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## **QUALITY OF LIFE IN PATIENTS AFTER KNOWN METHODS OF ANTI-REFLUX SURGERY OF HIATAL HERNIAS**

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To assess the quality of life, a retrospective study of the effectiveness of well-known methods of antireflux operations (Nissen, Toupet, Dor) was performed in 131 patients with hiatal hernias during a follow-up period of 2 to 4 years. According to the GERD-HRQL questionnaire, 21.6 % were dissatisfied with the Nissen fundoplication, Toupet – 19.0 %, and Dor – 15.0 %. According to MOS SF-36, patients' quality of life was worse after Nissen fundoplication ( $p < 0.05$ ). Complications were diagnosed more often after Nissen fundoplication (54.1 %,  $p < 0.05$ ). There was no significant difference ( $p > 0.05$ ) in the frequency of recurrences of hiatal hernias after fundoplications. According to the detection frequency, dysphagia, pylorospasm and dyspeptic disorders were diagnosed more often ( $p < 0.05$ ) after Nissen fundoplication than after Toupet and Dor. There was no significant difference in the detection frequency of esophageal strictures and reflux esophagitis ( $p > 0.05$ ).

**Key words:** hiatal hernia, laparoscopic fundoplication, results, quality of life.

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## **ЯКІСТЬ ЖИТТЯ ПАЦІЄНТІВ ПІСЛЯ ВІДОМИХ СПОСОБІВ АНТИРЕФЛЮКСНИХ ОПЕРАЦІЙ ПРИ ГРИЖАХ СТРАВОХІДНОГО ОТВОРУ ДІАФРАГМИ**

Для оцінки якості життя проведено ретроспективне дослідження ефективності відомих способів антирефлюксних операцій (Nissen, Toupet, Dor) при грижах стравохідного отвору діафрагми у 131 пацієнта в терміні спостереження від 2 до 4 років. За опитувальником GERD-HRQL незадоволені фундоплікацією за Nissen склали 21,6 %, Toupet – 19,0 %, Dor – 15,0 %. За MOS SF-36 гірша якість життя у пацієнтів після фундоплікації за Nissen ( $p < 0,05$ ). Ускладнення діагностовано частіше після фундоплікації за Nissen (54,1 %,  $p < 0,05$ ). Частота рецидивів ГСОД після фундоплікації не мала достовірної різниці ( $p > 0,05$ ). За частотою виявлення дисфагії, пілороспазм і диспепсичні розлади діагностовано частіше ( $p < 0,05$ ) після фундоплікації за Nissen, ніж після Toupet і Dor. За частотою виявлення стриктур стравоходу і рефлюкс-езофагіту достовірної різниці не визначено ( $p > 0,05$ ).

**Ключові слова:** грижа стравохідного отвору діафрагми, лапароскопічна фундоплікація, результати, якість життя.

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To date, it has been proven that hiatal hernias (HH) occupy one of the leading positions in the occurrence of gastroesophageal reflux disease [9, 13]. HH significantly worsens patients' quality of life (QoL) and is one of the main causes of such complications as erosive esophagitis, esophageal ulcer, esophageal stricture, Barrett's esophagus [14]. Violations of the anatomical features of the cardia in the presence of HH are prerequisites for gastroesophageal reflux pathology. Therefore, surgical intervention is a pathogenetically justified method of treating patients with HH [2, 3].

Prescribed in such a situation, conservative therapy alleviates the patient's condition. It is effective under constant, long-term medication, mainly proton pump inhibitors, alginates, and prokinetics. However, drug therapy alleviates the severity of symptoms but does not solve the problem itself. Failure to receive supportive treatment increases the risk of symptom recurrence, reaching 80 % within 6 months and 90–95 % within a year. From these data, a conclusion should be drawn for the necessity of mandatory prescription of permanent supportive therapy or the patient's decision on planned surgical treatment [7, 8, 12].

Currently, there are enough methods of performing surgical interventions, both open and laparoscopic [8, 12]. Nissen, Toupet and Dor fundoplications remain the main surgical treatment methods today. A positive effect of laparoscopic fundoplication was noted in 85–93 % of patients with ineffective drug therapy [1, 5].

