Brief Report

Safe Ambulation of Critically Ill Cardiac Patients With Femoral Balloon Pumps: A Case Cohort Study

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ABSTRACT

We sought to demonstrate the safety of ambulation of patients with intra-aortic balloon pumps (IABPs) inserted via the femoral approach in the setting of 1 cardiovascular surgical intensive care unit and 1 cardiac care unit. We studied 70 patients who had received femoral IABPs at our institution between December 2015 and June 2019 and who met standardized criteria for ambulation. These patients underwent initial standing trials with a specialty standing bed/tilt table and progressed to standing exercises and, ultimately, to ambulation (defined as covering a distance of at least 10 feet) with the physical therapist. A total of 323 sessions of ambulation were successfully performed in 70 patients with IABPs inserted via the femoral approach, for an average of 4.61 sessions per patient. The average ambulation session time was 45 minutes (3−62 minutes, covering a median distance of 420 ft [805 IQR]). Complications were defined as major or minor and were monitored for during and after ambulation. Major complications included limb ischemia, arterial dissection, aortic aneurysm, balloon rupture, significant hemodynamic compromise, and death. Minor complications included balloon migration, infection, paresthesia, changes in balloon augmentation, and hematoma at insertion site. No major complications were associated with ambulation, and only 11 minor complications were observed. The total complication rate was 3.40% for all ambulation sessions. Ambulation of selected patients with femoral IABPs appears to be a safe activity when using the enclosed protocol and selection process. Future studies are required to show that such activities decrease muscle deconditioning in these patients and enhance recovery. (*J Cardiac Fail 2020;26:621−625*)

Key Words: Intra-aortic balloon pump, cardiogenic shock, congestive heart failure, heart failure, coronary artery disease, physical therapy, ambulation.

Intra-aortic balloon pumps (IABPs) provide hemodynamic support by means of diastolic augmentation of aortic pressure, thereby enhancing coronary perfusion while reducing left ventricular afterload.[1] They have been used in the management of patients with angina refractory to maximal medical management and those with severe cardiac pump failure awaiting advanced surgical options (left ventricular assist device or heart transplant) and for treatment of the various complications involved with myocardial infarction in patients awaiting coronary revascularization.[2] IABPs canbe placed in multiple insertion sites, including axillary and subclavian arteries,[3] but the majority of IABPs are inserted into the common femoral artery because of the larger vessel size and fewer associated complications.[4]

The location of IABP insertion means that patients are commonly limited to bed rest and restricted mobility of the ipsilateral extremity due to concerns about complications and interruption of IABP support. Previous studies have shown bed rest for 3 or more days increases the incidence of negative physiological changes impacting functional outcomes and length of stay.[5]

This study proposes a protocol for the evaluation and implementation of mobilization of patients with femoral

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IABPs and reports the complications and safety issues that have occurred when mobilizing these patients.

Methods

Prior to the ambulation initiative, we performed a retrospective analysis of patients in our facility who required femoral IABP support, ranging from December 2013 to December 2015, in order to better quantify the amount of time patients were restricted to bed rest. Of a total of 337 patients, 248 were supported by a femoral IABP for at least 2 days (average of 5.1 days) and were required to remain immobile while the IABP remained in situ.

Therefore, a quality-improvement project was initiated to observe whether weight-bearing and ambulation were safe for patients with femoral IABPs in order to prevent prolonged bed rest from occurring. After recording no complications with initial trials, a mobility protocol was created by using a multidisciplinary team (Ramsey protocol), and institutional review board approval was obtained. Unit-based guidelines were used to identify appropriate candidates for ambulation. Ideal candidates were reported to be walking independently prior to admission to the hospital without requiring the use of assistive devices. Patients were excluded from ambulating if they demonstrated any lower-extremity weakness, defined as a modified manual muscle test grade of less than 3/5 conducted while supine. The lower extremity housing the IABP was not flexed at the hip more than 30˚ during the manual muscle test .

