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**ABSTRACT**


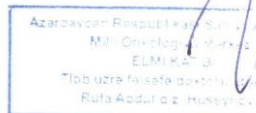
of the dissertation for the degree of Doctor of Philosophy

**ADVERSE PROPERTIES OF THE FOOD  
PIPELINE DEVELOPMENT OF ENDOSCOPIC  
STENTING IN TREATMENT**

Speciality: 3224.01 – Oncology

Field of science: Medicine

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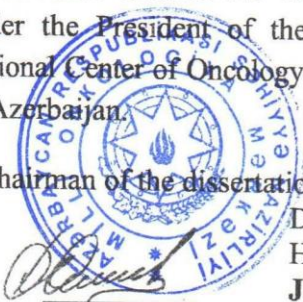


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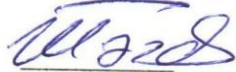
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## INTRODUCTION

**Relevance of the topic.** Esophageal cancer (EC) is more aggressive among the malignant derivatives, has an unsatisfactory prognosis, and is the 4th leading cause of death from cancer<sup>1,2</sup>. Despite the improvement of modern diagnostic methods and the application of new surgical methods, the mortality rates among patients with HF still remain high. According to the National Cancer Institute US, the 5-year survival rate for localized (cT1-2N0M0) forms of the tumor is 37%, for locally disseminated tumors (cT3-4N1-3M0) is 18%, and for distant metastases is 3%<sup>3,4</sup>. Currently, a surgical operation is considered the main method of treatment in local forms of esophageal cancer.<sup>5</sup> However, most of the patients approach the doctor in the late stage of this aggressive malignant derivative disease. In 60% of patients, resection surgery is impossible. At this stage, esophageal carcinoma has already spread to the surrounding tissues, causing esophageal stenosis and even in some cases, esophageal-tracheal fistulas. Dysphagia symptoms develop as a result of the deformation and narrowing of the opening with tumor tissue during stenosis of the esophagus, which makes it difficult or impossible to pass food through the digestive tract<sup>6,7</sup>. Improving the quality of life

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<sup>1</sup>Jackson, C.E. A viewpoint on material and design considerations for oesophageal stents with extended lifetime / C.E.Jackson, L.S.J.Johnson, D.A.Williams.[et al.] // *J Mater Sci.*, - 2022, v.57, - p.3–26.

<sup>2</sup>Napier, K.J. Esophageal cancer: a review of epidemiology, pathogenesis, staging workup and treatment modalities / K.J.Napier, M.Scheerer, S.Misra // *World J Gastrointest Oncol.*, - 2014, v.6, - p.112–120.

<sup>3</sup>Bray, F. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries / F.Bray, J.Ferlay, I.Soerjomataram [et al.] // *CA Cancer J Clin.*, - 2018, v.68, - p.394–424.

<sup>4</sup>Urmonov, U.B. Combined treatment of esophageal cancer using preoperative chemotherapy: // dissertation for the degree of candidate of medical sciences) / - Tomsk, 2020, - 114 p.

<sup>5</sup>Hasanova K.A. Esophageal cancer surgery / A.Askerov, A.Kh.Kaimov, A.R.Aliyev, E.Sh.Nagiyeu // *Health*, - Baku: - 2019, №4, - p.1-10.

<sup>6</sup>Kawakami, T., Tsushima, T., Omae, K. et al. Risk factors for esophageal fistula in thoracic esophageal squamous cell carcinoma invading adjacent organs treated with definitive chemoradiotherapy: a monocentric case-control study. *BMC Cancer* 18, 573 (2018).

with the help of only palliative methods plays an important role in the treatment of such patients. Palliative treatments include radiation therapy, chemotherapy (CDM), and the placement of stents in the esophagus. However, radiation therapy-induced esophagitis may aggravate dysphagia. In this regard, the placement of stents is considered the safest and most effective palliative method for restoring natural anatomical enteral nutrition during dysphagia<sup>8,9</sup>. For this purpose, self-expanding metallic stents are placed in the opening of the esophagus and the cardia-esophageal part by an endoscopic method. In modern literature, the method of the endoprosthesis of the upper and lower branches of the esophagus with self-expanding metallic stents is illuminated in a wide aspect<sup>10,11,12</sup>. This method is widely used in patients who have contraindications to surgical operation, as well as those who are being prepared for chemical and radiation treatment. In addition to the positive effect of stenting on the quality of life and treatment of patients, it should be noted that it can cause certain complications both during the operation and in subsequent periods, which creates certain contradictions. However, enteral nutrition remains the most optimal method<sup>13</sup>.

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<sup>7</sup>Sadaps, M., Bhatt, A., Chevalier, C., Sohal, D., Videtic, G., & McNamara, M. (2018). A practical guide to the management of dysphagia in patients with metastatic esophageal cancer. *Annals Of Esophagus*, 1(3). doi:10.21037/aoe.2018.03.01

<sup>8</sup>Smith, Z.L. Self-Expanding Metal Stents Improve Swallowing and Maintain Nutrition During Neoadjuvant Therapy for Esophageal Cancer / Z.L.Smith, J.E.Gonzaga, G.B.Haasler [et al.] // *Dig Dis Sci.*, - 2017. 62(6), - p. 1647-1656.

<sup>9</sup>Adamson, D. Palliative radiotherapy after oesophageal cancer stenting (ROCS): a multicentre, open-label, phase 3 randomised controlled trial / D.Adamson, A.Byrne, C.Porter [et al.] // *Lancet Gastroenterol Hepatol.*, - 2021. 6(4), - p. 292-303

<sup>10</sup>Godzhello, E.A. Endoscopic prosthetics of stenosis of the esophagus and cardia with self-expanding metal stents / E.A.Godzhello, M.V.Khrustaleva, Yu.I.Gallinger // *Guidelines for doctors*, - Moscow, - 2016. - 68 p.

<sup>11</sup>Wang, T.H. Review Article Esophageal stent types and clinical applications / T.Wang, H.Cui, Y.Shao [et al.] // *Int J Clin Exp Med.*, - 2021. 14(7), - p. 2054-2066.

