

The role of balloon aortic valvuloplasty in the era of transcatheter aortic valve implantation

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Abstract

Balloon aortic valvuloplasty is recommended in patients not suitable for transcatheter aortic valve implantation/aortic valve replacement (TAVI/AVR) or when such interventions are temporarily contraindicated. The number of performed balloon aortic valvuloplasty (BAV) procedures has been increasing in recent years. Valvuloplasty enables the selection of individuals with severe left ventricular dysfunction or with symptoms of uncertain origin resulting from concomitant disorders (including chronic obstructive pulmonary disease [COPD]) who can benefit from destination therapy (AVR/TAVI). Thanks to improved equipment, the number of adverse effects is now lower than it was in the first years after the advent of BAV. Valvuloplasty can be safely performed even in unstable patients, but long-term results remain poor. In view of the limited availability of TAVI in Poland, it is reasonable to qualify patients for BAV more often, as it is a relatively safe procedure improving the clinical condition of patients awaiting AVR/TAVI.

Key words: aortic stenosis, balloon valvuloplasty, TAVI, AVR.

Epidemiology

Patients with moderate or severe valvular defects constitute 2.5% of the general population. This percentage rises with age; for patients > 75 years, it is 13.3% [1]. Aortic valve stenosis is the most common valve defect, constituting 33.9% of native valve defects. The prevalence of aortic stenosis (AS) rises with age; the mean age of patients is 69 years; almost 59% of AS patients are > 70 years old, and

Streszczenie

Balonowa walwuloplastyka zastawki aortalnej (*balloon aortic valvuloplasty* – BAV) to metoda leczenia chorych, u których wykonanie klasycznego zabiegu kardiologicznego (*aortic valve replacement* – AVR) bądź przezcewnikowej wymiany zastawki aortalnej (*transcatheter aortic valve implantation* – TAVI) jest niemożliwe lub czasowo przeciwwskazane. W ciągu ostatnich lat obserwuje się wzrost liczby wykonywanych zabiegów BAV. Zabieg ten pozwala wyselekcjonować chorych z dużym uszkodzeniem lewej komory bądź z objawami niejasnego pochodzenia z powodu chorób współistniejących (w tym przewlekła obturacyjna choroba płuc) rokujących poprawę po leczeniu chirurgicznym lub TAVI. Balonowa walwuloplastyka zastawki aortalnej umożliwia przygotowanie chorych w ciężkim stanie do zabiegu AVR lub TAVI. Obecnie dzięki ulepszeniu sprzętu notuje się znacznie mniej powikłań niż w pierwszych latach po wprowadzeniu tej techniki. Zabiegi BAV są dobrze znoszone nawet przez chorych w stanie ciężkim lub bardzo ciężkim, lecz ich wyniki długoterminowe pozostają słabe. Wobec ograniczonej dostępności TAVI w Polsce uzasadniona wydaje się częstsza kwalifikacja chorych do zabiegu BAV jako relatywnie bezpiecznej procedury, która pozwala poprawić stan kliniczny w grupie chorych oczekujących na AVR lub TAVI.

Słowa kluczowe: stenoza aortalna, balonowa walwuloplastyka, TAVI, AVR.

13.8% are > 80 years old. The most common cause of AS is valve degeneration (> 80% of cases), followed by rheumatic disorders and congenital valve defects [2].

Diagnosis

Aortic stenosis is a chronic, progressive condition. It remains asymptomatic for a long time; during this period, the prognosis of AS patients is similar to that of the general

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population. From the onset of symptoms (exertional dyspnea, chest pain, vertigo, or syncope), the condition is associated with poor prognosis: only 50% of patients survive 2 years, while 20% survive 5 years from the onset of symptoms [3]. The diagnosis of severe aortic stenosis is based mostly on echocardiography. The fundamental parameter for determining the severity of the defect is aortic valve area (AVA) calculated from the continuity equation – area $< 1 \text{ cm}^2$ ($< 0.6 \text{ cm}^2$ per 1 cm^2 body surface area [BSA]) indicates severe AS [4, 5]. Aortic valve area is the parameter that is least dependent on valve flow. Mean valve gradient values of $> 40 \text{ mmHg}$ confirm the presence of severe AS. There is a group of patients in whom the mean valve gradient remains below 40 mmHg despite the presence of a tight constriction in the valve ($\text{AVA} < 1 \text{ cm}^2$). This typically occurs in patients with low left ventricular ejection fraction. Dobutamine stress echocardiography is an examination which allows the physician to differentiate true and pseudo-severe aortic stenosis in this patient group [6].

