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Transcatheter aortic valve replacement - initial experience with alternative access via brachiocephalic trunk

Experiência inicial com acesso alternativo via tronco braquiocefálico para implante transcateter de válvula aórtica

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ABSTRACT – Transcatheter aortic valve replacement is indicated as an alternative to conventional surgical treatment for elderly patients with low, moderate, and high surgical risk, or as the best therapeutic strategy for patients considered inoperable. The transfemoral vascular access is the preferred route for replacement. However, in a small portion of the population, this access is not possible for anatomical reasons. Access through the brachiocephalic trunk may be an option in specific cases. Nevertheless, data on feasibility and safety of this approach are still scarce in the literature. This report describes an initial experience with suprasternal brachiocephalic access through dissection and arterial puncture under direct visualization.

Keywords: Transcatheter aortic valve replacement/methods; Brachiocephalic trunk

RESUMO – O implante da válvula aórtica transcateter é indicado como alternativa ao tratamento cirúrgico convencional para os pacientes idosos com risco cirúrgico baixo, moderado e elevado, ou como a melhor estratégia de tratamento para os pacientes considerados inoperáveis. O acesso vascular transfemoral é a via preferencial para o implante. No entanto, em uma parcela da população, esta via não é factível, por questões anatômicas. O acesso pelo tronco braquiocefálico pode ser uma alternativa em casos específicos. Entretanto, dados sobre a factibilidade e a segurança dessa via ainda são escassos na literatura. O presente relato demonstra uma experiência inicial com o acesso braquiocefálico supraesternal por dissecção e punção arterial sob visualização direta.

Descritores: Substituição da valva aórtica transcateter/métodos; Tronco braquiocefálico

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) in patients with significant aortic stenosis (AS) is indicated as an alternative to conventional surgical treatment for elderly patients with low, moderate, and high surgical risk, or as the best therapeutic strategy for patients considered inoperable.[1] The transfemoral vascular access is currently the preferred route for implantation, being the first choice in >90% of cases.[2] However, in a small portion of the population, this access is not possible for anatomical reasons, and alternative routes have been increasingly described for the implantation.[3]

Subclavian artery, direct transaortic or transapical accesses are the most commonly used alternatives, and increasing experiences with transcarotid and transcaval approaches have been reported.[4,5] Brachiocephalic trunk access has three potential advantages as follows: a wider arterial diameter as compared to axillary and carotid accesses; it does not involve the origin of the left internal thoracic artery; and it can be carried out through suprasternal incision, avoiding sternotomy or lateral thoracotomy, as required in direct aortic access. Data on feasibility and safety of this route are still scarce in the literature, and mostly include case series reporting the isolated experience of some centres.

This study was evaluated and approved by the Research Ethics Committee, with protocol 4.048.763 and CAAE 32160720.3.0000.0087.

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CASE REPORTS

Case 1

An 85-year-old female patient, history of hypertension, stage 3 chronic kidney failure on conservative treatment, coronary artery disease with previous percutaneous coronary intervention (PCI), overweight (body mass index - BMI: 27.0kg/m^2), frail, admitted with decompensated congestive heart failure secondary to significant AS. Transthoracic echocardiogram (TTE) showed concentric left ventricular hypertrophy with preserved left ventricular ejection fraction (66%); tricuspid aortic valve with severe calcification and decreased leaflet mobility; aortic valve area 0.5mm^2; left ventricular-aortic gradients: maximum 95mmHg and mean 55mmHg; mild aortic and mitral regurgitation. The EuroSCORE II risk estimation was 8.3% and Society of Thoracic Surgeons (STS) score for mortality was 10.2%. Considering the need for intervention on the aortic valve and the patient's high surgical risk, an evaluation for TAVR was proposed. Coronary angiography showed a dominant right coronary artery (RCA) with 50% to 60% obstruction in the middle third and a patent stent in the distal middle third, in addition to mild diffuse atheromatosis in other vessels. The left ventricle was hypertrophic, with preserved systolic function. The aortic valve was very calcified with decreased mobility. The peak-to-peak left ventricular-aortic gradient was 60mmHg. Computed tomography (CT) angiography demonstrated severe obstructive atherosclerosis in bilateral iliac-femoral territory, with minimum luminal diameters <4.0mm in the common right and left iliac arteries, in addition to an 80% obstructive lesion at the origin of the left subclavian artery, 70% obstruction at the origin of a tortuous right subclavian artery, and long, rectilinear, and large (minimum diameter 11.5mm) brachiocephalic trunk (Figure 1A). The assessment of the aortic valve complex (Figures 1B and 1C) presented leaflets with severe calcification sparing the commissures, and the prosthesis was chosen according to our routine, considering the aortic annulus measurements. Additional measurements: distance from the upper aspect of the sternal manubrium to the bifurcation of the brachiocephalic trunk (suprasternal puncture window): 3.1mm; brachiocephalic trunk length: 4.5mm; angle between the left ventricular outflow tract and the annulus: 52°. After anatomical evaluation, surgical vascular access by dissection and puncture of the brachiocephalic trunk under direct vision was chosen.

