

**MINISTRY OF HIGHER AND SECONDARY SPECIAL EDUCATION OF  
THE REPUBLIC OF UZBEKISTAN**

**MINISTRY OF HEALTH OF UZBEKISTAN**

**TASHKENT MEDICAL ACADEMY**

**УДК: 616.333-009.12-089.819.5**

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**ENDOSCOPIC AND SURGICAL TREATMENT OF CARDIOSPASM**

**Thoracic surgery 5A-510112**

**Scientific header: Ph.D. Pakhomov G.L.**

**Tashkent-2014**

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## **LIST OF ABBREVIATIONS**

- EA – esophageal achalasia
- SID – Starck’s instrumental dilatation
- GB – gullet bougienage
- BTA – botulinum toxin type A
- HBC – hydro-balloon cardioidosis
- EGPG – esophagogastric pressure gradient
- CS –cardiospasm
- CEJ – cardio-esophageal junction
- LES –lower esophageal sphincter
- PC – pneumatic cardioidosis
- RD –recurrent dysphagia
- RE – reflux esophagitis
- SPV – selective proximal vagotomy
- GEG –gastroesophagostomy
- OGDFS – oesophagogastrroduodenofibrosopy
- ECA – esophagocoloanastomosis
- HO – Heller operation
- EE – extirpation of the esophagus

## INTRODUCTION

### Relevance of work

Selection of an optimal therapeutic approach patients with cardiospasm (CS) and esophageal achalasia (EA) still remains an urgent problem of esophageal surgery (Gajiyev A.N., 2000; Vasiliev Yu.V., 2002; Onopriev V.I., 2005; Janssens J. 1997). According to many authors all methods of conservative and instrumental treatment, as well as most of the operations, are just symptomatic and aimed at eliminating dysphagia (Yangiev B.A., 1994; Khadjibaev A.M., 2002; Achkar E., 1995).

Analysis of the modern world literature has shown existence of significant differences among surgeons regarding the effectiveness of conservative, instrumental and surgical treatment methods. Thus, some authors recommend endoscopic administration of botulinum toxin type A to the region of cardia, as they believe that this technique is safe, low-traumatic and gives good results in 75-85% of cases (Sigal E.I., Burmistrov V.Yu., 2003; Pasricha PJ, Rai R., 1996). However, most surgeons prefer instrumental method of cardia dilatation using either metal Starck's instrumental dilatation (SID), the effectiveness of which does not exceed 75% or pneumatic dilators of different designs with 85-90% of good and satisfactory results (Yangiev B.A., 1994; Chernousov A.F., 1999-2003; Oskretkov V.I., 2003; Yangiev A.Kh., Iskhakova S.M., 2003; Nazirs F.G., Nizamhodzhaev Z.M., 2011).

With accumulation of global experience in cardiodiosis, a great number of various effective cardia dilatation methods and are being reported. However, there are still some clinics which prefer to use SIDs in their courses despite the established low efficacy and higher risk of that method. Long-term cardiodiosis results are evaluated by many authors in different ways. Some consider the repeated cardiodiosis courses as routine preventive manipulations, and others regard the appearance of Recurrent Dysphagia (RD) as an indication for surgical treatment.

Apparently, it is necessary to consider each case of surgical indication determination individually, as in most cases a few courses cardioidosis are enough to restore esophageal patency. In our opinion another important aspect of the issue is a question of need and feasibility of local treatment. As we know, cardioidosis is a method of the forced strain of cardia muscles which often results in damage to cardio-esophageal junction mucous (CEJ). At the same time the excessive stretching of the lower esophageal sphincter (LES) may provoke another problem, a reflux esophagitis (RE). All of it leads to the formation of fibrous connective tissue and reflux that will clinically occur as dysphagia again. Thus, the question of the necessity of the local treatment which usually consists of administration of sea buckthorn oil and antacids still remains unsettled. Moreover, delivery of adequate antisecretory treatment can help prevent the RD associated with SE and thus requires further study and anatomical confirmation.

Improvement of medical technologies and development of minimally invasive and endoscopic surgery also affected the patients with KS and AK. And though previously hydro-balloon cardioidosis (HBC) has not been widely used due unhandy equipment and pressure adjustment problems, nowadays the sophisticated state-of-art hydro-balloon dilators are increasingly used in surgery. However, there are still no clear indications and contraindications to this approach. There are just a few reports on its effectiveness in the long term, depending on the disease state. Besides, the question of possibility of use the HBC in the treatment of recurrent dysphagia provided that the cardia was previously operated is still remains open.

Thus, there is still no clear comparative analysis of the early and long-term results of all possible methods of instrumental treatment which can show the advantages and disadvantages of each approach.

In this category of treatment of patients with cardiospasm and esophageal achalasia the modern modifications of Geller operations dominate. They are more than a

dozen of them. At the same time, a close study of the early and long-term results of the operations of this type has revealed that 5 to 25% of those results are unsatisfactory. And the main reason for such results is the reflux esophagitis that complicates the whole postoperative period. And majority of the researches are focused on settlement of this very problem (Kurbanov F.S., 1986; Tsarenko I.A., 1999; Gajiyev A.N., 2000; Chernousov A.F., 2000; Kiriakidi S.F., Botov A.V., 2001; Ligay R.E., 2002; Onopriev V.I., 2005; Zherlov G.K., Koshel A.P., 2005). However, even this question still has no unanimous opinion of the scientists. The proposed approaches again range from cardioidiosis to reconstructive surgical retreatment and emphasize the complexity and relevance of selected scientific research that determines the purpose and objectives of the present research work.

**Purpose of research:**

Development of optimal treatment for the patients with cardiospasm and esophageal achalasia through comparative analysis of the effectiveness of different instrumental treatment methods.

**Objectives:**

1. Analyze the effectiveness of instrumental therapeutic approaches to cardiospasm and esophageal achalasia, depending on the disease state.
2. Examine the nature of complications and recurrence rate of dysphagia after different methods of cardioidiosis in treating patients with cardiospasm and esophageal achalasia.
3. Study the efficacy of local and gastric antisecretory treatment in the prevention of reflux esophagitis after cardioidiosis in patients with cardiospasm and esophageal achalasia.

**Scientific novelty:**

Basing on a comparative analysis of results of the instrumental cardiospasm and esophageal achalasia treatment methods, depending on the disease state, it was found that the most effective one is a hydro-balloon dilatation.

After a close examination of the nature and frequency of specific complications of different cardiodiosis methods a number of ways that prevent and treat the revealed complications in patients with cardiospasm and esophageal achalasia were developed.

A high efficiency of modern hydro-balloon dilators in patients with cardiospasm and esophageal achalasia, especially in patients with recurrent dysphagia after prior operations on the cardia was established.

Efficiency of local and esophageal antisecretory treatment used in prevention of reflux esophagitis in patients with cardiospasm and esophageal achalasia after cardiodiosis was proven.

Basing on the studies and reseraches, the optimal algorithm for the diagnosis and treatment of patients with cardiospasm and esophageal achalasia was proposed.

**Scientific and practice value of the research:**

The results of various researches enabled us to develop a differentiated approach to selaction of the method of instrumental treatment that resulted in improvement of its results in patients with cardiospasm and esophageal achalasia.

Introduction of local and esophageal antisecretory treatment following the hydro-balloon dilatation into clinical practice has reduced the frequency of reflux esophagitis and thus improved the early and long-term results of instrumental methods of treatment, confirmed by results of the anatomical studies.

**Key provisions to be defended:**

1. Decisive factor in selection of an approach and method of surgical treatment is determination of the type of neuromuscular stenosing disorder of esophagus, followed by the establishment of the disease state.

2. Pneumatic cardiodyosis still remains the most popular, affordable and effective treatment for patients with cardiospasm and esophageal achalasia. Hydro-balloon dilatation can be considered as its competitive, more effective alternative in modern surgical gastroenterology, the prospects of which are highly appreciated especially when used for recurrent dysphagia after previous unsuccessful cardia operations. Against this background, the efficiency of dilation by Starcks's dilator is considerably lower; the technique is associated with an extremely high risk of complications. The procedure is highly traumatic and is poorly tolerated by the patients, and therefore, its use is impractical.

3. Gullet bougienage cannot be treated as a primary method of treatment of the patients with cardiospasm and has limited indications in patients with advanced disease stages, as well as in cases of stenosing reflux esophagitis after previously unsuccessful cardia operations.

4. It is desirable to add local and esophageal antisecretory treatment procedures to the hydro-balloon dilation, as they effectively prevent occurrence of reflux esophagitis, recurrent dysphagia and significantly improve the early and long-term results.

**Published papers:** 5 scientific papers, including 2 articles, 1 abstract were published on the topic of the thesis research.

**Scope and structure of the thesis research:** The thesis research consists of an introduction, literature review, materials and methods of research, chapters of personal researches, findings, conclusions and practice suggestions. The thesis is set out on pages 84 computer pages containing 15 tables and 20 figures. The reference list contains 49 Russian and 41 foreign sources.

# CHAPTER I

## THERAPEUTIC APPROACH TO CARDIOSPASM AND ESOPHAGEAL ACHALASIA

(literature review)

### 1.1. Definition and classification of cardiospasm and esophageal achalasia.

Cardiospasm and esophageal achalasia are the pluricasual esophagus diseases based on myenteric nervous plexus dystrophy which lead to disruption of the swallow-induced opening of the cardia. These diseases are characterized by the basic triad of dysphagia, regurgitation, and pain. Cardiospasm, esophageal achalasia and primary diffuse esophageal spasm are representatives of neuromuscular diseases of the esophagus which make 7 to 20% of all diseases of the organ [1,7,8,34,35,36,37].

Esophageal achalasia occurs approximately in the ratio of 1 to 100,000. [28] At the same time, men and women fall ill with equal frequency [55]. Although esophageal achalasia is diagnosed mainly in persons aged 25-60 years, it can occur at any age [87].

In view of a variety of different views on the etiopathogenesis of this disease, there was a necessity to systematize all of them. In 1973 Fedorova O.D. completed systematization of the theories by combining them into 4 groups:

1. Congenital cardiospasm theories include all the options that consider the hereditary factors, including formation of defects of the myenteric plexus as the key ones; and nothing but myenteric plexus enables the esophagus muscle atony.

2. Autonomic nervous system dysfunction theories. These theories are based on the concept of Mikulic who treated the parasympathetic dysfunction of the nervous system as the key factor in development of cardiospasm.

3. Reflectory cardiospasm theories are united by the opinion that all organs and systems that are anatomically and physiologically linked to the esophagus may transmit pathological impulses in various diseases. And this, in turn, may lead to esophagostenosis and dilataion of esophagus.

4. Psychoneurotic theory or a theory that links the occurrence of cardiospasm to psychic trauma and explains the disease in terms of the corticovisceral theory [11].

Generally the term “cardiospasm” is understood as the primary active stenosis of the cardia which leads to increase in lower esophageal sphincter pressure. At the same time the esophagostenosis appears to be insufficient to push the food through the cardia. The specific feature of the disease is increase in EGPG for more than 12 mm Hg.

The term “esophageal achalasia” is primarily refers to abnormal weakening of esophageal peristalsis without cardia spasm, causing reflex disclosure cardia in swallowing occurs. Esophagus also becomes unable to push food through the cardia, but in this case, the cause is the weakening or absence of peristalsis. Unlike cardiospasm, EGPG with achalasia cardia within the normal range [10,11,29].

The clinical and radiological classification, suggested by Petrovsky B.V. in 1957, has gained widespread acceptance and common recognition. According to this classification there are four stages of the disease:

Stage I is characterized by a temporary LES dysfunction, which influences the functionality. In this case there is no esophagostenosis and dilataion of esophagus. The characteristic feature of this stage is that the esophagus keeps its motor function with the diameter of up to 2.5 cm;

Stage II is characterized by stable LES dysfunction, delayed esophageal emptying, moderate esophagectasia up to 4 cm;

Stage III is characterized by organic changes in the cardia. One can see a rapid cardia scarry stricture that results in a stable esophageal emptying. The cardia diameter may vary from 4 to 8 cm. In the wall of the esophagus prevail hypertrophy and inflammatory changes;

Stage IV is characterized by an extreme cardia scarry stricture. One can see rapid dilation and atony of the esophagus, thinning of its walls, signs of esophagitis and periesophagitis, fibrotic changes in the mediastinum. The diameter of the esophagus is less than 8 cm, esophagus has a S-shape [11].

## **1.2. Treatment of cardiospasm and esophageal achalasia.**

The main objective of treatment is to reduce the pressure in the LES and thus to improve emptying of esophagus from its contents. There is a great number of methods aimed at solving this problem, including medical effect, LES cardioidiosis, surgical treatment (traditional and laparoscopic), BTA injections and esophagus stenting procedure [4,20].

Campos G.M. (2009) in his research shows the results of 3 meta-analysis of the various esophageal achalasia treatment methods, pointing out their advantages and disadvantages. For example, one of them includes the analysis of 105 articles that covers 7855 patients undergoing various treatments and analysis of the complications developed. Effectiveness of PC was more evident compared to the BTA injections (68% vs. 41%,  $P = 0.02$ ). Surgical myotomy combined with an antireflux procedure appeared to be the most effective (90%) compared to all other treatment methods. In addition, this method had the minimal complications (6.3%) [70]. Similarly, the results of another meta-analysis that included study of 17 articles and covered 761 patients, also count in favor of surgery which has a smaller number of complications, as well as low frequency of recurrences. It should be noted that when comparing conventional and laparoscopic treatment methods there were no significant differences in the early and long-term results found. Wang L. (2008) in a randomized trial gave preference to PD rather than to administration of the BTA [18]. The same author in another study showed for the best early and long-term results of the surgical treatment in comparison with the PC and the injection of botulinum toxin (43 articles covering 1791 patients). The

author also did not see any significant difference in the evaluation of conventional and surgical treatments [47]. Given that the laparoscopic method of treatment is not used everywhere and the number of the completed operations cannot be compared to the operations performed using the conventional surgical methods, the results still need further analysis.

### **1.2.1. Characteristics of drug therapies**

According Maydonovitch C.L. (1995) and other authors the nitrates and calcium channel blockers (such as nifedipine) have the ability to relax the smooth muscles of LES [83]. Usually these drugs are taken sublingually, 10-30 minutes prior to meal. Drug treatment with AK is usually ineffective and often accompanied by side effects (headache, hypotension, etc.). Therefore, nitrates and calcium channel blockers are primarily used for the group of patients who do not want to be or who are contraindicated for more effective but "aggressive" forms of treatment [72]. These methods of conservative treatment have only a short-term effect on restoration of the CEJ patency and very frequently have no results at all [62]. In this regard, according to the majority of local and foreign authors, these methods of drug therapy in most remain ineffective. However, in the initial stages of the disease they still can be used for 1 year and no more. When this method appears to be ineffective the cardioidosis shall be applied.

### **1.2.2. Botulinum toxin injections**

In 1993 P.J. Pasricha et al. hypothesized that local administration of botulinum toxin type A (BTA) into the spasmed lower esophageal sphincter in patients with EA will cause it to relaxation of the LES and thus reliefs the signs of dysphagia and regurgitation, typical for this disease. 60% of experiments in pigs confirm this theory [38]. Subsequently P.J. Pasricha et al. conducted clinical trials in patients suffering from EA. During 3 - 6 months of trial this therapy showed excellent and good effects in 90% of the patients. Six months later, the majority of patients required re-administration, and only 36% of patients had a good response to the initial injection during the period of more than a year [39]. In his work P.J. Pasricha used the BTA registered under the name Botox (Allergan). The drug was

diluted in 4 ml of 0.9% sodium chloride (BTA penetrates into the cell only in the presence of sodium ion). Using a 5 mm injection needle directed through the biopsy channel of an endoscope, the scientists administrated a dose of 80 units into four quadrants on the LES, 20 units each. The effect was observed in 48 - 72 hours after administration and peaked at the end of the 14th day. Starting from 1999 the esophageal achalasia was treated using the second generation BTA registered under the name Dysport (Bofur Ipsen). Unlike Botox the new drug contained a lighter protein fractions within its structure and has less allergenic properties. 1 dose per patient was 250 units. According to Burmistrov M.V. et al. the effect of the administrated BTA was more effective in patients aged more than 50 years, and less effective in patients younger than 30 years [3].

Toxin Botulinum is a potent inhibitor of the release of acetylcholine from nerve endings. The toxin relaxes the LES by blocking the cholinergic system of myenteric plexus and Meissner plexus [55]. Although the effect of BTA injection is shorter than that of other cardiospasm treatments, its impact can be useful under certain conditions. The injections of BTA are a good option for the patients who have contraindications to surgical treatments and cardiodiosis or who don't want to go through such treatments. Furthermore, according Annese V. (1998) this method is preferable and more effective in elder patients [65]. The same author two years later, basing on the results of a randomized study, suggested that a dose of BTA can act as an early outcome measure: the higher the dose, the better the response to treatment [66].

