ORIGINAL ARTICLE





Effectiveness of vialon biomaterial versus teflon catheters for peripheral intravenous placement: A randomized clinical trial

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Abstract

Aim: This study was to determine the effects of the two types of catheter material (vialon biomaterial and teflon) on pain intensity, dwell time, and phlebitis score for peripheral intravenous catheter (PIVC) placement.

Methods: Participants (N = 208) were randomly assigned to the vialon biomaterial group (n = 104), the teflon group (n = 104). After the PIVC placement, the intensity of pain and phlebitis score were evaluated. Catheter dwell mean time was determined.

Results: The pain intensity scores were similar immediately after inserting the PIVC. No difference was observed between the pain scores in both groups $(p \ge .050)$. Catheter dwell mean time for the vialon biomaterial catheter group $(4.72 \pm 1.20 \text{ days})$ was significantly longer compared to the teflon catheter group $(4.10 \pm 0.92 \text{ days})$ $(p \le .001)$. It was determined that the catheter was removed due to phlebitis development in 16.3% of the vialon biomaterial catheter group and 53.8% of the teflon catheter group. An advanced level of statistically significant difference was found between the two groups in terms of phlebitis development scores $(p \le .001)$.

Conclusions: This study concluded that vialon biomaterial catheter (BD InsyteTM AutoguardTM BC winged) demonstrates longer dwell time of PIVC, lower phlebitis rate and phlebitis score than teflon catheter (BD VenflonTM).

KEYWORDS

dwell duration, nursing, pain, peripheral intravenous catheter, phlebitis

1 | INTRODUCTION

As a result of the developments in technology and scientific knowledge, many interventions have been implemented to diagnose and treat individuals in healthcare services (Ay, 2011; Uzun, 2012). For the efficacy of intravenous (IV) intervention, which is very important for the effect and administration of the treatment, the peripheral intravenous catheter (PIVC) is inserted into the vein. PIVC placement is one of the most

common and the highest rate of invasive nursing interventions (Keleekai et al., 2016; Mihala et al., 2018). Studies report that more than 70% of inpatients are treated via PIVCs (Anabela, Pedro, & Pedro, 2012; Atay, Şen, & Cukurlu, 2018; Mihala et al., 2018; Pires Nobre & Da Silva Martins, 2018; Uzun, 2012). It is essential that PIVCs are safely used for the long term and without any complications. Many complications (such as pain, phlebitis, extravasation and hematoma, colonization etc.) may develop due to damaging the endothelial layer during

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PIVC placement, or lacking administration of PIVC care (Mihala et al., 2018; Palese et al., 2016). These complications and undesirable signs increase the risk of infection in individuals, threaten their safety, increase the duration of hospitalization and increase the cost of health care by causing redundant labor and material expenditures in healthcare institutions (Abadi, Etemadi, & Abed, 2013; Mermel, 2017; Palese et al., 2016).

1.1 | Background

The Centers for Disease Control and Prevention (CDC) and Infection Prevention Society prepared *Safe Application Guidelines* (Guidelines for the Prevention of Intravascular Catheter-Related Infections) for safe PIVC administration and minimization of complications. In this *Guidelines* it was stated that a catheter may be used safely up to 72–96 hr if the appropriate vein and vehicle are selected in adults for PIVC administration. In addition, this *Guidelines* suggest the surgical asepsis principle is taken into consideration during and after the intervention and that it is not necessary to replace it if phlebitis signs are not observed based on 8-hr evaluations (Abbas, Shaw, & Abbas, 2007; Hadaway, 2009; CDC, 2011; O'Grady et al., 2011; Dychter, Gold, Carson, & Haller, 2012; INS, 2017).

In this subject, Enes, Opitz, Faro, and Pedreira (2016) reported that 19.7% of PIVCs inserted to patients could remain up to over 96 hr and 31.1% had phlebitis. In addition, Roca et al. (2012) determined that PIVC (closed system valve and apparatus can be inserted in teflon), frequently used in clinics, could be used for up to 96 hr without signs/findings of phlebitis. In the literature it is reported that besides the knowledge and skill of the nurse who will perform the intervention, physicochemical characteristics of the catheter (biomaterial, number, length, etc.), the location of insertion site, the properties of the drug/solution applied (type, flow rate, density, etc.), the dwell time of the catheter, the type of medical dressing used, and the failure to apply surgical aseptic principles both during intervention and daily care are also effecting the development of phlebitis signs (Abbas et al., 2007; Çakar, 2008; Çelik & Anıl, 2004; INS, 2017; Mimoz et al., 2015; Tagalakis, Kahn, Libman, & Blostein, 2002; Uslusoy & Mete, 2008).

Vialon biomaterial catheter (manual control with closed valve and system) developed in the biomedical market helps optimize patient care and improves and clinical outcomes (especially dwell time, and phlebitis score). This vialon biomaterial catheter is thin-walled, hard during insertion, and soft when placed in the body. In addition this material has less irritant effect on vein

endothelial cells, decreases risk of thrombocyte adherence and bacterial colonization of catheter walls. Özsaraç et al. (2012) found that patients with vialon biomaterial catheters had lower pain intensity compared to a teflon catheter, and had a higher success rate for initial insertion into the vein. Salgueiro-Oliveira, Parreira, and Veiga (2012) determined that the mean dwell time of the catheter was 3.88 days in patients with vialon biomaterial PIVC. In another study by López et al. (2014), the mean dwell time of the vialon biomaterial catheters with a closed system (equipped with needle-free interference apparatus) was found to be 6.02 days, and the dwell time of the vialon catheters with an open system (equipped with three-way stopcock) was found to be 4.12 days. In addition, the researchers reported that the vialon biomaterial catheters had a lower risk for the development of phlebitis. Karadağ and Görgülü (2000) determined that phlebitis developed in 24% of patients who had a vialon biomaterial catheter (open system). Gupta, Mehta, Juneja, and Trehan (2007) found that vialon biomaterial PIVCs could be safely used up to 5 days without any signs of phlebitis and that half of the patients (49%) started to develop phlebitis after day 5. López et al. (2014) found that phlebitis development was detected only in 12% of the patients who had a vialon biomaterial PIVC.