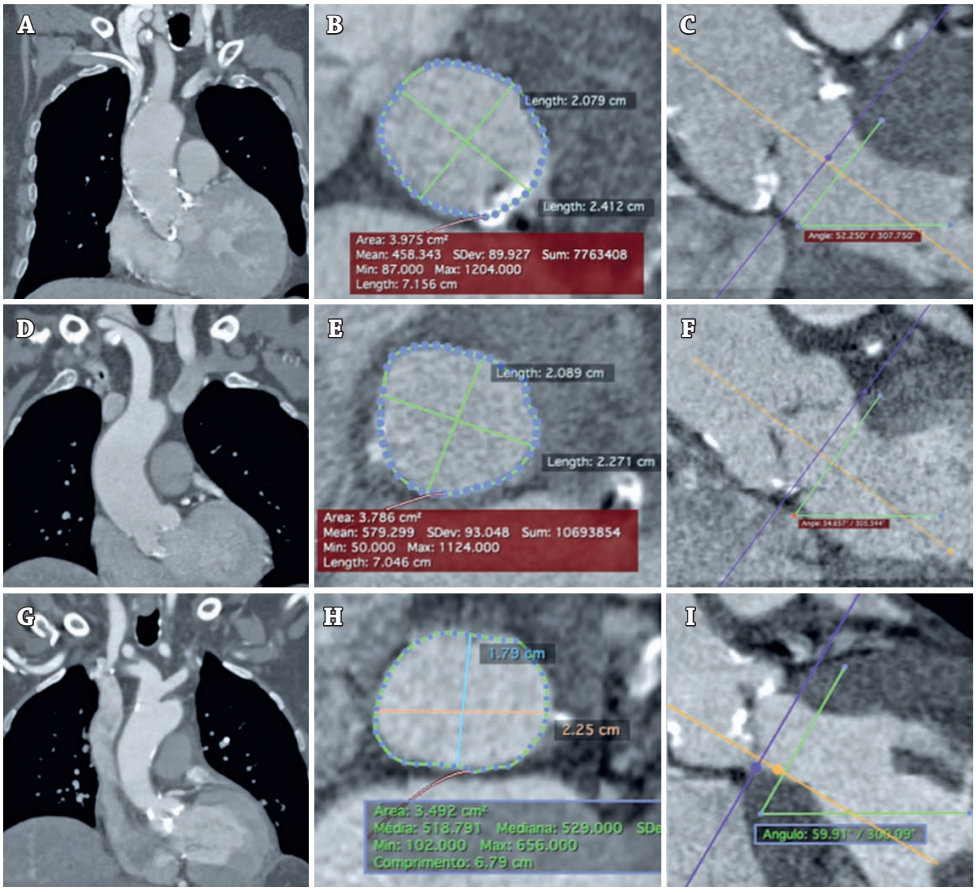

Figure 1. (A, B and C) Computed tomography angiography of case 1. (D, E and F) Computed tomography angiography of case 2. (G, H and I) Computed tomography angiography of case 3. (A, D and G) Course from brachiocephalic trunk to valvar plane. (B, E and H) Cross-section of aortic annulus. (C, F and I) Angle between annulus and left ventricle outflow tract.