According to many authors a single-dose BTA injection provides full recovery of 65-90% of patients just within one month. The effect of botulinum toxin lasts from 3 months to one year, although there are some publications reporting that effect lasted over longer periods [12,64,73,82,109].

However, according to Bassotti G. (1999), the effect of the injection significantly reduces during the year: 50% of patients within 6 months, compared to 30% of patients within 12 months, reported no cases of recurrent disease [68]. Annese V. et al. (1996) compared the effectiveness of PC and BTA and concluded that during

the first year results are just equivalent [65]. At the same time, more recent publications, for example Vaezi M.F. (1999) and Leyden J.E. (2006) reported that the effectiveness of PC lasts longer than the effect of BTA injection [92,114]. Mikaeli J. et al. (2001), basing on the conducted randomized study with participation of 40 patients, also told that the PC is more effective rather than the BTA: the number of patients without recurrence of the disease within a year was 52% and 15%, respectively [77].

Eaker E.Y. (1997) reported on the complications arising after BTA injection. So, 25% of patients complain of chest pain, and 5% of patients concerned of heartburn [78]. It is worth mentioning an interesting fact found out during that study: 5% of patients receiving long-term BTA injection have neutralizing antibodies. According to some researchers these antibodies could possibly cause RD after injection of the toxin [89].

Horgan S. (1999) reported on some technical difficulties he came across while carrying out the surgical treatment in AE patients who had previously received BTA injections; at the same time, the author told that there was no significant difference in long-term results of the patients who were operated with and without previous use of the toxin [86]. The researches on application of PC after BTA injection are of special interest. Mikaeli J. et al. (2004) in a retrospective study compared two groups of patients: 12 patients of the first group were exposed to cardioidosis after BTA injection, and 12 patients of the second group were exposed to PC (control group). Duration of remission of one of the patients within Group 1 lasted for 30 months, and the mean value of remission duration within Group 1 was 25.6 months.

In control group, the mean remission value was 12.6 months. The remission rates in the first group were significantly higher than in the control group ( $P < 0.01$ ). In a month after the treatment the remission rate was 76% in the combined therapy group and 53% in the control group. However, the current study didn't consider age, sex, duration and severity of symptoms before starting the treatment [85,89].

### 1.2.3. Instrumental cardioidiosis

Instrumental manipulations play a special role among conservative treatment methods. A forced dilation of the cardia using hydrostatic and later the metal and pneumatic cardioidiators with the simplest designs has spread since the late XIX - early XX century. In foreign countries, where the cardioidiosis was recognized long ago, it has been successfully competing with operative treatment. As for our country, here the cardioidiosis wasn't widely distributed up to 1960 (Yangiev B.A., 1994; Ligay R.E., 2002; Chernousov A.F., 2000). Dilation intends a forced dilation of the cardia through partial tear of the cardia muscles with decrease in resting pressure within the barrier zone which helps the food to pass through the esophagus, i.e. it eliminates the main symptom of the disease, dysphagia [5,13,21,50,54,60,63].

Vela M.F. (2006) and Emami M.H. (2008) reported on early and long-term results of application of myotomy in achalasia and PD. And though both of the studies revealed high efficiency of the methods used [81,116], Wang L. (2008) and other authors give preference to surgical myotomy than cardioidiosis [70]. Despite this, Kadakia S.C. (1993) and Zerbib F. (2006) consider the use of PC more justified because of the lower cost and satisfactory regression of symptoms of the disease [90,12]. Spiess A.E. (1998) performed a meta-analysis that revealed that a single session of cardia dilation provided a positive effect for 4.9 years in 72% of patients [11].

Zerbib F. (2006) during his randomized study involving 150 patients with achalasia, treated through PD sessions, noted the very satisfactory long-term results with this technique [121]. Furthermore, Cusumano A. (1991) and Anselmino M. (1997) noted that PC can also be effectively used in the patients who continue suffer from dysphagia even after surgical treatment [67,74]. For example in a study involving 27 patients with dysphagia after surgical treatment of achalasia, the PC had a positive effect in 76 % of patients [74]. Moreover, Zaninotto G. (2008) and Tsuboi K. (2009) stress the fact that even in case of failure

of pneumatic cardia dilation, it does not affect the results of the simultaneously performed surgical myotomy [32,44 ].

Currently there is a great variety of dilators with cylinders of different design. Vaezi M.F. (1998) presented the results of a systematic review of the PD treatment of achalasia. During the study the author compared the performance of different dilators: PC was performed in 2418 patients using "old" (classical) dilators, in 234 patients using "new" Witzel dilators, and 359 patients using Rigiflex dilators [45]. After the use of the old dilator and Witzel dilator, two-thirds of the patients had good and excellent results after one or more sessions of cardia dilation. The use of Rigiflex dilators showed equivalent improvement of the state achieved in 90% of patients, and it depended on the diameter of the dilator is used (74% for 3.0 cm, 86% for 3.5 cm and 90% for the 4.0 cm) [73].

Among the disadvantages of PC it is necessary to mention uneven expansion of the balloon within CEJ due to uneven resistance of the distal portion of the esophagus and cardia to the cylinder walls which reduces the efficiency of the forced cardia dilation [26]. This disadvantage is fixed by use of an improved model of PC with 3-5 metal plates attached to the caproic shell and served as a frame [20,21,39,40].

Mikaeli J. et al. (2009) performed cardiodyosis using Rigiflex dilators. Guide catheter is installed into the stomach under endoscopic control. During the first session of cardiodyosis they used a dilator with a balloon of 3.0 cm. At this the middle of the cylinder should necessarily be located at LES level. The balloon is gradually inflated to a pressure of 6 pounds per square inch (about 310 mm Hg). This pressure should be kept for 20 seconds. Then the balloon is inflated to 8 pounds per square inch (about 410 mm Hg) and kept in that state for 20 seconds, and then finally the balloon is inflated to 10 pounds per square inch (about 515 mm Hg) for the period of 60 seconds. After that procedure the balloon is deflated and removed along with the catheter. Patients should remain under the care of the doctor for 6 hours after dilation. If chest pain persists and the general state of the patient worsens, it is necessary to conduct an X-ray contrast study, using Gastrografin to rule out esophagus perforation [101].

In his study Emami M.H. (2008) compared 45 patients who underwent the PD procedure, with 19 patients who underwent open myotomy. Good and excellent results were achieved in 68% of patients with myotomy and 80% of patients with PD. After a follow-up that lasted for more than 2 years, the frequency of recurrences was not significantly distinguishable in both groups (39% in the surgery group and 25% of PD patients). The mean duration of the hospital stay and rehabilitation period was significantly lower in the PD group, namely, 9 days versus 39 days in the myotomy group [81].

According to Tuset J.A. (2009) one of the existing factors that may act as a probable indicators of the PD efficiency is the patient age [79]. And Eckardt V.F. (1992) suggests that not only the age is important but the rate of the pressure decrease within LES during dilation [79]. In a study of 111 patients, early and long-term results were good (98% and 75% at 24 and 60 months, respectively) however the young age of the patients ( $\leq 37.5$  years), high esophageal pressure and high LES pressure ( $\geq 17.5$  mmHg) after the first dilatation session were negative prognostic factors. According Dagli U (2009) the younger patients who needed more than 2 dilation sessions didn't notice the effect of this type of treatment [75]. At the same time, Mikaeli J. (2002) suggests that there is no significant link between age, gender, previous treatment, or the severity of the initial symptoms and the result of the pneumatic dilation (P 0.4) [100].

Esophageal perforation is the most dangerous PD complication. According Chernousova A.F. (1998) and Gajiyev A.N. (2000) the frequency of perforation PC depends on not the pressure rate and but on the frequency of its change [50,54]. According to Eckardt V.F. (1997) and Spechler S.J. (2008) perforation occurs in approximately 3-5 % of cases, although the other authors insist on that this complication can reach 21% [80]. Particular attention should be given to those who are suffer from a long-lasting pain and discomfort behind the breastbone after the procedure. As per Metman E.H. (1999) the other complications of the pneumatic dilation may include the following: intramural hematoma development, esophageal mucosa ruptures and the formation of diverticula in the gastric cardia

[94]. Leeuwenburgh I. (2006) noted the development of esophagitis signs in almost all patients who went through PD [91].

It was proved that it is practicable to hold not more than three courses of pneumo cardiodiosis, as the results of the subsequent courses progressively worsen, number of complications increase, and therefore it will be better to choose surgical treatment in such situations is [9,11,97].

#### **1.2.4. Surgical treatment**

Surgical treatment still remains a fairly common method to treat CS. To date, there are more than 60 kinds of surgeries known and this confirms the fact that the world surgeons are not satisfied with the treatment results.

The primary indication for surgical treatment is ineffectiveness of the cardiodiosis. Chernousov A.F. and Chernyavsky A.A. (1998) divide the indications into absolute and relative ones. So, the absolute ones include the reasonable suspicion of cardia cancer, impossibility to get the dilator through the cardia, phenomenon of the so-called "rubber cardia". The relative indications include inefficiency of several dilation courses, and combination of cardiospasm with other diseases of the esophagus, stomach and duodenum that need to be surgically corrected [55,56].

All the proposed and existing methods of surgical treatment can be divided into several groups. Given the fact that ideas about the nature of CS and EA were constantly changing for a long period of time, some types of transactions lost their significance due to inexpediency and unreasonableness of their performance. The groups are as follows:

1. The surgeries performed on the esophagus itself and aimed at enhancement of its peristalsis; in case of failure to remove a part or the whole organ: excision of the esophageal longitudinal muscle (Jaffe, 1897), esophagoplication (Meyer, 1911), subtotal resection, extirpation of the esophagus;
2. The surgeries performed on the diaphragm, based on the existing concept of hypertonicity of diaphragm crura that results in development of CS and EA: Porke's hiatotomy, 1914, as per Savinikh, 1983

3. The surgeries performed on the nerve trunks that are aimed at blocking the influence of the central nervous system on the muscular system of the esophagus: vagolysis, vagotomy, sympathectomy.
4. The surgeries aimed at restoration of food passage from the esophagus into the stomach without affecting the LES region, the so-called bypass surgeries: gastrostomy, jejunostomy, esophagofundoanastomosis (Heyrovsky, 1910);
5. The surgeries aimed at restoration of food passage from the esophagus into the stomach by removing barrier zone, i.e. cardia resection: Rumpel, 1897, Wangensteen, 1951;
6. Operations aimed at dilation a narrow segment of the cardia: a retrograde cardia dilation (Mikulicz, 1904), extramucous esophagogastratomy (Gottstein, 1901, Heller, 1913)
7. Esophagophrenoplasty surgeries:
  1. Intramucosal esophagophrenoplasty: Marwedel-Wendel, 1910;
  2. Extramucous esophagophrenoplasty: Girard, 1915, Petrovsky B.V., 1956 (phrenoplasty), Suvorova T.A., 1960 (gastroplasty), Chaykov I.M., 1932, Kolesov V.I., 1961 (epiploplasty).

These surgeries are only a small part of the known operations. The most widespread surgery was previously the operation of Heyrovsky (1910) known also as esophagofundoanastomosis, however, despite the good early results, in the long term the patients suffered from peptic RE with subsequent stricture of the esophagus. According Petrovsky B.V. the peptic RE occurs in 40-60% patients with the subsequent narrowing of the esophagus in 4-8% patients. Due to the large number of poor results, and also due to the fact of the serious post-surgery complications, the operation was rejected and recognized not only ineffective but faulty as well.

Currently the most popular surgery is the operation of Heller - Gottstein in its various modifications. Heller was the first who suggested the idea in 1901, and Gottstein was the first person who brought it to practice in 1913. The conventional "open" myotomy can be performed both abdominally and thoracically [72].

Most modifications of Heller operations were aimed at closing the formed muscle defect, and the most widely spread ones are Petrovsky's phrenoplasty (1956), Suvorova's gastropasty (1960), epiploplasty in accordance with the procedure of Chaykov (1932) and Kolesov (1961). Numerous and varied attempts to plastically close the muscle defects formed after the HO using various tissues and organs were unsuccessful. Moreover, they didn't even reduce the number of recurrences compared to the classical operations.

Currently laparoscopic and thoracoscopic treatment methods are being developed, though there are not enough operations performed to assess and compare the results of these methods [28,84,85,88,117].

According to different authors the modified Heller operation gives very good results varying from 70% to 90%, even in the category of patients who have already had complications of the disease. The mortality rate in this method (approximately 0.3%) is close to the one observed with PC [14,15,16,17,72]. The main disadvantages of surgery are: a high initial cost, a relatively long rehabilitation period, and a frequent development of gastroesophageal reflux disease that can be explained by the fact that the operations were aimed primarily at restoration of the cardia patency and restoration of the cardia pumping function was neglected. RE occurs in 10% of the patients who have undergone the surgical myotomy [72]; however, the use of proton pump inhibitors reduces or completely eliminates the clinical significance of this state. The authors still remain at odds over the use of an additional fundoplication for open myotomy. Some references report the development of the clinically significant gastroesophageal reflux disease caused by antireflux manipulations during open myotomy [71]. Campos G.M. (2009) noted that introduction of laparoscopic and thoracoscopic treatment to clinical practice became the method of choice in treating such patients.

According to the summary statistics of various authors, the number of the long-term recurrences following the performed ranges from 10 to 30% [6,9,58].

Chernousov A.F. (1998,2000,2001) also believes that the main recurrence cause is RE. In connection with this theory he proposes his own modification of the

operation: frontal HO, SPV and incomplete frontal fundoplication and believes that this procedure can be used both as a primary operation and as a reconstructive one after previous unsuccessful operations. And at stage IV Chernousov suggests performing EE through abdomino-cervical access with simultaneous gastroplasty [43,44,45,46,47,51,53,55,56,57,59] .

Allakhverdyan A.S. et al (2007) published the results of Geller operations performed in 102 patients with AE within the period of 1995 and 2007. Among them 54 patients (52.9 %) were operated through transabdominal access, 43 patients (42.2%) were operated laparoscopically, 5 persons (4.9%) - transpleurally. In all cases, the surgeons performed a wide mobilization of lower thoracic esophagus with the further rectification and restoration of the abdominal position. The HO was performed on 6-8 cm. Besides, the Heller operation was supplemented with a fundoplication: 5 (4.9%) patients in accordance with Nissen's method; 76 (74.5 %) patients were operated in accordance with Dor. In 21 (20.6%) cases the surgeons performed a modified oblique posterolateral fundoplication (270 degrees) by the original method. After the operation the dysphagia was immediately detected in 2 (2.0%) patients who underwent transabdominal surgery supplemented with Nissen fundoplication, and was removed by single gullet bougienage. Other complications were detected in 64 (5.9%) patients. Effectiveness of laparoscopic surgery did not differ from the standard one. The symptoms of gastroesophageal reflux disease (daily pH-metry) in the long term (6-12 months) were observed in 5 of 29 (17.2%) patients examined after Heller operation supplemented with Dor fundoplication. After the modified fundoplication the gastroesophageal reflux was not found (13 patients examined) [2].

All proposed methods of surgical treatment have their own drawbacks and require further differential search for optimal surgical options depending on the types of diseases: true cardiospasm and esophageal achalasia [19].

Despite a great variety of surgical operations to treat cardiospasm and esophageal achalasia, currently there are no options to avoid the recurrences that require

repeated surgeries. Most authors note that the poor results can be mostly caused by the following factors: too superficial or too short incision of esophagocardial muscles, scar formation or periesophageal fibrosis caused by local inflammation, coarse surgery technique, hematoma formation, and RE resulting from uncompleted antireflux surgeries during the surgical procedure or esophageal cancer as a deuteropathy [9,11]. Among the post-surgery RD causing factors Tsarenko I.A. (1998) names incomplete esophagogastromyotomy, hyperactivity fundoplication cuff and development of scar tissue in the surgery region. The author notes the effectiveness of the PC as an alternative to repeated surgeries in these patients [41].

According to some authors [9,41,43,44,45,46] the optimal re-intervention is the excision of scar tissue in the region of cardia and abdominal esophagus, repeated HO with SPV and fundoplication, disintegration of esophagofundoanastomosis after Heyrovsky surgery or reconstruction of anastomosis after cardia resection (if necessary) with the restoration of the esophagus and mandatory performance of antireflux surgery (fundoplication or esophagofundoraphy).

After a number of failed surgical interventions Orunov S.R. (1996) in his work "Repeated operations for recurrent dysphagia in patients with neuromuscular disorders of the esophagus" offered an effective conservative operation, namely HO with partial fundoplication according to Chernousova's procedure. The author suggested performing EE in case of development of irreversible scar stricture of the lower third of the esophagus and cardia, and especially for megadolichoesophagus and peptic ulcers of the esophagus [24].

