

Endovascular biometrics and engineering

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Abstract

Endovascular technology is justifiable in the treatment of most cardiovascular diseases, the possibilities and problems of which are not fully understood.

Aim. To study technical problems in the provision of endovascular care and to develop technological solutions for its improvement based on endovascular biometry.

Methods. For the period 2015–2019 an expert analysis of the results of endovascular treatment of 1546 patients with chronic lower limb ischemia was performed, in which it was not possible to perform lower limb revascularization according to the standard method using a guide catheter, guidewire and balloon catheter. The expert group included 5 interventional radiologists who performed endovascular procedures. The results were assessed by the effectiveness of revascularization using the developed innovative technology from a system of catheters of various diameters and stiffness in comparison with the results of using standard endovascular technique. Calculation of adequate statistical indicators and their reliability were undertaken using Statistica software (version 6.0).

Results. The “critical” and “weak” zones of the vascular bed were identified for the first time to substantiate the development of a technology for safe and effective endovascular revascularization. It has been established that technical difficulties in catheterization of vessels create the prevalence of atherosclerotic lesions and the limited technical capabilities of catheters and guidewires, which are manipulated under the conditions of increasing high friction with the vessel wall caused by tortuosity and atherosclerosis, the presence of “weak” and “critical” zones of the blood vessels, as well as a significant distance from the surgeon's hands to the area of medical manipulation, reaching 130–200 cm. The developed innovative design from the catheter system ensured the effectiveness of endovascular lower limb revascularization in all patients (100%) using the femoral and brachial accesses compare to the standard technique of endovascular care ($p < 0.001$).

Conclusion. Endovascular instruments offered on the domestic market do not guarantee the effective completion of revascularization. The technology of vascular catheterization developed based on endovascular biometry ensures the successful completion of revascularization in 100% of cases.

Keywords: atherosclerosis, cardiovascular disease, endovascular care, endovascular biometrics, endovascular engineering.

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Эндоваскулярная биометрия и инженерия

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Реферат

Эндоваскулярная технология наиболее эффективна и приоритетна при лечении большинства пациентов с сердечно-сосудистыми заболеваниями, но её возможности и проблемы применения ещё до конца не изучены.

Цель. Изучить технические проблемы при оказании эндоваскулярной помощи и разработать технологические решения для её совершенствования на основе эндоваскулярной биометрии.

Методы. За период 2015–2019 гг. проведён экспертный анализ результатов эндоваскулярного лечения 1546 пациентов с хронической ишемией нижних конечностей, у которых не удалось выполнить ревазуляризацию нижних конечностей по стандартно принятой методике с использованием проводниково-

го катетера, проводника и баллонного катетера. В экспертную группу вошли 5 рентгенэндоваскулярных специалистов, которые выполняли эндоваскулярные процедуры. Результаты оценивали по эффективности реваскуляризации с применением разработанной инновационной технологии из системы катетеров различного диаметра и жёсткости в сравнении с результатами применения стандартной эндоваскулярной техники. Статистическую обработку материала проводили на основе пакета Statistica 6.0 с расчётом адекватных статистических показателей и их достоверности.

Результаты. В работе впервые идентифицированы «критические» и «слабые» зоны сосудистого русла для обоснования разработки технологии безопасной и эффективной эндоваскулярной реваскуляризации. Установлено, что технические сложности при катетеризации сосудов создают распространённость атеросклеротического поражения артерий и ограничение технических возможностей катетеров и проводников, манипуляции которыми осуществляют в условиях возрастающего высокого трения со стенкой сосудов, что вызвано извитостью и атеросклерозом артерий, наличием «слабых» и «критических» зон сосудистого русла, а также значительным расстоянием от рук хирурга до зоны лечебной манипуляции, достигающим 130–200 см. Разработанная инновационная конструкция из системы катетеров обеспечивала эффективность эндоваскулярной реваскуляризации нижних конечностей у 100% больных при использовании бедренного и плечевого доступов, в сравнении с результатами применения стандартной методики эндоваскулярной помощи $p < 0,001$.