Aortic valve replacement

As the mean life span increases, the number of patients with severe aortic stenosis continues to rise. It is estimated that the number of AS patients will double within the next 15 years. The gold standard of treatment for symptomatic AS is cardiac surgery. Aortic valve replacement (AVR) is recommended for severe symptomatic AS (IB) and in asymptomatic patients with positive exercise test results (IC) or with lowered left ventricular systolic function after the elimination of other causes (IC); it should be considered in asymptomatic patients with low operative risk, massive calcifications on the valve cusps, maximal values of valve flow increasing by $> 0.3 \text{ m/s/year}$, maximal valve flow of $> 5.5 \text{ m/s}$ (IIaC), in patients with low-flow/low-gradient (LFLG) AS with reduced left ventricular ejection fraction and preserved contractile reserve (IIaC); it may be considered in patients with LFLG AS with reduced left ventricular ejection fraction without preserved contractile reserve (IIbC) and in asymptomatic patients with significant left ventricular hypertrophy or with elevated levels of natriuretic peptides (IIbC) [4].

The mortality rate of the AVR procedure is 1-4% in the population of moderate-risk patients [4]. Life expectancy after successful AVR is similar to that of the general population. Mortality and morbidity increase in patients with the following risk factors: age, reduced left ventricular ejection fraction, previous coronary artery bypass graft (CABG), concomitant diseases.

Even though the results of surgical treatment for aortic stenosis are very good, there is a group of elderly patients who, due to additional concomitant disorders, are burdened with significant operative risk. According to the European Heart Survey, over 22% of patients with severe symptomatic aortic stenosis are excluded from undergoing the surgical procedure, mostly due to reduced ejection fraction and age [2]. The percentage of patients excluded from the procedure is even higher in the group of patients > 75 years of age, reaching over 32%. The prognosis for

symptomatic aortic stenosis patients who do not undergo surgery is poor, with survival time of several months or, at best, several years [3].

Transcatheter aortic valve implantation

The search for solutions for this troubled group of patients has resulted in the development of prototypes of aortic valve grafts for transcatheter implantation. The first transcatheter aortic valve implantation (TAVI) in a human was conducted on March 16th, 2002 by Professor Alain Cribier in Rouen, France [7]. The procedure was performed using transseptal access. The promising results of the first procedures led to further development of this treatment method. Subsequent years saw the performance of transcatheter aortic valve implantation using transfemoral access (2004, Laborde, Lal, Grube) [8] and transapical access (2005, Webb, Lichtenstein) [9, 10]. In 2007, two commercially available valve prostheses received the CE mark: the self-expanding CoreValve device (Medtronic, USA) and the balloon-expandable Edwards SAPIEN valve (Edwards, USA). The introduction of TAVI was met with much enthusiasm around the world; the number of implanted valves began to rise yearly. In 2008, the first joint statement of European Society of Cardiology (ESC), European Association for Cardio-Thoracic Surgery (EACTS), and European Association of Percutaneous Cardiovascular Interventions (EAPCI) was published, underscoring that the method may be a promising alternative to cardiac surgery in selected patient groups: patients with high operative risk and those excluded from cardiac surgery [11].

In 2010, the results of the PARTNER trials (group B) were published; it was the first large randomized study to include patients with severe aortic stenosis who were excluded from cardiac surgery. The study demonstrated the advantages of TAVI over conservative therapy: 12-month mortality in the TAVI group was 30.7% in comparison to 50.7% in the group treated with conservative therapy (including balloon aortic valvuloplasty – BAV). Among the patients who survived the first 12 months after the TAVI procedure, 25.2% remained in New York Heart Association (NYHA) functional classes III and IV vs. 58% of patients in the conservative therapy group. In the group treated with conservative therapy, BAV was performed in 83.8% of patients [12].

