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Comparison of the surgical and transcatheter aortic valve replacement in high-risk patients

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ABSTRACT

Introduction: Transcatheter aortic valve implantation (TAVI) has evolved as an alternative method for surgical valve replacement in high-risk patients. Initially the transfemoral (TF) approach was used, later the transapical (TA) approach was adopted as an option for selected patients. The aim of our study was to compare the safety and anatomical and functional success of TAVI procedures with surgical aortic valve replacement (SAVR).
Material and methods: The study included 45 consecutive high-risk patients with symptomatic severe aortic stenosis indicated for aortic valve intervention who met the entry criteria (age > 75 years; logistic EuroSCORE > 15%). The patients were allocated to one of three groups according to the type of procedure: SAVR (n = 15), TAVI TA (n = 15), and TAVI TF (n = 15). The groups did not differ in their preoperative characteristics except for myocardial infarction, which was more common in the TAVI groups. The Edwards Sapien valve was implanted in the TAVI patients and Edwards Perimount bioprosthesis was used in the SAVR patients. The TA approach was used in patients who were not eligible for the TF approach.
Results: All procedures were technically successful. The prostheses used in the SAVR group were smaller in size than those implanted in the TA and TF groups (SAVR, 22.2 [21.7; 22.8]; TA, 24.0 [23.6; 24.3]; TF, 25.0 [24.6; 25.3]. The TA group patients were exposed to radiation for a shorter period and received a larger amount of contrast medium (TA, 9.7 [9.0; 10.5] min and 278.3 (238.5; 318.1) ml; TF, 15.0 [13.7; 16.4] min, 200.7 [179.2; 222.1] ml).There were no statistically significant differences in the duration of procedures, stay in the intensive care unit and in the hospital, and intra- and post-operative complications among the groups. Early mortality (30 days) was 2.2%. One patient died of clostridium sepsis on day 12 (early mortality, 2.2%). Another patient died due to the multi-organ failure on the 58th day of hospital stay. Five other patients died during one-year follow-up (one-year survival rate, 86.3%). The functional class highly improved in all the patients, of whom 80% were with NYHA classes I or II.
Conclusion: Our results show that TAVI is a safe method for treatment of aortic stenosis in high-risk patients and its early results are comparable with surgical aortic valve replacement. The TF and TA approaches are equally efficient, with similar outcomes and complication rates. Provided these results are confirmed at long-term follow-up, it can be assumed that the indication criteria for TAVI approaches will expand.

SOUHRN

Úvod: Transkatetrová implantace aortální chlopně (TAVI) se objevila jako alternativní metoda pro chirurgickou náhradu chlopně u vysoce rizikových nemocných. Původní transfemorální přístup (TF) byl pro vybranou skupinu nemocných doplněn o přístup transapikální (TA). Cílem naší studie bylo porovnání TAVI a chirurgické náhrady aortální chlopně (SAVR), co se týče bezpečnosti a anatomické i funkční úspěšnosti.

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Klíčová slova:
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Soubor nemocných a metodika: Do studie bylo zařazeno 45 po sobě jdoucích pacientů s významnou symptomatickou aortální stenózou, kteří byli indikováni k výkonu na aortální chlopni a splňovali vstupní kritéria (věk nad 75 roků a logistické EuroSCORE 15%). Pacienti byli rozděleni do tří skupin podle typu výkonu: klasická operace (SAVR, n = 15), TAVI TA přístupem (n = 15) a TAVI TF přístupem (n = 15). V předoperačních charakteristikách se jednotlivé skupiny mezi sebou nelišily s výjimkou prodělaného infarktu myokardu, který byl častější v TAVI skupinách. U klasicky operovaných pacientů byla použita bioprotéza Edwards Perimount, u TAVI přístupů chlopeň Edwards Sapien (Edwards Lifesciences, Inc., Irvine, California). TA přístup byl zvolen u nemocných nevhodných pro TF implantaci.
Výsledky: Všechny výkony byly technicky úspěšné. Při chirurgické implantaci byly použity menší velikosti protéz než u TAVI přístupů (SAVR, 22,2 [21,7; 22,8]; TA, 24,0 [23,6; 24,3]; TF, 25,0 [24,6; 25,3]). U TA přístupu byla kratší doba záření a větší množství spotřebované kontrastní látky (9,7 [9,0; 10,5], min resp. 278,3 [238,5; 318,1] ml) oproti TF přístupu (15,0 [13,7; 16,4] min, 200,7 [179,2; 222,1] ml). Mezi všemi skupinami nebyl statisticky významný rozdíl v trvání operace, době pobytu na JIP ani v době hospitalizace. Statisticky významný rozdíl nebyl zjištěn ani ve výskytu per- a pooperačních komplikací. Časně po operaci (do 30 dnů) zemřel jeden nemocný na klostridiovou sepsi (časná mortalita 2,2 %). Jeden další nemocný zemřel během hospitalizace (58. den na multiorgánové selhání). Během ročního sledování zemřelo dalších 5 nemocných (roční přežívání 86,3%). U všech nemocných se výrazně zlepšila jejich funkční třída, 80 % z nich bylo NYHA I nebo II.
Závěr: Naše zkušenosti ukázaly, že TAVI je bezpečná metoda léčby aortální stenózy u vysoce rizikových nemocných a její časné výsledky jsou plně srovnatelné s klasickou, tzn. chirurgickou náhradou aortální chlopně. Transfemorální i transapikální přístupy jsou stejně účinné a vykazují podobné výsledky i četnost komplikací. Pokud se při dlouhodobém sledování tyto výsledky potvrdí, lze předpokládat její rozšíření i do méně rizikových skupin.

