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CLINICAL STUDY

Use of EndoAnchors during index endovascular aortic aneurysm repair in patients with hostile proximal aortic neck anatomy

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ABSTRACT

PURPOSE: Standard endovascular aortic aneurysm repair **(**EVAR) is sometimes the only treatment option for patients with hostile aortic neck anatomy, but it carries an increased risk of both early and late procedure-related complications. The aim of this study was to report on single-center experience with the Heli-FX EndoAnchors (Medtronic, Santa Rosa, CA) as an adjunctive procedure to endovascular aneurysm repair (EVAR) for prevention and perioperative treatment of proximal neck complications in patients with hostile neck anatomy.

MATERIALS AND METHODS: A single-centre, retrospective study evaluating 24 consecutive patients treated with EndoAnchors during the index EVAR procedure between November 2018 and August 2021. EndoAnchor implantation was indicated for cases with hostile proximal aortic neck anatomy characterised by the presence of at least one of the following parameters: length of <15 mm, diameter of >28 mm, angle of >60°, circumferential thrombus/calcification involving ≥50%, and reverse taper.

RESULTS: Median follow-up period was 22.5 months (IQR 2–31.5 months) with no aneurysm-related death, rupture, or conversion to open surgical repair during the follow-up. The procedural success rate was 100%, with no type Ia endoleak at the completion angiography. A mean of 7 EndoAnchors was used per patient (range 4–12). There were no EndoAnchor fractures and dislocations or stent graft fabric damage due to anchor implants. Twenty-three patients (95.8%) remained free of type Ia endoleak and migration on follow-up imaging. Aneurysm sac regression was observed in 13 patients (54.1%), while in 8 patients (33.3%) the sac remained stable. Sac enlargement was present in 1 patient (4.2%) due to late type Ia endoleak. Two patients were lost to the follow-up immediately after the procedure. Between two groups of patients (sac regression versus failure to regress), the larger initial diameter of the proximal neck was the only significant independent factor associated with a lower possibility of sac regression (p= 0,021).

CONCLUSIONS: The use of EndoAnchors during the index EVAR procedure in cases with challenging aortic neck anatomy with or without perioperative type Ia endoleak was associated with good midterm results and led to sac regression in most of the patients *(Tab. 4, Fig. 3, Ref. 31)*. Text in PDF www.elis.sk

KEY WORDS: abdominal aortic aneurysm, endovascular aneurysm repair, hostile neck anatomy, EndoAnchor, endoleak, sac regression.

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Introduction

Endovascular aneurysm repair is currently the preferred option for infrarenal aortic aneurysm treatment (1–3). However, despite the technological advance related to the endograft design, complications in terms of type Ia endoleak and graft migration are still fairly common in case of unfavorable proximal aortic neck anatomy. The majority of early type Ia endoleaks are caused by insufficient sealing and fixation between the endograft and the aortic wall. The cause of late type Ia endoleak and distal migration is considered to lie in the continuous progression of aneurysmal degeneration to the previously unaffected segment of the aorta. This results in the loss of adequate apposition of the endograft to

the aortic wall and the necessity of reintervention or conversion to open surgical approach (4).

Most authors define hostile aortic neck anatomy as presence of at least one of the following parameters: neck length ≤15 mm, diameter >28 mm, angulation ≥60°, excessive thrombus or calcification involving more than 50% of the aortic circumference, and reverse taper morphology (5–11). This unfavorable anatomy has been documented in as many as 40–60% of treated AAA cases and is directly responsible for the poorer outcome (12–14).

The Heli-FX EndoAnchor System (Medtronic Vascular, Santa Rosa, CA, USA) aims to overcome this problem by providing better and more active fixation and sealing between the endograft and aortic wall.