For the patients with IV degree EA Zherlov G.K. et al. recommends demucosation of the esophagus muscle with putting a gastric transplant in the remaining muscle sheath. For the patients with II-III degree EA they suggest to perform demuscularization of the narrowed esophagus with SPV and formation of invaginated valve in CEJ region. In total 15 patients with IV degree EA were operated according to the first method, 37 patients with II-III degree EA underwent the second method procedure. Not a single case of the recurrent disease was found

our during the case follow-up which lasted from 1.5 months to 7 years after surgery [14,15,16,17].

### **1.2.5. Other treatment methods**

There is a great number of therapies that can be used to treat CS and EA, including physiotherapy, laser therapy and stenting [30,31,61,62]. Trukhmanov A.S. (1995) performed esophageal elektroendostimulation using the apparatus "Endoton - 01B" to treat hypokinetic type of disease. During the electrostimulation procedure he observed the increase in the amplitude of esophageal wall contractions in 75% of patients. After several treatments he noted activation of local reflex mechanisms which was not only local but general. Administration of metoclopramide in 75% of patients significantly reduced the symptoms of EA [35,36].

Efendiyeva M.T. (2002) reported on the efficacy of a restorative treatment complex in 25 patients with III degree CS/ The complex included procedures involving exposure to electromagnetic fields of ultrahigh frequency 460 MHz (UHF-therapy) and general baths with iodine-bromine water. After the treatment 80% of patients found disappearance of dysphagia after solid food. After endoscopical examination 53% of patients noted disappearance of edema and hyperemia of the esophageal mucosa, submucosal hemorrhage, and 47% of patients found a significant regression of the inflammatory process [61].

In the literature there is a small amount of works covering the use of self-dilating stents in EA. And the results of their use are very contradictory. Therefore, such stents cannot be recommended for use as a treatment for EA and require a further study [76,77,102,122].

Analysis of the studied modern national and foreign medical literature has shown that the problem of choosing the optimal treatment strategy in patients with CS and EA remains an urgent problem of esophageal surgery. This is primarily due to the fact that there is still no consensus among scientists on the development aetiopathogenesis of CS development. In this regard, all methods of conservative treatment, and well as the most surgical techniques are of a symptomatic temporary nature, and aimed at removal of its main symptom, dysphagia.

In the literature there are just a few reports on the use of the modern hydro-balloon dilators. There are no clear indications and contraindications for this procedure, and there is no data on their efficiency depending on the state of the disease.

Therefore, there is still no clear comparative analysis of all instrumental methods of treatment that would show the advantages and disadvantages of each of the methods.

There are still not fully disclosed the issues on long-term results of surgical treatment after application of instrumental methods of treatment.

So, such a diversity of opinions of the surgeons from different countries on the choice of optimal strategy of conservative, instrumental and surgical treatment of patients with cardiospasm and esophageal achalasia is just one more proof of the relevance of the problem, the solution of which is covered in the present research study.

## CHAPTER II

### MATERIAL AND RESEARCH METHODS

#### 2.1. General characteristics of the clinical trial material.

Material for this research was 109 patients who were under inpatient and outpatient treatment in the esophagus and stomach surgery department of the RSSC named after academician V. Vakhidov during the period from 2002 to August 2013 inclusive. Due to the nature of this disease of the esophagus (frequent recurrences, repeated courses of dilatation, repeated surgery), most patients were repeatedly examined and treated, and therefore, 138 medical records and outpatient cards were processed.

Standard separation of patients by age and sex according to the WHO classification (1976) is presented in Table 2.1.

**Table 2.1.**

#### Separation of patients by sex and age

	<b>under 19 years</b>	<b>19-44 years</b>	<b>45-59 years</b>	<b>60-74 years</b>	<b>&gt;75 years</b>	<b>Total</b>
<b>Men</b>	8	35	6	4	-	<b>53(48,2%)</b>
<b>Women</b>	11	31	7	5	1	<b>56(51,8%)</b>
<b>Total</b>	<b>19(17,43%)</b>	<b>67(61,4%)</b>	<b>13(11,9%)</b>	<b>9(9,25%)</b>	<b>1(0,97%)</b>	<b>109(100%)</b>

As it can be seen from the data in Table 2.1., the number of women, 56 (51.8%) is slightly exceeds the number of men, 53 (48.2%). Thus, our data do not correspond to the literature which tells that the number of women is almost 2 times higher than men, which previously was explained by lability of the nervous system of females.

In this regard, there is no doubt of great social importance of the pathology studied, as up to 10% of patients with CS and EA may even lose the ability to work due to limphothisis.

As it is known the etiopathogenesis of CS and EA is not fully disclosed, the proposed theories of disease development often contradict each other, but the major reason for the disease occurrence in our patients is previous nervous stress. Thus 48 (44.3%) of the patients associated their illness with nervous tension.

Despite a thorough history taking we failed to identify any causes of dysphagia in 56 (51.3%) patients. As for the rest patients, 5 (4.4%) persons reported on a number of various factors that, in their opinion, could be preceded by the appearance of the disease (taking too cold fluids and food, childbirth, chest injuries, infectious diseases, and other diseases of the abdominal and thoracic cavities).

Clinical symptoms in patients with CS and EA is well known and described in various monographs, so we do not consider it necessary to describe in detail each of them. Table 2.2 presents the main symptoms of our 109 patients.

**Table 2.2**

**Clinical symptoms**

<b>Symptom</b>	<b>Number</b>	<b>%</b>
Dysphagia	107	98,5
Regurgitation	88	81,3
Chest pain and epigastric pain	75	69,2
Hydrophagy	66	60,5
Aerophagy	17	15,7
Nausea	40	36,3
Hypersalivation	25	23,7
Asthenia	64	58,4
Weight loss	62	56,6
Pulmonary symptoms	21	18,9
Mediastinal compartment syndrome	11	10,9
Loss of labour capacity	10	9,4
<b>Total number of patients</b>	<b>109</b>	<b>100%</b>

As with majority of other esophageal disorders the main symptom of the disease in patients with CS and EA is dysphagia, i.e. impaired patency of the esophagus. In this connection, we consider it appropriate to subdivide 109 patients with dysphagia according to the classification Chernyavsky A.A. (1991):

- I degree (difficulty of solids passage) - 13 (11.92%) patients;
- II degree (difficulty of solids and stodge passage) - 56 (51.37%) patients;
- III degree (difficulty of liquids passage) - 30 (27.52%) patients;

- IV degree (complete obstruction) - 10 (9.17%) patients.

Thus, the majority of patients, 86 (78.89%) persons, had II-III degree dysphagia that made them to seek medical help. Complete obstruction was observed in 6 (5.5%) patients.

Duration of disease in patients varied. At the same time all the patients had a long medical history that distinguishes them from patients with esophageal cancer, in whom the disease development and depletion occur very quickly. Division of the patients by disease duration was as follows: up to 6 months - 19 (17.43%) patients; 6 months to 1 year - 28 (25.4%); 1 to 5 years - 44 (40.5 %) and more than 5 years - 18 (16.7 %) patients.

The patients were separated in accordance with the classification of Petrovsky B.V. (1957), and groups were as follows: I stage - 8 (7 %), II stage - 34 (31.2%), III stage - 55 (50.4 %) and IV stage was diagnosed in 12 (11.4%) patients. Thus, the total number of patients with advanced stages, including III and IV, was 61.8%.

Basing on differential and diagnostic criteria for the two types of the disease, proposed by Cherniavsky A.A. and Kasumyan S.A. (1979) and updated by Ligay R.E. (2002) the patients were divided as follows: cardiospasm group - 64 (58.71%) and esophageal achalasia group - 45 (41.29%) patients. Distribution by stage and type of the disease is shown in Table 2.3.

**Table 2.3**

**Distribution of patients by stage and type of the disease**

	<b>I stage</b>	<b>II stage</b>	<b>III stage</b>	<b>IV stage</b>	<b>Total</b>
<b>Cardiospasm</b>	7	33	30	4	<b>64(58,71%)</b>
<b>Esophageal achalasia</b>	1	11	25	8	<b>45(41,29%)</b>
<b>Total</b>	<b>8(7%)</b>	<b>34(31,2%)</b>	<b>55(50,4%)</b>	<b>12(11,4%)</b>	<b>109(100%)</b>

Distribution of patients of both cardiospasm and esophageal achalasia groups by sex and dilation method is shown in Table 2.4.

**Table 2.4**

**Distribution of patients by sex and cardioidosis method**

Dilation method	Mechanical dilation (9)		Pneumodilation (62)		Hydrodilation (38)	
	n	%	n	%	n	%
<b>Men</b>	4	44	28	45	19	50
<b>Women</b>	5	56	34	55	19	50
<b>Total</b>	9	100	62	100	38	100

## 2.2 Research Methods

The clinical picture of CS and EA is specific enough, however diagnostic errors still occur frequently enough and result in selection of wrong therapeutic approach to that given category of patients. In this regard, all patients with this disease need a complete physical examination that helps to determine not only the type and degree of pathology but also to reveal a number of comorbidities requiring parallel correction. We used following methods to examine patients with CS and EA:

1. X-ray method:
  - plain X-ray examination of the chest and abdomen;
  - polypositional radiopaque examination of the esophagus and stomach;
2. Endoscopic method: esophagogastroduodenoscopy;
3. Esophagomanometry;
4. Radionuclide scan of esophagus;
5. Morphological study method.

### **Radiopaque examination of the esophagus and stomach**

The leading method to date is radiopaque examination of the esophagus and stomach which was used to examine 109 (100%) patients. The examination was performed using the apparatus "Siregraf" ("Siemens", Germany) with electro-optical converter. Most of the patients were examined two or more times, including examination in the course of treatment, examination before release and during out-patient examination in the long term. The total number of the performed esophageal fluoroscopies and radiographies is 352. The study was conducted in the morning in the fasted state. The survey was started with a plain X-ray examination during which we assessed the presence of a gas bubble of the

stomach and occurrence of pathological changes in the lungs and heart. Very often during x-ray examination of the mediastinum fasting we saw a distinct horizontal fluid line in the patient esophagus that indicated a persistent delay of the liquids in the esophagus (mucus, debris of food and fluids taken a day before). Sometimes we had to pre-wash the esophagus to empty it. For examination we used the barium meal. Normally, the barium meal, taken in the upright position, reaches the cardia within 5-7 seconds owing to propulsive motility of the esophagus and its hydrostatic pressure. The cardia opens in response to sip, lets the barium meal to pass and closes. The patients with CS and EA have an abnormal flow of barium meal through the esophagus. During the study we assessed the characteristics of esophageal peristalsis (active, slow, completely absent, large atonic bag-like esophagus), occurrence of nonpropulsive tertiary contractions, occurrence of antiperistalsis, cardia dilation characteristics (spindle-shaped or "mouse tail"), degree and extent of narrowing of the cardia, expansion of the esophagus, the nature of the contrast evacuation from the esophagus ("syringe - phenomenon", by the type of passing due to an increase in hydrostatic contrast pressure on the cardia), duration of the absence of contrast evacuation from the esophagus and time of contrast presence in the esophagus. Also, the study was conducted to determine comorbidities, including occurrence of secondary esophageal spasm, esophageal diverticula, various pathologies of the stomach and duodenum. The courses of cardiodynia or surgical treatment were followed by mandatory was carefully controlled study of the esophagus which was conducted by evaluate the treatment result. During the examination we estimated the esophageal diameter dynamics, change in nature of peristalsis, evacuation of the contrast through the cardia, degree of the cardia expansion, presence or absence of gastroesophageal reflux disease to diagnose physiological cardia failure.

### **Oesophagogastroduodenofibroskopy (OGDFS).**

At the present time this method is considered efficient and quite informative to diagnose various diseases of the esophagus, including the CS and EA. The most important value of endoscopy is its use in advanced forms of the disease to identify

cicatrical cardia changes and in differential diagnosis of cardia cancer. During the procedure the doctor can visually evaluate the mucosa of esophagus and CEJ. Also there is the possibility to do targeted biopsy and then conduct a morphological examination for accurate differential diagnostics of cardia cancer, especially in elderly patients.

Oesophagogastroduodenofibroscope was held in 107 (98%) patients using Olympus fiberscopes (Japan). The examination was conducted in the morning in the fasted state, after a pre-washing of the esophagus to empty. During the endoscopy we can see the presence of esophagectasia and esophagectasis, state of the esophageal mucosa and cardia, severity of cicatrical cardia changes, esophageal peristalsis nature or its absence. In any doubtful cases we performed the targeted biopsy, followed by morphological examination of the preparations.

This type of endoscopy is very useful in difficult cases when it is impossible to perform the cardiodynia of GB not only under X-ray control. These manipulations under endoscopic control were successfully conducted in 14 patients

### **Esophagomanometry**

Currently this method of examination is mandatory for the patients with neuromuscular disorders of the esophagus. Owing to information value of this method it is considered the leading one in the differential diagnosis of CS and EA. Currently the following methods of esophagomanometry are known: electromagnetic method, esophageal balloon pressure manometry and open catheters method.

As you know, normally a human has a LES which includes: abdominal esophagus, interdiaphragmal and supradiaphragmatic esophageal segments with esophageal hiatal. In this region the increased resting pressure zone is registered, varying from 15 to 30 mm Hg. Normally during swallowing the LES pressure decreases and thus the food freely passes into the stomach. After that the pressure restores and prevents the gastroesophageal reflux. The most important criterion is the so-called EGPG (i.e. the difference in pressure in the bottom of the lower third of the stomach and esophagus), which normally is  $10 \pm 2$  mm Hg.

In the study group of patients the esophagomanometry was conducted through the most affordable method, open catheter technique, which is based on U-tube effect and uses probe with an open perfused channel as a data transmitter. The study was conducted in the morning in the fasted state. Patients were sitting. Through the patient's mouth we put a microprobe which is connected through a T-joint to Waldmann water gauge and a drop system for the perfusion (saline or 5% glucose solution). Before the start of perfusion we performed X-ray examination of abdomen for accurate visualization of the microprobe tip within the stomach. This became possible owing to the metal olive on the tip of the microprobe which allows us to determine the location of the probe visually. After putting the probe we started slow perfusion at rate of 1 ml/min with the gastric fundus pressure taken as an initial. After that we slowly pulled up the probe without ceasing the perfusion until increase in pressure as per water gauge, and this is the LES. During examination we have recorded the distance between the high pressure zone and the cutting teeth, the maximum increase in pressure in the LES, the length of the high pressure zone and its ratio to the length of the esophagus, the nature of the cardia reaction in response to a swallow. The pressure result, expressed in mm w.g. was converted into mm Hg in accordance with the standard formula. The value in mm w.g. was multiplied by the coefficient of 0.073 (Rabinovich V.A., 1991).

This esophagomanometry method was used in 64 patients with CS and EA, as well as in patients who were under follow-up examination after gastric cardia surgery to evaluate the effectiveness of surgical treatment in the long-term period. Moreover, these esophagomanometry results were the main criterion for differential diagnosis between CS and EA.

### **Morphological examination methods**

The morphological examinations of the esophageal wall were performed through the conventional method. The procedure was as follows: we took the pieces of mucosa and submucosa of the esophagus, taken during the endoscopic biopsy before the cardiomyotomy and at different times after the PC and HBC, as well as

pieces of wall of the lower third of the thoracic and abdominal esophagus and cardia, taken during surgery (Heller operation). Complete examination of all esophageal layers at all levels conducted only in patients with EA who underwent EP. Fixing of the pieces was performed in 10% neutral formalin solution. Paraffin sections, 5  $\mu\text{m}$  thick, were colored with hematoxylin-eosin. The micropreparations were examined by light microscope "Biolam-16". The morphological studies were performed in 4 patients.

### **2.3. General characteristics of the of treatment methods used**

For treatment of patients with cardiospasm and esophageal achalasia we used instrumental and surgical treatment methods. By "instrumental" treatment we shall basically mean the use of special "tools" for the expansion of the cardia which include bougies and dilators in their various modifications. Besides the metallic tools, we can use air or water for dilation. Depending on this factor, the dilators can be divided into metal (mechanical), hydrostatic and pneumatic dilators.

**Metal cardiodylator.** Metal cardiodylator of Starck (Figure 2.1) was developed in Germany in 1924, and it was one of the most popular dilators in both foreign and in the CIS countries up to the 60s of the last century.

**Figure 2.1**

**Starck's metal cardiodylator**



It is necessary to take into account the world experience of its use, a large frequency of complications, and the fact that the procedure of putting the device through the oropharynx into the stomach is the most painful and dangerous one compared to pneumatic apparatus, made of rubber or silicone.

Considering the complexity and danger of the procedure, this method is not currently used in RSSC named after academician V. Vakhidov, so, we think that it makes no sense describe the details of this manipulation which is provided with great circumstance in the monographs covering this disease.

