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Safety and feasibility of femoral catheters during physical rehabilitation in the intensive care unit☆,☆☆,★

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Abstract

Objective: Femoral catheters pose a potential barrier to early rehabilitation in the intensive care unit (ICU) due to concerns, such as catheter removal, local trauma, bleeding, and infection. We prospectively evaluated the feasibility and safety of physical therapy (PT) in ICU patients with femoral catheters.

Design, Setting, and Patients: We evaluated consecutive medical ICU patients who received PT with a femoral venous, arterial, or hemodialysis catheter(s) in situ.

Measurements and Main Results: Of 1074 consecutive patients, 239 (22%) received a femoral catheter (81% venous, 29% arterial, 6% hemodialysis; some patients had >1 catheter). Of those, 101 (42%) received PT interventions, while the catheter was in situ, for a total of 253 sessions over 210 medical ICU (MICU) days. On these 210 MICU days, the highest daily activity level achieved was 49 (23%) standing or walking, 57 (27%) sitting, 25 (12%) supine cycle ergometry, and 79 (38%) in-bed exercises. During 253 PT sessions, there were no catheter-related adverse events giving a 0% event rate (95% upper confidence limit of 2.1% for venous catheters).

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Conclusions: Physical therapy interventions in MICU patients with in situ femoral catheters appear to be feasible and safe. The presence of a femoral catheter should not automatically restrict ICU patients to bed rest.

1. Introduction

Survivors of critical illness often experience important impairments in their physical function and quality of life [1-7]. Early physical medicine and rehabilitation interventions in the intensive care unit (ICU) can improve these impairments [8-13]. However, perceived barriers often pose challenges for such early rehabilitation interventions [14-17]. An indwelling femoral catheter is one such perceived barrier, due to concerns such as catheter removal, local trauma, bleeding, and infection [15,18-20].

Arterial and venous femoral catheters are generally quick and easy to obtain and are widely used in ICUs [21]. There are relatively little data evaluating use of femoral catheters in conjunction with early rehabilitation and mobilization of patients in the ICU setting. Our objective was to prospectively evaluate the feasibility and safety of physical therapy (PT) interventions in ICU patients with venous, arterial, and/or hemodialysis femoral catheters.

2. Methods

2.1. Setting and patients

Data for this analysis were prospectively collected as part of the Critical Care Physical Medicine and Rehabilitation Program at the Johns Hopkins Hospital in Baltimore, MD. The program maintains a registry of all consecutive adult patients admitted to the hospital's 16-bed medical ICU (MICU). The program uses a number of physical therapists who complete rotations in the MICU (with durations ranging from several weeks to several months) to maintain a staffing level of 2.25 full-time equivalent physical therapists in the MICU. These physical therapists received on-the-job training on rehabilitation interventions in the ICU setting [8,10,11]. Rehabilitation interventions included active assisted and independent range of motion exercises in the supine position and supine cycle ergometry, advancing, over time, to bed mobility activities, upright sitting, transfer training, pregait exercises, and walking, as tolerated by patient. The estimated average time of each treatment session is 30 to 45 minutes.

From the program registry, we identified all consecutive adult patients who received any PT intervention with a femoral catheter in situ for the 16-month period from September 2009 to January 2011. For all patients, the following registry data, collected from medical records, were available and analyzed: patient demographics (age, sex, and race) and baseline ambulation status, MICU admission source (emergency department, ward, other ICU at Johns Hopkins, or transfer from other hospital), MICU admission diagnosis category, MICU and hospital length of stay, and mortality (with cause of death based on medical records). On a daily basis, the highest level of activity performed during all PT interventions provided that day was available and recorded using an ordinal scale with the following mutually exclusive categories: in-bed exercises, supine cycle ergometry (using a motorized MOTOMed Letto cycle [13,22]), sitting, and standing/walking. Finally, the daily status regarding the presence of 3 types of femoral catheters (arterial, venous, and hemodialysis) was separately recorded. For purposes of this analysis, data regarding a femoral catheter being in situ at the time of PT were independently confirmed via re-review of medical records.

