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# Impact of center experience on unibody anatomically fixed systems utilization: insight from a multicentric, international, non-randomized, prospective registry – the AFX2-LIVE Study

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## ABSTRACT

**Background:** The present study evaluates the impact of procedural volume on intraoperative and short-term outcomes of endovascular aneurysm repair (EVAR) using the AFX2 unibody endograft in a large, multicenter cohort.

**Methods:** A secondary analysis of the AFX2 LIVE study was conducted, including 535 EVAR procedures performed across 43 centers from November 2019 to August 2021. Centers were categorized into four quartiles based on case volume. Procedural efficiency (operative time, fluoroscopy time, contrast media use) and clinical

outcomes (technical success, 30-day clinical success, major adverse events) were analyzed. A nonlinear regression model identified a volume threshold for improved technical outcomes.

**Results:** Higher-volume centers demonstrated significantly shorter operative times (Q1=80 min vs. Q4=60 min, P=0.003), reduced contrast media usage (Q1=89.6 mL vs. Q4=61.9 mL, P=0.001), and lower fluoroscopy times (Q1=714 s vs. Q4=520 s, P=0.001). Logistic regression indicated that each additional 10 cases increased the likelihood of optimal procedural performance (OR=1.29, P=0.001). A threshold of 30 cases per center was identified, above which the probability of achieving optimal technical outcomes exceeded 50%. Despite these efficiency improvements, primary technical success (Q1-2=97.9% vs. Q3-4=98.0%, P=0.928) and 30-day MAE rates remained comparable across all quartiles.

**Conclusions:** Institutional experience significantly influences procedural efficiency in EVAR with the AFX2 device, with a learning curve effect evident beyond 30 cases. However, technical success and safety remain high across all centers, reinforcing the device's feasibility even in lower-volume institutions. These findings support current European guidelines recommending a minimum annual EVAR caseload of 30 procedures per center.

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**Key words:** Endovascular procedures; Abdominal aortic aneurysm; Learning curve; Operative time; Contrast media; Endovascular aneurysm repair.

Since its introduction in the early 1990s, endovascular aneurysm repair (EVAR) has established as the preferred choice for the treatment of abdominal aortic aneurysms (AAA) with permissive anatomy.<sup>1</sup> Over the past three decades, this minimally invasive approach has demonstrated significant benefits in terms of reduced perioperative morbidity and faster recovery.<sup>2-6</sup>

Optimizing technical outcomes and patient safety in EVAR depends heavily on the expertise of the surgical team and their familiarity with the materials and techniques involved. As a result, defining what constitutes a “high-volume center” for AAA treatment has been a subject of considerable debate and analysis. The available literature on this topic remains limited and somewhat inconsistent.<sup>7</sup> According to American guidelines, AAA repair should be performed in centers that conduct at least 10 EVAR and 10 open repairs per year.<sup>8</sup> Italian guidelines set the threshold at 30 procedures per year for both EVAR and open repair, despite the low level of supporting evidence for this recommendation.<sup>5</sup> Finally, European guidelines advise against performing these procedures in centers with an annual volume below the recommended minimum yearly caseload of at least 30 standard AAA re-

pairs per center (no less than 15 of each open and endovascular repair).<sup>6</sup>

Although theoretically applicable to all commercially available EVAR devices, the correlation between operator experience and improved outcomes may be particularly relevant when using the Powerlink/AFX/AFX2 unibody endograft (Endologix Inc., Irvine, CA, USA). Unlike modular endografts, the unibody device features a fully supported long-body design with short limbs, allowing for deployment at the aortoiliac bifurcation – the so called “anatomical fixation.” By preserving the aortic bifurcation, this design shifts columnar blood-disrupting forces away from the aortic neck and onto the carrefour, thereby reducing the risk of graft migration. Given its unique fixation and sealing mechanism, optimizing outcomes with the unibody device may require distinct technical expertise compared to conventional bifurcated endograft.<sup>9</sup>

Despite numerous studies examining EVAR outcomes with unibody devices, little research has focused on how implanting center experience influences procedural success and short-term outcomes.<sup>10</sup>

