

CLINICAL STUDY

Transapical transcatheter aortic valve replacement with the balloon expandable aortic bioprosthesis valve in high risk patients with severe aortic stenosis: Intermediate-term results from the register of the clinic of cardiac surgery

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ABSTRACT

BACKGROUND: The purpose of this study is to report our experience in performing transapical (TA) TAVR with a balloon-expandable valve only by cardiac surgeons, with on site interventional cardiology support.

METHODS: A retrospective review of 97 consecutive patients that underwent TA TAVR due to severe symptomatic aortic stenosis was performed from 2012 to 2016. Median follow-up time was 20.5 months. Preoperative risk factors and postoperative outcomes were evaluated using Valve Academic Research Consortium-2 definitions.

RESULTS: All patients were high risk with a mean Euroscore of 7.28 ± 7.77 . Five year and 30-day mortality were 9.3 % and 1.1 %, respectively. Ninety six (98.9 %) of the patients had no or mild paravalvular leak seen by transesophageal echocardiography after implantation. Device success was 91.8%. Postoperatively there was a significant increase of the ejection fraction (50.8 ± 7.1 % preoperatively vs 53.1 ± 7.7 % postoperatively, $p=0.009$) and reverse remodeling of the left ventricle (left ventricular end-diastolic diameter preoperatively 50.8 ± 7.1 mm vs 49.2 ± 8.1 mm postoperatively, $p=0.031$).

CONCLUSION: Our experience demonstrates that TA TAVR can be performed only by cardiac surgeons, with on site interventional cardiology support safely and successfully with low and comparable postoperative mortality and rate of complications (Tab. 4, Fig. 1, Ref. 26). Text in PDF www.elis.sk.

KEY WORDS: transapical TAVR, interdisciplinary heart team.

Introduction

Transcatheter aortic valve replacement (TAVR) has become a dominant topic in the field of cardiac surgery and cardiology over the last few years. TAVR has enabled treatment of severe aortic stenosis in inoperable and high-risk surgical aortic valve replacement candidates (1–4). This new approach has also led to the formation of heart teams at many cardiovascular centers which were established in the new guidelines (5).

The most commonly performed method of access is the transfemoral (TF) approach. However, there is a subset of patients for whom transfemoral access is not possible because of size, tortuosity, or calcification of the femoral vessel. In response, alternative access routes have been developed such as the transapical (TA) approach.

In our institute, from the beginning of 2013 TA TAVR procedures are performed only by cardiac surgeons with a stand-by invasive cardiologist that can be called without time delay in case of emergency.

We report our experience and 5 years results performing TAVR using the transapical approach

Patients and methods*Patients*

The TAVR program in our institute has started in October 2012 and by the end of December included 97 transapical and 9 transaortic TAVR. During the first few transapical TAVR implantations an invasive cardiologist was a part of the interdisciplinary team that performed the procedures, but with time and by gaining experience by the cardiac surgeons with the transcatheter techniques, from January 2013 the TA TAVR procedures are performed only by cardiac surgeons with a stand-by invasive cardiologist. Also, in our institute a parallel program of TF-TAVR is running by the invasive cardiologists and during the above period 141 procedures of TF-TAVR were performed.

In this retrospective observational study only the 97 consecutive patients with severe symptomatic aortic stenosis that under-

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went TA TAVR by cardiac surgeons alone in our institute from October 2012 to December 2016 are included. The nine transaortic TAVR were all combined procedures (coronary artery revascularization or tricuspid valve annuloplasty) and are not included in the study. All patients were at high risk for conventional surgery and had additional predisposing risk factors like porcelain aorta or redo-surgery. The patients were indicated for TA TAVR by the heart team because the transfemoral access was not possible due to size, tortuosity, or calcification of the femoral vessels. Patients that were candidates for TAVR underwent a standard preoperative diagnostic work-up including transthoracic and transesophageal echocardiography, pulmonary function tests, electrocardiogram, chest x-ray and baseline blood work. Preoperative computer tomography (CT) scanning is the method of choice for annulus measurements. The study was formally approved by the institutional review board and informed consent was obtained from all patients to present it.

Every six months there was a follow-up examination with a transthoracic echocardiogram for evaluation of the aortic bioprosthetic valve. The last postoperative echocardiogram was done at the last follow-up visit. Additional information concerning mortality, morbidity and the condition of the patient were obtained by phone with patients and family members, with supplemental information being supplied by family physicians and referring cardiologists. Valve related mortality and morbidity, perioperative, 30-day, and postoperative 5 year outcomes were evaluated according to VARC-2 criteria (6). The mean follow-up period was 22.55±14.2 months (0–50 months) and the median follow-up time was 20.5 months. The follow-up was complete in 95 %.

