The "two-cut monorail" technique, for the over-the-wire removal of the Impella CP device

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ABSTRACT

The Impella is a percutaneously placed intra-arterial flow pump positioned across the aortic valve for circulatory support. A limitation of the Impella is that it lacks a central wire channel, to maintain intra-arterial wire access when removing the device. Open surgical arterial cutdown is needed for the removal of the Impella CP placed emergently, without the use of preclose sutures. This case review describes an alternative removal method for the aforementioned occasions. (J Vasc Surg Cases and Innovative Techniques 2020;6:622-5.)

Keywords: Impella complications; Percutaneous wire access; Aortic devices

CASE REPORT

A 53-year-old man presented with an ST elevation myocardial infarction that required percutaneous coronary intervention. The patient progressed to cardiogenic shock, and an Impella CP device (Abiomed, Danvers, Mass) was placed through the right common femoral artery without the use of the standard "preclose" technique (Perclose ProClide vascular closure devices, Abbott Vascular, Chicago, III). Venoarterial extracorporeal membrane oxygenation was initiated through the left common femoral artery. Cradually the patient recovered, and the vascular surgery team was consulted for removal of the Impella on post-implant day 4. The patient had to remain anticoagulated secondary to his cardiovascular status and medical interventions.

After the patient was transferred into the operating hybrid suite and anesthesiology and cardiology staff were prepared, the groin was prepared and draped. The Impella CP device is placed through a 14F peel-away sheath and remains in the access vessel through a working sheath. The working sheath

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cannot be used to exchange the device shaft for a wire, because the Impella motor housing cannot be pulled out through that sheath and a wire will not fit in between. To perform percutaneous closure and avoid cut-down we used the following stepwise technique to remove it.

Step 1. The pump circuit system is disconnected according the manufacturer instructions. The Impella catheter is disconnected from the cable connector and the purge system (Fig 1, *arrow*). Other parts, catheter shaft (*arrowhead*) and pump with pigtail tip (*) as well-depicted (Fig 1).

Step 2. Under fluoroscopic guidance, the device system is retracted until the tip of the device is in the common iliac artery, keeping the repositioning sheath in place Fig 2, *A*). The motor and cannula outer diameter is 14F, catheter shaft 9F, and length from the pigtail tip to the catheter shaft approximately 13 cm (Fig 2, *B, arrows*).

Step 3. The shaft is retracted to the 30-cm mark at the repositioning sheath level (Fig 3, *A*). An 18G needle is used to stab the shaft allowing the introduction of a 0.035 wire at the 60-cm mark as shown in Fig 3, *B*. Subsequently, a 15 blade is used to remove a 2-cm-long, curvilinear sliver of material from the shaft wall of the catheter at the 35 cm mark (Fig 3, *C*, *D*). (The shaft contents are shown in Fig 3, *E*.)

Step 4. A short, floppy tip, nonhydrophilic 0.035-inch soft wire is introduced through the 60-cm mark hole and is advanced through the catheter (shaft) lumen, to the level of the 35-cm mark hole. The Impella shaft is then pushed in the repositioning sheath until the 60-cm mark reaches the hub of the repositioning sheath. This brings the 2-cm hole we created at the 35-cm mark site inside the arterial lumen. The wire is then advanced to allow it to exit the shaft of the device through that hole and to advance it inside the aortic lumen. Considering the exchange of devices and use of Proglide system, we recommend using non-hydrophilic 0.035-inch wires (eg, Bentson) for friction and stability.

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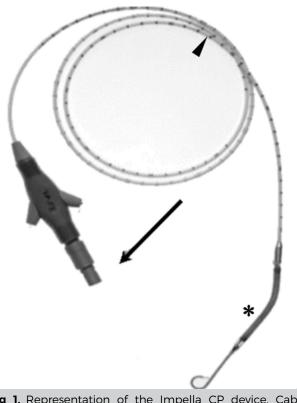


Fig 1. Representation of the Impella CP device. Cable connector and the purge system area (*arrow*). Catheter shaft (*arrow head*) and pump with pigtail tip (*).

Step 5. The guide wire is pushed until it exits the 35-cm mark hole and prolapses into the infrarenal aortic lumen (Fig 4, *A-D*, *arrows*).

Step 6. The repositioning sheath stitch is cut. While manually compressing the access site, the Impella motor housing and working sheath are removed as a single unit out of the body over the wire, in a "monorail" fashion.

Step 7. Two Proglide preclose devices are then introduced (late deployment of the Proglide devices and after the artery has been dilated without preclose technique is considered "off label") sequentially over the wire, oriented at 10:00 and 2:00 o'clock to close the access arteriotomy. The assistant needs to hold pressure at the access site during the remaining intervention, until the aforementioned Proglide devices are deployed.

The entire process was performed under direct fluoroscopy. The access site was successfully closed, hemostasis was achieved, the patient tolerated the procedure well without complications and maintained lower extremity perfusion postoperatively. The estimated blood loss was minimal (<10 mL). The total duration of the procedure was 1 hour and 12 minutes (including anesthesia patient preparation and cardiology staff to disconnect the Impella system); the skin-to-skin time for the removal technique was 38 minutes. The patient progressively recovered from this event without further complications, he was weaned

off extracorporeal membrane oxygenation (which was removed by the cardiac surgery team in an open cut-down fashion), his care was downgraded, and he was eventually discharged. Consent has been obtained by the involved patient for the case presentation.

