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Russian Consensus: Standardization of Indications for Surgical Treatment of GERD

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Aim: to present the results of an Expert Consensus on standardization of indications for surgical treatment of gastroesophageal reflux disease (GERD).

Materials and methods. The issues of standardization of indications for surgical treatment of GERD were discussed by 39 experts – leading gastroenterologists and surgeons from 7 cities of Russia, representing 17 institutions. The list of questions for discussion was formed by the initiative group and sent to the experts. The experts reviewed recent literature, including existing clinical guidelines and consensuses, assessed the evidence base and suggested statements for voting based on the analysis of relevant provisions of foreign consensuses, high-level scientific publications, which set out information obtained in the course of studies that meet the criteria of evidence-based medicine, positions on this issue in the Russian Federation, and suggested statements for voting. Delphi method was used to reach the consensus.

Results. GERD is the most common benign esophageal disorder. Surgery is considered one of the treatment methods for GERD. In real clinical practice, selection of patients who may benefit from surgery is challenging. The results of surgical and conservative treatment of GERD are comparable. Surgical treatment should be performed in a specialized hospital only after a joint examination with a gastroenterologist confirming the diagnosis of GERD. An appropriate volume of preoperative diagnostic workup, matters related to surgical interventions in case of incomplete response to proton pump inhibitors (PPIs) and when extraesophageal manifestations of GERD are present were discussed. The consensus reviews the indications, contraindications and possible results of antireflux operations in patients with GERD. The value of endoscopy, esophageal manometry, pH monitoring/pH-impedance monitoring and X-ray polypositional examination of the upper gastrointestinal tract as a preoperative examination of the patient is analysed.

Conclusions. The experts reached the consensus on 20 statements on standardization of indications for surgical treatment of GERD.

Keywords: gastroesophageal reflux disease, GERD, surgical treatment, esophageal manometry, esophageal pH monitoring, pH-impedance monitoring

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Российский консенсус: стандартизация показаний к хирургическому лечению ГЭРБ

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Цель: представить результаты соглашения экспертов по стандартизации показаний к хирургическому лечению гастроэзофагеальной рефлюксной болезни (ГЭРБ).
Материалы и методы. Вопросы стандартизации показаний к хирургическому лечению ГЭРБ были обсуждены 39 экспертами из числа ведущих гастроэнтерологов и хирургов из 7 городов России, представляющих 17 учреждений. Список вопросов для обсуждения был сформирован инициативной группой и разослан экспертам. Эксперты подготовили литературные справки на основе анализа соответствующих положений зарубежных консенсусов, публикаций высокого научного уровня, в которых изложены сведения, полученные в ходе исследований, соответствующих критериям медицины, основанной на доказательствах, позиции по данному вопросу в Российской Федерации, предложили положения для голосования. Голосование осуществлялось по Дельфийской системе.
Результаты. ГЭРБ — наиболее распространенное доброкачественное заболевание пищевода. Хирургическое лечение ГЭРБ рассматривается как один из методов лечения. Отбор пациентов для оперативного

вмешательства в реальной клинической практике представляет сложную задачу. Результаты хирургического и консервативного лечения ГЭРБ сопоставимы. Хирургическое лечение должно проводиться в специализированном стационаре только после совместного с гастроэнтерологом обследования, подтвердившего диагноз ГЭРБ. Обсуждается вопрос о месте хирургического лечения в случае неполного ответа на терапию ингибиторами протонной помпы, при наличии внепищеводных проявлений заболевания. Рассмотрены показания, противопоказания и возможные результаты антирефлюксной хирургии у пациентов с ГЭРБ. Проанализировано значение эзофагогастродуоденоскопии, манометрии пищевода, pH-мониторинга/pH-импеданс-мониторинга и рентгенологического полипозиционного исследования верхних отделов желудочно-кишечного тракта как предоперационного обследования пациента.

Выводы. Экспертами достигнуто согласие по 20 положениям по стандартизации показаний к хирургическому лечению ГЭРБ, представленным в настоящей публикации.

