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ORIGINAL ARTICLE

Balloon aortic valvuloplasty in the transcatheter aortic valve implantation era: A single-center registry

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KEYWORDS
Balloon aortic valvuloplasty;
Severe aortic stenosis;
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Abstract
Introduction: Percutaneous balloon aortic valvuloplasty (BAV) has been limited by the risk of complications and restenosis. However, growing use of transcatheter aortic valve implantation (TAVI) has revived interest in this technique. We analyzed the current indications for BAV and outcomes in a single center.
Methods: Acute results and long-term outcomes were analyzed in a retrospective single-center registry of patients undergoing BAV between January 2013 and January 2016.
Results: Twenty-three patients underwent BAV, 56.5% male, mean age 78±7 years. Indications were severe aortic stenosis and decompensated heart failure (n=5), urgent non-cardiac surgery (n=8), or bridge to definitive treatment (n=10). Peak invasive gradient decreased from a median of 54.0±19.0 mmHg to 28.5±13.8 mmHg (p=0.002). Complications included one ischemic stroke, one lower limb ischemia and one femoral pseudoaneurysm requiring surgery. During a mean follow-up of 11±10 months, eight patients underwent TAVI and two underwent surgical aortic valve replacement. Thirteen patients died, nine of non-cardiovascular causes. On Kaplan-Meier analysis mortality was significantly lower among patients undergoing definitive treatment (20.0% vs. 84.6% at two-year follow-up; p=0.005).
Conclusion: BAV should be considered for selected patients with temporary contraindications to definitive therapy or as palliative therapy.

Abbreviations: AF, Atrial fibrillation; AS, Aortic stenosis; BAV, Balloon aortic valvuloplasty; CAD, Coronary artery disease; CKD, Chronic kidney disease; COPD, Chronic obstructive pulmonary disease; LVEF, Left ventricular ejection fraction; NT-proBNP, N-terminal pro-B-type natriuretic peptide; PASP, Pulmonary artery systolic pressure; PCI, Percutaneous coronary intervention; SAVR, Surgical aortic valve replacement; TAVI, Transcatheter aortic valve implantation; VARC-2, Second Valve Academic Research Consortium statement.

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PALAVRAS-CHAVE
Valvuloplastia aórtica por balão;
Estenose aórtica grave;
Implantação valvular aórtica percutânea

Valvuloplastia aórtica por balão na era da implantação de válvula aórtica percutânea. Um registo unicêntrico

Resumo
Introdução: A implantação de próteses aórticas percutâneas reavivou o interesse na valvuloplastia aórtica por balão, habitualmente limitada por complicações e restenose. Analisámos as indicações e resultados desta técnica.
Métodos: Registo retrospetivo, unicêntrico, de doentes submetidos a valvuloplastia aórtica por balão, de janeiro de 2013 a janeiro de 2016. Analisaram-se os resultados imediatos e a longo prazo.
Resultados: Vinte e três doentes foram submetidos a valvuloplastia aórtica por balão, 56,5% homens, idade média 78 ± 7 anos. As indicações foram estenose aórtica grave com: insuficiência cardíaca descompensada (n = 5); cirurgia não-cardíaca urgente (n = 8); ponte para terapêutica definitiva (n = 10). O gradiente de pico invasivo reduziu-se de uma mediana de 54,0 (19,0) mmHg para 28,5 (13,8) mmHg (p = 0,002). Registaram-se um acidente vascular cerebral isquémico, uma isquemia aguda do membro inferior e um pseudoaneurisma femoral resolvidos cirurgicamente. Durante um seguimento médio de 11 ± 10 meses, efetuaram-se oito implantações percutâneas de prótese aórtica e duas substituições cirúrgicas. Treze doentes morreram, nove de causas não-cardiovasculares. Por análise de sobrevivência de Kaplan-Meier, a mortalidade foi menor nos doentes submetidos a tratamento definitivo (20,0 *versus* 84,6% a dois anos; p = 0,005).
Conclusão: A valvuloplastia aórtica por balão deve ser considerada em doentes selecionados com contraindicações temporárias ao tratamento definitivo ou como terapêutica paliativa.

Introduction

Symptomatic severe aortic stenosis (AS) conveys a high risk of cardiovascular death and rehospitalization for heart failure with medical therapy alone. Without treatment mean survival is only 1-3 years after symptom onset.[1] Surgical aortic valve replacement (SAVR) is the gold standard for the treatment of severe AS. However, mainly due to the high prevalence of comorbidities, up to one-quarter of patients do not undergo SAVR.[2,3]

For patients who are not suitable for surgical treatment, balloon aortic valvuloplasty (BAV) was first proposed in 1986 by Alain Cribier as a useful, low-risk, palliative treatment for symptomatic relief.[4,5] Despite promising initial results (reduction of maximum and mean aortic gradients and improvement in functional capacity), its popularity waned, due to the high rate of complications and early restenosis. Moreover, the long-term survival of these patients is low, resembling the natural course of untreated severe AS.[6]

The introduction of transcatheter aortic valve implantation (TAVI) has revived interest in BAV for clinically unstable patients as a bridge to definitive therapy (TAVI or SAVR) or as a destination therapy for palliative reasons. Cohort B of the PARTNER trial showed that patients managed conservatively have significantly higher 12-month mortality compared to patients undergoing TAVI. However, only a small difference in six-month mortality was noted: 22% in the TAVI group vs. 28% in patients treated conservatively (of whom 83% underwent BAV).[7] This good result in the first months supports BAV as a therapeutic bridge.

In the TAVI era, BAV is often performed to facilitate percutaneous delivery of the prosthesis, reduce paravalvular leaks and aid in ring size assessment. The growing number of BAV procedures, together with improvements in techniques and materials and use of vascular closure devices, has led to a reduction in procedural complications. While an older series had a 20% complication rate and 8% mortality, a more recent study reported much lower rates of major complications and overall mortality (6.8% and 2.5%, respectively).[8,9]

The aim of this study was to analyze the current indications for BAV and to determine the success, complication and survival rates after BAV of patients in a real-world setting.

Methods

This was a retrospective single-center registry of patients undergoing BAV between January 2013 and January 2016.

Inclusion criteria

All patients with symptomatic severe AS who underwent BAV were consecutively enrolled. The center's heart team assessed the indication for BAV.

Procedural indications were classified as: (1) bridge to recovery: refractory cardiogenic shock, pulmonary edema or congestive heart failure due to severe AS, including patients under invasive mechanical ventilation; (2) bridge to decision: patients in whom it was judged that LV systolic function might recover and clinical condition improve via BAV, enabling subsequent definitive treatment (TAVI or