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A scoping review on the approaches for cannulation of reno-visceral target vessels during complex endovascular aortic repair

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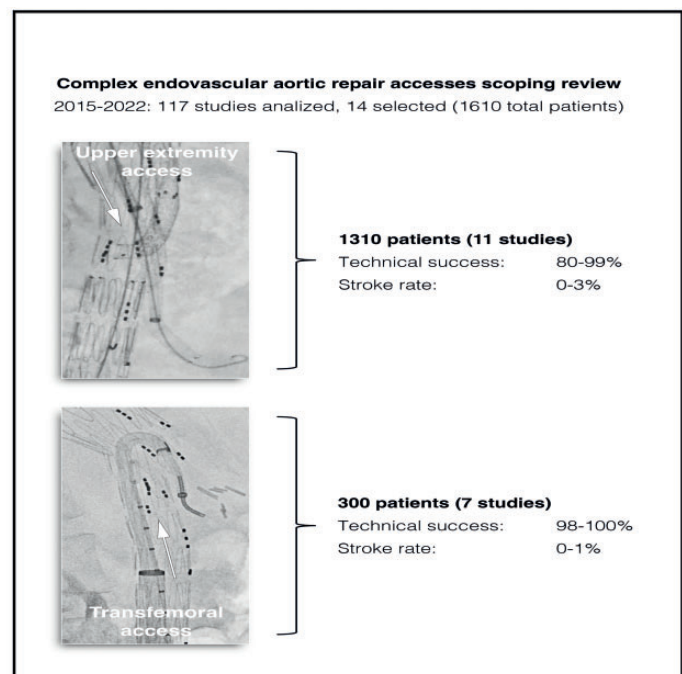
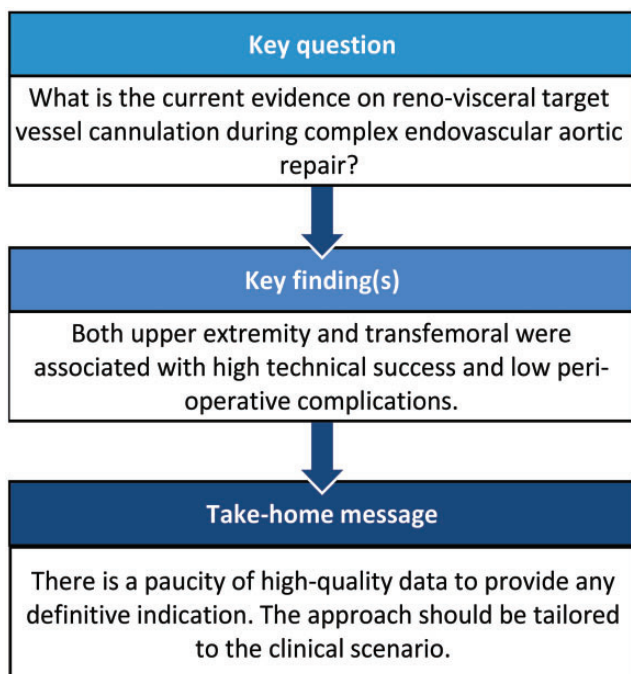
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Abstract

OBJECTIVES: The aim of this study was to assess the approaches to reno-visceral target vessels (TVs) cannulation during branched-fenestrated endovascular aortic repair, determine the evidence base that links these approaches to clinical outcomes and identify literature gaps.

METHODS: A scoping review following the PRISMA Protocols Extension for Scoping Reviews was performed. Available full-text studies published in English (PubMed, Cochrane and EMBASE databases; last queried, 31 June 2022) were systematically reviewed and analysed. Data were reported as descriptive narrative or tables, without any statistical analysis nor quality assessment.

[†]The first two authors contributed equally to this work and should co-share the first authorship.

