who are planning to undergo sleeve gastrectomy [8]. The literature data concerning the reasonability of combining LSG and CHE now are not free from significant discrepancies. However, some authors make a conclusion about the safety of simultaneous surgery in the above mentioned variant based on the study results, other ones point out an increase in postoperative complication rate and terms of in-patient treatment [7].

Until 2018, we routinely combined LSG and CHE in case of asymptomatic cholelithiasis. However, two above mentioned cases of complications directly related to CHE (one of them had fatal outcome) have become a meaningful reason to review the intraoperative tactics and to carry out this retrospective treatment.

According to the results, we have not obtained honestly significant difference in the complication, severity rate and in other basic values of postoperative period course in the groups. Only significant prolongation of surgical intervention time has become an exception, that in any event is very important in metabolic surgery. In particular, according to the data of modern studies, the duration of surgical intervention over 4 hours is an independent risk factor for the development of such a severe complication as rhabdomyolysis syndrome which often becomes fatal in obese patients [9]. Moreover, the prolongation of surgery time and, as a consequence, of general anesthesia, also predetermines a more frequent development of cardio-vascular and respiratory complications [8].

Given this, we started to consider potential surgery time more carefully, paying attention to both the duration of sleeve gastrectomy stage and technical conditions of CHE. In particular, it included the limitation of "working area", especially in the conditions of visceral obesity, the ergonomics of surgeon's work in case of atypical placement of trocars, hepatic hypertrophy with structural changes peculiar to nonalcoholic steatohepatitis, fibrosis or cirrhosis, primary visual evaluation of gallbladder anatomy (intrahepatic localization, adhesive process, volume of fat tissue in the neck zone etc.). In case of a real risk of surgery time prolongation for over 3.5 hours, mainly in comorbid patients with ASA III-IV, we did not consider the simultaneous CHE option.

In the context of this discussion, long-term effects of such a tactical decision are especially interesting. According to the literature data, the indications for CHE after LSG (due to the symptoms of cholelithiasis) are in 0.9-13.0 %

of patients and they are not significantly different from the value in total population within the range of 6-25 % [1,3]. That is why the fact of simultaneous operation refusal does not probably imply any additional risks for patient, that, however, could not be neither proven nor disproven based on the study which we have carried out, given the small number of such patients. This issue definitively requires further examination.

The reference to the fact that a recurrent surgical intervention (CHE) after LSG could probably be more complicated due to the adhesive process in the abdominal cavity is one of powerful arguments of those who support simultaneous surgery [6]. Having so far no an experience of phase operations in patients with obesity and simultaneous cholelithiasis, once again we would like to mention the following. While operating 8 patients due to secondary lithogenesis with a significant weigh regression (they were not enrolled into the study), we have not observed a single case of any significant adhesive process hampering or causing prolongation of surgical intervention time in CHE. At the same time, typical position of trocars and improvement of operating conditions related to body weight loss in patients significantly simplified the operative technique and approximated it to the level of standard primary CHE. Our point of view is also confirmed by a number of literature primary sources, that generally demonstrates the necessity of further examination of the above mentioned matter [7].

In general, taking into consideration the study results and giving a summary of the above-mentioned, we can state that in case of asymptomatic course of cholelithiasis, both simultaneous CHE and the refusal of it in case of LSG in obese patients with high operative and anesthetic risk, are now acceptable options. At the same time, the variation in tactics should be well-grounded and based on understanding patient particular characteristics in metabolic surgery and on potential risk to benefit ratio of one or another decision in each individual case.

## **Conclusions**

- 1. The simultaneous cholecystectomy during laparoscopic sleeve gastrectomy in obese patients with asymptomatic cholelithiasis has not led to an increased pain syndrome level, complication incidence rate and prolonged duration of postoperative in-patient treatment, having significantly prolonged the surgical intervention time in this case.
- 2. The decision concerning the reasonability or inadvisability of simultaneous cholecystectomy in the above-mentioned patients should be based on potential risks to benefits ratio of the chosen tactical option for each individual patient. Particularly, in case of choosing operative tactics, we should take into consideration the general level and specific factors of operative and anesthetic risk in metabolic surgery, surgical intervention time, intensity of morphological changes in hepatic parenchyma, technical conditions of cholecystectomy.
- 3. A reasonable refusal of simultaneous operation is an acceptable tactical decision.

Prospects for further research are to formulate standardized management tactics for patients with obesity and asymptomatic cholelithiasis.

# Original research

Conflicts of interest: authors have no conflict of interest to declare. Конфлікт інтересів: відсутній.

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