Ultrasonography guided percutaneous EVAR using the ProGlide® Perclose device. Single center preliminary results

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Abstract:

Introduction: Percutaneous EVAR (p-EVAR) has gained popularity after the introduction of arteriotomy closure devices, as it facilitates a totally minimal invasive technique having a lot of advantages. Duplex ultrasonography (DUS) guided arterial puncture could be mandatory in complications' prevention. The aim of this study was to evaluate the initial experience of p-EVAR in a tertiary vascular center.

Methods: A retrospective study (2017- 2019) with prospectively collected data was undertaken, including all consecutive AAA patients treated using completely percutaneous access. Demographics, pre-operative anatomic parameters and postoperative outcomes were collected. All patients underwent DUS pre- and post-operatively, while the percutaneous femoral access was also achieved under DUS guidance. The femoral artery out-wall diameter, the presence of atherosclerosis and the distance from the skin were recorded. The technical success, use of additional closure devices, volume of blood transfusion, site-related complications and open femoral artery conversions were recorded and analyzed.

Results: Thirty patients underwent p-EVAR (mean age 71 years, all men). Mean body mass index (BMI) was 26.5 kg/m^2. The mean common femoral artery (CFA) diameter was 11mm at the right (range 9-14mm) and 9mm (8-12mm) at the left side and the mean distance from the skin was 13mm (range 10-35mm). Sheath diameter was ranging between 7-18Fr. In 44 CFAs, 2 ProGlide® devices (Abbott, Santa Clara, California, USA) were applied vs 1 device in 16 access sites. The mean duration of operation was 115 min. Percutaneous closure primary technical success was 92% (55/60). Only 1 additional device was used to achieve accurate hemostasis in 1 patient. In 5 femoral arteries, an open conversion was performed. The median post-operative in-hospital stay was 1 day. Three patients presented a small inguinal hematoma and treated conservatively. Mean blood transfusion was 150cc. During the follow-up period (1-30 months), no further access site complication was recorded.

Conclusion: Percutaneous US guided access using the Proglide device was a safe and effective approach in many AAA patients treated with EVAR even at an initial experience level. Careful patient pre-operative evaluation and selection could lead in even better results in the future.

INTRODUCTION

Endovascular aortic aneurysm repair (EVAR) has been established as the standard of care in the management of abdominal aortic aneurysm (AAA) worldwide.[1] Fast-track EVAR protocols have been implemented in well-selected patients with a high clinical success rate and associated decrease in intensive care unit (ICU) admission and in-hospital length of stay. No negative effect on the peri-operative morbidity and mortality has been recorded so far in the literature.[2] The extensive use of EVAR in the daily practice has increased surgeon's experience, while the introduction of new generation endografts with much lower profile and the use of innovative arteriotomy closure devices made easier and safer the percutaneous access.[3]

Percutaneous EVAR (p-EVAR) has gained popularity during the recent years with a lower post-operative complication rate in comparison to conventional exposure, while closure device failure has been limited within an acceptable rate.[4,5] P-EVAR has permitted the wider use of local anesthesia and decreased the total operation time along with the need for blood transfusion, as well as wound infections of the groin.[4] Despite these encouraging data, failed access closure in p-EVAR is associated with the need of additional closure devices and higher cardiac adverse event rate.[4,6] Patients' selection according to body mass index and the adequacy of the femoral arteries seems to play a mandatory role in the prevention of complications.[4] A detailed pre-operative access vessels assessment is important to confirm the feasibility and safety of the technique.[4] Despite

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that duplex ultrasound is not obligatory during percutaneous access and there is no comparison study between ultrasound guided and unguided procedures, current literature confirm its wide use in percutaneous interventions.[1,4]

The aim of this study is to report and analyze the initial experience of p-EVAR using the ProGlide® Perclose closure device under duplex ultrasound (DUS) guidance in a single tertiary vascular center.

