

Nature of Cardioplasty Complications in Patients with Cardia Achalasia

Z. M. Nizamkhodjaev, R. E. Ligai, A. S. Babajanov, A. O. Tsoi, Kh. N. Bekchanov,
J. A. Khadjibaev, K. B. Babajanov, A. D. Abduraimov, J. Avalbayev

Republican Specialized Scientific and Practical Medical Center of Surgery Named after Academician V. Vakhidov, Tashkent, Uzbekistan

Abstract The aim of the research was to study the effect of infrared pulsed laser radiation and an improved cardioplastic model as methods of preventing complications of cardioplasty in patients with neuromuscular disorders of the esophagus. **Introduction.** For the first time, a pneumatic cardioplastic model for the treatment of the esophagus neuromuscular diseases was developed in the 50s of the last century, and in the Soviet Union it became widely used only since 1964 by modification developed in the same year by O.D. Fedorova and G.M. Melnik. After more than half a century, the device of the pneumatic cardioplastic model has not undergone much structural changes. The results of cardioplasty are evaluated by many authors in different ways. **Material and methods.** Clinical material was divided into two groups. In the comparison group, only pneumatic cardioplasty was used, and, a combination of low-intensity laser radiation and a new utility model of a dilator was used in the main group. **Results.** After dilatation courses, 685 (84.2%) patients had no complications, and 128 (15.7%) patients had various complications. The most common complication was reflux esophagitis, which was observed in 95 (37%) patients. **Discussions.** Thus, in the main group, the number of bleedings was observed in 12 (3.3%) patients, while in the comparison group this indicator was noted in 54 (11.8%) patients, and in the main group it decreased to 19 and made up 5.3%. Non-penetrating esophageal injuries in the comparison group were noted in 25 (5.4%) patients, while in the main group this indicator decreased to 4 (1.1%) patients. **Conclusion.** The use of low-intensity laser radiation in combination with a new model of cardioplastic model significantly reduced the total number of complications from 20% to 10%. In the structural analysis of complications, thanks to new technologies and our own developments, a significant reduction in almost all types of complications was also achieved from 44.8% to 14.3%.

Keywords Neuromuscular diseases of the esophagus, Achalasia cardia, Laser therapy, Pneumatic cardioplasty

1. Introduction

For the first time, a pneumatic cardioplastic model for the treatment of the esophagus neuromuscular diseases was developed in the 50s of the last century, and in the Soviet Union it became widely used only since 1964 by modification developed in the same year by O.D. Fedorova and G.M. Melnik [1-3]. Despite the fact that the pneumatic cardioplastic model has more than half a century of history in the post-Soviet space, the technique remains relevant to this day. After more than half a century, the device of the pneumatic cardioplastic model has not undergone much structural changes. The essence of pneumatic cardioplasty is the forced expansion of the lower esophageal sphincter (LES), which is associated with trauma to the mucous membrane, muscular layer and feeding vessels. Considering that the pressure pumped into the esophagogastric cuff increases from session to session, the risk of complications such as bleeding, severe

pain, reflux esophagitis and esophageal perforation increases accordingly with each subsequent session [4-5]. Evaluation of the cardioplasty efficiency is ambiguous. The results of cardioplasty are evaluated by many authors in different ways. According to D. Katzka, T. Vanuytsel and M. Vela, perforation of the esophageal wall during dilatation is observed in 1-8%, and bleeding from deep mucosal defects in 2-5%, and multiple courses of dilatation can lead to the development interstitial fibrosis, hiatal hernia (HH), traumatic diverticulum [6-8]. Special attention should be paid to the fact that there are no studies in the literature aimed at reducing these complications.

Summarizing the mentioned above, it should be noted that the issues for prevention of minimally invasive treatment methods complications of cardia achalasia are not fully solved at the moment.

Aim of the research was to study the effect of infrared pulsed laser radiation and an improved cardioplastic model as methods of preventing complications of cardioplasty in patients with neuromuscular disorders of the esophagus.

2. Material and Methods

The Department of the Esophagus and Stomach Surgery of the Republic Specialized Scientific and Practical Medical Center of Surgery named after academician V. Vakhidov has experience in the treatment of 813 patients with neuromuscular disorders of the esophagus who were on treatment in the period from 2010 to 2022. The standard distribution of patients by gender and age according to the WHO classification is presented in Table 1.