Ключевые слова: гастроэзофагеальная рефлюксная болезнь, ГЭРБ, хирургическое лечение, манометрия пищевода, pH-мониторинг пищевода, pH-импеданс-мониторинг

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Surgery is one of the treatment options for gastroesophageal reflux disease (GERD), together with lifestyle measures, modification of risk factors and conservative therapy. In real clinical practice, selection of patients for surgical intervention is challenging. In Russian clinical guidelines [1], a relatively small chapter is devoted to the issues of anti-reflux surgery focused on the indications in case of disease complications (repeated hemorrhage, peptic esophageal strictures, Barrett's esophagus with high-grade epithelial dysplasia proved by two morphologists, and frequent aspiration pneumonia), as well as in cases when a patient with GERD cannot be treated conservatively for any reason. Particular problems associated with a decision for surgical treatment are related to the cases of incomplete response to proton pump inhibitors (PPIs) therapy with persistent symptoms, extraesophageal manifestations of the disease, as well as the volume of preoperative diagnostic workup. These and many other issues were discussed by thirty-nine leading gastroenterologists and surgeons from seven cities of Russia, representing seventeen institutions. The list of matters for discussion was compiled by the initiative group and sent to the experts. The experts conducted a sophisticated literature review based on scrutinizing study and in-depth analysis of the relevant proceedings of the foreign consensuses and the top-ranking scientific publications, where presented information obtained from the studies met the criteria of evidence-based medicine and practical approaches eligible for the Russian Federation and suggested the statements for voting.

The Consensus statements were drawn up into a final document and circulated to all Consensus experts to justify their position by electronic voting. E-voting was carried out using the Delphi method with a Likert scale, where: "1 point" corresponded to "strongly agree" (A+); "2 points" — "agree with minor reservation" (A); "3 points" — "agree with major reservation" (A–); "4 points" — "disagree with major reservation" (D–); "5 points" — "disagree with minor reservation" (D); "6 points" — "strongly disagree" (D+). Consensus was considered to be reached if over 80 % of experts agreed with the statement (A+, A, A–) [2].

Consensus issues and statements

1. Is it necessary to conduct an 8-week course of conservative therapy prior to determination of the indications for anti-reflux surgery?

Prior to determination of the indications for anti-reflux surgery, an 8-week course of conservative therapy in combination with lifestyle modification is required.

Grade of recommendation — C;
level of evidence — 2.

Consensus level: "A+" — 79.5 %; "A" — 15.4 %; "A–" — 2.6 %; "D–" — 0 %; "D" — 2.6 %; "D+" — 0 %.

Most of the international and local guidelines do not require conservative therapy prior to determination of the indications for surgical

treatment of GERD due to the lack of relevant randomized clinical trials [1, 3–5].

Meanwhile, the use of PPIs prior to fundoplication is quite logical and justified due to the following reasons:

– achieving the control over the symptoms and healing of esophagitis, especially its severe forms, improves the perioperative prognosis, including the stabilization of the patient's psychological status;

– no response to PPIs therapy for 8 weeks, especially with extraesophageal manifestations of GERD, is associated with low efficacy of anti-reflux surgery.

2. What is the management strategy for patients with persistent typical symptoms of GERD and/or reflux esophagitis after an 8-week course of a standard dose PPIs therapy?

Persistence of typical symptoms of GERD and/or reflux esophagitis after 8 weeks of treatment with a standard dose of PPIs requires additional examination by a gastroenterologist.

Grade of recommendation – B;
level of evidence – 2.

Consensus level: "A+" – 82.1 %; "A" – 12.8 %; "A–" – 2.6 %; "D–" – 0 %; "D" – 2.6 %; "D+" – 0 %.

About 40 % of patients with symptoms of GERD have incomplete or no response to PPIs therapy, which may be caused either by the presence of another etiology of reflux-like symptoms (achalasia, eosinophilic esophagitis, functional heartburn, etc.), or in case of proven GERD, by inadequate PPI dose, low compliance, specific metabolism of PPIs in a subject ("rapid metabolizer"), presence of non-acid reflux, etc. [1, 3–5].

The gold standard for GERD diagnosis in patients with persistent typical symptoms and/or reflux esophagitis after an 8-week course of a standard dose of PPI therapy is 24-h esophageal pH monitoring (pH-impedance monitoring). Esophageal pH-impedance monitoring on PPIs treatment detects true refractoriness to PPI therapy (acid exposure time (AET, time with pH < 4) > 4 %), as well as non-acidic reflux (alkaline and weakly acidic) [5].

Treatment options for PPI-refractory GERD include switching to a less dependent on isoenzyme CYP2C19 cytochrome P450 representative of the same class (rabeprazole, esomeprazole) [6], and, if necessary, administration of the higher doses of the same PPI and the use of epithelium-protective therapy. Potassium channel blocker therapy may be promising for refractory GERD, but these drugs are currently not available in the Russian Federation.

Surgical treatment for GERD is most effective in cases of pathological reflux proven by the objective methods, exclusion of achalasia and other motor disorders of the esophagus [7]. Presence of persistent symptoms despite PPI therapy is considered as a predictor of an unsuccessful surgical outcome [8].

3. May a patient with typical symptoms of GERD (heartburn and/or regurgitation) with no preoperative diagnostic workup (endoscopy, esophageal manometry, pH monitoring/pH-impedance monitoring) be considered a candidate for anti-reflux surgery?

