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Optimizing Femoral Access In Evar: A Multi-Centric Comparison Of Percutaneous And Surgical Approaches In Elective And Urgent Settings

Short title: Femoral Access in EVAR: Percutaneous vs Surgical

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Key words: EVAR, common femoral artery, percutaneous puncture, surgical cut-down.

ABSTRACT

Objective: Endovascular aneurysm repair (EVAR) has become the preferred alternative to open repair (OR) for infrarenal abdominal aortic aneurysm (AAA), offering lower short-term mortality and morbidity. This study investigates the impact of percutaneous femoral access versus surgical cut-down in elective and urgent/emergent EVAR procedures.

Methods: A retrospective study was conducted on all femoral access procedure performed between 2015 and 2023 from two referral academic centers. Primary outcomes were technical success, access site complications, major adverse events (MAE) rates. Length of intensive care unit (ICU) stay, and hospital stay, bleeding requiring transfusion and wound infection rates were also collected. Moreover, anatomical and clinical factors potentially influencing the type of access were investigated.

Results: The study included 711 EVAR procedures and 1422 femoral access. One-hundred-two procedures (14.3%) were performed in an emergent/urgent setting. Percutaneous approach was performed in 636 (44.7%) cases, while surgical exposure was performed in 786 cases (55.3%). Percutaneous access was associated with lower rates of bleeding ($p<.001$), in-hospital mortality ($p<.001$), both in elective and urgent settings, as well as shorter hospital stays ($p<.001$) and less need for ICU ($p<.001$). Age ($p<.001$), Body Mass Index ($p<.001$), and sheath size (Fr > 16) ($p<.001$) were factors that influenced the choice of percutaneous or surgical approach, both in univariate and multivariate analysis.

Conclusions: the present study suggests that percutaneous approach achieves better short-term outcomes compared to surgical cut-down. However, these findings should be interpreted in light of the study's limitations, including its retrospective design and potential selection

bias in access type allocation. Moreover, the success of percutanous technique remains highly dependent on operator expertise and anatomical challenges. Therefore, the choice of approach should always be tailored for each patient.

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1.1 INTRODUCTION

Endovascular aneurysm repair (EVAR) has become a valid alternative to open repair (OR) for the treatment of infrarenal abdominal aortic aneurysm (AAA), accounting for more than 75% of AAA elective repairs annually performed, as it is associated with lower 30-day mortality and morbidity and faster discharge[1,2,3].

EVAR procedure requires a bilateral common femoral artery (CFA) access, classically performed via surgical exposure . Nevertheless, the latter technique is reported to be relatively time-consuming, and it is associated with a not negligible rate of wound complications, particularly in emergency settings, where the time-sensitive nature of the procedure and the hemodynamic instability of patients can adversely affect the outcomes [5,6,7].

In recent years, percutaneous techniques have been widely used and refined, allowing the placement of endograft sheath after delivering a suture-mediated closure device, with a technical success of 71 to 98 % [8,9]. The 2022 American Heart Association Aortic Guidelines now recommend percutaneous femoral access and closure over open surgical cut-down for endovascular aortic repair, reflecting the growing evidence supporting its safety and effectiveness[10] .

However, a recent systematic review, reported little to no difference in mortality, wound infection and major complications occurrences between percutaneous and surgical cut down

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approach[11] . In common clinical practice, the decision between the two techniques relies on surgeon's experience and preference [12].

Real-world evidence on femoral access strategies in EVAR is still limited, particularly in urgent settings, despite meta-analyses showing comparable outcomes.This study aims to fill this gap by comparing these two procedures and evaluating their respective benefits and drawbacks in both elective and emergency settings.

1.2 METHODS

A multicenter retrospective observational cohort study was conducted in two high-volume academic centers, collecting and analysing data from all patients who underwent standard EVAR between 2015 and 2023, in either an elective or urgent/emergency setting.

Urgent/emergent cases were defined as EVAR procedures performed for symptomatic abdominal aortic aneurysms (e.g., pain or tenderness) or in the presence of contained or free rupture, as confirmed by clinical evaluation and imaging.

