



One-Stage Procedure for High-Risk Patients with Aortic Valve Stenosis and Aortic Aneurysm; A Case Series

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ABSTRACT

Introduction: Aortic Stenosis (AS) and Abdominal Aortic Aneurysm (AAA) typically affect elderly patients, both being associated with adverse outcomes if not adequately managed. Notably, these conditions can be present simultaneously in a significant percentage of cases. Choosing the optimal treatment for these patients is challenging and no clear recommendations are available. Yet, simultaneous treatment by the percutaneous intervention, especially in high surgical risk patients, appears attractive.

Case Presentation: Herein, three cases of AAA and severe AS treated via Transcatheter Aortic Valve Implantation (TAVI) and Endovascular Aortic Repair (EVAR) within the same procedure have been reported in details for the first time.

Conclusions: The results indicated that one-stage intervention was an effective, safe, and feasible treatment for these two pathologies, especially in frail patients.

1. Introduction

The degeneration of Aortic Stenosis (AS) is characterized by progressive fibro-calcific remodeling and thickening of the aortic valve leaflets that evolve over time to cause severe obstruction to cardiac outflow. While uncommon in patients aged under 65 years in the absence of a congenital abnormality, severe AS is the second most common valvular lesion in high-income countries, being present in 3.4% of patients older than 75 years (1).

Abdominal aorta is the most common site of true arterial aneurysm, affecting predominantly the segment of aorta below the renal arteries (infrarenal aorta) (2). The well-defined risk factors associated with the development of Abdominal Aortic Aneurysm (AAA) include arterial hypertension, advanced age, male sex, Caucasian race, positive family history, smoking, presence of other large vessel aneurysms, and atherosclerosis. The prevalence of AAA has been found to range from 4% to 8% in screening studies, predominantly affecting males (3-6). Additionally, the annual incidence of new AAA diagnoses has been reported to be approximately 0.4 - 0.67% in Western populations (7).

Since AS and AAA share similar risk factors, the simultaneous diagnosis of AS and AAA is frequent. These conditions can be treated, especially in elderly individuals, preferentially through the percutaneous approach instead of surgery. In very old and frail patients, it is reasonable and possible to avoid two different procedures. Some researchers have reported few cases (at most two cases per center) of simultaneous transcatheter treatment of AS and AAA (8-12).

The present paper aims to provide a detailed description of the experiences related to three different patients.

2. Case Presentation

2.1. Case 1

A 78-year-old male patient had the ultrasound diagnosis of infrarenal AAA. Computed Tomography (CT) scan confirmed the presence of a large infrarenal aortic aneurysm of 55x59 mm with a parietal thrombus of 19 mm. His past medical history included hypertension, dyslipidemia, and type II diabetes mellitus. He underwent coronary artery bypass graft surgery at the age of 64 years, but he had an ischemic stroke with residual left hemiparesis four years later. He was symptomatic for NYHA class III dyspnea, being severely limited in his daily activities. Transthoracic echocardiography revealed the presence of a severe aortic

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stenosis (mean gradient of 45 mmHg and area of 0.6 cm²) with mild regurgitation and an ejection fraction of 48% with moderate concentric hypertrophy. The case was widely discussed by the multidisciplinary heart team in order to define the surgical strategy and the patient was finally scheduled for TAVI and EVAR.

