Immediate results and 12-month survival after balloon aortic valvuloplasty for critical aortic stenosis in end-stage heart failure patients at high risk of surgical aortic valve replacement

Ocena efektów bezpośrednich i 12-miesięcznego przeżycia po zabiegach balonowej walwuloplastyki aortalnej w krytycznej stenozie zastawki aortalnej u chorych ze schyłkową niewydolnością serca i dużym ryzykiem operacyjnej wymiany zastawki

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Abstract

Aim of the study: The aim of the study was to assess immediate haemodynamic results and 12-month survival of patients with critical aortic valve stenosis, severe heart failure and high surgical risk, treated with balloon aortic valvuloplasty (BAV).

Material and methods: The prospective registry comprised the first consecutive BAV-treated patients with NYHA class IV and operative risk ≥ 20% according to the Logistic EuroSCORE, and patients disqualified from surgical treatment for any reason. Baseline and post-BAV values of aortic valve area (AVA), left ventricle ejection fraction (LVEF) and pulmonary hypertension (RVSP) were compared. The primary end-point was 12-month survival. BAV procedures were performed via femoral artery access, under local anaesthesia.

Results: The study group consisted of 15 patients (11 female), aged 78.3 ±5.9 years with a mean Log EuroSCORE = 27.0 ±9.56%. Six patients had cardiogenic shock. One procedure was complicated by acute coronary artery occlusion. The mean aortic valve area increased from 0.57 ±0.18 cm^2 to 0.93 ±0.28 cm^2 (P = 0.0008). Four patients underwent transcatheter aor-

Streszczenie

Cel pracy: W artykule opisano własne doświadczenia w zastosowaniu metody balonowej walwuloplastyki aortalnej (ang. *balloon aortic valvuloplasty* – BAV) stosowanej u chorych z krytyczną stenozą zastawki, ciężką niewydolnością serca i dużym ryzykiem leczenia operacyjnego. Celem pracy była ocena bezpośrednich efektów hemodynamicznych i 12-miesięcznego przeżycia leczonych chorych.

Materiał i metody: Prospektywną obserwacją objęto pierwszych kolejnych chorych w IV klasie wg NYHA z ryzykiem operacyjnym ≥ 20% wg Logistic EuroSCORE lub z innych powodów dyskwalifikowanych z leczenia chirurgicznego leczonych metodą BAV. Porównywano wielkość ujścia aortalnego przed zabiegiem i po zabiegu, frakcję wyrzutową lewej komory, wielkość nadciśnienia płucnego. Punktem końcowym obserwacji było przeżycie po 12. miesiącu obserwacji. Zabiegi BAV wykonywano z dostępu udowego w znieczuleniu miejscowym.

Wyniki: W badanej grupie było 15 chorych (w tym 11 kobiet) w wieku 78,3 ±5,9 roku, ze średnim ryzykiem Log EuroSCORE = 27,0 ±9,56%. Sześciu chorych było we wstrząsie kardiogen-

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tic valve implantation (TAVI), three had surgical aortic valve replacement (AVR), two refused further treatment, whilst four were disqualified from TAVI and AVR. In two patients, the TAVI procedure was considered. The survival rate at 12 months was 53% (8 pts). Five out of the total of 7 deaths were in-hospital. Mortality was lower in patients treated with BAV followed by either TAVI or AVR (P log rank 0.07).

Conclusions: Patients with critical aortic valve stenosis in end-stage heart failure and high surgical risk can safely undergo BAV, which offers an immediate increase of aortic valve area. Thereafter, definitive treatment in the form of TAVI or AVR should be aimed for.

Key words: balloon aortic valvuloplasty, aortic stenosis, transcatheter aortic valve implantation, aortic valve replacement.

nym. U jednego chorego zabieg był powikłany zamknięciem tętnicy wieńcowej. Uzyskano średni przyrost pola powierzchni zastawki z 0,57 ±0,18 cm^2 do 0,93 ±0,28 cm^2 (p = 0.0008). Czworo chorych zostało poddanych zabiegowi TAVI, 3 przeszło operację AVR, 2 pacjentki odmówiły dalszego leczenia, 4 pacjentów zostało zdyskwalifikowanych z leczenia zabiegowego, u 2 pacjentek rozważano TAVI. Ogółem 12 miesięcy przeżyło 8 chorych (53%). Na 7 zgonów 5 nastąpiło w okresie wewnątrzszpitalnym. Odnotowano trend niższej śmiertelności w grupie leczonych BAV z następowym TAVI lub AVR (P log rank 0,07).