RESULTS: Fourteen retrospective articles were included. Seven articles studied the use of upper extremity access (UEA) during branched-fenestrated endovascular aortic repair, 3 studied the use of steerable sheaths and 4 included both approaches. A left UEA was used in 757 patients (technical success: 99%, stroke rate: 1–3%) and a right UEA in 215 patients (technical success: 92–98%, stroke rate: 0–13%). Seven studies (1066 patients) described a surgical access only (technical success: 80–99%, stroke rate: 0–13%), while 3 studies (146 patients) described a percutaneous access only (technical success: 83–90%, stroke rate: 3%) and lastly 4 studies compared UEA versus use of steerable sheaths from the transfemoral approach (TFA) (UEA: 563 patients, technical success: 95–98%, stroke rate: 1–8%; TFA: 209 patients, technical success: 98–100%, stroke rate: 0–1%).

CONCLUSIONS: Both UEA and TFA as cannulation approaches were associated with high technical success and low perioperative complications. Currently, there is a paucity of high-quality data to provide definitive indication. Optimal UEA in terms of side (left versus right) and approach (surgical versus percutaneous) needs further study.

Keywords: Thoraco-abdominal aortic aneurysms • Complex endovascular aortic repair • Review • Outcomes • Stroke

ABBREVIATIONS

B/FEVAR	Branched-fenestrated endovascular aortic repair
IFU	Instruction for use
IQR	Interquartile range
SBI	Silent brain infarction
TFA	Transfemoral approach
TV	Target vessel
UEA	Upper extremity access

INTRODUCTION

Over the last 2 decades, endovascular techniques have increasingly become the first-line treatment option for diseases in the paravisceral and thoraco-abdominal aorta, provided patients have suitable anatomy [1], mainly owing to their reduced invasiveness compared with classical open surgical repair. Branched-fenestrated endovascular aortic repair (B/FEVAR) invariably requires selective cannulation of reno-visceral target vessels (TVs), traditionally with antegrade approach from an upper extremity access (UEA) [2–4]. However, this would inevitably carry the risk of additional access-site complications at the arm level, owing to the need for intraoperative manipulation with large-bore sheaths. Furthermore, the risk of cerebral adverse events following UEA may not be insignificant [5, 6]. While the left arm has been historically preferred owing to reduced manipulation within the aortic arch, which is of absolute importance in cases of shaggy aorta or anatomical obstacles (aortic arch type III) to avoid any increased risk of embolization, more recent evidence has shown that use of the right arm may not necessarily entail increased risks of perioperative stroke [7–9]. Lastly, the introduction of steerable sheaths (whether commercially available or assembled on back-table by physicians) has allowed totally transfemoral approach (TFA) (i.e. retrograde) B/FEVAR to become a suitable alternative [10–12]. Nonetheless, this approach is still outside of the instruction for use of all the commercially available off-the-shelf devices, as opposed to the use of UEA, which is still the recommended method. Achieving the most expedite approach to TV cannulation with low risks for intraoperative complications remains the ultimate goal. Therefore, careful patient selection and mastery of different techniques represent crucial components of the surgical strategy. The primary objectives of this scoping review were to assess the approaches to cannulation of reno-visceral TV during B/FEVAR, determine the extent of the evidence base that links these approaches to clinical outcomes and

identify recurring themes or gaps in the literature to guide future research.

METHODS

Study design

A scoping review following the PRISMA Protocols Extension for Scoping Reviews was performed [13] (Fig. 1) Available full-text studies published in English in PubMed, Cochrane and EMBASE databases (last queried, 31 June 2022) were systematically reviewed and analysed. Reference lists from all included manuscripts were manually screened and included if necessary. The following population, intervention, comparison, outcome question was used to build the search equation: in patients with thoraco-abdominal aortic aneurysms (population) undergoing branched or fenestrated endovascular repair (intervention) how does the approach to TV cannulation (comparison) affect postoperative clinical outcomes (outcomes)? A list of predefined research questions was compiled as outlined in [Supplementary Material, Table S1](#). The search strings are provided in [Supplementary Material, Table S2](#). Duplicate copies of articles were identified and removed. Manuscripts were also excluded if they were case reports with ≤ 4 cases [14], letters, editorials, commentaries or were written in a language other than English.

