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A Simplified Protocol for Transcatheter Aortic Valve Implantation that Reduces Procedure-related Risk

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Abstract

Objectives: Transcatheter Aortic Valve Implantation is now a well-established procedure and continuous development has improved the technique. The object of this paper is to describe the successive steps taken at our department to improve our protocol, resulting in a more effective and patient-safe procedure.

Design: An echo-guided method for aortic cusp alignment was used in 229 patients. In 139 patients pre-dilatation was excluded from the protocol. In the last 47 of the patients we exchanged the stiff guide-wire in the left ventricle with a soft wire for valve placement.

Results: There was a significant decrease in the use of contrast medium during the period with 90% of patients receiving less than 50 ml contrast and 35% no contrast at all. In more than half the patients we only used rapid pacing in association with deployment of the stent valve. We had six cases of pericardial bleeding due to penetration of the stiff guide wire through the left ventricular (LV) wall. This complication was avoided in all subsequent patients where we exchanged the stiff catheter to a soft guidewire in the ascending aorta before introduction of the wire and stent valve into the LV.

Conclusions: We have successively modified our standard protocol for implantation of a balloon-expandable transcatheter aortic valve. This has simplified the procedure and reduced the risk for certain procedure-related complications.

Keywords: Aortic valve implantation; Heart valve implantation; Transcatheter aortic valve implantation; Transcatheter aortic valve replacement

Introduction

Transcatheter Aortic Valve Implantation (TAVI) is now a well-established procedure with many experienced centers around the world, and there are international guidelines for selection of patients and for the reporting of results [1,2]. Long- term results following the earliest intervention (TAVI) procedures have so far been convincing [3,4] and continuous technologic and material development has improved the technique. New options have been explored, and new procedures on mitral and tricuspid valves and valve-in-valve and valve-in–ring procedures developed. Focus is now changing towards optimization of the procedure and perioperative management of the patient to reduce risk and enable early discharge [5,6]. At our department we have simplified the original TAVI standard protocol over the years in an attempt to reduce or avoid any risk associated with the procedure. There is no doubt, for instance, that high doses of contrast medium impair renal function, and patients may proceed to renal failure with anuria, uremia and death [7,8]. Vascular complications at the access site remain a problem, though rates seem to be decreasing [3,9]. Protocols that include one or more periods of rapid pacing can lead to acute hemodynamic problems in patients with impaired heart function. The use of a stiff guidewire in the left ventricle (LV) to support the valve system creates a potential risk for perforation and myocardial bleeding [10]. The object of this paper is to describe the successive steps taken at our department to improve our TAVI protocol that have resulted in a more effective and patient-safe procedure.

Material and Methods

We started our TAVI program in Sept 2008 and we have so far performed 310 procedures. Valve-in-valve procedures and mitral and tricuspid procedures were excluded from this report, leaving 258 patients for data analysis.

Step 1: An Echo-guided method for aortic cusp alignment

From early on we began using transesophageal echocardiography to guide the fluoroscopy instrument setting for good alignment of the aortic cusps [11]. Once an optimal echocardiographic view was obtained, the image intensifier was adjusted to the transducer's direction. The principle is shown in Figures 1 and 2. Using this procedure good alignment of the cusps is regularly achieved, and this may be verified by aortic root angiography when necessary.

Step 2: Ultrasound guidance for femoral artery puncture

To begin with we punctured the femoral artery with the aid of manual palpation of the pulse. Following a few incidents where patients suffered vascular complications due to an inadequate puncture site, we decided to visualize the vascular anatomy with ultrasound before performing guided puncture with the needle positioned anterior and central to the common femoral artery.