Wnioski: Chorzy z krytyczną stenozą aortalną w schyłkowej niewydolności serca i dużym ryzykiem operacyjnym mogą być bezpiecznie poddani zabiegom BAV, z których odnoszą bezpośrednio korzyść w postaci zwiększenia pola powierzchni ujścia aortalnego. Po zabiegach BAV należy dążyć do definitywnego leczenia zabiegowego: TAVI lub AVR.

Słowa kluczowe: balonowa walwuloplastyka aortalna, stenoza aortalna, przezcewnikowa implantacja zastawki aortalnej, wymiana zastawki aortalnej.

Introduction

The mean survival of patients with aortic valve stenosis and signs of heart failure is 2-3 years [1]. Aortic stenosis in end-stage heart failure is associated with poor prognosis and, whenever possible, requires prompt surgery. Patients in a critical condition, in end-stage heart failure, in NYHA class IV are not good candidates for surgical aortic valve replacement (AVR), especially in the presence of concomitant factors which increase surgical risk, such as advanced age and low left ventricular ejection fraction [2]. According to the Euro Heart Survey, approx. 32% of patients aged > 75 years old eligible for AVR are not in fact operated on [3]. An alternative treatment in this group of patients may be transcatheter aortic valve implantation (TAVI) or balloon aortic valvuloplasty (BAV). TAVI is a new treatment method; it is costly, technically challenging, requires complex logistics, staff training and frequently also the participation of experts in the field [4, 5]. BAV, on the other hand, initiated in 1985 by Cribier [6], is easy to use and may improve the patients' condition. Although the effect of BAV treatment is usually not permanent, it allows time to optimise and stabilise the patient's condition in preparation for elective AVR or TAVI [7-11].

Aim of the study

This article presents the authors' experience in the treatment of patients with critical aortic stenosis and end-stage heart failure treated with BAV. The BAV programme was developed simultaneously with the TAVI programme. The aim of the study is to present immediate results of haemodynamic treatment and one-year survival.

Material and methods

Between December 2008 and February 2010, 29 BAV procedures were carried out in 28 patients. Fifteen patients in NYHA class IV were followed up prospectively. Patients qualified for BAV were those with tight aortic stenosis, i.e. aortic valve area (AVA) < 0.8 cm^2, high surgical risk ≥ 20% according to Logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation), and patients who for other reasons were disqualified from elective AVR by at least two cardiac surgeons experienced in the treatment of acquired heart valve diseases. The indication for BAV in the selected group was severe end-stage heart failure requiring heart team opinion and a fast intervention with a view to bring a palliative effect or to prepare the patient for AVR or TAVI. Coronary arteriography and percutaneous revascularisation according to individual indications were carried out in all patients. Baseline transthoracic echocardiography (TTE) was done in all patients, with precise evaluation of aortic valve area, aortic annulus diameter, left ventricular ejection fraction and right ventricular systolic pressure (RVSP) as a measurement of pulmonary hypertension. In patients with favourable clinical conditions, contrast tomography of the aorta and iliac arteries was performed. The efficiency of the procedure was assessed intraoperatively by means of TTE. The procedure was considered haemodynamically successful when AVA increased by at least 0.25 cm^2 (or AVA-Ix by at least 0.1 cm^2/m^2) in the absence of: new aortic regurgitation > 2^o, complications in the form of valvular damage, rupture of the aortic annulus or the aorta, ventricular perforation and major vascular complications at the access site (arterial or venous). The primary follow-up end-point was 12-month survival. Unfavourable clinical events occurring at any time between the procedure and 12 months post-BAV were: death, myocardial infarction, cerebrovascular accidents, haemorrhagic complications requiring blood transfusion, major vascular complications at the access site requiring surgical intervention, conduction disorders requiring electrotherapy, hospitalization for cardiac reasons, and BAV-related contrast-induced nephropathy requiring renal replacement therapy. The patients' condition was assessed 12 months after the procedure in the outpatient cardiology clinic.