Data extraction and evidence synthesis

Data were reported as descriptive narrative or tables, without any statistical analysis nor quality assessment of the included papers, in accordance with the PRISMA guidelines for scoping reviews. Data extraction was performed using Microsoft Excel software. Two authors (Alessandro Grandi and Mario D’Oria) independently assessed the studies for inclusion in the review; in case of disagreement, the third author (Luca Bertoglio) was involved to achieve consensus. The following data were extracted: authors’ list, publication year, number of patients in the study, access details (open/percutaneous, axillary artery segment and side, sheath dimensions), procedural details (technical success, adjunctive procedures) and perioperative complications rate (stroke, haematoma and nerve injury, spinal cord ischaemia).

RESULTS

Literature search

In this scoping review, 14 articles were included after screening, all of which were retrospective studies. Of those, 7 articles

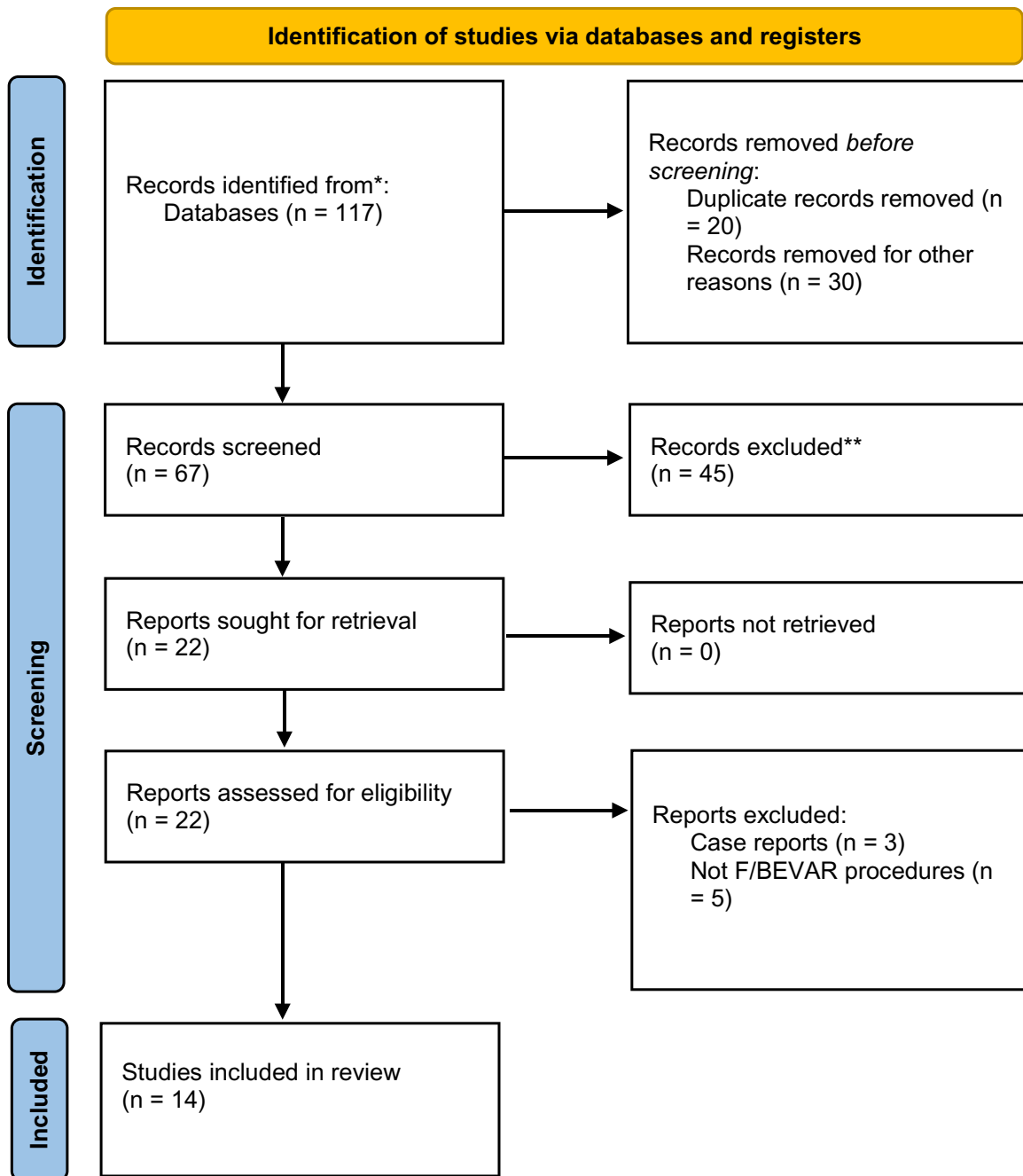


Figure 1: PRISMA flowchart of literature selection.

studied the use of UEA during B/FEVAR [9, 15–20], 3 the use of a TFA [11, 12, 21] and 4 including both approaches (UEA and TFA) [7, 10, 22, 23]. The articles were summarized in 2 tables. Table 1 depicts all articles with patients who received UEA, while Table 2 depicts all articles reporting the use of a TFA.

Right-side UEA versus Left-side UEA

Four articles analysed postoperative outcomes when using the right upper extremity as opposed to the left upper extremity. In total, the left side was used in 757 patients with a technical success of 99% and a stroke rate ranging between 1% and 3%. The

right side was used in 215 patients with a technical success ranging between 92% and 98%, and a stroke rate ranging between 0% and 13% [7, 18].