METHODS

Study Cohort

A retrospective study with prospectively collected data was undertaken including patients that were treated using completely percutaneous access from June 2017 to September 2019. Except two cases that were treated for a previous failed EVAR, all patients underwent a primary intervention. Demographics, pre-operative femoral artery anatomic parameters and post-operative outcomes were collected prospectively. Informed consent was obtained from all patients. The study was approved by the Institutional Review Board.

Imaging evaluation

Computed tomography angiography (CTA) of the abdominal aorta down to femoral arteries was performed as a part of the pre-operative assessment. Sizing and planning were performed based on the CTA using a workstation with 3Mensio dedicated reconstruction software (Medical Imaging B.V., Bilthoven, Netherlands). If the patient did not have diffuse calcification in the femoral arteries in CTA evaluation, the femoral bifurcation was below the inguinal ligament and the device planned needed introduction sheaths up to 18Fr (outer diameter of about 20Fr), he was considered a potential candidate for percutaneous access. All candidates for p-EVAR underwent DUS from an expertise vascular surgeon. Femoral access site was evaluated the day before the operation as well as the 1st post-operative day to confirm the successful deployment of the closure devices and possible site complications. The femoral artery out-wall diameter, the presence of atherosclerotic plaque (anterior and posterior) and the distance from the skin were also recorded.

Access and closure devices

All patients were treated in an adequately equipped operating room using a moveable radiolucent surgical table and a mobile digital angiographic system (Philips BV Endura, Philips Medical Systems, Release 2.2.3, the Netherlands). Bi-femoral access was used for the insertion of the main endograft and the contralateral limb extension. Previous intervention with femoral cut-down was not a criterion of exclusion for p-EVAR. Perclose ProGlide® (Abbott, Santa Clara, CA, USA) was used in all cases under DUS guidance in order to achieve a safe insertion of the device. With the US probe in transverse position to the underlining femoral artery, the artery was visualized from the femoral bifurcation and upwards ending at the level of the inguinal ligament (Figure 1A). Then the most adequate point for puncture was chosen in terms of the quality of the artery wall (at least no anterior atherosclerotic plaque) and the diameter of the artery (at least 8-9mm for large sheaths). Having the artery in the middle of the US image, direct puncture was then achieved with a large bore needle. After successful catheterization of the femoral artery, a standard J-shape guidewire was inserted and followed with the US up to the external iliac artery to ensure the uncomplicated, adequate position inside the artery (Figure 1B-D). Afterwards a standard 6F sheath was inserted, blood was withdrawn and finally local heparinization was performed. The sheath was withdrawn and one or two Proglide® devices inserted (depending on the diameter of the largest sheath that would be needed to pass through), according to the instructions for use (Figure 2A and B). One closure device was used for sheaths up to 11F and two devices for larger sheaths (Figure 2C). Upon the bilateral completion of the insertion of the closure devices, standard sheaths were inserted in the arteriotomies, arteriotomy sutures were carefully isolated and secured and the main procedure was started after systemic heparinization (Figure 2D). At the end of the main endovascular procedure, large sheaths and stiff guidewires were replaced by smaller sheaths and short standard J-type guidewires and after small sheaths removal, the Proglide® sutures were tighten with the guidewire in place (Figure 3A and B). If a satisfactory hemostasis was achieved the guidewire was removed, the knot was tightened again, locked and secured and the sutures were cut short, leaving just a small hole in the skin (Figure 3C and D). The need for any additional closure device was decided during the suture tightening process at the end of the operation according to hemostasis achieved at the arteriotomy closure (Figure 4). After the successful arteriotomy closure, mechanical compression was applied, which remained at the recovery room and until the patient was transferred to the ward. The compression was then removed and the patient was able to stand up after 3 additional hours. Thereafter, full mobilization was allowed.