Published in 2011, the results of the PARTNER trial's group A compared the results of treatment in a group of AS patients with high operative risk and estimated Society of Thoracic Surgeons (STS) risk scores of $> 10\%$ who were randomly selected for cardiac surgery (AVR) or TAVI. Thirty-day mortality was 3.4% in the TAVI group vs. 6.5% in the AVR group. One-year mortality was 24.2% in the TAVI group vs. 26.8% in the AVR group. The prevalence of stroke in 1-year follow-up was higher in the TAVI group: 5.1% vs. 2.4% in the AVR group. No statistically significant difference was observed between the groups in terms of the prevalence of symptoms 12 months after the procedure. Thus, the results of the PARTNER trial (group A) confirmed the hypothesis that TAVI was not inferior to AVR [13].

The present guidelines for the treatment of valve defects (2012) are the first to include recommendations pertaining to the performance of TAVI. They stress the fact that the qualification process for TAVI requires the participation of a multi-discipline expert "Heart Team" (composed of cardiologists, cardiac surgeons, and other specialists), and that TAVI can only be performed in medical centers with cardiac surgery wards. Transcatheter aortic valve implantation is recommended for severe AS patients excluded from cardiac surgery in whom the achievement of a quality of life improvement is probable, and life expectancy exceeds one year after considering all remaining concomitant disorders (IB). Transcatheter aortic valve implantation should be considered in the case of high-risk patients with severe symptomatic AS who still qualify for surgical treatment, but in whom TAVI is preferred by the Heart Team (IIaB) [4].

In previous years, patients, in order to qualify for TAVI, had to have specific estimated operative risk scores (EuroSCORE > 20% STS score > 10%), but this requirement is now being reevaluated. At present, it is believed that the group of patients in whom TAVI may be considered will increase in numbers in the coming years, and it will probably also include selected patients with moderate and low operative risk. This may be influenced by the awaited results of the PARTNER II trial comparing the results of AVR and TAVI conducted on moderate-risk patients.

Transcatheter aortic valve implantation in Poland

In Poland, TAVI was first conducted in 2008 in centers in Zabrze and Kraków. The first procedures were performed using transapical access (Edwards SAPIEN valve) [14, 15]; subsequently, the minimally invasive transfemoral access began to be employed. The first Polish implantation of the self-expanding CoreValve device (Medtronic, USA) took place in 2009 in Zabrze. CoreValve devices began to be implanted by surgically exposing the left subclavian artery and by exposing and directly puncturing the ascending aorta. These alternative access methods enable the performance of TAVI in patients with advanced atherosclerosis of femoral arteries, iliac arteries, or the aorta. In Zabrze, the year 2013 saw the first Polish implantation of a new self-expanding valve with structural elements facilitating its positioning – the ACURATE valve (Symetis, Switzerland);

the procedure was performed using transapical access with good results [16].

Destination therapy before transcatheter aortic valve implantation – balloon aortic valvuloplasty: treatment technique and results

The introduction of balloon aortic valvuloplasty by Alain Cribier in 1985 brought high hopes for the group of the most burdened patients excluded from cardiac surgery [17]. The procedure consists in the transcatheter introduction of a balloon into the area of the aortic valve and its single (or repeated) inflation. Balloon aortic valvuloplasty causes the stretching of the valve's cusps and annulus, micro-ruptures of valvular calcifications, and partial separation of the commissures. The goal of BAV is to increase the aortic valve area by 40% or to the value of > 1 cm² and to reduce the mean gradient by 40% or to the value of < 40 mmHg [18, 19].