<sup>12</sup>Black, S. Gastrointestinal stents: materials and designs / S.Black, D.Edwards, G.Smith [et al.] // *Dig Dis Interv.*, - 2018. 2(1), - p. 3-10.

<sup>13</sup>Darling, G.E. Quality of life in patients with esophageal cancer // *Thorac Surg Clin.*, - 2013. vol. 23, - p. 569-75.

**The object of the study.** During the period 2010-2021, 220 patients who applied to the endoscopy department of the National Oncology Center of the Ministry of Health of the Republic of Azerbaijan with cancer of the esophagus and cancer of the cardiac part of the stomach, in the anastomotic zone between the esophagus and the stomach or the esophagus and the small intestine in oncological patients who underwent surgery 112 patients with stenoses occurring during relapses were included.

**The aim of the research work** is to develop a complex endoscopic stenting method and restoration of natural nutrition in order to improve the quality of life and prolong the life of patients with dysphagia syndrome with esophageal cancer.

**Tasks of the study:**

1. Determining the frequency of dysphagia in esophageal cancer patients depending on tumor localization;
2. Determining the frequency of early and late complications after stenting in esophageal cancer patients, depending on tumor localization, histological type, T-descriptor (TNM) and the functional state of the body;
3. Results of treatment in esophageal cancer patients with relapsed and worsening clinical course;
4. Comparative analysis of the quality of life of patients with esophageal stenting and patients with gastrostomy and ileostomy.

**Research methods:** examinations and stenting were performed using the "Olympus Exera 180" endoscope. Roentgenoscopy, endoscopy, and stenting methods were used.

**The main provisions of the thesis defended:**

1. The frequency of dysphagia in esophageal cancer patients is more determined in the middle 1/3 of the esophagus. The incidence of dysphagia depends significantly on the T descriptor and the length of the affected area.
2. Complications observed in esophageal cancer patients after placement of a stent directly depend on the extent of the tumor process, tumor localization, morph structure, and functional status of the patient.
3. Esophageal endoprosthesis in patients with relapsing and

worsening clinical course of esophageal cancer can in most cases enable specific treatment to be carried out or continued.

4. The QLQ-30 quality of life indicators of esophageal cancer patients who underwent stenting showed better results compared to other treatment methods.

**Scientific novelty of the research.** The possibility of performing endoscopic endoprosthesis of the esophagus with self-expanding metallic stents, as well as the effectiveness and safety of stenting, depending on the etiology of dysphagia and the anatomical characteristics of the body (degree, length and localization of stenosis), were comprehensively and comparatively evaluated. For the first time, precise instructions were given on various placement methods of self-expanding stents in esophageal cancer patients, and the characteristics of the stent implantation method were determined depending on the patient's clinical condition. The performance of stenting and the frequency of early and late complications observed after stenting, depending on the location, histological type, classification, degree of spread and the functional state of the body of the malignant tumor were determined, and the methods of correction and prevention of these complications were shown. Delayed complications and quality of life of endoscopic stenting performed during relapses in both esophageal cancer and esophageal anatomies were comparatively analyzed based on the QLQ-C30 questionnaire. Quality of life of patients with esophageal stenting and patients with gastrostomy and ileostomy was compared.

**Theoretical-practical significance of the research:** The application of the complex of diagnostic measures that will be developed and proposed by us will make it possible to select the category of patients who are indicated for stenting as an alternative way when traditional surgical operation is not performed. The set of conducted studies will help us to select the methods of implantation of self-expanding stents depending on the localization of the tumor and to develop the stenting method, which will increase the effectiveness of the treatment of patients with pathologies of the esophagus, and will create the possibility of minimizing the complications that occur during stenting.

**Application of scientific research work.** The results of the research were applied in the treatment bases of the endoscopy department of the National Oncology Center of the Ministry of Health of the Republic of Azerbaijan and in the teaching materials of the oncology specialty.

**Discussion of dissertation materials.** The main provisions and results of the dissertation are presented in the scientific-practical conference of young scientists and specialists dedicated to the National Revival Day of the National Oncology Center (Baku, 2017), "Attend the Georgian Endoscopy Association VIII International Congress" (Tbilisi, 2019), "XI "Congress of oncologists and radiologists of the CIS countries and Eurasia" (Kazan, 2020), was discussed at the international scientific conference dedicated to the 85th anniversary of the birth of Professor Mina Muzaffar Davatdarova, Honored Scientist, Ph.D. (Baku, 2020).

The main provisions of the dissertation were discussed at the ARSN MOM interdepartmental conference (Baku, October 13, 2022, protocol №6) at the scientific seminar of the FD 1.02 Dissertation Council operating under the MOM on April 27, 2023 (protocol №1).

**Printing works.** 16 scientific works on the subject of the dissertation - 6 articles, 7 theses were published in the republic, 2 articles, 1 theses were published in foreign journals.

**The name of the institution where the dissertation work was performed.** The dissertation work was carried out at the National Oncology Center of the Ministry of Health of the Republic of Azerbaijan.

**The scope and structure of the dissertation.** Dissertation introduction (9980 marks), literature review (47500 marks), II chapter on research materials and methods (29700 marks), personal research (90600 marks), conclusion, results, practical Recommendations (28,100 signs) consist of 205,880 signs, including sections. 199 scientific sources are cited in the literature list (35 of them are Russian and 133 are literary sources in foreign languages). The dissertation is illustrated with 27 tables, 7 pictures and 12 graphs.

## MATERIALS AND METHODS OF RESEARCH

**General characteristics of patients.** The study included 332 patients treated with endoscopic stenting for esophageal stenoses of malignant etiology in the endoscopy department of the AR SN National Oncology Center in 2010-2021.

Depending on the etiology of malignant narrowing of the upper parts of the gastrointestinal tract, 332 patients included in the study were divided into two groups. The first group (I) included 220 patients with inoperable cancer of the esophagus, mainly III-IV grade. 149 of them were men (67.7%), and 71 (32.3%) were women. The average age of the patients was  $66.9 \pm 0.7$ . Based on the endoscopic and other examinations performed in group I, 172 (78.2%) of the patients who underwent esophageal stenting had esophageal cancer, and 48 (21.8%) had gastric cancer spreading to the esophagus.