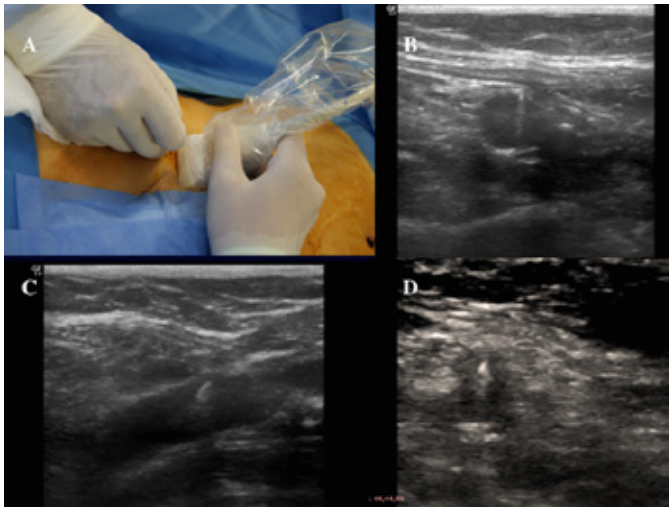

Figure 1. With the US probe in transverse position to the underlining femoral artery, the artery was visualized from the femoral bifurcation and upwards ending at the level of the inguinal ligament (A). The most adequate point of puncture was chosen and having the artery in the middle of the US image, direct puncture was achieved with a large bore needle (B). After catheterization of the femoral artery, the position of the guidewire was confirmed in the longitudinal (C) and transverse (D) view.

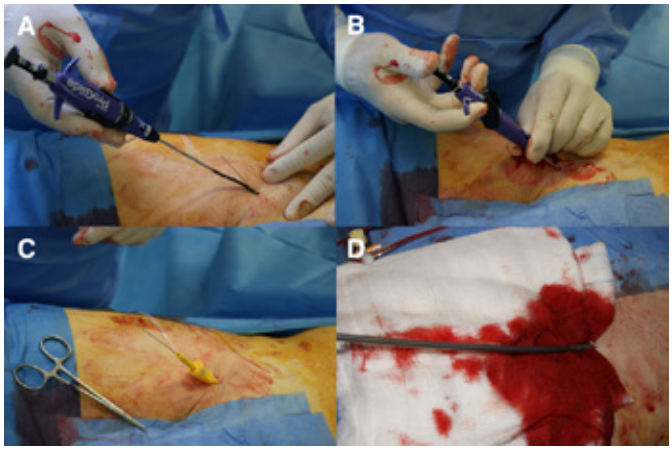

Figure 2. The Proglide® device inserted over the guidewire (A), and the suturing of the artery (B). Positioning of a standard sheath over the guidewire at the end of the Proglide® initial procedure (C). The main body of the endograft inserted via the puncture site during the procedure (D).

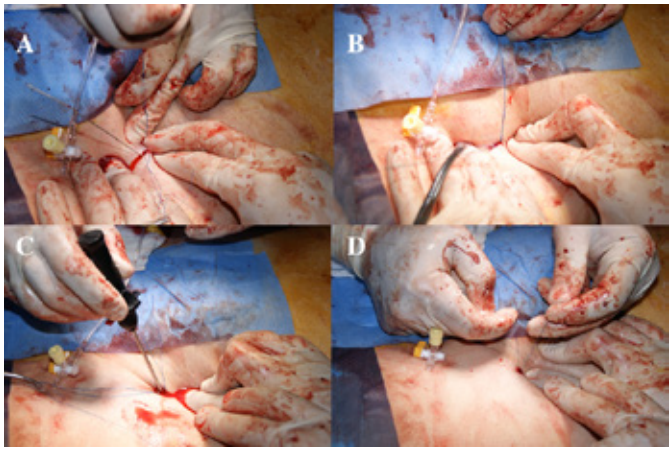

Figure 3. At the end of the procedure, large sheaths and stiff guidewires were replaced by smaller sheaths and short standard J-type guidewires (A). After small sheaths removal, the Proglide® sutures were tighten with the guidewire in place (B). If a satisfactory hemostasis was achieved the guidewire was removed, the knot was tightened again using the trimmer device (C), locked and secured (D) and cut short.

