Comparison of percutaneous and cutdown access-related minor complications after endovascular aortic repair

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Abstract. The aim of the present study was to compare the open surgical and percutaneous access for thoracic/endovascular aortic repair (T/EVAR) regarding in-hospital and post-hospital minor-complications. Percutaneous (pEVAR) and cutdown (cEVAR) techniques for femoral vessel access for T/EVAR were compared regarding their minor complications. The basic population of this retrospective cohort study consisted of 44 percutaneous and 215 cutdown accesses for endovascular aortic repair (T/EVAR-procedure) conducted between August 2008 and October 2019. The primary outcome consisted of conservatively treatable minor complications until hospital discharge and during follow up. Secondary outcomes comprised postoperative pain and complications requiring invasive treatment. Minor complications were observed in 11.4% (pEVAR) vs. 9% (cEVAR) of cases throughout index hospital stay and 10 vs. 13.7% during follow-up. No significant differences were noticed regarding overall complication rate between pEVAR and cEVAR. Only bleedings treatable through compression occurred significantly more often in the pEVAR-group (6.8 vs. 0.5%; P=0.02). In conclusions, the percutaneous technique represents a safe and quickly executable alternative to cutdown access. A significant difference in overall minor complications could not be observed. In both techniques, complications may occur even months after surgery. In order to demonstrate the superiority of the percutaneous technique compared with cutdown access, possible predictors for the use of the percutaneous technique should be defined in the future.

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Introduction

Treatment of aortic pathologies changed fundamentally during the last two decades: endovascular treatments and especially the use of stentgrafts have become more and more frequent (1). Treatment of the abdominal aorta is commonly referred to as endovascular aortic repair (EVAR), and that of the thoracic aorta as thoracic endovascular aortic repair (TEVAR) (1). With the establishment of thoracic/endovascular aortic repair (T/EVAR), during which stentgrafts are deployed minimally invasive through an arterial access vessel, risky open aortic repair (OAR) can mostly be circumvented. Potential benefits of T/EVAR vs. OAR include reduced perioperative and 1-year mortality, shortening of hospital stay and less periprocedural complications (2-5).

To establish large-bore vessel access in T/EVAR either classic cutdown or percutaneous technique may be performed. cEVAR consists of a skin incision and surgical preparation of the access vessel. In pEVAR, the access vessel is punctured through the skin. After puncture, a suture mediated closure device (SMCD) is used to prepare the sutures for closure of the puncture site (5). Commonly used SMCDs are the systems Perclose ProGlide or Prostar XL (both by Abbott Vascular) (6).

Both access techniques have been compared to a limited extent regarding different parameters (7). A meta-analysis from 2017 comparing both techniques analyzed two randomized controlled trials with 181 patients and suggested equivalence of pEVAR and cEVAR (7). Analyzed parameters included bleeding complications, wound infections and major vessel complications (7). Especially access-related major complications like thrombosis and access-vessel injury were rarely observed in both techniques throughout different studies (8,9).

Current evidence clearly shows a reduction of operation time in pEVAR (10-12). Also technical success rates of more than 90% imply good feasibility of the percutaneous technique (11,13,14). Achieving high success rates presupposes preoperative evaluation of the access vessel, usually the Common Femoral Artery (CFA). Particularly diameter, anterior calcification and possible kinking of the vessel are relevant (15,16). The impact of the CFA calcification level remains uncertain. Starnes *et al* (17) postulate safe feasibility of pEVAR even in calcified vessels, other studies suggest different results (18,19). Furthermore, routine ultrasound

guidance for pEVAR-access seems to reduce incidence of access-site complications, especially hematomas and injuries of the femoral nerve (20,21).

Complications of both techniques frequently have been recorded only for short term outcomes. A randomized controlled trial from 2019 shows no superiority for either approach with wound infection rates between 0 and 1.5% but a reduction of postoperative pain after pEVAR (22). Other studies also included access-related complications, however only until one month after surgery (11,13) or without comparing them to cEVAR (14,23). Nevertheless, overall acquired data shows a clear trend towards reduced access-related complication rates when using the percutaneous technique (9)

The aim of this study was to compare the incidence of short- and long-term minor complications after percutaneous and cutdown groin vessel access for T/EVAR. Because of several previous studies implying a rather low incidence of access-related major complications (8,9), those complications were not considered in the present study.

