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THE RESULTS OF THORACIC ENDOVASCULAR ARTIC REPAIR IN PATIENT WITH AORTIC DISSECTIONS

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Abstract: Purpose: to study the immediate and long-term results after thoracic endovascular aneurysm repair (TEVAR) and to conduct a comparative analysis with the group of nonsurgical treatment of aneurysms and dissections of the thoracic aorta.

Key words: aneurysm and aorta dissection, endovascular repair, nonsurgical treatment, early and long-term results, survival

Materials and methods. Clinical data of 42 patients with endovascular repair were analyzed (average age 58,7+4,1, 32 men, 10 women) and compared with the results of nonsurgical treatment of 18 patients (average age 53,8+3,3, 13 men, 5 women) with aneurysms and thoracic aorta dissection. Also, as in TEVAR group, the significant part of nonsurgical treatment patients group (72,2%; 13 out of 18) were cases with delaminating aneurysm. According to Stanford's classification, the groups were also comparable. The average follow-up period was 2.7ë0.25 years.

Results. Higher rates of hospital mortality were noted against the background of nonsurgical treatment - 38.9% (7 out of 18) versus 0.0% in the TEVAR group. Also, the 30-day mortality was statistically significantly high in the nonsurgical treatment group - 22.2% versus 2.4% in the TEVAR group. Long-term mortality up to 36 months on the background of drug therapy was also higher - 16.7% versus 11.9% with TEVAR. As a result, the total mortality during the study period was 77.8% in the nonsurgical treatment group and 14.3% in the TEVAR group. Long-term mortality up to 36 months on the background of drug therapy was also higher - 16.7% versus 11.9% with TEVAR. As a result, the total mortality during the study period was 77.8% in the conservative treatment group and 14.3% in the TEVAR group. The main causes of deaths in the nonsurgical treatment group were mainly represented by cardiovascular complications and multiple organ failure against the background of malperfusion and hemodynamic instability of target organs, whereas after TEVAR, no cases related to the procedure itself or stent graft were identified. The cumulative 30-day survival rate after all TEVARs was 97.6%, 6-month survival rate was 88.1%, two-year and three-year survival rate was 85.7%. In the nonsurgical treatment group, statistically significantly low survival rates were obtained during the entire study period, both in the early 38.89% and in the long-term 22.2% follow-up periods. In the TEVAR group, freedom from leaks (endoleak) Types I and III accounted for 92.86%. Cumulative freedom from stent graft-induced new distal message (dSINE) was 100% in one-year, 97.3% in two-year and 94.59% in three-year follow-up periods.

Conclusions. Endovascular repair for aneurysms and dissections of the thoracic aorta showed high efficiency both in the early and near, and in the long-term postoperative period. TEVAR demonstrates more favorable short-term and long-term clinical results of treatment for thoracic aortic aneurysms and dissections in the outcome of successful aortic remodeling compared with only drug treatment.

Introduction. Aneurysms and aortic dissections are a complex idiosyncratic disease, and with untimely treatment are characterized as a life-threatening pathology with a high mortality rate [1, 2]. According to the International Register of Acute Aortic Dissection (IRAD), about one third of all acute aortic dissections are complicated by malperfusion syndrome or hemodynamic instability, and if timely assistance is not provided, complicated dissection will lead to irreversible damage to the target organ or death [1, 3].

In turn, relapse of symptoms, aneurysmal dilation (55 mm) or an annual enlargement of the aorta by 4 mm indicate complicated chronic aortic dissection [3]. The term "uncomplicated" dissection is controversial, since many "uncomplicated" asymptomatic cases show signs of a high risk of dissection even without obvious complications. Prevention of chronic aneurysmal degeneration and achievement of aortic remodeling can prevent late degeneration and, consequently, complex open surgery on the aorta with its inherent risks [4, 5].

Optimal management tactics for patients with aneurysm and dissection of the thoracic aorta is a complex task and requires an interdisciplinary team approach. Medication remains the standard treatment for acute uncomplicated aortic dissection. Interventions by open surgery or endovascular access are currently indicated for patients who have or subsequently develop complications [6, 7]. In turn, thoracic aortic endorepair (TEVAR) is used as a method of choice in the surgical treatment of patients with aortic dissection, both as an independent approach and in staged hybrid surgical treatment [8-11]. Despite the success of drug therapy in the emergency treatment of uncomplicated dissection, long-term morbidity and mortality are far from ideal. Despite the urgency of the problem, there is currently small amount of information about the comparative long-term results of endovascular and nonsurgical methods of treatment of aneurysms and dissections of the thoracic aorta. Also, complications arising in the long-term follow-up period are insufficiently studied and require further changes in the approach to the treatment of this group of patients in order to prevent the development of complications.