Teflon catheters are widely used in spite of wellestablished clinical benefits (pain intensity, dwell time, and incidence of phlebitis) of vialon biomaterial PIVC. The reason for this situation may be explained that teflon PIVCs are made of fluorinated ethylene propylene (FEP-teflon), and can be produced at economical cost in the industrial market. Thus, the teflon catheter has a more affordable price than vialon biomaterial PIVC (approximately four times in USA dollars) and is government funded. However, catheters made of polyurethanes (PEU-vialon), have a smoother microsurface, are thermoplastic and more hydrophilic, making it much more flexible than teflon at body temperature, and have high costs and sales values. López et al. (2014) determined that using vialon biomaterial catheters with closed systems reduced episodes of phlebitis and risk of infection at a cost of only €0.09/day. When PIVCs are replaced based on clinical indication, vialon biomaterial PIVCs last for up to 144 hr without increased risk and with significant cost savings (€786,257/year/1,000 beds).

According to a review of the literature, there are few studies about comparing the two types of catheter material (vialon biomaterial and teflon) on pain intensity, dwell time, and development of phlebitis. There are no studies showing pain intensity, dwell time, phlebitis score for sequential times, and microbiological analysis in the same patient group. In this context, we planned to examine the clinical efficiencies of teflon-based products

versus vialon biomaterial catheters (manually controlled, with closed valve and system) that are frequently preferred in clinics for PIVC administration.

1.2 | Research hypotheses

Research Hypothesis (H)1. Vialon biomaterial catheter (manual control and closed valve and system) has lower pain intensity compared to teflon-based product.

Research Hypothesis (H)2. Dwell time of vialon biomaterial catheter (manual control and closed valve and system) is longer than the teflon-based product.

Research Hypothesis (H)3. Phlebitis score and bacterial colonization rate of vialon biomaterial catheter (manual control and closed valve and system) is lower than the teflon-based product.

2 | METHODS

2.1 | Study design

A prospective, randomized controlled trial design was used to determine the effects of the two types of catheter material (vialon biomaterial and teflon) on pain intensity, dwell time, and phlebitis score for PIVC placement. The primary outcome was dwell time, phlebitis score, and bacterial colonization of the PIVC. Secondary outcomes included technique-related pain scores.

2.2 | Setting and sample

The study was conducted in December 2016-November 2017 in the surgery clinic of Yozgat Bozok University Hospital in Yozgat, Turkey. The participants consisted of hospitalized patients who met the following inclusion criteria: (a) being older than 18 years of age; (b) not having any problem related to state of consciousness and sensory organs; (c) the absence of peripheral vascular disease; (d) not being morbidly obese according to the body mass index (BMI) classification made by the WHO (BMI < 40 kg/ m²) (WHO, 2013); (e) lack of hospitalization in the last month; (f) visible and/or identifiable veins through inspection and palpation; (g) lack of any value in the blood that indicates infection or bleeding (leukocytes, platelets, etc.); (h) insertion of PIVC by the researcher for the first time; (i) similar treatment protocol order by the physician in the postoperative period (nonopioid analgesics: paracetamol 10 mg/mL flacon., diclomec 3 mL/75 mg ampule, single or dual broad-spectrum antibiotic therapy: Equiceft 0.5 g flacon., Sulbactam 0.5 g flacon., Tazacin 4.5 g flacon., Cipro 400 mg/200 mL flacon.); (i) dwell time of catheters for at least 48 hr without phlebitis; (j) avoiding IV administration of blood and elements or total parenteral nutrition products; and (k) lack of vehicle that increases the risk of colonization (three-way stopcock, etc.). Exclusion criteria included the following: pregnant women and women with suspicion of pregnancy, patients who underwent outpatient surgery, abnormalities of coagulation, hematological or oncological and allergic diseases, or any incision or scar tissue at the IV area.

2.2.1 | Randomization

Based on similar studies in the literature, the number of samples was calculated on the basis of 95% confidence interval, 0.80 power level, 0.05 error level, 0.25 effect level and a total of 120 patients were determined to be included in the sampling (Gupta et al., 2007; Karadağ & Görgülü, 2000; Özsaraç et al., 2012; Pasalioğlu & Kaya, 2014; Roca et al., 2012; Uslusoy & Mete, 2008). The patients were evaluated according to the inclusion criteria and invited to participate in the study if found to be eligible. Overall, the research sample comprised 208 patients: 104 in the vialon biomaterial catheter group, and 104 in the teflon cathegroup (routine method). A computer-based random number generator appointed the groups. The flow diagram created by the researchers was based on the information obtained from a CONSORT (Consolidated Standards of Reporting Trials) statement (see Figure 1).