But we should not forget about the negative consequences of surgical interventions, namely complications (both in the early and late postoperative periods) and relapses [6]. Among the complications of surgical treatment with the use of these methods, the most important are recurrence of HH (10–84 %), slippage of the fundoplication cuff (1–8 %), dysphagia (2–70 %), gas-bloat syndrome (6–46 %) and return of the heartburn (5–9 %) [1, 4].

The criteria for the effectiveness of treatment in clinical trials are physical and laboratory-instrumental indicators. However, they cannot fully characterise the patient's well-being and functioning in everyday life, that is, QoL. In modern studies, attention is often paid to the following components of QoL: the effect of symptoms on well-being and activity, the type of attitude to the disease, self-assessment of general health, the degree of physical, mental, and social well-being, restriction of social functions, decreased energy, intellectual and emotional background [1, 11].

Assessing health-related quality of life is an important factor in determining the severity of the condition and the surgical treatment tactics of patients with gastrointestinal tract pathology. Although the differentiation between objective and subjective QoL criteria remains controversial, a “questionnaire” is considered the main tool for the “quantification” of this indicator. To assess the QoL in patients with HH before surgical treatment, surveys were performed using general questionnaires, such as GERD-HRQL and SF-36 [1, 6, 10].

Improving the QoL is one of the most important tasks and criteria for evaluating the effectiveness of surgical interventions in patients with HH [1, 7]. Therefore, despite the many years of experience with laparoscopic interventions in the surgery of HH, the development of methods of minimally invasive correction of pathological changes in HH remain relevant. The main task of modern antireflux surgery in treating HH complicated by GERD is to reduce the frequency of adverse consequences after laparoscopic Nissen, Toupet, and Dor funduplications with a comparative assessment of patients' QoL.

**The purpose** of the study was to evaluate the effectiveness of surgical interventions by comparing the quality of life of patients after laparoscopic Nissen, Toupet, and Dor fundoplication in the treatment of hiatal hernias complicated by gastroesophageal reflux disease.

**Materials and methods.** A retrospective study of the effectiveness of known anti-reflux surgical interventions for HH was conducted in 2 to 4 years of observation in 131 patients operated on from 2016 to 2021. Of them, 40 (30.5 %) were male, and 91 (69.5 %) were female. The mean age of patients was  $52.75 \pm 5.39$  (from 29 to 70 years). Patients were divided into 3 groups: Group 1 – 74 (56.5 %) patients after Nissen fundoplication, Group 2 – 37 (28.2 %) patients after Toupet fundoplication, and Group 3 – 20 (15.3 %) patients after Dor fundoplication.

The GERD-HRQL questionnaire was used to subjectively assess the QoL in the long-term postoperative period. The questionnaire consists of two parts: a quantitative indicator that allows you to calculate the quality of life in points from 0 to 50 and a qualitative indicator of satisfaction with the condition: “satisfied”, “partially satisfied”, and “dissatisfied”. To assess QoL after surgical treatment, we used the Medical Outcomes Study Short Form (MOS SF-36) [1]. The MOS SF-36 questionnaire includes 36 questions that reflect the scores of 8 health scales: physical capacity, social activity, degree of limitation of physical capacity and social activity, mental health, energy or fatigue, pain, general self-assessment of health and its changes during the last year and last month.

The MOS SF-36 questionnaire quantitatively determines the QoL according to the specified scales. At the same time, the indicators range from 0 to 100 points. The higher the value of the indicator, the better the score on the selected scale.

All patients underwent an endoscopic examination, which was performed in the department of minimally invasive endoscopic interventions and instrumental diagnostics of the institute using the EVIS EXERA III OLYMPUS 190 device (with NBI mode, high resolution – HD) and SonoScape UR-500 with VIST mode, which allows you to visually assess the condition of the mucous membrane (Co) of the esophagus, stomach, and duodenum.