### **Pneumatic cardioidiosis**

The most widely used pneumatic cardioidilator was developed by Fedorova O.D. in 1964. It shown in Fig. 2.2.

Pneumatic cardioidilator is a thick elastic rubber radiopaque probe of 1.3-1.5 meters. At a distance of 5-6 cm from the end it has a fixed dumbbell shaped balloon, up to 15 cm long, consisting of three layers: the inner and outer ones were made from rubber and the middle one from nylon. The middle layer restricts the elongation of the cylinder and ensures its certain form and rigidity. Rubber probe has a thin channel which allows in difficult cases to pass the cardioidilator over the conducting cord. Pneumatic cardioidilator cylinder consists of two balloons: the one is a fixing balloon ("stomach") which is extends after the dilator is put into the stomach and enables to set the dilator in the cardia, the second is a medical one ("esophageal"), which is used to extend the cardiac sphincter by a forcing air. The device is connected to a manometer Riva Rocha, allowing injecting into the balloons the exact dosage of air.

The modern model of the pneumatic cardioidilator is based on medical silicone featuring a high strength, resistance, elasticity, flexibility and security. Moreover, its various features are used for the respective components of the dilator. So for the basis of the probe they used such features of silicone as strength and elasticity which are indispensable for directing of dilator through the spasmed cardia,

**Figure 2.2****Pneumatic rubber cardioidilator**

especially in advanced stages and the presence of cicatrical cardia changes. Elasticity and resistance to gastric juices ensure reusability of silicone dilators, as one patient needs several sessions of cardia expansion. Appearance of the pneumatic cardioidilator is made from medical silicone, designed by "Medsil" (Mytisch, Moscow region, Russia), is shown in Figure 2.3.

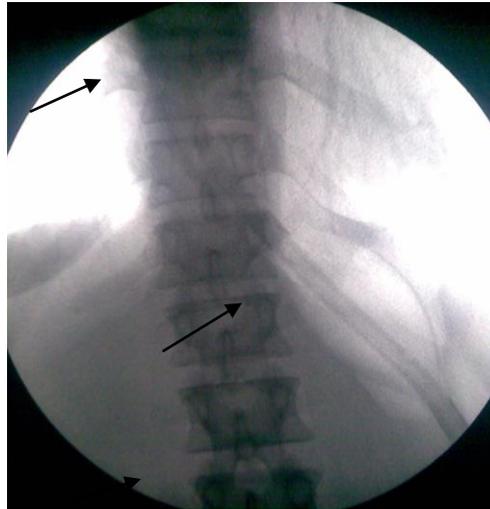
**Figure 2.3****Pneumatic silicone cardioidilator**

The dilatation performed using a silicone device is somewhat different. The difference lies in the fact that silicone is not radiopaque, so, the balloon dilator has

three contrasting mark on its surface, as shown in Figure 2.4. which demonstrate the correct location of the balloon.

**Figure 2.4**

**X-ray pattern of the pneumatic cardiodilator**

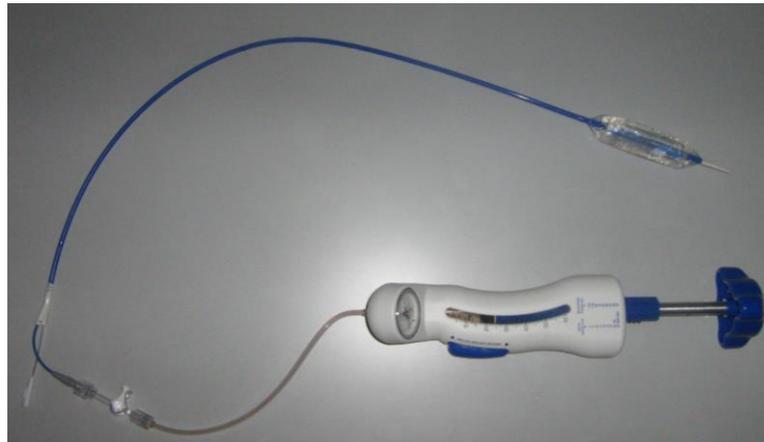


The first (bottom) mark should be below the diaphragm in cardiac projection. The second (middle) mark should be in lower esophageal sphincter projection. The third (top) mark should be in esophageal lumen. Nylon dilator sheath is formed as a "dumbbell", while "waist" of the balloon is in the middle mark projection that ensures downward movement towards the stomach and upward movement towards the esophagus. In this position of the balloon the cardiodiosis will be appropriate.

**Hydrostatic cardiodiosis**

Hydrostatic cardiodilator was firstly proposed by Plummer in 1908. However, due to unhandy water pumping equipment and pressure adjustment problems, it was not widely used in the last century. Nowadays the improvement of medical technologies, development of the modern hydro balloon dilators of various modifications make this industry one of the leading ones in many hospitals around the world and the CIS countries.

Improvement of medical technologies resulted in development of various new models of modern dilators which are very handy in practice. One of such devices is a hydro balloon dilator manufactured by Wilson-Cook, presented in Figure 2.5.

**Figure 2.5****Hydro balloon dilator manufactured by Wilson-Cook**

The length of the hydro balloon dilator is 90 cm, and diameter is 5 mm. The working section of the dilator is 8 cm in length. Depending on its number, the balloon can be expanded to 30, 35 and 40 mm. Before "working" balloon there is an elastic dilator directing tip, 3 cm long. In the lumen of the dilator there are two channels. One of them is designed for water supply, and another is for putting the conductor cord. Expansion of the balloon is performed by a special device that allows accurate dosing of pressurizing fluid. The inflating device is made in the form of a 100 ml pump. It allows using any liquid however for radiological imaging it is preferable to use a water-soluble.

Before the procedure the device is filled with the liquid and then is connected to hydro balloon dilator through a special cannula. This inflating apparatus can create a pressure within the "working" balloon up to 1 to 2 atmospheres. It is necessary to tell that the pressure increase should be performed gradually, from session to session, to prevent rupture of the gastroesophageal junction.

## CHAPTER III

### RESULTS OF INSTRUMENTAL METHODS OF TREATMENT OF THE PATIENTS WITH CARDIOSPASM AND ESOPHAGEAL ACHALASIA

In this chapter we will make a comparative analysis of the results of different methods of "instrumental" treatment. Any method of instrumental treatment in patients with CS and EA, including cardioidiosis, is aimed at eliminating the main symptom of the disease, dysphagia, and shall not be considered as a pathogenetic therapy. The purpose of cardioidiosis is to forcedly extend and partially lacerate the muscles of the distal part of esophagus and cardia to ensure passage of food through the cardia.

#### **3.1. Criteria for evaluating the effectiveness of "instrumental" treatment methods**

There are some certain criteria to assess the results of the instrumental treatment. At the same no one can make a decision basing on one of them only. So, it is necessary to make a comprehensive assessment of the dynamics of complaints and special factors of the investigation methods, to determine the result, both subjectively and objectively.

After treatment the following parameters, given in the table 3.1, were evaluated including: dynamics of complaints and objective state of the patient; radiopaque esophageal endoscopy results and results of esophagomanometry examination.

The results of the treatment can be considered good when patients note a free passage of any food or sometimes note a transient dysphagia for solids, complete absence of regurgitation and pain. According to physical examination the patients have an increase in body weight, their ability to work is completely preserved, and patients who have lost this ability due limphothisis re-obtained the ability to actively work. According to X-ray examination there is a free passage of contrast through the cardia without delay, however some patients (especially those with advanced stages) may still have some minor suprastenotic expansion of the esophagus; stomach gas bubble are preserved in all cases. According to the endoscopy a fiberscope with diameter of 1.2 cm, freely passes through the cardia,

spastic component during device withdrawal is missing. According to esophagomanometry EGPG is within normal limits.

**Table 3.1.**

**Criteria for evaluating the effectiveness of “instrumental” treatment methods**

	<b>Good</b>	<b>Satisfactory</b>	<b>Bad</b>
<b>Complaints</b>	Free passage of any food, periodical dysphagia for solid foods that runs its course, complete absence of pain and regurgitation. Normalization of body weight	Free passing of stodge and liquid food, persistent, insignificant dysphagia for solid food, periodic hydrophagy and regurgitation. Increase in body weight.	Passage of any food is not improved, continuing regurgitation, pain and hydrophagy. No increase in body weight.
<b>Ability to work</b>	Preserved	Preserved or slightly restricted	Sharply restricted or completely lost
<b>X-ray</b>	Stomach gas bubble is preserved. Passage of contrast is free. Esophagectasia is absent or insignificant.	Stomach gas bubble is not always preserved. A satisfactory passage of barium with a slight delay	Stomach gas bubble is absent, previous esophagectasia is preserved, passage of barium has not improved
<b>Endoscopy</b>	Free passage of the endoscope with diameter of 1.2 cm, no cardia spasms during withdrawal of the endoscope from the stomach	The endoscope passes through the cardia with a moderate resistance. During withdrawal of the device from stomach a repeated cardia spasm occurs.	The endoscope cannot pass through the cardia or passes with considerable resistance, cicatricial cardia changes observed
<b>Esophago manometry</b>	EGPG is a norm	EGPG is in a norm or within 15-20 mm Hg	EGPG after dilation is not changed, remains within 20-40 mm Hg

The results of the treatment are considered satisfactory in the following cases: after dilatation patients report significant improvement in passing stodge and liquid foods, though in case of solid food the patients had to drink water due to a stable but unexpressed dysphagia. Periodically the patients had regurgitation and sometimes pain. The physical examination revealed some increase in body weight. The ability to work is preserved and slightly restricted. According to X-ray examination revealed the preserved suprastenotic expansion of the esophagus with a satisfactory passage of contrast through the cardia. Also, there was a slight delay

of barium in the esophagus. A gas bubble is not always preserved or appears during the examination. According to esophagomanometry in the patients with I type EGPG remains, despite the fact that the clinical effect is above the norm.

The treatment results are considered unsatisfactory in case of the following: the patient has a persisting or progressing dysphagia, regurgitation and pain crises; the radiological, endoscopic and esophagomanometrical examinations reveal no positive dynamics; body weight reduces; the ability to actively work is reduced or completely lost.

### **3.2. Bougienage results in the treatment of patients with cardiospasm**

GB as a primary method of treatment is intended for patients with cicatricial esophageal strictures. However, often bougienage is used in treating patients with cardiospasm. Actually, the essence and the procedure of the GB is different from cardiodiosis. During the GB the cardia is forcedly expanded to the diameter corresponding to the size of the bougie passed. For example, bougie No. 40 is 1.2 cm in diameter. So, from an objective point of view, this method of treatment cannot have a positive effect. The only exception is a constrictive RE performed after previous cardia operations.

During the current study we have analyzed 7 patients who underwent GB, including 5 patients with stage III and 2 patients stage IV. At the same time 4 patients with RD have previously underwent the following cardioplastic operations, including Petrovsky's surgery in 2 persons and Suvorova's operation in 2 patients. The number of bougienage sessions ranged from 1 to 5. Analysis of the GB results showed its low efficacy in patients with CS.

**Table 3.2.**

#### **Bougienage effectiveness in the treatment of cardiospasm**

Stage	Number of bougienage sessions				Bougienage result			Total
	1	3	4	5	good	satisfactory	unsatisfactory	
<b>III</b>	1	3	1	-	-	3	2	5
<b>IV</b>	-	1	-	1	-	-	2	2
<b>Total</b>					-	3	4	7

So, as it is shown in Table 3.2., not a single case had good results. Satisfactory result was obtained in only 3 patients, and 4 patients had unsatisfactory results. Later 3 patients underwent the PD courses. The rest patients refused the proposed cardioidiosis, thus, the result of treatment was assessed as unsatisfactory.

The presented treatment results of the patients with cardiospasm cannot be associated only with the fact that all patients had advanced stages. Apparently, this result is due to the difference in the principles of bougienage and cardioidiosis. In view of the small number of patients we have not presented the bougienage results in percentage, though the absolute numbers allowed us to make a brief summary about the role of this method in treatment of the patients with cardiospasm.

**Summary:** The bougienage cannot be regarded as the primary method of treatment of patients with cardiospasm. Its performance requires strong evidences, including a developed organic narration which is frequently occurs in association with the stenosing RE after previous unsuccessful cardioplastic operations. For optimal results it is necessary to perform cardioidiosis immediately after bougienage.

### **3.3. Cardioidiosis principles**

Basing on the literature data and experience of the clinic of RSSC named after V. Vakhidov RSCS, we consider it possible to draw several conclusions regarding principles of use of cardioidiosis in patients with CS and EA:

1. Dilation is a complex surgical procedure requiring specific skills for achieving the optimal results;
2. Cardioidiosis must be performed in a hospital because of possible complications (perforation, bleeding, exacerbation of esophagitis), requiring dynamic supervision of a physician. In exceptional cases it is allowed to perform the outpatient dilatation in patients with early stages or in patients who undergo the preventive treatment;
3. Prior to determining the indications for cardioidiosis it is necessary to exclude both local and general contraindications to this manipulation;

4. Cardiodylisis must be performed under X-ray control as the good results can be achieved only in case of a correctly located balloon;
5. The development of the most dangerous cardiodylisis complication can be caused not by the pressure value but the pressure increase rate within in the balloon. In view of this fact the air supply to the balloon should be gradual during each session, the increase in pressure should be stepwise;
6. The correct assessment of cardiodylisis effectiveness should be mandatorily based not only on the clinical picture but on the of radiological and esophagomanometrical examination results as well.

Indications for cardiodylisis are as follows: proven cases of CS and EA, secondary diffuse esophageal spasm associated with the primary cardiospasm. Indications for dilatation depending on the stage of the disease, as well as its effectiveness will be discussed in the further subchapters.

Contraindications to cardiodylisis can be divided into general and local one, both are widely covered in the literature. However, compared to the last century the number of the so-called general contraindications decreased significantly, and they became more relative: severe cardiovascular and pulmonary insufficiency, myocardial infarction, severe stroke, malignant blood diseases, early and late stages of pregnancy, decompensated form of endocrine diseases. Currently, local contraindications are divided into absolute and relative ones.

The absolute contraindications include:

1. Proven suspicion and inability to exclude the cardioesophageal passage cancer, even in case of a negative histological result, and especially in the elderly. Currently, however, age should not be considered in cases of the suspected cardia cancer, as the age structure of malignant tumors, including CEJ, has changed. Thus one of the criteria for suspected cardia cancer is the first unsuccessful attempt to pass the cardiodylator through the cardia with satisfactory passing of the fiberscope.
2. Failure to pass the cardiodylator through the cardia, even after preliminary GB. Most often it is caused by the severe cicatricial cardia strictures or S-shaped

deformation of the esophagus in advanced stages. In this regard, numerous attempts to perform a dilation become hopeless and hazardous, as they may result in perforation of the chronically inflamed esophageal wall.

The relative contraindications include:

1. Primary diffuse esophageal spasm. Despite the similarity of the clinical picture (dysphagia, regurgitation, pain) the dilation will have no effect as obstruction is caused by spastic contractions of the whole esophagus, not only cardia. Such situation requires a comprehensive conservative therapy. The only exception is the secondary esophageal spasm which always develops in association with the primary cardiospasm. In such cases the treatment should include both cardiodynia and medications;
2. Peptic cicatricial cardia strictures;
3. Esophageal varicose veins dilatation of stage II-III, associated with portal hypertension (due to the risk of bleeding);
4. Obvious spondylosis with osteophytes of the spine;
5. Large esophagus diverticulum;

### **3.4. Analysis of the early and long-term results of the cardiodynia performed using Starck's apparatus**

The cardiodynia by Starck's apparatus was performed in 9 patients. Distribution of patients by stage of disease was as follows: I stage - 1 (11.1%) patients; stage II - 3 (33.3%) patients; stage III - 3 (33.3 %) and stage IV - 2 ( 22.2% ) patients.

Analysis of the early results of this treatment are shown in Table 3.3. The total number of good (44.4%) and satisfactory (44.4%) results reached 88.8%, however a more objective criterion here is dependence of the results on the disease stage.

So, the patients of I stage had a 100% good results of treatment, the number of good results in patients with stage III has decreased to 52.9 %, and not a single good result was obtained with the patients of IV stage. At the same time, the number of bad results in advanced stages has also increased. So in patients with III stage, their number was 11.8%, and with stage IV, their number has reached 25%.

**Table 3.3.****Effectiveness of the cardioidosis performed using Starck's apparatus**

Stage	Result			Total
	good	satisfactory	unsatisfactory	
<b>I</b>	1(100%)	-	-	<b>1(11,1%)</b>
<b>II</b>	2(66,3%)	1(33,5%)	-	<b>3(33,3%)</b>
<b>III</b>	1(33,3%)	2(66,6%)	-	<b>3(33,3%)</b>
<b>IV</b>	-	1 (50%)	1(50%)	<b>2(22,2%)</b>
<b>Total</b>	<b>4(44,4%)</b>	<b>4(44,4%)</b>	<b>1(22,2%)</b>	<b>9(100%)</b>

However, despite the high efficiency of the Starck's apparatus dilation, nowadays this method of expanding the cardia is not widely used and in 1991 it was completely excluded from the clinical practice due to development of several complications.