After general anesthesia, orotracheal intubation and placement of a transesophageal echocardiography (TEE) probe, the left subclavian vein was punctured for the implantation of a temporary 5F pacemaker. A 6F introducer was used to puncture the right femoral artery and a 3-cm longitudinal surgical incision was made in the region of the sternal furcula, exposing the brachiocephalic trunk. Arterial puncture was then conducted under direct visualization with a 10F introducer, subsequently replaced by a Cook Extra Large Check-Flo 18F hydrophilic introducer (Cook Medical, Bloomington, IN, USA).

Aortography was followed by transcatheter aortic valve replacement according to the usual technique. After passing the aortic valve with a 0.035'' hydrophilic Radifocus straight-tip guidewire (Terumo Corporation, Shibuya, Tokyo, Japan), a Multipurpose 1 catheter was positioned inside the left ventricle. The hydrophilic guidewire was replaced by a pre-shaped 0.035'' high support Safari Extra Small guidewire (Boston Scientific, Marlborough, MA, USA).

A 20×40mm balloon was used for pre-dilation, followed by implantation of the Evolut™ R valve 29mm (Medtronic, Dublin, Ireland) (Figure 2A). A recapture was necessary due to the deep positioning of the prosthesis. The control aortography showed a well-placed prosthetic valve with minimal aortic regurgitation. The control echocardiography, likewise, demonstrated a well-placed prosthesis with mild paravalvular leak and mean gradient left ventricular-aortic of 5mmHg. The 18F introducer was removed, with vascular suture and closure of the surgical access.

After implantation, in the intensive care unit (ICU), the patient had stable cardiological parameters until the fourth postoperative day, when she presented respiratory infection, progressing to death on the eight postoperative day due to septic shock refractory to drug therapy.

Case 2

A 95-year-old female patient with history of hypertension, dyslipidemia, non-insulin-dependent diabetes mellitus, coronary artery disease (previous coronary artery bypass surgery and PCI), permanent pacemaker, overweight (BMI 26.6kg/m^2), frailty admitted with decompensated congestive heart failure secondary to significant AS. The initial dosage of atrial natriuretic peptide (BNP) was 1,850pg/dL. TTE showed concentric left ventricular hypertrophy with preserved left ventricular ejection fraction (55%), tricuspid aortic valve with severe calcification and decreased leaflet mobility; aortic valve area 0.55mm^2; left ventricular-aortic gradients: maximum 56mmHg, mean 40mmHg; absence of aortic reflux and mild mitral regurgitation. The estimated EuroSCORE II risk was 17.1% and STS mortality risk 10.1%.

Considering the need for intervention on the aortic valve and the patient's surgical risk, an evaluation for TAVR was proposed. Coronary angiography showed a good caliber left main coronary artery (LMCA), with a 30% obstruction in the middle third. Left anterior descending artery (LAD) had a subocclusive lesion (95%) in the middle third. RCA had 50% segmental obstructive lesion in the middle third. The left internal mammary artery graft for the LAD was well developed and with good flow, presenting mild parietal irregularities; there was mild diffuse atheromatosis in the other vessels. Aortography showed a competent aortic valve with significant calcification. No other aortocoronary grafts were seen. CT angiography demonstrated severe obstructive atherosclerosis in bilateral iliac-femoral territory, with minimum luminal diameters <4.0mm in the right and left external iliac arteries; left subclavian artery giving rise to a patent graft, left internal mammary artery for LAD; 80% obstructive lesion in the origin of the right subclavian artery, and long, straight and large (minimum diameter of 10.0mm) brachiocephalic trunk (Figure 1D). The