Introduction

Until recently, surgical valve replacement was the only treatment for symptomatic aortic stenosis. Although this method has achieved excellent results, for certain groups of patients (those at advanced age or with serious co-morbidities) it could present an increased risk of severe complications or even death. However, such patients could benefit from a less invasive method, such as transcatheter aortic valve implantation (TAVI). The Sapien valve (Edwards Lifesciences, Inc., Irvine, California) is an expandable valve made of bovine pericardium which is delivered into the target site by means of a catheter. Calcified leaflets of the existing valve are pushed laterally towards the annulus and the new valve is firmly anchored in them. This procedure can be carried out through either the retrograde transfemoral (TF) or the antegrade transapical (TA) approach. The aim of this study was to ascertain the safety of the TAVI procedure and to compare its outcomes with those of surgical aortic valve replacement (SAVR).

Material and methods

The study comprised 45 patients with symptomatic severe aortic stenosis in whom surgical valve replacement was considered to be associated with high risk, as assessed by the logistic EuroSCORE [1]. The contraindications included a bicuspid aortic valve, ischaemic heart disease requiring revascularization, left ventricular ejection fraction ≤ 20% and severe (3+) mitral or aortic regurgitation. Also, patients with serious co-morbidities and an estimate of life expectancy less than three years were not considered. The multidisciplinary team that included cardiac surgeons, interventional cardiologists, and cardiologists specialized in echocardiography assessed all the patients and decided to recommend the specific procedure to each patient. SAVR was not recommended in patients with serious clinical co-morbidities that are not measurable by EuroSCORE (worse mental status, limited physical activity etc.). In the TAVI groups TF approach was considered as the first choice. According to the procedure used, the patients were assigned to the SAVR (n = 15), TF (n = 15) and TA (n = 15) groups

The characteristics of the patients before the procedure are presented in Table 1. This shows that the group consisted of elderly patients at high surgical risk (average age, 82.0 ± 4.5 years; logistic EuroSCORE, 22.3 ± 7.6), with more women than men and with a high number of diabetic patients. Atherosclerotic coronary artery disease (CAD) was diagnosed in 45% of them (18% of the patients with severe stenoses had undergone revascularization, seven patients by means of percutaneous intervention and one patient by coronary artery bypass grafting). CAD did not influence the choice between SAVR and TAVI. Renal failure was diagnosed by biochemical tests in 29%. There were no significant differences in the recorded characteristics among the groups, with the exception of myocardial infarction which occurred more often in both TAVI groups.

All patients were examined according to an established protocol. In addition to routine clinical and laboratory examination, this included CT angiography, transoesophageal echocardiography (TEE), cardiac catheterization, coronarography, aortography, and pelvic arterial angiography. The findings were assessed by a multidisciplinary team of cardiologists and cardiac surgeons who decided the type of procedure to be performed in the patient. In TAVI procedures, the TF approach was given priority. The TA approach was used when femoral artery diameters were not large enough, severe calcifications were present or pelvic and femoral arteries were affected by serious atherosclerotic disease. All

Table 1 – Pre-operative patient characteristics.