Knowles *et al.* [7] in their single-centre series reported the use of UEA in 98 patients. The right upper extremity was accessed 6 times without any stroke (0%) compared with the left being accessed 92 times with 1 stroke (1%; $P = 0.8$). Mirza *et al.* reported 2 different case series in 2 different periods and both were analysed (even if a 3-year overlap was present, 2007–2016 and 2013–2018). The first series [18] analysed 243 patients treated through a brachial cut down for TV cannulation, 94% of whom were on the left side. The overall technical success rate was 99%. One patient presented with an access-site haematoma

Table 1: Summary of studies reporting outcomes of upper extremity access use during branched and fenestrated endovascular aortic repair

Author, year	Study period	Open/percutaneous	N	Left AXA (%)	AXA segment	Branch/fenestration per patient	Sheath range (F)	Technical success (%)	Any open procedure, n (%)	Any endo procedure, n (%)	Any stroke, n (%)	Haematoma nerve injury (%)
Knowles, 2015 [6]	2009–2013	Both	98	94	III	3.25	7–12	–	2 (2) haematoma evacuations	–	RUE: 0 (0) LUE: 1 (1)	4% haematoma 2% nerve injury
Fiorucci, 2017 [8]	2011–2016	Open	61	0	III	–	10–12	97	–	–	RUE: 2 (3)	–
Stern, 2017 [13]	2014–2016	Open	29	93	I	3.8	12	99	0	0	1 (3) ^a	0% haematoma 3% nerve injury
Mirza, 2019 [15]	2007–2016	Open	243	94	III	3.6	7–12	99	30 (13) patch angioplasty	0	RUE: 2 (13) LUE: 3 (1)	0.5% haematoma 1% nerve injury
Branzan, 2019 [14]	2013–2017	Perc	40	100	III	–	12	83	0	7 (17)	–	8% haematoma 0% nerve injury
Agrusa, 2019 [17]	2017–2019	Perc	46	96	III	–	8–16	89	0	5 (11)	–	0% haematoma 4% nerve injury ^a
Bertoglio, 2020 [5]	2016–2019	Perc	60	90	I	–	10–16	90	0	6 (10)	2 (3)	12% haematoma 5% nerve injury ^a
Eilenberg, 2020 [9]	2016–2019	Open	92	–	III	3.8	10–12	95	–	–	5 (5) ^a 3 (3) ^b	3% haematoma 0% nerve injury
Mirza, 2021 [16]	2013–2028	Open	270	76	III	3.9	7–12	RUE: 92 LUE: 99	30 (13) patch angioplasty	–	RUE: 1 (2) LUE: 6 (3)	0.4% haematoma 1% nerve injury
Scott, 2022 [19]	–	Open	361	94	III	–	12	98	–	–	RUE: 5 (1) LUE: 0 (0)	2% haematoma 3% nerve injury
Hauck, 2022 [20]	2020–2021	Open	10	100	I/III	Branch: 3.2 Fen: 1.5	7–8	80	–	–	–	–

AXA segment I: axillary artery A1; AXA segment III: axillary artery A3/high brachial artery; LUE: left upper extremity access; RUE: right upper extremity access.

