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Endovascular aneurysm repair under local anesthesia through bilateral percutaneous femoral access is a safe strategy to improve early outcomes and reduce hospital stay

Davide ESPOSITO ¹ *, Aaron T. FARGION ¹, Walter DORIGO ¹, Caterina MELANI ², Francesca MAURI ³, Sergio ZACÀ ⁴, Giovanni PRATESI ², Gabriele PIFFARETTI ³, Domenico ANGILETTA ⁴, Carlo PRATESI ¹, Raffaele PULLI ¹ on behalf of the Italian Collaborators for EVAR (ICE) Group ‡

¹Department of Cardiothoracic and Vascular Surgery, Careggi University Teaching Hospital, University of Florence, Florence, Italy; ²Department of Surgical and Integrated Diagnostic Sciences, University of Genoa School of Medicine, Genoa, Italy; ³Unit of Vascular Surgery, Department of Medicine and Surgery, University of Insubria School of Medicine, Varese, Italy; ⁴Department of Emergency and Organ Transplantation, University of Bari School of Medicine, Bari, Italy

‡Members are listed at the end of the paper

*Corresponding author: Davide Esposito, Department of Cardiothoracic and Vascular Surgery, Careggi University Teaching Hospital, University of Florence, largo Brambilla 3, 50134 Florence, Italy. E-mail: davide.esposito@unifi.it

ABSTRACT

Background: To estimate the impact of anesthetic conduct, alone and in combination with the type of femoral access, on early results after endovascular aneurysm repair (EVAR).

Methods: A retrospective multicenter analysis on patients undergoing elective standard EVAR at four academic centers was performed. Patients undergoing the procedure through either local or general anesthesia were compared. Comparative subanalyses of the two groups were performed for the type of femoral access to evaluate further impact on outcomes.

Results: Five hundred twenty-four patients underwent elective standard EVAR, of which 207 (39.5%) under general anesthesia and 317 (60.5%) under local anesthesia. Patients who underwent general anesthesia had higher 30-day mortality rates (3.4% vs. 0.3%, $P=0.005$), as well as slightly worse 30-day major systemic complication rates (8.2% vs. 5.4%, $P=0.195$). There were no differences in terms of reinterventions (2.1% vs. 2.5%, $P=0.768$) and aneurysm-related mortality (0% vs. 0.4%, $P=0.422$) at one year. Total intervention times were significantly longer in the general anesthesia group (126 vs. 89 minutes, $P=0.001$), as well as the total length of hospital stay (7.6 vs. 5.3 days, $P=0.007$). At subanalyses, the combination of local anesthesia with bilateral percutaneous femoral access further improved 30-day outcomes and determined an additional reduction in total intervention times and ICU stays.

Conclusions: EVAR performed under local anesthesia has a significantly better impact on early results when compared to general anesthesia. Combining percutaneous bilateral femoral access to local anesthesia reduced procedural times, ICU stays and consequently improved early results.

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Key words: Aortic aneurysm; Endovascular procedures; Anesthesia, local; Survival.

Endovascular repair (EVAR) is currently the most performed procedure to treat abdominal aortic aneurysm in cases with adequate anatomical characteristics.¹⁻³ Results are constantly improving as techniques and materials become more reliable.⁴ Theoretically, the performances of the procedure itself could be further improved by mitigating the systemic impact that this kind of surgery has on patients. Indeed, modifiable approaches, such as a lower invasiveness in the type of anesthesia and of access to femoral arteries, might potentially play a role in decreasing procedure-related systemic and surgical complications. The aim of the study was to estimate the impact of anesthetic conduct, alone and in combination with the type of femoral access, on early outcomes after elective EVAR.

Materials and methods

Study design

From January 2018 to March 2021, 602 consecutive patients underwent standard EVAR at four academic high-volume centers. Data regarding pre-, intra-, and post-operative characteristics and outcomes were collected in dedicated prospective datasets from each institution and followed the definitions of the Society for Vascular Surgery (SVS) Reporting Standards for EVAR and comorbidity grading system;^{5,6} adjunctive intraoperative maneuvers executed along with standard EVAR and major systemic complications were reported as per Reporting Standards categorization.⁵ Data from individual institutions were then merged into a collective database and retrospectively analyzed. Informed consent was obtained from all patients for the inclusion of their data in our records and for the retrospective analysis of the results. In agreement with national law, owing to the retrospective nature of the present study based on anonymized data, the approval of each Ethical Committee was not mandatory. The indications to perform EVAR procedure were in accordance with National and International guidelines.⁷⁻¹⁰ Follow-up consisted of plain computed tomography (CT) or CT angiography

at one month from surgery, Duplex ultrasound (DUS) at three-six months, plain CT/CT angiography/DUS at one year.

