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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Balloon aortic valvuloplasty — ups and downs — are we facing a procedure comeback?

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Abstract

Background: Recently, there has been renewed interest in balloon aortic valvuloplasty (BAV).

Aim: To analyse the indications and short-term outcome of BAV since transcatheter aortic valve implantation (TAVI) was launched in our institution.

Methods: Between September 2010 and September 2014, 25 consecutive patients (19 female, 6 male) underwent BAV. The mean age was 72 ± 11.4 years, mean EuroScore II was 10.4 ± 11.7%, mean logistic EuroScore 23.5 ± 23.6%, mean Society of Thoracic Surgeons mortality risk score was 21.8 ± 13.6%. The indications for BAV were: advanced haemodynamically unstable heart failure (HF) including cardiogenic shock or pulmonary oedema (n = 7), co-morbidities requiring urgent non-cardiac surgery (n = 8), palliative treatment (n = 6), and an intension to bridge to TAVI or aortic valve replacement in patients with severe HF (n = 4).

Results: In-hospital mortality was 20% (n = 5) and occurred in patients who underwent BAV in the setting of haemodynamically unstable HF. Other major complications included pacemaker implantation (n = 2), major vascular complications (n = 4), and cardiac tamponade (n = 1). There were no patients who required conversion to cardiac surgery. The mean peak aortic transvalvular gradient decreased from 96.9 ± 29.5 to 60.3 ± 15.5 mm Hg (p = 0.0001) after BAV. We did not observe significant aortic regurgitation.

Conclusions: Treatment of advanced and haemodynamically unstable aortic stenosis, bridge to non-cardiac surgery and palliative therapy are the main reasons for BAV in recent years. BAV as a bridge to TAVI or aortic valve replacement may be an option for some patients. Short-term results are good with relatively low mortality and morbidity related to the procedure. Mortality in haemodynamically unstable patients presenting with cardiogenic shock or pulmonary oedema treated with BAV is very high.

Key words: aortic valve stenosis, cardiac surgery, percutaneous aortic balloon valvuloplasty, transcatheter

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INTRODUCTION

Balloon aortic valvuloplasty (BAV) was introduced in 1985 and was first described in 1986 by Cribier et al. [1]. The procedure emerged with initial enthusiasm and was proposed as a simple and cost-effective alternative to aortic valve replacement in elderly patients with high surgical risk [1, 2]. The first results of BAV in 92 patients were very promising — maximal transaortic gradient dropped from 75 ± 26 mm Hg to 30 ±13 mm Hg, and the aortic orifice area increased from 0.49 ± 0.7 cm^2 to 0.93 ± 0.36 cm^2 [2]. Significant subjective clinical improvement was noted — 90% of subjects who survived were in New York Heart Association (NYHA) I and II. Further observations did not confirm the excellent results of BAV. High complication rate, lack of durability due to restenosis for several months, and poor long-term outcome were pointed out [3, 4]. BAV lost many of its supporters and was restricted to very high-risk patients as a palliative procedure or as a bridge to aortic valve replacement (AVR). However, recently, renewed interest in BAV occurred after development of transcatheter aortic valve

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implantation (TAVI) technique and technical improvements in interventional cardiology.

The aim of our study was to retrospectively analyse the indications and short-term outcome of BAV, not directly associated with TAVI, since that procedure was launched in our institution.

METHODS

Between September 2010 and September 2014, 25 consecutive patients (19 female, 6 male) underwent BAV. The mean age of our study group was 72 ± 11.4 years, mean EuroScore II was 10.4 ± 11.7%, mean logistic EuroScore 23.5 ± 23.6%, mean Society of Thoracic Surgeons score 21.8 ± 13.6% in term of mortality risk and 68.4 ± 14.9 in term of mortality and morbidity risk. Moreover, 18 (76%) patients had severe risk factors that were not included in the risk scores. The demographic and clinical data are presented in Table 1.

The indications for BAV were: advanced haemodynamically unstable heart failure (HF) including cardiogenic shock or pulmonary oedema (n = 7), co-morbidities requiring urgent non-cardiac surgery (n = 8), palliative treatment (n = 6), and an intension to bridge to TAVI or AVR in patients with severe HF (n = 4).