A patient with typical symptoms of GERD (heartburn and/or regurgitation) may be considered as a candidate for anti-reflux surgery only when the results of preoperative diagnostic procedures proved GERD (EGD, esophageal manometry, pH monitoring/pH-impedance monitoring).

Grade of recommendation – A;
level of evidence – 2.

Consensus level: "A+" – 79.5 %; "A" – 2.8 %; "A–" – 2.6 %; "D–" – 0 %; "D" – 2.6 %; "D+" – 2.6 %.

Typical GERD symptoms (heartburn and regurgitation) are not specific and may be present in other esophageal diseases (achalasia, eosinophilic esophagitis, functional heartburn, etc.). EGD is an objective method for diagnosis of esophageal organic disorders [9]. Pathomorphological examination of the esophageal mucosa biopsies allows excluding complicated course of the disease (Barrett's esophagus), and esophagitis of other etiologies (eosinophilic and/or infectious esophagitis, etc.). Beyond that, eosinophilic esophagitis and GERD are not mutually exclusive and can coexist [10].

There have been conflicting opinions on the issue of PPI discontinuation before the investigation. The American College of Gastroenterology and the authors of the updated Lyon Consensus 2.0 recommend to perform endoscopy 2 to 4 weeks after PPI discontinuation [11]. In contrast, ICARUS guidelines [12] suppose that PPI discontinuation is unreasonable in patients undergoing preoperative evaluation. PPI discontinuation is also impractical in patients with a previously proven GERD

(Barrett's esophagus, esophageal stricture, or erosive esophagitis B, C, and D) [11].

pH-impedance monitoring can help to prove GERD in patients with no significant esophageal mucosa breaks (erosive esophagitis stages B, C and D, Barrett's esophagus, peptic esophageal stricture). Acid exposure time in the distal esophagus > 6 % off PPI therapy or > 4 % on PPI serve a diagnostic criterion for GERD [11]. Moreover, pH-impedance monitoring reveals the association of symptoms with reflux and excludes functional esophageal disorders, in which anti-reflux surgery has no satisfactory outcomes [11, 12].

Esophageal manometry is an optional diagnostic test for the diagnosis of GERD. However, it helps to exclude esophageal motility disorders (achalasia, diffuse esophageal spasm, hypercontractile esophagus) and is mandatory for preoperative examination, according to the most international guidelines [9, 12].

4. May a patient with extraesophageal manifestations of GERD (chronic cough, laryngitis, bronchial asthma) and no preoperative examination (endoscopy, manometry, pH-impedance monitoring) be considered a candidate for anti-reflux surgery?

A patient with extraesophageal manifestations of GERD can be considered as a candidate for anti-reflux surgery only after preoperative examination (endoscopy, manometry, pH-impedance monitoring), that proved association of extraesophageal manifestations with gastroesophageal reflux according to pH-impedance results.

Grade of recommendation — C;
level of evidence — 2.

Consensus level: "A+" — 89.7 %; "A" — 7.7 %; "A–" — 0 %; "D–" — 0 %; "D" — 0 %; "D+" — 2.6 %.

Interaction between chronic cough, bronchial asthma, laryngopharyngeal disorders and GERD is complex [13, 14]. There is no established diagnostic gold standard for laryngopharyngeal and pulmonary manifestations of GERD. Available methods (EGD, laryngoscopy, bronchoscopy, pH-impedance monitoring, esophageal manometry, etc.) are of low sensitivity and specificity [15]. The presence of extraesophageal manifestations in the lack of typical GERD symptoms has a low likelihood. The outcomes of antireflux therapy for extraesophageal symptoms are controversial [16, 17], and the success rates range from 15 to 95 %. Anti-reflux surgery shows low efficacy in patients with isolated extraesophageal symptoms. The predictors for a favorable response to surgical treatment are the presence of typical reflux symptoms, prior response to PPI treatment, and confirmed acid reflux (AET > 6 %) by pH monitoring [18–21].

In extraesophageal manifestations of GERD, anti-reflux surgery should be considered if pathological reflux is proved by pH-impedance monitoring and esophageal motility disorders are excluded based on esophageal manometry data.

5. May a patient with typical GERD symptoms (heartburn and/or regurgitation) with a good response to PPIs be considered a candidate for anti-reflux surgery?

A patient with typical GERD symptoms (heartburn and/or regurgitation) who responds to PPIs therapy may be considered as a candidate for anti-reflux surgery. The diagnosis of GERD should be confirmed by pH monitoring/pH-impedance monitoring without PPI therapy. Patients with typical symptoms and good response to PPI therapy demonstrate the best surgical outcome.