No funding was obtained from companies or other institutions for conducting data collection, analyses, and paper production. Checklist of items followed the STROBE statement.¹¹

Endpoints and subanalyses

Primary outcomes were major systemic complications and overall mortality at 30 days, and reinterventions and aneurysm-related mortality at one year. Secondary outcomes were total intervention times, and length of intensive care unit (ICU) and total hospital stays.

A subanalysis was planned to evaluate and compare the same outcomes stratifying the two groups according to the type of femoral access (percutaneous *versus* surgical).

Anesthetic conducts

The decision whether to choose local or general anesthesia was left to the discretion and experience of the surgical and anesthesiology teams, as well as to patients' prefer-



Figure 1.—Ultrasound-guided anaesthetic injections for ilio-inguinal and ilio-hypogastric nerve blocks.

ence.⁷ Local anesthesia consisted of either local anesthetic infiltrations or loco-regional ultrasound-guided ilio-inguinal and ilio-hypogastric nerve blocks, performed by the anesthetist (Figure 1); patients were administered sedative/hypnotic short-acting agents during the procedure to achieve sedation, analgesia or anxiolysis in case of non-compliance.

General anesthesia was generally induced with a short-acting hypnotic, combined with an opioid and myorelaxants to facilitate intubation, and maintained *via* a volatile inhalation anesthetic.

Femoral accesses

Mono- or bilateral surgical cut-down performed to reach common femoral arteries was labelled as surgical access. Percutaneous access consisted of bilateral ultrasound-guided needle puncture of the common femoral arteries and subsequent closure with closure devices. The rate of intraoperative percutaneous access conversions to surgical cut-down was recorded. The adoption of a percutaneous or surgical access depended on vessels anatomical characteristics (diameters, presence and burden of calcifications and thrombus) as well as on surgeons' experience and discretion.

Statistical analysis

The statistical analysis was performed with the "SPSS v. 25 statistical software" (IBM Corporation, Armonk, NY, USA). Statistical and data reporting followed guidelines

indications.¹² Continuous variables were tested for normality through the Shapiro-Wilk's Test and visual evaluation of Quantile-Quantile (Q-Q) plots; variables were presented as mean±standard deviation (SD) if normally distributed, otherwise as median, and interquartile range (IQR). Categorical variables were presented as frequencies and percentages. Quantitative variables were compared through One-way ANOVA, Mann-Whitney U or Student's *t*-test and qualitative variables through Pearson χ^2 test. Univariate analysis was used to identify potential predictors of 30-day outcomes, and when associations yielded P values <0.20 a binary logistic regression analysis was performed using the Wald's forward stepwise model. The strength of association of variables with the outcome was estimated by calculating odds ratios (OR) and 95% confidence Intervals (95%CI). Statistical significance was considered for P values <0.05.

Results

Study group

During the study period, 602 patients underwent standard EVAR, of which 78 (13%) were in an urgent setting and were excluded from the analysis, resulting in a final study cohort of 524 patients. The type of anesthesia adopted was general in 207 (39.5%) cases and local in 317 (60.5%). Mean age was 75.3±7.7 years, 92.7% were males. The two groups had similar preoperative characteristics (Table I).

TABLE I.—Details on preoperative characteristics.