Materials and methods. The study includes an analysis of the results of endovascular repair of 42 patients with aneurysms and dissections of the thoracic aorta who received hospital treatment at the Republican Specialized Scientific and Practical Medical Center of Surgery in the name of Academician V.Vakhidov (Tashkent, Uzbekistan) and the Republican Cardiology Center (Ufa, Russian Federation). A comparative analysis was carried out with a group of patients after hospital nonsurgical treatment (n=18) at the Republic scientific center of emergency and medical care (Tashkent, Uzbekistan).

Statistical processing of the initial data of patients did not show significant differences between the groups when comparing by age, gender and severity of the condition when patients were admitted to hospital treatment. The average age of patients in the nonsurgical treatment group was 53.8+3.3 (from 22 to 87) years, most were aged from 60 to 74 years. Also, as in the TEVAR group, a significant part of patients in the nonsurgical treatment group (72.2%; 13 out of 18) were cases of a delaminating thoracic aortic aneurysm. According to the Stanford classification, the groups were also comparable with a small difference (Table 1).

Table 1. Comparison of study groups by type of aneurysms and the presence of aortic dissection

Type of aorta aneurysm	Nonsurgical treatment (n=18)	TEVAR (n=42)
Without dissection	**5 (27,8%)**	**11 (26,2%)**
True aneurysm	5 (27,8%)	5 (12,0%)
Sac shaped aneurysm	-	3 (7,1%
Penetrating atherosclerotic ulcer (PAU)	-	3 (7,1%)
Aneurysm dissection	**13 (72,2%)**	**31 (73,8%)**
Type A	**2 (11,1%)**	**3 (7,1%)**
Acute (< 14 days)	1 (5,6%)	1 (2,4%)
Sub-acute (14-90 days)	-	-
Chronic (>90 days)	1 (5,6%)	2 (4,8%)
Type B	**11 (61,1%)**	**24 (57,1%)**
Acute (< 14 days)	4 (22,2%)	8 (19,0%)
Sub-acute (14-90 days)	5 (27,8%)	12 (28,6%)
Chronic (>90 days)	2 (11,1%)	4 (9,5%)
Type not A not B	**-**	**4 (9,5%)**
Acute (< 14 days)	-	-
Sub-acute (14-90 days)	-	4 (9,5%)
Chronic (>90 days)	-	-

Among the prehospital complications in the TEVAR group, a significantly greater number of different consequences of the underlying pathology of patients were revealed, which served as the reason for the use of an invasive treatment method (Table 2). Among the patients who underwent nonsurgical treatment and follow-up were acute visceral ischemia in 1 case (5.6%) and severe anemia due to aneurysm rupture and posthemorrhagic condition - 3 (16.7%).

Table 2. Prehospital complications of thoracic aortic aneurysms

Type of preshospital complication	Nonsurgical treatment (n=18)		TEVAR group (n=42)	
	n	%	n	%
Left side hydrothorax	-	-	8	19,0%
Intramural hematoma	-	-	8	19,0%
Hydropericardium	-	-	6	14,3%
Malperfusion syndrome/ lower limb ischemia	2	11,1%	5	12,0%
Pain syndrome	-	-	5	12,0%
Left side blocked hemothorax	-	-	4	9,5%
Aneurysm rupture	3	16,7%	4	9,5%
Hemomediastinum	-	-	2	4,8%
Partial collapse of the lower lobe of the left lung	-	-	1	2,4%
N. vagus compression	-	-	1	2,4%
Thrombosed sac-shaped aneurysm	-	-	1	2,4%
Subadventional hematoma	-	-	1	2,4%
Distal stent-induced tear (dSINE)	-	-	1	2,4%
Esophagus compression	-	-	1	2,4%
Acute visceral ischemia	1	5,6%	-	
Severe anemia	3	16,7%	9	21,4%

The incidence of concomitant pathology in patients with thoracic aortic aneurysms in the conservative treatment and TEVAR groups is presented in detail in Table 3, where the comparability of the groups can also be seen. Concomitant cardiovascular conditions affecting the prognosis of therapy were identified in all patients. There were also cases with a history of stroke in the TEVAR group. Chronic kidney disease was more often accompanied by patients with nonsurgical therapy.