To identify insufficiency of the esophageal-gastric junction and HH, the patients underwent an X-ray examination of the esophagus with the use of barium sulfate (ATC code VO8BF02) on the OPERA T90 CEX device.

Statistical processing of research data was carried out using MS Excel and IBM SPSS STATISTICS 17 programs. The results are presented in the form of absolute and relative frequencies. A comparison of the data, presented in the form of a table of conjugation of traits, was carried out using Fisher's exact test (F).

The study was conducted in compliance with bioethical norms by the WMA regulations, Helsinki Declaration of the General Assembly of the World Medical Association (2013) – “Ethical principles for medical research involving human subjects”, by the current legislation of Ukraine, approved by the Bioethics Commission of the State University “Institute of Gastroenterology of the National Academy of Sciences of Ukraine”. All patients signed informed consent to participate in this study.

**Results of the study and their discussion.** QoL comparison data in examined patients using the GERD-HRQL quality of life questionnaire presented in Table 1.

Table 1

**Comparison of quality of life according to the GERD-HRQL questionnaire in patients in the long-term postoperative period**

Parameter	Group 1, Nissen (n=74)		Group 2, Toupet (n=37)		Group 3, Dor (n=20)	
QoL for GERD-HRQL, points	11.0±5.5		19.0±8.0		16.0±7.3	
Satisfaction with the condition:						
number, n/frequency, %	n	%	n	%	n	%
satisfied	34	45.9	16	43.2	9	45.0
partially satisfied	24	32.4	14	37.8	8	40.0
not satisfied	16	21.6	7	19.0	3	15.0

As can be seen from the presented data in patients of Group 1, the average QoL score according to the GERD-HRQL questionnaire was 11.0±5.5 points, in patients of Group 2 – 19.0±8.0 points, in Group 3 – 16.0±7.3 points, which was high in all groups. In terms of condition satisfaction distribution, 21.6 % of patients were dissatisfied with Nissen surgery versus 19.0 % and 15.0 % of patients after Toupet and Dor interventions, respectively (no confidence was found between the groups,  $p>0.05$ ).

When comparing QoL indicators in the long-term postoperative period of patients with the control group according to the MOS SF-36 questionnaire, it was found that in patients of all groups, QoL was lower than in the control group, affecting all levels of vital activity: physical, emotional, role, mental, social functioning (Table 2).

Table 2

**Comparative characteristics of the quality of life of patients in the long-term postoperative period according to the general questionnaire MOS SF-36, (M±m)**

Questionnaire scale	Control group (n=21)	Group 1, Nissen (n=74)	Group 2, Toupet (n=37)	Group 3, Dor (n=20)
PF	P	69.23±2.15*	78.25±3.64**	74.62±3.55***
RP	86.30±12.30	41.55±6.31*	60.47±6.22**	48.71±5.27***
BP	86.40±7.30	58.37±4.09*	66.19±5.39	63.11±4.88
GH	75.40±5.90	55.99±3.15*	68.27±3.18	66.13±3.37
VT	69.30±5.02	43.12±3.64*	56.41±2.34	65.51±2.99*****
SF	80.00±8.60	53.21±2.70*	62.95±3.11	68.17±3.03
RE	81.70±14.80	50.22±4.16*	48.27±3.99**	57.36±4.21
MH	70.20±6.30	32.89±3.05*,*****	63.61±4.16*****	55.69±3.74***
Health components				
Physical component of health	86.65±6.65	56.28±3.92*	68.29±4.60*	63.14±4.26*
Mental component of health	75.3±8.68	44.86±3.38*	57.81±3.40#	61.68±3.49#

Note: 1. \* –  $p<0.05$  – the reliability of the difference in indicators of Group 1 relative to the control group; 2. \*\* –  $p<0.05$  – reliability of the difference in indices of Group 2 relative to the control group; 3. \*\*\* –  $p<0.05$  – the reliability of the difference in indices of the Group 3 relative to the control group; 4. \*\*\*\* –  $p<0.05$  – the reliability of the difference between the indices of Groups 1 and 2 relative to the control group; 5. \*\*\*\*\* –  $p<0.05$  – the reliability of the difference between Groups 1 and 3 indices relative to the control group. 6. # –  $p<0.05$  – reliability of the difference in indices compared to Group 1.