Вывод. Предлагаемые на отечественном рынке эндоваскулярные инструменты не гарантируют эффективного завершения реваскуляризации; разработанная на основе эндоваскулярной биометрии технология катетеризации сосудов обеспечивает успешное завершение реваскуляризации в 100% случаев.

Ключевые слова: атеросклероз, сердечно-сосудистые заболевания, эндоваскулярная помощь, эндоваскулярная биометрия, эндоваскулярная инженерия.

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Introduction. More than 50 years have passed since the application of the first effective technological solutions for endovascular treatment of atherosclerotic stenosis of blood vessels when in 1964 the radiologist of the University of Oregon (USA) Ch. Dotter and his assistant M. Judkins first performed recanalization of lower limb artery occlusion. For more than 30 years, endovascular technology has been scientifically sound and safe in the treatment of various cardiovascular diseases. Catheters, guidewires, vascular stents, balloons and radiopaque agents have been developed. To safely provide endovascular care, new drugs have been synthesized that reduce the risks of intravascular thrombosis during instrument manipulation in blood vessels and after implantation of vascular stents [1,2].

The progression of arterial atherosclerosis throughout life, increasing prevalence of diabetes among the population, increasing average life expectancy of the population and the number of people aged over 75 are the reasons for increasing the number of patients with diffuse, multilevel stenosis and occlusive vascular lesions, including arteries of vital organs like the heart, brain, kidneys and arteries of extremities, the violation of blood supply of which leads to myocardial infarction, stroke, kidney failure and gangrene of the low extremities. The traditional surgical treatment of patients with advanced atherosclerosis is associated with risks of cardiovascular

complications, and with lesions of small-diameter arteries (less than 2 mm), it is often not effective. The endovascular care is a priority for the treatment of elderly patients who have concomitant diseases that increase the risks of cardiovascular complications, as well as for widespread multilevel stenosis and/or occlusive lesions of limb arteries [3–6].

When providing endovascular care, doctors may encounter difficulties in manipulating catheters, guidewires and delivery systems for balloons and vascular stents, which are due to the significant length of the instruments, pronounced tortuosity and critical atherosclerotic narrowing of blood vessels, the rigidity and fragility of their walls, as well as a significant increase in friction between the surfaces of the instruments and vascular wall. Carrying out an endovascular operation only under visual control on a monitor and the lack of tactile control of successful recanalization of an artery or perforation of its wall requires highly qualified operators and skills.

Unresolved endovascular care tasks may result in negative treatment outcomes consisting in the technical failure to restore blood flow through the target artery or the development of an adverse outcome and a change in treatment strategy in favor of traditional surgery or conservative treatment.

A guiding endovascular catheter is an important instrument whose properties — stiffness, controllability, x-ray contrast, anti-thrombogenicity

of the inner coating, optimal lumen diameter and length should ensure an effective and safe endovascular procedure. The catheters according to the structure of the wall are divided into single-layer and multi-layer. The rigidity, thin-walled and controllability of modern catheters are provided by the multilayer structure. The inner layer is made of a Teflon tube coated with a layer of nylon or dacron, the middle layer is a mesh braid of stainless steel or nylon, the outer one is polyethylene or polyurethane. The outer layer, depending on the modification of the catheter, can be fully or partially coated with a hydrophilic coating to increase sliding and reduce friction with the vessel wall [7].

When performing endovascular procedures, technical difficulties associated with the use of catheters can arise, such as insufficient stiffness, patency and lack of reliable vertical stability of the catheters for manipulation with a conductor, balloon or stent in the affected distal arterial segment. In the available literature, the described technical failures of endovascular care are associated with the complexity of blood vessel lesions, vessel tortuosity, the stiffness of the “tire” of the atherosclerotic plaque, but not with the limited capabilities of modern instruments and physical properties [8,9].

This paper highlights the possible methods and solutions of complex technical problems in performing endovascular lower extremities revascularization procedures, as well as the first description of the “Weak” and “Critical” areas of blood vessels, which create technical difficulties in performing endovascular procedures.