Table 3. The incidence of concomitant pathology in patients with thoracic aortic aneurysms in the nonsurgical treatment and TEVAR groups

Concomitant pathology	Nonsurgical treatment (n=18)		TEVAR group (n=42)	
	n	%	n	%
Hypertension	18	100%	42	100%
Respiratory failure	7	27,8%	12	28,6%
Chronic heart failure	4	22,2%	9	21,4%
Coronary artery disease	3	16,7%	6	14,2%
Stroke	-	-	4	9,5%
Chronic kidney disease	3	16,7%	4	9,5%
Postinfarction cardiosclerosis	1	5,6%	3	2,4%

TEVAR tactics depended on the presence or absence of dissection, the type and stage of dissection, as well as associated specific cardiovascular complications. TEVAR in the classical form (TEVAR) was performed in 9 (21.4%) patients, in 21 (50%) cases the SF-TEAM technique with modified doctor fenestration in a stent graft was used (Table 4).

Table 4. Types of interventions in the endovascular prosthetics group (n=42)

Types of procedures	TEVAR group (n=42)	
	n	%
Endovascular interventions only	30	71,4%
SF-TEVAR	21	50%
TEVAR	9	21,4%
Hybrid operations	12	28,6%
TEVAR after ascending aorta repair	3	7,1%
TEVAR with carotid-subclavian bypass	3	7,1%
TEVAR with left CCA and LSA stenting	6	14,2%

Hybrid operations were performed in 12 (28.6%) patients, including 3 (7.1%) major operations with ascending and arch of the aorta repair and 3 (7.1%) cases with parallel carotid-subclavian bypass surgery and 6 (14.2%) cases with stenting of the common carotid artery and stenting of the left subclavian artery (Table 4).

The proximal landing zone was located in 7.1% (3 out of 42) of cases in Z-0 (all cases with Stanford type A dissection), in 21.4% (3 with true aneurysms and 6 with dissection) of cases in zone Z-1. The vast majority (54.9%; 23 out of 42) of proximal landing zones were Z-2, including 5 (12.0%) patients with aneurysms without dissection and 18 (42.9%) with dissection of the thoracic aorta. The remaining 7 (16.6%) patients with the landing zone were Z-3-4 (Fig. 1).

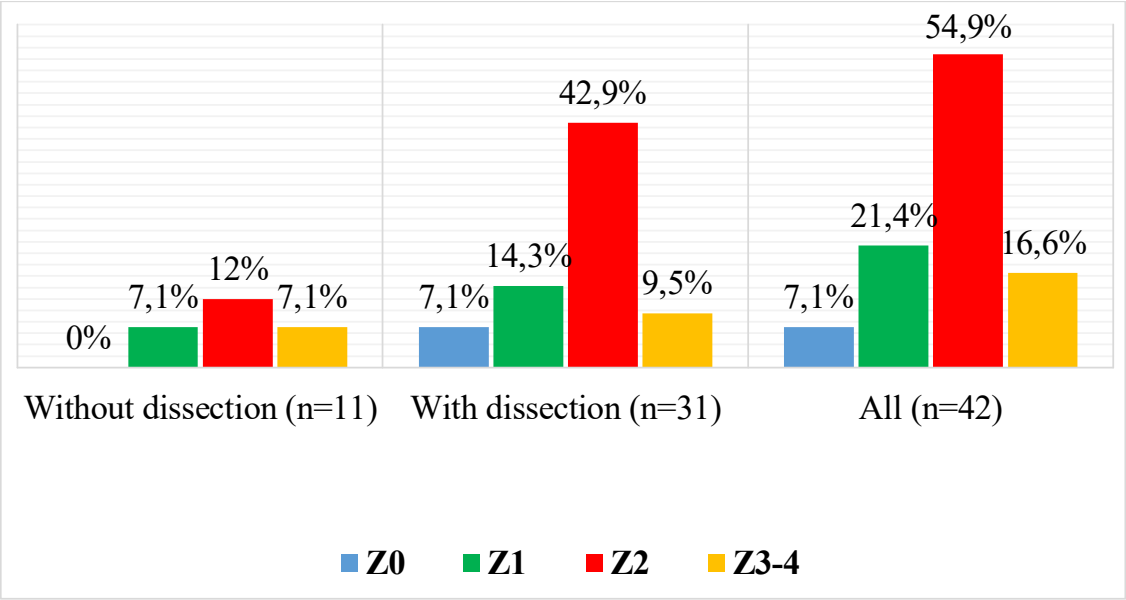

Fig. 1. Distribution of patients in the TEVAR group (n=42) depending on the landing zone of the proximal part of the stent graft