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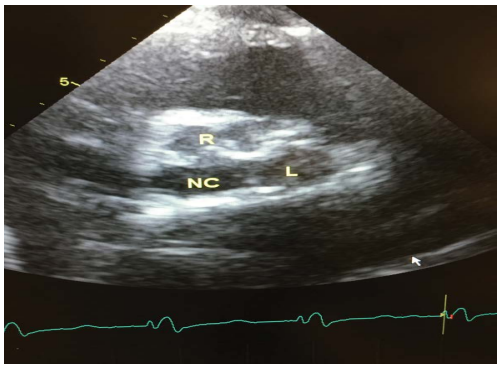

Figure 1: Image from transcutaneous ultrasound showing three cusps. This is reference for adjustment of the fluoroscopic equipment giving a good radiological alignment of the cusps without need for contrast.

Figure 2: Our procedure to adjust the fluoroscopic image intensifier after ultrasound visualization of the aortic cusps. The intensifier then has the same angulation as the ultrasound probe.

The obvious advantages of ultrasound-guided femoral artery puncture are:

1) visualization of vessel diameter; 2) safe puncture proximal to the common femoral artery bifurcation avoiding transarterial venous puncture; 3) central arterial puncture is facilitated; 4) plaques can be visualized and avoided; and 5) a vascular suture is more easily applied in case of inadequate function of the percutaneous closure system.

Following puncture, two suture-mediated closure devices (Proglide™) are introduced into the vessel before it is dilated with the introducer (16-18 Fr).

Step 3: Avoidance of pre-dilatation

When we started our TAVI program Sept 2008, we followed the standard protocol including pre-dilatation of the stenotic valve with a balloon before stent deployment. At least two periods of rapid pacing (RP) were needed for a TAVI procedure, and should the balloon slide during inflation, additional periods of RP were necessary. Some patients reacted with slow recovery of heart function, and over a short period of time we even had three patients requiring resuscitation and in one case we were obliged to use temporary extra-corporeal circulation to support the patient. In June 2011 we therefore started to avoid pre-dilatation beginning with the transapical approach where we used the introducer itself to dilate or secure sufficient valve lumen. We later found that even transfemoral insertion of the valve worked well without pre-dilatation, so we decided to exclude this maneuver from our protocol. Of the 258 TAVI patients in this report, pre-dilatation was avoided in 139.

Step 4: Avoidance of a stiff LV guidewire

Use of a stiff guidewire in the LV was part of the standard protocol. The wire can induce arrhythmias, perforate the LV wall, and cause hemopericardium. In all our cases with guidewire -induced hemipericardium, bleeding did not stop after pericardiocentesis and the patients eventually required sternotomy and suture of the LV wall. We have therefore modified our protocol to exclude the use of a stiff guidewire in the LV. Our new sequence retains the following stages:1) a Lunderquist® extra stiff guidewire to load the valve in the descending aorta and to pass it into the ascending aorta; 2) exchange of the stiff wire for a soft Terumo Glidewire® that is introduced into the LV; and 3) the stent valve is then guided through the stenotic valve over this soft wire. We have used this technique with both the Sapien XT and Sapien3 system. We have also performed transapical cases without a stiff guidewire.

Step 5: A single puncture

The original standard protocol included the introduction of arterial and venous sheaths in the contralateral groin. The reasons for the contralateral arterial sheath are: 1) to perform aortograms; 2) to secure easy access in the case of acute cardio-pulmonary bypass (CPB); and 3) to be able to quickly introduce an aortic occlusion balloon for hemostasis.

The reason for the venous sheath is to provide easy access for acute CPB. After the introduction of Step 1 of our protocol using transoesophageal echocardiography we have reduced the need for aortograms, and in most cases we avoid injection of contrast medium. Acute CPB has been a rare event for many years now. With the echo-guided puncture technique it is a fast procedure to introduce an occlusion balloon when needed. This is why we have excluded contralateral punctures in our current protocol.

After introduction of a 6 Fr introducer and Proglide™ we proceed with a pigtail catheter to the aortic valve and compare the landing zone of the catheter with the calcified zone on the fluoroscopy and the TEE images. If there is a good correspondence we continue with the valve introducer without puncturing any other vessels.

