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Difficult Neck in Endovascular Aneurysm Repair (EVAR)

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http://dx.doi.org/10.5772/intechopen.76645

Abstract

Endovascular approach in abdominal aortic aneurysm (AAA) treatment (EVAR) became the treatment of choice for most patients suffering from that disease. However, a successful endovascular therapy of the AAA depends on some key anatomical and morphological factors highly influencing the procedure outcome. Among them, the most important feature is the anatomical situation in the aneurysm neck. The definitions of the terms "hostile neck" and "difficult neck" are explained in order to present unfavorable conditions in the landing zone of most commercially available stent graft models. In this chapter, a description of various criteria of the difficult neck and their basic features and shapes as well was presented. Also, the most popular methods of solving that clinical problem were outlined. At the end, an overall (APPROACH) strategy in the treatment of a hostile neck patient is described.

Keywords: difficult neck, hostile neck, type 1 endoleak, abdominal aortic aneurysm, EVAR

1. Introduction

The term "aneurysm neck" is used to describe an aortic fragment between the lowest renal artery and the beginning of the aortic sack (**Figure 1**). That part of the aorta is used as a landing zone for the main bodies of most commercially used stent graft systems. The neck length and diameter as well as its shape are crucial factors leading to successful endograft implantation.

However, during the procedure planning in patients with difficult anatomy, a broader look into the patient's general condition, the way of accessing the vascular system and potential benefits and risks as a result of endovascular approach, should be taken into consideration.

During qualification process, a careful look into the preoperative CT scans should be done to avoid procedural failures, such as endoleaks, graft migration, or occlusion of the renal and visceral arteries.



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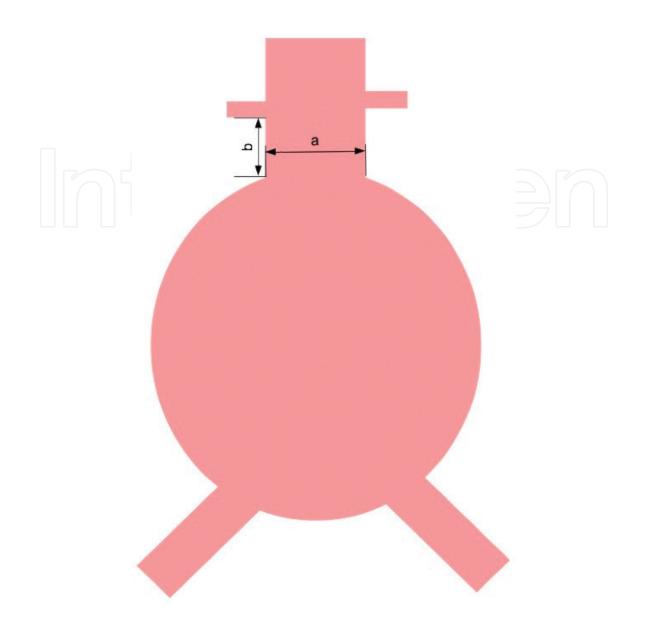


Figure 1. A definition of aneurysm neck: (a) neck length and (b) neck diameter.

From the opposite point of view, a difficult anatomical condition in the aortic neck or no neck at all (when renal arteries originate directly from the aneurysm sac) is one of the main reasons excluding the patient from minimally invasive option.

2. Hostile neck

2.1. Hostile neck definition

The hostile neck definition was first used by Dillavou [6] in 2003 in order to describe a set of anatomical criteria of the proximal landing zone in patients in which an EVAR procedure was considered.

Stather et al. used classification criteria, defining hostile neck anatomy as any of the following: neck length <15 mm, neck diameter >28 mm, and angulation >60 [22]. Jordan et al. in the article in 2015 noted that difficult anatomic criteria in the aortic neck significantly influence adverse event rate [15]. The authors concluded that there is no uniform set of anatomical factors describing the term of difficult neck. Nevertheless, after the data analysis from ANCHOR study, there are two independent risk factors leading to elevated risk of the type Ia endoleak. These factors are neck length and diameter [10]. Other features such as neck angulation (suprarenal and infrarenal), the presence of calcification, or thrombus in the neck lumen resulted in higher rates of complications but without statistical significance [14].

