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Author for correspondence:
Mohammad Waqas
e-mail: waqasfarhat99@gmail.com

Impella vs. Intra-aortic Balloon: Studying Effectiveness in Myocardial Infarction Complicated by Cardiogenic Shock

M.Waqas[1], Rasha konane Afthab[1], Deva David John Samuel[1], Ynah Joyce Lerios Orna[1]

[1]Ivane Javakhishvilli Tbilisi State University Tbilisi, Georgia

Abstract

Background: Cardiogenic shock, impacting 7% of myocardial infarction (MI) patients, necessitates urgent revascularization through surgical interventions. Mechanical assist devices, such as Impella and intra-aortic balloon pump (IABP), serve as adjunctive therapies to provide temporary perfusion before surgery.

Methods: A comprehensive literature search, encompassing studies from 2012 onwards, was conducted to compare the effectiveness of Impella and IABP in cardiogenic shock patients. Data extraction and synthesis were independently performed to analyze the current evidence surrounding these mechanical assist devices.

Results: Findings from various studies present conflicting results. Impella demonstrates a reduction in inotropic score, lactate levels, and improvement in left ventricular ejection fraction. However, its impact on mortality rates remains uncertain. Comparative analyses reveal similar mortality risks between Impella and IABP. The choice between these devices is dependent on individual patient characteristics and goals.

Conclusions: This study highlights the current ambiguity in comparing the effectiveness of Impella and IABP in cardiogenic shock management. Despite the observed benefits with Impella in specific aspects, its impact on mortality remains inconclusive. Future research, particularly larger trials, is imperative to establish a clearer understanding of Impella's safety, efficacy, and potential superiority over IABP in the long-term management of cardiogenic shock.

INTRODUCTION

Cardiogenic shock is a serious complication of myocardial infarction that affects about 7% of MI patients. It is commonly seen accompanied by hypotension and hypoperfusion; it is quite lethal and revascularization in most patients is done through surgical intervention in the form of angioplasty or coronary bypass graft surgery.

These interventions have a better outcome in most cases compared to other methods that include intensive medical therapies, which have less favourable outcomes. There also exists adjunctive therapies in the form of vasopressor therapy, mechanical ventilatory support, intra-aortic balloon pump counterpulsation (IABP) and impeller. The purpose of these interventions, however, is to stabilize the patient and provide perfusion temporarily before revascularization through surgical intervention is carried out.[1]

Several studies have been conducted to test the effectiveness of each of these modalities, however, in this paper we will be discussing the effectiveness of percutaneous mechanical assist devices: Impella and IABP.

An intra-aortic balloon pump, or IABP, is a long, skinny balloon that controls the flow of blood through your largest blood vessel, the aorta. The device gets smaller when your heart pumps so blood can flow out to the rest of your body. Then it gets bigger when your heart relaxes to keep more blood in your heart.[2]

Impella Ventricular Support System is a small Left Ventricular Assist Device (LVAD). The device is a tiny pump inside of a catheter with an electric motor that can deliver about 2.5 liters of blood per minute to the body. It helps pump blood through the body by pulling blood out of the heart and pumping it into the aorta, bypassing the left ventricle.

In this research article tries to shed light on the following question: What is the effectiveness of impella versus intra-aortic balloon pump in patients with MI complicated by cardiogenic shock?

Acute myocardial infarction complicated by cardiogenic shock (AMICS) presents a challenge in maintaining adequate cardiac output while reducing cardiac workload. Various treatment approaches have been explored, including the use of Impella devices, which are catheter-based ventricular assist devices. These devices aim to reduce ventricular load and provide necessary cardiac output by actively unloading the left ventricle into the ascending aorta. However, the evidence supporting the effectiveness of Impella devices in reducing mortality rates in cardiogenic shock remains limited.

The current standard of care for AMICS patients involves the use of IABP. Although IABP is commonly used, its efficacy in improving hemodynamics in cardiogenic shock may be limited. In such cases, Impella devices may offer a viable alternative, as they have shown potential in maintaining cardiac output when IABP fails to do so. While IABP has been widely utilized, studies have highlighted its limitations, including minimal effects on preload and inadequate support for the systemic circulation in cardiogenic shock. On the other hand, Impella devices have demonstrated advantages in managing arrhythmias, improving hemodynamics, and providing right ventricular support. However, they come with their own set of challenges, such as the need for larger surgical cutdown and an increased risk of peripheral ischemia.

