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<Short title>International Registry of Open Surgical vs. Upper Extremity Access in Endovascular Aortic Procedures

Multicentre International Registry of Open Surgical *Versus* Percutaneous Upper Extremity Access During Endovascular Aortic Procedures

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WHAT THIS PAPER ADDS

Data on upper extremity access (UEA) related complications during complex endovascular aortic repair is lacking, with significant variation in reporting standards and no large comparative studies evaluating open surgical and percutaneous access techniques. This study analysed 1 098 patients enrolled in a multicentre international registry, and identified access failure and stroke rates of 6.8% and 3.0%, respectively. There is equivalence in complication rates between the percutaneous and open surgical upper extremity approaches. These data support a more limited use of UEA favouring transfemoral approach with steerable sheaths whenever possible.

Objective: To investigate access failure (AF) and stroke rates of aortic procedures performed with upper extremity access (UEA), and compare results of open surgical *vs.* percutaneous UEA techniques with closure devices.

Methods: A physician initiated, multicentre, ambispective, observational registry (SUPERAXA - NCT04589962) was carried out of patients undergoing aortic procedures requiring UEA, including transcatheter aortic valve replacement, aortic arch, and thoraco-abdominal aortic endovascular repair, pararenal parallel grafts, renovisceral and iliac vessels repair. Only vascular procedures performed with an open surgical or percutaneous (with a suture mediated vessel closure device) UEA were analysed. Risk factors and endpoints were classified according to the Society for Vascular Surgery and VARC-3 (Valve Academic Research Consortium) reporting standards. A logistic regression model was used to identify AF and stroke risk predictors, and propensity matching was employed to compare the UEA closure techniques.

Results: Sixteen centres registered 1 098 patients (806 men [73.4%]; median age 74 years, interquartile range 69 – 79 years) undergoing vascular procedures using open surgical (76%) or percutaneous (24%) UEA. Overall AF and stroke rates were 6.8% and 3.0%, respectively. Independent predictors of AF by multivariable analysis included pacemaker ipsilateral to the access (odds ratio [OR] 3.8, 95% confidence interval [CI] 1.2 – 12.1; p = .026), branched/fenestrated procedure (OR 3.4, 95% CI 1.2 – 9.6; p = .019) and introducer internal diameter ≥ 14 F (OR 6.6, 95% CI 2.1 – 20.7; p = .001). Stroke was associated with female sex (OR 3.4, 95% CI 1.3 – 9.0; p = .013), vessel diameter > 7 mm (OR 3.9, 95% CI 1.1 – 13.8; p = .037), and aortic arch procedure (OR 7.3, 95% CI 1.7 – 31.1; p = .007). After 1:1

propensity matching, there was no difference between open surgical and percutaneous cohorts. However, a statistically significantly higher number of endovascular adjunctive procedures were recorded in the percutaneous cohort ($p < .001$).

Conclusions: AF and stroke rates during complex aortic procedures employing UEA are non-negligible. Therefore, selective use of UEA is warranted. Percutaneous access with vessel closure devices is associated with similar complication rates, but more adjunctive endovascular procedures are required to avoid surgical exposure.

Keywords: Fenestrated/branched endovascular aneurysm repair, Percutaneous, Stroke, Thoracic aorta aneurysm, Upper extremity access

<H1>INTRODUCTION

Upper extremity access (UEA) is routinely employed in several complex aortic procedures, particularly those involving incorporation of renal and splanchnic vessels such as parallel grafts and branched and fenestrated endovascular aortic repairs (B/FEVAR). Instructions for use of off the shelf branched stent grafts for the treatment of thoraco-abdominal aortic aneurysms recommend antegrade deployment of target vessel bridging stents using UEA.[1] Unfortunately, brachial or axillary artery puncture, followed by simple manual compression after sheath removal, is associated with the potential risk of haematoma, pseudoaneurysm, and nerve injury.[2,3] The risk of access failure (AF) with manual compression is higher with larger profile sheaths; therefore, open surgical exposure and repair has been proposed when a ≥ 7 F sheath is used.[4–6]

The two major concerns associated with UEA are AF and stroke during aortic arch manipulation.[6,7] While some centres with established protocols for totally percutaneous procedures, including UEA, have reported favourable results, a systematic review and meta-analysis, including only six series with percutaneous access, demonstrated an increased risk of AF.[5,6,8–10] More recently, several centres have adopted percutaneous UEAs with satisfactory results and low rates of neurological complications or open surgical conversion.[7–9,11–13] Nonetheless, the use of a total transfemoral approach has been increasingly used since the introduction of steerable sheaths and catheters, to avoid arch manipulations and limit stroke rates.[14–16]

The aim of this study was to report the results of a retrospective physician initiated, multicentre international registry designed to investigate AF and stroke rates of UEAs during complex endovascular aortic procedures, and to ascertain whether percutaneous access with vascular closure devices (VCDs) might have a role in lowering such complications *vs.* a standard open surgical technique.