Analysis of the results included the following:

- assessment of hospital outcomes after nonsurgical treatment, the nature and frequency of postoperative complications after all TEVAR;
- the structure of the immediate postoperative mortality and its causes;
- comparative analysis of cumulative patient survival and analysis of stent-graft-free associated complications in TEVAR.

Specific criteria for the effectiveness of the use of TEVAR included: technical success, duration of the procedure, complications at the site of access, leakage during the hospital period, stent graft infection, the need for re-operation, post-implantation syndrome, TIA/ischemic stroke, myocardial infarction, spinal cord ischemia, transient paraplegia and retrograde dissection.

Technical success of TEVAR was determined by implanting all components of the stent graft and removing the delivery device without the need to switch to open cavity surgery.

The clinical effectiveness of TEVAR was determined with stabilization or regression of the diameter of the aneurysmal sac according to the control CT.

In statistical data processing, the obtained value of the exact Fisher criterion P more than 0.05 indicated the absence of significant differences, the value of P less than 0.05 indicated their presence. The evaluation of the survival function of patients was carried out using the Kaplan-Meyer method.

Results and discussion. The average duration of the TEVAR procedure was 130±3.7 minutes, blood loss was 284.4±9.4 ml, the average amount of contrast agent consumed was 197.5±4.5 ml. The average length of the covered aortic segment was 191.4±2.9 mm (Table 5). The technical success of all operations was 97.6%. With dissection of the aortic aneurysm – 96.8% (30 out of 31), with an aneurysm without dissection – 100% (11 out of 11).

Table 5. Immediate and hospital results of TEVAR

Parameter	TEVAR group (n=42)	
	n	%
Technical success	41	97,6%
Procedure duration, min (M±m)	130,4±3,7	
Blood loss, ml (M±m)	284,4±9,4	
Quantity of contrast agent, ml (M±m)	197,5±4,5	
The average length of the covered aortic segment, mm (M±m)	191,4±2,9	
Duration of hospitalization, 24 hour (M±m)	14,1±1,4	
Spinal cord ischemia, transient paraplegia	0	0,0%
Myocardial infarction	0	0,0%
Acute cerebrovascular accident	1	2,4%
Acute kindey failure without dialysis	1	2,4%
Respiratory failure	1	2,4%
Leaks (endoleak)	1	2,4%
Stent graft infection	0	0,0%
Stent graft stenosis	0	0,0%
Migration of the stent graft	0	0,0%
Re -operation	0	0,0%
Still syndrome	0	0,0%
Post - implantation syndrome	16	38,1%
Retrograde dissection of the ascending aorta (RDTA)	0	0,0%
Prolonged ventilation	8	19,0%
Combined complications, n (%)	5	12,0%

The reason for technical failure was the development of leakage (endoleak type 3) in the early postoperative period in patient M, 50 years old, with subacute dissection of the thoracic aorta of type not A not B. The patient underwent TEVAR (SF-TEVAR on a table) in zone Z-1, stenting of the left common carotid artery and stenting of the left subclavian arteries. The complication was revealed during a control CT scan 5 days after the procedure. The leakage was resolved by endovascular embolization.

Stroke was detected in one patient H., 86 years old, who had a history of coronary artery bypass grafting. The patient was admitted with a thoracic aortic aneurysm without dissection. TEVAR was performed with a proximal stent graft landing zone in zone Z-2 In the early postoperative period, a circulatory disorder was detected in the left middle cerebral artery basin. The case is not considered a technical error due to the development of stroke against the background of hemodynamic instability of the patient in the early period with a tendency to hypotension. However, the patient had a fatal outcome against the background of the progression of multiple organ failure syndrome.

