Nursing management and prevention of complications in patients carrying Impella ventricular assistance device

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Introduction: recently, the use of the ventricular assistance device Impella in patients with acute heart failure has been reported to have benefits, such as increasing its use. However, the complications related to the Impella device are multiple and of different magnitudes. In light of all this, it is critical that the registered nurse be adequately trained to ensure proper care for the patient carrying such a device in any circumstance.

Aim: the purpose of the study is to identify the complications associated with the patient carrying the Impella device and the related monitoring, management and prevention methods the registered nurse is called to act upon.

Materials and Methods: the literature of the last 10 years in the main online databases, such as Pubmed and Google Scholar, was reviewed, and the PIO method was used for developing keywords.

Results: 29 articles were selected from the search. From these articles, it appears that the most common complications related to the Impella device concern bleeding, vascular injury, and ischemia of the limb, but infections and hemolysis are also worthy of attention.

Conclusions: analyzing the complications found in the literature suggests that these conditions require specific training of registered nurses in critical care, even simulations and checklists, given the absence of common international guidelines or protocols for the management of the patient carrying and Impella device. The study suggests a checklist drawn up from the evidence found in the literature.

Key words: impella device, impella complications, impella prevention, impella management, impella nurse assessment...

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Introduction

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Cardiogenic Shock (CS) is currently very common.¹

This condition, characterized by high mortality, makes it essential to use increasingly innovative hemodynamic support devices such as the Impella device.

The introduction of this device in the treatment of acute heart failure, including cases of CS, has led to such benefits that it has been classified as a class IIA recommendation (supports that should be considered) within the guidelines of the European Society of Cardiology for $2021.^2$

However, this device is not without complications, and early intervention in identifying signs and symptoms allows for better outcomes for patients treated with the Impella device.

Complications related to the access site include bleeding (9.6%), vascular injuries (5.2%), and limb ischemia (2.6%), requiring close monitoring and proper management by nurses to avoid alterations in hemodynamic parameters or the onset of further complications such as sepsis, hemolysis, death, and inadequate device performance.

The use of Impella highlights the crucial and indispensable role of the professional nurse, who, with adequate training, can identify and manage the care needs of patients with the device, even in the presence of related complications.³⁻¹⁴

Given the lack of nursing studies on this topic, a review of the scientific literature was necessary to clarify more precisely the Impella-related complications and the nursing interventions necessary for prevention and management, improving the quality of care and impacting the outcomes of this patient population.

Materials and Methods

A literature review was conducted by consulting the main electronic databases such as PubMed and Google Scholar using the following terms: "Impella Device," "Cardiogenic Shock,""Impella Complications," "Impella Prevention," "Impella Management," "Nurse Management," "Impella Nurse Assessment" with the Boolean operator "AND." These keywords were identified using a PICO model starting from each individual research question. CIN-HAL and SCOPUS databases were also consulted, but they did not provide results relevant to the study's inclusion criteria; therefore, they were not included in the results flow chart. Studies published between 2013 and 2023, in Italian or English, of a medical-nursing nature focusing on humans of any gender and aged between 18 and 80+ years were included. Studies related to adult patients with cardiogenic shock, undergoing Percutaneous Coronary Intervention (PCI), admitted to the intensive care unit, and treated with any type of Impella device were included. Studies involving pediatric patients, patients not treated with Impella, patients with non-cardiogenic shock, and studies in languages other than English or Italian were excluded (Table 1, Table 2).

Results

A total of 29 articles relevant to the purpose of the review were selected and summarized in the flowchart (Figure 1).

It should be noted that the 9 articles excluded from the full reading consisted of case reports of individual patients that did not contribute to providing a generalizable view regarding the Impella device or editorial articles reporting personal, non-objectifiable views on the considered phenomena.
 Table 1. PIO related to the first research question "What are the main complications in patients with Impella?".

PIO

Р	Patient with Cardiogenic Shock
Ι	Impella device
0	Complications

 Table 2. PIO related to the second research question "What are the methods of prevention and monitoring of complications in patients with Impella and the relevant nursing.competencies?"

PIO

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- Complications of patients with Impella
 - Research nurse specific skills and ways to prevent and monitor complications in patients with Impella
- O Identify nurse skills, preventing and tracking complications



Figure 1. Flow chart of the selection of pertaining articles.



The following results emerged from the study in response to the questions.