A decrease in the number of points on the scale of physical functioning (PF) was found by 29 % ( $p<0.05$ ) in Group 1, by 21 % ( $p<0.05$ ) in Group 2, and by 24 % ( $p<0.05$ ) in Group 3, compared to the control group. In the long-term postoperative period, there was a limitation in the patient's daily activities due to physical problems, which was manifested by a decrease in the number of points on the scale of role physical functioning (RP) by 2.0 ( $p<0.05$ ) times in patients of Group 1, by 1.4 ( $p<0.05$ ) times in Group 2 and by 1.8 ( $p<0.05$ ) times in Group 3.

In group 1 patients, pain significantly limited the ability to engage in daily activities, including work at home and outside, as expressed by low scores on the Physical Pain Scale (BP). In general, this group had the lowest number of points on the scale of the general state of health (GH) compared to the control group ( $p<0.05$ ). Patients in Group 1 reported a decrease in the level of communication due to a deterioration in their physical and emotional state, as evidenced by a low number of points on the social functioning (SF) scale.

Viability (VT), as a subjective assessment by the respondent regarding feeling full of strength and energy, or, on the contrary, weakened in the last four weeks, in the postoperative period, was significantly reduced by 37.6 % ( $p<0.05$ ) in 1 group and by 18.8 % – in the 2nd group. Restrictions on their daily activities due to emotional problems were also noted by patients of Groups 1 and 2, who had a decrease in the number of RE points by 1.6 ( $p<0.05$ ) times.

The lowest values on the mental health scale (MH) were found in patients of Group 1 in comparison with the control group – by 2.2 ( $p<0.05$ ) times, with Group 2 – by 2.0 ( $p<0.05$ ) times and with Group 3 – by 1.7 ( $p<0.05$ ) times, which indicated the presence of more pronounced depressive and anxiety disorders.

The effectiveness of the treatment in patients was evaluated according to the following criteria: clinical disappearance of heartburn, belching, regurgitation, pain in the epigastrium; according to endoscopy – the absence of erosions in the lower third of the esophagus, absence of prolapse of the MM of the stomach into the esophagus; the absence of prolapse of the stomach lobe into the chest cavity, the absence of sphincter insufficiency; according to X-ray examination – the prolapse of the MM of the stomach.

When analyzing the complaints of examined patients of Groups 1, 2, and 3 in the long-term postoperative period, it was found that the most statistically significant indicators were dysphagia, bloating, belching, regurgitation, heartburn, and cough.

When analyzing the complaints of patients in Group 1, it was found that the most characteristic was dysphagia in 28 (37.8 %) patients ( $p<0.05$ ), abdominal distension in 25 (33.8 %) patients ( $p<0.05$ ), belching in 14 (18.9 %) patients ( $p<0.05$ ). Group 2 was characterized by belching in 8 (10.8 %) patients and the absence of dysphagia ( $p<0.05$ ). In Group 3, typical complaints were regurgitation and heartburn in 4 (20.0 %) patients ( $p<0.05$ ) and cough in 3 (15.0 %) patients ( $p<0.05$ ).

During endoscopic examination, reflux esophagitis was diagnosed in 16 (21.6 %) patients of Group 1, in 7 (18.9 %) patients of Group 2, and in 2 (10.0 %) patients of Group 3 (Figure 1a). Erosions of the lower third of the esophagus were diagnosed in 14 (18.9 %) patients of Group 1, in 6 (16.2 %) patients of Group 2 and 2 (10.0 %) patients of Group 3 (Fig. 1b).

