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ORIGINAL ARTICLE

Safety and efficacy of using vascular closure devices for hemostasis on sheath removal after a transfemoral artery percutaneous coronary intervention

Shu-Fen SU,[1] Mei-Yu CHANG,[2] Meng-Shan WU[3] and Ying-Chin LIAO[4]

[1]*Department of Nursing, National Taichung University of Science and Technology,* [2]*Department of Nursing, Taichung Veterans General Hospital,* [3]*Department of Nursing, Taichung Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Taichung and* [4]*Department of Nursing, Dalin Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Fuxing Township, Taiwan*

Abstract

Aim: To determine the efficacy of vascular closure devices (VCDs) for hemostasis following transfemoral percutaneous coronary interventions (PCIs).

Methods: This two-group pre–post-test observational study with purposive sampling enrolled 73 patients between January, 2014 and February, 2015. The patients were allocated to either the intervention (vascular closure devices group, n = 34) or the control group (manual compression [MC] group, n = 39). Questionnaires were used to assess their demographic and clinical characteristics, vascular complications, visual analogue scale score for pain, and discomfort levels. Pain and discomfort were measured before and after the PCI.

Results: Vascular complications were observed in 15 (44.1%) VCD patients and 13 (33.3%) MC patients, with no significant between-group difference. However, the VCD patients had a higher relative risk of bruising, hematomas, and need for further treatment. After the PCI, the pain scores and discomfort levels increased significantly in both groups, but the VCD patients had more successful hemostasis, less pain, and less physical and psychological discomfort (lower-limb numbness, shoulder pain, restlessness, and worrying about walking ability, being unable to lift heavy objects in the future, and taking time off from work).

Conclusion: The VCDs seem to be superior to the MCs, providing more successful hemostasis, less pain and discomfort, and earlier ambulation after a transfemoral PCI. These findings aid clinical nurses in understanding the risk of vascular complications, discomfort, and pain that are associated with VCD use for improving the quality of clinical care and help clinicians in determining the appropriate hemostatic method for patients undergoing a transfemoral PCI, particularly in the Chinese population.

Key words: femoral artery, hemostatic technique, percutaneous coronary intervention, postoperative complication, vascular closure device.

INTRODUCTION

A percutaneous coronary intervention (PCI) is a common procedure that is carried out to improve myocardial blood flow in the treatment of coronary artery disease (CAD). In the USA, >1 million persons undergo a PCI annually (National Institute for Cardiovascular Outcomes Research, 2014). A transfemoral PCI is often used when patients have acute myocardial ischemia or coronary arteries with small diameters. However, the progressively increasing use of antithrombotic and antiplatelet medications concurrently with a PCI has been known to lead to vascular complications, such as bleeding, bruising, hematomas, pseudoaneurysms, femoral neuropathy, arteriovenous fistulae, infection, and retroperitoneal hematomas (Robertson, Andras, Colgan, & Jackson, 2016; Walter *et al.*, 2017).

Correspondence: Ying-Chin Liao, Department of Nursing, Dalin Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, No. 151, Ln. 736, Sect. 6, Zhanglu Rd., Fuxing Township, Changhua County 506, Taiwan (R.O.C).
Email: i720615@yahoo.com.tw

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Bleeding after a PCI is particularly noteworthy because of its potential to become severe. The prevalence of this complication after a PCI ranges from 1% to 14% (Lee *et al.*, 2015), increasing the length of the hospital stay, associated medical costs, and risk of mortality (Smilowitz *et al.*, 2012). Clinical nurses therefore should closely monitor their patients following a transfemoral PCI, particularly in terms of the bleeding status and compliance with bed rest. Moreover, a PCI can cause psychological discomfort, such as anxiety, restlessness, and low self-esteem (Lombardo *et al.*, 2013). Thus, providing holistic nursing care to PCI patients is of great importance.

The standard nursing assessment of PCI access sites includes monitoring the arterial puncture site for bleeding, hematomas, ecchymosis, localized tenderness, a pulsating mass, and new bruits. Additionally, nurses should ensure that the PCI patients receive detailed and regular evaluations (physical assessment, wound care, electrocardiography, vital sign assessment, laboratory examinations, and monitoring of complications) and that they have sufficient comfort and safety during bed rest (Lee *et al.*, 2015; Mohammady, Heidari, Sari, Zolfaghari, & Janani, 2014). However, the constant monitoring of vascular complications in patients undergoing a PCI can increase the workload of nurses substantially, resulting in physical fatigue. Thus, various methods have been developed to ensure hemostasis on the removal of the arterial sheath following a PCI, such as manual compression (MC) or the use of C-clamps, pneumatic devices, and vascular closure devices (VCDs) (Lee *et al.*, 2015). The most commonly used hemostasis methods after a transfemoral PCI are MC and VCDs (Jin & Zhang, 2013). There are two categories of VCDs: sealed collagen and thrombin-based VCDs, which help induce platelet aggregation and clot formation in order to achieve quick hemostasis, and mechanical suturing device-based VCDs, which use a suture line with a nickel–titanium staple or clips to quickly and directly seal the blood vessels after the PCI. The VCDs can effectively shorten the time to hemostasis, thereby avoiding prolonged immobility (Robertson *et al.*, 2016) and allowing for early ambulation (Theodos *et al.*, 2013).