A total of 6 different femoral catheter-related adverse events potentially attributable to rehabilitation therapy were evaluated. Four events were prospectively evaluated based on previously established classifications: nonfunctioning catheter, removal of catheter, bleeding at the catheter site, and acute limb ischemia within 24 hours after rehabilitation intervention [23,24]. The catheter was *non-functional* when it was not consistently functioning in the same manner after vs before the treatment session. *Removal* was defined as the catheter being removed from its insertion site. *Bleeding at the catheter site* was defined as visible blood at the insertion site or on a dressing that is greater than the blood, if any, present before the PT session. *Acute limb ischemia* was defined as any documented evidence of decreased blood flow to a lower extremity within 24 hours after a treatment session that was not present before the treatment. All 4 of these adverse events were evaluated with each PT session by the treating physical therapists. Each physical therapist received one-on-one didactic instruction from the MICU PT leader (JMZ) who was involved in creating the system of safety events monitoring, along with the Critical Care Physical Medicine and Rehabilitation Program's medical director (DMN). There was real-time availability of program staff to clarify any questions regarding recording events. To help ensure accurate and complete recording of any adverse events associated with PT interventions in the MICU, a weekly rehabilitation meeting was held with the MICU physical therapists, the program's medical director (DMN), and program assistant (EM) in which rehabilitation issues are discussed for all MICU patients. In addition, on a monthly basis, a MICU PT report is prepared and reviewed with the entire MICU rehabilitation team, which specifically includes

a description of any reported adverse events during the current month and prior months.

In addition to the above 4 adverse events recorded as part of the Critical Care Physical Medicine and Rehabilitation Program, 2 other potential femoral catheter-related adverse events were evaluated for purposes of this report: retroperitoneal hematomas and catheter line–associated blood stream infections. We collected these data retrospectively to help more comprehensively evaluate for potentially rare complications related to femoral catheters during rehabilitation therapy. Retroperitoneal hematoma events were evaluated based on retrospective review of the final radiology reports of all abdominal/pelvic computed tomographic scans completed from the first day of a PT intervention conducted with a femoral line in situ until 7 days after the last such intervention. Catheter line–associated blood stream infection data were obtained from a prospective database of independent evaluations completed by hospital epidemiology and infection control staff.

2.2. Statistical analysis

Descriptive statistics, including proportions for binary and categorical data, and median and interquartile range (IQR) for continuous data were presented. Comparisons were performed using Wilcoxon rank sum, the Student *t*, and χ^2 tests, as appropriate. *Statistical significance* was defined as a 2-sided $P < .05$. We determined the total number of safety events as a proportion of the total number of PT sessions and calculated the 95% confidence interval around

Table 1 Characteristics of MICU patients with femoral catheters, by PT status

Characteristic	All patients with femoral catheters, n = 239	Patients who received PT treatment, n = 101	Patients who never received PT treatment, n = 138	*P*
Demographic and baseline data				
Age, median (IQR), y	55 (46-66)	55 (46-68)	55 (47-66)	.718
Male, n (%)	116 (49)	41 (41)	75 (54)	.036
Race, n (%)				.239
White	75 (31)	27 (27)	48 (35)	
Black	144 (60)	69 (68)	75 (54)	
Other	20 (8)	5 (5)	15 (11)	
Location before hospital admission, n (%)				.025
Home (independent)	131 (55)	55 (54)	76 (55)	
Home (with assistance)	70 (29)	37 (37)	33 (24)	
Other [a]	38 (16)	9 (9)	29 (21)	
Able to stand and/or walk before hospital admission, n (%)	182 (76)	86 (85)	96 (70)	.005
MICU data				
MICU admission source				.925
Emergency department	100 (41)	40 (40)	60 (43)	
Ward	84 (35)	37 (37)	47 (34)	
Other ICU at Johns Hopkins Hospital	6 (3)	3 (3)	3 (2)	
Other hospital	49 (21)	21 (21)	28 (20)	
ICU admission diagnosis category, n (%)				.059
Respiratory failure (including pneumonia)	65 (27)	24 (24)	41 (30)	
Gastrointestinal	40 (17)	21 (21)	19 (14)	
Cardiovascular	52 (22)	17 (17)	35 (25)	
Sepsis (nonpulmonary source)	33 (14)	15 (15)	18 (13)	
Central nervous system	15 (6)	8 (8)	7 (5)	
Nephrology/acute renal failure	10 (4)	5 (5)	5 (4)	
Other	24 (10)	11 (11)	13 (9)	
Mechanically ventilated, n (%)	184 (77)	68 (67)	116 (84)	.002
Length of stay and mortality				
MICU length of stay, median (IQR), d	2 (1-6)	4 (3-8)	2 (1-5)	<.001
Hospital length of stay, median (IQR), d	12 (7-23)	14 (9-33)	11 (5-19)	<.001
Died in MICU, n (%)	63 (26)	11 (11)	52 (38)	<.001
Died in hospital, n (%)	79 (33)	21 (21)	58 (42)	.001

