Sizes of endografts for endovascular aortic repair: do few fit most?

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Daniela Mazzaccaro*, Lorenzo Muzzarelli*, Alfredo Modafferi*, Giovanni Nano*/**

**First Unit of Vascular Surgery, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy*
***Department of Biomedical Sciences for Health, University of Milan, Milan, Italy*

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AIM: *The endoprostheses for the endovascular aortic repair (EVAR) of abdominal aortic aneurysms (AAA), are currently available in many sizes in reference to the aortic diameters of the proximal neck, but often not all of them are really used. Aim of our work was to review in our experience the most frequent proximal aortic diameters of main bodies that were used, among all those available for EVAR, with respect to the native proximal aortic neck.*
METHODS: *All the sizes of main bodies of the different endografts used for EVAR from 2000 to 2016 were retrospectively counted. For each endograft, we calculated the number of times each size of main bodies' proximal diameter was used. The mean diameter of the proximal aortic neck was also calculated for each group of main bodies.*
RESULTS: *From 2000 to 2016, 607 patients underwent EVAR for infrarenal AAA. Overall, mean diameter of the proximal aortic neck was 23.4 ± 0.5 mm (median 23.1 mm, IQR 22.2–23.7 mm). The most frequently used main bodies had a 28 mm, 26 mm and 25 mm proximal diameter (161/607, 26.5%; 147/607, 24.2%; 122/607, 20.1% respectively), for a mean proximal neck diameter of 23.2 ± 0.5 mm, 22.2 ± 0.4 mm and 22.1 ± 0.2 respectively. The least frequently used main bodies had a 21 mm and a 36 mm proximal diameter (3/607 times each, 0.5%), for a mean proximal neck diameter of 18.1 ± 0.2 mm and 32.4 ± 0.8 mm respectively.*
CONCLUSIONS: *In our experience, the most frequently used main bodies had a 25, 26 and 28 mm proximal diameters.*

KEY WORDS: Abdominal aortic aneurysm, EVAR, Sizing endografts

Introduction

Since the first pioneering procedure by Parodi in 1991 [1], the endovascular aortic repair (EVAR) of abdominal aortic aneurysms (AAA) has gradually assumed an important role beside the open surgical treatment [2,3].
The endografts are currently available on the market in a large range of diameters and lengths, both for the aorta and for the iliac axis. The initial experience was performed using both a single proximal stent technique and a double (proximal and distal) stent method to anchor a graft in the aneurysm lumen [4].
Current configurations in the majority of cases consist of a main body, which is placed with one or more iliac extensions of different sizes and shapes (conical, straight, etc). Even the main bodies are available in different shapes, sizes and configurations (with either suprarenal or infrarenal hooks/barbs, without any hooks/barbs, etc.), to fit best the anatomy of the individual patient according to vessel caliber, tortuosity, and angulations.
Three modular devices are more flexible than 1- or 2-modular devices because a small number of main body configurations fit in few aortic diameters and can be combined with a greater number of legs. However, 2-modular devices can be converted into 3 modular devices by choosing short-leg-main bodies, which decreases the

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Correspondence to: Daniela Mazzaccaro, Ist Unit of Vascular Surgery, IRCCS Policlinico "San Donato" Piazza Malan 1, 20097 San Donato Milanese (MI), Italy (e-mail:ydanymazzak83@libero.it; daniela.mazzaccaro@gmail.com)

need for a larger number of different main body sizes. Therefore the aortic diameter is the most limiting condition.
Probably, however, not all of these configurations are used in the daily clinical experience.
Moreover, despite the possibility to have a "tailored" approach to each patient, the presence of more measures may bring some difficulties in the management of an inventory facility, especially in the context of emergent EVAR [5], where the storage of materials should be wide enough to accomplish most anatomies.
Aim of our work was to review in our experience the most frequent proximal aortic diameters of main bodies that were used, among all those available for EVAR, with respect to the native proximal aortic neck.