During support with Impella in patients with acute CS, signs of improvement were shown.¹⁵ However, this device is not without possible complications. The complications found in patients with Impella devices are numerous.^{4,5,9,16-19} The incidence of device-related complications in CS patients is higher compared to patients with high-risk PCI.²⁰ Early weaning tests are useful in reducing device-related complications.²¹

In the comparison between IABP and Impella device, the latter showed higher rates of severe or potentially lethal bleeding events, peripheral vascular complications, and sepsis.^{22,23}

Impella 5.5 and 5.0 allow patient mobility due to placement in the axillary artery, reducing limb complications from the device and the risk of infection.^{24,25} Axillary access is the best approach for patients requiring temporary advanced mechanical support, diabetics, and obese patients.²⁵

To continue reducing the risk of bleeding related to access and the onset of vascular complications in patients supported by pLVAD, it is necessary to focus on some fundamental principles.²⁶

Vascular complications in patients with Impella devices are more frequent in women and in procedures performed in emergencies.²⁷

The use of the Manta device for femoral artery closure after Impella device removal is better than manual compression.²⁸

A common complication in patients with Impella devices is major bleeding, which occurs more frequently in patients with predisposing factors.^{23,29,30} Optimizing the angle between the sheath and skin is one of the interventions useful in reducing the risk of bleeding.³¹ Extreme care is necessary during Impella device implantation, use, and removal to prevent bleeding and vascular access complications.⁵

The most common bleeding at the puncture site occurs within 24 hours of Impella insertion.³² Standard anticoagulant therapeutic goals in patients with Impella device support are essential to prevent bleeding risk.^{4,33,34} Impella requires a specific purge pressure range for optimal pump flow.³⁴

Post-procedural elements in patients treated with Impella are essential, including device position control, regular monitoring of hemodynamic parameters, laboratory parameter control, urine output monitoring, and potential complication monitoring. Impella patients require laboratory tests for monitoring.³¹

Patients treated with an Impella device may develop Heparin-Induced Thrombocytopenia (HIT). Proper management of anticoagulant therapy is necessary to prevent this complication.³³

Nurses are responsible for changing some parts of the Impella system to ensure its functioning. Attention should be paid to the amount of heparin administered to the patient when two concomitant devices are present.¹⁰

Infectious complications in patients with prolonged Impella device support include access site infections, central line infections, and aspiration pneumonia. Early detection of these complications is crucial.³¹ Essential competencies for the care and maintenance of Central Venous Access Devices (CVAD) are fundamental for nurses in all healthcare settings.¹²

High body mass index and other patient-related factors are predisposing factors for infectious complications.¹³

Postoperative bleeding requiring a new intervention is a significant factor contributing to infectious complications in MCS.¹³

Each Impella catheter is controlled by an Automated Impella Controller (AIC) displaying numerous indicators. Many nursing considerations for Impella devices involve monitoring these parameters.¹⁰ Nurses are required to intervene by modifying the Impella controller in certain situations such as cardiac arrest.^{4,10} Nurses ' knowledge of Impella console alarms is crucial.³⁶ Adequate knowledge of the entire Impella system is essential to provide proper patient care.⁹ Close collaboration between qualified intensive care physicians and intensive care nursing staff is necessary.³⁵

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Hemolysis is a complication that can develop in patients with support devices. Recognizing the signs of this complication early is crucial, as outcomes secondary to hemolysis can be detrimental to the patient.^{10,37}

Managing post-implantation patients with the Impella device in the intensive care unit is crucial to maximize the device's potential and ensure acceptable outcomes.²¹ Implementing an Impella educational program provides nurses with numerous benefits and ensures competent patient care by nurses.³⁶

The use of a safety checklist can improve team performance by acting on various aspects and reducing the likelihood of errors.¹⁹

Study limitations include limited literature is available regarding exclusive nursing care for patients with Impella devices; the multifactorial nature of complications in CS patients is potentially independent of proper Impella management; fragmentation of statistical data often affects individual contexts rather than national and international perspectives, making it challenging to provide a complete epidemiological overview; the absence of institutionally recognized protocols at the regulatory level for nursing management of complications related to Impella ventricular assist devices; failure to consider complications common to all Impella devices and subsequent management without distinguishing individual device characteristics; failure to investigate the psychosocial impact and therapeutic impact of the device itself on conscious patients with Impella; failure to investigate the economic impact of the device within usage contexts.

