ORIGINAL ARTICLE

Endovascular Treatment of Aortic Aneurysms with Minimalistic Approach

Tratamiento endovascular de aneurismas de aorta con estrategia minimalista

PAUL GAMBOA, CARLOS M FAVA, GUSTAVO A. LEV, LEÓN R VALDIVIESO, HUGO FRAGUAS, GASPAR M CAPONI, OSCAR A. MENDIZ

ABSTRACT

Background: Aortic aneurysms, particularly of the abdominal aorta, are still common. Since 1990, conventional surgery is no longer the only treatment option due to advances in endovascular devices and techniques. We present our results in the management of aortic aneurysms with a minimally invasive endovascular technique.
Objectives: The aim of this study was to analyze the 30-day outcomes of endograft implantation in the thoracic aorta and abdominal aorta using a minimally invasive approach.
Methods: Between March 2012 and April 2019, 395 consecutive endografts were implanted in the aorta, and 264 (67%) were performed using a minimally invasive approach (MIN-A). Among this group, 240 (90.9%) corresponded to abdominal endovascular aortic repair (EVAR) and 24 (9.1%) to thoracic endovascular aortic repair (TEVAR).
Results: Technical success (TS) of the implant was achieved in 99.6% of the 264 patients and clinical success (CS) in 97.7%. Thirty-day mortality was 1.1% due to pneumonia, heart failure and chronic obstructive pulmonary disease. There were no cases of myocardial infarction, stroke or need for conversion to urgent surgical repair. Mean duration of the procedure was 62 minutes (SD ± 17). Some patients required conversion to surgical closure of the access site [20 (7%) during the first 100 cases and 7 (3%) in the final 164 patients, p = 0.05]. Three (1.1%) patients presented major bleeding requiring transfusion. Mean time to ambulation was 18 hours (SD ± 10) that significantly decreased to 13 hours after the first 100 patients (SD ± 2.9; p= 0.05). Mean length of hospital stay was 1.4 days (SD ± 1.14) with 5 patients discharged on the same day of the procedure.
Conclusions: Endovascular aortic aneurysm repair using a minimally invasive strategy was feasible and safe, turning this procedure into a percutaneous approach, with low access site-related complications, shorter operative time, rapid ambulation and shorter length of hospital stay, without modifying overall safety of the procedure. The learning curve resulted in reduced rate of conversion to surgery and earlier ambulation.

Key words: Aortic Aneurysm -Aortic Aneurysm, Abdominal - Endovascular Procedures/Methods - Blood Vessel Prosthesis Implantation - Conscious Sedation - Minimally Invasive Surgical Procedures

RESUMEN

Introducción: Los aneurismas de aorta siguen siendo una patología frecuente, en especial aquellos localizados en la aorta abdominal. Desde 1990, gracias al avance en los dispositivos y las técnicas endovasculares, la cirugía convencional ha dejado de ser la única opción de tratamiento. Presentamos nuestros resultados en el manejo del aneurisma de aorta con técnica endovascular mínimamente invasiva.
Objetivos: Analizar los resultados a 30 días del implante de endoprótesis en la aorta torácica y abdominal con una estrategia mínimamente invasiva.
Material y métodos: Entre marzo de 2012 y abril de 2019 se realizaron 395 implantes consecutivos de endoprótesis de aorta, en 264 (67%) de los cuales se utilizó una técnica mínimamente invasiva (MIN-A). De este grupo 240 procedimientos (90,9%) fueron llevados a cabo para reparar la aorta abdominal (EVAR) y 24 (9,1%) la aorta torácica (TEVAR).
Resultados: De 264 pacientes se logró éxito técnico (ET) del implante en el 99,6% y éxito clínico (EC) en el 97,7%. La mortalidad a 30 días fue del 1,1% dado por neumonía, insuficiencia cardíaca y EPOC. Ningún paciente presentó IAM, ACV o necesitó de conversión a reparación quirúrgica de urgencia. El tiempo promedio del procedimiento fue de 62 minutos (SD ± 17). Algunos pacientes requirieron conversión a cierre quirúrgico del acceso [20 (7%) durante los primeros 100 casos, y 7 (3%) en los últimos 164 pacientes p = 0,05)]. El sangrado mayor que requirió transfusión fue del 1,1%. El tiempo promedio para la deambulación fue de 18 horas (SD ± 10), que luego de los primeros 100 pacientes disminuyó en forma significativa a 13 horas (SD ± 2,9 p = 0,05). La estadía hospitalaria en promedio fue de 1,4 días (SD ± 1,14) con 5 casos externados el mismo día del procedimiento.
Conclusiones: Los procedimientos de reparación endovascular de aneurismas de la aorta con una estrategia miniinvasiva fueron factibles y seguros, ya que permitieron convertir estos procedimientos en abordajes percutáneos, con bajas tasas de complicaciones asociadas al acceso, menor tiempo quirúrgico, rápida deambulación y menor estadía hospitalaria, sin modificar la seguridad global del procedimiento. La curva de aprendizaje permitió bajar la tasa de conversiones a cirugía, así como los tiempos de deambulación.

