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IMPLANTATION OF A LONG BIOLOGICAL PATCH IN CLASSICAL CAROTID ENDARTERECTOMY FOR EXTENDED ATHEROSCLEROTIC LESIONS. LONG-TERM OUTCOMES

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Objective: to analyze the in-hospital and long-term outcomes of classical carotid endarterectomy (CEE) in extended atherosclerotic lesions in comparison with the outcomes of this operation in local atherosclerotic plaque (AP). **Materials and Methods.** This study, which lasted from January 2010 to December 2020, included 148 patients with extended AP and hemodynamically significant internal carotid artery (ICA) stenosis. The term "extended" was understood as a hemodynamically significant lesion ≥5 cm long. These patients made up Group 1. Group 2 was formed over the same period of time from 632 patients with hemodynamically significant stenosis <5 cm long. In both cohorts, CEE with repair of the reconstruction zone with a diepoxide-treated xenopericardial patch was performed. Long-term follow-up was 71.4 ± 45.6 months. **Results.** The groups were comparable in terms of frequency of in-hospital complications: death (group 1: 0.67%, n = 1; group 2: 0.5%, n = 3; p = 0.74; OR = 1.42; 95% CI 0.14–13.6), myocardial infarction (MI) (group 1: 0.67%, n = 1; group 2: 0.5%, n = 3; p = 0.74; OR = 1.42; 95% CI 0.14–13.6), ischemic stroke (group 1: 0%; group 2: 0.5%, n = 3; p = 0.91; OR = 0.6; 95% CI 0.03–11.8), combined endpoint (death + MI + stroke) (group 1: 1.35%, n = 2; group 2: 1.4%, n = 9; p = 0.74; OR = 0.94; 95% CI 0.2–4.43). The groups were also comparable in terms of frequency of long-term complications: death (group 1: 2.0%, n = 3; group 2: 2.05%, n = 13; p = 0.76; OR = 0.98; 95% CI 0.27–3.5), MI (group 1: 2.7%, n = 4; group 2: 2.4%, n = 15; p = 0.95; OR = 1.14; 95% CI 0.37–3.49), ischemic stroke (group 1: 5.4%, n = 8; group 2: 5.2%, n = 33; p = 0.9; OR = 1.03; 95% CI 0.46–2.29), ICA occlusion and restenosis (group 1: 12.8%, n = 19; group 2: 13.3%, n = 84; p = 0.99; OR = 0.96; 95% CI 0.56–1.63), combined endpoint (death + MI + stroke) (group 1: 10.1%, n = 15; group 2: 9.6%, n = 61; p = 0.98; OR = 1.05; 95% CI 0.58–1.91). Analysis of survival graphs revealed no significant intergroup differences for all types of complications (lethal outcome: p = 0.56; MI: p = 0.73; stroke/mini-stroke: p = 0.89; ICA restenosis/occlusion: p = 0.82; combined end point: p = 0.71). Their increase was uniform in both groups. However, more than half of all ICA restenoses and occlusions were visualized in the first 6 months after CEE. **Conclusion.** Implantation of a long patch (≥5 cm) is not characterized by increased incidence of restenosis and all adverse cardiovascular events during in-hospital and long-term follow-up.

Keywords: carotid endarterectomy, classical carotid endarterectomy, patch, restenosis, extended lesion, extended atherosclerotic plaque, temporary shunt, neointimal hyperplasia.

INTRODUCTION

Carotid endarterectomy (CEA) has long been a routine operation in vascular hospitals [1–5]. At the same time, despite the entire arsenal of reconstruction methods, existing national guidelines consider only two types of CEA as the reference ones: 1. Eversion; 2. Classical with patch angioplasty of the reconstructed zone [1]. In this case, only the preferences of the operating surgeon and the experience of the medical institution are sufficient for choosing the intervention technique for each individual patient [1]. However, if with a standard lesion volume

