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LAPAROSCOPIC REPAIR OF HIATAL HERNIAS AND NISSEN FUNDOPLICATION: ANALYSIS OF LONG-TERM RESULTS, NEW CLASSIFICATION AND FUTURE TRENDS

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ЛАПАРОСКОПИЧЕСКАЯ ПЛАСТИКА ГРЫЖ ПИЩЕВОДНОГО ОТВЕРСТИЯ ДИАФРАГМЫ И ФУНДОПЛИКАЦИЯ ПО НИССЕНУ: АНАЛИЗ ОТДАЛЕННЫХ РЕЗУЛЬТАТОВ, НОВАЯ КЛАССИФИКАЦИЯ И НАУЧНЫЕ ТЕНДЕНЦИИ

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Проанализированы результаты 787 операций (с фундопликацией только по Ниссену). Пациентов разделили на три группы в зависимости от HSA по Granderath (2007): I группа — 343 пациента с HSA < 10 см^2 (малые грыжи), которым выполнялась крурорафия; II група — 358 пациентов с HSA 10–20 см^2 (большие грыжи), которым выполнялась крурорафия (подгруппа А) или пластика сеткой (подгруппа Б). В последней погруппе выполнялась on-lay фиксация полипропиленовой сетки Prolene либо оригинальная методика sub-lay пластики облегченной сеткой UltraPro, которая частично рассасывается; III группа — 86 пациентов с HSA > 20 см^2 (гигантские грыжи), которым выполнялась пластика сеткой. Как и во II группе, они были разделены на 2 подгруппы на основе метода пластики.

Авторы советуют рутинно вымерять HSA и использовать новую классификацию. Оптимальным методом пластики малых грыж является крурорафия. При больших грыжах оригинальная методика sub-lay пластики облегченной сеткой, которая частично рассасывается, представляется наилучшей. Для гигантских грыж оригинальная методика дает результаты, соответствующие литературе, хотя эти результаты нуждаются в улучшении.

Ключевые слова: грыжа пищеводного отверстия диафрагмы, сетчатый трансплантат, площадь поверхности пищеводного отверстия диафрагмы.

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Background. The choice of method of hiatal hernia repair is still controversial. Recurrences after repair of large and giant hiatal hernia reach 42%. Mesh repair may decrease failure rate but bears risk of oesophageal complications. Thus, development of optimal methods of hiatal closure for prevention of repair-related recurrences and dysphagia is a very actual question.

Aim of the study was to analyse long-term results (i. e. anatomical recurrences and repair-related dysphagia) of different types of laparoscopic hiatal repair depending on hiatal surface area (HSA).

Methods. Results from 787 procedures were analysed (fundoplication — Nissen only). Patients were divided into 3 groups according to HSA measured as described by Granderath et al. (2007). I group — 343 patients with HSA < 10 cm^2 (*small* hernias) whom primary crural repair was performed. II group — 358 patients with HSA 10–20 cm^2 (*large* hernias) whom primary crural repair (subgroup A) or mesh repair (Subgroup B) was performed. Among the latter subgroup, on-lay fixation of polypropylene mesh Prolene^{TM} or the original technique of sub-lay repair by lightweight partially absorbable mesh Ultrapro^{TM} was used. III group — 86 patients with HSA > 20 cm^2 (*giant* hernias) whom mesh repair was performed. Similarly to II group, they were divided into 2 subgroups based on method of repair.

Results. In I group there were 3.5% recurrence and 1.9% dysphagia rates. In II group there were 7.1% recurrence and 6.5% dysphagia rates. In II group subgroup A there were 11.9% recurrence and 2.2% dysphagia rates. In II group subgroup B there were 5.2% recurrence and 8.2% dysphagia rates. Comparing recurrence rates I group vs II group subgroup A, we obtained statistically significant difference in favor of I group. Comparing recurrence rates of II group subgroup A vs subgroup B, we obtained difference in favor of subgroup B. Original method of sub-lay lightweight partially absorbable mesh repair provides similar dysphagia rate as primary repair. In III group there were 19% recurrence and 8.8% dysphagia rates. Comparisons between subgroups of III group provided similar results as for II group.

Conclusions. 1. We advice to routinely measure HSA and use relative classification. 2. Optimal repair for small hernias is primary suturing. 3. For large hernias, original technique of sub-lay lightweight partially absorbable mesh repair seems to be the best. 4. For giant hernias original technique provides results corresponding to the literature, although these results require improvement.

