A Randomized Controlled Study to Evaluate the Effectiveness of 2 Treatment Methods in Reducing Incidence of Short Peripheral Catheter-Related Phlebitis

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ABSTRACT

Short peripheral catheter (SPC)-related phlebitis can lead to bloodstream infections and affect patients' quality of life. A randomized trial was carried out to evaluate the effectiveness of 2 treatment methods in reducing the incidence of SPC-related phlebitis. The 2 treatment methods differed in terms of the cleansing solution used before insertion and dressing material used after removal. The results demonstrated that the type of cleansing solution and postremoval dressing material did not make a difference in the incidence of phlebitis. Strict adherence to aseptic techniques and prompt removal of the SPC remained the cornerstone in the prevention of phlebitis.

Key words: 2% chlorhexidine, 70% isopropyl alcohol, phlebitis, short peripheral catheter, visual infusion phlebitis score

Short peripheral catheter (SPC) insertion is a common procedure in hospitals and is the most frequently used method for drug, fluid, and blood product administration.[1,2] It is estimated that up to 85% of patients in acute care hospitals require infusion therapy, with 70% of patients needing an SPC.[3,4]

However, the procedure of SPC insertion is not risk free. Skin integrity is breached when the skin is punctured with a needle to allow the insertion of an SPC into a vein.[5] A common complication is phlebitis, which causes pain, interrupts infusion therapy, and necessitates insertion of a new catheter. Phlebitis may also compromise subsequent vascular access and lead to bloodstream infections.[6,7] For these reasons, prevention and early detection of phlebitis is important. This study aimed to compare the effectiveness of 2 treatment methods in reducing the incidence of SPC-related phlebitis. The 2 treatment methods differed in terms of the cleansing solution used before insertion and dressing material used after removal.

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BACKGROUND

Phlebitis is defined as an "inflammation of the vein; which may be accompanied by pain, erythema, edema, streak formation and/or palpable cord."[8(pS153)] Phlebitis can occur while the catheter is in situ and up to 96 hours after removal of the catheter.[9] According to Lamb and Dougherty,[10] the common classifications of phlebitis are:

- Mechanical phlebitis—associated with catheter size, insertion site, insertion techniques, and methods of catheter and joint stabilization;
- Chemical phlebitis—associated with infusion of hyperosmolar fluids greater than 600 mOsm per liter and/or solutions and medications with a pH <5 and >9; and

- Bacterial phlebitis—associated with deficits in skin antisepsis, catheter handling and stabilization, and dressing materials.

Most studies in the literature have focused on the prevention and reduction of bacterial infections associated with the use of central venous catheters.[11-13] However, a study by Pujol et al[3] reported that the incidence rate of bloodstream infections associated with short-term SPCs (0.19 cases/1000 patient days) was similar to that associated with central venous catheters (0.18 cases/1000 patient days). An integrative literature review conducted by Hadaway[14] estimated that as many as 10 000 cases of *Staphylococcus aureus* bacteremia from SPCs occur annually in the United States.

The primary responsibility for the care of SPCs usually lies with nurses. This is because nurses are the most frequent health care personnel to insert SPCs, administer intravenous (IV) medications, and change IV administration sets and dressings.[15] Therefore, nurses are tasked as the most strategic group of health care personnel to prevent the occurrence of phlebitis.

Skin antisepsis or cleansing of the catheter site is regarded as a critically important measure in the prevention of SPC infections.[16] Strict adherence to hand washing and aseptic techniques in caring for SPCs is a preventive strategy against contamination of the catheter site and IV administration sets, and helps eradicate the presence of microorganisms at the catheter site, which can migrate into and around the catheter and cause bacterial phlebitis.

Preinsertion Skin Antisepsis

Recent studies have suggested the superiority of chlorhexidine gluconate in the removal of skin microorganisms.[17-20] The use of 2% aqueous chlorhexidine was associated with a lower incidence of SPC infections in studies by Small et al[21] and Adams et al.[22] Other studies demonstrated that its use was more effective than 70% isopropyl alcohol in the reduction of the number of skin microorganisms and risk of subsequent SPC contaminations.[22,23]

Postremoval Phlebitis and Dressing

Being an inflammation process, phlebitis may also occur after IV infusion has ceased and the SPC has been removed.[14] There are limited studies that have reported on the incidence of phlebitis after removal. In a more recent study,[24] it was reported that 1.8% of patients experienced postinfusion phlebitis at 48 hours after catheter removal. Although rare, there were also reports of postinfusion phlebitis among patients in this current study site.