Material and methods. For the period 2015–2019 an expert analysis of the results of the endovascular treatment of 1546 patients with chronic lower limb ischemia who were treated at the Central Clinical Hospital “Russian Railways-Medicine” and could not undergo lower limb revascularization by the standard method using a guide catheter, guidewire and balloon catheter. All patients were divided into 2 groups by access site for catheterization of lower limb arteries: the first group included 933 patients who underwent retrograde puncture and catheterization of the right brachial artery; the second group included 613 patients who underwent retrograde puncture and catheterization of the common femoral artery. The expert group included 5 interventional radiologists who performed endovascular procedures. Puncture and catheterization of arteries were performed by using the method developed and described by S. Seldinger in 1953 [10].

The number of observations to be included in the sample was estimated by the method described in ref [11]. The minimum sample size was 400 people.

Table 1. Characteristics of the patients

Indicators	Femoral access (n=613)	Brachial access (n=933)
Average age	66.1±4.6	68.3±4.4
Number of women in study	18 (2.9%)	24 (2.6%)
Arterial hypertension	613 (100%)	933 (100%)
Type II diabetes	202 (33%)	270 (29%)
A history of smoking	499 (81.4%)	811 (87%)
A history of myocardial infarction	201 (32.7%)	242 (26%)
Chronic renal failure	98 (16%)	93 (1%)
Critical chronic lower limb ischemia	613 (100%)	933 (100%)

Table 1 shows the characteristics of the patients included in the study.

A biometric study of the blood vessels (length) using the marked catheter was performed. Based on biometric data of blood vessels (length), “Weak” and “Critical” areas of blood vessel were described. Those areas may cause technical difficulties in performing endovascular procedures, such as catheter folding into a loop in the vessel lumen and increasing the risk of adverse outcomes — dissection of the wall or arterial luminal thrombosis. The “Critical” zone of a blood vessel is the zone of intimate contact of the endovascular instrument (catheter or guidewire) with the vessel wall, which undergoes the highest friction during manual movement of the instrument forward, backward or during rotation, increasing the risk of arterial dissection. The “Weak” zone of the arterial bed is the zone of lack of contact between the endovascular instrument (catheter or guidewire) and the vessel wall at the branching sites due to its anatomical absence, which helps to reduce the vertical force applied by the catheter and intravascular folding of the instrument into the loop during manipulation but increases the risk of thrombosis.

Based on biometric data of human blood vessels with atherosclerotic lesions, progressive technological solutions were developed by the expert consensus method. The technology improves the design of endovascular guide catheters in vessel tortuosity and increasing friction with the arterial wall, which allows safe and effective passing through the blood vessels and puncturing in the lower extremity arteries through the brachial and femoral access. Also, the solutions create optimal vertical strength of the catheter system for hasty implementation of recanalization of “hard” and extended arterial occlusions.

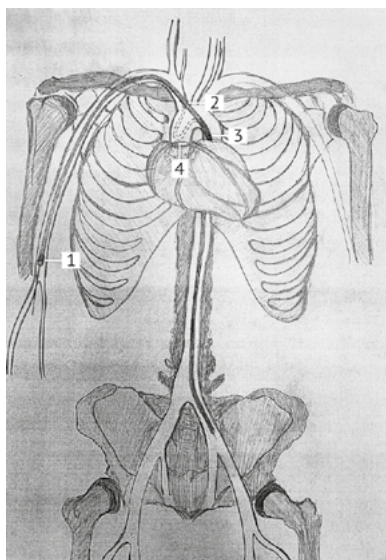


Fig. 1. The scheme of the left common iliac artery catheterization through the right brachial arteria— 1. “Critical” zone in the site where the aortic arch gives rise to the brachiocephalic trunk — 2. “Critical” zone in the site of the transition of the aortic arch into the descending part of the thoracic aorta — 3. A catheter formed in a loop with a diameter of 2.7 mm in the “Weak” zone of transition of the ascending part of the thoracic aorta to the aortic arch, with a diameter of 28 mm — 4

