https://doi.org/10.35336/VA-1039

THE USE OF DISTAL FEMORAL VENOUS ACCESS FOR PULMONARY VEIN CRYOBALLOON ABLATION AND LEFT ATRIAL APPENDAGE OCCLUDER IMPLANTATION: RANDOMIZED STUDY DESIGN AND PRELIMINARY RESULTS

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Aim. This study aims to compare the results of the distal femoral access with the classic approach in patients undergoing pulmonary vein cryoballoon ablation and left atrial appendage occluder implantation.

Methods. The primary results of the 1:1 randomized single-center study are presented. The study group recruited 47 patients who underwent the catheter-based procedure using ultrasound-assisted distal femoral access. 38 patients with traditional ultrasound-guided proximal femoral access were involved in the control group.

Results. Total 85 patients were included: 47 in the study group and 38 in the control group. The median age was 61 years, and pulmonary vein cryo-ablation was performed in 84%. 95% of patients were taking direct oral anticoagulants. In the study group, the most frequent topographic and anatomical variant was the location of the superficial femoral vein on the lateral side from the artery (81%), whereas in the control group it was on the medial side (81%). The median access time was 30 s in the study group for the right leg and 35 s for the left leg. In the control group, access time was 33 s and 39 s for the right and left leg respectively. Unintentional arterial puncture occurred more frequently in both groups when the vein was fully overlapped by the artery for both right and left legs, but the differences were statistical unsignificant ($p>0.05$ and $p=0.09$ in the main group, $p=0.24$ and $p=0.72$ in the control group). In a correlation analysis, neither body mass index ($p=0.19$) nor femoral circumference ($p=0.19$ for right and $p=0.06$ for left legs) influenced the access time and did not increase the number of unintended arterial punctures. Two patients in the control group required additional manual hemostasis. There was no postprocedural venous thrombosis in both groups. Back pain was observed only in patients in the control group.

Conclusion. The efficacy and safety of the distal femoral access approach are comparable to the traditional proximal approach. Earlier postprocedural activation of patients can help improve quality of life.

Key words: atrial fibrillation; quality of life; catheter ablation; radiofrequency ablation; cryoballon isolation of the pulmonary veins; percutaneous left atrial appendage occlusion; anticoagulant therapy; ultrasound procedure; vascular complications; vascular access

Conflict of interest: none
Funding: none
Received: 04.03.2022 **Revision received:** 25.05.2023 **Accepted:** 05.06.2023
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For citation: Abdullaev AM, Davtyan KV, Topchyan AG. The use of distal femoral venous access for pulmonary vein cryoballoon ablation and left atrial appendage occluder implantation: randomized study design and preliminary results. *Journal of Arrhythmology.* 2023;30(3): 5-15. https://doi.org/10.35336/VA-1039.

Atrial fibrillation (AF) is the most frequent heart rhythm disorder, the prevalence of which increases with age [1, 2]. Arrhythmias lead to a significant decrease in patients' quality of life (QoL), increased hospitalizations, and worse prognosis, which is associated with a large burden on the healthcare system [3-6].

The dynamics of morbidity in the Russian Federation does not differ much from the global one. Thus, according to the data for 2010, the incidence of AF was 1766 per 100 thousand population, whereas for 2017 it was 2536 per 100 thousand population, indicating a 44% increase in the prevalence of arrhythmia [7].

Currently, catheter-based techniques, particularly pulmonary vein isolation procedures, have become a gold standard in rhythm control strategy and are significantly superior to drug therapy [8]. Also catheter-based interventions improve the prognosis even in patients with chronic heart failure with low reduced ejection fraction [9]. In terms of reducing the number of systemic emboli, in particular stroke, methods of endovascular occlusion of the left atrial appendage are not inferior to anticoagulant therapy and have economic advantages in the long-term perspective [10, 11]. Advances in catheter-based procedures for AF have led to their widespread use and thus an increase in the number of procedures performed annually.

Nevertheless, there are still concerns about potential complications of interventional procedures. These complications increase in-hospital time and lead to additional ex-

penses [12]. The necessity of vascular access leads to the prevalence of local vascular complications: hematomas, arteriovenous fistulas, pseudoaneurysms, venous thrombosis and infectious complications. Additional risk factors are usage of large diameter delivery systems and active intra- and postoperative anticoagulant therapy. The search for possible ways to reduce vascular complications in the electrophysiology laboratory has led to the widespread use of ultrasound-guided vascular access techniques to navigate the direction of the puncture needle. However standard femoral vein access wich is performed in the proximal segment of the femoral triangle under the inguinal ligament requires immobilization of patients for at least 8 hours after hemostasis. It often leads to the development of back pain, difficulty in urination, especially in men. Also the proximity of the access point to the inguinal region is fraught with the development of local infections and bleeding into the pelvic and retroperitoneal spaces. A possible way to resolve the problem is finding new areas of access, such as superficial femoral vein puncture in the mid-thigh segment. Such techniques have been used for the first time in the emergency department setting. The technique of distal femoral access for arrhythmological procedures was developed and patented by the author's team (Invention Patent No. 2748776).