Manual compression involves using the fingertips to provide continual downward pressure on the puncture site of the blood vessels immediately after removing the arterial sheath until hemostasis is achieved (usually after 15–20 min). Subsequently, a sand bag is used to compress the punctured artery. The patient usually must remain in bed for at least 6–8 h once this process is initiated (Robertson *et al.*, 2016). However, MC is not considered to be an effective method for patients with obesity or lumbar or pelvic disease (Bechara, Annambhotla, & Lin, 2010). Importantly, the prolonged bed rest that is required for MC also can increase the severity of pain and discomfort of the patients who are undergoing the PCI and might interfere with their daily activities (Mohammady *et al.*, 2014). The patients' rest and sleep quality also can be affected, which can lead to higher levels of anxiety and depression. Ultimately, such disturbances can have a negative influence on the effectiveness of PCI treatment and cardiac recovery (Watkins *et al.*, 2013).

Research has shown that, compared with MC, using VCDs might be associated with fewer complications and better hemostatic efficacy for transfemoral PCI patients (Liao & Su, 2015; Smilowitz *et al.*, 2012). In particular, patients with a VCD showed a lower incidence of vascular complications (Jin & Zhang, 2013), with fewer pseudoaneurysms (Allen, Marso, Lindsey, Kennedy, & Safley, 2011), less hematomas of > 10 cm (Iqtidar, Li, Mather, & McKay, 2011), a higher hemostasis success rate, shorter hospital stay (Allen *et al.*, 2011), shorter time to hemostasis (Jin & Zhang, 2013), and shorter duration of bed rest (Martin *et al.*, 2008).

However, the findings of Stegemann *et al.* (2011) contradict these previous observations, suggesting that VCDs and MC do not significantly differ in terms of the incidence of vascular complications. In fact, in their meta-analysis of 34 studies and 15,805 patients who underwent a transfemoral PCI, Das, Ahmed, Athanasiou, Morgan, & Belli (2011) found no significant differences in vascular complications between the MC and VCD groups. Therefore, whether the use of VCDs is indeed superior to MC in terms of hemostasis and the incidence of vascular complications remains controversial.

Studies have shown that strict bed rest after a PCI leads to a higher incidence of trembling, anxiety, low back pain, leg pain, numbness, stiffness, difficulty in urinating, and inconvenience in eating and drinking, all causing discomfort (Liao & Su, 2015; Mohammady *et al.*, 2014). The PCI patients with VCDs showed less discomfort and a shorter duration of bed rest than the patients who received MC (Martin *et al.*, 2008). Moreover, Sciahbasi *et al.* (2009) found that those patients who received MC required strict bed rest, causing them to experience greater discomfort, including symptoms of dysuria, eating and drinking inconvenience, compression-induced pain, bed rest discomfort, and general discomfort, than experienced by the VCD group. Early ambulation has been suggested to increase patient

comfort and satisfaction levels without increasing the risk of bleeding or hematomas (Rezaei-Adaryani, Ahmadi, & Asghari-Jafarabadi, 2009). Studies revealed that early ambulation (i.e. within 3–4 h after the PCI) can reduce low back pain and analgesic use (Augustin, de Quadros, & Sarmento-Leite, 2010), back pain and urinary discomfort, and increase overall comfort (Chair *et al.*, 2012). Finally, in the meta-analysis study of 29 studies and 4,019 PCI patients, Mohammady *et al.* (2014) concluded that early ambulation (within 2–4 h after the PCI) reduced low back pain and urinary discomfort.

However, all the above-mentioned studies used a visual analogue scale (VAS) to measure discomfort and focused on only three physiological indicators of discomfort (back pain, dysuria, and inconvenience in eating and drinking) following a transfemoral artery PCI. Additional aspects of physical and psychological discomfort that are experienced in conjunction with a PCI should be considered because cardiac recovery and the incidence of complications could be affected, not only by physical discomfort but also by psychological discomfort. Moreover, bleeding after a PCI has come to be recognized as more dangerous than previously believed. Therefore, all healthcare providers should take measures to reduce the risk of bleeding and thus prevent bleeding-related complications (Chhatriwalla *et al.*, 2013). However, although it is accepted that the use of VCDs might shorten the time to hemostasis and facilitate early ambulation, whether VCD use is superior to MC in terms of efficacy and preventing vascular complications remains controversial. In order to address the shortage of data on the safety and efficacy of VCDs after a PCI, a two-group, pre–post-test clinical observational study was designed that focused on determining the efficacy of VCDs on hemostasis, incidence of vascular complications, pain score, and discomfort levels in patients who underwent a transfemoral artery PCI.

METHODS

Study design, setting, and participants

This study used a two-group, pre–post-test clinical observational design. Purposive sampling was used to recruit 85 patients with CAD who had been referred for a transfemoral PCI at the coronary care units (CCUs) of two 1500 bed teaching hospitals in Taiwan. The eligible participants: (i) were >20 years; (ii) had been diagnosed with CAD by a cardiologist, who then referred them for a transfemoral PCI; and (iii) provided written informed consent to participate. The exclusion criteria were: (i) coagulopathy; (ii) the prescription of long-term bed rest; (iii) chronic lumbar pain; and (iv) dysuria or voiding difficulties. The sample size was calculated by using G*Power v. 3.1.9.2 (http://www.gpower.hhu.de/) by selecting the *t*-test to assess the difference between two independent means (two groups). The effect size was set at 0.5 (two-sided), α error at 0.05, and power at 0.7. A minimum sample size of at least 51 in each group (102 participants in total) was required.

