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Successful Transfemoral Aortic Edwards® SAPIEN® Bioprosthesis Implantation Without Using Iodinated Contrast Media in a Woman With Severe Allergy to Contrast Agent

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Severe anaphylactoid reaction after the use of iodinated contrast media are rare but can contraindicate the use of contrast agent. It was the case of a 53-year-old woman suffering from symptomatic severe aortic stenosis, recused for cardiac surgery because of deleterious effects of chest-wall irradiation, with porcelain aorta. We decided to implant a 23-mm Edwards® SAPIEN® transcatheter aortic valve via a femoral route without using any contrast media. The implantation was successful after surgical approach of the femoral artery, transesophageal echocardiography guiding, and localization of native leaflets and coronary trunk with catheters. Immediate and one month post-interventional follow-up was favorable and echocardiography showed a good functioning of the aortic bioprosthesis. Although conventional angiography is the best way to visualize the good positioning of the valve before deployment, our case suggests that, in special situations, transfemoral implantation of an Edwards® SAPIEN® aortic bioprosthesis is feasible without any contrast injection. © 2012 Wiley Periodicals, Inc.

Key words: valvular heart disease; transcatheter aortic valve implantation; contrast media; contrast media allergy; anaphylactoid reaction

INTRODUCTION

Severe adverse reactions after the use of iodinated contrast media (ICM) are rare, ranging from an angioedema to fatal reactions such as anaphylactic shock and cardiac arrest. The risk for severe reactions is estimated at 0.03% with low-osmolality agents [1].

Despite decades of use, current understanding of the pathogenesis of these contrast-mediated reactions is limited. Immediate reactions are mainly induced by the release of vasoactive mediators, such as histamine. Skin tests and specific IgE assays are carried out to diagnose immediate hypersensitivity reactions but have produced variable results. Positive skin tests are observed in approximately 50% of patients with prior ICM hypersensitivity reactions. These data suggest that 50% of these reactions are caused by an immunological mechanism [2] but sensitivity, specificity, and predictive values of these allergologic tests have not yet been established [3].

radiotherapy at the age of 11 years and mastectomy for breast cancer at the age of 51 years. This woman had previously presented hypersensitivity reaction after injection of contrast agent with bronchospasm, respiratory failure, and Quincke edema. Other comorbidities

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CASE

We report the case of a 53-year-old woman, suffering from symptomatic severe aortic stenosis, with a history of Hodgkin's lymphoma exposed to mediastinal



Fig. 1. Noncontrast aorta CT-scanner. Radiation-induced calcification of the ascending aorta is a late deleterious effect of chest-wall irradiation. The porcelain aorta contraindicates a conventional surgical aortic valve replacement.

include hypothyroidism and a chronic obstructive pulmonary disease.

The transthoracic echocardiography revealed a left ventricle ejection fraction at 55% and a severe calcified trileaflet aortic stenosis associated with a moderate aortic regurgitation. The mean transvalvular aortic gradient was measured at 45 mm Hg and the aortic valve area was under 0.45 cm². Annulus diameter was measured at 21 mm.

Computed tomography (CT) without contrast injection revealed a porcelain aorta contraindicating a classical surgical aortic valve replacement (Fig. 1). Then, a 23 mm Edwards® SAPIEN® transcatheter aortic valve implantation via a femoral route was decided. The pre-treatment coronary angiogram and the implantation were planned after a standardized premedication for prevention of allergic-like reactions to contrast agent.

After corticoid and antihistamine premedication, we performed coronary angiogram. Despite this premedication, the patient presented severe reaction after the injection of 5 ml of contrast agent, with bronchospasm and pulmonary edema without decrease of blood pressure. The procedure was disrupted and the patient admitted in intensive care unit. The evolution was favorable under conventional treatment.

Considering that premedication was unable to prevent reaction, skin prick and intradermal tests with three different contrast media and test for latex sensitization were performed few weeks later. The purpose of these tests was to investigate the mechanism of reaction and identify a safe alternative agent without cross-reactivity. All these tests were negative and did not induce any abnormal reaction, suggesting immediate non-IgE-mediated and non-specific anaphylactoid reaction to ICM without possibility to select an alternative safe product. Consequently, the use of ICM was finally contraindicated for this patient.

We then proposed to perform Edwards® SAPIEN® transcatheter aortic valve implantation without any use of contrast agent.

PROCEDURE

CT scanner (CT scan), without contrast media injection, showed 10 mm diameter large regular and non-calcified femoral arteries (Fig. 2) allowing transfemoral approach, which requires a diameter of 6.5 mm or above.

The entire procedure was performed under general anesthesia.

A temporary right ventricle pacing lead was inserted as recommended after left femoral venous catheterization. Two femoral 6-F sheaths were introduced in left femoral artery for pigtail catheters, and one 6-F radial sheath was inserted for a Judkins Left catheter. A surgical approach of the right femoral artery was chosen to completely avoid contrast injection before 18-F delivery catheter introduction under fluoroscopic visualization. The procedure was performed as usually after heparinization.

The best C-arm fluoroscopy orientation for the valve implantation, perpendicular to the aortic valve plane, was determined by CT scan analysis before starting the procedure.