The introduction of distal superficial femoral vein puncture into arrhythmological practice may lead to the possibility of early activation of patients and an in-hospital and cost of patient treatment time reduction.

The aim of the study is to compare distal femoral venous access which allows to activate patients in the early postoperative period with the standard one in terms of its efficacy and safety as well as patients' QoL.

METHODS

Currently, a randomized single-center open trial with randomization of patients in the ratio of 1:1 into the group of standard and distal accesses is being conducted in FSBI «NMIC of therapy and preventive medicine» of the Ministry of Health of the Russian Federation. The study is performed in accordance with Good Clinical Practice standards and the principles of the Declaration of Helsinki. The study protocol was approved by the local ethical committee. Patients were informed and agreed to participate in study. The study design is shown in Fig. 1. The study tests the hypothesis that standard access and distal femoral venous puncture are comparable in terms of safety and efficacy with benefits in patients' quality of life.

The study included patients older than 18 years of age with AF hospitalized for primary catheter isolation of pulmonary vein by cryoballoon ablation or implantation of left atrial appendage occluding devices in accordance with current clinical guidelines. Inclusion in the study did not depend on sex, anthropometric characteristics, concomitant pathology of patients and data of instrumental methods of investigation. Cryoballoon isolation of pulmonary vein was performed in patients with both paroxysmal and persistent forms of AF when the arrhythmia affected the patient's quality of life (EHRA IIa and higher). Patients with thromboembolic risk according to the CHA_2DS_2-VASc scale of more than 2 and 3 points for males and females, respectively. Also patients with contraindications to oral anticoagulant therapy or bleeding history or patients refusing to take therapy were included for implantation of left atrial appendage occluders.

Patients who refused to participate in the study, who did not comply with the study design, as well as patients with anatomical features of the pulmonary veins and left atrial appendage that were not suitable for pulmonary vein isolation by cryoballoon ablation and percutaneous endovascular implantation of occluders of the left atrial auricle were excluded from the study. Patients with left atrial appendage thrombosis, previous pulmonary embolism, known procoagulant conditions, deep vein thrombosis and chronic dermatitis were not included in the study.

The choice of this category of patients is conditioned using larger diameter introducers for vascular access according to the protocol of these interventions and the necessity of antithrombotic therapy - anticoagulant therapy during pulmonary vein isolation procedures and combined therapy during implantation of occlusive devices.

The primary efficacy end point included procedural success, defined as achieving complete electrical isolation of the pulmonary vein in cryoballoon ablation procedures or complete occlusion of the left atrial appendage in occluding device implantation procedures according to PASS criteria, number of unintentional arterial punctures during access, success with puncture on the first attempt and time to access. The primary safety endpoint included the number of local complications (arteriovenous fistulas, pseudoaneurysms, BARC 1-5 bleeding), and the need for re-hemostasis in the early postoperative period. Secondary endpoints included patients' QoL, need for urinary catheter placement, and analgesic therapy.

It is the center's practice to temporarily interrupt all previous anticoagulant therapy prior the procedure for one half-life period for direct oral anticoagulants or to an INR level less than 2.0 for patients taking vitamin K antagonists. Prior surgery, a duplex study of the femoral vessels was performed to exclude existing anomalies of the structure and thrombosis of the deep veins of the lower extremities. A linear transducer with frequency from 7 to 8 MHz (Transducer 9L-RS (General Electric, Horten, Norway) connected to the Vivid device (General Electric, Horten, Norway) or a portable transducer Lumify L12-4 (Philips, Amsterdam, The Netherlands) is used to examine the vessels of the lower extremities. Point-of-care ultrasound 3-point protocol (Point-

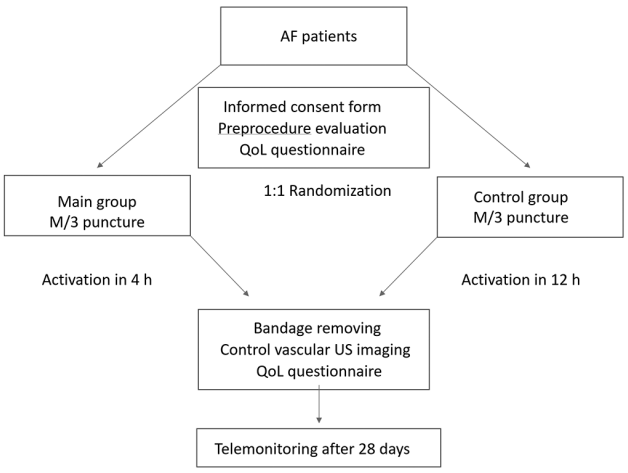

Fig. 1. Study Design. Note: QoL - quality of life.