Key words: hiatal hernia, mesh repair, hiatal surface area.

Background

Surgical procedure of choice for treatment of hiatal hernias and gastro-oesophageal reflux disease (GERD) is laparoscopic hiatal repair and fundoplication. Methods of laparoscopic repair of large and giant hiatal hernias are the most actual questions in gastrointestinal minimally invasive surgery. The literature demonstrates high rates of anatomical failures of hiatal repair and recurrences of GERD following laparoscopic procedures, particularly after primary crural repair, reaching 42% [5; 8; 18; 20]. Different methods of mesh repair were introduced and several trials showed their benefits [1; 7; 8; 10; 17]. However, necessity and method of prosthetic repair remain questionable as mesh repair may result in long-term functional dysphagia, oesophageal strictures and erosions [6; 8; 9; 20]. In addition, within most of the literature, there is no strong criterion to classify hiatal hernias, although universal classification is necessary as recurrence rate is strongly dependent on hernia size, and, therefore, chosen method of repair must be tailored to each type of hernia.

The aims of this observational study are following: (1) to analyse long-term results (i. e. anatomical recurrences and repair-related dysphagia) of different methods of laparoscopic repairs of hiatal hernias, (2) to ground new classification of hiatal hernias based on hiatal surface area (HSA), (3) to issue most optimal method of repair for each type of hiatal hernia.

Methods

From 1994 to 2011, 1780 laparoscopic procedures for hiatal hernias and GERD were performed at the department of minimally-invasive digestive surgery of large academic hospital by a single team of surgeons. For statistical accuracy, the following patients were excluded from the analysis: 1) 300 patients operated from 1994 to 2000 (learning curve); 2) 69 patients with advanced oesophageal motility disorders; 3) 29 patients with severe comorbidities (ASA III and IV) and more than 75 years old; 4) 315 patients with non-Nissen fundoplications: Toupet (255), Rosetti (25), Dor (35); 5) patients with GERD only, i. e. not associated with hiatal hernia (99), or associated with initial type I hernia (109). Thus, results from 787 procedures were analyzed. Of them 463 patients had type I hiatal hernia, 48 patients — type II, 264 — type III, and 12 patients — type IV hiatal hernia.

Further, these patients were divided into 3 groups (Table 1) according to HSA measured as described by F. A. Granderath et al. (2007) [11]. According to new classification, I group consisted of 343 patients with HSA < 10 cm^2 (*small* hernias) whom primary crural repair was performed. II group consisted of 358 patients with HSA 10–20 cm^2 (*large* hernias) whom primary crural repair (Subgroup A, 103 patients) or combination of primary and mesh repair (Subgroup B, 255 patients) was performed. Among the latter subgroup, on-lay fixation of polypropylene mesh Prolene™ was used (97 patients) or the original technique of sub-lay repair by lightweight partially absorbable mesh Ultrapro™ was used (158 patients). III group consisted of 86 patients with HSA > 20 cm^2 (*giant* hernias) whom a combination of primary and mesh repair was performed. Similarly, they were divided into 2 subgroups: 32 patients with on-lay polypropylene mesh repair, and 54 patients with sub-lay lightweight mesh repair.

The original "sandwich" technique of sub-lay repair was widely published in the literature and presented at EAES and SAGES meetings [12–14]. First, the triangular patch of lightweight partially absorbable mesh Ultrapro™ is sutured to the crura with 3 stiches as done in tension-free hiatal repair (Fig. 1), then, the crura are approximated with 2 or 3 additional sutures to cover the mesh precluding its contact with the esophagus (Fig. 2). Repair by partially absorbable lightweight meshes is promising technique and may become an optimal because it can minimize both recurrences and oesophageal complications. Some recent studies showed feasibility of this method of repair. For example, F. W. J. Hazebroek et al. (2008) reported good functional, endoscopic, and radiological out-

Table 1

Long-term Results, abs. (%)

Groups according to new classification / subgroups	n	Recurrences	Dysphagia
Group I: Small hernias: HSA<10 cm^2 — Primary repair	314	11 (3.5)	6 (1.9)
Group II: Large hernias: HSA 10–20 cm^2 — Primary and mesh repair	323	23 (7.1)	21 (6.5)
Subgroup A: Primary repair	92	11 (11.9)	2 (2.2)
Subgroup B: Mesh repair	231	12 (5.2)	19 (8.2)
On-lay polypropylene	89	5 (5.6)	16 (17.9)
Sub-lay lightweight partially absorbable	142	7 (4.9)	3 (2.1)
Group III: Giant hernias: HSA > 20 cm^2 — Mesh repair	79	15 (19)	7 (8.8)
Subgroup A: On-lay polypropylene	29	5 (17.2)	6 (20.7)
Subgroup B: Sub-lay lightweight partially absorbable	50	10 (20)	1 (2)

