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Safety of mid-thigh exit site venous catheters in multidrug resistant colonized patients

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Abstract

Introduction: Venous catheters inserted in superficial femoral vein and with mid-thigh exit site have emerged as a feasible and safe technique for central or peripheral tip's venous access, especially in agitated, delirious patients. The spread of multidrug-resistant bacterial (MDR) strains is an emerging clinical problem and more and more patients are being colonized by these types of bacteria. The aim of this study is to evaluate the incidence of central line associated bloodstream infections (CLABSI) or catheter related bloodstream infections (CRBSI) in mid-thigh catheters in patients with positive rectal swabs to evaluate the safety of this procedure and the real infection risk.

Methods: In this retrospective observational study, we analyzed data on patients with mid-tight catheters inserted from May 2021 to November 2022. All surveillance rectal swabs were recorded. In addition, to collect data on CLABSI and CRBSI, the results of all blood and catheter tip cultures performed during the hospital stay were acquired.

Results: Six hundred two patients were enrolled, 304 patients (50.5%) had a rectal swab; 128 (42.1%) swabs were positive for MDR. Nine CLABSI (only two in patients with a positive rectal swab) and three CRBSI were detected. No statistical difference in the absolute number of CLABSI and CRBSI and in the number of infections per 1000 catheter days emerged between the overall population and patients with positive rectal swabs (respectively $p = 0.45$ and $p = 0.53$). Similarly, no statistical difference in the number of CLABSI and CRBSI was found among patients with a negative swab and patients with a positive one (respectively $p = 0.43$ and $p = 0.51$).

Conclusions: According to our data, cannulation of the superficial femoral vein represents a safe location in patients with positive rectal swabs.

Keywords

Mid-thigh catheters, MDR infections, CRBSI, CLABS, rectal swab, femoral inserted central catheter (FICC), peripherally inserted central catheter (PICC), Midline

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Introduction

Historically, the use of vascular accesses in the lower limb involves the puncture of the common femoral vein with groin exit site. Recently ultrasound guided puncture and cannulation of the superficial femoral vein has emerged as a feasible and safe technique of central and peripherical venous access, especially in agitated, delirious patients and in bedridden patients with severe physical disabilities.[1,2]

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At the state of the art, it is known that the rate of infectious complications in the case of femoral inserted central catheters (FICCs) is 1.2%.[3] This value can be decreased by moving the exit site away from the groin, which is the region with the greatest bacterial colonization.[4]

In the superficial femoral vein approach, the exit site is located at least 10 cm away from the groin region, allowing a reduction of the risk of complications, such as infections[5] owed to the high bacterial contamination of the groin region.[4] This is even more true in bedridden patients, where intimate hygiene maneuvers are performed in bed.

The spread of multidrug-resistant bacterial (MDR) strains is an emerging clinical problem. These bacteria are frequently responsible for nosocomial infections, and they can colonize human skin, respiratory tract, and digestive tract, behaving as opportunistic pathogens in at-risk individuals. Diffusion of MDRs is associated with an increase in morbidity and mortality.[6]

Many centers have proposed surveillance protocols, often using rectal swabs, to early recognize MDR enteric colonization and to introduce a proper infection control program. Skin and rectal microorganisms may contribute to the development of vascular access device infections, in particular central line associated bloodstream infections (CLABSI) or catheter related bloodstream infections (CRBSI).

The literature is unanimous in describing an increased infectious risk in patients with skin colonization and a vascular access.[4,7] On the other hand, to the best of our knowledge, there are no studies evaluating the infectious risk of mid-thigh catheters in patients with bacterial skin colonization. This could be of particular interest because the patients who usually require a mid-thigh venous catheter insertion are often the same ones who are at higher risk of skin colonization (advanced age, bedridden, delirium, frequent hospitalization, dementia).

The aim of this study is to evaluate the rate of catheter-related infections of mid-thigh catheters in patients with positive rectal swabs to evaluate the safety of this procedure and the real infection risk.

Material and methods

In this retrospective observational study, we analyzed data on catheters with a mid-thigh exit site inserted from 1st May 2021 to 30th November 2022 (18 months) at L. Sacco Hospital, Milan, in non-intensive clinical wards. The inclusion criteria were:

- Inpatients that required a venous catheter because of difficult intravenous access (DIVA) or an expected need for intravenous therapy longer than 6 days.

