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Endovascular management of infrarenal aortic aneurysm with hostile neck, comparative study

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Abstract

Objective: is to compare results of endovascular management in patients with hostile and favorable neck infrarenal abdominal aortic aneurysms.**Methods**: We conducted a non randomized control study assigning patients with infrarenal abdominal aortic aneurysm (AAA) treated with commercially available endoprosthesis from January 2019 through January 2020 over one year follow up. Two groups were studied, favorable neck group (FNG, n=17) and hostile neck group (HNG, n=18). The hostile neck anatomy was defined as, neck length of <15 mm, infrarenal angle of >60°, neck diameter of >28 mm, more than 50% circumferential thrombus, more than 50% calcified neck, and/or reverse taper neck. Endpoints include technical and assisted technical success, early and late primary outcomes (Endoleak, stent graft patency, aortic sac expansion, conversion to open repair, stent graft migration, aneurysm rupture, secondary interventions, and aneurysm-related mortality), and secondary outcomes (operative blood loss, fluoroscopy time, volume of contrast used, and hospital stay).All outcome measures were calculated using SPSS version 21.0 (SPSS IBM).**Results**: The difference in the primary (FNG=100%, HNG=83%) and assisted primary success, between both groups of patients was statistically insignificant (p=0.229).We had non-significant statistical difference between both groups in the incidence of systemic and local complications. There was no graft related mortality in both groups; also no patient experienced graft migration, endoleak, sac expansion, surgical conversion or wound complications within 30 days, however Complete thrombotic iliac limb occlusion occurred in one patient (5.6%) of HNG (P=1.0). One patient (5.6%) in the HNG experienced graft migration and sac expansion because of type IA endoleak. The patient passed away leading to 5.6% incidence of late graft related mortality (p=1.0). there was significant increase of hospital stay and the volume of contrast used in the HNG (p = 0.019 and 0.01, respectively). The difference in technical success between the FNG and the outside the IFU patients was statistically significant (P=0.024, OR 4.4, 95% CI 2.03-9.5).**Conclusion**: EVAR in patients with hostile neck is feasible and effective with an acceptable rate of complications and increased technical difficulty.

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

Key words: Abdominal aortic aneurysm, EVAR, Hostile neck, Favorable neck, instruction for use, Endoleak.

Introduction

EVAR was established as the treatment of choice in management of infrarenal AAA (1).The anatomy of the aortic neck is the cornerstone of maintaining the seal of the endgraft (2).Therefore patients with hostile neck anatomy (HNA) represent a challenge for the use of EVAR (2).

Those patients was offered either open surgical repair which carries the risk of extensive dissection and suprarenal clamping (3), or fenestrated and branched EVAR which requires high volume centers in addition to the long time required for planning. (2).

There was a conflicting data in literature about the efficacy of standard EVAR in management of infrarenal AAA with HNA (4). Therefore we aimed in this study to evaluate the effectiveness of EVAR in HNA and compare its results with favorable neck anatomy (FNA).

Materials and methods

Patient selection:

Prospectively collected data from 35 patients electively treated with EVAR at the vascular unit at Kasr-Alainy teaching hospital in the period between January 2019 and January 2020 and followed up for one year.

The following general inclusion criteria were applied

- The standard criteria for AAA repair using the endovascular technique either due to their high operative risk or due to the patient preference in case of low to moderate risk.
- Patient capability to provide Informed consent
- Life expectancy of at least 1 year.

Additional patient's demographic data and comorbidities were collected and routine preoperative laboratory and radiological investigations were conducted.

All patients underwent contrast enhanced multi-slice CT, with 1 mm axial cuts, whole aorta to lower extremities with particular attention to the aortic neck anatomy, upon which the patients were divided into two groups; 18 patients in the hostile neck group (HNG) and 17 patients in the favorable neck group (FNG) according to the anatomical characteristics of the proximal neck.

Under general or regional (spinal or epidural) anesthesia bilateral femoral artery longitudinal exposure was done and the EVAR procedure was accomplished. The choice of the type of anesthesia was tailored according to the patient's comorbidities and body habitus.

Follow-up:

CTA scan was performed for all patients at one month, followed by Doppler ultrasound(DUS) imaging between 3 to 6 months and CTA at 1 year. If an endoleak is detected on color DUS

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

imaging or there is an increase in sac size at any time, the patient will undergo CTA scanning and management accordingly.

