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ORIGINAL ARTICLE

Impact of the failure of initial insertion of a peripheral intravascular catheter on the development of adverse events in patients admitted to the intensive care unit from the emergency room: A post hoc analysis of the AMOR-VENUS study

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Abstract

Aim: To investigate an association between failure of initial peripheral intravascular catheter (PIVC) insertion and adverse events in patients admitted to the intensive care unit (ICU) from the emergency room (ER).

Methods: This study was a post hoc analysis of the AMOR-VENUS study, a multicenter cohort study that included 22 institutions and 23 ICUs in Japan between January and March of 2018. Study participants included consecutive adult patients admitted to the ICU with PIVCs inserted in ICU during the study period exclusively from the ER. The primary outcome was adverse events. Adverse events were composite of arterial puncture, hematoma, extravasation, nerve injury, tendon injury, compartment syndrome, pain, redness, bad location, and effusion. Multivariate logistic regression analyses were performed to assess the association between adverse events and the failure of initial PIVC insertion.

Results: In total, 363 patients and 1121 PIVCs were analyzed. Moreover, 199 catheters failed to insert properly, and 36 patients and 107 catheters experienced adverse events. After performing multivariate logistic regression analysis, there were statistically significant associations in the odds ratio (OR) and 95% confidence interval (CI) for the failure of initial insertion (OR, 1.66 [1.02–2.71]; $p = 0.04$).

Conclusion: Failure of initial insertion may be a risk factor for adverse events. We could potentially provide various interventions to avoid failure of initial PIVC insertion. For example, PIVC insertion could be performed by experienced practitioners.

KEYWORDS
catheters, critical illness, equipment failure, intensive care units, risk factors

INTRODUCTION

Peripheral intravascular catheters (PIVCs) insertions are commonly inserted in emergency rooms (ERs) and intensive care units (ICUs). The adverse events associated with PIVC insertion include hematoma, arterial puncture, superficial venous thrombosis, necrosis associated with drug leakage, and so forth.[1,2] Although not severe, complications can occur in 1% to 10% of catheter insertions and can significantly impact patient treatment because of the large number of PIVC insertions.[3,4]

In previous studies, two or more PIVC insertions require added staff resources, causing increased patient discomfort and decreasing patient satisfaction.[5–7] Furthermore, failure of initial insertion may increase the likelihood of future failure and risk of complications in central venous catheter (CVC) insertions.[8] Although this study was for CVC, its findings could be extended to PIVC because CVC and PIVC are identical in terms of catheter insertion.

A Japanese study found that PIVC insertion in patients admitted from the ER accounted for ~40% of all PIVC insertions during ICU stays.[9] This means that patients admitted to the ICU from the ER are likely to have more PIVC insertions during the ICU stay than other patient groups.[9]

Failure of the initial insertion may be associated with adverse events in PIVC insertion, and studies in patients admitted to the ICU from the ER may benefit both patient comfort and the medical economy. However, no previous studies have investigated the association between failure of initial PIVC insertion and adverse events. This study aimed to investigate the association between failure of initial PIVC insertion and adverse events in patients admitted to the ICU from the ER.

MATERIALS AND METHODS

Study design

This study was a post hoc analysis of the AMOR-VENUS database from a previous multicenter cohort study involving 22 institutions and 23 ICUs in Japan between January and March of 2018.[9] The AMOR-VENUS study was registered in the Medical Information Network Clinical Trials Registry of the University Hospital under the Japanese Clinical Trial Registry (registration number: UMIN000028019) and was approved by each institution. A new ethical review for our study was waived because our study was a post hoc analysis. Our study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines[10] (Table S1).

Patients

The inclusion criteria for patients in the AMOR-VENUS study were as follows: (1) ≥18 years of age and (2) consecutive patients admitted to the ICU with PIVC inserted during ICU admission during the study period, with details described in the AMOR-VENUS study.[9] The exclusion criteria for patients in our study were as follows: (1) patients admitted to the ICU from other than the ER and (2) data missing in the failure of initial insertion. In contrast, exclusion criteria for PIVCs were as follows: (1) PIVCs inserted outside the ICU and (2) use of unclassifiable catheter material, because estimating the effect of materials for adverse events is problematic in the case of mixed materials. Furthermore, PIVC inserted in the ER were excluded from our study because data in the ER, such as medical staff inserting the catheter, results of initial insertion, number of punctures until insertion success, and administered drugs, were not collected in the AMOR-VENUS study.

