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Scriptwriter Name: Mithila Boche
Supervisor Name: Bridget Colvin
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Title: Utilizing Percutaneous Ventricular Assist Devices in Acute Myocardial Infarction Complicated by Cardiogenic Shock

Authors and Affiliations:
Shuktika Nandkeolyar[1], Poonam Velagapudi[2], Mir B. Basir[3], and Aditya S. Bharadwaj[1]

[1]Loma Linda University Medical Center, Division of Cardiology
[2]University of Nebraska, Division of Cardiology
[3]Henry Ford Health System, Division of Cardiology

Corresponding Authors:
Aditya S. Bharadwaj abharadwaj@llu.edu

Email Addresses for All Authors:
snandkeolyar@llu.edu
velagapudi@unmc.edu
mbasir1@hfhs.org
abharadwaj@llu.edu

Author Questionnaire

1. **Microscopy**: Does your protocol require the use of a dissecting or stereomicroscope for performing a complex dissection, microinjection technique, or something similar? **No**

2. **Software:** Does the part of your protocol being filmed include step-by-step descriptions of software usage? **No**

3. **Interview statements:** Considering the COVID-19-imposed mask-wearing and social distancing recommendations, which interview statement filming option is the most appropriate for your group?

   ☒ Interview Statements are read by JoVE's voiceover talent.

4. **Filming location:** Will the filming need to take place in multiple locations? **No**

Current Protocol Length

Number of Steps: 16
Number of Shots: 41

Introduction

1. Introductory Interview Statements

NOTE to VO talent: Please record the introduction and conclusion statements

REQUIRED:

1.1. Percutaneous ventricular assist devices are increasingly being utilized in patients with acute myocardial infarction and cardiogenic shock. This video demonstrates best practices for insertion of the Impella catheter.

1.1.1. *2.8.1.*

1.2. Utilization of best practices for femoral arterial access and insertion of percutaneous ventricular assist device is extremely important to reduce the risk of vascular complications in patients with cardiogenic shock.

1.2.1. *2.1.2, 2.7.2*

Ethics Title Card

1.3. These procedures should be standard of care at any institution treating patients with cardiogenic shock.

Protocol

2. Insertion of the Percutaneous Ventricular Assist Devices (PVAD)

(Note to Assistant Editor: the A camera (Canon 5D) stops every 30 minutes. Use visual of fluoroscopy monitor (leftmost monitor) in A cam angle to sync the screen capture of the fluoroscopy)

2.1. Begin by using a micro-puncture needle to obtain common femoral access over the lower half femoral head under fluoroscopic and ultrasound guidance **[1]**. To confirm an appropriate arteriotomy location, position the micro-puncture sheath ~~**[2]**~~ and acquire an angiogram of the femoral artery **[3]**.

2.1.1. WIDE: Talent inserting micro-puncture needled. (Note to video editor: earlier takes have incorrect needle gauge. Use pickup take from end of camera roll. Pickup take also has ultrasound use, which should be shown.)

2.1.2. ~~SCREEN: Sheath being positioned.~~ (Note to video editor: sheath was not available on the day. Cover with surrounding shots.)

2.1.3. SCREEN: Angiogram being obtained. (Angiogram not available on the day. Dr. Bharadwaj sending add'l clip to cover.)

2.2. Insert a 6-French sheath into the femoral artery **[1-TXT]** and a pigtail catheter into the inferior portion of the abdominal aorta **[2]**. To ensure the absence of peripheral artery disease, obtain an angiogram of the iliofemoral system **[3]**.

2.2.1. Sheath being inserted. **TEXT: In disease/ calcification of iliac arteries, use 25 cm 14-French sheath**

2.2.2. Catheter being inserted.

2.2.3. SCREEN: Angiogram. (Angiogram not available on the day. Dr. Bharadwaj sending add'l clip to cover.)

2.3. Using 8-, 10-, and 12-French dilators, serially dilate the arteriotomy site over a stiff 0.035-inch wire **[1]** before inserting the 14-French peel-away sheath under fluoroscopic guidance **[2-TXT]**.