<H1>MATERIALS AND METHODS

<H2>*Registry and Participating Centres*

The SUPER-AXA (SUrgical Versus PERcutaneous AXillary Artery) International Registry is a physician initiated, international, multicentre, retrospective registry (ClinicalTrials.gov identifier: NCT04589962). The study protocol, electronic case report form, and patient consent form were approved by the institutional Ethics Committee of the coordinating centre in October 2020 and complied with the principles of the Declaration of Helsinki. Each participating centre (Table 1) had Institutional Review Board approval, and all patients consented for minimal risk retrospective reviews. All centres consented for data sharing agreement, and clinical data were recorded in a deidentified electronic database for subsequent analysis.

<H2>*Registry inclusion/exclusion criteria*

The registry enrolled patients receiving a UEA during cardiac (i.e., transcatheter aortic valve replacement or intra-aortic balloon pump) or endovascular aortic procedures. Surgical accesses were eligible for enrolment regardless of the repair technique employed. Percutaneous accesses were eligible only if a Perclose Proglide VCD (Abbott Vascular, Santa Clara, CA, USA) was primarily employed to close the access. Patients with a previous vascular graft (i.e., bypass or patch) at the intended access site were excluded. Indication for UEA and access viability were reviewed by the operating physician at the time of the index procedure, and no patient was retrospectively excluded according to access vessel anatomy. Patients analysed in previously published series were included when they met the abovementioned criteria.[7,8,17,18]

<H2>*Study design*

Data from all patients who received a UEA to treat vascular aortic or its side branch pathology at the participating centres from 2008 to 2021 were included in the present study and subsequently analysed. Previously published cardiac procedures (i.e., transcatheter aortic valve replacement) were excluded from the present analysis (Fig. 1).[7]

<H2>*Access technique*

Percutaneous and open surgical UEA techniques have been extensively described by registry participants.[5,7,19] Briefly, in the case of standard open surgical access, the intended arterial segment was surgically exposed at the beginning or at the end of the endovascular procedure, as a planned strategy. Arteriotomy closure was intended to be primarily achieved by direct running or interrupted sutures. In the case of percutaneous access, the axillary or proximal brachial artery was catheterised under palpation, ultrasound, or angiographic guidance, according to the implanting physician's preference. When a preclose technique was used, one or two VCDs (Perclose ProGlide; Abbott Vascular) were deployed according to the intended introducer sheath to be used thereafter. In the case of introducer sheaths smaller than 8 F, one VCD might be implanted at the end of the procedure (no preclose). The access status (i.e., haemostasis and limb perfusion) at the end of the procedure was assessed by clinical inspection, ultrasonography, and/or angiography according to the standard participant clinical practice.

<H2>*Definitions, reporting standards, and outcome measures*

The Society for Vascular Surgery reporting standards were used to describe the pre-operative characteristics and comorbidities.[20,21] The primary endpoints were the AF and stroke rates and predictors, stratified by the UEA technique.[22] AF was defined, according to modified VARC-3 (Valve Academic Research Consortium) classification, as the presence of any access site or access related major vascular complication (e.g., vascular perforation, dissection, stenosis, thrombosis, arteriovenous fistula, pseudoaneurysm, or haematoma; or compartment syndrome; or distal non-cerebral embolisation; or unplanned endovascular or surgical intervention; or closure device failure) resulting in death, bleeding, limb or visceral ischaemia, amputation, or irreversible neurological impairment.[22] Stroke was classified as any new onset neurological deficit with a positive neuroimaging study, regardless of the severity and the disability score.

Secondary endpoints considered within 30 days included minor access site vascular complications (haematoma, deep venous thrombosis, arteriovenous fistula, lymphocoele, infection, pneumothorax, and transient peripheral nerve injury) not requiring adjunctive invasive procedures, and type and incidence of open surgical and/or endovascular adjunctive procedures at the access site.

<H2>*Data analysis*

Variables were assessed for normality with the Shapiro–Wilk test. Normal continuous variables are expressed as mean ± standard deviation, and differences were tested with the two-sided *t* test. Non-normal continuous variables were expressed as median (interquartile range [IQR]), and differences were tested with the Mann–Whitney *U* test. Categorical variables were expressed as counts and percentages, and the chi- square or Fischer's exact test were used for analysis. Variables with > 50% missing data were excluded from analysis. A logistic regression model was used to identify risk factors for AF and stroke. Data were entered into the model if they had a univariate *p* value < .10; the UEA technique (surgical *vs.* percutaneous) was forced into the model to assess its impact and cross-relation with the other predictors. In the multivariable analyses, risk factors for AF were expressed as odds ratios (OR) with a 95% confidence interval (CI). To furtherly clarify the impact of the UEA closure technique on AF, a 1:1 propensity score matching was designed with the "nearest neighbor" method on a logistical regression model to identify two comparable subcohorts (surgical *vs.* percutaneous) in terms of pre-operative variables.[23] Covariates balance was assessed before and after matching to confirm the improvement in the balance achieved by matching ("matchit object" function of R-studio "MatchIt" package). Wizard Statistics (version 1.9.38; evanmiller.org) and R-Studio (version 1.4.1106; RStudio, Boston, MA, USA) software for macOS were used.