	Total cohort (N.=524)	General anesthesia (N.=207)	Local anesthesia (N.=317)	OR	P value
Demographics					
Age, mean±SD	75.3±7.7	75.6±8.3	75.2±7.3		0.113
Male, N. (%)	486 (92.7)	194 (93.7)	292 (92.1)	0.98	0.488
Comorbidities					
Hypertension, (N. %)	438 (83.6)	174 (84.1)	264 (83.3)	1.05	0.814
CAD, (N. %)	159 (30.3)	65 (31.4)	94 (29.7)	1.02	0.67
CKD, (N. %)	104 (19.8)	50 (24.2)	55 (17)	1.09	0.06
COPD, (N. %)	158 (30.2)	66 (31.9)	92 (29)	1.04	0.485
Diabetes, (N. %)	74 (14.1)	30 (14.5)	44 (13.9)	1.01	0.844
Risk factors					
SVS score, mean±SD	6±3.5	5.9±3.6	6±3.5		0.762
Previous CABG/PTCA, (N. %)	140 (26.7)	49 (23.7)	91 (28.7)	0.93	0.203
Preoperative lab values					
Hemoglobin (g/dL), median (IQR)	14 (2.5)	13.9 (2.8)	14 (2.4)		0.358
CPK (U/L), median (IQR)	84 (61)	80 (66.5)	85 (57.5)		0.413
LDH (U/L), median (IQR)	190 (47)	186 (53)	192.5 (46)		0.161
eGFR*, median (IQR)	71 (29.1)	67.7 (29.8)	71.9 (28.5)		0.232

N.: number; OR: odds ratio; SD: standard deviation; IQR: interquartile range; CAD: coronary artery disease; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; SVS: Society for Vascular Surgery; CABG: coronary artery bypass graft; PTCA: percutaneous transluminal coronary angioplasty; CPK: creatine phosphokinase; LDH: lactate dehydrogenase; eGFR: estimated glomerular filtration rate)

*eGFR: calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.

Intraoperative results

Total intervention times were longer in patients treated under general anesthesia (126.1 ± 64.4 vs. 89.1 ± 43.1 minutes, $P=0.001$), mainly due to a lower proportion of bilateral percutaneous femoral access (40.6% vs. 79.5% , $P<0.001$). In 7 cases (1.3%) of percutaneous femoral accesses, it was

intraoperatively necessary to convert the access to a surgical cut-down due to either femoral rupture or dissection determining bleeding or occlusion after ineffective closure through the dedicated device. The median amount of iodine contrast medium used during EVAR was 82 mL (IQR, 70-100), and 26 (5%) procedures were carried out using

TABLE II.—Specifics on type and grading of complications.

Systemic complication type	Grading	General anesthesia (N.=207)	Local anesthesia (N.=317)	OR	P value
Cardiac	Mild	5	2	1.03	0.05
	Moderate	2	-		
	Severe	1	2		
	Total, (N. %)	8 (3.9)	4 (1.3)		
Pulmonary	Mild	1	3	0.99	0.702
	Moderate	2	2		
	Severe	-	1		
	Total, (N. %)	3 (1.4)	6 (1.9)		
Renal	Mild	2	1	1.01	0.337
	Moderate	1	2		
	Severe	1	-		
	Total, (N. %)	4 (1.9)	3 (0.9)		
Cerebrovascular	Mild	-	-	-	-
	Moderate	-	-		
	Severe	-	-		
	Total, (N. %)	-	-		
Deep venous thrombosis	Moderate	-	-	-	-
	Severe	-	-		
	Total, (N. %)	-	-		
Pulmonary embolism	Moderate	-	-	-	-
	Severe	-	-		
	Total, (N. %)	-	-		
Coagulopathy	Moderate	2	3	0.99	0.756
	Severe	-	1		
	Total, (N. %)	2 (1)	4 (1.3)		
Bowel ischemia	Mild	-	-	-	-
	Moderate	-	-		
	Severe	-	-		
	Total, (N. %)	-	-		
Spinal cord ischemia	Mild	-	-	-	-
	Moderate	-	-		
	Severe	-	-		
	Total, (N. %)	-	-		
Erectile dysfunction	Mild	-	-	-	-
	Moderate	-	-		
	Severe	-	-		
	Total, (N. %)	-	-		

N.: number; OR: odds ratio.

solely CO₂ as the contrast media of choice. Adjunctive intraoperative maneuvers additional to the standard EVAR procedure were performed in 35.9% of cases (41.1% vs. 32.5%, $P=0.05$). Neither intraoperative conversions to open repair nor conversions from local to general anesthesia were registered.