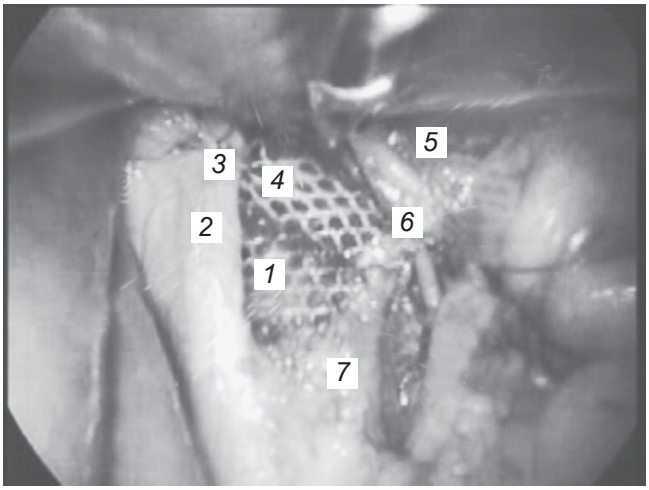

Fig. 1. Internal layer of hiatal repair using original technique: *1* — hiatal opening; *2* — right crus; *3* — suture fixing mesh to right crus; *4* — lightweight partially absorbable mesh Ultrapro™; *5* — oesophagus; *6* — suture fixing mesh to left crus; *7* — left crus

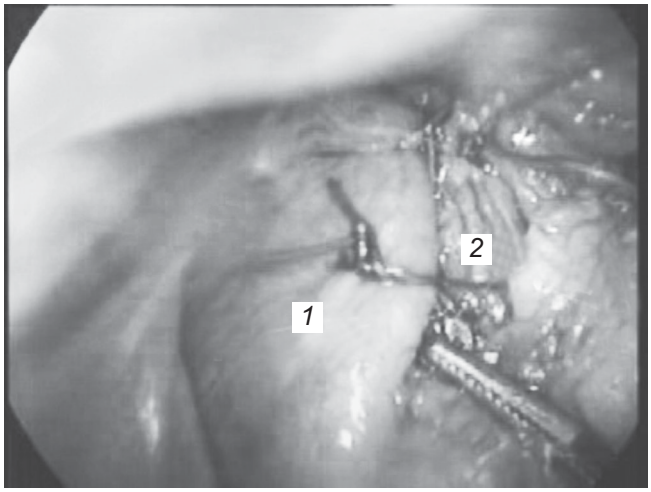

Fig. 2. External layer of hiatal repair using original technique: *1* — right crus, *2* — left crus approximated to right covering mesh

comes in terms of esophageal complications after on-lay placement of titanium-coated lightweight polypropylene mesh (non-randomized prospective study) [15].

Subjective methods included analysis of symptoms of hiatal hernias and GERD. To reveal recurrence or mesh-related oesophageal complications, objective evaluation included upper gastrointestinal series, endoscopic examination, and 24 h pH testing.

Statistical analysis was performed using variety of parametrical and non-parametrical criteria with StatSoft STATISTICA 10.0 software. There were no statistically significant differences between groups and subgroups in demographic data and data of preoperative subjective and objective evaluation. Analysis of rates of recurrences and repair-related long-term dysphagia which this study is focused on, was performed using chi-square test.

Results

Intraoperative and postoperative complications that did not exceed median literature rates (1.3% postoperative complications) were not primary focuses of this study. We also did not focus the study on operative time, hospital stay, ect. which correspond to the published results [5]. Long-term results were studied in 716 patients (90.9%) within mean follow-up of 32 months (range, 10–60). Radiolological surveillance was used for every of these patients.