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both methods have proven to be effective and safe, then in the presence of an extended atherosclerotic plaque (EAP), traditional reconstruction techniques cannot always be justified [6–8]. The counterparts of surgery allowing to achieve a confident effect of revascularization in these conditions, include internal carotid artery (ICA) replacement, formation of new bifurcation, autoarterial reconstruction, and ICA autotransplantation [6, 7, 9, 10]. But in some cases, the operating team may have more conservative views on the choice of CEA type, giving preference to the classical technique. In addition, a prosthesis is not always available, and the autovein can be preserved for future coronary revascularization. However, it is known that the arterial surface after endarterectomy is characterized by severe inflammatory process, the risk of parietal thrombosis and a high probability of progression of neointimal hyperplasia, which may cause early loss of the vessel lumen [11]. But there have been no large, randomized studies on this issue, and, as a result, this conclusion can be considered as an opinion rather than a postulate [1]. Thus, the long-term patency of the reconstructed zone after implantation of a long patch in the presence of extended EAP remains unclear. The answer to this question can be obtained only by comparing the long-term outcomes of such operations with the outcomes of traditional classical CEA in local atherosclerotic lesions.

The aim of this study was to analyze the in-hospital and long-term outcomes of classical CEA in extended atherosclerotic lesions in comparison with the outcomes of this intervention in local EAP.

MATERIALS AND METHODS

This cohort, comparative, retrospective, open-label study from January 2010 to December 2020 enrolled 148 patients with extended EAP and hemodynamically significant ICA stenosis. The term "extended" (in view of the absence of definition and gradation of EAP sizes in the current guidelines) was understood as a hemodynamically significant lesion of the common and internal carotid arteries ≥5 cm in length (since the standard patch size does not exceed 5 cm) (Fig. 1). These patients were included in group 1. Group 2 was formed over the same period from 632 patients with hemodynamically significant stenosis <5 cm in length. In both cohorts, classical CEA with diepoxide-treated xenopericardial patch angioplasty of the reconstructed zone was performed. Classical CEA was chosen based on national guidelines, according to which the decision in favor of a particular type of revascularization is made, relying on the preferences and experience of the operating surgeon.

Inclusion criteria were: 1) Indications for CEA according to current guidelines; exclusion criteria were: 1) Contraindications to CEA according to current guidelines; 2) The presence of pathology limiting patient follow-up in the long-term.

Risk stratification of postoperative complications and comorbid background severity were assessed using the EuroSCORE II scale. Severity of coronary atherosclerosis was measured using the SYNTAX Score interactive calculator (www.syntaxscore.com). This calculator provides the following gradation based on severity of lesion: low lesion level (≤22 points), intermediate (23–32) and high (≥33).

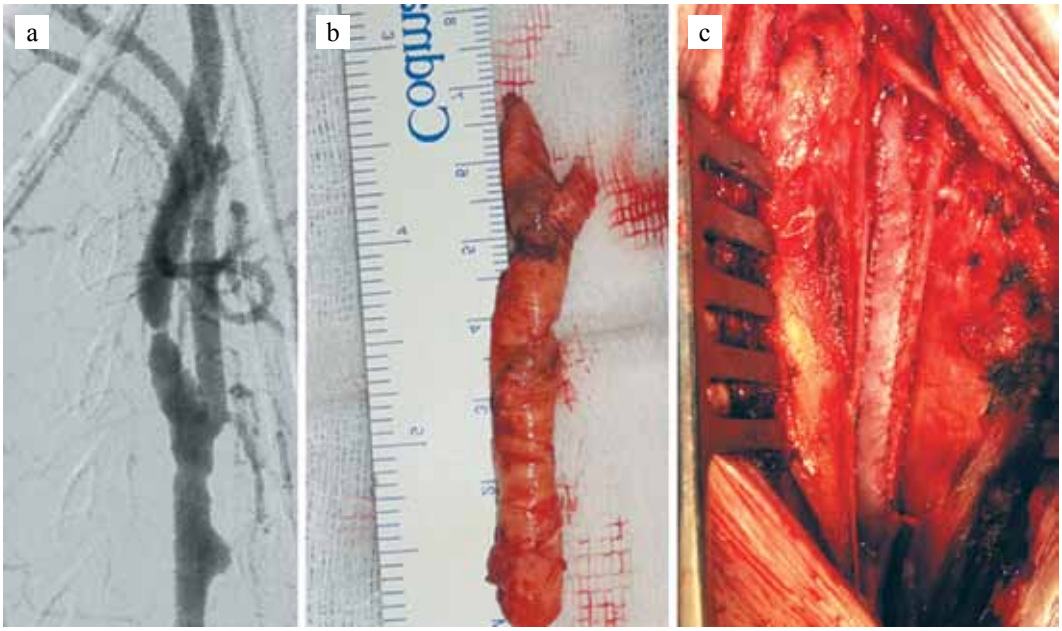


Fig. 1. A clinical example of the presence of an extended atherosclerotic lesion: a) right carotid bifurcation CT angiography (90% ICA stenosis); b) removed atherosclerotic plaque, 7 cm long; c) diepoxide-treated xenopericardial implanted patch

