



Is Thrombus With Subcutaneous Edema Detected by Ultrasonography Related to Short Peripheral Catheter Failure?

A Prospective Observational Study

Toshiaki Takahashi, MHS, RN ● Ryoko Murayama, PhD, RN, RMW ● Makoto Oe, PhD, RN ● Gojiro Nakagami, PhD, RN ● Hidenori Tanabe, ME ● Koichi Yabunaka, PhD, RT ● Rika Arai, MS ● Chieko Komiyama, RN ● Miho Uchida, RN ● Hiromi Sanada, PhD, RN, WOCN

ABSTRACT

Short peripheral catheter (SPC) failure is an important clinical problem. The purpose of this study was to clarify the relationship between SPC failure and etiologies such as thrombus, subcutaneous edema, and catheter dislodgment using ultrasonography and to explore the risk factors associated with the etiologies. Two hundred catheters that were in use for infusion, excluding chemotherapy, were observed. Risk factors were examined by logistic regression analysis. Sixty catheters were removed as the result of SPC failure. Frequency of thrombus with subcutaneous edema in SPC failure cases was significantly greater than in those cases where therapy was completed without complications ($P < .01$). Multivariate analysis demonstrated that 2 or more insertion attempts were significantly associated with thrombus with subcutaneous edema. Results suggest that subsurface skin assessment for catheterization could prevent SPC failure.

Key words: dislodgment, infusion, short peripheral catheter, phlebitis, thrombus, ultrasonography

Author Affiliations: Department of Gerontological Nursing/Wound Care Management, Graduate School of Medicine, University of Tokyo, Tokyo, Japan (Drs Nakagami, Yabunaka, and Sanada; Mr Takahashi); Department of Advanced Nursing Technology, Graduate School of Medicine, University of Tokyo, Tokyo, Japan (Drs Murayama and Oe; Mr Tanabe and Mrs Arai); Terumo Corporation, Tokyo, Japan (Mr Tanabe and Mrs Arai); and Department of Nursing, University of Tokyo Hospital, Tokyo, Japan (Mrs Komiyama and Mrs Uchida).

Toshiaki Takahashi, MHS, RN, is a student in the Department of Gerontological Nursing/Wound Care Management in the Graduate School of Medicine of the University of Tokyo, Tokyo, Japan. **Ryoko Murayama, PhD, RN, RMW,** is a project associate professor in the Department of Advanced Nursing Technology in the Graduate School of Medicine of the University of Tokyo in Tokyo, Japan. **Makoto Oe, PhD, RN,** is a project lecturer in the Department of Advanced Nursing Technology in the Graduate School of Medicine of the University of Tokyo in Tokyo, Japan. **Gojiro Nakagami, PhD, RN,** is a project lecturer in the Department of Gerontological Nursing/Wound Care Management in the Graduate School of Medicine of the University of Tokyo, Tokyo, Japan. **Hidenori Tanabe, ME,** is a collaborative researcher in the Department of Advanced Nursing Technology in the Graduate School of Medicine of the University of Tokyo in Tokyo, Japan. He is also a research

associate at Terumo Corporation in Tokyo. **Koichi Yabunaka, PhD, RT,** is an assistant professor in the Department of Gerontological Nursing/Wound Care Management in the Graduate School of Medicine of the University of Tokyo in Tokyo, Japan. **Rika Arai, MS,** is a collaborative researcher in the Department of Advanced Nursing Technology in the Graduate School of Medicine of the University of Tokyo in Tokyo, Japan, and is a research associate at Terumo Corporation in Tokyo. **Chieko Komiyama, RN,** is a director of the nursing department at the University of Tokyo Hospital in Tokyo, Japan. **Miho Uchida, RN,** is a vice director of the nursing department at the University of Tokyo Hospital in Tokyo, Japan. **Hiromi Sanada, PhD, RN, WOCN,** is a professor in the Department of Gerontological Nursing/Wound Care Management in the Graduate School of Medicine of the University of Tokyo in Tokyo, Japan.

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Corresponding Author: Hiromi Sanada, PhD, RN, WOCN, Faculty of Medicine, Building 5-306, 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan (hsanada-tky@umin.ac.jp).