Mid-thigh exit site is usually considered in bedridden patients, with psychomotor agitation or delirium, uncooperative with invasive maneuvers where the cervical and thorax site is avoided for high risk of pneumothorax during the insertion or with unsuitable arm veins.

The exclusion criteria were:

- Patients in the Intensive Care Unit
- Extensive sacral pressure sores grade III or IV based on European Pressure Ulcer Advisory Panel guidelines[8]
- Bilateral open heel ulcers

The last two exclusion criteria were in accord to our hospital indications for the insertion of vascular access that don't recommend the use of mid-thighs in patients with these kind of skin problems due to the high infectious risk.

All catheters were implanted by the local vascular access team composed of trained physicians and nurses.

When a peripheral tip's catheter was needed, a non-pressure injectable polyurethane non-valved catheter was used (Arrow®, Teleflex; 20 cm of length; 4 Fr single lumen and 7 Fr dual lumen). In this case a direct Seldinger technique through tissue dilator before catheter on wire implantation was used. When a central tip's catheter was needed, a pressure injectable polyurethane non valved PICC was inserted (Deltamed; 55 cm length; 4 Fr single lumen and 5 Fr dual lumen). The insertion of PICCs was performed using indirect Seldinger technique.

The devices have been positioned following a standardized bundle, recommended by our hospital policies. Our insertion bundle for mid-thigh placement follows the latest evidence from the literature[1] and it includes:

- Pre-procedural systematic evaluation of groin and thigh's veins using the RaFeVA protocol (Rapid Femoral Vein Assessment)[9]
- Local anesthesia with subcutaneous Lidocaine 2%
- Ultrasound-guided puncture and cannulation of the vein
- Ultrasound-based tip navigation and tip location through direct vision of the tip for all peripheral catheters. Bubble test with direct vision of the catheter's tip[10] or bubble time less than 1 s was performed for all central catheters.[11]
- Stabilization of the exit site with sutureless devices as StatLock® (BD Franklin Lake, NJ, USA) for all the peripheral tip catheters or subcutaneous anchor device SecurAcath™ (Interrad Medical, Inc) for all the PICC lines.
- Protection of the exit site with semipermeable transparent membrane with chlorhexidine gel (3 M™

Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing). The dressing was changed at least every 7 days or immediately if its integrity was disrupted.

All the procedures were performed with an aseptic technique.

All surveillance rectal swabs performed as part of the local surveillance protocol (previous hospital recovery in the last 90 days, institutionalized patients, previous positive rectal swab in the last 12 months) were recorded. In addition, to collect data on CLABSI and CRBSI, the results of all blood and catheter tip cultures performed during the hospital stay were recorded. Specifically, CLABSI has been diagnosed in cases of bloodstream infection that develops within 48 h of catheter placement. In contrast, the diagnostic criteria for CRBSI were the detection of a positive culture at the catheter tip or a differential time to positivity of at least 2 h between the catheter and a peripheral blood culture. In this study the term CRBSI was used for both central and peripheral tip lines.

The study protocol complied with the Declaration of Helsinki and the Institutional Review Board of our University Hospital (Luigi Sacco Hospital, University of Milan, Italy) approved the study protocol.

In a previous clinical study, the prevalence of CRBSI was 2.5/1000 catheter days[2] in a Covid-19 cohort. In the sample size calculation, we consider a non-Inferiority or superiority significant difference between patients with a positive rectal swab and patients with a negative one in terms of sensitivity ($\alpha = 0.05$, power = 90%). We calculated a sample size of at least 3241 catheter days with a number of expected CRBSI in patients with a positive swab of 5/1000 versus 1/1000 in patients with a negative swab; we used a non-inferiority or superiority margin of 10% and a sampling Ratio of 1.

Data were expressed as mean and standard deviation (normally distributed data), median and interquartile range (non-normally distributed data) or as absolute frequency and percentage (binary or ordinal data), as appropriate. Chi-square or Fisher exact tests were used in the group's comparison. Student *t*-test and Mann-Whitney test (for non-parametric data) were used for comparisons between groups. *p*-Value less than 0.05 was considered statistically significant.

The statistical analysis of the data was carried out with Excel (Office program 2016) and SPSS (statistical package for social science-SPSS, Inc., Chicago, IL version 20).

Results

We enrolled a total of 602 patients; the median age was 83 (74–88) and 47% were males, clinical characteristics of the enrolled population are represented in Table 1. The catheters implanted were mid-thigh single-lumen (82.1%) or bi-lumen (17.9%). One hundred sixteen patients had a PICC (19.4%), while 486 (80.6%) had a Midline with the tip in the femoral veins.

