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The Impact Sex-Related Differences of Infrarenal Aortic Neck Morphology on Endovascular Aneurysm Repair for Similar-Sized Aortic Aneurysms

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Abstract: Objectives: the purpose of this study was to determine whether gender-related proximal neck anatomic variables influence the applicability and outcomes of aortic endografting in women with abdominal aortic aneurysms of similar size. **Methods**: this retrospective study includes all consecutive patients who underwent elective EVAR for abdominal aortic aneurysms (AAA) with a maximum diameter ranging from 5.0 to 6.0 cm between January 2019 and December 2023. **Results**: a total of 117 patients were consecutively enrolled between January 2019 and December 2023, comprising 56 females (47.9%) and 61 males (52.1%). Females were older than males (mean age: 78.2 vs. 74.3 years, respectively; p<0.001). Hostile anatomic features of the proximal aortic neck were observed more frequently in women than in men (33.9% vs. 16.3%; p<0.01), including neck length <10 mm (30.3% vs. 10%; p<0.01) and/or a diameter at the seal zone >28 mm (10.7% vs. 3.3%; p<0.01). Women also exhibited a higher frequency of neck angulation >60° compared to men, although this difference was not statistically significant (7.1% vs. 6.6%; p<0.2). No significant sex-based differences were observed concerning the presence of circumferential calcification/thrombosis >50% or a conical neck shape. Technical success was achieved in 98.2% of women and 98.3% of men. Similarly, no significant differences were found between sexes regarding proximal neck-related complications, re-interventions, or open conversions due to these complications.Due to the more challenging aortic neck anatomy, endografts with suprarenal fixation were used more frequently in women than in men (46.4% vs. 30%; *p*<0.01). Additionally, a significantly higher proportion of EVAR procedures performed outside the IFU were observed in women compared to men (26.7% vs. 18%; *p*<0.01). Univariate analysis revealed that off-IFU procedures were associated with a significantly higher risk of type IA endoleak and endoleak-related interventions (*p*<0.001). However, the rate of complications following off-label procedures did not significantly differ between men and women. **Conclusions**: A more complex and even hostile aortic neck anatomy was observed in women compared to men in our series, despite matched AAA sizes. The more challenging proximal neck features may have led to more frequent supra-renal fixation of the stent graft and off-label EVAR procedures performed in women than in men. Despite a statistically significant higher incidence of type 1A endoleaks following EVAR performed outside the IFU, the outcomes were comparable between genders. Accurate endograft selection and the availability of more versatile devices have improved the feasibility of EVAR, reducing complications related to proximal seal zones caused by the hostile aortic neck characteristics often associated with the female gender.

Keywords: abdominal aortic aneurysm; endovascular repair; gender-related aortic neck anatomy; neck-related outcomes; off-label EVAR

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1. Introduction

Endovascular repair (EVAR) is now considered the first-choice treatment modality for abdominal aortic aneurysm (AAA) due to its lower morbidity and mortality compared to open surgery. Several studies have shown that females tend to have more complex AAA geometries, including smaller diameters, a larger maximum-to-normal diameter ratio, and a wider lumbar vertebral curvature, compared to males [1].

The higher anatomical complexity of AAAs in women increases with aneurysm size and may lead to hostile aortic neck features as well as juxta- and suprarenal involvement when the AAA reaches the diameters currently indicated for treatment [2,3]. Since EVAR procedures require adequate sealing zones for successful outcomes, the infrarenal aortic neck anatomy is a crucial factor and may explain the disparity in EVAR eligibility between sexes [4,5].

When EVAR is considered technically feasible, the presence of more than one hostile neck characteristic significantly increases the risk of immediate or delayed complications and the need for re-interventions **[6–8]**. Additionally, hostile neck anatomy often places EVAR procedures **'o**utside the instructions for use (IFU)**'** for some or all off-the-shelf endografts currently available on the market. Although the outcomes of off-label EVAR use remain largely undocumented, adverse events are reported more frequently when EVAR is performed outside IFU guidelines [9,10].

This study was designed to assess differences in aortic neck morphology between women and men with similarly sized AAAs and to determine whether these gender-related differences influence the applicability and outcomes of endografting in women.

2. Materials and Methods

A retrospective analysis of single-center data was conducted using an anonymized database (Microsoft Excel®)containing prospectively collected consecutive cases of elective EVAR for AAA performed between January 2019 and December 2023. Only elective EVAR procedures for AAAs ranging from 5.0 to 6.0 cm in size were included to ensure two homogeneous populations for comparison.