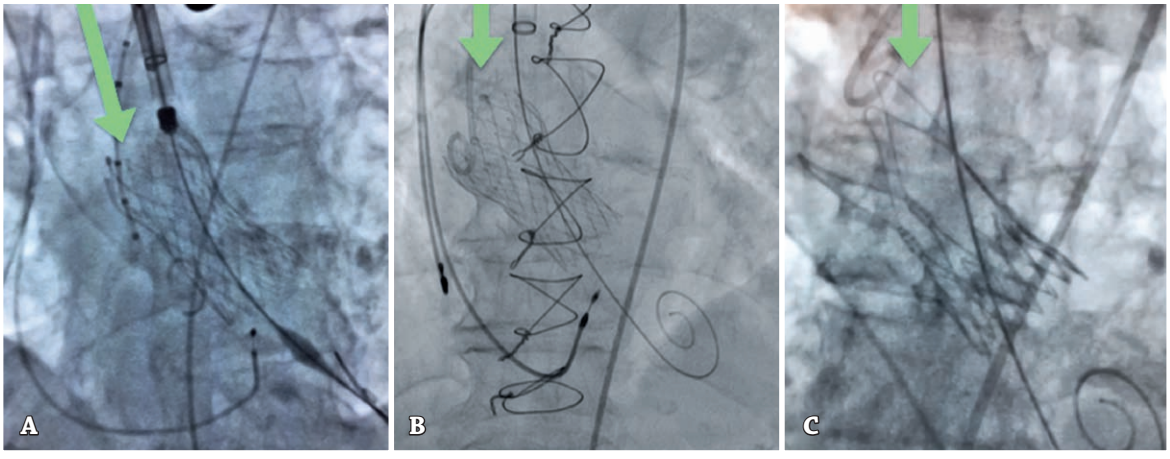

Figure 2. Angiography showing control after replacement of self-expandable device and the vertical direction (green arrows) of the delivery system directed from the brachiocephalic trunk towards the valvar plane. (A) Case 1. (B) Case 2. (C) Case 3.

assessment of the aortic valve complex (Figures 1E and 1F) showed leaflets with severe calcification, sparing the commissures. The prosthesis was chosen according to our routine, considering the measurements of the aortic annulus. Additional measurements: distance from the upper aspect of the sternal manubrium to the bifurcation of the brachiocephalic trunk (suprasternal puncture window) 3.5mm; brachiocephalic trunk length 4.1mm; and angle between the left ventricular outflow tract and the annulus 54°. After anatomical evaluation, surgical vascular access by dissection and puncture of the brachiocephalic trunk under direct vision was chosen.

After general anesthesia, orotracheal intubation and placement of TEE probe, the left subclavian vein was punctured for the placement of a temporary 5F pacemaker. A 6F introducer was used to puncture the right femoral artery and a 3-cm transverse surgical incision was made in the region of the sternal furcula, exposing the brachiocephalic trunk (Figure 3A), arterial puncture was then conducted under direct visualization (Figure 3B) with a 10F introducer, subsequently replaced by a Sentrant 18F hydrophilic introducer (Medtronic, Dublin, Ireland) (Figure 3C). Aortography was followed by transcatheter aortic valve replacement according to the usual technique. After passing the aortic valve with 0.035'' hydrophilic Radifocus straight-tip guidewire (Terumo Corporation, Shibuya, Tokyo, Japan), the MP1 catheter was positioned inside the left ventricle. The hydrophilic guidewire was replaced by a pre-shaped 0.035'' high-support guidewire Confida (Medtronic, Dublin, Ireland). Direct implantation of Evolut™ R 26mm aortic valve (Medtronic, Dublin, Ireland) (Figure 2B), which required one recapture. The control aortography showed a well-placed prosthesis and no paravalvular leak. Likewise, the echocardiographic control demonstrated a well-placed prosthesis, absence of paravalvular leak and mean gradient left ventricular-aortic after replacement of 4mmHg. The 18F introducer was removed, with vascular suture and closure of the surgical access (Figure 3D); the other introducers were removed.

After implantation, the patient's cardiological parameters were stable, being discharged from the ICU after 48 hours and from the hospital on the fourth postoperative day. Currently, in a 10-month follow-up, remains asymptomatic and with stable echocardiographic result.