Study procedure and data collection

Prior to the PCI, two cardiovascular specialists used standardized language to explain the hemostasis procedures (MC and VCD [Angio-seal VIP; Terumo Medical Corporation, Tokyo, Japan]) to the participants in detail; subsequently, the participants selected their preferred method for hemostasis. Informed written consent was obtained from all the participants. A pilot study of 20 patients who had undergone a transfemoral PCI then was conducted in order to verify the validity of the evaluation instruments. Subsequently, the 73 participants who had been recruited between January, 2014 and February, 2015 were allocated to one of two groups. Both the MC and VCD groups were not randomly divided. The 34 patients who were allocated to the experimental group received VCDs to achieve hemostasis, while the 39 patients who were allocated to the control group received MC. On the day of the intervention, the participants' demographic and clinical characteristics, along with their pain and discomfort levels, were recorded before they underwent the PCI. After the procedure was completed, the participants' pain and discomfort levels and any vascular complication were assessed during the 48 h CCU stay, before discharge (Fig. 1). The post-PCI vascular complications were assessed by the cardiologist who carried out the PCI and recorded them as they occurred. Then, the researchers measured the vascular complication questionnaire through the medical records and discussed these complications with the cardiologists.

Sample size considerations

Of the 85 patients who had been recruited for this study, 10 did not fulfill the inclusion criteria and two declined to participate. As the VCD is a self-payment device, the participants were free to decide whether to use the device. Finally, 73 patients were included in the analysis. G*Power v. 3.1.9.2 was used again for a post-hoc power calculation. For a sample size of 73 patients (VCD group: $n = 34$; MC group: $n = 39$), an effect size of 0.5

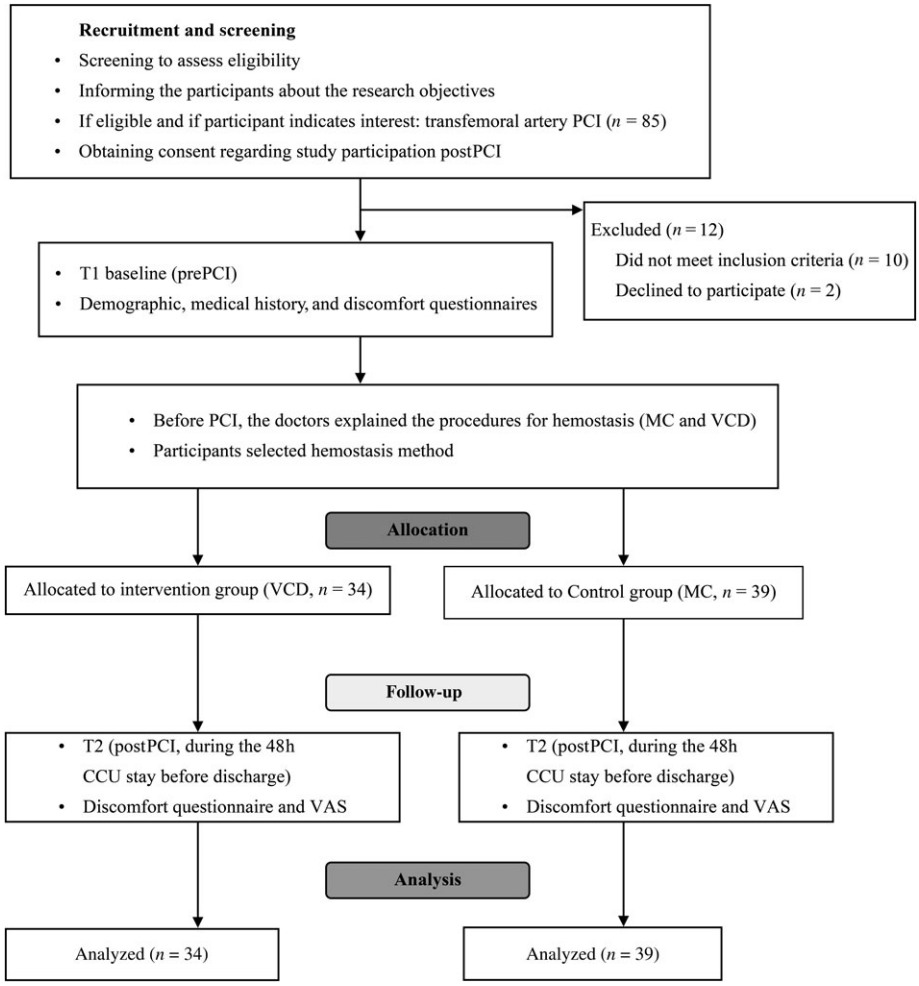

Figure 1 Flowchart of study enrolment, allocation, intervention, and data analysis. CCU, coronary care unit; MC, manual compression; PCI, percutaneous coronary intervention; T1, first questionnaire administration; T2, second questionnaire administration; VAS, visual analog scale; VCD, vascular closure device.

was determined to be detected with an α-level of 0.05 (two-sided independent *t*-test) at a power level of 0.68.

Intervention and control groups

In order to maintain as much stringency as possible, all the PCI procedures were conducted by two well-trained cardiovascular specialists. After the PCI had been completed, the arterial sheaths were removed. The patients in the intervention group received a VCD for hemostasis, while those in the control group received MC, using a 2 kg sand bag.

Outcome measures

Demographic and clinical characteristic questionnaire

This questionnaire was composed of 11 items that assessed the following: age, sex, Body Mass Index (BMI), educational level, presence of a chronic disease, medical history, arterial sheath size, duration of the PCI, postoperative anticoagulant use, whether successful hemostasis was achieved after the PCI, and the duration of bed rest.