Postoperative outcomes

Patients undergoing general anesthesia had shorter ICU (0.1 ± 0.7 vs. 0.4 ± 0.9 days, $P<0.001$), but longer total hospital (7.6 ± 6.9 vs. 5.3 ± 5.7 days, $P=0.007$) stays. Patients receiving general anesthesia presented slightly higher 30-day major systemic complication rates (8.2% vs. 5.4%, $P=0.195$), which mainly consisted in reversible cardiac, pulmonary, and renal problems (details in Table II). Specifically, cardiac complications (of which seven out of a total of 12 of mild grade) were more common in the general anesthesia group (3.9% vs. 1.3%, OR: 1.03; $P=0.05$).

In the first 30 postoperative days the overall mortality was 1.5%, of which seven deaths occurred in the general anesthesia group and one in the local anesthesia group (30-day mortality: 3.4% vs. 0.3%, $P=0.005$). Three deaths (two in the general anesthesia group and one in the local anesthe-

sia group) were attributed to SARS-CoV-2 infection leading to pneumonia and respiratory failure; these fatalities occurred during the initial peak of the COVID-19 pandemic.

General anesthesia was a significant risk factor for 30-day mortality at univariate analysis. Preoperative chronic kidney disease (CKD) (OR: 4.77; 95%CI: 1.38-16.32; $P=0.013$) and chronic obstructive pulmonary disease (COPD) (OR: 3.02; 95%CI: 1.05-8.67; $P=0.04$) were significantly associated with the risk of 30-day major complications at multivariate analysis; CKD was also identified as an independent factor associated with the risk of 30-day mortality (OR: 10.17; 95%CI: 1.63-63.45; $P=0.013$). Uni- and multivariate analysis for 30-day outcomes risks are showed in Table III.

At one-year follow-up, the two groups had comparable reintervention rates (2.1% vs. 2.5%, $P=0.768$) and aneurysm-related mortality rates (0% vs. 0.4%, $P=0.422$). Details are available in Table IV.

Subanalyses of the outcomes stratified by type of femoral access

After stratifying patients according to the type of femoral access, in the local anesthesia group, 252 (48.1%) patients

TABLE III.—Univariate and binary logistic regression analyses for the risk of major systemic complications and mortality in the first 30 postoperative days.

Covariates	30-day major systemic complications risk					30-day mortality risk				
	Univariate		Multivariate			Univariate		Multivariate		
	OR	P value	OR	95%CI	P value	OR	P value	OR	95%CI	P value
Females	0.96	0.32				0.98	0.42			
Octogenarians	1.01	0.61				1.02	0.11	2.11	0.46-9.62	0.34
Hypertension	1.04	0.22				1.01	0.77			
CAD	1.08	0.12	1.69	0.49-5.89	0.41	0.98	0.48			
CKD	1.25	0.002	4.77	1.38-16.32	0.013	1.13	<0.001	10.17	1.63-63.45	0.013
COPD	1.11	0.04	3.02	1.05-8.67	0.04	0.98	0.46			
Diabetes	0.95	0.15	0.35	0.08-1.51	0.16	0.98	0.25			
Previous CABG/PTCA	1.04	0.12	1.73	0.82-3.63	0.15	1.02	0.13	3.98	0.88-17.97	0.07
General anesthesia	1.03	0.19	1.69	0.83-3.46	0.15	1.03	0.005	7.09	0.76-65.81	0.085
Percutaneous access	0.98	0.51				0.97	0.002	0.13	0.01-1.23	0.076
Adjunctive procedures	1.03	0.16	1.58	0.76-3.26	0.22	1.01	0.40			

OR: odds ratio; 95%CI: 95% confidence interval; CAD: coronary artery disease; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; CABG: coronary artery bypass graft; PTCA: percutaneous transluminal coronary angioplasty.

TABLE IV.—Thirty-day and one-year primary outcomes.

	Local anesthesia (N.=317)	General anesthesia (N.=207)	OR	P value
30-day				
Major systemic complications, N.%)	17 (5.4)	17 (8.2)	1.58	0.195
Overall mortality, N.%)	1 (0.3)	7 (3.4)	11.03	0.005
1-year				
Reinterventions, N.%)	7 (2.5)	4 (2.1)	0.83	0.768
Aneurysm-related mortality, N.%)	1 (0.4)	0 (0)	1	0.422

N.: number; OR: odds ratio.