Existing studies comparing the mortality outcomes of Impella and IABP in AMICS patients have produced conflicting results, making it difficult to determine the superior device. While Impella holds theoretical advantages, particularly in reducing cardiac workload, its safety profile requires further investigation. Notably, a retrospective study showed comparable mortality risks between Impella and IABP, but Impella exhibited significant reductions in inotropic score, lactate levels, and SAPS II, along with improved left ventricular ejection fraction. Additionally, a large clinical investigation demonstrated higher survival rates when Impella was used as a first-line treatment.

Despite these findings, a comprehensive and detailed trial is necessary to establish the true effectiveness of Impella compared to IABP in AMICS patients. As the current evidence remains limited, further research is warranted to inform clinical decision-making and optimize patient outcomes. AMICS, is a condition when there is low cardiac output (CO), and the cardiac contractility has reduced. Theoretically, the most appropriate treatment would be to reduce the workload on the heart and bring back the CO levels without increasing the cardiac oxygen demand. This can be achieved by using axial flow pumps like impella devices.[3] Impella is a small heart pump device which is catheter based and is used as a ventricular assist device. It is inserted through the femoral artery and is placed in the left ventricle across the aortic valve.

Impella's work towards reducing the load on the ventricle and supplying the heart with the necessary output. Even though they have shown potential in reducing mortality in cases of cardiogenic shocks, there is no trial based evidence to support this hypothesis.[4]

According to the medical IABP is the go-to device used in AMICS patients.[5] A clinical presentation of a 68-year-old female with systemic lupus erythematosus, migraine headaches and transient ischemic attacks admitted for heart failure exacerbation was recorded. At first, the guidelines were followed and an IABP was placed. However, the patient's hemodynamics worsened. After the procedure, the patient's condition degraded further and at this stage her systolic function reduced with ejection fraction of 35%, there was mild regurgitation and she developed pulmonary edema requiring immediate intubation. The patient was then given impella as a replacement. This stabilized her condition. IABP has minimal effects on preload and cannot independently support the systemic circulation in cases of cardiogenic shock. Impella actively unloads the left ventricle into the ascending aorta and reduces the oxygen demand on the left ventricle. If the IABP does not improve hemodynamics in cardiogenic shock, Impella can maintain cardiac output.[6]

According to the largest randomized trial IABP- SHOCK II, IABP did not show control in the death ratio when compared to therapeutic control. In this 2+ year study a total of 301 patients were assigned IABP and a another froup of 299 patients were under other control methods. In comparative analysis, 52% patients of the IABP group and 51% patient of the control group had died by the end of a 12 month follow up. This showed that there was no significant difference in survival rate in patients give IABP as a treatment.[7] Hence, the use of IABP has been discouraged.[8] Even though the patients received IABP, the mortality recorded was high.[9]

Feasibility towards the two options for AMICS patients has led to variable and conflicting preferences. The advantages of both the devices seem to be equally weighed, whereas the disadvantages are higher with IABP. Impella helps in arrhythmias, has shown to improve the patient's condition hemodynamically and can also be used for right ventricle support in case of right ventricular failure when compared to IABP.

Though IABP has its own benefits, such as a smaller cannula with easier insertion, decreased risk of peripheral ischemia, and that can be moved if placed in the axillary artery, Impellas shows fewer disadvantages as it requires larger surgical cutdown and a comparatively increased risk of peripheral ischemia. IABP has a higher risk of aortic injury and doesn't support cases of arrythmia's or tachycardia and shows no mobility if placed in the femoral artery.[10]

A few studies have been conducted to assess the mortality in both the devices in these patients.[11] There isn't enough evidence to support which device is better when compared to each other. When viewed to relieve the theoretical causes, impella stands superior but the safety of the device is yet unknown hence, the frequency and intensity of the disadvantages remains unknown.[12]

A retrospective study observing 116 patients getting treatment for AMICS with both impella and IABP showed identical risk of mortality (In IABP-SHOCK II high-risk score of 18 % vs 20 % for impella and IABP respectively ; p = 0.76) however Impella significantly reduced the inotropic score (p < 0.001), lactate levels (p < 0.001) and SAPS II (p =0.02) and improved left ventricular ejection fraction (p = 0.01) (7). Both devices showed a similar effects on 1-month mortality rates and stroke incidence (52 % in impeller and 67 % in IABP ; p = 0.13).[11]