After excluding cases of suprarenal AAAs and those who underwent complex EVAR procedures (fenestrated, branched, chimney) or endovascular sealing repair with the Nellix endograft, a total of 117 patients met the eligibility criteria and were divided into two groups based on sex.

This study complied with the principles of the Declaration of Helsinki, and approval was obtained from the local ethics committee, which waived the need for patient consent due to the retrospective and de-identified nature of the study.

The aortic neck anatomic characteristics, rates of suprarenal fixation, use of aortic cuffs, aortic neck-related complications, re-interventions, open conversions, and mortality were recorded and analyzed by sex. The incidence of EVAR performed outside IFU was also assessed. Cases with missing data for these variables were excluded from the analysis. Both the terms 'sex' and 'gender' are used to refer to males and females.

In accordance with the European Society of Vascular Surgery (ESVS) guidelines [11], the suitability of aortic neck anatomy for EVAR was retrospectively evaluated through the review of patients' CT images using dedicated software with multiplanar and volume reconstructions (OsiriX MD; Pixmeo SARL, Bernex, Switzerland). The maximal aneurysm diameter was measured via CTA, from outer wall to outer wall, perpendicularly to the aorta, in an anterior–posterior plane [12]. The infrarenal aortic neck length was defined as the first diameter showing a 10% increase over the diameter at the most caudal renal artery, while the aortic neck angulation was measured as the maximum angle observed in all views between the proximal aortic neck and the longitudinal axis of the aneurysm.

In agreement with the Delphi Consensus Group (Italy, 2017) [13], a hostile aortic neck was defined by the presence of one or more of the following characteristics: length between the lowest renal artery and the aneurysm sac <10 mm, angulation >60°, diameter at the seal zone >28 mm, conical shape, or circumferential calcium or thrombosis >50% in the proximal seal zone.

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For subgroup analysis regarding IFU adherence with respect to proximal neck anatomy, procedures were classified as 'outside IFU' or 'off-label' if at least one anatomical parameter violated the manufacturer's criteria for the specific device.

Standard EVAR procedures were performed using the following devices: Endurant II and Endurant IIS (Medtronic, Santa Rosa, CA, USA), Gore Excluder (W.L. Gore and Associates, Flagstaff, AZ, USA), Gore C3-CONFORMABLE (W.L. Gore and Associates, Flagstaff, AZ, USA), Zenith (Cook, Bloomington, IN, USA), INCRAFT (Cordis Corp, Bridgewater, NJ, USA), Ovation (Endologix, Irvine, CA, USA), AFX (Endologix, Irvine, CA, USA), and Alto (Endologix, Irvine, CA, USA).

An aortic cuff was employed to achieve adequate sealing at the proximal aortic neck in cases with marginally favorable anatomy.

As recommended by the Society for Vascular Surgery guidelines [14], technical success was defined as the successful introduction and deployment of the device without the need for additional or secondary surgical or endovascular procedures, death, type I or III endoleaks, or graft limb occlusion within 24 hours after the procedure. Aortic neck-related mortality was defined as death resulting from AAA rupture after EVAR, complications from secondary procedures, or surgical conversion [15,16].

According to our follow-up protocol, all patients underwent Duplex ultrasound (DUS) or contrast-enhanced ultrasound (CEUS) at 1, 3, 6, and 12 months post-procedure, followed by annual examinations thereafter. A CTA scan was performed at 1 month and subsequently only if DUS or CEUS detected endoleaks or a significant change in the residual AAA sac size (≥0.5 cm).

Statistical analysis was performed using SPSS version 27. Between-group differences in gender-related characteristics were assessed using chi-square tests for categorical variables and t-tests for continuous variables. A p-value <0.05 was considered statistically significant.

A univariate analysis using Cox regression modeling was conducted to evaluate whether off-label EVAR procedureswere more prone to complications and to identify potential sex-related differences in these complications.

3. Results

A total of 117 patients were consecutively enrolled, comprising 56 females (47.9%) and 61 males (52.1%). Females were significantly older than males (mean age: 78.2 years vs. 74.3 years, respectively; p<0.001). The mean AAA diameter was 56.0 mm in the female group and 57.3 mm in the male group. The main preoperative demographic characteristics and co-morbidities for each gender are summarized in Table 1. A statistically significant gender difference was observed in the preoperative status according to the American Society of Anesthesiologists (ASA) score, with ASA III recorded in 9 women and 4 men.