Hostile neck definition however may vary, according to different stent graft models. Neck maximum diameters and minimum lengths as well as possible suprarenal and infrarenal angulations are different in manufacturers' instructions for use (IFU) for particular stent graft models. For example, a 13-mm-long neck is outside IFU of AFX and Zenith graft but may be resolved on label with Endurant or Ovation model. **Table 1** shows the most important IFU parameters of popular stent graft models available on the market.

On the base of ENGAGE multicenter registry data [2, 23], in which a big cohort of patients after Endurant implantation was observed, Goncalves et al. tested a set of different factors which could lead to unfavorable procedural outcomes such as type Ia endoleak. Authors identified independent risk factors significantly increasing a rate of major procedural complications. These factors were neck length, female gender, AAA diameter higher than 65 mm, calcifications, and thrombus in the neck lumen. The neck length was identified as a major risk factor, increasing the complication rate ninefold.

In parallel to diameter and neck length, there is also a neck shape as a very important feature which can influence on the procedure outcome.

2.2. Hostile neck types

The ideal "friendly" neck is a regular, smooth cylinder with the proper length and diameter. In real life, about 20–25% of cases do not fulfill these criteria. Besides of variable diameter and

Manufacturer	Model	Diameter (mm)	Min. neck length (mm)	Infrarenal angle	Suprarenal Angle	Other
Cook	Zenith	18-32	15	60	45	
Cordis	Incraft	17-31	10	60		
Endologix	Nellix	18-28	10	60		
Endologix	AFX	18-28	15	60		
Endologix	Ovation	30	10 (<10**)	60(45**)		
Gore	Anaconda	19-32	15	60		
Jotec	e-Tegra	24-36	15	75	60	
Medtronic	Endurant II	18-32	10 (15*)	60(75*)	45 (60*)	Calcification or thrombus >50% of perimeter
Vascutek-Terumo	Anaconda	17.5-31	15	90		

Table 1. Aneurysm neck features in the instruction for the use of different stent graft models available on the market: *neck length < 10 mm with angulation < 45° ; **neck length > 15 mm with angulation < 75° .

length and eventual presence of calcifications or thrombus mentioned before, there are also irregularities in shape. If there is no cylindrical shape in the landing zone, the graft fabric may not adhere enough to the aortic wall effecting in improper sealing and an endoleak occurrence. The most frequent "unfriendly" shape is the conical neck. Conical neck was described as a strongest risk factor of type Ia endoleak by Pitoulias et al. [19] (**Figure 2**).

At present, as a quick reminder of the difficult neck features, an acronym **SWAC** is used. The letters of an acronym are the words describing most popular types of the difficult neck:

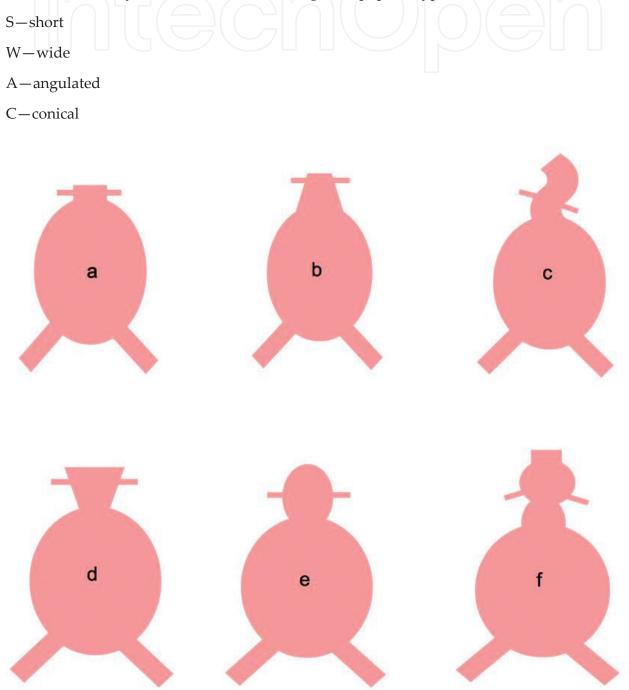


Figure 2. Different shapes of the difficult necks: (a) short, (b) conical, (c) angulated, (d) reverse conical, (e) barrel, and (f) dumbbell or double barrel.

