From EVAR Suitability Criteria to Device Sizing and Planning: An Evolving Paradigm of MSCTA in AAA Management

Magdy Haggag*, Usama Lotfi*, Randa Kaddah**
Departments of Vascular Surgery * and Diagnostic & Interventional Radiology**
Faculty of Medicine - Cairo University

ABSTRACT

Background: *The number of abdominal aortic aneurysm (AAA) patients who are potential candidates of endovascular aortic aneurysm repair (EVAR) is continuously increasing. The analysis of data collected and best projections depicted in contrast enhanced spiral multi-slice computed tomography (MSCTA), answers many questions with resultant perpetuation in managing such subset of patients.* ***Aim of the study:*** *To determine a clue about the rate of suitability of EVAR in Egyptian AAA patients and to sort out the anatomical features responsible for unsuitability. In view of the anatomical features depicted, the impact of MSCTA on both device selection and technique chosen was also highlighted.* ***Patients and methods:*** *One hundred AAA patients were studied in the period from 2012 through 2015. MSCTA was used as the basic tool of diagnosis, preoperative planning and sizing using best projections to comment on: Aortic aneurysm neck diameter, neck length, neck angulation, calcifications & thrombus burden and iliac arteries diameter, tortuousity, & patency. The clinical impact of these data on EVAR suitability was evaluated and possible additional endovascular technique for management was proposed.* ***Results:*** *Sixty one patients fulfilling the instructions for use (IFUs) of at least one FDA approved device have been identified as standard EVAR-suitable. The remaining 39 patients were not fulfilling the same criteria and thus have been identified as standard EVAR-unsuitable. Unfavorable neck anatomy and iliac artery related factors were incriminated as the most common causes of unsuitability. Seventeen patients were believed to have unsuitability criterion amenable to endovascular management if a more sophisticated device or technique is adopted.* ***Conclusion:*** *The rate of EVAR suitability among Egyptian AAA patients is not far different from those of other populations. MSCTA depicted morphologic criteria are essential not only as a mere indicator of EVAR suitability, but also as a crucial predictor of the ideal device and technique adoption. The ever increasing number of available devices and techniques can guarantee a wider inclusion of AAA patients to lie within the scope of EVAR technology.*
Key words: *Aortic Aneurysm, MSCTA, Aortic Surgery, standard EVAR.*

INTRODUCTION

Since initially described, EVAR has evolved to an extent where some 70% to 80% of AAA patients are treated with such modality while conventional open surgical repair have been reserved for patients in whom anatomic considerations disallow EVAR. [1-5] The design of currently available devices is sometimes not ideal or even not feasible to deal with aneurysms that have challenging anatomic features. [6-11] The suitability of certain population to EVAR procedure have been studied in several reports mostly reproduced from Western and far eastern countries with only a few similar data from Egyptian and other African populations where this type of management is relatively recent. [12, 13]

MSCTA has long been an established modality of diagnosis in the context of AAA, moreover, its role has been gradually evolving to impact aneurysm sizing and planning future treatment. The continuous evolution of available EVAR devices and techniques that aim to overcome the EVAR related “Achilles heel” points; lead to a belief that the rate of EVAR-suitable candidates would progressively increase. Such EVAR suitability depends mainly on detailed anatomic features depicted in preoperative investigations; of which, MSCTA forms an integral cornerstone. [14, 15]

This retrospective study was applied to a group of Egyptian AAA patients with a concept that such analysis would be considered as a pilot study to determine:

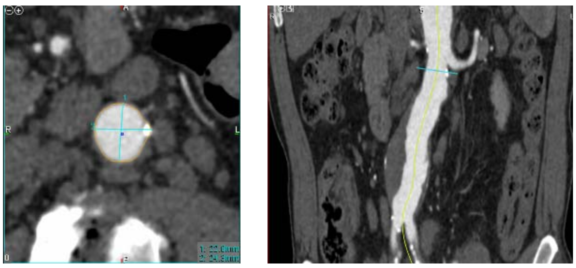
- The rate of EVAR suitability among this population sample.
- The main anatomic features explaining unsuitability.
- Impact of morphologic criteria depicted in MSCTA on recommending certain device or technique.