Discussion

Mortality in CS remains high despite advances in treatment. Short-term mechanical circulatory support devices improve patient conditions; in particular, patients with Impella mechanical support have shown improvement in end-organ function, increased diuresis, and decreased serum lactate levels.¹⁵ Despite these improvements, the use of such a device comes with possible complications. Therefore, specific knowledge of these complications by nursing staff is crucial as they play an essential role in recognizing and managing them.

The most commonly encountered complications in patients with Impella devices are: device malfunction, high purge pressure, access site hematoma¹⁶ or bleeding, hemolysis, vascular injury, limb ischemia, pigmentary nephropathy, and pump thrombosis,¹⁷ sudden pump stoppage (caused by biofilm/thrombus formation),¹⁸ embolic stroke, device migration,⁴ aortic injury or left ventricular perforation, infection,¹⁹ and sepsis. Other less common complications have also been reported.^{9,5}

Analyzing the study by Ancona *et al.*,²⁰ it is evident that the incidence of Device- Related Complications (DRC) in CS patients is higher compared to patients with high-risk PCI.

This statement, associated with the high rates of severe or potentially lethal bleeding events, peripheral vascular complications, and sepsis in Impella-supported patients compared to those with IABP^{22,23} support, demonstrates the importance of knowing the Impella device and its related complications to provide appropriate prevention and management.



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Main complications

Complications related to the access site include bleeding, vascular injuries, and limb ischemia.¹⁷

Access site bleeding occurs within 24 hours of Impella system insertion, necessitating close monitoring by the nursing team of both the site and hemodynamic parameters.³²

To prevent this complication, ensuring a 30-40° between the sheath and the patient's skin using a gauze pad is crucial, and marking the initial insertion depth of Impella on the catheter is helpful. Ensuring proper anticoagulant therapy management by monitoring ACT and APTT at least 4 times a day is essential.

Daily laboratory tests, including hemoglobin and platelet count, free hemoglobin, lactate dehydrogenase, haptoglobin, and bilirubin, are crucial for early detection of bleeding, HIT, or disseminated intravascular coagulation; creatinine and electrolytes for monitoring acute kidney injury; white blood cell count and lactates for assessing infectious complications. Standard anticoagulant therapeutic goals in patients with the Impella device are fundamental to prevent bleeding risk.^{4,34} For this reason, the use of a systematic approach to anticoagulant therapy is fundamental to optimize patient outcomes and meet the National Patient Safety Goals.³³

In the case of bleeding, applying compression with a gauze soaked in Tranexamic Acid while awaiting medical intervention can be useful.³¹

Major bleeding occurs more frequently in patients with a history of hypertension, female gender, advanced age,²⁹ post-PCI therapy (dual antiplatelet therapy),²³ prolonged Impella device usage,²⁹ and thrombocytopenia.³⁰

Abaunza *et al.*²⁷ highlight that vascular complications in patients with Impella devices are more common in women and in patients undergoing emergency procedures. The care of these patients requires closer monitoring through inspection, palpation, and auscultation to detect hematoma or limb ischemia early.

During Impella device implantation, use, and removal, attention must be paid to preventing bleeding and vascular complications⁵ using standardized protocols, continuous training, and experience to optimize access and closure, anticoagulant management, and post-procedural care.²⁶

Infectious complications

Patients with prolonged Impella device support may experience infectious complications, with predisposing factors being high body mass index, diabetes mellitus, advanced age, chronic kidney disease and dialysis, pre-implantation frailty, and postoperative bleeding requiring a new intervention.¹³

Pietrasik *et al.*³¹ highlight access site infections, central line infections, and aspiration pneumonia as predominant in patients with Left Ventricular Assist Devices (LVAD). Daily evaluation is essential to detect early signs of systemic inflammatory response syndrome: body temperature (fever), heart and respiratory rate (tachypnea and tachycardia), and white blood cell count (leukocytosis or leukopenia). The presence of at least 2 criteria associated with high procalcitonin levels may indicate sepsis, requiring the initiation of the surviving sepsis campaign's 5 phases, necessitating collaboration between physicians and nurses to ensure lactate level measurement, blood culture sampling, antibiotic and vasopressor administration, and potential crystalloid infusion.³¹

To prevent infectious access site complications, following central venous access device care and maintenance guidelines is crucial.