Once a candidate for ambulation was identified, the Ramsey mobility protocol was used by a physical therapist, and ambulation would commence with assistance from the registered nurse to mobilize the IABP console. The physical therapist and registered nurse remained with the patient throughout the gait process, cuing the patient to adhere to a short-stride gait pattern so as not to flex the leg with the IABP more than 30˚ during the swing phase or overextend the leg in the terminal stance. The ambulation distance was dependent on patient tolerance per subjective report as well as on objective data obtained from the available hemodynamic monitors. Ambulation was to be stopped immediately if the IABP became dislodged or appeared to have migrated or if bleeding began at the insertion site. The process was also to be stopped if the patient complained of symptoms in response to activity or became hemodynamically unstable as indicated by changes in vital signs. The pertinent vital signs included intra-aortic pressures and augmented diastolic pressures via the IABP console, as well as heart rate, respiratory rate and oxygen saturation.

Ambulation was defined as walking forward and covering 10 feet or more. The physical therapist and other medical team members monitored the patient during and after therapy for any complications related to ambulation. Complications were defined as major or minor. Major complications included vascular compromise (dissection, aneurysm or ischemia), cerebrovascular accidents, myocardial infarctions, IABP malfunction, and death. Minor complications were defined as balloon migration without hemodynamic compromise, paresthesia, hematoma, infection, minor bleeding, and transient console dysfunction. After data collection concluded, descriptive statistics were run on anthropomorphic data with median and interquartile range for all continuous variables and total and percentage of total included for categorical variables.

Table 1. Anthropomorphic Data

Characteristics	Total (N = 70)	CAD (n = 33)	HF (n = 37)
Male (%)	58 (83%)	28 (85%)	30 (81%)
Median age, yrs.	57 [18.75]	60 [16.00]	54 [16.00]
Median height, inches	69 [5.00]	68[5.00]	69 [4.00]
Median weight, kg	90.05 [26.85]	91.70 [25.7]	87.20 [26.50]
Median BMI	29.10 [7.93]	31.85 [6.68]	27.86 [6.53]
Ambulation sessions, total	323	47	276
Ambulation sessions, per patient	4.61	1.42	7.45
Median distance ambulated	420 [805.00]	250 [240.00]	518 [852.50]
Comorbidities			
DM	28 (40%)	14 (42%)	14 (38%)
HTN	47 (67%)	30 (91%)	17 (46%)
CAD	41 (59%)	33 (100%)	8 (22%)
HLD	38 (54%)	21 (64%)	17 (46%)
Mean modified MMT grade	4+/5	4+/5	4+/5
RLE IABP insertion site	66 (94%)	32 (97%)	34 (92%)

BMI, body mass index; CAD, coronary artery disease; DM, diabetes mellitus; HLD, hyperlipidemia; HTN, hypertension; IABP, intra-aortic balloon pump; [ ], interquartile range; MMT, manual muscle test; RLE, right lower extremity.

Results

Seventy patients participated in ambulation while requiring femoral IABP support and using the protocol described above. There were 323 total trials of ambulation, with the median distance of ambulation being 420 feet [805] (Table 1). The candidates for ambulation included patients with coronary artery disease and heart failure (HF) in the

Table 2. Complications Associated With Ambulation

Categories	N = 70
Ambulation sessions total	323
Total complications (%)	11 (3.40)
Major (%)	0 (0)
Limb ischemia (%)	0 (0)
Aneurysm/dissection (%)	0 (0)
Balloon rupture (%)	0 (0)
Significant hemodynamic compromise (%)	0 (0)
Death (%)	0 (0)
Minor (%)	11 (3.40)
Balloon migration (%)	3 (0.93)
Infection (%)	3 (0.93)
Paresthesia (%)	0 (0)
Changes in augmentation (%)	0 (0)
Console malfunction (%)	2 (0.62)
Hematoma at insertion site (%)	3 (0.93)