As follows from the table, there were 454 (55.8%) females and 359 (44.1%) males. As it is known, neuromuscular disorders of the esophagus (NMDE), to a greater extent, affect young and middle-aged people, i.e. the most able-bodied part of the population. Thus, the number of young and middle-aged patients made up 717 (88.2%) patients, which indicates the great social significance of the problem being studied.

An endoscopic and X-ray contrast study was sufficient to establish a diagnosis, as well as to determine the stage of the disease according to the classification of Petrovsky B.V. The distribution of patients depending on the stage of the disease, as well as the endoscopic and X-ray picture are shown in Figure 1.

In our opinion, regardless of the disease stage, NMDE treatment should be started with cardiodilation.

At the treatment of patients with cardiospasm and achalasia of the cardia, cardiodilatation has been supplemented with laser therapy using a semiconductor laser device "Impulse-100" in the Department of the Esophagus and Stomach Surgery since 2020. The patent for the utility model FAP 82352 "Method for the treatment of cardio-spasm" was obtained for this method of treatment of neuromuscular disorders of the esophagus.

Table 1. Distribution of patients by sex and age

Sex	< 19 years	19-44 years	45-59 years	60-75 years	> 75 years	Total
Males	31	200	84	40	4	359 (44.1%)
Females	25	247	130	51	1	454 (55.8%)
Total	56 (6.8%)	447 (55%)	214 (26.3%)	91 (11.2%)	5 (0.6%)	813 (100%)