A super-stiff wire was inserted in the left ventricle and a 20-mm balloon dilation of the native aortic valve was performed using calcifications of the leaflets as markers.

Then, a 23-mm Edwards® SAPIEN® valve was positioned and centered on cusps calcifications. The two pigtails and the left coronary artery catheter were positioned to locate two of the three leaflets and the left coronary trunk. As shown Fig. 3A, combination of transoesophageal echocardiography (TEE) guiding with radio-opaque markers allowed a very fine adjustment of the valve positioning before deployment without using contrast media injection (Fig. 3A).

After starting rapid temporary pacing, the two pigtail catheters were removed in the ascending aorta and the valve was deployed as usual. After deployment (Fig. 3B), the good positioning and functioning of the device and the absence of significant periprosthetic leak was checked by TEE.

The 18-F sheath was removed, femoral artery surgically closed and permeability checked by Doppler.

No complication was experienced during post-intervention follow-up. Patient returned home 8 days after intervention. Transthoracic echocardiography performed after 1 month showed good functioning of the aortic bioprosthesis.

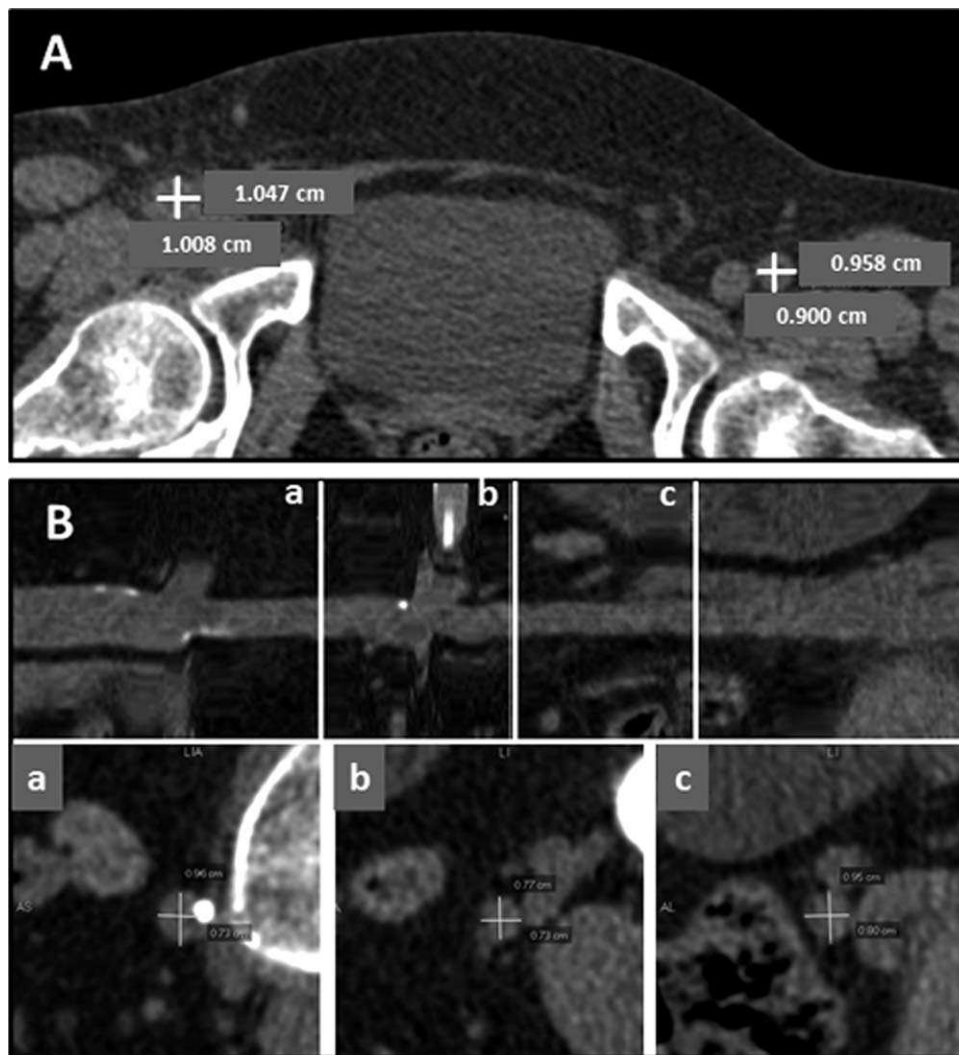


Fig. 2. Non-contrast CT imaging of the femoral arteries. Diameter of arteries can be estimated on axial view (A) or after 2D-reconstruction (B).

DISCUSSION

Contrast medium-induced nephropathy and anaphylactoid reaction to contrast agents have to be prevented by identification of high-risk patients and appropriate premedication. However, in rare cases, the use of ICM can be contraindicated in the field of interventional cardiology, precluding their use for preoperative computed tomography, coronary angiography, or aortographies.