Materials and Methods

Written consent was obtained from the local Ethics Committee to report the present study.
Data about the proximal aortic diameters of the main bodies used during elective EVAR procedures for infrarenal AAA performed in our Operative Unit from 01/01/2000 to 31/12/2016 were retrospectively collected, along with data about the proximal neck aortic diameter.
In our clinical experience, any patient who undergoes EVAR usually receives a pre-operative planning on the basis of the computed tomography angiography (CTA) for precise sizing of the graft to be used in each specific case.
In particular, from 2011 ongoing, preoperative CTAs have been performed with 1 mm slices. These images are usually analyzed using a dedicated three-dimensional workstation (3mensio Vascular™; 3mensio Medical Imaging BV, Bilthoven, the Netherlands). Using multiplanar reconstructions, the anteroposterior, cranio-caudal, and latero-lateral anatomy of the aorta and its vessels can be reconstructed. From these data, the reconstruction software automatically builds the centerline (i.e., the line that ideally passes through the center of the aortic lumen) and makes the curved planar reconstruction (CPR), the axis of which is perpendicular to the centerline. Thanks to the CPR an accurate measurement of distances and diameters can be performed for the proper preoperative planning. Moreover the use of maximum intensity projection images contributes to the accurate quantification of calcification in the aortic neck.
The size of the graft to be used, therefore, is usually decided for each patient according to the Instruction For Use (IFU).
The choice of the proper device depended both on the aorto-iliac anatomical features and on the operator's preference. For example, in case of small iliac-femoral access vessels, either Trivascular Ovation or Cordis Incraft were used, preferring the latter over the former if the proximal neck was not straight. If iliac-femoral vessels were tortuous, the Vascutek Anaconda endograft was chosen when anatomical features were permissive.
The brochures of all the used models of endograft were then analyzed, focusing on the different available sizes of diameter of the main body (Table I). For each type of endograft, the most used proximal aortic diameters were then recorded.

Results

From 2000 to 2016, 607 main bodies were used on 607 patients who underwent EVAR for infrarenal AAA in our Operative Unit. A total of 13 different models of endograft were used (Table II).

Table I - *Available measures of diameter and length of the main body according to the brochure of each endograft.*

	Device proximal diameter (mm)	Device distal diameter (mm)	Stent graft total length - ipsilateral (mm)	N° of modules
Vascutek Anaconda	21.5-23.5-25.5-28-30.5-32-34	10.5	77	3
Trivascular Ovation	20-23-26-29-34	14	80	3
Cordis Incraft	22-26-30-34	11	94	3
Gore Excluder C3	23-26-28.5-31-35	12-14.5	120-140-160-180 (for 31 and 35 mm diameters: 130-150-170)	2
Gore Excluder (2000-2013)	23-26-28-31	12-14	120-140-160-180 (for 31 mm diameter: 130-150-170)	2
Cook Zenith Alpha	22-24-26-28-30-32-36	11	94-108-122-132-142-152	3
Cook Zenith Low Profile	22-24-26-28-30-32-36	11	94-108-122-132-142-152	3
Cook Zenith Flex	22-24-26-28-30-32-36	12	112-126-141-155-170	3
Medtronic Talent	22-24-26-28-30-32-34-36	12-14-16-18-20	155-170-185	2
Medtronic Endurant II	23-25-28-32-36	13-16-20	124-145-166	2
Endologix Powerlink RBL*	25-28-34	16	155-175	
Endologix Powerlink BL**	25-28-34	16	120-135-140-155	1
Endologix AFX	22-25-28	13-16-20	80-100-120-135-140-160	1
Jotec E-vita	24-26-28-30-32-34	12-14-16-18-20-22	150-170	2
Lombard Aorfix	24-25-26-27-28-29-30-31	10-12-14-16-18-20	81-96-111-126-142	2

TABLE II - *Number of treated patients and number of times each proximal diameter of main bodies (MB) was used among those available for each type of endograft.*