of-care ultrasound 3-point protocol) was used. For segmentation, markings were made preoperatively with a marker on the anterior surface of the femur into three segments, proximal, distal, and medial (Fig. 2).

Preoperative (not more than 48 hours before the procedure) transesophageal echocardiography or multispiral computed tomography was used to exclude left atrial appendage thrombosis, to clarify its anatomy and the anatomy of the pulmonary vein inlet. During the procedure of implantation of the left atrial appendage occluder, the linear dimensions of the left atrial appendage, its shape, apex direction, number of lobes, anatomy of pulmonary vein appendages were also specified, the initial selection of the necessary occluding device was performed, the strategy of transseptal access was developed, and the projections of fluoroscopy convenient for the procedure were selected.

Femoral vein puncture was performed using the Seldinger technique under real-time ultrasound guidance. The linear transducer was placed in a sterile gel pouch for use in the operating field. The method of visualization of the puncture (longitudinal or transverse projection, in-plane, or out-of-plane) was not regulated and was performed at the operator's discretion.

In standard access, puncture of the common femoral vein was performed after combining the superficial and deep branches. When performing distal access, the superficial femoral vein was punctured below the line separating the middle and proximal segments at a distance of at least 10 cm from the inguinal ligament. Confirmation of needle location in the femoral vein lumen was performed by aspiration sampling, followed by placement of the introducer. Atrial septal puncture was performed under fluoroscopic and ultrasound guidance (intracardiac or transesophageal echocardiography), followed by intravenous heparin until a target ACT greater than 300 s was achieved and was maintained throughout the procedure. After the puncture, contrasting of the left atrial cavity was performed during frequent ventricular stimulation (250-300 ms) to clarify the anatomy of the pulmonary veins and to estimate their diameter. During implantation of left atrial appendage occluding device through the transseptal introducer, a diagnostic pigtail catheter was inserted into the appendage cavity, contrasting of the left atrial appendage was performed to clarify its anatomy and to choose a fluoroscopy projection convenient for implantation, after which the transseptal introducer was replaced by the delivery system of either occluding device or cryoballoon according to the surgical intervention plan.

After the procedure is completed, manual compression hemostasis was performed for 10 minutes, then pressure bandage were applied to the cannulation areas. Hemostatic devices and suture techniques were not used in both groups. Transthoracic echocardiography was performed postoperatively to exclude fluid accumulation in the pericardial cavity, after which direct oral anticoagulants were resumed in the cryoballoon ablation group and combination therapy in the left atrial appendage occluding device group. Intraoperatively, data on the topographic-anatomic relationship of vessels, namely arteries and veins in the selected area of cannulation, the time required for puncture, the number of unintentional arterial punctures, the diameter of the used intraducers and their number were recorded. In addition, the residual length of the working part of the used transseptal intraducers device necessary for predilatation of the puncture hole was recorded.

