Endovascular Treatment of Aortic Aneurysms with Complex Proximal Anatomy

Tratamiento endovascular de aneurismas aórticos con anatomía compleja proximal

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ABSTRACT

Background: There are few publications on patients with juxta or pararenal aneurysms, defined as abdominal aortic aneurysms without a proximal neck suitable for standard endovascular anchoring. We present our experience for their endoluminal repair. **Methods:** This was an observational and prospective study. The results were evaluated at 30 days and up to 2 years in patients consecutively treated with fenestrated or chimney endografts.

Results: Between July 2015 and July 2017, 21 complex endovascular procedures were performed. Thirteen industrially tailored fenestrated devices and 4 physician-fenestrated devices were implanted. Four patients were treated using the chimney technique. Thirty-three fenestrations (2.5 fenestrations/patient) and 15 chimneys (1.8 stents/patient) were manufactured. Events at 30 days included 4.7% mortality and 9.4% branch occlusions, which were re-permeabilized. Among these patients, 2 presented type I endoleak that was repaired. Mean follow-up time was 15 months. In the 2-year Kaplan-Meier analysis, overall survival was 91.7%; primary blood vessel patency was 85.7% and secondary patency 100%. Type I or type III endoleak-free survival was 91.7% at 1 year, and 81.5% at two years. No mortality associated with the aneurysm or its rupture was recorded during follow-up.

Conclusions: These results show a current, effective and safe option for patients with complex aortic aneurysms, using a minimally invasive tailored approach. Probably, these results have consolidated a more important role of these techniques in the treatment of patients with complex aortic aneurysms.

Key words: Aneurysm - Aortic Aneurysm - Abdominal Surgery - Blood Vessel Prosthesis - Implantation

RESUMEN

Introducción: Existen pocas publicaciones sobre pacientes con aneurismas yuxta o pararrenales, definiendo así a los aneurismas de aorta abdominal sin un cuello proximal adecuado para el anclaje endovascular estándar. Presentamos nuestra experiencia para su reparación endoluminal.

Material y métodos: Estudio observacional y prospectivo. Se evaluaron los resultados a 30 días y hasta 2 años en los pacientes consecutivamente tratados mediante endoprótesis fenestradas o endoprótesis en chimeneas.

Resultados: Entre julio de 2015 a julio de 2017 realizamos 21 procedimientos endovasculares complejos. Se implantaron 13 dispositivos fenestrados hechos industrialmente a medida, 4 dispositivos fenestrados por los cirujanos. Fueron tratados 4 pacientes mediante técnica de chimenea. Se confeccionaron 33 fenestraciones (2,5 fenestraciones/paciente) y 15 chimeneas (1,8 stents/paciente). Eventos a 30 días: 4,7% mortalidad; 9,4% oclusión de rama, ambas repermeabilizadas. De esos pacientes, 2 presentaron un endoleak tipo I, y ambos fueron reparados. El tiempo medio de seguimiento fue de 15 meses. En el análisis de Kaplan-Meier a 2 años, la supervivencia global fue de 91,7%; la permeabilidad primaria del vaso fue de 85,7% y, la secundaria, de 100%. La supervivencia libre de endoleak tipo I o III fue de 91,7% al año, y de 81,5% a dos años. No se registró mortalidad asociada al aneurisma o a su ruptura mismo durante el seguimiento.

Conclusiones: Estos resultados muestran una opción actual, efectiva y segura, para pacientes con aneurismas aórticos complejos, mediante un abordaje mínimamente invasivo, diseñado a medida. Es probable que estos resultados hayan consolidado un papel más importante de estas técnicas en el tratamiento de los pacientes con aneurismas aórticos complejos.

Palabras clave: Aneurisma - aneurisma de aorta abdominal/cirugía - Implantación de Prótesis Vascular

INTRODUCTION

The endovascular approach for the treatment of abdominal aortic aneurysms (AAA) has become the first treatment of choice. (1, 2) Its success is mainly based on arterial anatomical requirements, strictly defined in the instructions for the use of each available endograft. (3) But there is a significant number of patients, in whom the anatomy of the proximal segment of the aorta (proximal neck) prevents the proper sealing of the aneurysm and the proper fixation of a standard

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endograft. It is for those patients in particular that techniques, approaches and specially designed endografts have been described, incorporating the visceral segment of the aorta as a neck on which the endograft will be anchored. (4, 5)

The aim of this study was to show our experience in patients with juxta and pararenal abdominal aortic aneurysm (AAA).