There is also a dearth of studies that investigated the impact of spray-on film dressings (transparent vapor permeable spray) on postinfusion phlebitis.

Significance of Current Study

In the tertiary hospital where this study was conducted, standard practice involves the use of 70% isopropyl alcohol swabs for preinsertion skin antisepsis and the application of adhesive bandages to the wound site following removal of the catheter. Institutional guidelines currently stipulate that catheters can be kept in situ for up to 96 hours in the absence of signs and symptoms of infection. Given recent evidence on the benefits of chlorhexidine gluconate and increased patient requests for spray-on film dressings, it is of interest to evaluate the use of these 2 products on the incidence of SPC-related phlebitis.

METHODS

Study Design and Participants

A randomized controlled trial was carried out. Participants were recruited from an 87-bed medical ward in an acute tertiary hospital in Singapore. Recruitment and data collection took place between April 2014 and July 2015.

Inclusion criteria involved patients:

- Requiring an SPC in an upper limb
- Ranging in age between 21 and 99 years

Exclusion criteria involved patients who were:

- Critically ill
- Allergic to alcohol and/or chlorhexidine
- Admitted for upper limb(s) phlebitis and/or cellulitis
- Known to have dermatological issues

Randomization and Interventions

Cluster randomization using a computer-generated table of random numbers was used to assign allocation of treatment method to each week during the data collection period. Specifically, all patients admitted to the ward in the particular week received the same treatment method.

Cluster randomization was deemed the most practical approach to prevent any forms of treatment contamination given that the study took place in a busy, large, acute medical ward setting. Each participant was recruited only once during the period of data collection. If the participant had more than 1 SPC inserted in the upper limb(s), only 1 site of insertion was monitored and followed up on (Table 1, Figure 1).

Sample Size

Based on an estimated incidence of phlebitis of 2% in treatment method 2 versus 5% in treatment method 1, a total sample size of 926 participants (1:1 allocation ratio) was needed to attain 80% power at 5% level of significance. Accounting for a 10% dropout rate, 1020 participants were recruited.

Outcomes and Follow-up

The primary outcome was signs of phlebitis during the course of infusion therapy or within 48 hours after removal. The participants were followed and evaluated for signs of phlebitis on a daily basis, once every shift, by an independent assessor for the duration of the time the SPC was in situ. The visual infusion phlebitis (VIP) score tool was

TABLE 1

Treatment Methods: Preinsertion Skin Antisepsis and Postremoval Dressing Material

	Treatment Method 1	Treatment Method 2
Preinsertion skin antisepsis	70% isopropyl alcohol swabs were used in circular motion and allowed the site to dry after cleaning	2% chlorhexidine in 70% isopropyl alcohol swab sticks were used in circular motion, allowing the site to dry after cleaning
While catheter is in situ	Aseptic technique when manipulating the SPC, flushing of SPC before and after drug administration, and routine removal after 72-96 hours	
Postremoval dressing material	Use of sterile gauze Application of adhesive bandage after hemostasis achieved	Use of sterile gauze Application of film dressing (spray-on) after hemostasis achieved

Abbreviation: SPC, short peripheral catheter.

used to determine the presence and severity of phlebitis.[25] The tool grades the presence of phlebitis and its severity using 6 symptoms: pain, erythema, swelling, induration, palpable venous cord, and pyrexia. The scale ranges from 0 to 5, and phlebitis was considered present if the VIP score was ≥2, with an associated recommendation for SPC removal. The tool was chosen because it is easy to use in clinical practice and has been adopted as a standardized assessment tool in hospitals.[6]

If the participant was discharged from the hospital before the 48 hours following the removal of the catheter, the patient was educated on the signs and symptoms of phlebitis before discharge. The research team then contacted these participants via telephone calls to inquire about their experience with signs and symptoms of phlebitis.