Pre-operative diagnostics included clinical assessment, laboratory evaluation (creatinine, glomerular filtration rate, NT-proBNP), angio-computed tomography of the aorta to evaluate the aortic valve, aortic root and the access site (femoral and iliac arteries), coronary angiography, and transthoracic (TTE) and transoesophageal echocardiography (TEE).

Procedure

All procedures were performed under local anaesthesia with short sedation under fluoroscopic and TEE guidance from the femoral approach. The femoral artery was precisely punctured after contrast injection from the contralateral site. After introduction of a closure system (PROSTAR or two PROGLIDES) an arterial sheath (12 F or 14 F) was introduced. Then heparin was administered and activated clotting time was checked (target value above 200 s). After aortography with a 6 F pigtail catheter aortic valve was crossed with a straight tip soft guidewire (Balton) and pressures in the aorta and left ventricle were registered and transaortic gradient was calculated. Subsequently, a stiff guidewire (Amplatzer Super Stiff, Boston Scientific) was placed in the left ventricle and was used to introduce a balloon catheter for valvuloplasty. The appropriate balloon (Numed Z-Med II-X) was inflated in the aortic valve by hand injection (Fig. 1). Selection of balloon size was based on the combination of TEE and in some cases pre-procedural computed tomography. A stable balloon position during inflation was achieved by rapid stimulation at 160–220 bpm. Balloon inflations were repeated 3–6 times. Pressure assessments in the ventricle and in the aorta, as well as aortography and echocardiography after the procedure, helped to determine the acute haemodynamic effect of the procedure and the degree of aortic regurgitation. The goal of the procedure was to obtain at least 50% reduction in maximal transaortic gradient obtained in haemodynamic measurement. The femoral artery was closed at the end of procedure with previously inserted prepared closure devices.

Transthoracic echocardiography was performed after the procedure and at discharge. Patients who were not treated

Table 1. Clinical data

Data	N (%) or mean ± SD
Hypertension	12 (48%)
Diabetes	11 (44%)
GFR [mL/min]	44.9 ± 23.3
COPD or asthma	4 (16%)
Prior PCI	8 (32%)
Myocardial infarction in history	6 (24%)
Atrial fibrillation	7 (28%)
Stroke or TIA in history	2 (8%)
Risk factors not included in EuroScore and STS score	Cancer or tumour in diagnostics Parkinson disease Cachexia Anaemia
NYHA classification:	
III	17 (68%)
IV	8 (32%)

COPD — chronic obstructive pulmonary disease; GFR — glomerular filtration rate; NYHA — New York Heart Association; PCI — percutaneous coronary intervention; SD — standard deviation; STS — Society of Thoracic Surgeons; TIA — transient ischaemic attack