<H1>RESULTS

<H2>*Study cohort description*

The SUPER-AXA registry database included 1 461 patients who had UEA during an aortic procedure. Seventy per cent were male, with a median age of 75 years. Of these, 1 098 patients (75.2%) treated at 16 centre underwent a vascular procedure (Fig. 1 and Table 1). These were mostly elective, but 65 patients (5.9%) had emergent/urgent procedures. Overall, open surgical access and repair was used in 833 patients (75.9%) with a 12 F inner diameter (ID) sheath in 746 (67.9%). The preferred access vessels were the axillary artery or the proximal brachial artery at the level of the armpit in 911 patients (83.0%). An interposition graft was required in three patients (0.3%). None of the percutaneous accesses was performed at the level of distal brachial or elbow crease.[24] In the percutaneous group (*n* = 265), ultrasound guided puncture was employed in 221 patients (83.4%) using preclosure technique with one VCD in 70 patients (26.4%) or two VCDs in 174 patients (65.7%). Balloon assisted sheath removal was employed in 123 patients (46.4%).[8,25,26] An adjunctive VCD was used in

32 patients (12.2%). Pre-operative risk factors and procedural details are summarised in Table 2.

<H2>*Access related complications*

Any AF was observed in 75 patients (6.8%). Of these, three experienced permanent nerve injury (0.3%), while temporary nerve injury was recorded in nine (0.8%). Table 3 summarises the aetiology, management failure, and its correlation with the type of access employed. No differences in AF were observed between open surgical and percutaneous access closure, but percutaneous access was more frequently associated with bleeding complications ($p = .002$). The complications of the percutaneous group were more frequently ($p < .001$) managed with adjunctive endovascular procedures, and six patients (2.3%) required conversion to open exposure and repair to manage the AF. Conversely, the majority ($p = .03$) of the open surgical access groups were managed with an adjunctive or redo open procedure. Overall, 63 patients (84%) had the AF corrected during their index aortic procedure, the remaining in a secondary procedure during the index hospitalisation. With regard to other access complications, arteriovenous fistula was reported in nine patients (0.8%; all open access), wound infection in eight (0.7%), deep venous thrombosis in one (0.1%; percutaneous), and pneumothorax in one (0.1%; percutaneous). Median duration of hospital stay was shorter in the percutaneous group (percutaneous 4 [IQR 3 – 7] days *vs*. open 7 [IQR 5 – 13] days; $p <.001$). Table 4 reports the factors associated with AF according to univariable and multivariable analysis: AF was negatively affected by the presence of a pacemaker in the proximity of the access (OR 3.77, 95% CI 1.17 – 12.1; $p = .026$), F/BEVAR procedure (OR 3.41, 95% CI 1.22 – 9.56; $p = .019$), and introducer ID ≥ 14 F (OR 6.57, 95% CI 2.08 – 20.74; $p = .001$).

<H2>*Stroke*

Ischaemic or haemorrhagic strokes were observed in 33 patients (3.0%), with an incidence of 27/894 for B/FEVAR (3.0%), 0/67 for parallel grafts, 1/55 for renovisceral or iliac branch procedures (1.8%), and 5/82 for aortic arch endovascular repair procedures (6.1%). Table 5 summarises the type, region, laterality, and its correlation with the type of access employed. No differences were observed between open surgical and percutaneous access closure with respect to stroke rates, but percutaneous access was more frequently associated with a cerebral (*vs.* cerebellar) distribution of the lesion ($p = .017$) and with contralateral (to UEA) location of the lesions ($p = .002$). The right and left UAE access showed similar stroke incidence (4.2% *vs.* 2.4% respectively; $p = .11$). Table 4 reports the results of the univariable and multivariable analysis of factors associated with stroke: cerebrovascular events were more common in female patients (OR 3.41, 95% CI 1.29 – 9.0; $p = .013$), UEA vessel diameter > 7 mm (OR 3.87, 95% CI 1.08 – 13.8; $p = .037$), and after aortic arch procedures (OR 7.29, 95% CI 1.71 – 31.05; $p = .007$).

<H2>*Surgical versus percutaneous access*

To compare the two endpoints between the two UEA closure techniques groups, and considering the multiple significant differences between the two cohorts highlighted in Table 2, a 1:1 propensity matching was performed for the following variables: smoking habit, diabetes, dyslipidaemia, hypertension, chronic obstructive pulmonary disease, female sex, anticoagulant and antiplatelet therapy, aortic procedure, and ID of the introducer. After propensity matching (168 *vs*. 168), the two cohorts proved different only for the following pre-operative and procedural variables: the use of local anaesthesia ($p < .001$), subclavicular access ($p < .001$), and left side access ($p < .001$) were more frequently employed in the percutaneous cohort and elbow crease access ($p < .001$) in the open surgical arm. The first three factors were differences related to access management, while the access side was not propensity matched because only 37 patients in the percutaneous cohort received right side access. After propensity matching, no significant differences in AF and stroke rate were found between the percutaneous and open surgical access subgroups (Table 6).