The immediate and 30-day outcomes of BAV were satisfactory. Most patients qualified for the procedure were elderly (83% were > 70 years old). On average, the procedure increased the AVA from 0.5 cm² to 0.8 cm² and reduced the mean aortic valve gradient from 55 mmHg to 29 mmHg. It also significantly improved the clinical condition of patients: the NYHA functional class was improved in 75% of cases. Out of the initial 76% of patients in NYHA functional classes III and IV, only 30% remained in these classes 30 days after the procedure. Perioperative mortality was 3%, while 30-day mortality was 14%.

Unfortunately, the results of long-term follow-up of patients after BAV brought disappointment. Restenosis occurred as early as after several months, causing the deterioration of clinical condition. One-, two- and three-year survival rates were 55%, 35% and 23%; the survival rates were, therefore, comparable with those observed in the population of severe AS patients treated conservatively. Most deaths (70%) resulted from cardiovascular causes [21].

According to other observations (3.9-year follow-up), 93% of patients after BAV died or underwent AVR. The probability of survival without cardiovascular events (death, AVR, repeat BAV) was 40% in 1-year follow-up, 19% in 2-year follow-up, and 6% in 3-year follow-up. In comparison, the 3-year survival rate of patients after BAV who subsequently underwent AVR was 84%. These results confirmed that the long-term survival of patients undergoing BAV is low and resembles the natural course of untreated severe aortic stenosis [22]. Due to the unfavorable long-term results and only transient clinical condition improvement, the number of performed BAV procedures dropped significantly in the early 1990s. Many centers abandoned the procedure entirely or performed it sporadically as a palliative treatment. A substantial percentage of severe AS patients excluded from surgical treatment continued to be deprived of a destination therapy.

The renaissance of balloon aortic valvuloplasty as a bridging therapy

With the development of TAVI and the aging of the population, the number of performed aortic valvuloplasty

Tab. I. Complications after balloon aortic valvuloplasty [20]

Blood transfusion required	23%
Vascular complications	7%
Cerebral accidents	3%
Peripheral embolism	2%
Myocardial infarction	2%
Acute kidney injury	1%
Cardiac surgery required	1%

procedures increased significantly, not only as an integral part of the TAVI procedure, but also as a bridging therapy. Recent years have seen the publication of many studies underscoring the purposefulness of BAV in the presence of specified indications (Table II).

According to the present recommendations for the treatment of valve defects (2012), BAV may be considered in hemodynamically unstable patients with high operative risk as a bridging therapy before planned TAVI or in severe AS patients who require urgent and extensive non-cardiac surgery (IIbC). Balloon aortic valvuloplasty may also be considered as a palliative treatment in individual cases when, due to severe concomitant diseases, surgical treatment is contraindicated and the performance of TAVI is impossible [4].

Patients in whom the performance of AVR or TAVI is impossible may be considered as potential candidates for BAV (Table III).

The favorable results of BAV within the first months after the procedure gave rise to the idea to employ valvuloplasty as a bridging therapy. There are reports confirming that BAV enables the stabilization of the patient's clinical condition and reduces the operative risk of subsequent AVR/TAVI [19, 23].

Recent years have seen the publication of many studies underscoring the purposefulness of using BAV as a bridging therapy. Saia *et al.* presented the results of treatment of 415 patients admitted to a clinic in Bologna between the years 2000 and 2010, underscoring the rapid increase of the number of BAV procedures since the introduction of TAVI (< 10/year until 2003, 80/year in 2008, 160/year in 2010) [24]. Patients undergoing BAV were assigned to 4 groups: a group undergoing BAV as a bridging therapy before TAVI (B-TAVI), a group undergoing BAV as a bridging therapy before cardiac surgical aortic valve replacement (B-AVR), patients in cardiogenic shock, and a group undergoing BAV as a form of palliative treatment. Intrahospital mortality was 5.1% (56% in the cardiogenic shock group and only 2% in total in the remaining groups). One-year and two-year mortality rates were 32.2% and 57.4%, respectively (the highest mortality rates, 70.7% and 80.4%, were noted in the cardiogenic shock group; the lowest, 21.7% and 38.4%, were noted in the B-AVR group). The group receiving palliative treatment was significantly older than the remaining groups; the patients undergoing B-AVR more frequently suffered from concomitant neoplasms; finally, the patients undergoing B-TAVI more often had "porcelain" aortas, COPD, peripheral artery atherosclerosis, or previous coronary interventions. The authors underscore the role of BAV in reevaluating the selection of the definitive treatment method. The improvement of clinical condition after BAV also appears to be significant, as it increases the safety of subsequent TAVI or AVR.