2.3.1. ~~SCREEN:~~ Dilator being advanced (Shown in live action)

2.3.2. SCREEN: Sheath being inserted. **TEXT: Ensure tip advances without resistance** (Dr. Bharadwaj sending add'l clip to cover.)

2.4. Administer an approximately 100 unit/kilogram heparin bolus for an ACT *(A-C-T)* goal of 250-300 seconds, and flush the sheath. **[1-TXT]** Use a 0.035-inch J tipped wire to position the pigtail catheter within the left ventricle **[2]**. Then remove the J wire to check the left ventricular end-diastolic pressure **[3]**.

2.4.1. Talent administering heparin bolus. **TEXT: Alternative anti-coagulants: bivalirudin and argatroban**

2.4.2. SCREEN: Pigtail catheter positioned in left ventricle.

2.4.3. SCREEN: Shot of LVEDP response after wire removal. (Note to video editor: This should be somewhere in the waveform screen capture.)

2.5. Shape the tip of the exchange length 0.018-inch wire included in the kit **[1]** and insert the wire into the left ventricle so that it forms a stable curve at the left ventricular apex **[2]**.

2.5.1. Talent adjusting the tip of the exchange length 0.018-inch wire.

2.5.2. SCREEN: Wire being inserted into the left ventricle. (Dr. Bharadwaj sending add'l clip to cover.)

2.6. Then, use a pre-assembled loading red lumen to replace the catheter with an axial flow Archimedes-screw pump at a 45-degree angle of insertion **[2]**.

2.6.1. SCREEN: The pump being inserted. (Note to video editor: Long pause on this step due to difficulties with wire.)

2.7. Gently pull on the label while holding the catheter to remove the loading red lumen and advance the device in small increments into the left ventricle over the 0.018-inch wire **[2]**.

~~2.7.1. Label being pulled/lumen being removed.~~ (Device not available on the day. May need to cut 2.7)

2.7.2. SCREEN: Device is being advanced into the left ventricle.

2.8. Position the pump in the left ventricle with the inlet 4 centimeters below the aortic valve, taking care that that the pump is free from the mitral chordae **[1-TXT]**, and remove the 0.018-inch wire **[2]** to allow the pump to be started **[3]**.

2.8.1. SCREEN: Inlet being positioned in left ventricle. **TEXT: Being too close to apex can cause PVCs and trigger "suction alarms"** . (Dr. Bharadwaj sending add'l clip to cover.)

2.8.2. Wire being removed.

2.8.3. SCREEN: Talent starting pump. (Action starts at 1:47 in waveform capture clip. Action lasts ~30 sec)

2.9. Remove excess slack so the pump rests against the lesser curvature of the aorta **[1]** and monitor the console to make sure that the motor current is pulsatile and that the aortic waveform is displayed **[2]**. If a ventricular waveform is displayed, the pump may need to be retracted **[3]**.

2.9.1. SCREEN: Slack being removed/pump resting against aorta (In fluoroscopy screen capture clip)

2.9.2. SCREEN: Pulsatile current (bottom green) and aortic waveform (top red) being displayed. (Starts 2:45 in waveform capture clip.)

2.9.3. SCREEN: Ventricular waveform displayed (Starts 3:40 in waveform capture clip.)

2.10. If the device needs to be left in situ, replace the peal-away sheath with the repositioning sheath pre-loaded on the device **[1]** and check the device position by fluoroscopy **[2]** and the waveforms on the console **[3]**.

2.10.1. Repositioning sheath being inserted (Note to video editor: Do not use 1st attempt.)

2.10.2. SCREEN: Shot of device position

2.10.3. Talent checking waveforms on console

~~2.11. When the device is in place, palpate the distal lower extremity arterial pulses as previously demonstrated **[1-TXT].**~~

~~2.11.1. Talent checking arterial pulses. **TEXT: Alternative: Obtain lower extremity angiogram using wire re-introducing port**~~

2.12. If the flow is obstructed, place a reperfusion sheath prior to transferring the patient to the critical care unit **[1]**. Then apply sterile dressing **[2]** and have the patient monitored by personnel trained in the use of the device **[3]**.