<H1>DISCUSSION

<H2>*Access related complications*

AF after UEA surgical exposure is not uniformly reported in the literature, ranging from 0 to 25%, with a rate of peripheral nerve injury ranging from 0 to 9%.[6,27,28] More recently, many authors have started to use VCDs to repair percutaneous axillary access in an attempt to lower access related complications, with AF rates ranging from 2 to 18%, but no comparative studies have yet been published.[7,9,29] The present multicentre registry reports an overall AF rate of 6.8%, including 0.8% permanent nerve injury, using a uniform definition of failure. In the percutaneous UEA cohort, bleeding rather than occlusive complications occurred more frequently, and were often managed with adjunctive endovascular procedures (i.e., covered stenting at the level of vessel puncture). In 2.3% of patients, an open conversion was needed. By contrast, patients receiving primary surgical exposure were more prone to occlusive complications, frequently requiring a patch angioplasty at the level of sheath insertion. The multivariable analysis identified three factors associated with AF (Table 4), and, unsurprisingly, of these, a sheath ID size ≥ 14 F (OR 6.6; p = .001) was the strongest predictor. It is quite intuitive that, in UEAs of 8 mm in diameter (Table 2), the use of larger sheaths might trigger percutaneous VCD failures, as well as dissection flaps that eventually require a surgical correction. A pacemaker at the access site might hamper percutaneous access and VCD placement, while a F/BEVAR procedure might be associated with multiple manipulations of the sheaths, thus increasing the likelihood of vessel damage. Interestingly, even after the inclusion of open/percutaneous UEA management in the multivariable models or after the propensity matching, no significant increase in the AF rates was noted for the percutaneous approach.

The real Achilles' heel of UEA remains cerebrovascular complications. The registry results confirmed that the stroke rate of UEA for complex endovascular aortic procedures is not negligible, ranging from 1.8 to 3% of the procedures performed in the thoraco-abdominal region, with no difference observed comparing both the aortic procedure performed (i.e., parallel graft *vs*. F/BEVAR) and the UEA side employed.[12,19] However, multivariable analysis confirmed that an arch procedure (zone 0 – 2) was associated with higher stroke incidence (OR 7.3; p = .007), in keeping with previous literature findings.[30] Another risk factor for stroke was female sex, supporting the evidence of a poorer peri-operative outcome of complex aortic procedures in women.[31,32] Despite no difference in stroke rates between the two UEA closure techniques, stroke was more commonly cerebral (*vs.* cerebellar) and contralateral to the UEA in the patients receiving percutaneous access rather than a surgical one. This finding might suggest that the arch endovascular manipulation of percutaneous access extends more proximally, for example related to the guidewire placement in deploying the VCD, while the manipulation of open surgical access is more limited to the side of the UEA and therefore cerebellar. In the last three years, UEA use decreased in many aortic centres due to the introduction of the transfemoral approach employing homemade or standard steerable sheaths, thereby reducing the incidence of stroke related to the intrinsic arch manipulation when the target vessels are bridged from above.[14,33] Future studies should confirm whether avoiding a UEA will significantly lower both the rates of ischaemic and haemorrhagic cerebrovascular complications of complex aortic procedures.[34]

This large international registry highlights that percutaneous UEA during vascular procedures is not burdened by higher rates of stroke or AF at both multivariable analysis and propensity matched comparison. The possible clinical advantages of incorporating routine percutaneous UEA require further investigation, but reduced operative time, duration of hospital stay, and blood loss might be beneficial in terms of reduced procedural invasiveness and increased patient quality of life. For example, the present study observed that percutaneous UEA was associated with a shorter hospital stay ($p < .001$ both in the general and propensity matched groups). Reports of total percutaneous arch branched repair suggest that the applicability of percutaneous techniques to complex endovascular aortic repair will continue to expand,[35,36] and this will have a positive impact on healthcare systems by reducing overall costs.[37]

Study limitations principally reside in its retrospective nature. It is not possible to report the number of patients in whom a UEA was not considered feasible at the time of procedural planning by the performing physicians and therefore selection bias cannot be excluded. Reporting bias may have affected adverse event rates by under-reporting rates of peripheral nerve injury, for example, which was rarely assessed by an independent neurologist, and cerebrovascular events in asymptomatic patients who were not assessed by imaging. Furthermore, the study cohort includes patients in which UEA was used for a wide range of procedures ranging from ascending, arch, and descending aortic repair. Although the larger sample increases the study power, it provides fewer insights on neurological outcomes for each specific vascular intervention. Moreover, certain variables such as blood loss and transfusions have been inconsistently reported, so a dedicated analysis was not possible. Finally, only two of 16 centres employed (and provided data from) both open surgical and percutaneous UEA, while the vast majority appear to favour a single approach.