^aTemporary deficit.

^bPermanent deficit.

Table 2: Summary of studies reporting outcomes after use of femoral access during branched and fenestrated endovascular aortic repair

Author, year	Study period	Open/percutaneous	N	Branch/fenestration per patient	Sheath range (F)	Technical success (%)	Any open procedure, n (%)	Any endo procedure, n (%)	Any stroke, n (%)	Any SCI, n (%)
Knowles, 2015 [6]	2009–2013	–	50	2.72	7–12	–	–	–	1 (1)	–
Makaloski, 2018 [18]	–	Open	4	2	18	100	0 (0)	0 (0)	0 (0)	0 (0)
Gallitto, 2020 [10]	2016–2018	Both	33	1.9	7–12	98	–	3 (9)	–	2 (6)
Eilenberg, 2020 [9]	2016–2019	Perc	60	3.5	14	100	–	–	0 (0)	4 (7)
Scott, 2022 [19]	–	–	93	–	–	98	–	–	1 (1)	–
Kapahnke, 2022 [11]	2016–2019	Open	53	3.7	–	99	3 (2)	–	0 (0)	6 (12%)
Hauck, 2022 [20]	2020–2021	Both	7	Branch: 2.7 Fen: 2.7	16–20	100	–	–	–	–

SCI: spinal cord ischaemia.

and 2 patients presented access-site-related nerve injury. Thirty patients required a patch angioplasty or interposition at the access site due to arterial damage and 5 strokes were reported, 2/15 (13%) for the patients treated through a right brachial cut down and 3/228 (1%) for patients treated through a left brachial cutdown ($P = 0.03$). In their second published cases series, Mirza *et al.* [19] specifically compared cerebral events in 270 patients treated by right (65/270, 24%) or left (205/270, 76%) UEA cut-down for TV cannulation. The technical success was higher when using the left side (99% vs 92%, $P = 0.02$), with 799/802 TV cannulated from the left and 245/249 from the right ($P = 0.04$). The reported access-site complications were the same as the first case series published by the authors, while the reported strokes were 1 (2%) in the right-side group and 6 (3%) in the left side group ($P > 0.99$). Procedural metrics were similar for both sides, including endovascular time, fluoroscopy time and contrast volume. Total patient radiation exposure was significantly higher for left UEA versus right UEA (2463 ± 1912 vs 1757 ± 1494 mGy, respectively; $P = 0.02$). Scott *et al.* [22] analysed 361 patients, 232 in the right UEA group and 129 in the left UEA group. Five perioperative strokes occurred in patients undergoing right UEA (2%), of whom 3 were ischaemic and 2 were haemorrhagic. No transient ischaemic attacks occurred perioperatively. One haemorrhagic stroke was associated with permissive hypertension to prevent spinal cord ischaemia. No perioperative strokes occurred in patients undergoing left UEA ($P = 0.16$). Arm access-related complications occurred in 15 (5%) patients, 11 (5%) on the right side and 4 (3%) on the left side ($P = 0.45$), with neuropraxia was as the most prevalent complication (4/15 patients, 1% of all UEA).

Surgical UEA versus Percutaneous UEA

Only 1 study reported comparative outcomes after both surgical and percutaneous. Knowles *et al.* [7] reported in their single-centre series that all patients who required a sheath size <7 F underwent high brachial percutaneous access, while all those who required a sheath size >7 F underwent high brachial open access, except for 1 patient who underwent percutaneous axillary access with a 12-F sheath. Complications in the percutaneous access group were significantly more frequent than in the open group (2/12, 17% vs 2/86, 2%; $P = 0.02$). Perclose ProGlide devices (Abbott Vascular, Santa Clara, CA, USA) were used in this study for all percutaneous closures.