Data collection

The following data were collected: patient characteristics (age, sex, height, weight, body mass index [BMI], Charlson comorbidity index, Acute Physiology and Chronic Health Evaluation [APACHE] II score,[11] ICU admission category, presence of sepsis at ICU admission and mechanical ventilation[12]), provision of standardized drug administration measures, features of PIVC (medical personnel inserting the catheter, insertion site, catheter materials, catheter size, number of insertion trials, and duration of catheter dwell), administered drugs (albumin, amiodarone, dobutamine, fat emulsion, fentanyl, heparin, magnesium, meropenem, midazolam, nicardipine, nitroglycerin, noradrenaline, potassium, and vancomycin), ICU mortality, and adverse events. The APACHE II score was calculated using the worst value after 24 h of hospitalization.

The data collection was unmasked, as the physicians in charge of this investigation collected the data individually, and the outcome assessors were unblinded.

Study outcomes

The primary outcome was adverse events. Adverse events were a composite of arterial puncture, hematoma, extravasation, nerve injury, tendon injury, compartment syndrome, pain, redness, bad location, and effusion.

Statistical methods

Continuous variables are presented as mean and standard deviations (SD) or median and interquartile range (IQR) and analyzed using the *t*-test or the Mann–Whitney *U* test. Categorical variables are presented as absolute counts and percentages (%) and analyzed using Fisher's exact test or Pearson χ^2 test.

To adjust covariates, univariate and multivariate logistic regression analyses were performed. In these logistic regression analyses, adverse events were treated as the response variable and with reference to a previous study,[11] the following presumed covariates for adverse events were extracted: age, BMI, APACHE II score, medical personnel inserting a catheter, insertion site, catheter materials, failure of initial insertion, and administered drugs (amiodarone, fat emulsion, nicardipine, noradrenaline, potassium, and vancomycin). The cutoff value of the APACHE II score was established as follows with reference to a previous study: ≤15, 16–25, and ≥26.[13] Furthermore, the cutoff value of the BMI was established as follows

with reference to the World Health Organization classification: ≤18.5, 18.5–25, and ≥25.[14] The insertion site was categorized into two categories based on the mobility of the insertion site because mobility is considered to play a significant role in the occurrence of adverse events. For example, the wrist and elbow are determined to be mobile. The catheter material was categorized as polyurethane or other because polyurethane is the most used material in a previous study in Japan.[13] The drugs were treated as binary data and selected with the following criteria: (1) administered at a percentage more frequently than 5% of all PIVCs, (2) *p*-values for phlebitis in a previous study were <0.1, and (3) clinical significance.[11] We did not use imputation for missing data and performed logistic regression analyses using only complete cases.

Effect estimates were described using odds ratios (OR) and 95% confidence intervals (CI). All statistical analyses were performed with EZR version 1.38 (Saitama Medical Center, Jichi Medical University), which is a graphical user interface for R (The R Foundation for Statistical Computing). A statistical significance was established at $p < 0.05$.

RESULTS

PIVCs were inserted in 1359 patients, and 3429 were inserted in the ICU (Figure 1). In total, 835 patients and 2060 PIVCs were excluded from this post-hoc analysis. Finally, 363 patients and 1121 PIVCs were analyzed, and 36 patients (10.0%) and 107 catheters (9.6%) experienced adverse events.

Patient characteristics

Overall, the mean age (SD) was 69.7 (15.5) years; 235 patients (64.8%) were men, 138 (38.0%) were admitted to the ICU for cardiogenic disease, and 43 (11.9%) died in the hospital. There was one (0.3%) missing data for body height, body weight, and BMI, 22 (6.1%) for the APACHE II score, and four (1.1%) for admission to the ICU (Table 1).

PIVC characteristics

Overall, 1118 catheters (99.7%) were inserted with the provision of standardized drug administration measures, 1027 (91.6%) were inserted by the nurse, 601 (53.6%) were inserted in the forearm, and 555 of the catheter materials (49.5%) were tetrafluoroethylene. The failure of initial insertion occurred in 199 catheters (17.8%), the median days from ICU admission to catheter insertion (IQR) was 8 days,[4–13] and the median duration of catheter dwelling (IQR) was 45.9 h (21.8–74.2). There was one missing data (0.1%) for the variable in the catheter inserting medical personnel, 15 (1.3%) for the catheter size, and 7 (0.6%) for the duration of catheter dwell (Table 2). In addition, the details of adverse events are shown in Table S2.

Administered drug characteristics

Amiodarone, a fat emulsion, nicardipine, noradrenaline, potassium, and vancomycin were administered in 23 (2.1%), 102 (9.1%), 72 (6.4%), 38 (3.4%), 49 (4.4%), and 38 (3.4%) catheters, respectively (Table 3). There were no missing data.