Of course, SWAC acronym does not cover all features of the difficult neck definition; however, it is very useful to remind a basic identifier of the hostile neck during a procedure planning.

3. Type Ia endoleak as a complication of hostile neck anatomy

One of the most common proximal failure representation in hostile neck cases is an occurrence of type Ia endoleak [3]. The leak channel is formed between a graft fabric and aortic wall at the proximal part of the endoprosthesis (**Figures 3** and 4). Type Ia endoleak inevitably causes aneurysm sac growth and finally may be a reason of a rupture. The overall rate of type Ia endoleaks varies between 3.6 and 5.4% [9, 20]; however, some researchers reported up to 12% incidence of proximal endoleaks in groups of patients with difficult anatomy and big aneurysm sac diameter [10]. The data analysis from ANCHOR study revealed 9.2% endoleak incidence in patients with hostile neck [14, 17].

The fenestrated graft implantation (FEVAR) has been considered as a gold standard method in endoleak prevention and treatment in patients presenting short necked (4–10 mm) or juxtarenal aneurysms (<4 mm) for a very long time [25]. A fenestrated stent graft body tailored to individual anatomy of a specific patient makes possible to effectively seal the aneurysm sac after positioning covered stent extensions in the lumen of the renal and visceral branches. However, FEVAR procedure has also its limitations like technical complexity, graft availability, and cost.

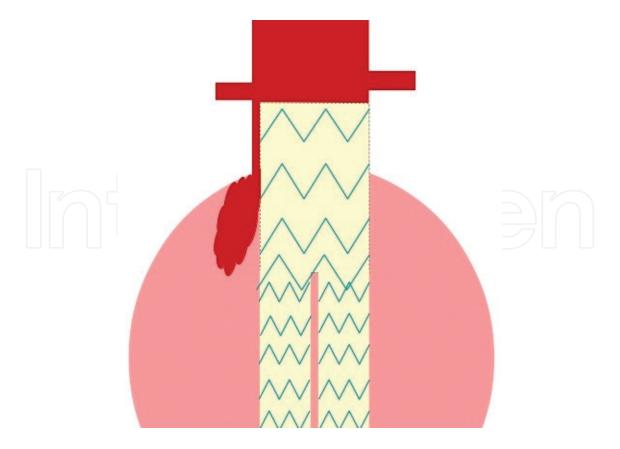


Figure 3. A schematic view of a type 1a endoleak.



Figure 4. CT angiography with large type Ia endoleak.

As technically challenging, FEVAR is available only in high-volume centers, and usually a potential candidate has to wait few weeks for endoprosthesis to be manufactured. A substantial group of patients is excluded from that treatment option due to comorbidities, the FEVAR average time, as well radiation dose, and contrast media volumes are higher than during the complex EVAR procedures described below.

During the development of EVAR procedure, a wide range of techniques have been designed either to prevent the procedure failure or to seal the endoleak which occurs during the followup period. The most popular methods of sealing the acute or chronic endoleaks are to add additional aortic segments and reshape the landing zone area by the balloon inflation, thus remodeling the landing zone (**Figure 5**).

In a substantial number of cases that simple solution is effective, the neck is reshaped and effective seal is achieved. If that technique is not sufficient, other sealing methods can be used, such as endostapling, chimney technique, or transcatheter embolization.

3.1. Endostapling

In 2001 the first stapling system was described by Trout and Tanner [4]. A laser beam was used to form a hole in the endograft fabric, in which an endostaple was inserted. Unfortunately, there is no report about in vivo use in humans or animal models.