A full percutaneous technique was performed and arterial vascular access (bilateral femoral artery) was obtained. In doing so, two PROSTAR® XL 10 F (Abbott Percutaneous Vascular Surgical System) were pre-implanted in the left common femoral artery and one Perclose ProGlide® 6F Suture-Mediated Closure (Abbott Vascular) in the right common femoral artery. Edwards E-sheath was introduced across the AAA under controlled hypotension. A 29 mm Edwards Sapien valve was successfully deployed. Transesophageal Echocardiography (TEE) confirmed the correct positioning of the prosthesis with the presence of a moderate paravalvular leakage treated with post-dilatation of the valve. EVAR was directly performed afterwards. At first, a diagnostic Digital Subtraction Angiography (DSA) was performed in order to confirm the preoperative CT measurements and to identify the exact location of the lowest renal artery. The stent-graft diameter was chosen according to the aortic diameter (assessed by CT scan and angiography) with a 10 – 15% over-sizing. Through a 0.035-inch extra-stiff guidewire (Backup Meier), the main prosthetic body (GORE® EXCLUDER®) was introduced from the left side and was deployed below the right renal artery. The procedure was completed by introducing the right contralateral leg (GORE® EXCLUDER®). Additional proximal and distal ballooning was performed with appropriately sized balloons to obtain the optimal apposition of the stent-graft to the aortic wall, with particular care at the proximal and distal necks. A DSA was finally performed to confirm the correct positioning of the stent-graft, complete exclusion of the aneurysm sac, and absence of endovascular leaks as well as to assess the maintained patency of the ilio-femoral vessels. The length and anatomy of the proximal neck of the aneurysm allowed the utilization of a Gore prosthesis that could provide optimal sealing and security against endoleaks. Anchor's Gore prosthesis provided an active fixation and migration resistance. Furthermore, a fast positioning was needed after TAVI, and Gore prosthesis provided a simple delivery and deployment. An abdominal ultrasound confirmed the complete exclusion of the aneurysm with no endoleaks. At the three-month follow-up, the patient was in NYHA class I. Moreover, the echocardiography showed the good position of the transcatheter prosthesis with a medium gradient of 10 mmHg and an area of 1.9 cmq.

2.2. Case 2

A 77-year-old male was referred with NYHA class III dyspnea. Echocardiography revealed severe calcific aortic stenosis (mean transvalvular pressure gradient of 50 mmHg), mild aortic regurgitation, and left ventricular hypertrophy. His cardiovascular risk factors were arterial hypertension, dyslipidemia, and type II diabetes mellitus. He was a former smoker and he was affected by chronic obstructive pulmonary disease. The Society of Thoracic

Surgeons (STS) score was above 4% and, consequently, he was referred for TAVI. In preparatory imaging, angio-CT showed a fusiform AAA (52×49×65 mm) in the infrarenal tract of the aorta near the aortic bifurcation, with a parietal thrombus of 17 mm. Therefore, it was decided to perform TAVI and EVAR in one step.

Before the intervention, an ultrasound-guided left femoral artery vascular access was obtained to perform an Invasive Coronary Angiography (ICA). In doing so, a Prostar XL was pre-implanted. The angiography revealed a Left Main (LM) and Left Anterior Descending (LAD) artery stenosis inferior to 50% as well as a significant stenosis (75%) in the first obtuse marginal branch of the Circumflex Artery (CA). However, the Right Coronary Artery (RCA) had no stenosis. After ICA, a 6 F Pigtail was positioned through the left femoral artery in the ascending aorta. Then, a right femoral artery and a left venous femoral access were obtained using the previous technique. A Perclose ProGlide closure system was pre-implanted in the arterial access. TAVI procedure was then performed as usual with the implantation of a 23 mm Edwards Sapien valve followed by balloon post-dilatation due to a moderate paravalvular leak, which was completely resolved at the final aortic angiography.

After the aortic valve implantation, the intervention was continued with EVAR. In so doing, a Back-up Meir guidewire was advanced into the right femoral artery, reaching the abdominal aorta. Then, a Gore EXCLUDER 28 × 12 × 16 mm endovascular prosthesis was positioned in the infrarenal aorta. After that, the second Back-up Meier guidewire was advanced into the left femoral artery up to the inner part of the prosthesis. A Gore EXCLUDER 16x12x12 mm was then positioned through the second guidewire, as the left branch of the prosthesis. Afterwards, multiple dilations were performed using a Reliant catheter in the main and left branches of the prosthesis. The angiography demonstrated no endoleaks and a normal antegrade flow in iliac and femoral arteries.

After two months, a coronary revascularization procedure was performed, positioning a Drug Eluting Stent (DES) in the first obtuse marginal branch and restoring a TIMI3 flow in this vessel. At the three-month follow-up visit, the patient was free from mild effort dyspnea and any form of angina.