Three hundred four patients (50.5%) had a rectal swab; 176 (57.9%) swabs were negative and 128 (42.1%) were positive (Table 1).

The death rate of the population included in the study was 29%.

Five different MDR strains were detected: 34 Escherichia coli ESBL+ (E. coli ESBL+) (26.6%); 37 Klebsiella pneumoniae KPC+ (K. pneumoniae KPC+) (28.1%); 38 Vancomycin-resistant Enterococci (VRE) (28.9%); 6 Multidrug Resistant Pseudomonas aeruginosa (MDR-PA) (4.7%); 1 Methicillin Resistant Staphylococcus aureus (MRSA) (0.8%); 2 double colonization by E. coli and K. pneumoniae ESBL+ (1.5%); 2 double colonization by Acinetobacter and E. coli ESBL+ (1.5%), 1 by E. coli MDR-PA and Acinetobacter (0.8%) and 1 by VRE and Acinetobacter (0.8%) (Table 2).

The median catheter dwell time was 7 days in the whole population, 6 days in patients without a rectal swab, and 9 days in patients with a rectal swab.

Concerning infections, nine CLABSI (only two in patients with a positive rectal swab) and three CRBSI were detected. Among them, four were observed in patients with a central line while five in patients with a peripheral line (Table 3).

In the general population, total catheter days were 6502, resulting in a catheter-related infection rate of 0.46 per 1000 catheter days. Among patients with a positive rectal swab, the CRBSI rate was 0.6 per 1000 catheter days.

The total number of catheter days in patients with a rectal swab was 3687, which was higher than the sample size calculation, so we could compare the subgroups.

No statistical difference in the absolute number of CLABSI and CRBSI emerged between the overall population and patients with positive rectal swabs (respectively $p = 0.45$ and $p = 0.53$). Similarly, no statistical difference in the number of CLABSI and CRBSI was found among patients with a negative swab and patients with a positive one (respectively $p = 0.43$ and $p = 0.51$).

The result was confirmed by comparing 1000 days CRBSI rate between the overall population and patients with a positive rectal swab ($p = 0.21$) or among patients with a negative swab and patients with a positive one ($p = 0.34$).

Patients with double-lumen catheters had a higher incidence of infection than those with single-lumen catheters (0.9% vs 0.4%).

In addition, the number of infections in SARS-CoV-2 positive patients was higher than in the general population (Table 3).

Discussion

The use of mid-thigh catheters is becoming increasingly common in hospitals, particularly in bedridden patients

Table 1. Study population and complications of the mid-thighs insertion.

	Whole population	Not performed rectal swab patients	Negative rectal swab	Positive rectal swab
Number of catheters	602	298	176	128
Age	83 (74–88)	83 (73–88)	83 (74–88)	82.5 (75–88)
Male sex	283 (47%)	147 (49.3%)	78 (44.3%)	58 (43.3%)
COVID-19 patients	208 (34.6%)	112 (37.6%)	70 (39.8%)	26 (20.3%)
Clinical characteristics				
Cancer	101 (16.8%)	50 (16.8%)	28 (15.9%)	23 (17.9%)
Recent surgery	23 (3.8%)	19 (6.7%)	2 (0.8%)	1 (0.8%)
Dementia	88 (14.6%)	38 (12.8%)	25 (14.2%)	25 (19.5%)
Heart failure	246 (40.9%)	120 (40.2%)	65 (36.9%)	61 (47.7%)
Renal failure	147 (24.4%)	60 (20.1%)	35 (19.9%)	42 32.8%)
Obesity	46 (7.6%)	25 (8.4%)	12 (6.8%)	9 (7%)
Liver disease	48 (8%)	22 (7.4%)	14 (8%)	12 (9.3%)
Inflammatory bowel disease	13 (2.2%)	8 (2.7%)	3 (1.7%)	2 (1.6%)
Reason for insertion				
DIVA patients	545 (90.5%)	269 (90.3%)	157 (89.2%)	118 (93%)
Parenteral nutrition	57 (9.5%)	29 (9.7%)	19 (10.8%)	9 (7%)
Type of catheter				
PICC lines	116 (19.4%)	51 (17.1%)	33 (13.1%)	32 (25%)
MIDLINE lines	486 (80.6%)	247 (82.9%)	143 (86.9%)	96 (75%)
Lumens				
One lumen catheters	494 (82.1%)	247 (83%)	141 (80%)	106 (83%)
Dual lumen catheters	108 (17.9%)	51 (17%)	35 (20%)	22 (17%)
Reasons for removal				
End of therapy	187 (31.2%)	84 (28.2%)	68 (38.7%)	36 (28.1%)
Occlusion	22 (3.7%)	11 (3.8%)	6 (3.7%)	5 (3.9%)
Accidental removals	217 (36.1%)	120 (40.2%)	50 (28.7%)	47 (36.5%)
Death	175 (29%)	83 (27.8%)	52 (29.9%)	40 (31.5%)
Complications				
Thrombosis	2 (0.3%)	2 (0.6%)	0	0
CLABSI	9 (1.5%)	2 (0.7%)	4 (2.3%)	3 (2.3%)
CRBSI	3 (0.5%)	1 (0.33%)	1 (0.57%)	1 (0.78%)
Total days of observation	6502	2715	2026	1661
Catheter dwell time (days)	7 (3–14)	6 (3–12)	9 (4.5–17)	9 (3–17.5)
CRBSI rate (events/1000 catheters days)	0.46	0.37	0.49	0.6

