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Comparing the effect of warm moist compress and Calendula ointment on the severity of phlebitis caused by 50% dextrose infusion: A clinical trial

Neda Jourabloo[1], Tahereh Nasrabadi[2], Ebrahim Ebrahimi Abyaneh[3]

1. MSc Student of Medical-surgical Nursing, School of Nursing and Midwifery, Islamic Azad University, Tehran Medical Branch, Tehran, Iran
2. Assistant Professor, Department of Nursing, Tehran Medical Sciences Branch, Islamic Azad University, Tehran, Iran
3. Instructor, Department of MBA, School of Nursing and Midwifery, Islamic Azad University, Tehran Medical Branch, Tehran, Iran

*Correspondence: Tahereh Nasrabadi, Department of Nursing, Tehran Medical Sciences Branch, Islamic Azad University, Tehran, Iran. Email: taherehnasrabadi2009@gmail.com

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ABSTRACT

Background: One of the important hypertonic solutions is 50% dextrose. Phlebitis is the most common complication of this solution, the management of which is quite necessary. Regarding this, the present study aimed to compare the effect of warm moist compress and Calendula ointment on the severity of phlebitis caused by 50% dextrose infusion.

Methods: This clinical trial was conducted on 96 patients admitted to five surgery units of a teaching hospital in Tehran, Iran, who received 50% dextrose through intravenous catheter in 2016-2017. The study population was selected through convenience sampling technique, and then randomly assigned into three groups of Calendula, compress, and control. The site of intravenous catheters was constantly evaluated from the beginning of dextrose infusion to the emergence of phlebitis. After the onset of phlebitis, the affected locations were managed with the application of warm moist compress (for 20 min) and Calendula ointment (2.5 g) in the compress and Calendula groups, respectively. The interventions were performed every 8 h for three days, and the severity of phlebitis was assessed before and three days after the interventions using Visual Infusion Phlebitis score. Data analysis was performed in SPSS version 22 using Chi-square test, one-way ANOVA, and repeated measures ANOVA.

Results: According to the results, the severity of phlebitis had a more significant reduction in the Calendula group (P=0.002), compared to that in the compress group (P=0.006) after the intervention. This difference between the groups was significant only on the second (P=0.003) and third (P<0.001) days post-intervention.

Conclusion: As the findings of the present study indicated, the application of Calendula ointment decreased the severity of phlebitis in a shorter duration, compared to the use of warm moist compress. Therefore, this ointment is recommended to be used for the reduction of phlebitis severity.

1. Introduction

One of the important components of patient care in the healthcare centers is intravenous therapy. There are multiple medications, fluids, blood products, and dietary supplements injected through veins.[1, 2] One of the hypertonic products is 50% dextrose, which is infused through peripheral veins to supply energy and calories for the patients inflicted with cancer, hypoglycemia, and insulinemia in short term.[3] The peripheral vein infusion of this solution is associated with such complications as high levels of phlebitis and necrosis in the injected area.[4]

The occurrence of phlebitis and its progress in peripheral vessels leads to swelling, pain, and discomfort, which can sometimes be dangerous and cause fatal complications, such as thrombophlebitis, systemic infections, pulmonary embolism, and stroke.[5, 6] This complication not only interrupts intravenous therapy, but also leads to additional expenses and time-wasting of the healthcare personnel.[7]

Therefore, the prevention, early diagnosis, and implementation of necessary measures to treat phlebitis by the nursing team are of paramount importance. Although no definite treatment has been proposed for the prevention of phlebitis,[8]

several medications, such as heparin, corticosteroids, and piroxicam, have been introduced as therapeutic agents in addition to the immediate removal of catheter.[9-13]