Study aim was to analyze procedural volume per center and its effect on intraprocedural and short-term results in a

large, multicenter, and coordinated series – the AFX2 Less InVasive and Faster EVAR (LIVE) Study, an international, multicenter study exclusively enrolling patients treated with the latest-generation AFX2 endograft.<sup>11</sup>

## Materials and methods

### Study design and patients population

This prospective observational investigation was conducted as a secondary analysis of the AFX-2 LIVE study sharing the same data and design.<sup>11</sup> The original protocol of the study was already published similarly to the preliminary results of the registry.<sup>12</sup> The registry encompassed 535 EVAR procedures conducted across 43 medical centers from November 2019 to August 2021. All information used in this analysis was extracted from the AFX2-LIVE registry.

This research adhered to the Declaration of Helsinki's guidelines, and when necessary, ethical approval for data collection was obtained from local ethics committees and institutional review boards at each location (#114847). The study's International Registered Report Identifier is PRR1-10.2196/16959. Participants provided written informed consent for both the procedure and data collection.

Fully trained Vascular Surgeons conducted endovascular procedures in operating rooms equipped with either mobile fluoroscopy units or in hybrid settings with fixed-arm imaging systems.

### Operative details and CTA evaluation

All the procedure were carried out by Fully trained Vascular Surgeons (>50 EVAR procedures) in operating rooms equipped with either mobile fluoroscopy units or in hybrid settings with fixed-arm imaging systems.

Planning, as well as device selection, was performed by the implanting surgeon through preoperative evaluation of computed tomography angiography scans. To avoid any potential interpretation bias, preoperative and postoperative CTA data were collected and analyzed in a centralized core laboratory located in Modena and Rome using dedicated software with multiplanar and volume reconstructions (Endosize; Therenva SAS, Rennes, France) on a Mac OS computer (Apple Inc., Cupertino, CA, USA).

Treated aortic pathologies were categorized in AAA, penetrating aortic ulcers (PAU), and isolated infrarenal aortic dissections (i-IAD). The maximum aortic diameter, aortic neck diameter and length,  $\alpha$  and  $\beta$  angles, aortic bifurcation diameter, distal common iliac arteries, narrowest access diameter, and aortic and common iliac artery lengths were noted and evaluated as potentially influ-

encing outcomes. All CTAs findings were independently evaluated by two vascular surgeons directly involved also in the procedure of implantation. Disagreements were resolved through consensus.

### Outcomes and definitions

The study's main objective was to assess how the center's case volume affected the outcome of EVAR using the AFX2 endograft. Based on previous analysis of the same registry, the key parameters examined were procedure duration, contrast media usage, and fluoroscopy time. Secondary outcomes included primary technical success, 30-day clinical success, 30-day major adverse events (MAE), need and length of stay in intensive care unit (ICU), length of postoperative in-hospital stay. Furthermore, a composite outcome was settled to assess what could be considered a good technical performance, according with existing literature:<sup>10, 13</sup> primary technical success, fluoroscopy time less than 10 minutes, and iodinated contrast medium usage less than 100ml. This composite outcome was evaluated with a logistic regression model and then the threshold where there is a significant change in composite outcome rate assessed with a nonlinear regression analysis (as better defined in statistical analysis).

Technical success was defined as correct graft deployment from a remote site with a secure proximal and distal fixation, with aneurysm exclusion confirmed by intraoperative angiography, no signs of type I or III endoleak, or conversion to open surgery and absence of significant twist, kinks, or obstruction (>30% luminal stenosis or a pressure gradient >10 mmHg) by intraoperative measurements.

Clinical success included successful deployment of the endovascular device at the intended location without any cause of death, as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion (>5 mm), aneurysm rupture, or conversion to open repair (OR), as well as the presence of graft dilatation of 20% or more by diameter, graft migration, or a failure of device integrity.<sup>8</sup>

Thirty-day MAEs included myocardial infarction, respiratory failure, acute kidney injury (serum creatinine increase >2 mg/dL), stroke, paraplegia, pulmonary embolism, hemorrhagic shock limb/bowel ischemia, and aortic dissection.

### Statistical analysis

Findings were displayed in four experience quartiles (Q1-Q4) shown in Table I and presented as quartiles in Table II and Table III. In the text, results were grouped as initial

TABLE I.—Number of patients treated in each quartile and case-load distribution.