As described in the article Jarding Maggiore *et al.*,¹² the correct execution of hand hygiene in the 5 designated moments is the most effective way to reduce infection spread. Site dressing should be done with a sterile technique using Chlorhexidine gluconate

>0.5% to cleanse the skin and applying a new dressing only after the solution dries. Dressing change should occur every 5-7 days or when dirty, wet, or loose. Evaluation of the dressing should be done at each shift, and site assessment should be done each time the dressing is changed. Palpation of the access site through intact dressing should be performed daily to assess for tenderness and swelling.

Tan et al.¹³ suggest that line infections are common, presenting with erythema, tenderness, and purulent discharge at the device entry site. Diagnosis can be confirmed through a wound swab culture. To prevent this, avoiding the femoral access site in favor of axillary Impella insertion, particularly in diabetic and obese patients predisposed to infectious complications due to inguinal incision and surgical division of lymphatic channels within the groin, posing a risk for limb lymphedema and seroma formation, is recommended.²⁵ It has been shown by Vetrovec et al.²⁶ that a percutaneous transaxillary approach for aortic valve transcatheter implantation or pLVAD insertion has similar mortality, stroke, and vascular complication rates compared to surgical approaches; however, significantly lower bleeding occurs with the percutaneous approach. The use of Impella 5.5 and 5.0 allows patient mobility due to axillary artery placement, reducing limb complications and infection risk.24,25

Automated Impella Controller

Managing patients with Impella devices requires knowledge of the AIC, a specific controller displaying flow, performance level (P), purge fluid flow, purge fluid pressure, alarm notes, and catheter position information.

As reported in the article by Asbar *et al.*,¹⁰ many nursing considerations for Impella devices involve monitoring these parameters (including the purge pressure, which requires a range of 300-1100 mm Hg)³⁴ and performing essential maneuvers to ensure device functionality.

Nurses are responsible for changing the purge fluid bag and tube, pressure cassette and tube according to hospital policy, and preparing the purge solution consisting of 5% Dextrose in Water for injection preparations with 50 units/mL of heparin. The heparin dosage delivered to the patient through the Impella catheter by the AIC is displayed hourly and must be documented. When two different Impella types are used concurrently due to two separate purge systems, the heparin concentration of each bag must be carefully evaluated to prevent inadvertently administering higher heparin doses to the patient.

Understanding the types of alarms that may occur during care is crucial, in addition to necessary nursing actions to ensure device function. Alarms to recognize include the aspiration alarm (may require intravenous fluid administration and lowering P level while potential causes are evaluated), high-pressure alarm (requires purge cassette replacement), and incorrect catheter position alarm (device migration), where nurses must request an echocardiogram from the physician to verify positioning. If the device has migrated, the patient loses device support function and may become unstable due to lack of device support. The physician is responsible for repositioning the Impella catheter.³⁶

In the event of cardiac arrest, standard life-saving procedures should be performed by setting Impella to a lower power level (P2) to avoid continuous aspiration.

Cardiac resuscitation can cause device migration, so nurses must assess device positioning signals, followed by chest X-ray and echocardiogram as per medical prescription.^{4,10}

Understanding device variations, clinical application, and physiological impact of device use, as well as understanding alarms and potential risks, are crucial when considering a patient



for percutaneous circulatory support. Close collaboration between intensive care physicians and nursing staff is fundamental.^{9,35}

Hemolysis

Hemolysis is a complication in patients with Impella devices, as blood cells can be damaged during pump passage. It is often due to incorrect pump position, low preload, or high-speed setting in Impella 2.5 or CP. Hemolysis is less common with the Impella 5.0 pump. Clinical signs may include dark or bloody urine, low hemoglobin levels, and renal failure while the patient is using the device.

Early recognition of these manifestations is crucial, and daily monitoring of serum creatinine, haptoglobin, free plasma hemoglobin, or lactate dehydrogenase is necessary.