2.2.2 | Intervention

All patients were inserted with PIVC in the preoperative period, during the 08:00–16:00 hours shift, in their beds, by the researcher nurse (registered nurse with 8 years experience) (Acaroğlu, Şendir, & Kaya, 2012; Craven & Hirnle, 2009; http://catalog.bd.com). Before inserting the PIVCs, no topical anesthetic was used, as it is not the standard practice of the clinic. In patients in the vialon biomaterial catheter (BD InsyteTM AutoguardTM BC winged) group, according to the manufacturer instructions, if the piston tip was covered with blood upon insertion into the vein, the tourniquet was unwound by the active hand and the needle was pulled inside by a manual controlled button on the catheter without manual fixing and the mandrel was advanced. In patients in the teflon catheter

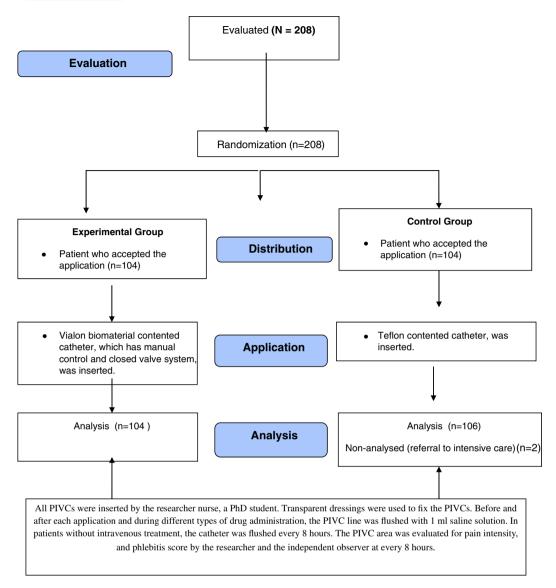


FIGURE 1 Research design (Consolidated Standards of Reporting Trials, 2010).

(BD VenflonTM) group, according to the manufacturer instructions, upon insertion into the vein, the plastic cannula of the PIVC was fixed by the passive hand while it was advanced within the vein, while the mandrel was removed by the active hand and the catheter inlet was covered (http://catalog.bd.com). After inserting the PIVC, the same research nurse applied transparent, self-adhesive, semi-permeable dressings made of polyurethane film (Tegaderm; 3M, St Paul, MN, USA) for both groups. All PIVCs were flushed with 1 mL of ready-to-use injectable saline solution (BD PosiFlushTM) before the administration prior to, during and after different types of treatment. In addition, flushing was repeated with 1 mL at 8-hr intervals in the patients who did not receive IV treatment during the day. According to Safe Application Guidelines (Guidelines for the Prevention of Intravascular Catheter-Related Infections), two types of catheters were not removed unless there were any complications

determined before 72–96 hr or the occurrence of any clinical reasons. Pain intensity was determined immediately after inserting the PIVC. In addition, independent observer nurses assessed phlebitis scores at 8-hr intervals. Catheter indwell times were monitored. Catheters of patients with phlebitis development were sent to the microbiology laboratory for examination of bacterial colonization.

2.2.3 | Measurements

Various patient characteristics were collected for both groups, including age, gender, BMI, having chronic disease, and current medical diagnosis. Weight and height were determined by using a platform scale and BMI was calculated by the researcher nurse. Also pain intensity and phlebitis scores were assessed.

2.2.4 | Visual analog scale

The pain was assessed by visual analog scale (VAS). The VAS is a unidimensional measure of pain intensity. Pain intensity was measured by using a 10 cm VAS, where 0 was representation of the absence of pain and 10 equated to extreme pain. Immediately after PIVC insertion, the other observer nurse asked patients about the pain intensity experienced by the patients regarding the intervention.

2.2.5 | Visual infusion phlebitis assessment scale (VIPS)

Phlebitis scores were determined with the VIPS. The VIPS is a validated visual tool used to determine the phlebitis score in patients following IV infusion (Kuş & Büyükyılmaz, 2018). This scale provides a numerical rating based on observable phlebitis symptoms (e.g., pain, pallor, erythema, swelling, and induration). According to each rating score, this scale recommends specific actions for healthcare providers (see Table 1). The standardized use of this scale eliminates catheter dwell time as a prominent variable when changing peripheral IV sites. The scores range from 0 (absence of phlebitis) to 5 (the presence of advanced thrombophlebitis) (Gallant & Schultz, 2006).

2.3 | Statistical analysis

The data were analyzed by using Statistical Package for the Social Sciences® for Windows® version 21.0 (IBM Corp., Armonk, NY, USA). The demographic and outcome variables (PIVC dwell time, VAS, and VIPS scores for both groups) were analyzed using frequency distributions for the categorical variables and means and standard deviation for the continuous variables. The Chi-square test was used to examine differences between the categorical variables. The independent sample t test was used to assess any differences in the continuous variables. The VIPS scores from the two nurses were analyzed for differences, and a concordance coefficient was calculated. A comparison of the VIPS scores for five sequential times for the two groups was conducted using analysis of variance (ANOVA) for repeated measures. Statistical significance was set at a p value of \leq .050. The Friedman test was used in the advanced analysis of repeated follow-ups and Bonferonni correction was used for the assessment of the difference between two means.

