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Modified 'dumbbell' technique: a simple and intuitive method to position balloon-expandable stent valves

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Abstract

Intraoperative cardiac imaging plays a key role during transcatheter aortic valve replacement. In recent years, new techniques and new tools for improved image quality and virtual navigation have been proposed, in order to simplify and standardize stent valve positioning and implantation. But routine performance of the new techniques may require major economic investments or specific knowledge and skills and, for this reason, they may not be accessible to the majority of cardiac centres involved in transcatheter valve replacement projects. Additionally, they still require injections of contrast medium to obtain computed images. Therefore, we have developed and describe here a very simple and intuitive method of positioning balloon-expandable stent valves, which represents the evolution of the 'dumbbell' technique for echocardiography-guided transcatheter valve replacement without angiography. This method, based on the partial inflation of the balloon catheter during positioning, traps the crimped valve in the aortic valve orifice and, consequently, very near to the ideal landing zone. It does not require specific echocardiographic knowledge; it does not require angiographies that increase the risk of postoperative kidney failure in elderly patients, and it can be also performed in centres not equipped with a hybrid operating room.

Keywords: Transcatheter aortic valve replacement • Aortic valve stenosis • High-risk patients

INTRODUCTION

Imaging for transcatheter aortic valve replacement (TAVR) plays a key role during stent valve positioning and implantation and several techniques have been proposed to simplify and standardize this procedure [1–3]. However, sophisticated technologies require a degree of investment in such facilities as hybrid suites and DynaCT, in addition to specific competencies. Also, they still need injections of contrast agents that increase the risk of postoperative kidney failure in elderly, high-risk patients [4, 5]. We have already described a simple and safe expedient for transoesophageal echocardiography (TEE)-guided transcatheter stent valve implantation without angiography (the so-called 'dumbbell' technique) that requires good echocardiographic views and TEE experience [6–8]. However, rare circumstances such as heavy calcifications, shadows from mechanical mitral prostheses or a bad echocardiographic 'window' can adversely affect the image quality. Thus, we have developed a modified 'dumbbell' technique for balloon-expandable stent valves (specifically Sapien™ XT, Edwards Lifesciences, Irvine, CA) which is safe and reproducible, does not require special skills, and can be performed by teams with limited access to high-end imaging equipment.

PROCEDURAL DETAILS

The standard 'dumbbell' technique for TAVR is based on partial inflation of a balloon catheter during valve positioning, which increases the TEE visualization of the stent and allows implantation without angiography [6–8]. In this case, the stent valve positioning is based on TEE images and the TAVR-team's experience is crucial.

However, in the course of a series of tests in our laboratory, we demonstrated that a partially inflated balloon catheter with a mounted, crimped Sapien™ XT stent valve creates two balloons of about 20 mm and 22 mm diameters, respectively, for the 23 mm and 26 mm valve sizes (Fig. 1A). We also demonstrated that a partially inflated balloon catheter cannot pass through a severely calcified aortic valve when carefully pulled or pushed against the leaflets: for this purpose we used a flexible, perforated mask that mimics a 1 cm^2 aortic surface area with an orifice diameter of 11.3 mm (Fig. 1B). Consequently, during TAVR, the crimped Sapien™ XT remains trapped in the valve orifice, surrounded by thick, calcified and degenerated aortic leaflets; due to the partially-inflated status of the balloon catheter, it cannot migrate or embolize during movements of the balloon catheter. Thus, we have designed a simple method for positioning balloon-expandable stent valves, with no need for perfect TEE images, extensive TEE experience, special skills or angiographies.