All the other published studies only described either surgical or percutaneous accesses. Seven studies [9, 10, 15, 18, 19, 22, 23] (1066 patients in total) described a surgical access only. Technical success ranged between 80% and 99%, stroke rate between 0% and 13%, haematoma rate between 0% and 3% and nerve injury rate between 0% and 3%. Three studies [16, 17, 20] (146 patients) described a percutaneous access only (all used Perclose ProGlide devices). Technical success ranged between 83% and 90%, stroke rate of 3%, haematoma rate between 0% and 12% and nerve injury rate between 0% and 5%.

UEA versus Transfemoral approach with steerable sheaths

Four studies compared UEA versus use of a TFA [7, 10, 22, 23]. In total, the UEA was used in 563 patients with a technical success rate ranging between 95% and 98%, and a stroke rate ranging between 1% and 8%. The TFA was used in 209 patients with a

technical success rate ranging between 98% and 100% and a stroke rate ranging between 0% and 1%.

Knowles *et al.* [7] in a series of 148 patients compared 98 cases with UEA and 50 cases with a TFA. One haemorrhagic stroke [1 of 98 (1%)] occurred in the UEA group, and 1 ischaemic stroke [1 of 54 (2%)] occurred in the TFA group ($P = 0.67$). The stroke in the UEA group occurred 5 days after B/FEVAR and was related to uncontrolled hypertension, whereas the stroke in the TFA group occurred on postoperative day 3. Neither patient had signs or symptoms of stroke immediately after the index procedure. Eilenberg *et al.* [10] compared 60 patients treated through a TFA and 92 patients treated through UEA. Brachial access complications (0/60 vs 3/92 patients) and perioperative strokes/transient ischaemic attacks (0/60 vs 8/92 patients) only occurred in the UEA group ($P = 0.018$). Technical success was significantly greater ($P < 0.01$) in the TFA group (60/60 patients; 209/209 TVs) than in the UEA group (87/92 patients; 334/346 TVs). The fluoroscopy time and contrast agent volume were similar in both groups. However, radiation exposure [221 Gy cm^2 ; interquartile range (IQR), 138–406 Gy cm^2 ; versus median, 255 Gy cm^2 ; IQR, 148–425 Gy cm^2 ; $P = 0.05$] was lower and operation time (median, 300 min; IQR, 240–356 min; versus median, 364 min; IQR, 290–475 min; $P = 0.01$) was shorter in the TFA group. Scott *et al.* [22] also compared UEA (361 patients) to the use of a TFA (92 patients) in their cohort of patients. The technical success rate for the TFA was 98% and only 1 stroke was reported in the TFA group as opposed to 5 in the UEA group ($P = 0.99$). Hauck *et al.* [23] in a series of 19 patients compared 7 TFA (19 branches) and 12 UEA (32 branches). The reported technical success rate was 100% (19/19) in the TFA and 97% (31/32) in the UEA group. Branch cannulation was quicker in the TFA group (17 vs 29 min; $P = 0.003$).

DISCUSSION

UEA has been the standard approach to TV catheterization during complex endovascular aortic repair [2–4]. However, this would inevitably carry the risk of additional access-site complications at the arm level, owing to the need for intraoperative manipulation with large-bore sheaths.

Findings from the present review appear to agree with those reported in prior publications. In their recent literature review on UEA during B/EVAR, Malgor *et al.* [2] reported the outcomes of 495 patients. A total of 41 (8%) UEA-related complications were noticed. Of those 41 complications, 17 (41.5%) were access-site bleedings, 10 (24%) were ischaemic strokes, 7 (17%) were arterial occlusions, 4 (10%) were upper extremity neurologic deficits, 2 (5%) were arterial stenoses and 1 (2%) was a pseudoaneurysm. UEA-related complications were reported in 15/56 (27%) patients undergoing percutaneous UEA and 26/439 (6%) undergoing open UEA ($P < 0.001$). Previous studies have demonstrated that the high brachial artery should preferably be approached surgically, due to the smaller calibre of this artery and the associated high incidence of complications following percutaneous procedures with large-bore sheaths. Kret *et al.* [24] demonstrated that surgical cutdown was associated with significantly decreased rates of access-site complications when compared with a percutaneous approach (odds ratio 0.25, $P = 0.004$). Furthermore, complications after surgical exposure at the upper arm level are not uniformly reported in the literature ranging from 0% to 25% with a rate of peripheral nerve injury ranging from 0% to 9%