Table 1. Main population baseline characteristics and comorbidities.

Variable	**Group 1 (females)**	**Group 2 (males)**	***p***
Number	56 (47.9%)	61 (52.1%)	
Mean Age (years)	78.2	74.3	p<0.001
Coronary arterial disease	16 (30.1)	19 (32.7)	ns
Arrhythmia	28 (52.8)	19 (31.1)	<0.001
Arterial Hypertension	38 (71.6)	45 (73.7)	ns
Diabetes	26 (49.0)	31 (50.8)	ns
Chronic kidney disease	12 (22.6)	15 (24.5)	ns
Carotid disease	26 (49.0)	30 (49.1)	ns

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Previous TIA/stroke	7 (13.2)	10 (16.3)	ns
Severe atherosclerotic disease of the aorta	17 (32.0)	18 (29.5)	ns
Chronic peripheral arterial disease	9 (16.9)	23 (37.7)	<0.001
Previous deep venous thrombosis	12 (23.2)	6 (9.8)	<0.001
ASA score III*	9 (19.1)	4 (6,55)	<0.001

*ASA (American Society of Anesthesiologists) score III: patients with substantive functional limitations and one or more moderate to severe diseases.

Anatomic characteristics of the proximal aortic neck by gender are reported in Table 2. One or more hostile anatomic features of the proximal aortic neck were found in 19 women (33.9%) and 10 men (16.3%) (p<0.015), neck length <15 mm was observed in 30.3% of women and 10% of men (p<0.01), diameter at the seal zone >28 mm was observed in 10.7% of women and 3.3% of men (p<0.01). Neck angulation >60° was more frequent in women (7.1%) than in men (6.6%), but this difference was not statistically significant (p<0.2). The incidence of circumferential calcification/thrombosis or conical neck shape was similar between groups (Table 3).

Table 2. Anatomical characteristics of the proximal aortic neck in the cohort (percentages in brackets).

Variable (mm)	**Group 1 (females)**	**Group 2 (males)**	***p***
AAA axial diameter: mean (range)	56,0 (50-67)	58,9 ± 4.9 (50-78)	ns
Neck length mean (range)	13.6 (8-28)	19.9 ± 6.5 (8-32)	**ns**
Neck diameter mean (range)	25.8 (16-32)	21.8 ± 32.6 (17-29)	<0.01
Neck angle mean (range)	48.8 (16-69)	40.1 ± 23.7 (11-64)	<0.01

Table 3. Anatomical characteristics of AAA and of proximal aortic neck according with the sex.

Variables	**Group 1 (females)**	**Group 2 (males)**	***p***
Hostile neck features	19 (33.9%)	10 (16.3%	<0.01
Neck length <10mm	17 (30.3%)	6 (10.0%)	<0.01
Neck diameter >28 mm	6 (10.7%)	2 (3.3%)	<0.01
Neck angle >60°	4 (7.1%)	4 (6.6%)	ns
Circumferential calcification/thrombosis >50%	5 (8.9%)	5(8.3%)	ns
Conical shape	3 (5.6%)	4(6.6%)	ns

Technical success was achieved in 98.2% of women and 98.3% of men. The types of endografts used, the number of suprarenal fixations, proximal cuffs, and non-adherence to IFU by gender are listed in Table 4. No significant differences were found in the choice of endograft or number of proximal cuffs used between women and men, while suprarenal fixation was significantly more frequent in women (46.6%) than in men (30.0%; p<0.01).

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Table 4. Anatomical characteristics of AAA and of proximal aortic neck according with the sex.

Device (percentage)	**Group 1 (females)**	**Group 2 (males)**	*p*
Zenith Flex	10 (17.8%)	8 (13.3%)	ns
Endurant II/IIS	8 (14.2%)	6 (11.6%)	
Gore Excluder	8 (14.2%)	11 (18.3%)	
INCRAFT	1 (1.7%)	0	
Ovation	3 (5.3%)	1 (5.0%)	
AFX	12 (21.4%)	17 (20.0%)	
Alto	4 (7.1%)	3 (5.0%)	
Gore C3 Conformable	10 (17.8%)	14 (21.6%)	
Suprarenal fixation	26 (46.4%)	18 (30.0%)	P< 0.01
Proximal cuff	7 (12.5%)	6 (10.0%)	ns
Non-adherence to IFU	15 (26.7)	11 (18.0)	P< 0.01

During a comparable follow-up period (mean: 34.8 ± 22.2 months in women vs. 36.7 ± 23.4 months in men), no significant differences were observed in proximal neck-related complications, re-interventions, or open conversions (Table 5). Due to the challenging aortic neck anatomy, a significantly higher proportion of women underwent EVAR outside IFU criteria (26.7% vs. 18%; p<0.01).