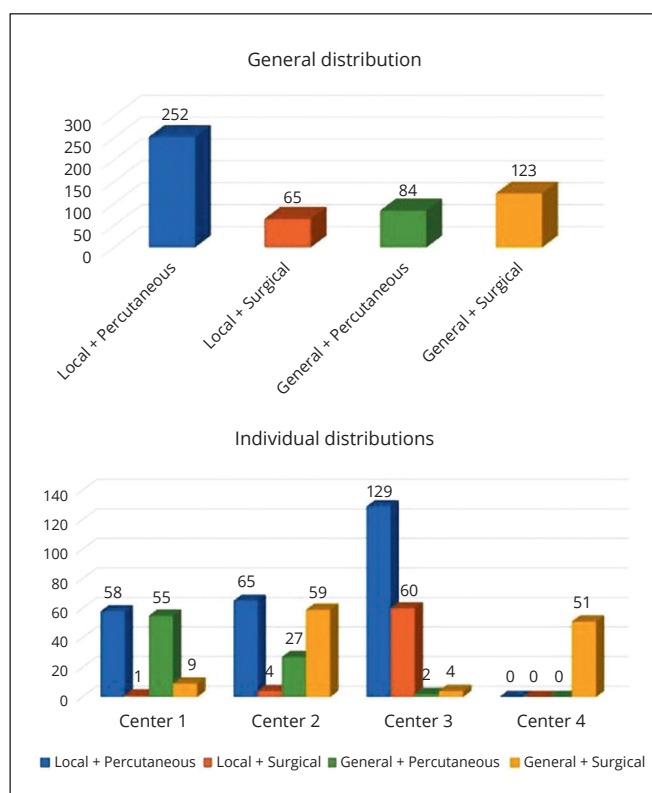


Figure 2.—General and individual centers' distributions of treatment strategies depending on the combinations of type of anesthesia (local/general) and femoral access (percutaneous/surgical).

had a total percutaneous access and 65 (12.4%) a mono/bilateral surgical access, while in the general anesthesia group, the corresponding figures were 84 (16%) and 123 (23.5%), respectively. The general and center-specific distributions of treatment strategies according to combination of type of anesthesia and femoral access are illustrated in Figure 2.

Patients undergoing EVAR under local anesthesia and bilateral femoral percutaneous access had the lowest 30-day complication and overall mortality rates, while 1-year outcomes were similar among groups (Table V); the latter strategy determined further improvement in terms of total intervention times (81.7 ± 38.3 minutes, $P < 0.001$) and ICU stays (0.3 ± 0.8 days, $P < 0.001$). Secondary outcomes after stratification for the type of femoral access are available in Table VI, and pairwise combinations are shown in Figure 3.

Discussion

The lower rates of complication and mortality showed by our analysis demonstrated that it is safer to perform EVAR under local rather than general anesthesia, and it is likewise meaningful when observing that operating times and hospital stay were significantly reduced.

Several studies pooled in meta-analyses already showed the non-inferiority of local over general anesthesia,¹³⁻¹⁸ and the advantages of choosing it in the urgent setting for ruptured aneurysms as well.¹⁶⁻¹⁸ According to a very re-

TABLE V.—Subanalyses of the primary outcomes stratified for the type of femoral access.

	Local anesthesia		General anesthesia		P value
	Percutaneous access (N.=252)	Surgical access (N.=65)	Percutaneous access (N.=84)	Surgical access (N.=123)	
30-day					
Major systemic complications, N.%)	12 (4.8)	5 (7.7)	8 (9.5)	9 (7.3)	0.422
Overall mortality, N.%)	0 (0)	1 (1.5)	1 (1.2)	6 (4.9)	0.004
1-year					
Reinterventions, N.%)	5 (2.3)	2 (3.4)	0 (0)	4 (3.6)	0.411
Aneurysm-related mortality, N.%)	1 (0.5)	0 (0)	0 (0)	0 (0)	0.784

N.: number.

TABLE VI.—Secondary outcomes after stratification for the type of femoral access.