Vascular complication questionnaire

This questionnaire was developed based on the literature review (Lee *et al.*, 2015; Robertson *et al.*, 2016) and it comprised 11 items to assess the incidence of vascular complications after a PCI, including the following items: bruising (i.e. a minor complication) and major complications, such as thrombolysis in myocardial infarction (TIMI) minimal bleeding, TIMI minor bleeding, TIMI major bleeding (measured in the volume according to the TIMI bleeding scale), hematomas of <5 cm, hematomas of > 5 cm, pseudoaneurysms, arteriovenous fistulae, retroperitoneal hematomas, femoral

neuropathy, and infection. The strategies for managing complications also were noted. The TIMI bleeding criteria, which are widely used to grade hemorrhagic episodes in patients with a myocardial infarction that is treated with fibrinolytic drugs, classify bleeds as minimal, minor, or major. Within TIMI, minimal bleeding is defined as a decrease of <3 g/dL in the hemoglobin level or <9% in the hematocrit. In contrast, TIMI minor bleeding is defined as a decrease of 3–5 g/dL in the hemoglobin level or ≥10% in the hematocrit with an obvious hemorrhage or no observed blood loss but a decrease of ≥4 g/dL in the hemoglobin level or ≥12% in the hematocrit. Finally, TIMI major bleeding refers to a decrease of >5 g/dL in the hemoglobin level or ≥15% in the hematocrit, with massive bleeding (Gibson, 2016). These vascular complications were assessed by the cardiologist who carried out the PCIs and it was noted as "yes" or "no" in the medical records.

Discomfort questionnaire

This questionnaire was composed of 18 items, of which 10 items assess the physiological aspects of discomfort and eight items assess the psychological aspects. The questionnaire that was used in the present study was developed based on the PCI discomfort questionnaire by Beattie and Geden (1990) and on a comprehensive literature review (Mohammady *et al.*, 2014). The items are rated on a 5-point Likert scale to describe the patients' experience of discomfort, with higher scores representing greater discomfort (ranging from 1 "never happened" to 5 "always happened"). The content validity of the questionnaire that was used in the present study, as assessed by a panel of five clinical experts, was 94.2%. An exploratory factor analysis was carried out on the 18 items in order to examine their interrelationships. The Kaiser–Meyer–Olkin index was 0.792, which indicated that the correlation matrix was appropriate for the factor analysis. The Eigenvalues were 3.97 and 3.11 for the factors representing the physiological and psychological aspects, respectively, confirming that both factors are relevant (i.e. both satisfied the Kaiser criterion: Eigenvalue > 1.0). The cumulative explanatory variance of these factors was 69.67%. The Cronbach's α coefficient for the entire questionnaire was 0.888 and 0.885 before and after the PCI, respectively. Furthermore, after the PCI, the Cronbach's α coefficients for the two relevant factors (i.e. physical and psychological aspects) were 0.890 and 0.738, respectively.

Pain score on the visual analog scale

The patients' subjective feeling of pain was scored on a 10 point VAS, with 0 indicating "no pain" and 10 indicating "unbearable pain" (Augustin *et al.*, 2010).

Ethical considerations

Ethical approval for this clinical study (ID: CE14046) was obtained from the institutional review board of the participating hospital that initiated this research, Taichung Veterans General Hospital, in order to ensure the safety and rights of the participants. They were well informed via letters regarding the study's aims, procedures, confidentiality, and anonymity and their human rights were fully considered at all times by the researchers. All the patients provided written informed consent for participation. They were free to continue or withdraw at any time. The study was designed and conducted in such a way as to minimize any harm and to maximize the potential benefits to the participants.

Data analysis

In order to perform the data analysis, IBM SPSS Statistics v. 22.0 (IBM Corporation, Armonk, NY, USA) was used. An alpha level of 0.05 was used for all the statistical tests, along with 95% confidence intervals (CIs). As the sample sizes of both groups were small, the Mann–Whitney U-test, χ^2-test, and independent *t*-tests were used to examine the homogeneity of the demographic data between groups. The χ^2-test and relative risk (RR) ratio were used to evaluate the risk of post-PCI vascular complications in the VCD group relative to those in the MC group. The Mann–Whitney U-test and Wilcoxon's signed-rank test were used to examine the changes in Pain VAS scores and discomfort levels following the PCI.

RESULTS

Sample characteristics

The average age of the participants in this study was 66.78 ± 11.99 years. The mean BMI was 25.77 ± 4.30 kg/m^2, and 52 (71.2%) participants were male. The Mann–Whitney U-test, χ^2-test, and independent *t*-tests revealed no significant differences in the demographic or clinical characteristics between the VCD (n = 34) and MC (n = 39) groups. Thus, the groups were homogeneous. The most common chronic diseases were hypertension and diabetes mellitus. Seven-French (Fr) arterial sheaths were most commonly used in both the VCD and MC groups (94.1% *vs* 87.2%,

respectively). For most of the participants, the duration of the PCI procedure was >60 min (84.9%, $n = 62$). The rates of success for initial hemostasis were 100% and 89.7% in the VCD and MC groups, respectively (see Table 1).