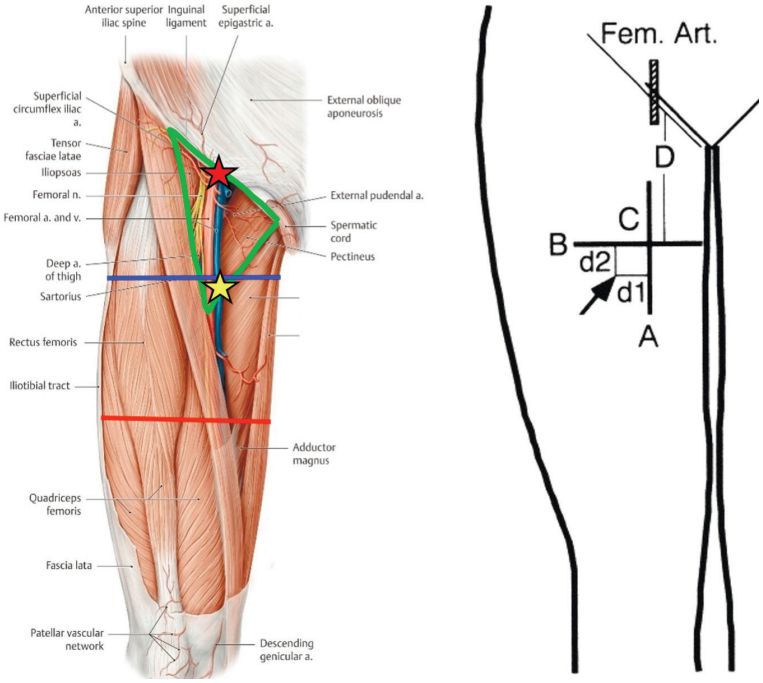

Fig. 2. Femoral venous access technique: left - the femoral triangle (adapted from Atlas of Human Anatomy. Sinelnikov R.D., Sinelnikov Y.R., Sinelnikov A.Ya. 2009. Moscow); right - distal access technique (as described by Shigehito Sato et al., 1998). Note: The borders of the femoral triangle are highlighted in green. The blue line separates the proximal and middle segments of the femur, the red line separates the middle and distal segments. The red asterisk indicates the puncture area for classic access, yellow - for distal access, where A - long axis of the vessel, B - transverse line drawn at the level of the area with the most suitable topographic-anatomic relationships of vessels for puncture. Skin puncture is performed 2 cm lateral to line A (d1) and 2 cm below line B (d2).

The Fast Cath Guiding Introducer SR0 and SL0 8/8.5F 63 cm (Abbott Medical, USA) and Transseptal Needle BRK-1 71 cm (Abbott Medical, USA), Medtronic Flex Cath Advance 15F cryoballoon delivery system (Medtronic Inc., Dublin, Ireland) (working length 65 cm) were considered standard length instruments. Longer length instruments include the Fast Cath Guiding Introducer SR0 and SL0 8F 81 cm (Abbott Medical, USA) and Transseptal Needle BRK-1 89 cm (Abbott Medical, USA), and the Boston Scientific DiRex 15.9F Delivery System (Boston Scientific Corporation, Marlborough, USA) (71 cm working length).

Patients in the standard puncture group maintained a horizontal body position for 12 hours after achieving hemostasis by manual compression; patients in the study group were active after no longer than 4 hours. Pressure bandages were removed after 12 hours in both

groups, then repeated duplex scanning of the lower limb vessels was performed to exclude deep vein thrombosis and postoperative complications.

In the pre- and postoperative periods, the patients' QoL and the intensity of back and leg pain syndrome were evaluated. The intensity of the pain syndrome was assessed by means of a visual analog scale (VAS), which is a straight-line segment 10 cm long with divisions from 0 to 10, where 0 is the absence of pain sensations, and 10 is unbearable pain. The intensity of pain syndrome according to the VAS is determined separately for the back and lower extremities.

The Russian-language version of the EQ-5D-5L questionnaire, consisting of two parts, was used to assess QoL. The form contains a health assessment in five areas (mobility, self-care, ability to perform activities of daily living, pain/discomfort, anxiety/depression) and allowed each section to be rated on a 5-point scale: 1 being taken as no problem, 5 being extreme severity. The second part was a VAS in the form of a 20-centimeter graduated line, on which the maximum bad health is taken as «0» and the maximum good health is taken as «100». The patients' quality of life was assessed preoperatively and after bandage removal in both groups.

The number of analgesics used, prescribed for pain syndrome in the back and cannulation area, as well as their effectiveness, the need for urine catheter placement associated with urinary retention, the number of infectious, hemorrhagic complications requiring hemotransfusion and repeated surgical interventions or interruption of antithrombotic therapy were recorded. Twenty-eight days after the intervention, the patients were interviewed by telephone: pain sensations in cannulation, possible delayed complications were clarified.

Statistical analysis was performed on a personal computer using Stata software (Version 15, StatSoft inc., USA). The Shapiro-Wilk test was used to test the normality of samples with quantitative variables. For quantitative measures, the mean and standard deviation or median with interquartile range were determined, and Student's t test or Mann-Whitney U-test were used for their comparison. Qualitative variables were described by absolute and relative frequencies (percentages). Pearson's criterion was used to compare qualitative indicators. Spearman's correlation coefficient (r) was calculated to determine the relationship between the parameters. Differences were considered statistically significant at a two-sided p value < 0.05.

The main aim of the study was to evaluate the effect of early activation of patients on quality of life compared to standard activation after 8-12 hours. In accordance with ultrasound usage for vascular puncture in both groups, no differences in the efficacy and safety of the different vascular access strategies were expected. It is known from the literature that up to 30-40% of patients experience pain in the back and access areas in the early postoperative period, with earlier activation within 4 hours reducing this percentage to 0-10%. An online calculator (clincalc.com/stats/samplesize.aspx) was used to calculate the sample size. Setting the confidence interval at 95% and the probability of first-order error equal to 0.05 required the recruit-

Table 1.

