https://doi.org/10.33878/2073-7556-2023-22-2-172-183

Consensus on controversial issues of the surgery for Crohn's disease by Delphi method

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ABSTRACT *AIM: to establish the consensus on controversial issues of the surgery for Crohn's disease by Delphi method.*
METHODS: a cross-sectional study was conducted by the Delphi method. 62 experts voted intramural and anonymous (31.03.23). 5 statements from the current edition of clinical guidelines were selected for correction by working group and further voting [2]. Based on the practical experience of the working group and literature data, 3 new statements were created also. Statements that do not reach the required level of agreement (80% or more) will be subjected to Round 2 of the Delphi method.
RESULTS: all experts took part in the anonymous voting. The panel of experts is represented by 8 different areas of practical medicine and the median of the professional experience of the respondents was 30 (12–49) years. Of the 8 statements submitted for voting, consensus (80% or more) was reached on 6 out of 8. 2 statements have been revised by working group for the distance 2nd round of the Delphi study. Consensus (more than 80%) was reached on both.
CONCLUSION: a cross-sectional study by the Delphi method provided the opinions of a panel of experts on controversial issues in the surgical treatment of Crohn's disease. Statements that reach consensus will be included by the working group in a new edition of clinical guidelines of Crohn's disease.

KEYWORDS: *Crohn's disease, clinical guidelines, surgery, Delphi method*

CONFLICT OF INTEREST: *the authors declare no conflict of interest*

FOR CITATION: Shelygin Y.A., Achkasov S.I., Reshetov I.V. et al. Consensus on controversial issues of the surgery for Crohn's disease by Delphi method. *Koloproktologia.* 2023;22(2):172–183. (in Russ.). https://doi.org/10.33878/2073-7556-2023-22-2-172-183

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Received — 01.04.2023 *Revised — 01.04.2023* *Accepted for publication — 17.05.2023*

INTRODUCTION

Crohn's disease (CD) is a disease located in the plane of contact of a large number of medical specialties. Diagnosis and treatment of CD are associated with significant difficulties and represent one of the most pressing problems of modern medicine. Special attention should be paid to the fact that the provisions of the majority of clinical guidelines published in the world on certain CD issues are based only on the opinion of experts, which corresponds to the lowest level of evidence [2,7,21]. Due to the impossibility of large clinical trials, mainly on surgical issues, the authors of many clinical guidelines resort to the help of a panel of experts to consolidate expert opinions [5,8,23].

To achieve consensus on certain issues, the Delphic method is widely used, which allows structuring the process of collecting and consolidating expert opinions. Thus, the Delphi method in modern medicine is widely used in the process of writing clinical guidelines for various specialties [12,26]. In this matter, the methodologically strictly planned Delphic method is able to increase the level of evidence on certain controversial statements, in the absence of relevant literature. To this aim, the working group on the development of a new version of Russian Clinical Guidelines for the diagnosis and treatment of Crohn's disease made this cross-section of experts' opinions on surgical treatment using the Delphic method.

MATERIALS AND METHODS

A cross-sectional study (a cross-section of expert opinions) was done using the Delphi method, by anonymous voting. The completed opinion section is the 1st round of the Delphic Study. The study was done through the successive stages presented below.

The First Stage. The working group has carried out an audit of the current version of the clinical guidelines. In total, 33 statements-recommendations are reflected in the *surgical treatment* section, 19 (57.6%) of which correspond to the level of evidence 5, that is, they are based on the described clinical cases or expert opinions [2]. According to 19 statements, the working group made a literary

Table 1. *Statements of the current version of clinical guidelines 2020 which were selected for voting*

3.2.1 Indications for Surgical Treatment of CD In patients with a complicated CD, when threatening symptoms are detected (peritoneal symptoms, free gas in the abdominal cavity according to abdominal X-ray), emergency surgery is recommended, which in such a situation may be limited to resection of the affected part with anastomosis or stoma [9].	EL — 5
3.2.3 Surgical Treatment of Large Intestine CD If possible, abdominal-perineal extirpation is not recommended in patients with severe perianal lesions [14].	EL — 5
3.2.4 Surgical Treatment of CD with Lesions of the Upper Gastrointestinal Tract In patients of this group, a bypass anastomosis is recommended only in exceptional cases, since the risk of bacterial overgrowth in the diverted part of the small intestine is high, and cancer may also develop. At the same time, extended resections cause the short bowel syndrome [10].	EL — 5
3.2.4 Surgical Treatment of CD with Lesions of the Upper Gastrointestinal Tract In patients of this group, in the presence of single or multiple short strictures, the surgery of choice may be various options for dissection of cicatricial strictures of the small intestine (strictureplasty) [13].	EL — 4
3.2.5 Treatment of CD with Perianal Lesions (Perianal CD) In patients with perianal manifestations of CD, in the presence of stricture of the low rectum or anal canal stenosis, proctosigmoidectomy (or proctectomy) or intersphincteric rectal resectionis recommended [15].	EL — 5