In I group, the recurrence rate was 3.5% (11 patients), and dysphagia rate was 1.9% (6 patients). In II group, 23 patients (7.1%) had recurrences, and 21 patients (6.5%) had dysphagia. Comparing recurrence rates between I group and subgroup A of II group, we obtained statistically significant difference in favor of I group: 11 patients (3.5%) versus 11 patients (11.9%) (p=0.0016). Then, there was statistically significant difference between subgroups of II group both in recurrence and dysphagia rates: 11 (11.9%) versus 12 (5.2%) (p=0.0212) for recurrence in favor of mesh repair, and 2 (2.2%) versus 19 (8.2%) (p=0.0446) for dysphagia in favor of primary repair. After comparing two alternative methods of mesh repair within subgroup B, we obtained similar results in terms of recurrences: 5 (5.6%) versus 7 (4.9%) (p=0.8185). Better results were obtained for dysphagia in favor of original sub-lay lightweight mesh repair: 16 (17.9%) versus 3 (2.1%) (p=0.0001). In III group, the rate of recurrences reached 19%. Comparing results of mesh repair between III group and subgroup B, we obtained statistically significant difference in recurrences in favor of large hernias: 15 patients (19%) versus 12 patients (5.2%) (p=0.0002). No difference in terms of disphagia rates were detected among these groups: 7 (8.98%) versus 19 (8.2%) (p=0.2046). Similarly to the II group, comparing results of two alternative techniques of mesh repair of giant hernias, we revealed no difference between them in recurrence rate: 10 (20.0%) versus 5 (17.2%) (p=0.7632). Instead, we obtained better results in favor of original sub-lay lightweight mesh repair in dysphagia rate: 6 (20.7%) versus 1 (2.0%) (p=0.0048).

Discussion

The long-term results showed that general rate of successful laparoscopic procedures for GERD and small sliding hiatal hernias performed in experienced centers is ranging from 80 to 90% [2; 4; 19]. Primary repair is mainly used for closure of hiatal defect, and anatomical recurrences are not of a great concern for these patients. The most actual question discussed in the last decade was technique of

fundoplication as failures occured mostly due to wrap dehiscence or fundoplication-associated dysphagia. Recently, two large meta-analyses, published in 2010, produced an important issue which, as we believe, finished the longstanding controversy of Nissen and Toupet supporters: Toupet wrap is not inferior to Nissen in terms of reflux control, but dysphagia is more frequent after Nissen wrap in patients with esophageal motility disorders [2; 19].

Contrarily, the rate of recurrences following laparoscopic repair of large and giant mixed or paraoesophageal hernias is twofold or threefold higher. Recent meta-analysis showed that the mean rate of anatomical recurrence following repair of paraoesophageal hernias is 25% reaching 42% in some centers [18]. Several review articles showed similar results: W. A. Draaisma et al. described mean rate of recurrence of 7% (range, 0–42%), J. M. Johnson et al. demonstrated mean recurrence rate for patients who underwent primary repair of 10.7% (range, 0–26%) [5; 16]. This, repair of large and giant hiatal hernias is still a great challenge of laparoscopic upper gastrointestinal surgery. According to the literature and our own experience, the most common variants of failures following laparoscopic procedures for this disorder are: hernia recurrence with migration of fundoplication wrap into the posterior mediastinum (anatomical recurrence), weakness or rupture of fundoplication wrap (functional recurrence), a combination of two, and prolonged dysphagia associated with hiatal closure [5; 8; 9; 20].

As the most concerning problem is anatomical recurrence, a conception of prosthetic repair was applied for hiatal closure using different types of meshes. This significantly decreased recurrence rate as demonstrated by several recent studies. C. T. Frantzides et al. prospectively compared primary repair with on-lay PTFE repair and obtained statistically significant decrease of recurrence rate in favor of mesh arm: 0% versus 22% [7]. Then, F. A. Granderath et al. compared primary suturing and on-lay polypropylene mesh repair in prospective randomized trial; the rate of recurrence was statistically significantly lower in the mesh arm: 8% versus 26% [10]. A review of Johnson et al. demonstrated decrease of mean recurrence rate in the mesh group compared to primary repair group: 10.7% versus 1.9% [16]. Other reviews reported the similar results [5; 8; 20]. But, the definition of a recurrence is an uncertain aspect of some studies analyzed in available reviews. From one hand, many of them did not report routine usage of radiological surveillance [5]. Hence, the recurrence rate was significantly higher in articles with barium esophagograms performed in more than 75% of patients in long-term follow-up [5]. From the other hand, a part of patients with complete or near-complete rupture of hiatal repair and migration of proximal stomach into the mediastinum does not experience any pain or reflux symptoms [1; 5]. If they has no reflux-esophagitis and 24 hour pH study remains normal, such recurrence should form a separate type of recurrence, the *asymptomatic true recurrence*, as most of these patients may not require reoperation. It is different from a combination of hernia recurrence and recurrence of GERD, or recurrence producing pain or dysphagia, the *symptomatic true recurrence*, which often requires redo surgery. Finally, opposite to true recurrences described above, the presence of a small sliding asymptomatic hernia or a small paraesophageal herniation may be found at radiological follow-up. Patients with giant hiatal hernias have a large esophageal hiatus and, consequently, it is not surprising to find such "recurrence" postoperatively. Such recurrent herniations, perhaps, should be named as *false recurrences* if they are really asymptomatic and do not enlarge for a long time. For example, J. J. Andujar et al. reported 20% of recurrent small sliding asymptomatic hernias, nor of them required reoperation [1]. Thus, the unified definitions of types of recurrences are necessary to make final conclusions regarding effectiveness of repair of large and giant hiatal hernias. For accuracy of this study, we summarized all types of recurrences listed above as it clearly reproduces results of compared methods. Similarly, for the correctness of the analysis, we summarized all dysphagia variants, i. e. long-term functional dysphagia (without radiologically confirmed esophageal stenosis), mesh-related oesophageal strictures, and tight fundoplication. The latter did not influence the results focused on repair-related complications as every patient has typical floppy Nissen fundoplication. In fact, it is difficult to differentiate between hiatal repair-related dysphagia and fundoplication-related dysphagia based on radiological or endoscopic studies, and final determination of the distinct mechanism is made at reoperation. We had no mesh erosions in our patients.