[2, 25, 26]. While surgical cutdown at the brachial/axillary artery level has been the standard approach for TV cannulation, percutaneous axillary access has been recently showed to represent a safe and feasible alternative [16]. More recently, different authors started using vessel closure devices to repair percutaneous axillary access in an attempt to lower the access-related complication such as median nerve compression due to haematomas, with an overall morbidity rate ranging from 2% to 18%, but no comparative studies have yet been published [17, 20, 27–30]. Interestingly, it was demonstrated that, if compared with the ilio-femoral arteries, the axillary artery showed substantially lower rates of significant stenosis (2% vs 12%, $P < 0.01$) and significantly lower rates of moderate to severe calcification (9% vs 64%, $P < 0.01$). Diabetes and tobacco use were independently associated with smaller luminal diameters ($P < 0.01$) but not with significant stenotic disease [31]. This may translate to lower complication rates for percutaneous accesses in the axillary artery if a correct puncture protocol is followed [4, 16]. In the present review, 89 cases were performed through an axillary artery access (A1 segment) and 1211 through a high brachial access (A3 segment), but for 10 cases, it was not specified the access site between these 2.

The risk of cerebral adverse events following UEA may not be insignificant [5, 6]. Traditionally, the left side has been preferred over the right one because of concerns with crossing all 3 supra-aortic vessels with endovascular devices. Whether using the right arm (versus the left arm) may actually carry a significant benefit to patients in terms of reduced stroke rates remains another area of ongoing research. Taking into consideration published differences between left and right UEA, a definitive answer on which side presents the lowest risk is yet to come. It is worth noting that an intrinsic selection bias could be inferred due to the lower use of the left UEA as opposed to the right UEA in most published series [7, 15–20, 22, 23], and no randomized controlled trials have ever been performed. Cross-comparison of available case series is challenging, as the data are very heterogeneous and often lacking detailed assessment of the aortic morphology. Moreover, the axillary artery segments used are different in each series (first/third), and the techniques used to access the upper extremity arteries are different (percutaneous puncture/surgical exposure). What can be seen from the literature is that operators who started using a left UEA are moving to a right UEA, when anatomically feasible, due to lower radiation doses during the procedures, with a comparable stroke rate [19].

Furthermore, an important limitation of studies on the relationship between UEA and cerebrovascular events is that minor neurological deficits and asymptomatic lesions may have been underestimated because independent assessment from neurologists is often lacking and silent brain infarctions (SBI) as seen on brain imaging are not investigated outside clinical trials. Recently, the preliminary results of the STEP Registry were published [32]. This registry aimed at quantifying the rate of SBI following endovascular treatment of the aortic arch. At 30 days, with no deaths or clinically evident strokes, a total of 245 SBI were identified in 45 patients (50%) on cerebral diffusion weighted magnetic resonance imaging. And were significantly associated on univariable analysis with deployment in zone 0–1 ($P = 0.026$), placement of a branched or fenestrated endograft ($P = 0.038$), a proximal endoprosthesis diameter ≥ 40 mm ($P = 0.038$) and an urgent procedure ($P = 0.005$). This and further studies will provide us with more insights and a better understanding on how to reduce stroke rates. However, it should be borne in mind that stroke is multifactorial and associated with several variables such as stent graft

flushing, the shagginess of the aorta and haemodynamic changes during and after the procedure [33,34].