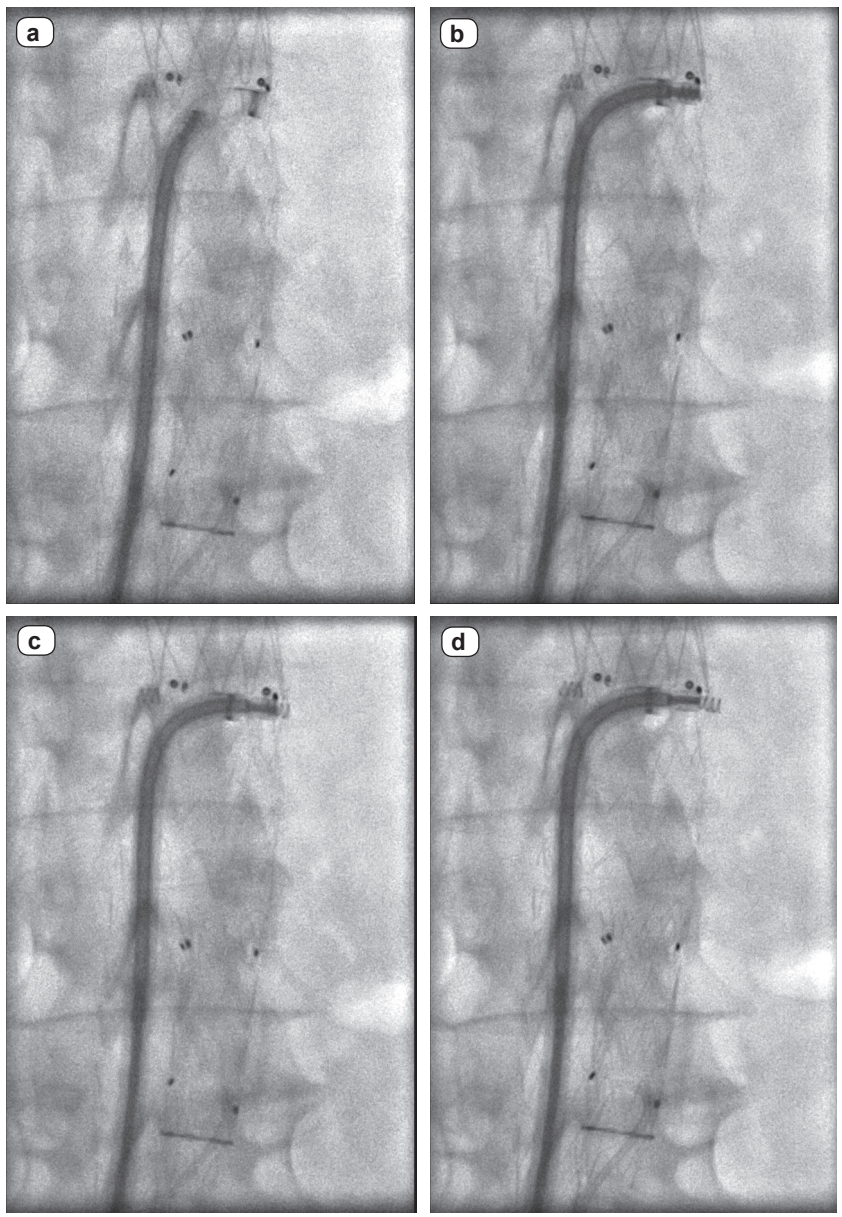

Fig. 1. Perpendicular position of Heli-Fx system against aortic wall (a) and two-stage process of EndoAnchor implantation (b, c, d)

The Heli-Fx EndoAnchor System

Heli-Fx EndoAnchor System (Medtronic, Santa Rosa, CA) is the first FDA-approved and CE-marked system that provides active fixation and sealing between the aortic wall and endograft by implantation of EndoAnchors. In principle, it takes the concept of surgical anastomoses and applies it to the endovascular portfolio (15, 16). According to the manufacturer's recommendations (IFU), it is intended for the prevention and therapy of complications associated with EVAR, in particular early and late type I endoleaks and graft migration. The system consists of three main components – applier, deflectable guide and cassette containing 10 EndoAnchor implants. Electronically controlled applier can deploy only one EndoAnchor at a time. The EndoAnchor of the Heli-Fx EndoAnchor System (Medtronic, Santa Rosa, CA) is a metal spiral, 4.5 mm in length and 3 mm in diameter. The spiral shape ensures two-way fixation between the graft and aortic wall and minimizes the risk of progressive dilatation at the fixation site.

Anchors are released in two stages (the first stage is reversible), which allows repositioning in case of incorrect or insufficient penetration through the endograft fabric to the aortic wall (Fig. 1). The Heli-Fx guide is designed to direct the applier to the intended location. Using the control handle, we form the distal, deflectable tip of the guide to achieve a perpendicular position against the endograft wall (17).