Quartile	Patients	Case-Load
Q1	122 (22.8%)	<11 cases
Q2	114 (21.3%)	11-16 cases
Q3	155 (29.0%)	17-32 cases
Q4	144 (26.9%)	>32 cases

two (Q1 and Q2) versus final two (Q3 and Q4) quartiles to better highlight differences. Categorical variables were reported as absolute and relative frequencies and percentages, with inter-group differences evaluated using the  $\chi^2$  test. For normally distributed variables, the mean and standard deviation were used, while the median and interquartile range [IQR] were employed for skewed distributions. Inter-group differences were assessed using Student's *t*-test and Kruskal-Wallis Test, respectively.

Scatterplots with fitted values provided a visual representation of the trend between continuous procedural vari-

ables (contrast volume, operative and fluoroscopy time) and center experience. The potential correlation between continuous variants and each center's case load was examined using linear regression. The assumptions of linearity, independence of observations, and errors' normality and homoscedasticity were verified.

A nonlinear regression analysis was conducted to evaluate the relationship between caseload volume and a composite outcome and to evaluate if there is a case-load threshold of significant change. The nonlinear model was specified as: Composite =  $\beta_0 + \beta_1 \cdot \text{Case-load} + \beta_2 \cdot (\text{Case-load} - c) \cdot (\text{Case-load} > c)$ , where  $\beta_0$  represent the baseline coefficient for the positive outcome,  $\beta_1$  the coefficient before *c* and  $\beta_2$  the coefficient after *c*; *c* represents the estimated threshold beyond which the effect of caseload on the outcome changes. The model was fitted using the nonlinear least squares (NLS) approach.

To visualize the relationship, predicted values were computed for a range of caseload values, and a smoothed trend

TABLE II.—Baseline anatomical, clinical, and demographic characteristics of all patients enrolled in present series.

Characteristics	Overall (N.=535)	Q1 (N.=122)	Q2 (N.=114)	Q3 (N.=155)	Q4 (N.=144)	P value
Male sex	489 (91.40%)	110 (90.16%)	107 (93.86%)	135 (87.10%)	137 (95.14%)	0.062
CKD	195 (36.45%)	44 (36.07%)	47 (41.23%)	54 (34.84%)	50 (34.72%)	0.684
eGFR	70.97±24.49	69.86±29.08	65.71±21.29	73±21.28	74.74±25.19	<0.001
CAD	174 (35.52%)	39 (31.97%)	41 (35.36%)	51 (32.90%)	43 (28.86%)	0.775
Recent AMI	14 (2.62%)	5 (4.10%)	3 (2.63%)	4 (2.58%)	2 (1.39%)	0.593
PAD	63 (11.78%)	24 (19.67%)	11 (9.65%)	16 (10.32%)	12 (8.33%)	0.021
DM	85 (15.89%)	18 (14.75%)	15 (13.16%)	25 (16.13%)	27 (18.75%)	0.650
HTN	445 (83.18%)	98 (80.33%)	93 (81.58%)	127 (81.94%)	127 (88.19%)	0.298
COPD	195 (36.45%)	42 (34.43%)	33 (28.95%)	52 (33.55%)	68 (47.22%)	0.061
Smoke	274 (51.21%)	56 (45.9%)	41 (35.96%)	84 (54.19%)	93 (64.58%)	<0.001
Obesity	93 (17.38%)	15 (12.30%)	19 (16.67%)	32 (20.65%)	27 (18.75%)	0.311
Dyslipidemia	350 (65.42%)	79 (64.75%)	75 (65.79%)	104 (67.10%)	92 (63.89%)	0.946
Cerebrovascular disease	54 (10.09%)	13 (10.66%)	5 (4.39%)	16 (10.32%)	20 (13.89%)	0.092
Previous laparotomy	105 (19.63%)	29 (23.77%)	24 (21.05%)	24 (15.48%)	28 (19.44%)	0.367
Malignancy	88 (16.45%)	27 (22.13%)	22 (19.30%)	24 (15.48%)	15 (10.42%)	0.059
ASA Score						0.001
I	29 (5.42%)	1 (0.82%)	3 (2.63%)	13 (8.39%)	12 (8.33%)	
II	128 (23.93%)	28 (22.95%)	24 (21.05%)	41 (26.45%)	35 (24.31%)	
III	332 (62.06%)	83 (68.03%)	83 (72.81%)	79 (50.97%)	87 (60.42%)	
IV	46 (8.60%)	10 (8.20%)	4 (3.51%)	22 (14.19%)	10 (6.94%)	
Age	75.00±8.92	74.95±10.28	76.76±7.48	73.99±9.66	74.71±7.71	0.028
Suprarenal angulation°	14.37±15.03	13.54±8.73	14.91±21.48	15.52±17.79	13.45±8.15	0.9923
Infrarenal angulation°	25.82±12.71	24.43±12.19	25.17±9.97	25.40±16.09	28.02±10.09	0.026
Proximal neck diameter, mm	21.83±3.57	21.67±3.15	21.30±4.39	21.28±3.20	22.96±3.29	<0.001
Proximal neck length, mm	33.67±15.91	36.38±16.19	29.10±13.13	34.16±17.84	34.74±15.05	0.0031
Maximum AAA diameter, mm	46.43±13.09	45.42±12.71	44.74±12.86	43.60±14.28	51.53±10.90	0.0001
Etiology						0.001
AAA	466 (87.10%)	102 (83.61%)	102 (89.47%)	124 (80.00%)	138 (95.83%)	
PAU	49 (9.16%)	13 (10.66%)	6 (5.26%)	24 (15.48%)	6 (4.17%)	
i-IAD	20 (3.74%)	7 (5.74%)	6 (5.26%)	7 (4.52%)	0 (0%)	