Percentage may not add to 100% due to rounding.

[a] Other: Acute and subacute rehabilitation facilities, long-term vent facility, nursing home, or homeless.

Table 2 Femoral catheter data for 101 patients in MICU receiving PT

Patients with any femoral catheter during MICU stay, n (%) [a]	101 (100)
Venous catheter, n (%)	82 (81)
Arterial catheter, n (%)	29 (29)
Dialysis catheter, n (%)	6 (6)
Patient-days with any femoral catheter during MICU stay, n (%) [a]	210 (100)
Venous catheter, n (%)	149 (71)
Arterial catheter, n (%)	82 (39)
Dialysis catheter, n (%)	13 (6)

[a] Patients may have more than 1 type of femoral catheter simultaneously.

it. All analyses were performed using Stata 11.0 software (Stata Corporation, College Station, TX). The Institutional Review Board at Johns Hopkins University approved this evaluation with a waiver of consent (Johns Hopkins IRB-X, NA00048180).

3. Results

Of 1074 consecutive patients admitted to the MICU during the 16-month period from September 2009 to January 2011, 239 (22%) received a femoral catheter. Of these, 101 patients (42%) received PT interventions, while a femoral catheter was in situ. Of the 101 patients, 67% were mechanically ventilated in the MICU during their ICU stay, and 41% were male, with a median (IQR) age of 55 years (46-68 years) (Table 1). A large majority of patients (85%) were able to stand and/or walk before hospital admission. The most common primary MICU admission diagnosis categories were respiratory failure (24%), gastrointestinal (21%), and cardiovascular (17%). Patients' median (IQR) MICU and hospital lengths of stay were 4 (3-8) and 14 (9-33) days, respectively. The MICU mortality rate was 11% with all the causes of death being unassociated with PT interventions or related to femoral catheter complications. The median (IQR) time from MICU admission to first PT intervention was 3 days (2-4), with little difference in this median time between ventilated vs nonventilated patients (3 [2-7] vs 3 [2-4] days, respectively, $P = .051$). Overall, the 101 MICU patients received 707 PT sessions (with or without a femoral catheter in situ) over 602 days, with a median (IQR) of 2 (1-6) sessions per person while in the MICU.

For the 101 patients evaluated in this report, the median (IQR) number of MICU days with any femoral catheter in situ was 4 (2-8) days, with no significant difference in duration of femoral catheter use when comparing venous, arterial, and dialysis catheters ($P = .095$). Venous femoral catheters were more common than arterial or dialysis femoral catheters, being used in 71% of the 210 patient days of PT treatment sessions occurring with any type of indwelling femoral catheter (Table 2).

Patients had a femoral catheter in situ, for a total of 253 PT treatment sessions over 210 days, provided by 9 different physical therapists. Considering only days with any femoral catheter in situ, these 101 patients received a median (IQR) and mean (SD) of 1 (1-3) and 2.5 (2.5) sessions per person, respectively. Among the PT treatment sessions conducted with a femoral catheter in situ, the highest daily level of activity achieved was standing or walking (23%), sitting (27%), supine cycle ergometry (12%), and in-bed exercises (38%). No physical activity sessions were stopped prematurely due to concerns regarding femoral catheter in situ; however, patients underwent active monitoring to ensure that the waveform of femoral arterial catheters was maintained during therapy to guide the PT interventions. During all 253 PT treatment sessions, none of the 6 potential femoral catheter-related adverse events (as previously defined) occurred, yielding a 0% event rate and a 95% upper confidence limit of 1.4%. Safety events rates (with 95% confidence interval) by type of femoral catheters and type of intervention are further described in Table 3.