Methods

This is a single-arm, retrospective, non-randomized single-center study evaluating patients treated with EndoAnchors during the index EVAR procedure. Endoanchor implantation was indicated for cases with the presence of hostile proximal neck anatomy with or without periprocedural type Ia endoleak. We analyzed data from 24 consecutive patients treated at our institution between November 2018 and August 2021 that fulfilled the criteria of hostile aortic neck anatomy defined as a presence of at least one of the following parameters: neck length ≤15 mm, diameter >28 mm, angulation ≥60°, excessive thrombus or calcification involving more than 50% of the aortic circumference, and reverse taper morphology.

Most of the patients were men (22, i.e., 91.7%), mean age was 73.0 ± 6.8 years. Preoperative semiautomatic *centerline* analysis for the *assessment* of *aneurysmal neck and*

sac anatomy parameters was conducted using 3mensio Vascular (Pie Medical Imaging BV, Maastricht, Netherlands) imaging software.

Procedural success was defined as the deployment of the recommended minimum number of anchors according to IFU with no visible type Ia endoleak present at completion angiography. Patients' characteristics, as well as preoperative, intraoperative, and follow-up data were obtained from a prospectively maintained computer database and analyzed retrospectively. The use of accessory device during the procedure, early (≤30 days) and late complications, freedom from type Ia endoleak and migration, aneurysm-related mortality and sac regression during follow-up, as well as reinterventions were recorded.

This study was conducted in accordance with the principles of the Declaration of Helsinki, and all patients provided written informed consent prior to procedure. All information used was obtained from the review of medical charts and CT-scan images, thus no approval from an ethics committee was required.

Statistics

All analyses were performed using IBM SPSS Statistics Software Version 23 (IBM, Armonk, New York, USA). Measured values are reported as percentages for nominal variables and mean standard deviations (SDs) or medians (range) for continuous variables. Descriptive statistics were used to present the baseline patient characteristics, anatomic variables, procedure details, and outcomes during follow-up. Quantitative parameters were compared using the Mann–Whitney U test, and Fisher's exact test was used to compare qualitative parameters. The estimates are presented with a 95% confidence interval (CI). The threshold of statistical significance was $p<0.05$.

Procedure and follow-up

All procedures were performed in the catheterization laboratory under local anesthesia through bilateral percutaneous transfemoral access. In all cases, the Endurant II stent-graft system (Medtronic Cardiovascular, Santa Rosa, CA) and Perclose Proglide SMC System (Abbott, Ontario, Canada) for arterial closure were used. The number and location of EndoAnchors were dependent on aortic diameter and angulation. According to IFU, the recommended minimum numbers of EndoAnchors is 4 in diameter ≤29 mm and 6 in diameter 30–32 mm (Fig. 2). The position of EndoAnchors was modified based on the location of thrombus or calcifications. In cases with periprocedural type Ia endoleak treatment, more EndoAnchors were placed focally and more densely. The second row of EndoAnchors below the first one was implanted if needed and feasible (Fig. 3).

All patients underwent computed tomography (CT) evaluation with an intravenous contrast agent for detection of early endoleaks 3–5 days after the procedure, and then after 1 and 12 months. Based on the 12-month result, the patients were scheduled for CTA or ultrasonography check-ups annually. Follow-up imaging reports were assessed for complications, including endoleaks, stentgraft migration, limb occlusions and sac regression. All observations and measurements of sac regression during the follow-up were conducted using SyngoVia imaging software (Siemens Healthcare GmbH, Erlangen, Germany).

Results

Patient characteristics

Between November 2018 and August 2021, of the total of 24 patients with AAA, 22 male patients, (91.7%), mean age 73.0±6.8 years (range 59–88 years) were identified as being suitable for the treatment using the EndoAnchors of the Heli-Fx EndoAnchor System (Medtronic, Santa Rosa, CA). Demographic