Case 3

A 90-year-old female patient, history of hypertension, non-insulin-dependent diabetes mellitus, frailty admitted with decompensated congestive heart failure secondary to significant AS. TTE showed concentric left ventricular hypertrophy (LVH), with preserved left ventricular ejection fraction (67%), tricuspid aortic valve with severe calcification and decreased leaflet mobility; aortic valve area 0.61mm^2; left ventricular-aortic gradients: maximum 59mmHg, mean 41 mmHg; mild aortic and mitral regurgitation. The estimated EuroSCORE II surgical risk was 5.1% and STS for mortality 8.1%.

Considering the need for intervention on the aortic valve and the patient's surgical risk, an evaluation for TAVR was proposed. Coronary angiography showed 50% obstructive lesion in the proximal third of the RCA. The other coronary arteries had mild parietal irregularities. CT angiography demonstrated severe obstructive atherosclerosis in bilateral iliac-femoral territory with minimum luminal diameters

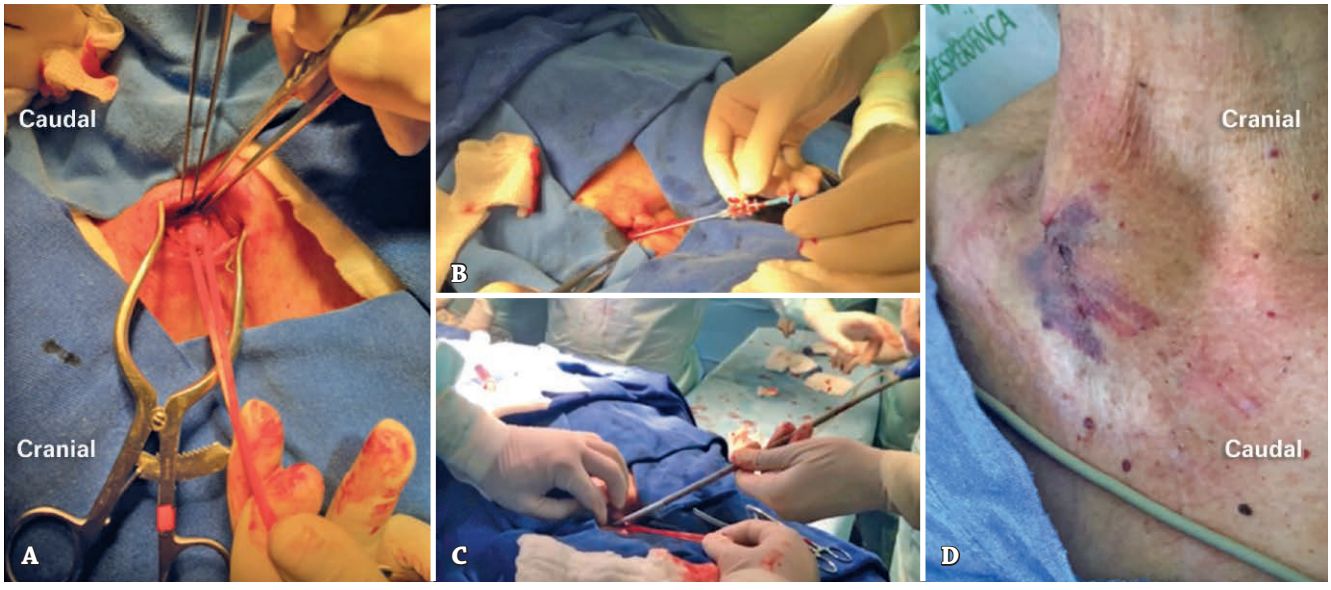

Figure 3. Intraoperative images of case 2. (A) Suprasternal surgical incision. (B) Arterial puncture of the brachiocephalic trunk under direct visualization. (C) Positioning of the 18F introducer. (D) Closure of surgical access.