AAA: abdominal aortic aneurysm; AMI: acute myocardial infarction; CAD: coronary artery disease; CKD: chronic kidney injury; COPD: congestive obstructive pulmonary disease; DM: diabetes mellitus; eGFR: estimated glomerular filtration rate; HTN: hypertension; i-IAD: isolated infrarenal aortic dissection; PAD: peripheral artery disease; PAU: penetrating aortic ulcers; SD: standard deviation.

TABLE III.—*Intraoperative details and early outcomes of all patients enrolled in present series.*

Parameter	Overall (N.=535)	Q1 (N.=122)	Q2 (N.=114)	Q3 (N.=155)	Q4 (N.=144)	P value
Percutaneous procedure	280 (52.34%)	71 (58.20%)	63 (55.26%)	94 (60.65%)	52 (36.11%)	<0.001
Intraoperative IVUS	6 (1.12%)	1 (0.81%)	0 (0.00%)	4 (2.58%)	1 (0.69%)	0.203
Local/locoregional anesthesia	383 (71.59%)	94 (77.05%)	85 (74.56%)	131 (84.52%)	73 (50.69%)	<0.001
Procedural time, min (median; IQR)	75 (55-100)	77 (50-105)	90 (60-105)	85 (65-103)	60 (45-90)	0.0001
Fluoroscopy time, s (median; IQR)	690 (330-1020)	714 (435-1051)	685 (194-1276)	800 (450-1107)	520 (282.5-780)	0.0002
Contrast volume, mL	76.43±52.43	89.64±64.78	76.41±65.24	79.52±34.04	61.94±41.61	0.0001
Planned additional procedures	65 (12.17%)	18 (14.75%)	11 (9.65%)	21 (13.64%)	15 (10.42%)	0.539
Technical success						
Primary	523 (97.76%)	121 (99.18%)	112 (98.25%)	152 (98.06%)	138 (95.83%)	0.290
Total	534 (99.81%)	122 (100%)	114 (100%)	154 (99.35%)	144 (100%)	0.483
ICU stay, h	2.51±8.80	2.56±7.15	0.33±2.51	2.82±10.88	3.86±10.40	0.0003
Hospital stay, day	4.31±3.53	4.09±3.30	3.60±2.37	5.79±4.99	3.47±1.62	0.0001
30-day MAE	9 (1.68%)	1 (0.82%)	3 (2.63%)	4 (2.58%)	1 (0.69%)	0.427
30-day clinical success	524 (97.94%)	119 (97.54%)	112 (98.25%)	151 (97.42%)	142 (98.61%)	0.878
Composite endpoint	186 (34.77%)	34 (27.87%)	45 (39.47%)	39 (25.16%)	68 (47.22%)	<0.001

ICU: intensive care unit; IVUS: intravascular ultrasound; MAE: major adverse events.

line was plotted along with observed data points. The estimated threshold  $c$  was highlighted with a vertical reference line.