Warm moist compress is among the low-risk methods without any complications, which reduces pain and inflammation through the dilation of the vessels and enhancement of blood supply to the targeted area.[14] Although various studies have affirmed the positive effect of this method on phlebitis, they have not accurately specified the duration and number of repetitions for this technique, the recognition of which is significantly crucial.[5, 15, 16] Meanwhile, Calendula officinalis (C. officinalis), or pot marigold, is one of the most recognized medicinal plants, having been used for at least 12 centuries. This plant contains large amounts of antioxidant flavonoids. According to the literature, this medicinal herb can be used to treat all types of inflammations. This medication is safe to use, and just a rare number of people might allergically react to this plant.[17, 18] Flavonoids in marigold prevent the release of histamine and production of prostaglandins. In addition, they inhibit the secretion of blood plasma into tissues, reduce the migration of the white blood cells to the inflamed area, and preclude the growth of bacteria and fungi through the reduction of capillary permeability.[18, 19] Studies have shown that carotenoids in marigold, especially beta-carotene, help improve the anti-inflammatory effects of flavonoids and saponosides, and that it can be used as a medication to reduce pain and edema.[17-23] Given the fact that this plant is associated with almost no complications, it might be applied as a solution for the mitigation of the vascular inflammation and early control of phlebitis.

Therefore, with regard to the importance of the detection and early treatment of phlebitis in the patients with intravenous line, especially during the injection of hypertonic solutions (e.g., 50% dextrose), it is crucial to identify and accurately use the methods that are available and have low complications. With this background in mind, the present study aimed to compare the effect of warm moist compress and Calendula ointment on the severity of phlebitis caused by 50% dextrose infusion.

2. Methods

2.1. Design

This clinical trial was conducted on the patients hospitalized in five surgery units of a teaching hospital in Tehran, Iran, who received 50% dextrose through peripheral venous catheter within 2015-2016.

2.2. Participants and settings

Sample size was estimated as 96 individuals (32 cases per each group) using the Cohen's formula as follows: ($Z_{1-\alpha/2}=1.95$, $Z_{1-\beta}=0.84$, $\Delta=0.7$)

The participants were selected through convenience sampling technique, and then randomly assigned into three groups of moist warm compress, Calendula ointment, and control, each of which contained 32 cases. The inclusion criteria were: 1) intravenous access as confirmed by a physician, 2) infusion of 50% dextrose serum, 3) lack of allergic reaction to Calendula, 4) non-use of anticoagulants and steroids, 5) age range of 20-70 years, and 6) adequate consciousness to participate in the research. On the other hand, the exclusion criteria were: 1) lack of cooperation for accurate and timely use of Calendula ointment and warm moist compress during the study, 2) accidental withdrawal of intravenous catheter, 3) catheter failure due to fluid leakage or reasons other than phlebitis, 4) transfer of patients to other wards, 5) discharge, and 6) mortality.

2.3. Instruments

The data were collected using demographic characteristics form and Visual Infusion Phlebitis score (VIP), developed by Jackson. The demographic form included such information as age, gender, type of disease, gauge number of catheter, catheter site, and times of dextrose administration per day. The VIP scale was developed by Jackson to evaluate the severity of phlebitis in 1996, and its reliability and validity were confirmed.[24] The scoring of this tool is explained in Table 1. In the present study, grade one and higher in this scale was considered as phlebitis.

The reliability of the mentioned scale was confirmed in a study conducted by Galant et al. in 2013, reporting a coefficient of 0.85.[25] In addition, Pourmohammadi et al. investigated the reliability and validity of this tool In Iran, rendering a Cohen's kappa coefficient of 0.93.[13] In the current study, the reliability of this instrument was evaluated using inter-observer agreement method. In this regard, observation was performed by two observers (i.e., the researcher and a trained nursing expert as the researcher's assistant). Evaluation was equally carried out on 10 patients, and the validity of the scale was determined at the Cohen's kappa coefficient of 0.84.

Table 1. Visual infusion phlebitis scale by Jackson

Grade	Clinical symptoms
zero	Lack of pain in insertion site, redness, swelling and tightness to touch.
one	Without pain, tightness, or redness at intravenous site, lack of palpation cord, pain at the top of the insertion site**.**
two	Swollen, red, painful, lack of palpable cord.
three	Swollen, red, palpable cord greater than 7.5 cm above the injection site**.**
four	Swollen and painful, redness, tightness at insertion site, palpable cord greater than 7.5 cm above the injection site.