The second group (II) included 112 patients with stenoses that occurred as a result of relapses in the anastomotic zone between the esophagus-stomach or esophagus-small intestine in oncological patients who underwent surgery. 52 of them were men (46.4%), and 60 (53.6%) were women. The average age of the patients was  $65.8 \pm 0.5$  (table 1).

**Table 1**

**Characteristics of the research contingent**

Disease Groups	Number of patients	Male	Female	Average age of patients
esophagus cancer (group I)	220	149 (67,7%)	71 (32,3%)	$66,9 \pm 0,7$
relapse in the anastomotic zone between esophagus-stomach or esophagus-small intestine (group II)	112	52 (46,4%)	60 (53,6%)	$65,8 \pm 0,5$
Total	332	201 (60,5%)	131 (39,5%)	$66,5 \pm 0,5$



72 (63%) of esophageal cancer patients included in group II underwent upper middle laparotomy using the Lewis method, followed by gastric mobilization and resection of the upper 1/3 part. In this group, 25 (21%) people underwent gastrectomy with resection of the distal part of the esophagus, 12 (10%) people underwent resection of the proximal part of the stomach with resection of the distal part of the esophagus, 8 (6%) people underwent gastric tube plastic surgery and extirpation was performed according to TorekDobromoslov.

**Research methods.** The level of damage to the esophagus, the upper border of narrowings, the degree, length and localization of tumor stenosis were determined based on x-ray examination with the help of barium solution or water-soluble contrast material. The diagnosis of esophageal cancer was confirmed based on the histopathological analysis of samples taken during endoscopic examination.

Local and distant metastases of the tumor, X-ray of the lungs with 2nd projection, esophagogastroscopy, ultrasound examination of the chest and abdominal cavity organs (USM), computed tomography (CT) and magnetic resonance imaging (MRI) of the chest organs, clinical and laboratory analyzes and others was determined on the basis of preliminary and clarifying diagnostics, which includes functional methods.

Based on pathohistological examination, 66.3% (146 people) of patients with EC had squamous cell carcinoma, 15% (33 people) had poorly differentiated adenocarcinoma, 8.2% (18 people) had moderately differentiated adenocarcinoma, 4.1% (9 people) highly differentiated adenocarcinoma, 6.4% (14 people) ring cell cancer was detected.

42 (37.5%) of patients who relapsed in esophageal anastomoses had squamous cell cancer, 47 (41.9%) had poorly differentiated adenocarcinoma, 12 (10.7%) had moderately differentiated adenocarcinoma, 5 (4.5%) - adenocarcinoma with an undifferentiated degree was detected.

Based on the clinical classification of patients with EC according to TNM, patients T3 (108 people, 32.5%) and T4 (91 patients, 27.4%) prevailed. Most of the EC patients are in the III (74 people,

33.6%) and IV (70 people, 31.8%) stages; most of the patients who relapsed after surgery were classified as stage II (90 people, 80.4%). The delayed stage of the disease was determined in 75% of patients.

Before the implantation of the stent, each patient underwent an endoscopic examination in order to determine the size and degree of damage to the esophagus, anatomic localization, as well as the distance between the upper and lower sphincter of the esophagus. Endoscopic examination: esophagogastroduodenoscopy or esophago-intestinoscopy was performed using endoscopes of different diameters. GIF Exera 2 model endoscopes with a diameter of 9.6 mm were used for stenting. After the diagnosis of the patient was confirmed, the necessary stent was selected depending on the size of the tumor and the degree of narrowing of the esophagus. Fully coated and semi-coated self-expanding metallic stents were used in the research. A distinctive feature of these stents is the presence of a "Shim Mechanism" designed to prevent stent migration. The minimum diameter of the esophagus to accommodate the stent should be 6.0-8.0 mm. If the required diameter was not available, y-bulging or balloon dilatation was performed to obtain the desired size. Augmentation was performed with the help of endoscopic burs with a diameter of 9.0-11 mm. After stenting, stents with an antireflux mechanism were placed in some patients to prevent regurgitation.

200 (59.8%) patients had esophageal stents with a diameter of 20 mm, and 85 (25.8%) and 47 (14.4%) patients had stents with a diameter of 18 mm and 22 mm. After deployment, the length of the stents varied from 100 mm to 160 mm. Stents with a length of 120-140 mm were implanted in 128 (38.6%) patients, and stents with an antireflux valve at the distal end were implanted in 282 (84.5%) patients. In order to correct the position of the stent or completely remove it, there are special threads - lasso - in the proximal, and in some models - in the distal corners of the stent. It is possible to catch them with the help of a device inserted through the channel of the endoscope.

Of the 332 primary placed esophageal stents, 126 (37.9%) were partially covered with synthetic material (silicone), and 206 (62.1%) were fully covered.

**Methods of statistical analysis.** According to the method of research - clinical; by design – analytical; according to the volume - selection; by type – scientific; according to the material - prospective; according to the duration - transversely; according to location - clinically evaluated. Statistical researches were carried out in IBM Statistics SPSS-26 program with the application of variation, discriminant, dispersion, and correlation methods.

QLQ-C30 (Quality of Life Questionnaire — Core 30, EORTC QLQ-C30) quality of life questionnaire was used to assess the quality of life of patients after esophageal stenting.

### **CLINICAL CHARACTERISTICS OF PATIENTS UNDERGOING STENTING**

The degree of dysphagia and the location of the tumor were determined on the basis of endoscopic and other examinations performed in patients with EC.

In order to objectively characterize dysphagia, the Bown scale was used: 0 points - normal swallowing, 1 point - occasional difficulties in taking solid food, 2 points - feeding with semi-solid food, 3 points - feeding only with solid food, 4 points - difficulty in swallowing saliva. impossibility. The degree of dysphagia determined in patients is shown in the table (table 2).

