

# Valvular Complications Following the Impella Device Implantation

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## Abstract

**Background:** Despite clear clinical benefits, there is limited evidence regarding possible complications of the novel mechanical support device Impella. Aortic and mitral valve regurgitation or injury are rare but potential complications following implantation of the Impella device. **Methods:** To evaluate valvular complications after the Impella device implantation, we have performed a comprehensive search of literature on multiple sites on this topic. **Results and Conclusion:** Ten case reports and one observational retrospective study were identified, with a total number of 19 patients identified. This article aims to draw attention to potential periprocedural complications relating to the Impella, in particular iatrogenic aortic and mitral valve injuries. Moreover, we have summarized our recommendations emphasizing the need for careful management and meticulous follow-up of these patients to avoid such potentially devastating complications.

## INTRODUCTION

Despite clear clinical benefits, there is limited evidence regarding possible complications relating to the Impella (Abiomed Inc., Danvers, Massachusetts) mechanical support device. The Impella device is being increasingly used as an alternative to the intra-aortic balloon pump (IABP) and veno-arterial extracorporeal membrane oxygenation (VA ECMO) for haemodynamic support in patients with cardiogenic shock and high-risk percutaneous coronary intervention [1]. It can also effectively vent the left ventricle, especially in the setting of incomplete unloading of the left ventricle during VA ECMO support [2-5]. Furthermore, several percutaneous mechanical circulatory support devices (VA ECMO, CentriMag, TandemHeart) including Impella have been introduced into clinical practice for bridging patients with end-stage heart failure to recovery, durable left ventricular assist device support or orthotopic heart transplantation [6, 7]. Placement and use of the Impella device bear potential risks. To date, complications that have been reported are device-related, peripheral vascular, distal thrombus formation with subsequent strokes, and valvular injuries. The objective of this article is to draw specific attention to valvular injuries as potential periprocedural complications during Impella device support.

## METHODS

Using MEDLINE/PubMed, Scopus and the Cochrane Library, we performed searches of case reports and clinical studies published until 30 October 2020. Eligible studies were identified using various combinations of Medical Subject Headings and keywords in the abstract or title: Impella, aortic regurgitation, mitral regurgitation, aortic valve injury, mitral valve injury, and mechanical circulatory support. Ethics Committee approval was not required as this is a review manuscript.

## RESULTS

As recent evidence still remains scarce due to the novelty of the device and potential underreporting, we have reviewed literature in order to highlight potentially life-threatening valvular complications. Ten case reports and one observational retrospective study were identified, with a total number of 19 patients identified,

reporting periprocedural complications of either aortic or mitral regurgitation related to the Impella device. The characteristics of included studies and case reports are presented in Table 1.

## DISCUSSION

### Utilisation of Impella

The Impella can provide haemodynamic support similar to ventricular assist devices with the advantages of unloading the left ventricle and being miniaturised and able to be placed percutaneously (2.5, CP) [8]. By continuously aspirating blood from the left ventricle, the Impella has a beneficial effect on LV unloading, coronary flow, and overall cardiac output [9]. A recent study has demonstrated that in acute myocardial infarction complicated by cardiogenic shock, treatment with Impella, as compared with IABP, can improve shock severity parameters due to superior haemodynamic support, although with no significant effect on 30-day mortality [10, 11]. In addition, it has been demonstrated that Impella can provide effective haemodynamic support in several other indications such as high-risk percutaneous coronary interventions (PCI), bridge to destination or transplant [3, 9, 12].

### Contraindications and complications

As with other mechanical support devices, severe peripheral vascular disease is a relative contraindication for femoral access due to the risk of limb ischaemia. The presence of a mechanical aortic valve is considered an absolute contraindication, while severe aortic stenosis as a relative contraindication [8].

Potential complications related to the use of Impella are device-related, peripheral vascular and distal thrombus formation with subsequent strokes. According to a recent report, the most common complications reported were bleeding requiring transfusion (17.5%), vascular access complications (15.2%), infection (12.9%), haemolysis (10.3%), vascular complications with a need of surgical repair (9.7%), limb ischaemia (3.9%) and bleeding requiring surgical intervention (2.6%) [8, 13]. Valvular complications included aortic and mitral valve injury or regurgitation.