DIVA: difficult intravenous access; CLABSI: central line associated bloodstream infections; CRBSI: catheter related bloodstream infections.

Table 2. Characteristics of the rectal swabs: distribution and pathogens.

	Whole population	PICC	MIDLINE
Rectal swab performed	304 (50.5%)	65 (56%)	239 (49.2%)
Negative	176 (57.9%)	33 (50.7%)	143 (59.8%)
Positive	128 (42.1%)	32 (49.3%)	96 (40.2%)
E. coli ESBL+	34 (26.6%)	8 (25%)	26 (27%)
K. Pneumoniae KPC+	37 (28.1%)	8 (25%)	29 (30%)
MRSA	1 (0.8%)	0	1 (1%)
P. aeruginosa MDR	6 (4.7%)	2 (6%)	4 (4%)
VRE	38 (28.9%)	10 (31%)	28 (29%)
E.coli ESBL+ K. pneumoniae KPC+	7 (5.5%)	2 (6%)	5 (5%)
E.coli ESBL+ Acinetobacter	2 (1.6%)	1 (2.5%)	1 (1%)
P. aeruginosa MDR + VRE	2 (1.6%)	1 (2.5%)	1 (1%)
VRE + Acinetobacter	1 (0.8%)	0	1 (1%)
Rectal swab not performed	298 (49.5%)	51 (46%)	247 (50.8%)

E. coli: Escherichia coli; K. pneumoniae: Klebsiella pneumoniae; P. aeruginosa: Peudomonas aeriginosa; ESBL: extended spectrum beta lactamanse; KPC: Klebsiella pneumoniae carbapenemase producing; MRSA: Methicillin resistan Staphylococcus aureus; MDR: multi drug resistent; VRE: Vancomycin resistant Enterococci.

Table 3. Characteristics of the patients with CLABSI or CRBSI.

		Sex	Age	Covid	Catheters	No. of lumens	Dwell times (days)	Rectal swab	Catheter tips culture	Blood culture
CLABSI	1	Female	90	Covid19	MIDLINE	1	19	Not performed	Negative	Not performed for PWO
	2	Female	60	Covid19	MIDLINE	1	6	K. Pneumoniae KPC+	Not performed	Negative for DTI
	3	Female	91	Negative	MIDLINE	2	17	Negative	Negative	Not performed for PWO
	4	Female	81	Negative	MIDLINE	1	25	VRE + Acinetobacter	Not performed	Negative for DTI
	5	Female	84	Negative	PICC	1	22	Negative	Not performed	Negative for DTI
	6	Male	67	Negative	PICC	1	10	Negative	Negative	Not performed for PWO
CRBSI	7	Male	79	Negative	MIDLINE	2	21	VRE	VRE	VRE
	8	Male	63	Negative	PICC	1	28	Not performed	E. faecium	E. faecium
	9	Male	50	Covid19	PICC	1	8	Negative	Not performed	Candida

K. pneumoniae: Klebsiella pneumoniae; KPC: Klebsiella pneumoniae carbapenemase producing; VRE: Vancomycin resistant Enterococci; E. faecium: Enterococcus faecium ; PWO: persistent whitdrawal occlusion; DTP: Differential Time to Positivity.

with psychomotor agitation, delirium, and dementia. These patients are, among others, those at greater risk of bacterial skin colonization: indeed, many of them live in nursing homes, have had several hospital stays and perform bed hygiene when bedridden. In addition, the mid-thigh is an easier implantation solution than other exit site in cases of prolonged bedridden status and dementia with initial ankylosis and assumption of a fetal position.