METHODS

A prospective, single-center study was performed on 21 patients with juxta or pararenal aneurysms. Industriallymanufactured fenestrated endografts (Zenith® Fenestrated AAA Endovascular Graft, William A. Cook Australia, Ltd, Brisbane, Australia), physician-modified standard endografts (Zenith Flex, Cook Medical, Inc., Bloomington, Ind, USA) or a combination of standard grafts and parallel stents (chimney technique, "Ch-EVAR") were used. The choice of each technique is specified below and was based on the anatomy of the juxta or pararenal sealing zone and the risk of aneurysm rupture. Clinical characteristics and operative and postoperative variables were prospectively collected. The classification of the aneurysm was based on the extent of the aneurysmal disease evaluated by high resolution angiotomography (AT).

Choice of surgical approach

All patients were at high risk for conventional surgery, defined by absence of proximal neck suitable for standard stents (juxta or pararenal aneurysms). The choice of technique varied according to the extension and diameter of the aneurysm, vessel angulation and the internal aortic diameter, and it included standard or specific devices designed for each patient. A minimal proximal sealing zone was selected in normal suprarenal aortic segments, defined by parallel aortic wall without evidence of thrombus, calcium or increased diameter >10%.

In the absence of infrarenal proximal neck, the technique used was the implantation of a fenestrated endograft. These endografts are characterized by holes or fenestras specially tailored for each patient, allowing visceral arterial flow through the endograft. The association of the affected visceral branches is transferred to the endograft, and they all become situated in the same clockwise orientation and height arrangement. The majority of the fenestrated endografts used were industrially manufactured (Zenith® Fenestrated AAA Endovascular Graft, William A. Cook Australia, Ltd, Brisbane, Australia). On the contrary, in patients with a high rupture risk to wait for the industrial construction of the device $(\geq 6.5 \text{ cm})$, we proceeded to manufacture it in the operating room (physician-modified endograft). Under strict sterile conditions, the fully bifurcated Zenith® stent was unsheathed, leaving the bare-metal stents free and removing the first fixation lock.

According to the measurements made using the OSIRIX program, the clockwise orientation and height to make each fenestration were determined. Stent-free 6 to 8 mm in diameter fenestrations were manufactured under magnification (Figure 1), making a hole in the Dacron prosthesis and reinforcing its circumference suturing a radio-opaque coronary guideline.

This reinforcement gave rigidity to the fenestration and turned it visible to the X-rays. Restriction sutures were then made on the posterior side of the stent to keep it partially open after being unsheathed. Finally, the endograft was resheathed, starting with the proximal bare stent. (Figure 1)



Fig. 1



Fig. 2

In patients who had less than 5 mm of proximal neck, but normal visceral aorta, the chimney technique was indicated, provided only the renal arteries were involved, and the distance between the origin of the most caudal renal artery and the superior mesenteric artery were equal or greater than 2 cm. In this way we secured at least 2 cm of contact between the endograft and the wall of the aorta.

The chimney technique consists of placing the covered stents alongside the aortic endograft to maintain blood flow at the origin of the renal arteries. Thus, the upper edge of the endograft is at the level of the superior mesenteric artery, and the parallel stents lift the origin of the renal arteries to that level.

The alignment stents for fenestrations and chimneys were deployed with Advanta V12 balloon (Maquet Atrium, Hudson, NH) or BeGraft (Bentley Innomed GmbH, Hechingen, Germany).

Statistical analysis

Major adverse events were mortality, severe acute kidney injury (>50% decrease in the estimated glomerular filtration rate), recent onset dialysis, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or reintubation, paraplegia, stroke, intestinal ischemia requiring surgical resection or intensive medical care. Primary and secondary patency was defined by uninterrupted patency from the procedure to occlusion or any stent reintervention due to stenosis and occlusion treated with bypass or endovascular rescue, respectively. Time-dependent results were reported using Kaplan-Meier estimates for up to two years, and were reported as percentage for categorical variables, and mean \pm standard deviation for continuous variables.

Ethical considerations

The study was approved by the institutional Ethics Committee and Directory, as it complies with normal treatment standards at our institution.