Patients undergoing elective EVAR were selected in accordance with the progressive updates of national and international guidelines on abdominal aortic aneurysm repair during the study period12 Exclusion criteria included cases of EVAR performed outside the device's instruction for use (IFU), lacking postoperative computed tomographic angiography (CTA), and history of previous percutaneous or surgical femoral access, regardless of complications. All consecutive patients meeting these inclusion criteria during the study period were included.

Prior to EVAR, all patients underwent an extensive assessment, including clinical history reporting, physical examination and laboratory testing [13].

Patients also underwent CTA of the entire thoracic and abdominal aorta to evaluate the presence of other aortic lesions and to determine the feasibility of EVAR. All measurements were performed using a dedicated software (Horos v4.0.0 RC open-source software; https://horosproject.org/#content-1). Post-analysis included 3-dimensional volume rendering, preoperative simulated angiography, and multiplanar reconstruction [14].

EVAR procedures were all performed with commercially available devices according with their IFU. Endograft selection, type of anesthesia, surgical or percutaneous access, and necessity for adjunctive intraoperative procedures, type of anesthesia and the choice of femoral access (surgical or percutaneous) was based on patients' clinical and anatomical characteristics, and operators' preference and experience [12,15,16]. All cases in which specific features of the CFA prevented the selection of percutaneous access, due to the necessity for additional procedures such as CFA endarterectomy, were excluded from the study.

The surgical access was performed by a longitudinal incision at the groin, according to the previously described "Surgiclose technique" , and the vessel was punctured in the middle of the purse-string suture according to "Seldinger" technique [17,18] .

Percutaneous femoral punctures were performed under ultrasound guidance and suture-mediated closure devices were positioned according to the "Preclose technique" [19]. Two suture-mediated closure devices were used, and at the end of the procedure the arteriotomy was closed by pulling and pushing down the preformed slipknot. Surgical conversion was indicated when bleeding control was not achieved after the third device deployment, in case of arterial occlusion or narrowing dissection following the device deployment, and in the event of distal embolization.

Following the surgical procedure, a physical examination was performed to assess the consistency of distal pulses (posterior tibial and dorsalis pedis) with their preoperative status and to detect any signs of acute ischemia, such as hypothermia or pallor, allowing early

identification of potential complications related to percutaneous access. In cases where distal pulses differed from preoperative findings, a duplex ultrasound (DUS) was performed to investigate possible iatrogenic vascular injury.

In both centers, EVAR follow-up protocol included physical examination, DUS, and CTA at 30 days after the procedure.

Study outcomes were technical success, access site complications, major adverse events (MAE) rates, evaluated during hospitalization and at 30 days follow-up. Length of intensive care unit (ICU) stay, and hospital stay, bleeding requiring transfusion (type 3a bleeding following Bleeding Academic Research Consortium [20]) and wound infection rates were also collected. MAE included death, re-interventions, acute kidney injury and myocardial infarction. Technical success was defined, as correct graft from a remote site with a secure proximal and distal fixation, with aneurysm exclusion confirmed by intraoperative angiography, no signs of type I or III endoleak, or conversion to open surgery and absence of significant twist, kinks, or obstruction (>30% luminal stenosis or a pressure gradient >10 mm Hg) by intraoperative measurements, in accordance with Society of Vascular Surgery reporting standard for aortic aneurysm repair [21] .

Patients' demographics characteristics, type of endograft, endograft sheath size, type of femoral access, type of anesthesia, need of blood transfusions, access site complications, major adverse events and length of hospital stay were collected. Endograft sheath size was categorized as ≤16 Fr or >16 Fr, based on prior literature showing that closure devices, particularly the ProGlide® system (Abbott Vascular, Redwood City, CA, USA), carry a higher risk of peri-procedural failure when the French size exceeds 16 [22] .

Since often EVAR procedure required bilateral femoral access, and the choice of percutaneous or surgical approach was independently made for each groin based on anatomical and clinical considerations, the unit of analysis was the individual femoral access

site, not the patient. In some cases, a hybrid approach was used, with percutaneous access on one side and surgical cut-down on the contralateral side.