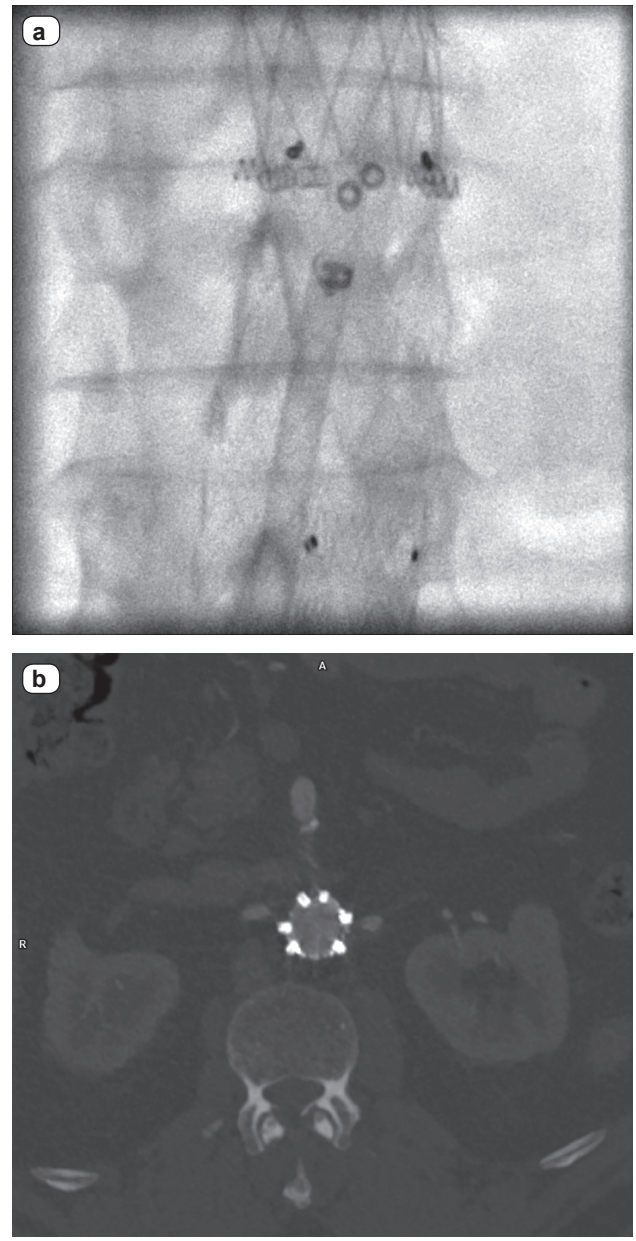

Fig. 2. DSA (a) and CTA (b) images demonstrate distribution of EndoAnchors around the circumference of the endograft.