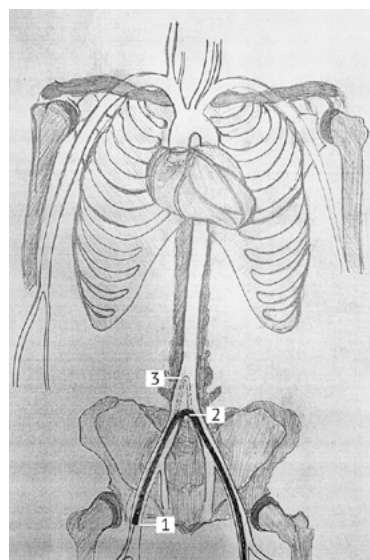


Fig. 2. The scheme of catheterization of arteries of the left lower limb through the right arterial femoral approach — 1. “Critical” zone in the lower wall of the abdominal aortic bifurcation — 2. Catheter formed in a loop with a diameter of 2.7 in the “Weak” zone in the area of bifurcation of the abdominal aorta with a diameter of 19 mm — 3

The results were assessed by comparing the effectiveness of revascularization using the developed innovative technology from a system of catheters of various diameters and stiffness and the standard endovascular technique within one group of patients.

We used statistical, mathematical and expert assessment methods in the research. Statistical analysis was performed using Microsoft Office 2013 programs. The statistical method included distribution analysis of attributes and the representativeness error calculated for relative indicators. Calculation of adequate statistical indicators and their reliability were undertaken using Statistica software (version 6.0).

Results. On average, men’s height was 176 ± 7.8 cm (from 161 to 184 cm) and women’s height 169 ± 3.1 cm (from 166 to 172 cm). The average length of the arterial segments from the right brachial artery to the bifurcation of the abdominal aorta was 78 ± 3.2 cm in men and 64 ± 2.2 cm in women, which allows effective catheterization of a 100 cm common iliac artery through the right brachial access using a catheter.

It was found that a guide catheter 100 cm long ensures the successful implementation of recanalization, angioplasty and stenting of the aorto-iliac and iliac-femoral arterial segments in 100% of cases, regardless of the patient’s growth and pathological changes in the blood vessels.

The effectiveness and safety of manipulations with endovascular guidewires and catheters in the thoracic aorta, abdominal aorta, and lower limb arteries in catheterization through the right brachial arterial access (fig. 1) and contralateral femoral arterial access (fig. 2) in 1546 patients were assessed by experts. Based on the results of this assessment, we introduce the concept of the “Critical” zone of the blood vessel. The small diameter of the coronary and tibial arteries (2–4 mm), locally sited atherosclerotic plaque, luminal narrowing, common atherosclerotic stenosis, the spastic response of the vascular wall to the presence of a catheter or guidewire inside the vessel make it difficult to move the instruments inside the vessels. On the other hand, the large diameter of the aorta or other vessels (12–30 mm) relative to the diameter of the catheter or conductor advanced along it (0.2–2.7 mm) creates the possibility of folding the catheter and guidewire inside the vessel into a loop and disrupts the manual management and functions. The dividing the blood vessels into branches is also the reason for the loop deformation of long flexible equipment for endovascular care.

The established “Weak” and “Critical” zones of blood vessels exist in all the people with normal anatomy of the location of the heart and arteries. Studies have shown that a significant difference in the diameters of the vessel and single-layer or multi-layer catheters (more than 5 times) creates



Fig. 3. Computer angiogram of the arteries of the lower extremities of a patient with chronic critical ischemia of the left lower limb. Stenosis of the left common iliac artery 80% (1), left external iliac artery 95% (2), left superficial femoral artery 95% (3) and proximal occlusion of the tibial and fibular arteries (4), stenosis of the proximal right common iliac artery 70% (5)

the conditions for their loop deformation inside the vascular space and the violation of its functions and properties.

It is important to remember that arterial hypertension, atherosclerosis, and injuries can affect the anatomy of the vessels and lead to pronounced tortuosity and angulation of the arteries. This makes it difficult to advance catheters and guidewires along vessels during the endovascular care and require the use of assistive devices or engineering solutions to effectively complete and complete operations.