The incomplete, 'dumbbell-like' smooth balloon dilatation is performed after transapical, transaortic or transfemoral introduction of the crimped stent valve into the degenerated valve. This does not require rapid cardiac pacing, does not enlarge the crimped Sapien™ stent valve (under fluoroscopy, it is easy to

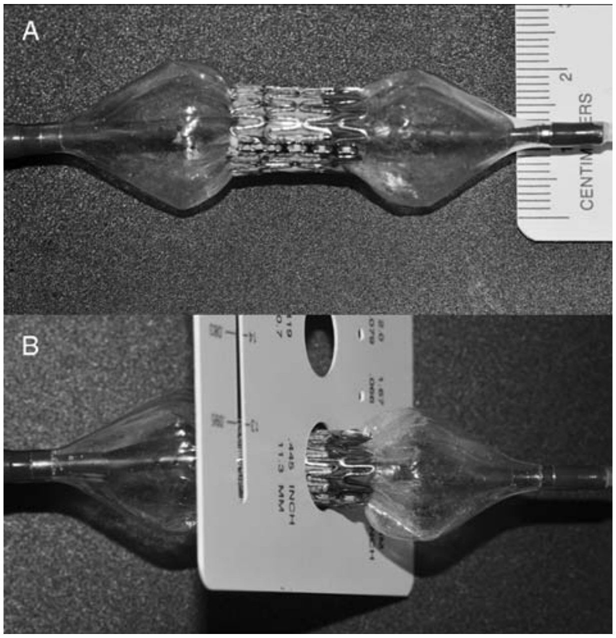

Figure 1: (**A**) The image shows a crimped 23 mm Sapien™ valve with the partially inflated balloon catheter (dumbbell): the two balloons have a diameter of 20 mm. We also tested the 26 mm Sapien™ valve: the balloons have a diameter of 22 mm. (**B**) the crimped stent valve with the dumbbell is tested in a flexible plastic mask with a hole of 11.3 mm diameter that mimics a stenosed aortic valve with an orifice area of 1 cm^2.

evaluate the degree of the balloon inflation and, according to our clinical experience, is haemodynamically irrelevant. Moreover, there is no risk of balloon rupture because no forces are applied between the balloon and the calcium. At this moment, the Ascendra introducer has to remain at a fixed point, whereas the balloon catheter can be manipulated.

In transapical procedures, the balloon catheter is gently pushed towards the valve (Step 1) stopping when the ventricular balloon touches the valve (Fig. 2A). The second manoeuvre (Step 2) is to gently pull the system back until the aortic balloon stops against the aortic side of the diseased valve (Fig. 2B). Then (Step 3) the balloon catheter is carefully pushed to an intermediate position that corresponds to the landing zone (Fig. 2C). During retrograde transaortic or transfemoral procedures, Steps 1 and 2 are reversed.

A key point to note is that the balloon catheter can gently move backward and forward within the introducer but, in the meantime, we have to identify a fixed point in order to know the range of free movement between the two stops and, consequently, determine the mid-point for final positioning (Figs. 2D–F). Angiography (using single 15 ml shots) can always be used for the final adjustment, together with TEE images but, in our experience, this has not been necessary and we always used the TEE images to confirm good valve positioning, valve function and the haemodynamics. The rest of the procedure remains unchanged.

