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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-ballons (NCB) (True Dilatation, Bard Inc.) were compared to (semi-)compliant-ballons (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.