A novel pressure-regulated deployment strategy for improving the safety and efficacy of balloon-expandable transcatheter aortic valves

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Topic(s):
Aortic Valve Intervention

Background: Annular rupture is a catastrophic complication of Transcatheter Aortic Valve Implantation, more commonly seen with balloon expandable valves. Size selection and deployment of these valves often presents a serious challenge as prosthesis oversizing increases the risk of rupture, while undersizing results in greater paravalvular regurgitation (PVR). Current deployment protocols are volume-regulated and susceptible to undesired prosthesis over or under-expansion. Laplace’s Law demonstrates that the stress exerted on the aortic wall is determined by both the valve area and internal pressure during deployment. Yet the issue of balloon pressure during deployment has been thus far ignored.

Purpose: In this feasibility study, we aimed to develop a novel pressure-regulated deployment method that allows optimising apposition between valve and annulus, while preventing significant tissue injury and rupture.

Methods: We analysed a cohort of 278 consecutive patients with severe aortic stenosis and intermediate-severe surgical risk who underwent TAVI using Sapien 3 valves. This included 88 patients (32%) considered at high risk of annular rupture based on accepted factors such as moderate-severe subannular calcification. A pressure gauge was connected to the apparatus and in each case the valve was deployed until reaching a pre-determined pressure limit. In earlier cases lower pressures of 4-4.5atm were used to establish safety, while in later cases pressure limit was increased to maximum of 7atm. In some patients post-dilatation was performed to improve angiographic regurgitation. Using a biomechanical application of Laplace’s Law, the estimated annular wall stress was calculated for each case and assessed against recorded complications such as annular rupture, PPM insertion, new LBBB and PVR on post-procedure TTE. Based on these analyses we then determined the optimal pressure limit for each available valve size.

Results: Distribution of deployment pressures and associated estimated wall stress are shown in attached Figure. 1 case of annular rupture (0.4%) occurred in high risk patient at 3.81MPa. Wall stress levels >3.0MPa were associated with reduced rates of post dilatation (13% vs 37%, p<0.001) and ≥mild PVR (10.7% vs 20%, p=0.093). In patients (148) with estimated wall stress between 3-3.8MPa rates of new PPM and LBBB were 7.4% and 8.1%, respectively. Greater wall stress was not associated with increased new PPM/LBBB risk. Therefore, we suggest the optimal deployment pressure limit to minimise risk of rupture, rates of post-dilatation and clinically significant PVR is: 6atm for 23mm valves, 5.5atm for 26mm valves and 5atm for 29mm valves.

Conclusion: Pressure-regulated deployment strategy is a reproducible, safe and effective method for balloon expandable TAVI, alleviating concerns of valve oversizing in high risk patients. Further trials are needed to validate this novel method and compare it with current volume-regulated techniques.
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