Grade of recommendation — B;
level of evidence — 2.

Consensus level: "A+" — 61.5 %; "A" — 17.9 %; "A–" — 7.7 %; "D–" — 7.7 %; "D" — 5.1 %; "D+" — 0 %.

PPIs are the gold standard treatment for GERD [22]. According to a meta-analysis of 59 studies (n = 26,885), PPI therapy for 4 weeks resulted in complete relief of heartburn in patients with both erosive (OR = 0.72; 95% CI: 0.69–0.74) and non-erosive forms of the disease (OR = 0.49; 95% CI: 0.44–0.55) [23]. According to these data, the best candidates for anti-reflux surgery should be patients with GERD who cannot receive conservative therapy for any reason, as well as subjects with casuistically rare adverse events on antisecretory therapy [24]. In this case, GERD should be proved by pH monitoring/pH-impedance monitoring performed off PPIs therapy. The best response to surgery is observed in patients with typical GERD symptoms (heartburn and/or regurgitation) and a good response to PPIs therapy, which should be taken into account when surgical intervention is considered [25].

6. May a patient with erosive esophagitis (grade A) according to the Los Angeles (LA) classification considered as

a candidate for anti-reflux surgery with no preoperative examinations (manometry, pH monitoring/pH-impedance monitoring)?

A patient with reflux esophagitis (grade A) according to the LA classification may be considered as a candidate for anti-reflux surgery only after preoperative examinations (manometry, pH monitoring/pH-impedance monitoring) proved GERD.

Grade of recommendation — B;
level of evidence — 2.

Consensus level: "A+" — 66.7 %; "A" — 20.5 %; "A—" — 10.3 %; "D—" — 0 %; "D" — 2.6 %; "D+" — 0 %.

Identification of esophageal mucosal breaks on endoscopy allows suspecting GERD, but it is not always a reliable criterion for the diagnosis. Recent studies have demonstrated that single and small esophageal erosions (grade A according to LA classification) can be detected in 5–7.5 % of cases in patients without any clinical manifestations and any signs of pathological reflux [26], while more severe grades (B, C, D) of esophagitis in healthy individuals are almost never found [27].

At the same time, some patients with erosive esophagitis may have clinical manifestations caused by functional esophageal disorders, therefore it is reasonable to conduct functional examination (pH monitoring, pH-impedance monitoring, manometry) prior to anti-reflux surgery to verify the presence of pathological gastroesophageal reflux and exclude other causes underlying the symptoms [11]. These methods are essential in refractory GERD and when extraesophageal manifestations of the disease are present [28–32].

High-resolution esophageal manometry is not the primary diagnostic test for GERD but may be useful when no convincing features of the disease are detected on endoscopy [33–35]. According to the updated Lyon Consensus 2.0, such criteria include detection of a hiatal hernia (HH), hypotensive lower esophageal sphincter, ineffective esophageal motility, and absent contractility [11].

7. May a patient with erosive esophagitis of grades B, C and D according to LA classification be considered as a candidate for anti-reflux surgery with no preoperative examinations (manometry, pH monitoring/pH-impedance monitoring)?

Reflux esophagitis of grades B, C and D according to LA classification is a reliable criterion for GERD. In such a case, anti-reflux surgery may be considered, as well as conservative therapy, after esophageal manometry.

Grade of recommendation — B;
level of evidence — 2.

Consensus level: "A+" — 76.9 %; "A" — 15.4 %; "A—" — 5.1 %; "D—" — 0 %; "D" — 2.6 %; "D+" — 0 %.

According to the updated Lyon Consensus 2.0 esophagitis of grades B, C or D serve as conclusive evidence of GERD and pH-impedance monitoring is not required [11]. However, when anti-reflux surgery is considered, additional examinations (manometry) are reasonable.

8. May a patient with peptic esophageal stricture complicating GERD be considered as a candidate for anti-reflux surgery with no preoperative examinations (manometry, pH monitoring/pH-impedance monitoring)?

A patient with peptic esophageal stricture complicating GERD is considered as a candidate for anti-reflux surgery after esophageal manometry.

Grade of recommendation — B;
level of evidence — 2.

Consensus level: "A+" — 69.2 %; "A" — 25.6 %; "A—" — 2.6 %; "D—" — 0 %; "D" — 2.6 %; "D+" — 0 %.

Esophageal stricture is an esophageal manifestation of GERD [1, 9, 11, 12]. National clinical guidelines [1], recommend endoscopic examination with biopsy for patients with complications of GERD (strictures) followed by histological examination to exclude eosinophilic esophagitis, Barrett's esophagus and adenocarcinoma.