All tests were two-tailed with a 95% confidence interval (CI), and a P value <0.05 was deemed statistically significant. Analyses were conducted using Stata 18 (StataCorp College Station, TX, USA).

## Results

The cumulative results of the study have been already published.<sup>11</sup> Overall, 535 consecutive procedures performed for AAAs (N.=466), i-IADs (N.=20), PAUs (N.=49), and were included in this study. Among the 43 centers involved 22 presented less than 11 patients (Q1), 11 were in the second quartile, seven in Q3 and finally only four centers performed more than 32 cases (Table I).

Demographics and comorbidities were summarized in Table II. Patients suffering of chronic obstructive pulmonary disease (COPD) as well as smoker patients were slightly more prevalent in Q3-Q4 (31.8% vs. 40.13%, P=0.05 and 41.1% vs. 59.20%, P<0.001). Surprisingly patients with malignancy were more frequent treated in Q1-Q2 centers (20.76% vs. 13.04%, P=0.02). No differences between group were recorded about presence of CKD, but the mean of eGFR resulted significantly lower in Q1-Q2 vs. Q3-Q4 (67.34±25.06 vs. 73.83±24.49, P=0.002). Centers with a greater case load tended to treat patients with a higher ASA score (ASA 4; Q1-2 vs. Q3-4, 5.39% vs. 10.70%, P<0.005) and aneurysms of a slightly greater diameter (Q1-2 vs. Q3-4; 45.1±12.76mm vs. 47.58±13.28, P=0.034). The type of pathologies treated (AAA, PAU and i-IAD) resulted distributed equally.

## Intraoperative and immediate outcomes

Procedural details and first 30-day clinical outcomes are detailed in Table III and described extensively in a previous publication.<sup>11</sup> Group in the higher quartile less often perform the intervention with a total endovascular fashion (Q1-2 vs. Q3-4 56.8% vs. 48.8%, P=0.06) but with a higher usage of local/locoregional anesthesia (Q1-2 vs. Q3-4 68.2% vs. 75.8%, P=0.05).

Operative time was significantly reduced over quartiles with a median difference of at least 15 minutes in favor of Q4 centers (80 [55-105] vs. 75 [50-95], P=0.003; Q4 median 60 [45-90]). Usage of iodinated contrast volume showed a similar pattern (Q1=89.6±64.8 vs. Q4=61.9±41.6 mL, P=0.001) as well as fluoroscopy time (Q1=714 [435-1051] vs. Q4=520 [282.5-780], P=0.001).

The trend of planned additional maneuvers remained equally distributed between groups (12.9% vs. 12.1%, P=0.942) and no differences in primary and assisted technical success was reported from Q1 to Q4 (Q1-2 vs. Q3-4; 27.3% vs. 7.3%; P=0.135). The of postoperative inward show a slightly reduction in Q4 (Q1-2 vs. Q3-4 3.86±2.89 days vs. 4.67±3.92 days, P=0.0082).

Thirty-day MAE rate remained very low in all the quartile (Q1-2 vs. Q3-4; 1.69% vs. 1.67%; P=0.984) with a great 30-day clinical success rate (Q1-2 vs. Q3-4; 97.9% vs. 98.0%, P=0.928).