PATIENTS AND METHODS

In two Egyptian referral centers, Kasr EL AINI University and Nasser Institute hospitals, a total of 100 patients who had AAA as one of their diagnosis and whose maximum diameter was ≥ 5cm were included in this three year period study from 2012 through 2015. MSCTA images of these patients were revised, and their aneurysms morphology was thoroughly investigated for EVAR suitability. MSCTA was performed to all studied patients using multislice 64 detector row scanner (Toshiba Aquilion) using a slice thickness of 1.0 to 5.0 mm. Morphologic characteristics of the aneurysm such as neck diameter, neck length, infra-renal angle and common iliac arteries diameters (CIA), and length were measured with digital calipers on a PACS workstation. The diameters were measured in the perpendicular plane to the vessels' long axes on the sagittal or coronal images while the lengths were measured in three-dimensionally rendered images. Infrarenal neck angulation was determined with the digital goniometer (in degrees). For access vessels assessment, the maximal diameter of CIA, and the narrowest diameter of both external iliac (EIA) and common femoral arteries (CFA) at both sides were all recorded. All the measurements were performed by a single reviewer.

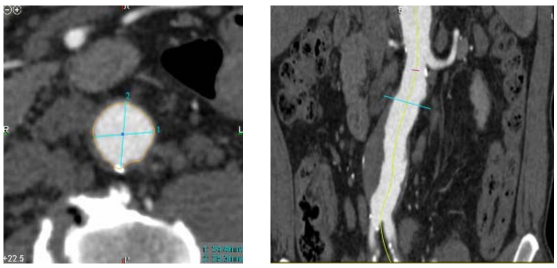
EVAR suitability was determined by assessing the compliance of an aneurysm morphology to the IFUs recommended by the manufacturers of popular FDA-approved devices. The devices used as reference are AneuRx® (Medtronic Cardiovascular, Santa Rosa, CA, USA), Talent® and Endurant® (Medtronic CardioVascular), Zenith® (Cook Medical., Bloomington, IN, USA), and Excluder® (W. L. Gore & Associates, Flagstaff, AZ, USA) (Table1).

In determining the suitability, only the above-mentioned characteristics that were measurable in numerical values were considered. (Figures 1-5 show AAA with EVAR suitability criteria in axial & coronal multiplanar reformatting (MPR) images and 3D volume rendering (VR) images). Factors prone to subjective variation such as wall calcification, luminal thrombus or atheroma, shape of the neck (straight vs. conical), and iliac artery tortuousity were taken into consideration but in separate analysis. The collected MSCTA data were compared to the treatment plan that was actually carried out in each patient. The whole study was approved by the ethical committee, faculty of medicine, Cairo University.



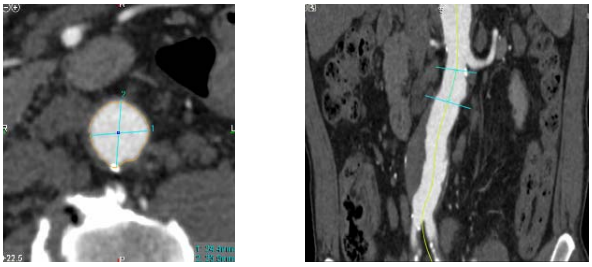
MSCTA axial cut MSCTA coronal mutiplanar reformatting (MPR)

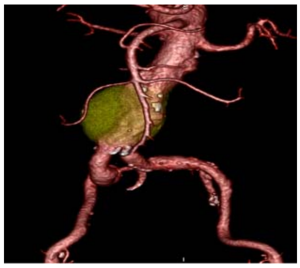
Fig. 1A: Proximal neck diameter : 22 / 24.3 mm