Table 5. Technical success, AAA-related mortality and neck-related complications, re-interventions, open conversion.

Variable	**Women**	**Men**	**P**
Technical success	55 (98.2%)	60 (98.3%)	ns
Neck-related mortality	2 (3.5%)	2 (3.2%)	
Type IA	10 (17.8%)	6 (9.8%)	
Distal migration	3 (5.6%)	3 (4.9%)	
EL/migration reinteventions	9 (16.0%)	5 (8.1%)	
Open conversion	3 (5.6%)	3 (9.8%)	

In the female group, complications during off-label EVAR included 6/10 type IA endoleaks (60%), 2/3 stent graft migrations (66.6%), 6/9 secondary interventions (66.6%), and 2/3 open conversions (66.6%). In the male cohort, complications included 3/9 type IA endoleaks (33.3%), 2/3 stent graft migrations (66.6%), 2/5 secondary interventions (40%), and 2/3 open conversions (66.6%).

One noteworthy case in the female group involved a low-flow type IA endoleak detected during completion angiography. Despite intraoperative efforts, the endoleak could not be resolved. Given the patient's fragile clinical condition, a conservative 'watchful waiting' approach was chosen over aggressive open repair. The endoleak sealed spontaneously within one month, as confirmed by contrast-enhanced ultrasound (CEUS) and CTA.

On univariate analysis, off-label EVAR procedures were associated with a statistically significant higher incidence of type IA endoleaks and their related re-interventions (p<0.001), while the incidence

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of other complications was not significantly affected by IFU adherence. A greater number of women underwent off-label EVAR procedures(p<0.01). However, univariate analysis revealed no significant sex-related differences in complication rates, re-interventions, or neck-related complications.

4. Discussion

This study has shown that, for the same size of AAA, women were older and had a significantly higher ASA III score than men, indicating a greater surgical risk for open AAA repair. Given their higher surgical risk burden, it would be expected that the less invasive EVAR procedure should be the preferred choice for women. However, it is reported that fewer women than men are deemed eligible for elective EVAR [20,21]. This gender disparity in EVAR eligibility might be attributed to the more advanced and complex AAA anatomy related to the smaller native aortic dimensions in women at the time of operation [22,23].

Since challenging aortic neck morphology is the most common factor prohibiting EVAR [24,25], we found that women had more frequent hostile neck features than men with aneurysms of the same diameter. These gender differences in neck anatomy may be attributable to a greater aortic degenerative process and subsequent more pronounced neck remodeling in women when the AAA reaches dimensions indicated for treatment.

Our findings align with previous studies showing a higher prevalence of pathological neck anatomy in women compared to men, although those studies did not control for aneurysm size [26,27]. When women do undergo EVAR, their more frequent hostile neck characteristics may challenge procedural outcomes. It would follow that women might experience higher rates of mortality, neck-related complications, re-interventions, and open conversions [28,29].

Interestingly, in our study, although women had shorter, larger, and more angulated aortic necks, these factors did not affect technical success or overall procedural outcomes when compared to men. Although women experienced a higher incidence of type IA endoleaks and related re-intervention rates, these differences were not statistically significant and did not compromise EVAR feasibility or outcomes in terms of AAA rupture or open conversion.

These findings are consistent with recent studies, including the Lucy Trial by Ash et al. and the Engage Registry by O'Donnell et al., both of which reported comparable EVAR outcomes between sexes despite more complex aortic morphology in females [30,31].

The similar outcomes between men and women in our study, despite hostile neck anatomy in females, can likely be attributed to the use of modern endografts with low profiles and high conformability, which are better suited for the complex anatomy often seen in women **[32–34]**. Additionally, the experience of operators in EVAR surgical planning and the use of active suprarenal fixation or proximal cuffs to extend the effective seal length beyond the hostile neck anatomy may have contributed to these positive outcomes.

Notably, women in our study were more likely to undergo suprarenal fixation to achieve adequate sealing compared to men.

Although suprarenal bare-metal stenting has been associated with risks of kidney dysfunction, endovascular stent graft separation, and subsequent endoleaks or aneurysm rupture , none of these complications were observed in our patients [35–38].