Surgical technique

All the procedures were performed in a hybrid operating room under fluoroscopic and transesophageal guidance. For all patients, a temporary right ventricular epicardial pacemaker was placed. Ascending aortography was performed through the femoral artery. The patient was heparinized and maintained at an activated clotting time greater than 250 seconds.

All patients underwent transapical TAVR using the 23, 26.29 mm Sapien S3 and Sapien XT bioprosthesis (Edwards Lifesciences, Irvine, CA, USA) with the Ascendra or Centritude delivery system.

A left minithoracotomy was performed to expose the apex of the heart, after which a pericardial well was created and double purse-string sutures were placed on the apex. The left ventricle was accessed and a guidewire was inserted across the stenotic valve. A pigtail catheter was placed in the sinus of Valsalva through the right femoral artery to inject the contrast medium. It is also used to facilitate valve positioning and deployment as well as for the final angiogram and coronary angiography.

After introducing the Ascendra or the Centritude delivery system through a 18F sheath, balloon valvuloplasty was performed under rapid pacing (180/min) to obtain a systolic pressure of 50 mmHg. The Edwards Sapien S3 and XT valves were introduced through the delivery system across the aortic valve in an antegrade fashion and then carefully positioned and deployed

under rapid pacing. Finally, the guidewire was removed, and the double purse-string sutures were tied down securely under rapid ventricular pacing.

Statistical analysis

All variables were expressed as mean± standard deviation, median and interquartile range, and qualitative variables as numbers and percentages. A paired two-tailed t-test probability was used to compare the preoperative variables as well as the postoperative variables. The Kaplan–Meier survival curve analysis was performed with the Greenwood formula of variance. A p value of less than 0.05 was considered statistically significant. The statistical analyses were performed using the XL STAT 2016 (New York, N, USA).

Results

In the period from October 2012 to December 2016 a total of 97 patients with severe aortic stenosis were treated with the transapical TAVR procedure. All of these patients belonged to a typical

Tab. 1. Preoperative demographic and clinical characteristics.

Variable	n=97
Age, mean±SD, median (IQR 25–75%), years	77.3±8.5, 79.2 (74.3–83)
Female, n (%)	48 (47.5%)
Body mass index, mean±SD, median (IQR 25–75%)	28±4.5, 28.2(24.8–30.5)
Cerebrovascular disease, n (%)	35 (36%)
Diabetes mellitus, n (%)	42 (43.2%)
Chronic obstructive pulmonary disease, n (%)	41 (42%)
Peripheral vascular disease, n (%)	40 (41%)
Ischemic heart disease, n (%)	54 (55.7%)
Myocardial infarction, n (%)	28 (28.9%)
Previous PCI, n (%)	11 (11.3%)
Previous CABG, n (%)	13 (13.4%)
Previous valve procedure, n (%)	1 (1.1%)
Previous pacemaker implantation, n (%)	1 (1.1%)
Atrial fibrillation, n (%)	26 (26.8%)
Paroxysmal	11 (11.3%)
Persistent	2 (2.1%)
Permanent	13 (13.4%)
Euroscore, mean±SD, median, (IQR 25–75%)	7.28±7.77, 5.3(4–8.2)
NYHA class III or IV, n (%)	92 (94.8%)
Porcelain aorta, n (%)	86 (88.7%)
Ejection fraction, mean±SD, median, (IQR 25–75%), %	50.5±10.7, 53(45–60)
Aortic valve regurgitation, n (%)	79 (81.4%)
Grade 1, n (%)	70 (72.2%)
Grade 2, n (%)	9 (9.3%)
Mitral valve regurgitation, n (%)	77 (79.3%)
Grade 1, n (%)	50 (51.5%)
Grade 2, n (%)	25 (25.8%)
Grade 3, n (%)	2 (2.1%)
Tricuspid valve regurgitation, n (%)	55 (56.7%)
Grade 1, n (%)	36 (37.1%)
Grade 2, n (%)	14 (14.4%)
Grade 3, n (%)	5 (5.2%)

IQR = Interquartile range, PCI = Percutaneous coronary intervention, CABG = Coronary artery bypass graft

Tab. 2. Perioperative outcomes.