Figure 3 shows a computer angiogram of the lower extremities arteries from patients with chronic critical ischemia of the left lower extremities, caused by atherosclerotic stenosis of the left common iliac artery 80% (1), left external iliac artery 95% (2), left superficial femoral artery 95% (3) and proximal occlusion of the tibial and fibular arteries (4). The patient also revealed a narrowing of the proximal right common iliac artery 70% (5).

For the effective treatment of critical ischemia, endovascular revascularization of the left lower limb (angioplasty of the left iliac, superficial femoral and tibial arteries) was chosen. The patient's height was 184 cm. To perform complete revascularization of the left lower limb, the right common femoral artery was punctured and catheterized. For safe contralateral catheterization of the left lower extremity arteries and prevention of dissection of

the wall of an acute angle (60°) of abdominal bifurcation of the aortic section, an unreinforced single-layer conductor catheter introducer with a diameter of 6 French was selected.

The use of a relatively soft and flexible single-layer catheter ensured the safety of its movement through atherosclerotic altered vessels but reduced the efficiency of the process. We were not able to catheterize through the narrowed segments of the arteries of the aorta-femoral segment on the left despite the already installed guidewire 0.035 inches in the lumen of the left superficial femoral artery.

To safely and efficiently advance the catheter forward, as well as to create a reliable structure when performing arterial recanalization with minimal risk of a folding catheter in the "Weak" aortic zone, we propose the creation of an engineering structure that includes several catheters of various modifications of different diameters inserted into each other.

The proposed bioengineered design, including a single-layer polyethylene catheter introducer 6 French 45 cm length (2), a conductive multilayer thin-walled reinforced catheter 6 French 100 cm length (3), a Y-connector (4) and an unreinforced multilayer catheter with a hydrophilic coating 5 French 125 cm length (5), is shown in fig. 4. The catheter system is installed in the lumen of blood vessels along the guidewire with a diameter of 0.035 inches (6).

The system algorithm is the sequential advancement of catheters along the guidewire to the zone of vascular injury and angioplasty of the narrowed segment. Firstly, the smallest diameter catheter with a hydrophilic coating is inserted, which reinforces the conductor system to advance larger diameter catheters. Then a multilayer guide catheter moves along it and at the end, a guide catheter introducer. The creation of a multilayer catheter structure contributed to the successful completion of the endovascular procedure.

The results of endovascular care for 1546 patients with critical lower limb ischemia and adherence to the algorithm and technique for arterial cannulation showed the reliable safety of modern catheters and guides when using both femoral and brachial accesses.

There were no complications associated with "Critical" areas of blood vessels, such as dissection of the vessel wall, separation of atherosclerotic plaques by the tip of catheters, and embolization of the femoral, popliteal, or tibial arteries. The use of the technology for vascular catheterization using a design of catheters of various modifications ensured the reliability of the system in blood vessels, resistance to folding in "Weak" zones and contributed to the successful revascularization in all