Materials and methods

Definitions. In this retrospective cohort study minor complications after groin vessel access were compared between pEVAR and cEVAR. As the term 'minor complication' is not subject to a specific definition it was defined as a conservatively treatable complication. In the 'Classification of Surgical Complications' by Dindo *et al* (24), this corresponds to severity degrees I and II. Thus, the following primary endpoints have been chosen: Secondary wound healing, wound infection, lymphocele, lymphorrhea, bleeding, hematoma, femoral neuropathy.

Every event chosen as a primary endpoint was defined to be conservatively treatable (e.g. through cooling and analgesia). Complications requiring invasive treatment, such as hematomas requiring surgical intervention, were not considered as primary endpoints. Bleeding was defined as a failure of vascular closure manageable by manual compression. Hematomas were defined as a collection of blood in the vessel access area. Femoral neuropathy was defined as sensomotoric symptoms relating to the femoral nerve caused by direct affection in the vessel access area. There were no events of neuropathy being generated by other complications such as retroperitoneal or intraspinal hematoma.

Complications were stratified into those occurring during the index hospital stay and early (0-1 months postoperative), medium (2-6 months postoperative) and late (>6 months postoperative) during follow-up, based on their first documentation.

Postoperative pain was chosen as a secondary endpoint. Patients were asked to assess their pain on a scale from 0 (no pain) to 10 (highest imaginable pain). Given that many of the patients were in the intensive care unit (ICU) on the first postoperative day, the second postoperative day was selected for recording of patients' pain level.

Additionally, the relatively frequent complications hematomata and lymphoceles requiring revision were defined as secondary endpoints.

Study design and population. This study retrospectively evaluates data from all patients who received a single T/EVAR at our institution between August 2008 and October 2019. The minimum follow-up of the latest included patients was three months.

Overall, 269 patients had an operation during the previously mentioned period. Out of this cohort, 110 patients were not eligible for this study. Exclusion criteria are displayed in Table I. Only two of the 12 exclusions because of periprocedural major complications were caused by access-related events (aneurysm of the CFA and bleeding from the access vessel requiring open patching).

Data of 159 patients with 259 femoral access sites were included in the study. Results were analyzed per patient (e.g. pain level) or per access site (e.g. complication), as appropriate. 47 percutaneous accesses were conducted initially, in which 3 needed conversions to cutdown due to technical failure. For vessel access in pEVAR, ultrasound guidance was not routinely used. For closure of the percutaneous vessel access site, SMCD's Perclose ProGlide, Prostar XL (both by Abbott Vascular) or AngioSeal (Terumo) were used. Technical failure of percutaneous access was caused by a failure of the SMCD's in all 3 cases. Thus 44 percutaneous and 215 cutdown accesses (31 patients vs. 128 patients) were included into the analysis of postoperative complications. The first eligible cEVAR patient underwent surgery in November 2008, the first included pEVAR patient was operated on in January 2017. Each involved surgeon had conducted at least 350 percutaneous accesses for different interventions before performing the first pEVAR.

Follow-Up at the study site is conducted regularly one, three and six months after surgery and from then on in an annual cycle. It includes clinical examination of the access site and a CT angiogram of the aorta, iliac arteries, and access vessels or, if contraindicated, ultrasound examination of the access vessels. 97 patients presented for follow-up. 30 percutaneous and 131 cutdown access sites (19 patients vs. 78 patients) were eligible for analysis of follow-up complications. The main reasons for follow-up interruptions were lack of understanding regarding the necessity of follow-up, unawareness of appointment schedule and follow-up performed in another hospital as we are a tertiary referral hospital. Table II gives an overview of included patients and access sites.

Statistical analysis. Data were retrospectively collected with Excel (Version 2019, Microsoft, Redmond) and analyzed using SPSS (Statistics subscription, Build 1.0.0.1347; IBM Corp.). For descriptive statistics, the absolute number and percentage or, if appropriate, mean value and standard deviation (MV ± SD) were reported. Nominal variables were compared by Fisher's exact test and an unpaired t-test was used for comparison of metric variables. Statistical significance was defined as $P<0.05$.

Ethical approval. The study was approved by the ethics committee of the University Hospital Halle (Saale), Germany (ID 2019-037).

Results

Baseline characteristics and comorbidities. Table III shows baseline characteristics and comorbidities of both groups. No significant differences occurred, the pEVAR- and cEVAR-group were well balanced. Regarding comorbidities,

Table I. Exclusion criteria.