## Center-experience

The linear regression analysis showed that with increasing experience, there was a parallel decrease in operative time (coef. -0.35; 95% CI -0.63-0.89; P=0.009), use of

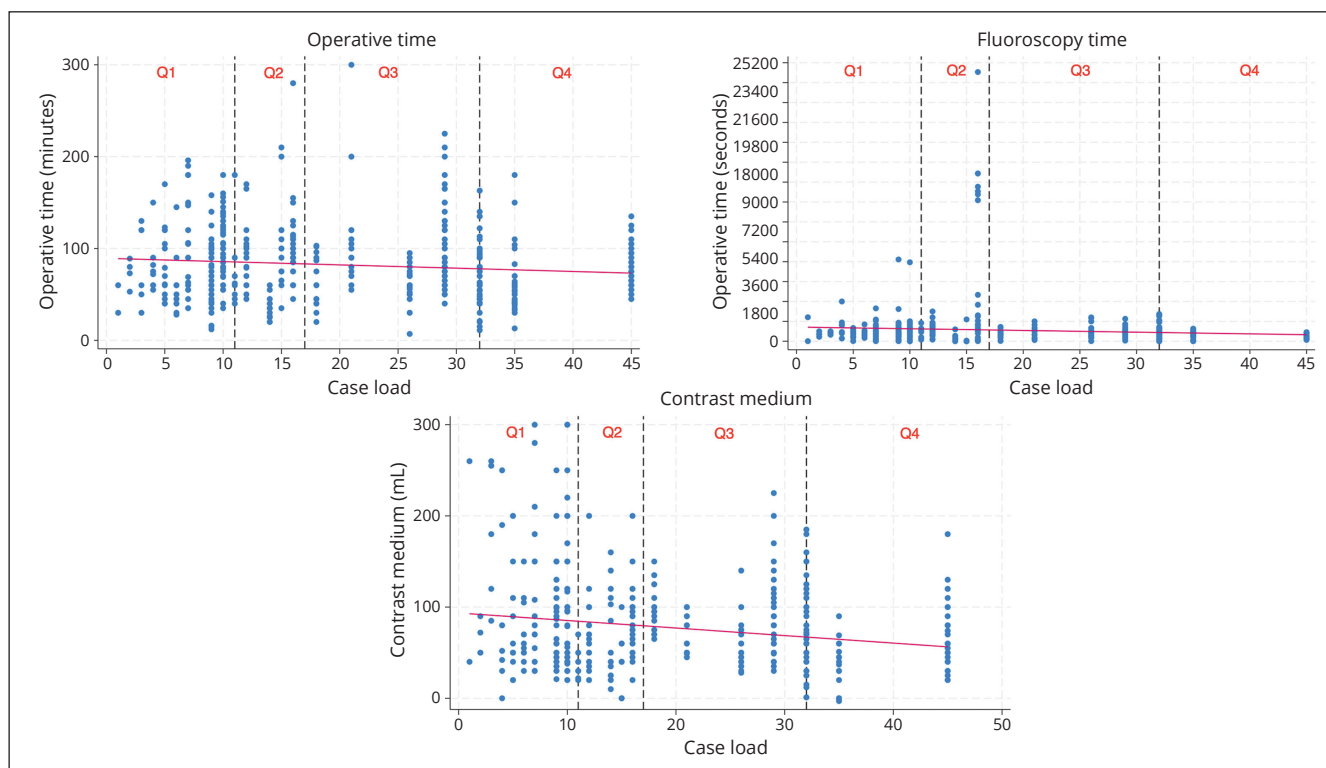


Figure 1.—Trends over center case load (case number) of operative time, fluoroscopy time, and contrast volume for 535 patients included in the AFX2-LIVE registry.

iodinated contrast medium (coef. -0.82; 95% CI -1.18-0.47;  $P < 0.001$ ), and fluoroscopy time (coef. -15.46; 95% CI -28.24-2.66;  $P < 0.02$ ). In easier words each 10 cases of case load experience the average operative time decreased of 3.6 minutes, the fluoroscopy time of 2.6 minutes and the mean contrast media usage of 8.25 mL. The abovementioned trend is graphically depicted in Figure 1.

Concerning the composite outcome above defined, logistic regression model resulted of an OR of 1.29 (95% CI 1.11-1.49;  $P = 0.001$ ) each additional 10 cases performed. The cumulative rate of composite outcome was 34.8% (N=186) with a positive trend with the increment of case-load (Q1=27.9% vs. Q4=47.2%;  $P < 0.001$ ).

Thirty cases were the threshold estimated as value after that the probability of positive outcome overcome 50% (limit value 29.6, 95% CI 24.15-34.97;  $P < 0.001$ ). Results were better depicted in Figure 2 and the regression model reported in Table IV.