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Short peripheral catheters (SPCs) are devices commonly used for the administration of fluid and medications. A recent study reported that more than 70% of all patients in acute care hospitals use SPCs.¹ In addition, more than 30% of SPCs are reportedly removed for unplanned reasons rather than replaced when clinically indicated, which is called catheter failure.² Catheter failure is associated with the occurrence of signs and symptoms such as erythema, swelling, induration, bleeding, pain, and insufficient infusion rate.³⁻⁵ Such problems negatively affect the patient's comfort and treatment, because when catheter failure occurs it is difficult to continue fluid therapy. Catheter replacement cannot be avoided in catheter failure, and this makes patients uncomfortable. Moreover, replacing catheters because of catheter failure increases labor costs and the costs of medical resources.^{1,2} For these reasons, it's important to prevent catheter failure in SPCs, with attention to signs, symptoms, and changes in the infusion rate. SPC failure is a generic term used to refer to local complications associated with SPCs, such as phlebitis and infiltration.

The reason SPC failure has not been prevented completely may be that no effective preventive methods have been established because the etiology of catheter failure has not yet been fully investigated. Intravascular thrombus, subcutaneous edema, and catheter dislodgment have been discussed previously with regard to the possible etiology of SPC failure.^{1,3,6-11} Intravascular thrombus is thought to increase intravascular pressure, causing infusion fluids to flow into the surrounding tissue, with swelling and pain occurring as a result. In addition, it has been suggested that intravascular thrombus induces inflammation, and thereafter, pain, erythema, swelling, and induration occur as inflammatory responses.⁸⁻¹⁰ Moreover, thrombus also may cause intravascular blockage, which leads to an insufficient infusion rate.¹¹ It has also been reported that edema of the surrounding tissue caused by the accumulation of infusion fluids in the intercellular spaces leads to pain and swelling on the skin surface.⁹ The dislodgment of catheters also has been suggested as the cause of direct flow of infusion fluids into the surrounding tissue, leading to pain, swelling, and an insufficient infusion rate.^{6,7} These etiologies may help explain the causes of SPC failure; however, such effects have been extrapolated from case studies and observational studies with indirect confirmation, or direct confirmation has been obtained only in other types of catheters, such as central vascular access devices (CVADs) using some available modalities.

Modalities such as x-ray, computed tomography, and ultrasonography (US) are known to be useful observation methods regarding causes of catheter failure.^{10,12-14} In CVADs and peripherally inserted central catheters, these modalities are widely used to detect the presence of thrombus and catheter dislodgment because these etiologies sometimes cause life-threatening complications, such as pulmonary embolism or catheter malposition. However,

when using these modalities for SPCs, it has been difficult to observe the causes of catheter failure. Conventional portable US has not been appropriate for assessing the superficial structure of the skin because of its poor image quality. So far, there have been no investigations that have directly observed the etiologies of catheter failure, such as intravascular thrombus, subcutaneous edema, and catheter dislodgment in SPCs.

In recent years, advances have been made in US image quality and portability, making it possible to observe fine superficial structures of the skin using portable US equipment. The authors' previous research defined US features for intravascular thrombus, subcutaneous edema, and catheter dislodgment using US in patients who received infusion therapy through SPCs¹⁵; however, it was still unclear whether thrombus, subcutaneous edema, and/or catheter dislodgment were related to SPC failure.

The purpose of this study was to clarify the relationship between the etiologies and SPC failure using US. It further explored the risk factors associated with the etiologies related to SPC failure to establish effective preventive methods. These results are expected to help reduce patient discomfort, as well as associated signs and symptoms, insufficient infusion rates, and the health care burden associated with catheter replacement.

METHODS

Study Design and Participants

In this prospective observational study, all SPCs were observed just before catheter removal. Participants were recruited who had been admitted to a medical ward of an acute care hospital in a city in Japan and required an SPC for fluid therapy from January 2014 to June 2014. Patients who received chemotherapy, were under 20 years of age, had a low cognitive level, or had unstable physical conditions were excluded. Patients who received multiple SPCs were observed in order to include all SPCs in this analysis.

Observation Procedure

The characteristics of subjects were collected either from medical records or from observations of the indwelling site before infusion therapy started, which included the circumference of the arm at the SPC site. Researchers remained on call in the ward from 6 AM to 9 PM every weekday. The nurses were asked to call the team just before catheter removal so the signs and symptoms could be observed by macroscopic observations, and the vessel lumen, surrounding tissues, and catheter tip position by US. After the researchers completed all observations, the nurse then removed the SPC. Researchers confirmed the accuracy of the infusion rate with nurses. A researcher who observed signs and symptoms without being called by the clinical nurses did not report assessments or suggestions for catheter management—only signs and symptoms.