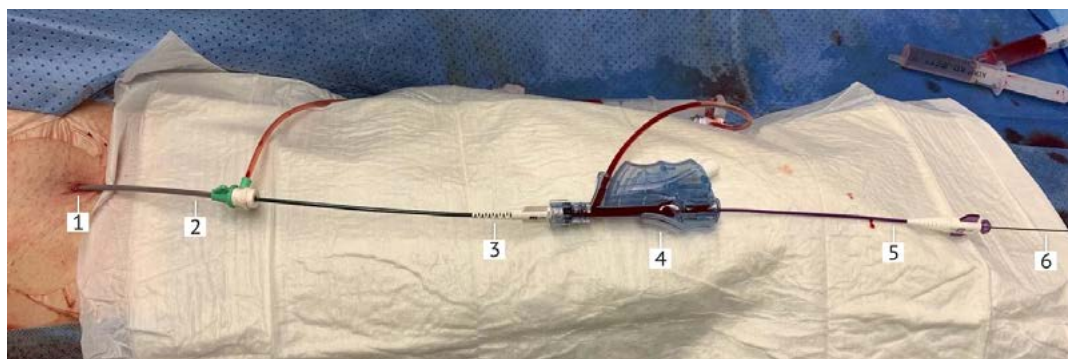


Fig. 4. A bioengineered design of three catheters of various modifications, diameters and lengths, mounted in each other and a Y-connector and a guide for safe and effective advancement through the atherosclerotic vascular bed, tortuosity and angulation of arteries: 1 — the site of puncture and catheterization of the right common femoral artery; 2 — single-layer polyethylene catheter-introducer 6 French sheath 45 cm length; 3 — conductive multilayer thin-walled reinforced catheter 6 French sheath 100 cm length; 4 — Y-connector; 5 — non-reinforced multilayer catheter with hydrophilic coating 5 French 125 cm length; 6 — metal guidewire (diameter 0.035 inches)

patients (100%) of cases in comparison with the results of applying the standard endovascular care technique ($p < 0.001$).

CONCLUSIONS

1. Endovascular instruments offered on the domestic market do not guarantee the effective completion of revascularization. The technology of vascular catheterization developed by the authors of the article based on endovascular biometry ensures the successful completion of revascularization in 100% of cases.

2. Engineering developments and the introduction into practice of technically perfect medical instruments of greater length will provide an opportunity for more frequent use of the right brachial artery access for endovascular revascularization of the lower extremities, which is safer than the femoral access.

Author contributions. D.I.K. supervised and coordinated the project, interpreted the results; R.S.G.-A. devised the main conceptual ideas, systematized and evaluated analysis results.

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Conflict of interest. The authors declare no conflict of interest.

REFERENCES

1. Dotter Ch., Judkins M. Transluminal treatment of arteriosclerotic obstruction. *Circulation*. 1964; 30 (5): 654–670. DOI: 10.1161/01.CIR.30.5.654.

2. Maingard J., Kok H., Ranatunga D. et al. The future of interventional and neurointerventional radiology: lessons of the past. *Brit. J. Radiol*. 2017; 90 (1080): 1–9. DOI: 10.1259/bjr.20170473.

3. Bradbury A.W. Bypass versus angioplasty in severe ischemia of the leg (BASIL) Trial: What are its implications? *Sem. Vasc. Surg.* 2009; 22 (4): 267–274. DOI: 10.1053/j.semvascsurg.2009.10.010.

4. Asadi H., Lee R., Sheehan M. et al. Endovascular therapy research in lower limb peripheral arterial disease published over a 5-year period: who is publishing and where? *Cardiovasc. Intervent. Radiol*. 2017; 40: 343–350. DOI: 10.1007/s00270-016-1504-1.

5. Gerhard-Herman M.D., Gornik H.L., Barrett C. et al. AHA/ACC Lower Extremity PAD Guideline: Executive summary. *Circulation*. 2017; 135 (12): 686–725. DOI: 10.1161/CIR.0000000000000470.

6. Dieter R.S. *Principles of endovascular treatment of critical limb ischemia*. *Critical limb ischemia*. Springer, Cham. 2017; 373–386. DOI: 10.1007/978-3-319-31991-9_34.

7. Sarkar K., Sharma S., Kini A. Catheter selection for coronary angiography and intervention in anomalous right coronary arteries. *J. Interv. Cardiol*. 2009; 22 (3): 234–239. DOI: 10.1111/j.1540-8183.2009.00463.x.

8. Lessne M., Holly B., Huang S., Kim Ch. Diagnosis and management of hemorrhagic complications of interventional radiology procedures. *Semin. Intervent. Radiol*. 2015; 32 (2): 89–97. DOI: 10.1055/s-0035-1549373.

9. Inagaki E., Farber A., Kalish J. et al. Outcomes of peripheral vascular interventions in select patients with lower extremity acute limb ischemia. *J. Am. Heart Assoc*. 2018; 7: 1–10; e004782. DOI: 10.1161/JAHA.116.004782.

10. Seldinger S.I. Catheter replacement of the needle in percutaneous arteriography; a new technique. *Acta. Radiol*. 1953; 39: 368–376. DOI: 10.3109/00016925309136722.

11. Merkov A.M., Polyakov L.E. *Sanitary statistics (a manual for doctors)*. M.: Medicine. 1974; 384 p. (In Russ.)