<4.0mm in the femoral arteries and right and left external iliac arteries. The left and right subclavian arteries had diffuse atheromatosis and minimum luminal diameter <5.0mm; the brachiocephalic trunk was short, straight and large (minimum diameter: 10.0mm) (Figure 1G). The assessment of the aortic valve apparatus (Figures 1H and 1I) demonstrated leaflets with severe calcification predominantly in the commissures. The prosthesis was chosen according to our routine, considering the measurements of the aortic annulus. Additional measurements: bovine brachiocephalic trunk, distance from the upper aspect of the sternal manubrium to the bifurcation of the brachiocephalic trunk (suprasternal puncture window): 2.1mm; brachiocephalic trunk length: 4.0mm; angle between the left ventricular outflow tract and the annulus of 59°. After anatomical evaluation, surgical vascular access by dissection and puncture of the brachiocephalic trunk under direct vision was chosen.

After general anesthesia, orotracheal intubation and placement of TEE probe, the left subclavian vein was punctured for the implantation of a temporary 5F pacemaker. A 6F introducer was used to puncture the right femoral artery and a 2-cm transverse surgical incision was made in the region of the sternal furcula, exposing the brachiocephalic trunk (Figure 4A), arterial puncture was then conducted under direct visualization (Figure 4B) with a 10F introducer, subsequently replaced by a hydrophilic Lotus Small 18F introducer (Boston Scientific, Marlborough, MA, USA) (Figure 4C). Aortography was followed by transcatheter aortic valve replacement according to the usual technique. After passing the aortic valve with 0.035'' hydrophilic Radifocus straight-tip guide wire (Terumo Corporation, Shibuya, Tokyo, Japan), a MP1 catheter was positioned inside the left ventricle. The hydrophilic guidewire was replaced by a pre-shaped 0.035'' high support Safari Extra Small guidewire (Boston Scientific, Marlborough, MA, USA). A 15×40-mm balloon was used for predilation, followed by implantation of ACURATE neo™ 23mm aortic valve (Boston Scientific, Marlborough, MA, USA) (Figure 2C). The control aortography showed a well-placed prosthesis and no paravalvular leak. Likewise, the echocardiographic control demonstrated a well-placed prosthesis, absence of paravalvular leak, and left ventricular-aortic gradient after implantation of 5mmHg. The 18F introducer was removed, with vascular suture and closure of the surgical access (Figure 4D), in addition to removal of the other introducers.

After replacement, the patient progressed with stable cardiological parameters and was discharged from the ICU after 48 hours and from the hospital on the fifth postoperative day. Currently, in a 7-month follow-up, remains asymptomatic and with stable echocardiographic result.

DISCUSSION

This case series reports an initial experience in Brazil, with suprasternal access by dissection and arterial puncture, under direct visualization of the brachiocephalic trunk. We present three cases in which self-expanding prosthetic valve replacement was technically successful. There are no reports in the literature and this manuscript is the first to describe the implantation of the device ACURATE neo™. In all procedures, there was some initial difficulty in adjusting the device coaxial positioning with the valve plane and the left ventricular outflow tract, which required additional