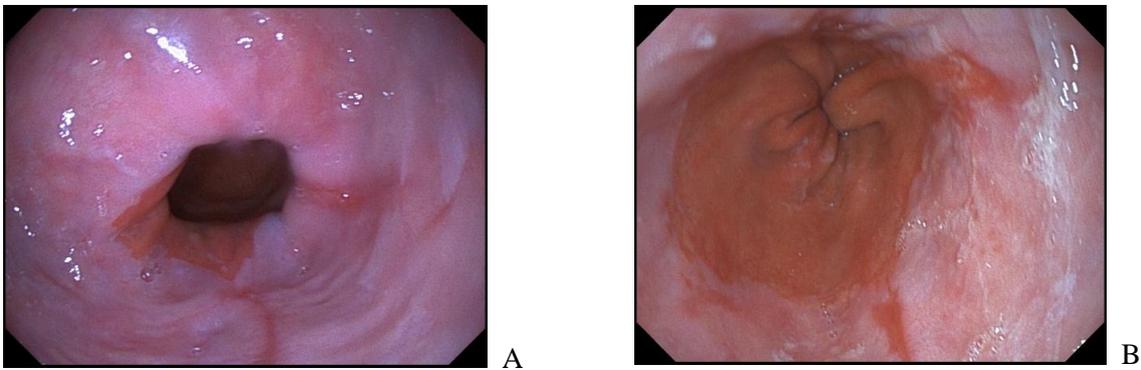


Fig. 1. Endophoto: endoscopic signs of erosive esophagitis: A – Endoscopic signs of reflux esophagitis; B – Erosion of the lower third of the esophagus.

In 1 (1.4 %) patient of Group 1, endoscopic examination revealed esophageal stricture. Signs of a “second entrance” to the stomach were found in 16 (13.5 %) patients of Group 1, 5 (13.5 %) patients of Group 2, and 2 (10.0 %) patients of Group 3 (Figure 2a). Dislocation of the fundoplication cuff was determined in 1 (1.3 %) patient of Group 1, resulting in deformation of the gastro-esophageal junction and pain syndrome (Fig. 2 b, c).

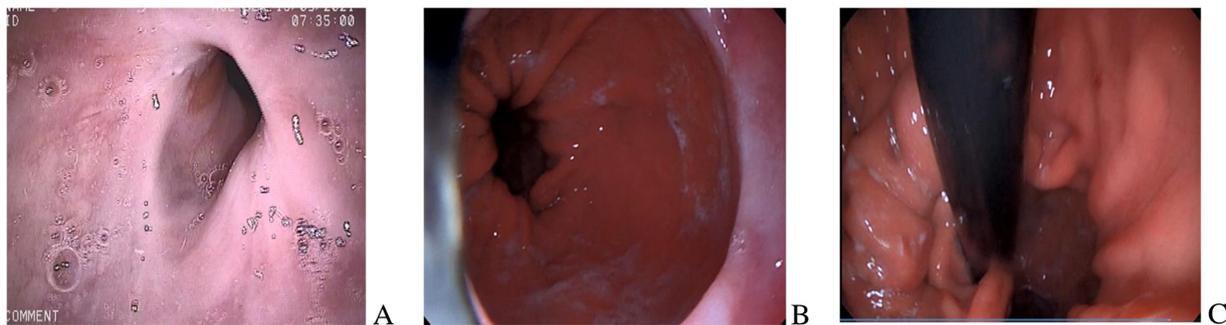
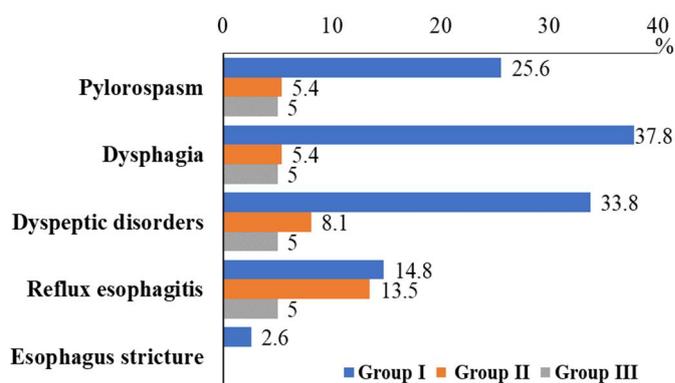