Statistics

Data were prospectively registered on a clinical report form, and transferred to and saved in an Excel database for future analysis. Our protocol has been modified step-by-step over time and since the patients with balloon predilatation represent an early learning curve cohort, we did not regard statistical comparison with the group avoiding this meaningful. Our conclusions are based on the way we have been able to omit and avoid some risky steps of the procedure.

Results

There was a significant decrease in the use of contrast medium after introduction of our ultrasound-guided method for the alignment of the aortic cusps (Table 1). Of the 229 patients 204 (89%) were given less than 50 ml contrast, and 81 (35%) did not receive any contrast at all. In these cases, fluoroscopy and transesophageal echocardiography were used to guide positioning and deployment of the stent valve.

Reduction of vascular complications

Before ultrasound-guided vascular punction became routine we

Patients	Contrast delivery ml Mean ± SD	Range ml	p Before and after L
All pts (n=258)	34+41	0-375	
Before E (n=29)	96+78	20-375	
After E (n=229)	26+26	0-163	<0,001, chi-square test

Table 1: Contrast delivery for all patients before and after introduction of the echo-guided cusp alignment method (E).

had two cases of puncture in the lateral wall of the femoral artery at the origin of the profunda femoral artery that needed surgical reconstruction. The closed suture-device secured the incision in a more predictable way when a guided central vessel puncture was performed. If this was not good enough for adequate hemostasis a cut-down with suture or the vessel was performed while occluding the abdominal aorta with a balloon catheter introduced in the contralateral groin.

Frequency of rapid pacing has fallen

Since June 2011, when we began to exclude pre-dilatation for AS patients, the frequency of rapid pacing has fallen. The results from the first 139 patients without pre-dilatation were compared with data from the previous 119 patients from the start of our TAVI program where we used the standard protocol including pre-dilatation. We needed at least two periods of rapid pacing for balloon predilatation and stent deployment. Demographic, procedural and post-procedural data according to VARC 2 criteria [12] are shown in Tables 2-4. The results indicated that the TAVI procedure could be performed safely without pre-dilatation. In these patients we needed just one period of rapid pacing in association with deployment of the stent valve. Since some of the 119 patients represent an early learning curve cohort, we did not regard statistical comparison meaningful.

Avoidance of a stiff LV guidewire reduces the risk of LV penetration

Introduction of a stiff guidewire in the LV to stabilize the valve system was included in the standard protocol. We had 6/258 (2.3%) cases of pericardial bleeding due to penetration of the wire through the LV wall. All patients were initially managed by pericardial drainage, but in 5 of these cases we were forced to perform a sternotomy to secure hemostasis. Two patients had intramural bleeding requiring extensive patching of the anterior wall. They deteriorated and died before completion of the procedure.

We have performed 47 procedures with exchange of the stiff for a soft Terumo guidewire in the ascending aorta and have had no case of LV perforation in this series. The demographic data and early results are shown in Table 5. We had one case of hemopericardium where right ventricular wall perforation was caused by a pacemaker electrode.

Puncture on one side only

When the level of the annulus was clearly defined by calcification and we had a good TEE image of the aortic root, we were able to deliver the valve safely in this way. We have used this method in more than one hundred patients and thus been able to totally avoid access bleeding in the contralateral groin.

Discussion

TAVI has been widely accepted as a method to treat aortic stenosis in high-risk patients [1-3]. Experience has made the procedure safer, and the development of technology has led to the simplification of standard protocols. When widening the indications to include intermediate-risk patients, who nowadays are operated on surgically with low morbidity and mortality, it is important to further reduce the inherent complications of TAVI. The process of optimizing patient selection and perioperative management, as well as the procedure itself, has developed over the years [9]. Guidelines are helpful [1,2] and the international consensus when reporting results [12] has facilitated comparison of results from different studies. The length of stay (LoS) in hospital after TAVI still varies widely between centers from two to more than ten days [3,13]. The total cost for the procedure can thus vary greatly [3]. There is still an obvious need for further optimization of the TAVI process. One important factor is reduction of risks associated with the procedure. We have successively simplified our procedure protocol with the result that some complications associated with the procedure have been reduced or totally avoided.