**Table 2**

#### **Bown scale assessment of dysphagia in esophageal cancer patients**

The nature of the food taken	Degree of dysphagia	Number of patients	
		absolute number	%
Firm but very chewy	1 point	17	7,7%
Porridge-like (shredded with a mixer or blender)	2 points	69	31,4%
Solid	3 points	118	53,6%
Does not feed orally, spits saliva	4 points	16	7,3%
Total		220	100%

As can be seen from the table, most patients took only porridge-like or solid food, that is, the degree of dysphagia was 2-3 points on the Bowen scale in 84.3% of cases. In group I patients, 17 people (7.7%) could eat solid but very chewed food, 69 people (31.4%) could only eat porridge-like food (mixed with a mixer or blender), 118 people (53.6%) could eat solid food. 16 people (7.3%) could not feed orally at all, and encountered difficulties even when swallowing saliva.

The localization of tumor lesions in patients with esophageal cancer is presented in the following table (table 3).

**Table 3**

**Localization of the lesion site in patients with esophageal cancer**

Departments of the esophagus	Number of patients, n	Number of patients, %
Upper part 1/3 of esophagus	37	16,8%
Middle part 1/3 of esophagus	112	50,9%
Lower part 1/3 of esophagus	71	32,3%
Total	220	100%

As can be seen from the table, in 37 (16.8%) patients out of 220 patients, the area of tumor damage was in the upper 1/3 of the esophagus, in 112 (50.9%) patients in the middle 1/3 of the esophagus, in 71 patients (32.3%) it is localized in the lower 1/3 abdominal part. The tumor is mainly localized in the middle 1/3 of the thoracic part of the esophagus.

In 16 of the 48 patients with gastric cancer spreading to the esophagus, the pathological process covered a large part of the esophagus. Thus, in 4 patients, the lower surface of the tumor was located in the antral part of the stomach, in 7 patients - in 1/3 of the stomach body, and 5 patients in the middle part of the stomach body.

The length of stenosis detected in patients in group I varied from 2 to 18.6 cm. Thus, the size of the tumor in 35 (15.9%) patients

- from 2 cm to 5 cm, in 128 (58.2%) patients from 6 cm to 10 cm, in 52 (23.6%) patients from 11 cm Up to 15 cm, in 5 (2.3%) patients it was over 15 cm.

Table 4 presents the degree of narrowing of the cardiac part of the esophagus or stomach as a result of the tumor in the studied group.

**Table 4**

**Rates of esophageal stricture in patients with esophageal cancer**

Diameter, mm	Number of patients (average)	%
I degree - 9-11 mm	16	7,3%
II degree - 6-8 mm	93	42,3%
III degree - 3-5 mm	99	45,0%
IV degree - 0-2 mm	12	5,5%
Total	220	100%

In about half of the patients, the narrowing of the esophageal opening is significant and ranges from 3-8 mm. From the results presented in the table, it can be seen that the narrowing of the esophageal opening was grade I (9-11 mm) in 16 patients (7.3%), grade II (6-8 mm) in 93 patients (42.3%), and grade II (6-8 mm) in 99 patients (45, 6%) grade III (3-5 mm), 12 patients (5.5%) grade IV (0-2 mm). It should be noted that no correlation was found between the length of gastric cancer stenoses and the degree of dysphagia involving the esophagus, cardia and cardioesophageal zone ( $\rho=0.089$ ,  $p=0.187$ ). This is due to the fact that the passage of food does not depend only on the diameter of the opening of the esophagus, but also on the length, localization, preservation of motility of the lesion, including the visually undamaged area of the stomach, and this, in turn, is reflected in the subsequent results of stenting. According to the results of the correlation statistical analysis, the degree of dysphagia in esophageal cancer patients varies depending on the degree of narrowing of the stenosis ( $\rho=0.341$ ;  $p<0.001$ ). There is a positive correlation between the degree of dysphagia ( $\rho=0.133$ ;  $p=0.049$ ) and the diameter of the stenosis orifice ( $\rho=0.146$ ;  $p=0.031$ ) and the T-descriptor.

During the endoscopy examination, tumors were detected directly in the zone of esophageal anastomoses in group II patients: esophagus-stomach anastomosis - in 70 (62.5%) patients, esophagus-small intestine anastomosis - in 42 (37.5%) patients.

Clinically, grade III dysphagia was identified in most of these patients (41.6%) (table 5).

**Table 5**

**Assessment of dysphagia according to the Bown scale in patients with recurrences in the anastomotic zone**

The nature of the food taken	Degree of dysphagia	Number of patients	
		Absolute number	%
Firm but very chewy	1 point	1	0,9%
Porridge (shredded with a mixer or blender)	2 points	9	8,0%
Solid	3 points	84	75,0%
Does not feed orally, spits out saliva	4 points	34	16,1%
Total		112	100%

As can be seen from the table, 1 person (0.9%) of the patients in this group ate solid but very chewed food, 9 people (8.0%) only ate porridge-like food (made with a mixer or blender), 84 people (75.0%) could take food. 34 people (16.1%) could not feed orally at all, and encountered difficulties even when swallowing saliva. As it can be seen, in this group, compared to group I, symptoms of grade III and IV dysphagia were registered more often ( $\chi^2=34.763$ ;  $Pp<0.001$ ;  $pU<0.001$ ).

In general, the length of the stented area in primary or secondary esophageal anastomose tumor lesions ranged from 3.2 cm to 15.7 cm, and the majority of patients were 8 cm to 15 cm. Thus, 37\5 (31.3%) of the patients were less than 5 cm, 43 (38.4%) were 5-10 cm, 33 (29.5%) were 10-15 cm, 1 (0.9 %) was more than 15 cm. Endoscopically, narrowing of the esophageal opening from 4 mm to 8 mm was determined (89.3%) (table 6).

**Table 6****The degree of narrowing of the lumen in patients with recurrence of the anastomotic zone**

Diameter, mm	Number of patients(average)	%
I degree - 9-11 mm	12	10,7%
II degree - 6-8 mm	59	52,7%
III degree - 3-5 mm	41	36,6%
IV degree - 0-2 mm	0	0%
Total	112	100%

As can be seen from the table, 12 (10.7%) of the patients in this group had a diameter of 9-11 mm (grade I), 59 (52.7%) patients had a diameter of 6-8 mm (grade II), 41 (36.6 %) varies between 3-5 mm (grade III) in the patient.