<H2>*Conclusion*

AF and stroke rates during complex aortic procedures employing UEA are non-negligible; therefore, selective use is warranted. Percutaneous access with vessel closure devices is associated with similar complication rates, but adjunctive endovascular procedures are required to avoid surgical exposure. Registry data appear to refute previous meta-analysis conclusions asserting that a percutaneous UEA is burdened by increased AF *vs.* surgical exposure.[6] The true clinical implications of the two approaches, as well as the incidence and impact of minor complications such as temporary peripheral nerve injury, could be better clarified only by prospective and randomised studies.

CONFLICT OF INTEREST

Abbott Vascular, Santa Clara, CA, USA paid IRCCS San Raffaele Hospital a research grant for the study (NCT04589962) Principal Investigator Luca Bertoglio is a consultant for Abbott Vascular, Santa Clara, CA, USA. The other authors and collaborators have no conflicts of interest to declare.

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FIGURE LEGEND

Figure 1. Study flowchart. UEA = upper extremity access; TAVR = transcatheter aortic valve replacement; IABP = intra-aortic balloon pump; LSA = left subclavian artery; B/FEVAR = branched/fenestrated endovascular aortic repair; PTA = percutaneous transluminal angioplasty; VCD = vascular closure device.

Table 1. Centres involved in the SUPER-AXA multicentre registry, including enrolment data and distribution of percutaneous and surgical management of upper extremity access.				
Centre	**Location**	**Surgical (*n* = 833)**	**Percutaneous (*n* = 265)**	**Overall (*n* = 1 098)**
Mayo Clinic	Rochester, MN, USA	344 (41.3)	0	344 (31.3)
IRCCS San Raffaele	Milan, Italy	78 (9.4)	119 (44.9)	197 (17.9)
IRCCS S. Orsola	Bologna, Italy	142 (17.0)	0	142 (12.9)
Heart and Vascular Center	Hamburg, Germany	96 (11.5)	0	96 (8.7)
University Hospitals NHS Foundation Trust	Birmingham, UK	80 (9.6)	0	80 (7.3)
Policlinico Umberto I	Rome, Italy	43 (5.2)	3 (1.1)	46 (4.2)
Insubria School of Medicine	Varese, Italy	43 (5.2)	0	43 (3.9)
Weill Cornell Medical Center	New York, USA	0	38 (14.3)	38 (3.5)
Imelda Hospital	Bonheiden, Belgium	0	35 (13.2)	35 (3.2)
NHS Foundation Trust	Oxford, UK	0	18 (6.8)	18 (1.6)
Hospital General Gregorio Marañón	Madrid, Spain	0	15 (5.7)	15 (1.4)
University of Rome Tor Vergata	Rome, Italy	0	11 (4.2)	11 (1.0)
Skåne University hospital	Malmo, Sweden	0	10 (3.8)	10 (0.9)
San Filippo Neri hospital	Rome, Italy	0	9 (3.4)	9 (0.8)
S. Maria Misericordia Hospital	Perugia, Italy	0	7 (2.6)	7 (0.6)
University Hospital of Trieste	Trieste, Italy	7 (0.8)	0	7 (0.6)

Data are provided as *n* (%).

Table 2. Pre-operative and procedural variables of 1 098 patients who received an upper extremity access during vascular complex aortic procedures.

Variable	Surgical (*n* = 833)	Percutaneous (*n* = 265)	*p* value	Overall (n = 1 098)
Age – y	74 (69–78)	74 (69–79)	.93	74 (69–79)
Male sex	597 (71.7)	209 (78.9)	.021	806 (73.4)
Body mass index – kg/m^2	27 (24–30)	27 (24–29)	.69	27 (24–30)
Any smoking habit	556 (66.7)	176 (66.4)	.96	732 (66.7)
Diabetes	72 (8.6)	16 (6.0)	.18	88 (8.0)
Dyslipidaemia	476 (57.1)	138 (52.1)	.18	614 (55.9)
Hypertension	754 (90.5)	203 (76.6)	<.001	957 (87.2)
Chronic obstructive pulmonary disease	264 (31.7)	45 (17.0)	<.001	309 (28.1)
Coronary artery disease	388 (46.6)	111 (41.9)	.19	499 (45.4)
Chronic renal failure	349 (41.9)	105 (39.6)	.74	454 (41.3)
Previous CABG	110 (13.2)	27 (10.2)	.54	137 (12.5)
Previous percutaneous coronary intervention	72 (8.6)	58 (21.9)	<.001	130 (11.8)
Society for Vascular Surgery score	8 (5–12)	7 (4–11)	<.001	8 (5–12)
American Society of Anesthesiologists grade 4	139 (16.7)	81 (30.6)	<.001	220 (20.0)
Anticoagulant therapy	130 (15.6)	51 (19.5)	.14	181 (16.5)
Antiplatelet therapy	603 (72.4)	222 (83.8)	<.001	825 (75.1)
Procedure				
F/BEVAR TAAA	715 (85.8)	179 (67.5)	<.001	894 (81.4)
Parallel graft TAAA	42 (5.0)	25 (9.4)	.009	67 (6.1)
Peripheral stenting	5 (0.6)	50 (18.9)	<.001	55 (5.0)
Renovisceral procedures	5 (0.6)	29 (10.9)	<.001	34 (3.1)
Iliac procedures	0	21 (7.9)	<.001	21 (1.9)
LSA plug during arch repair	43 (5.2)	3 (1.1)	.004	46 (4.2)
Endovascular arch repair	28 (3.4)	8 (3.0)	.78	36 (3.3)
Fenestrated/branched	10 (1.2)	2 (0.8)	.55	12 (1.1)
Parallel grafts	18 (2.2)	6 (2.3)	.92	24 (2.2)