Another clinical investigation that was conducted for about 15,000 patients over 7 years who presented with AMICS showed that when impella is used as a first-line treatment, it demonstrated a 51% survival rate when compared to any other treatment. Data reflected on the information that male survival rates were higher than females and that increasing age had lower survival chances. The study also proved that careful examination and early implantation of impella in these patients showed better results[13] A wider and detailed trial is required to prove the effectiveness of impella over IABP as currently the evidence show very little positive result towards the benefits of impella over IABP.[11]

METHODOLOGY

A comprehensive literature search was conducted using the databases PubMed, Elsevier, and Google Scholar to identify relevant research articles published from 2012 onwards. The search strategy employed specific keywords and search terms related to the topic, including "IABP," "Impella," "MI," "shock," "cardiogenic shock," "Impella vs IABP," "Impella," "cardiac IAB," "acute MI," "mechanical support," and "hemodynamic support."

The inclusion criteria for article selection encompassed original research articles, clinical trials, systematic reviews, and meta-analyses that directly compared the effectiveness of Impella and IABP in patients with myocardial infarction complicated by cardiogenic shock.

Two independent researchers conducted the literature search and screening process. Initially, titles and abstracts were assessed to determine the relevance of the articles. Subsequently, full text articles were reviewed to ensure they met the inclusion criteria. Any disagreements between the researchers were resolved through discussion and consensus.

To ensure a comprehensive coverage of the available literature, the reference lists of the selected articles were manually searched for additional relevant studies. The selected articles were critically evaluated for quality and relevance. Data extraction included study characteristics, patient demographics, sample size, study design, details of the interventions (Impella and IABP), outcome measures, and reported findings. One researcher performed the data extraction, and another researcher cross-verified the extracted data for accuracy.

The findings from the selected studies were synthesized and analyzed to provide a comprehensive overview of the effectiveness of Impella and IABP in patients with myocardial infarction complicated by cardiogenic shock. The strengths and limitations of each study were carefully considered, and any discrepancies or conflicting results were addressed. It is important to acknowledge that this review is based on previously published studies, and as such, it may be subject to inherent biases or limitations associated with the included articles.

Ethical considerations were not applicable in this review article as it is based on existing published data and does not involve direct human subjects.

RESULTS

AMICS is a condition characterized by low cardiac output and reduced cardiac contractility. The most suitable treatment approach is to reduce the workload on the heart and restore cardiac output without increasing the cardiac oxygen demand. Axial flow pumps such as Impella devices have been proposed for this exact purpose.[5]

Impella, as stated earlier, is a catheter-based ventricular assist device inserted through the femoral artery into the left ventricle across the aortic valve. It works by reducing ventricular load and providing the necessary cardiac output. Although Impella devices have shown potential in reducing mortality in cases of cardiogenic shock, there is a lack of trial-based evidence to support this hypothesis.[4]

Medical guidelines currently recommend the use of IABP as the standard device for AMICS patients.[4]However, there are instances where IABP fails to improve hemodynamics in cardiogenic shock. In such cases, Impella can be considered as an alternative to maintain cardiac output. Unlike IABP, which has minimal effects on preload and cannot independently support systemic circulation, Impella actively unloads the left ventricle into the ascending aorta, thereby reducing the oxygen demand on the left ventricle.[6]

The largest randomized trial, IABP-SHOCK II, revealed no significant difference in survival rates between patients treated with IABP and those receiving other control methods, even though the mechanism of action and the effect of these interventions are not similar.[7] These findings have led to discouragement regarding the use of IABP.[8] Despite the administration of IABP, high mortality rates have been recorded.[9]

Comparing the feasibility of both options for AMICS patients has yielded conflicting preferences. The two interventions at hand, as is in any intervention, have both advantages and disadvantages different from each other, Impella has advantages in managing arrhythmias, improving hemodynamic condition, and providing right ventricle support in cases of right ventricular failure compared to IABP.

