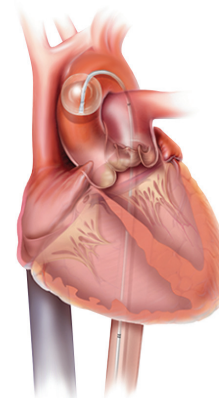


Rationale

- External aortic clamping (EAC) and endo-aortic balloon occlusion (EABO) with the IntraClude device are two common techniques used during the set up of cardiopulmonary bypass for minimally invasive mitral valve surgery (MIMVS).
- A previous analysis of the STS Adult Cardiac Surgery Database found similar safety profiles and success rates among EAC and EABO, and an association of EABO with a shorter hospital length of stay was also observed.
- There are minimal data in the literature regarding the economic considerations of MIMVS.¹



Endo-aortic balloon occlusion with the IntraClude device

Objective: To validate the results of the STS Database study and evaluate costs associated with EAC versus EABO using the Premier Healthcare Database

Premier Healthcare Database Analysis

- The Premier Healthcare Database is a real-world claims database containing all-payer hospital data that captures ~25% of inpatient admissions in the US.
- A 3:1 propensity score- and exact-matched cohort was extracted of 1,663 cases of EABO-eligible cardiac surgery (10/2015 to 03/2020).
- We examined cost outcomes and clinical outcomes (**Table 1**) using multivariable generalized linear models to detect differences between groups.

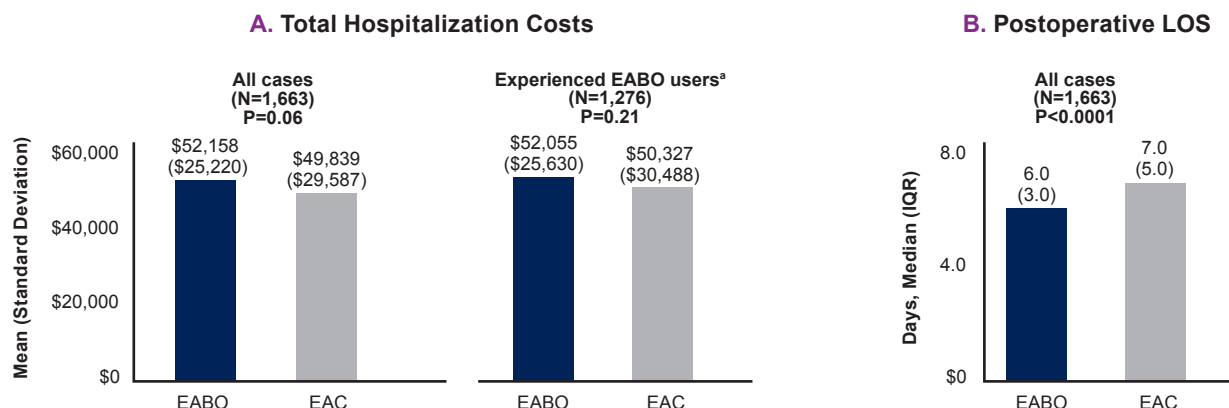
Table 1. Study Outcomes

- Length of stay (LOS)
- Total hospitalization cost
- MARCE components:
 - Mortality
 - Atrial fibrillation
 - Acute kidney injury (AKI)
 - Myocardial infarction
 - Postcardiotomy syndrome
 - Stroke/transient ischemic attack (TIA)
- Aortic dissection

Cost Results

- There was no statistically significant difference in total hospitalization costs between EABO versus EAC patient stays (**Figure 1A**).
- Cost difference was even further reduced when the procedure was performed by more experienced EABO surgeons (**Figure 1A**).
- EABO was associated with a 1-day reduction in LOS when compared to EAC (**Figure 1B**), which aligns with findings from the STS database analysis.

Figure 1. The difference in total hospitalization costs (A) and hospital length of stay (B) between EABO and EAC



*Experienced physicians were those who had conducted 10 or more EABO procedures in the study period.

Clinical Results

- Rates of myocardial infarction and postcardiotomy syndrome were significantly lower in patients with EABO versus EAC (Figure 2).
- There were no significant differences in any other clinical outcomes (MARCE, mortality, atrial fibrillation, AKI, or stroke/TIA) (Table 2).
- There were no incidences of aortic dissection in the EABO group and 2 in the EAC group.

Figure 2. Rates of myocardial infarction and postcardiotomy syndrome (P<0.01)

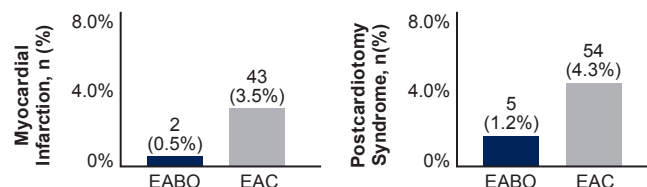


Table 2. Comparison of the Premier database to the STS database analysis presented at the American Association for Thoracic Surgery Annual Meeting, May 2022

| | Premier Healthcare Database | | | STS Adult Cardiac Surgery Database | | |
|-----------------------------------|-----------------------------|---------------|---------|------------------------------------|---------------|---------|
| | EABO (n=419) | EAC (n=1,244) | P-value | EABO (n=1,163) | EAC (n=1,163) | P-value |
| Mortality, n (%) | 5 (1.2%) | 21 (1.7%) | 0.5 | 12 (1.0%) | 18 (1.6%) | 0.3 |
| Atrial fibrillation, n (%) | 56 (13.4%) | 179 (14.4%) | 0.6 | 181 (16.7%) | 214 (18.9%) | 0.2 |
| AKI, n (%) | 32 (7.6%) | 118 (9.5%) | 0.3 | 63 (6.5%) | 79 (8.2%) | 0.1 |
| Stroke/TIA, n (%) | 9 (2.2%) | 21 (1.7%) | 0.6 | 19 (2.0%) | 17 (1.8%) | 0.8 |

Conclusions

- This real-world evidence suggests that endo-aortic balloon occlusion has similar costs and clinical outcomes as the external aortic clamp
- Similar to the STS database study, the endo-aortic balloon was associated with a 1-day reduction in hospital length of stay compared to the clamp.
- Similar to the clamp, the endo-aortic balloon protects the heart during cardiopulmonary bypass with the advantage of minimizing manipulation of the aorta.

Abbreviations: AKI, acute kidney injury; CPB, cardiopulmonary bypass; EABO, endo-aortic balloon occlusion; EAC, external aortic clamping; IQR, interquartile range; LOS, length of stay; MARCE, major adverse renal and cardiac events; MIMVS, minimally invasive mitral valve surgery; SD, standard deviation; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

References

1. Atluri P, Stetson RL, Hung G, et al. J Thorac Cardiovasc Surg. 2016;151:385-388.

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