BAV

BAV was carried out under local anaesthesia via femoral artery access, using a vascular sheath of a diameter matching the size of the balloon catheter. Both femoral veins were prepared for the insertion of the Swan-Ganz catheter into the pulmonary artery and of the right ventricular pacing lead. After placing the vascular and arterial sheaths, intravenous heparin was administered at a dose of 5000 IU, if necessary, followed by subsequent doses depending on the value of frequently assessed ACT. The nominal diameter of the balloon catheter was 1-2 mm smaller than the calculated diameter of the valvular annulus. The aortic valve was reached in an antegrade fashion with the Amplatz L 1 or 2 (6F) coronary diagnostic catheter and a standard 0.036" guidewire. After exchanging the Amplatz catheter with the Pig-tail catheter, pressure gradient measurement was made. Cardiac output was assessed by thermodilution and the aortic valve area was calculated using the Gorlins' formula. Valvuloplasty was preceded by aortography carried out in an optimal projection, usually left oblique. The "Cristal" – BALT™ (F) balloon catheters were filled with a mixture of saline solution and contrast (85 : 15) as indicated by the manufacturer, with a view to achieve the desired balloon diameter. Balloon inflation was performed during rapid ventricular pacing 180-200/min, giving a decrease in systemic pressure to < 50 mmHg. Three to five balloon inflations were performed. The immediate effect of the procedure was monitored by means of TTE and haemodynamically, i.e. by calculating AVA using the Gorlins' formula. TEE was repeated at discharge.

Statistical methods

Pre- and post-aortic valvuloplasty numerical parameters were compared using Student's t-test for dependent samples. Differences in survival were plotted on the Kaplan-Meier and log-rank curves. $P < 0.05$ was considered statistically significant.

Results

The basic characteristics of the study group are shown in Table I. Pre- and post-valvuloplasty haemodynamic results are presented in Table II.

Tab. I. Characteristics of the study group

Characteristic	
Age (years)	78.3 ±5.9
Women	11 (73%)
Logistic EuroSCORE	27.0 ±9.56
NYHA class IV	15 (100%)
Cardiogenic shock	6 (40%)
BMI ≥ 25	9 (60%)
Arterial hypertension	7 (47%)
Hyperlipidaemia	10 (67%)
Diabetes	9 (60%)
Coronary artery disease	7 (47%)
Prior cardiac surgery	2 (13%)
COPD	3 (20%)
Neoplastic disease	2 (13%)

Tab. II. Comparison of baseline and post-valvuloplasty haemodynamic parameters

	Baseline data				Post valvuloplasty					
Patient	EF (%)	AVA (cm^2)	AVA-I (cm^2/m^2)	RVSP (mm Hg)	EF (%)	AVA (cm^2)	AVA-I (cm^2/m^2)	RVSP (mm Hg)	Δ AVA	Δ AVA-I
1	27	0.65	0.42	62	35	0.9	0.58	61	0.25	0.16
2*	20	0.35	0.23	65	20	1.53	0.99	60	1.18	0.76
3	47	0.7	0.43	50	50	1.3	0.80	50	0.60	0.37
4	47	0.59	0.39	57	50	0.84	0.55	55	0.25	0.16
5	21	0.42	0.25	55	21	0.7	0.42	50	0.28	0.17
6	20	0.78	0.40	82	25	1.1	0.57	60	0.32	0.16
7*	40	0.65	0.32	62	40	0.9	0.45	54	0.25	0.12
8	54	0.55	0.34	64	50	0.68	0.42	46	0.13	0.08
9*	23	0.56	0.30	70	35	0.9	0.48	41	0.34	0.18
10	45	0.26	0.16	67	55	0.6	0.36	50	0.34	0.20
11*	23	0.6	0.34	61	25	0.9	0.50	65	0.30	0.17
12*	37	0.3	0.19	80	35	0.6	0.38	42	0.30	0.19
13	36	0.74	0.40	51	35	1.1	0.59	50	0.36	0.19
14*	52	0.86	0.42	45	52	1.24	0.61	45	0.38	0.19
15	30	0.5	0.29	57	30	0.6	0.34	55	0.10	0.06
mean	**35**	**0.57**	**0.32**	**62**	**37**	**0.93**	**0.54**	**52**	**0.36**	**0.21**
SD	**12**	**0.18**	**0.09**	**10**	**12**	**0.28**	**0.17**	**7**	**0.25**	**0.17**
p**	**0.060**	**0.00008**	**0.00023**	**0.00940**	-	-	-	-	-	-