Criteria	No. of patients (%)
Overall excluded cases	110 (41)
Missing/incomplete data	57 (21.4)
Concomitant open procedure[a]	7 (2.6)
Rare indication[b]	15 (5.5)
Major complication	12 (4.4)
Previous femoral access[c]	15 (5.5)
'Learning curve' for percutaneous technique[d]	4 (1.5)

[a]Simultaneous treatment of two aortic segments: One by T/EVAR, another one by open aortic repair. [b]Indication for T/EVAR in less than 5 patients each: Contains atherosclerosis of common iliac artery, iatrogenic damage, revision after therapy at other hospital, thrombus, malignoma and transection. [c]Previous large-bore access (e.g., for endovascular aortic valve replacement) led to exclusion, previous small-bore access up to 6 French (e.g., for coronary intervention) was not an exclusion criterion. [d]Quantifying the learning curve with percutaneous technique is discussed controversially in the literature: A study published in 2013 describes an amount of 30 cases to reach 90% technical success for the percutaneous technique (26). Nelson *et al* (11) assess this number critically because of the initially low success rate of 45% and suggest a far lower number of cases, whereas a third study highlights the importance of ultrasound guidance for achieving high technical success rates (19). As the involved surgeons had each conducted at least 350 percutaneous accesses for different interventions before performing the first percutaneous endovascular aortic repair, only the first 5 percutaneous T/EVAR-accesses (corresponds to n=4 patients) were excluded. T/EVAR, thoracic/endovascular aortic repair.

Table II. Number of included patients and access sites.

Analysis	pEVAR, n	cEVAR, n
Postoperative analysis		
Patients	31	128
Femoral access sites	44	215
Follow-Up analysis		
Patients	19	78
Femoral access sites	30	131

cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

hypertension occurred in a high number of patients in both cohorts (pEVAR: 87.1%, cEVAR, 75%).

Indications for surgery. Indications for T/EVAR included abdominal (AAA), thoracic (TAA) and thoracoabdominal aortic aneurysms (TAAA) as well as penetrating aortic ulcers (PAU) and aortic dissections (AD). For cEVAR, AAA-patients made up the largest part of the cohort (67.2%). This contrasts with the pEVAR-subgroup in which the proportion was minor with 32.3%. Emergency indication for surgery made up a remarkable part in both groups (pEVAR: 22.6%, cEVAR: 16%) (Table IV). However, no significant correlation between emergent procedures and complications could be observed in a subgroup analysis.

Perioperative parameters. Table V summarizes recorded perioperative parameters. Patients receiving pEVAR got local anesthesia in 64.5% of cases compared to 25% of patients in the cEVAR-group (P=<0.01). After cEVAR, a significantly more frequent use of local hemostyptic agents could be observed. Mean duration of surgery differed by 24.7 min in favor of pEVAR (79.7 min vs. 104.4 min, P=0.03).

Primary endpoints. Regarding minor complications until postoperative hospital discharge (Table VI) no significant overall difference could be observed between both techniques. The overall incidence of complications was at a similar level (11.4 vs. 9%, P=0.78). Only conservatively treatable bleedings occurred significantly more often after pEVAR (6.8 vs. <1%, P=0.02).

Likewise, complications recorded during follow-up (Table VII) had a similar incidence (10 vs. 13.7%, P=0.77) with no significant difference in any complication. Table VIII depicts temporal distribution of first appearance of follow-up complications. Persisting of complications was not registered.

Secondary endpoints. Regarding secondary endpoints, subjective pain levels were different among the two groups with mean values of 0.9 (pEVAR) and 1.3 (cEVAR) (P=0.02). Furthermore, hematomas needing invasive revision occurred significantly more often in the pEVAR-group (pEVAR: 4.5%, cEVAR: 1%, P=0.03) (Table IX).

Discussion

This study suggests equivalence of percutaneous and cutdown technique for vessel access in T/EVAR regarding minor complications after surgery. Neither postoperative nor follow-up complications occurred significantly more often overall. Nevertheless, the results of the study suggest that despite ongoing development of improved closure systems, the percutaneous access technique does not reach superiority over cutdown access concerning minor complications. Although several studies reported a reduction of single types of complications, a consistent benefit for patients did not become apparent (7-9).

In contrast to complication rates, clearer advantages of percutaneous technique emerged elsewhere: Besides a reduction in the duration of surgery, which was consistently observed in past research, also a significant reduction of postoperative pain is remarkable. Additionally, the possibility of a more frequent use of local compared to general anesthesia represents an important alternative for patients who are limited in undergoing intubation anesthesia because of their multimorbidity. Even though cutdown access is theoretically also possible in local anesthesia, especially for obese and non-compliant patients it is often not feasible.

As complications during follow-up emerge in approximately the same number of cases as during hospital stay, clinical examination of the access site should always be conducted and properly documented on follow-up appointments. Future

Table III. Baseline characteristics and comorbidities.