Postoperative complications of the transfemoral artery percutaneous coronary intervention

A total of 28 (38.4%) patients developed postoperative vascular complications, including 15 (44.1%) patients in the VCD group and 13 (33.3%) in the MC group. In the MC group, the major complications included hematomas > 5 cm (5.1%, $n = 2$), hematomas < 5 cm (2.6%, $n = 1$), and TIMI minor bleeding (2.6%, $n = 1$); all 13 patients had bruising. In the VCD group, the major complications included hematomas < 5 cm (5.9%, $n = 2$) and hematomas > 5 cm (11.8%, $n = 4$); all 15 patients had bruising. The χ^2-test indicated no significant differences in the incidence of major vascular complications ($P = 0.36$) or bruising ($P = 0.35$) between the MC and VCD groups. The risk of vascular complications and bruising was 32% higher in the VCD group than in the MC group (RR: 1.32; 95% CI: 0.74–2.37; $P = 0.35$), although the difference was not significant. Similarly, the major complication of hematomas > 5 cm was 1.72-fold more likely to occur in the VCD group

Table 1 General characteristics of the participants

Variable	Experimental group (VCD) ($n = 34$) Mean ± SD/N (%)	Control group (MC) ($n = 39$) Mean ± SD/N (%)	*t*-/ χ^2-value	*P*-value
Age (years)	67.12 ± 9.60	66.49 ± 13.87	–0.183*	0.855†
Sex			0.399	0.527‡
Male	23 (67.6)	29 (74.4)		
Female	11 (32.4)	10 (25.6)		
Body Mass Index	26.22 ± 3.34	25.38 ± 5.00	0.981	0.325§
Educational level			1.486	0.686‡
None	3 (8.8)	3 (7.7)		
Elementary school	11 (32.4)	8 (20.5)		
Middle school	4 (11.8)	6 (15.4)		
High school and above	16 (47.1)	22 (56.4)		
Chronic disease				
Diabetes	20 (58.8)	15 (38.5)	3.018	0.082‡
Hypertension	22 (64.7)	24 (61.5)	0.003	0.957‡
Renal insufficiency	12 (35.3)	7 (17.9)	2.838	0.092‡
Medical history			0.996	0.608‡
Oral antiplatelet drugs	22 (64.7)	26 (66.7)		
Oral anticoagulants	0 (0.0)	1 (2.6)		
Size of arterial sheath			1.927	0.382‡
6 Fr	2 (5.9)	3 (7.7)		
7 Fr	32 (94.1)	34 (87.2)		
8 Fr	0 (0.0)	2 (5.1)		
Duration of PCI procedure			0.543	0.762‡
<60 min	6 (17.6)	5 (12.8)		
60–120 min	14 (41.2)	19 (48.7)		
>120 min	14 (41.2)	15 (38.5)		
Postoperative use of anticoagulants			0.745	0.388‡
Yes	14 (41.2)	20 (51.3)		
No	20 (58.8)	19 (48.7)		
Successful hemostasis after PCI			3.689	0.055‡
Yes	34 (100.0)	35 (89.7)		
No	0 (0.0)	4 (10.3)		

† Mann–Whitney U-test; ‡ χ^2-test; § Independent *t*-test. Fr, French; MC, manual compression; PCI, percutaneous coronary intervention; SD, standard deviation; VCD, vascular closure device.

than in the MC group (RR: 1.72; 95% CI: 0.52–5.59; $P = 0.36$), although this difference was not statistically significant either. The risk of hematomas < 5 cm (RR: 2.29; 95% CI: 0.22–24.2) and hematomas > 5 cm (RR: 2.29; 95% CI: 0.45–11.76) were both 129% greater in the VCD group than in the MC group.

None of the participants required additional surgery to repair puncture wounds or to achieve hemostasis and only seven patients in total (9.6%: four in the VCD group and three in the MC group) required additional MC for hemostasis. The need for further treatment of complications did not differ significantly between groups ($P = 0.56$), although the risk was somewhat higher in the VCD group than in the MC group (RR: 1.53; 95% CI: 0.37–6.36; $P = 0.56$) (Table 2).

Effect of the vascular closure device on pain and discomfort following the percutaneous coronary intervention

Table 3 summarizes the pre- and post-PCI pain and discomfort levels. Before the PCI, the MC and VCD groups showed no significant differences in the mean Pain VAS score (2.59 ± 0.64 and 2.59 ± 0.78, respectively; $P = 0.725$) or discomfort level (19.54 ± 3.4 and 18.76 ± 2.03, respectively; $P = 0.682$). However, after the PCI, both groups showed a significant increase in the Pain VAS score (MC group: 5.00 ± 1.67; VCD group: 3.87 ± 1.02; $P = 0.002$) and discomfort level (MC group: 40.23 ± 10.64; VCD group: 26.85 ± 7.99; $P < 0.001$). Notably, the Pain VAS and discomfort levels showed substantial increases, compared with the corresponding values before the PCI, both in the MC group (differences of 2.41 and 20.69, respectively; $P < 0.001$) and in the VCD group (differences of 1.28 and 8.09, respectively; $P < 0.001$). These observations suggest that the pain and discomfort levels increased substantially following the PCI, regardless of the hemostasis method that had been applied on sheath removal. However, the discomfort level showed a greater increase in the MC group.