Demographic and clinical data were displayed as mean (±standard deviation) for normally distributed data, as median (25th to 75th percentile) for non-parametric data, and as frequencies (percentages) for the categorical data. The distribution of continuous data was tested using Kolmogorov-Smirnov tests. Categorical data were compared using Fisher exact test and continuous variables were compared using independent sample T-test or Mann-Whitney U test. Multivariate analysis was performed using binary logistic regression to identify independent factors associated with the choice of femoral access (percutaneous vs surgical). All variables included in the model were dichotomous. Only variables that showed statistical significance ($p < 0.05$) in univariate analysis were entered into the multivariate model. Results were expressed as odds ratios (OR) with 95% confidence intervals (CI).All statistical analyses were performed using SPSS, version 27.0 (IBM Corp, Armonk, NY, USA, 2020)

This study was performed in agreement with the Declaration of Helsinki and the STROBE guidelines for observational studies. All patients enrolled in this study gave their informed written consent to be submitted for intervention and to be included in the present analysis.

1.3 RESULTS

The present study included 711 EVAR procedures and 1422 femoral access. One-hundred-two procedures (14.3%) were performed in an emergent/urgent setting.

Six-hundred-thirty-nine (89.9%) patients were male, with a mean age of 74.2 ±7.7 years. Details of further clinical and demographic factors are depicted in Table I.

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Mean AAA diameter was 58.1±13.9mm), and a concomitant iliac artery aneurysm was present in 152 (21.3%) cases.

Percutaneous approach was performed in 636 (44.7%) femoral accesses, while surgical exposure was performed in 786 cases (55.3%). Local anaesthesia was performed in 50.6% (360) of EVAR procedures.

According to the study protocol, all enrolled procedures were performed based on implanted devices IFU; details of implanted endograft are reported in Table II.

In 1154 (81.1%) of performed arterial accesses, a sheath greater or equal to 16Fr was employed.

Technical success was achieved in 99.7% of femoral access; 4 reported failures were due to intraoperative high-flow type Ia endoleak left untreated. Intensive Care Unit stay was required for 271 (38.1%) patients, with a mean time of 26.2 ±62.5 hours. Mean postoperative hospital stay was 4.5±4.6 days (0-48).

Specifically concerning the type of performed femoral access, covariates entered into the univariate analysis included sex, age, kidney disease, BMI, dyslipidemia, iliac involvement, sheath size and procedure urgency (Table III).

Variables with $p < 0.05$ (age, BMI, Dyslipidemia, Fr, emergency/urgency setting) were included in the multivariate model. The present data show that age >65 years, Fr > 16 and dyslipidaemia were associated with open femoral exposure, while BMI was associated with percutaneous access, both at univariate (Table III) and multivariate analysis (Table IV). Between 2015 and 2023, the proportion of percutaneous approaches ranged from 60% in 2015 to 31.7% in 2019, and subsequently stabilized at around 40% in the following years..

Percutaneous access was significantly associated with a shorter post-operative stay (4.4 ± 4.4 vs 4.7±4.8 days, $p <.001$) and less need for ICU compared to surgical cut down ($p <.001$).