RAMSEY PROTOCOL FOR AMBULATING PATIENTS WITH INTRA-AORTIC BALLOON PUMP

- **History:**
  - Determine patient's prior level of function. Must be ambulatory with or without assistive device.
  - Inquire about strength and sensation
- **Examination: (Abnormalities observed in the follow examination categories may exclude patient from ambulation)**
  - Cognition
    - Patient alert and oriented x4. Short- and long-term memory assessed during history questions.
  - Manual Muscle Test (MMT)
    - In supine, test bilateral hip flexion, knee flexion, knee extension, ankle dorsiflexion and plantarflexion.
      - *Note: For limb housing IABP, do not exceed 30 degrees hip flexion during hip and knee MMT*
  - Sensation
    - In supine, grossly test dermatomes bilaterally.
  - Pulses
    - Bilateral dorsalis pedis and posterior tibial
  - IABP site check
    - Examine insertion site for hematoma, bleeding.
    - Examine integrity of sutures and/or other securing device (i.e. Stat Lock) distal to site
- **Treatment Set-up:**
  - With assistance, slide patient from supine in hospital bed to supine on tilt table
    - *Note: Not necessary if patient is on hospital bed capable of tilting*
  - Apply safety straps (2 to 3) to patient
    - One across abdomen (between naval and xiphoid process)
      - *Note: If pt. has line/tube exiting abdomen, move strap above/below this line*
    - One across knee (Either at tibial tuberosity or at superior pole of patella)
    - If using a third strap, apply across mid-thigh.
  - Once secured onto tilt table/bed, level transducer for invasive lines as well as IABP console and begin tilting process
    - *Note: Intra-aortic pressure, augmented diastolic pressure, HR, RR, and SpO2 should be recorded throughout treatment.*
- **Treatment- Tilting**
  - In supine (0 degrees)
    - Print/record vital signs (from IABP console)
  - Tilt to 30 degrees
    - Print/record vital signs
    - Assess for signs of intolerance (dizziness, chest pain, numbness/tingling in legs or arms)
  - Tilt to 60 degrees
    - Print/record vital signs
    - Assess for signs of intolerance
  - Tilt to 90 degrees
    - Print/record vital signs
    - Assess for signs of intolerance
- **Treatment- Pre-ambulation**
  - In upright standing, check IABP function and reassess insertion site
  - Begin to loosen and remove strap across abdomen
    - Cue patient to keep back in contact with tilt table
  - Begin to loosen and remove strap across knees
    - Cue patient to straighten knees
  - Once straps removed, provide RW to patient.
  - Begin weight shifting, progressing to marching in place while remaining on tilt table/bed.
    - Print/record vital signs
    - Assess for signs of intolerance
  - Step off tilt table with leg housing IABP, and follow with opposite leg
- **Treatment- Ambulation**
  - Have registered nurse (RN) mobilize IABP console, ensuring transducer is level to phlebostatic axis throughout if needed
    - *Note: Fiberoptic IABP does not require level transducer*
  - Have second RN if needed to assist with IV pole/oxygen tank if physical therapist is unable.
  - Pending adequate strength/balance, begin walking with RW support cueing patient to take short strides (no hip flexion >30 degrees)
    - Print/record vital signs every 30 feet
    - Assess for signs of intolerance every 30 feet.
- **Treatment- Returning onto tilt table/bed**
  - Tilt table/bed is in full upright position
  - Patient approaches table/bed and turns back to bed
  - Step backwards onto table/bed with leg <u>not</u> housing IABP, followed by opposite leg.
  - Secure straps if needed onto knee and abdomen
    - Print/record vital signs
    - Assess for signs of intolerance
  - Begin tilting back to supine, stopping at 45 degrees, or as often as patient requests
    - Print/record vital signs at 45 degrees
    - Assess for signs of intolerance at 45 degrees
  - In supine, remove straps.
    - Print/record vital signs
    - Assess for signs of intolerance
  - With assistance slide patient from tilt table back onto hospital bed.
- **Conclusion of treatment**
  - Reassess sensation
  - Reassess pulses
  - Reassess insertion site and securing devices/sutures
    - *Note: If any changes to insertion site, bleeding in IABP tubing, or changes in pulses or sensation, notify physician immediately.*
- **Contraindications to Ambulation- Included but not limited to:**
  - Abnormal baseline cognition, sensation, strength, pulses observed during examination
  - Hemodynamic Compromise: Symptomatic hypotension or unstable heart rate/rhythm during ambulation or tilting process that does not improve with time
  - Changes to IABP function/IABP insertion site
    - IABP dislodged
    - Helium tubing disconnected
    - Bleeding/hematoma at insertion
  - Patient Intolerance
    - Subjective complaints of lower extremity/upper extremity numbness or pain, chest pain, shortness of breath, dizziness
    - Evidence of instability with loss of balance or weakness

Fig. 1. Ramsey protocol for ambulation of patients with IABPs.

cardiac care unit and cardiovascular surgical intensive care unit. The size of the IABP inserted was appropriate for the patient's height.