Currently, used helical EndoAnchor device was developed by Aptus Endosystems in 2002 and first used in human in 2005. Currently, these devices are available on the market as Heli-FX made by Medtronic (Santa Rosa, USA). The helical endostaples are delivered through



Figure 5. Low-pressure balloon remodeling of the neck with an endoleak.

a shapeable 16 F sheath and electrically powered screwing system which allows to input the EndoAnchors through the graft fabric on the right angle. Each EndoAnchor is 4 mm long, and the system is designed do "pin" the graft fabric to the aortic wall [4, 26].

In 2012 an ANCHOR registry was established to collect the data of the long-term efficacy and outcome in patients requiring a Heli-FX use. The results are promising so far, especially in cases of acute and late endoleak sealing. The device is also useful in prophylactic use in difficult anatomy, when a type Ia endoleak occurrence probability is high.

In 2017 a CE mark was granted for Endurant II graft model to be used together with Heli-FX in short aortic necks (4–10 mm).

3.2. Transcatheter embolization of type 1 endoleaks

A different approach in endoleak sealing is transcatheter embolization by the use of coils or liquid medium such as glue. During the procedure one can successfully combine both of these methods which are highly effective in sealing. The limitations are however the size of the endoleak channel and a fact that method cannot be used as a prevention of the endoleak occurrence. The method is efficient in small and medium volume flow endoleaks. In case of high-volume lesion, even the big amounts of the glue and coils do not stop the leakage, but there is a possibility to merge embolization procedure with endostapling with a good effect (**Figure 6**).

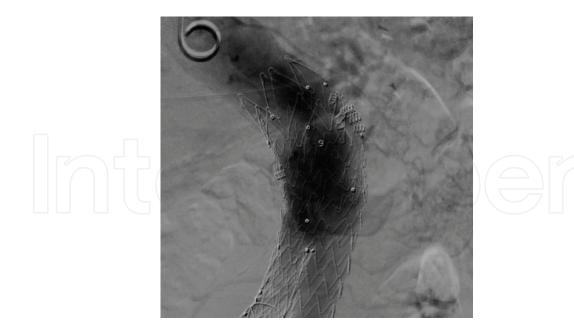


Figure 6. Sealed type Ia endoleak after additional aortic cuff implantation followed by endostapling (Heli-FX EndoAnchor).

Currently, there are two commercially available glue brands on the market: Onyx and Squid. Both Squid and Onyx are based on ethylene vinyl alcohol (EVOH) copolymer dissolved in dimethyl sulfoxide (DMSO), with the additive of micronized tantalum for radiopacity. There are differences of tantalum amount between both compounds that affects viscosity and density of the medium. Onyx is delivered in two viscosity types (Onyx 18 and Onyx 34), while Squid comes in two different viscosity types (Squid 18 and Squid 12) mixed with two opacity possibilities (normal and low density with 30% reduced Ta) that finally gives four different drug types.

Both agents were initially developed for the treatment of saccular aneurysms that are not surgically removable, especially in the cerebral circulation and to embolic therapy of arteriovenous fistulas and malformations (**Figure 7**).

3.3. Chimney technique

Another widely used option in type I endoleak prevention and treatment is a chimney technique by the use of standard endograft which extends over the renal or visceral arteries which are previously secured by the insertion of covered or uncovered stents forming the conduits providing the blood supply for abdominal organs. The first application of renal artery stenting in order to restore the flow after its unintended covering by the graft fabric was reported in 1999 and as elective use in 2001 [1]. The first use as a method in landing zone extension was made by Greenberg in 2003 [12]. Since then, the chimney technique has become a well-established option, which allows physicians to treat AAA with challenging neck anatomy using endografts and off-the-shelf stents [5]. It allows to extend a sealing zone to the desired length, and its simplicity in comparison with FEVAR makes it a favored technique in the case of urgent procedures when time is limited and complex FEVAR systems are not readily available.