Association between the failure of initial PIVC insertion and adverse events

A statistically significant association in OR (95% CI) in failure of initial insertion was found in multivariate logistic

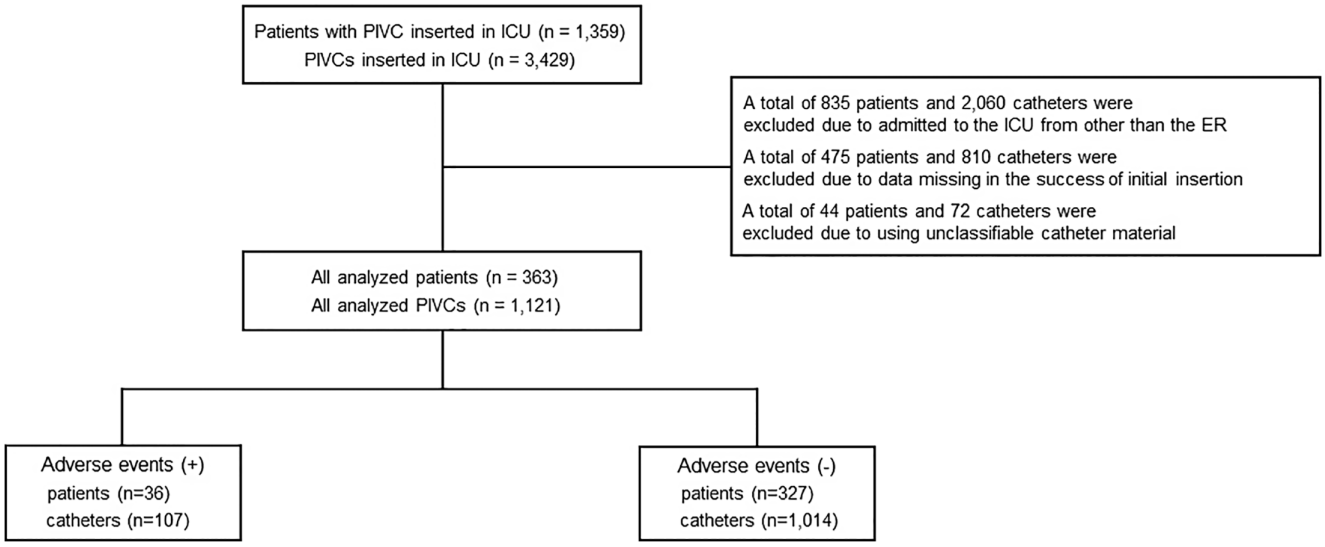

FIGURE 1 Flowchart depicting the screening and enrolment process within the study. ER, emergency room; ICU, intensive care unit; PIVC, peripheral intravascular catheter.

TABLE 1 Patient characteristics at ICU admission.

Variables	Overall $n=363$	Adverse events (+) $n=36$	Adverse events (–) $n=327$	p Value
Age, mean (SD), years	69.7 (15.5)	74.8 (10.9)	69.1 (15.8)	0.04
Men (n, %)	235 (64.8)	23 (63.9)	212 (64.8)	1.0
Body height[a], mean (SD), cm	160.8 (9.3)	159.8 (9.0)	160.9 (9.3)	0.49
Body weight[b], mean (SD), kg	60.2 (15.0)	57.2 (12.9)	60.6 (15.2)	0.2
BMI[b], mean (SD)	23.1 (4.7)	22.2 (3.7)	23.2 (4.7)	0.21
APACHE II score[c], mean (SD)	19.9 (8.2)	21.4 (7.9)	19.7 (8.2)	0.25
Charlson Comorbidity Index, mean (SD)	4.3 (2.7)	4.7 (2.1)	4.2 (2.8)	0.28
ICU admission category[d] (n, %)				
Cardiology	138 (38.0)	9 (25.0)	129 (39.4)	<0.01
Pulmonary	53 (14.6)	10 (27.8)	43 (13.1)	<0.01
Gastrointestinal	18 (5.0)	3 (8.3)	15 (4.6)	<0.01
Neurology	56 (15.4)	8 (22.2)	48 (14.7)	<0.01
Trauma	25 (6.9)	1 (2.8)	24 (7.3)	<0.01
Urology	0 (0)	0 (0)	0 (0)	–
Gynecology	0 (0)	0 (0)	0 (0)	–
Skin/tissue	6 (1.7)	0 (0)	6 (1.8)	–
Others	14 (3.9)	1 (2.8)	13 (4.0)	<0.01
Sepsis at ICU admission (n, %)				
Sepsis	38 (10.5)	7 (19.4)	31 (9.5)	<0.01
Septic shock	33 (9.1)	6 (16.7)	27 (8.3)	<0.01
Hospital mortality (n, %)	43 (11.9)	6 (16.7)	30 (9.2)	0.5

Note: Missing data: [a] $n=1$ (0.3%); [b] $n=1$ (0.3%); [c] $n=22$ (6.1%); [d] $n=4$ (1.1%).