2.3. Case 3

An 83-year-old male was referred for NYHA class IIB dyspnea. His cardiovascular risk factors were arterial hypertension and dyslipidemia. He had a previous coronary revascularization of the medium tract of the LAD artery and the CA. He was also affected by a severe pulmonary emphysema. Echocardiography showed left ventricular systolic dysfunction (ejection fraction of 40%) with apical akynesia, mean trans-valvular aortic pressure gradient of 35 mmHg, and aortic valve area of 0.6 cmq (Figure 1A). A dobutamine echocardiography was performed and the aortic stenosis was considered severe (low-flow, low-gradient aortic stenosis). The patient was thus considered high-risk for a surgical aortic valve repair. Furthermore, the pre-surgical angio-CT revealed a fusiform 57 × 56 × 110 mm AAA (Figure 1B-2A) near the aortic bifurcation, with a parietal thrombus of 25 mm. Thus, both valvular



Figure 1. A, CT Scan of the Calcified Aortic Valve; **B,** CT Scan of the Abdominal Aortic Aneurysm

and vascular diseases were decided to be addressed by the endovascular approach within the same procedure.

An ultrasound-guided left femoral artery access was obtained and a coronary angiography was performed.

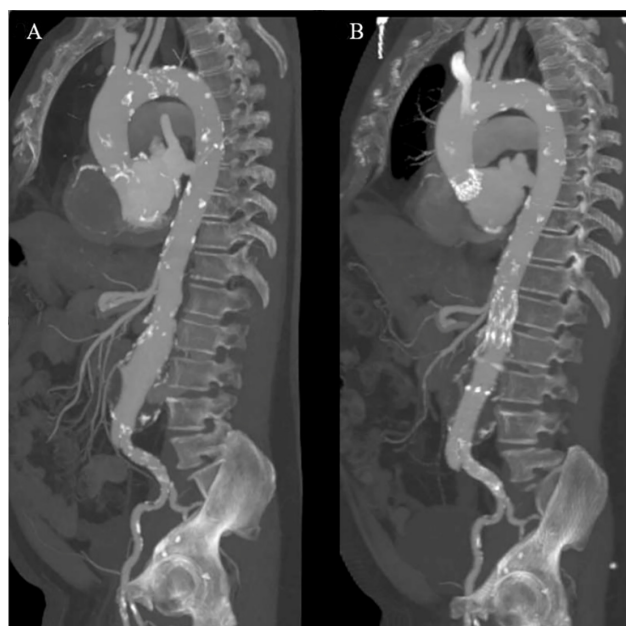


Figure 2. A, The Sagittal CT Scan before the Procedure; **B,** The Sagittal CT Scan after the Procedure

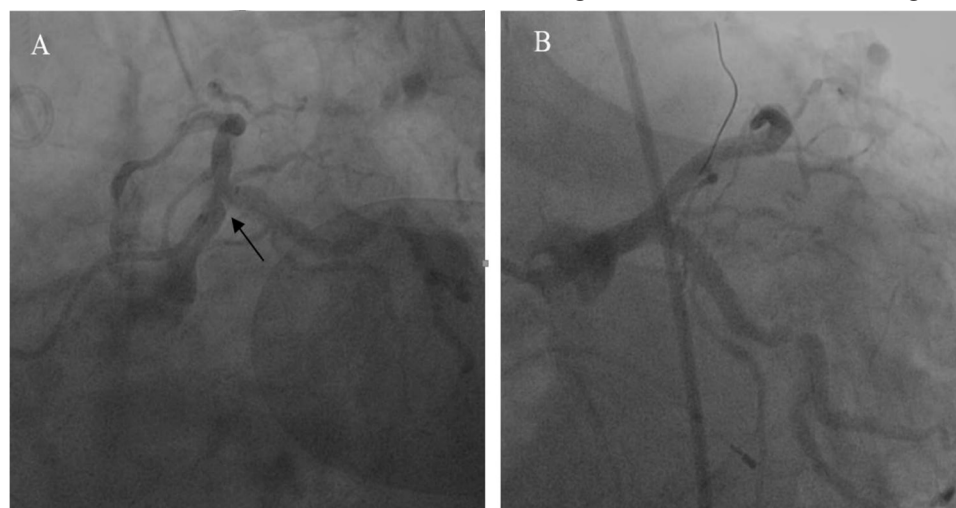


Figure 3. A, Coronary Angiogram of the Left Main Coronary Artery Stenosis (Black Arrow); **B,** Coronary Angiogram after Percutaneous Coronary Intervention