Local/regional anaesthesia	21 (2.5)	74 (27.9)	<.001	95 (8.7)
Access/puncture site				
Left side	510 (61.2)	228 (86.0)	<.001	738 (67.2)
Subclavicular, proximal axillary	242 (29.1)	170 (64.2)	<.001	412 (37.5)
Armpit, distal axillary/proximal brachial	404 (48.5)	95 (35.8)	<.001	499 (45.4)
Elbow crease, distal brachial	187 (22.4)	0	<.001	187 (17.0)
Diameter at the access site – mm	9 (7–10)	8 (7–9)	.036	8 (7–10)
Surgical scar at the access site	8 (1.0)	4 (1.5)	.67	12 (1.1)
Pacemaker ipsilateral to access	7 (0.8)	18 (6.8)	<.001	25 (2.3)
Left internal mammary artery CABG ipsilateral to access	28 (3.4)	9 (3.4)	.12	37 (3.4)
Dialysis fistula ipsilateral to access	15 (1.8)	1 (0.4)	.11	16 (1.5)
Introducer internal diameter – F	12 (12–12)	12 (8–12)	<.001	12 (10–12)
5–6	18 (2.2)	26 (9.8)	<.001	44 (4.0)
7–8	119 (14.3)	46 (17.4)	.27	165 (15.0)
9–10	61 (7.3)	39 (14.7)	<.001	100 (9.1)
12	612 (73.5)	134 (50.6)	<.001	746 (67.9)
14–16	6 (0.7)	20 (7.5)	<.001	26 (2.4)

Unmatched statistical comparison is reported between the surgical and percutaneous access closure cohorts. Data are presented as *n* (%) or median (interquartile range). CABG = coronary artery bypass graft; F/BEVAR = fenestrated/branched endovascular aneurysm repair; TAAA = thoraco-abdominal aortic aneurysm.

Table 3. Descriptions of surgical and percutaneous upper extremity access in the non-matched cohort of 1 098 patients.

	Surgical (*n* = 833)	**Percutaneous (*n* = 265)**	***p* value**	**Overall (*n* = 1 098)**
Overall access failure rate	53 (6.4)	22 (8.3)	.28	75 (6.8)
Aetiology				
Bleeding	10 (1.2)	12 (4.5)	.002	22 (2.0)
Pseudoaneurysm	5 (0.6)	3 (1.1)	.41	8 (0.7)
Vessel stenosis/occlusion	7 (0.8)	4 (1.5)	.31	11 (1.0)
Vessel dissection/flap	29 (3.5)	3 (1.1)	.057	32 (2.9)
Permanent nerve injury	2 (0.2)	1 (0.4)	.71	3 (0.3)
Management				
Endovascular	5 (0.6)	15 (5.7)	<.001	21 (1.9)
Bare stent	4 (0.5)	3 (1.1)		7 (0.6)
Covered stent	1 (0.1)	12 (4.5)		13 (1.2)
Surgical	46 (5.5)	6 (2.3)	.03	52 (4.7)
Patch repair	29 (3.5)	0		29 (2.6)
Haematoma drainage	9 (1.1)	0		9 (0.8)
Thrombectomy	5 (0.6)	1 (0.4)		6 (0.5)
Direct repair	–	5 (1.9)		5 (0.5)
Bypass	1 (0.1)	0		1 (0.1)
Other	2 (0.2)	0		2 (0.2)

Data are presented as *n* (%).

Table 4. Factors associated with stroke and access failure according to the VARC-3 (Valve Academic Research Consortium) reporting standards in the non-matched cohort of 1 098 patients according to univariable and multivariable analysis.