**Discussion**

The current sub-analysis of the AFX2-LIVE registry highlights the significance of center expertise on procedural ef-

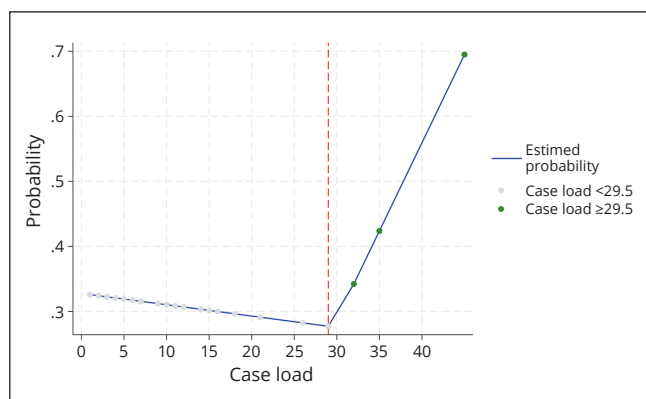


Figure 2.—Relationship between the case-load and the composite outcome, incorporating the estimated threshold effect. The blue line represents the predicted values from the nonlinear regression model. The grey dots are the observed data points, and the red dashed line indicates the estimated threshold, beyond which the effect of caseload on the outcome changes.

fectiveness and technical results when conducting EVAR using the AFX2 unibody endograft. Our analysis reveals that higher procedural volume correlates with decreased operative time, fluoroscopy duration, and contrast media

TABLE IV.—Nonlinear regression model used to estimate the case-load threshold.

Parameter	Coef	95% CI	P value
Intercept	0.3276	0.2313-0.4239	<0.001
Case-load < threshold	-0.0017	-0.0074-0.039	0.548
Case-load > threshold	0.02887	0.0142-0.0434	<0.001
Threshold	29.5643	0.88-1.05	<0.001

Coef: coefficient; 95% CI: 95% confidence interval.

use, indicating a clear learning curve effect. Centers in the top experience quartiles (Q3-Q4) demonstrated superior technical performance, achieving notably shorter procedure times and lower contrast agent usage compared to centers with lower volumes. These results align with previous studies emphasizing the role of institutional experience in enhancing EVAR outcomes.

The AFX2 endograft incorporates unique features such as Anatomical FiXation and the VELA effect, distinguishing it from other endografts.<sup>9-13</sup> The authors believe that expertise with standard modular endografts may not directly apply to this graft due to its distinct concept, deployment technique, and planning strategies. Consequently, they sought to evaluate the impact of case numbers presented in the AFX2-LIVE registry on intraoperative and perioperative outcomes.

Various well-designed and informative studies have extensively demonstrated the importance of center volume and surgeon experience on the outcomes of EVAR, TEVAR, and b/fEVAR.<sup>14-18</sup> However, to the authors' knowledge, the Anatomically Fixed endograft has not been previously evaluated in this context.

Our research revealed a significant finding: a procedural volume threshold of about 30 cases, very consistent with current guidelines,<sup>5,6,8</sup> above which the likelihood of achieving optimal technical outcomes exceeded 50%. This threshold is consistent with current European guidelines that recommend a minimum yearly EVAR caseload of 30 procedures per center. Although our data is limited to a single graft model over a three-year period, these results provide additional support for these recommendations, emphasizing that centers performing fewer procedures may encounter a steeper learning curve and increased risk of suboptimal outcomes.

Interestingly, despite differences in procedural efficiency, primary technical success and 30-day clinical success rates remained high across all experience levels. This indicates that while increased experience enhances efficiency and resource use, the fundamental safety and feasibility of the procedure are maintained even in lower-volume centers.

Notably, the low rates of 30-day MAEs across all quartiles underscore the safety profile of the AFX2 device, regardless of center experience. While the authors of this study strongly emphasize the importance of experience with this device, the high rate of short-term technical success confirms the low complexity of the procedure with a device that has become increasingly user-friendly through subsequent generations.<sup>9,10</sup>

The efficiency benefits of a highly experienced center do not immediately translate into short-term results. The decrease in operative times should be seen as an improvement in hospital resource allocation, while the reduction in radiation and contrast media usage has long-term implications that need to be assessed over the years. However, in an era where life expectancy is increasing and healthcare resources are limited, the influence of a center's experience on these "soft" outcomes should be given significant consideration.