Brachiocephalic atherosclerosis was visualized using transcranial doppler ultrasound (TCDU), color triplex scanning of the brachiocephalic arteries (CTSBA) (using a 7–7.5 MHz linear transducer) on MySono U6-RUS devices (Samsung Electronics), Philips Affiniti 30. Multispiral CT (MSCT) angiography was performed if significant stenosis is detected by CTSBA, there is increased blood flow rate according to TCDU, and there is unstable EAP in the ICA. The degree of stenosis was determined according to the NASCET classification.

The compensatory capabilities of cerebral blood flow during CEA were assessed as follows. When the level of systolic blood pressure (SBP) ≤160 mmHg, the latter was increased pharmacologically to 190–200 mm Hg. Then 5 5,000 IU of heparin were injected intravenously, the arteries were clamped. Invasive measurement of ICA retrograde pressure was performed. When the blood pressure was less than 60% of the systemic blood pressure, a temporary shunt was used.

The control points were understood as the development of unfavorable cardiovascular events like death, myocardial infarction (MI), acute cerebrovascular accident/transient ischemic attack (ACVA/TIA), thrombosis of the reconstructed area, bleeding type 3b and higher on the Bleeding Academic Research Consortium (BARC) scale, composite endpoint (death + ACVA/TIA + hemorrhagic transformation + MI), ICA restenosis, and ICA occlusion. The reconstruction area was visualized using TCDU on day 3 after surgery. Information about the condition of patients in the long-term period was obtained by phone survey and by inviting patients to the clinic for examination by a cardiovascular surgeon, cardiologist, neurologist, control imaging of the reconstructed area using TCDU and, if necessary, MSCT angiography. The long-term follow-up period was 71.4 ± 45.6 months.

The study was performed in accordance with the principles of Good Clinical Practice and Declaration of Helsinki.

Distribution type was determined using the Kolmogorov–Smirnov test. Groups were compared using Mann–Whitney U test and Pearson chi-square with Yates's correction. Survival charts were plotted using the Kaplan–Meier analysis. The graphs were compared using the Logrank test. Differences were assessed as significant at $p < 0.05$. Study results were processed using the Graph Pad Prism software package (www.graphpad.com).

The groups were comparable in all clinical and anamnestic parameters. The overwhelming majority were male and the elderly. One in five had a history of MI and percutaneous coronary intervention (PCI). Multifocal atherosclerosis (MFA) with hemodynamically significant stenoses in three arterial basins was diagnosed in a quarter of cases. In more than half of the cases, stenosis was symptomatic. According to the EuroSCORE II interactive calculator, the severity of the comorbid background in the presented sample corresponded to the average level (Table 1).

RESULTS

Brachiocephalic angiography showed that the groups were comparable in most parameters. The degree of ICA stenosis most often exceeded 80%; unstable EAP was visualized in every fifth patient. Moreover, the extent of lesion was statistically greater in Group 1. The severity

Table 1

Comparative clinical and anamnestic characteristics of patient groups

Indicator	Group 1 (lesion ≥5 cm) n = 148	Group 2 (lesion <5 cm) n = 632	p	OR	95% CI
Age, M ± m, years	65.2 ± 5.3	64.8 ± 5.1	0.35	–	–
Male, n (%)	94 (63.5)	406 (64.2)	0.94	0.96	0.66–1.40
NYHA FC 1–2, n (%)	61 (41.2)	249 (39.4)	0.75	1.07	0.74–1.55
PICS, n (%)	27 (18.2)	117 (18.5)	0.96	0.98	0.61–1.56
COPD, n (%)	4 (2.7)	13 (2.05)	0.86	1.32	0.42–4.11
MFA with hemodynamically significant lesions of three arterial basins, n (%)	36 (24.3)	155 (24.5)	0.95	0.98	0.65–1.50
DM, n (%)	15 (10.1)	71 (11.2)	0.81	0.89	0.49–1.60
CKD, n (%)	5 (3.4)	20 (3.2)	0.89	1.07	0.39–2.90
LVEF, M ± m, %	59.1 ± 3.7	58.8 ± 4.2	0.11	–	–
Left ventricular aneurysm, n (%)	1 (0.7)	3 (0.5)	0.74	1.42	0.14–13.82
EuroSCORE II, M ± m	2.6 ± 0.4	2.5 ± 0.3	0.26	–	–
History of PCI, n (%)	35 (23.6)	147 (23.2)	0.99	1.02	0.67–1.55
History of CABG, n (%)	2 (1.35)	9 (1.4)	0.74	0.94	0.20–4.43
History of stroke/mini stroke, n (%)	89 (60.1)	394 (62.3)	0.68	0.91	0.63–1.31