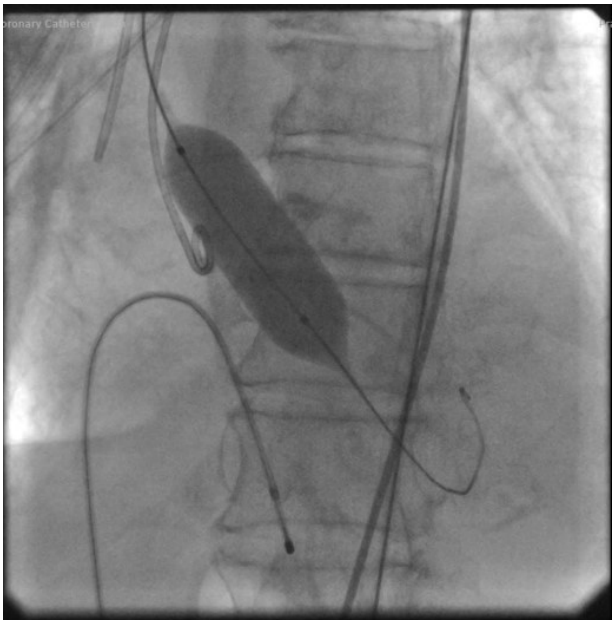

Figure 1. Balloon dilatation of the aortic valve

Table 2. Follow-up

Reason of BAV	Follow-up
BAV in patients requiring urgent non-cardiac surgery (n = 8)	Stable HF, in oncological treatment
Haemodynamically unstable HF including cardiogenic shock or pulmonary oedema (n = 7)	Five died in perioperative period; two other underwent subsequent TAVI
Advanced HF treated with BAV with intension to subsequent AVR/TAVI (n = 4)	One stable HF after BAV, refused subsequent therapy; one — lost to follow-up; two — stable HF for two years and refused subsequent invasive therapy; however, they both deteriorated, and finally TAVI was performed
Palliative BAV — many co-morbidities (n = 6)	One died due to advanced HF, one due to complications of leukaemia; four presented with stable HF in good clinical status

AVR — aortic valve replacement; BAV — balloon aortic valvuloplasty; HF — heart failure; TAVI — transcatheter aortic valve replacement

with subsequent TAVI or AVR were followed up every six months to detect clinical symptoms of deterioration. Careful physical examination, TTE, chest X-ray, and lab tests were performed at every follow-up visit.

The study complied with the Declaration of Helsinki regarding ethical conduct of research involving human subjects.

Statistical analysis

Continuous variables were reported as mean and standard deviation. For nonparametric data, the nonparametric Mann-Whitney test was used for continuous variables. Discrete variables were reported as counts or percentages. P values less than 0.05 were considered statistically significant. Statistical analysis was performed using GraphPad InStat.

RESULTS

In-hospital mortality was 20% (n = 5) and occurred in patients who underwent BAV in the setting of haemodynamically unstable HF (cardiogenic shock or resistant pulmonary oedema). Other major complications included permanent pacemaker implantation (n = 2), major vascular complications (n = 4) (one patient required bailout vascular surgery), and cardiac tamponade in one patient. There were no patients who required conversion to cardiac surgery.

The goal of the procedure (at least 50% reduction in peak transaortic gradient obtained in haemodynamic measurement) was obtained in all patients who survived the procedure. The mean peak aortic transvalvular gradient assessed in TTE examination at discharge was often slightly higher than the gradient obtained intra-procedurally. However, it also significantly decreased from 96.9 ± 29.5 mm Hg at baseline to 60.3 ± 15.5 mm Hg at discharge (p = 0.0001). We did not observe significant aortic regurgitation in any of the patients.

The median follow-up was 20.5 ± 11.4 months. Two patients died during follow-up, both of them three months after the procedure; one because of decompensated HF and the second because of complications of leukaemia. One patient with very low ejection fraction and left ventricle non-compaction was lost from follow-up. The results of follow-up observation are presented in Table 2.

DISCUSSION

The TAVI procedure was introduced in September 2010 in our institution. Up to September 2014 we performed 99 TAVI procedures, the majority from femoral approach with BAV immediately before valve implantation. However, since the beginning of the TAVI programme another 25 patients were treated with BAV not directly associated with TAVI. The main indications were advanced and haemodynamically unstable HF including cardiogenic shock or pulmonary oedema and palliative treatment in elderly patients with many severe co-morbidities. Moreover, BAV was also performed as a temporary solution for eight patients who required urgent non-cardiac surgery. If advanced HF enabled proper diagnostics or co-morbidities raised doubts on the source of complaints, BAV was used as a bridge to TAVI.

According to current guidelines [5] BAV may be considered as a bridge to surgery or TAVI in haemodynamically unstable patients who are at high risk for immediate surgery, or in patients with symptomatic severe aortic stenosis who require urgent non-cardiac surgery (IIb C), or as a palliative measure in patients with contraindication for surgery because of severe comorbidities and poor life expectancy, in whom TAVI is also not considered to be an option. Saia et al. [6] concluded that the number of BAV is increasing, mainly due to increased referral of high-risk patients and to the emerging indication of bridge for TAVI.

Our study confirms the observations of other authors [6, 7], that currently BAV has favourable acute outcome with a low rate of major complications, and is an acceptable bridge to subsequent intervention in the very high-risk population not immediately suitable for definite therapy.