Investigation Items

SPC failure, signs and symptoms, and infusion rate

Researchers confirmed with nurses the reasons for catheter removal. If the catheter had been removed for unplanned reasons with associated signs, symptoms, or insufficient infusion rate, the case was defined as SPC failure. Signs and symptoms of phlebitis and infiltration, such as erythema, swelling, induration, bleeding, and pain, as referenced in the *Infusion Nursing Standards of Practice*,³ were observed by researchers just before catheter removal. The maximum diameter of erythema, swelling, and induration was measured, and when the diameter was greater than 1 cm around the insertion site, such cases were defined as positive for erythema, swelling, and induration. Pain was measured using the standardized Wong-Baker face scale (grades 0-5).¹⁶ If the face scale score was 1 or more, the case was defined as positive for pain. Bleeding was determined by the presence or absence of bleeding around the insertion site. Researchers confirmed the infusion rate status with the nurse. If the nurse's assessment was that the infusion rate was insufficient, the case was defined as positive for insufficient infusion rate.

Etiologies related to SPC failure

In this study, US scanning technique was based on the researchers' previous study.¹⁵ Images were obtained using a sufficient amount of ultrasound gel (Aquasonic100; Parker Laboratories, Fairfield, NJ) to avoid pressure on the vessel by the transducer. A gel stand-off pad (Sonar Pad; Nippon BXI, Tokyo, Japan) was used on the insertion site covered by

a transparent dressing to reduce friction during transducer operation. The position of the SPC tip was used as the anatomic landmark for determining the US scanning point. Researchers transversely scanned for a length exceeding 5 cm, both proximally and distally in the arm from the landmark. Similarly, researchers longitudinally scanned to detect the vessel wall and catheter. The motion images were recorded on a hard disk that was attached to the US equipment (Noblus; Hitachi Aloka Medical, Tokyo, Japan), which included a linear-array (5.0-18.0 MHz) transducer. When US imaging was performed, the focal range and the image depth were 1.5 to 2.5 cm for determining the correct display range. The echo gain and the dynamic range were tuned to a proper level for each measurement. The echo gain was set on a rate of 25, and the dynamic range was set on a rate of 65. All US image acquisitions were performed by 2 researchers who had received sufficient US training before the start of the study. US images of thrombus, subcutaneous edema, and catheter tip position were obtained by a certified sonographer with more than 10 years' experience. All US images were evaluated by the sonographer, who was blinded to all information related to the patients and the SPCs.

The definitions of *thrombus*, *subcutaneous edema*, and *catheter dislodgment* were based on the researchers' previous study.¹⁵ Intravenous *thrombus* was defined as a marked echogenic mass with an uneven surface. *Subcutaneous edema* was defined by a homogeneous cobblestone appearance in the subcutaneous fat layer attributable to excessive fluid in the interstitium with a slightly edematous dermis. *Catheter dislodgment* was determined when the catheter tip position was located outside the vessel wall. Figure 1 shows typical US features for (A) no etiologies,

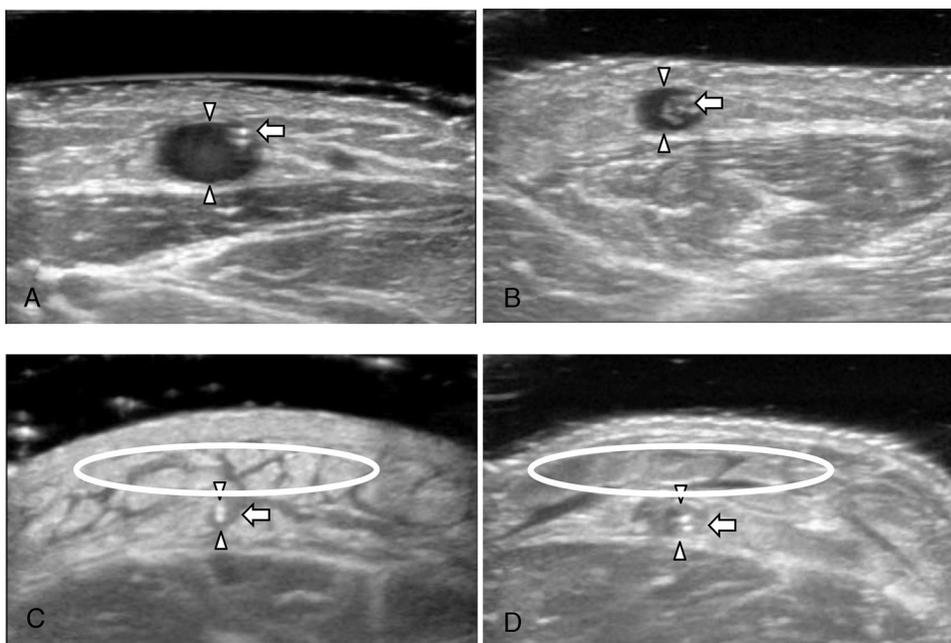


Figure 1 Typical ultrasonography features: A, no etiologies; B, only thrombus; C, only subcutaneous edema; and D, thrombus with subcutaneous edema. A transverse scan shows the oval shape of the vessel wall (see arrowheads). The high echo spots show the SPC tips (arrows). The mild high echo spots in the vein show partial occlusion of a vein by thrombus. The area surrounding the vein with the SPC tip appeared as edema of the subcutaneous fat layer (circles). *Abbreviation: SPC, short peripheral catheter.*