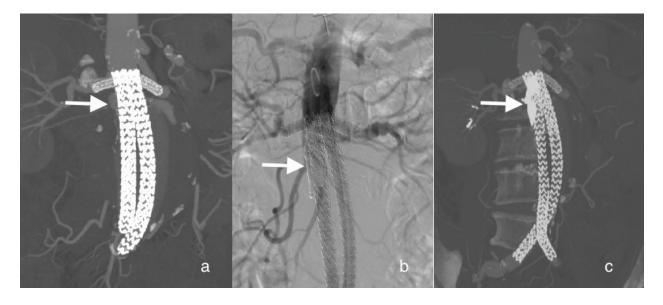


Figure 7. Endoleak embolization by squid delivered directly to the leak site: (a) preoperative CT angiography, (b) final angiography directly after procedure, and (c) control CT angiography. (Courtesy of B. Żabicki, MD, PhD).

Currently, in most cases, covered balloon-expandable stents (BES) are in use during the chimney formation. However, bare metallic devices are still in use in some centers, and some reports showed their non-inferiority during the follow-up especially when EVAS is applied and the endobag fabric covers the bare metallic stents and prevents a gutter formation. Ducasse et al. presented a series of 22 patients treated with Nellix graft with an open chimney technique, with promising results after 18 months of follow-up with one endoleak which was resolved spontaneously [8]. Another report of Garriboli and Jannello described two cases of open chimney grafting with a good result after 18 months of follow-up showing no endoleaks [11].

As of the writing of this paper, the chimney technique has CE mark approval in one covered device (Medtronic Endurant II) with the use of the covered stents limited with no more two chimneys in renal arteries. Other manufacturers do not recommend the chimney technique inside the limits of instruction for use (**Figure 8**).

3.4. Other methods of a type Ia endoleak prevention

3.4.1. Kilt technique

In 2009 Minion et al. [16] proposed a predeployment of a covered cuff into a challenging neck using the Gore Excluder AAA Endoprosthesis which was described as a kilt technique. In 2011 Jimenez and Quinones-Baldrich [13] reported a successful kilt implantation in four hostile neck patients with good long-term results in three of them and one reintervention with Palmaz stent implantation in order to seal type I endoleak.

The method was called a kilt technique according to its similarity to the traditional Scottish male dress (kilt). In a case report, Park and Kim [18] described a successful predeployed thoracic stent graft as a kilt prior to bifurcated graft implantation.

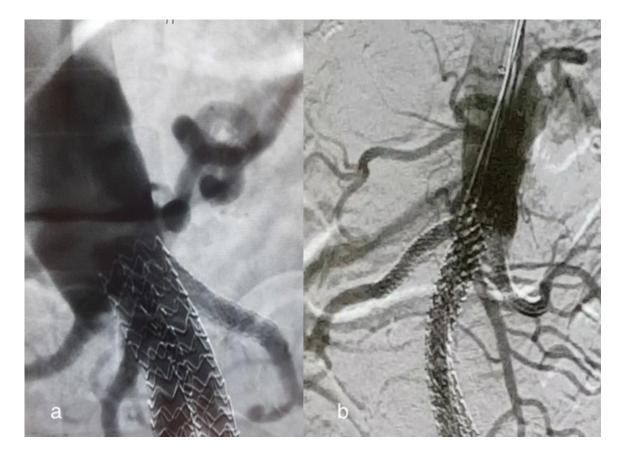


Figure 8. Chimney technique in EVAS procedure: (a) single chimney and (b) double chimney.

The author's experience with the kilt technique was described in the report in 2016 on a series of 11 patients with difficult neck anatomy not suitable for standard EVAR approach. An aortic extension cuff was predeployed below the renal arteries. The element was initially oversized in order to straighten the neck in case of angulation higher than 60° and to secure smooth landing zone in case of other irregularities like conical or barrel-shaped neck [24].

By using two oversized elements one in another, we also achieve higher radial force, being a derivative of radial forces of the cuff and main body. Higher radial force and better adherence of the kilt fabric to the aortic wall and the main body fabric to the inner surface of the cuff are probably responsible for good sealing and fixation. The preliminary results showed the efficacy of the method in cases of difficult anatomy. Kilt implantation is also a readily available procedure that can be completed using off-the-shelf endovascular equipment without additional procedures such as visceral catheterization or stenting (**Figure 9**).