Moreno et al. [8] described BAV in 21 patients in cardiogenic shock with 57% survival rate. The clinical improvement was significant, but only short-term. In our analysis two out of seven patients presenting with cardiogenic shock

or pulmonary oedema survived BAV and were successfully followed to TAVI with very good long-term results. However, five patients died during or shortly after the procedure, so they definitely did not benefit from BAV. We underline that qualification to BAV in this group of haemodynamically unstable no-option patients should be considered as a life-saving procedure, which, however, may be associated with a very high risk of death. A similar observation of worse prognosis of BAV in course of cardiogenic shock was established in the large analysis performed by Saia at al. [6]. They presented in-hospital mortality of 56.5% in patients who underwent BAV in the setting of cardiogenic shock compared with 2% in the stable subgroups of patients treated with BAV. Doquet et al. [9] presented the results of the AVR preceded by valvuloplasty in 25 patients initially disqualified from the surgery because of their poor clinical condition. BAV permitted sufficient stabilisation of clinical condition before the final surgery, which was performed in all patients within 8–14 weeks. Agarwal et al. [10] suggest the possibility of multiple BAV procedures. We did not practice such a strategy in our institution — if the result was not optimal, we decided to perform TAVI. In our opinion multiple BAV increases the risk of complications; however, such a solution may be an option if TAVI technique is not available.

The operator's experience and technological progress have significantly improved the safety of the procedure. This observation is confirmed by the decline in the incidence of serious vascular complications from 13.5% in the 1990s to 4.6–7% observed currently [4, 10–12]. We observed five in-hospital deaths, need for pacemaker implantation in two patients, major vascular access complications in four patients, and cardiac tamponade requiring pericardiocentesis in one patient. We did not observe significant aortic regurgitation in any of our patients. According to Saia et al. [6], low incidence of stroke suggests that major embolisation with debris from the aortic valve is a rare phenomenon with experienced operators, although silent micro-embolisation cannot be ruled out.

The prognosis worsens with time. The results of several studies proved that BAV decreases the degree of stenosis, but the results are not durable. Otto et al. [3] showed recurrence of stenosis as soon as six months after the procedure, with clinical worsening and the need for re-hospitalisation within 6–12 months. The PARTNER [13] trail demonstrated that TAVI is superior to medical therapy and BAV for inoperable patients with aortic stenosis. We also observed recurrence of stenosis in a short period of time after BAV; however, despite restenosis many patients presented good clinical status and relatively stable HF NYHA II, and eight of them refused subsequent therapy because of well-being. They were followed up every half year to detect symptoms of deterioration and, if present, to proceed to final invasive therapy. Kogoj et al. [14] presented BAV procedures performed in six cancer patients who required urgent non-cardiac surgery. They pointed out that since the results of BAV are transient, the timescale between percutaneous procedure and planned non-cardiac surgery is important and should be optimised to achieve the best possible outcome without major cardiovascular complications.

In our department the majority of patients with severe aortic stenosis, co-morbidities, and high peri-operative risk are treated with TAVI. A small number of patients with advanced end-stage HF or necessity of urgent non-cardiac surgery, whom in recent decades would have been offered invasive treatment, are currently considered for BAV.

CONCLUSIONS

Treatment of advanced and haemodynamically unstable aortic stenosis, bridge to non-cardiac surgery, and palliative therapy have been the main reasons for BAV in recent years. BAV as a bridge to TAVI or aortic valve replacement may also be an option for some patients.

Short-term results are good with relatively low mortality and morbidity related to the procedure. Mortality in haemodynamically unstable patients presenting with cardiogenic shock or pulmonary oedema treated with BAV is very high. Thus qualification to BAV in this group of haemodynamically unstable no-option patients should be considered as a life-saving procedure with a very high risk of death.

Conflict of interest: *none declared*

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Walwuloplastyka balonowa zastawki aortalnej — wzloty i upadki — czy mamy do czynienia z powrotem metody?

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Streszczenie

Wstęp: W ostatnich latach w związku z rozwojem techniki przezcewnikowej implantacji protezy zastawki aortalnej ponownie wzrosło zainteresowanie metodą przezskórnej walwuloplastyki balonowej zastawki aortalnej.