	Total number of patients = 45	SAVR group n = 15	TA group n = 15	TF group n = 15	*p*
Age	82.0 (80.8; 83.2)	82.1 (81.2; 82.9)	80.3 (79.0; 81.6)	83.6 (82.4; 84.8)	0.132
EuroSCORE	22.3 (20.4; 24.3)	18.6 (17.3; 19.9)	23.5 (21.2; 25.9)	24.9 (23.0; 26.7)	0.058
NYHA					
II	6 (13.3%)	3 (20.0%)	1 (6.7%)	2 (13.3%)	0.572
III	29 (64.4%)	10 (66.7%)	11 (73.3%)	8 (53.3%)	
IV	10 (22.2%)	2 (13.3%)	3 (20.0%)	5 (33.3%)	
Body weight	71.6 (68.3; 74.8)	74.5 (71.7; 77.4)	73.2 (70.0; 76.4)	66.9 (63.4; 70.4)	0.211
Body height	161.0 (158.1; 163.9)	161.5 (159.1; 163.9)	160.3 (157.1; 163.5)	161.2 (158.0; 164.4)	0.961
Body mass index	27.6 (26.5; 28.8)	28.7 (27.5; 29.9)	28.5 (27.5; 29.5)	25.7 (24.6; 26.8)	0.106
Men/women	14/31 (31.1/68.9%)	6/9 (40.0/60.0%)	4/11 (26.7/73.3%)	4/11 (26.7/73.3%)	0.666
Obesity	14 (31.1%)	5 (33.3%)	6 (40.0%)	3 (20.0%)	0.472
Hyperlipidemia	19 (42.2%)	5 (33.3%)	8 (53.3%)	6 (40.0%)	0.528
Hypertension	35 (77.8%)	11 (73.3%)	11 (73.3%)	13 (86.7%)	0.577
Smoking habits	5 (11.1%)	1 (6.7%)	1 (6.7%)	3 (20.0%)	0.430
Diabetes mellitus	19 (42.2%)	6 (40.0%)	7 (46.7%)	6 (40.0%)	0.913
CAD					
1 vessel	10 (22.7%)	3 (20.0%)	3 (21.4%)	4 (26.7%)	0.097
2 vessels	7 (15.9%)	1 (6.7%)	5 (35.7%)	1 (6.7%)	
3 vessels	3 (6.8%)	0 (0.0%)	2 (14.3%)	1 (6.7%)	
Main stem	5 (11.4%)	1 (6.7%)	4 (28.6%)	0 (0.0%)	0.029*
Status post MI	7 (15.6%)	0 (0.0%)[a]	3 (20.0%)[b]	4 (26.7%)[b]	0.039*
Status post PCI	7 (15.6%)	2 (13.3%)	2 (13.3%)	3 (20.0%)	0.849
Status post CABG	1 (2.2%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0.326
Peripheral vascular disease	1 (2.2%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0.326
Status post PAR	3 (6.7%)	1 (6.7%)	0 (0.0%)	2 (13.3%)	0.233
TIA/CVA	7 (15.6%)	3 (20.0%)	2 (13.3%)	2 (13.3%)	0.849
Renal failure	13 (28.9%)	4 (26.7%)	5 (33.3%)	4 (26.7%)	0.899

CABG – coronary artery bypass grafting; CAD – coronary artery disease; CVA – cerebrovascular accident; MI –myocardial infarction; PAR – peripheral arterial reconstruction; PCI – percutaneous coronary intervention; TIA – transient ischaemic attack.
* Significant difference.
[a, b] – index numbers denote statistical differences between two patient groups (post hoc test with Bonferroni correction).

Table 2 – Surgical characteristics.

		Total number of patients = 45	SAVR group n = 15	TA group n = 15	TF group n = 15	*p*
Valve size (mm)	20	4	4			
	21	4	4			
	23	18	3	10	5	
	25	3	3			
	26	15		5	10	
	27	1	1			
Mean		23.7 (23.2; 24.2)	22.2 (21.7; 22.8)[a]	24.0 (23.6; 24.3)[b]	25.0 (24.6; 25.3)[b]	< 0.001*
Operative time (min)		148.9 (139.5; 158.9)	143.8 (135.3; 152.8)	137.3 (130.6; 144.3)	167.2 (155.2; 180.3)	0.078
Radiation exposure time (min)		12.1 (10.5; 13.9)	–	9.7 (9.0; 10.5)	15.0 (13.7; 16.4)	< 0.001*
Contrast medium volume (ml)		239.5 (193.7; 285.3)	–	278.3 (238.5; 318.1)	200.7 (179.2; 222.1)	< 0.001*

* Significant difference.
[a, b] – index numbers denote statistical differences between two patient groups (post hoc test with Bonferroni correction).

the procedures were carried out in the hybrid operating theatre.