(B) only thrombus, (C) only subcutaneous edema, and (D) thrombus with subcutaneous edema. If US images could not detect the vessel wall or the catheter tip position, those images were excluded from the analysis.

Risk factors of etiologies related to SPC failure

Characteristics regarding participants' age, gender, diagnosis, body mass index, oral medicine, and the presence or absence of diabetes were collected from the medical records. Information related to catheterization, such as the anatomical site of the insertion and the distance between the insertion point and the antecubital fossa, was collected at the bedside by the researchers. Pharmacologic factors, including types of fluid therapy solutions, were collected for each patient from the medical records. The fluid therapy solutions were categorized into hyperosmotic solutions, antibiotic solutions, or fat emulsions, which have been suggested to be risk factors for phlebitis in SPCs.^{2,3} Researchers also collected information related to the characteristics of the catheter and dressing, such as the types of catheters and dressings; the specialty of the person who inserted the catheter (physician or nurse); the number of insertion attempts; the number of placements during the hospitalization; and reasons for removal, such as *completed to use* or *unplanned removal*.

Classifications of Catheter Removal

Signs and symptoms, insufficient infusion rate, and etiologies detected by US were evaluated just before catheter removal. A catheter removed when clinically indicated was classified as a *completed catheter*. A catheter that was removed for unplanned reasons with associated signs, symptoms, or an insufficient infusion rate was classified as an *SPC failure*. If a researcher confirmed signs or symptoms, such as erythema, swelling, induration, bleeding, pain, or insufficient infusion rate, a *completed catheter* was then classified as a *suspected catheter*, but otherwise as a *normal catheter*, in which infusion therapy was completed with no signs or symptoms of complications.

Statistical Analyses

Data were represented by the mean \pm standard deviation or number (%) unless otherwise specified. The relationships between SPC failure and the etiologies were examined by the chi-square test. If the etiologies were related to SPC failure, the researcher selected 1 etiology based on 2 reasons: the most frequently seen in SPC failure and the most severe situation from a pathophysiological perspective.

To focus on patient risk factors, as well as any other risk factors associated with the etiology related to SPC failure, the SPC data were analyzed at the patient level. If patients received multiple SPCs, information related to a specific catheter was selected for analysis in the following ways: for patients who had 1 catheter failure, that SPC and vessel were analyzed; for patients with 2 or more catheter failures, data on the SPC and vessel were randomly selected; for patients with no catheter failures, data related to

a specific catheter were selected. Patients who did not demonstrate any etiologies confirmed by US in the normal catheters constituted the control group.

Univariate analyses for each independent variable were performed by the chi-square test or Fisher exact test for categorical variables and the *t* test for continuous variables. The odds ratios and 95% confidence intervals of independent variables for the presence of the etiology related to SPC failure were estimated using logistic regression analyses. The variables were subjected to multiple logistic regression analyses when $P < .2$. Spearman rank correlation coefficients among the candidates for multiple logistic regression analyses were calculated for continuous variables. If coefficients > 0.4 were found between the independent variables, only 1 of the variables was entered in the model. If 1 variable for multiple logistic regression was a categorical variable, then the *t* test or the chi-square test was used. If the *P* value was less than .05, only 1 of the variables was entered. The adjusted model was constructed by the forced entry method. $P < .05$ was regarded as statistically significant. All statistical analyses were performed using JMP Pro software version 11.0.0 (SAS Institute, Cary, NC).

Ethical Considerations

The study protocol was approved by the Research Ethics Committee of the University of Tokyo (#10348). Written informed consent to participate in the study was obtained from all patients or their proxies. All participants were always free to retract their consent and were frequently asked if there was anything wrong, such as pain or discomfort, during the US examination. If any severe abnormality was observed, such as catheter dislodgment confirmed by US, the researcher had to report it to the nurses immediately.