Table 2. *New statements were created by working group*

3.2.2 Surgical Treatment of CD in the Form of Terminal Ileitis or Ileocolitis In patients with a penetrating CD with abdominal abscess, it is recommended to drain it under the control of ultrasound or CT with subsequent conservative treatment (antibacterial, steroids and biotherapy) as an alternative to surgical resection [7,11].	EL — 3
3.2.2 Surgical Treatment of CD in the Form of Terminal Ileitis or Ileocolitis In a patient with a clinical picture of acute appendicitis, upon revision of the abdominal cavity and detection of a macroscopically unchanged appendix and terminal ileitis, is recommended to avoid appendectomy, as well as intestinal resection or ileocecal resection of the intestine [7].	EL — 5
3.2.3 Surgical Treatment of Large Intestine CD In the surgical treatment of large intestine CD with purulent-septic process in the ischioanalregion and perineum, rectal resection is recommended to be performed in the volume of total mesorectumectomy [16].	EL — 3

search, including revision of the statements-recommendations in the latest versions of the world clinical guidelines [3,7,21].

The Second Stage. After a literary revision of 19 statements, 4 theses-recommendations were selected without new level of evidence (5). One statement was allocated by the expert group additionally to reach consensus on the new wording and has the level of evidence (EL) 4 (Table 1).

The Third Stage. All selected statements and recommendations were discussed by the working group in order to clarify new formulations for voting. At this stage, experts also proposed 3 new statements-recommendations for inclusion in the relevant sections of clinical guidelines. It is worth noting that 2 new theses were formulated based on the experience and opinion of experts, and 1 statement has the EL — 3 (Table 2). Thus, at this stage, 8 theses — recommendations for voting have been finalized.

The Fourth Stage. A list of experts involved in the treatment of CD in their clinical practice was compiled for face-to-face voting. Sixty-two experts of different medical specialties were included to achieve one of the principles of the Delphi method — heterogeneity of voters (Table 3).

The Fifth Stage. All 62 experts participated in a secret ballot (31.03.23) on each of the 8 theses-recommendations. The answers to the final formulation of the thesis were as follows: “I agree”, “Partially agree”, “Disagree”, “I find it difficult to answer.”

The prevailing majority of experts participated in the voting in person — 47 (75.8%), online — 15 (24.2%) respondents. Consensus on the thesis was considered achieved with the consent of at least 80% of experts.

RESULTS

Voting was completed on all 8 selected statements, the panel of the experts participated in full (Fig. 1).

Statement No. 1
3.2.1 Indications for Surgical Treatment of CD
In patients with a complicated form of CD, when threatening symptoms are detected (peritoneal symptoms, free gas in the abdominal cavity), emergency surgery is recommended, which in such a situation may be limited to resection of the affected part with the formation of an intestinal stoma.

Agree with the proposed statement — 37 (59.7%), partially agree — 6 (9.7%), disagree — 6 (9.7%), find it difficult to answer — 13 (20.9%). Thus, a consensus of the experts on this issue has not been reached.

Table 3. *Descriptive of voted experts*

Specialty:	***n***
Gastroenterology (internal diseases)	25 (40.4%)
Coloproctology	16 (25.8%)
Surgery, oncology	8 (12.9%)
Pediatric surgery	4 (6.5%)
Pediatrics	3 (4.8%)
Endoscopy	2 (3.2%)
Obstetrics and gynecology	2 (3.2%)
Healthcare organization	2 (3.2%)
Academic degree:	
– Doctor of Medical Sciences – Candidate of Medical Sciences – No degree	46 (74.2%) 14 (22.6%) 2 (3.2%)
Academic title:	
– Academician of the Russian Academy of Sciences – Corresponding Member of the RAS – Professor – Associate Professor – No	7 (11.3%) 4 (6.5%) 19 (30.6%) 11 (17.7%) 21 (33.9%)
Median medical experience, *(min–max), years*	30 (12–49)

Statement No. 2
3.2.4 Surgical Treatment of CD with Lesions of the Upper Gastrointestinal Tract
In patients of this group, it is recommended to resort to the formation of a bypass anastomosis only in exceptional cases, since the risk of bacterial overgrowth in the diverted part of the small intestine is high, and cancer may also develop. At the same time, extended resections cause the short bowel syndrome.