TAVI procedures were performed by the technique described in the literature [2,3] with the use of Edwards Sapien or Sapien XT aortic valves. The definitive size of the valve to be implanted was determined on the basis of intra-operative TEE, with a 23-mm valve for aortal annuli 17 to 21 mm in diameter, and a 26-mm valve for annuli 22 to 25 mm in diameter. When an annular diameter of 21 to 22 mm made the decision difficult, the final

decision was based on the degree of regurgitation of contrast medium at angiography during balloon dilatation of the valve. After the procedure, the patients received an anti-platelet therapy with acetylsalicylic acid (100 g daily) and clopidogrel (75 g daily).

SAVR was carried out in cardiopulmonary bypass during cardiac arrest with crystalloid cardioplegia. The bioprosthetic valve was sutured in a supra-annular position, using sutures with pledgets from the ventricular side. The patients received warfarin therapy for three months post-operatively. Their follow-ups at regular intervals included clinical examination, laboratory tests and transthoracic echocardiography.

Statistical analysis

Continuous parameters were described using the mean and a 95% confidence interval, and categorial parameters were described by absolute and relative numbers. In case of non-normal data distribution, logarithmic transformation was applied and data were described by the geometric mean with a 95% confidence interval. The significance of differences amongst the groups of patients was tested by ANOVA and ML χ^2 tests for continuous and categorial parameters, respectively. In the case of a significant difference amongst all groups, an analysis of homogenous patient groups was performed using a post hoc test with the Bonferroni correction for multiple comparisons. The difference between time points was evaluated using the t-test for paired values. The level of statistical significance was set at $p < 0.05$. All analyses were carried out with the software SPSS 19.0.1 (IBM, 2010).

Results

No complication was recorded during surgical aortic valve replacement and all TAVI procedures were technically successful. The bioprosthetic valves used at SAVR were smaller in size than those at TAVI. The TF approach was associated with a longer time of radiation exposure and a lower contrast medium volume used than the TA approach (Table 2).

Procedural complications were found in seven patients (Table 3). In two patients, a rapid ventricular stimulation during the implantation procedure resulted in ventricular fibrillation requiring a short-term indirect cardiac massage followed by external defibrillation. In one TF group patient, the valve failed to be pushed through the sheath and the whole device had to be removed; however, the valve remained undamaged and was implanted by means of another catheter. In one patient, implantation through the TF approach led to pelvic artery rupture. This patient was urgently operated on and the ruptured artery was replaced with a vascular prosthesis. One TA group patient experienced persisting post-operative grade II regurgitation which, during the post-operative period, slightly progressed with aggravation of symptoms. The patient had to undergo reoperation. During the procedure it appeared that the valve was implanted at a position that was too low and a part of the native leaflet folded over the implanted valve and thus interfered with diastolic valve closure. The Sapien valve was removed and the native valve was replaced with a conventional bioprosthetic valve.

The duration of mechanical ventilation, and the length of stay at the intensive care unit and in the hospital did not differ among the groups. More than half of the patients had at least one post-operative complication, with similar figures in all groups (Table 4). Six patients had acute renal failure with the necessity of using renal replacement therapy. Six patients experienced respiratory failure and accordingly had to undergo repeated intubation or remain on mechanical ventilation for more than three days. Four patients had neurological complications. Three patients had reoperations, one from the SAVR (due to tamponade) and two from the TA group; out of these, one was the patient with valve replacement described above and the other had reoperation for bleeding from the cardiac apex.

One patient after SAVR died of clostridium sepsis in the early post-operative period (on day 12). One very high risk patient (EuroSCORE, 42) in the TF group died due to multiorgan failure during the initial hospital stay on day 58. Four more patients died due to cardiac reasons, though with well-functioning aortic valves, on post-operative days 41, 235, 274 and 305, respectively. One patient died of a cerebrovascular accident on day 69 after procedure.

Echocardiographic examination before surgery did not show any differences among the groups. After surgery, a significant decrease in aortic valve gradients and an increase in the aortic valve area were recorded in comparison with the pre-operative values in all groups. These

Table 3 – Intra-operative complications.