Further analyses also revealed that the two groups differed significantly in both physical and psychological discomfort levels ($P < 0.001$) and in the Pain VAS score ($P < 0.001$). Specifically, in the MC group, all the physical discomfort scores increased significantly after the PCI, whereas most, but not all, physical discomfort scores increased significantly in the VCD group; specifically, the VCD group showed no significant increase in the scores for a feeling of numbness in the lower limbs or shoulder pain. As for psychological discomfort after the PCI, the MC group showed a significant increase in

Table 2 Vascular complications after transfemoral artery the percutaneous coronary intervention (PCI)

Variable	Experimental group (VCD) ($n = 34$) N	%	Control group (MC) ($n = 39$) N	%	*RR*	95% CI	*P*-value
Incidence of vascular complications after PCI					1.32	0.74–2.37	0.347
Yes	15	44.1	13	33.3			
No	19	55.9	26	66.7			
Minor complications (bruising)	15	44.1	13	33.3	1.32	0.74–2.37	0.347
Major complications	6	17.6	4	10.3	1.72	0.52–5.59	0.360
TIMI: minimal bleeding	0	0.0	0	0.0			
TIMI: minor bleeding	0	0.0	1	2.6	–		
TIMI: major bleeding	0	0.0	0	0.0			
Hematoma < 5 cm	2	5.9	1	2.6	2.29	0.22–24.20	
Hematoma > 5 cm	4	11.8	2	5.1	2.29	0.45–11.76	
Pseudoaneurysm	0	0.0	0	0.0			
Arteriovenous fistula	0	0.0	0	0.0			
Retroperitoneal hematoma	0	0.0	0	0.0			
Femoral neuropathy	0	0.0	0	0.0			
Infection	0	0.0	0	0.0			
Treatment of complications							0.556
Manual compression	4	11.8	3	7.7	1.53	0.37–6.36	
Surgical wound repair	0	0.0	0	0.0			

P-values were obtained via the χ^2-test. Relative risk (RR) ratio was used to evaluate the risk of post-PCI vascular complications in the VCD group, relative to those in the MC group. –, not applicable; MC, manual compression; TIMI, thrombolysis in myocardial infarction; VCD, vascular closure device.

Table 3 Changes in the pain and discomfort levels following the percutaneous coronary intervention (PCI)

Variable	Experimental group (VCD) (n = 34)			Control group (MC) (n = 39)		
	Before PCI Mean (SD)	After PCI Mean (SD)	P-value	Before PCI Mean (SD)	After PCI Mean (SD)	P-value
Pre-PCI Pain VAS score (1–10)	2.59 (0.78)			2.59 (0.64)		0.725†
Post-PCI Pain VAS score (1–10)	3.87 (1.02)			5.00 (1.67)		**0.002****,†
P-value	**<0.001*****,‡			**< 0.001*****,‡		
Pre-PCI discomfort level (1–5)	18.76 (2.03)			19.54 (3.40)		0.682†
Post-PCI discomfort level (1–5)	26.85 (7.99)			40.23 (10.64)		**<0.001*****,†
P-value	**<0.001*****,‡			**<0.001*****,‡		
Physical aspects	10.32 (1.30)	16.21 (6.30)	**<0.001*****,‡	10.95 (2.80)	27.18 (6.20)	**<0.001*****,‡
I feel pain in my back	1.59 (0.50)	1.94 (0.90)	**0.048***,‡	1.44 (0.60)	4.13 (1.00)	**<0.001*****,‡
I feel pain at the PCI puncture site	0.00 (0.00)	1.68 (0.80)	**<0.001*****,‡	0.00 (0.00)	2.67 (1.00)	**<0.001*****,‡
I feel numbness in my lower limbs	1.29 (0.60)	1.29 (0.50)	1.000‡	1.31 (0.50)	1.95 (1.00)	**0.001****,‡
My shoulder feels painful	1.09 (0.40)	1.26 (0.50)	0.145‡	1.08 (0.30)	1.92 (1.20)	**<0.001*****,‡
My body feels stiff	1.06 (0.20)	1.29 (0.50)	**0.033***,‡	1.10 (0.30)	2.23 (1.30)	**<0.001*****,‡
I have difficulty in urinating	0.97 (0.20)	1.97 (1.00)	**<0.001*****,‡	1.10 (0.30)	3.77 (1.20)	**<0.001*****,‡
I feel inconvenience in eating and drinking	1.00 (1.00)	1.50 (0.50)	**<0.001*****,‡	1.28 (1.60)	2.54 (1.00)	**<0.001*****,‡
I have trouble sleeping	1.06 (0.20)	2.38 (3.50)	**<0.001*****,‡	1.00 (0.00)	2.85 (1.20)	**<0.001*****,‡
My back feels sweaty and uncomfortable	1.26 (0.40)	1.56 (0.70)	**0.020***,‡	1.36 (0.70)	2.90 (1.10)	**<0.001*****,‡
Psychological aspects	8.44 (1.00)	10.65 (3.40)	**<0.001*****,‡	8.59 (1.30)	13.05 (5.00)	**<0.001*****,‡
I feel restless	1.03 (0.20)	1.15 (0.40)	0.157‡	1.05 (0.20)	2.31 (1.40)	**<0.001*****,‡
I have low self-esteem	1.00 (0.00)	1.18 (0.40)	**0.014***,‡	1.08 (0.40)	1.51 (0.90)	**0.004****,‡
I feel weakness and powerless	1.00 (0.00)	1.06 (0.20)	0.157‡	1.00 (0.00)	1.15 (0.70)	0.102‡
I am afraid of complications	1.12 (0.30)	1.44 (0.70)	**0.008****,‡	1.28 (0.60)	2.03 (2.20)	**0.001****,‡
I have feelings of suffering and being punished	1.09 (0.30)	1.85 (1.80)	**0.003****,‡	1.05 (0.20)	2.03 (1.10)	**<0.001*****,‡
I worry that my walking ability might be affected	1.15 (0.40)	1.41 (1.00)	0.129‡	1.10 (0.30)	1.56 (0.90)	**0.001****,‡
I worry that I may not be able to lift heavy objects in the future	1.03 (0.20)	1.12 (0.30)	0.083‡	1.03 (0.20)	1.26 (0.50)	**0.007****,‡
I worry I may need to take time off from work	1.03 (0.20)	1.44 (1.70)	0.066‡	1.00 (0.00)	1.21 (0.50)	**0.023***,‡

*P < 0.05, **P < 0.01, and ***P < 0.001. † Mann–Whitney U-test; ‡ Wilcoxon's signed-rank test. The Pain VAS score was measured on a 10 point scale. Discomfort level was measured on a 5 point scale. Bold values mean significant. MC, manual compression; PCI, percutaneous coronary intervention; SD, standard deviation; VAS, visual analogue scale; VCD, vascular closure device.

most scores (except those for feelings of weakness and powerlessness), whereas the VCD group showed a significant increase in only some scores (no significant increase was noted for the scores describing feelings of weakness or powerlessness, worrying that the walking ability might be affected, worrying about not being able to lift heavy objects in the future, and worrying about having to take time off from work).