According to the Lyon Consensus, in patients with proved GERD (including peptic stricture) and persistent symptoms on PPIs, reflux monitoring should be performed on PPI treatment [11]. Manometry helps to assess lower esophageal sphincter pressure and detect esophageal motility disorders, which has high prognostic value and impacts subsequent treatment. However, pH-impedance monitoring and esophageal manometry may be technically challenging in the presence of dense strictures [36].

9. May a patient with Barrett's esophagus without dysplasia be considered as a candidate for anti-reflux surgery with no preoperative examination (manometry, pH monitoring/pH-impedance monitoring)?

Barrett's esophagus is a reliable criterion for GERD. A patient with Barrett's esophagus without dysplasia, confirmed by an experienced morphologist along with the conservative therapy, may be offered anti-reflux surgery after esophageal manometry.

Grade of recommendation — B;
level of evidence — 3.

Consensus level: "A+" — 74.4 %; "A" — 23.1 %; "A–" — 0 %; "D–" — 0 %; "D" — 2.6 %; "D+" — 0 %.

According to the Russian clinical guidelines for Barrett's esophagus, anti-reflux surgery does not shorten the length of the Barrett's esophagus segment, does not reduce the risk of adenocarcinoma, and in most cases does not lead to the complete discontinuation of antisecretory therapy [37].

Clinical guidelines on GERD diagnosis and treatment consider complicated course of GERD (Barrett's esophagus with high-grade epithelial dysplasia proved by two morphologists) as an indication for anti-reflux surgery [1].

10. Which method of reflux monitoring is preferable prior to anti-reflux surgery?

The pH-impedance monitoring is more accurate than pH monitoring for GERD diagnosis and for differential diagnosis between GERD and functional heartburn, therefore the pH-impedance monitoring test is preferable in preoperative examination if available.

Grade of recommendation — B;
level of evidence — 3.

Consensus level: "A+" — 84.6 %; "A" — 15.4 %; "A–" — 0 %; "D–" — 0 %; "D" — 0 %; "D+" — 0 %.

In patients with GERD pH monitoring/pH-impedance monitoring are recommended prior to surgical treatment [1].

The data obtained during pH monitoring (acid exposure time in the distal esophagus, a number of GERs, association of symptoms (heartburn)) with gastroesophageal reflux, help to prove or exclude GERD [38].

Patients with heartburn and/or regurgitation, chest pain, sore throat, or respiratory manifestations (cough, hoarseness, tickle in the throat, etc.) with no response to PPI should undergo esophageal pH-impedance monitoring, not just pH monitoring, to confirm abnormal acid exposure, presence of weak-acid or non-acid refluxes, their proximal extent, and/or association of symptoms and refluxes prior to anti-reflux surgery.

If a patient poorly tolerates trans-nasal catheter, then capsule pH-metry may be an option; in this case, 96-hour monitoring test is more informative (currently, it is unavailable in Russia) [11].

11. What is the role of esophageal manometry in preoperative workup?

Esophageal manometry helps to exclude major disorders of peristalsis, accurately locate lower esophageal sphincter and assess its function. Esophageal manometry allows precise positioning of the catheter for pH- or pH-impedance monitoring.

Grade of recommendation — C;
level of evidence — 3.

Consensus level: "A+" — 84.6 %; "A" — 10.3 %; "A–" — 2.6 %; "D–" — 2.6 %, "D" — 0 %; "D+" — 0 %.

High-resolution esophageal manometry is recommended for all patients prior to anti-reflux surgery. This test, especially combined with impedance measurement (high-resolution esophageal impedance-manometry) plays a crucial role in exclusion of GERD-mimicking conditions, such as rumination syndrome, supragastric belch etc. [39].

Manometry demonstrates higher sensitivity, specificity, and both positive and negative predictive values compared to X-ray examination and endoscopy in diagnosis of axial HH [40].

Hypercontractile esophagus, esophageal spasm (primary, non-GERD-related), esophagogastric junction outflow obstruction, and achalasia confirmed by high-resolution esophageal manometry are contraindications to anti-reflux surgical interventions. For patients with absent peristalsis, which is a relative contraindication for surgical treatment, multiple rapid swallows test is recommended to evaluate the esophageal contraction reserve [41–43].

Moreover, esophageal manometry provides valuable guidance in selecting between partial and complete fundoplication to minimize the risk of postoperative dysphagia. For patients with absent peristalsis, ineffective esophageal motility, or absent contraction reserve, 270-degrees partial fundoplication by Toupet is preferable to 360-degree complete fundoplication by Nissen [44–46].

Esophageal manometry facilitates accurate location of the upper border of lower esophageal sphincter (LES), which is critical for appropriate esophageal pH probe placement and enhancing the diagnostic accuracy and reliability of pH and pH-impedance monitoring.