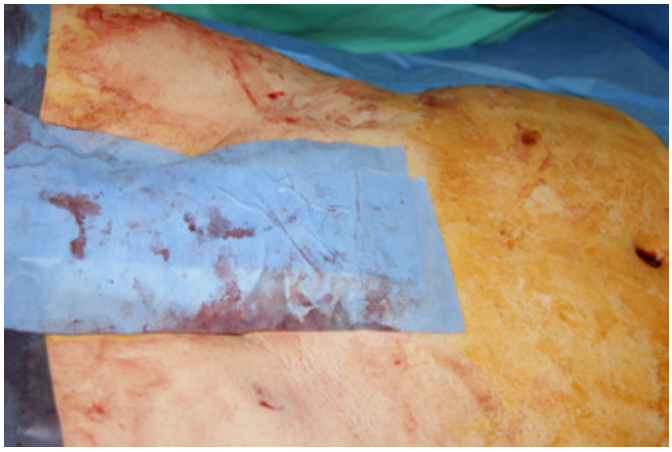

Figure 4. At the end of the operation, two small puncture holes are present at the access sites.

Type of sheaths and endografts

A bifurcated endograft was applied in all patients. Percutaneous technique was preferred initially in lower profile endografts, mainly Incraft (Cardinal Health, Ohio, USA) that needs a 14-16Fr sheath for the main graft and 11-12Fr for the contralateral side, depending on the diameter of the limb. As surgeon's experience became higher, different type of grafts with wider insertion sheaths were used, as AFX 2 (Endologix, California, USA) that needs a 17Fr sheath for the main graft and just 7Fr sheath for the contralateral side, Nellix (Endologix, California, USA) that needs 17Fr sheaths on both sides, Excluder C3 with or without Excluder IBE (W. L. Gore & Associates, Delaware, USA) that needs 16-18Fr for the main graft and 12-14Fr for the contralateral side and Altura (Lombart Medical, California, USA) hat needs 14Fr sheaths bilaterally.

Follow-up

All patients underwent DUS evaluation the 1st post-operative day in order to control the complete closure of the artery wall and to diagnose any further complication (pseudo-aneurysm formation, inguinal hematoma and leak). A standardized EVAR follow-up protocol including CTA of the abdominal aorta, iliac and femoral arteries as well as laboratory testing was performed at 1 and 12 months and yearly, thereafter. DUS was used as standard follow-up method at 6-month follow-up. Any complications from access sites were recorded during standard evaluation.

Outcomes

The primary technical arteriotomy closure success, use of additional devices, volume of blood loss, site-related complications as well as need for open access conversion were recorded and analyzed.

Statistical Analysis

Continuous data were reported as a mean ± standard deviation. Categorical data were expressed as absolute numbers and percentage of prevalence (%) in the study cohort. In the statistical analysis for continuous variables the independent t-test for normally distributed data and the Mann-Whitney U test for nonparametric data were used. The Pearson x^2 test or the Fisher exact test was used for categorical variables, as appropriate. P value was considered significant at <0.05. Statistical analysis was performed by SPSS 22.0 for Windows software (IBM Corp, Armonk, NY).

RESULTS

Thirty patients underwent p-EVAR (mean age 71 years, all men). Patients' mean body mass index (BMI) was estimated at 26.5kg/m^2 (range 18-34.4kg/m^2). Patients' demographics are presented in Table I. The mean AAA diameter was 68 mm (range 55-82mm), while the mean femoral artery diameter was calculated at 11mm (range 9-14mm) at the right and 9mm (8-12mm) at the left side. The mean distance between the anterior wall of the common femoral artery (CFA) and the skin was 13mm (range 11-38mm) in both access sites.