Transapical access	97 (100%)
Valve implanted	
SAPIEN XT, n (%)	31 (32%)
23 mm, n (%)	7 (7.2%)
26 mm, n (%)	9 (9.3%)
29 mm, n (%)	15 (15.5%)
SAPIEN S3, n (%)	66 (68%)
23 mm, n (%)	23 (23.7%)
26 mm, n (%)	32 (33%)
29 mm, n (%)	11 (11.3%)
Paravalvular leak	
None, n (%)	88 (90.7%)
Grade 1, n (%)	8 (8.2%)
Grade 2, n (%)	0 (0%)
Grade 3, n (%)	1 (1.1%)
Transvalvular leak	
None, n (%)	19 (19.6%)
Grade 1, n (%)	71 (73.2%)
Grade 2, n (%)	7 (7.6%)
Grade 3, n (%)	0 (0%)
Concomitant procedures	
TMVR valve-in-valve	1 (1.1%)
TMVR valve-in-ring	1 (1.1%)
TMVR valve-in-MAC	1 (1.1%)
Valve in previous tissue valve	2 (2.1%)
Device success, n (%)	89 (91.8%)

TMVR = Transcatheter mitral valve replacement, MAC = Mitral annular calcification

high-risk patient cohort, with a mean age of 77.3 ± 8.5 years and mean Euroscore of 7.28 ± 7.77 . The preoperative demographic and clinical characteristics are presented in Table 1.

The procedure was performed using the Edwards Sapien XT valve in 31 (32 %) patients and the Edwards Sapien S3 in 66 (68 %) patients. Ninety six (98.9 %) patients had no or mild paravalvular leak seen by transesophageal echocardiography after implantation. Only 1 (1.1 %) patient had a grade 3 paravalvular leak. Two patients (2.1 %) had valve-in-valve TMVR. Device success was 91.8 %. The perioperative outcomes are presented in Table 2.

Postoperative echocardiogram at discharge showed that there was a significant drop in mean aortic gradient (55.8 ± 11.3 mmHg preoperatively vs 19.98 ± 3.9 mmHg postoperatively, $p <$

Tab. 3. Preoperative and postoperative echocardiography.

Variable	Preoperative	Postoperative	p
Mean aortic valve gradient, mean \pm SD, median, (IQR 25–75%), mmHg	55.8 ± 11.3 , 55 (48–61)	19.98 ± 3.9 , 19 (18–21)	< 0.05
Aortic valve area, mean \pm SD, median, (IQR 25–75%), cm ²	0.64 ± 0.14 , 0.60 (0.56–0.70)		
Left ventricular end-diastolic diameter, mean \pm SD, median, (IQR 25–75%), mm	50.8 ± 7.1 , 50 (46–55)	49.2 ± 8.1 , 50 (45–54)	0.031
Ejection fraction, mean \pm SD, median (IQR 25–75%), %	50.5 ± 10.7 , 53 (45–60)	53.1 ± 7.7 , 55 (49–60)	0.009
Paravalvular leak			
Grade 0, n (%)		86 (88.7%)	
Grade 1, n (%)		11 (11.3%)	
Aortic regurgitation			
Grade 0, n (%)		89 (91.8%)	
Grade 1, n (%)		8 (8.2%)	

IQR = Interquartile range

Tab. 4. Postoperative, 30-day and intermediate term outcomes.

Variable	n=97
Intermediate term mortality, n (%)	9 (9.3%)
Perioperative mortality, 30 day, n (%)	1 (1.1%)
Total hospitalization, mean \pm SD, median, (IQR 25–75%), days	9.6 ± 5.7 , 7 (6–8)
ICU stay, mean \pm SD, median, (IQR 25–75%) days	5.7 ± 5.8 , 4 (3–5)
Bleeding, re-exploration, n (%)	1 (1.1%)
Respiratory failure, n (%)	6 (6.2%)
Stroke, TIA, n (%)	4 (4.1%)
Renal injury, n (%)	5 (5.2%)
Wound infection, n (%)	4 (4.1%)
Redo operation due to valve failure, intermediate, n (%)	0 (0%)
Pacemaker implantation, intermediate, n (%)	5 (2%)
Paravalvular leak, intermediate	
Grade 1, n (%)	11 (11.3%)
Grade 2,3,4, n (%)	0 (0%)

IQR = Interquartile range, ICU = Intensive care unit, TIA = transitory ischemic attack

0.05). Also, there was a significant increase of the ejection fraction (50.8 ± 7.1 preoperatively vs 53.1 ± 7.7 postoperatively, $p = 0.009$). Moreover, there was also a reverse remodeling of the left ventricle (left ventricular end-diastolic diameter preoperatively 50.8 ± 7.1 mm vs 49.2 ± 8.1 mm postoperatively, $p = 0.031$). Grade 1 paravalvular leak and grade 1 aortic regurgitation were present only in 11 (11.3 %) and 8 (8.2 %) patients, respectively. The preoperative and postoperative (at discharge) echocardiography results are presented in Table 3.