RESULTS

Clinical characteristics

From July 2015 to July 2017, 21 patients were enrolled in our complex aortic disease program. Mean age was 73±10 years, 18 patients were men and mean maximum aneurysm diameter was 65.8±7 mm. History of prior aortic repair was 9.4%. The most prevalent risk factors were 100% smoking, 85.7% hypertension, 57.1% hypercholesterolemia, 33.3% history of myocardial revascularization, 50% chronic obstructive pulmonary disease and 23.8% chronic kidney disease. Twenty patients were ASA III/IV. For context purposes, another 79 patients with abdominal aortic aneurysms received, except for one, endovascular treatment with standard endografts.

Stent graft design

Endovascular repair was performed using specific devices for the patient (fenestrated endografts, 4 manufactured in the operating room) in 13 patients (61.7%) and Ch-EVAR, in the other 8. A total of 48 visceral arteries were incorporated, (5 celiac trunks, 9 superior mesenteric arteries, 34 renal arteries) with 33 fenestrations (2.5/patient), and 15 chimneys with an average of 1.8 vessels per patient. One patient also received a branch device for the internal iliac artery.

Procedure

All procedures were performed in a hybrid endovascular lab with a Philips Allura FD20 system, using cone beam computed tomography (XperCT) accompanied by special Vessel Navigator software (Philips, Best, the Netherlands). The procedures were performed mostly using general endotracheal anesthesia (19 patients). One patient needed an iliac tube to insert the endograft.

Initial results

Technical success was achieved in all patients, eliminating the aneurysm. One patient died in the hospital due to reperfusion of an ischemic limb (4.7%). At 30 days, 2 patients experienced one occlusion in the renal artery (both Ch-EVAR). One of the occlusions was related to lack of double antiplatelet therapy indicated by the surgical team. A second patient developed occlusion of the renal artery, due to severe bending of the parallel stent. Both cases were successfully repermeabilized. The average surgical time was 3.9 hours, and the volume of contrast material was 87 ml. The average intensive care unit and hospital stay was 2.3 days and 4.2 days, respectively.

There were no cases of myocardial infarction, paralysis or stroke.

In all patients, a first computed tomography study was performed at discharge or within the first 30 days and no type I or type III endoleaks or other complications related to the aneurysm were evidenced.

Long-term results

Reinterventions were necessary in 4 patients (9.5%).

Five patients presented endoleaks identified with TCA during follow-up, including two type I endoleaks (9.5%), and four type II endoleaks. One patient with type IA endoleak due to folds on the posterior face of the endograft at the level of the proximal neck was resolved using endostaples, and another patient had type 1A endoleak due to an iliac extension.

Mean follow-up was 15 months (range, 1 to 23), including >30-day follow-up in all patients, >6-month follow-up in 13 patients, and >12-month follow-up in 6 patients. None of the patients were lost to follow-up. One death occurred at 4 months, for a cause unrelated with the aorta. One-year survival was 91.7%. Primary and secondary patencies were 85.7% and 100%, respectively. There were no ruptures or conversions.

The aneurysmal sac diameter was stable in 12 patients, and decreased in the rest of the patients. To date, no aneurysm ruptures or mortality events related with aneurysms or physician-modified or company manufactured graft integrity problems (eg, stent fracture, tissue rupture, migration) have been identified.

DISCUSSION

The presence of complex anatomy in the proximal neck, defined as a non-existent or short infrarenal aortic segment, angulated or with visceral artery involvement continues to limit the use of standard endovascular devices. (3) In a recent publication on hostile proximal necks, greater than 28 mm in diameter, Haulon et al. described 12% of type IA endoleaks, 3.4% endoleak-related mortality and 7% reinterventions at 2 years. (6) All the infrarenal and suprarenal aortic diameters were increased at 24 months. Mean increase was 11% for the aorta at the lowest renal artery level. Neck length <15 mm (p=0.032), stainless steel endograft (p=0.003) and type IA endoleak at 24 months (p=0.001) were predictors of proximal neck enlargement. Clearly, this article, among others, shows that a hostile neck is associated with anatomical consequences and in many cases, even dangerous technical complications.

On the other hand, open surgery in these patients represents greater complexity, since it entails a more extensive dissection, high aortic cross-clamping, with possible prolonged visceral ischemia and a more complicated reconstruction. It is logical to speculate that the advantages of endovascular surgery for standard anatomy could be extrapolated to these patients at high technical risk for open surgery. (7)

The first report of a fenestrated graft was performed by Park et al. in 1996, who described the use of a fenestration to incorporate a lower mesenteric artery. This initial report was followed by the development of a more versatile fenestrated device using the Cook Zenith[™] from Anderson, Lawrence-Brown and Hartley platform. Since then, experience with fenestrated endografts to treat juxta and pararenal aortic aneurysms has been shown to be an effective procedure associated with low morbidity and mortality rates. This technique considered as standard for patients with complex anatomies was the most used by our group. During the last decade, several centers have accumulated a great experience with this type of repairs. Early postoperative mortality is exceptional and the conversion to open surgery has frankly declined.