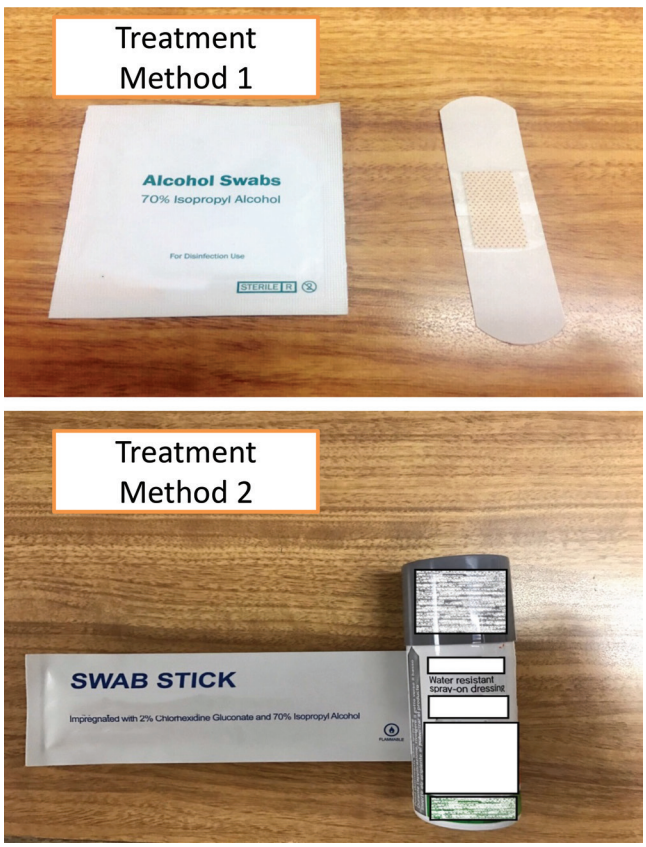

Figure 1 Preinsertion and postremoval dressing material.

Data Collection Procedure

Waiver of informed consent was obtained from the ethics board. According to hospital policies and regulations, the insertion of an SPC is considered a routine clinical procedure, so written consent was unnecessary. However, when possible, the ward nurses obtained verbal consent from the patients to perform the insertion of an SPC according to standard practice. SPCs were inserted by ward nurses who had demonstrated competency in the insertion of SPCs.

Before the start of every shift, during roll calls, the ward nurses were reminded of the SPC treatment method that was randomly assigned for the week. The nurses also attended in-service sessions and completed competency tests to refresh their knowledge on the aseptic techniques and standard care of SPCs in situ, as well as the use of the study trial preinsertion cleansing solution and postremoval dressing material.

Training was also provided for the 2 independent assessors who evaluated the participants for signs of phlebitis. Before data collection, the assessors were shown a series of photographs and asked to identify signs and symptoms of phlebitis using the VIP scoring tool. Their scores were individually compared with that of a senior nurse to determine their interrater reliability using Cohen's kappa.[26] There was high agreement among all 3 parties, with significant Cohen's kappa values between 0.86 and 0.93. The 2 assessors were blinded to the randomization outcomes of the SPC treatment method for the week.

Data Analysis

The observed number of incidents of phlebitis was presented using frequencies and percentages. The Fisher exact test was used to evaluate for any differences in the incidence of phlebitis between participants in the 2 treatment methods. *P* values less than .05 were considered statistically significant.

TABLE 2

Participant Demographics (N = 960)

			Treatment Method 1: 70% Isopropyl Alcohol Swabs and Adhesive Bandages n = 538 n (%)	Treatment Method 2: 2% Chlorhexidine in 70% Isopropyl Alcohol Swab Sticks and Film Dressing (Spray-on) n = 422 n (%)	Chi-Square Value	*P* Value
Presence of systemic infection on admission	Yes		78 (15)	46 (11)	2.7	.12
	No		459 (85)	375 (89)		
Site of inserted SPC	Dorsum		181 (34)	144 (34)	2.5	.29
	Forearm		286 (53)	236 (56)		
	Antecubital fossa		71 (13)	42 (10)		
Size of SPC	18-gauge		4 (1)	12 (3)	6.4	.04[a]
	20-gauge		95 (18)	75 (18)		
	22-gauge		437 (81)	334 (79)		
Hours of SPC in situ	≤24 hours		121 (23)	97 (23)	1.0	.79
	>24 to ≤48 hours		177 (33)	145 (34)		
	>48 to ≤72 hours		119 (22)	82 (19)		
	>72 to ≤96 hours		121 (23)	98 (23)		
Drugs administered	Phenytoin or diazepam	Yes	1 (0.2)	0 (0)	0.3	1.00
		No	537 (99.8)	422 (100)		
	Potassium chloride, amino acids, or high-dose dextrose	Yes	89 (17)	61 (14)	0.4	.20
		No	449 (83)	361 (86)		
	Erythromycin, tetracycline, vancomycin, or amphotericin B	Yes	18 (3)	16 (4)	0.7	.70
		No	520 (97)	406 (6)		

Abbreviation: SPC, short peripheral catheter.
[a]$P < .05$.