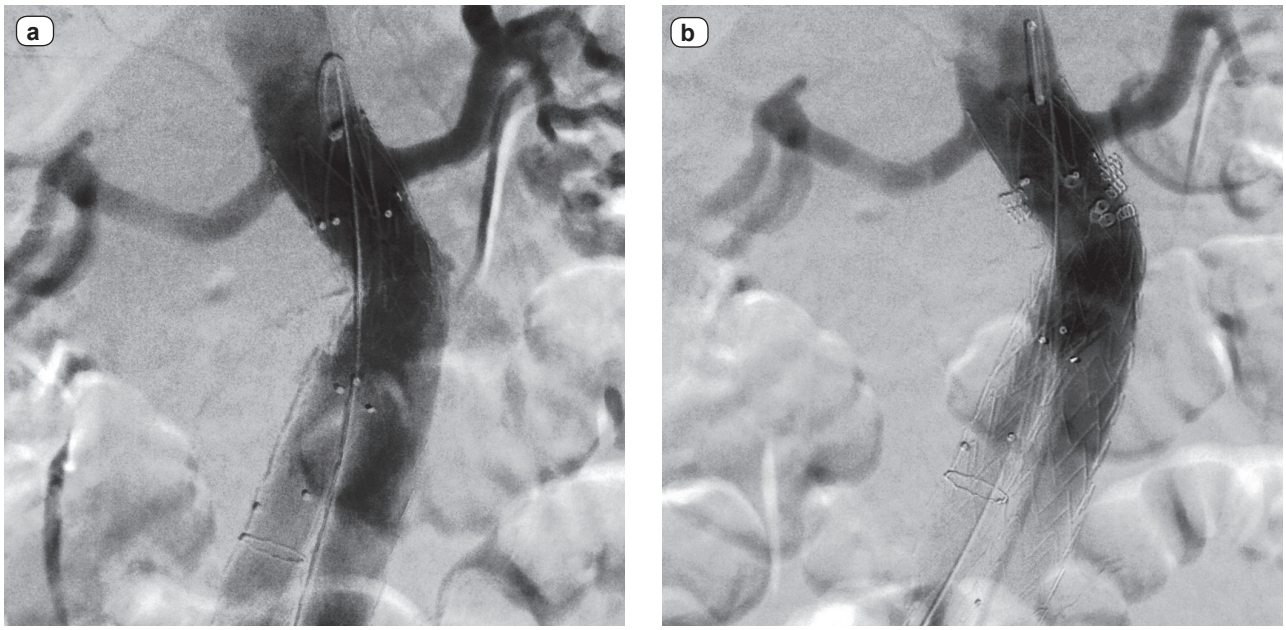

Fig. 3. Perioperative type Ia endoleak (a) treated with EndoAnchors (b)

characteristics and baseline clinical data of the analyzed patients are detailed in Table 1.

The criteria for hostile aortic neck anatomy were defined as the presence of neck length ≤15 mm, diameter ≥28 mm, angulation ≥60°, thrombus or calcification involving 50% of the aortic circumference, and reverse tapering morphology. Table 2 shows the anatomic characteristics in terms of aneurysm diameter, neck anatomy and hostile neck criteria.

Patient outcomes

The procedural success rate, defined as implantation of the recommended minimum number of EndoAnchors according to IFU with no visible Ia endoleak present at completion angiography, reached 100%. An aortic extension cuff was deployed during the index procedure in 1 patient (4.2%). The cuff was deployed before implanting the EndoAnchors because of the distal displacement of the endograft in the aortic neck by 4mm. In our cohort, there was no need for other adjunctive procedures during index EVAR (Tab. 3). A mean of 7 EndoAnchors was used per patient (range 4–12). There were no EndoAnchor fractures, dislocations or stent-graft fabric damage due to anchor implants or any major intraoperative complications in our group. All patients had a CTA scan during their hospitalization with no type I endoleak or endograft migration detected before discharge.

The median follow-up period was 22.5 months (IQR 2–31.5 months) with no early all-cause mortality within 30 days, aneurysm-related death, aneurysm rupture or conversion to open surgical repair during the follow-up. Twenty-three patients (95.8%) remained free of type Ia endoleak and migration on imaging during the follow-up. Aneurysm sac regression was observed in 13 patients (54.1%), and in 8 patients (33.3%), the sac remained

Tab. 1. Baseline patient characteristics*.

Number of patients	24
Men	22 (91.7%)
Age (years), mean ± SD (range)	73.0±6.8 (59–88)
Hyperlipidemia	19 (79.2%)
Smoking (current or former)	19 (79.2%)
Coronary artery disease, IM	10 (41.7%)
COPD	4 (16.87%)
Malignancy in medical history	7 (29.2%)
Arterial hypertension	18 (75%)
Diabetes mellitus	4 (16.7%)
Stroke/TIA	6 (25%)
Peripheral artery disease	4 (16.8%)
Chronic kidney disease**	6 (25%)

* Nominal variables are presented as numbers (percentage), continuous variables are presented as median values (range); ** estimated glomerular filtration rate (eGFR) less than 60 ml/min per 1.73 square meters

Tab. 2. The morphologic characteristics of AAA and proximal aortic neck*.

Diameter of aneurysm (mm), median (range)	55.8 (50.1–75.8)
Infrarenal neck angulation (°), median (range)	40.0 (20–84)
Neck length (mm), median (range)	15.0 (7–46)
Neck diameter (mm), median (range)	22.9 (20.0–28.2)
Hostile neck anatomy	
Diameter ≥28 mm	2 (8.3%)
Infrarenal neck angulation ≥60°	7 (29.2%)
Neck length ≤10 mm	8 (33.3%)
Neck length ≤15 mm	5 (20.8%)
Thrombus/calcifications (≥50% Ø, ≥2 mm)	7 (29.2%)

* Nominal variables are presented as numbers (percentage), continuous variables are presented as median values (range)

stable. Sac enlargement was present in 1 patient (4.2%) due to late type Ia endoleak. Two patients were lost to follow-up immediately after the procedure, both of them with no signs of type Ia endoleak and migration present on discharge CT scan.

The initial value of diameter of the proximal aortic neck was the only significant independent factor associated with the success rate of sac regression. A larger diameter was associated with a lower probability of successful sac regression (p=0.021) (Tab. 4).