Clinical and demographic characteristics of patients

	General group (n=85)	Distal puncture (n=47)	Standard puncture (n=38)	p
Age, years, M (min-max)	61 (51-67)	60 (50-67)	63 (52-68)	0.142
Male gender, n (%)	57 (67)	27 (57)	30 (79)	0.03
AF history, years M (min-max)	3 (2-6)	3 (1-5)	4 (2-10)	0.78
CHA_2DS_2-VASc risk, points, M (min-max)	2 (2-3)	2 (2-4)	2 (1-3)	0.526
HAS-BLED risk, scores, M (min-max)	1 (0-1)	1 (0-1)	1 (0-1)	0.09
Height, cm, M (min-max)	175 (169-180)	173 (164-178)	177 (172-180)	0.37
Weight, kg, M (min-max)	89 (80-96)	86 (79-95)	90 (83-98)	0.89
BMI, kg/m^2, M (min-max)	29 (27-31)	29 (27-31)	29 (27-31)	0.47
Right LE circumference, cm, M (min-max)	56 (51-60)	56 (52-60)	56 (50-59)	0.81
Left LE circumference, cm, M (min-max)	56 (51-59)	56 (52-60)	55 (50-59)	0.97
Hypertension, n (%)	70 (82)	39 (83)	31 (82)	0.9
Coronary heart disease, n (%)	9 (11)	6 (13)	3 (8)	0.5
Diabetes mellitus, n (%)	10 (11)	4 (11)	6 (13)	1.0
Stroke, n (%)	8 (9)	6 (13)	2 (5)	0.3
Additional therapy, n (%)	13 (16)	4 (9)	9 (24)	0.07
LE varicose veins, n (%)	16 (19)	9 (19)	7 (18)	0.9
Urinary system pathology, n (%)	21 (25)	11 (23)	10 (26)	0.8
Musculoskeletal system pathology, n (%)	45 (53)	28 (60)	17 (45)	0.2
Cryoballoon isolation of pulmonary vein orifices, n (%)	71 (83)	39 (83)	32 (84)	0.91
Percutaneous occlusion of the left atrial appendage, n (%)	14 (17)	8 (17)	6 (15)	0.93

Note: AF - atrial fibrillation; BMI - body mass index; LE - lower extremity.

ment of 125 patients in each group to achieve statistically significant differences between groups.

RESULTS

Eighty-five patients were included in the analysis, of whom 47 underwent distal puncture. The median age was 61 years (51.5-67.0 years). The paroxysmal form of AF was present in 73% of included patients, and the median duration of arrhythmia history was 3 years (2-6 years). Cryoballoon ablation procedure was performed in 84% of cases. Detailed information about the patients is presented in Table 1.

In the postoperative period, 95% of patients were on therapy with direct oral anticoagulants: 47% received apixaban (40% in the main group and 55% in the control group, p=0.2), 29% received rivaroxaban (36% in the main group and 21% in the control group, p=0.1), 18% received dabigatran etaxylate (21% in the main group and 16% in the control group, p=0.5); 6% of patients were on combination therapy (2% in the main group and 11% in the control group, p=0.1). No differences in antithrombotic therapy were noted between the groups.

In the distal puncture group, lateral location of the vein was observed in 81.6% of patients, whereas complete overlap was observed in 15.8% of observations. For the standard access group, the most frequent vessel relationship was the location of the vein on the medial side relative to the artery (81.2%), with complete overlap in 12.5% of observations (Table 2, Fig. 3). Complete arterial overlap of the vein on the right side was noted in 13 patients of the main group and 5 patients of the control group and did not differ significantly between the groups (p=0.1). On the left, complete overlap was observed in 7 patients in the main group and 6 in the control group and was also not significantly different (p=1). When comparing the groups, complete overlap was more frequently observed on the right side but did not reach statistical significance.

In both groups, all steps of the procedure were performed successfully. In the main group, unintentional arterial puncture was observed in 12% of cases, whereas in the control group it was observed in 9%. The differences did not reach a statistically significant difference. First attempt puncture was performed in 85% in the main group and 89% in the control group (p>0.05). The main reason for failure to provide access on the first attempt was arterial puncture.

The median time to distal puncture was 30 seconds (25-50 seconds) for the right limb and 35 seconds (21-70 seconds) for the left limb. In the standard puncture group, the median times were 33 (27-57 seconds) and 39 (30-60) for the right and left lower extremities, respectively. Time to access was not significantly different between groups for both limbs (p>0.05). Unintentional arterial puncture in both groups was more frequent when the vein was completely blocked by an artery for both the right and left lower limb, but the differences did not reach a statistically significant difference (p>0.05 and p=0.09 in the main group, p=0.24 and p=0.72 in the control group). Also, a slight increase in the time required for puncture was noted with this anatomy.