RESULTS

One-thousand twenty participants were recruited. Sixty participants were transferred to other wards and dropped out of the study. Distribution of the participant characteristics (N = 960) is outlined in Table 2. The majority of participants did not have systemic infection when admitted (n = 834; 86.9%). The most common site of insertion was the forearm (n = 522; 54.4%), followed by the dorsum of the hand (n = 325; 33.9%) and the antecubital fossa (n = 113; 11.8%). Overall, more participants had a 22-gauge SPC (n = 771; 80.3%) compared with a 20-gauge SPC (n = 170; 17.7%). Only a few participants (n = 16; 1.7%) had an 18-gauge SPC.

Baseline characteristics were similar among participants in the 2 treatment methods in terms of systemic infection at admission, site of the SPC, hours the catheter was in situ, and drugs administered. However, there was a significant difference in the size of SPC inserted; more participants in treatment method 2 (3%) had an 18-gauge catheter inserted compared with participants in treatment method 1 (1%).

Incidence of Phlebitis

As summarized in Table 3, there was no significant difference in the incidence of phlebitis between participants in the 2 treatment methods. For participants who had catheters in situ for 24 hours or less, only 1 (0.5%) had phlebitis (VIP score of 2). Most scored 1 on the VIP score tool within 48 hours after removal. This is unsurprising because an early indication of phlebitis (VIP score of 1) would have prompted the nurses to remove catheters early. For participants who had catheters in situ for >24 to ≤48 hours, 2 (1%) had phlebitis (VIP score of 2 or greater).

Although more participants in treatment method 1 experienced phlebitis, the difference was not significant. Similar findings were reported for participants with catheters in

TABLE 3

Incidence of Phlebitis Using Visual Infusion Phlebitis Score

		Treatment Method 1 (All Patients) n = 538	Treatment Method 2 (All Patients) n = 422	Fisher Exact Test 2-Sided
		n (%)	n (%)	
Developed phlebitis	Yes	6 (1)	1 (0.2)	0.143
	No	532 (99)	421 (99.8)	
		Treatment Method 1 (Patients With 20- and 22-Gauge Catheters Only) n = 532	**Treatment Method 2 (Patients With 20- and 22-Gauge Catheters Only) n = 409**	**Fisher Exact Test 2-Sided**
		n (%)	**n (%)**	
Developed phlebitis	Yes	5 (1)	1 (0.2)	0.241
	No	527 (99)	408 (99.8)	

situ for >48 to ≤72 hours (n = 201). Four participants (2%) experienced phlebitis at day 2. Surprisingly, the catheters for these participants were not removed, and signs and symptoms were resolved by day 3 only to resurface after the catheter was removed. None of the participants with catheters in situ for up to 96 hours experienced phlebitis (Table 4).

DISCUSSION

SPC-related phlebitis remains the most frequent complication for patients receiving infusion therapy and can lead to severe catheter-related bloodstream infections.[27,28] Phlebitis not only affects the patient's health and quality of life but also has an impact on the consumption of health care resources.[29]

This study compared the effectiveness of 2 treatment methods in reducing the incidence of SPC-related phlebitis. Different types of preinsertion cleansing solutions and postremoval dressing material under treatment methods 1 and 2 were compared to determine whether one treatment method was superior to the other. Treatment method 1 has been the standard care in this institution for many years.

A number of factors are known to be associated with the development of phlebitis, such as chemical factors (irritant drugs, etc), mechanical factors (location and catheter material, etc), and infection.[24] This study showed that despite more patients with larger-gauge SPCs in treatment method 2, there was no significant difference between the 2 treatment methods in the proportion of participants who developed phlebitis in the same time frame and across different time frames (*P* value ranged from .05 to 1.0).

Other recent studies have demonstrated the superiority of using 2% chlorhexidine gluconate in 70% isopropyl alcohol in reducing the number of skin microorganisms and risk of subsequent SPC contamination compared with the use of 70% isopropyl alcohol alone.[21-23] For example, Small et al[21] found in their study that the use of 2% chlorhexidine gluconate in 70% isopropyl alcohol before the insertion of SPCs may reduce the risk of subsequent contamination or colonization compared with the use of 70% isopropyl alcohol alone. Their study also indicated that 70% isopropyl alcohol for skin antisepsis provides a rapid reduction in the number of skin microorganisms but does not have any residual activity. In comparison, 2% chlorhexidine gluconate in 70% isopropyl alcohol had residual activity on the skin that lasted up to 24 hours. A longer residual activity is also indicated to have a longer antimicrobial effect on the skin surface to reduce bacterial load.