TABLE 1 Visual Infusion Phlebitis Assessment Scale (VIPS)

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Grades	Typical symptoms of phlebitis	Recommendations	
0	No signs of phlebitis	Observe cannula	
1	One of the following is evident: • slight pain near IV site or • slight redness near IV site	Possible first signs Observe cannula	
2	Two of the following are evident: Pain at IV site • erythema • swelling	Early stage of phlebitis Resite cannula	
3	All of the following signs are evident: • pain along path of cannula • erythema • induration	Mid-stage of phlebitis Resite cannula and consider treatment	
4	All of the following signs are evident and extensive: pain along path of cannula erythema induration palpable venous cord	Advanced stage of phlebitis or start of thrombophlebitis Resite cannula and consider treatment	
5	All of the following signs are evident and extensive: • pain along path of cannula • erythema • induration • palpable venous cord • pyrexia	Advanced stage of thrombophlebitis Initiate treatment	

2.4 | Ethical consideration

Permission to conduct this research was received from the local Hospital Ethics Committee (Number: June 28, 2016/58) and Institution (Number: 16142545–903.99/e.353). Before the study, all patients were informed of the purpose of the research and were assured of their right to refuse to participate or to withdraw from the study at any stage.

3 | RESULTS

3.1 | Patients, treatment, and PIVC characteristics

A total of 208 patients participated in the study (119 women, 89 men; mean age 43.39 ± 10.69 years, mean BMI 26.92 ± 3.83 kg/m²). In addition, patients were hospitalized for a mean of 5.37 ± 2.35 days, 79.8% of patients were determined not to have chronic disease

TABLE 2 Comparison of patient characteristics (N = 208)

Characteristics	Vialon biomaterial catheter group $(n = 104)$	Teflon catheter group (n = 104)	Total groups (N = 208)	Statistical tests and <i>p</i> value
Age, year, mean (SD) [range]	43.55 (10.55) [22–64]	43.20 (10.66) [22–64]	43.39 (10.69) [22–64]	t = 0.267 $p = .790$
Gender, <i>n</i> (%)				
Female	60 (57.7)	59 (56.7)	119 (57.2)	$\chi^2 = 0.000$
Male	44 (42.3)	45 (43.3)	89 (42.8)	p = 1.000
Body mass index, kg/m², mean (SD) [range]	26.55 (3.42) [19.25–34.58]	27.29 (4.19) [18.47–34.58]	26.92 (3.83) [18.47–34.58]	t = 1.400 p = .163
Average length of hospitalization days, mean (SD) [range]	5.12 (1.85) [3–13]	5.63 (2.75) [3–21]	5.37 (2.35) [3–21]	t = 1.564 $p = .119$
The presence of chronic disease, n	(%)			
Yes	18 (17.3)	24 (23.1)	42 (20.2)	$\chi^2 = 0.746$
None	86 (82.7)	80 (76.9)	166 (79.8)	p = .388
Type of operation patient underwent, n (%)				
Total arthroplasty	82 (78.8)	79 (76.0)	161 (77.4)	$\chi^2 = 0.110$
Hemiarthroplasty	22 (21.2)	25 (24.0)	47 (22.6)	p = .740

Note: p > .05 SD, standard deviation.

and 77.4% of the patients had total arthroplasty surgery (Table 2). Table 3 describes treatment characteristics that included the postoperative period of the sample: 53.8% of patients were administered PIVC (22 gage) at the inner face of the forearm (37.5%) or antecubital (28.8%) and dosiflow was substantially used (97.4%) as the fluid regulator (Table 4). No significant differences were found between the two groups with respect to any of the individual, treatment and catheter characteristics in the postoperative period (p > .05).

3.2 | Outcome measures

Research Hypothesis 1. Pain intensity score immediately after inserting the PIVC.

The VAS scores immediately after inserting the PIVC for both groups are provided in Table 5. In the vialon biomaterial catheter group, the mean pain intensity was 2.74 ± 2.18 and 3.04 ± 1.86 in the teflon catheter group. For both groups, VAS showed similar pain intensity scores immediately after inserting the PIVC. No difference was observed between the pain scores in both groups (p > .050). Therefore, *Research Hypothesis 1* was not confirmed.

Research Hypothesis 2. PIVC dwell time.

The PIVC dwell time of the two groups is shown in Table 6. In the majority of patients in the vialon biomaterial catheter group (54.8%) the dwell time was 96 hr and over, while it was 73–95 hr in the teflon catheter group

(45.2%). In addition, only a few (27.9%) PIVCs came to 96 hr and over in the teflon group. Catheter dwell mean time for the vialon biomaterial catheter group (4.72 \pm 1.20 days) was significantly longer compared to the teflon catheter group (4.10 \pm 0.92 days) ($p \le$.001) (Table 6). As a result, the PIVC dwell time of the vialon biomaterial catheter group was longer than the teflon group. Thus, *Research Hypothesis 2* was confirmed.

Research Hypothesis 3. PIVC phlebitis score.