In one case with initial pleural complications in the form of a hydrothorax (it can be distinguished separately who had a hemothorax and in the table), respiratory failure with prolonged ventilation in the intensive care unit was noted after the TEVAR procedure. In total, prolonged lung ventilation was needed in 8 (19.0%) patients. All cases with a favorable course and disconnection from the ventilator.

It should be noted that there were no cases of stent graft infections, stenosis or stent graft migration. There was also no need for repeated surgery in any complicated case.

The literature describes a specific early complication - retrograde dissection of the arch and ascending aorta, which is observed in 3-6% of cases when stent grafts are implanted into the descending thoracic aorta. No such complication was noted among our patients, which is most likely due to a small sample of patients.

The literature also describes the so-called steal syndrome with blocked left subclavian artery, which is observed in 2-3% of cases, which was also not noted among our patients.

In one case, we observed acute kidney failure (AKF), which resolved without the need for extracorporeal detoxification in the form of hemodialysis. This complication developed in a patient with chronic aortic dissection and a history of chronic kidney disease. The reason for the development of acute kidney failure in the early period after TEVAR was the use of a contrast agent.

Also, when analyzing the hospital results of TEVAR, attention was paid to the so-called post-implantation syndrome, observed in 16 (38.1%) patients, and manifested as a transient increase in body temperature for 4-7 days after TEVAR and did not require prolonged administration of nonsteroidal anti-inflammatory drugs.

In aortic aneurysms without dissection, only 1 (9.1%) case with a combination of complications was noted, and in aortic aneurysm dissection - 4 (12.9%). In total, there were 5 (12.0%) patients with several complications in the TEVAR group.

The development of distal stent-induced tear (dSINE) was detected in 2 patients. In one case, dSINE was associated with the first stage of surgical treatment of type A aortic dissection - after a high-tech operation using the Borst technique "frozen elephant trunk" (frozen elephant trunk - FET) - the ascending aortic arch repair with a hybrid stent graft E-Vita Open. The dSINE complication with chronic sac-like dissection involving the iliac arteries was diagnosed 4 years after this operation. We performed TEVAR with the landing of the proximal part of the stent graft with a size of 32?24?200 mm in the Z-3 zone. A good early and long-term postoperative result was obtained.

In the near and long-term period, we studied the occurrence of endoleak after TEVAR, depending on the implantation zones and the state of the thoracic aortic aneurysm, based on control CT scans performed 1, 6 and 12 months after the discharge of patients. There were no cases of endoleaks in TEVAR for aneurysms without dissection. All 4 endoleaks were found after TEVAR with aortic dissections. In this structure, type III endoleak was detected in three cases (1 in zone Z-0 and 2 in zone Z-1) and in 1 case type IV endoleak in zone Z-2. As a result, the analysis showed that the incidence of leakage is higher after TEVAR for dissections (12.9% vs. 0.0% after TEVAR for aneurysms) and at the Z-0 zone of the proximal part of the stent graft (33.3%; 1 of 3) than at Z-1 (22.2%; 2 of 9), Z-2 (4.3%; 1 out of 23) and Z-3-4 (0.0%).

The total mortality after all TEVARs for 30 days was 2.4% (1 out of 42), hospital - 0.0%, long-term mortality - 11.9% (5 out of 42).

The total mortality from all causes after all TEVARs during the study period was 14.3% (6 out of 42). The analysis showed a higher mortality after TEVAR in aortic dissections than in aneurysms - 16.1% (5 out of 31) versus 9.1% (1 out of 11), p=0.551 (Fig. 2).