The results showed an LM artery stenosis superior to 75% involving the proximal LAD artery and the CA as well as the Chronic Total Occlusion (CTO) of the distal LAD artery. Additionally, the previously implanted DESs in the LAD artery and CA were patent, and the RCA had no stenosis.

Due to the severity of coronary artery disease, a coronary revascularization was initially performed through the implantation of two DESs in LM bifurcation and another DES in the CA (Figure 3A-3B). Then, TAVI was performed. In so doing, a full percutaneous right radial access was obtained and a 6 F Pigtail was positioned in the ascending aorta. An ultrasound-guided right femoral artery access was obtained, as well. Afterwards, two Perclose Proglide closure-systems were pre-implanted, and a guide catheter with a guidewire through the left femoral artery access was positioned in the LM artery. Then, a bipolar endocardial pacing catheter with a balloon (Spike Flow, FIAB) was introduced from the left femoral vein and advanced in the right ventricle for temporary pacing. After that, a 23 mm Sapien 3 Ultra (Edwards) was implanted. At this stage, a native aortic cusp dislodgement was observed in the LM artery and a DES (Resolute Onyx 5.0 × 15 mm) was implanted in the LM ostium. The aortic angiography showed no leaks and TIMI 3 flow in the LM artery.

Finally, EVAR was carried out. Initially, a Back-up Meier guidewire was advanced through the right femoral

artery access up to the abdominal aorta and an Ovation 34 mm endovascular prosthesis was positioned as the main branch. The second Back-up Meier guidewire was advanced through the left femoral artery access up to the inner part of the prosthesis and the left branch of the prosthesis was positioned in the descending aorta, the left common iliac artery (14 × 120 mm). The right branch of the prosthesis (12 × 100 mm) was positioned in the descending aorta, the right common iliac artery. Dilations in the main, left, and right branches were performed via the kissing balloon technique. The aortic angiography showed aneurysm exclusion and no endoleaks (Figure 2B). However, the left access-site angiography revealed a left femoral artery dissection with the consequent partial lumen obstruction that was treated by implanting a stent (Epic 8 × 40 mm) positioned through a right brachial artery access. At the three-month follow-up visit, the patient was in NYHA class I and free from anginal symptoms.

3. Discussion

Aortic stenosis is the most common valvular disease in the elderly population. Specifically, 12.4% of individuals aged > 75 years have been reported to suffer from AS and 3.4% from severe AS (13). At this age, the prevalence of AAA is even higher, as it occurs in approximately 5% of males over the age of 50 years (14).

Surgical Aortic Valve Replacement (sAVR) has been the gold standard treatment for a long time. However, with an ageing and increasingly multimorbid population, the need for less invasive therapies resulted in the development of transcatheter aortic valve implantation. The aim of this surgery is to immediately restore the normal aortic valve function with a low incidence of Paravalvular Leakage (PVL), Patient-Prosthesis Mismatch (PPM), Atrioventricular (AV) blockage, and peri-operative mortality. TAVI reduces surgical trauma and avoids cardiac arrest and cardiopulmonary bypass. TAVI is not inferior to sAVR and the patients who are suitable candidates for transfemoral access have an additional benefit. Randomized controlled trials have demonstrated that TAVI is a therapeutic option in inoperable patients. Recently, this therapeutic option has been performed successfully in moderate- and low-risk patients (15, 16). Moreover, TAVI is the treatment option in patients with bioprosthetic valve failure facing repeated sAVR with its potentially increased surgical trauma.