12. Is classical multipositional radiographic evaluation of the upper gastrointestinal tract mandatory before anti-reflux surgery?

Classical multipositional radiographic evaluation of the upper gastrointestinal tract is deemed essential before surgery, as it enables the identification and classification of hiatal hernias, registration of reflux, detection of esophageal motility disorders, and assessment of pyloric and duodenal patency.

Grade of recommendation — C;
level of evidence — 4.

Consensus level: "A+" — 89.7 %; "A" — 10.3 %; "A–" — 0 %; "D–" — 0 %; "D" — 0 %; "D+" — 0 %.

Classical multipositional radiographic evaluation of the upper gastrointestinal tract is considered mandatory prior to surgery, as it remains one of the most crucial methods for diagnosing HH [47, 48]. This imaging technique allows for the detection and characterization of HH, including its type, size, and degree of fixation [49], as well as the identification of gastric volvulus, measurement of esophageal hiatus width [50–54], evaluation of esophageal strictures, assessment of esophageal shortening, and identification of diverticula. Additionally, it facilitates the evaluation of pyloric and duodenal patency, which is particularly critical in the postoperative period and before reoperation [55–58].

13. Can computed tomography data replace classical multipositional radiographic evaluation of the upper gastrointestinal tract?

Computed tomography cannot replace classical multipositional radiographic evaluation of the upper gastrointestinal tract.

Grade of recommendation — C;
level of evidence — 4.

Consensus level: "A+" — 84.6 %; "A" — 10.3 %; "A–" — 0 %; "D–" — 0 %; "D" — 0 %; "D+" — 5.1 %.

Compared to classical multipositional radiographic evaluation, computed tomography (CT) has limitations in identifying HH, determining their true size, and classifying their type, primarily because it is conducted exclusively in the supine horizontal position. Additionally, CT does not allow for the assessment of esophageal shortening, the presence of pathological reflux, or motility disorders in the upper gastrointestinal tract. In cases of small HH, CT may lack diagnostic value.

CT is primarily indicated for the differential diagnosis of cardioesophageal neoplasms and HH, as well as assessing the extent of tumor-like lesions and their spread to adjacent anatomical structures [59–61]. Furthermore, CT's cross-sectional imaging capabilities provide detailed visualization of structures like the esophageal hiatus and diaphragmatic crura, offering essential insights for a more precise assessment of their condition [62], and enabling the identification of other organs within the hernial sac, such as the small or large intestine, omentum, pancreas, spleen, or the left lobe of the liver [51, 52, 62].

14. Is anti-reflux surgery an effective approach to prevent the progression of Barrett's esophagus to adenocarcinoma?

Surgical management of GERD does not reduce the incidence of adenocarcinoma and should not be considered an antineoplastic approach for patients with Barrett's esophagus.

Grade of recommendation — B;
level of evidence — 3.

Consensus level: "A+" — 61.5 %; "A" — 23.1 %; "A–" — 2.6 %; "D–" — 5.1 %; "D" — 2.6 %; "D+" — 5.1 %.

Evidence from prior studies suggests that while anti-reflux surgery reduces the risk of progression from columnar cell metaplasia to esophageal adenocarcinoma, it does not completely eliminate this risk, which remains significantly higher than in the general population [63]. As a result, anti-reflux surgery cannot be regarded as a definitive treatment for Barrett's esophagus in GERD patients. Ongoing monitoring and sustained PPI therapy are essential for patients with columnar cell metaplasia who have undergone anti-reflux surgery [63].

15. What is the appropriate sequence of treatment methods for Barrett's esophagus requiring both endoscopic and surgical interventions?

When both endoscopic and surgical interventions are indicated for Barrett's esophagus, the endoscopic intervention should be performed prior to anti-reflux surgery.

Grade of recommendation — C;
level of evidence — 5.

Consensus level: "A+" — 69.2 %; "A" — 15.4 %; "A–" — 2.6 %; "D–" — 7.7 %; "D" — 2.6 %; "D+" — 2.6 %.

Since anti-reflux surgery is not regarded as the standard treatment for patients with Barrett's esophagus, this topic is seldom addressed in specialized literature. The authors of this consensus concluded that surgical intervention modifies the anatomy of the esophagogastric junction, significantly compromising the visualization and accessibility of the metaplastic mucosal segment during endoscopic procedures, which may result in reduced treatment efficacy or an increased need for staged interventions.

16. Is anti-reflux surgery indicated for patients with a sliding hiatal hernia?

A sliding hiatal hernia alone does not constitute an indication for anti-reflux surgery.

Grade of recommendation — B;
level of evidence — 3.