Definitions and end points:

HNA was defined as having one or more of six neck features:

(a) Short neck: a distance of <15 mm between the most caudal renal artery and the superior aspect of the aneurysm.

(b) Angulated neck: angle between the proximal aortic neck and the longitudinal axis of the aneurysm measuring >60 degree.

(c) Diameter of the aneurysmal neck >28 mm up to 32.

(d) Degree of aneurysm neck thrombus was recorded as a percentage based on the proportion of the volume taken up by thrombus in that segment in relation to the total volume of the neck, we considered it significant if >50%).

(e) More than 50% calcified neck

(f) Reverse taper; it was defined as gradual neck dilatation of 2 mm within the first 10 mm after the most caudal renal artery.

Significant AAA sac expansion was defined as >5 mm increase of the sac size, and significant shrinkage was defined as a decrease of >5mm/ 6 months.

Endograft migration was determined by measuring the distance from the lowest renal artery and the most cephalad portion of the stent graft, as seen on CTA images. Significant migration was defined as displacement of >10 mm or any displacement requiring secondary intervention.

Endoleakwas diagnosed using CT, based on extravasation of contrast between the prosthesis and the aneurysm wall, or by color DUS imaging where the flow and spectral signals were outside the prosthesis, or both. If the CT and DUS results differed, contrast arteriography was done to confirm the endoleak.

Early endoleak was defined as a leak detected intraoperatively or <30 days of the procedure, and **a late endoleak**was defined as a leak observed >30 days postoperatively.

Technical successwhich is defined as proper positioning of the endoprosthesis with patency of the renal arteries, in the absence of intraoperative endoleak, surgical conversion, or stent graft limb occlusion.

Assisted technical success defined as: unplanned adjunctive endovascular or surgical procedures were necessary to achieve proximal seal.

The parameters analyzed in the two groups:

- Technical and assisted technical success
- Early (30 days post-operatively), and late primary outcomes (one month to one year) include:Type I endoleak, Other types of endoleak, Stent graft patency, Aortic sac expansion, Conversion to open repair, Stent graft migration, Aneurysm rupture, Secondary interventions, And aneurysm-related mortality.

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

- Secondary outcome include: Operative blood loss, Fluoroscopy time, hospital stay, And volume of contrast used during stent graft implantation.
- Access site and systemic complications

Statistical analysis:

Sample size measurement:

Epi-calc 2000 was used to calculate the sample size of this non randomized case control study. Assuming 80% power, 0.05 level of significance, 40% proportion of controls exposed,to detect odds ratio OR=8 with ratio of cases to controls =1.05

Statistical methods:

Data will be entered and processed using SPSS version 21.0 (SPSS IBM), comparison will be analyzed and reported as per protocol. Descriptive and inferential statistical analyses was carried out as appropriate.

Results

Patient demographics, classification of aortic neck and stent grafts:

Eighteen patients out of the 35 patients had at least one adverse character of the proximal aortic neck and they were classified as hostile neck group "HNG", the remaining 17 patients were classified as favorable neck group "FNG". And all patients followed up for one year.

There was no significant difference between both groups regarding the demographics and mean aneurysm size (Table 1).

Table 1: Baseline characteristics of EVAR patients.

Group	FNG(n=17)	HNG(n=18)	P value
Age (mean)	62.9	65.2	0.39
Male	17 (100.0%)	16 (88.9%)	0.48
DM	2 (11.8%)	1 (5.6%)	0.6
HTN	13 (76.5%)	16 (88.9%)	0.4
Cardiac	6 (35.3%)	9 (50%)	0.3
ESKD	1 (5.9%)	0 (0.0%)	0.48
Smoking	17(100%)	15 (83.3%)	0.22
AAA diameter (mean)	64.4	65.7	0.8

The most common hostile feature was the neck length (n=13), followed by neck angulation (n=5), neck diameter (n=4), and tapered neck (n=1). We had two patients with three and one patient with two hostile neck characters (Fig.1 and Table 2).

We used different types of stent grafts (The Medtronic Endurant II (n=14), The Bolton Treovance (n=14), and The Cook Zenith Flex (n=7)).