Fig. 2. Endophoto: A – Endoscopic manifestations of esophageal stricture; B – Endoscopic signs of displacement of the fundoplication cuff, examination of the gastro-esophageal junction from the side of the esophagus; C – Endoscopic signs of displacement of the fundoplication cuff, examination of the gastro-esophageal junction from the side of the stomach (the presence of a “second entrance” to the stomach)

To confirm or, on the contrary, exclude anatomical recurrence or complications, all patients underwent an X-ray examination, during which the following signs were studied: displacement of part of the stomach into the chest cavity, prolapse of the MM of the stomach into the distal part of the esophagus, presence and location of the gas bubble of the stomach, straightening of the angle of His, antiperistaltic movements of the esophagus. So, during the study relapse of HH was detected: in Group 1 – in 10 (13.5 %) patients, in Group 2 – in 5 (13.5 %) patients, and in Group 3 – in 2 (10.0 %) patients. There was no significant intergroup difference.

In the long-term postoperative period, complications were analyzed among patients of Groups 1, 2 and 3 during the follow-up period from 2 to 4 years. Complications (pylorospasm, dysphagia, dyspeptic disorders, reflux esophagitis, esophageal stricture) were diagnosed more often in patients of Group 1 (40/54.1 %,  $p < 0.05$ ) compared to patients of Group 2 (14/37.8 %) and patients of Group 3 (6/30.0 %), (Fig. 3).



When evaluating individual types of complications, it was established that dysphagia and pylorospasm were found more often in Group 1 by 7.0 ( $p < 0.05$ ) times and 5.0 ( $p < 0.05$ ) times compared to Groups 2 and 3, respectively. According to the frequency of dysphagia detection, there was a significant difference between the indicators of Groups 1 and 2 (37.8 % vs 5.4 %,  $p < 0.05$ , exact F-test) and the indicators of Groups 1 and 3 (32.4 % vs 5.0 %,  $p < 0.05$ , exact F-test). According to

the frequency of pylorospasm, a significant difference was found between the indicators of Groups 1 and 2 (25.6 % vs. 5.4 %,  $p < 0.05$ , exact F-test) and the indicators of Groups 1 and 3 (25.6 % vs. 5.0 %,  $p < 0.05$ , exact F-test).

Dyspeptic disorders were also most often observed in Group 1 – 33.8 % of cases, which exceeded the detection rate in Groups 2 and 3 by 6.7 ( $p < 0.05$ ) times and 4.1 ( $p < 0.05$ ) times, respectively. In terms of the frequency of dyspepsia detection, a significant difference was found between the indicators of Groups 1 and 2 (33.8 % vs. 8.1 %,  $p < 0.05$ , exact F-test) and the indicators of Groups 1 and 3 (33.8 % vs. 5.0 %,  $p < 0.05$ , exact F-test).

There was no significant difference in the frequency of reflux esophagitis: between the indicators of Groups 1 and 2 (14.8 % vs 13.5 %,  $p > 0.05$ ), between the indicators of Groups 1 and 3 (14.8 % vs 5.0 %,  $p > 0.05$ , exact F-test), between the indicators of groups 2 and 3 (13.5 % vs 5.0 %,  $p > 0.05$ , exact F-test).

Esophageal stricture was detected in 2 (2.6 %) patients in Group 1. There was no significant difference in the frequency of esophageal stricture detection (2.2 % vs 0 %,  $p > 0.05$ , exact F-test).

The results of clinical, laboratory, and instrumental research methods were used to evaluate the effectiveness of treatment of patients with HH: assessment of general esophageal symptoms (heartburn, belching, retrosternal/epigastric pain, dysphagia) and extra-esophageal symptoms (cough, suffocation, hoarseness); use of GERD-HRQL, SF 36 quality of life questionnaires and satisfaction with surgical intervention; X-ray examination of the esophagus, stomach with a study in the Trendelenburg position; endoscopic examination of the esophagus, stomach; daily intraesophageal pH monitoring; manometry of the esophagus [1, 13].