There was 1 (1.1 %) perioperative/30-day death. The cause of death was respiratory and renal failure after the procedure. Five year mortality was 9.3 % (9 patients). After discharge 3 patients died in hospice from unknown causes, and 5 patients died in hospital after readmission in peripheral hospitals from cardiac (3 patients) and respiratory (2 patients) complications. In the intermediate period only 11 (11.3 %) patients had grade 1 paravalvular leak. Also, there was no reoperation due to valve failure.

The postoperative, 30-day and intermediate term outcomes are presented in Table 4.

The 5 year mortality is presented by the Kaplan-Meier curve (Fig. 1).

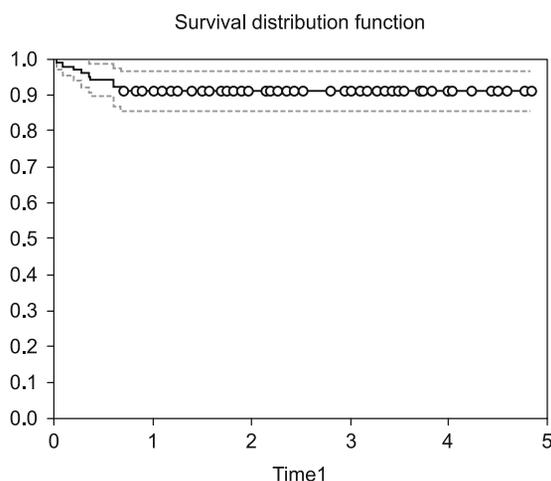


Fig. 1. 5-year Kaplan–Meier survival curve.

Discussion

The advent of TAVR has changed the management of aortic valve disease for high risk or inoperable patients for traditional surgical aortic valve replacement. Although TF TAVR may be the first option, we find that many patients are not candidates for the TF approach because of femoral vessel tortuosity, caliber or calcification. Rodes-Cabau et al (7) documented that 51.3% of 339 patients could not undergo implantation through the femoral route. The large number of patients who can potentially benefit from TAVR but cannot receive TF TAVR argues strongly for the use of alternative approaches like the TA TAVR. All-cause 30-day mortality rates for TF TAVR have been reported to be 1.7 % to 14.5 %, and published data thus far show that these alternative routes of access can have results similar to those in TF TAVR cohorts (8).

Invasive cardiologists are more familiar than the cardiac surgeons with the transcatheter techniques. The introduction of the TAVR led to the formation of heart teams in many centers consisting of cardiac surgeons and invasive cardiologists. The development of non-TF routes, the transapical and transaortic TAVR raised the importance of the presence of an invasive cardiologist during the valve implantation in order to assist the cardiac surgeon to perform the procedure (9–12). That was the case also in our institute. When we started the TA TAVR program in October 2012 an invasive cardiologist was a part of the team that performed the procedures. With time the cardiac surgeons became more familiar with the transcatheter techniques and gained more experience so from the beginning of 2013 the TA TAVR procedures are performed only by cardiac surgeons with a stand-by invasive cardiologist that can be called without time delay in case of emergency.

The Israeli Society of Cardiothoracic Surgery in the revised cardiothoracic surgery residency training program in Israel, after the first four years of common basic training module introduced a hybrid subspecialty program consisting of 12 months of interventional cardiology and 3 months of interventional radiology (13). Cardiac surgeons after attending such residency training program

would be capable to perform transapical or transaortic TAVR procedures without the assistance of an invasive cardiologist. This is the future direction that also would change the composition and function of the heart team. With the emergence of new transcatheter procedures such as the transcatheter mitral valve replacement and paravalvular leak closure (14, 15) where the transapical approach is the simplest and preferred method, the training of the cardiac surgeons in the transcatheter technology becomes more timely and essential.