3.4.2. Funnel technique

In report published by Valdivia [21], a very interesting concept of "intentionally migrated endograft body" followed by endostapled cuff was presented with a good effect. The authors intentionally positioned the main endograft body lower than expected in IFU and then, after fixing it by Heli-FX system, implanted the second cuff also endostapled with Heli-FX that effected in smooth landing zone in difficult anatomical conditions.

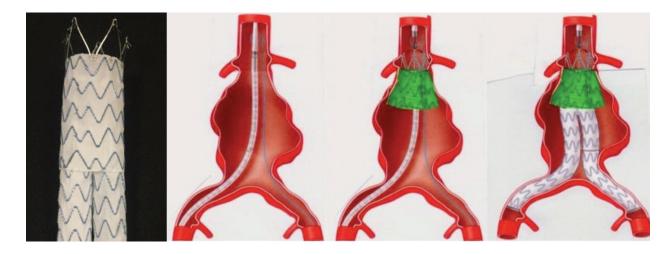


Figure 9. A concept of the kilt technique.

4. APPROACH concept as a possible future strategy in procedure planning in case of hostile neck anatomy

As mentioned previously in introduction, difficult anatomy of the aortic neck is only a part of a wider range of the topic which is a successful treatment of a patient with complex pararenal aneurysm. In order to achieve treatment success after EVAR in such patients, during the procedure planning, a physician should not only focus on possible technical pitfalls in the landing zone area but also take an overall look at the patient as well as technical solutions available in particular center and finally the financial aspects.

For this purpose, an APPROACH concept was proposed by Donas and Torsello [7] which is an acronym of the first letters of the following:

A–Aortic pathology

- **P**—Patient profile
- **P**–Proven literature evidence
- R—Renovisceral anatomy
- O-Operator preference/skills
- A-Access
- C–Costs
- H-Hostile neck (discussed above)

4.1. Aortic pathology

Depending on the aortic pathology we consider to treat by the use of endograft, the approach to it may vary. For example, in a case of 55 mm juxtarenal aneurysm embracing an SMA, the

procedure planning will be completely different than in a case of the same size PAU located just below the left renal artery orifice. In case of PAU, the risk of rupture is much higher, and the equipment used to the procedure will be quite different. That is why a careful study of the aortic anatomy is important during the qualification process.

4.2. Patient profile

Overall patient condition and as age or life expectancy strongly influence a decision-making process during preoperative arrangements.

4.2.1. Cardiac status

Poor cardiac status usually makes an open surgery impossible and significantly elevates a perioperative risk of FEVAR. In most of these patients, the EVAR approach, very often with additions as chimneys, EndoAnchors, or kilts, is the only treatment option in contrast to conservative therapy. Of course, careful cardiac status checkup is needed prior to the final decision, however, in comparison with open repair or FEVAR that is a least invasive option from the cardiac point of view.

4.2.2. Renal function

A substantial number of patients with juxtarenal aortic pathology suffer from chronic renal failure as well. Therefore, a risk of contrast-induced renal failure increases significantly if renal function parameters are disturbed. During endograft implantation with additional endovascular procedures (chimneys, endostapling, etc.) or during the fenestrated endograft implantation, the volume of contrast media is usually higher than during the standard EVAR, and renal function plays an important role in future outcome and therapeutic success.

The use of carbon dioxide as a contrast medium is possible only to the level of diaphragm and not available in every center due to technical reasons.

4.2.3. Life expectancy

This is an important factor during the patient stratification to the different types of treatment. If we consider a long-term therapeutic effect in case of short-neck aneurysm in 65-year-old male without cardiac comorbidities, then open repair would be a first choice. On the other hand, the same morphology of aneurysmatic aorta in 93-year-old woman with positive history of myocardial infarction and EF 25% would result in endovascular solution as a first choice.

4.3. Proven literature evidence

In spite of a limited number of evidence-based reports concerning the sufficient groups of patients with complex pararenal aneurysms, a lot of case reports in which surgeons describe different ways of solving the complicated neck problem, usually pushing the envelope far beyond the IFU limits. Unfortunately, a small series of patients and different endograft systems used make a statistical analysis difficult or impossible.