Our analysis uncovered notable variations in patient selection based on center experience. Centers with higher volumes tended to manage patients with more complex profiles, including a higher prevalence of COPD and larger aneurysm diameters. These observations underscore the shifting role of high-volume centers in handling more challenging cases, possibly due to their greater familiarity with advanced EVAR techniques and enhanced perioperative care approaches. Interestingly, the number of PAU and i-IAD cases treated was comparable between Q1-Q2 and Q3-Q4, with a high crude rate even in low-volume centers. This finding may be attributed to the endograft being an effective tool for focal aortic lesions, allowing for quick deployment without aortic extension, using minimal or no contrast media.<sup>19</sup>

Low-volume centers were significantly more likely to perform the procedure using a double percutaneous access compared to higher-volume centers, which more frequently adopted a cut-down approach. This difference could be explained by the presence of various teaching hospitals among Q3 and Q4 institutions, where it is crucial to familiarize young surgeons with femoral accesses. Conversely, these higher-volume centers showed a preference for local anesthesia over general sedation, potentially balancing the time spent on surgical access. Notably, the total procedure time demonstrated a clear correlation with the number of cases treated, without any reduction due to the type of access used.

The present study provides some interesting implications for the accreditation of training center. Our findings suggest that while volume correlates with procedural ef-

iciency, technical success and early safety outcomes can be maintained across centers with varying caseloads. In an era where EVAR is performed also in spoke hospital with limited catchment area and consequent limited experience with the plethora of commercially available devices. The present results underline the importance of standardized credentialing criteria to ensure competency in EVAR with the different commercially available devices, like the AFX2. Lower-volume centers with training accreditation should benefit from targeted mentorship or proctoring programs to optimize efficiency and guarantee the best training role.

### Strengths and limitations of the study

This research possesses notable strengths, including its forward-looking design, involvement of multiple centers, and standardized CTA-based outcome evaluated independently by two surgeons from the centralized core laboratory. Nevertheless, it is crucial to recognize certain constraints.

Primarily, the experience quartiles were not evenly distributed in number due to varying caseloads across centers; however, the total patient count in the first two quartiles matches that of the last two. Additionally, the study portrays the cases entered by each center into the registry over a three-year period; it did not examine individual surgeons' learning curves or the overall center experience with this device, which could offer further insights into operator-related factors affecting outcomes. The author acknowledge that the individual surgeon experience plays a crucial role in procedure success and patient safety and might be a confounding factor for the results of the present analysis. Further analysis driven to directly evaluate the individual learning curve were awaited to address the present gap. Moreover, long-term durability data are currently unavailable, and future research should assess whether the observed improvements in short-term efficiency translate into lasting clinical benefits and long-term complication rates.

Despite these various limitations, the current study demonstrates the significance of center volume in making the intervention with the AFX2 endograft as minimally invasive as possible.

### Conclusions

The present analysis of AFX2-LIVE registry provides compelling evidence that center experience plays a significant role in optimizing procedural efficiency in AFX2-based EVAR, with a notable threshold effect at approximately 30 cases. These findings support current guideline

recommendations and emphasize the importance of structured training and case-volume centralization to enhance EVAR outcomes. Future research should focus on long-term follow-up data and the impact of individual surgeon experience on procedural success.

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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*

Francesco Andreoli and Pasqualino Sirignano shared first authorship. Francesco Andreoli and Pasqualino Sirignano have given substantial contributions to the conception, design, data analysis and writing of the manuscript; Andrea Gaggiano, Giancarlo Acciarino, Nicola Tusini, Filippo Benedetto, Pierfrancesco Veroux and Stefano Pirelli to acquisition, and interpretation of the data; Nicola Leone give substantial contribution to data analysis. All authors have participated to drafting the manuscript, Roberto Silingardi, Maurizio Taurino and Francesco Speziale revised it critically. All authors read and approved the final version of the manuscript.

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