2.12.1. Sheath being placed. . (Dr. Bharadwaj sending add'l still image to cover.)

2.12.2. Talent applying dressing. (Dr. Bharadwaj sending add'l still image to cover.)

2.12.3. Talent checking Patient chart or monitor or similar representative action. (Dr. Bharadwaj sending add'l still image to cover.)

3. Device Position Confirmation

3.1. Immediately upon arrival to the cardiac intensive care unit, use bedside transthoracic echocardiography in the parasternal long axis view **[1]** to confirm that the inlet of the device is positioned 3-4 centimeters from the aortic valve and note the position of the device in relation to the mitral valve **[2-TXT]**.

3.1.1. WIDE: Talent applying ultrasound probe to device location. (Note to video editor: Use 2nd take)

3.1.2. SCREEN: Device in position. **TEXT: Alternative: Check position in subxyphoid view** *Video Editor: please emphasize mitral valve/position of device in relation to mitral valve when mentioned as possible*

3.2. If the device needs to be repositioned, turn down the device to P2 **[1]** and unscrew the locking mechanism on the sterile cover to allow the device to be advanced or retracted **[2]**.

3.2.1. Talent setting device to P2 (Starts 4:16 in waveform capture clip.)

3.2.2. Locking mechanism being unscrewed/device being re-positioned.

3.3. Then, lock the device in the new position **[1]**, document the position ~~**[2]**~~, and increase the device to the desired level of support **[3]**.

3.3.1. Device being locked in the new position.

~~3.3.2. Talent documenting position~~

3.3.3. Talent setting device support level (Starts 6:25 in waveform capture clip where the green readout starts ramping up.)

Note to editor and AE: There is a lot of extra screen capture at the end of the longer screen capture. This can be ignored.

Results

4. Results: Efficacy and Risk Assessment Related to PVAD

4.1. Early diagnosis of cardiogenic shock, early insertion of PVAD, and a protocolized and multidisciplinary approach to cardiogenic shock has been shown to improve outcomes in observational data.

4.1.1. LAB MEDIA: Table 1. *Video Editor: Emphasize Study column.*

4.1.2. LAB MEDIA: Table 1. *Video Editor: Emphasize appropriate 1st and 6th rows.*

4.2. Vascular complications and limb ischemia due to PVAD is a real concern in patients with cardiogenic shock because it can lead to increased morbidity and mortality. **[1]**.

4.2.1. LAB MEDIA: Table 1. *Video Editor: Emphasize 2nd-5th rows*

4.3. Therefore, it is imperative for the implanting physician to follow best practices for vascular access and insertion of PVAD in order to minimize complications and improve clinical outcomes. Additionally, it is important to assess for limb ischemia in patients with PVAD and ensure reperfusion to the ischemic limb.

4.3.1. LAB MEDIA: Table 2.

4.3.2. LAB MEDIA: Table 2. *Video Editor: Emphasize Management column.*

4.3.3. LAB MEDIA: Table 2. *Video Editor: Emphasize Prevention column.*

Conclusion

5. Conclusion Interview Statements

NOTE to VO talent: Please record the introduction and conclusion statements

5.1. It is important to diagnose cardiogenic shock early and follow a protocol-based approach to treat it. Additionally, operators should ensure safe vascular access with utilization of ultrasound and fluoroscopy. It is also important to assess limb perfusion in patients with PVAD and perform reperfusion in case of compromised flow.

5.1.1. *2.2.1*

5.2. Robust observational data have shown improved survival in patients with cardiogenic shock with utilization of a protocol-based multidisciplinary approach. On the horizon are large, randomized control trials to assess for best treatment strategies in patients with cardiogenic shock.

5.2.1. *2.6.1*