In this context, non-contrast CT, which allows visualization of calcifications and artery wall (Fig. 2) can be very helpful to assess feasibility of femoral approach. In this precise case, measurement by non-contrast CT of a 10 mm diameter regular right femoral artery, without abnormally pronounced tortuosity of the arterial route was considered sufficient. In intermediate situations, with measured diameter below 8 mm, other

techniques like conventional ultrasound imaging or intravascular ultrasound can be helpful [4].

For coronary angiography, gadolinium (Gd) can be used in such situations, because it has different chemical structure with no cross-reactivity with ICM in patients with iodine allergy [5]. The use of Gd is very common in contrast-enhanced magnetic resonance imaging (MRI) and it demonstrates properties that attenuate photon energy of X-ray beam. When used in recommended doses (< 0.3 mmol/kg body weight per examination), Gd has been shown to be safe, well-tolerated, and not nephrotoxic. However, Gd-based agents have been associated with malignant ventricular arrhythmias and suboptimal quality in coronary angiography [6]. Moreover, even if it appears with low incidence, immediate hypersensitivity reaction to MRI contrast media (0.1%) is possible [7].

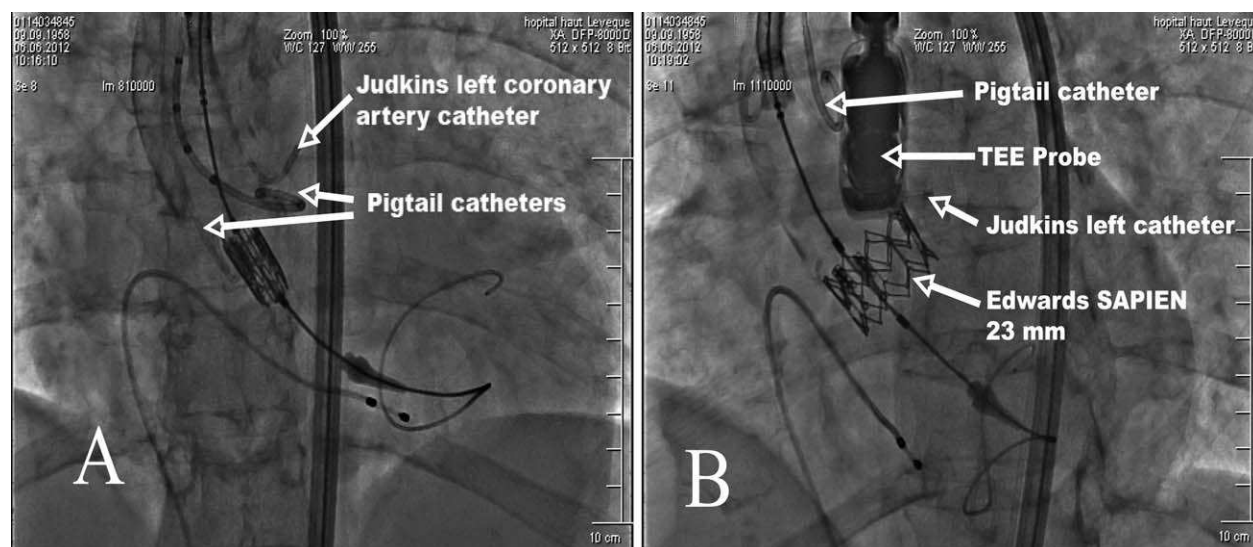


Fig. 3. Fluoroscopic images of the thorax before and after deployment of the device. Two of the three leaflets and the coronary artery trunk were localized using catheters which allowed us to correctly position the valve before deployment (A). The good positioning and functioning of the bioprosthesis was assessed by transesophageal echocardiography (B).

During transcatheter aortic valve implantation (TAVI), echocardiography guiding is an efficient tool to reduce the use of ICM as shown by several studies [8,9]. It allows a fine positioning of the device before deployment and a precise post-implantation control: occurrence of a complication, assessment of bioprosthesis function, estimation of paraprosthesis leak [10], and in favorable situations, assessment of coronary flow [11].

The development of new technologies and methods as angiographic 3-dimensional reconstruction of the aortic root [12,13] or CT co-registration integrated into the angiographic C-arm system [14–16] will probably be very helpful in the future for these complex cases.

Ferrari et al. published in 2010 the results of the only series of 30 valves implanted by transapical approach without the use of contrast agents to avoid nephrotoxicity in patients at risk [17]. Twenty-nine procedures were successful and one patient experienced valve embolization. An aortic three-dimensional CT scan reconstruction was used to determine the C-arm fluoroscopy preorientation and stent-valve positioning was guided by TEE and fluoroscopic visualization of the calcifications. One pigtail catheter was introduced via a femoral route. Postoperative control was performed by TEE. The authors conclude that transapical aortic valve implantation without angiography can be performed routinely by experienced teams.

In our particular case, the femoral route was the best choice and the implantation was successful thanks to echo guiding and localization of the leaflets and the coronary trunk with catheters.

Nevertheless, in the absence of contraindication, limited aortography remains recommended to confirm the adequate positioning of the valve before deployment.

CONCLUSION

Our case suggests that in particular situations, transfemoral implantation of an Edwards® SAPIEN® aortic bioprosthesis is feasible without any contrast injection.

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