Procedural characteristics:

The primary technical success in the FNG was 100% compared with 83.3% (15/18) primary technical success in the HNG (Fig.2) with no statistically significant difference between both groups (p=0.229).

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

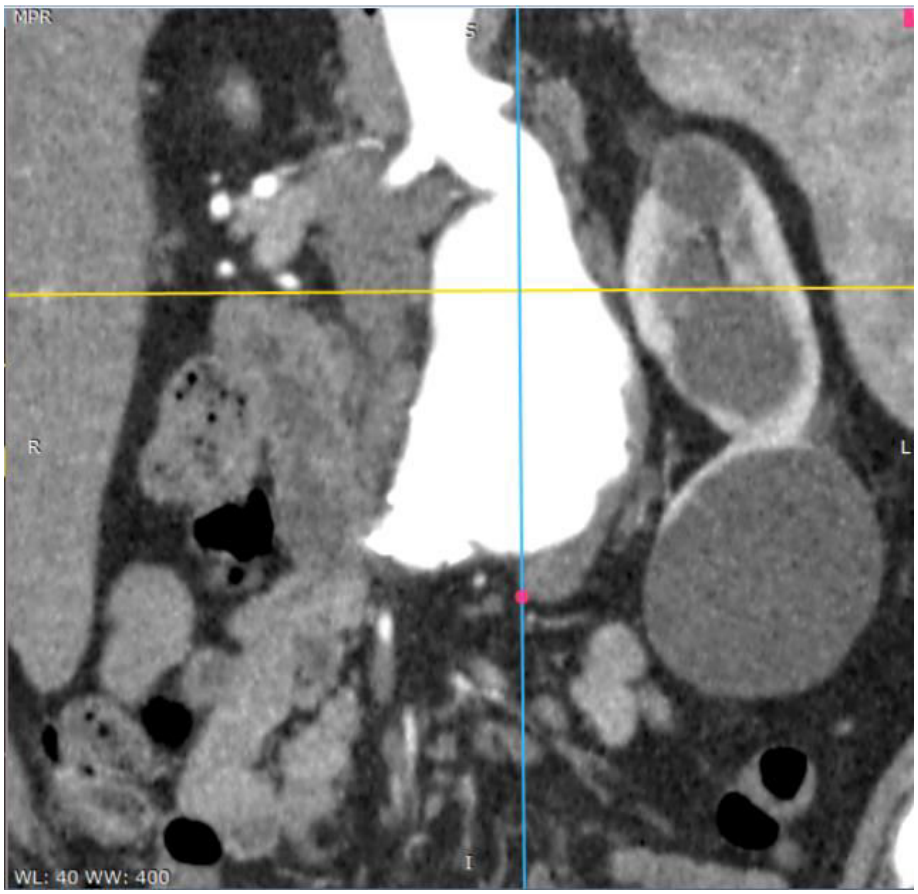


Fig.1: CTA showing 2 hostile neck characters (neck length 12mm and infrarenal angle 65°).

Table 2: Anatomical characteristics of HNG

Neck character	**Number of patients**
Length only	10
Angle only	4
Diameter only	2
Thrombus only	0
Calcification only	0
Reversed tapered only	0
Length and angle	1
Length, diameter and angle	1
Length, diameter and reversed tapered	1