Palabras clave: Aneurisma de la aorta - Aneurisma de la Aorta abdominal - Procedimientos endovasculares/métodos - Implantación de prótesis vascular - Sedación consciente - Procedimientos quirúrgicos mínimamente invasivos

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Address for reprints: Oscar A. Mendiz - Avda. Belgrano 1746 – (C1093AAS) CABA, Argentina- Phone: +54 11 4378-1359 - e-mail: omendiz@ffavaloro.org

Institute of Cardiology and Cardiovascular Surgery. Department of Interventional Cardiology. Hospital Universitario Fundación Favaloro. CABA, Argentina

Abbreviations

AAA	Abdominal aortic aneurysm	**Fr**	French
CTA	Computed tomography angiography	**AMI**	Acute myocardial infarction
EVAR	Endovascular aneurysm repair	**MA**	Minimalistic approach
CS	Clinical success	**CT**	Computed tomography
COPD	Chronic obstructive pulmonary disease	**TEVAR**	Thoracic endovascular aortic repair
TS	Technical success	**TAVI**	Transcatheter aortic valve implantation

INTRODUCTION

Aortic diseases are a group of prevalent and usually serious conditions that may present acutely or can be asymptomatic for long periods and diagnosed by routine tests or incidentally. The Global Burden Disease Study 2010 reported that mortality rate due to aortic aneurysm and aortic dissection increased form 2.49 per 100,000 population in 1990 to 2.78 per 100,000 population in 2010. (1)

Until the late 20th century, conventional surgery was the only effective treatment for aortic disease, until Parodi and Palmaz presented the first publication of percutaneous treatment of abdominal aortic aneurysm (AAA) in 1991. (2)

Technological development and improved technique, together with new endografts, have allowed a major advance in the treatment of aortic aneurysms and increased the scope of treatment to those aneurysms with more complex anatomy.

Percutaneous closure devices have become an effective and safe option for the surgical closure of vascular accesses, especially when using high profile devices, simplifying the procedure and reducing the rate of complications. (3, 4) Besides the development of percutaneous closure devices, there has also been an improvement in anesthetic techniques resulting in the development of minimally invasive strategies. One of the current challenges is to perform complex procedures using less invasive approaches, while maintaining their efficacy and safety.

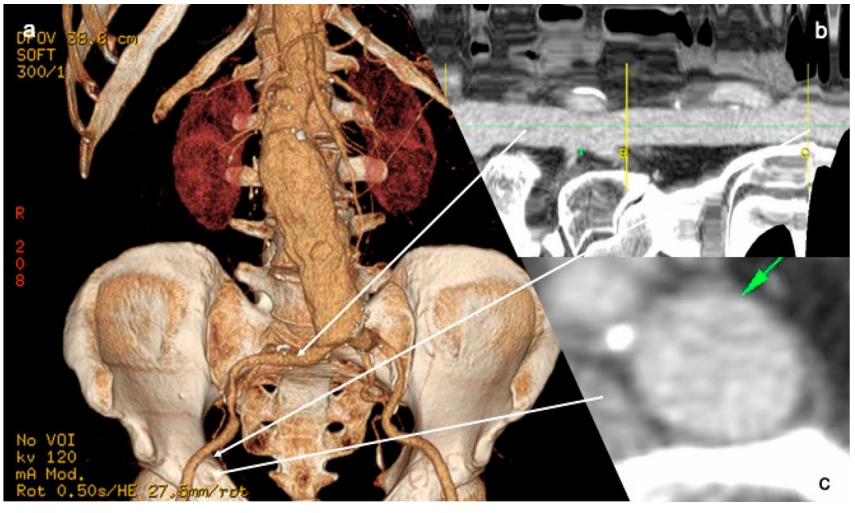
In this report, we describe our experience and the short-term outcomes of abdominal endovascular aneurysm repair (EVAR) and thoracic endovascular aortic repair (TEVAR) using a minimalistic approach (MIN-A).