Model of endograft	Nr. of treated patients	Proximal aortic diameter of MB used and number of times used
Vascutek Anaconda	112	21 (3/112)23 (18/112)25 (34/112)28 (35/112)30 (17/112)32 (5/112)
Trivascular Ovation	27	23 (1/27)26 (3/27)29 (11/27)34 (12/27)
Cordis Incraft	30	26 (13/30)30 (12/30)34 (5/30)
Gore Excluder (2000-2013)	167	23 (22/167)26 (99/167)28 (42/167)31 (4/167)
Cook Zenith Alpha	19	22 (3/19)24 (6/19)26 (6/19)28 (2/19)30 (1/19)32 (1/19)
Cook Zenith Low Profile	37	22 (1/37)24 (2/37)26 (10/37)28 (16/37)30 (5/37)32 (3/37)
Cook Zenith Flex	12	24 (3/12)26 (3/12)28 (2/12)32 (2/12)36 (2/12)
Medtronic Talent	66	24 (4/66)26 (25/66)28 (26/66)30 (4/66)32 (2/66)34 (5/66)
Medtronic Endurant II	16	25 (5/16)28 (10/16)36 (1/16)
Endologix Powerlink	72	25 (47/72)28 (15/72)
Endologix AFX	25	22 (4/25)25 (11/25)28 (10/25)
Jotec E-vita	10	24 (1/10)26 (5/10)28 (3/10)32 (1/10)
Lombard Aorfix	14	24 (6/14)26 (8/14)

MB=main bodies

TABLE III - *Proximal aortic diameter of main bodies used (MB) with number of times used, irrespectively of the type of endograft. In the last column, we reported the mean diameter of the proximal aortic neck in which each group of MB was used (± 2SD).*

Proximal aortic diameter of MB	Number of times used	Mean diameter of the proximal aortic neck in which each group of MB was used (± 2SD)
21	3/607 (0.5%)	18.1 ± 0.2 mm
22	4/607 (0.6%)	19.2 ± 0.3 mm
23	50/607 (8.3%)	20.5 ± 0.5 mm
24	22/607 (3.6%)	21.8 ± 0.3 mm
25	122/607 (20.1%)	22.1 ± 0.2 mm
26	147/607 (24.2%)	22.2 ± 0.4 mm
28	161/607 (26.5%)	23.2 ± 0.5 mm
29	11/607 (1.8%)	24.8 ± 0.6 mm
30	39/607 (6.4%)	25.2 ± 0.5 mm
31	4/607 (0.6%)	26.1 ± 0.2 mm
32	14/607 (2.3%)	27.2 ± 0.4 mm
34	22/607 (3.6%)	29.3 ± 0.7 mm
36	3/607 (0.5%)	32.4 ± 0.8 mm

MB=main bodies

Overall, mean diameter of the proximal aortic neck was 23.4 ± 0.5 mm (median 23.1 mm, IQR 22.2–23.7 mm). The most frequently used main bodies had a 28 mm, 26 mm and 25 mm proximal diameter (161/607, 26.5%; 147/607, 24.2%; 122/607, 20.1% respectively), for a mean proximal neck diameter of 23.2 ± 0.5 mm, 22.2 ± 0.4 mm and 22.1 ± 0.2 respectively. The least frequently used main bodies had a 21 mm and a 36 mm proximal diameter (3/607 times each, 0.5%), for a mean proximal neck diameter of 18.1 ± 0.2 mm and 32.4 ± 0.8 mm respectively (Table II and Table III).

Considering the most frequently used main bodies, there was no statistically significant difference between the diameters of proximal aortic neck among the group of patients who received a main body of 25 versus 26 and versus 28 mm (P=0.4, and 0.3), neither between the group of 26 versus 28 mm (P=0.5).

Discussion

Introduced in the early Nineties as a therapy for patients considered unsuitable for conventional open repair [6] due to the presence of severe comorbidities, such as older patients 7, the endovascular treatment of AAA has gradually played a major role, when anatomically feasible, also in the treatment of patients deemed to be at "low surgical risk". Moreover, it represents a safe strategy in patients presenting other important abdominal disease that would be complicated by the open treatment of AAA [8].

The widespread of the technique, in addition with the technological improvements of materials and endografts available on the market, has also enabled to expand the anatomical indications for treatment [9]. In fact, currently, the endografts available on the market allow the treat-

ment of more and more challenging anatomies, such as AAA with small and tortuous iliac-femoral accesses, with short and angled proximal neck or even involving the ostia of renal and splanchnic vessels [10].

The wide range of measures offered by the different types of endograft, on one hand allows treating a greater number of patients, providing a "customization" case by case. On the other hand, however, it clashes with the practical needs of each individual center to have a limited number of endografts available in the inventory.

This need has led some industries to provide endografts that are available on the market with few units, which however can allow a tailored approach to EVAR for each patient for the treatment of a broad spectrum of anatomies. This is for example the case of the endograft Cordis Incraft with its "few-fits-most design" concept, which allows the use of fewer units to optimize procedures planning and inventory management.