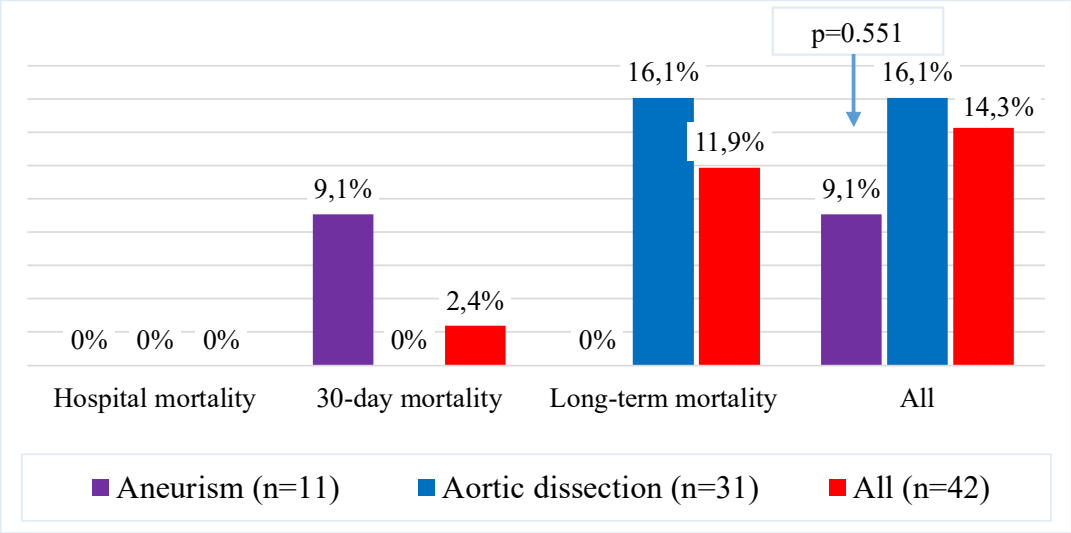

Fig. 2. Mortality rates after TEVAR

Higher rates of hospital mortality against the background of nonsurgical treatment of patients - 38.9% (7 out of 18) versus 0.0% in the TEVAR group. Also from Fig. 3 it can be seen that the 30-day mortality after receiving treatment was statistically significantly high in the nonsurgical treatment group - 22.2% versus 2.4% in the TEVAR group. Long-term mortality up to 36 months on the background of drug therapy was also higher - 16.7% versus 11.9% with TEVAR. As a result, the total mortality during the study period was 77.8% in the nonsurgical treatment group and 14.3% in the TEVAR group.

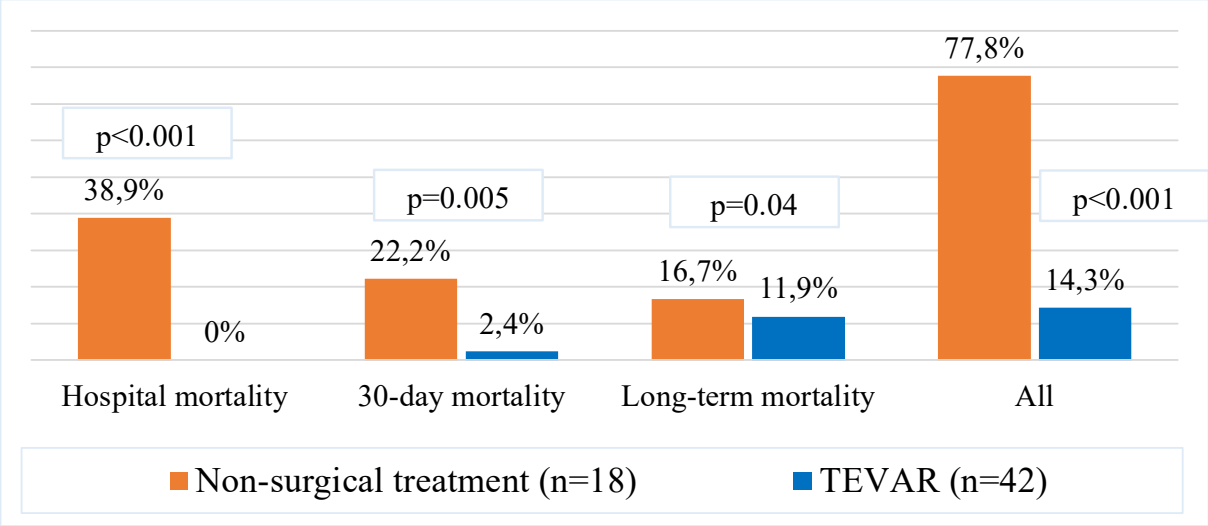

Fig. 3. Mortality rates comparison of nonsurgical treatment and TEVAR

The main causes of mortality in the nonsurgical treatment group were mainly represented by cardiovascular complications and multiple organ failure syndrome, whereas after TEVAR, no cases related to the procedure itself or a stent graft were identified (Table 6).