Note. NYHA FC – New York Heart Association Functional Classification, PICS – Postinfarction cardiosclerosis, DM – diabetes mellitus, AH – arterial hypertension, COPD – chronic obstructive pulmonary disease, CKD – Chronic kidney disease, MFA – multifocal atherosclerosis, LVEF – left ventricular ejection fraction, PCI – percutaneous coronary intervention, CABG – coronary artery bypass grafting.

of coronary bed stenosis, as calculated by the SYNTAX score interactive calculator, was mild (Table 2).

There should be a special focus on perioperative characteristics. Expectedly, in terms of clamping time, group 1 showed the highest values in terms of clamping time (Fig. 2). This indicator in 9 cases exceeded 60 minutes (maximum 73 minutes). In a situation where the clamping time exceeded 50 minutes and it was impossible to start blood flow, we installed a temporary shunt (despite satisfactory retrograde pressure values initially at baseline), which made it possible to avoid the development of intraoperative ischemic stroke. This trend was reflected in the fact that temporary shunt was used statistically more often in Group 1 (Table 2).

The groups did not differ in the incidence of postoperative complications. In Group 1, death occurred on day 9 after operation. The EAP in the ICA spread above the hypoglossal nerve, necessitating transection of the glossopharyngeal plexus to isolate the ICA. The patient had contralateral dysphagia as an outcome of ischemic stroke. Intervention from the ipsilateral side resulted in total dysphagia. In the postoperative period, against the background of inability to swallow food, the patient was inserted with a gastrostomy tube. Nevertheless, on day 9, the patient tried to swallow cooked oat cereal on his own, which resulted in airway obstruction and prolonged asphyxia with cardiac arrest.

The causes of death in Group 2 were: hemispheric ischemic stroke resulting from intimal detachment distal to the reconstructed zone with further ICA thrombosis (1 patient) and hemorrhagic transformation (two patients).

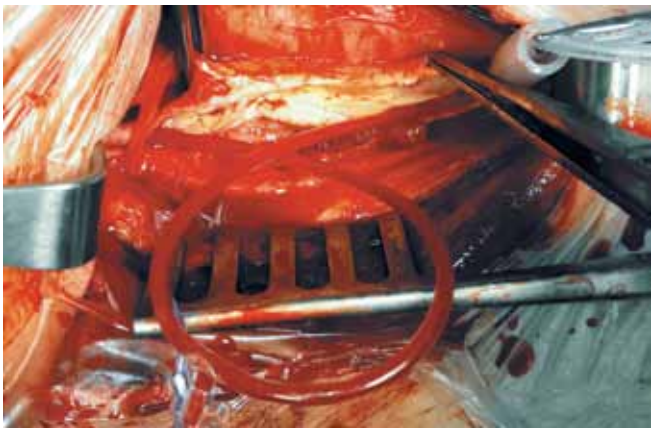


Fig. 2. Installed temporary shunt in a patient with extended atherosclerotic lesion

All intraoperative nonfatal ischemic stroke (n = 3) was observed only in Group 2 in patients who had a temporary shunt installed. Distal embolism was the likely cause. The cause of MI in both groups was stent thrombosis in the coronary artery, which required repeated unplanned revascularization with a successful outcome (Table 3).

