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# Concerns for the Use of Impella in Patients with Cardiogenic Shock Complicating Acute Myocardial Infarction

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## Abstract

**Introduction:** To our knowledge, there has been no conclusive evidence so far to guide the choice between impella and intra-aortic balloon pump (IABP) in patients with ischemic cardiogenic shock. Using the 2016 National Inpatient Sample (NIS), this work aims to compare in-hospital outcomes among patients presenting with ischemic cardiogenic shock treated without mechanical support, with impella, or with IABP.

**Methods:** Data was obtained from the 2016 NIS database. The primary outcome was in-patient mortality. Secondary outcomes were hospital length of stay and total hospital charge. A series of univariate and multivariate regression analyses were conducted on STATA 15.1.

**Results:** In this dataset, 11710 observations met the criteria of adults, acute ischemia and cardiogenic shock. Among these, 7727 were treated without mechanical support, 649 were treated with impella, and 3,334 were treated with IABP. Patients treated with impella had higher inpatient mortality (OR 1.75; 95% CI 1.46 - 2.11), whereas patient treated with IABP had lower inpatient mortality (OR 0.77; 95% CI 0.70 - 0.85). In addition, compared with no mechanical support and IABP, the use of impella was associated with higher hospital cost ($\beta1=198269$, $p<0.001$). Furthermore, the use of impella was not associated with change in length of stay when compared to no mechanical support. IABP was associated with longer length of stay ($\beta1=1.53$, $p<0.001$).

**Conclusion:** In conclusion, among patients was ischemic cardiogenic shock, compared with no mechanical support, inpatient mortality was higher with impella and lower with IABP use. In addition, impella use was associated with increase hospital cost without change in hospital length of stay. Lastly, IABP was associated with increased length of stay. Despite the limitations of the NIS dataset, including selection bias, this work should prompt further research to validate the use impella.

**Keywords:** Intra-aortic balloon pump; Impella; Cardiogenic shock; Acute coronary syndrome

**Abbreviations:** IABP: Intra-Aortic Balloon Pump; AMI: Acute Myocardial Infarction; CS: Cardiogenic Shock

## Introduction

Cardiogenic shock (CS) in the setting of acute myocardial infarction (AMI) remains a significant cause of death despite timely percutaneous coronary revascularization [1]. It has been shown that inpatient and long-term mortality in these patients can be as high as 66% and 88%, respectively [2]. Several devices have been created to provide additional cardiovascular support in the hope of optimizing cardiac function and improving clinical outcomes. Among these, the intra-aortic balloon pump (IABP) and the impella are the most commonly used. The current evidence does not support the routine use of IABP in most patients with AMI complicated by CS. This was best shown in the IABP-SHOCK II trial, where no difference in all-cause mortality was observed at 30 days, 12 months and 6.2 years follow up whether IABP was used or not [3]. The impella is a newer device and a promising alternative. It consists of a small axial flow pump that can provide a cardiac output up to 5.0 L/min [4]. However, the evidence surrounding impella use is not conclusive. In 2019, a retrospective study comparing patients treated with impella with matched patients from the IABP-SHOCK trial treated with an IABP or medical therapy showed no difference in 30-day mortality [5]. These findings were reproduced in two randomized controlled trials (RCT) and meta-analysis of RCTs [6,7]. Nonetheless, impella use continues to be approved by the Food and Drug Administration (FDA) since 2016 based solely on circulatory support rather than clinical outcomes. Our study aimed to investigate the difference in inpatient mortality, length of stay and cost of hospitalization with IABP vs. impella use in AMI complicated by CS.