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

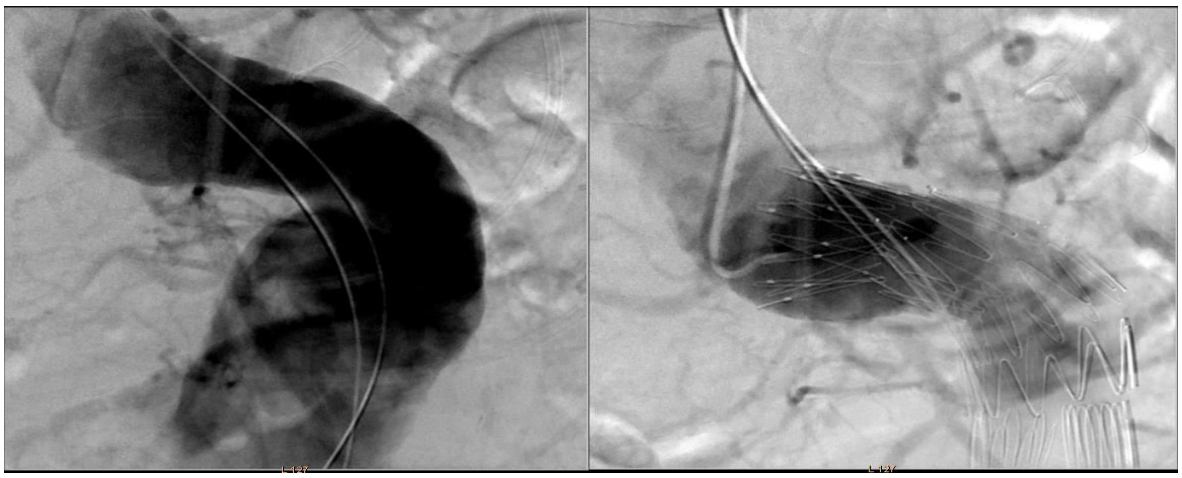


Fig.2: Pre-deployement angiography of a patient (neck diameter26 mm, length 23 mm, angle 90°) (A), completion angiography with successful placement of the endogeaft (B).

In three patients (16.7%) of the HNG post-deployment angioplasty of the proximal neck was performed due to presence of modest type IA endoleak, using large caliber balloons (Equalizer 33 mm balloon catheter, Boston Scientific, Natick, MA, USA) and (Reliant 46 mm balloon, Medtronic Cardiovascular, INC, Santa Rosa, CA, USA) with complete resolution of endoleak in two patients. In the third patient,balloon angioplasty was not enough. This called in cuff (EndurantII proximal cuff, diameter 28mm) deployment in the same setting with full obliteration of the leakage achieving 100% assisted primary technical success.

Inraoperative left brachial arterythrombosis issued in one patient in the HNG and was treated with open thrombectomy. While in the FNG one patient suffered from common femoral artery thrombosis which was treated with vein patch angioplasty. There was no statistically significant difference in local complication between both groups, (P=1.0).

There was no statistically significant difference between the two groups regarding the fluoroscopy time (HNG=46 min, FNG=41 min, p=0.47) and estimated blood loss (HNG=373, FNG=332, p=0.57).

While the volume of the contrast was significantly higher (HNG=179 ml vs FNG=111 ml) in the HNG with significantly longer hospital stay(HNG=3 days vs FNG=2 days) (p = 0.019 and 0.01, respectively).

Follow up:

Postoperatively, both groups had satisfactory outcomes in early follow up. There was no graft related mortality in both groups; also no patient experienced graft migration, endoleak, sac expansion, surgical conversion or wound complications.

Complete thrombotic iliac limb occlusion occurred in one patient (5.6%) of HNG after 2 weeks postoperative, which was managed with a femoral-femoral cross over bypass. All other EVAR limbs remained patent with no stent fractures or migrations. The incidence of iliac limb occlusion was not statistically significant, (P=1.0).

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

Outcomes occurring after 30 days postoperatively revealed that, In the HNG maximum aneurysm diameter was reduced in 17 patients. One patient (5.6%) experienced graft migration and type IA endoleak with consequent AAA rupture which warrant expeditious deployment of aortic cuff (Endurant II proximal cuff, diameter=36mm). Despite successful sealing of aneurysm leakage, the patient did not recover from the hypovolemic shock and died the next day. It worth noting that patient had three hostile neck characters in addition tobe outside the IFU (aortic neck angle of 88.5°) of the device that have been used (The Medtronic Endurant II). There was no significant difference between both groups of patients regarding the late primary outcomes (P=1.0) (Table 3).