Demographic characteristics	
Age (mean)	71
Male	100%
BMI (mean, kg/m^2)	26.5
Comorbidities	**Number of patients (%)**
Obesity (BMI>25kg/m^2)	19 (63)
Hypertension	30 (100)
Dyslipidemia	27 (90)
Diabetes Mellitus	16 (53)
COPD	25 (83)
Tobacco use (current or previous)	26 (86)
CAD	19 (63)
Previous EVAR	2 (6.7)

Table I. Patients' demographic characteristics and comorbidities. BMI: body mass index; COPD: chronic obstructive pulmonary disease; CAD: coronary artery disease; EVAR: endovascular aneurysm repair

Sheath diameter was ranging between 7-18Fr. The distribution of sheath diameters is presented in Table II. In 44 femoral arteries, 2 ProGlide® devices were applied to achieve hemostasis, versus 16 access sites were 1 device was used. In most cases, a low profile endograft was applied. Fourteen patients were treated with Incraft, 2 with AFX 2 and 1 with Altura device (Lombart Medical, California, USA). In 9 cases, a Nellix sealing device was applied while in 3 cases, a bifurcated Excluder device was used. In one of these cases, an Internal Branch Endoprothesis (IBE) was also used to preserve internal iliac artery flow. In this case, a bilateral percutaneous access was achieved without any complication.

Sheath inner diameter (in Fr)	Number of sheaths used
7	2
11	14
14	17
16	3
17	19
18	5

Table II. The distribution of sheath size in femoral artery access sites

Primary technical success was 92% (55/60 access sites). In three cases (5 access sites), a conversion to conventional exposure was performed. In the first patient, even percutaneous access was achieved; the adequate insertion of the closure device was incomplete due to severe posterior plaque and distal iliac artery tortuosity. The presence of posterior plaque was not included in standard contraindications for p-EVAR. Although in this case, the remaining lumen did not permit the smooth insertion of the closure device. Including that this event occurred during the very initial experience, a conversion to open exposure was chosen to accomplish the intervention. In the second patient, who was obese with a BMI of 31kg/m2, an adequate catheterization was initially achieved in a very deep situated femoral artery on both sides. The depth of the artery made impossible for the closure device to be inserted properly in a manner that would allow the suturing of it. Thus, both sides were converted to open exposure. This was the only case of technical failure recorded in the group of patients with BMI>25kg/m2 (overweight). In the last case, the malposition of the ProGlide® device during puncture (lateral to the CFA wall because of atherosclerosis in the anterior part of the artery) provoked a left CFA occlusion after closure. The patient was treated immediately with endarterectomy and patch-closure. During the same procedure, a third ProGlide® device was applied at the contralateral site in order to achieve complete hemostasis. It is remarkable that this patient had a very low BMI (18kg/m^2) and suffered a post-operative coagulopathy, fortunately without any serious consequences.

The median post-operative in-hospital stay was calculated at 1 day (1-5 days). Three patients presented a small inguinal hematoma. All cases were treated conservatively without any further intervention. No trauma infection was detected during hospitalization or early follow-up. Mean blood transfusion was recorded at 150cc (range 0-500cc) without any difference between converted and percutaneous cases. During the follow-up period (range 1-30 months), no further access site complication was recorded.

DISCUSSION

Percutaneous procedures, highlighting even more the minimal invasive approach of endovascular techniques, gain more and more popularity in vascular surgery. Percutaneous approach seems as safe and efficient as open trans-femoral exposure for the treatment of AAA, with a high technical success rate up to 95%.[7,8] In cases of failed percutaneous access, additional device usage or even transfemoral cut-down is needed to achieve a successful arteriotomy closure, but still the rate remains low.[4,5] During early post-operative follow-up, the re-admission rate for access complications after pEVAR is estimated at 4%. All re-admissions are due to access vessel stenosis or pseudoaneurysm formation.[9] In this study, the technical success rate was 92% (55/60). In 2 patients (4 CFAs), an open conversion was decided intra-operatively to achieve access because of the failure of the device to adequately inserted for different reasons, because of excessive BMI in one case and calcification along with tortuosity of the external iliac artery in the second case. One has to keep in mind that the Proglide® device is very smooth having also a significant length and so needs a quite healthy long segment in the distal external iliac artery for adequate placement. Additionally, CFA depth may hamper the insertion and suturing of the artery. Only in one case, there was a malposition of the Proglide® device during puncture, even if it was done under DUS guidance. In the remaining femoral artery, an additional 3rd device was used to achieve hemostasis. In this particular patient, we might have underestimated the atherosclerosis on the anterior wall of both femoral arteries, because of the very small BMI of the patient. In any case it is quite obvious that careful evaluation of the femoral arteries not only pre-operatively but also during the procedure is crucial for a successful p-EVAR.