According to the results of the correlation statistical analysis, dysphagia in patients with recurrent esophageal cancer depends on the length of the stenosis ( $\rho=0.186$ ;  $p=0.049$ ), T-descriptor ( $\rho=0.379$ ;  $p<0.001$ ), stage of the disease ( $\rho=0.423$ ;  $p<0.001$ ). The length of stenosis is also influenced by T-descriptor ( $\rho=0.461$ ;  $p<0.001$ ) and disease stage ( $\rho=0.371$ ;  $p<0.001$ ).

In general, according to the results of both groups, the degree of dysphagia directly depends on the diameter of the stenosis orifice ( $\rho=0.223$ ;  $p<0.001$ ). At the same time, it should be noted that the diameter of the stenosis depends on the T-descriptor ( $\rho=0.205$ ;  $p<0.001$ ) and the stage of the disease ( $\rho=0.164$ ;  $p=0.003$ ). It was determined that the length of sepsis depends on the T-descriptor ( $\rho=0.263$ ;  $p<0.001$ ) and the stage of the disease ( $\rho=0.242$ ;  $p<0.001$ ),

Based on the clinical characteristics of the patients included in the study, it can be said that individual characteristics of the patients were observed even within the study groups. 225 stents were selected for 220 patients. The length of stents was 100 mm in 81% of them, and 140 mm in 19% of patients. In 77% of cases, stents have a classic "esophagus" construction, and in 23% of cases, they have additional constructive elements. 33 of them (12.6%) had stents with an antireflux valve, and 26.6% (59 people) had additional MexaHH3M (shim) fixation mechanism stents

placed. 40% of used antireflux stents, 50% of "neck" stents, and 25% of classic stents are Shim technology stents.

## **COMPLICATIONS AFTER STENTING IN PATIENTS WITH ESOPHAGEAL INJURY AND THEIR CORRECTION METHODS**

Along with the positive results of stenting, such as reducing the degree of dysphagia, complications requiring endoscopic or surgical correction have also been observed. Such patients make up 36.4%.

Complications observed during the stenting process are divided into 2 groups: 1) During stenting; 2) After performing stenting. Group 2 itself is divided into 2 groups: early (up to 2 weeks) and delayed complications (more than 2 weeks). Currently, complications observed within 7 days after placement of self-expanding metallic stents are considered as early complications.

Complications during stenting were observed in 21 (12.7%) of 220 esophageal cancer patients included in the study. Of these patients, 7 (3.2%) had perforation of the esophagus, 11 (5.0%) had stent dislocation, and 2 (0.9%) had bleeding from the tumor surface (table 7).

In our study, early complications after stenting were recorded in 63 (28.6%) of 220 esophageal cancer patients who underwent stenting. In 16 (7.3%) patients, stent dislocation was recorded as a result of improper feeding during the first day. In 6 (2.7%) patients, complete migration of the stent was determined, and in 5 (2.3%) patients, obturation of the stent with food was determined. Acute pain was recorded in 27 (12.3%) patients, severe profuse bleeding in 9 (4.1%) patients, but all cases were resolved by endoscopic or conservative treatment.

There was no statistically significant difference in the frequency of early complications according to the etiology, localization and length of narrowing, but early complications were more often recorded in the upper 1/3 of the esophagus: The upper border of the injury was localized in the upper 1/3 of the esophagus 37 (16.8%) in 21 (56.8%) of the patients, in 27 (24.1%) of the 112 (50.9%) patients, the upper border of the stenosis was in the middle 1/3 of the esophagus, and the lesion was located in the lower 1/3 of the esophagus Early complications occurred in 16 (21.1%) of



69 (32.3%) patients. Dislocation of the stent was mainly observed when the localization of the tumor was in the lower 1/3 of the esophagus (7 patients, 9.9%).

**Table 7**

**Complications after stenting in esophageal cancer patients and methods of their correction**

<b>Analyzed parameters</b>	Number of Patients
<b>The nature of the aggravation</b>	
<b>Complications during the execution of the stand:</b>	21 (12,7%)
Perforation of the esophagus	7 (3,2%)
Dislocation of the stent	11 (5,0%)
Bleeding from the surface of the tumor	2 (0,9%)
<b>Early complications:</b>	63 (28,6%)
Dislocation of the stent as a result of improper feeding of patients during the first day	16 (7,3%)
Complete migration of the stent	6 (2,7%)
Profuse bleeding	9 (4,1%)
Stent obturation with food	5 (2,3%)
Sharp pains	27 (12,3)
<b>Late complications:</b>	75
Fragmentation of the stent	22 (10,0%)
Complete migration of the stent	10 (4,5%)
Scar or tumor tissue covering the proximal or distal edges of the stent	37 (16,8%)
Bleeding	6 (2,7%)
<b>Method of correction of the applied complication</b>	Number of interventions
Endoscopic correction of the stent position with the help of a lasso	50 (22,7%)
Stent-to-stent restenosis as a result of perforation of the esophagus	31 (14,1%)
"Stent-to-stent" type endoprosthesis of the esophagus with fixation of the stent to the ear canal with the Shim mechanism	25 (11,4%)
Endoscopic removal of the stent-obstructing food particle by flushing with water	11 (5,0%)
Conservative hemostatic treatment	6 (4,5%)

Delayed complications after stenting were recorded in 75 (34.1%) patients in this group. Thus, complete fragmentation of the stent in 22 (10.0%) patients, complete migration in 10 (4.5%) patients, covering of the proximal or distal edges of the stent with scar or tumor tissue in 37 (16.8%) patients, 6 (2.7%) patient had esophageal bleeding. It should be noted that several complications were observed simultaneously in 34 patients. Stent fragmentation was mainly observed in the middle 1/3 of the esophagus (15 patients, 13.4%), stent migration was mainly in the lower 1/3, and bleeding (3 patients, 8.1%) was observed in the upper 1/3.