On the other hand, IABP offers benefits such as a smaller cannula with easier insertion, reduced risk of peripheral ischemia, and the ability to be repositioned if initially placed in the axillary artery. However, Impella has fewer disadvantages overall, although it requires a larger surgical cutdown and entails a comparatively increased risk of peripheral ischemia. Additionally, IABP carries a higher risk of aortic injury and does not effectively support cases of arrhythmias or tachycardia, nor does it allow mobility when placed in the femoral artery.[10]

Hence, it can be said that the choice made for an intervention is subjective to the condition of the patient, the stage of their disease, what advantages are required and what disadvantages need to be avoided in order to have a better outcome, both in the short as well as the long term. One important measure that should be considered in order to assess the success of an intervention is the mortality rate.

Several studies have been conducted to assess the mortality outcomes associated with both devices in AMICS patients.[11] However, there is insufficient evidence to determine which device is superior. While Impella appears to be more effective in addressing the theoretical cause of AMICS, its safety profile remains uncertain.[12] A retrospective study comparing 116 patients treated with both Impella and IABP found similar mortality risks, but Impella significantly reduced inotropic score, lactate levels, and SAPS II, while also improving left ventricular ejection fraction.[11]

Another clinical investigation involving 15,000 patients over 7 years demonstrated a 51% survival rate when Impella was used as a first-line treatment compared to other approaches. The study also revealed that patients who were male had higher survival rates than female patients, and an increase in age was associated with lower survival chances. Early implantation of Impella following careful examination yielded better results.[13] However, a wider and more detailed trial is necessary to establish the effectiveness of Impella over IABP, as the current evidence provides limited support for the benefits of Impella in comparison.[14]

The results presented in this section highlight the outcomes of various studies and investigations comparing Impella devices and intra-aortic balloon pump counterpulsation (IABP) in the treatment of acute myocardial infarction complicated by cardiogenic shock (AMICS). To provide a visual representation of these findings, Figure 1 presents a summarized table displaying the name of each research study, the corresponding patient numbers, and the respective outcomes. The table serves as a comprehensive reference to support the discussion and conclusions drawn regarding the effectiveness and safety of Impella and IABP in managing AMICS patients.

DISCUSSION

The treatment of AMICS is challenging. The effectiveness of Impella devices in reducing mortality rates in cardiogenic shock remains uncertain due to a lack of robust clinical trials. While Impella devices show promise in reducing ventricular load and providing cardiac output, more research is needed to evaluate their safety and long-term outcomes.

Current guidelines recommend IABP as the standard treatment for AMICS. However, in cases where IABP fails to improve hemodynamics, Impella devices offer an alternative approach by actively unloading the left ventricle into the ascending aorta. The decision to use Impella or IABP should consider individual patient needs, treatment goals that need to be achieved and the disadvantages that must be avoided.

Comparative studies have conflicting results regarding mortality outcomes. Although one study showed comparable risks, Impella demonstrated benefits in improving cardiac function and hemodynamics. IABP, on the other hand, has limitations in preload effects and independent support of systemic circulation, questioning its efficacy as a standalone treatment for AMICS.

Impella devices are not a 100% solution for AMICS. Even though they have advantages in managing arrhythmias and providing right ventricular support, it requires larger surgical cutdown and poses a higher risk of peripheral ischemia. IABP has benefits like smaller cannula size and decreased risk of peripheral ischemia.

CONCLUSION

The current evidence does not definitively establish the superiority of Impella over IABP in managing AMICS. Both devices have pros and cons that need to be considered. More research, including large-scale trials, is necessary to clarify the effectiveness, safety, and long-term outcomes of Impella and IABP in AMICS management. Clinicians should evaluate patient characteristics and weigh the advantages and limitations of each device when making treatment decisions in AMICS cases.

DECLARATION

Ethical Statement

The research conducted in this study has received approval from the Institutional Review Board/Ethics Committee at Ivane Javakhishvili Tbilisi State University. All procedures performed in this study involving human participants were in accordance with the ethical standards of Ivane Javakhishvili Tbilisi State University and with the 1964 Helsinki Declaration and its later amendments, or comparable ethical standards.

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Conflicts of Interest

The authors maintain that there are no conflicts of interest related to this research. Neither financial nor non-financial competing interests are present.

Data Availability

The data supporting the findings of this study are comprehensively presented within the article and its supplementary materials. For any additional data, interested parties may request access, and such requests will be considered.

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