Although mesh repair may decrease recurrence rate it may produce oesophageal complications which are not characteristic for primary suturing: prolonged dysphagia, oesophageal strictures, and mesh erosions. According to most of the literature, mesh-related dysphagia rate does not exceed 10% in the long-term follow-up. As an example, in prospective randomized trial of F. A. Granderath et al. the dysphagia rate was significantly higher in the mesh arm compared to primary repair arm: 35.3% versus 19.8% [10]. However, 1 year after surgery, comparison of the two groups no longer showed a diference in the

extent of dysphagia: 4.9% versus 4.4% [9]. A SAGES trial reported by C. T. Frantzides et al. showed that polypropylene or PTFE meshes are characterized by higher incidence of oesophageal complications although they demonstrated relatively lower recurrence rates [6]. Interestingly, that composite, i. e. partially absorbable meshes, occupied middle position in terms of recurrence and complications rates in this study [6]. Fortunately, severe mesh strictures and mesh erosions are not frequent although some authors reported fatal complications [8; 20]. Therefore, to remove the risk of mesh-related oesophageal complications of polypropylene or PTFE meshes, biological prostheses were introduced for hiatal repair. A prospective randomized study by B. K. Oeschlager et al. demonstrated insignificant difference in recurrence rates in prosthesis arm compared to primary repair arm, but no cases of mesh-related complications were observed in prosthesis arm [17]. Similar data regarding biological prostheses were retrieved in the study of C. T. Frantzides et al. [6]. Data from another literature and international congresses suggest that biological devices cannot be widely used in the setting of large or giant hiatal hernias due to high rate of recurrences and their high price. In summary, data from numerous publications made the conclusions that large and giant hiatal hernias do require mesh repair but search for the optimal prosthesis and fashion of its fixation is ongoing.

To our own opinion, as mesh repair bears risk of oesophageal complications, we must have distinct indications for its usage. The main criterion for mesh repair is large size of hernia defect as supposed by many authors. One of the first who concluded that the threshold diameter between small hiatal hernias and large ones is 5 cm, was J. K. Champion et al. (1998) [3]. He obtained more recurrences in the latter group, and most of esophageal surgeons started to use mesh when diameter of the defect exceeded 5 cm. A SAGES survey performed by S. T. Frandzides et al. confirmed this tactics as 45% of responders use size of hiatus as the main criterion for mesh usage, and approximately 50% of them use mesh when diameter of hiatus exceeds 5 cm [6]. The measurement of HSA was first described by F. A. Granderath et al. and it is more sensitive measure than circumferential diameter of hiatal hernia defect [11]. These authors tailored the method of repair to the HSA and proved that the larger is HSA the greater is recurrence rate thus the stronger is indication for usage of mesh [11]. The formula for calculation of HSA is:

$$HSA = \arcsin(s/2/r) \cdot r^2,$$

where s is transversal dimension of hiatus, and r is vertical dimension [3].