In the long-term follow-up period, there were no significant intergroup differences in the incidence of complications. All ACVA/TIAs occurred against the back-

Table 2

Angiographic and perioperative characteristics

Indicator	Group 1 (lesion ≥5 cm)	Group 2 (lesion <5 cm)	p	OR	95% CI
	n = 148	n = 632			
% ICA stenosis	81.3 ± 5.1	82.6 ± 6.3	0.24	–	–
Unstable AP, n (%)	34 (22.9)	148 (23.4)	0.99	0.97	0.63–1.49
AP length, M ± m	7.1 ± 1.2	3.3 ± 1.1	0.001	–	–
SYNTAX score with a history of myocardial revascularization, M ± m	15.1 ± 3.5	16.2 ± 3.2	0.38	–	–
ICA clamping time, min	51.5 ± 6.6	27.0 ± 2.7	0.03	–	–
TS placement	23 (15.5)	57 (9.0)	0.02	1.85	1.10–3.12

Note. ICA – internal carotid artery, ECA – external carotid artery, AP – atherosclerotic plaque, TS – temporary shunt.

Table 3

In-hospital outcomes

Indicator	Group 1 (lesion ≥5 cm)	Group 2 (lesion <5 cm)	p	OR	95% CI
	n = 148	n = 632			
Death, n (%)	1 (0.67)	3 (0.5)	0.74	1.42	0.14–13.6
MI (non-fatal), n (%)	1 (0.67)	3 (0.5)	0.74	1.42	0.14–13.6
Stroke/mini stroke (non-fatal), n (%)	0	3 (0.5)	0.91	0.60	0.03–11.8
BARC type 3b bleeding and higher, n (%)	1 (0.67)	4 (0.63)	0.60	1.06	0.11–9.63
ICA thrombosis, n (%)	0	1 (0.15)	0.42	1.41	0.05–35.0
Combined end point, n (%)	2 (1.35)	9 (1.4)	0.74	0.94	0.20–4.43

Note. MI – Myocardial infarction, ICA – internal carotid artery.

ground of development of hemodynamically significant ICA restenosis 9.5 ± 3.7 months after CEA. In all cases, unplanned cerebral revascularization in the volume of reCEA was performed (group 1: 40%, n = 6; group 2: 36.7%, n = 25; p = 0.95; OR = 1.14; 95% CI = 0.36–3.60) or CAS (group 1: 60%, n = 9; group 2: 63.2%, n = 43; p = 0.95; OR = 0.87; 95% CI = 0.27–2.74) (Table 4).

Analysis of survival charts also revealed no significant intergroup differences for all types of complications (death: p = 0.56; MI: p = 0.73; ACVA/TIA: p = 0.89; ICA restenosis/occlusion: p = 0.82; composite endpoint: p = 0.71). They increased uniformly in both groups (Figs. 3–7). However, more than half of all ICA restenoses and occlusions were visualized in the first six months after CEA. Histological examination after the implemented reCEA showed that neointimal hyperplasia was the cause of lumen loss (Fig. 6).

DISCUSSION

This study has shown that implantation of a long patch in extended atherosclerotic lesions does not exceed the risks of developing restenosis in the reconstructed area relative to classical CEA with local EAP. However, it should be noted that in the long-term period in the whole sample, there was increased incidence of lumen loss, reaching 13.2% (n = 103). And it was precisely this condition that became decisive in the formation of secondary ischemic events in the brain, which, in some cases, led to death. This trend is widely known and has already been discussed many times in large studies and meta-analyzes [12–16]. Several authors have argued that

Table 4

Long-term follow-up complications

Indicator	Group 1 (lesion ≥5 cm) n = 148	Group 2 (lesion <5 cm) n = 632	p	OR	95% CI
Death, n (%)	3 (2.0)	13 (2.05)	0.76	0.98	0.27–3.50
MI (non-fatal), n (%)	4 (2.7)	15 (2.4)	0.95	1.14	0.37–3.49
Stroke/mini stroke (non-fatal), n (%)	8 (5.4)	33 (5.2)	0.90	1.03	0.46–2.29
ICA restenosis >60%, n (%)	15 (10.1)	68 (10.7)	0.94	0.93	0.51–1.68
Repeated unplanned cerebral revascularization (reCEA, CAS), n (%)	15 (10.1)	68 (10.7)	0.94	0.93	0.51–1.68
ICA occlusion, n (%)	4 (2.7)	16 (2.5)	0.86	1.06	0.35–3.24
Total occlusions and restenosis, n (%)	19 (12.8)	84 (13.3)	0.99	0.96	0.56–1.63
Combined end point, n (%)	15 (10.1)	61 (9.6)	0.98	1.05	0.58–1.91

Note. MI – myocardial infarction, ICA – internal carotid artery, reCEA – repeated carotid endarterectomy, CAS – carotid angioplasty and stenting.