When correlation analysis was performed, neither body mass index (p=0.19) nor thigh volume (p=0.19 for the right and p=0.06 for the left lower extremity) affected puncture time or increased the number of unintended arterial punctures.

Stable hemostasis was achieved within 10 minutes of manual compression in both groups, and there was no need for heparin inactivation. All patients in the main group were activated up to 4 hours after the end of the procedure, whereas patients in the control group maintained a horizontal position for at least 12 hours. In 2 patients of the control group there was a need for repeated hemostasis due to bleeding from the puncture site within 4 hours from the end of the procedure, whereas in the main group no additional hemostasis was required.

According to duplex scanning of the lower limb vessels, no deep and superficial vein thrombosis after the procedure was detected in both groups. In one patient of the main group, the postoperative period was complicated by the development of a hematoma of the left lower limb, which was not accompanied by a decrease in hemoglobin level and did not require additional interventions. When intraoperative data were analyzed, complete arterial overlap of the vein was noted, which increased the time to access the vein to 80 seconds (with an average of 30 seconds in the distal access group). Also, in the distal puncture group, one patient developed hemopericardium in the early postoperative period, requiring drainage without conversion to open surgery.

The need to use transseptal introducer and longer delivery systems occurred only in the main group of patients and was not associated with height or distance from the inguinal ligament to the puncture site, nor did it lead to difficulties in performing the main stage of the procedure.

Analysis of back pain intensity revealed a statistically significant increase in VAS scores in the standard access group (0 points preoperatively vs. 2 points postoperatively, p<0.005). No such trend was observed in the main group (0 points preoperatively and 0 points postoperatively, p>0.05). In terms of pain in the puncture area, the preoperative VAS score in both groups was 0 points (p = 0.9). In the postoperative period, the pain score did not change in the main group, whereas in the control group the score increased to 2 (p=0.0024). The data on the visual analog scale of the EQ-5D-5L questionnaire

Table 2.

Topographo-anatomic relationships of the vessels of the femoral triangle

	Medial vein location		Lateral vein location		Complete overlap	
	RL	LL	RL	LL	RL	LL
General group (n=85)	29	28	43	25	13	18
Distal puncture (n=47)	1	1	39	25	7	13
Standard puncture (n=38)	28	27	4	0	6	5

Note: RL - right leg; LL - left leg.

are presented in Table 3. There were no significant differences in the components of the questionnaire between the groups.

Additional pain-related therapy was administered to 9 patients in the control group and 4 in the main group. In all cases, the drugs of choice were non-steroidal anti-inflammatory drugs. Pathology of the urogenital system was noted in 21 patients: 11 in the main group and 10 in the control group. Bladder catheterization for acute urinary retention was performed in 3 patients in the control group and 1 patient in the main group. No statistically significant difference was observed ($p>0.05$). No late complications or pain syndrome in the access areas were reported in both groups when patients were interviewed by telephone.

DISCUSSION

According to the results, it can be concluded that the use of distal femoral venous access is not inferior in efficacy and safety to the standard femoral vein access but allows to improve QoL and reduce the frequency of additional therapy and urethral catheterizations.

The variability of the anatomic relationships of the femoral triangle vessels, namely the degree of arterial overlap with the vein and the location of the vein relative to the axis of the artery, often leads to difficulties in access, which is classically performed medial to the pulsation of the artery. The introduction of ultrasound-assisted access methods will reduce the number of complications to almost zero [13], as it allows a more detailed assessment of the topographic-anatomical relationships of the vein with adjacent arterial trunks and real-time tracking of the direction of the puncture needle.

According to the paper, the main factor associated with increased time to puncture was complete occlusion of the vein by the artery, which was also associated with an increased number of unintentional arterial punctures, potentially increasing local complications, and generally increasing local pain syndrome even without the development of complications. This relationship has been noted in earlier studies as well. The ULTRA-FAST study reported the development of arteriovenous fistula in a patient with complete arterial occlusion and an associated high number of inadvertent arterial punctures [14]. According to studies using multispiral computed tomography, the incidence of arterial vein occlusion can reach more than 60%; however, these data refer to the common femoral artery and vein located in the proximal femoral triangle [15]. In our study, the incidence of overlap in the proximal segment was 29%, with the vein passing distally to the lateral side from the artery, which facilitates puncture. Such an observation is consistent with data obtained in studies on the use of distal accesses in the ICU setting, especially pediatric ICUs.