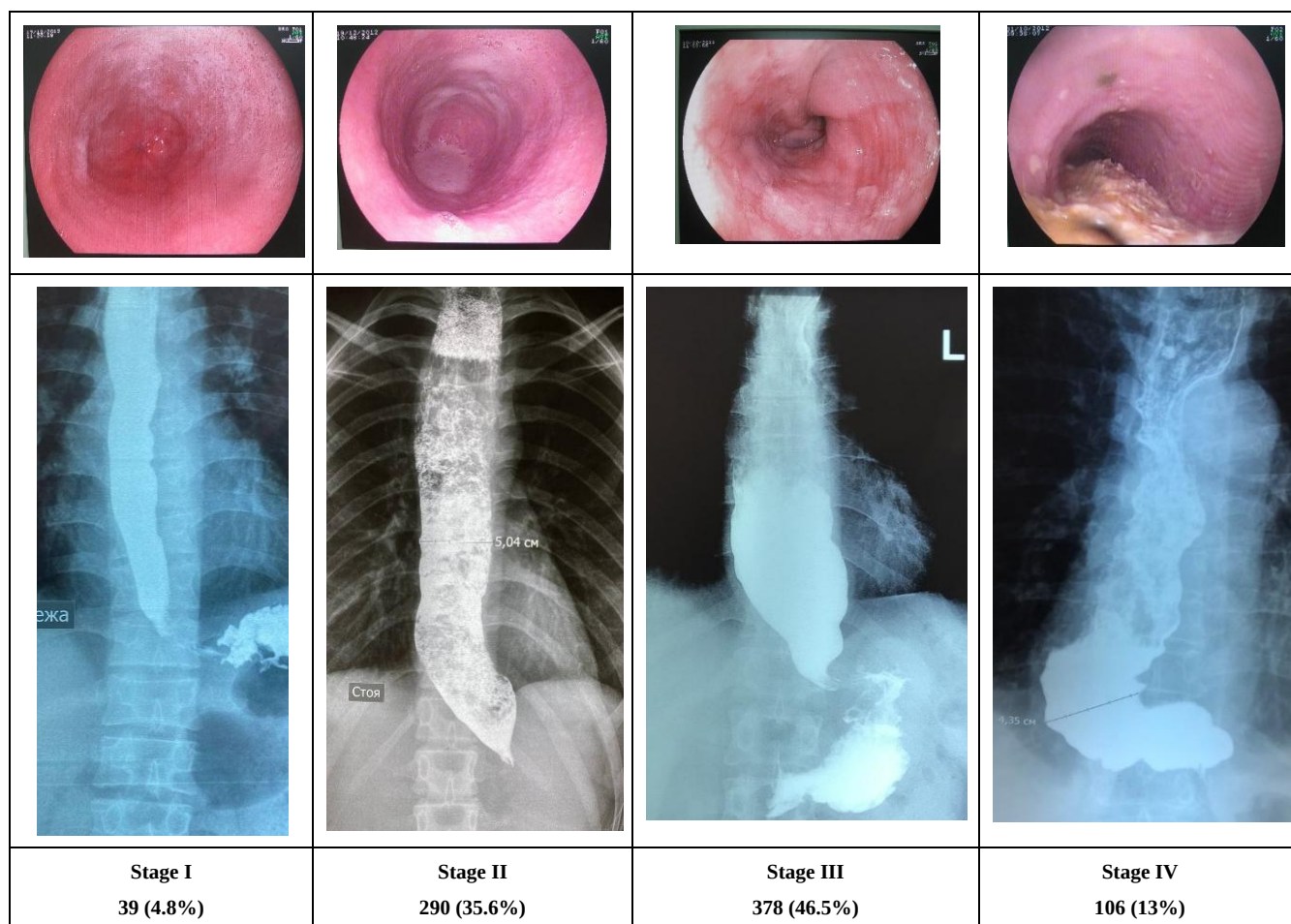


Figure 1. Stages of the disease according to Petrovsky B.V.

In 2015, a utility model of a pneumatic cardiostator (FAP 01357) was developed and introduced into clinical practice, as well as an original method of cardiostation in patients with stages III and IV of the disease (IAP 06163) and a patent was obtained.

The clinical material was divided into two groups, considering the use of new developments in the minimally invasive treatment of NMDE.

The comparison group (CG) consisted of 457 patients treated in the period from 2010 to 2016, who received only cardiostation as treatment.

The main group (MG) consisted of 356 patients who received treatment from 2017 to 2022, in whom cardiostation was supplemented by the combined use of laser therapy, and in stages III and IV, cardiostation was carried out with an improved model of a pneumatic cardiostator using a new original technique for its implementation.

The distribution of patients depending on the stage of the disease, considering the division into groups, is presented in Table 2.

As follows from the table, there were 24 (5.2%) patients with stage I, 179 (39.1%) patients with stage II, 204 (44.6%) patients with stage III, and with stage IV - 50 (10.9%) patients in the comparison group. There were 15 (4.2%) patients with stage I, 111 (31.1%) patients with stage II, 174 (48.8%) patients with stage III and 56 (10.9%) patients with stage IV (17.7%) patients in the main group.

The laser therapy technique was carried out by us before, immediately before cardiostation and after manipulation.

Laser irradiation was carried out through the epigastric region immediately below the xiphoid process with the emitter tube oriented towards the anatomical localization of the gastric cardia. Irradiation was carried out with a pulse power of 100 W and a frequency of 100 Hz. Irradiation was carried out through this point for 2 minutes at the beginning of treatment, and subsequently the dose of laser irradiation increased to 4 minutes. The patient was lying on his back in a relaxed state during the irradiation session (Fig. 2).

The developed useful model of a pneumatic cardiostator is a probe in the form of a silicone tube, the channel of which serves to supply air, and an expanding multi-layer dumbbell-shaped balloon connected to it, the inner and outer layers of which are made of silicone. The middle reinforcing layer is made of dense synthetic fabric, while the end of the probe is closed with a radiopaque mark in the form of a plug, equipped with a metal string for placement in the channel for air supply, while one end of the string rests against the radiopaque mark, and the other extends beyond the probe (Fig. 3).

Pulling outwards and passing the metal string to the end of the cardiostator - the variable rigidity of the working surface allows to pass and correctly install the dumbbell-shaped balloon into the cardioesophageal junction, taking into account the pathological changes in the esophagus mentioned earlier. The developed cardiostator received a utility model patent from the Intellectual Property Agency of the Republic of Uzbekistan FAP No. 01357 "Pneumatic cardiostator".

Table 2. Distribution by disease stage

	I	II	III	IV	
CG	24 (5.2%)	179 (39.1%)	204 (44.6%)	50 (10.9%)	457 (100%)
MG	15 (4.2%)	111 (31.1%)	174 (48.8%)	56 (17.7%)	356 (100%)
TOTAL:	39 (4.8%)	290 (35.6%)	378 (46.5%)	106 (13%)	813 (100%)