In a significant percentage of patients who were initially assigned to the B-AVR or B-TAVI group, the performance of BAV resulted in the selection of other, apparently more suitable treatment strategies. Within 2 years in the B-TAVI group, TAVI was performed in 58.1% of patients, AVR in

Tab. II. Indications for the performance of balloon aortic valvuloplasty

1. Hemodynamic instability, BAV as a bridging therapy before AVR or TAVI
2. Emergency BAV in severe AS patients in cardiogenic shock
3. Unavailability of TAVI due to logistic or economic issues
4. Necessity of performing an urgent non-cardiac surgical procedure in a patient with severe symptomatic AS
5. The presence of concomitant neoplasms requiring further diagnostics
6. Therapeutic testing due to unclear AS symptoms with concomitant severe lung conditions or due to doubts concerning AS severity [9, 23]

BAV – balloon aortic valvuloplasty, AVR – aortic valve replacement, TAVI – transcatheter aortic valve implantation, AS – aortic stenosis

2.9%, and repeat BAV in 39.6%. Within 2 years in the B-AVR group, surgical valve replacement was performed in 33.2% of patients, TAVI in 19.7%, and repeat BAV in 27.9%.

Changes in the clinical condition of patients after BAV and better assessment of reported ailments may allow the Heart Team to make appropriate therapeutic decisions for individual patients.

In the study published by Claire-Marie Tissot, encompassing 253 patients qualified for TAVI, 55.3% of patients underwent primary TAVI or AVR, 28.45% of patients were treated conservatively, while 41 patients (16.2%) had temporary contraindications for TAVI or AVR [23]. The latter group underwent BAV (with no perioperative mortality). As the second stage of treatment in this group of patients, TAVI was performed in 23 patients, AVR in 4 patients, and 18 patients were treated conservatively. In the group undergoing BAV as a bridging therapy before destination therapy, 1-year and 2-year survival rates were 94% and 85%, respectively. No statistically significant differences were noted in terms of mortality between the group treated with primary

Tab. III. Potential balloon aortic valvuloplasty candidates

The performance of AVR is not possible in patients:
with high-operative risk (previously: EuroSCORE > 20%, STS > 10%)
with massive calcifications within the ascending aorta ("porcelain aorta")
with substantial chest malformation after chest radiation therapy
The performance of TAVI is not possible in patients:
who do not meet the anatomic criteria (annulus, valve, aorta)
with life expectancy < 1 year due to reasons other than the valve defect
after surgical remodeling of the left ventricle
with very low left ventricular ejection fraction
with significant stenoses of the main coronary arteries, disqualified from coronary angioplasty (PCI)
who suffer from cachexia

AVR – aortic valve replacement, TAVI – transcatheter aortic valve implantation, PCI – percutaneous coronary interventions

Tab. IV. Balloon aortic valvuloplasty procedure data (own material)

Data	Mean	Stand. dev.
Balloon size [mm]	21	2.29
Number of inflations	3.69	1.28
Balloon rupture	0	0
Duration of the procedure [min]	112.66	24.48
Radiation dose [Gy]	0.84	0.62
Contrast amount [ml]	86.66	78.29
Total duration of fluoroscopy [min]	18	8.46
Sheath size [F]	9.75	1.03

AVR/TAVI and the group undergoing BAV as a bridging therapy before AVR/TAVI. The mean time between BAV and TAVI/AVR was 48 days; it was significantly shorter in the cardiogenic shock group (12 days) than in the group of stable patients (145 days).