This study demonstrated that the types of cleansing solutions and postremoval dressing materials affected the incidence of phlebitis. This contradicted the earlier findings by Small et al.[21] However, the outcome of this study was clinically diagnosed phlebitis and not bacterial load.

There was no significant difference between the 2 treatment methods in the proportion of participants who developed phlebitis across different time frames. Interestingly, some participants had a score of 1 on the VIP score tool after insertion and also after removal across the different time frames. This is congruent with another study conducted by Uslusoy and Mete,[30] which reported grade 1 phlebitis as the most frequent complication (44.5%). Hence, it is possible that manipulation of the SPC on insertion and postremoval might have irritated the site of the SPC, leading to slight pain or redness.

Following the removal of an SPC, the insertion site of the SPC is considered an open wound and should be dressed appropriately. This study comparing the 2 treatment methods found no significant difference between the 2 methods in the types of postremoval dressing materials. A spray-on film dressing, applied after hemostasis had been achieved, did not seem to yield any clinical advantages over the use of the adhesive bandages alone.

TABLE 4

Incidence of Phlebitis Across Different Time Frames Using Visual Infusion Phlebitis Score

	VIP Score	Treatment Method 1 n (%)	Treatment Method 2 n (%)	Fisher Exact Test 2-Sided *P* Value
Catheters In Situ for Time Frame 1: ≤ 24 hours (n = 218)				
First assessment	0-1	120 (99)	97 (100)	.491
	2	1 (1)	0	
First assessment (on removal)	0-1	121 (100)	97 (100)	—
Second assessment (after removal)	0-1	121 (100)	97 (100)	—
Catheters In Situ for Time Frame 2: > 24 to ≤ 48 hours (n = 322)				
First assessment	1	176 (99)	144 (99)	.699
	2	1 (1)	1 (1)	
Second assessment	0-1	175 (99)	145 (100)	.508
	2	2 (1)	0	
First assessment (on removal)	0-1	175 (99)	145 (100)	.503
	2-3	2 (1)	0 (0)	
Second assessment (after removal)	0-1	176 (99)	145 (100)	1.000
	2	1 (1)	0 (0)	
Catheters In Situ for Time Frame 3: > 48 to ≤ 72 hours (n = 201)				
First assessment	0-1	119 (100)	82 (100)	—
Second assessment	0-1	116 (98)	81 (99)	.647
	2	3 (2.5)	1 (1)	
Third assessment	0-1	119 (100)	82 (100)	—
First assessment (on removal)	0-1	117 (98)	81 (99)	1.000
	2	2 (2)	1 (1)	
Second assessment (after removal)	0-1	119 (100)	82 (100)	—
Catheters In Situ for Time Frame 4: > 72 to ≤ 96 hours (n = 219)				
First assessment	0-1	121 (2)	98 (0)	—
Second assessment	0-1	121 (1)	98 (0)	—
Third assessment	0-1	121 (1)	98 (0)	—
Fourth assessment	0-1	121 (1)	98 (0)	—
First assessment (on removal)	0-1	121 (1)	98 (0)	—
Second assessment (after removal)	0-1	121 (1)	98 (0)	—

Abbreviation: VIP, visual infusion phlebitis.

Limitations

Patient-level randomization could not be implemented practically in this study given the high rates of inpatient admissions, transfer, and discharges that may confuse researchers in the allocation of a treatment method for each patient. Cluster randomization was therefore viewed as the preferred form of randomization because it is a more practical approach to keep track of the weekly allocation of treatment methods while still achieving an acceptable degree of variability.

In addition, by testing treatment methods (combination of cleansing and dressing products), this study was not able to discern the effectiveness of each clinical product toward the prevention of SPC-associated phlebitis. More resources are required to conduct the study with a larger sample size if a 4-armed trial is to be conducted. Data on the number of attempts made during insertion of the SPCs were not collected, which could have influenced the incidence of phlebitis.

CONCLUSION

Despite more patients having larger-gauge catheters in treatment method 2, there was no difference in VIP score between

the participants from the 2 treatment methods across the different time frames. The results of the study demonstrate that the types of cleansing solutions and postremoval dressing materials did not affect the incidence of phlebitis. Strict adherence to aseptic techniques, such as compliance with hand hygiene practices and adherence to universal infection prevention measures, continues to remain the cornerstone in the prevention of bacterial phlebitis.

Relevance to Clinical Practice

Phlebitis can put patients' safety at risk. This study has shown that safe clinical practices during the insertion and care management of SPCs are more important than the use of different (superior) products.

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