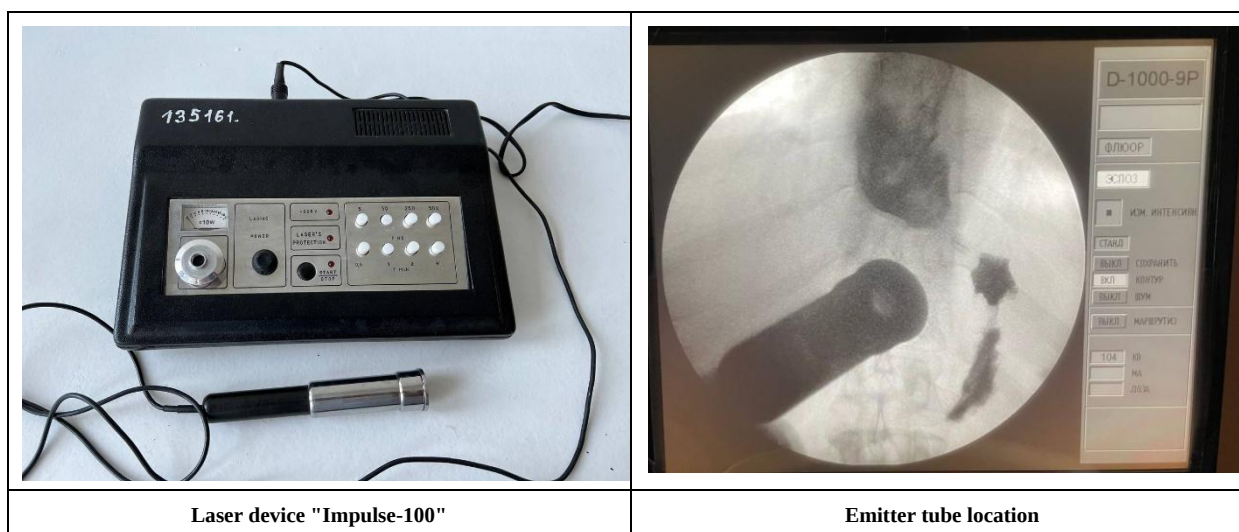


Figure 2. Laser device and methodology

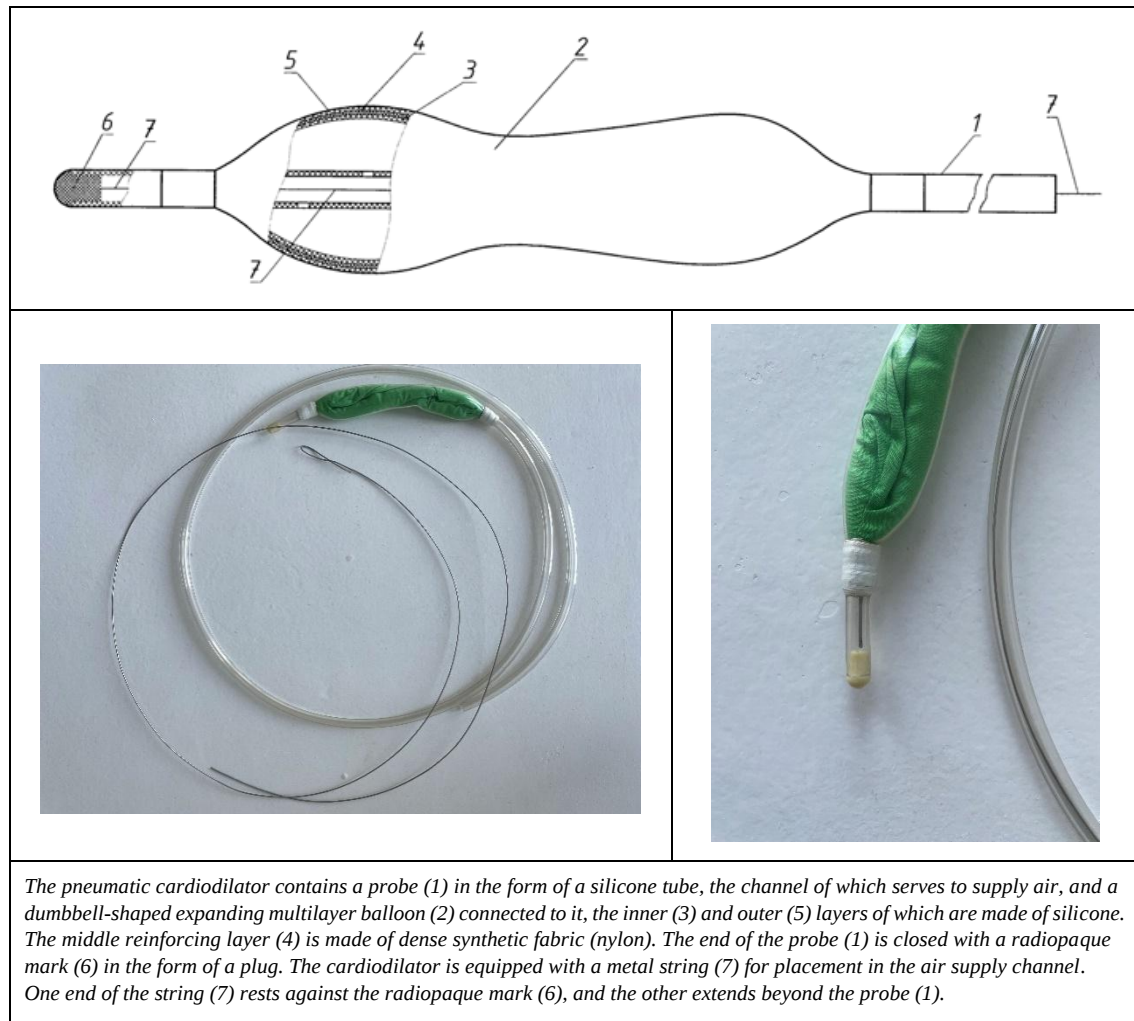


Figure 3. Utility model "Pneumatic cardiodilator"

3. Results

After dilatation courses, 685 (84.2%) patients had no complications, and 128 (15.7%) patients had various complications. The distribution of patients according to the total number of complications is presented in Table 3.

Table 3. Distribution of patients by total number of complications

	CG (N=457)	MG (N=356)	Total (N=813).
No complications	365 (80%)	320(90%)	685(84.2%)
Complications	92 (20%)	36(10%)	128(15.7%)
	P=0.257 and for no complications and <0.001 for complications		

As it follows from the table, in the comparison group, the number of patients who had no complications was 365 (80%), and various complications were observed in 92 (20%) patients.

In the main group, thanks to the implemented technologies and own developments, the number of patients with no complications was increased to 90%, and the number of complications significantly decreased to 10%.

Table 4. Patients distribution by nature of complications

Complications nature	CG (N=457)	MG (N=356)	Reliability	%
Bleeding	54 (11.8%)	12 (3.3%)	P<0.001	66 (25.6%)
Reflux	76 (16.8%)	19 (5.3%)	P<0.001	95 (37%)
Non-penetrating injury	25 (5.4%)	4 (1.1%)	P=0.002	29 (11.2%)
Iatrogenic injury	-	3 (0.8%)	P=0.051	3 (1.1%)
Severe pain syndrome	50 (11%)	14 (4%)	P<0.001	64 (25%)
	205 (44.8%)	52 (14.3%)	P<0.001	257 (100%)

The most common complication was reflux esophagitis, which was observed in 95 (37%) patients. The second most common complication was bleeding from the cardia area, which was diagnosed in 66 (25.6%) patients. Severe pain syndrome that is not relieved by non-narcotic analgesics was noted in 64 (25%) patients. Non-penetrating injury to the esophagus was diagnosed in 29 (11.2%) patients, and