EVAR has been rapidly expanded as the preferred approach for the treatment of AAA since the first report more than 25 years ago. Since the introduction of EVAR, the annual number of deaths from intact and ruptured AAAs has significantly decreased. EVAR has evolved since its inception with the development of lower profile delivery sheaths that are tapered, flexible, and coated for low-resistance introduction into the femoral arteries. Compared to open repair, EVAR has been found to be accompanied by lower blood loss as well as with fewer major complications including pneumonia, acute renal failure, myocardial infarction, and bowel ischemia. A review also confirmed that these results were representative of the current outcomes, with an overall mortality of 5.2% for open repair and 1.6% for EVAR. As advantages reduce with time, this

kind of intervention appears to be more appropriate in frail patients and those with low life expectancy (17).

Finding AAA together with severe AS is not uncommon, especially in elderly patients. According to the European Society of Cardiology (ESC) guidelines, AAA open surgery repair is considered a high-risk procedure. When severe AS and AAA coexist, this risk becomes unacceptable. Therefore, aortic valve replacement should be considered before elective surgery in symptomatic patients. In high-risk patients as well as those contraindicated for aortic valve replacement, balloon aortic valvuloplasty or, preferably, TAVI may be a reasonable therapeutic option before surgery (18).

In the cases presented in the current investigation, it was reasonable and feasible to treat two life-threatening diseases using one less invasive procedure. Some practical details of this combined procedure are needed to be emphasized.

The first and obvious advantage is using the same arterial access for both procedures, reducing the vascular complications of the two different percutaneous interventions. Moreover, this approach reduces the number of hospitalizations and the correlated risks. Although the one-stage procedure requires a major amount of time, this intervention is not related to an increased risk of post-procedural infections. Secondly, TAVI has to be performed followed by EVAR, because once the aortic valve prosthesis is implanted, the cardiac output is improved and the risk of cerebral (or peripheral) hypoperfusion and endovascular prosthesis dislodgement is reduced. Although the present study data were limited, there was no need to provide cerebral protection during the intervention since none of the patients had transient ischemic attack or stroke. Thirdly, to minimize the risk of aneurysm fissuration, the Edwards E-sheath has to be carefully introduced during a period of controlled hypotension and to be advanced well beyond the proximal end of the aneurysm in order to avoid the direct contact of the Transcatheter Heart Valve (THV) stent with the diseased aortic wall. The last advantage is that this combined procedure has a lower mortality even in centers with a normal volume of cases. Earlier studies suggested that the minimum hospital threshold for optimal outcomes was 8 - 10 EVAR cases per year (19, 20). Additionally, the Odds Ratio (OR) for elective peri-operative mortality adjusted for the volume of surgeons was lowest for the centers that performed at least 30 EVARs per year (21). However, some disadvantages are associated with this kind of intervention, the most important of which being iatrogenic renal impairment due to the use of the major contrast medium. This risk is particularly evident in frail patients referred for TAVI and/or EVAR since most of them have chronic kidney disease at baseline. The second potential disadvantage is the long duration of radiation exposure.

3.1. Conclusion

Considering the population aging, the number of patients with multiple cardiovascular diseases requiring complex interventions is likely to increase. The current case series presented new examples of the importance of the heart team in tailored operative strategies and emphasized the potential of interventional cardiology to treat two different

cardiovascular diseases via the same procedure. This approach can reduce multiple hospitalizations and peri-procedural complications in future.

3.2. Informed Consent

In this case series all the patients' names are omitted and their privacy is respected. All the patients gave their approval to published this manuscript.

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Authors' Contribution

A R: Interventional Cardiologist, expert in aortic disease; he performed EVAR in all 3 cases; F N: Cardiologist; he collected patients' clinical data and images; he wrote the manuscript; C P: Interventional Cardiologist; he performed EVAR in all 3 cases; A R C: Interventional Cardiologist; critical reviewer of the manuscript; G R T: Interventional Cardiologist; he performed TAVI in case 1 and 2; M R: Interventional Cardiologist; he performed TAVI in case 3; S B: Interventional Cardiologist; Director of our Interventional Cardiology Unit and Guarantor of this paper

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