RESULTS

Characteristics of the Subjects

Figure 2 shows a flow diagram of the participants and SPCs. Among the 399 eligible subjects, 82 patients were excluded because they received chemotherapy, were under 20 years of age, had a low cognitive level, or had unstable physical conditions. Three hundred seventeen subjects were finally

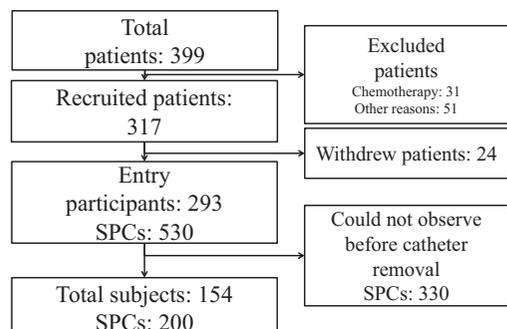


Figure 2 Participants and short peripheral catheter flow diagram. Abbreviation: SPC, short peripheral catheter.

enrolled. Among them, 24 patients withdrew their consent. The remaining 293 participated in the study and received a total of 530 SPCs, of which 330 SPCs were not observed before catheter removal. Finally, 200 SPCs in 154 subjects were analyzed.

Subject data were obtained for 200 SPCs from 154 subjects (64 females) with a mean age of 74.4 ± 17.3 years. The most frequent diagnosis was neoplasm (63.6%). Classifications of diagnosis were based on the US Centers for Disease Control and Prevention's ICD-10-CM (Table 1).¹⁷

Among 200 SPCs, 60 SPCs (30.0%) were classified as demonstrating SPC failure. Among the 60 SPCs, swelling, erythema, pain, induration, bleeding, and insufficient infusion rate were observed in 35 (58.3%), 21 (35.0%), 30 (50.0%), 9 (15.0%), 21 (35.0%), and 24 (40.0%), respectively.

Frequency of Etiologies and the Relationship Between the Etiologies and SPC Failure

Twelve catheters were excluded from the analysis (SPC failures: 7; normal catheters: 5) because the researchers could not define either the vessel wall or catheter tip position by US. No catheter dislodgment was observed during the study period. Table 2 shows the frequency of etiology and the relationship between the etiologies and SPC failure. There were a total of 60 SPC failure cases. Seven failed due to unclear US images. Among the remaining 53 SPC failures, *only thrombus*, *only edema*, and *thrombus with edema* were observed in 5 (9.4%), 10 (18.9%), and 34 (64.2%) SPCs, respectively (several cases were excluded in these comparisons). There was a significant difference in the frequency of subcutaneous edema between the SPC failures and the normal catheters ($P < .01$). Regarding thrombus with subcutaneous edema, its frequency was also significantly higher among the SPC failures ($P < .01$) (Table 2). Considering the most frequent etiology of SPC failure and its severity from a

TABLE 1

Characteristics of the Subjects

			N = 154
Gender		n	(%)
Female		64	(41.6)
Male		90	(58.4)
Age (years)	Mean \pm SD	74.4	\pm 17.3
BMI	Mean \pm SD	21.9	\pm 3.8
History of present illness ^a		n	(%)
Neoplasms		98	(63.6)
Digestive system		35	(22.7)
Infections ^b		11	(7.1)
Circulatory system		5	(3.2)
Nervous system		2	(1.3)
Musculoskeletal system and connective tissue		2	(1.3)
Respiratory system		1	(0.6)

Abbreviation: BMI, body mass index.
^aHistory of present illness was classified based on ICD-10.¹⁷
^bDiagnosis of infections included, for example, cellulitis, herpes, bacteremia, and the like.

pathophysiological perspective, thrombus with subcutaneous edema was focused on for further analysis to explore the risk factors.

Risk Factor Analysis of Thrombus With Subcutaneous Edema Related to SPC Failure

Among the 34 patients who developed an SPC failure, 3 patients needed 2 SPCs, so 31 patients were included for this analysis. Among the 42 patients with SPCs that did not

TABLE 2

Frequency of Etiologies and the Relationship Between Etiologies and Short Peripheral Catheter Failure

Etiologies	n	SPC Failures		Normal Catheters ^a		P Value
		n	(%)	n	(%)	
Only thrombus	38	5	(55.6)	33	(44.0)	
No etiologies	46	4	(44.4)	42	(56.0)	.51 ^b
Only subcutaneous edema	25	10	(71.4)	15	(26.3)	
No etiologies	46	4	(28.6)	42	(73.7)	< .01 ^b
Thrombus with subcutaneous edema	44	34	(64.2)	10	(10.0)	
No thrombus with subcutaneous edema	109	19	(35.8)	90	(90.0)	< .01 ^c

Abbreviation: SPC, short peripheral catheter.