	Total number of patients = 45	SAVR group n = 15	TA group n = 15	TF group n = 15	*p*
Total	7 (15.6%)	0	3 (20.0%)	4 (26.7%)	0.305
Ventricular fibrillation	2 (4.4%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	0.434
AoR (grade 2 and more)	2 (4.4%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	0.434
Local (groin, apex, sternum)	1 (2.2%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0.326
Device failure	1 (2.2%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0.434
Valve malposition	1 (2.2%)	0	1 (6.7%)	0	0.434

AoR – aortic regurgitation.

Table 4 – Postoperative results.

	Total number of patients = 45	SAVR group n = 15	TA group n = 15	TF group n = 15	*p*
MPV duration (hours)	8.67 (7.17; 10.17)	10.6 (9.0; 12.1)	7.89 (6.71; 9.08)	7.46 (5.76; 9.16)	0.321
ICU stay (days)	7.69 (6.40; 9.21)	7.76 (6.81; 8.82)	8.60 (6.92; 10.63)	6.81 (5.57; 8.28)	0.671
Hospital stay (days)	14.4 (12.6; 16.3)	13.7 (12.4; 15.1)	15.3 (13.3; 17.7)	14.1 (12.2; 16.3)	0.815
Complications	24 (53.3%)	7 (46.7%)	11 (73.3%)	6 (40.0%)	0.145
Fever	10 (22.2%)	4 (26.7%)	5 (33.3%)	1 (6.7%)	0.147
ARI	6 (13.3%)	2 (13.3%)	3 (20.0%)	1 (6.7%)	0.549
Respiratory failure	6 (13.3%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	1.000
Impaired wound healing	5 (11.4%)	0 (0.0%)[a]	1 (6.7%)[a]	4 (26.7%)[b]	0.036*
Reoperation	3 (6.6%)	1 (6.7%)	2 (13.3%)	0 (0.0%)	0.233
TIA/CVA	4 (8.8%)	1 (6.7%)	1 (6.7%)	2 (13.3%)	0.771
Mortality					
Early (up to 30 days)	1 (2.2%)	1 (6.7%)	0	0	0.326
Annual	6 (13.3)	2 (13.3%)	2 (13.3)	2 (13.3%)	1.000

ARI – acute renal insufficiency; CVA – cerebrovascular accident; ICU – intensive care unit; MPV – mechanical pulmonary ventilation; TIA – transient ischaemic attack.
* Significant difference.
[a, b] – index numbers denote statistical differences between two patient groups (post hoc test with Bonferroni correction).

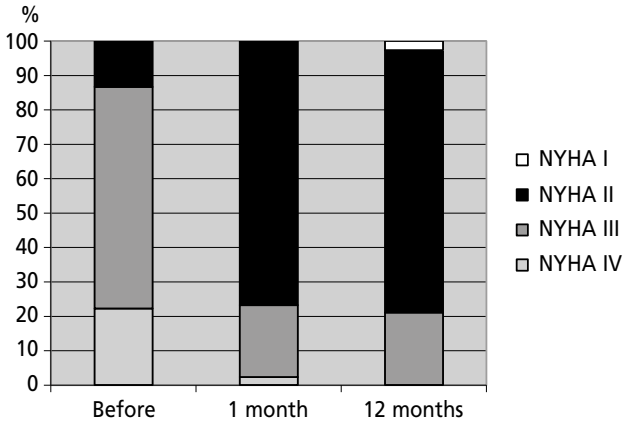

Fig. 1 – Patients' functional status before and after surgery.

values remained unchanged during follow-up. Neither the ejection fraction nor the size of the left ventricle was significantly changed after surgery. Both the interventricular septum and the posterior left ventricular wall significantly decreased in thickness. Grade II regurgitation due to periprosthetic leakage was found in two patients one month after surgery, but this had no effects on symptoms or left ventricular function. Regurgitation in the remaining patients was not more than grade I (Table 5). The New York Heart Association (NYHA) functional classification improved after surgery, with nearly 80 % of the patients having NYHA classes I or II (Fig. 1).