It is possible to carry out timely correction of complications caused by radiological and endoscopic studies. These complications were serious and were corrected by repeated endoscopy. In 50 (22.7%) patients, the position of the stent was endoscopically corrected using a lasso, in 31 (14.1%) patients, "stent-to-stent" type restenosis was caused by perforation of the esophagus, in 25 (11.4%) patients, the stent was attached to the eardrum with the Shim mechanism. "stent-to-stent" type endoprosthesis of the esophagus was performed with fixation. In 11 (5.0%) patients, endoscopic removal of the food fragment obturating the stent was done by washing it with water. Conservative hemostatic treatment was prescribed to 6 (4.5%) patients (table 8).

As the degree of dysphagia increases in esophageal cancer patients, complications recorded during stenting ( $\rho=0.202$ ;  $p=0.003$ ) also increase. Delayed complications are accompanied by acute pain ( $\rho=0.390$ ;  $p<0.001$ ) and weight loss ( $\rho=0.197$ ;  $p=0.003$ ) in patients.

In our study, during the stenting of recurrent esophageal cancer patients, 19 (17.0%) patients had complications during stenting. Among them, 7 (6.3%) people had perforation of the esophagus, 9 (8.0%) had stent dislocation, and 3 (2.7%) had bleeding from the surface of the tumor. As can be seen from the results, statistically significant more complications during stenting were recorded in this group compared to group I ( $\chi^2=9.329$ ;  $p_p=0.025$ ;  $p_U=0.015$ ).

Early complications after stenting were recorded in 37 (33.0%) patients. In 10 (8.9%) patients, the displacement of the stent as a result of improper feeding of the patients during the first day resulted

in stent dislocation, in 11 (9.8%) patients, complete migration of the stent, in 2 (1.8%) patients, profuse bleeding, in 7 (6.3 %) obturation of the stent with food, acute pain was observed in 7 (6.3%) people

**Table 8**

**Complications during stenting of patients with recurrent esophageal cancer**

<b>Analyzed parameters</b>	Number of Patients
<b>The nature of the aggravation</b>	
<b>Complications during the execution of the stand:</b>	19 (17,0%)
Perforation of the esophagus	7 (6,3%)
Dislocation of the stent	9 (8,0%)
Bleeding from the surface of the tumor	2 (2,7%)
<b>Early complications:</b>	37 (33,0%)
Dislocation of the stent as a result of improper feeding of patients during the first day	10 (8,9%)
Complete migration of the stent	11 (9,8%)
Profuse bleeding	2 (1,8%)
Stent obturation with food	7 (6,3%)
Sharp pains	7 (6,3%)
<b>Late complications:</b>	46 (41,1%)
Fragmentation of the stent	21 (18,8%)
Complete migration of the stent	13 (11,6%)
Scar or tumor tissue covering the proximal or distal edges of the stent	5 (4,5%)
Erosive bleeding	3 (2,7%)
Ulcerative esophagitis (related to reflux)	4 (3,6%)
<b>Method of correction of the applied complication</b>	Number of interventions
Endoscopic correction of the stent position with the help of a lasso	33 (29,5%)
Stent-to-stent restenosis as a result of perforation of the esophagus	21 (18,8%)
Stent-to-stent endoprosthesis of the esophagus with fixation of the stent to the ear canal with the Shim mechanism	14 (12,5%)
Endoscopic removal of the stent-obstructing food particle by flushing with water	7 (6,3%)
Conservative hemostatic treatment	8 (7,1%)

Full displacement (migration) of the stent below the stenosis zone - 5 times, upward - 2 times, partial downward displacement (dislocation) - 4 times. In addition, external compression of the esophagus and grade 3 and 4 scarring above the stent with stricture formation was recorded in 2 observations.

In this group, delayed complications (21-18.8%) occurred in 46 (41.1) patients - fragmentation of the stent with the disintegration of the polymer coating (cases of complete or partial separation of the stent fragments were detected, that is, a violation of the integrity of the metallic structure (fragmentations); 13 ( in 11.6%) people - complete migration; in 5 (4.5%) people - covering the proximal or distal edges of the stent with a scar or tumor tissue, in 3 (2.7%) people - erosion bleeding, in 4 (3.6 %) patient with reflux-related ulcer esophagitis) was recorded. In 4 patients, problems related to the progression of the tumor were recorded: invasion of the recurrence of the esophagus tumor into the trachea, development of stenosis in the distal direction to the pulporobulbar zone. In 2 patients, the growth of the tumor involved the proximal part of the stent (due to the occurrence of stenosis above the proximal end of the stent) and a tracheoesophageal fistula was formed as a result of the disintegration of the tumor. As can be seen from the results, there was no statistically significant difference in this group compared to group I in terms of both early ( $\chi^2=14.827$ ;  $pp=0.011$ ;  $pU=0.655$ ) and late complications ( $\chi^2=25.325$ ;  $pp<0.001$ ;  $pU=0.513$ ).

In our study, it was determined that complications after stenting are observed more often in the distal 1/3 of the esophagus than in the middle 1/3.

After stenting, the pain of different localization and intensity in patients was not directly related to the stent. So, pains arise either as a result of the stent pressing on the surrounding organs and tissues or based on the manifestations of the tumor process itself. During the study, during the analysis of pain symptoms for both groups, it was determined that 36.4% of patients in group I (80 patients) had mild pains (these patients were not given painkillers), mild pains (these patients used painkillers up to 2 times a day) in 44.1% (97 patients),

and severe pain (these patients used painkillers more than 2 times a day) was observed in 18.2% (40 patients). In patients included in the anastomosis group (group II), these indicators were slightly severe in 27.7% of patients (31 patients), mild pain in 57.1% (64 patients) and severe pain in 15.2% (17 patients) registered.

In our study, 33 (29.5%) patients underwent endoscopic correction of the stent position employing a lasso (using polypectomy loops or biopsy forceps, holding the lasso, and gathering upper and lower holes to remove migrating stents or their fragments), 21 (18.8%) as a result of perforation of the esophagus, "stent-to-stent" rasterization was performed, so a stent-to-stent correction was performed with nitinol stents, in 14 (12.5%) persons, stent-to-stent was fixed to the auricle with the Shim mechanism, and the esophagus was "stent-to-stent" type endoprosthesis was performed. In 7 (6.3%) people, the food piece obturating the stent was removed endoscopically by washing it with water (bulging from the stent port). Conservative hemostatic treatment was prescribed to 8 (7.1%) patients. Double stenting was performed in 2 patients, that is, a new stent was placed in the pylorobulbar zone through the port of the esophageal stent.