iatrogenic injury to the esophagus occurred in 3 (1.1%) patients. The discrepancy between the actual number of complications and the number of patients in whom they were developed was due to the fact that one patient could experience several types of complications. Structural analysis of the complications that have occurred is presented in Table 4.

4. Discussions

As the structural analysis of complications in the compared groups showed, in the main group, thanks to the implemented technologies and own developments, it was possible to significantly reduce the number of almost all complications by two or more times. Thus, in the main group, the number of bleedings was observed in 12 (3.3%) patients, while in the comparison group this indicator was noted in 54 (11.8%) patients, and in the main group it decreased to 19 and made up 5.3%. Non-penetrating esophageal injuries in the comparison group were noted in 25 (5.4%) patients, while in the main group this indicator decreased to 4 (1.1%) patients. Iatrogenic injury of the esophagus was observed only in 3 (0.8%) patients of the main group. Pronounced pain syndrome not relieved by non-narcotic analgesics in the comparison group occurred in 50 (11%) patients, in the main group this indicator decreased to 14 (4%) patients.

5. Conclusions

The use of low-intensity laser radiation in combination with a new model of cardiostimulator significantly reduced the total number of complications from 20% to 10%.

In the structural analysis of complications, thanks to new technologies and our own developments, a significant reduction in almost all types of complications was also achieved from 44.8% to 14.3%.

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The article is published for the first time and is part of a scientific work.

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