Agree with the proposed statement — 50 (80.6%), partially agree — 3 (4.8%), disagree — 0, find it difficult to answer — 9 (14.6%). A consensus of the experts has been reached.

Statement No. 3
3.2.3 Surgical Treatment of Large Intestine CD
Abdomino-perineal resection (extirpation) is not recommended for patients with severe perianal lesions.

Agree with the proposed statement — 51 (82.2%), partially agree — 1 (1.6%), disagree — 1 (1.6%), find it difficult to answer — 9 (14.6%). A consensus of the experts has been reached.

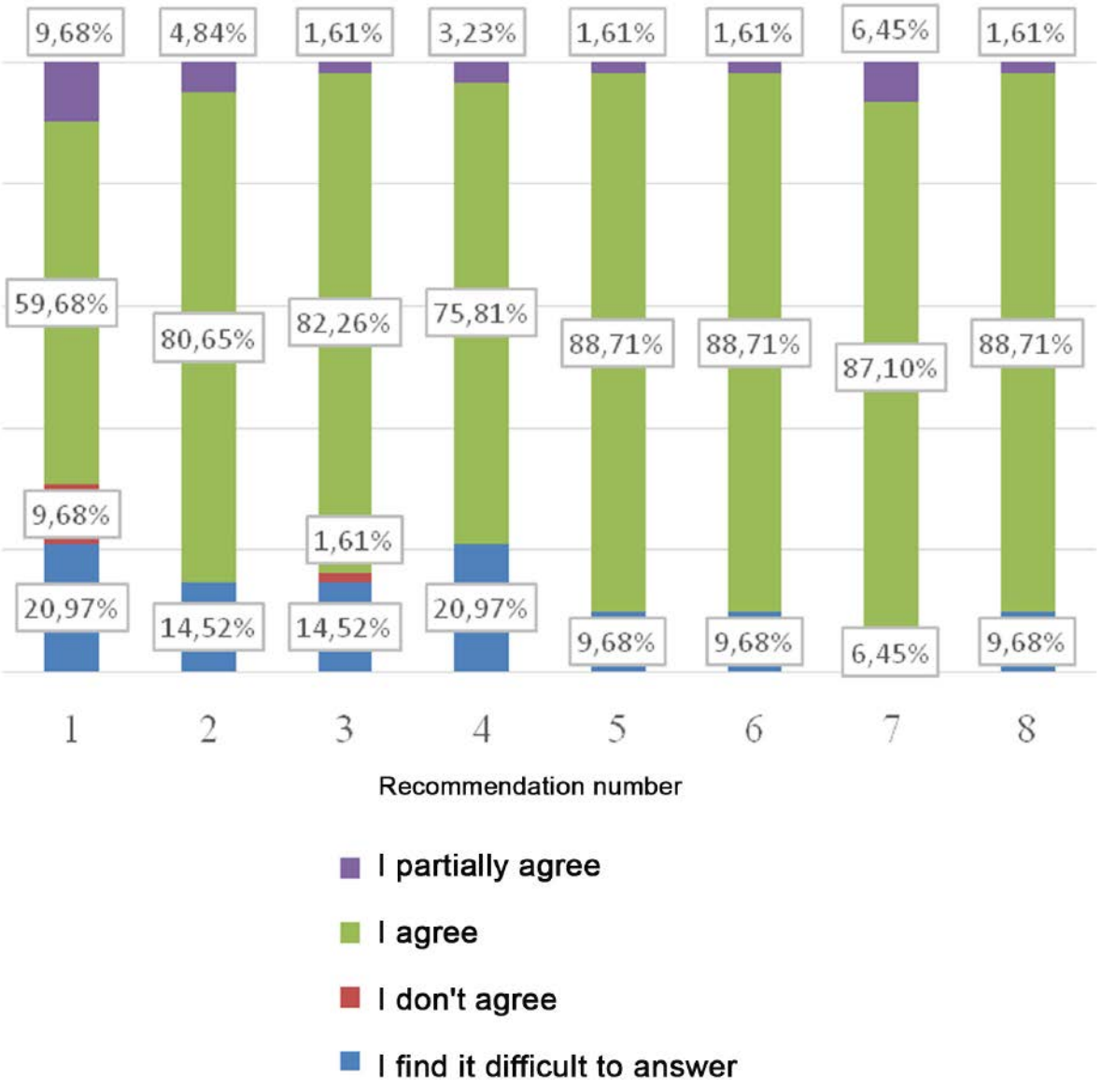

Figure 1. *Histogram of first voting results*

Statement No. 4
3.2.4 Surgical Treatment of CD with Lesions of the Upper Gastrointestinal Tract
In patients of this group, in the presence of strictures, it is recommended to perform various options for dissection of cicatricial strictures of the small intestine (strictureplasty), as an alternative to intestinal resection.

Agree with the proposed statement — 47 (75.8%), partially agree — 2 (3.2%), disagree — 0, find it difficult to answer — 13 (21%). A consensus of the experts was not reached due to the share of those who agreed less than 80%.

Statement No. 5
3.2.5 Treatment of CD with Perianal Lesions (Perianal CD)
Patients with perianal lesions in CD, accompanied by evacuatory disorders and anal incontinence, leading to a significant decrease in the quality of life, are recommended to undergointersphincteric rectal resection.

Agree with the proposed statement — 55 (88.7%), partially agree — 1 (1.6%), disagree — 0, find it difficult to answer — 6 (9.7%). A consensus of the experts has been reached.

Statement No. 6
3.2.2 Surgical Treatment of CD in the Form of Terminal Ileitis or Ileocolitis
In the penetrating form of CD with abdominal abscess, it is recommended to drain it under the control of ultrasound or CT with subsequent conservative treatment (antibacterial, steroid therapy and biotherapy) as an alternative to surgical treatment by resection.

Agree with the proposed statement — 55 (88.7%), partially agree — 1 (1.6%), disagree — 0, find it difficult to answer — 6 (9.7%). A consensus of the experts has been reached.

Statement No. 7
3.2.2 Surgical Treatment of CD in the Form of Terminal Ileitis or Ileocolitis
In a patient, with a clinical picture of acute appendicitis during the revision of the abdominal cavity and the detection of a macroscopically unchanged appendix and terminal ileitis, it is recommended to avoid appendectomy, as well as small intestine resection or ileocecal resection.