In patients with recurrent esophageal cancer, dysphagia directly causes an increase in complications ( $p=0.710$ ;  $p<0.001$ ) and acute pain ( $p=0.277$ ;  $p=0.003$ ) during the performance of stenting. Complications during stenting ( $p=0.453$ ;  $p<0.001$ ) depended on T-descriptor, disease stage ( $p=0.479$ ;  $p<0.001$ ) and were accompanied by acute pain ( $p=0.345$ ;  $p<0.001$ ).

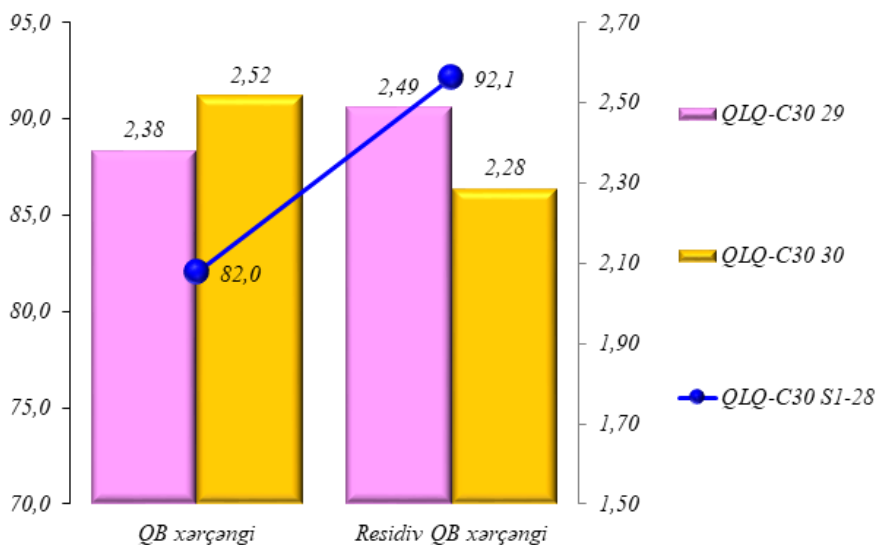
Complications during stenting ( $p=0.386$ ;  $p<0.001$ ), pain ( $p=0.166$ ;  $p=0.002$ ) and weight loss ( $p=0.196$ ;  $p<0.001$ ) depended on the degree of dysphagia in both groups. Narrowing of the orifice of stenosis plays an important role in early complications after stenting ( $p=0.109$ ;  $p=0.048$ ).

Thus, differential X-ray endoscopic control 1-3 days after stenting allows timely detection of complications. In 90% of cases, complications caused by the progression of the main process can be corrected in time with the help of modern endoscopic methods.

## QUALITIES OF LIFE OF ESOPHAGAL CANCER PATIENTS

The quality of life of the patients during the next 1-2 weeks after esophageal stenting was evaluated based on the QLQ-C30 questionnaire, and their quality of life was compared with the quality of life of gastrostomy and ileostomy patients. For this purpose, the quality of life of patients who underwent gastrostomy (35 patients) and ileostomy (2 patients) surgery at the National Oncology Center and other clinics was comparatively analyzed.

According to the results of the questionnaire survey, patients in group I were unable to engage in their work or daily activities after esophageal stenting (51.0%; QLQ-C30-6;  $p_p=0.025$ ), as well as unable to engage in hobbies or leisure activities (58.6%; QLQ-C30-7;  $p_p<0.001$ ). 51.0% of patients (QLQ-C30-9;  $p_p<0.001$ ) had severe pain. Among patients undergoing esophageal stenting, 33 (21.0%) rated their general health last week (QLQ-C30-29;  $p_p=0.477$ ) as bad, and 16 (10.2%) as slightly better. 32 people (20.4%) note deterioration of their quality of life (QLQ-C30-30;  $p_p=0.057$ ). 26 (16.6%) people rated their quality of life as average (graph 1).



**Graph 1. Quality of life of esophageal cancer patients after stenting**

According to the general results of the QLQ-30-1-28 questionnaire obtained during the evaluation of the quality of life in patients with stenoses in the anastomotic zone between the esophagus-stomach or the esophagus-small intestine, the quality of life was lower in the relapsed group (QLQ-C30 1- 28;  $p_U < 0.001$ ). Despite this, no statistically significant difference between the groups was determined according to the patients' assessment of their general health and quality of life.

As can be seen from the table, the total response score of the QLQ-C30-S1-28 questionnaire depends on the degree of narrowing of the esophageal opening. So, as the diameter of the orifice decreases, the quality of life of patients decreases. Although this result was statistically significant ( $p_F = 0.035$ ) according to the results of the Anova test, it was not confirmed by the KruskalVallis criterion ( $p_K = 0.091$ ). The degree of narrowing of the diameter of the opening of the esophagus negatively affects the general health and quality of life of patients, but this was not statistically significant.

In relapsed esophageal cancer patients, the degree of narrowing of the esophageal opening significantly reduces the quality of life ( $p_F < 0.001$ ;  $p_K < 0.001$ ).

It was determined that the quality of life indicator depends on the localization of the tumor in the esophagus. Thus, when the tumor is localized in the upper 1/3 neck of the esophagus, the patients' quality of life after stenting is lower (QLQ-C30 S1-28;  $p_F < 0.001$ ;  $p_K < 0.001$ ).

During observation, 36.1% of 332 patients who survived after 30 days had a good appetite, and 63.9% had a decreased or complete lack of appetite. As a result, a decrease in body weight was observed in most of the patients. A significant decrease in body weight was observed in both groups of patients after esophageal stenting ( $p_U < 0.001$ ).

A positive correlation ( $\rho = 0.197$ ;  $p = 0.015$ ) was found between the degree of narrowing of the stenosis and lower quality of life (QLQ C30-1-28) in esophageal cancer patients.