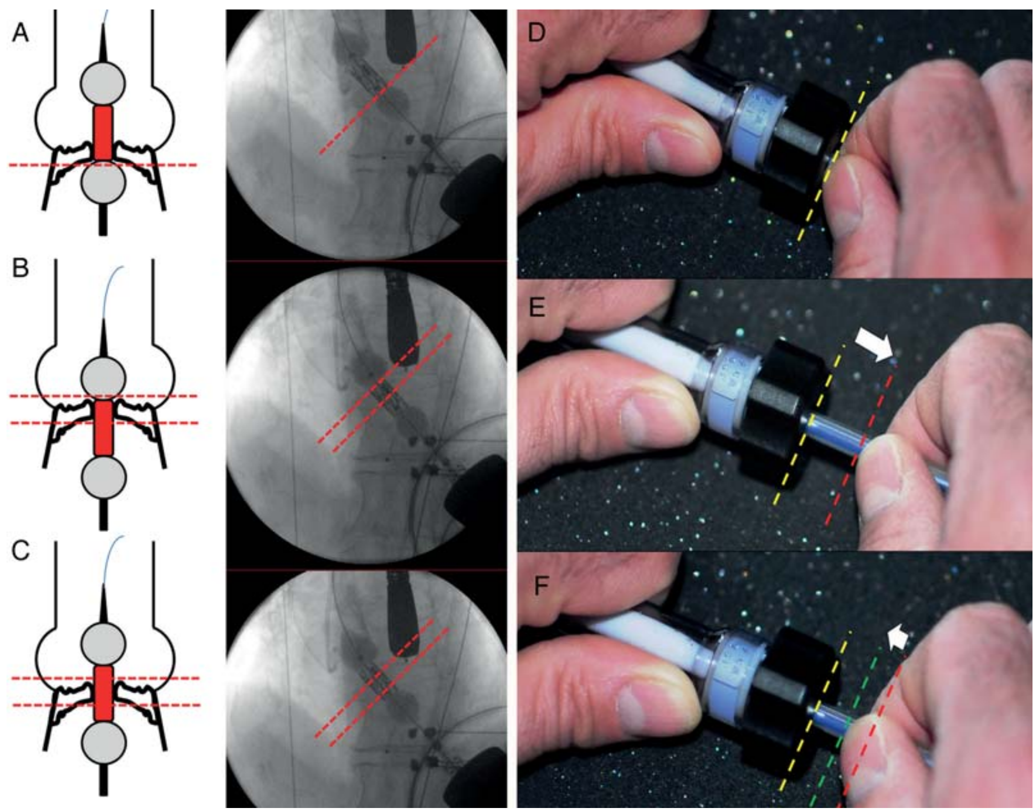

Figure 2: (**A**–**C**) Schemes (left) and fluoroscopic images (right) of the modified 'dumbbell' technique during a transapical TAVR: (**A**) the partially inflated balloon catheter carrying the crimped stent valve is gently pushed towards the stenosed aortic valve: when it stops, this indicates that the inner balloon is touching the valve and this represents the ventricular limit of the diseased aortic valve; (**B**) the partially inflated balloon catheter is pulled back and, when the balloon touches the valve and stops, this represents the aortic board of the diseased aortic valve; (**C**) the catheter is pushed again for a length corresponding to half of the distance between the inner and the external board: in this final position, the crimped Sapien™ stent valve is seated in the optimal landing zone. (**D**–**F**) The sequence shows the three steps for stent valve positioning with the modified 'dumbbell' technique during a transapical TAVR. The introducer has to remain immobile. (D) Step 1: the device is gently pushed into the sheet and stops when the inner balloon touches the valve. (B) Step 2: the device is pulled back and stops when the outer balloon touches the valve. (C) Step 3: the stent valve is positioned at the centre of its range of movement. During a transfemoral or a transaortic procedure, Steps 1 and 2 are reversed.

CONCLUSION

TAVR is an evolving technique and more and more cardiac centres will be ready to perform transcatheter heart valve procedures in the near future. However, few will enjoy the advantages of a hybrid suit and, thus far, TAVRs are performed in cath. labs or in operating theatres with basic portable C-arm fluoroscopic systems. Thus, the image quality depends on the available equipment and still requires contrast medium to acquire aortographies.

One step further was the TEE-guided TAVR with the 'dumbbell' technique that does not require angiographies but instead relies on experience and a good-quality TEE image [8]. With the modified 'dumbbell' technique, valve positioning becomes even easier, with no need for angiography or high-grade TEE images and experience: it is safe, reproducible and special skills are not required.

At the time of writing, 10 consecutive TAVR procedures have been successfully performed at our institution with the modified 'dumbbell' technique: Sapien™ stent valves were fully deployed without embolization, migration, distortion or coronary occlusion, and no patient treated with this method suffered acute renal failure. In none of the cases was a valve-in-valve procedure required to treat a severe regurgitation and no strokes were recorded. At no time did the balloon positioning compromise the patient's haemodynamic status, even when (for few seconds only) the balloons were gently pulled and pushed towards the valve leaflets.

In conclusion, performance of the modified 'dumbbell' technique does not require special skills, is intuitive and all cardiac teams can offer this approach to their TAVR patients.

Conflict of interest: Enrico Ferrari is a consultant for Edwards Lifesciences.

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