In one case, after the second dilatation session there was a gastric intussusception into the distal esophagus caused by technical failures of the dilator (jaws failed to close during withdrawal). The patient underwent the gastric disinvagination procedure with fundoplication. The postoperative period was uneventful and the patient was discharged. During the two-year follow-up monitoring there was no dysphagia observed.

In another case, during the first dilatation session a perforation of the lower esophagus occurred. The patient underwent the laparotomy, closure of the esophageal defects, sanitation, drainage and grouting of the mediastinum. The postoperative period was favorable.

During the long-term period ranging from 1 to 10 years 4 patients had the recurrent RD that made 44.4 %. The recurrence occurred within the first 6 months in 1 patient, and within 1 year in 3 persons after the first course of cardioidosis performed using SID. At the same time 2 patients with stages III-IV underwent the surgical treatment that was necessary due to impossibility to pass the device through the cardia. 1 patient refused all treatment methods.

**Summary:** Thuswise, the cardioidosis performed using Starck's apparatus is an effective treatment, as in most cases it helps to satisfactorily expand the cardia, which is proved by a retrospective analysis. However, cardioidosis using SID id

tolerated much heavier compared to the pneumatic models (following subchapters). It is also more dangerous in terms of complications (bleeding, perforation, gastric intussusception into the esophagus). Moreover, these complications are caused precisely by the product design featuring rigid metal jaws.

### 3.5. Analysis of the early and long-term results of pneumatic cardioidiosis

Pneumatic cardioidiosis is performed in 62 patients with various stages of CS and EA. Distribution of patients by stage of disease was as follows: stage I - 6 (9.68%) patients ; stage II - 17 (27.41%) patients; stage III - 31 (50%) patients and stage IV - 8 (12.92%) patients.

The main advantage of this design over the metal dilators is the safety of the device achieved due to its structure as it has been described previously. However, on the other hand sometimes there can be some difficulties in passing the pneumatic cardioidilator through the spasmed cardia or cicatricial cardia strictures (in advanced stages and recurrence). Also the appropriate dilation requires a greater number of manipulations, as presented in Table 3.5.

**Table 3.5**

#### The required number of pneumatic dilation sessions

Stage	Number of dilation stages during 1 treatment course							N
	0	1	2	3	4	5	5 <	
<b>I</b>	-	1(16,6%)	2(33,12%)	2(33,12%)	1(16,6%)	-	-	<b>6</b>
<b>II</b>	-	1(5,88%)	3(17,64%)	10(58,82%)	2(11,76%)	1(5,88%)	-	<b>17</b>
<b>III</b>	2(6,45%)	-	4(12,90%)	16(51,61%)	4(12,9%)	2(6,45%)	2(6,45%)	<b>31</b>
<b>IV</b>	-	-	-	4(50%)	1(33,3%)	1(33,3%)	1(33,3%)	<b>8</b>
	2(3,22%)	2(3,22%)	9(14,51%)	32(51,61%)	7(11,29%)	4(6,45%)	3(4,83%)	<b>62</b>

So, all the patients with stages I and II have successfully passed the procedures of passing the pneumatic cardioidilator through the cardia and the cardioidiosis itself. However, in 2 of 31 patients with stage III, representing 6.45% of the total number, the numerous attempts to pass the pneumatic cardioidilator were successful even

despite the fact of the use of endoscopic equipment. Thus, the failure to pass the cardiodylator occurred in 2 (3.22%) of 62 patients.

Table 3.5 provides a detailed analysis of dependence of the frequency of required cardiodylosis courses on the disease stage. It also clearly shows that in most cases, it is necessary to conduct 3 dilation sessions during 1 treatment course, regardless of the disease stage - in 32 of 62 patients, making 52.61%.

However, in the advanced stages the number of required dilatation sessions was 5 or more (up to 10 procedures) in 2 (8.50%) patients with stage III and in 1 (33.3%) patient with stage IV. The patients with stage I and II didn't require 5 or more sessions in any case.

The result of treatment of the patients with a pneumatic cardiodylator was assessed in the same way after the other methods of instrumental treatment. So, good 37 (59.67%) and satisfactory 21 (33.87%) results were obtained in 58 (93.54%) patients, and the unsatisfactory result was revealed in only 4 (6.45%) persons. However, despite the findings, the most objective was the determination of the dependence of the dilation results on the disease stage, presented in Table 3.6.

**Table 3.6.**

**Effectiveness of the pneumatic dilation depending on the disease stage**

Stage	Result			Total
	Good	Satisfactory	Unsatisfactory	
<b>I</b>	6(100%)	-	-	<b>6(9,67%)</b>
<b>II</b>	13(82,35%)	4(17,65%)	-	<b>17(27,41%)</b>
<b>III</b>	17(54,83%)	13(41,93%)	1(3,22%)	<b>31(50%)</b>
<b>IV</b>	1(12,5%)	4(50%)	3(37,5%)	<b>8(12,90%)</b>
	<b>37(59,67%)</b>	<b>21(33,87%)</b>	<b>4(6,45%)</b>	<b>62(100%)</b>

All patients with stage I had good results that were similar to the SID results. 82.35% of patients with stage II had good result and 17.65% of patients from the same group had satisfactory results. There were no unsatisfactory results at all. In patients with stage III the number of good results decreased to 54.83%, the number of satisfactory ones was 41.93% and unsatisfactory results were found in 3.22%. As for the patients with stage IV, they had the following results: good results had

12.5% of the patients, satisfactory results were revealed in 50% and the number of unsatisfactory results increased to 37.5%.

A large number of unsatisfactory results in advanced stages (III-IV) can be explained by the fact that the evident cardia scarry stricture obstructs putting the dilator into the stomach. And in rare cases of the successfully placed dilator, the evident esophagectasia and a weak esophageal peristalsis cannot ensure the appropriate passage of food through the cardia.

Comparative analysis of the direct complications caused by the SID and pneumatic apparatus dilation is shown in Table 3.7. So bleeding from mucous cardia during PC was observed in 6 (6.45%) patients. The most frequent adverse effect of cardia expansion was a worsening esophagitis which occurred in 8 (12.9%) patients. The similar results were observed after SID. All the complications were arrested by the conservative non-surgery actions operations.

**Table 3.7.**

**Comparative assessment of cardioidiosis complications**

<b>Dilation method</b>	<b>Number</b>	<b>Bleeding</b>	<b>Esophagitis</b>	<b>Perforation</b>	<b>Gastric intussusception</b>
<b>Starck's apparatus</b>	<b>7</b>	-	1(14,28%)	1(14,28%)	1(14,28%)
<b>Pneumatic cardioidilation</b>	<b>62</b>	4(6,45%)	8(12,90%)	-	-

According to the results of our investigations the PC is more preferable for the treatment of the patients with CS and EA for the following reasons:

1. Passing of elastic dilator is significantly less painful and psychologically easier for the patient compared to SID and this fact is a very important factor for obtaining good results;
2. When using pneumatic model of the dilator good and satisfactory results were obtained in 93.54%;
3. The number of complications developed after the use of a pneumatic device is less than after metal SID. The results are 42.85 % with SID against 19.35% with PD.

4. One more advantage of the PC over SID is absence of such complications as perforation and gastric intussusception that require emergency surgery.

One of the main criteria of the cardioidosis effectiveness is the analysis of not only the early results but the recurrences in long-term period as well. The issue of the term "recurrence" itself is covered in a number of scientific publications. It was generally recognized that the most correct term is "recurrent dysphagia" (RD). This can be explained by the fact that the "disease recurrence" is diagnosed only after the pathogenetic treatment. All known methods of conservative, instrumental and surgical treatment, except for esophageal extirpation, are symptomatic, i.e. they remove the main symptom, dysphagia. In view of this fact we use only the term "recurrent dysphagia".

In the long-term period ranging from 1 to 8 years 25 patients of 62 were examined due to RD clinical picture, accounting for 41.3%. The patients were admitted at different times after the treatment during the first 6 months - 5 patients; within the period of 6 months to 1 year - 6, and after 1 year - 14 persons.

At various times after cardioidosis 4 patients with stage III-IV underwent the surgical treatment which was required due to impossibility to pass the device through the cardia. 2 patients refused all treatment and 19 patients underwent the repeated courses of cardioidosis.

**Summary:** Therefore, basing on an analysis of the early and long-term results of PD, this method can be considered the most popular one, as it is very efficient and affordable. Besides, it is very safe as after the operation no complications occurred, and there was not necessary to perform any emergency surgeries. All bleedings and worsening of esophagitis was eliminated through conservative actions.

PC is an effective treatment, as in 93.54 % of cases they obtained good and satisfactory results. In patients with advanced stages of CS dilation is the most optimal preoperative procedure before the complex reconstructive esophageal surgeries. On the one hand, elasticity of the pneumatic cardioidilator is a safety-ensuring advantage, and on the other hand this feature is a disadvantage (little

rigidity) that causes difficulties in passing the device in the situation when the stenotic segment is crimped or eccentrically located.

### **3.6. Local and gastric antisecretory therapy in complex treatment of patients with cardiospasm and esophageal achalasia**

The gastric and esophageal surgery department of RSSC named after V. Vakhidov has developed and implemented its own tactics of the so-called local therapy. It is understood to be the "local defense" of the esophageal and CEJ mucosa. It is known that during the cardiodiosis not only cardia muscles are forcedly torn but also the mucosal and submucosal layer as well. Very often it can be seen from the blood traces appearing on the dilators withdrawn. Moreover, some authors even consider that the blood stains on the dilator is one of the objective indicators of the dilatation validity. However, the torn mucosal and submucosal layer will result in formation of rough scar tissue that can cause the RD. Among other causes of the recurrence are RE that result from excessive expansion of the cardia. Thus, the attempts to restore the food passage through cardia extension may lead to reflux development. In view of this fact we use both local and antisecretory therapies together with cardiodiosis. The local therapy is based on the papers of Shagzatov D.B. (2006) in which he offered to use a special "mixture" per os during bougienage in patients with post-burn strictures of the oesophagus. The morphological study has proven positive impact of local therapy on the healing process of the esophageal mucosa. Accordingly, the same effect can be expected in the healing of small injuries of mucosa during dilation in patients with CS and EA. The content of "mixture" was the following: sea buckthorn oil (100 ml), hydrocortisone (125 mg), an antibiotic (2 g), procaine (2% 50 ml) and Suprastin (1 ml).

The antisecretory therapy included the use of: proton pump inhibitors (Omeprazole, Pantoprazole, Lansoprazola) and antacids (Almagel, Maalox, Phosphalugel). We consider it inappropriate to describe in detail the antisecretory therapy as it has no features compared to the therapy of the patients with ulcer.

The local and antisecretory therapy began the day before the first cardiodynia and lasted for 14 days. Nature of the influence of local and antisecretory therapy on cardiodynia results and morphological studies data will be described in details in subchapter 3.9.

### **3.7. Potential of modern hydro-balloon cardiodynia dilators in treatment of patients with cardiodynia and esophageal achalasia**

The principle of using water for the cardia expansion was first proposed in the beginning of the last century. The water density is higher than the density of air, so it is less prone to deformation. One of the causes of unsatisfactory results and the need for frequent dilatation sessions is the air-filled balloon deformation. Therefore, it is logical to use water, as it has more resistance to deformation as compared to air. However, some technical difficulties have arisen in the use of hydrostatic dilator: unhandy water pumping equipment, impossibility to accurately dose the pressure forces. In this regard, it was not widely used in the last century.

HBC can be used in two ways: endoscopically and under X-ray control. The most frequently used method of dilatation is the one performed under fluoroscopic control using the conducting cord. Hydro balloon dilator is not radiopaque, though its "working" balloon has three metal marks to monitor the accuracy of its location during manipulation. The HBC technique differs from the one of PC and includes the following steps:

1. Pass the conducting cord with the mandatory visualization of cord tip in the proximal section of the stomach;

#### **Figure 3.1**

#### **Hydro balloon dilation under X-ray control**



Figure 3.1. shows the correct location hydro balloon dilator before the expansion - radiopaque marks are located in the stomach, esophagus and cardia

1. The hydro balloon dilator is inserted by the cord. The accuracy of its location is controlled radiographically (Figure 3.1). It is necessary to put it so that the bottom mark was in the projection of the stomach, the middle one in CEJ, and the top one in the lower third of the thoracic esophagus.

2. The hydro balloon dilator is connected through a special cannula to inflating device which is pre-filled with liquid (water-soluble contrast or water). Pumping of the fluid into the cylinder is performed gradually, without forcing. It is always necessary to monitor the severity of pain in the patient at the time dilation. The dilatation starts from the pressure of 1 atmosphere with a gradual increase during each session to 2 atmospheres (see Figure 3.2).

3. Exposure dilatation lasts for 2-3 min. After that the fluid is withdrawn through the inflating device and the dilator is removed.

HBC should be performed under endoscopic control in cases when it is impossible to pass the cord under radiographical control. Usually it happens in two cases:

1. At advanced stages of the disease with a narrow and tortuous path in the lower third of the thoracic esophagus;

2. In case of a diverticulum of the esophagus, in which the cord bear against the wall of the diverticulum and a forcing may result in perforation.

### **Figure 3.2**

#### **Hydro balloon dilation under X-ray control**

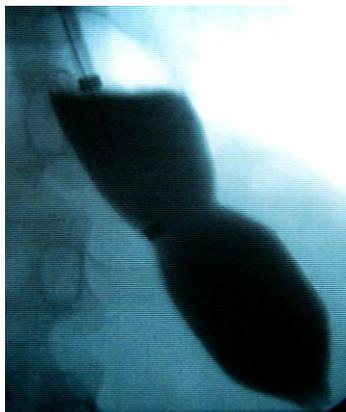


Figure 3.2 presents an X-ray picture of hydro balloon dilator at the time of extension (a water-soluble contrast Urografin 76%, 60 ml is injected). One can clearly see the dilator "waist" located in the zone of the spasmed cardia.

The HBC technique performed under endoscopic control also consists of several stages:

1. It is necessary to perform a diagnostic endoscopy to visualize the CEJ. Simultaneously is necessary to insert the cord. The cord is inserted into the stomach under the supervision, as shown in Figure 3.3.

**Figure 3.3**

**Hydro balloon dilatation under endoscopic control**

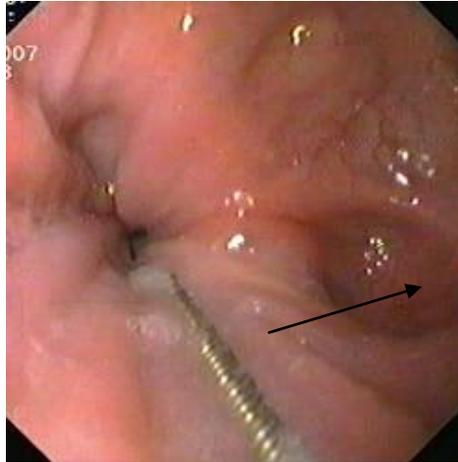


Figure 3.3 presents the endoscopic insertion of the conducting cord into the stomach through cardioesophageal junction. Implementation of the endoscopic cardioidiosis was caused by the presence of diverticulum (shown by arrow) of the lower third of the thoracic esophagus.

2. After than it is necessary to insert the hydro balloon dilator along the cord and start the extending it with the liquid to a pressure of 1-2 atm. The correctness of the dilator location should be controlled through a visual endoscopic supervision, as it is shown in Figure 3.4.

**Figure 3.4**

**Hydro balloon dilatation under endoscopic control**

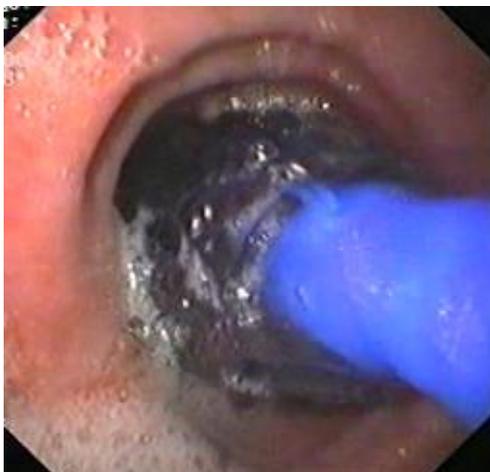


Figure 3.4 presents the moment of the balloon expansion during the hydro balloon dilatation under endoscopic control.

3. After the dilatation session the liquid is withdrawn from the balloon, and the apparatus is removed from the lumen of the esophagus.