Consensus level: "A+" — 92.3 %; "A" — 5.1 %; "A–" — 0 %; "D–" — 0 %; "D" — 2.6 %; "D+" — 0 %.

Surgical reconstruction or anti-reflux surgery is not required for a sliding HH that is not associated with GERD symptoms [64, 65]. The presence of GERD, rather than the hernia itself, serves as the indication for anti-reflux surgery, but if surgery is indicated, hernia repair should be included as part of the procedure [66].

17. Does diffuse esophageal spasm affect the treatment approach in patients planned for anti-reflux surgery?

Anti-reflux surgery is not advised for patients with diffuse esophageal spasm.

Grade of recommendation — B;
level of evidence — 4.

Consensus level: "A+" — 69.2 %; "A" — 17.9 %; "A–" — 5.1 %; "D–" — 0 %; "D" — 7.7 %; "D+" — 0 %.

Diffuse esophageal spasm (or distal esophageal spasm) is defined as the presence of ≥ 20 % premature contractions (distal latency < 4.5 seconds), in the setting of a distal contractile integral > 450 mmHg × s × cm in patients with normal integrated relaxation pressure, based on high-resolution esophageal manometry data [42]. According to the International Consensus regarding preoperative examinations and clinical characteristics assessment to select adult patients for anti-reflux surgery, 64 % of experts agree that such patients are not suitable for surgical intervention [12].

18. Does ineffective esophageal motility affect the approach to treatment?

Depending on its severity, ineffective esophageal motility may present significant challenges to anti-reflux surgery, with the criteria for selecting the type of fundoplication remaining uncertain.

Grade of recommendation — B;
level of evidence — 4.

Consensus level: "A+" — 74.4 %; "A" — 17.9 %; "A–" — 2.6 %; "D–" — 5.1 %; "D" — 0 %; "D+" — 0 %.

Effective esophageal clearance relies on peristaltic (propulsive) contractions, while non-peristaltic (non-propulsive) contractions are ineffective, resulting in prolonged exposure of esophageal mucosa to acidic gastric content and subsequent mucosal injury [67]. Studies have established a relationship between acid exposure and disturbed esophageal motility [68].

The widely accepted perspective today is that impaired esophageal peristalsis plays a primary role in the pathogenesis of GERD [69]. Accordingly, some authors recommend partial fundoplication for patients with ineffective esophageal motility due to the high risk of postoperative dysphagia.

Ineffective esophageal motility and GERD may be secondary to systemic diseases affecting esophageal innervation, such as scleroderma and diabetes mellitus, with progressive dysphagia after anti-reflux surgery potentially reflecting the progression of these underlying conditions [70].

19. In carefully selected patients following thorough evaluation, are the outcomes of surgical treatment for GERD equivalent to those of medical therapy?

Surgical and conservative treatments for GERD demonstrate comparable effectiveness. Surgical intervention should be performed in specialized centers and only after a comprehensive evaluation with a gastroenterologist to confirm the GERD diagnosis.

Grade of recommendation — A;
level of evidence — 2.

Consensus level: "A+" — 82.1 %; "A" — 12.8 %; "A–" — 5.1 %; "D–" — 0 %; "D" — 0 %; "D+" — 0 %.

Current clinical guidelines for the diagnosis and treatment of GERD recommend surgery for patients experiencing a complicated disease

course or for those with uncomplicated GERD when medical treatment is not an option [1].

According to the American College of Gastroenterology (ACG), surgical or endoscopic intervention for refractory GERD should be carried out by skilled surgeons in specialized centers after thorough evaluation. Surgical indications include severe reflux esophagitis (Los Angeles grades C or D), large HH exceeding 2 cm, and/or persistent and troubling GERD symptoms. While anti-reflux surgery carries a risk of serious complications, most patients experience favorable long-term outcomes after fundoplication, with satisfaction levels surpassing those seen with lifelong medical therapy [9].

Reflecting the emphasis on personalized GERD management, the American Gastroenterological Association (AGA) has developed clinical guidelines. Invasive anti-reflux procedures require prior confirmation of GERD, exclusion of achalasia, and evaluation of esophageal peristaltic function. Laparoscopic fundoplication and magnetic augmentation of the lower esophageal sphincter are effective surgical treatments for patients with confirmed GERD, whereas transoral incisionless fundoplication is a viable endoscopic option for well-selected patients [5].

As reported in a 2021 systematic review and meta-analysis, 28 % of patients who underwent anti-reflux surgery required continued PPI therapy [71].