	Percutaneous access and local anesthesia (N.=252)	Surgical access and local anesthesia (N.=65)	Percutaneous access and general anesthesia (N.=84)	Surgical access and general anesthesia (N.=123)	P value
Total intervention time (minutes), mean±SD	81.7±38.3	117.9±48.8	118.2±50.8	131.5±71.9	<0.001
ICU stay (days), mean±SD	0.3±0.8	0.9±1.3	0.1±0.3	0.2±0.8	<0.001
Total hospital stay (days), mean±SD	5.5±6.3	4.4±2.2	7.9±6.1	7.4±7.4	<0.001

N.: number; SD: standard deviation; ICU: intensive care unit.

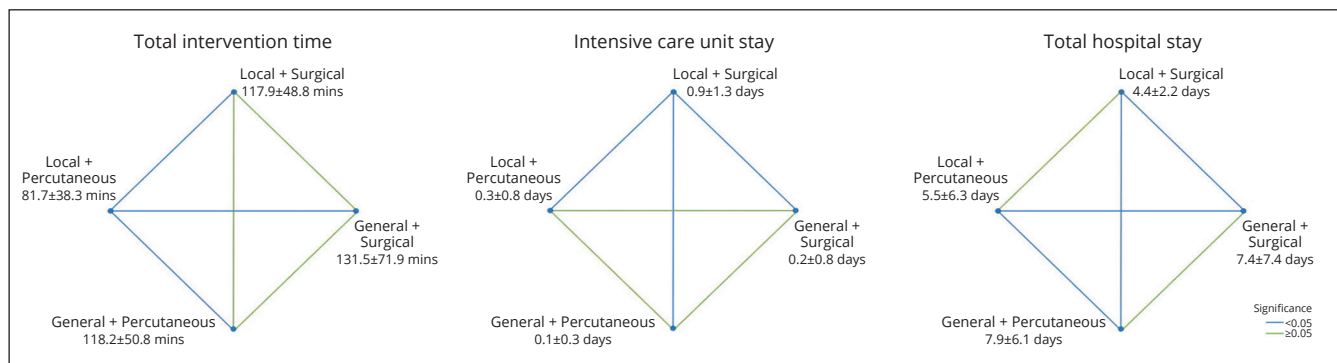


Figure 3.—Pairwise comparisons of anesthetic and femoral access combination strategies for the secondary outcomes (each node shows the sample mean with standard deviation).

cent Cochrane review,¹⁹ to date no randomized controlled trials (RCT) comparing anesthetic modalities for EVAR have been conducted. The previously mentioned meta-analyzed results must be looked at carefully, given the fact that the majority of included studies were single-center and retrospective in nature, many times comparing unbalanced cohorts.

Our paper represented a large series that reported on outcomes of balanced and comparable cohorts, manifested by similar prevalence of comorbidities, the latter being further combined by the SVS comorbidity grading system.⁶ This data might indicate that the choice of the type of anesthesia did not much take into account the possible state of frailty of the single patient, but was dictated by the attitudes and experience of the individual centers. Indeed, two out of the four centers participating to the registry have had a clear predisposition to the selection of one or the other type of anesthesia (Centers 3 and 4 in Figure 2), consequently balancing the more selective attitude of the remaining centers and possibly reducing the risk of allocation bias.

From the analysis of extensive registries such as the UK's National Vascular Registry and the SVS Vascular Quality Initiative (VQI), authors reported that patients had a faster discharge from hospital when treated under local anesthesia²⁰ and that the length of interventions and ICU stay were significantly longer when performing general anesthesia.²¹ Our data confirmed the benefits of local anesthesia in significantly lowering intervention times, ICU, and total length of stay, meaning that anesthesiologic conduct alone has a high impact on the procedure itself and on patients' hospital stay.

Additionally, we observed that bilateral percutaneous femoral access in combination with local anesthesia guaranteed further improvements in intervention times and