Agree with the proposed statement — 54 (87.2%), partially agree — 4 (6.4%), disagree — 0, find it difficult to answer — 4 (6.4%). A consensus of the experts has been reached.

Statement No. 8
3.2.3 Surgical Treatment of Large Intestine CD
In the surgical treatment of large intestine CD with purulent-septic process in the ischioanal region and perineum, rectal resection is recommended to be performed in the volume of total mesorectumectomy.

Agree with the proposed statement — 55 (88.7%), partially agree — 1 (1.6%), disagree — 0, find it difficult to answer — 6 (9.7%). A consensus of the experts has been reached.

DISCUSSION

The cross-sectional study made it possible to reach a consensus of the panel of experts on 6 statements out of 8. To obtain a consensus, a consensus value of 80% or more was chosen. At the same time, to date, there is no unambiguous threshold value of the frequency of consent of respondents in the literature. A systematic review by Diamond, R., et al., summarizing 98 studies on the Delphi method, demonstrated a median frequency of expert consent — 75% [12]. Along with this, for a full assessment, it is extremely important to objectify the degree of expert consent. For this purpose, the Likert scale is most often used in the literature [8]. In this study, no such assessment was made, since the main purpose of the vote was to obtain only a cross-section of experts' opinions on controversial issues for further full-fledged rounds of the Delphic Study. It is important to note that the entire methodology of the study is based on a set of literary data combined in a systematic review and published guidelines by Spranger, J., et al., as well as in the domestic study by Zabolotskikh, I.B., Grigoriev, S.V., et al. [1,26].

An important aspect in the results obtained is that in the absence of any response from the expert, it was recorded as "I find it difficult to answer."

A similar situation is registered in less than 10% of all responses. Fixing the omissions, as the answer "I find it difficult to answer," made it possible to eliminate the bias of the results towards the positive and objectify the result of the vote, reducing the proportion of consenting experts. No consensus was reached by the panel of experts on the 2 statements presented.