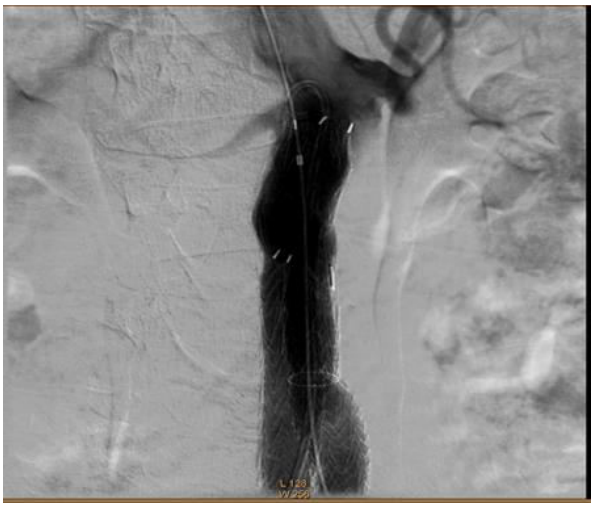
Subgroup analysis:

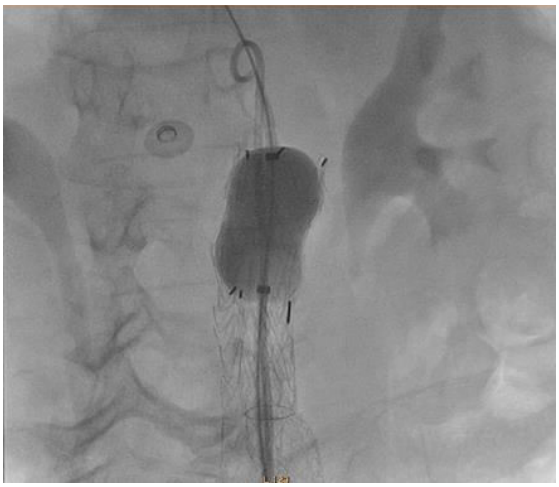
In the HNG, we had eight patients that didn't fit the IFU of the used device. Four patients had aortic neck angle of 65° to 90°, three patients with aortic neck length <10 mm, and one patient with neck diameter 33mm.

Table 3: Clinical outcomes for all grafts:

	FNG(n=17)	HNG(n=18)	P value
Primary technical success	17 (100%)	15 (83.3%)	0.22
30 day reintervention	0.0%	1 (5.6%)	1
Late (> 30 days) type IA endoleak	0.0%	1 (5.6%)	1
One year mortality	0.0%	1 (5.65)	1

Violating the IFU of the used devices resulted in increased incidence of intraoperative type IA endoleak and adjunctive procedures with significant difference in primary technical success (P=0.024, OR 4.4, 95% CI 2.03-9.5)





ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

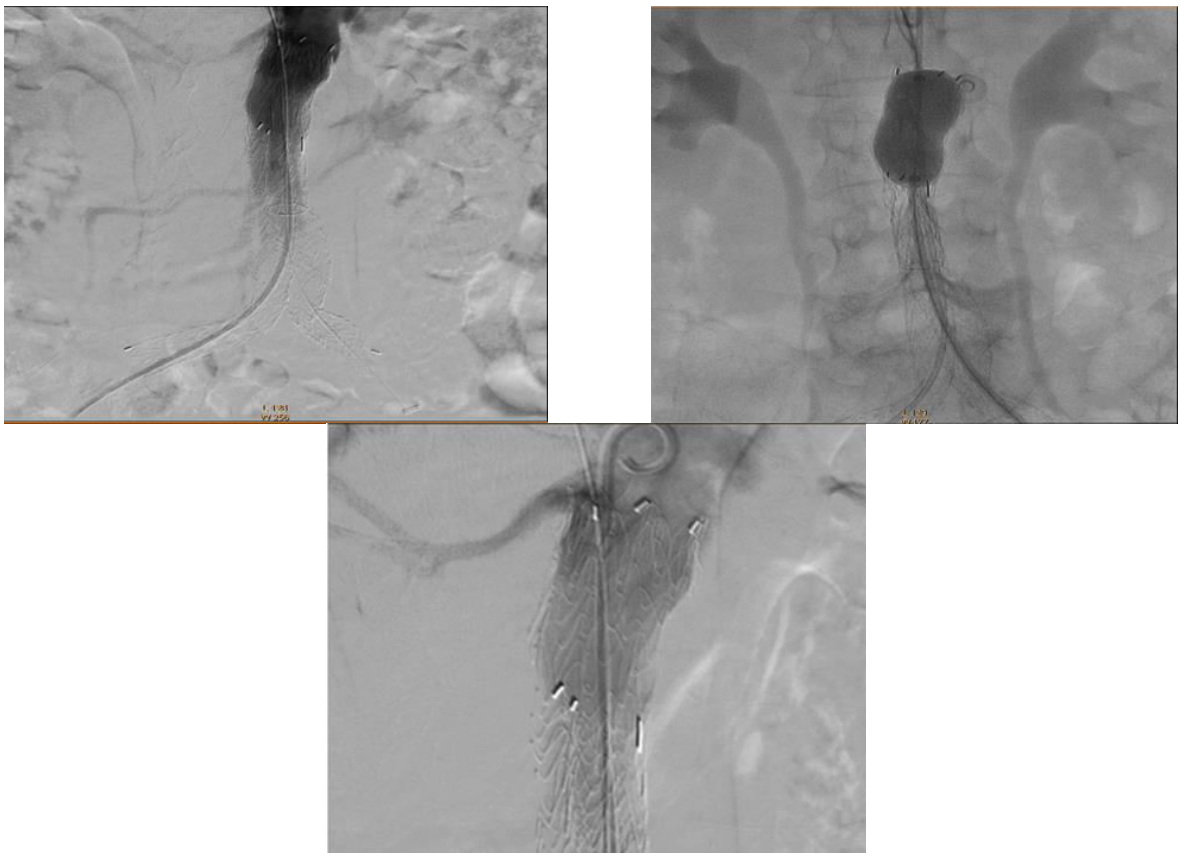


Fig.3: angiography showing type IA endoleak in patient with infrarenal angle =80° (A), using balloon angioplasty to seal the endoleak (B), angiography showing persistent type IA endoleak (C), using balloon angioplasty to seal the endoleak (D), completion angiogram showing complete seal of the endoleak (E).

Discussion

Since the inception of EVAR in the early 1990s, the link between aortic neck anatomy and the development of complications, such as type IA endoleak and endograft migration, has been evident.

Because of that, EVAR was mostly offered to patients with ideal aortic neck anatomy.

Lower operative and postoperative mortality, exponential increase in patient age and comorbidities and growing experience of surgeons have made EVAR the first choice in the majority of infrarenal aortic aneurysms management. Moreover, clinicians tend to extend the legibility of EVAR to include not only favorable neck anatomy but aneurysm with hostile neck as well.

The advance in technology is dynamic, as is the definition of hostile aneurysm neck. The definition of hostile neck differs among different publications according to the available endografts at each center.

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

At our institution, patients with hostile neck anatomy currently form substantial proportion of patients undergoing EVAR, with the hostile necks aneurysms even outnumber those with good necks in the past 2 years. This reflects the growing dexterity & gumption in the application of endovascular grafts to individual patients from one side and the advance of endograft technology and manufacture on the other side.

We compared the result of EVAR procedure between favorable and hostile neck aneurysms in terms of technical success, systemic and local complications, early and late re-intervention, early and late mortalities.

There was no difference in patient demographics or clinical demographics between the compared two groups.

The patients with hostile neck anatomy (HNA) had more complicated aneurysms and represented group at higher anatomical risk.

Technical success in the FNG and the HNG was achieved in 100% and 83.3%, respectively (P=0.229, <0.05). In accordance with our results **Stather et al. (5)** had a technical success rate of 97% and 80% in the FNG and the HNG, respectively.

Stather et al. (6) performed a meta-analysis of data collected from six studies on EVAR with HNA, found no significant difference in technical success between the FNG and the HNG.

It is logical to think that patients with HNA would be more likely to require intra-operative adjuncts and re-intervention due to increased risk of type IA endoleak.

In our study the incidence of type IA endoleak was 16.7% (three patients) in the HNG, with no intraoperative type IA endoleak in the FNG. The endoleak was treated with balloon angioplasty in two and an aortic cuff extension in one case which lead to assisted technical success of 100%.

In meta-analysis performed by **Antoniou et al. (7)** they found that adjunctive procedures were required in 22% of patients with hostile neck anatomy and in 9% of patients with friendly anatomy (P<0.001).

Cerini et al. (4) and his colleagues compared 94 patients with suitable anatomy (wIFU) and 86 patients with unsuitable anatomy (oIFU). One (1.4 % wIFU vs 1.1 % oIFU) case in each group required placement of proximal cuff to treat type IA endoleak. In the same study 17 patients (18.8%) of the OIFU group require angioplasty of the proximal neck due to presence of modest type IA endoleak.