Overall, the results indicated that the most common postoperative causes of physiological discomfort were back pain, dysuria, difficulty in sleeping, and an inability to rest adequately. In contrast, psychological discomfort was caused by a fear of complications, feeling of weakness, concern about the inability to carry heavy objects in the future, trembling, and uneasiness.

DISCUSSION

The mean BMI of the participants in this study was 25.77 ± 4.30 kg/m^2, which is classified as overweight. Similar results were found in the study by Theodos *et al.* (2013), which indicates that overweight or obese patients are more prone to having CAD. It was found that the most common comorbidities among the PCI patients were hypertension (63.0%, n = 46) and

diabetes mellitus (47.9%, $n = 35$), echoing the findings of Iqtidar *et al.* (2011) and Theodos *et al.* (2013). Finally, in this study population, the arterial sheath diameter that was most commonly used for the transfemoral PCI was 7 Fr, which is consistent with the results of Stegemann *et al.* (2011), who found that sheath diameters of ≥7 Fr often were used for cardiovascular catheterization. Using an arterial sheath with a larger diameter can increase the ease and speed of the PCI but also can increase the risk of vascular complications (Amoroso, Laarman, & Kiemeneji, 2007).

In the current study, the VCDs achieved a successful initial hemostasis in 100% of the patients, whereas MC achieved a hemostasis rate of only 89.7%. This result is consistent with those of the studies that were conducted by Liao and Su (2015), Sciahbasi *et al.* (2009), and Wong *et al.* (2009), which showed that, compared to MC, the VCDs facilitated earlier hemostasis after a PCI. Therefore, although both methods can achieve hemostasis after a transfemoral PCI, the VCDs appear to have better efficacy than does MC.

This study found that neither the VCDs nor MC demonstrated a significant association with vascular complications, which is consistent with the findings of several individual studies (Das *et al.*, 2011; Elmasri *et al.*, 2017; Scott *et al.*, 2018; Stegemann *et al.*, 2011), as well as those of a systematic review of 11 studies (120,742 patients) from Western nations, all of which reported significant differences between MC and VCDs in the incidence of vascular complications, such as bleeding, hematomas, pseudoaneurysms, and arteriovenous fistulae (Liao & Su, 2015). The present study also showed that the risk of major vascular complications, bruising, and hematomas was slightly greater in the VCD group than in the MC group. This observation is consistent with the findings of Hermiller *et al.* (2015) and Stegemann *et al.*, (2011) who reported that VCD use incurs a higher risk of hematomas than does MC. Conversely, Stegemann *et al.* (2011) found that MC, rather than VCDs, might have a significantly higher risk of pseudoaneurysms. Iqtidar *et al.* (2011) also reported a lower incidence of hematomas ≥ 10 cm in the VCD group than in the MC group (1.1% *vs* 2.1%; $P < 0.01$). Thus, it is suggested that clinical healthcare workers carefully monitor PCI patients for vascular complications, regardless of the hemostasis method. Further large-scale studies that involve multiple centers or countries are recommended to clarify the institutional and regional differences in hemostasis outcomes on sheath removal after a PCI.

This study found that the transfemoral PCI patients who received VCDs exhibited less pain and discomfort than did those who received MC. These findings are supported by the observations that were reported in the following studies. Martin *et al.* (2008) used a 1–4-point VAS to measure discomfort among 200 transfemoral PCI patients and found that those patients who received VCDs had lower discomfort levels at discharge ($P < 0.01$) and reported less inconvenience caused by bed rest ($n = 200$). Chair *et al.* (2012) found that early ambulation after a PCI might reduce back pain and urinary discomfort. In a systematic review of 34 randomized studies (14,401 patients), Cox *et al.* (2015) found that VCDs shortened the time to hemostasis and helped to promote earlier ambulation ($P < 0.05$) among transfemoral PCI patients. Overall, VCD use seems to be associated with a significantly shorter hemostasis time, time to ambulation, and time to discharge, compared to the values that have been noted for MC (Hermiller *et al.*, 2015), which is particularly relevant because all these aspects contribute to increasing patient comfort (Wu, Dai, Kao, Chang, & Lou, 2015).