Table 3 Safety events rate (%, with 95% confidence interval), by type of femoral catheter and type of PT intervention

	All femoral catheter	Venous femoral catheter	Arterial femoral catheter	Dialysis femoral catheter
All interventions	0 (0, 1.4)	0 (0, 2.1)	0 (0, 3.6)	0 (0, 23.1)
Interventions by type				
In-bed exercises	0 (0, 4.2)	0 (0, 6.2)	0 (0, 7.5)	0 (0, 28.5)
Supine cycle ergometry	0 (0, 11.9)	0 (0, 16.8)	0 (0, 33.6)	0 (0, 97.5)
Sitting	0 (0, 4.5)	0 (0, 6.7)	0 (0, 12.8)	0 (0, 84.1)
Standing/walking [a]	0 (0, 5.8)	0 (0, 7.7)	0 (0, 19.5)	No observations

The total number of PT treatments within each group represents the denominator for calculation of each event rate. Patients may have more than 1 type of femoral catheter simultaneously. The denominator for each cell of the table is as follows: All interventions: all catheters 253, venous 176, arterial 100, dialysis 14; in-bed exercises: all catheters 84, venous 57, arterial 47, dialysis 11; supine cycle ergometry: all catheters 29, venous 20, arterial 9, dialysis 1; sitting: all catheters 79, venous 53, arterial 27, dialysis 2; and standing/walking: all catheters 61, venous 46, arterial 17, dialysis 0.

[a] Of the 61 instances in this category, 49 (80%) were walking, and the remainder were standing.

4. Discussion

We conducted a prospective evaluation of the feasibility and safety of MICU patients receiving PT, as part of routine care, with a femoral catheter in situ. Over a 16-month period, 239 (22%) of all 1074 MICU patients ever had a femoral catheter, and 101 patients received 253 PT treatment sessions with a femoral catheter in situ (average 2.5 sessions per patient). These sessions included standing/walking, sitting, supine cycle ergometry, and in-bed exercises. Physical therapy sessions were not stopped prematurely due to complications related to femoral catheters. Among all 253 sessions, there were no safety events associated with a femoral catheter for a 0% event rate, with an overall 95% upper confidence limit of 1.4% (upper confidence limit of 2.1% for femoral venous catheters alone and higher for the less frequently used arterial and dialysis types of catheters).

Recent clinical trials have demonstrated that physical rehabilitation is safe, feasible, and beneficial for improving physical function and quality of life in ICU survivors [8,11,13]. Critically ill patients commonly require central venous and arterial vascular access for a variety of reasons, including fluid resuscitation, administration of vasoactive medications, hemodynamic monitoring, and hemodialysis [25]. Femoral vascular access is a perceived barrier in providing rehabilitation therapy for ICU patients due to concerns that patient movement and site manipulation could lead to catheter, vascular, or other complications [15,20,23,26].

In healthy subjects participating in various laboratory and clinical studies, the use of femoral catheters appears safe. For instance, Dreyer et al [27] reported no major complications in 11 healthy research participants with arterial and venous femoral catheters who performed 10 sets of 10 repetitions of leg extension on a Cybex machine over 60 minutes. In addition, multiple studies, conducted outside the ICU setting, reported safe and reliable long-term femoral hemodialysis access with low rate of adverse events. For example, Gerasimovska et al [28] reported that use of dual-lumen, polyurethane, noncuffed hemodialysis catheters (Gambro GAM CATH) in ambulatory end-stage renal disease patients, for a mean duration of 39 days, occurred without major complications. A similar safety report was presented by Sombolos et al [29] in 37 patients with 57 femoral dialysis catheters and a mean catheter duration of 37 days. Of those 37 patients, 30 (81%) were ambulatory from the time of insertion with no major adverse events related to physical activities. In addition, Highstead et al [24] reviewed studies conducted over a 10-year period to evaluate the records of 161 healthy participants who underwent resistance or treadmill exercises with simultaneous unilateral femoral arterial and venous catheters in situ. No major adverse events (including vascular insufficiency and bleeding) were reported among the 346 femoral arterial and venous catheters reviewed in the study. However, 11.8% of femoral catheters had to be repositioned or rethreaded due to difficulty in blood draw or displacement during exercise. This increased rate of femoral catheter displacement, compared with results in our report, may be due to the higher level of physical activity conducted in the healthy research participants vs in our critically ill patients.