In a recent Mayo Clinic publication on more than 120 patients with pararenal and thoracoabdominal aneurysms, technical success was 99.6% without 30-day or in-hospital mortality, dialysis, ruptures or conversions to open surgical repair. After an average followup of 9.2 ± 7 months, 18% of patients had reinterventions (15 aortic), there were 4 occluded renal stents; five patients presented with type IA or III endoleaks; but none had enlarged aneurysmal sac. The patency of the primary and secondary branches was $96\% \pm 1\%$ and $98\% \pm 0.7\%$ at 1 year. Survival was $96\% \pm 2\%$ at 1 year.

Schanzer et al., from the University of Massachusetts Medical School, present a similar experience on 100 consecutive complex endovascular aortic aneurysmal repairs (from November 2010 to March 2016), using 58 (58%) commercially tailored devices and 42 (42%) modified devices. Three deaths, six visceral artery occlusions, five progressions to dialysis, one paraparesis, and one intestinal ischemia were registered with 10% type I or type III endoleaks. In the Kaplan-Meier analysis at 1 year, survival was 87%, absence of type I or type III endoleak was 97%, patency of the culprit vessel was 92% and absence of aortic rupture was 100%. (9)

These experiences are similar to our results, including, as in the second group, patients operated-on with physician-modified prostheses in the operating room. The indication in these patients was based on the presence of large aneurysms (>6.5cm), which could not wait for the normal manufacturing times of these tailored endografts (more than 4 months). The complex analysis of the computed tomographies was decisive to obtain the necessary information to manufacture the fenestrations (clockwise and longitudinal location).

On the other hand, the technique of parallel stents, called "chimney technique," was initially described as a "rescue" technique in patients with short landing zones, or in cases of accidental occlusion of visceral arteries. The technique has been increasingly used, but currently as a treatment for complex aneurysms including aortic arch, thoracoabdominal, pararenal, and iliac artery bifurcation aneurysms. The potential advantages of parallel devices include their universal and all-time availability, as well as the ability to access the origins of the visceral arteries before placement of the aortic endograft, eliminating the problems of fenestrated device alignment. These procedures can also be performed with lower profile endografts, which may be an advantage in patients with small iliac arteries.

Potential complications, which occur at higher rates with parallel grafts, associate sheath access through the upper limbs with the consequent possibility of stroke and the presence of peri-chimney space endoleaks, called "gutters", secondary to the space that is generated between the stents, the endograft and the wall of the aorta. Branch occlusions may also occur, but reported rates are low (<5%).

However, in our experience, the two renal occlusions were in patients with chimneys. The recently published PERICLES study on 517 patients in the USA and Europe, reported 612 preserved visceral arteries, with an average of 1.73 vessels/patient. (10) The results showed 4.9% mortality, 8% intraoperative endoleaks and 2.9% postoperative endoleaks, with 94% patency at 17 months. It is also interesting to note that the registry also reports 29 patients with ruptured aneurysms and 24% mortality rate.

Endoleaks and stent occlusions are infrequent in the case of fenestrated endografts but not in the case of chimneys. Endoleaks may be associated to endograft folding or to the presence of peri-stent gutters. (11)

On the other hand, the occlusion of stents used to preserve the vessel patency in the case of chimneys have an arrangement that in certain cases implies a severe angulation, inside or at the end of the stent. Surveillance is mandatory for the early identification of stenosis or pre-occlusive lesions usually within the first post-operative year. As in our case, early detection and reoperation allow to restore renal flow.

The results of our work are similar to those of these large series, which used fenestrated endografts as standard treatment for patients with complex proximal neck anatomy, leaving other techniques only for the coincidence of a clinical indication and specific anatomical characteristics.

With more mature and developed evidence, the safety, efficacy and durability of endovascular treatment of pararenal and juxtarenal aortic aneurysms has been established by randomized, long-term trials. Improvements in preoperative planning, patient selection, as well as implantation and perioperative care techniques, have reduced the associated morbidity and mortality rate

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material)

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