Abbreviations: –, Value cannot be calculated; APACHE, Acute Physiology and Chronic Health Evaluation; BMI, body mass index; ICU, intensive care unit; PIVC, peripheral intravascular catheter; SD, standard deviation.

regression analysis (OR, 1.66 [1.02–2.71]; $p=0.04$) (Table 4). Other results are described in Table S3.

DISCUSSION

This study analyzed 363 patients and 1121 inserted PIVCs, with 36 patients (10.0%) and 107 PIVCs (9.6%) experiencing adverse events. After multivariate logistic regression analysis, there was a statistically significant association between the failure of initial PIVC insertion and adverse events.

There are several interpretations for the results of our study. When inserting PIVCs, peripheral veins in the upper arm, cubital fossa, and forearm are close to arteries, nerves, and tendons. As such, complications of PIVC insertion include accidental arterial puncture, hematoma, extravasation, nerve injury, tendon injury, compartment syndrome, and effusion.[15,16] To explain the mechanism of these adverse events, it is useful to classify insertion failure into two patterns: (1) "If the needle hits a vein," and (2) "If the needle does not hit a vein." In instances where the needle hits a vein, insertions damage the vascular endothelium, and multiple insertion failures increase damage to the vascular endothelium, which increases vascular permeability.[17] A previous study reported that increased vascular permeability associated with inflammatory response reduces the vascular endothelial barrier function.[18] Therefore, insertion failures might reduce the barrier function of the vascular endothelium and lead to increased extravasation and effusion. In addition, extravasation from the peripheral vein could cause a hematoma in PIVC insertion and extravasation or hematoma could cause compartment syndrome in severe cases. If the needle does not hit a vein, the needle might injure surrounding structures near the veins such as arteries, nerves, and tendons. Therefore, in PIVC insertion, accidental arterial puncture, nerve injury, and tendon injury could occur.[15,16] Additionally, accidental arterial puncture could cause compartment syndrome in severe cases. These mechanisms of adverse event occurrence in PIVC insertion may explain the results of our study where PIVC showed a statistically significant correlation between failure of initial insertion and adverse events.

We investigated the association between failure of initial PIVC insertion and adverse events. In previous studies, risk factors associated with PIVCs insertion failure can be

TABLE 2 All PIVC characteristics during insertion.

Variables	Overall $n = 1121$	Adverse events (+) $n = 107$	Adverse events (–) $n = 1014$	p Value
Provision of standardized drug administration measures in the ICU (n, %)	1118 (99.7)	107 (100)	1011 (99.7)	1.0
Medical staff inserting the catheter[a] (n, %)				
Doctor	92 (8.2)	8 (7.5)	84 (8.3)	<0.01
Nurse	1027 (91.6)	99 (92.5)	928 (91.5)	<0.01
Medical technologist	1 (0.1)	0 (0)	1 (0.1)	–
Insertion site (n, %)				
Forearm	601 (53.6)	55 (51.4)	546 (53.8)	<0.01
Upper arm	167 (14.9)	20 (18.7)	147 (14.5)	<0.01
Elbow	45 (4.0)	4 (3.7)	41 (4.0)	<0.01
Wrist	44 (3.9)	9 (8.4)	35 (3.5)	<0.01
Hand	117 (10.4)	9 (8.4)	108 (10.7)	<0.01
Lower leg	91 (8.1)	6 (5.6)	85 (8.4)	<0.01
Dorsal foot	49 (4.4)	3 (2.8)	46 (4.5)	<0.01
Catheter material (n, %)				
PEU-Vialon	237 (21.1)	18 (16.8)	219 (21.6)	<0.01
Polyethylene	329 (29.4)	36 (33.6)	293 (28.9)	<0.01
Tetrafluoroethylene	555 (49.5)	53 (49.6)	502 (49.5)	<0.01
Catheter size[b] (n, %)				
14G	0 (0)	0 (0)	0 (0)	–
16G	1 (0.09)	0 (0)	1 (0.1)	–
18G	9 (0.8)	0 (0)	9 (0.9)	–
20G	246 (21.9)	12 (11.2)	234 (23.1)	<0.01
22G	839 (74.8)	93 (86.9)	746 (73.6)	<0.01
24G	11 (1.0)	2 (1.9)	9 (0.9)	0.03
Failure of initial insertion (n, %)	199 (17.8)	26 (24.2)	173 (17.1)	0.08
Days from ICU admission to catheter insertion[c] (IQR), day	8 (4–13)	7 (4–14)	8 (4–13)	0.39
Duration of catheter dwell[d], median (IQR), hour	45.9 (21.8–74.2)	45.9 (24.1–71.4)	45.8 (21.7–74.4)	0.95

Note: Missing data: [a] $n = 1$ (0.1%); [b] $n = 15$ (1.3%); [c] $n = 290$ (25.9%); [d] $n = 7$ (0.6%).