Watkins *et al.* (2013) proposed that anxiety or depression can influence cardiac recovery and the outcomes of PCI; thus, psychological discomfort following a PCI should not be ignored. In this study, it was found that both the physiological and psychological aspects of postoperative discomfort increased after the PCI. This observation might be related to the fact that surgery, hospitalization, and a lack of knowledge of the outcomes are major sources of anxiety and stress for patients, which might increase their discomfort (Lombardo *et al.*, 2013). A further analysis showed that, following the PCI, all physical discomfort items increased significantly in the MC group. The same was true for the VCD group, except for the scores regarding the feeling of lower-limb numbness or shoulder pain, which did not increase. A possible reason for these results is that VCDs allow for a shorter bed rest period (Martin *et al.*, 2008) and earlier ambulation (Rezaei-Adaryani *et al.*, 2009), which can reduce discomfort (Martin *et al.*, 2008) and back pain (Chair *et al.*, 2012), as well as increase comfort (Rezaei-Adaryani *et al.*, 2009) after a transfemoral PCI. However, as most of the studies only used the Pain VAS score (Chair *et al.*, 2012; Robertson *et al.*, 2016; Sciahbasi *et al.*, 2009), voiding difficulty (Chair *et al.*, 2012; Mohammady *et al.*, 2014; Sciahbasi *et al.*, 2009), and difficulty while eating (Mohammady *et al.*, 2014; Robertson *et al.*, 2016; Sciahbasi *et al.*, 2009) as indicators of physical discomfort, carrying out detailed comparisons between

this study's findings and those of previous studies was difficult. This study's findings showed that VCDs can decrease discomfort, not only in terms of the three aspects previously reported (i.e. pain, voiding difficulty, and difficulty while eating), but also in terms of lower-limb numbness and shoulder pain.

As for the psychological aspects of discomfort, neither group experienced feelings of weakness or powerlessness after the transfemoral PCI. However, unlike in the MC group, certain scores of psychological discomfort did not increase in the VCD group following the PCI, including the scores for feelings of restlessness (Cronqvist, Wredling, Nordlander, Langius, & Björvell, 2000), worrying about the effect on walking ability (Trotter, Gallagher, & Donoghue, 2011), worrying about not being able to lift heavy objects in the future (Trotter *et al.*, 2011), and worrying about having to take time off from work (Delewi *et al.*, 2017). These findings indicated that VCDs might help in limiting these four aspects of psychological discomfort. As research on psychological discomfort in this population is very limited, it is suggested that other forms of psychological discomfort that are experienced in conjunction with a PCI be considered in the future. Moreover, it is recommended that further studies use appropriate measurement tools to evaluate pain levels and discomfort among transfemoral PCI patients in order to obtain a better understanding of their real feelings and nursing care needs. The current findings might help clinical care workers to provide more appropriate, individualized, and thus higher quality care to PCI patients.

Batiha, Abu-Shaikha, Alhalaiqa, Jarrad, & Abu Ramadan (2016) proposed that the removal of the sheath during post-PCI care should be considered among the responsibilities of critical care nurses. However, the monitoring and management of post-PCI complications require the involvement of not only nurses, but also other health professionals; such a team would use critical assessment skills to anticipate and detect any vascular problem, allowing them to manage PCI complications at the earliest possible opportunity. Studies have revealed that the standardization of postoperative PCI nursing care can significantly reduce the incidence of vascular complications and improve patient comfort (Gonzales, Fields, McGinty, & Gallo, 2010; Klemsová & Žiaková, 2014). Therefore, regardless of the hemostasis method used on sheath removal after a transfemoral artery PCI, it is recommended that nurses, clinical doctors, and other care providers closely and thoroughly evaluate the patients' clinical situation, including their physiological or psychological discomfort, in order to facilitate the early detection and treatment of complications. This approach will ensure that the patients receive the best-quality health care.

Implications for clinical practice

Compared to MC, VCD use is an effective hemostatic modality that results in early ambulation and reduced pain and discomfort among Chinese patients undergoing a transfemoral artery PCI. Thus, using VCDs could be beneficial for achieving early ambulation and improving the comfort of patients undergoing a PCI, which also would help hospitals to improve bed rotation logistics for such patients. A dedicated discomfort questionnaire, which included physiological and psychological factors, was developed for this study in order to improve the assessment of the psychological discomfort of PCI patients. However, as bleeding and vascular complications can still occur with the use of VCDs, clinical nurses should carefully monitor the vital signs and potential complications, such as puncture site bleeding, to help the patients achieve early ambulation and reduce discomfort. This study's results can help nurses and doctors to understand the hemostatic effects of VCDs, as well as the associated patient discomfort and pain levels, which can be applied to improve the quality of clinical care. These findings also can be used as a reference for developing postoperative care or nursing standards for the management of PCI patients.

Limitations of the study

This study has several limitations. Specifically, the data were collected solely from two large hospitals in Taiwan and the sample was rather small. Thus, generalization of these results might be premature. The patients also had the right to select a particular hemostasis method, which precluded them from being blinded to the group allocation scheme, which might have introduced some bias during data collection.

CONCLUSION

Following a transfemoral artery PCI, the pain and discomfort levels increased, regardless of the hemostasis method that was used on sheath removal. Compared to MC, the use of VCDs led to better hemostasis, less postoperative pain, and lower levels of physical and psychological discomfort. Although neither method was associated with an increased incidence of vascular complications, a non-negligible risk remains. Under these

circumstances, nurses and medical professionals are in a vital position to assess, detect, prevent, and manage post-PCI complications at the earliest time, as well as to plan strategies to minimize the risk of such complications and discomfort. As a result of a lack of relevant studies on the discomfort of PCI patients, it is recommended that large-scale, multicenter, randomized, double-blind, transnational trials be conducted in Western countries with Chinese populations to allow for a comparison to be made with the obtained outcomes of this study.

DISCLOSURE

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

S-F. S. and Y-C. L. designed the study; S-F. S., M-Y. C., M-S. W., and Y-C. L. collected and analyzed the data; S-F. S., M-S. W., and Y-C. L. prepared the manuscript. All the authors reviewed the manuscript critically and approved its final version.

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