As a result of the analysis of the points collected based on the 28 questions of the questionnaire conducted during the evaluation of the quality of life, it was determined that ( $\rho = 0.197$ ;  $p = 0.015$ ) the quality of life of the patients after esophageal stenting decreased as

the diameter of the stenosis orifice narrowed ( $\rho=0.197$ ;  $p=0.015$ ). The increase in the feeling of pain after stenting ( $\rho=0.176$ ;  $p=0.009$ ) depends on the T-descriptor and the stage of the disease ( $\rho=0.269$ ;  $p<0.001$ ). Delayed complications in these patients (QLQ-C30-S1-28;  $\rho=0.175$ ;  $p=0.031$ ) are accompanied by lower quality of life. Loss of body weight was observed in patients with decreased quality of life (QLQ-C30 S1-28) ( $\rho= -0.194$ ;  $p=0.015$ ).

In patients with recurrent esophageal cancer, the QLQ-C30-29 questionnaire was evaluated depending on the length of stenosis ( $\rho= -0.216$ ;  $p=0.024$ ) and weight loss ( $\rho=0.282$ ;  $p=0.003$ ). In addition, QLQ-C30-30 questionnaire assessment was significantly different from stenosis length ( $\rho= -0.341$ ;  $p<0.001$ ), disease stage ( $\rho= -0.197$ ;  $p=0.040$ ) and early complications after stenting ( $\rho=0.211$ ;  $p= 0.028$ ) directly depends. In general, the degree of dysphagia in both groups is significant in decreasing QLQ-C30-1-28 ( $\rho=0.203$ ;  $p=0.001$ ) quality of life.

As mentioned above, gastrostomy was performed on 35 patients, and ileostomy was performed on 2 patients.

A comparative analysis of the quality of life of esophageal cancer patients with gastrostomy and esophageal cancer patients undergoing stenting showed that compared to esophageal cancer patients undergoing stenting (QLQ-CA30 S 1-28), the quality of life of gastrostomy patients (QLQ-C30-1-28);  $103.6\pm 0.06$ ) (QLQ-C30-1-28;  $86.2\pm 0.08$ ) is statistically significantly lower ( $pU<0.001$ ).

Patients who underwent gastrostomy had better overall health (QLQ-C30-29;  $1.73\pm 0.14$ ;  $pU<0.001$ ) and quality of life (QLQ-C30-30;  $1.59\pm 0.08$ ;  $pU<0.001$ ) last week than stenting. evaluated worse than patients (graph 2).

Thus, compared to other palliative treatment methods, the application of stenting method with self-expanding metal endoprostheses to esophageal cancer patients is the most optimal option in the complex treatment scheme, has a positive clinical and functional effect, improves the patient's quality of life and causes fewer complications. In this case, self-expanding stents should be preferred. Complications caused by stenting can be quickly corrected, allowing to restore the body's nutritional status and vital qualities.



## RESULTS

1. In patients with esophageal cancer, the symptom of dysphagia is found in 69% of cases, and the frequency of dysphagia is in the upper 1/3 of the esophagus - 16.8%, in the middle 1/3 - 50.9%, in the lower 1/3 - 32, is set between 3%. At this time, first-degree dysphagia – 7.7%; second degree dysphagia – 31.4%, third degree dysphagia – 53.6%, fourth degree dysphagia – 7.3% [8, 9, 14].

2. The incidence of dysphagia in esophageal cancer patients depends on the T descriptor ( $p=0.379$ ;  $p<0.001$ ), the diameter of the orifice of the damaged area ( $p=0.146$ ;  $p=0.031$ ), the length of the stenosis ( $p=0.186$ ;  $p=0.049$ ) and the stage of the disease ( $p=0.423$ ;  $p<0.001$ ) is significantly dependent [16].

3. It was determined that early complications occur in 28.6% of esophageal cancer patients after stent placement, and the degree of spread of the tumor process ( $p=0.202$ ;  $p=0.003$ ) and the patient's functional status are considered factorial signs. Delayed complications of stenting were found in 34.1% of esophageal cancer patients, factorial symptoms in these patients depend on tumor localization and morphostructure [9, 12, 14].

4. Esophageal endoprosthesis in patients with relapsing and aggravated clinical course of esophageal cancer makes it possible to carry out or continue specific treatment in 74.1% of cases [10, 14].

5. A comparison of quality of life indicators (QLQ-C30-1-28;  $86.2\pm 0.08$ ) of esophageal cancer patients who underwent stenting was made on the QLQ-C30 scale, and it was found that these patients were better than patients who underwent gastrostomy or ileostomy surgery. (QLQ-C30-1-28;  $103.6\pm 0.06$ ) showed better results ( $p_U<0.001$ ) [15].

## PRACTICAL RECOMMENDATIONS

1. Before performing endoscopic stenting for esophageal cancer patients, the length, localization, degree of dysphagia, size of the tumor damage area should be determined with the help of various examination methods, and appropriate stents should be selected. It

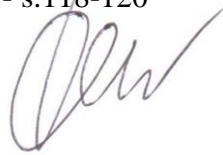
- is more appropriate to use stents with anti-reflux valve when the damage center is located in the lower 1/3 of the abdominal part of the esophagus, especially in the esophagus-stomach passage.
2. Any early and delayed complications observed during stenting or after stenting, especially perforation of the small intestine and large intestine during stent migration, as well as intestinal obstruction, should be immediately removed or "stent-to-stent" restenization should be performed.

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## **LIST OF ABBREVIATION**

EC –Esophageal cancer

QLQ – Quality of Life Questionary

CT – Copmuter tomografy

CDT – Chemical drug treatment

MRI – Magnetic resonance imaging

NES– Novolimus-eluting stent

SEMS– Self expandable metallic stent

WHO – World Health Organization

The defense of the dissertation will be held on 27 June 2023, at 14<sup>00</sup> at the meeting of the Dissertation council FD 1.02 of Supreme Attestation Commission under the President of the Republic of Azerbaijan operating at the National Center of Oncology of the Ministry of Health of the Republic of Azerbaijan.

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The dissertation is accessible at the library of the National Center of Oncology of the Ministry of Health of the Republic of Azerbaijan.

Electronic versions of the dissertation and its abstract are available on the official website [aak.gov.az](http://aak.gov.az).

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