Abbreviations: –, Value cannot be calculated; ICU, intensive care unit; IQR, interquartile range; PEU-Vialon, polyurethane; PIVC, peripheral intravascular catheter; SD, standard deviation.

broadly classified into three categories: factors related to the practitioner, factors related to patients, and factors related to PIVCs.[5,19] Concerning these factors, we might offer different interventions to avoid failure of initial PIVC insertion; for example, practitioners who are particularly experienced in performing PIVC insertions may perform the insertion, or less experienced practitioners may perform insertion with echocardiographic guidance.[7]

This study presents several limitations. First, the external validity might be low because ~20% of the patients had sepsis, and the mean value of the APACHE II score was ~20, with a predicted mortality rate of 10% to 20%, which may not be considered severely ill.[11] Different results could have been obtained if patients with different characteristics such as postoperative cardiovascular surgery patients had been included. Second, the analysis results may be incorrect because of insufficient adjustment for covariates used in logistic regression analyses. The covariates were extracted using multiple criteria, considering previous studies and clinical importance. However, the criteria for drug selection and the categorization for insertion site and catheter material might have been arbitrary or inappropriate. Third, our study results might be incorrect because of missing data. In our study, a total of 810 catheters were excluded because of missing data regarding the success of initial insertion. The impact of this missing data on the results is not considered small because the number of missing data amounts to ~25% of all PIVCs. Therefore, if this missing data had not existed, the results may have been different from the results of the present study. Finally, because we considered each drug as a binary variable for multivariate logistic regression analyses,

TABLE 3 Administered drug characteristics during insertion[a].

Variables (*n*, %)	Overall *n* = 1121	Adverse events (+) *n* = 107	Adverse events (–) *n* = 1014	*p* Value
Albumin	46 (4.1)	8 (7.5)	38 (3.7)	0.11
Amiodarone	23 (2.1)	2 (1.9)	21 (2.1)	1.0
Dobutamine	25 (2.2)	2 (1.9)	23 (2.3)	1.0
Fat emulsion	102 (9.1)	19 (17.8)	83 (8.2)	<0.01
Fentanyl	159 (14.2)	21 (19.6)	138 (13.6)	0.12
Heparin	66 (5.9)	5 (4.7)	61 (6.0)	0.73
Magnesium	37 (3.3)	5 (4.7)	32 (3.2)	0.58
Meropenem	14 (1.3)	4 (3.7)	10 (1.0)	0.05
Midazolam	26 (2.3)	2 (1.9)	24 (2.4)	1.0
Nicardipine	72 (6.4)	2 (1.9)	70 (6.9)	0.07
Noradrenaline	38 (3.4)	6 (5.6)	32 (3.2)	0.29
Nitroglycerin	18 (1.6)	2 (1.9)	16 (1.6)	1.0
Potassium	49 (4.4)	5 (4.7)	44 (4.3)	1.0
Vancomycin	38 (3.4)	5 (4.7)	33 (3.3)	0.62

[a]There are no missing data.

TABLE 4 Result of logistic regression analysis for the failure of initial PIVC insertion and adverse events.

	Univariate analysis		Multivariable analysis	
	n = 1121		*n* = 1078	
	Adverse events: *n* = 107		Adverse events: *n* = 106	
Variable	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Failure of initial insertion	1.56 (0.97–2.50)	0.06	1.66 (1.02–2.71)	0.04

Abbreviations: CI, confidence interval; OR, odds ratio.

the drug risk may have been underestimated or overestimated. Specifically, drug effects are influenced by the drug dose and duration of administration; because we treated drugs as binary variables in our study, these effects are not reflected. Therefore, the results of our study may have differed if the drugs were treated with other methods.

CONCLUSION

The risk of adverse events associated with PIVC insertion may increase with initial failure. Potential interventions to avoid failure include PIVC insertion by experienced practitioners.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

All data and materials are available on reasonable request to the corresponding author.

ETHICS STATEMENT

Approval of the Research Protocol: Not applicable.
Informed Consent: Not applicable.
Registration no.: This study was not registered.
Animal Studies: Not applicable.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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