Despite advancements in endograft technology, hostile aortic neck anatomy may render EVAR "outside IFU" for some or all off-the-shelf devices. In our series, a significantly higher proportion of women underwent EVAR outside IFU criteria compared to men. Although several studies have explored the relationship between IFU adherence and EVAR outcomes, no clear consensus has been reached.

In our study, non-adherence to IFU resulted in a higher incidence of type IA endoleaks, but these endoleaks were effectively managed without impacting other complications or re-intervention rates (Table 6). Univariate analysis showed that outcomes of off-label EVAR were independent of sex (Table 7).

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Table 6. Univariate analysis of the correlation between EVAR outside IFU and incidence of neck-related complications.

EVAR outside IFU	
	p
Endoleak I A	< 0.001
Migration	0.137 (ns)
Endoleak related reintervention	<0.001
Open conversion	0.532 (ns)
Postoperative renal insufficiency	0.78 (ns)

Table 7. Univariate analysis of the correlation between EVAR outside IFU and incidence of neck-related complications in the two groups.

EVAR outside IFU			*p*
	Females **15**	**Males** **11**	<0.01
Endoleak 1A	7 (46.6%)	5 (45.4%)	0.698
Migration	2 (13.3%)	3 (27.2%)	0.035
Endoleak related re-intervention	7 (46.6%)	7 (63.6%	0.238
Open conversion	1 (6.6%)	2 (18.1%)	0.235

These findings are consistent with those of Ramirez et al., who reported a higher risk of type IA endoleaks and re-interventions in off-label EVAR patients, but no difference in 2-year survival compared to on-label EVAR [39]. Similarly, Candell et al. found that adherence to IFU did not significantly impact EVAR outcomes [40].

Conversely, Barry et al. reported worse outcomes for EVAR outside IFU, regardless of suprarenal or infrarenal fixation, while Hahl et al. demonstrated that neck angulation and short neck length negatively affected all-cause mortality, aneurysm-related mortality, and graft-related adverse events [41,42].

In one noteworthy case from our female cohort, a type IA endoleak detected during off-label endografting could not be treated promptly due to the lack of an adequate proximal infrarenal aortic segment for extending the Ovation stent graft and the high risk of immediate open conversion. Remarkably, this endoleak resolved spontaneously within one month, as confirmed by contrast-enhanced ultrasound (CEUS) and CTA. The exact cause of this spontaneous resolution remains unclear but may be related to gradual improved wall accommodation by the polymer-filled rings of the Ovation device. Similar findings were reported by Bastos Gonçalves et al., who observed only one rupture in a series of 21 untreated type IA endoleaks over a mean follow-up period of 2.5 years [43]. Likewise, Kontopodis et al. described six cases of spontaneously resolved type IA endoleaks following Ovation device implantation, five of which occurred outside IFU [44].

These observations suggest that, although the correction of type IA endoleaks is strongly recommended, a conservative approach might be justified in selected high-risk cases, at least until sac enlargement necessitates re-intervention. In fact, while the use of off-the-shelf thoracoabdominal grafts, which can also be employed in the correction of type IA endoleaks, has become increasingly safe and effective, it should always be considered that many patients may be frail [45]. As demonstrated by Cuozzo et al. in the context of complex thoracoabdominal endovascular treatment, each additional procedure may result in poor short-term outcomes [46].

Despite the small sample size and the inherent limitations of a retrospective, non-randomized study, the strength of this work lies in its novel focus on gender-related differences in aortic neck

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morphology in similarly sized AAAs treated with EVAR, highlighting treatment challenges and outcomes.

5. Conclusions

Our study reveals a clear gender difference in the anatomical characteristics of the aortic neck among men and women with AAAs of similar size. However, this difference does not appear to adversely affect EVAR feasibility or overall outcomes, which were comparable between the sexes. The precise explanation for our findings remains unclear, but it may be attributed to the current availability of more versatile endografts and the appropriate use of suprarenal fixation to address AAAs with hostile proximal neck anatomy.

Despite the more challenging proximal neck anatomy leading to a higher frequency of off-label EVAR in women, we did not observe any statistically significant differences in the outcomes of EVAR performed outside IFU between genders.

Overall, our findings indicate that the gender gap in EVAR outcomes has narrowed, while also highlighting the potential for further improvement through the application of more advanced technologies in patients with adverse neck anatomy.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Ethics Committee of "University of Rome, La Sapienza" (protocol code SUR 2024-60, 8 February 2024).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not available due to privacy restriction.

Conflicts of Interest: The authors declare no conflicts of interest.

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