At the time of the balloon expansion the patients experience some moderate pain, caused by the tear of cardia muscles which almost immediately arrested after

withdrawal of liquid from a balloon. Duration (exposure) of 1 dilatation session is 2-3 min; the interval between sessions is 1-3 days, the number of repeated sessions per course ranges from 2 to 3 depending on the stage and clinical efficacy of dilation.

HBC was performed under fluoroscopic control in 29 patients and under endoscopical control in 1 patient.

### **Results of the hydro balloon dilatation**

The hydro balloon dilation was performed in 38 patients; the distribution by stage was as follows: I stage - 4, II stage - 12, III stage - 17 and 5 patients had stage IV disease. All patients underwent the developed procedures of local and antisecretory therapy.

The result of the performed HBC was traditionally evaluated and presented in Table 3.10. It is necessary to note that the 22 patients required only 2 sessions for 1 treatment course and 14 patients underwent 3 sessions. Thus, compared to other dilation methods, this technique demanded a much smaller number of sessions to achieve the appropriate patency. A good result was obtained in 5 patients and 2 patients had satisfactory results.

**Table 3.10**

#### **Effectiveness of the hydro balloon dilation**

Stage	N	Number of sessions		Result		
		2	3	Good	Satisfactory	Unsatisfactory
<b>I</b>	<b>4</b>	4	-	4(100%)	-	-
<b>II</b>	<b>12</b>	9	3	10(83,33%)	2(16,66%)	-
<b>III</b>	<b>17</b>	10	7	11(64,7%)	6(35,29%)	-
<b>IV</b>	<b>5</b>	-	5	-	4 (80%)	1 (20%)
<b>Total</b>	<b>38</b>	23	15	25 (65,78)	12(31,57%)	1(2,63%)

Table 3.11 presents a comparative analysis of the early complications after HBC, SID and the pneumatic device. The table clearly shows the reduction in complications. At the same time there are no life-threatening complications, such as bleeding and perforation.

**Table 3.11**

### Comparative evaluation of cardioidosis complications

Dilation method	Number of patients	Bleeding	Esophagitis	Perforation	Gastric intussusception
Starck's apparatus	9	-	1(14,28%)	1(14,28%)	1(14,28%)
Pneumatic cardioidilation	62	4(6,45%)	8(12,90%)	-	-
Hydro balloon cardioidilation	38	-	6(15,78%)	-	-

Reduction in complications with HBC compared with pneumatic dilation and the SID is provided by 3 factors:

1. Hydro balloon cardioidilator has a significantly smaller diameter that ensures a less traumatic manipulation;
2. Use of the hydro balloon apparatus requires fewer number of dilation sessions;
3. All patients with HBC underwent the local and antisecretory therapy.

Accuracy of the comparative assessment of the complication occurrence frequency after different cardioidosis methods is presented in Table 3.12.

**Table 3.12**

#### Accuracy of the comparative assessment of the cardioidosis complications

Dilation method	Complication rates	
	N	%
Starck's apparatus (n=9)	3	42,85
Pneumatic cardioidilation (n=62)	12	19,35
Hydro balloon cardioidilation (n=38)	6	15,78

**Table 3.13**

#### Accuracy of the various dilation method results

Results	Starck's apparatus		Pneumatic cardioidilation		Hydro balloon cardioidilation	
	N	%	N	%	N	%
Good	4	44,4	37	56,67	25	65,78
Satisfactory	4	44,4	21	33,87	12	31,57
Unsatisfactory	1	22,2	4	6,45	1	2,63

Here is a clinical example of a successful HBC in patient with EA stage III.

*A patient Zhabborov A., 41 years old, admitted on 9.11.2007*

*Clinical diagnosis is esophageal achalasia stage III*

*Complaints of dysphagia for solid and stodge food, nausea, followed by vomiting, hydrophagy, aerophagy, weakness, and body weight reduce by 26 kg. History: gradual onset of the disease which began with dysphagia for solid foods. The patient associates the disease with nervous stress. The disease lasts for 1.5 years.*

*Endoscopy: cardiospasm. Esophagectasis. Esophageal lumen ectasia.*

*X-ray examination (Fig. 3.10): The esophagus is extended to 6 cm. There is a great amount of liquid contents in the lumen. Peristalsis is not observed. Abdominal segment of the esophagus is narrowed featuring clear smooth contours as a symptom of "mouse tail".*

*Treatment provided: anesthesia, antispasmodics, Lidaza, local and antiulcer treatment.*

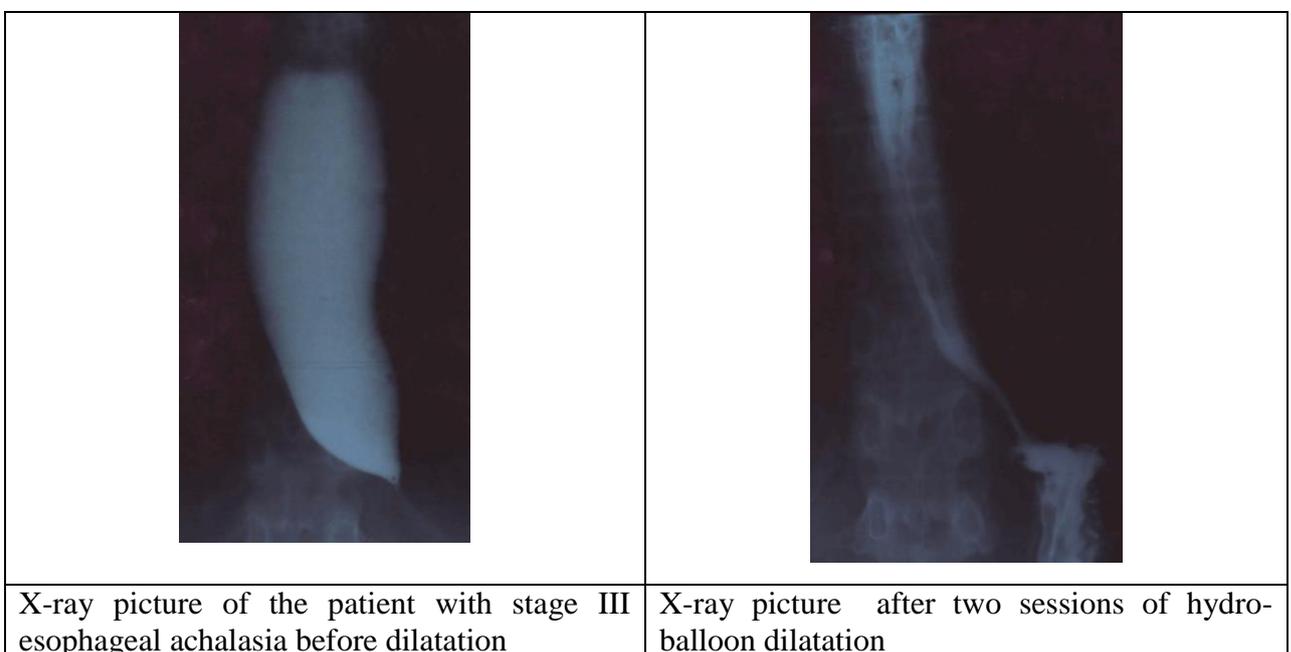
*Dilatation method: hydro-balloon cardioidiosis, number of sessions is 3, periodicity is 2 days, pressure during each session is 1,5-2,0-2,0 atmospheres, exposure is 2 min.*

*X-ray examination after dilatation (Figure 3.5): no esophagectasia, contrast passes freely without delay.*

*The result of the treatment is good.*

**Figure 3.5**

**X-ray picture before and after the hydro-balloon dilation**



During the long-term period lasting from 1 to 4 years 8 patients of 38 patients who underwent HBD were admitted with RD symptoms. Thus, the recurrence rate was 21.05%. Of these, 1 patient was admitted during the first year after dilatation, and the rest 7 persons came in a year after treatment.

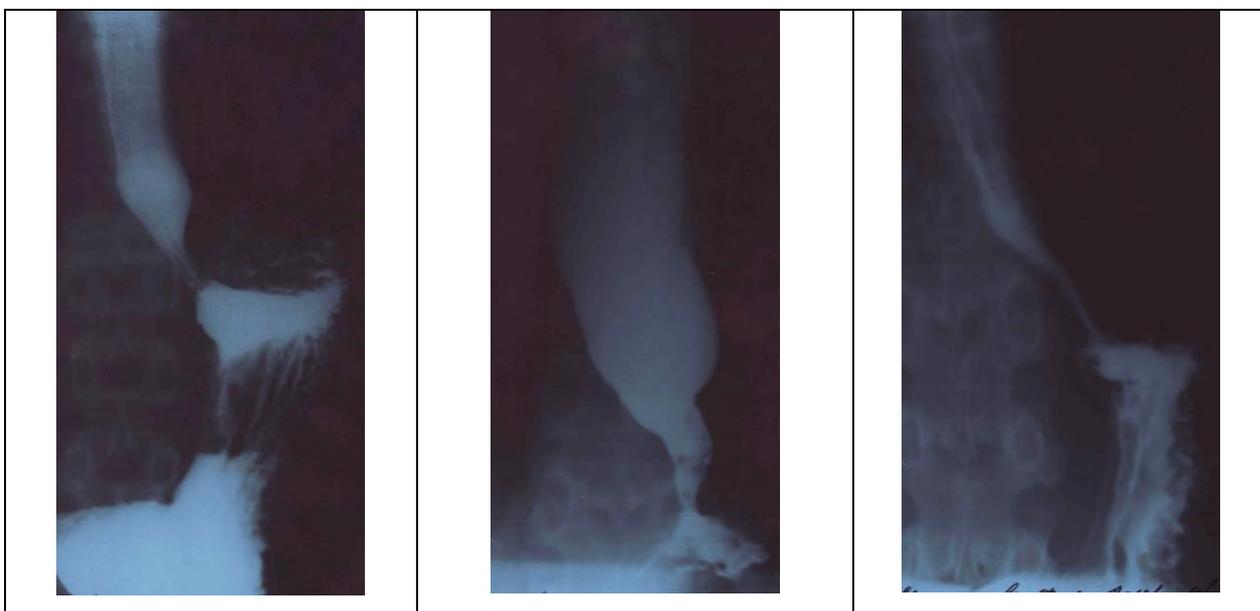
The first patient underwent the repeated HBD sessions upon completion of which he didn't apply for medical help any more. One patient with stage IV underwent the surgical treatment in a year after dilatation, due to the futility of the instrumental treatment.

Basing on the HBC results in patients with CS we revealed the obvious advantages of this method over other cardia expansion techniques:

1. Possibility to use the endoscope which allows using this method in difficult cases provided that the diverticula, eccentric location and cicatrical cardia changes occurred. Moreover, a radiation load on both the patient and a doctor is excluded;
2. Owing to the smaller diameter of the dilator the process of its insertion is tolerated much easier by the patients;
3. This method requires the fewer number of dilation sessions per course of treatment;
4. A low frequency of the bleeding and exacerbation of esophagitis.

**Figure 3.6**

**HBC in patient with recurrence the Suvorova's operation**



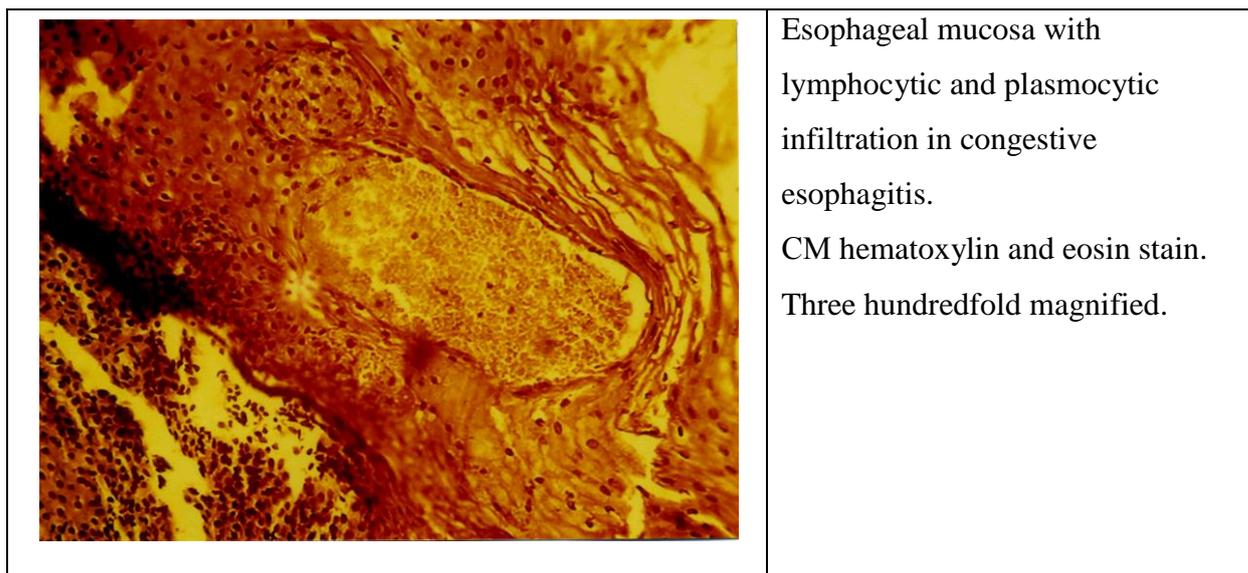
X-ray picture of the patient with stage II cardiospasm before surgery	X-ray picture in a year after the Suvorova's operation – Recurrent cardiospasm, II-III stages	X-ray picture after 2 sessions of the hydro-balloon cardiodilation
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### 3.8. Morphological specifics of the esophageal wall and cardia healing after dilation

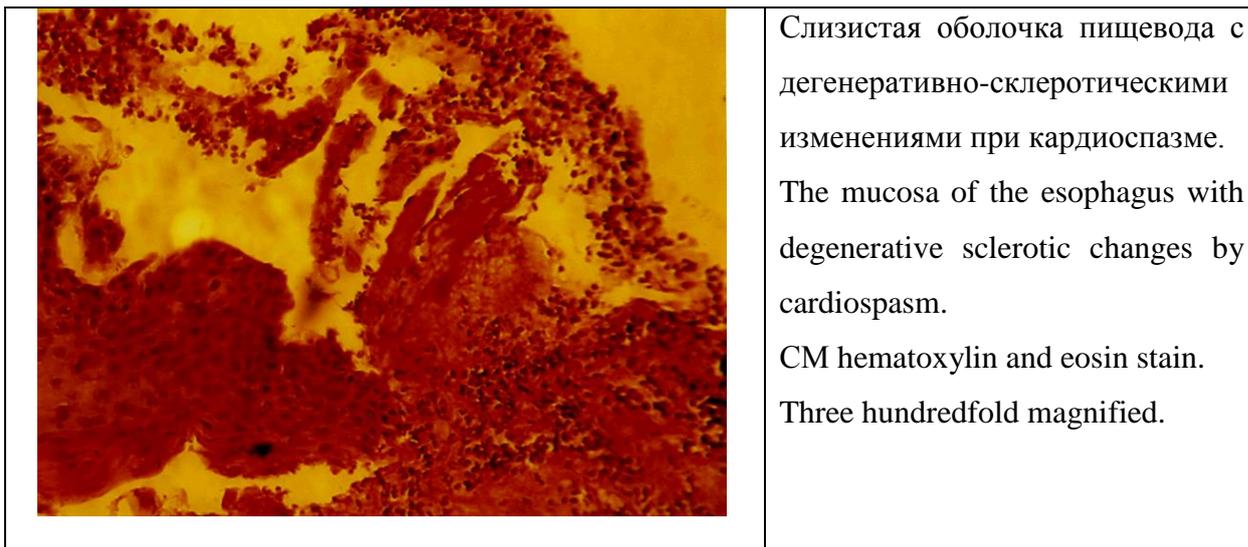
The first series of morphological studies was performed in 4 patients with stage III-IV CS and EA to determine the initial state of the mucosal and submucosal layer of the esophagus.

For this purpose before cardiodilation during the endoscopy we performed GB of mucosal and submucosal layers of the lower and middle third of the thoracic esophagus. Microscopic examination of the esophageal mucosa revealed a hyperparakeratosis, lymphocytic and plasmocytic infiltration of the submucosal layer (Fig. 3.7).