METHODS

Between March 2012 and April 2019, 395 consecutive endografts were implanted in the aorta, 264 (67%) of which were performed using a MIN-A. Among this group, 240 (90.9%) corresponded to EVAR and 24 (9.1%) to TEVAR.

All patients underwent contrast-enhanced computed tomography angiography (CTA) before the procedure (Figure 1). Axial and coronal sections and three-dimensional reconstructions were analyzed to decide the endovascular treatment, choose the type and size of the endograft and the vascular access through which the main body of the device would be advanced and, eventually, the contralateral iliac branch to be used according to the type of endograft chosen.

The choice of MIN-A was made by an operator according to the type of procedure, the anatomy of the artery and the clinical condition of the patient. The exclusion criteria for a totally percutaneous approach were the presence of considerable calcification in the anterior wall of the common femoral artery, an iliac artery diameter <6 mm and need for complex procedures, such as implantation of fenestrated or branched grafts, or chimney techniques. Nevertheless, two



a- Computed tomography angiography with 3D reconstruction b-Reconstruction of the right iliac artery. c-Cross section of the right common femoral artery with absence of calcium in the anterior wall.

Fig. 1. Computed tomography angiography before the procedure

of these procedures were also performed with a MIN-A using femoral and radial/brachial accesses according to the decision of the operators and were included in the analysis.

The decision about the type of procedure, device and vascular access was left at the discretion of the operators. The definitions of the study protocol are included in Table 1.

All the patients were evaluated one month after discharge at the outpatient clinic with CTA of the aorta and iliac arteries.

Implant technique

Under conscious sedation and local anesthesia, the fist vascular access was punctured guided by CTA-fluoroscopy fusion imaging (Vessel Navigator®, Philips Electronics, Koninklijke, Netherlands) 1 cm lateral to the most medial aspect of the femoral head (Rupp's rule). A 6-French (Fr) sheath was advanced over a 0.035-inch guidewire using the modified Seldinger technique. In all cases, a 1-cm skin incision was made with a scalpel blade No.11 and the subcutaneous tissue was bluntly dissected to facilitate insertion of the device and advance the percutaneous suture threads.

A pre-shaped 5 Fr Pigtail-type catheter was then advanced towards the aortic bifurcation and, under direct angiographic guidance, the second femoral access was punctured at the site planned to advance the main body of the device, taking care to puncture the anterior wall of the artery and avoid its bifurcation and collateral branches. Then, a 0.035-inch J-tip guidewire was inserted and the introducer was removed. After repeating the skin incision and bluntly dissecting the subcutaneous tissue on that side, the suture-mediated percutaneous closure device (Prostar XL® Abbott Vascular, Redwood City, CA) was advanced into the common femoral artery over the guidewire.

After the Prostar device was deployed, a 0.035-inch stiff guidewire was introduced in the inner side of the device and was used for exchange to place a sheath or the delivery system of the endograft which has a greater diameter than the Prostar system (pre-close technique). (4)

The second Prostar® device was similarly implanted via the contralateral access site and the introducers were inserted according to the type of endograft chosen (usually with smaller diameter).

After the artery was punctured, a 70 IU/kg heparin sodium bolus was administered for anticoagulation to maintain an activated coagulation time of 250 seconds; usually half of the dose is given after the first puncture and completed after the insertion of the larger introducers.

Once the endograft was implanted according to the instructions for use of each type of device, the introducers were removed starting with the one with the largest diameter, and the accesses were closed with the previously implanted Prostar XL® devices, tying the sutures according to the pre-close technique. Finally, anticoagulation was reverted (Figure 2). Manual compression was necessary for a few minutes in case some bleeding persisted.

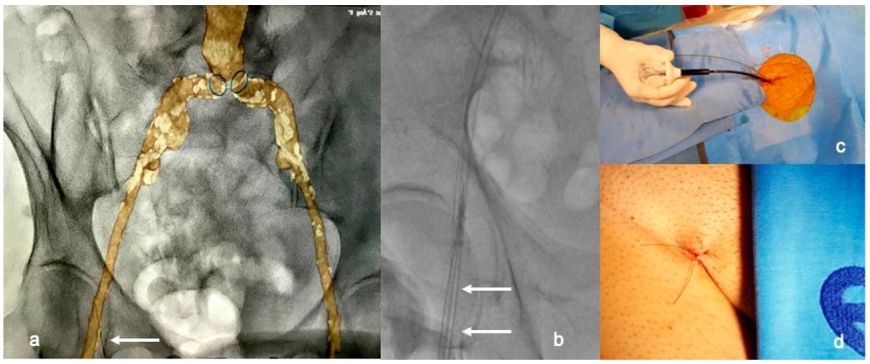
In the case of thoracic devices (through a single large access) or unibody stent grafts for abdominal aortic aneurysms that allow easy contralateral access (cross-over technique) a 7.0 balloon catheter (equivalent to 8.0 x 20 mm over-the-wire) was advanced over a 0.035-inch guidewire and was insufflated at the access site where the percutaneous suture was placed. The angiographic control was made through this balloon catheter to confirm that the puncture site was completely sealed.