Another issue to be clarified is the need of a stand-by invasive cardiologist in cases where the non-TF TAVR procedure is performed only by cardiac surgeons. Coronary artery occlusion is a rare but life-threatening complication of TAVR, and this may be a reason to have an interventional cardiologist present at the operation. The incidence of this complication in subsequent TAVR series and registries has been low, nearly systematically lower than 1 %. It occurred more frequently in women, in patients receiving a balloon-expandable valves and the left coronary artery is the most commonly involved artery. Lower-lying coronary ostium and shallow sinus of Valsalva were associated anatomic factors. Percutaneous coronary intervention (PCI) was the preferred strategy for the treatment with a success rate of more than 80%. Other options were urgent coronary artery bypass graft revascularization (CABG) and mechanical hemodynamic support. The mortality rate was high even after successful PCI (22 %) or CABG (50 %) and increased to as much as 100 % in case of unsuccessful PCI (16, 17). Although, in our series of TA-TAVR we did not report this type of complication, in our institute there is always stand-by an invasive cardiologist, who in cases of emergency can be called to intervene with minimal time delay. In complicated cases, or if coronary flow is not restored within a few minutes of the attempted PCI, might be a change of the therapeutic strategy (cardiopulmonary bypass, CABG) necessary.

On the other hand, in our institute a parallel TF-TAVR program is running by the invasive cardiologists. With the same concept as before, there is an on-site cardiac surgical unit service available in order to cover for complications during and after TF-TAVR. We are in an era of increasing numbers of TF-TAVR (over 90 % of the TAVR procedures) where the TA access is reserved for patients with poor vascular status as a second choice procedure (18, 19), and the cardiac surgeons cannot be left behind. They can be a part of the TF-TAVR as stand-by surgeons, even though they would not be directly involved in the procedure.

In this study, we reported our experience of TA TAVR performed exclusively by cardiac surgeons. Five year and 30-day mortality were 9.3 % and 1.1 %, respectively. Our results are comparable to the others groups results where a heart team with the presence of an invasive cardiologist performed the procedures. The 30-day mortality of 1.1 % was lower than in a Canadian registry (10.4 %) (7), SOURCE (8.5 %) (20), a FRANCE registry (12.7 %) (21), a German registry (8.2 %) (22), and the Italian registry (5.4 %) (23). A probable explanation for the higher 30-day mortality with the transapical access in other centers may be the learning curve that might be prolonged with the transapical procedure.

The 5 year mortality in our study was 9.3 %. Thourani et al (9) reported 7.4 % and 11.7 % mortality in high-risk and inoperable patients, respectively.

Post implantation paravalvular leak is believed to be an independent predictor of mortality, with increased morbidity and mortality in patients with greater than mild (4, 23). In our study only one (1.1 %) had grade 3 paravalvular leak. In contrast Thourani et al (9) reported a 2.2 % incidence of moderate or severe paravalvular leak. Our result is comparable to the PARTNER trial, in which there was moderate or severe paravalvular aortic regurgitation in 11.8 % of inoperable patients and 12.2 % in high-risk patients (1, 2). At follow-up, paravalvular aortic regurgitation remained stable without significant worsening in both cohorts (1, 2). In our report in the intermediate term period no patient presented with moderate or severe paravalvular aortic valve leak.

We observed a significant increase in the left ventricular ejection fraction and a significant decrease in the left ventricular end-diastolic diameter after the procedure. Other authors presented similar results (24, 25) and our findings concur with the PARTNER trial finding that included patients with left ventricular dysfunction between 40–50 % (1, 2).

The postprocedural recovery of the left ventricle is not affected by the technique (transfemoral or non-transfemoral) of the TAVR but is determined by different predictors like baseline ejection function less than 35 % (25, 26).

The present study is limited by being observational and retrospective in nature. There is potential selection bias of patients because of the specific referral pattern to the institution and unique selection criteria of the cardiologists and surgeons. This study is also limited by the selection of patients categorized as high risk or inoperable, inherently putting this population at higher operative risk. Moreover, there is no control group (procedures when a cardiologist was involved) in order to compare the outcomes. Finally, based on our results we confirm in the conclusions the null hypothesis that outcomes are equally good with or without an interventional cardiologist as part of the heart team. This, may be questioned for potential type II statistical error due to the relatively low number of patients (97 patients) that took part in this study.

In conclusion, our experience demonstrates that TA TAVR can be performed only by cardiac surgeons, with on site interventional cardiology support safely and successfully with low and comparable postoperative mortality and rate of complications. We observed a significant recovery of the left ventricle after the TA TAVR.

Learning points

Transapical transcatheter aortic valve replacement can be performed safely with low postoperative morbidity and mortality in high risk patients, exclusively by cardiac surgeons with stand-by invasive cardiology support.

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