Meta-analyses have shown that p-EVAR has a shorter procedural time and a lower complication rate than conventional exposure.[7,8] In the present analysis, the mean duration of op-

eration was estimated at 115min, which is highly acceptable. The reduction of post-operative in-hospital length of stay is established in many case series of percutaneous approach.[10,1110] The post-operative in-hospital stay was 1 day in this study. In terms of puncture site complications, it seems that p-EVAR is associated with a lower or at least equal site infection rate and reduced blood loss. [3,7,8,12,13] No infection was recorded during follow-up in this study while the mean blood transfusion was limited at 150cc. Furthermore, percutaneous approach as a primary access in EVAR seems to be technically beneficial in terms of re-intervention. As femoral artery stays intact after p-EVAR, an open transfemoral approach during a secondary operation would be easier and safer.

Furthermore, percutaneous approach offers a better quality of life in patients by reducing the peri-operative pain and the post-operative wound inflammatory reaction.[12] In our experience, there is no need for opioids post-operatively. Paracetamol on demand according to pain estimation was used for pain relief. Patients were allowed to walk since the day of operation, 6-8 hours after the accomplishment of the procedure, according to their general status. For the rest of site complications, there are controversial results comparing percutaneous and open access. [6,7,8] In a case study comparing TAVI and EVAR procedures, the use of percutaneous access with ProGlide® in AAA repair was associated with a higher bleeding and device failure rate than in aortic valve replacement, which looks quite strange having in mind the nature of these two different diseases.[14] This result may reflect different experience with closure devices between the two operative teams, as well as the different diameters of the devices used that are usually wider in the EVAR case.

Pre-operative assessment of the femoral bifurcation with ultrasonography has an important role in patients' selection and furthermore, a mandatory impact in reduction of systematic and site complications.[13,15] Factors independently associated with percutaneous access failure are femoral artery diameter, femoral artery stenosis>50% and emergent interventions.[1] The role of atherosclerosis, especially of an anterior plaque, may be dominant in the Perclose-Proglide® technique and is associated with a higher usage of additional closure devices.[6] A pre-operative DUS evaluation can identify all these risk factors, while predictive score systems are created in order to avoid technical failure.[1] On the other hand, the distance from the skin may not have an impact in puncture site outcome.[6] In obese patients, p-EVAR seems safe and feasible with a lower infection rate and a decrease in operative duration.[11] In this study, there was only one technical failure recorded in the group of patients with BMI>25 (overweight).

The low complication rate as well as the reduced post-operative length of stay may have a beneficial economic impact. Unfortunately, in our country there are not financial data to calculate the cost effectiveness of p-EVAR. Percutaneous aneurysm repair even though was associated with increased closure device cost, lead in reductions in procedural duration, hospitalization and complications and thus offset the additional device cost, confirming that p-EVAR may be a cost-effective option.[9,16] In Europe, financial data have shown that p-EVAR, even in cases of access failure where an additional device is needed, is a cost-effective technique with a low complication rate.[17] Future studies, and broader use of percutaneous approach in EVAR patients will lead to more objective outcomes.

Conclusion

Percutaneous US guided access using the Proglide® device was a safe and effective approach in many AAA patients treated with EVAR even at an initial experience level. Careful patient pre-operative evaluation and selection could lead in even better results in the future.