^aNormal catheters: Cases of completed infusion therapy with no signs or symptoms of complications.

^bFisher exact test.

^cChi-square test.

TABLE 3

Subjects' Characteristics and Crude Outcome Counts by Thrombus With Subcutaneous Edema in Short Peripheral Catheter Failure

		All Subjects		No Etiologies in Normal Catheters ^a		Thrombus With Subcutaneous Edema in SPC Failure		OR	95% CI		P Value
		N = 67		n = 36		n = 31			LL	UL	
Gender											
Female	Reference ^b	27	(40.3)	14	(38.9)	13	(41.9)	1.00			
Male		40	(59.7)	22	(61.1)	18	(58.1)	0.88	0.33	2.36	.80
Age (years)		69.0	± 12.3	69.6	± 11.3	68.3	± 13.5	1.01	0.97	1.05	.66
BMI		22.8	± 3.6	22.7	± 3.6	22.8	± 3.8	0.99	0.86	1.13	.84
Diabetes											
Yes		19	(28.4)	11	(30.6)	8	(25.8)	0.79	0.26	2.30	.67
No	Reference	48	(71.6)	25	(69.4)	23	(74.2)	1.00			
Circumference of arm at insertion point (cm) (1.0)		7.6	± 2.7	8.3	± 2.0	6.9	± 3.1	0.87	0.73	1.01	.08 ^c
Oral medicine (anticoagulant)											
Yes		9	(13.4)	7	(19.4)	2	(6.5)	0.29	0.04	1.30	.11 ^c
No	Reference	58	(86.6)	29	(80.6)	29	(93.5)	1.00			
SPC size											
20 gauge		2	(3.0)	0	(0.0)	2	(6.5)	—	0.66	—	.09 ^c
22 gauge	Reference	53	(79.1)	28	(77.8)	25	(80.6)	1.00			
24 gauge		12	(17.9)	8	(22.2)	4	(12.9)	0.56	0.14	2.01	.38
Anatomical site											
Forearm	Reference	63	(94.0)	34	(94.4)	29	(93.5)	1.00			
Upper arm		2	(3.0)	1	(2.8)	1	(3.2)	1.17	0.05	30.51	.91
Hand		2	(3.0)	1	(2.8)	1	(3.2)	1.17	0.05	30.51	.91
Distance between the insertion point and the antecubital fossa (0.01 cm) ^d		7.6	± 2.7	8.3	± 2	6.9	± 3.1	0.68	0.50	0.88	< .01 ^c
Dressing (transparent dressing and bandage)											
Transparent dressing and bandage	Reference	8	(11.9)	2	(5.6)	6	(19.4)	1.00			
Other		59	(88.1)	34	(94.4)	25	(80.6)	0.24	0.03	1.16	.07 ^c
Duration of catheterization											
0-24 h		9	(13.4)	4	(11.1)	5	(16.1)	1.25	0.26	6.27	.78
24-48 h	Reference	22	(32.8)	11	(30.6)	11	(35.5)	1.00			
48-72 h		17	(25.4)	9	(25.0)	8	(25.8)	0.89	0.24	3.17	.85
72-96 h		9	(13.4)	5	(13.9)	4	(12.9)	0.80	0.16	3.28	.77
> 96 h		10	(14.9)	7	(19.4)	3	(9.7)	0.43	0.07	1.19	.28
IV solution											
Yes		11	(16.4)	3	(8.3)	8	(25.8)	3.82	0.99	3.82	.05 ^c
No	Reference	56	(83.6)	33	(91.7)	23	(74.2)				

(continues)

TABLE 3

Subjects' Characteristics and Crude Outcome Counts by Thrombus With Subcutaneous Edema in Short Peripheral Catheter Failure (Continued)

		All Subjects		No Etiologies in Normal Catheters ^a		Thrombus With Subcutaneous Edema in SPC Failure		OR	95% CI		P Value
		N = 67	(%)	n = 36	(%)	n = 31	(%)		LL	UL	
IV antibiotic solution											
Yes		27	(40.3)	13	(36.1)	14	(45.2)	1.46	0.54	3.93	.45
No	Reference	40	(59.7)	23	(63.9)	17	(54.8)				
IV lipid solution											
Yes		5	(7.5)	2	(5.6)	3	(9.7)	1.82	0.28	14.60	.52
No	Reference	62	(92.5)	34	(94.4)	28	(90.3)				
Number of insertion attempts ^e											
1	Reference	42	(72.4)	28	(84.8)	14	(56.0)				
2 or more		16	(27.6)	5	(15.2)	11	(44.0)	4.40	1.33	16.37	.01 ^c
Inserted by ^f											
Physician	Reference	8	(14.8)	3	(10.0)	5	(20.8)				
Nurse		46	(85.2)	27	(90.0)	19	(79.2)	0.42	0.08	1.93	.27
Diagnosis											
Neoplasms		37	(44.8)	19	(52.8)	18	(58.1)	1.24	0.47	3.30	.66
Other	Reference	30	(55.2)	17	(47.2)	13	(41.9)				

Abbreviations: BMI, body mass index; CI, confidence interval; IV, intravenous; LL, lower limit; ND, no data; OR, odds ratio; SD, standard deviation; SPC, short peripheral catheter; UL, upper limit.