In our study, we recorded a mortality rate during hospitalization of 29%. The high rate observed in our study, is probably due to the high frailty of the population considered: they are old, with a high rate of bedridden status, dementia, and severe physical disabilities. All these characteristics are negative prognostic factors that lead to a higher mortality rate.

According to our data, the presence of MDR rectal colonization should not preclude the insertion of mid-thigh venous catheters. In fact, the observed infection rate in the two groups (patients with and without rectal positive swab) was comparable and no statistically significant differences were recorded. It should be noted, however, that none of the patients in our study had extensive sacral pressure sores or open heel ulcers. Indeed, it is known that the presence of a break in continuity in the skin tissue increases the overall risk of infection, especially in bedridden patients with pressure ulcers.[12]

The rate of catheter-related infections observed in our study proved to be very low at 0.5%. When this figure is compared to the literature, it appears that the catheter insertion site in the mid-thigh is preferable to the insertion site in the common femoral vein. Indeed, the CRBSI rate for FICCs in the common femoral vein ranges from 1.2%[3] to 1.49%.[13,14]

The lower incidence of infections in case of mid-thigh catheters is because the mid-thigh insertion site is at least 10 cm from the groin, a region with very high bacterial contamination.

This is of particular interest because the occurrence of catheter-related infections increases not only mortality but also morbidity. For example, Rello et al.[15] found that patients who developed a CRBSI episode had a 19.6 day increase in hospital stay.

However, it should be noted that most studies investigating the incidence of infectious events in central venous catheters have been conducted in intensive care units, while there is a lack of studies conducted in low- or moderate-intensity wards, such as those where our study was conducted.

Patients with double-lumen catheters are found to have a higher incidence of infection than those with single-lumen catheters (0.9% vs 0.4%). This is consistent with the literature showing an increased risk of infection with increasing catheter lumens.[16,17] However, the number of infections observed in our sample is so small that it does not result in a statistically significant difference.

Previous studies found that a longer total catheter dwell time increased the risk of infection.[18,19]

Also in our study, the average length of stay of the catheter was significantly higher in patients with infections (CLABSI or CRBSI) than in the general population. Indeed, the dwell time for patients with infections was 17.3 days, compared to 7 days for the rest of the population.

The number of infections in SARS-CoV-2 positive patients was higher than in the general population. This is consistent with many studies describing an increased risk of catheter-associated and catheter-related infections in Covid positive patients.[20,21] Again, the sample size was very small (only three infections in Covid patients), so statistical significance of the data cannot be achieved.

Finally, mid-thighs have, on average, a lower risk of infection than FICCs in common femoral veins, but true reduction/abatement of the infectious risk can only be achieved through an appropriate implantation and management protocol. Indeed, in patients at higher risk of infection, such as those with bacterial colonization, a correct choice of puncture site, a standardized implantation procedure and good daily management of the catheter and its medication are undoubtedly the factors that make the difference in reducing the risk of infection.

The study has several limitations: firstly, it is a monocentric study with a limited sample size. Further studies are needed to confirm these data. Secondly, the number of central catheters with an inferior vena cava tip was lower than peripheral tips catheters. Furthermore, the data comparing the risk of infection of mid-thigh catheters and FICCs in the common femoral vein are from the literature, whereas a randomized controlled trial comparing the two methods would certainly lead to more robust data. Finally, skin colonization data were only collected from patients at highest risk of MDR according to hospital infectious surveillance protocols.

Conclusions

The number of CLABSI and CRBSI was very low, and it wasn't significantly higher in patients with a positive rectal swab. Although to be confirmed by further studies, the results of our study suggest that mid-thigh catheter placement is safe even in patients with a MDR positive rectal swab.

Declaration of conflicting interests

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Ethical approval

All the data were anonymized. The Institutional Review Board of our University Hospital (Luigi Sacco Hospital, University of Milan, Italy) approved the study protocol. The study was carried out in compliance with the ethical principles of the Declaration of Helsinki (with amendments) and Good Clinical Practice.

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