Conclusions: There has been a significant decrease in the proportion of high risk PCIs with elective support device insertion, especially in those performed in patients with new or recent myocardial infarction in absence of shock.

TCT-69
Evaluating The Learning Curve In A Clinical Trial Using A New Percutaneous Left Ventricular Support System. Observations From The PROTECT II Trial
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Background: The introduction of new medical devices may be accompanied by a learning curve.

Methods: To evaluate the impact of the device learning curve on the outcomes of PROTECT II trial, comparing Impella 2.5 versus the intra-aortic balloon pump (IABP) during high-risk percutaneous coronary intervention, we report on additional analysis excluding not only the first Impella 2.5 and IABP patients at each site but also the first 2 and first 5 patients.

Results: A total of 448 patients were enrolled at 74 sites. Among these, 58 patients were the first to receive Impella 2.5 at their site, 62 were the first to receive IABP, and 195 were the first to receive both. After exclusion of the first patient in each group, MAE rates for Impella 2.5 and IABP were 38.0% versus 50.0% (p = 0.029) at 90 days. After excluding the first 2 patients, the MAE rates were 51.7% versus 37.1% and after excluding the first 5 patients the MAE rates were 57.1% versus 37.3%.

Conclusions: Significantly lower 90-day MAE rates were observed with the use of Impella 2.5 compared to the use of IABP after excluding the first patient per site. When excluding more patients, the MAE rates change, however, it also drastically reduces the number of sites included in this analysis. This analysis suggests a learning curve associated with initial introduction of the Impella 2.5. Clinical trials should better address the training aspect of new devices, especially when compared with more established devices.

TCT-70
No Survival Benefit with Use of Intra-Aortic Balloon Pump in Extracorporeal Membrane Oxygenation: A Pooled Experience of 1,517 Patients
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Background: Use of intra-aortic balloon pump (IABP) in addition to extracorporeal membrane oxygenation (ECMO) for treatment of cardiac failure has become routine in many institutions. However, data is conflicting on whether IABP utilization leads to any incremental clinical benefit on top of ECMO support.

Methods: A systematic Medline search was performed for studies reporting on survival to hospital discharge for cardiogenic shock or cardiac arrest requiring ECMO which also reported IABP outcomes. Survival to hospital discharge for patients who received concurrent IABP was compared to those who did not. Outcomes in the incremental use of IABP in acute myocardial infarction, postcardiotomy cardiogenic shock, when placed prior to initiation of ECMO, and in its routine use at initiation of ECMO were also analyzed.

Results: Sixteen studies were included in the main analysis encompassing 1,517 patients. The cumulative survival rate for patients on ECMO only was 256/683 (37.5%) compared with 294/834 (35.3%) for patients also supported with IABP. The risk ratio for survival for 1,143 (0.973 – 1.343) favored IABP use but was not statistically significant p = 0.105. After removal of one extreme outlier on funnel plot, the risk ratio for survival on reanalysis of 1,430 patients was 1.052 (0.886 – 1.249) p = 0.563. The risk ratios for survival for IABP use in acute myocardial infarction and postcardiotomy cardiogenic shock were 1.120 (0.772 – 1.624) p = 0.552 and 1.121 (0.826 – 1.520) p = 0.463, respectively. The risk ratios for survival for IABP when placed prior to initiation of ECMO or as a routine measure at the initiation of ECMO were 0.948 (0.718 – 1.252) p = 0.706 and 1.102 (0.806 – 1.506) p = 0.543, respectively. Funnel plot analysis suggested a publication bias in favor of IABP use.

Conclusions: There was no survival benefit observed with IABP use in addition to ECMO only. Our analysis of existing literature does not provide support for routine use of IABP in addition to ECMO. Further studies are needed to assess whether other modalities of left ventricular venting such as percutaneous ventricular assist devices add incremental benefit to ECMO use.

TCT-71
Outcomes of Transcatheter Aortic Valve Replacement (TAVR) in Patients Presenting with Circulatory Shock Secondary to Inoperable Aortic Stenosis
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Background: TAVR is a novel procedure to treat high-risk or inoperable patients with severe symptomatic aortic stenosis. Randomized trials have excluded TAVR for patients requiring urgent or emergent procedures or in circulatory shock. The purpose of this study is to evaluate outcomes of urgent or emergent TAVR in patients with circulatory shock secondary to severe aortic valve disease (AVD).

Methods: This retrospective case series included patients presenting to an academic hospital on inotropes and/or vasopressors who underwent TAVR for inoperable severe AVD. Data collection included morbidity, resource utilization, and immediate procedural mortality (< 72 hours post procedure), 1-month, and 6-month all-cause mortality. Other outcomes collected were based on the standardized endpoint definitions for TAVR of the Valve Academic Research Consortium-2 (VARC-2).

Results: The study cohort consisted of 11 consecutive patients in cardiogenic shock with severe AVD. Most were men (10/11, 90.9%) and the median age was 75 years (IQR: 67-85). All patients were on either vasopressors or inotropes prior to the TAVR procedure. The median Society of Thoracic Surgeons Score (STS) for predicted risk of mortality was 32 (IQR: 23-53). There were no operative deaths. Only 1 patient of the 11 (9.1%) had an in-hospital mortality, while 10 (90.9%) survived to discharge. The survival rate at 1 month was 91% (n = 10) and 72.7% (n = 8) at 3 and 6 months. The rate of device success on initial deployment was 91% (n = 10) with 1 patient requiring an emergent but successful TAVR-in-TAVR deployment. The median length of hospital stay was 8 days (IQR: 7-20). Other VARC-2 outcomes included: stroke (n=0), acute kidney injury (5/11, 45.5%), peri-procedural myocardial infarction (2/11, 18.2%), requirement of TAV-in-TAV deployment (1/11, 9.0%), conduction disturbances (n=0).

Conclusions: In this retrospective, single-institution study, we demonstrate that TAVR appears to be safe and feasible in selected high-risk or inoperable patients with severe AVD and circulatory shock. Furthermore, a multi-institutional trial is needed to evaluate the safety and feasibility of TAVR in this high-risk patient population.

TCT-72
Timing of Intra-aortic Balloon Therapy in ST Elevation Myocardial Infarction
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Background: Cardiogenic shock (CS) occurs in up to 25% of patients with ST elevation myocardial infarction (STEMI). Use of peripheral ventricular assist devices (p-VAD) such as intra-aortic balloon pump (IABP) is recommended in these patients. However, there is conflicting evidence regarding the timing of initiation of IABP therapy in STEMI patients with CS. We aimed to determine if there was a difference in outcomes between patients who had initiation of IABP therapy in STEMI patients, pre- and post-percutaneous coronary intervention (PCI) patients.

Methods: Medical records of 613 consecutive patients undergoing primary PCI for STEMI were screened to identify 174 patients receiving IABP therapy. Baseline clinical and outcome data were compared between those receiving IABP pre (n = 76) and post PCI (n = 98).

Results: Post-PCI IABP group had a higher association with ventricular arrhythmia (p = 0.05), use of defibrillation (p = 0.04), refractory shock (p = 0.05), cardiac arrest during hospitalization (p = 0.05), and death at 1 year post index event (p = 0.05). (Table 1) On logistic regression model using significant baseline variables as covariates, refractory shock retained its association with post-PCI IABP placement (p = 0.005).

Conclusions: In patients with STEMI with CS, pre-PCI initiation of IABP therapy led to fewer cases of refractory shock without affecting the door to balloon times, indicating that early myocardial unloading improves overall clinical outcomes in STEMI patients.