The patients remained in bed in supine position for at least 6 hours with a compressed bandage at the access sites, and then they were allowed to walk around.

After discharge, all the patients underwent CTA within the first 30 days and, if the aneurysm had been correctly sealed, they were followed-up with color-Doppler echocardiography. A new CTA was required only in case of suspected long-term complications.

Table 1. Definitions of the study protocol

Term	Definition
MIN-A technique	Use of suture-mediated percutaneous closure device (Prostar XL®) to close the vascular access sites, local anesthesia at the puncture site and conscious sedation performed with opiates, anxiolytics or hypnotic drugs, ensuring that the patient remains sedated and in a comfortable situation, without losing consciousness, without suppressing his or her reflexes and, therefore, without the need for mechanical ventilation.
Technical success (TS)	Successful endograft implantation with complete exclusion of the aneurysm without vascular access-related complications.
Clinical success (CS)	TS without major adverse events.
Major adverse events[5]	All-cause mortality; aneurysm rupture; bowel ischemia; acute myocardial infarction; conversion to open repair; neurologic complications (paraplegia, spinal ischemia, stroke.
Major vascular access site complications[5]	Those occurring within 30 days after percutaneous or surgical closure. Vascular injury or pseudoaneurysm confirmed by ultrasound; arteriovenous fistula; femoral neuropathy; hematoma > 6 cm; hemorrhage (access site bleeding requiring blood transfusion or surgical conversion); infection; lymphocele; emboli or thrombosis/occlusion.
Time to ambulation[5]	Time elapsed between arterial closure and patient independent ambulation for a minimum of 20 steps.
Operative time	Time from start to end of the procedure.



a-Fusion imaging for puncture (arrow) b-Removal of percutaneous suture needles (arrows) c-Percutaneous suture; d-Final result.

Fig. 2. Access site closure after graft implantation

Statistical analysis

Discrete variables are expressed as percentage and continuous variables as mean ± standard deviation or median, according to their normal or non-normal distribution. Groups were compared using Student's t test, the Wilcoxon test, the chi-square test or Fisher's exact test, as applicable. A p value <0.05 was considered statistically significant. All calculations were performed using Epi Info 2000 software.

Ethical considerations

The study was conducted following the recommendations of the Declaration of Helsinki. All patients signed an informed consent form to undergo the procedures proposed. As this was a retrospective analysis which followed the institutional regulations for data security and privacy, all data were anonymized by the authors before the analysis.

RESULTS

The clinical characteristics of the 264 patients are summarized in Table 2. The following endografts were used: Zenith® (Cook, Bloomington, Ind.) 14-24 Fr (161, 61%), Endologix/Endologix AFX® (Powerlink, Irvin, Calif) 19 Fr (64, 24%), Endurant® (Medtronic, Santa Rosa, Calif.) 14-20 Fr (23, 9%), E-Tegra and E-Vita® (Jotec, Lotzenäcker, Hechingen, Germany) 18-20 Fr (12, 4.5%), Ovation Prime® (TriVascular, Inc. Santa Rosa, Calif.) (2, 0.7%), RelayPlus® (Bolton Medical, Sunrise, FL) 20 Fr (1, 0.3%) and Hercules® (Microport, Shanghai, China) 20 Fr (1, 0.3%).

Technical success (TS) of the implant was achieved in 99.6% of the patients and clinical success (CS) in 97.7%. Thirty-day mortality was 1.1% due to pneumonia, heart failure and chronic obstructive pulmonary disease (COPD). There were no cases of acute myocardial infarction (AMI), stroke or need for conversion to urgent surgical repair (Table 3). Mean duration of the procedure was 62 minutes (SD ± 17). Some patients required conversion to surgical closure of the access site [20 (7%) during the first 100 cases and 7 (3%) in the final 164 patients, p= 0.05]. Three (1.1%) patients presented major bleeding requiring transfusion. Mean time to ambulation was 18 hours (SD ± 10) that significantly decreased to 13 hours after the first 100 patients (SD ± 2.9; p = 0.05). Mean length of hospital stay was 1.4 days (SD ± 1.14) with 5 patients discharged on the same day of the procedure.

