Clinical Summary:

A Retrospective Evaluation of Endo-Aortic Balloon Occlusion Compared to External Clamping in Minimally Invasive Mitral Valve Surgery

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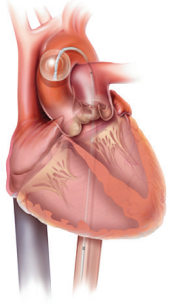
Rationale

- External aortic clamping (EAC) or endo-aortic balloon occlusion (EABO) with the IntraClude device are common techniques used during the set up of cardiopulmonary bypass for minimally invasive mitral valve surgery (MIMVS).
- Few studies have compared outcomes of EAC and EABO in MIMVS and most have been limited in size.[1-6]

Objective: To compare safety and efficacy outcomes between EAC and EABO techniques in a large patient population using the STS Adult Cardiac Surgery Database



Endo-aortic balloon occlusion with the IntraClude device

STS Database Analysis

- The STS Database is the leading clinical outcomes registry for adult cardiac surgery, worldwide.
- A cohort was extracted of 7,978 patients who underwent isolated MIMVS (repair or replacement) with EAC or EABO after exclusion criteria (7/2017 to 12/2018); a total of 2,326 patients were 1:1 propensity score matched.
- Intra- and post-operative outcomes were compared using generalized linear modeling and negative binomial or logistic regression (**Table 1**).

Table 1. STS Study Outcomes

Intraoperative Outcomes
• Cardiopulmonary bypass (CPB) time
• Cross-clamp time
• Intraoperative aortic dissection
• Intraoperative major bleeding[a]
Postoperative Outcomes
• Success of repair[b]
• Post-operative length of stay (LOS)
• 30-day mortality, stroke/TIA, and AKI[c]
• ICU duration through 30 days or discharge
• New onset of atrial fibrillation through discharge

Note: Myocardial infarction is not available as a postoperative diagnosis in the STS Database

[a] Transfusion of ≥3 units of red blood cells and a hemoglobin drop of ≥3 units

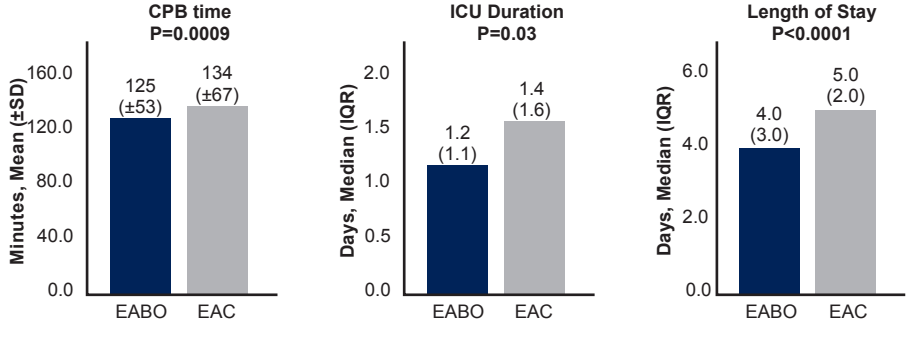
[b] Measured by postoperative moderate/sever mitral regurgitation

[c] Serum creatinine level increase 2x > baseline, a new requirement for dialysis postoperatively, or any readmission with primary cause of renal insufficiency, renal failure, or primary readmission procedure of dialysis

Results

- CPB time and LOS were significantly shorter in the EABO group versus EAC group (**Figure 1**).
- For all outcomes other than CPB time and postoperative LOS, there were no statistically significant differences detected between groups.

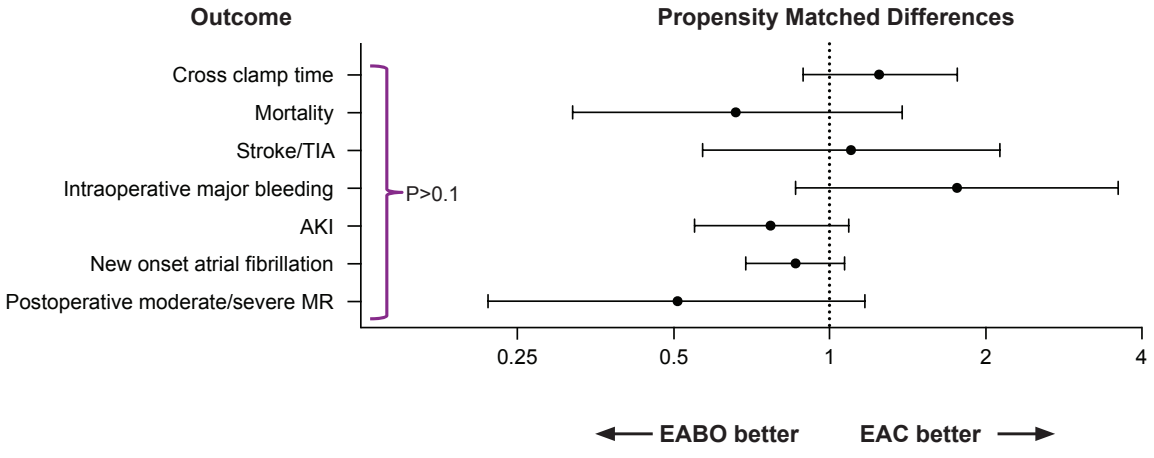
Figure 1. Across the continuum of patient care, EABO was associated with significantly shorter CPB time and postoperative ICU and hospital stay compared to EAC



Results (continued)

- Effectiveness was similar between EAC and EABO (**Figure 2**), as measured by postoperative moderate/severe mitral regurgitation.
- There were no aortic dissections in the EABO group and one in the EAC group.

Figure 2. EABO and EAC were associated with similar safety and effectiveness



Conclusions

- Endo-aortic occlusion was associated with shorter cardiopulmonary bypass times and hospital length of stay compared to external clamping, which could translate to lower overall costs and lower risks of complications as manipulation to the aorta is minimized.
- External aortic clamping and endo-aortic balloon occlusion had similar safety profiles and success rates, including no aortic dissections, suggesting that the endo-aortic balloon is a safe option for aortic occlusion during MIMVS.
- These results suggest that the endo-aortic balloon was similar to the external aortic clamp in most major outcomes and has potential for greater efficiencies in the operating room and improvements in patient recovery time.

Abbreviations: AKI, acute kidney injury; CPB, cardiopulmonary bypass; EABO, endo-aortic balloon occlusion; EAC, external aortic clamping; ICU, intensive care unit; IQR, interquartile range; LOS, length of stay; MIMVS, minimally invasive mitral valve surgery; MR, mitral regurgitation; SD, standard deviation; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack

References
1. Bentala M, Heuts S, Vos R, et al. Interact Cardiovasc Thorac Surg. 2015;21:359-365. 2. Barbero C, Krakor R, Bentala M, et al. Ann Thorac Surg. 2018;105:794-798. 3. Barbero C, Rinaldi M, Pocar M, et al. Front Cardiovasc Med. 2021;8:719687. 4. Casselman F, Aramendi J, Bentala M, et al. Ann Thorac Surg. 2015;100:1334-1339. 5. Loforte A, Luzi G, Montalto A, et al. Innovations (Phila). 2010;5:413-418. 6. Mazine A, Pellerin M, Lebon JS, et al. Ann Thorac Surg. 2013;96:2116-2122.

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