The use of intraoperative ultrasound allows real-time diagnosis of complete overlap and selection of a more convenient area for puncture, which facilitates access and reduces local complications in the postoperative period.

Technically, performing distal access using ultrasound does not differ from standard access. The more frequent location of the vein on the lateral side of the artery dictates the need to enter the vessel with the needle directed from the lateral to the medial side, whereas with standard access, the needle is directed in the opposite direction. If the vein is completely occluded, it is more effective to perform the puncture with the needle directed from the lateral to the medial side.

In 2016, a group of authors led by Robert P. Richter published results on the use of distal femoral access in neonates with cardiovascular disease. Of the 31 patients, access was successfully performed in 92% of cases, and the mean number of attempts for access was 1. It should be noted that 11% of cases developed thrombotic complications, and 61% required systemic thrombolysis [16].

Distal femoral venous puncture was confirmed to be advantageous in a randomized trial that included neonates in the ICU with difficulty in placing peripheral venous lines. Patients were allocated in a 1:1 ratio to the axillary vein puncture group and the distal femoral venous access group performed under ultrasound guidance. A total of 60 neonates were included in the analysis. Successful puncture on the first attempt was significantly more common in the distal puncture group (77% vs. 37%, $p=0.001$). Also, distal puncture had advantages in terms of procedure time (309 vs. 523 seconds, $p<0.001$) and peri-procedural complications (4 vs. 12, $p=0.019$) [17].

A group of researchers from the Cancer Center of Wuhan University Hospital compared the placement of the central venous line by superficial femoral vein puncture in the middle third of the thigh with the use of superficial veins of the upper extremities in patients with superior vena cava syndrome. In both groups, access was performed using ultrasound-guided navigation. There were no significant differences in time and success on the first attempt ($p>0.05$). The number of infectious ($\chi^2 = 0.72$, $p>0.05$) and thrombotic complications ($\chi^2 = 0.28$, $p>0.05$) were not significantly different between groups [18, 19].

In our series, catheter steerability and procedural success did not differ between groups. However, when distal access was used in 17% of cases, a longer transseptal introducer length was necessary. No clear anthropometric predictors have been identified at this time. It should be noted that the average height of these patients was at least 179 cm, and the distance from the puncture hole to the inguinal fold was 13 cm. One patient in the control group also re-

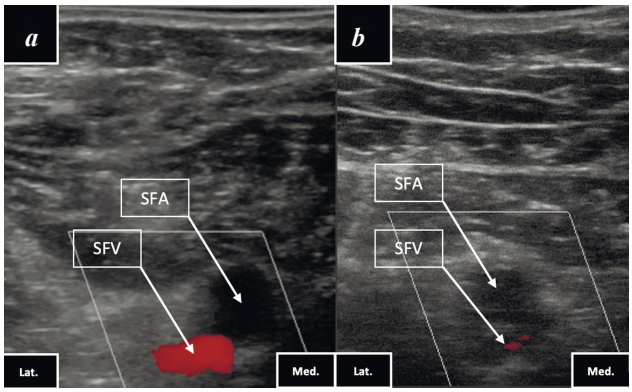

Fig. 3. Topographic-anatomical relationships at distal access: a - location of the vein lateral to the artery, b - complete overlap of the superficial femoral vein with the artery. Note: Lat. - lateral femoral edge; Med. - medial femoral edge; SFA and SFV - superficial femoral artery and vein, respectively.

quired the use of a long transseptal introducer; the patient's height was 182 cm.

The quality of life of patients in the postoperative period is considered in studies in isolation in terms of the impact of arrhythmic events on it. However, patients experience the most stress in the early postoperative period.

The topic of early activation looks quite relevant given the expanding indications for catheter procedures, including older patients with more comorbid pathology and, consequently, greater risks.

The peculiarities of management immediately after catheter procedures, namely the need to follow a special activity regime, are associated with the development of pain syndrome of various localizations, which causes emotional discomfort, has a negative immune effect, and can increase the length of stay of patients in hospital [20]. This issue has previously been insufficiently addressed in the studies conducted.

In this regard, adequate pain management is the cornerstone of postoperative management. Kerstin Bode first drew attention to the peculiarities of the course of the early postoperative period. In a prospective study performed, 61 of 102 included patients reported the development of pain syndrome, 44% of which was back pain; more than 90% required active therapy [21]. Nonsteroidal anti-inflammatory drugs are the drugs of choice for pain management; however, they increase the risks of acute kidney injury, gastropathies, and hemorrhagic events, which are more common in the older age group [22].