In wIFU group, one case (1.1%) of intraoperative occlusion of one renal artery occurred; in the oIFU group five cases of intraoperative occlusion of the renal arteries occurred (4.7%), (in four cases one renal artery and in one case both renal arteries). The difference in intraoperative occlusion of the renal arteries was statistically significant (P = 0.019).

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

We didn't experience renal artery occlusion in our two study groups.

Gaibar et al. (8) reported seven (7/52 (13.4%)) out of the 8 intraoperative endoleaks that required treatment in the HNG and 1 (1/75 (1.3%)) in the FNG. The need for perioperative adjunct procedure in hostile necks was statistically significant (p=0.006). Technical and clinical success was 100% in both groups.

Stather et al. (5) analyzed data collected from 552 elective EVAR and found no significant difference in type IA endoleak (FNA 0.8%, HNA 2.5%; P=0.12), or 30-day mortality (FNA 1.1%, HNA 0.5%; P=0.45).

Likewise, **Antoniou et al. (7)** found no significant difference in type IA endoleak and re-intervention rates within 30 days between the HNG and FNG.

Choke et al. (9) reported statistically insignificant aneurysm related mortality rate within the 30 days follow up between the FNG and the HNG (6% and 3% respectively).

In accordance with that and similar to **Gaibar et al. (8),** we reported no cases of 30 day endoleak or mortality in both groups.

Although the rate of intraoperative type IA endoleak and consequently the rate of re-intervention is higher in the HNG. This was not reflected by most of studies.

Stather et al.(5) found no significant difference in 30-day re-intervention (FNA 2.8%, HNA 5%; P=0.12), likewise **Antoniou et al. (7)**found no significant difference re-intervention rates within 30 days between the HNG and FNG.

In our study we had only one case (5.6%) of graft limb occlusion in the HNG treated with femoral to femoral cross over bypass graft (P=1), which was statistically insignificant, whereas **Georgiadis et al. (10)**had only one case in the FNG with no cases in the HNG.

In contrast **AbuRahma et al. (2)** reported statistically significant early all types of interventions (HNA (28%) vs FNA (9%), P.0006). most of them were proximal aortic extension cuffs and only five graft thrombectomy and three patients had graft thrombectomy and femoral-to femoral crossover bypass grafts.

We reported one (5.6%) case of graft migration at 6 month in the HNG with no cases in the FNG. Similar results reported by **Gaibar et al. (8).**

We have no graft migration in either groups at 12 month, whereas **Stather et al. (5)** reported rate of migration of 2.5% and 3% in the FNG and HNG, respectively at the same follow up period.

In contrast to those results **Georgiadis et al. (10)** reported no cases of migration.

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

In our study we have one (5.6%) case of late type IA endoleak in the HNG, with no case in the FNG (P=1) similar to what **Gaibar et al. (8)**had. Our results contradict **Choke et al. (9)** who reported on late type IA enodleak in 1% of the FNG and 3% of the HNG, although the difference between both groups was statistically insignificant, the 1% incidence of late type IA endoleak contrasted our result (0% late type IA endoleake in the FNG)

Regarding sac expansion within one year postoperative, our study reports incidence of 5.6% in the HNG and 0% in FNG. Our results are congruent to the results of **AbuRahma et al. (2)** who reported on 7% and 1% incidence of one year sac expansion in HNG & FNG, and **Choke et al. (9)**7% and 3%in the HNG and the FNG, respectively.

We had 5.9% rate of rupture in the HNG and no case experienced rupture in the FNG, however, **Stather et al. (5)** had 3.5% rate of rupture in the HNG and 1.1% in the FNG at 12 month follow up.