MSCTA axial cut MSCTA coronal MPR

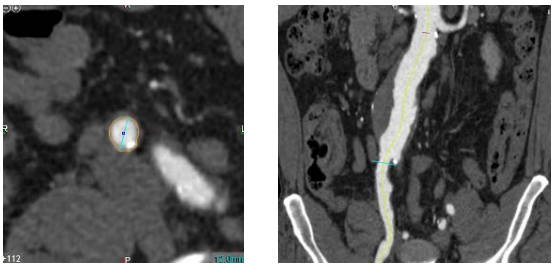
Fig. 1B: Distal neck Diameter : 24.4 / 25.5 mm

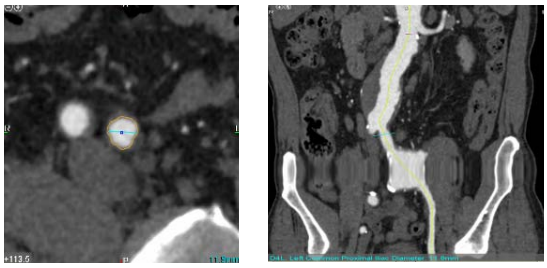




MSCTA axial cut MSCTA coronal (MPR) MSCT 3D Volume rendering (VR)

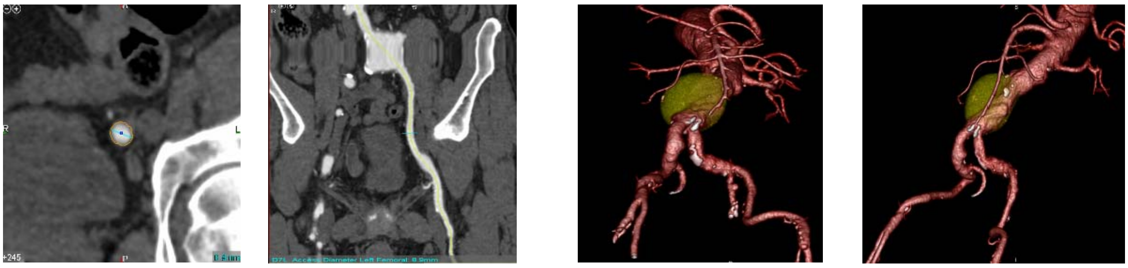
Fig. 2 : Neck Length : 22.5 mm **Fig. 3:** Infrarenal Angulation 20º





MSCTA axial cut MSCTA coronal MPR MSCTA axial cut MSCTA coronal MPR

Fig. 4 A: Rt.Common Iliac Diameter: - 12.6 mm **Fig. 4 B:** Left Common. Iliac Diameter: 11.9mm



a: MSCTA axial cut b: MSCTA coronal MP c: RAO 24 CAU 51 d: LAO 28 CAU 23

Fig. 5: Essential preplanning data showed Lt. Femoral artery (access) diameter 8.9 mm in (A & B). Best projection that make both the angle and lowest renal in best view for the operator in (C & D).

Table 1: Manufacturer's IFUs for patient suitability to EVAR procedure

Parameters	*AneuRx ®*	*Talent ®*	*Endurant II ®*	*Zenith ®*	*Excluder ®*
Neck angle	≤ 45°	≤ 60°	≤ 60°	≤60°	≤60°
Neck diameter	18-25.5 mm	18-32 mm	19-32 mm	18-28mm	19-29 mm
Neck length	≥15mm	≥10 mm	≥10 mm	≥15mm	≥15mm
CIA diameter	10-21 mm	8-22 mm	8-25 mm	7.5-20 mm	8-18.5 mm
CIA length	≥25 mm	≥15mm	≥15mm	≥10mm	≥10mm
Femoral artery diameter	≥8 mm	≥8 mm	≥8 mm	≥8 mm	≥8 mm

RESULTS

One hundred patients (92 males and 8 females) were included in this study between 2012 through 2015 in 2 referral centers. Their age range was 72.9±9 years. Coronary artery disease was the commonest co-morbidity in the studied patients (61%). Other co-morbidities included hypertension, hyperlipidemia, diabetes, and renal impairment with an incidence of 45%, 41%, 14%, and 12% respectively.