Of the 70 total patients included in this study, 37 were patients with HF awaiting left ventricular assist devices or heart transplantation, and 33 were patients with coronary artery disease. The majority of ambulation sessions (276 of the 323) were conducted in patients with HF. Baseline hemodynamics were observed at the onset of ambulation in the patients with HF, revealing an average ejection fraction of 15.4%, a central venous pressure of 13.9 mmHg, a pulmonary capillary wedge pressure of 21.9 mmHg, and a cardiac index of 2.36 L/min/m^2. Most (66%) of these patients also required dual inotropic support at the time of ambulation. There were 11 minor complications and no major complications associated with ambulation (Table 2). We observed 3 instances of migration of more than 1 cm on chest radiographs. There were 2 instances of console malfunctions that occurred while standing. One instance occurred while standing on the tilt table prior to ambulation and was resolved within 30 seconds without intervention, and it never recurred. The second was observed while standing after ambulation had been completed, and despite basic troubleshooting by the medical team, the IABP console and IABP itself were exchanged in the cardiac catheterization laboratory. Upon examination of the balloon, once it had been removed from the patient, there was no evidence of rupture, kinking or air leak and, therefore, the malfunction was attributed to the IABP console. Three hematomas were observed by palpation alone in 2 patients, each slightly superior to the insertion site of the IABP, and each measured < 5 cm in diameter. Finally, there were 3 occurrences of infection in 3 separate patients. In each case, the first clinical sign of infection was a fever. Multiple sets of blood cultures were drawn from multiple sites, revealing gram-positive cocci in pairs and clusters. The appropriate antibiotics were started by the medical team and, ultimately, the IABP was removed and placed in a different location (2 in the opposite leg and 1 in the axillary artery).

Discussion

To the best of our knowledge, this is the first study to describe the safety of ambulation of patients with femoral IABPs. Traditionally, femoral artery sheaths are considered a contraindication to ambulation because of the necessity of hip and knee movement with ambulation. However, when joint movement during mobility is minimized as described in this protocol, much of the perceived risk can be neutralized.

The 11 reported complications were noted in only 6 patients, all of whom were patients with HF awaiting ASO and requiring prolonged IABP support time (> 14 days) and who had a mean femoral IABP duration of 37.8 days ($\pm$ 24.8). This appears to suggest that prolonged IABP treatment time leads to increased vascular complications, and this has also been confirmed in other studies examining incidence of complication in patients requiring IABPs.[6] Finally, there appears to be a correlation between migration and infection in our cohort, with 2 of the 3 instances of infection presenting 3−5 days after discovery of migration and requiring IABP repositioning.

With a low incidence of overall complication during ambulation, this study provides a protocol for ambulation with femoral IABPs and demonstrates that ambulation is safe for cardiac patients in the intensive care unit (Fig. 1).

Study limitations

Limitations of this study include the small sample size at a single institution. Additionally, the timing of chest radiographs to assess for migration of the catheter resulting from ambulation varied. Imaging was done each morning unless the care team was suspicious of possible migration, in which case imaging was conducted immediately following ambulation. However, with chest radiographs occurring each morning, it is not possible to confirm that any migration was truly attributed to ambulation as opposed to other events throughout the day or night, such as rolling and positioning by the bedside care team or by the patients themselves. For this study's purpose, we included all the instances of migration we observed in ambulatory patients.

Conclusion

A protocol for ambulating patients with femoral IABPs is provided in this study; it resulted in a 3.4% total complication rate across all ambulation sessions in a small group of patients with either coronary artery disease or HF. Not all patients with femoral IABPs are appropriate for ambulation. A multidisciplinary approach should be applied during the evaluation of potential candidates for early mobility. It is recommended this multidisciplinary team include cardiothoracic surgeons, interventional cardiologists, physician assistants/nurse practitioners, physical therapists, and nurses working in collaboration to ensure safe ambulation. In conclusion, it appears that the ambulation of critically ill patients with femoral IABPs can be successfully completed without significant risk to the patients.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.cardfail.2020.05.010.

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