	Access failure					
	Univariable analysis			**Multivariable analysis**		
Variable	**OR**	**95% CI**	***p* value**	**OR**	**95% CI**	***p* value**
Female sex	2.19	1.35–3.53	.001	2.09	0.93–4.69	.073
Diabetes	0.30	0.07–1.23	.077	0.75	0.08–6.48	.80
Previous coronary artery bypass graft	0.26	0.08–0.85	.017	0.47	0.11–2.22	.34
Direct anticoagulant	3.00	1.35–6.68	.005	2.31	0.75–7.17	.14
Pacemaker at the access site	6.16	2.28–16.69	<.001	3.77	1.17–12.11	.026
F/BEVAR procedure	3.38	1.35–8.49	.006	3.41	1.22–9.56	.019
Introducer internal diameter ≥14 F	4.62	2.01–10.59	<.001	6.57	2.08–20.74	.001
Percutaneous access	1.33	0.07–1.23	.28	2.12	0.91–4.94	.082
	Stroke					
Female sex	3.05	1.52–6.12	.001	3.41	1.29–9.00	.013
Hypertension	4.60	0.76–3.34	.10	0.74	0.09–6.01	.78
Chronic kidney disease	2.15	1.06–4.37	.030	2.16	0.81–5.75	.12
SVS score ≥10	1.78	0.89–3.57	.098	1.56	0.55–4.46	.40
Access vessel diameter >7 mm	7.52	2.53–22.32	.038	3.87	1.08–13.83	.037
Scar at the access site	6.12	1.26–29.71	.011	2.37	0.36–15.72	.37
Aortic arch procedure	4.45	1.48–13.42	.004	7.29	1.71–31.05	.007
Introducer internal diameter ≥14 F	4.62	1.31–16.26	.009	1.41	0.27–7.36	.69
Access failure	3.95	1.65–9.42	<.001	2.21	0.60–8.17	.23

Percutaneous access	1.60	0.76–3.34	.21	1.90	0.68–5.27	.22

OR = odds ratio; CI = confidence interval; F/BEVAR = fenestrated/branched endovascular aneurysm repair; SVS = Society for Vascular Surgery.

Table 5. Type, region, and distribution of strokes in patients receiving upper extremity access (UEA) during different complex aortic procedures

Variable	**Surgical (*n* = 833)**	**Percutaneous (*n* = 265)**	***p* value**	**Overall (*n* = 1 098)**
Overall stroke rate	22 (2.6)	11 (4.2)	.21	33 (3.0)
Type				
Ischaemic	13 (65)	6 (54)	.57	19 (61)
Haemorrhagic	7 (35)	5 (45)	.57	12 (39)
Missing	2	–	–	2
Region				
Cerebral/anterior	10 (53)	9 (82)	.017	19 (63)
Cerebellar/posterior	6 (32)	1 (9)	.16	7 (23)
Both	3 (16)	1 (9)	.60	4 (13)
Missing	3	–	–	3
Side				
Ipsilateral to UEA	10 (53)	3 (27)	.18	13 (43)
Contralateral to UEA	2 (10)	7 (64)	**.002**	9 (30)
Bilateral	7 (37)	1 (9)	.098	8 (27)
Missing	3	–	–	3

Data are presented as *n* (%).

Table 6. Pre-operative and procedural patient and access characteristics, intra-operative details, and primary outcomes in the matched patient cohorts according to upper extremity access closure modality.

Variable	**Surgical (*n* = 168)**	**Percutaneous (*n* = 168)**	***p* value**	**Overall (*n* = 336)**
Age – y	74 (68–78)	78 (70–87)	.74	74 (68–78)
Male sex	129 (76.8)	136 (81.0)	.35	265 (78.9)
Body mass index – kg/m^2	26 (23–30)	26 (24–29)	.93	26 (24–29)
Any smoking habit	113 (67.3)	111 (66.1)	.88	224 (66.7)
Diabetes	8 (4.8)	7 (4.2)	.80	15 (4.5)
Dyslipidaemia	97 (57.7)	86 (51.2)	.25	183 (54.5)
Hypertension	138 (82.1)	138 (82.1)	.91	276 (82.1)
Chronic obstructive pulmonary disease	42 (25.0)	37 (22.0)	.60	79 (23.5)
Coronary artery disease	83 (49.4)	72 (42.9)	.25	155 (46.1)
Chronic renal failure	78 (46.4)	71 (42.3)	.72	150 (44.3)
Previous CABG	28 (16.7)	19 (11.3)	.34	47 (14.0)
Previous percutaneous coronary intervention	22 (13.1)	35 (20.8)	.25	57 (17.0)
Society for Vascular Surgery score	8 (5–12)	7 (4–12)	.71	8 (5–12)
American Society of Anesthesiologists score 4	34 (20.2)	44 (26.2)	.20	78 (23.2)
Anticoagulant therapy	24 (14.3)	22 (13.1)	.77	46 (13.7)
Antiplatelet therapy	141 (83.9)	142 (84.5)	.88	283 (84.2)
Procedure				
F/BEVAR TAAA	137 (81.5)	134 (79.8)	.68	271 (80.7)
Parallel graft TAAA	21 (12.5)	20 (11.9)	.87	41 (12.2)
Peripheral stenting	5 (3.0)	6 (3.6)	.76	11 (3.3)
Left subclavian artery plug during arch	0	3 (1.8)	.082	3 (0.9)
F/BEVAR or parallel arch	5 (3.0)	5 (3.0)	1.0	10 (3.0)
Local/regional anaesthesia	10 (6.0)	46 (27.4)	<.001	56 (16.7)
Access/puncture site				
Left side	103 (61.3)	144 (85.7)	<.001	247 (73.5)
Subclavicular, proximal axillary	65 (38.7)	110 (65.5)	<.001	175 (52.1)