Reviewing MSCTA images of the studied patients and comparison with their subsequent management were done. With abidance to the manufacturer's guidelines without compromise of the criteria, 61 patients (61%) have shown to be standard EVAR-suitable. In contrary, 39 patients (39%) were considered standard EVAR-unsuitable due to either challenging neck or unfavorable iliac vessels as the most frequent causes of unsuitability.

There was no significant predilection of gender on either group as standard EVAR-suitable group included 56/61 males (91.8%) and 5/61 females (8.19%) while standard EVAR-unsuitable group included 36/39 males (92.3%) and 3/39 females (7.6%). However, Female patients showed more likelihood of having smaller access arteries (EIA and CFA diameter < 8 mm) than male patients (8.6% versus 3.8% respectively). Patient's demographics and baseline clinical features are shown in table 2.

Table 2: Demographic and baseline clinical features of study patients.

Parameters		**Findings**			
		All patients (n=100)	**Standard EVAR-suitable (n=61)**	**Standard EVAR-unsuitable (n=39)**	**P value**
Age(yr), mean ± SD		72.9±9.0	72.2±8.3	73.6±7.6	>0.05
Male/female		92/8	56/5	36/3	>0.05
Coronary heart disease		61%	43 (70.4)%	18 (46.1%)	<0.05
Hypertension		45%	28 (45.9)%	17 (43.5%)	>0.05
Diabetes		14%	11 (18%)	3 (7.6%)	<0.05
Hyperlipidemia		41%	22 (36%)	19 (48.7%)	<0.05
Smoking		58%	35 (57.3%)	23 (58.9%)	>0.05
Renal impairment		12%	4(6.5%)	8 (20.5%)	<0.05
Management plan	**Elective open repair**	47%	19 (31.1%)	28 (71.1%)	<0.05
	Emergency open repair	8%	5 (8.1%)	3 (7.6%)	>0.05
	EVAR	40%	34 (55.7%)	6 (15.3%)	<0.05
	No intervention	5%	3 (4.9%)	2 (5.1%)	>0.05

The measurements depicted in MSCTA were maximum aneurysm diameter, aortic neck length, aortic neck diameter, infrarenal aortic neck angle, suprarenal aortic angle and the diameters of CIA, EIA & CFA with special concern to the presence of calcification, significant thrombus load, tortuousity and/or stenosis ± occlusion of iliac vessels. The measurements depicted are summarized in table 3.

Table 3: Measurements depicted in MSCTA in all patients.

		Value (Mean)	**SD***	**(%)**
Measurements depicted in MSCTA	**Aortic aneurysm diameter (mm)**	52-92 (62)	9.2	
	Aortic neck length (mm)	4- 43 (26)	7.3	
	Aortic neck diameter (mm)	22-32 (26.3)	2.39	
	Infrarenal aortic neck angle (º)	20-62° (38°)	9.98	
	Suprarenal angle (º)	45-52° (36.5°)	6.96	
	Common iliac artery diameter (mm)	4.2-50.2 (16.8)	9.96	
	External iliac artery diameter (mm)	8.1-40.4 (10.9)	3.21	
	Common femoral artery diameter (mm)	7.8-11.3 (8.8)	0.76	
	Calcifications			16%
	Mural thrombosis			44%
	Tortuous iliac arteries			26%
	Stenosis/occlusion of iliac arteries			3%

SD= standard deviation

Unfavorable proximal neck morphology was the most frequently encountered problem to admit unsuitability of an aneurysm; a problem which was found in 26/39 (66.6%) patients. challenging neck was confronted in the form of excessive angulation in 10/39 (25.6%) patients (Figure 6A). The problem of short proximal landing zone was found in 9/39 patients (23%) (Figure 6B). More than one unfavorable neck criterion was encountered in 5/39 (7.6%) patients **(Figure 6C)**.