Discussion

The transcatheter aortic valve implantation (TAVI) was firstly used nearly ten years ago. Thanks to huge advances in technology allowing for much improvement [4], the numbers of patients with TAVI have grown exponentially and today they amount to tens of thousands. Two types of valves are available on the market. One is a self-expanding valve prosthesis suitable only for the retrograde transarterial approach (CoreValve, Medtronic Inc, Minneapolis, Minn), the other is a balloon expandable valve made of bovine pericardium (Edwards Sapien) which can be used for both the retrograde transfemoral and the antegrade transapical approach. Because of its greater versatility, the Edwards Sapien valve was chosen for our study. Our decision was supported by the literature data showing that TAVI, with both the TF and the TA approaches, makes it possible to treat 50% to 76% of the patients who have been inoperable by SAVR because of a high surgical risk [5,6]. These surgically inoperable patients have very poor prognosis, even if in the Placement AoRtic TraNscathetER (PARTNER) Trial, the Cohort B patients showed very good early outcomes, but some doubts about their reproducibility have appeared later [7,8].

A decision for either SAVR or TAVI should be made by a multidisciplinary team and should be based on a thorough evaluation of the patient's health status, and particularly co-morbidities. When indicating TAVI, the patient's life expectancy should also be taken into account since, at present, the cost of valves is enormous and therefore limits their use in our circumstances. A judicious selection of patients for TAVI is the reason why Czech centres can report better results than are those of large international studies [9–11]. In this study there was no early mortality and one-year survival rate was 86.3%, while evidence from the relevant literature suggests an early mortality rate up to 10% and one-year survival rate of about 80% [12–15]. Other studies describe even higher mortality. In the Vancouver study, for instance, the early mortality rate was 16.9% and the two-year survival rate was 66.3% [16]. With growing experience, however, clinical outcomes are improving [17].

Table 5 – Echographic parameters before surgery and at 1 and 12 months after surgery.

