

Safety and Feasibility of Distal Radial Balloon Aortic Valvuloplasty - The DR-BAV Study

Authors : Alexandru Achim, Tamás Szűcsborus, Viktor Sasi, Ferenc Nagy, Zoltán Jambrik, Attila Nemes, Albert Varga, Călin Homorodean, Olivier F. Bertrand, Zoltán Ruzsa

Abstract : Aim: Our study aimed to establish the safety and the technical success of distal radial access for balloon aortic valvuloplasty (DR-BAV). The secondary objective was to determine the effectiveness and appropriate role of DR-BAV within half year follow-up. Methods: Clinical and angiographic data from 32 consecutive patients with symptomatic aortic stenosis were evaluated in a prospective pilot single-center study. Between 2020 and 2021, the patients were treated utilizing dual distal radial access with 6-10F compatible balloons. The efficacy endpoint was divided into technical success (successful valvuloplasty balloon inflation at the aortic valve and absence of intra- or periprocedural major complications), hemodynamic success (a reduction of the mean invasive gradient >30%), and clinical success (an improvement of at least one clinical category in the NYHA classification). The safety endpoints were vascular complications (major and minor Valve Academic Research Consortium (VARC)-2 bleeding, diminished or lost arterial pulse or the presence of any pseudo-aneurysm or arteriovenous fistula during the clinical follow-up) and major adverse events, MAEs (the composite of death, stroke, myocardial infarction, and urgent major aortic valve replacement or implantation during the hospital stay and or at one-month follow-up). Results: 32 patients (40 % male, mean age $80 \pm 8,5$) with severe aortic valve stenosis were included in the study and 4 patients were excluded. Technical success was achieved in all patients (100%). Hemodynamic success was achieved in 30 patients (93,75%). Invasive max and mean gradients were reduced from 73 ± 22 mm Hg and 49 ± 22 mm Hg to 49 ± 19 mm Hg and 20 ± 13 mm Hg, respectively ($p = <.001$). Clinical success was achieved in 29 patients (90,6%). In total, no major adverse cardiac or cerebrovascular event nor vascular complications (according to VARC 2 criteria) occurred during the intervention. All-cause death at 6 months was 12%. Conclusion: According to our study, dual distal radial artery access is a safe and effective option for balloon aortic valvuloplasty in patients with severe aortic valve stenosis and can be performed in all patients with sufficient lumen diameter. Future randomized studies are warranted to investigate whether this technique is superior to other approaches.

Keywords : mean invasive gradient, distal radial access for balloon aortic valvuloplasty (DR-BAV), aortic valve stenosis, pseudo-aneurysm, arteriovenous fistula, valve academic research consortium (VARC)-2

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