In 2022, the European Association for Endoscopic Surgery (EAES) and the United European Gastroenterology (UEG) society issued recommendations for the surgical management of GERD, based on accumulated expertise and systematic reviews of anti-reflux interventions. Experts recommended partial posterior fundoplication as the optimal anti-reflux surgical technique, given its lower risk of short-term complications and dysphagia. Additionally, it may reduce the chances of severe complications and reoperation relative to the commonly performed total posterior fundoplication [72]. Endoscopic techniques, including magnetic sphincter augmentation and transoral incisionless fundoplication (TIF 2.0), demonstrate superior outcomes compared to PPI monotherapy [73].

The current primary approach to GERD management involves lifestyle modifications and medical therapy. For cases of refractory GERD, large hiatal hernias, or medication intolerance, additional evaluation is necessary to determine whether surgical or endoscopic intervention could improve symptoms. Minimally invasive fundoplication is the preferred surgical option. In patients with a BMI < 35, a small or absent hiatal hernia, normal esophageal motility, and confirmed GERD, magnetic sphincter augmentation is a viable consideration. Endoscopic approaches such as the STRETTA radiofrequency method or TIF 2.0 should be considered for patients unwilling to undergo fundoplication or magnetic sphincter augmentation. Meta-analyses suggest that while endoscopic therapy is superior to medical management in the short term, it is less effective than surgery in the long term [74].

Not all of the outlined surgical correction options are currently available in the Russian Federation. Fundoplication is the most prevalent technique.

20. Can disease recurrence and the need for long-term PPI therapy occur following surgical treatment of GERD?

Disease recurrence and the need for prolonged PPI therapy may affect some patients following surgical treatment for GERD.

Grade of recommendation — A;
level of evidence — 1.

Consensus level: "A+" — 94.9 %; "A" — 2.6 %; "A–" — 2.6 %; "D–" — 0 %; "D" — 0 %; "D+" — 0 %.

Recurrence of gastroesophageal reflux disease after different types of fundoplication can result from several factors. Key contributors include undiagnosed esophageal shortening, obesity, and increased intra-abdominal pressure due to vomiting, coughing, straining, or abdominal trauma [74, 75].

Analysis of long-term outcomes for the most commonly performed procedures, such as Nissen and Toupet fundoplication, indicates that as many as 62 % of patients continue using antisecretory drugs to control reflux symptoms [76]. According to the literature, partial fundoplication (e.g., Toupet) or procedures like esophagofundoraphy are less effective at correcting pathological reflux compared to complete 360° fundoplication [77, 78]. However, complete wraps (360°) are linked to a higher incidence of dysphagia [74].

Analysis of postoperative complications indicates that previous abdominal surgeries, female sex, obesity, low socioeconomic status, and normal preoperative pH monitoring results (suggesting no pathological GERD) are predictive factors for GERD symptom recurrence [79, 80].

Long-term studies on laparoscopic surgeries for hiatal hernia have demonstrated a high incidence of anatomical recurrences, observed in

5–60 % of patients who underwent the procedure [81–85]. The complication rate varies by the type of hernia: cardia-fundal hernias (type 3, according to the SAGES classification) show rates of up to 11.1 %, whereas giant hernias (type 4) report the highest complication rate at 23.3 % [86].

Anti-reflux surgery performed by an experienced and highly skilled surgeon in a specialized hospital for uncomplicated reflux esophagitis achieves positive outcomes in 80–95 % of patients [87–90]. By contrast, surgeries performed in private centers by less experienced surgeons result in success rates of only 40–50 % within the first postoperative year [7].

The most frequently observed complications include wrap slippage, migration of the wrap into the mediastinum (resulting in a double-chamber stomach), partial or complete unraveling of the wrap caused by suture failure and wraps that are either overly tight or excessively long [85, 90–93].

Conclusion

Gastroesophageal reflux disease is highly prevalent in Russia [94] and worldwide [95], that makes development of optimal treatment approaches actual. Leading Russian experts of various specialties, whose professional interests are related to the treatment of patients with GERD, including surgery and endoscopic technologies, have been involved in the development of the current Consensus. The key statements of the Consensus were publicly discussed at the 50th Scientific Conference "Consensus is the basis for Clinical Guidelines" held by Central Research Institute of Gastroenterology on March 1, 2024, and the final version of Consensus was adopted taking into consideration the consensus level reached according to the Delphi method.

The Consensus is a document demonstrating the most complete and comprehensive analysis of available Russian and international data specifying the indications and criteria for the selection of patients with GERD for surgical treatment, considering both the extent of necessary preoperative investigations and the most complex clinical cases, including extraesophageal manifestations of the disease, incomplete response/lack of response to PPI therapy. Implementation of the Consensus statements will facilitate proper and optimal selection of patients to improve the efficacy of surgical treatment of GERD.

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All the authors contributed with data collection and analysis, writing of the manuscript, approving final version and its publication.

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