Statement No. 1. Section 3.2.1 Indications for Surgical Treatment of CD *In patients with a complicated form of CD, when threatening symptoms are detected(peritoneal symptoms, free gas in the abdominal cavity), emergency surgery is recommended, which in such a situation may be limited to resection of the affected part with the formation of an intestinal stoma.*

Intestinal perforation is recorded in no more than 3% of patients with Crohn's disease. Perforation is one of the rare complications in the natural course of CD. However, it may be the first manifestation of the disease in one quarter of these patients [27]. It is known that more often perforation in CD develops in the small intestine, which leads to acute peritonitis, which is most often generalized and requires emergency surgery [22].

It has been shown that postponement of surgery by more than 6 hours in patients with septic shock due to gastro-intestinal perforation is accompanied by zero 60-day survival [6]. At the same time, there is currently no consensus on the optimal volume of surgery. There is no convincing evidence that intestinal resection with the formation of an anastomosis in stable patients with intestinal perforation significantly increases the rate of postoperative complications and mortality. In some situations, especially in the case of an unstable condition of the patient, it is impossible to perform resection or exteriorization of the bowel loop with a perforated segment due to a severe infiltrative process. In this regard, Statement No. 1 needs to be corrected in its wording for subsequent rounds of Delphi.

Statement No. 4. Section 3.2.4 Surgical Treatment of CD with Lesions of the Upper Gastrointestinal Tract

In patients of this group, in the presence of strictures, it is recommended to perform various options for dissection of cicatricial strictures of the small intestine (strictureplasty), as an alternative to intestinal resection. As it is known, surgeries for strictures in Crohn's disease include strictureplasty or segmental resection of the intestine [25]. There are many different types of strictureplasty, the choice of each of which depends on the extent of the stricture. The most commonly performed plastic surgery is the Heinecke-Mikulicz method, in which a longitudinal incision is made along a narrow section of the stricture and sutured in the transverse direction. According to the literature, it has been established that this type of strictureplasty can be performed with a stricture length of no more than 10 cm [2]. With a longer length of strictures, it is possible to perform procedures by Finneyor Michelassi [7]. It should be noted that in the Russian literature there are only isolated publications on the topic of strictureplasty, which may indicate insufficient experience in performing such procedures in the country. In addition, the presented statement looks rather generalized, does not contain specific criteria for selecting patients to perform strictureplasty. All this probably caused the lack of the required level of consent of respondents and Statement No. 4 will be adjusted before the next round of the Delphic study.

Of course, special attention should be paid to the new statements formed by the working group based on the clinical practice and literature data.

In the surgical treatment of colorectal CD with purulent-septic process in the ischioanalregion and perineum, rectal resection is recommended to be performed in the volume of total mesorectumectomy.

Recently, evidence has accumulated that in CD, the mesentery of the intestine plays a key role in the pathogenesis of the inflammatory process in the intestinal wall. Thus, according to de Groof et al., mesorectum contains an increased number of activated CD14 + macrophages producing anti-TNF, as well as a reduced concentration of the wound healing marker CD206 compared to similar tissue in ulcerative colitis. These fundamental data are also of practical importance, since the performance of total mesorectumectomy, in comparison with the resection of the rectum along the wall with the preservation of adipose tissue in the pelvic cavity, is accompanied by a lower rate of postoperative complications in the perineum, including recurrence of CD: 17.6% and 59.5%, $p = 0.007$ [16]. It is important to note that we are talking about Crohn's disease with pronounced perianal lesions, purulent-septic process in the perineum. The decision on the need to perform mesorectumectomy in other situations remains at the discretion of the operating surgeon.

In the penetrating form of CD with abdominal abscess, it is recommended to drain it under the control of ultrasound or CT with subsequent conservative

treatment (antibacterial, steroid therapy and biotherapy) as an alternative to surgical resection.

The selection of this statement is mainly based on the practical experience of the authors of the working group, as well as on the data of publications on the surgical treatment of CD [21]. Drainage of the abdominal abscess and subsequent conservative treatment serve as a bridge to resection, allowing to reduce the extent of surgery due to the reduction in the size of inflammatory changes. It is also important to note that the conservative treatment after drainage reduces the likelihood of failure of intestinal anastomosis, the formation of external intestinal fistulas and the need for the formation of an intestinal stoma after elective intestinal resection [18,22]. In particular, in the meta-analysis by He, X., et al. a significant decrease in the probability of postoperative complications was revealed (OR = 0.44; 95% CI, 0.23–0.83; p = 0.03) [17]. In the case of primary resection of the intestine in conditions of infiltration and abscess of the abdominal cavity in CD, the extent of resection increases, which can subsequently lead to the short bowel syndrome [19].