N (%), mean ± SD

^aNormal catheter: Cases of completion of infusion therapy with no signs or symptoms of complications.

^bRefers to a reference in calculating the odds ratio of multiple logistic regression analysis.

^c $P \leq .2$ for bivariate association.

^d7 subjects had ND and were excluded from the analysis.

^e9 subjects had ND and were excluded from the analysis.

^f13 subjects had ND and were excluded from the analysis.

The ORs and 95% CIs of thrombus with edema were estimated using logistic regression analyses.

have any thrombus or subcutaneous edema, 6 patients needed 2 SPCs, so 36 patients were included as the control group.

The results from univariate analyses for each independent variable are shown in Table 3. Variables including circumference of the arm at the insertion point, using an anticoagulant drug, using a 20-gauge catheter versus a 22-gauge catheter, distance between the insertion point and the antecubital fossa adjusted by height, use of transparent dressing with bandage, intravenous hyperosmotic solution, and 2 or more attempts of insertion were found to be possible factors for the multivariate analysis. Among these candidates, the multicollinearity was evaluated and a correlation was found between arm circumference and distance between the insertion point and the antecubital fossa. As a result, distance between the insertion point and the antecubital fossa was entered.

The number of 20-gauge catheters used compared with 22-gauge catheters was not sufficient for analysis, and was

excluded for analysis. Age and gender also were treated as independent variables in the multivariate model. A multivariate analysis demonstrated that 2 or more insertion attempts were significantly associated with thrombus with subcutaneous edema related to SPC failure (Tables 3 and 4). The Hosmer-Lemeshow goodness of fit test for logistic regression was performed ($P = .14$).

DISCUSSION

This is the first study to observe vessel lumen, subcutaneous tissue, and catheter tip position using US to reveal the relationship between etiologies and SPC failure. Unexpectedly, no catheter dislodgment was observed, although catheter dislodgment has been suggested previously to be an important cause of SPC failure. On the other hand, the relationship between thrombus with subcutaneous edema and SPC failure was identified. Furthermore, 2 or more insertion

TABLE 4

Independent Risk Factors for Thrombus With Subcutaneous Edema Related to Short Peripheral Catheter Failure

Risk Factors	95% CI			P Value
	OR	LL	UL	
2 or more insertion attempts compared with 1 attempt	13.90	2.56	128.50	< .01
Distance between the insertion point and the antecubital fossa	0.77	0.53	1.05	.10
Dressing (transparent dressing and bandage compared with other dressing)	1.01	0.09	1.87	.16
IV hyperosmotic agent	4.89	0.53	109.70	.17
Oral medicine (anticoagulant)	0.29	0.01	2.23	.21
Male compared with female	0.70	0.17	2.70	.61
Age (per 1 year)	0.99	0.93	1.06	.86

Abbreviations: CI, confidence interval; cm, centimeters; IV, intravenous; LL, lower limit; OR, odds ratio; UL, upper limit.
 Note: Distance between the insertion point and the antecubital fossa (cm) was standardized by height (cm) per 0.01.
 Findings are from a multivariate logistic model.

attempts were associated with thrombus with subcutaneous edema related to SPC failure. These findings may help establish etiology-based preventive methods to reduce the occurrence of SPC failure.

In this study, the SPCs were observed just before removal. In a clinical setting, it is difficult to observe the SPC just before removal because nurses immediately remove the SPC to prevent any further patient discomfort when they identify any signs and symptoms or an insufficient infusion rate. To address this challenge, researchers stayed on call in the ward during the daytime shift every weekday.

US observation just before SPC removal using a portable US system to perform timely bedside evaluations is important because it is difficult to determine catheter location and to evaluate thrombus and subcutaneous edema without the use of US landmarks (ie, the catheter tip position in this study). As a result, US images in this study were of high quality for assessing etiologies related to SPC failure.