## Research Methodology

The data in this study was obtained from the 2016 National Inpatient Sample, which relies on the ICD 10 coding system to identify diagnoses and procedures. Table 1 list's all the codes used in this study. STATA 15.1 was used for statistical analysis. We identified adults with ischemic cardiogenic shock and whether they received an IABP, an impella, or no device. The primary endpoint was inpatient mortality. Secondary endpoints were hospital length of stay, and total hospital cost.

| ICD 10 Code | Description |
|---|---|
| I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.9, I21.A1, I21.A9 | Diagnoses related to acute coronary ischemia |
| R57.0 | Cardiogenic shock |
| 5A0211D, 5A0221D | Impella |
| 5A02110, 5A02210 | Intra-aortic Balloon pump |

**Table 1:** ICD 10 codes used in this study.

| Baseline characteristics | No mechanical support | IABP | Impella | p-value |
|---|---|---|---|---|
| Female | 40% | 29% | 31% | p<0.05 |
| Age | 69.8 | 65.6 | 66.5 | p<0.05 |
| Median household income | $1 - $42,999: (31%) | 30% | 29% | p>0.05 |
| | $43,000 - $53,999: (26%) | 27% | 26% | |
| | $54,000 - $70,999: (24%) | 26% | 24% | |
| | $71,000 or more: (19%) | 17% | 19% | |
| Insurance | Medicare (67%) | 50% | 56% | p<0.05 |
| | Medicaid (9%) | 10% | 10% | |
| | Private including HMO (18%) | 30% | 27% | |
| | Other (6%) | 10% | 7% | |
| Hospital region | Northeast (17%) | 15% | 18% | p<0.05 |
| | Midwest (22%) | 16% | 24% | |
| | South (40%) | 47% | 38% | |
| | West (22%) | 22% | 21% | |
| Hospital bedsize | Small (13%) | 10% | 11% | p>0.05 |
| | Medium (27%) | 25% | 27% | |
| | Large (60%) | 65% | 61% | |
| Teaching Hospital | 47% | 4% | 21% | p<0.05 |
| Charlson comorbidity index | 3.9 | 3.5 | 3.4 | p>0.05 |

**Table 2:** Patients baseline characteristics.

Co-variates included in the study were sex, age, race, median household income for patient's ZIP Code, insurance status, hospital region, hospital bed size, hospital teaching status. Also, to adjust for multiple comorbidities, the Charlson Comorbidity Index was used. This is a validated tool that takes into account 17 common diseases to generate a single score estimating 10-year survival. Multivariate logistic and linear regressions were used to evaluate our primary and secondary endpoints [8].

## Results

In this dataset, 11710 observations met the criteria of adults, acute ischemia, and cardiogenic shock. Among these, 7727 were treated without mechanical support, 649 were treated with impella, and 3,334 were treated with IABP (Figure 1).