### Aortic valve regurgitation or injury

Iatrogenic injury of the aortic valve (AV) is a potential complication related to the Impella resulting in significant aortic valve regurgitation (AR) (Figure 1). There are various contributing factors that can be considered that may lead to AR (Table 1). Recent studies have described several mechanisms that can cause injury of the AV during the implantation, repositioning, and removal of the Impella device [14-16]. The aortic valve might be damaged by the stiff guidewire during the insertion or with the Impella device itself following the guidewire going through the leaflet. Alternatively, improper handling of the device such as insertion across the aortic valve without the guidewire or without echocardiographic guidance might be one of the mechanisms. In addition, direct contact of the inlet during repositioning or removal of the Impella might damage the valve due to the effect of suction if the flow is not reduced as per guidelines. Severe AR caused by aortic valve injury may necessitate further treatment such as aortic valve replacement or transcatheter aortic valve intervention. It is important to distinguish AR caused by commissural malcoaptation of the two leaflets related to the device, which might improve after its removal [17]. AR can be challenging to detect with echocardiography because of the artefacts generated by the device [15]. Importantly, a recent observational study has demonstrated that even after short-term Impella support, a significant proportion of patients may develop progression of AR [18]. The authors have observed this complication in 9 patients despite an extremely short support duration in their cohort (median less than 1 day) [18]. However, the causality of AR and follow-up of these patients were not investigated.

### Mitral valve regurgitation or injury

There have been several reports of acute severe mitral regurgitation (MR) caused by iatrogenic injury of the mitral valve apparatus related to the Impella, in particular due to chordal rupture [19-22]. A possible mechanism of chordae tendineae injury during the initial positioning of the Impella across the aortic valve is from mechanical damage from either guidewire, or the Impella device [21]. If not diagnosed, acute severe

MR may lead to rapid decompensation after Impella removal, therefore, prompt diagnosis is of paramount importance [19]. If there is extensive damage of the mitral valve apparatus, mitral valve repair or replacement may be required. However, surgical treatment might not be successful despite supportive measures, due to the severity of complications in combination with the underlying clinical condition [22].

There are several limitations to this study. Firstly, available literature about complications related to Impella remains limited. Data are derived from case reports and observational retrospective studies. Furthermore, there is a lack of follow-up and detailed description of mechanisms of valve injury in some of the reports.

## CONCLUSION

This present study contributes to the emerging evidence about rare but potentially life-threatening complications related to the Impella device, emphasising the need for careful management and meticulous follow-up of these patients so as to recognise complications early and prevent potentially devastating complications. In order to reduce the risk of these complications, our recommendation would be to use continuous echocardiographic and/or fluoroscopy guidance during Impella implantation. Furthermore, device repositioning or removal should be always performed under echocardiographic guidance. Optimal placement of the Impella device should be accomplished by positioning the inlet approximately 3.5cm from the aortic valve annulus (in a normal ventricular cavity) and avoiding displacement towards the mitral valve leaflets [23]. Special care must be taken that the Impella catheter is properly fixed and secured to avoid any dislodgment. This includes documentation of the exact position. In our opinion, it is very important that the flow is either stopped or nearly completely reduced before either repositioning or removal of the Impella to avoid any leaflet damage related to the effect of suction. Further prospective studies with long-term follow-up are still needed.

**Author contributions:** **DS** : Conceptualization; Formal analysis; Investigation; Methodology; Writing - Original Draft; Writing - Review & Editing. **TK, NJL, US** , Conceptualization, Investigation; Methodology; Writing - Review & Editing.

## Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

**Table 1. Characteristics of included studies.**

Study name	Year	Country	Study design	Device	Type of valve complication	n	Age (yrs)	F
Toggweiler[24]	2008	Switzerland	CR	Impella 2.5	Functional mitral stenosis	1	70	D
Chandola[14]	2012	Canada	CR	Impella 2.5	Aortic valve injury	1	45	D
Elhussein[22]	2014	Canada	CR	Impella 5.0	Acute MR	1	75	C
Sharma[17]	2014	USA	CR	Impella 2.5	AR	1	18	C
Bhatia[19]	2017	USA	CR	Impella CP	Acute MR	1	52	C
Hong[15]	2019	USA	CR	Impella 5.0	Aortic valve injury	1	50	D
Khalid[20]	2020	USA	CR	Impella 5.0	Acute severe MR	1	47	C
Pivato[21]	2020	Italy	CR	Impella CP	Acute severe MR	1	85	C
Butala[18]	2020	USA	RO	Impella	Increase in AR	9	64±5.5	N
Vila[16]	2020	UK	CR	Impella CP	Aortic valve injury	1	34	D

Abbreviations: AR, aortic regurgitation; AVR, aortic valve replacement; CABG, coronary artery bypass graft; CR, case report; MOF, multiorgan failure; MR, mitral regurgitation; MVR, mitral valve replacement; N/A, not applicable; RO, retrospective observational study; TAVI, transcatheter aortic valve intervention

## FIGURE LEGENDS

**FIGURE 1.** Intraoperative transoesophageal echocardiogram: A - immediately after removal of the Impella

CP, midesophageal aortic valve long axis view, and B - midesophageal aortic valve short axis view. Figure 1A shows the same view with severe aortic regurgitation despite removal of the Impella device. Nearly complete right coronary cusp injury is visualized in the Figure 1B. Written informed consent to publication was provided by the patient.

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