Armpit, distal axillary/proximal brachial	59 (35.1)	58 (34.5)	.91	117 (34.8)
Elbow crease, distal brachial	44 (26.2)	0	<.001	44 (13.1)
Diameter at the access site – mm	8 (6–10)	9 (7–9)	.34	8 (7–10)
Surgical scar at the access site	3 (1.8)	2 (1.2)	.65	5 (1.5)
Pacemaker ipsilateral to access	3 (1.8)	9 (5.4)	.40	12 (3.6)
Left internal mammary artery CABG ipsilateral to access	7 (4.2)	4 (2.4)	.095	11 (3.3)
Dialysis fistula ipsilateral to access	4 (2.4)	1 (0.6)	.19	5 (1.5)
Introducer internal diameter – F	12 (10–12)	12 (10–12)	.45	12 (10–12)
5–6	7 (4.2)	8 (4.8)	.79	15 (4.5)
7–8	23 (13.7)	29 (17.3)	.36	52 (15.5)
9–10	19 (11.3)	20 (11.9)	.86	39 (11.6)
12	114 (67.9)	107 (63.7)	.42	221 (65.8)
14–16	4 (2.4)	4 (2.4)	1.0	8 (2.4)
UEA access failure	10 (6.0)	12 (7.1)	.66	22 (6.5)
Stroke	6 (3.6)	6 (3.6)	1.0	12 (3.6)

Data are presented as *n* (%) or median (interquartile range). CABG = coronary artery bypass graft; F/BEVAR = fenestrated/branched endovascular aneurysm repair; TAAA= thoraco-abdominal aortic aneurysm.

APPENDIX A

SUPER-AXA Registry Collaborators

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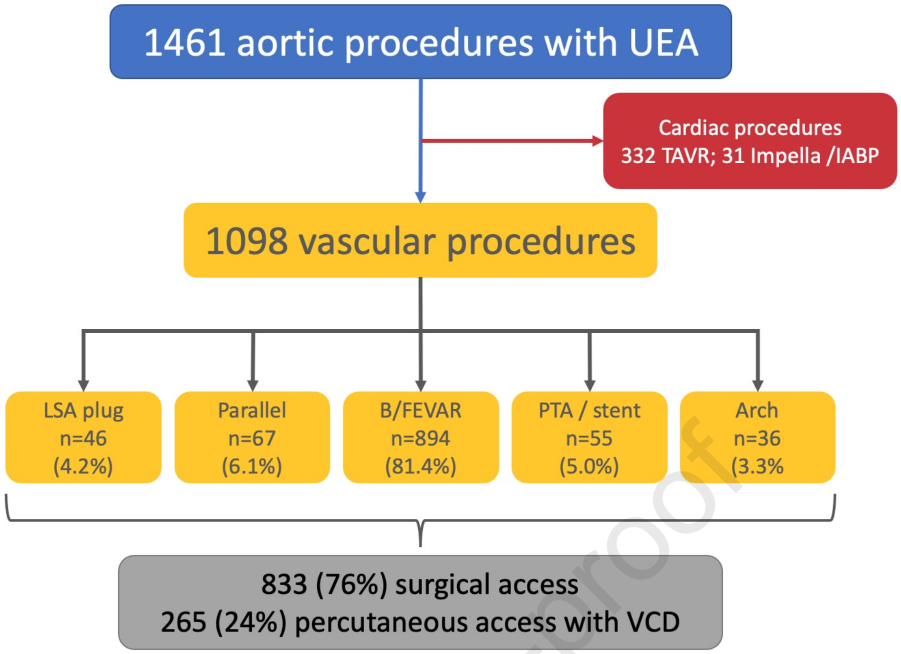
1461 aortic procedures with UEA
Cardiac procedures
332 TAVR; 31 Impella /IABP
1098 vascular procedures
LSA plug
n=46
(4.2%)
Parallel
n=67
(6.1%)
B/FEVAR
n=894
(81.4%)
PTA / stent
n=55
(5.0%)
Arch
n=36
(3.3%
833 (76%) surgical access
265 (24%) percutaneous access with VCD

Short title:

International Registry of Open Surgical vs. Upper Extremity Access in Endovascular Aortic Procedures

Appendix A:

Appendix A is provided with the full list of collaborators

Supplementary material:

None

Figures:

Figure 1 is a flowchart. Follow the instructions on page C1 for the correct layout and design. Please also make the following changes:

- Insert a thin space in 1 461 and 1 098.
- All ‘n’ should be in italics and there should be a thin space on either side of all ‘=’ symbols.