Catheter dislodgment was found not to be a cause of SPC failure in this study. It is generally considered that catheter dislodgment is an important cause of SPC failure because catheter dislodgment can cause the direct infusion of fluid into surrounding tissue.^{6,18} Hadaway⁷ also discussed the fact that catheter penetration was caused by joint movement. Schmit and Freshwater¹⁹ suggested that excessive vessel fragility and insufficient securement of the catheter could cause catheter dislodgment, which might lead to a direct flow of the administered fluids into the surrounding tissue. However, these discussions were not based on direct confirmation of catheter dislodgment. The results of this study suggest that SPC failure may be caused by reasons other than catheter dislodgment. This is a reasonable explanation because an earlier study of CVADs suggested that unintentional infusion of the fluid into surrounding tissue might reflect an inflammatory response of

the vein, rather than a simple misplacement of the catheter tip.²⁰ Consequently, SPC failure might be caused by inflammation, which was demonstrated by the direct observation of thrombus and subcutaneous edema.

This study identified that 92.5% (49/53) of SPC failures were accompanied by thrombus or subcutaneous edema. This is one of the most important findings because almost all SPC failures had abnormal intravascular or subcutaneous tissue changes. Specifically, thrombus with subcutaneous edema, which is considered a severe condition, was found in 64.2% (34/53) of SPC failures. On the other hand, the etiology was observed in only 10.0% (10/100) of the normal catheters, and thrombus with subcutaneous edema detected by US was significantly related to SPC failure. Based on these observations, nurses' decisions for SPC removal are considered clinically relevant from an etiological perspective. Thrombus with edema confirmed by US may represent thrombophlebitis, which can be observed in clinical settings. Preventive measures regarding thrombus with subcutaneous edema related to SPC failure should be established to reduce the high incidence of SPC failure (30.0%) seen in this study.

Numerous studies have focused on the risk factors related to SPC complications.^{3,18,21-23} However, they have not directly explained the etiology of SPC failure, and it has been difficult to establish effective preventive measures. The risk factors for the causes related to SPC failure were investigated, and 2 or more insertion attempts were found to be significantly related to the etiology. Two or more insertion attempts indicate that the health care professional could not successfully insert the catheter on the first attempt. In such a case, it is highly possible that tortuous or small veins were selected for insertion because SPC replacement in the same blood vessel is contraindicated. This may enhance mechanical stimulation in the vessel lumen by the catheter, resulting in thrombus and inflammation.^{21,22}

Although it was not found to be significant, a short distance between the insertion point and the antecubital fossa tended to be related to thrombus with edema. If catheters are inserted near joints, they tend to move more frequently. An unstable catheter might also harm vascular endothelial cells, leading to thrombus in the vessel lumen and inflammation in the surrounding tissue.

In this study, no relationship was found between pharmacologic factors and factors related to SPC failure. This might suggest that thrombus and subcutaneous tissue can be more affected by mechanical stimulation than by chemical stimulation. A previous study suggested that catheters indwelling in blood vessels may induce hemodynamic changes attributable to the disturbance of the blood flow caused by such catheters, while also causing disorders of the vascular endothelial cells attributable to the insertion and indwelling catheter, which leads to the formation of thrombus.^{24,25}

There are several limitations associated with this study. Data were collected in internal medicine wards at a university hospital. Caution is needed when extrapolating the results to pediatrics and patients in an emergency. Furthermore, the data of 1 specific catheter were selected regardless of the number of observed times in this study, so it was difficult to analyze the risk factors, especially for repeated SPC failure. Stratified analysis for repeated SPC failure would be beneficial in addressing this challenge.

Regarding clinical implications, results based on etiological investigations could provide new approaches using US to recognize signs and symptoms of SPC failure and prevent it. First, thrombus and subcutaneous edema were observed by US in SPC failure, so US evaluation of the vessel lumen and its surrounding tissue might be useful in the early identification of SPC failure before problems appear. Second, vein selection was related to thrombus with subcutaneous edema. Because health care professionals may visually select the vein for catheterization, selection of the appropriate vein was limited to the vessels located in superficial skin layers.²⁶ The use of US-guided selection of the appropriate vein for catheter placement, which may be located in deeper layers, would be effective.

CONCLUSION

This study investigated the relationship between the etiology confirmed by US and the occurrence of SPC failure. Notably, no catheter dislodgment among the SPC failure cases was found. On the other hand, thrombus with subcutaneous edema was found to be significantly related to the occurrence of SPC failure. Furthermore, 2 or more insertion attempts were found to be significantly associated with thrombus with subcutaneous edema related to SPC failure. The prevention of SPC failure could be achieved by an accurate assessment of the blood vessels with US.

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