Lastly, the recent introduction of TFA approach with steerable sheaths has been gaining traction, mainly owing to its intrinsic lower stroke rate as it may enable a totally retrograde approach to TV cannulation. Different series have been published stating the almost negligible stroke rate associated with this access route for TV cannulation, as also showed in the present analysis [10–12, 21, 22]. However, different technical considerations should be made. While it is true that using a steerable sheath might allow operators to cannulate caudally oriented branches and vessels without any need to be close to the supra-aortic vessels, attention should be paid to longer occlusion times of the pelvic and lower limb circulation. Several technical adjuncts, such as early main graft removal [35], the use of preloaded stent grafts [36–38] and downsizing of the TFA may be performed to reduce ischaemic times to the pelvis and leg [39]. Another factor to consider when planning a TFA approach relates to the endograft inner diameter above the visceral segment, which should be enough for the steerable sheath to complete its curvature and grant stability to the system. In fact, if the curvature of the steerable sheath results too acute, the devices may not advance into the downwards branch or vessel or may not be as precise during deployment. Radiation exposure is an important concern in complex endovascular aortic repair and depends on the operator's position relative to the radiation source. Different studies have shown a lower radiation exposure during TFA compared to UEA, which may represent another advantage to the former approach [10, 40]. The number of branches/fenestration per patient was similar for both accesses, as shown in Tables 1 and 2. No definitive answer on which access is better can be given at this time as both may present with their own advantages and shortcomings, which should be carefully weighted based on operators' experience and patients' anatomy.

Limitations

Findings from the present analysis should be interpreted within the context of some intrinsic limitations. A scoping review is an exploratory but systematic literature search to find out how much is known about a broad topic or to discover gaps in the evidence and provide a narrative review without formal meta-analysis. As highlighted in the present analysis, the question(s) being addressed is usually broader and also more complex and heterogeneous than that in a systematic review. However, a scoping review can identify specific unanswered questions and gaps in current literature which can be addressed either with new original research or some that could be answered by a systematic review. Our rigorous scoping review that was conducted following up-to-date methodological guidance and reporting criteria can help shape future research on the broad and clinically relevant topic of how to select the best access for cannulation of target reno-visceral vessels at time of complex endovascular aortic repair, while also highlighting the need for more homogeneous reporting of data to make cross-comparison of series and pooling of results feasible going further [41, 42]. Given the scoping nature of this review, there is an element of selection bias in the identification of articles for inclusion. Relevant articles may also have been missed using the search parameters and literature search. This review presents heterogeneous study designs and methods; furthermore, there was a variety of definitions used for

the postoperative outcomes assessed as well as techniques adopted by operators for included studies. However, despite all the limitations cited, this review represents a comprehensive assessment of a complex and clinically relevant topic and may possibly assist with planning of further research on the subject, with the ultimate goal of improving perioperative care to patients undergoing complex endovascular aortic repair [43].

CONCLUSIONS

Both UEA and TFA for TV cannulation in patients undergoing complex aortic endovascular repair were associated with high technical success and low perioperative complication rates. Currently, there is a paucity of high-quality data to provide any definitive indication on the best approach as both present benefits, drawbacks and risks that must be tailored to the clinical scenario. Other areas needing further research remain the optimal UEA in terms of side (left versus right) and approach (surgical versus percutaneous). Operators' experience, patients' selection and preoperative planning remain key to achieving optimal clinical outcomes.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

Conflict of interest: none declared.

Data availability statement

Data collected for the study will be made available by the corresponding author upon reasonable request after publication.

Author contributions

Alessandro Grandi: Data curation; Formal analysis; Investigation; Methodology; Validation; Visualization; Writing—original draft. **Mario D'Oria:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Supervision; Validation; Writing—original draft. **Andrea Melloni:** Data curation; Formal analysis; Writing—review & editing. **Cristiano Calvagna:** Data curation; Formal analysis; Writing—review & editing. **Jacopo Tagliavaloro:** Data curation; Formal analysis; Writing—review & editing. **Roberto Chiesa:** Data curation; Formal analysis; Supervision; Writing—review & editing. **Sandro Lepidi:** Data curation; Formal analysis; Supervision; Writing—review & editing. **Luca Bertoglio:** Data curation; Formal analysis; Methodology; Supervision; Writing—review & editing.

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