**Patients in cardiogenic shock, **p values refer to the comparison of differences in the selected parameters before and after BAV.*

There were no deaths during BAV. In two cases (patients #8 and #15) the desired effect, i.e. aortic valve widening, was not achieved. In one patient, ventricular fibrillation induced by rapid pacing occurred but was successfully defibrillated. There were no severe complications, such as damage to the valve structure, aortic wall or heart chambers. BAV did not aggravate the existing aortic insufficiency, nor did it cause the occurrence of new aortic insufficiency significantly affecting haemodynamics. In one patient (#13; Log EuroSCORE = 11.47%) signs of NSTEMI occurred on the first post-operative day. Coronary arteriography revealed occlusion of the medial segment of the left anterior descending artery (LAD), and percutaneous revascularisation of the infarct-related artery failed. The patient was qualified for emergency cardiac surgery. The aortic valve was replaced with a mechanical prosthesis and a LIMA to LAD bypass was implanted. In the perioperative period, an ischaemic CNS stroke occurred, which subsequently regressed partly during treatment and rehabilitation. Within the 12-month follow-up period, 7 patients (47%) died. Six patients (40%) died in hospital between the 3rd and 47th day, of whom four had undergone treatment in cardiogenic shock. In one patient (#6), after a period of relative clinical improvement, stenosis recurred, and on day 23 BAV was repeated, giving no clinical improvement. The patient, disqualified again from AVR (Log EuroSCORE = 23.4%; LVEF = 20%), died on the 47th day after the first BAV. One patient (#15; 75 y.o., Log EuroSCORE = 41.98%), expecting TAVI, died suddenly on the 8th day after BAV, with signs of rapidly developing pulmonary oedema and irreversible shock. Patient #3 died 287 days after BAV due to an extensive cerebrovascular accident. The patient had been discharged in good condition, NYHA class III and refused further treatment with AVR or TAVI (Log EuroSCORE = 15.46%). The results of 12-month follow-up are presented in Table III.