It was determined that the catheter was removed due to phlebitis development in 16.3% of the vialon biomaterial catheter group and 53.8% of the teflon catheter group. An advanced level of statistically significant difference was found between the two groups in terms of phlebitis development ($p \le .001$) (Table 7). In addition, VIPS assessed the PIVC phlebitis score. The interclass correlation coefficient of VIPS related to intra-observer concordance in phlebitis follow-up was found to be statistically significantly higher in all measurements with 0.925, 0.925, 0.894, 0.844, 0.812, respectively ($p \le .001$). For both groups, VIPS showed similar phlebitis scores at 0-24 hr and 25-48 hr. No difference was observed between the phlebitis scores in these measurement times in both groups (p > .050). In addition, in the teflon catheter group phlebitis scores were higher than the vialon biomaterial group at 49-72 hr, 73-95 hr, and 96 hr and over. The repeated measures ANOVA test showed statistically significant differences in phlebitis scores measured with VIPS between the two groups at 49-72 hr, 73-95 hr, and 96 hr and over ($p \le .01$). In particular, the phlebitis score

TABLE 3 Comparison of patients' treatment characteristics (N = 208)

Treatment characteristics	Vialon biomaterial catheter group (n = 104)	Teflon catheter group $(n = 104)$	Total groups (N = 208)	Statistical tests and p value
Type of drug, n (%)				
Broad-spectrum antibiotics	17 (9.6)	31 (29.8)	48 (23.1)	$\chi^2 = 5.362$
Fluid replacement (infusion)	33 (39.4)	29 (27.9)	62 (29.8)	p = .069
Fluid replacement (infusion) + broad-spectrum antibiotics	54 (51)	44 (42.3)	98 (47.1)	
Daily drug administration frequency	y, n (%)			
1-3 times/day	52 (50.0)	48 (46.2)	100 (48.1)	$\chi^2 = 1.487$
4-6 times/day	45 (43.3)		89 (42.8)	p = .475
7 times and more/day	7 (6.7)	1,211.5	19 (9.1)	
Type of fluid, n (%)				
0.9% NaCl	60 (57.7)	52 (50.0)	112 (53.8)	$\chi^2 = 5.829$
Isolyte	21 (20.2)	18 (17.3)	39 (18.8)	p = .120
Isolyte M	5 (4.8)	15 (14.4)	20 (9.6)	
Isolyte S	18 (17.3)	19 (18.3)	37 (17.8)	
Total amount of fluid received in 24	hr, n (%)			
0–999 mL	21 (20.2)	21 (10.6)	42 (20.2)	$\chi^2 = 1.638$
1,000-1,999 mL	45 (43.3)	53 (51.0)	98 (47.1)	p = .651
2,000-2,999 mL	25 (24.0)	19 (18.3)	44 (21.2)	
3,000 mL and above	13 (12.5)	11 (10.6)	24 (11.5)	

Note: p > .05.

TABLE 4 Comparison of PIVC characteristics (N = 208)

	Vialon biomaterial			Statistical
PIVC characteristics	catheter group $(n = 104)$	Teflon catheter group $(n = 104)$	Total groups <i>N</i> = (208)	analysis and p value
Catheter number, n (%)				
20 G	37 (35.6)	47 (45.2)	84 (40.4)	$\chi^2 = 4.274$
22 G	63 (60.6)	49 (47.1)	112 (53.8)	p = .118
24 G	4 (3.8)	8 (7.7)	12 (5.8)	
PIVC area, n (%)				
Antecubital	32 (30.8)	28 (26.9)	60 (28.9)	$\chi^2 = 1.964$
Inner face of the forearm	41 (39.4)	37 (35.6)	78 (37.5)	p = .580
Upper side of the hand	7 (6.7)	12 (11.5)	19 (9.1)	
Inner face of the wrist	24 (23.1)	27 (26.0)	51 (24.5)	
Fluid regulator, n (%)				
Dosiflow	77 (85.7)	78 (100)	155 (97.4)	KW = 5.735
Infusion pump	4 (14.3)	00	4 (2.60)	p = .570

Note: p > .05. KW, Kruskal Wallis; PIVC, peripheral intravenous catheter; SD, standard deviation.

started to rise at the 49–72 hr measurement point. Furthermore, grade 2 phlebitis (according to VIPS) developed in the teflon catheter group at the 96 hr and over

measurement point (Table 8). Thus, the teflon catheters were removed at this time because of early symptoms of phlebitis according to VIPS suggestion (n = 56 patients)

TABLE 5 Comparison of pain intensity immediately after the peripheral intravenous catheter placement (N = 208)

Pain intensity	Vialon biomaterial catheter group (n = 104)	Teflon catheter group (n = 104)	Statistical analysis
VAS, mean (SD) (0–10)	2.74 (2.18)	3.04 (1.86)	t = 1.198 $p = .275$

Abbreviations: VAS, visual analog scale; SD, standard deviation. p > .05.

TABLE 6 Comparison of peripheral intravenous catheter dwell time (N = 208)

	Vialon biomaterial catheter group (n = 104)	Teflon catheter group (n = 104)	Statistical analysis
Dwell time, n (%)		
≥72 hr	17 (16.4)	28 (26.9)	$\chi^2 = 15.558$
73–95 hr	30 (28.8)	47 (45.2)	p = .000
Over 96 hr	57 (54.8)	29 (27.9)	
Mean (SD)	4.72 (1.20)	4.10 (0.92)	t = 3.610
(Min-max)	(3-8 days)	(3-7 days)	p = .000

Abbreviations: max, maximum; min., minimum; SD, standard deviation. $p \le .001$.

TABLE 7 Comparison of phlebitis development in peripheral intravenous catheter (N = 208)

Development of phlebitis, n (%)	Vialon biomaterial catheter group (n = 104)	Teflon catheter group (n = 104)	Statistical analysis
Yes	17 (16.3)	56 (53.8)	$\chi^2 = 29.080$
No	87 (83.7)	48 (46.2)	p = .000

Note: $p \leq .001$.