DISCUSSION

In this series of patients, the MIN-A technique for EVAR and TEVAR was feasible and safe with results similar to those reported by international publications (5) (Table 4). Mean time to ambulation was 18 hours, which is within the range reported by other studies, and far below the average time for conventional surgical repair, which in some publications reaches 33 hours after surgery. (6)

Even more, this time was reduced to 13 hours after the first 100 patients, and 5 of them were discharged on the same day after the procedure. Probably this reduction was due to the learning curve of the percutaneous technique and to the implementation of checklists that helped verify early ambulation and detect possible complications at the access sites.

Table 2. Population characteristics

	n (%)
N°	264
Age (years)	71 ± 20
Men	237 (89.7)
Hypertension	193 (73.1)
Smoking habit	187 (70.8)
Diabetes	31 (11.7)
Chronic obstructive pulmonary disease (COPD)	31 (11.7)
Stroke	12 (4.5)
Acute myocardial infarction (AMI)	9 (3.4)
Average aneurysm diameter	56 mm

Table 3. Population characteristics

	n (%)
Technical success	263 (99.6)
Clinical success	258 (97.7)
Mortality	3 (1.1)
AMI	0 (0)
Major vascular complications	3 (1.1)

Although extensive calcification of the anterior wall of the common femoral artery was one of our exclusion criteria, without considering patients' weight or other comorbidities, the registry shows a very low rate of major access site-related complications. (Conversion to uncomplicated surgical closure of the access site was not considered a major complication taking the study of Nelson et al. as reference). Only 1.1% of complications were observed, a low value compared with other published series (5), probably as a consequence of the improved percutaneous closure technique used in other procedures, such as transcatheter aortic valve implantation (TAVI) and strict monitoring during and after the procedure.

It should be noted that there is no global consensus on definitions of access-related complications in EVAR as there is with TAVI; therefore, comparisons between studies should be made cautiously.

Our study included only 10% of women, so our conclusions could not be generalized to both sexes.

The significant reduction in the need for conversion to surgical closure from 7% in the first 100 cases to 3% in the last 164 cases is noteworthy, demonstrating improvement with the learning curve.

Femoral artery puncture and endograft implantation were guided by CTA-fluoroscopy fusion imaging with the Vessel Navigator, providing real three-dimensional imaging while reducing the use of contrast by 70% and the procedure time by up to 18% (9). For this reason, we decided to use this tool and not ultrasound during the initial approach.

Although the registry was not designed for cost-effectiveness analysis, this strategy seems to be cost-effective when we compare the extra cost of the Prostar XL device, which is approximately USD 1000, with the fees per hour of the surgical team, which would be around USD 250 plus the cost-opportunity of a surgical team performing another procedure at the same time.

Furthermore, when we compare the mean operative time of this series (60 minutes) with that of surgical closure which ranges from 130 to 200 minutes (8, 9), we might conclude that the values are not so different. On the other hand, we must take into account that hospital stay costs an average of USD 300 per day, and that the mean length of hospital stay in our study was 1.4 days versus 1.8 days for patients with surgical closure according to the literature. (4)

Early ambulation and lower incidence of lymphocele, infections and femoral neuropathy after discharge may also impact on patient safety. In addition, it would be easier to approach the same vascular access in patients who are likely to undergo future interventions, due to the lack of fibrosis at the surgical access site, which would otherwise hinder subsequent puncture and sheath advancement. It is important to consider that the values mentioned are subject to considerable variations due to the changing economic situation in our environment.

The limitations of this study are due to the methodological design of a retrospective single-center study. In addition, the different devices used have implications for the safety and effectiveness of this technique, which, in turn, have undergone important modifications in their design during the study period.

Although the procedures were performed by interventional cardiologists, teamwork and the presence of a surgeon are very important, both for patient selection and for the resolution of complications in case he/she is not the operator. Therefore, despite being a minimally invasive technique, it must be performed in high complexity centers with complete availability of human and physical resources.

CONCLUSIONS

Endovascular aortic aneurysm repair using a minimally invasive strategy was feasible and safe, turning this procedure into a percutaneous approach with low access site-related complications, shorter operative time, rapid ambulation and shorter length of hospital stay without modifying the overall safety of the procedure. The learning curve resulted in reduced rate of conversion to surgery and earlier ambulation.

Conflicts of interest

None declared.

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

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