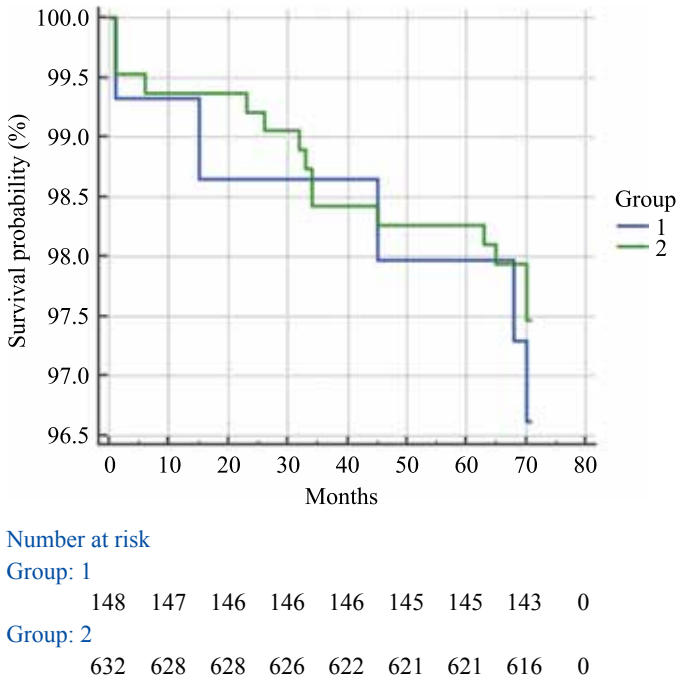
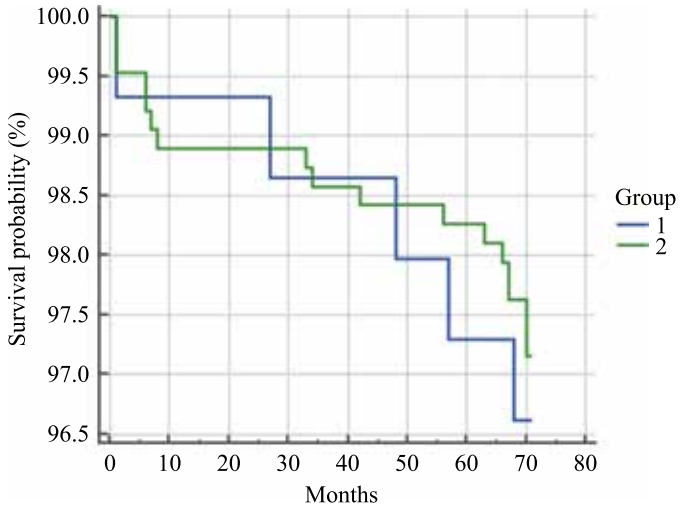


Fig. 3. Death-free survival

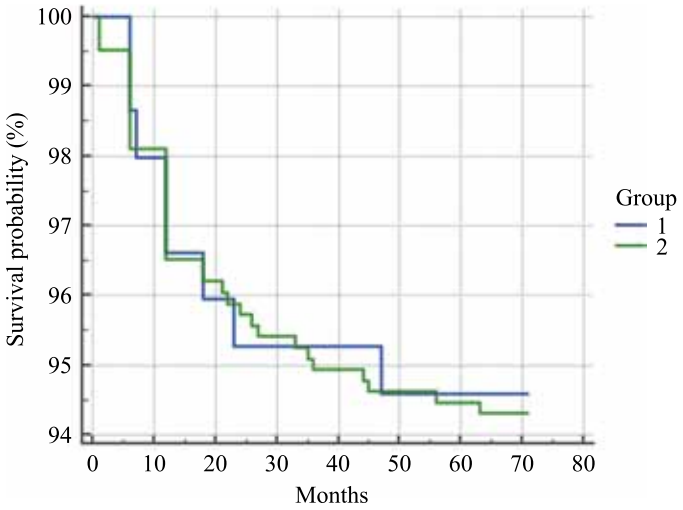
the most likely cause is the distortion of the physical characteristics of blood flow with the formation of stagnation and turbulence zones, which provokes increased neointimal hyperplasia as early as six months after CEA (Fig. 6) [17–19].