In total, there were 4 aneurysm-related reinterventions, only one of them involving the proximal aortic neck. Two of them occurred after the index procedure, during the same hospitalization period. One case of type Ib and one case of type IIIa endoleak were detected on the CTA imaging; both were treated with a covered stent. Early graft limb thrombosis presented as acute limb ischemia occurred in one patient after 6 days following EVAR. The complication was managed by mechanical thrombectomy and balloon angioplasty. One patient developed late type Ia endoleak with aneurysm sac expansion 18 months after EVAR. An aortic extension cuff was used to treat the endoleak and there was no new case of type Ia endoleak or aneurysm sac growth observed during the continuous follow-up for subsequent 18 months.

Tab. 3. Procedural specifics and outcome (n=24).

Procedural success	24 (100.0%)
Endoanchors per patient, median (range)	7 (4–12)
Adjunct procedures involving proximal neck	1 (4.2%)
AAA-related reinterventions	4 (16.7%)
Early	3 (12.5%)
Late	1 (4.2%)
Type Ia endoleak at 30 days	0 (0.0%)
Type Ia endoleak at 1 year	0 (0.0%)
Late type Ia endoleak >1 year	1 (4.2%)

Discussion

Endovascular aneurysm repair has become the preferred method in the treatment of patients with infrarenal AAA. The procedure's success depends on the anatomy and morphology of the aneurysm, with proximal aortic neck anatomy being the most critical factor. The hostile anatomy of the proximal neck poses an increased risk of both early and late procedure-related complications after standard EVAR as it is harder to achieve and maintain adequate sealing and fixations in the attachment site (18).

In their meta-analysis of seven large EVAR studies (n=1,559), Antoniou et al. compared the safety and efficacy of endovascular treatment in patients with favorable and unfavorable types of morphology. Technical success, type Ia endoleak occurrence, reintervention rate, and AAA-associated mortality after 30 days and 1 year were evaluated. Patients with unfavorable anatomy of the aortic neck had a 4-times higher risk of developing type Ia endoleak. Hostile aortic neck anatomy was also associated with a significantly higher rate of reinterventions and AAA-related mortality (6). Similarly, Stather et al. reported a significantly increased need for adjunctive EVAR (8.8% vs 15.4%; p=0.01) and secondary reinterventions (OR 1.29, 95% CI 1.00 to 1.66; p=0.05), higher 30-day mortality (2.4% vs 3.5%; p<0.01), and higher rates of early (OR 2.92, 95% CI 1.61 to 5.30; p<0.001) and late Ia types of endoleak (OR 1.71, 95% CI 1.31 to 2.23; p<0.0001) in patients with hostile aortic neck anatomy compared to those with favorable anatomy. (5) Aburahma et al conducted a retrospective study (n=526) and observed the occurrence of complications in patients after EVAR. Patients were divided into 2 cohorts according to whether the anatomy of the proximal fixation zone met the manufacturer's recommendations (IFU) as opposed to whether at least one parameter was outside the IFU. Their data analysis confirmed a significantly higher risk of aneurysm sac growth, reintervention and death in patients treated with endograft outside IFU (19).

Unfavorable anatomy might be present in as many as 40–60% of AAA and is directly responsible for the poorer outcome. Open surgery repair and fenestrated EVAR (FEVAR) are usually the treatments of choice in such complex cases (20, 21).

Although considered the gold standard in the endovascular treatment of aneurysms with a short proximal fixation zone and complex anatomy, the use of FEVAR is also restricted by the anatomy of the aorta and visceral arteries. The diameter of visceral arteries ≤4 mm, severe atherosclerosis and sharp caudal orientation represent an increased risk of early and medium-term complications in terms of fracture, thrombosis and need for reintervention (22). Tortuosity of access vessels and aorta increases the risk of incorrect positioning of fenestrations; therefore, most manufacturers do not recommend implantation if aortic angulation exceeds 45°. As seen in our cohort, the majority of patients were also unfit for open surgery repair (often involving suprarenal/supramesenteric or even supraceliac aortic cross-clamping) due to severe cardiovascular and renal comorbidities predisposing them to a significant risk for perioperative morbidity and mortality.