Our large experience with laparoscopic repair using variety of methods also brought us to strongly supported conclusion that the rate of recurrence is seriously dependent on diameter of hiatus. Therefore we created new classification of hiatal hernias based on HSA. To our belief, this classification could unify approaches not only between practitioners, but also between scientists within further papers. Of course, future prospective randomized trials focused on dependence of recurrences on method of repair with HSA stratification may offer another figures of HAS to classify hiatal hernias. But current classification is strongly supported by results obtained in this study and could be widely recommended. Moreover, even studies of grade 1 evidence did not primarily focused on results depending on hiatal size. For example, although C. T. Frantzides et al. showed decrease of recurrence rate in PTFE mesh arm compared to primary repair, the study included only patients with diameter of defect of 8 cm and greater, thus it is unknown whether mesh should be used for hernias with smaller diameter of hernia defect, for example, between 5 and 8 cm [7].

Returning to our outcomes, the results obtained in I group, both recurrences and dysphagia rates (see table 1), were satisfactory and corresponded to literature data [4; 11]. The possibility to improve these results is incredible, and mesh repair for such small hernias seems to be unreasonable. In II group, overall recurrence rate was 7.1% which is natural for large hernias as we discussed above. In this group 6.5% of patients had dysphagia which is also normal for mesh repair as debated before. Comparing recurrence rates between I group and subgroup A of II group, we obtained statistically significant difference in favor of I group. This produce an important practical and scientific issue: the recurrence rate using primary repair dramatically rises in hernias with HSA 10–20 cm^2, thus confirming correctness of differentiation of hiatal hernias into small and large based on HSA. Subsequently, small hernias should be repaired using primary suturing, and large hernias should be probably repaired using mesh. Then, there was statistically significant difference between subgroups of II group both in recurrence rate in favor of mesh repair, and in dysphagia rates in favor of primary repair. The first one reconfirms the necessity of mesh repair for large hernias, the second one demonstrates the need for searching for an optimal mesh and fashion of its fixation to prevent oesophageal complications. After comparing two alternative methods of mesh repair within subgroup B, we obtained similar results in terms of recurrences, and better results in favor of original sub-lay lightweight mesh repair. We have widely published and reported these results pre-

viously, and now we continue to consider our original technique to be optimal repair of large hiatal hernias [12–14]. A final conclusion that sub-lay lightweight mesh repair decreases recurrence rates of such hernias and does not increase dysphagia rate can be made only after completion of prospective randomized trial which was recently started by us.

In III group, the rate of recurrences reached 19%, which is characteristic for giant hernias according to the literature as discussed before, and, surely, requires further improvement. Comparing results of mesh repair between III group and subgroup B of II group we obtained statistically significant difference in recurrences in favor of large hernias, and no difference in repair-related disphagia rates. Likewise II group, these results support correctness of division hiatal hernias into large and giant ones according to HSA as the recurrence rate rapidly increases when HSA exceeds 20 cm^2. Therefore, mesh repair is certainly indicated for giant hernias but current techniques strongly require further improvement to decrease recurrence rates. To date, the main course here is creation of new meshes that will appropriately maintain the structures of hiatus from one hand, and be more safe in means of oesophageal complications from the other hand. Unfortunately any existing mesh does not meet both criteria, and search for some new technical decisions is ongoing. We also should consider that the problem of recurrence is not only depend on largeness and weakness of the hiatus structures. The oesophageal shortening is also a considerable factor of recurrence as supposed by many authors [5]. To elongate abdominal part of esophagus, some of them suggest Collis gastroplasty, another advocate advanced mediastinal perioesophageal dissection [5]. No reliable retrospective comparative or prospective randomized trials were performed to support any issue. Thus, this aspect of surgical treatment of giant hernias needs future development. Similarly to the II group, comparing results of two alternative techniques of mesh repair of giant hernias, we revealed no difference between them in recurrence rate, and obtained better results in favor of original sub-lay lightweight mesh repair in dysphagia rate. This confirms again that our technique is safe for prevention of oesophageal complications and merits wide usage.

Conclusions

1. Based on obtained differences between groups in recurrence rates depending on HSA we advice to routinely measure HSA and use relative classification.

2. Optimal repair for small hiatal hernias (HSA < 10 cm^2) is primary suturing.

3. For large hiatal hernias (HSA 10–20 cm^2), original technique of sub-lay lightweight partially absorbable mesh repair seems to be the most optimal.

4. For giant hiatal hernias (HSA > 20 cm^2), original technique of sub-lay lightweight partially absorbable mesh repair provides results corresponding to the literature data, although these results require further improvement by creation of new meshes and techniques.

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