Disclosures: None

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REFERENCES

1 Liang P, O'Donnell T, Swerdlow NJ, Li C, Lee A, Wyers M, et al. Preoperative risk score for access site failure in ultrasound-guided percutaneous aortic procedures. J Vasc Surg. 2019;70:1254-62

2 Rajasinghe HA, Miller LE, Krajcer Z. Early Outcomes with Fast-track EVAR in Teaching and Nonteaching Hospitals. Ann Vasc Surg. 2018;49:134-43

3 Vierhout BP, Pol RA, El Moumni R, Zeebregts JC. Arteriotomy Closure Devices in EVAR, TEVAR, and TAVR: A Systematic Review and Meta-analysis of Randomised Clinical Trials and Cohort Studies. Eur J Vasc Endovasc Surg, 2017;54:104-15

4 Agrusa C, Meltzer A, Schneider D, Connolly P. Safety and effectiveness of a "percutaneous first" approach to endovascular aortic aneurysm repair. Ann Vasc Surg. 2017;43:79-84

5 Moonen H, Koning OHJ, van den Haak RF, Verhoeven BAN, Hinnen JW, Short-term outcome and mid-term access site complications of the percutaneous approach to endovascular abdominal aortic aneurysm repair (PEVAR) after introduction in a vascular teaching hospital. Cardiovasc Interv Ther. 2019;34:226-33

6 Lin SY, Lyu SY, Su TW, Chu SY, Chen CM, Hung CF, et al. Predictive Factors for Additional ProGlide Deployment in Percutaneous Endovascular Aortic Repair. J Vasc Interv Radiol. 2017;28:570-5

7 Cao Z, Wu W, Zhao K, Zhao J, Yang Y, Jiang C, et al. Safety and Efficacy of Totally Percutaneous Access Compared With Open Femoral Exposure for Endovascular Aneurysm Repair: A Meta-analysis. J Endovasc Ther. 2017;24:246-53

8 Jackson A, Yeoh S, Clarke M. Totally percutaneous versus standard femoral artery access for elective bifurcated abdominal endovascular aneurysm repair. Cochrane Database Syst Rev. 2014 Feb 27;(2):CD010185

9 Lachat ML, Pecoraro F, Mayer D, Guillet C, Glenck M, Rancic Z, et al. Outpatient endovascular aortic aneurysm repair: experience in 100 consecutive patients. J Ann Surg. 2013;258:754-8

10 Gimzewska M, Jackson A, Yeoh S, Clarke M. Totally per-

cutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair. Cochrane Database Syst Rev. 2017 Feb 21;2:CD010185.

11 Chin JA, Skrip L, Sumpio BE, Cardella JA, Indes JE, Sarac TP, et al. Percutaneous endovascular aneurysm repair in morbidly obese patients. J Vasc Surg. 2017;65:643-50

12 Vierhout BP, Pol RA, Ott MA, Pierie MEN, van Andringa de Kempenaer TMG, Hissink RJ, et al. Randomized multicenter trial on percutaneous versus open access in endovascular aneurysm repair (PiERO). J Vasc Surg. 201;69:1429-36

13 Siracuse JJ, Farber A, Kalish JA, Jones DW, Rybin D, Doros G, et al. Comparison of access type on perioperative outcomes after endovascular aortic aneurysm repair. J Vasc Surg. 2018;68:91-9

14 Durmus G, Belen E, Bayyigit A, Can MM. Comparison of Complication and Success Rates of ProGlide Closure Device in Patients Undergoing TAVI and Endovascular Aneurysm Repair. Biomed Res Int. 2018 Aug 9;2018:2687862.

15 Vatakencherry G, Molloy C, Sheth N, Liao M, Lam CK. Percutaneous access planning, techniques and considerations for endovascular aortic repair (EVAR). Cardiovasc Diagn Ther. 2018;8:S184-S190

16 Roche-Nagle G, Hazel M, Rajan DK. Financial Impact of PEVAR Compared with Standard Endovascular Repair in Canadian Hospitals. Can Assoc Radiol J. 2018;69:215-9

17 Uhlmann ME, Walter C, Taher F, Plimon M, Falkensammer J, Assadian A. Successful percutaneous access for endovascular aneurysm repair is significantly cheaper than femoral cutdown in a prospective randomized trial. J Vasc Surg. 2018;68:384-91