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Soften the blow - A comparison of semi- and non-compliant balloon systems in TAVI

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THEME: Interventions for Valvular Disease

TOPIC(S): TAVI

AIMS

The benefit of percutaneous balloon aortic valvuloplasty (BAV) during transcatheter aortic valve implantation (TAVI) has recently been questioned. Therefore, due to the growing relevance of TAVI-procedures, there is intensified research on the role of BAV during TAVI. However, there has been little focus on the difference in the outcome of compliant- and non-compliant-balloon use. The aim of this study was the evaluation of possible differences in mortality and complication rates between compliant- and non-compliant-balloon use during TAVI-procedures.

METHODS AND RESULTS

Between June 2009 and December 2016, 532 TAVI patients were examined throughout this retrospective single-center cohort study. The primary endpoint of the study was the grade of residual paravalvular leak (PVL) after TAVI. Secondary endpoints were 30-day mortality as well as a composite safety endpoint. Furthermore, complication rates of VARC-2 defined endpoints had been investigated. Non-compliant-balloons (NCB) (True Dilatation, Bard Inc.) were compared to (semi-)compliant-balloons (CB), such as Nucleus, Z-MED or Z-MED II by NuMed Inc., VACS II and III by Ospyka or the standard Edwards Transfemoral Balloon Catheter. Pre- and post-dilatation (PreD / PostD), as well as inflation time, had been measured during the implantation. A postprocedural paravalvular leak was not influenced by balloon type or inflation time, however the overall incidence of PVL was more often observed after pre-dilatation (no PreD: 59 [38.1%] vs. PreD: 181 [52.8%], $p=0.002$). Clinically relevant PVL (more than trace) on the other hand was more often observed after post-dilatation (no PostD: 30 [7.3%] vs. PostD: 14 [15.7%], $p=0.014$). Balloon type nor pre-dilatation or post-dilatation had any effect on 30-day mortality, however, during long-term follow-up, the use of post-dilatation had a trend towards impaired long-term survival (log rank: 0.064). Evaluating adverse events, predilatation was associated with a higher rate of pacemaker implantation (no PreD: 12 [7.4%] vs. PreD: 58 [16.5%], $p=0.003$), conversion to open surgery (no PreD: 0 [0%] vs. PreD: 8 [2.3%], $p=0.047$), the need for valve-in-valve (VIV) implantation (no PreD: 0 [0%] vs. PreD: 8 [2.3%], $p=0.047$) and less often met the criteria for the composite safety endpoint (no PreD: 116 [69.9%] vs. PreD: 216 [59.0%], $p=0.010$). The use of non-compliant balloons during predilatation led to a higher rate of VIV-implantations during index procedure (CB: 2 [0.6%] vs. NCB: 5 [5.7%], $p=0.005$) and conversions to open surgery (CB: 1 [0.3%] vs. NCB: 3 [3.4%], $p=0.030$). Furthermore a trend towards neurological adverse events had been observed (CB: 6 [1.7%] vs. NCB: 5 [5.5%], $p=0.058$).

CONCLUSIONS

Reviewing our results, pre-dilatation entails serious operational risk factors as well as a higher rate of postprocedural PVL - mainly consisting of minimal or trace regurgitation. And even though post-dilatation generally reduces PVL, a significant difference in clinically relevant PVL remains, thus leaving balloon- and THV companies room for improvement on sealing and valve expansion. The use of non-compliant balloon systems during predilatation must be discouraged in the light of a higher rate of VIV implantations and conversion to open surgery as well as a trend towards neurological adverse events in

our study.

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