Variables	pEVAR (n=31 patients)	cEVAR (n=128 patients)	P-value
Female, n (%)	10 (32.3)	24 (19.0)	0.14[a]
Male, n (%)	21 (67.7)	104 (81.0)	
Age, years (MV ± SD)	71 (9.9)	71.6 (10.0)	0.91[b]
Hypertension, n (%)	27 (87.1)	96 (75.0)	0.23[a]
Diabetes Mellitus Type I, n (%)	1 (3.2)	2 (2.0)	0.48[a]
Diabetes Mellitus Type II, n (%)	5 (16.1)	21 (16.0)	0.19[a]
COPD, n (%)	7 (22.6)	21 (16.0)	0.44[a]
Marfan-Syndrome, N (%)	1 (3.2)	2 (2.0)	0.48[a]
BMI, kg/m2 (MV ± SD)	27.2 (4.9)	27.3 (5.1)	0.92[b]
ASA-levels 2 and 3, n (%)	26 (83.9)	96 (75.0)	0.47[a]
ASA-levels 4 and 5, n (%)	5 (16.1)	29 (23.0)	

[a]P-value determined by Fisher's exact test. [b]P-value determined by t-test. Results are presented as the absolute number (percentage of cohort patient number) unless indicated otherwise. MV ± SD, mean value ± standard deviation; COPD, chronic obstructive pulmonary disease; ASA, American Society of Anesthesiology; cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

Table IV. Indications for surgery.

Indications for surgery	pEVAR, n (%) (n=31 patients)	cEVAR, n (%) (n=128 patients)
AAA	10 (32.3)	86 (67.0)
TAA	6 (19.4)	3 (2.0)
TAAA	3 (9.7)	6 (5.0)
PAU	6 (19.4)	13 (10.0)
AD	6 (19.4)	20 (16.0)
Emergency	7 (22.6)	20 (16.0)

AAA, abdominal aortic aneurysm; TAA, thoracic aortic aneurysm; TAAA, thoracoabdominal aortic aneurysm; PAU, penetrating aortic ulcers; AD, aortic dissection; cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

Table V. Perioperative parameters.

Parameters	pEVAR (n=31 patients)	cEVAR (n=128 patients)	P-value
Local anesthesia[a], n (%)	20 (64.5)	32 (25.0)	<0.01[c]
Use of hemostyptic agents[b], n (%)	1 (3.2)	52 (41.0)	<0.01[c]
Duration of surgery, min (MV ± SD)	79.7±59.1	104.4±53.9	0.03[d]
Blood transfusion (red cell concentrates), n (%)	1 (3.2)	4 (3.0)	0.42[c]
ICU stay, days (MV ± SD)	1.4±1.5	1.3±1.2	0.83[d]
Hospital stay, days (MV ± SD)	8.7±6.9	7.9±4.8	0.56[d]
Start of physiotherapy, days (MV ± SD)	1.9±1.4	2.1±2.3	0.59[d]

[a]Without additional sedation. [b]Includes hemostyptic products Tabotamp (Johnson & Johnson), Tachosil (Takeda Pharmaceutical Company, Ltd.) and Cellistypt (B. Braun Melsungen AG). [c]P-value determined by Fisher's exact test. [d]P-value determined by t-test. Results are presented as the absolute number (percentage of cohort patient number) unless indicated otherwise. ICU, intensive care unit; MV ± SD, mean value ± standard deviation; cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

studies might quantify the period in which access-related complications might be able to appear after T/EVAR.

Besides the retrospective design implying possible selection bias regarding the chosen technique for vessel access, the limitations of this study include a low cohort size mainly in the pEVAR group. The main reason for this lies in incompletely accessible data especially from older cases. Moreover, the fact that ultrasound guidance was not routinely used for

Table VI. Primary endpoints until hospital discharge.

Complication	pEVAR, n (%) (n=44 access sites)	cEVAR, n (%) (n=215 access sites)	P-value[a]
Secondary wound healing	0	5 (2.0)	0.59
Wound infection	0	1 (<1)	>0.99
Lymphocele	0	0	-
Lymphorrhea	0	6 (3.0)	0.59
Bleeding	3 (6.8)	1 (<1)	0.02
Hematoma	1 (2.3)	5 (2.0)	>0.99
Femoral neuropathy	1 (2.3)	2 (1.0)	0.43
Overall	5 (11.4)	20 (9.0)	0.78

[a]P-value determined by Fisher's exact test. Results are presented as the absolute number of events (percentage of cohort groin access number). cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

Table VII. Primary endpoints during follow-up.

