Optimal Device Performance Guidance

Reminder of Best Practices with the Use of Impella CP in Relation to Limb Ischemia

PRODUCT: Impella CP with SmartAssist (UDI 00813502012279)

DATE: May 2024

REASON FOR GUIDANCE

Abiomed would like to remind the healthcare professional community of the known risk of limb ischemia (LI) that can result when the Impella CP device is used in patients with STEMI-related cardiogenic shock, and provide best practices with regards to Impella CP management including identification, management and resolution of LI. This communication primarily focuses on the Impella CP with SmartAssist placed in the common femoral artery (CFA) since this is the most-used Impella device and the most common access point.

BACKGROUND

In a recently published prospective, multi-center, randomized controlled trial, DanGer Shock, (Moeller, J et al. New England Journal of Medicine, 2024.), the routine use of Impella CP in the treatment of patients with STEMI-related cardiogenic shock led to a lower all-cause mortality at 180 days than standard care alone (45.8% Impella CP arm, 58.5% standard care arm, HR 0.74, p = 0.04). The incidence of certain complications, such as limb ischemia, was noted to be higher in the Impella CP arm than standard care (5.6% Impella CP arm, 1.1% standard care arm). Limb ischemia, if not promptly recognized and treated, can potentially lead to severe consequences such as limb loss. Results from the DanGer study highlight the importance of early identification of this complication when using Impella CP via insertion in the common femoral artery.

IMPELLA CP CLINICAL EXPERIENCE IN THE INSTRUCTIONS FOR USE (IFU)

Abiomed provides data on the clinical experience of the Impella CP device in the Instructions for Use (IFU), spanning multiple years of experience with the product. Summarized in Table 1 below is a consolidation of LI adverse event data reported in several clinical studies as part of the Impella CP IFU and the recently published DanGer Shock RCT. This includes distinct patient populations where Impella CP is used - in high-risk PCI and cardiogenic shock patients. Specific IFU pages are listed in Table 1.

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Table 1: LI Rates Associated with Clinical Experience in the Impella CP IFU and Published Literature

Study Name	Patient Population	Impella Limb Ischemia Rate	IFU Ref. Page
Impella Registry	CS due to cardiomyopathy, myocarditis, PPCM	4% (4/93) – all subjects at discharge	6.95
Impella AMI CS Post-Approval Study (RECOVER III)	AMI CS	10.41% (43/413) at 30 days	6.105
DanGer Shock Trial [3]	CS due to STEMI	5.6% (10/179) at 180 days	Not in IFU
Protect II [1,2]	High-risk PCI	1.8% (4/225) at 30 days 2.2% (5/224) at 90 days	6.21
USpella Registry	High-risk PCI	0.63% (4/637) in hospital for 2.5 1.39% (1/72) in hospital for CP	6.29
Impella Protected PCI Post-Approval Study [2]	High-risk PCI	1.0% (3/293) at 30 days for 2.5 0.8% (6/708) at 30 days for CP	6.47

[1] Used Impella 2.5
[2] adverse event definition includes the need for cardiac, thoracic or abdominal vascular operation or femoral artery bypass graft
[3] conducted as an independent investigator-initiated study

The LI rate for the Impella CP arm of the DanGer Shock RCT was within the rates published in the Impella CP IFU within this patient population. In a safety review by Kapur et al., the authors summarized existing data on complications associated with the three most widely used acute MCS platforms. The review showed an LI rate with the Impella among the cited studies that ranges from 0.0% to 18.0%, with a weighted average of 4.2%.

