



## Úvodník | Editorial

# Transcatheter aortic valve replacement – 10 years of clinical experience

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## INFORMACE O ČLÁNKU

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## Introduction

Surgical aortic valve replacement used for patients with aortic stenosis reduces symptoms and improves survival, operative mortality is generally low. But about one third of patients with severe aortic stenosis are not candidates for surgical replacement due to older age, left ventricular dysfunction or other comorbidities. Therefore, availability of aortic valve replacement using transcatheter technology opened quite a new option for improvement of lives of patients with aortic valve stenosis. This procedure (transcatheter aortic valve implantation – TAVI) was introduced by A. Cribier in 2002 [1], since then started the widespread use of this procedure, used for treatment for specific group of high-surgical-risk patients with symptomatic aortic stenosis [2,3]. This year we celebrate ten years of experience with TAVI, over 20 000 cases performed and long list of publications on this topic published. Currently, two TAVI systems are commercially available: the Edwards transcatheter heart valve (THV) Sapien XT system which consists of three bovine pericardial leaflets mounted on low profile Novaflex delivery system – a tubular slotted stainless steel, balloon expandable stent, which is optimally placed in the subcoronary

position. The second is the CoreValve ReValving System which consists of three porcine pericardial leaflets mounted on self-expanding multistage nitinol frame, and housed in low profile percutaneous delivery catheter. The specific feature of CoreValve device is that it is anchored not only within aortic bulb, but extends in the supraco-ronary area, where it is also anchored. Both systems are currently available with low profile delivery catheters, which means that they could be used in majority of patients with aortic stenosis [4]. Procedural success was initially about 80%, in most recent series increased to over 95% [5,6], thirty-day survival from registries is referred between 90–95%.

In this issue of the journal Němec et al. report their results of comparison of the surgical and transcatheter aortic valve replacement in high risk patients [7]. In the small group of 45 patients (mean age 82 years) with severe aortic stenosis they compare three modalities of treatment: 15 patients underwent surgical valve replacement, 30 patients had TAVI – either transfemoral (15 patients) or antegrade transapical (15 patients) approach. Technically, all procedures have been successful, there were seven complications during TAVI, in 30 days after procedure only one patient died due to sepsis after surgical

replacement, one year survival was 86,3%. Authors emphasised, that overall results and frequency of complications were similar in transfemoral as well as in transapical approach. They concluded that TAVI is a safe procedure, with results comparable with surgery in high-risk group of patients with severe aortic stenosis.

Data about TAVI use in the last years are fast growing, and results of the procedure are promising, current experience with TAVI is summarized in this editorial. When focused on available data we can see, that the first and still the only one randomized trial with TAVI is PARTNER Trial [8,9], a lot of information was published from results of several non-randomized studies and registries [10,11].

## PARTNER Trial

PARTNER Trial (Placement of Aortic Transcatheter Valves) was a multicenter randomized clinical trial which compared standard surgical therapy – first part of the trial, or standard non-surgical therapy – second part of the trial – with TAVI procedure. In *the surgical part* of the trial [9], 699 high-risk patients with severe aortic stenosis were randomized to either surgical or catheter transfemoral aortic valve replacement. The rates of death were similar in both groups at 30 days as well as at one-year follow up (6.5% surgery, 3.4% TAVI at 30 days, 26.8% surgery, resp. 24.2% TAVI at 1 year). Main periprocedural adverse events in surgical group were major bleeding and new onset of atrial fibrillation, there was higher stroke rate in TAVI group (3.8% resp. 2.1%). In *the second (non-surgical) part* of the trial [8] authors assigned randomly 358 patients with severe aortic stenosis not suitable for surgery into two groups: it was either standard therapy including balloon aortic angioplasty (performed in 83.8% of patients), or TAVI procedure using transfemoral approach. When compared to standard therapy, patients with TAVI showed significant reduction of mortality from any cause at one year – it was 30.7% in patients with TAVI and 49.7% in standard group (44.6% from cardiovascular causes). When compared to the data of Czech authors, presented in this issue [7], survival rates at one year are lower than in the PARTNER trial (13.3% vs 24.2%).

## Non-randomized studies and registries

Several non-randomized studies and registries documented safety and efficacy of TAVI, they also showed improvement in functional class, quality of life and positive changes in gradient on aortic valve as well as an increase of aortic valve area after TAVI [3,9,12,13]. The success rate rose with increasing experience from initial 75% up to 93–98% in currently referred series [14,15]. The mortality rates are also decreasing with increasing experience of operating teams, 30-day survival is 85–95%, one-year survival rate ranges from 70% to 85%. Predictive for mortality are mainly comorbidities, such as pulmonary hypertension, severe mitral regurgitation, need for hemodynamic support during and after procedure, as well as post-procedural sepsis and chronic kidney disease

[12,16]. Contrary, there are also several conditions which favour TAVI against surgery: TAVI is an excellent alternative to surgical replacement of aortic valve in patients with reduced left ventricular ejection fraction (LVEF), the greater reported increase in LVEF with the TAVI is probably due to better improvement in aortic valve hemodynamics [17]. A possible promising indication of TAVI is catheterization treatment of bioprosthesis which developed degenerative changes. Since bioprosthetic valves are used in elderly patients, who suffer more often from severe comorbidities, TAVI treatment option is a preferred alternative approach and has been already successfully used in this group of patients [18].

## Summary

Transcatheter aortic valve implantation emerged in 2002 as a new modality of treatment in high-surgical-risk patients with severe aortic valve stenosis. Since its introduction TAVI procedure was continually integrated into daily clinical practice and today is becoming the standard of care for symptomatic patients with severe aortic stenosis who are not surgical candidates. When compared to surgical treatment, TAVI showed similar procedural success as well as similar rate of major complications, also survival rates up to one year are comparable. Great importance must be stressed on patients' indications, proper training of operators and close cooperation of cardiologist, surgeons and intensive care professionals. Today, transcatheter valve technology is used not only in aortic stenosis, but also in patients with pulmonary conduit valve dysfunction (Melody transcatheter pulmonary valve), the same Melody valve was also used in stenotic or regurgitant tricuspid valves (off label indication). Other transcatheter procedures are performed for percutaneous mitral valve repair [19]. Those are new challenges for interventional cardiologists, future will show, whether we will be able to use them for the benefit of our patients.

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