ICU stay, as well as the best results in terms of 30-day complications and mortality when compared to the other possible combination strategies, without negatively impacting reintervention and survival rates at one year. Although a meta-analysis of three RCTs found that a totally percutaneous access for EVAR might not improve short-term mortality, failure of aneurysm exclusion, bleeding, wound infection, and major complications (within 30 days and at six months) compared to surgical cut-down,²² we believe that, even in presence of demanding anatomies,²³ its association with a less invasive anesthetic conduct might be the preferential strategy to improve results. Some authors have observed that anatomical factors such as increased common femoral artery depth, technical factors including the choice of closure device and complex EVAR procedures, and physiological factors like low estimated glomerular filtration rate (eGFR) levels might be associated with access-related complications.²⁴ These factors should be carefully considered in the selection of patients; in our cohort, indeed, 7 cases necessitated access conversion from percutaneous to surgical cut-down, which could potentially have had an impact on outcomes. Furthermore, in logistic regression analysis, it was determined that preoperative CKD was independently associated with 30-day complications and mortality; therefore, opting for local anesthetics instead of systemic drugs would be preferable to minimize the operative impact on kidney function.²⁵

Retrospective monocentric experiences proved the feasibility and safety of performing percutaneous EVARs with local anesthesia, but did not have a comparison group;^{26, 27} besides, other authors investigated perioperative outcomes comparing types of anesthesia for percutaneous EVARs collected in the VQI database and found out that local anesthesia had the potential of lowering pulmonary complications.²⁸

Our study proved the immediate and early advantages of adopting this minimally invasive strategy, but longer-term results are still needed to validate its effectiveness. Undoubtedly, the reduction of operating times and length of hospitalization determines a great benefit in terms of costs and patient satisfaction,^{29, 30} for this reason an effort should be made to orient the procedure towards this approach.

Limitations of the study

Although representing a real-life scenario of EVAR performances among four high-volume institutions, the current study has the main limitations of its retrospective nature and possible heterogeneity in the choice of both type of anesthesia and femoral access among different centers. The registry was not created with the sole purpose of investigating the impact of the type of anesthesia on outcomes and, even if the amount of collected data was considerable, the number of variables consistent with the objectives of the present study was limited. Likewise, the register was intended to look at early and one-year outcomes only, as medium, and long-term follow-up data are currently being collected.

Furthermore, since the majority of interventions performed under local anesthesia were carried out through a percutaneous bilateral access (252 percutaneous EVARs out of 317 performed under local anesthesia, 79.5%), the latter could have played a more consistent role than that currently demonstrated by the analyses, even though percutaneous access did not have a high impact in the general anesthesia patients populations, for which the numbers were reasonably comparable (84 percutaneous of 207 under general anesthesia, 40.6%).

Lastly, the study period of this paper coincided with the COVID-19 pandemic, which having caused an alteration in vascular services likely influenced the results,^{31, 32} with SARS-CoV-2-related deaths that might explain the elevated 30-day mortality of 3.4% in the general anesthesia group.

Conclusions

The choice of the type of anesthesia to be adopted to carry out EVAR does have an impact on early results. When performing the procedure under local anesthesia, outcomes such as early major complications and survival are significantly better. Moreover, the strategy of combining local anesthesia with a bilateral percutaneous femoral access further reduces operative times and ICU stays, making the entire EVAR procedure even less invasive, without in-

fluencing the risk of complications. Therefore, whenever suitable for the patient and in the presence of adequate femoral access characteristics, the first-line EVAR strategy should be to perform the procedure percutaneously under local anesthesia.

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Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions

Davide Esposito, Giovanni Pratesi, Gabriele Piffaretti, Domenico Angiletta, Carlo Pratesi and Raffaele Pulli have given substantial contributions to the conception or the design of the manuscript; all the collaborative group members contributed to data acquisition; Davide Esposito, Caterina Melani, Francesca Mauri and Sergio Zacà to analysis and interpretation of the data; Davide Esposito drafted the manuscript; Gabriele Piffaretti, Carlo Pratesi and Raffaele Pulli revised it critically. All authors read and approved the final version of the manuscript.

Group author members

Domenico ANGILETTA; STEFANO Attolini; Martina BASTIANON; Nabile BELOUFA; Amedeo CAPONE; Andrea CASINI; Andrea S. CUCCI; Sara DI GREGORIO; Lucia DI STEFANO; Walter DORIGO; Davide ESPOSITO; Aaron T. FARGION; Francesca MAURI; Caterina MELANI; Gaddiel MOZZETTA; Dario PALERMO; Vincenzo PALERMO; Gabriele PIFFARETTI; Elisa PISCITELLO; Carlo PRATESI; Giovanni PRATESI; Raffaele PULLI; Sara SPEZIALI; Federico VILLA; Sergio ZACA.

History

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