COST-EFFECTIVENESS AND QUALITY OF LIFE IMPROVEMENTS: IMPELLA HEMODYNAMIC SUPPORT COMPARED WITH INTRA- AORTIC BALLOON PUMP IN HIGH RISK PATIENTS RECEIVING PCI

i2 Poster Contributions
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Background: Clinical outcomes and cost-effectiveness of new technologies for hemodynamic support in patients with left ventricular dysfunction and complex anatomy have not been previously studied.

Methods: PROTECT II studied patients with 3 vessel disease and LV ejection fraction ≤ 30% or with unprotected left main/last patent conduit and LV ejection fraction ≤ 35% during PCI. Patients were randomized to either intra aortic balloon pump (IABP) or Impella (Abiomed). The primary endpoint was a composite of ten major adverse events (MAE) measured at 30 and 90 days. Economic analyses were performed to assess resource utilization for patients treated with Impella compared to IABP from index stay up to 90 days. Itemized hospital bills were collected for U.S. patients that consented for the economic study (N=260), converted to costs using department level cost-to-charge ratios, and modeled for the complete trial patient population at 90 days. Estimated costs were validated via comparison with MedPAR. Measures of episode-of-care costs, major adverse cardiac and cerebral events (MACCE), and Quality-Adjusted Life Years (QALYs) for both study arms served as inputs to a Markov model to estimate the incremental cost-effectiveness ratio (ICER).

Results: MAE at 90 days for Impella were 40.8% vs. IABP 51.4% (p=0.029) including a 51% relative reduction in repeat revascularization (Impella 6.1% vs. IABP 12.4%, p=0.026). Improvement in ejection fraction and NYHA Class of heart failure were significant. Median hospital days for entire episode-of-care for Impella were 7 days vs. IABP 9 days (p=0.048). Reduction in MAE was associated with a gain in QALY for Impella patients. Base case ICER of $39,367 was well below the $100,000 value often given as a threshold for innovative technologies.

Conclusions: For patients with severe LV dysfunction and complex anatomy, prophylactic use of Impella during PCI reduced MAE at an incremental cost per quality-adjusted life year considered to be cost-effective for advanced cardiovascular technologies. Improvements in overall quality of life metrics such as ejection fraction and NYHA Class of heart failure were significant in this study.