(Table 7). Thus, *Research Hypothesis 3* was confirmed. In addition, in the microbiological examination of PIVCs in patients with phlebitis development, the most bacterial growth in PIVC was determined to be *Staphylococcus aureus* (Table 9).

4 | DISCUSSION

The PIVC procedure is one of the most common invasive procedures in healthcare settings. It is very important that PIVC can be used safely and for a long time (INS, 2017; Simin, Milutinović, Turkulov, & Brkić, 2019; Xu, Hu,

TABLE 8 Comparison of phlebitis score (N = 208)

Phlebitis score	Vialon biomaterial catheter group (n = 104)	Teflon catheter group (n = 104)	Statistical analysis
0–24 hr, mean (SD)	ND	ND	$U = 54.080$ $p \ge 1.000$
25–48 hr, mean (SD)	ND	ND	$U = 54.080$ $p \ge 1.000$
49–72 hr, mean (SD)	1.01 (0.57)	1.05 (0.12)	U = 48.360 $p \le .003*$
73–95 hr, mean (SD)	1.06 (0.21)	1.43 (0.50)	U = 26.040 $p \le .001**$
96 hr and over, mean (SD)	1.33 (0.61)	2.11 (0.68)	U = 9.440 $p \le .001**$

 $[*]p \le .01$.

Abbreviations: ND, not done; SD, standard deviation.

Huang, Fu, & Zhang, 2017; Zhu, Wang, & Wen, 2016). Routinely, teflon catheters are widely used in clinical areas due to having cost effective material. But considering that PIVCs need to be safely used over a long dwell time, with low phlebitis scores, these outputs provide high satisfaction for patients and healthcare providers, and are cost effective for health care systems (López et al., 2014). In this context, PIVCs with different biomaterial properties have been developed in healthcare technology. VialonTM biomaterial softens up to 70% in the vein, enabling longer dwell times and reducing the chance of mechanical phlebitis by up to 50% (Maki & Ringer, 1991).

In this study, the similar pain intensity scores were determined between two groups immediately after inserting the PIVC. In this context, *Research Hypothesis 1* was not confirmed. However, similar mean scores of experimental and control groups may be explained with the intervention by the same researcher nurse and the use of catheters of the same manufacturer, although the catheter material (teflon/vialon biomaterial) is different. Considering the research ethics in line with the principle of beneficence/non-maleficence, it can be suggested that this finding points to a positive result in mild pain experience in both groups.

The catheter dwell time, which was determined as the primary research hypothesis, was found to be statistically longer in the vialon biomaterial catheter group $(4.72 \pm 1.20 \text{ days})$ compared to the teflon catheter group $(4.10 \pm 0.92 \text{ days})$ (difference = $0.62 \pm 0.28 \text{ days}$) (Table 5). In studies related to the subject and conducted with vialon biomaterial catheters, it is reported that it can be used safely up to 3–6 days (Gupta et al., 2007;

^{**} $p \le .001$.

TABLE 9 Colonization results of patients developing phlebitis

Colonization result, n (%)	Vialon biomaterial catheter group $(n = 17)$	Teflon catheter group (n = 56)
Growth present	6 (35.3)	11 (19.7)
No growth	11 (64.7)	45 (80.3)
Bacteria type, n (%)		
Staphylococcus epidermidis	1 (16.7)	4 (36.4)
S. aureus	4 (66.6)	5 (45.5)
Candida albicans	1 (16.7)	2 (18.1)

López et al., 2014; Salgueiro-Oliveira et al., 2012). The catheter dwell time was found to be over 4 days in both groups, which is longer than the mean dwell time (72 hr) indicated in published by the Infusion Nurses Society (Gorski, 2017). The administration of PIVCs by the same researcher nurse and taking into consideration the recommendations (selection of vein, determination of catheter length and diameter, catheter care, complication follow-up, etc.) included in throughout the research period is thought to be a favorable result for the patients in both groups (Gorski, 2017).

When independent observers evaluated the phlebitis score at 8-hr intervals after PIVC administration, phlebitis levels were similar in both groups until 49-72 hr. In particular, the phlebitis score began to increase at 49-72 hr for both groups. Furthermore, phlebitis score had peak scores at 73-95 hr, and 96 hr and over in the teflon catheter group. For this reason, most PIVCs were removed at the 96 hr and over time in the teflon group. In Table 6, only a few (27.9%) PIVCs came to the 96 hr and over measurement time. On the other hand, the vialon biomaterial group had longer dwell time, lower phlebitis development rate (16.3%) than teflon (Tables 7 and 8). Accordingly, it can be suggested that in patients with vialon biomaterial catheters, phlebitis signs/symptoms are observed at a lower rate and level. In vialon biomaterial catheter studies it was reported that phlebitis develops at a lower rate compared to teflon catheters (Enes et al., 2016; Gupta et al., 2007; Karadağ & Görgülü, 2000; López et al., 2014; Maki & Ringer, 1991).