Complication	pEVAR (n=30 access sites)	cEVAR (n=131 access sites)	P-value[a]
Secondary wound healing, n (%)	0	3 (2.0)	>0.99
Wound infection, n (%)	0	5 (4.0)	0.56
Lymphocele, n (%)	1 (3.3)	2 (2.0)	0.46
Lymphorrhea, n (%)	0	4 (3.0)	>0.99
Hematoma, n (%)	1 (3.3)	0	0.19
Femoral neuropathy, n (%)	1 (3.3)	4 (3.0)	>0.99
Overall, n (%) (mean ± SD)	3 (10) (2.3±1.2)	18 (13.7) (4.3±4.6)	0.77

[a]P-value determined by Fisher's exact test. Results are presented as the absolute number of events (percentage of cohort groin access number) or as absolute number of events (percentage of cohort groin access number) (mean value ± standard deviation of months after surgery until first documentation of complication). cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

Table VIII. Time of first documentation of complications during follow-up.

Months after surgery	pEVAR, n (%) (n=3 complications)	cEVAR, n (%) (n=18 complications)
Early (0-1 months)	1 (33.3)	4 (22.2)
Medium (2-6 months)	2 (66.6)	10 (55.5)
Late (>6 months)	0 (0.0)	4 (22.2)

cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

Table IX. Secondary endpoints.

Secondary endpoints	pEVAR	cEVAR	P-value[a]
Complications until hospital discharge	n=44 access sites	n=215 access sites	
Pain level (MV ± SD)	0.9±1.0	1.3±0.9	0.02
Hematoma requiring invasive therapy, n (%)	2 (4.5)	3 (1.0)	0.03
Lymphocele requiring invasive therapy, n (%)	0	0	-
Complications during follow-up	n=30 access sites	n=131 access sites	
Hematoma requiring invasive therapy, n (%)	0	0	-
Lymphocele requiring invasive therapy, n (%)	0	3 (2.0)	>0.99

[a]P-value determined by t-test (pain level) and Fisher's exact test (hematoma and lymphocele). Results are presented as the absolute number of events (percentage of cohort groin access number) or as the MV ± SD. MV ± SD, mean value ± standard deviation; cEVAR, cutdown endovascular aortic repair; pEVAR, percutaneous endovascular aortic repair.

vessel access in pEVAR might have had a negative impact on the technical success and complication rates of this subgroup. Lastly, albeit excluding the first five percutaneous accesses to account for possible effects of a learning curve, a lack of experience of the operating surgeons with pT/EVAR might have had a negative impact on the results observed for the technique (25). Further prospective studies are needed to identify which group of patients who may profit from each technique.

As of today, the individual surgeon's decision regarding the vessel access technique is mainly based on own preference and expected technical success. The current German guidelines for treatment of AAA suggest only the degree of calcification of the access vessel and the respective surgeon's experience as factors for the decision (26). Prospectively, this decision process should be complemented by evidence-based data for complication rate of access techniques and the related improvement of patient's quality of life. Factors which are associated with percutaneous access with few complications and high technical success should be investigated and defined in the future. By doing so, the technique for vessel access that potentially achieves the best outcome could be chosen more individually.

In conclusion, the percutaneous technique for vessel access in T/EVAR proved to be a safe and quickly executable alternative to cutdown vessel access. No technique reached superiority in terms of minor complications. For patients being dependent on or wishing for local anesthesia for T/EVAR, the percutaneous technique should be the first choice for groin access if anatomical suitability is given. A thorough clinical examination of the groin access site should not be neglected during follow-up as access-related complications might appear even months after surgery. Future studies and guidelines should aim for investigation and definition of more precise criteria for selection of the individually best fitting access technique.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

JU, UR and AR were involved in the conceptualization of the study. CS was involved in the study methodology and in the provision of software. JU and UR were involved in data validation. CS and PV were involved in formal analysis. JU, AR, UR and PV were involved in the investigative aspects of the study, as well as in data curation, study supervision and project administration. AR, PV and UR were involved in the provision of resources, in the writing of the original draft, in the reviewing and editing of the manuscript. AR, PV, CS, UR and JU confirm the authenticity of all the raw data and all authors have read and approved the final manuscript.

Ethics approval and consent to participate

This study retrospectively evaluates data from all patients who received a single T/EVAR at our institution between August 2008 and October 2019. Ethical approval for this study was gained from the ethics committee of the University Hospital Halle (Saale) [Halle (Saale), Germany; ID 2019-037]. As all data were processed anonymously, no patient consent was required by the ethics committee.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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