Aneurysmal CIA was the second most frequently found problem in 15/39 (38.4%) patients **(Figure 7)**. Bilateral CIA dilatation was present in almost the same number of patients as unilateral dilatation. EVAR unsuitability was found to be due to both neck and CIA morphological characteristics in 22/39 (56.4%) patients **(Figure 8)**. Other factors such as steno-occlusive CIA, EIA &/or CFA were less abundant cause of unsuitability that was found in 4/39 (1%) **(Figure 9)**.

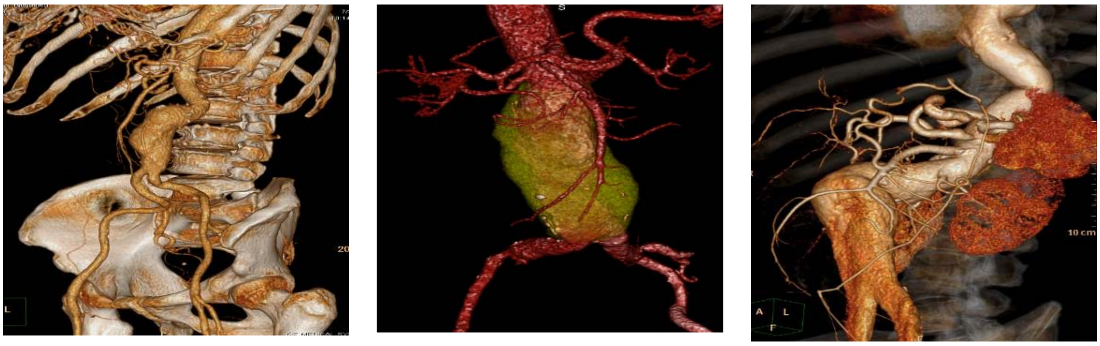


Fig. (6): MSCTA VR showing Different forms of EVAR unsuitability due to unfavorable proximal neck. A: shows excessive angulation ≥ 60º. **B:** shows neck length of 8.5 mm. **C:** shows combined excessive angulation together with bilateral CIA aneurysms

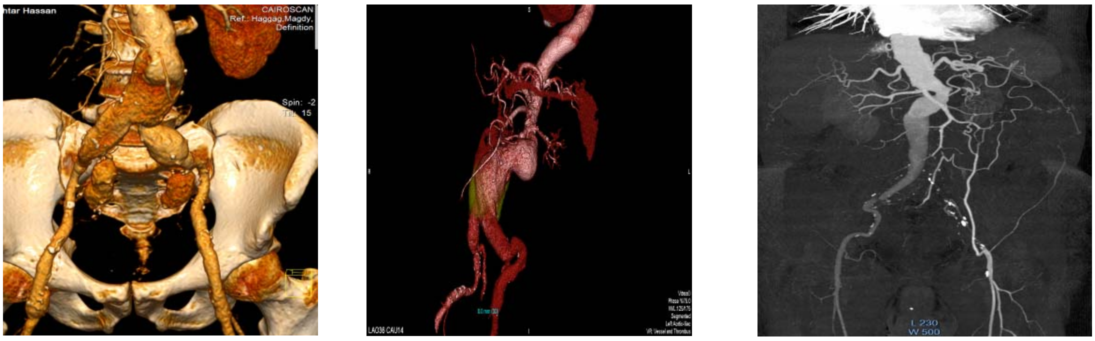


Fig. (7): MSCTA VR shows EVAR unsuitability due to bilateral CIA and bilateral internal iliac artery aneurysms. Figure 8: MSCTA VR showing EVAR unsuitability due to excessive neck angulation with aneurysmal tortuous CIA arteries. Figure 9: MSCTA MPR shows EVAR unsuitability due to combined neck angulation and unfavorable access due to iliac steno-occlusive disease.

In 6/39 high surgical risk patients with provisional EVAR-unsuitable morphologic criteria (3 with short neck, 1 with excessive angulation and 2 with steno-occlusive iliac disease) were successfully managed by an endovascular technique. Chimney-EVAR was used in those with short neck. A flexible endograft was used to overcome neck angulation. Iliac artery steno-occlusive disease was managed by the aid of a uni-iliac device together with femoro-femoral crossover bypass graft in 1 patient and covered endograft as endo-conduit of the stenosed segment before EVAR insertion in the other one respectively. Causes of unsuitability in 39 patients are summarized in Table 4.