Table 6. Mortality in the near and long-term period and their causes after TEVAR

Cause of mortality	Nonsurgical treatment, n=18	TEVAR, n=42
Stroke, multiple organ failure syndrome	5	1
Pulmonary thromboembolism	3	0
Myocardial infarction	4	1
Intracranial aneurysm with rupture	-	1
Aneurysm rupture	2	-
Cancer	-	1
COVID-19	-	2
Total	14/18 (77,8%)	6/42 (14,3%)

The construction of the actuarial survival curve according to Kaplan-Meyer after all TEVAR showed that the cumulative proportion of survivors in the 30-day period was 97.6%, 6-month survival was 88.1%, two-year and three-year survival was 85.7%.

In the nonsurgical treatment group, statistically significantly low survival rates were obtained during the entire study period, both in the early 38.89% (95% CI 0.175-0.599) and in the long-term 22.2% (95% CI 0.07-0.4) terms of observation.

At the same time, freedom from leaks (endoleak) Types I and III after TEVAR, as the most significant and required surgical correction, amounted to 92.86% during the first year and this indicator remained in the longer term up to 36 months after TEVAR. As a result, we observed 3 cases of leaks, all of type III, which developed as a result of the formation of a structural defect in the graft wall (Fig. 4).

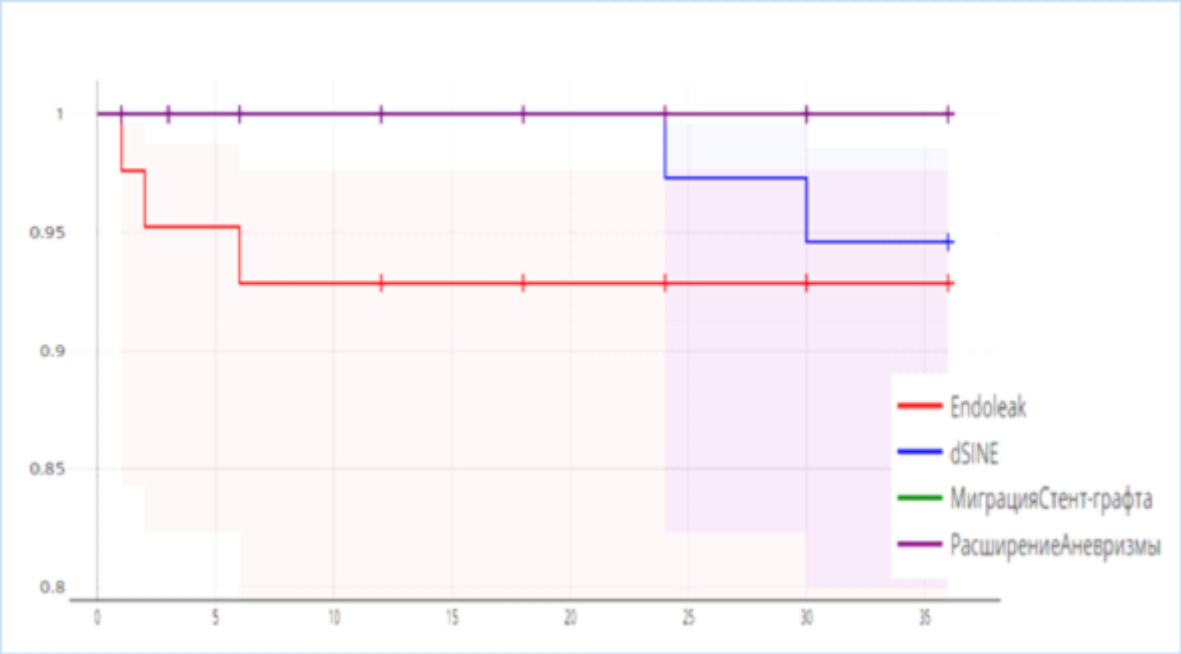

Fig. 4. Cumulative share of freedom from stent graft-associated complications after TEVAR (n=42)

Cumulative freedom from stent-graft-induced new distal message (dSINE) was 100% in the one-year follow-up period, 97.3% in the two-year follow-up period and 94.59% in the three-year follow-up period of patients (Fig. 4). As a result, there were 2 cases with dSINE during the study period. Cumulative freedom from stent graft migration and proximal aneurysm expansion was 100% at all stages of the study after all TEVARs

(n=42).