Technical errors/errors of primary intervention should also be considered. Bleeding from the anastomotic zone after blood flow had been initiated often requires additional single sutures, which can narrow the arterial lumen [17, 18]. However, according to other authors, another cause of restenosis is implantation of a patch that is too wide, which will lead to increased carotid bulb volume [20]. It is known from the laws of physics that in a situation where the size of the afferent vessel is greater than the total size of the efferent vessels, hydrodynamic resistance increases, conditions for blood stagnation and thrombosis are formed [20]. Such circumstances will undoubtedly lead to restenosis and even occlusion [20]. The use of computer simulation methods can be the way out of the situation [17–19]. So, in the future, in order to



Number at risk
Group: 1
148 147 147 146 146 145 144 143 0
Group: 2
632 625 625 625 623 622 621 614 0

Fig. 4. Myocardial infarction-free survival



Number at risk
Group: 1
148 145 142 141 141 140 140 140 0
Group: 2
632 620 608 603 600 598 597 596 0

Fig. 5. Ischemic stroke-free survival

select a personalized reconstruction technique associated with low risks of arterial lumen loss, a computer model of the carotid bifurcation will be constructed preoperatively for each individual patient [17–19]. Further, thanks to the projection of various CEA methods, as well as virtual implantation of patches of different widths, it will be possible to determine the type of reconstruction that would result in minimal changes in the physical parameters of hemodynamics and would be most preferable for that patient [17–19]. At present, the surgery method is chosen based on the surgeon's preferences, which does not correspond to the principles of personalized medicine [1]. Such actions can be characterized as "at random" because the surgeon does not know the physical changes that would follow after applying this type of reconstruction. Externally, the angioplasty will look perfect, while at the hydrodynamic level, there may be dramatic shifts in flow homeostasis in favor of turbulent nature [17, 18]. Therefore, the surgeon's conservative "restraint" on the most common types of CEA should be eradicated in