Table 4: Reasons for unsuitability for EVAR in 39/100 (39%) patients.

Criterion of unsuitability	Reason of unsuitability to standard EVAR	Number (%)
Unfavorable Proximal (infrarenal) neck (n=26)	- Neck angulation ≥ 60° - Neck length < 10 mm - Neck diameter <18 mm - Neck diameter > 32 mm - Conical neck - More than one unfavorable criterion	10 (25.6%) 9 (23%) 4 (10.2%) 3 (7.6%) 5 (12.8%) 5 (12.8%)
Unfavorable Iliac/Access Arteries	- CIA diameter > 22 mm Unilateral Bilateral -CIA diameter <7.5 mm -CIA length <10mm -EIA diameter <8mm	15 (38.4%) 8 (20.5%) 7 (17.9%) 3 (7.6%) 2 (5.1%) 1 (2.5%)
Unfavorable neck anatomy as the only reason		17 (43.5%)
Unfavorable iliac arteries anatomy as the only reason		15 (38.4%)
Unfavorable access as the only reason		4 (10.2%)
Two or more unfavorable reasons		22 (56.4%)
Potentially correctable reason of unsuitability		17 (43.5%)

Although it does not belong to the IFUs of manufacturers, revision of the diameter of studied aneurysms showed that more than 60% of relatively small aneurysms ≤ 6 cm had favorable anatomic criteria thus proved as standard EVAR-suitable. Larger aneurysms that have a diameter ≥ 6 cm had a higher incidence of unfavorable proximal and the distal landing zones. Moreover, almost 65% of the aneurysms with the maximal diameter ≥ 8 cm had unfavorable morphology in the neck and CIA at the same time. (Figure 10). Table 5 shows comparison of our results with previous similar reports.

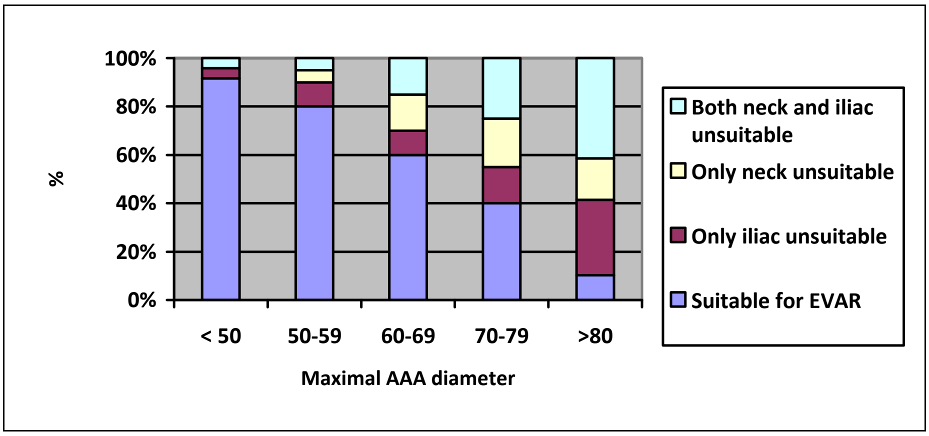


Fig. 10: Maximal AAA diameter versus EVAR suitability

Table 5: Morphological characteristics of AAA, iliac & femoral arteries: comparison with previous studies of different populations