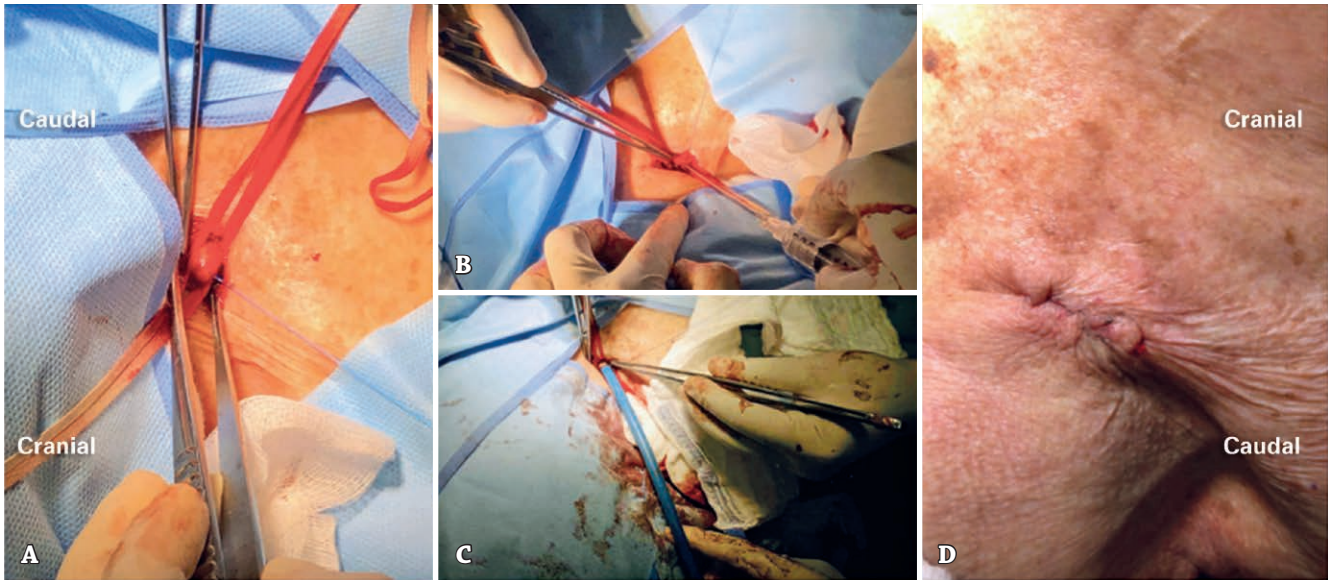

Figure 4. Intraoperative images of case 3. (A) Suprasternal surgical incision. (B) Arterial puncture of the brachiocephalic trunk under direct visualization. (C) Positioning the 18F introducer. (D) Closure of the surgical access.

maneuvers with the delivery system. The unusual setup of the laboratory and the positioning of the surgical team in the room did not hamper handling of the device.

In patients not eligible for femoral access, an alternative route that avoids sternotomy and thoracotomy seems attractive. The suprasternal approach, with an incision in the sternal furcula and puncture of the brachiocephalic trunk, has been described in a series of single-center cases, which report the initial experience of the services with this access. Philipsen et al. published a series of 20 patients undergoing TAVR (with balloon-expandable and self-expanding prosthesis), using suprasternal access; in that, 5 cases required mini-sternotomy and 15 did not.[6] In this study, in the beginning of the procedure, the brachiocephalic trunk was routinely clamped, with cerebral oximetry simultaneously measured in order to rule out brain ischemia. However, the investigators did not describe adverse cerebral vascular events, and attributed the potential reason to the fact of the brachiocephalic trunk being larger than the carotid or subclavian arteries. The risk for periprocedural ischemia due to total vessel occlusion after the insertion of the TAVR introducer would therefore be less than in transcarotid or subclavian accesses.

In another series, Capretti et al. described the clinical outcomes of 26 patients who underwent TAVR by suprasternal access.[7] Within 30 days, no deaths were reported; three patients (11.5%) had major vascular complications, and one (3.8%) had a stroke related to carotid artery dissection as a result of the access. According to the investigators, the cases occurred at the beginning of the experiment, and the suprasternal approach was feasible and safe in most cases. In 2018, Codner et al., in a series of 11 patients treated with TAVR via brachiocephalic trunk, using both balloon-expandable and self-expanding prostheses, compared the results with transapical, direct transaortic, and subclavian artery accesses.[8] With subclavian and suprasternal artery approaches through the brachiocephalic trunk, the authors reported shorter time until ambulation as compared to the aortic approach, shorter hospital stay, and less need for narcotics for pain control as compared to transapical and direct transaortic routes.

In our experience, the suprasternal access proved to be feasible, safe and relatively simple. However, since it is short, if the ascending aorta is very horizontal, this approach can render the implantation more challenging, taking into account the greater difficulty in making the delivery system rest on the greater curvature of the ascending aorta and, therefore, adjust coaxial positioning with the left ventricular outflow tract.

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None.

DECLARATION OF CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

CONTRIBUTION OF THE AUTHORS

Conception and design of the study: EPM, FMN, JBSN, LVB, CEGS and JBSF; data collection: EPM, FMN, JBSN, LVB, CEGS and JBSF; data interpretation: EPM, FMN, JBSN, LVB, CEGS and JBSF; writing of the text: EPM, FMN, JBSN, LVB, CEGS and JBSF; approval of the final version to be published: EPM, FMN, JBSN, LVB, CEGS and JBSF.

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