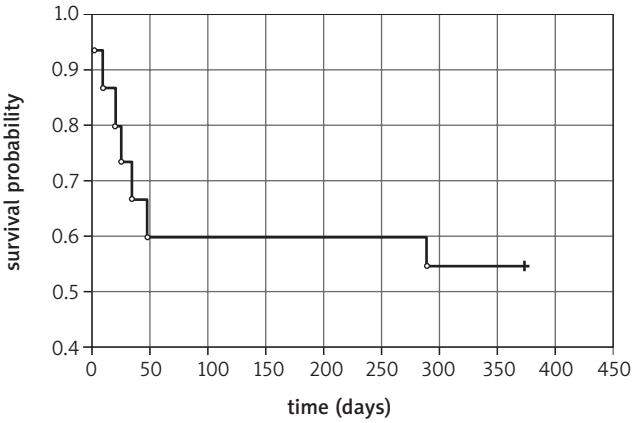

Fig. 1. Post-BAV 12-month survival probability

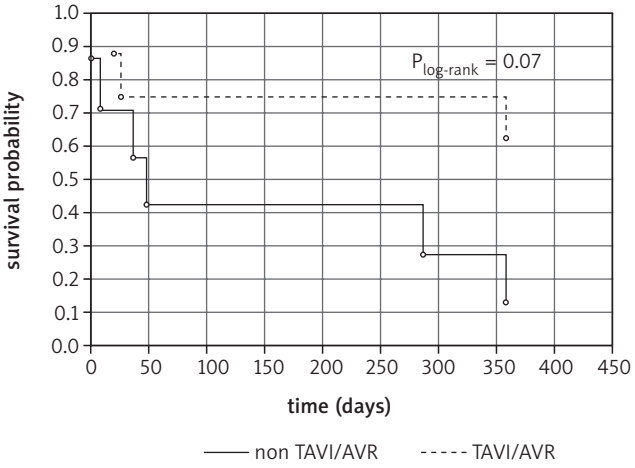

Fig. 2. Survival probability of patients undergoing valve implantation (AVR or TAVI) as compared to the remaining patients

Tab. III. Results of 12-month follow-up

Patient	Gender	Age	Further treatment after BAV	Status 12 months after BAV	NYHA class after 12 months
1	F	78	TAVI on day 259	alive	2
2	F	81	conservative; considered TAVI	in-hospital death on day 3	-
3	F	85	conservative – refused treatment (TAVI/AVR)	death at home – extensive CNS stroke on day 287	-
4	F	87	TAVI on day 85	alive	3
5	M	78	AVR on day 241	alive	2
6	M	76	conservative; disqualified from TAVI and AVR	hospital death on day 47 (2 x BAV)	-
7	F	77	TAVI on day 50	alive	3
8	F	75	TAVI on day 154	alive	3
9	F	81	conservative – refused treatment (TAVI/AVR)	alive	3
10	F	86	conservative – disqualified from TAVI/AVR	alive	3
11	M	63	AVR	hospital death on day 25	-
12	F	82	conservative; disqualified from TAVI/AVR	hospital death on day 20	-
13	M	75	AVR + CABG on day 0	alive, after CNS stroke	3
14	F	76	conservative; disqualified from AVR + MVR	hospital death on day 35	-
15	F	75	conservative, considered TAVI	hospital death on day 8	-

The 12-month survival of patients after BAV is presented in Figs. 1 and 2.

In all patients who survived 12 months, an improvement in NYHA class was observed, with two patients in class II, and six patients in class III.

Discussion

The performed BAV procedures resulted in a mean increase of the valve area from 0.57 ±18 cm^2 to 0.93 ±28 cm^2, which is a slightly better result than that reported by Otto et al. (a mean increase of valve area from 0.57 ±0.21 cm^2 to 0.78 ±0.38 cm^2) [12]. A result similar to ours was obtained by Ben-Dor et al. (area increase from 0.58 ±0.3 cm^2 to 0.96 ±0.3 cm^2) [13]. We achieved a significant reduction of pulmonary hypertension: from 62 ±10 mmHg to 52 ±7 mm Hg ($p = 0.009$). LVEF in this small group did not increase significantly (from 35 ±12% to 37 ±12%), although it seems that patients with low baseline fraction obtain greater improvement after BAV [14].

Patients who after BAV underwent definitive treatment with surgical valve replacement or TAVI ($n = 8$) did not benefit significantly with regard to 12-month survival as compared with the remaining patients who, for various reasons, were treated conservatively (Fig. 2), though there is a clear trend towards better results in the group treated surgically ($p = 0.07$).