Parameters	*Current study*	*Korean Study*	*Chinese 2004*	*Asian 2004 Hawaiian*	*Eurostar 2003*	*US 2003 multicenter*
Number of patients	100	191	65	40	4242	235
Male	92%	81.7%	89%	67.5%	94%	87%
Female	8%	18.3%	11%	32.5%	6%	13%
Age (yr)	72.9±9	73.0±8.0	73.8±6.8	77.9±8.3	71.8±8.0	73.0±0.5
Maximum diameter (mm)	62.36±0.9	62.2±15.7	62.7±0.9	50±15	57.3±11.2	55.6±0.6
Neck diameter (mm)	22.33±2.39	21.9±3.8	23.3±3.6	21.8±2.8	23.7±3.1	22.3±0.1
Neck length (mm)	26.17 ± 0.73	28±14.1	23.0±9.7	-	27.1±12.9	28.9±0.7
Infrarenal angle (°)	38.03± 9.98	47.5±26.3	22.0±18.5	-	-	-
Rt. CIA diameter (mm)	16.89 ±9.96	20.9±11.6	20.2±8.7	16.4±10.5	15.7±8.4	12.4±0.2
Lt. CIA diameter (mm)	17.05±10.05	18.8±9.6	17.9±8.6	-	14.7±7.4	11.8±0.2
Rt. CIA length (mm)	41.5±14.5	41.1±14.4	29.9±13.1	-	51.5	-
Lt. CIA length (mm)	43.6±15.4	43.2±15.3	34.2±13.7	-	53.9	-
Rt. EIA diameter (mm)	9.0±0.21	9.9±2.2	9.0±1.2	8.2±1.1	-	-
Lt. EIA diameter (mm)	8.9±1.1	9.7±2.1	8.9±1.3	-	-	-
Rt. CFA diameter (mm)	8.873±0.76	-	-	-	-	-
Lt. CFA diameter (mm)	8.96±0.69	-	-	-	-	-

DISCUSSION

The increase in life expectancy and consequent ongoing increase in the elderly population have resulted in increasing incidence of patients newly diagnosed as having AAA. Such subsets of patients are considered possible potential candidates of EVAR technique making use of this minimally invasive intervention. The anatomical and morphological characteristics of an aneurysm are considered the primary determinants of suitability to EVAR. [16]

The advent of new generations of MSCTA machines that can provide detailed measurements by the images depicted in axial, coronal, and sagittal views accompanied evolution of EVAR technology with resultant maximized role to recognize whether an aneurysm is suitable for EVAR technique or not, to judge whether a standard EVAR or more sophisticated technique is needed, and moreover to adopt the ideal device size with the best plan needed. [17, 37]

Previous reports concluded that the compliance with anatomic guidelines for EVAR is strongly correlated with the presence or absence of post-EVAR sac enlargement; an issue that is related to the presence or absence of 3 main risk factors namely, aortic neck diameter >28 mm, an aortic neck angle >60˚ or a common iliac artery length of <20 mm. In patients without these risk factors the freedom from sac enlargement was 87% at 3 years, in patients with 2 risk factors, it was 68% at 3 years and in those with 3 risk factors, sac enlargement was present in 66% of the patients at 3 years post-EVAR. [18]

Reports studying EVAR suitability on western populations showed that unfavorable proximal neck, especially inadequate neck length was the commonest cause of EVAR unsuitability rather than inadequate iliac anatomy, [7, 12] while unsuitability to EVAR was related to unfavorable iliac anatomy in Asian population as reported in another study. [19] Our results concluded that unfavorable neck anatomy was the commonest criterion of standard EVAR unsuitability. Even more unsuitability rate would be mounted if additional factors prone to subjective variation are taken in consideration such as wall calcification, luminal thrombus, shape of the neck, and iliac artery tortuousity.

In our series, we did not find significant relation between either age or gender on EVAR suitability, meanwhile, our results were similar to previous studies [20-22] which concluded more likelihood of EVAR unsuitability in larger aneurysms ≥6 cm. It is worthwhile denoting that an unfavorable criterion does not typically present in isolation; owing to the fact that an aneurysm expansion does so not only in diameter, but also in length. This pattern of growth introduces angulation and tortuousity as well; an evidence which has been well described in the literature that angulation is more frequently encountered in larger aneurysms. Similarly, patients with CIA aneurysms often have a stenotic aortoiliac bifurcation resulting from calcium or thrombus at CIA origin. [23-26] In this study, out of 39 standard EVAR-unsuitable patients, 5 (12.8%) had more than one unfavorable neck criteria and 22 (56.4%) had coexisting unfavorable neck and iliac anatomy.