To our knowledge, the only published study evaluating the safety of rehabilitation interventions with femoral catheters in critically ill patients was performed by Perme et al [23]. In a single cardiovascular and thoracic ICU setting, the authors retrospectively reviewed the safety of femoral arterial catheters, with a mean duration of use of 7.9 days. The 30-patient cohort received a total of 47 PT treatment sessions (average [SD], 1.6 [0.9] sessions per patient) that included a total 156 activity events. All rehabilitation sessions were provided by a single physical therapist throughout the entire evaluation period. No femoral arterial catheter-related adverse events occurred, giving a 0% event rate per session with a calculated 95% upper confidence limit of 7.5%.

Our report evaluated all consecutive adult MICU patients admitted over a 16-month period who received PT, as part routine care, with a femoral catheter(s) in situ. The highest level of activity achieved during these PT treatment sessions was sitting and standing/walking in half of all treatment days. We found no femoral catheter-related adverse events occurred with these PT sessions. In contrast to the ICU study by Perme et al [23], our report evaluated the safety of multiple types of femoral catheters (arterial, venous, and dialysis) used in our MICU, with the majority being venous (rather than arterial) femoral catheters. In addition, our evaluation of adverse events was performed prospectively, occurred in a MICU setting, and had rehabilitation sessions performed by 9 different physical therapists.

Our report has potential limitations. First, we relied on therapists' clinical judgment for reports of adverse events and could have missed an adverse event report (eg, nonclinically important bleeding at the catheter site). However, to ensure accuracy of data collection and minimize misclassification bias, several quality assurance steps were undertaken, including: (1) physical therapists receiving training on the definitions of adverse events and the process of data collection; (2) review of each potential event by a dedicated, full-time clinical program coordinator; (3) discussion of questions regarding events at weekly rehabilitation meetings; and (4) review of a monthly program report (including all adverse event data) among all members of the critical care and rehabilitation team. Second, there were relatively few patient-days of treatment available for certain interventions (eg, supine cycle ergometry) and catheter types (eg, hemodialysis catheters) that limit the generalizability of the findings to all interventions and catheter types. However, no safety events were recorded across a wide range of interventions

and catheter types with the greatest experience (and narrowest 95% confidence interval) for femoral venous catheters.

Finally, these safety results may not be generalizable to other centers because this evaluation was conducted in a single MICU with rehabilitation therapy sessions provided by physical therapists, who received on-the-job training in providing interventions to ICU patients. We believe that ICU competency training is important for rehabilitation clinicians to develop appropriate clinical judgment for evaluating, on a daily basis, the relative risks and benefits of providing rehabilitation therapy for critically ill patients. This limitation is common to prior research publications of ICU rehabilitation, which have used trained ICU rehabilitation clinicians [8-13]. However, generalizability of our findings is aided by the data being collected as part of routine care, rather than as part of a research protocol that typically includes only highly selected patients and may provide additional resources for delivering research sessions. Additional prospective studies are important to further help understand the generalizability of these results in other centers, other types of ICUs, and across all types of catheters and rehabilitation interventions.

5. Conclusion

We prospectively evaluated the feasibility and safety of physical rehabilitation interventions in adult MICU patients with in situ femoral catheters. Among 101 consecutive MICU patients, 253 PT treatment sessions were successfully performed, including standing/walking, sitting, cycle ergometry, and in-bed exercises. No adverse events were identified with the greatest number of interventions occurring with a femoral venous catheter in situ (0% event rate; 95% upper confidence limit, 2.1 %). Hence, we suggest that the presence of a femoral catheter should not automatically limit ICU patients to bed rest and preclude participation in physical rehabilitation. With careful clinical judgment regarding the relative risks and benefits, trained physical therapists can feasibly and safely provide rehabilitation interventions in ICU patients with indwelling femoral catheters.

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