	Total number of patients = 45	SAVR group n = 15	TA group n = 15	TF group n = 15	*p*
Peak gradient (mmHg)					
Before operation	84.6 (78.6; 90.6)	87.7 (80.2; 95.1)	79.9 (75.3; 84.6)	86.2 (80.3; 92.1)	0.638
1 month	20.2 (18.5; 21.8)	23.2 (21.2; 25.1)	19.9 (18.8; 21.0)	17.9 (16.2; 19.5)	0.091
12 months	19.8 (17.9; 21.7)	21.5 (19.2; 23.8)	19.9 (18.2; 21.5)	17.4 (15.6; 19.2)	0.430
Before × 1 month	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
1 month × 12 months	0.455	0.415	0.690	0.970	
Before × 12 months	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
Mean gradient (mmHg)					
Before operation	51.2 (47.2; 55.2)	53.0 (48.1; 57.9)	49.7 (46.7; 52.8)	50.8 (46.7; 54.9)	0.848
1 month	10.7 (9.7; 11.7)	12.0 (10.9; 13.1)	10.7 (10.0; 11.4)	9.5 (8.5; 10.5)	0.229
12 months	10.1 (9.1; 11.2)	11.0 (9.7; 12.3)	10.1 (9.4; 10.9)	9.00 (8.11; 9.89)	0.494
Before × 1 month	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
1 month × 12 months	0.134	0.309	0.156	0.782	
Before × 12 months	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
AVA (cm^2)					
Before operation	0.61 (0.56; 0.66)	0.69 (0.64; 0.74)	0.60 (0.55; 0.64)	0.54 (0.49; 0.59)	0.092
1 month	1.93 (1.82; 2.03)	2.01 (1.88; 2.14)	1.82 (1.74; 1.89)	1.95 (1.85; 2.05)	0.458
12 months	1.78 (1.68; 1.89)	1.70 (1.58; 1.82)	1.79 (1.69; 1.90)	1.87 (1.79; 1.95)	0.623
Before × 1 month	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
1 month × 12 months	0.051	0.072	0.986	0.276	
Before × 12 months	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
AVAi (cm^2/m^2)					
Before operation	0.34 (0.32; 0.37)	0.39 (0.36; 0.42)	0.33 (0.31; 0.35)	0.31 (0.28; 0.34)	0.112
1 month	1.10 (1.05; 1.16)	1.14 (1.07; 1.21)	1.04 (0.99; 1.08)	1.13 (1.09; 1.18)	0.402
12 months	1.01 (0.94; 1.07)	0.91 (0.85; 0.97)	1.01 (0.93; 1.08)	1.12 (1.07; 1.17)	0.160
Before × 1 month	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
1 month × 12 months	0.090	0.022*	0.820	1.000	
Before × 12 months	< 0.001*	< 0.001*	< 0.001*	< 0.001*	
LV EF (%)					
Before operation	55.7 (52.5; 59.0)	58.0 (54.7; 61.3)	56.6 (53.8; 59.4)	52.6 (49.0; 56.2)	0.482
1 month	57.5 (54.0; 60.9)	62.1 (59.2; 64.9)	55.7 (52.3; 59.2)	55.1 (51.3; 59.0)	0.330
12 months	58.2 (55.7; 60.8)	58.8 (55.9; 61.8)	58.4 (56.0; 60.9)	57.2 (54.8; 59.6)	0.924
Before × 1 month	0.182	0.107	0.770	0.244	
1 month × 12 months	0.436	0.145	0.561	0.474	
Before × 12 months	0.560	0.835	0.722	0.616	
LVEDD (mm)					
Before operation	46.6 (45.1; 48.1)	47.5 (46.1; 48.9)	45.1 (43.9; 46.4)	47.2 (45.3; 49.1)	0.512
1 month	46.1 (44.5; 47.6)	45.4 (43.9; 46.9)	45.9 (44.5; 47.3)	46.9 (45.1; 48.6)	0.809
12 months	44.6 (42.9; 46.3)	45.5 (43.5; 47.6)	43.4 (41.7; 45.0)	45.1 (43.9; 46.3)	0.665
Before × 1 month	0.450	0.090	0.281	0.755	
1 month × 12 months	0.353	0.921	0.136	0.940	
Before × 12 months	0.168	0.182	0.369	0.901	
LVESD (mm)					
Before operation	33.1 (31.1; 35.1)	33.0 (31.0; 35.0)	31.7 (30.1; 33.2)	34.7 (32.3; 37.0)	0.569
1 month	32.0 (30.1; 34.0)	30.3 (28.5; 32.1)	32.4 (30.6; 34.3)	33.1 (30.9; 35.4)	0.612
12 months	30.9 (29.1; 32.8)	31.5 (29.1; 33.8)	30.1 (28.4; 31.7)	31.5 (30.2; 32.8)	0.846
Before × 1 month	0.162	0.064	0.502	0.204	
1 month × 12 months	0.940	0.429	0.180	0.460	
Before × 12 months	0.209	0.353	0.471	0.743	
IVS (mm)					
Before operation	15.3 (14.8; 15.7)	14.6 (14.2; 15.0)	15.6 (15.3; 15.9)	15.6 (15.0; 16.2)	0.223
1 month	13.9 (13.4; 14.3)	13.8 (13.4; 14.3)	13.7 (13.2; 14.2)	14.0 (13.5; 14.5)	0.922
12 months	13.4 (12.9; 13.8)	13.2 (12.8; 13.6)	13.4 (13.1; 13.8)	13.4 (12.9; 13.9)	0.947
Before × 1 month	< 0.001*	0.188	0.005*	0.010*	
1 month × 12 months	0.033*	0.120	0.351	0.260	
Before × 12 months	< 0.001*	0.015*	< 0.001*	0.031*	
PW (mm)					
Before operation	13.7 (13.2; 14.1)	13.4 (13.1; 13.7)	13.6 (13.1; 14.0)	14.0 (13.5; 14.5)	0.646
1 month	13.2 (12.8; 13.5)	12.9 (12.6; 13.3)	13.2 (12.8; 13.6)	13.3 (13.0; 13.7)	0.766
12 months	12.2 (11.9; 12.5)	11.8 (11.5; 12.1)	12.6 (12.4; 12.7)	12.2 (11.9; 12.4)	0.166
Before × 1 month	0.034*	0.124	0.454	0.125	
1 month × 12 months	< 0.001*	0.026*	0.050	0.003*	
Before × 12 months	< 0.001*	0.002*	0.024*	0.009*	

AVA – aortic valve orifice area; AVAi – indexed aortic valve orifice area; IVS – interventricular septum thickness; LVEDD – left ventricular end-diastolic diameter; LV EF – left ventricular ejection fraction; LVESD – left ventricular end-systolic diameter; PW – posterior wall thickness.
* Significant difference.