QoL assessment is an important factor in determining the patient's condition in the preoperative period and determining indications for surgical treatment of patients with HH [7]. Studying the QoL allows you to get a complete picture of the patient's well-being in the postoperative period and evaluate the effectiveness of treatment. Therefore, improving QoL is one of the most important tasks of surgical treatment, as well as one of the main criteria for evaluating its effectiveness [1, 9].

When evaluating QoL, we determined that the percentage of patients who are satisfied with the results of surgical intervention according to GERD-HRQL after Nissen fundoplication was 45.9 % of patients ( $11.0 \pm 5.5$  points), after Toupet fundoplication – 43.2 % ( $19.0 \pm 8.0$  points), after Dor fundoplication – 45.0 % ( $16.0 \pm 7.3$  points). Compared with Rettura F. et al. (2021) data, GERD-HRQL ranged from 2.9 % to 85.3 % after Nissen fundoplication and depended on the number of recurrences and complications. The mean score 1 year after surgery was 7.0. It was also noted that patient satisfaction and QoL after surgery improved significantly [9].

According to Su F. et al. (2016), the GERD-HRQL score decreased after the Dor fundoplication ( $7.18 \pm 1.33$ ) in comparison with the values after the Nissen fundoplication ( $10.94 \pm 2.20$ ) and after the Toupet fundoplication ( $10.91 \pm 2.02$ ), but without a significant difference [10].

When assessing the quality of life using the MOS SF-36 questionnaire, according to Aiolfi A. et al. (2022), patients after Toupet fundoplication had significantly better results of indicators of the mental component of health compared to the physical ( $p < 0.05$ ) [2]. At that time, Liu DS et al. (2018) reported that according to the SF-36 questionnaire, all patients after fundoplications had significantly lower indicators of the physical component of health relative to mental health and a delay in the improvement of health status ( $p < 0.001$ ) [6].

Thus, laparoscopic antireflux operations are widely used. Still, the percentage of unsatisfactory results remains high, which does not change patients' quality of life, and in a significant percentage of cases, worsens it. In turn, the unsatisfactory results of known antireflux interventions provide a basis for the development of new methods of surgical treatment of HH aimed at eliminating the hernia, preserving the anatomical relationship between the diaphragm and the gastro-esophageal junction zone, and ensuring reliable restoration of the physiological cardia.

### Conclusions

1. The GERD-HRQL questionnaire showed that 21.6 % of patients (11.0±5.5 points) were dissatisfied with surgery after Nissen fundoplication, compared to 19.0 % (19.0±8.0 points) of Toupet and 15.0 % (16.0±7.3 points) of Dor. According to the scales of the MOS SF-36 questionnaire, it was established that patients after fundoplication had the worst quality of life according to Nissen indicators of both physical ( $p<0.05$ ) and mental ( $p<0.05$ ) components of health, while in patients after fundoplications according to Toupet and Dor – only according to the physical component of health ( $p<0.05$ ).

2. In the long-term postoperative period, complications were diagnosed more often in patients with Nissen fundoplication (54.1 %,  $p<0.05$ ) in comparison with the frequency of complications after Toupet fundoplication (37.8 %) and after Dor fundoplication (30, 0 %). Recurrences of HH were found in 13.5 % of patients after Nissen fundoplication, in 13.5 % after Toupet fundoplication, and in 10.0 % after Dor fundoplication ( $p>0.05$ ).

3. According to the frequency of detection, dysphagia, pylorospasm and dyspeptic disorders were diagnosed more often after Nissen fundoplication than after Toupet fundoplications (37.8 % vs 5.4 %,  $p<0.05$ , exact F-test; 25.6 % vs 5.4 %,  $p<0.05$ , exact F-test; 33.8 % vs 8.1 %,  $p<0.05$ , exact F-test) and Dor (32.4 % vs 5.0 %,  $p<0.05$ , exact F-test; 25.6 % vs 5.0 %,  $p<0.05$ , exact F-test; 33.8 % vs 5.0 %,  $p<0.05$ , exact F-test) respectively. There was no significant difference in the detection frequency of esophageal strictures and reflux esophagitis ( $p>0.05$ ).

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