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198 Additionally, patients who underwent percutaneous access had significantly lower rates of
199 bleeding requiring transfusion ($p < .001$, OR: 0.13 , CI: 0.1-0.2) and in-hospital mortality ($p <$
200 .001, OR: 0.05, CI: 0.01-0.2) compared to those treated via surgical access. Despite being
201 rare in both groups, percutaneous access was associated with a lower risk of wound infection
202 at one month ($p = .05$, OR 0.16, CI: 0.03-0.71). MAE during hospitalization occurred in 15
203 cases (2.3%) following percutaneous access, 6 of which were iatrogenic femoral
204 pseudoaneurysms requiring thrombin injection or surgical repair, and in 26 cases (3.3%) after
205 CFA surgical cut-down. At one month, 7 MAE (1.1%) were recorded in the percutaneous
206 group, including 1 iatrogenic pseudoaneurysm, and 19 MAE (2.4%) occurred in the surgical
207 cut-down group, with no statistically significant difference between the two approaches.
208 More details are shown in Table 5.
209 In urgent/emergent cases, patients undergoing percutaneous access had significantly lower
210 rates of bleeding requiring transfusion ($p < .001$, OR: 0.04, CI: 0.15-0.83), major
211 complications ($p = .003$, OR 0.09, CI:0.11-0.64), and in-hospital mortality ($p < .001$,
212 OR:0.66, CI: 0.15-0.29) compared to surgical access (Table 6).
213
214 **1.4 DISCUSSION:**
215 Our study suggests that percutaneous access is significantly associated with lower rates of
216 wound infections, major complications, and short-term mortality compared to surgical cut-
217 down in elective and urgent/emergent settings. Without compromising the immediate
218 technical success of EVAR, percutaneous access was also linked to a reduced need for ICU
219 admission and a shorter hospital stay.
220 These findings diverge from a recent Cochrane review, which reported a little to no
221 difference between the two access approaches regarding short-term outcomes[11] and agree
222 with other research, where the Preclose technique for percutaneous access demonstrated s

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higher technical success and low complication rates compared to femoral cut [8]. Additionally, given the consistent frequency of reintervention after EVAR, the avoidance of femoral exposure can decrease the risk of inguinal complications in a scarred groin [23] . However, it is worth considering that the inclusion of urgent cases and larger sheat sizes in our cohort my explain the differences observed with the results of the Cochrane review. The present outcomes may reflect operator expertise in high-volume centers, limiting generalizability for low-volume settings.

The strength of the present study lies in the large number of femoral access procedures conducted at two high-volume referral centers, as well as the exploration of factors that may influence the operator's choice of access method.

Regarding the choice of the type of approach, advanced age, sheath size >16 Fr, and urgent/emergency settings were factors driving toward surgical cut-down, while patients with BMI >30 were preferably treated with percutaneous puncture.

Speculatively, older patients are more prone to present severe femoral artery calcification, which may reduce the effectiveness of suture-based devices and lead operators to prefer surgical artery exposure. Anterior plaque or circumferential calcification may be a major determinant of failure [24] , as well iliac tortuosity, previous groin scar, and femoral artery occlusion [25] , all features that are typically found in advanced-age patients.

A recent meta-analysis demonstrated better results in percutaneous closure devices when EVAR was performed with <18Fr sheath [26]. Therefore, in cases requiring larger-profile sheaths, femoral artery cut-down remains the preferred approach, as supported by our findings.

Over the study period, the proportion of percutaneous femoral access initially declined and later stabilized at around 40%, a trend that likely reflects the increasing anatomical complexity of patients referred for EVAR in recent years.

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As previously mentioned, the short-term outcomes of percutaneous access in the present study were superior to those of surgical cut-down. However, the limits of these conclusions lay in the retrospective nature of this research. The two selected groups of patients who underwent percutaneous or surgical cut-down access were undoubtedly different, and the clinical and anatomical factors presented above may have influenced the choice of the approach, as well as the outcomes. Additionally certain factors, such as limited operator experience, may hinder the outcomes, especially the incidence of pseudoaneurysms [27]. Conversely, some authors reported comparable wound complication rates between percutaneous access and surgical cut-down [28,29].

As reported by previous studies, up to 17.4% of patients undergoing EVAR needs a common femoral artery reconstruction, in mostly of the cases unplanned [30] . Surgical cut-down of "hostile" CFA not only prevents complications linked to percutaneous puncture, but in selected cases, allows to perform adjunctive surgical procedures, such as CFA endarterectomy, that improve limb vascularization [31] .

Moreover, the success of percutaneous common femoral artery punctures is highly dependent on the use of ultrasound guidance, which enables precise localization of the puncture site and offers valuable anatomical informations [32] .