Bifurcated endografts are in general modular devices, and main bodies and leg configuration can be combined in different ways. Three modular devices are more flexible than 1- or 2-modular devices because a small number of main body configurations fit in few aortic diameters and can be combined with a greater number of legs. However, 2-modular devices can be converted into 3 modular devices by choosing short-leg-main bodies, which decreases the need for a larger number of different main body sizes. This choice is finally taken by preference of each operator. Therefore, the aortic diameter is the most limiting condition.

In our clinical experience, we assumed the hypothesis that the choice of proximal diameters of the main bodies used always fell on some more frequent measures. If this were the case, some sizes would likely be redundant.

In fact, in our experience, more than 70% of patients received a main body of either 25, 26 or 28 mm, for a reference proximal aortic neck diameter that was similar among the three groups. In some cases, even, some measures were not used at all (such as the Ovation 20 mm).

In the literature up to now, no paper has assessed the hypothesis of an overproduction of endograft measures if compared to the real clinical need.

Probably most surgeons could argue that they don't really concern about this problem. In fact, for elective procedures, the device is ordered case by case to fit a specific anatomy, adding some additional devices to be able to perform both proximal and distal extension. Usually, devices that are not used are resent to the manufacturer and not stored in the department.

However, it's important to note that this could represent a logistic issue in the context of emergent EVAR, where the discussion of optimal inventory is crucial to fulfil the large majority of configuration. Manufactures must know that they have some references that are not often used and they must control production of such references. The reduction of available combinations is also achieved through the development of main bodies with different diameters but of the same length. While this feature may simplify both the choice of the main body and inventory management, on the other hand it may result in a reduced columnar strength in case of short main bodies [11].

In our experience, 13 models of endograft were used, but this wide choice reflected the whole duration of our experience. For each period of time, the choice of the graft to be used was among 3 or 4 with which we were more familiar at that time.

Based on the results of our retrospective study, we suggest that in each center where EVAR is performed, the choice of the optimal inventory should be focused basically on few types of endograft that can adapt to the most of anatomical condition and with which the operator is more familiar. According to the chosen model of endograft, the most frequently needed measures should be adaptable to a proximal aortic neck of 22-24 mm.

Conclusions

In our experience, the most frequently used main bodies had a 25, 26 and 28 mm proximal diameters.

Riassunto

Le endoprotesi per il trattamento endovascolare (EVAR) degli aneurismi dell'aorta addominale (AAA), sono attualmente disponibili in molte misure in riferimento al diametro del colletto aortico prossimale, anche se spesso non tutte sono realmente utilizzate.

Con il presente lavoro si intende rivedere, all'interno della nostra esperienza, le misure di diametro prossimale del corpo principale più frequentemente utilizzate, tra tutte quelle disponibili per EVAR, rispetto al colletto aortico prossimale nativo.

Sono state analizzate le dimensioni dei corpi principali dei diversi endograft utilizzati in 607 EVAR consecutivi dal 2000 al 2016 per AAA sottorenale. Per ciascun tipo di endoprotesi, è stato calcolato il numero di volte in cui è stata utilizzata ciascuna dimensione di diametro prossimale dei corpi principali. Per ciascun gruppo di corpi principali è stato calcolato anche il diametro medio del colletto aortico prossimale.

Complessivamente, il diametro medio del colletto aortico prossimale è risultato essere 23,4 ± 0,5 mm (mediana 23,1 mm, IQR 22,2-23,7 mm), mentre sono stati utilizzati più frequentemente i corpi principali di diametro prossimale di 28, 26 e 25 mm (161/607, 26,5%, 147/607, 24,2%, 122/607, 20,1% rispettivamente), per un diametro medio prossimale del colletto aortico di 23,2 ± 0,5 mm, 22,2 ± 0,4 mm e 22,1 ± 0,2 mm rispettivamente.

Sono stati posizionati meno frequentemente i corpi principali di diametro prossimale di 21 e 36 mm (3/607

volte ciascuno, 0,5%), per un diametro medio del colletto aortico prossimale di 18,1 ± 0,2 mm e 32,4 ± 0,8 mm rispettivamente. In conclusione, nella nostra esperienza i corpi principali più frequentemente usati avevano diametri prossimali di 25, 26 e 28 mm.

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