However, ANCHOR and ENGAGE [14, 17, 23] studies described before provided a reliable information about durability and efficacy of the two main methods used in approaching difficult neck. These studies are still limited by the use of single-manufacturer endograft model.

One method successfully proven to be effective in the case of chEVAR may not work with chEVAS, and the successful use of endostaples with polyester endograft may not be effective in PTFE models and impossible in EVAS.

As the APPROACH concept, the authors noted that there is a need for well-designed national or international registries where the APPROACH parameters, including local resources, infrastructure logistics, costs, availability of devices, and surgical expertise, would be considered [7].

4.4. Renovisceral anatomy

The distance between aortic sac and the lowest renal artery is not only a parameter one has to consider in planning advanced procedures in hostile neck aneurysm. The distances between all visceral arteries and their layout on the aortic perimeter play an important role as well. In chimney graft implantation, usually that is a crucial factor necessary to implant a proper number of stents in order to achieve an effective sealing zone. In case where renal arteries and SMA originate at one level, usually three stents instead of two are needed. That fact can make the procedure more complicated and prolonged.

In case of a ortic angulation at this level, the situation can be complicated by the technical issues such as extremely difficult access to the target vessel in which the chimney stent is targeted.

Other difficulties may arise from vessel diameters either natural or resulting from arteriosclerotic lesions in the lumen of renal or visceral arteries which also can make chimney implantation hard and laborious.

One has to remember also about the presence of additional renal arteries and carefully consider our options to avoid type II endoleak or renal ischemia. We have to decide if eq. embolization prior to endografting is necessary and doing it if there are collaterals feeding that part of the renal tissue able to maintain the blood supply after closing it orifice.

4.5. Operator preferences

Every operator has his/her own preferences in difficult neck anatomy cases, which may significantly change an approach to the procedure. The more experienced team in endostapling will use that method in cases of "difficult neck" moving the boundaries more further than the inexperienced one. On the other hand in high-volume center experienced in FEVAR that will be a preferred method of hostile neck treatment with acceptable mortality and complication rates.

4.6. Access

Difficult access may complicate almost every seemingly easy procedure. There are numerous examples of poor access conditions which excluded patients from treatment or ended up with surgical conversion. Two important factors influence on the procedure outcome: access vessel diameters and the presence of angulations in the vessel course.

When discussing a vessel diameter, we have to remember about the patient's past endovascular history.

During the chimney procedures, an aortic arch and supra-aortic vessel anatomy should be considered very carefully, because the most difficult part of the procedure is performed via that access point. Arteriosclerotic lesions in the orifices of vessels arising from the aortic arch may be a source of a cerebral embolization. Asymptomatic stenosis or occlusion of the left subclavian may exclude the patient from chimney procedure when more than one chimney formation is necessary.

4.7. Cost

The overall cost of the patient treatment and its further reimbursement is regional and country specific and also is an important factor limiting the treatment options. In some EU countries, the hospital is paid by the insurance company for every segment of EVAR (body, extensions) system separately, while in others the reimbursement rate is fixed no matter how many segments are used. In hostile neck patients, the overall treatment cost is significantly higher than in standard EVAR that favors the insurance systems where every piece of inventory is reimbursed. That fact may be an issue for hospitals being paid flat rate, where in such cases an extra permission from the financial board of the hospital or from the insurance company is needed that is time-consuming.

5. Summary

Hostile neck in complex pararenal abdominal aortic aneurysm is not only a problem of difficult anatomy. As described above, many factors exist, sometimes not medical, which can influence on patient eligibility to the endovascular therapy, on the final decision about specific procedure, and on the positive outcome of the treatment process in the long term. During the procedure planning, a medical team shall carefully analyze all factors described in APPROACH strategy and then choose a best treatment for a particular patient to achieve a therapeutic goal.

Conflict of interest

The author declares no conflict of interest.

Thanks

The author would like to thank M. Żabicki, MD, PhD, and R. Maciąg MD, PhD, for pictures with embolization cases.

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