Additionally, the results of this study come from two academic University Hospitals, where, in an elective setting, femoral artery isolation represents a crucial opportunity for residents to develop their arterial dissection and repair skills. As isolating the femoral tripod under the supervision of a tutor is one of the first technical skills acquired and serves as a valuable learning experience, the duration of the procedure may inherently extend, as well as the technical complexity [33] . This practice, however, reflects an institution-specific educational preference and may not be representative of the broader endovascular community, where percutaneous access is often adopted as the preferred approach

This study in not free from limitations. First, as previously reported, the retrospective nature of the study carries an inherent risk of bias. Second, the number of complications related to the two presented procedures was relatively low, potentially influencing the statistical power of the analyses. Third, the present study lacks of stratified data regarding bilateral versus mixed femoral access per patient. Since some patients may have received a combination of percutaneous and surgical approaches, the per-groin analysis does not considers the potential interactions or cumulative effects at the patient level. Future studies should include this distinction to assess the impact of unilateral versus bilateral access strategies on patient outcomes. Additionally, the study was conducted in two high-volume tertiary referral centers, which may limit the generalizability of the findings to lower-volume institutions with different procedural expertise and patient populations. Lastly, although multivariate regression was used to adjust for key confounders, a propensity score matching approach could have allowed a more balanced comparison between access types. A possible confounder to acknowledge is the absence of consistent data on prior femoral surgical procedures, such as endarterectomy or femoral–popliteal/tibial bypass. Given that previous femoral interventions may strongly influence the feasibility of percutaneous access, this unmeasured factor may have introduced residual confounding in the present comparison.

1.5 CONCLUSION:

In conclusion, our study suggests that percutaneous access offers significant benefits over surgical cut-down, including lower complication rates and shorter hospital stays. However, the success of percutaneous access is highly operator-dependent and may be limited by challenging anatomical conditions. Moreover, patient selection and anatomical factors remain crucial in determining the most suitable approach. Given the retrospective nature of this

study, prospective randomized studies are needed to validate these findings and establish standardized criteria for selecting femoral access in EVAR.

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Table 1 Clinical characteristics of the cohort of present study (n = 711)

	N (%)
Sex – male	639 (90)
Age – in years – Mean (SD)	74 (7)
CKD	106 (15)
CAD	253 (36)
DM	148 (21)
HTN	582 (82)
COPD	251 (35)
Smoking	357 (50)
BMI >30 – kg/m^2	169 (24)
Dyslipidemia	423 (59)
stroke/TIA	56 (8)

* *CKD* Chronic kidney disease, *CAD* Coronary artery disease, *DM* Diabetes mellitus, *HTN* Hypertension, *COPD* Chronic obstructive pulmonary disease, *BMI* Body mass index, TIA Transitory ischemic attack.

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Table 2. Details of implanted endografts of the present series.

	N (%)
AFX/AFX2 (n;%)	97 (13.6)
Anaconda (n;%)	2 (0.3)
Aorfix (n;%)	4 (0.6)
Excluder/C3/Conformable (n;%)	261 (36.8)
Endurant I/II/Iis (n;%)	197 (27.7)
Incraft	6 (0.9)
Nellix (n;%)	31 (4.3)
Prime/iX/Alto (n;%)	50 (7)
Treo (n;%)	30 (4.2)
Zenith (n;%)	33 (4.6)

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Table 3 Univariate analysis of factors potentially condinctioning the choice on the type of access.

	Total (n=1422)	**Percutaneous access (n=636)**	**Surgical access (n = 786)**	**OR**	***P* value**
Sex (male)	1278 (89.9)	569 (89.4)	709(90.2)	0.92(CI: 0.65 -1.30)	.66
Age > 65aa	1218 (85.7)	519 (81.6)	699 (88.9)	0.57 (CI: 0.41-0.74)	<.001
Kidney disease	212 (14.9)	91 (14.4)	121 (16.1)	0.87 (CI: 0.65-1.18)	.21
BMI>30	338 (23.8)	186 (29.4)	152 (20.2)	1.65 (CI: 1.29-2.11)	<.001
Dyslipidemia	1160 (81.6)	481 (75.6)	679 (86.4)	1.99 (CI: 1.59-2.48)	<.001
Iliac involvement	304 (21.4)	139 (22.1)	165 (21.8)	1.02 (CI: 0.79-1.02)	.47
Fr >16	846 (59.5)	405 (53.7)	441 (69.8)	.59 (CI: 0.37-0.64)	<.001
Emergency/urgency	204 (14.3)	69 (10.8)	135 (17.2)	.59 (CI:.0.43-0.80)	<.001

Fr French, *N* number, *OR* odds ratio

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Table 4 Multivariate analysis of factors potentially conditioning the choice on the type of access.