In TAVI procedures, the TF approach is usually described as the method of choice because it is less invasive. On the other hand, it needs more manipulation with catheters in the aorta and therefore carries a higher risk of damage to the vascular wall or of embolization with corpuscular material. The TA approach is used when the patient has stenotic, calcified or tortuous pelvic arteries. Both approaches are reported to be used at almost the same frequency although some centres may prefer one of the approaches over the other [11,14,18]. Implantation of the valve is less technically demanding via the TA approach because the device is shorter and thus easier to manipulate. This is a probable explanation of a tendency to shorter operative time and exposure to radiation for a shorter time, as recorded in our study. Certain concern about potential injury to the left ventricular wall and a subsequent decrease in its systolic function in the TA approach was not found to be justified. The benefits of eliminating aortic stenosis much exceed the threat of minor injury to the left ventricular apex and will be manifested by a post-operative increase in ejection fraction [19]. However, certain caution should always be adopted because serious complications, such as apical pseudoaneurysm, have been described [20].

The overall short-term results, in terms of early complications and mortality, in the two TAVI groups are comparable, which is in accordance with the relevant literature data. When the outcomes were different, it was due to different pre-operative risk factors and/or intra-operative complications [18]. This fact is documented by the data from the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry recording, in a group of 1 038 patients, a higher mortality rate in patients treated with use of the TA approach. However, these patients suffered from more co-morbidities and had a significantly higher logistic EuroSCORE [14].

A comparison of the two procedures (surgical vs transcatheter) in a randomized trial has so far been reported in one prospective study only. In the PARTNER trial, Cohort A included high-risk patients with severe aortic stenosis assigned to undergo either TAVI or SAVR. The primary endpoint was death from any cause at one year and, according to this criterion, the TAVI technique was not inferior to traditional surgical treatment. Early mortality was 3.4% in the TAVI group and 6.5% in the surgical group; one-year mortality was 24.2% in the TAVI and 26.8% in the surgical group. However, there were differences in early complications. The TAVI group had a significantly higher rate of major vascular complications, and the surgical group had higher rates of major bleeding events and new-onset arterial fibrillation [21]. The results of our study assessed by the survival rate are in full agreement with those of the PARTNER trial. The one-year mortality rate was the same in all our groups, but on the whole was lower (13.3%) than in the PARTNER trial.

In our study, renal failure requiring a temporary renal replacement therapy was the most frequent post-operative complication. It appeared particularly in the first patients in whom larger volumes of contrast medium were used. After this experience, the necessary medium amount was reduced to minimum, which resulted in fewer cases of renal failure. Central nervous system involvement was the most serious complication. It was slightly more frequent in the TAVI procedure, particularly with the TF approach, but the difference, as compared with the surgical procedure, was not significant. This is consistent with the literature data [21].

Echographic examination showed a decrease in aortic valve gradients and an increase in the aortic valve orifice area. Our results confirmed the literature information on very low gradients in TAVI implantation even though the leaflets of the native calcified valve remained in place and were merely pushed aside with a bioprosthetic valve. The gradients were lower than in surgical replacement, in which the whole calcified valve is removed, but the difference was not significant. This can probably be explained by a rigid annulus of the bioprosthesis which, even with supra-annular implantation, presents an obstruction to blood flow. The same results have been reported by Clavel et al. [22] in a larger patient group; the mean and peak gradient values (10 mmHg and 13 mmHg, respectively) in their study correspond with ours.

Study limitation

Due to its focus on the population of the Czech Republic the study is limited in the sample size and subsequently in its statistical power; this fact was taken into consideration during the interpretation and discussion of statistical results.

Conclusions

Our results, in agreement with the literature data, show that TAVI is a safe method of treating aortic stenosis in high-risk patients. Its early outcomes are very good and fully comparable with the traditional surgical aortic valve replacement. The use of either a TF or a TA approach is equivalent. The overall results and frequency of complications are also similar in both methods [23]. If a long-term follow-up confirms these results, it can be anticipated that the indications for TAVI will expand to include lower-risk patients [24]. In order to be truly beneficial to patients indicated for it, the transcatheter valve therapy needs to keep to the guidelines published, in a joined expert consensus document, by the American College of Cardiology Foundation and the Society of Thoracic Surgeons in 2011 [8]. This document recommends the establishment of regional heart centres specializing in TAVI procedures, existence of multidisciplinary, well cooperating specialist teams, and establishment of central data registries for long-term result reporting. This will allow for result interpretation after consensus of all experts and the establishment of relevant educational programmes in this field. In the Czech Republic, most of the recommendations have been fulfilled or are currently implemented (with the exception of a systematic educational programme), which testifies to a high standard of health care in cardiology and cardiac surgery.

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