4.1 | Recommendations for future research

The use of a vialon biomaterial catheter (BD InsyteTM AutoguardTM BC winged) demonstrates efficacy on dwell time of the PIVC, and phlebitis rate and phlebitis scores compared with the teflon catheter (BD VenflonTM) for adult patients in the postoperative

period. In this context, it is recommended that: (a) the prevalence of clinical use of vialon biomaterial catheters (manually controlled, with closed valve system) is increased; (b) student nurses and graduates acquire the ability to use vialon biomaterial catheters; (c) all catheters are followed-up and maintained according to (dwell time and phlebitis development) (Gorski, 2017); (d) different age groups (children / elderly), medical record properties and treatment groups (chemotherapy, contrast substance, total parenteral nutrition, etc.) are used; (e) physiological and behavioral parameters of patients, apart from their verbal responses, are taken into consideration for pain assessment; (f) the effects of different variables such as safety of healthcare professionals (especially needle stick injuries) and satisfaction are examined in addition to patient responses such as pain and phlebitis; and (g) maintenance costs of different catheters are calculated and evaluated.

4.1.1 | Limitations of the study

This study has some limitations: first, it was conducted on adult patients in the postoperative period. In addition, the study was performed in a group of drugs with broadspectrum antibiotics and fluid supplementation. Hence, the findings may not be generalizable to all age group patients, and all medication groups. Blinding was not feasible and there may be bias against vialon biomaterial or teflon catheters from the research nurse.

5 | CONCLUSION

This is important research because of determining pain intensity, dwell time, phlebitis score for sequential times, and microbiological analysis in the same patient groups. This study concluded that vialon biomaterial catheter (BD InsyteTM AutoguardTM BC winged) demonstrates longer dwell time of PIVC, lower phlebitis rate and phlebitis score than teflon catheter (BD VenflonTM). In addition, this study compared phlebitis score for sequential measurements times. These results show that vialon biomaterial catheter was safely used for more than 96 hr. The use of a vialon biomaterial catheter (BD InsyteTM AutoguardTM BC winged) demonstrates longer dwell time of the PIVC, lower phlebitis rate and phlebitis scores than teflon catheter (BD VenflonTM) for adult patients in the postoperative period.

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DISCLOSURE

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

B. K. and F. B. contributed to the design of the study; B. K. coordinated the data collection, analyzed the data, and wrote the manuscript; and F.B., as a doctorate thesis advisor, created the study design, and revised the manuscript. Both authors read and approved the final version of the manuscript.

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REFERENCES

- Abadi, P., Etemadi, S., & Abed, S. Z. (2013). Investigating role of mechanical and chemical factors in the creation of peripheral vein in flammarion in hospitalization patients in hospital in Zahedan, Iran. *Life Science Journal*, 10, 379–383.
- Abbas, S. Z., Shaw, S., & Abbas, S. Q. (2007). Use and complications of peripheral vascular catheters: A prospective and study. *British Journal of Nursing*, *16*, 648–652.
- Acaroğlu, R., Şendir, M., & Kaya, H. (2012). Nursing process. In K. Babadağ & T. A. Aşti (Eds.), Fundamentals of nursing practice guide (pp. 8–20). İstanbul, Turkey: İstanbul Tıp Kitapevi (in Turkish).
- Anabela, S. O., Pedro, P., & Pedro, V. (2012). Incidence of phlebitis in patients with peripheral intravenous catheters: The influence of some risk factors. *The Australian Journal of Advanced Nursing*, *30*, 32–39.
- Atay, S., Şen, S., & Cukurlu, D. (2018). Phlebitis-related peripheral venous catheterization and the associated risk factors. *Nigerian Journal of Clinical Practice*, 21, 827–831.
- Ay, A. (2011). Basic concepts and skills in health practices (pp. 421–473). Nobel Tip Kitabevi: İstanbul, Turkey (in Turkish).
- Çakar, V. (2008). Intravenous catheters and infection control applications in peripheral venous catheters. *Hemşirelikte Eğitim and Araştırma Dergisi*, 5, 24–33 (in Turkish).
- CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections (2011). https://www.cdc.gov/infection control/guidelines/bsi/recommendations.html
- Çelik, Z., & Anıl, C. (2004). Complications of intravenous administration. *Güncel Gastroenteroloji*, 8, 1–6 (in Turkish).
- Craven, R. F., & Hirnle, C. J. (Eds.). (2009). Fundamentals of nursing (6th ed.). Philadelphia, PA: Wolters Kluwer Lippincott Williams & Wilkins.
- Dychter, S. S., Gold, D. A., Carson, D., & Haller, M. (2012). Intravenous therapy: A review of complications and economic considerations of peripheral access. *Journal of Infusion Nursing*, *35*, 84–91.
- Enes, S. M. S., Opitz, S. P., Faro, A. R. M. D. C., & Pedreira, M. D. L. G. (2016). Phlebitis associated with peripheral intravenous catheters in adults admitted to hospital in the Western Brazilian Amazon. Revista da Escola de Enfermagem da USP, 50, 263–271.