It is important to emphasize that according to a systematic review by Clancy, S., et al., abscess drainage in combination with conservative treatment allowed to avoid resectional surgery in more than 30% of patients [11].

In a patient with a clinical picture of acute appendicitis, during the revision of the abdominal cavity and the detection of a macroscopically unchanged appendix and terminal ileitis, is recommended to avoid appendectomy, as well as small intestine resection or ileocecal resection.

Sometimes the onset of Crohn's disease in the form of terminal ileitis can occur under the guise of acute appendicitis, which leads to hospitalization of the patient in a general surgical hospital and often to appendectomy and unjustified resection of the affected ileum [4,20]. In the clinical guidelines of the Russian Society of Surgeons in 2020, this situation is described as "secondary appendicitis". In this case, it is strongly recommended to refrain from performing appendectomy in the absence of macroscopic signs of secondary inflammation in the appendix.

There are no prospective studies on this topic. In 2021, a systematic review by Quaresma, A.B. was published, based on data from 6 retrospective studies, most of which are descriptions of clinical cases. As a result of the review, the authors do not recommend appendectomy and primary resection of the ileum in uncomplicated CD [24]. It is important to note that this statement is consistent with the consensus position of the panel of experts of the European Organization for the Study of UC and CD (ECCO) and the European Association of Coloproctologists (ESCP) [3,7].

CONCLUSION

The study using the Delphi method allowed us to obtain a cross-section of the opinions of a panel of experts on controversial issues of surgical treatment of Crohn's disease. The statements that initially reached consensus will be included by the working group in the new edition of clinical guidelines for the diagnosis and treatment of CD. Statements that have not reached the required level of agreement will be corrected and an additional round of Delphic Research will be conducted. In conclusion, it should be noted separately that the methodology used to achieve consensus on certain controversial issues demonstrates itself as one of the useful methods for increasing the level of evidence credibility in future versions of clinical recommendations.

SECOND ROUND OF DELPHI VOTING

According to the results of the voting on April 31, 23, two statements did not reach the required level of agreement of experts (80%). In this regard, statements were subjected to a second revision and correction by the working group in order to conduct the 2nd round of the Delphic voting in order to reach a consensus.

In the period from 05 May 2023 to 16 May 23, absentee voting was held using a questionnaire in the form of an online form with the participation of representatives of the previous panel of experts. New formulations of statements are presented in the online form. To objectify the 2nd round of voting, an assessment of the level of agreement of the expert on the Likert scale was added (from 1 — "strongly disagree" to 9 — "strongly agree"). The level of agreement to reach consensus was chosen as the previous one — 80%,

and the value on the Likert's scale was determined to be at least 8 points.

3.2.1 Indications for surgical treatment of CD
In patients with a complicated CD, in case of perforation of the small/colon into the free abdomen, with the development of acute peritonitis, emergency surgical intervention is recommended with resection of the affected intestine and, preferably, with the formation of an intestinal stoma [30].
EL — 4.
Comment: *The formation of an intestinal stoma, as an alternative to primary anastomosis, in complicated CD and contamination of the abdominal cavity due to perforation into the free abdominal cavity, reduces the risk of septic complications and recurrence of CD.*

Agree with the proposed statement — 91.3%, partially agree — 2.9%, disagree — 0, find it difficult to answer — 1.4%. The median of the Likert's scale is 9 (8, 9). A consensus of the experts has been reached.

3.2.4 Surgical treatment of CD with lesions of the upper GI
In patients of this group in the presence of isolated strictures of the small intestine, it is recommended to perform various types of strictureplasty as an alternative to bowel resection [28,29].
EL — 2
Comment: *In the case of a stricture of the small intestine less than 10 cm, the Heineke-Mikulich's strictureplasty should be chosen. With a greater length of strictures or the presence of multiple consecutive stenosises, it is preferable to perform bowel resection or Finney's, Michelasi's strictureplasty, if there is appropriate surgical experience.*

Agree with the proposed statement — 89.9%, partially agree — 8.7%, disagree — 0, find it difficult to answer — 1.4%. The median of the Likert's scale is 9 (9, 9). A consensus of the experts has been reached.
As a result of the 2nd round of the Delphi voting, a panel of experts reached a consensus on the new statements. Thus, the submitted abstracts will be included by the working group in the new edition of clinical guidelines for the diagnosis and treatment of Crohn's disease.

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