In the period between one month and one year, we have one (5.6%) patient re-intervention in the HNG and no re-intervention was required in the FNG, the difference was statistically insignificant. This patient had aortic cuff to treat proximal type IA endoleak. The incidence, indications and type of re-intervention in the same period of follow up vary across publications as well as their relevant statistical difference between FNG & HNG. **Stather et al. (5)** reported statistically significant difference in the rate of re-intervention to treat type IA endoleak between FNG (0.6%) and HNG (2.5%), $P < 0.05$. **Choke et al. (9)** reported 8% in both groups and **AbuRahma et al. (2)** 6% and 7% re-intervention rate in FNG & HNG respectively. Type II endoleak constituted the majority of late endoleak in both studies and anatomical type of neck (favorable or hostile neck) posed no influence on its incidence or its management either. Moreover, late type I endoleake (proximal or distal) came in the next tier to type II endoleak; without statistical difference between FN and HN

We had one case of aneurysm related mortality in the HNG (5.6%), due to late type IA endoleak at sixth month. The patient was admitted to the hospital due to severe abdominal pain. CTA confirmed the clinical diagnosis of aneurysm rupture. Shortly thereafter, he developed hypovolemic shock. Hypotensive hemostasis allowed expeditious insertion of aortic cuff. Despite adequate management, the patient passed away the next day due to irreversible shock.

AbuRahma et al. (2) reported one late death caused by rupture AAA. This patient had an 8.5-cm aneurysm, which was treated with a Zenith Cook device. A late type I endoleak developed at 6 months with an increase in aneurysm size to 10 cm; however, the patient refused treatment and died of aneurysm rupture 5 months later.

In contrast, both **Cerini et al. (4)** and **Gaibar et al. (8)**reported no anuerysm related mortality in both groups (FNG & HNG).

IFU of endograft is generated upon bench tests results and validated through clinical trials, often before the endograft is doled out in the market. The exact safety and effectiveness of performing EVAR outside a particular IFU is not completely known. Post-marketing studies on EVAR

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

outside the IFU are more comprehensive and accurate in determining the safety and effectiveness of defying the IFU. In fact, it is the impetus behind the cases of EVAR outside the IFU. The other one is the presence of serious comorbidities in patients deemed high surgical risk. The latter was the reason we included eight patients done outside the IFU in our study.

We have four patients with outside IFU infrarenal angles (P=0.006, OR;5.2 , 95% CI;2.1 -12.6), three patients with outside IFU neck length (P=0.001, OR;6.6, 95% CI;2.3-18.8), and one patient with outside IFU neck diameter (P=0.093).

Technical success in EVAR outside the IFU was 62.5% (5/8 patients), with assisted technical success rate of 100%. Therefore the difference in technical success between the oIFU and the FNG of patients was statistically significant (P=0.024, OR;4.4, 95% CI;2.03-9.5)

During the duration between one month and one year, one patient in the outside IFU group experienced AAA rupture due to type IA endoleak, at 6 month follow up, and treated with cuff but the patient passed away.

Therefore the difference between both groups in the incidence of late primary outcomes was statistically insignificant (P=0.32).

Oliveira-Pinto et al. (11) conducted systematic review and found 8800 patients receiving EVAR outside the IFU in the period between 1991 and 2016. They compared the results from publications citing the results of EVAR outside IFU with the control patient included in the same study or with the large controlled trials (EVAR-1, DREAM, OVER& ACE). They concluded that overall and aneurysm related mortalities insignificantly differ at long-term, though, short neck aneurysm are attained by higher rate of type I A endoleak in EVAR outside than EVAR inside the IFU. In contrary, when the IFU was violated for the angulation or high thrombus load, the results of EVAR outside the IFU and wIFU were similar.

As expected, patients with more complex neck anatomy require angiography in different views to correct the parallax and to adjust the device position exactly below the lowest renal artery without wasting length from the already short neck.

This was reflected on our study as we had a significant difference in the contrast volume between the HNG and the FNG, however, we had non-statistically significant difference in the fluoroscopy time. **Georgiadis et al. (10)** reported non-statistically significant difference in contrast volume and significant difference in fluoroscopy time.

We didn't report statistically significant difference regarding the blood loss in both groups, this was in accordance with **Lee et al. (1)** however we reported a significantly longer hospital stay in the HNG in contrast tothe same study.

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 05, 2021

Conclusion

EVAR in patients with hostile neck is feasible and effective with an acceptable short term rate of complications despite the increased technical difficulty.Violating the IFU of the EVAR devices was associated with significant increase in usage of adjunctive procedures. RigorousImaging surveillance is necessary in patients with HNA to detect and treat late type I endoleaks.Large sample size is required to assess the effect of each individual hostile neck criterion on the EVAR outcomes and to allow subgroup analysis.

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