The construction of the actuarial cumulative survival curve according to Kaplan-Meyer after TEVAR, depending on the pathology of the thoracic aorta, showed that the proportion of survivors in the 30-day period was 90.9% for aneurysms and 100% for aortic dissections without statistical difference (p=0.262), 6-month survival was 90.9% for aneurysms and 93.55% for dissections. In the future, the survival rate in the group of patients after TEVAR for aneurysms remained at the level of 90.9% until the three-year follow-up period. After TEVAR with aortic dissections, the survival rate after 12 months was 87.1%, and the two-year and three-year survival rate was 83.87%.

In earlier studies, C.A. Nienaber et al. (2010) presented prospective results of Investigation of Stent-grafts in patients with type B Aortic Dissection (INSTEAD) in 140 patients with chronic type B dissection, who were divided by random sampling into two groups, the first after the planned installation of a stent graft in addition to drug therapy (n = 72) and the second group that received only drug therapy (n= 68). Cumulative survival during the first year was 97.0%ë3.4% with optimal drug therapy compared to 91.3%ë2.1% after TEVAR (p=0.16). Also, there was no significant difference from the mortality associated with aortic pathology (p=0.42). Remodeling of the aorta (with restoration of the true lumen and thrombosis of the false lumen of the chest) occurred in 91.3% of cases with endovascular plastic surgery of the thoracic aorta compared with 19.4% with drug treatment (p<0.001). However, despite aortic remodeling in the group of patients with stent graft, the one-year survival rate did not differ [12].

In a subsequent study of this database, which was already formed as INSTEAD-XL, C.A. Nienaber et al. (2013) presented an analysis and results of 5-year survival. The indicative analysis showed the undoubted benefit of TEVAR for all endpoints in the period from 2 to 5 years; for example, for mortality regardless of cause (0% vs. 16.9%; P = 0.0003), for mortality associated with aortic complications (0% vs. 16.9%, P = 0.0005) and progression (4.1% against 28.1%, P = 0.004). The authors conclude that in chronic type B dissection with favorable anatomy, TEVAR should be considered to improve late results [13].

Also noteworthy is the study of the effectiveness of endovascular bypass surgery in uncomplicated acute dissection of the descending aorta, the so-called ADSORB, whose early results indicate the advantages of TEVAR in combination with drug therapy compared only with drug therapy in relation to the outcomes of aortic remodeling 1 year after dissection [14, 15].

Recent studies by J.J. Du bois et al. (2021) used the Aortic Trauma Foundation registry to study demographic data, injury characteristics, management and outcomes in patients with varying degrees of severity of blunt aortic injury [16].

296 patients from 28 international centers were analyzed (average age 44.5 years; 76% [225/296] men; average injury severity score, 34). Blunt trauma of the thoracic aorta was classified as grade I, 22.6% (67/296); grade II, 17.6% (52/296); grade III, 47.3% (140/296) and grade IV, 12.5% (37/296). The total mortality associated with aortic rupture was 4.7% (14/296), which was 33% (14/42) among all deaths. Open surgery was required only in 2% of cases, in most cases (58.4%) TEVAR or drug treatment was performed (28.0%). Complications after TEVAR occurred in 3.4% (6/173), most often type 1 endoleak (2.3%; 4/173). Among patients with minimal aortic injury (grade I and II), 59.7% (71/119) received medication, and 40.3% (48/119) underwent TEVAR. However, the authors did not note a significant difference between drug treatment and TEVAR for grade I and II injuries [16].

In our study, endovascular repair for aneurysms and dissections of the thoracic aorta showed high efficiency both in the early and near, and in the long-term postoperative

period. Technical success reached 100% with dissections and 96.8% with true aneurysms without dissection, with a complication rate of 12% at the hospital stage of treatment and a 30-day mortality rate of 2.4%. The survival rate was 97.6% (95% CI 0.84-0.997) in the early stages with a decrease to 85.7% (95% CI 0.71-0.93) by three years of follow-up. At the same time, the cumulative share of freedom from leaks (endoleak) Types I and III accounted for 92.86% (95% CI 0.795-0.98), from dSINE - 94.59% (95% CI 0.80-0.986), from stent graft migrations and aneurysm expansion - 100%.

Conclusion. TEVAR demonstrates more favorable short-term and long-term clinical results of treatment for thoracic aortic aneurysms and dissections in the outcome of successful aortic remodeling compared with only drug treatment. The overall mortality rate is 63.5% less in comparison with the conservative therapy group.

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