The goal of the Heli-FX EndoAnchor System is to overcome the above-mentioned limitations by providing better and more active fixation and sealing between the endograft and aortic wall, all without renal or visceral artery involvement. Best evidence regarding the Heli-FX EndoAnchor system's effectiveness in treating complex AAAs comes from Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) prospective multicenter study (319 patients, 43 sites in the United States and Europe). Patients were enrolled in the

Tab. 4. Sac behavior during follow-up based on proximal neck characteristics.

	Sac regression	Stable sac/sac increase	p
Number of patients	13	9	–
Diameter of aneurysm (mm), median (range)	53.7 (50.1–73.7)	60.2 (51.1–75.8)	0.171
Diameter of the neck (mm), median (range)	21.7 (20.0–25.0)	24.0 (21.0–28.2)	**0.021**
Neck angulation (°), median (range)	40.0 (26–80)	40.0 (20–84)	0.738
Neck length (mm), median (range)	19.0 (8–46)	14.0 (7–26)	0.401

primary arm (76%) if they had EndoAnchors implanted during the first EVAR procedure or into the revision arm (24%) if treated for complications involving the proximal aortic neck after initial EVAR procedure. Procedural success, defined as technical success without type Ia endoleak at completion angiography, was 89.7% in the primary arm and 80.5% in the revision arm. During a mean follow-up period of 9.3 months, no patient developed a new occurrence of type Ia endoleak or endograft migration after the initial EVAR procedure. There were no aneurysm ruptures or AAA-related deaths. Overall, 304 patients (95.6%) were free from secondary interventions. A total of 18 secondary procedures were necessary (5.6%), only 7 (2.9%) of those in the primary arm (23).

In the last few years, we have witnessed paradigm shifts in AAA treatment, with aneurysm sac shrinkage being the most important indicator for long-term EVAR success. In another meta-analysis (8 studies, n=17,086), Antoniou et al. compared the outcomes of patients with sac shrinkage (n=8518) with patients with stable or expanded sac after EVAR. Sac shrinkage was associated with significant improvement in terms of survival, EVAR-related complications, and need for secondary interventions. Due to the significance of this parameter, the authors also concluded that aneurysm sac behavior should be considered in follow-up protocols (24).

Analysis of 100 patients enrolled in ANCHOR study (73 and 27 patients in the primary and revision arms, respectively) with at least one-year follow-up and imaging studies available within the one-year window or beyond showed sac regression in 45% and 25% of patients in the primary and revision arms, respectively. Sac enlargement was observed in one patient (25).

Although a small cohort of patients was evaluated, our results are comparable with the data from the above-mentioned studies, with 95.8% freedom from type Ia endoleak and 87.5% freedom from secondary procedures, with only one of them (4.2%) being related to the proximal neck. Sac regression was observed in 54.2% of patients. Sac enlargement was present in 1 patient (4.2%) due to late type Ia endoleak. Anatomical factors predicting sac behavior during follow-up after EVAR are not well identified, and data from studies are rather inconsistent. Two studies found a shorter proximal neck length to be a significant risk factor for sac shrinkage failure (26, 27). Other studies found an association between a larger initial AAA diameter and increased likelihood of sac shrinkage (28, 29), whereas older age and larger preoperative infrarenal β angle were associated with poorer sac behavior (28, 29, 30). In our group of patients with hostile aortic neck anatomy, a larger initial proximal neck diameter was the only predictor associated with a lower chance of sac shrinkage. Adjunctive procedure during index EVAR was less frequent in our study (4.2%) compared to other studies (23, 31).

The limitations of this study stem mainly from its nonrandomized, single-centre, retrospective design, and a smaller number of patients. Also, a notable amount of patient was lost to or refused long-term follow-up due to the COVID-19 pandemic. Penetration of EndoAnchors into the aortic wall and their symmetrical circumferential distribution were not evaluated in this cohort.

Conclusion

With a significant percentage of patients unfit for extensive open surgery repair or FEVAR, standard EVAR is often the only therapeutic option for a large group of AAA patients with hostile neck anatomy. The results from our cohort suggest that the Heli-Fx EndoAnchor system is a safe and effective addition to the endovascular treatment of these complex AAA cases with low rates of early and late type Ia endoleak and endograft migration occurrence. In our study, it also seems to have provided sac regression in the majority of patients, which, according to latest data, is one of the most important factor of freedom from late reintervention, AAA-related complications and good long-term prognosis. A larger initial proximal neck diameter was associated with a higher risk of sac failure to regress.

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