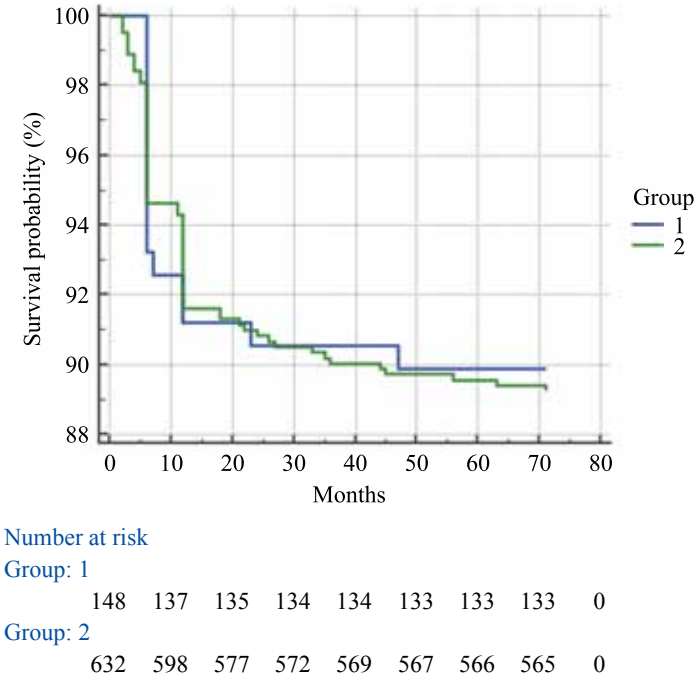


Fig. 6. ICA restenosis/occlusion-free survival

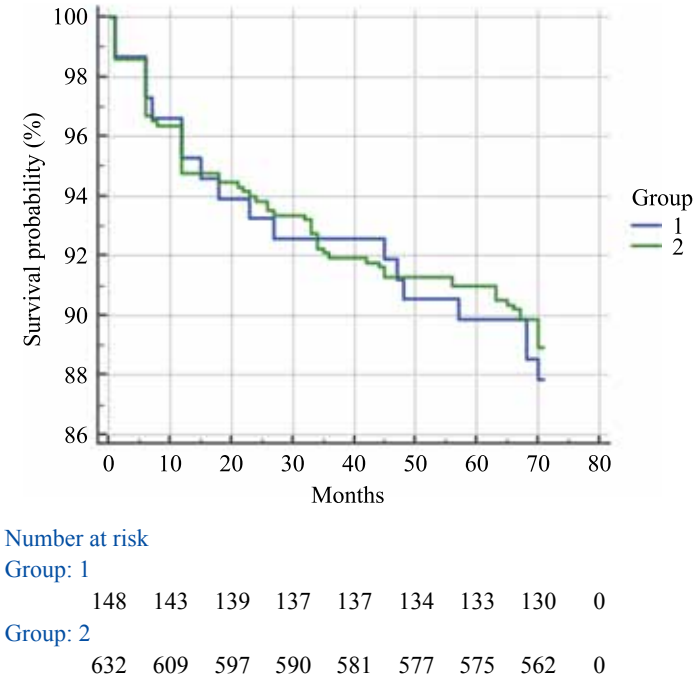


Fig. 7. Combined endpoint-free survival

modern medicine. A vascular surgeon must have a full range of available interventions for precision selection of the most optimal one. In the context of computer-assisted options, such an approach would reduce the incidence of developing vascular lumen loss with an improvement in the quality of life of each individual patient [17, 18]. In addition, it is known that there has always been a human factor and external subjective processes, ranging from troubles in the family to hormonal background, which can affect the psyche of even the most experienced expert, because a surgeon is not a robot. Thus, in the present technical environment, until computer modelling becomes a routine method used in vascular surgery in a personalized manner, the choice of a revascularization strategy should not be based on the preferences of the operating surgeon, as described in the guidelines, but only by a multidisciplinary team meeting.

Geneticists, in turn, add a hereditary component of susceptibility to restenosis [21, 22]. After all, hemodynamics in the reconstruction area changes in everyone, and lumen loss is diagnosed in fact only in one out of every ten persons (Table 4). According to scientists, the presence of some genes and their precision shutdown in the future will allow avoiding activation of conditions for lumen loss, which will lead to optimization of long-term outcomes of classical CEA [21, 22]. However, such tools of influence do not yet exist today.

In summary, it should be emphasized once again that the length of the lesion does not affect the incidence of in-hospital and long-term complications. However, extended plasty objectively requires more time to clamp the arteries. Prolonged cerebral ischemia can lead to intraoperative stroke, which should diminish interest in implantation of a long patch. Current guidelines do not provide maximum safe ICA clamping times. There has been no study on this indicator. The way out of the situation may be the use of cerebral oximetry throughout the CEA. But not all medical institutions have the necessary equipment, limiting themselves, as we do, to retrograde pressure measurement or to Matas test [23–26]. In addition, some authors claim that both retrograde pressure measurement in ICA and cerebral oximetry do not allow to, with high accuracy, determine the cerebral tolerance to ischemia. It has been demonstrated in some studies that intraoperative stroke was still recorded in the presence of optimal parameters under these methods [27–31]. Considering these data, in our practice, if ICA clamping lasted for more than 50 minutes, we interrupted the anastomosis to place a temporary shunt. In our study, this step was not accompanied by ischemic stroke, which emphasized the effectiveness and safety of this procedure. However, if one has the skills to implement other reconstruction types that require less ICA clamping time (ICA prosthetics, formation of a new bifurcation, autoarterial reconstruction, ICA autotransplantation), then one should abandon the classical CEA [6, 7, 10]. In fact, installation of a temporary shunt itself is accompanied by high probability of arterial dissection, distal embolism, ischemic stroke and silent strokes [31–35]. Thus, it is more justified to avoid these risks by considering other possible similar interventions, accompanied by a lower likelihood of adverse cardiovascular events.

CONCLUSION

Implantation of a long patch (≥5 cm) is not characterized by increased incidence of restenosis and all adverse cardiovascular events at in-hospital and long-term follow-up stages. A temporary shunt should be used to prevent development of intraoperative stroke resulting from prolonged ICA clamping. If the surgeon has the skills to perform other types of CEA that are associated with lower risks of complications and restenosis in the long-term follow-up, then the classical CEA should be abandoned, in case of extended atherosclerotic lesion.

The authors declare no conflict of interest.

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