Considering the above, systems for vascular hemostasis of different designs were developed and tested: Angio-SealTM (Terumo Corporation, Tokyo, Japan), Perclose ProGlideTM (Abbott Laboratories, Abbott Park, IL, USA) ExoSeal1 (Cordis Corporation, Milpitas, CA, USA), VASCADE device (Cardiva medical inc., Santa Clara, USA). In a retrospective evaluation of VASCADE device use after cryoballoon ablations, where patient activation was performed within 2 hours, only 15 patients (4.9%) required bladder catheterization, whereas in the manual compression group, the procedure was performed in all patients. Subsequently, one patient with a diagnosed urethral injury required emergency surgical treatment. At follow-up, a higher incidence of infectious complications as well as urethral strictures was noted in the manual hemostasis group. Back pain syndrome and administration of analgesics were more frequently observed in the chiropractic hemostasis group [23].

However, hemostatic devices are not without disadvantages. This relates to their cost and concerns about the puncture technique and outcomes in patients requiring repeat procedures, which has not been tested in prospective studies. In our study, the distal access group recorded a significantly lower VAS score, which less often required additional analgesic therapy. In this regard, the use of distal femoral venous access appears to be a convenient and cost-effective alternative.

In addition, perioperative infusion support often leads to volume overload, requires the provision of comfortable conditions for urine evacuation, necessitating the need to perform bladder catheterization, which raises concerns in the focus of complications in the male group [24]. Minimizing the catheterizations performed can reduce the risks of genitourinary infection and traumatic urinary tract injury, and therefore reduce hematuria, dysuria, and the incidence of urethral strictures [25]. In numerous studies with both prospective and retrospective designs, catheterization avoidance significantly reduced the risks of problems such as urinary retention, need for repeat catheterization, hematuria, dysuria, urinary tract infection, and injury [26, 27]. The main risk factor for these complications is still age. Our center is committed to the tactics of maximal sharp catheterization, which in combination with a small sample does not currently provide definitive answers regarding the impact of access features.

When planning the study, there were concerns about the incidence of complications associated with lower extremity deep vein thrombosis due to direct damage to the vascular wall as well as venous stasis associated with intra-arterial placement.

The greater propensity for thrombosis, including venous thrombosis, in patients with AF and surgical stress must be considered [28]. Placing more introducers, especially large diameter ones, is a direct risk factor for thrombosis as reported by J.Y.Chen et al. (2004) in a prospective study of patients after catheter procedures, but did not increase the risk of thromboembolism [29]. The incidence of thrombosis in the routine use of duplex scanning after procedures ranges from 1 to 2% and varies depending on the type of procedure performed, as well as the duration of the procedure and the intra- and postoperative management of patients. According to the data of a systematic review, the detection of thrombosis after AF procedures is significantly lower despite the use of many vascular ports and, as a rule, a longer duration of surgery, which is associated with both intraoperative administration of heparin, especially against the background of continuous anticoagulation, and with the continuation of therapy in the postoperative period [30].

Table 3.

Components of the EQ-5D-5L questionnaire

	Main group		Control group	
	Before	After	Before	After
Mobility	1	1	1	1
Self-care	1	1	1	1
Habitual activities	1	1	1	1
Pain / Discomfort	1	1	1	1.5
Anxiety / Depression	2	1	2	1

At present, there is no evidence that a revised strategy of antithrombotic therapy is needed in these patients and it usually resolves on its own at follow-up. A randomized study led by Dimitrios Karakitsos reported an increased incidence of deep vein thrombosis in emergency department patients with low femoral access, probably due to the smaller distal vein diameter [31]. However, according to our work using placement of larger diameter delivery

systems, no such complications were noted, which emphasizes the importance of anticoagulant therapy in the postoperative period. One of the leading risk factors is also prolonged immobilization of patients, aggravating the outflow of blood from the lower extremities, which also speaks in favor of early activation after catheter procedures.

The possibility of discharging patients after catheter-based treatment of AF on the day of the procedure is now widely discussed. Data from numerous studies indicate the safety and cost-effectiveness of early transfer of patients to outpatient follow-up [32-35]. The use of distal femoral access can further reduce economic costs as it does not require the use of additional consumables per se, without compromising patient safety. The main limitation of this work is the single-center nature of the study, and the inability to blind these patients due to different activation times.

CONCLUSION

According to the preliminary data of the study, the use of distal femoral venous access in catheter-based treatment of AF is not inferior to standard access in terms of efficacy and safety. Distal access allows to activate patients in the earliest postoperative period, which has a positive effect on QoL without requiring additional treatment costs. However, final conclusions regarding the methodology can be made after the study is completed. Patient enrollment is currently ongoing.

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