ABIOMED'S CURRENT INSTRUCTIONS FOR USE, AND TRAINING AND SUPPORT PROGRAMS

The Impella CP IFU and product materials inform the clinical community of the techniques for management of the Impella CP device including references to clinical publications. The IFU contains step-by-step instructions for the user before, during, and after Impella CP placement and recommendations regarding prevention, identification, and when appropriate, treatment of LI. These include:

- **Recommendation of femoral angiography and vessel sizing** (IFU Ref. 6.110);
  IFU Ref 6.110 *"Femoral access should ideally be obtained using imaging techniques including fluoroscopy, ultrasound, and femoral angiography. Implementation of these techniques may increase procedural success and reduce access related complications. …Femoral angiography also enables confirmation of vessel caliber and identification of potential pitfalls such as…calcification and obstruction… […] Vessel diameters less than 6mm may require antegrade perfusion to prevent limb ischemia."*

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- **Guidance on the use of ultrasound and micropuncture for access site assessment** (IFU Ref. 5.1, 5.12, 6.110, 6.111);
  IFU Ref 5.1 – This section illustrates evaluation prior to inserting the Impella CP Catheter. The IFU suggests utilizing technology such as standard traditional angiography, magnetic resonance angiography (MRA), coronary computed tomography angiography (CTA), ultrasound, echocardiography to observe various disease states such as severe peripheral arterial obstructive disease. See Table 5.1 for more detail.

  IFU Ref 5.12, and 6.111 *"Use ultrasound-guided arterial puncture technique to ensure good visualization of the proper arterial puncture site (common femoral artery in a non-calcified segment), assisted by fluoroscopy."*

  IFU Ref 6.110 *"Femoral access should ideally be obtained using imaging techniques including fluoroscopy, ultrasound, and femoral angiography. Implementation of these techniques may increase procedural success and reduce access related complications."*

- **Recommendation for distal pulse palpation assessment** (IFU Ref. 5.13, 6.111); and
  IFU Ref 5.13 *"Once the 14Fr peel-away sheath is in place, assess distal limb patency using angiography, distal pulse palpation, ultrasound, or infrared tissue oximetry. If there is poor limb perfusion, consider placement of an antegrade perfusion sheath, prior to leaving the procedural site."*

  IFU Ref 6.111*" … After placement of the 14 Fr peel-away sheath, assessment of distal limb perfusion using angiography, distal pulse palpation, ultrasound, or infrared tissue oximetry."*

- **Consideration of the utility of antegrade limb perfusion** (IFU Ref. 5.13, 6.110, 6.111).
  IFU Ref 5.13 *"If there is poor limb perfusion, consider placement of an antegrade perfusion sheath, prior to leaving the procedural site."*

  IFU Ref 6.110 *"Vessel diameters less than 6mm may require antegrade perfusion to prevent limb ischemia."*

  IFU Ref 6.111 *"If there is continued poor limb perfusion, placement of an antegrade perfusion sheath should be considered."*

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The Impella CP IFU is available to all healthcare professionals at HeartRecovery.com.

In addition, Abiomed deploys extensive physician and nurse training programs through its clinical field team. Abiomed provides field support, 24/7 Impella support, and professional education programs on the safe and effective use of Impella CP that includes awareness of the potential risk of LI and strategies for early diagnosis and best practices to help treat this complication. These training programs include awareness about both the benefit and potential risks associated with the use of Impella CP, including LI.

Specifically, Abiomed offers hands-on and didactic training courses led by trained Abiomed personnel on femoral access and groin management, which provides information on best practices with regards to Impella CP management including identification, management, and resolution of LI. For more information about these training opportunities, please contact your Abiomed field representative.

- Femoral Access Management Best Practices – Impella Access Course that focuses on best practices for obtaining access, insertion of the device, and preparation of the device to transfer to the ICU.
- Access and Groin Management – Impella Access Course that focuses on access management in the ICU.
- Professional Education Experience Opportunities, including both live and on-demand digital offerings:
    - Skills Workshops;
    - Lab-based courses;
    - Fellows courses, specifically tailored to early-career professionals; and
    - Physician Speaker Programs with local physicians.

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CONCLUSION

Abiomed is continuously seeking opportunities to educate the clinical community on the safe and effective use of Impella CP and best practices with regards to Impella CP management including identification, management, and resolution of LI. Adverse reactions or quality problems experienced with the use of this product may be reported to your Abiomed clinical field representative or Abiomed's Clinical Support Center at 1-800-422-8666, or the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

REFERENCES

CP with SmartAssist Instructions for Use Document # 0048-9007 rQ

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