The presented patients constitute the most difficult group of patients with aortic valve stenosis. Age and low LVEF are independent risk factors in patients with aortic stenosis, both treated conservatively and with BAV [2, 11]. Introduced in 2002 by Cribier et al., TAVI has been an unquestionable help in solving the challenging problem of treatment of high-risk patients [15]. However, the availability of TAVI is limited, and in urgent situations, such as shock, organising the procedure may prove difficult. In such cases, BAV is a simple and safe choice that may lead to an immediate improvement of the patient's condition, and as a result, lower the risks for further surgery (TAVI or AVR). In most patients in our group, the high risk of death (mean Log EuroSCORE = 27.0 ±9.56) was associated with factors that were potentially reversible in cases of successful valve dilatation, such as high pulmonary hypertension and low LVEF. The experience gained so far shows that the beneficial effect of valvuloplasty is not permanent and rarely lasts longer than several months [13, 16]. The randomised PARTNER US study showed that patients qualified for conservative treatment but eligible for BAV (a procedure conducted in as many as 83.4%), had significantly worse prognosis: 12-month mortality was 49.7% vs. 30.7% in the TAVI group [17], which means that BAV had no significant impact on the natural process of aortic stenosis. In our group of patients, further surgical treatment was planned, with BAV being a bridge to the definitive treatment in the form of TAVI or AVR (eventually applied in seven patients). Three patients who survived the in-hospital period were discharged; two of them refused further treatment, of whom one died, whilst the other remains in good clinical condition. The third patient was disqualified due to significant concomitant mitral and tricuspid regurgitation. The strategy of bridge aortic valvuloplasty is implemented particularly in the highest risk patients. Ussia et al. describe a group of 43 high-risk patients (mean log EuroSCORE 35%), NYHA class 3 or 4, undergoing BAV with subsequent TAVI performed after a mean of 59 days. The authors conclude that BAV before TAVI can be a safe and effective option reducing the incidence of complications in high-risk patients [18]. Bridge BAV procedures before surgical valve replacement were performed before the era of TAVI and are still used today [19-22]. In our group, there was one perioperative complication in the form of coronary artery occlusion. The patient was operated on (AVR and CABG), but a cerebral stroke occurred perioperatively. Valvuloplasty carries a high risk of complications, the most serious of which are procedure-related death, left ventricular perforation, valve annulus rupture, aortic damage, myocardial infarction, stroke, peripheral embolism, and vascular damage requiring blood transfusion or surgical repair. In the NHLBI register (National Heart, Lung and Blood Institute) encompassing 674 patients who underwent BAV between 1987 and 1989, severe complications occurred in 25% of patients, whilst mortality was 3% on the first day, 10% within the in-hospital period and 14% in 30-day follow-up [9]. Ben-Dor et al. present the results of 301 BAV procedures performed in 262 consecutive patients between 2000 and 2009. The procedures were carried out for the following reasons: alleviation of symptoms (80%), cardiogenic shock (9%), bridge to AVR (6%), and bridge to TAVI (5%). Death during the procedure occurred in 1.6% of patients, stroke in 1.99%, coronary artery occlusion in 0.66%, hypotonia in 1.6%, tamponade in 0.3%, necessity of pacemaker implantation in 1.6%, and vascular complications requiring intervention in 6.9%. In total, there were 15.6% severe complications [13].

The prognosis of critically ill patients with aortic stenosis undergoing valve dilatation is very serious. In our material, we observed 40% in-hospital mortality and a 53% one-year survival rate. Moreno et al., in a group of 21 patients in cardiogenic shock undergoing BAV, report 43% in-hospital deaths and one-year survival of 33% [23]. In a similar group of patients, Buchwald et al. observed 71% in-hospital deaths and one-year survival of 29% [24].

The present study describes our first experiences with the use of BAV in end-stage patients with high surgical risk. The material comprises a relatively small group of patients, which naturally constitutes an obvious limitation of the paper. The use of BAV as a bridge strategy to TAVI or AVR is largely intuitive. Was the widely used valvuloplasty equally intuitive within the conservative branch of the PARTNER US study where doctors desperately searched for methods of saving patients whose one-year prognosis was poor? There are no randomised studies comparing BAV with conservative treatment or BAV as a bridge to TAVI or AVR. BAV is a class IIb indication according to ACC/AHA, level of evidence C, and it is recommended as a bridge procedure to AVR in high-risk patients or as a palliative procedure in cases where, for various reasons, surgical valve replacement cannot be performed [25].

Conclusions

BAV can be safely performed in patients with critical aortic stenosis, with NYHA class IV and additional comorbidities which increase their surgical risk. Although it helps to obtain hemodynamic improvement, the prognosis of these patients is poor. Patients in cardiogenic shock also benefit from BAV. There is a trend towards higher 12-month survival in patients subsequently treated with TAVI or AVR.

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