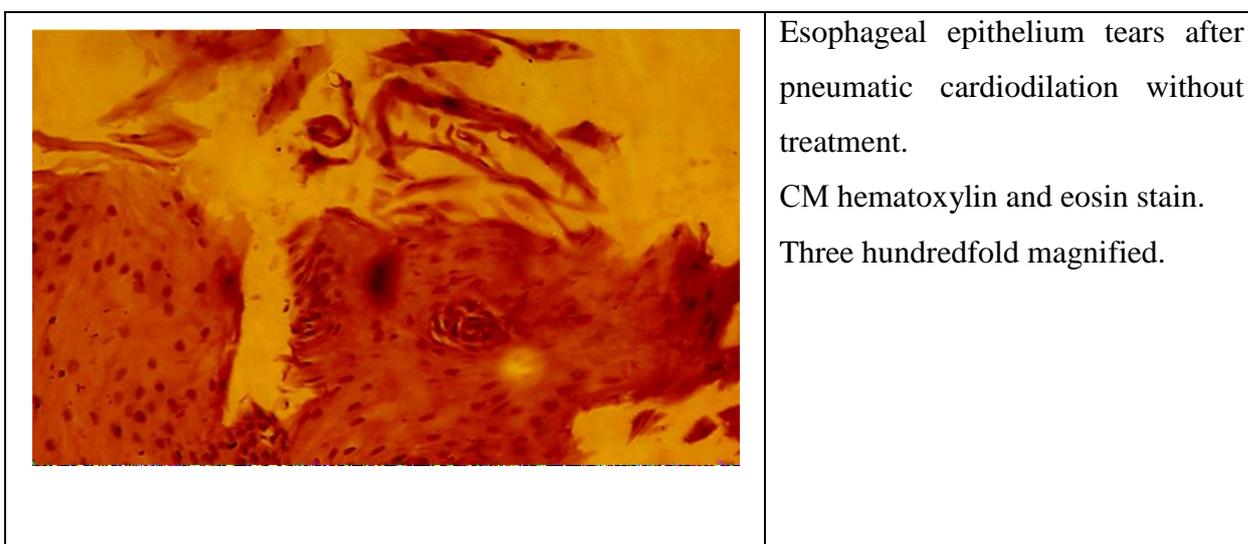
**Figure 3.7**



In later stages of chronic diseases, in particular in cardiospasm, there are some degenerative sclerotic changes in all layers of the esophageal wall (Fig. 3.8).

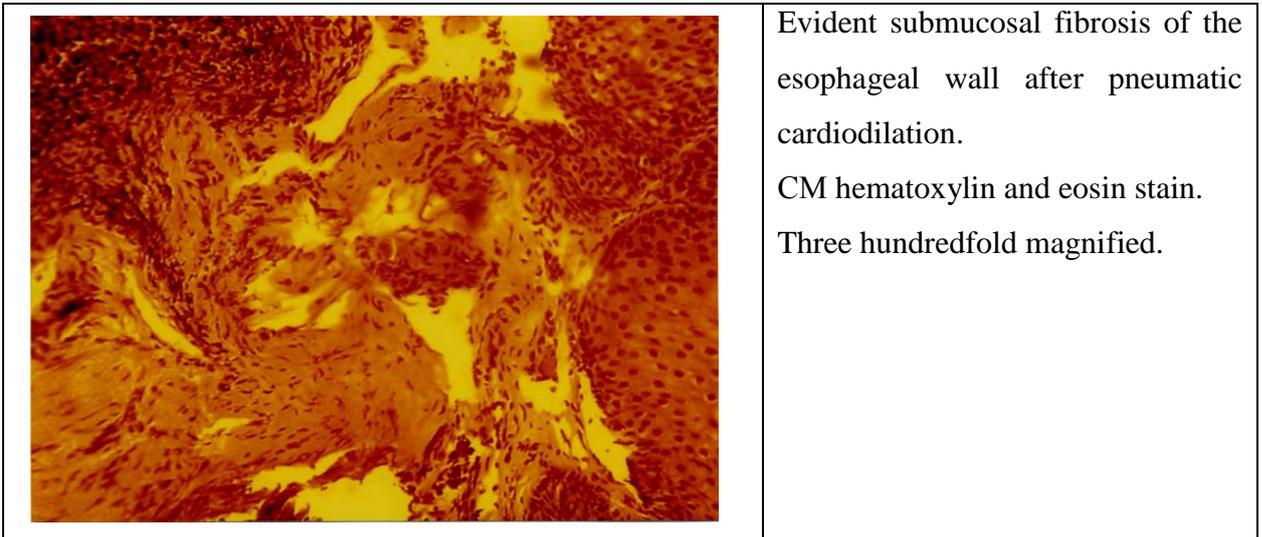
**Figure 3.8**

In 3 months after the PD we have conducted a morphological examination in 5 patients who took only the coating medications (sea buckthorn oil) and didn't undergo any targeted local RE prevention treatment after the operation. Morphological examination have shown that PC causes the focal mucosal tears (Figure 3.9) and

**Figure 3.9**

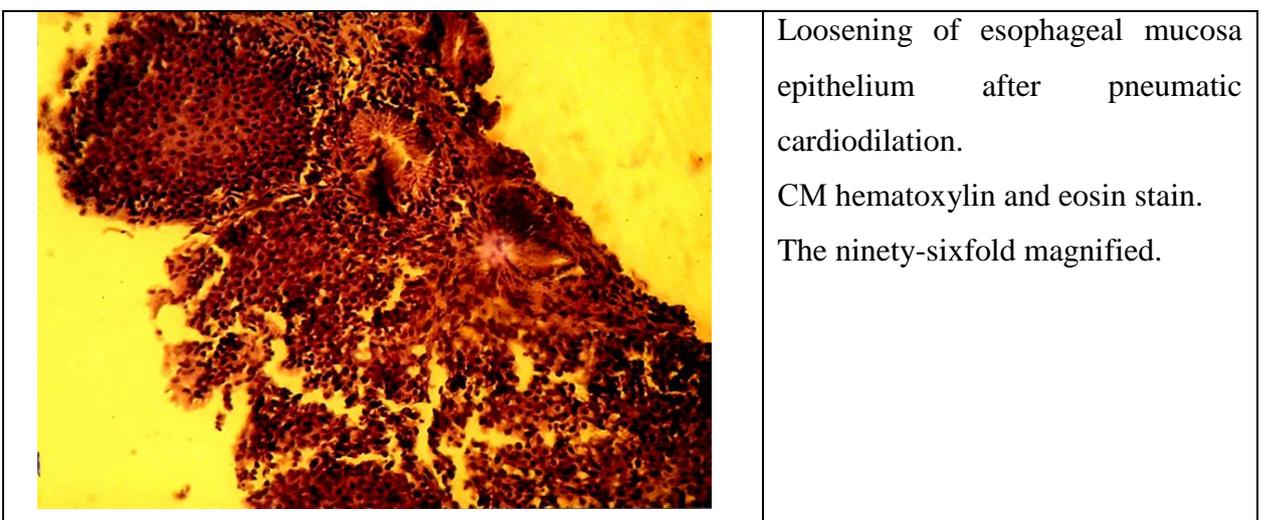
evident submucosal fibrosis of the esophageal wall (Fig. 3.10) that exacerbate the clinical course of the CS and EA in the long term, and with the occurring RD.

**Figure 3.10**



Pneumatic cardiodilation performed in patients with cardiospasm without local treatment and antisecretory therapy results in severe trauma of esophageal walls with loosening of mucous membrane (Fig. 3.11), submucosa and cardiac glands stroma.

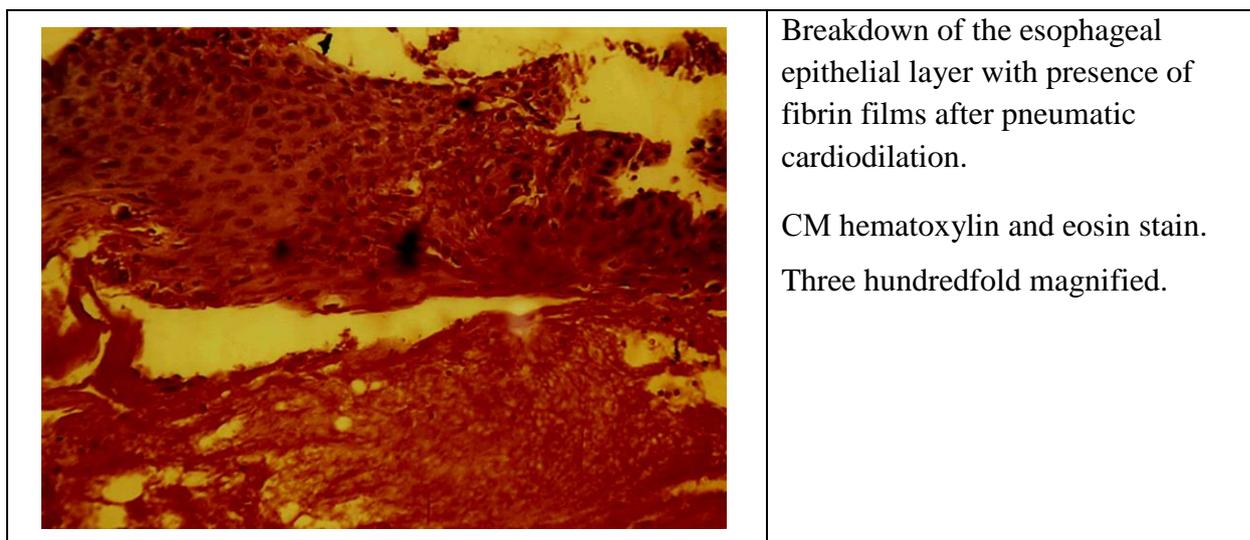
**Figure 3.11**



Light microscopy of the esophageal mucosa after PC showed epithelial layer cell layer breakdown, presence of fibrin films with edema (Fig. 3.12) that are the

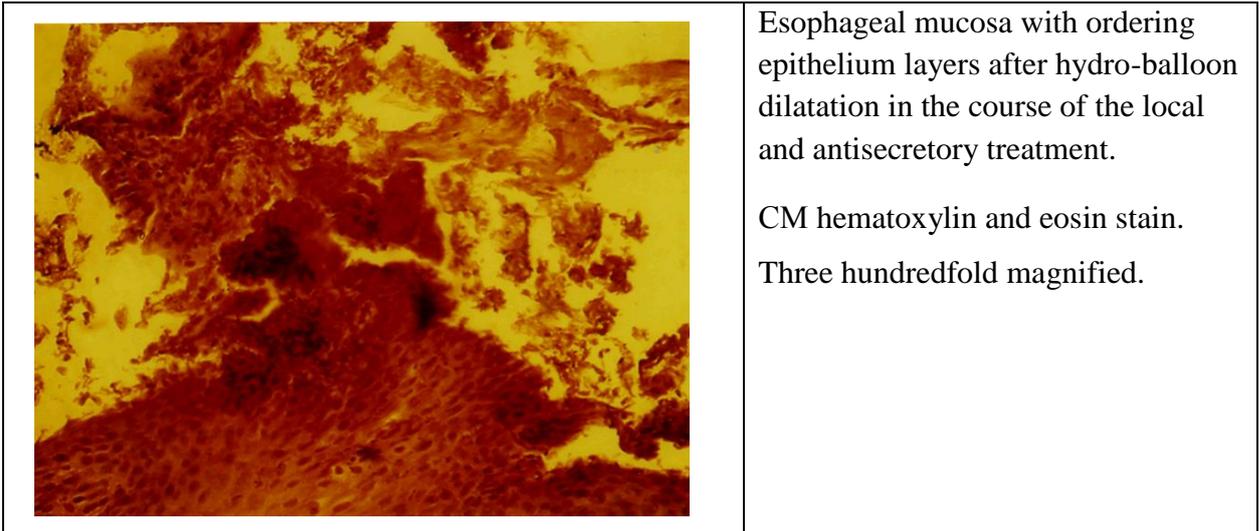
morphological criteria of chronic inflammation, declaring itself as the CS clinical picture.

**Figure 3.12**

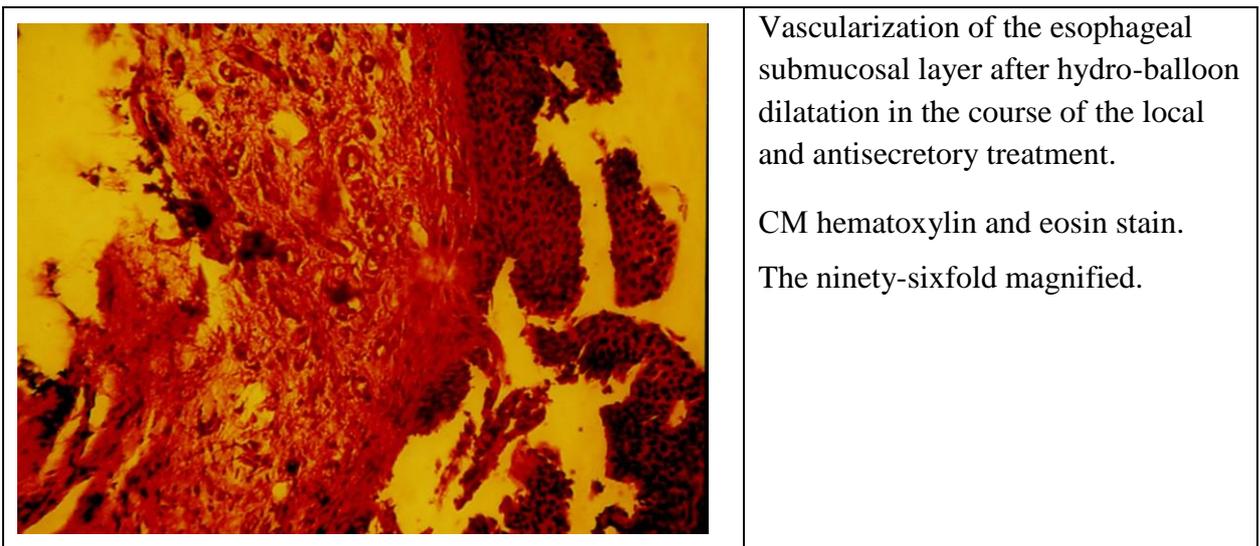


Thus, our morphological examination of the esophageal mucosa biopsy materials in patients with CS showed inflammatory degenerative changes involving all layers of the esophageal wall with development of fibroplastic process. After PC without local therapy we have also observed the raptures of mucosa with loosening of the submucosal during the early period following the treatment. Later we observed formation of fibrous connective tissue in the esophageal wall that definitely contributes to the progression and recurrence of the disease. These results of morphological examination of the patients with CS which occurred after PC have made us conducting the further research. We proposed and put into practice the previously described complex of local and antisecretory therapy in these patients.

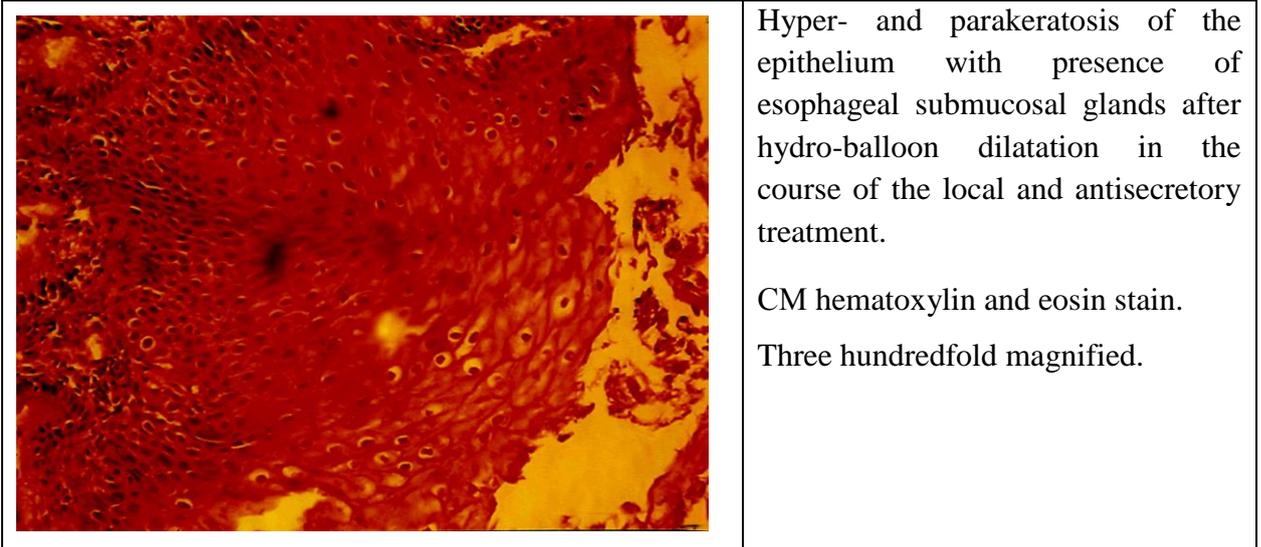
In 3 months after the HBC followed by the local and antisecretory treatment we performed the microscopic examination of esophageal biopsy materials in 5 patients, which showed the ordering of the epithelium layers (Fig. 3.13).