- Gallant, P., & Schultz, A. A. (2006). Evaluation of a visual infusion phlebitis scale for determining appropriate discontinuation of peripheral intravenous catheters. *Journal of Infusion Nursing*, 29, 338–345.
- Gorski, L. A. (2017). The 2016 Infusion Therapy Standards of Practice. *Home Healthcare Now*, *35*, 10–18.
- Gupta, A., Mehta, Y., Juneja, R., & Trehan, N. (2007). The effect of cannula material on the incidence of peripheral venous thrombophlebitis. *Anaesthesia*, 62, 1139–1142.
- Hadaway, L. (2009). Protect patients from IV infiltration. *American Nurse Today*, 4, 10–12.
- Karadağ, A., & Görgülü, S. (2000). Effect of two different short peripheral catheter materials on phlebitis development. *Journal* of *Intravenous Nursing*, 23, 158–166.
- Keleekai, N. L., Schuster, C. A., Murray, C. L., King, M. A., Stahl, B. R., Labrozzi, L. J., & Glover, K. R. (2016). Improving nurses' peripheral intravenous catheter insertion knowledge, confidence, and skills using a simulation-based blended learning program: A randomized trial. Simulation in Healthcare, 11, 376.
- Kuş, B., & Büyükyılmaz, F. (2018). Visual infusion phlebitis assessment scale: Study of independent inter-observer compliance. Florence Nightingale Journal of Nursing, 26, 179–186 (in Turkish).
- López, J. G., Vilela, A. A., Palacio, E. F., Corral, J. O., Martí, C. B., & Portal, P. H. (2014). Indwell times, complications and costs of open vs closed safety peripheral intravenous catheters: A randomized study. *Journal of Hospital Infection*, 86, 117–126.
- Maki, D. G., & Ringer, M. (1991). Risk factors for infusion-related phlebitis with small peripheral venous catheters: A randomized controlled trial. *Annals of Internal Medicine*, 114, 845–854.
- Mermel, L. A. (2017). Short-term peripheral venous catheterrelated bloodstream infections: A systematic review. Clinical Infectious Diseases, 65, 1757–1762.
- Mihala, G., Ray-Barruel, G., Chopra, V., Webster, J., Wallis, M., Marsh, N., & Rickard, C. M. (2018). Phlebitis signs and symptoms with peripheral intravenous catheters: Incidence and correlation study. *Journal of Infusion Nursing*, 41, 260–263.
- Mimoz, O., Lucet, J. C., Kerforne, T., Pascal, J., Souweine, B., Goudet, V., et al. (2015). Skin antisepsis with chlorhexidine– alcohol versus povidone iodine–alcohol, with and without skin scrubbing, for prevention of intravascular-catheter-related infection (CLEAN): An open-label, multicentre, randomised, controlled, two-by-two factorial trial. *The Lancet*, 386, 2069–2077.
- O'Grady, N. P., Alexander, M., Burns, L. A., Dellinger, E. P., Garland, J., Heard, S. O., et al. (2011). Guidelines for the prevention of intravascular catheter-related infections. *American Journal of Infection Control*, *39*, 1–34.
- Özsaraç, M., Dolek, M., Sarsilmaz, M., Sever, M., Sener, S., Kiyan, S., et al. (2012). The effect of cannula material on the pain of peripheral intravenous cannulation in the emergency department: A prospective, randomized controlled study. *Turk-ish Journal of Emergency Medicine*, 12, 151–156.
- Palese, A., Ambrosi, E., Fabris, F., Guarnier, A., Barelli, P., Zambiasi, P., & Padovan, M. (2016). Nursing care as a predictor of phlebitis related to insertion of a peripheral venous cannula in emergency departments: Findings from a prospectiandstudy. *Journal of Hospital Infection*, 92, 280–286.

- Pasalioğlu, K. B., & Kaya, H. (2014). Catheter indwell time and phlebitis development during peripheral intravenous catheter administration. *Pakistan Journal Medical Science*, 30, 725–730.
- Pires Nobre, A. S., & da Silva Martins, M. D. (2018). Prevalence of peripheral intravenous catheter-related phlebitis: Associated factors. *Revista de Enfermagem Referência*, 4, 127–138.
- Roca, G. M., Bertolo, C. B., Lopez, P. T., Samaranch, G. G., Ramirez, M. C. A., Buqueras, J. C., ... Martinez, J. A. (2012). Assessing the influence of risk factors on rates and dynamics of peripheral vein phlebitis: An observational cohort study. *Medicina Clinica*, 139, 185–191.
- Salgueiro-Oliveira, A., Parreira, P., & Veiga, P. (2012). Incidence of phlebitis in patients with peripheral intravenous catheters: The influence of some risk factors. *Australian Journal of Advanced Nursing*, 30, 32.
- Simin, D., Milutinović, D., Turkulov, V., & Brkić, S. (2019). Incidence, severity and risk factors of peripheral intravenous cannula induced complications: An observational prospecti and study. *Journal of Clinical Nursing*, 28, 1585–1599. https://doi.org/10.1111/jocn.1476
- Tagalakis, V., Kahn, S. R., Libman, M., & Blostein, M. (2002). The epidemiology of peripheral vein infusion thrombophlebitis: A critical review. *The American Journal of Medicine*, *113*, 146–151.
- Uslusoy, E., & Mete, S. (2008). Predisposing factors to phlebitis in patients with peripheral intravenous catheters: A descriptive

- study. Journal of the American Academy of Nurse Practitioners, 20, 172–180.
- Uzun, Ş (2012). In T. Atabek Aşti & A. Karadağ (Eds.), *Intravenous fluid therapy. Fundamentals of nursing in nursing science* (pp. 485–487). İstanbul, Turkey: Akademi Basın and Yayıncılık (in Turkish).
- Xu, L., Hu, Y., Huang, X., Fu, J., & Zhang, J. (2017). Clinically indicated replacement versus routine replacement of peripheral venous catheters in adults: A non blinded, cluster randomized trial in China. *International Journal of Nursing Practice*, 23, e12595.
- Zhu, A., Wang, T., & Wen, S. (2016). Peripheral intravenous catheters in situ for more than 96 h in adults: What factors affect removal? *International Journal of Nursing Practice*, 22, 529–537 http://catalog.bd.com/

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