Proximal neck length is very crucial in EVAR suitability and planning, but it is very important to understand that the absolute length of the infrarenal neck is not the only determinant of accurate deployment or long-term success as EVAR performed in a patient with a 10-mm, straight, uniform diameter neck is more likely to be successful than that done for diseased, conical-shaped thrombus-laden 15 mm neck. In addition, most endograft manufacturers have deemed AAA with excessive neck angulation as an anatomic exclusion to the use of their device because of the potential associated difficulties and morbidities. [27] In this study, such hostile anatomy was encountered and managed in high surgical risk patients where successful EVAR could overcome the angulation by covering a longer neck lengths thus achieving good “sealing” of the aneurysm and by selection of an endograft with high radial force & supplemental suprarenal fixation elements to achieve good “fixation”.

Short proximal necks < 15 mm and > 10 mm can be treated successfully with most modern stent grafts with excellent results.[28,29] Fenestrated or branched stent grafts have recently demonstrated promising results in juxtarenal AAA, but in addition to their relatively high cost, the use of such devices mandates highly precise planning and 6 to 12 weeks manufacturing delay. “Chimney” grafts have been advocated as a possible endovascular option in these situations. [30, 31] In this study, 2 unilateral and 1 bilateral (renal arteries) chimney-EVAR were done in spite of the provisional unsuitability to endovascular management.

Challenging iliac artery anatomy can seriously complicate EVAR. *Armon et al.* reported that the mean CIA diameter was significantly larger in AAA patients compared with general population and suggested that CIA aneurysm in AAA patients should be defined as those greater than 24 mm in diameter, a conclusion that might include more AAA patients with “dilated” rather than “aneurysmal” iliac arteries. [32] In addition, the use of recently available iliac side branch device can increase more morphologically challenging CIA patients into the direction of endovascular treatment. [26]

Masuda et al. reported that significant steno-occlusive disease of CIA or EIA comprised a true access problem in another study of Hawaiian patients. [13] In the current study, similar problems were corrected either by using a uni-iliac device with femoro-femoral crossover bypass graft or covered stent as endo-conduit. Again, both patients were considered provisionally EVAR-unsuitable and by the aid of such suggestions in the planning phase, they have been converted to be EVAR-suitable.

In this study, preplanning for uni/bi-chimney EVAR, using recent low profile flexible devices as Endurant Medtronic device® and Aorfix device® to overcome both neck and iliac problems had an integral role in offering an endovascular solution to a number of patients that have shown provisional morphologic criteria lying outside the IFUs. In other words, short necks could be lengthened by chimney-EVAR while excessive angulation and tortuousity of either the neck or iliac arteries could be overcome by the flexibility, conformability and easy deployment of the aforementioned devices. In the same context, at least 17 patients in this study who were originally classified as EVAR-unsuitable might be considered as potentially EVAR-suitable thus expanding the rate of EVAR-suitability among Egyptian AAA patients to mount near the highest recorded rates.

Our collected data are believed to shed some light on EVAR practice among the entire AAA Egyptian population and to highlight the commonest reasons for EVAR unsuitability. Moving outside the IFUs of current endovascular devices to off label margin can achieve satisfactory results. The evolution of chimney & fenestrated EVAR in juxtarenal AAA, polymer-filled endografts and iliac side branch device [33-36] are all valid options suggesting that an ideal future device requires examining the pitfalls of the past.

CONCLUSION

The rate of EVAR suitability among Egyptian AAA patients is not far different from those of other populations. MSCTA depicted morphologic criteria are essential not only as a mere indicator of EVAR suitability, but also as a crucial predictor of the ideal device and technique adoption. The ever increasing number of available devices and techniques can guarantee a wider inclusion of AAA patients to lie within the scope of EVAR technology.

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