TAVI (n=258)	Predilatation (n=119)	No predilatation (n=139)
Women (%)	66	56
Age (mean)	80 (42-92)	81 (50-94)
Euroscore STS	17 (3-57) 6 (1-17)	18 (2-68) 7 (1-29)
PPM (%)	5.9	8.6
Degenerative valve (%) Radiation (%)	96 4	99 1
Vmax m/s Mean gradient mmHg Area cm2	4.6 (3.2-6.5) 54 (23-108)	4.3 (2.5-6.4) 48 (9-103) 0.6 (0.2-1.2)
AR≥moderate (%)	7.6	7.9
Previous BAV (%)	3.4	3.6

Table 2: Demographic data from two different patient groups where more recent patients with a simplified protocol excluding pre-dilatation were compared with patients treated according to a standard protocol. STS=Society of Thoracic Surgeons, PPM=permanent pacemaker, AR=aortic regurgitation, BAV=balloon aortic valvuloplasty.

TAVI (n=258)	Predilatation (n=119)	No predilatation (n=139)
TF/TA/TAO (%)	69/30/1	81/19/0
Valve size 23/26/29mm (%)	40/52/8	42/43/15
Rapid pacing periods	2 (74%), 3(21%), 4(5%)	1 (96%), 2 (4%)
Postdilatation (%)	9%	4%
Procedural complications (%)		
Minor vascular	13.4	2.2
Major vascular	0	2.9
Bleeding complications	5.9	3.6
Acute kidney injury	2.5	0
Conduction disturbances	3.4	1.3
Stroke	4.2	2.2
Other (CPB, valve embolization)	3.4	2.2
Death	1.7	0.7

Table 3: Procedure: TF=transfemoral, TA=Transapical, TAO=transaortal approach. Procedural complications according to VARC 2 criteria. CPB=cardiopulmonary bypass.

30 days follow up	Predilatation (n=119)	No predilatation (n=139)
Vmax m/s Mean gradient mm Hg	2.1 (1.2-3.1) 10 (3-18)	2.1 (1.4-3.0) 10 (3-19)
PVL ≥ moderate (%)	0	1.4
Valvular leak ≥ mild (%)	1.7	0
Stroke (%)	5.0	2.2
New PPM (n)	1.7	2.2
Death (%)	9.2	3.6

Table 4: Thirty days follow up data according to VARC 2 criteria. PVL=paravalvular leak, PPM=permanent pacemaker.

No of TAVI patients	47
Age	80 (50-91)
Euroscore I	19 (2-68)
Euroscore II	9 (2-41)
STS	7 (2-29)
Vmax m/s	4.2 (2.5-6.4)
Mean gradient mmHg	45 (9-103)
Previous BAV (%)	2
Permanent PM before procedure	11
Procedure time (min)	41 (18-125)
Fluoroscopy (min)	14 (5-40)
Contrast (ml)	10 (0-60) - 57% without contrast
Pre-/postdilatation	0
Rapid pacing periods	0 = 3 pat* - 1 =44 pat
Echo-guided vascular access	100%
General anesthesia	64%

Table 5: Transfemoral TAVI without stiff guidewire was carried out in 47 patients. STS=Society of Thoracic Surgeons, BAV=balloon aortic valvuloplasty, PPM=permanent pacemaker. * Spontaneous drop in blood pressure with Sapien™ in native valve.