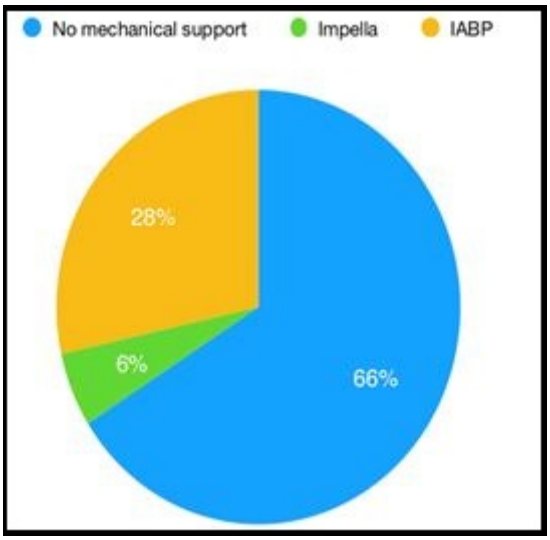


**Figure 1:** Proportion of patients with CS and AMI who received no mechanical support, IABP, or impella.

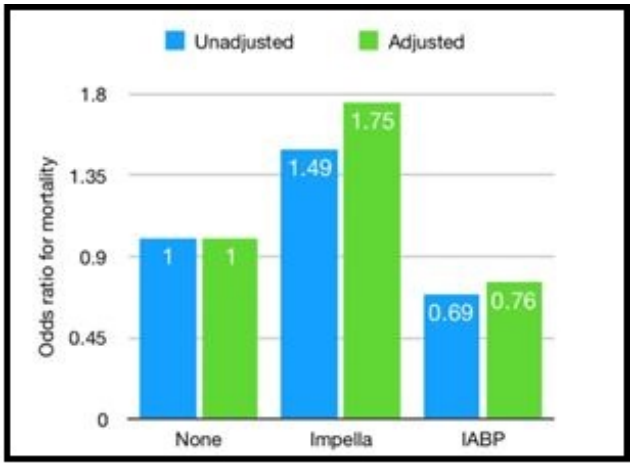


**Figure 2:** Adjusted and unadjusted inpatient mortality ratios when no mechanical support, IABP or impella was used.

Table 2 summaries the patient characteristics. Patients treated with impella had higher inpatient mortality (OR 1.75; 95% CI 1.46 - 2.11), whereas patients treated with IABP had lower inpatient mortality (OR 0.77; 95% CI 0.70 - 0.85), compared to no mechanical support (Figure 2). In addition, compared with no mechanical support and IABP, the use of impella was associated with higher hospital costs (β1=198269, p<0.001). Furthermore, the use of imeplla was not associated with a change in length of stay when compared to no mechanical support. IABP was associated with longer length of stay (β1=1.53, p<0.001)

(Figure 3). Lastly, patients with private insurances experienced overall less mortality compared to Medicare and Medicaid, regardless of whether or not they received mechanical support.

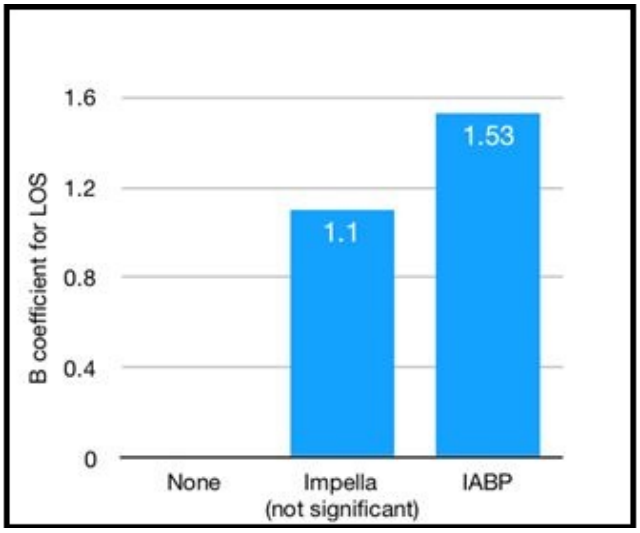


**Figure 3:** Difference in hospital length of stay when IABP or impella were compared to when no device was used.

## Discussion

Our results showed that the use of impella in AMI is associated with higher inpatient mortality and remarkably higher costs of hospitalization, without offering any advantage in terms of length of stay. While these results do not entirely contradict findings in prior studies, they somewhat challenge the current trends among interventional cardiologist to support routine application of impella. Current practices, as well as the FDA's support of impella application, are based solely on promising improvements in hemodynamic parameters rather than patient important outcomes. Prior studies, although not numerous, did not show any significant mortality benefit nor harm with impella use over IABP. Our analysis, however, is the first to our knowledge to associate impella with higher rates of inpatient mortality, when compared to IABP or no mechanical support. This increase in mortality is likely multifactorial. The main complications with impella devices are related to vascular access, which requires a large 14F sheath compared to the 6F sheath for the angioplasty guide catheter and the 8F sheath for the IABP. Hence, it is not surprising that the impella is associated with vascular injury requiring surgical intervention and serious bleeds. In addition, around 10% of patients develop hemolysis caused by sheared red blood cells passing through the device, often leading to kidney injury [4]. Also, since the device is often placed urgently, allowing no time for echocardiography, a left ventricular blood clot, and severe aortic regurgitation could be missed which could lead to systemic embolization and worsening of aortic regurgitation [9].

## Conclusion

It is important, however, to acknowledge several limitations in this study. The 2016 NIS database is based on ICD10 codes, and hence it does not capture vital signs, laboratory and imaging results, nor medications. Also, the data did not discriminate between the several types of impella devices in the market, ranging from Impella LP 2.5 (low power), Impella CP (cardiac power), and Impella 5.0. Lastly, selection bias is likely overestimating the mortality associated with impella use, as the latter is usually used as a last resort when the CS is severe and refractory.

## Limitations

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## Conflicts of Interest

The authors declare that there is no potential conflict of interest.

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