A PFH >40 mg/dL or an acute increase in PFH or LDH indicates increased hemolysis.^{4,10}

Outcomes secondary to hemolysis can include incidence of ischemic or hemorrhagic stroke and incidence of additional Mechanical Circulatory Support (MCS) requiring an upgrade to Impella 5.0/LD or Extracorporeal Membrane Oxygenation (ECMO).³⁷

Removal

Prolonged use of the Impella device is closely related to the onset of complications; therefore, early weaning tests are useful to reduce their occurrence.²¹

Analyzing the study by Pietrasik *et al.*,³¹ regular monitoring of hemodynamic parameters during prolonged MCS is crucial to assess the effectiveness of hemodynamic support and select the optimal weaning time. At the end of Impella device use, it is crucial to remove and close the artery where it was placed. This medical procedure may encounter possible bleeding or vascular complications. As described in the study by Cuculi *et al.*,²⁸ the use of

the MANTA device for femoral artery closure reduces the incidence of the aforementioned complications. This device causes less discomfort to patients compared to manual compression, is more effective, and, if used correctly, poses a very low risk of infectious complications.

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Nursing team

Managing post-implantation patients with the Impella device in the intensive care unit is crucial to maximize the device's potential and ensure acceptable outcomes.

In-depth knowledge of specific issues such as hemocompatibility and its implications for anticoagulant therapy, correct device positioning, and managing patients with inadequate hemodynamic support is essential to address common issues.²¹ Therefore, implementing an Impella educational program is crucial because it provides nurses with the information and knowledge necessary to assess and manage device-bearing patients, enhancing nursing staff self-confidence. In Jackson's study,36 it is evident that the Impella training program for intensive care nurses is crucial to: assess and intervene on signs and symptoms of adverse reactions, provide support through a common protocol and policy for managing affected individuals, ensuring the safety and best possible care for highly dynamic critical patients. As described in the study by Turkelson et al., 19 the use of checklists ensures that all relevant data are evaluated and understood, problems are anticipated, and the correct course of action is taken. Therefore, communication, teamwork, and compliance with evidence-based established protocols are improved, resulting in a reduced likelihood of errors. Checklists also reduce reliance on memory, especially in critical situations, as they are highly dynamic and unpredictable. In healthcare, simulation has been shown to lead to better performance and maintenance of Knowledge, Skills, Attitudes (KSA) both technical and non-technical.

ATTACHMENT 12: Daily checklist for managing the Impella device

		PATIENT PARAMETERS				ACCESS SITE				AUTOMATIC IMPELLA CONTROLLER		
DATE / / h.	SIGN	Vital Signs	ACT (160s- 180s)	APTT (60s- 90s)	Daily exams *	N° of centimeters of the catheter	Gauze skin- introducer**	Monitoring and evaluation of dressing	Change dressing (only if performed)	Level of P and flow rate (l/min)	Purge pressure ***	Change purge solution bag ****
					1							

Tick the action carried out in your turn with an ✓ or enter the numerical value of the data detected.

* Check if the following tests have been performed: HB, PFH, PLT, LDH, APTOGLOBIN, BILIRUBIN, CREATININE, ELECTROLYTES, WHITE BLOOD CELLS, LACTATES.

** Insertion angle 30-40°

***300-1100 mm Hg

*** 5% Dextrose in water for injectable preparations with 50 units/ml of heparin (the use of a solution with 5% dextrose and 25U/ml of heparin is also approved by the Italian Ministry of Health)

Figure 2. Daily checklist for the management of the Impella device.



Conclusions

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The execution of this study has allowed the identification of the main complications of patients with the Impella ventricular assist device and their management by the nursing team called to provide specific, direct, and continuous care.

From the review carried out, it emerges that the onset of complications is closely related to the prolonged use of the device; however, from the selected studies, it is essential to pay attention to bleeding complications, vascular injury, and limb ischemia through careful monitoring of the access site and hemodynamic parameters.

It is also essential to ensure proper management of anticoagulant therapy through the performance of specific blood tests by the nurse.

Regarding infectious complications, the nurse is required to detect signs and symptoms of possible infection, follow care instructions, maintain the central venous access device, and perform blood tests indicative of infection.

To ensure the correct functioning of the Impella device, nurses need to be adequately trained on the AIC so that they can understand alarms (often the cause of hemolysis complications) and correctly perform device maintenance procedures. Comprehensive and specific knowledge allows for better management of the device during use, especially in emergency situations.

The nursing team involved in managing patients with Impella devices requires continuous training, which can be carried out through the implementation of a dedicated training program. It is also useful to use checklists to ensure a correct course of action, considering that there are no shared guidelines or common protocols internationally for managing patients with Impella devices. For this reason, a checklist proposal was adapted to the literature investigated in this study (Figure 2).

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