Cel: Celem niniejszego badania była analiza wskazań i wyników zabiegów przezskórnej walwuloplastyki balonowej zastawki aortalnej od momentu wprowadzenia w ośrodku autorów metody przezcewnikowej implantacji protezy zastawki aortalnej.

Metody: Pomiędzy wrześniem 2010 a wrześniem 2014 r. 25 kolejnych pacjentów (19 kobiet, 6 mężczyzn) poddano zabiegowi przezskórnej walwuloplastyki balonowej zastawki aortalnej. Jednocześnie w tym okresie przeprowadzono 99 zabiegów przezcewnikowej implantacji protezy zastawki aortalnej. Średni wiek chorych w grupie badanej wynosił 72 ± 11,4 roku, średni EuroScore II 10,4 ± 11,7%, średni logistic EuroScore 23,5 ± 23,6%, a średni STS score w odniesieniu do śmiertelności 21,8 ± 13,6%. U 17 (68%) chorych stwierdzono cechy niewydolności serca (HF) w III klasie czynnościowej wg NYHA, a u 8 (32%) — w IV klasie wg NYHA. Ponadto u 18 (76%) pacjentów występowały istotne czynniki ryzyka niezawarte w tradycyjnych skalach oceny ryzyka. Wskazania do przezskórnej walwuloplastyki balonowej zastawki aortalnej obejmowały: zaawansowaną hemodynamicznie niestabilną HF, w tym wstrząs kardiogenny i obrzęk płuc (n = 7), schorzenia współistniejące, głównie onkologiczne, wymagające wykonania pilnej operacji niekardiologicznej (n = 8), terapię paliatywną (n = 6) oraz intencję wykonania zabiegu walwuloplastyki balonowej w ramach leczenia pomostowego do przezcewnikowej implantacji protezy zastawki aortalnej lub wymiany zastawki aortalnej u pacjentów z ciężką HF (n = 4).

Wyniki: Śmiertelność wewnątrzszpitalna wyniosła 20% (n = 5), zgony wystąpiły u chorych poddanych zabiegowi przezskórnej walwuloplastyki balonowej zastawki aortalnej w przebiegu hemodynamicznie niestabilnej HF. Spośród innych dużych powikłań zaobserwowano konieczność wszczepienia stymulatora serca (n = 2), duże powikłania naczyniowe (n = 4) i tamponadę serca (n = 1). Żaden z pacjentów nie wymagał konwersji do operacji kardiochirurgicznej. Średni gradient przezzastawkowy zmniejszył się z 96,9 ± 29,5 mm Hg do 60,3 ± 15,5 mm Hg (p = 0,0001). Po zabiegu nie stwierdzono u chorych istotnej hemodynamicznie niedomykalności aortalnej. Średni okres obserwacji wynosił 20,5 ± 11,4 miesiąca. W trakcie obserwacji u 4 chorych wykonano zabieg przezcewnikowej implantacji protezy zastawki aortalnej. Dwoje chorych zmarło w ciągu 3 miesięcy od zabiegu, 1 z powodu zaawansowanej HF, drugi z powodu powikłań schorzeń dodatkowych.

Wnioski: Obecnie głównymi wskazaniami do wykonania przezskórnej walwuloplastyki balonowej zastawki aortalnej jest leczenie zaawansowanej i hemodynamicznie niestabilnej HF w przebiegu ciężkiego zwężenia zastawki aortalnej, leczenie pomostowe do operacji niekardiologicznej i terapia paliatywna. Przezskórna walwuloplastyka balonowa zastawki aortalnej jako leczenie pomostowe do przezcewnikowej implantacji protezy zastawki aortalnej lub wymiany zastawki aortalnej może być opcją leczniczą u niektórych pacjentów. Wyniki krótkoterminowe przezskórnej waluloplastyki balonowej są dobre, z relatywnie niską śmiertelnością i chorobowością.

Słowa kluczowe: zwężenie zastawki aortalnej, przezskórna walwuloplastyka balonowa zastawki aortalnej, implantacja przezcewnikowa

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