Elderly patients with impaired kidney function are more at risk for acute renal failure and are sensitive to contrast medium, though some controversy exists about the negative effect of contrast delivery in association with TAVI [14,15]. In a large multicenter study, Barbanti et al. [7] reported that acute kidney injury is a frequent complication and has significant impact on both early and long-term TAVI survival [7]. On the other hand Goebel et al. [16] stated that the amount of contrast agent given during the procedure does not increase the risk for acute kidney injury [16]. In a study on over 7500 patients who underwent percutaneous coronary intervention Rihal et al. [8] found that acute renal failure correlated with the volume of contrast medium administered [8]. Echo guidance of fluoroscopic equipment has meant that we can reduce and in many cases avoid contrast delivery to verify good alignment of the aortic cusps [11]. In our series of 229 patients using this method 1/3 did not receive any contrast and 90% received 50 ml or less. Today half of the TAVI procedures performed at our center are done without contrast, and the average contrast volume per procedure is 10 ml and with no patients given more than 60 ml (n=47). Compared to other published series this is a very low dose of contrast medium [15].

Ultrasound has been shown to enable good visualization and safe puncture of the common femoral artery [17,18]. We choose a puncture site at the central anterior wall that is free from atherosclerotic plaques. Our protocol includes two suture-mediated closure devices where the introducer is inserted. Use of a vascular sealing device is effective in achieving rapid hemostasis and probably facilitates early ambulation [19,20] even if direct or fascia suture techniques are feasible and cost-effective [21]. Puncture of contralateral vessels is nowadays deemed unnecessary and avoided and the number of vascular complications is thereby reduced. Should the closure device fail to provide good hemostasis, we introduce an aortic occlusion balloon catheter via the contralateral groin, thereby creating good conditions for a cut-down and suture of a well-exposed vessel. Using the VARC 2 criteria, our frequency of major vascular complications is in the lower range of previous reports [3,9,22].

Myocardial hypoperfusion and even circulatory collapse were rare but serious events after multiple rapid pacing periods in our early experience of TAVI. We began, quite early on, by excluding pre-dilatation and were thereby able to reduce the number of rapid pacing periods without any observed drawbacks using this modification. We were also able to avoid risking dislodgement of emboli from nearby sources at the aortic arch with a balloon system. TAVI with the Sapien™ valve without pre-dilatation was shown to be feasible with good valve positioning and function, with no increase in complications. This has also been reported by other authors [23]. The advantages are fewer rapid pacing periods, less manipulation of the aorta and the aortic root, less arrhythmias, and avoidance of aortic regurgitation before valve implant. It also shortens the procedure. If a balloon is used for sizing this would obviously be a drawback. It is clear that that more and more centers avoid this maneuver to simplify their protocols.

TAVI is commonly associated with arrhythmias where AV-block may occur immediately or within the first week. The frequency of pacemaker intervention varies between about 5 to 30% in the literature depending on the TAVI device system and even when using the same device in different patients [24]. We have observed a very low (below 3%) frequency of arrhythmias requiring permanent pacemaker treatment after TAVI. The reason for this is not totally understood but may be related to valve positioning. We regularly deploy the valve as high as possible using both fluoroscopic and echo guidance. A low pacemaker frequency is an important factor affecting the need for postoperative ECG-monitoring and length of stay.

Most TAVI protocols include a stiff guidewire placed in the left ventricle to support the valve system. This has the potential risk of arrhythmias and perforation of the LV wall. We have found that the use of a stiff guidewire in the LV is unnecessary and have therefore excluded it from our current protocol. This modification has to our knowledge not been described before.

All in all, these improvement steps have reduced the risk of TAVI as well as the time taken for the procedure, and have led to it becoming a more straightforward procedure. Together with new valve stent generations and further development of the perioperative management of patients, TAVI will more and more become an option for patients that are nowadays treated with SAVR [25].

Conclusion

We have successively modified the standard protocol for implantation of a balloon-expandable transcatheter aortic valve. This has simplified the procedure and reduced the risk for certain procedure-related complications [26].

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