	Total (n=1422)	**Percutaneous access (n=636)**	**Surgical access (n = 786)**	**OR**	***P* value**
Age > 65 years	1218 (85.7)	519 (81.6)	699 (88.9)	0.85 (CI: 0.83-0.87)	<.001
BMI >30	338 (23.8)	186 (29.4)	152 (20.2)	0.25 (CI: 0.22-0.27)	<.001
Dyslipidemia	1160 (81.6)	481 (75.6)	679 (86.4)	0.62(CI: 0.59-0.64)	<.001
Fr >16	846 (59.5)	405 (53.7)	441 (69.8)	0.80 (CI: 0.78-0.83)	<.001
Emergency/urgency	204 (14.3)	69 (10.8)	135 (17.2)	0.14 (CI:0.11-0.16)	.055

Fr French, *N* number, *OR* odds ratio

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Table 5 Outcomes during hospitalization and at the first month of follow-up broken down by type of access in the present series.

	Total (n=1422)	**Percutaneous access (n=636)**	**Surgical access (n = 786)**	**OR**	***P* value**
Bleeding requiring transfusion	160 (11.3)	18 (2.8)	142(18.1)	0.13(CI: 0.1 - 0.2)	<.001
Wound infection	3 (0.2)	0 (0)	3 (0.4)	NA	.11
MAE	41 (2.9)	15 (2.3)	26 (3.3)	0.70 (CI: 0.4-1.3)	.28
Death within discharge	47 (3.3)	2 (0.3)	45 (5.7)	0.05 (CI: 0.01 – 0.2)	<.001
1 Month Death	1 (0.1)	0 (0)	1 (0.1)	NA	.36
1 Month Wound Infection	17 (1.2)	2 (0.3)	15 (1.9)	0.16(CI: 0.03-0.71)	0.05
1 Month MAE	26 (1.8)	7 (1.1)	19 (2.4)	0.44 (CI: 0.18-1.07)	0.06

N number, *OR* odds ratio, *MAE* major adverse event

* Death within discharge" refers to in-hospital mortality, regardless of the number of days from the procedure. "1 Month Death" refers to all-cause mortality occurring within 30 days from the intervention.

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Table 6 Outcomes during hospitalization and at the first month of follow-up broken down by type of access in emergent/urgent cases. (N=204)

	Total (n=1422)	**Percutaneous access (n=69)**	**Surgical access (n = 135)**	**OR**	***P* value**
Bleeding requiring transfusion	114 (55.9)	8 (11.6)	106 (78.5)	0.04 (CI: 0.15-0.83)	<.001
Wound infection	2 (1.0)	0 (0)	2 (1.5)	NA	.55
MAE	21 (10.3)	1 (1.4)	20 (14.8)	0.09 (CI: 0.11-0.64)	.003
Death within discharge	44 (21.6)	2 (2.9)	42 (31.3)	0.66 (CI: 0.15-0.29)	<.001
1 Month Death	0 (0)	0 (0)	0 (0)	NA	NA
1 Month Wound Infection	0 (0)	0 (0)	0 (0)	NA	NA
1 Month MAE	1 (0.5)	1 (1.4)	0 (0)	NA	.34

N number, *OR* odds ratio; *MAE* major adverse event; *NA* not available

* Death within discharge" refers to in-hospital mortality, regardless of the number of days from the procedure. "1 Month Death" refers to all-cause mortality occurring within 30 days from the intervention.

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Highlihts:

- Comparable technical success between percutaneous and surgical access
- Percutaneous femoral access reduces bleeding and hospital stay in EVAR
- Age, BMI, and sheath size influence femoral access choice
- Choice of approach must be tailored to operator skill and patient anatomy

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