Polish experiences also indicate the purposefulness of using BAV as a bridging therapy in patients with end-stage heart failure and high operative risk of valve replacement. Wilczek *et al.* presented a group of 15 patients with severe heart failure in NYHA functional class IV, with high operative risk (> 20% according to logistic EuroSCORE) or disqualified from surgical treatment for other reasons, in whom BAV was performed [25]. The group included 6 patients in cardiogenic shock. Destination therapy was subsequently performed in 7 patients (4 patients underwent TAVI, 3 AVR). In total, the 12-month survival rate was 53% (8 patients).

Agarwal *et al.* analyzed the possibility of reducing mortality in patients undergoing repeat BAV [26]. In the study group of 212 patients, 51 underwent repeat BAV. The mean duration of symptom abatement in patients undergoing their first, second, and third BAV was, respectively: 18 ± 3 , 15 ± 4 , and 10 ± 3 months. One-year, two-year, and three-year mortality rates among patients treated with BAV for the first time ($n = 161$) were 58%, 42%, and 26%, respectively; the respective rates in the group undergoing repeat BAV were: 84%, 65%, and 33%.

Over the years, the observed number of complications associated with BAV has been decreasing. This can be attributed to the evolution of medical equipment, changes in the operative technique, and the introduction of devices for maintaining vascular hemostasis. The complication rate after BAV was 22.6% according to the Mansfield register from 1986 to 2008 [27]; according to reports from Rouen, it was 7.3% between 2005 and 2008. The percentage of deaths associated with the procedure was 4.9% and 2.1%, respectively, while the rate of vascular complications was 11% and 0.9% (Table I).

In our own material (47 patients undergoing BAV between 2008 and 2013 at the 3rd Chair and Clinical Department of Cardiology, Silesian Center for Heart Diseases in Zabrze), the procedure was successful (according to the criteria presented above) in 40 patients (85.1%). The pro-

cedures were conducted using Cristal balloons for valvuloplasty (manufactured by BALTON).

Deciding whether to use balloon aortic valvuloplasty as a bridging treatment

Based on the yearly number of AVR procedures performed in Poland and the percentage of patients who, according to registers, are not operated on, it can be estimated that, in Poland, approximately 1000 patients are potential TAVI candidates. In 2011, the European average (based on 11 countries of Western Europe) was 32 TAVI implantations/1 million inhabitants/year, which suggests 1200 procedures per year in the case of Poland. Considering the number of procedures in Germany (over 90/1 million inhabitants/year), the estimated number of potential TAVI candidates is even higher. In the meantime, mostly due to economic issues, the yearly number of TAVI procedures performed in Poland is approximately 380. Among elderly patients (> 80 years) waiting for TAVI, 30% die within 3 months.

In this context, it is worthwhile to consider the results of the PARTNER B trial [12]; in its conservative treatment arm, over 83% of patients underwent BAV, and only a relatively small difference was noted in terms of general mortality 6 months after the procedure: 22% in the TAVI group and 28% in the group of patients treated conservatively (of whom 83% underwent BAV). Only in the subsequent months does the difference in mortality noted in both groups become much more pronounced (probably due to the temporary character of BAV effects).

In view of the limited availability of TAVI in Poland, we postulate that patients should be more frequently qualified for BAV, as it is a relatively safe procedure enabling the improvement of the clinical condition and survival of patients awaiting AVR or TAVI. Balloon aortic valvuloplasty may also be an effective tool for making definitive therapeutic decisions in patients with unclear symptoms due to concomitant diseases (including COPD) or with severe LFLG AS with limited contractile reserve.

Conclusions

The number of performed BAV procedures has increased since the introduction of TAVI and will probably rise further in the coming years. In the era of TAVI, new clinical indications have been found for BAV.

Balloon aortic valvuloplasty allows one to identify patients with significant left ventricular damage whose condition is likely to improve after surgical treatment or TAVI, and it facilitates the preparation of patients for AVR or TAVI procedures. These procedures are well tolerated even by patients in severe or very severe condition. Balloon aortic valvuloplasty is a relatively safe procedure in selected cases, although its long-term results remain poor. Therefore, BAV does not constitute an alternative to the definitive methods of treating aortic stenosis (AVR, TAVI).

Disclosure

Authors report no conflict of interest.

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