**Figure 3.13**

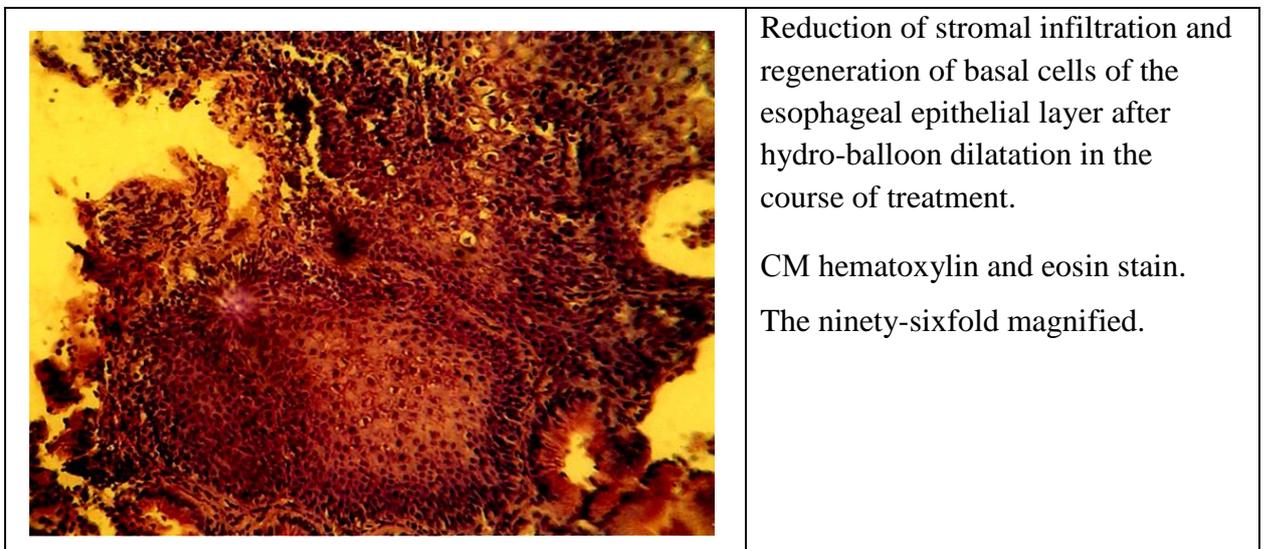
At the same time we still observed the desquamatory changes in upper layers of the epithelial layer, vascularization of the submucosal layer and formation of a loose connective tissue (Fig. 3.14) that indicate a beneficial effect of medications and instrumental procedures.

**Figure 3.14**

It should be noted that the hyper- and parakeratosis of the esophageal mucosa (Figure 3.15) is observed as the focal changes even after the HBC combined with the local treatment.

**Figure 3.15**

However, basically we observed reduction of stromal lymphoid infiltration, regeneration of basal cells of the esophageal epithelial layer (Figure 3.16).

**Figure 3.16**

Thus, the microscopic examination of the esophageal wall after the HBC in the course of the local and antisecretory treatment showed improvement in regenerative processes with vascularization, formation of loose connective tissue in the esophageal wall and the generally favorable clinical course of the disease in the long term.

### **SUMMARY:**

Analysis of the results of instrumental treatment methods in patients with cardiospasm and esophageal achalasia has shown that the most efficient method is cardioidiosis.

The use of the GB did not provided any encouraging results and this treatment method can only be used in patients with stenosing RE after the previously unsuccessful cardia operations.

Cardioidiosis using the Starck's apparatus is an effective way of treating patients with CS, however this method is the most dangerous in terms of the development of various kinds of complications, including bleeding, worsening of esophagitis, esophageal perforation, etc. Nowadays the newly introduced pneumatic and other models have completely replaced this method of treatment.

Pneumatic cardioidiosis still remains the most common, safe and effective method of treatment, however sometimes it cannot be used due to the difficulties in carrying the device through the cardia, especially in advanced stages, when the cardioesophageal passage is cicatrically narrowed or located eccentrically.

Hydro-balloon cardioidiosis performed using the modern devices, is an effective alternative to traditional pneumatic dilation. It features the high efficiency, safety and the possibility of endoscopic use.

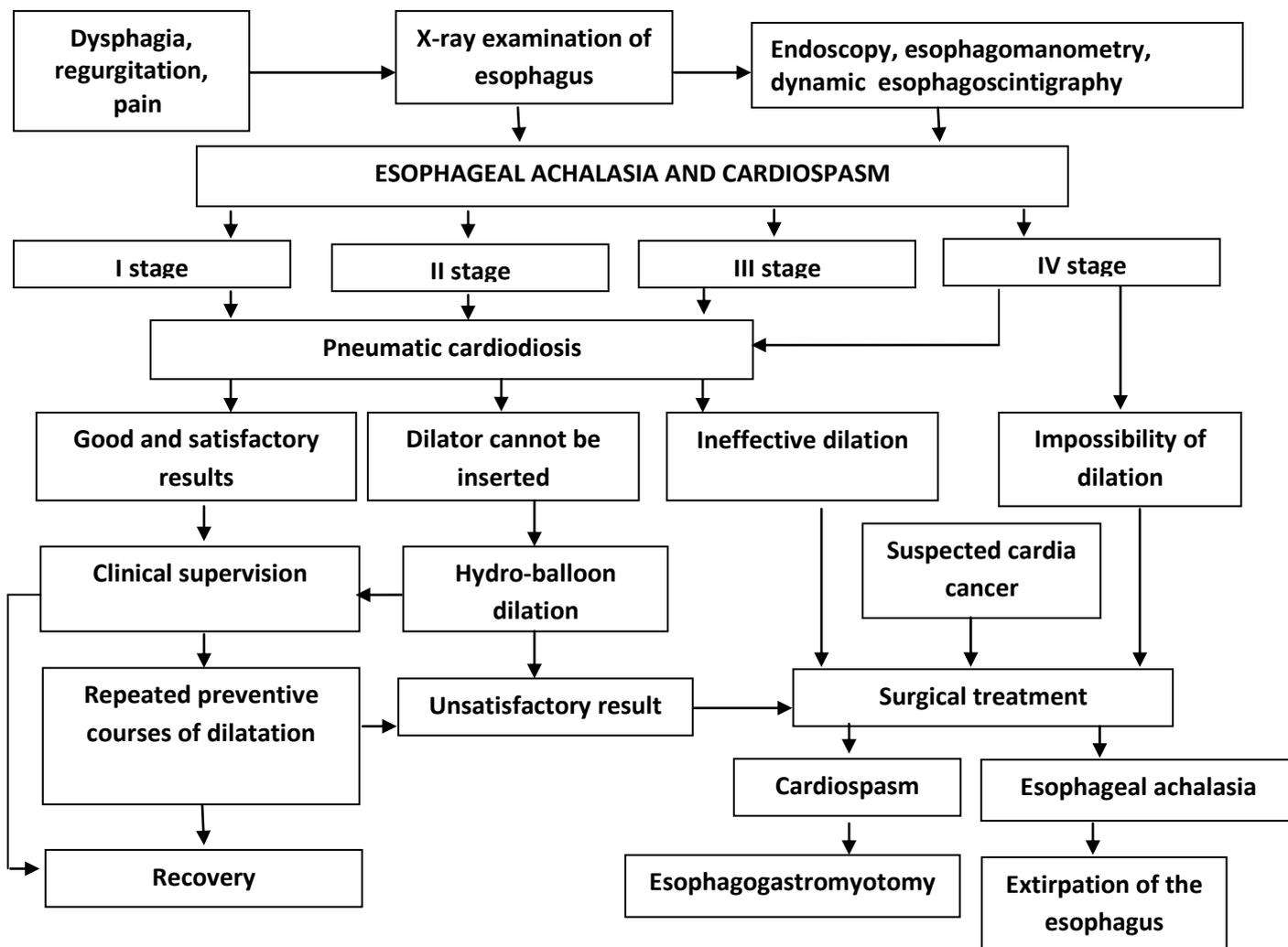
The proposed scheme of the local and antisecretory therapy can significantly improve the cardioidiosis results. This fact was proved by the results of morphological examination of the esophageal wall, which revealed an improvement in regenerative processes with vascularization, formation of loose connective tissue in the esophageal wall and the generally favorable clinical course of the disease in the long term.

## DIAGNOSTIC AND TREATMENT ALGORITHM IN PATIENTS WITH ESOPHAGEAL ACHALASIA AND CARDIOSPASM

Basing on the studies, the results of the diagnosis and treatment of patients with esophageal achalasia and cardiospasm, we have developed a diagnostic and treatment algorithm shown in Figure 4.11. This algorithm contains the issues influencing the choice of instrumental and surgical treatment method depending on the stage and type of disease.

**Figure 4.11**

### Diagnostic and treatment algorithm in patients with esophageal achalasia and cardiospasm



## SUMMARY

Neuromuscular diseases of the esophagus, including esophageal achalasia and cardiospasm, still engender the argument of the doctors, debating on the choice of the optimal treatment strategy. Actually, owing to the improved medical technologies and the gained experience in many treatment clinics, the short-term results of the treatment were improved significantly. However, there are still some disagreements on the selection of the treatment method at different stages of the disease. Cardioidiosis remains the most affordable, safe and effective treatment for patients with CS and EA. Despite the undoubted advantages of PC and HBD some specialist still perform the SID.

The long-term cardioidiosis results were evaluated by many authors in different ways. Some of them think that it is necessary to perform the repeated courses of cardioidiosis through routine preventive manipulations; others consider the occurrence of the RD symptoms as an indication for surgical treatment. Apparently, it is necessary to consider each case individually to determine indications for surgery as in most cases several courses of cardioidiosis are enough to ensure a satisfactory food passage.

In our view, another important issue is the necessity and feasibility of local therapy. As you know, cardioidiosis is a method intending the "forced" tear of cardia muscles that often results in the CEJ mucous damage. Moreover, the excessive stretching of the LES may result in another problem – occurrence of RE. All this leads to the formation of fibrous connective tissue and reflux that will clinically manifest as dysphagia. Thus, the question concerning the necessity of the local therapy which usually involves administration of antacids and local coating medications, still remains unsolved. Moreover, an appropriate antisecretory therapy can help in preventing the RD in the course of the RE and requires further study.

The history of cardiospasm study goes back to XVII century. During the period of more than three centuries, the opinions regarding various treatment methods and efficiency of dilation techniques changed several times. In view of this fact we

decided to make a comparative analysis of the early and long-term results of all possible methods of instrumental treatment to show the advantages and disadvantages of each of them.

Instrumental surgery of CS and EA is still a subject of debate. This fact can be proved by a large number of the proposed surgery techniques. This plethora of modifications can only be explained by the fact that sometimes nobody but the authors can perform the proposed operation.

In reference with the above, the purpose of this research was to compare the available instrumental surgical treatments of EA and CS. Material for this research study were the 109 patients in the period from 2002 to August 2013 inclusive.

The research was based on examination of 109 patients, followed up within the period of 2002 to August 2013 inclusive.

According to classification of Petrovsky B.V. (1957) the patients after a complete physical examination were distributed as follows: I stage – 8 (7%), II stage - 34 (31,2%), III stage - 55 (50.4 %) and stage IV was diagnosed in 12 (11 4%) patients. Thus, the total number of patients with advanced stages, namely with stages III and IV, was 61.8%.

The GB is intended to be the primary treatment method for the patients with cicatricial esophageal strictures. However this method is often used to treat patients with CS and EA. Analysis of the early results of GB has showed its low efficiency. Thus, GB cannot be used as the primary method to treat the patients with CS and EA. This operation should be indicated on the basis of strong evidence only, e.g. in case of the developed organic narration which is frequently occurs in association with the stenosing RE after previous unsuccessful cardioplastic operations.

The SID was performed in 9 patients. Analysis of the early results of this treatment showed that the total number of good (44.4%) and satisfactory (44.4%) results was 88.8%. The occurred complications included the following: exacerbation of erosive esophagitis in 1 (14.2.8%) person. Moreover, the SID operation resulted in severe complications in 2 patients that required emergency surgery. One of those patients

had the gastric intussusception to the distal esophagus which was eliminated by reduction of gastric intussusception coupled with a fundoplication. The second case was a perforation of the lower third of the esophagus. The patient was urgently operated on. The surgery intended suturing of the esophageal defect.

Thus, cardioidosis through SID is considered an effective treatment method, as according to the retrospective analysis in most cases the cardia was expanded appropriately. However, the patients suffer from SID cardioidosis much heavier. Moreover, this manipulation may cause serious complications (bleeding, perforation, gastroesophageal intussusception) arising from the design features of the device itself.

Pneumatic cardioidosis was performed in 62 patients. The main advantage of this method over ones performed with the metal dilators is its safety achieved owing to the design of the device. The results of the treatment performed using the pneumatic cardioidilator were assessed similarly to the ones achieved using other methods of instrumental treatment. 37 (59.67%) patients had good results and 21 (33.87%) patients gained satisfactory results, totaling 58 (93.54%) patients against 4 (6.45%) patients with unsatisfactory results.

All patients with stage I had good results, just similar to the data achieved with SID operations. 82.35% of patients with stage II had good results and 17.65% patients managed to the satisfactory results, the unsatisfactory results were not observed. In group of the patients with stage III the results the distributed as follows: good in 54.83%, satisfactory in 41.93% and unsatisfactory in 3.22% of patients. In group of the patients with stage IV the number of good results was 12.5%, satisfactory results were registered in 50% and the number of unsatisfactory results increased up to 37.5%.

In department of esophagus and stomach surgery of the RSSC named after academician V. Vakhidov the patients undergo the locally introduced treatment method. This method intends the use of the "local protection" of the distal esophagus and CEJ mucosa. Also the treatment includes the prevention of RE which may result from excessive expansion of the cardia. Local and antisecretory

therapy usually starts a day before the first cardioidiosis session and lasts for 14 days.

The improving medical technologies resulted in development of various new models of modern dilators that are very convenient in practice. One of them is a hydro balloon dilator manufactured by Wilson-Cook. The length of the hydro balloon dilator is 90 cm, and the channel diameter is 5 mm. The length of the dilator working part is 8 cm. Depending on its number the balloon can be expanded up to 30, 35 and 40 mm. Expansion of the balloon is performed by a special device that allows accurate dosing of pressurizing fluid. The device allows using any liquid however a water-soluble contrast is preferable for radiological imaging.

The HBC is used in two ways: and under X-ray control. The results of the treatment were assessed estimated traditionally. At the same time, 5 patients required only 2 sessions for 1 treatment course and 2 patients underwent 3 sessions. Thus, compared to other dilation methods, this technique demanded a much smaller number of sessions to achieve the appropriate patency. Moreover, all patients had either good or satisfactory results.

A reduced number of early complications after HBC compared to PC and especially to the SID can be explained by three factors: the hydro balloon cardioidilators have a significantly smaller diameter and thus make the manipulations less traumatic; this method requires a fewer number of dilation sessions; all patients with HBC underwent the local and antisecretory therapy.

Thus, the microscopic examination of the esophageal wall after the HBC in the course of the local and antisecretory treatment showed improvement in regenerative processes with vascularization, formation of loose connective tissue in the esophageal wall and the generally favorable clinical course of the CS in the long term.

## CONCLUSIONS

1. Comparative analysis of different dilation methods showed a significant improvement in early results achieved with hydro balloon cardioidosis. So, 65.78% of patients had good results, 31.57% of them had satisfactory results, and 2.63% of patients had unsatisfactory results. At the same time the results of the dilation with Starck's apparatus were as follows: 44.4% of patients had good results, 44.4% achieved satisfactory results and 22.2% of patients had unsatisfactory results. The results of pneumatic cardioidosis included 56.67% of good results, 33.87% of satisfactory and 6.45% of unsatisfactory results.
2. The frequency of the after-dilation complications occurred after the use of the Starck's apparatus was 42.85%. The comparative analysis of complications after pneumatic dilatation showed a significant decrease in their frequency up to 19.35%, and after hydro balloon dilatation to 15.78%.
3. Local and gastric antisecretory therapy is an effective therapy in the prevention of reflux esophagitis after hydro balloon dilatation, the efficiency of which was proved by the morphological studies.

## **PRACTICAL GUIDELINES**

1. Gullet bougienage can only be used only as a part of treatment in patients with cardiospasm and stenosing reflux esophagitis after phrenoplasty operations followed by cardioidiosis.
2. For the patients with I-III stage cardiospasm and esophageal achalasia the best way of treatment is the cardioidiosis in the course of the local and gastric antisecretory therapy. After the course cardioidiosis the patients should be under close medical supervision to early detect the signs of recurrent dysphagia and timely conduct the re-treatment.
3. Patients with recurrent dysphagia after previously performed phrenoplasty operations should be treated by the hydro balloon cardioidiosis which allows to achieve a clinical effect even in the course of the stenosing reflux esophagitis.
4. The use of hydro balloon dilator helps to reduce the number of dilatation sessions required for one course of treatment, and thus, reduces the risk of a esophageal perforation and significantly reduces the radiation exposure to the physician and patient.

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