DISCUSSION

The Impella CP is a percutaneously placed intra-arterial flow pump (with the preclose technique), positioned across the aortic valve for circulatory support.¹ The device is introduced using Seldinger technique, over a guidewire for its initial intra-arterial placement; however, an engineering limitation of the Impella CP is that it lacks a central wire access channel to maintain intra-arterial wire access after removing the device, which precludes reinsertion of a guidewire. Therefore, open arterial cutdown is needed for the device removal if no preclose sutures were placed during initial access.² In our case, the Impella device was instrumented (off label and outside the manufacturer instructions for use) to allow placement of a wire through the device shaft into the aorta permitting the removal of the device while maintaining wire access.

Emergent Impella placement without the use of a preclose devices has typically required an open cutdown for closure. Although a device like this can be removed with manual compression, in our experience removing a large sheath on anticoagulation, with atherocalcific disease is high risk for access complications. The Impella CP has no space to advance an 0.035-inch guidewire to maintain intra-arterial wire access between the repositioning sheath for the Impella CP (shorter diameter 9F) and the motor housing (outer diameter 14F). Previous case reports attempt to pass smaller wires between the device and the repositioning sheath³ by accessing the shaft with an 0.018 wire. The main limitations with smaller wires, 0.018-inch or 0.014-inch, is the stability for device exchange (eg, Proglide) and the force needed to overcome the friction in this tight space, which is significant. In prior modification case reports a more extensive modification for the Impella required a circumferential cut of the shaft which disrupted the integrity of the catheter shaft⁴; this created a potential risk for device material debris embolism or creating dissections in the arterial wall due to the extensive catheter surface irregularities. Our technique allows the use of an 0.035-inch wire to gain access to the arterial lumen. The limited modification of the original catheter (shaft) design decreases the potential risk for arterial wall injuries and intra-arterial debris from the shaft contents. Considering intra-arterial pressure and the back-bleeding visualized from the wire lumen (shaft), the likelihood of air embolism is low. To further decrease this risk, when the device is modified and the wire advanced through the shaft, the system is withdrawn and located at the level of the aortoiliac

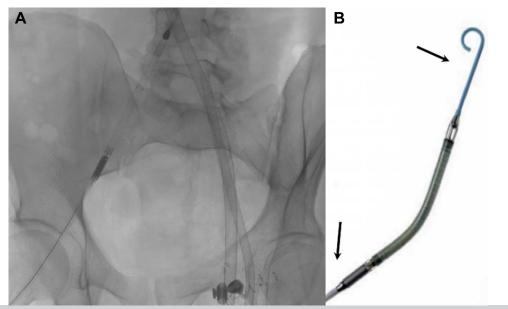


Fig 2. A, Impella Motor housing and cannula visualized at the level of the right common and external iliac arteries. **B**, Pigtail (*top arrow*) and motor housing (*bottom arrow*).

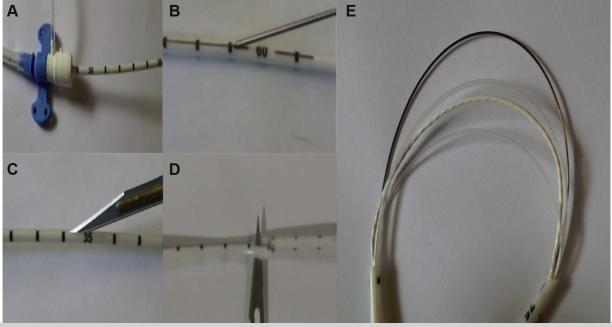


Fig 3. Modification steps. A, Intact device. B, Needle access. C and D, Catheter cut with 11 blade. E, Catheter contents.

bifurcation, well below the diaphragm. This technique decreased the procedure time, avoiding cutdown, in a high-risk, anticoagulated, critically ill patient (on extracorporeal membrane oxygenation) while achieving bleeding control with percutaneous closure.⁵

CONCLUSIONS

We describe an alternative technique for the safe salvage and removal of an Impella CP device, placed percutaneously without prior preclose technique. This technique requires further research

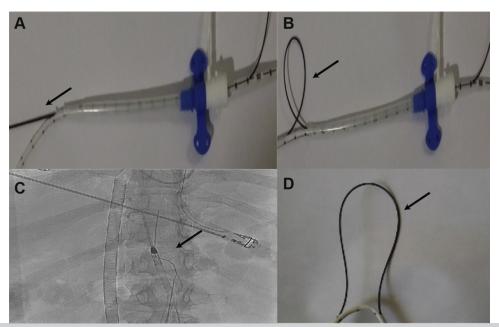


Fig 4. A-D, Wire exit point from the modified catheter *arrows*. C, Intraoperative fluoroscopy, *arrow* depicting prolapsed wire in the aortic lumen.

evaluation and experience is required to assess the safety and use of the technique by high-volume centers.

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