

## Safety and feasibility of retrograde Inoue balloon for balloon aortic valvuloplasty without rapid ventricular pacing during transcatheter aortic valve implantation

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**Background:** Although rapid ventricular pacing (RVP) is commonly performed for preparation of transcatheter aortic valve implantation (TAVI). It has been reported that multiple and / or prolonged RVP is associated with adverse clinical outcomes of TAVI. Retrograde Inoue-Balloon was designed for balloon aortic valvuloplasty (BAV) without RVP to prevent slip of balloon by way of central waist during biphasic inflation.

**Purpose:** The purpose of this study was to evaluate safety and feasibility of Retrograde Inoue-Balloon for TAVI preparation.

**Methods:** From December 2013 to December 2019, 427 consecutive patients who performed TAVI for severe aortic valve stenosis, were retrospectively enrolled in Iwate Medical University. Of them, 227 (53%) patients (mean age 83±5 years, male 41%), underwent retrograde BAV before prosthetic valve implantation, comprised this study population. Retrograde BAV procedures were divided into two groups; patients used Inoue-Balloon without RVP and those did conventional balloon with RVP. The primary endpoint was defined as combined adverse events of 30-day mortality, cerebral infarction, and critical complications after BAV (aortic dissection, aortic

rupture and cardiopulmonary arrest). The secondary endpoint was set as prolonged hypotension after BAV.

**Result:** Inoue-Balloon (IB) and conventional balloon (CB) were used for 73 patients (32%) and 154 (68%) patients, respectively. Both balloons were succeeded to through and expand of aortic valve in all cases. In the CB group, cardiopulmonary arrest occurred in 2.0% after BAV, cerebral infarction was observed in 3.9%, and 30-day death in 3.3%. On the other hand, no major complications were observed except one aortic dissection in the IB group. In logistic regression analysis adjusted by sex and age, the incidence of combined adverse events was significantly lower in the IB group (OR 0.17, 95% CI 0.009–0.917, P=0.037). Furthermore, the IB group had significantly a lower incidence of prolonged hypotension following BAV compared with CB group (4.1% vs 19.5%, p=0.002).

**Conclusion:** Balloon aortic valvuloplasty using retrograde Inoue-balloon without rapid ventricular pacing is safe and feasible, and may improve clinical outcomes of TAVI.

Odds Ratio for combined adverse events

	Adjusted OR	95% CI	p value
STS score	1.00	0.780–1.219	0.994
EF (Simpson)	1.01	0.945–1.074	0.827
Clinical Frailty Score	0.87	0.430–1.766	0.700
Prolonged Hypotension	2.07	0.528–8.115	0.297
Usage of Inoue	0.17	0.009–0.917	0.037