2.4. Data Collection

With regard to the ethical considerations, the eligible patients were entered in the study. The demographic characteristics of the patients were obtained through demographic and clinical characteristics form. Prior to the intervention, the researcher provided the participants with necessary trainings regarding the catheter care in a face-to-face meeting. The daily evaluation of intravenous site in the three groups was initiated from the beginning of 50% dextrose infusion using the VIP scale. The intervention was started in the intervention groups upon the observation of the early symptoms of phlebitis.

In the Calendula group, an area of 4×2 cm (2.5 g) of the phlebitis was covered by the Calendula ointment (Dineh Co., Iran) every 8 h for three days while using gloves.[12] On the other hand, in the compress group, a compress containing warm water of 45°C was placed on the phlebitis area for 20 min every 8 h for three days.[14] Furthermore, the control group received no intervention. The severity of phlebitis was evaluated and recorded daily in all three groups using the VIP scale.

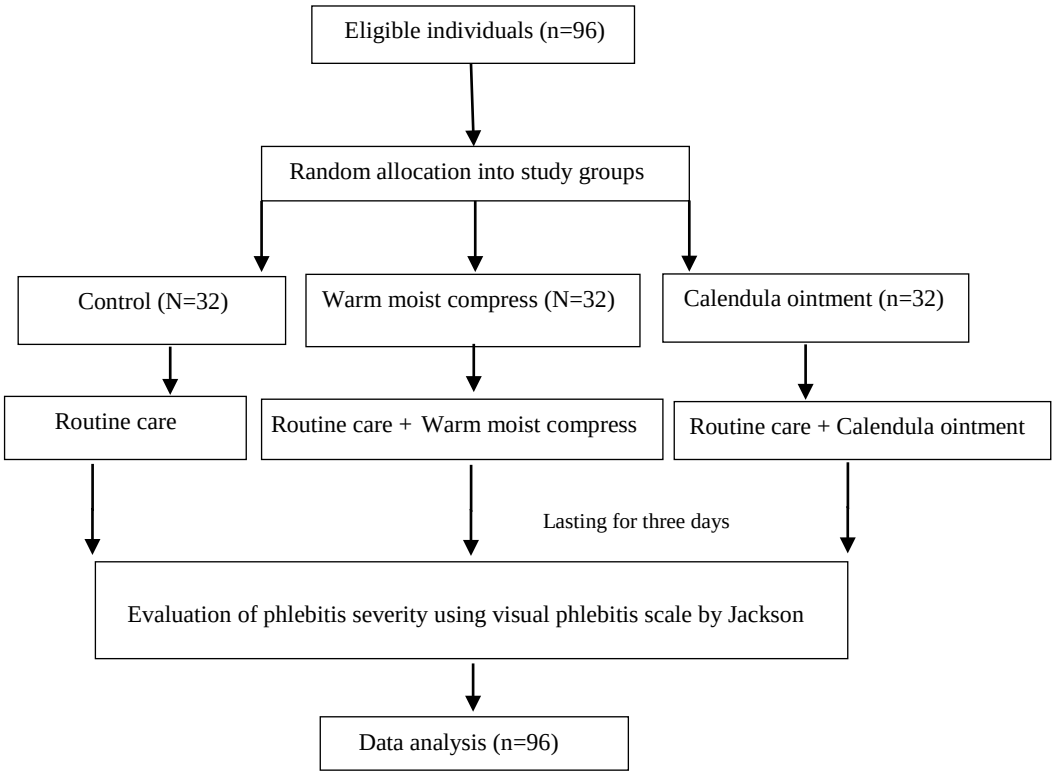

Diagram 1. Flow chart of the study

2.5. Ethical considerations

The objectives of the research were individually explained to the participants. Furthermore, they were assured that their withdrawal from the research at any time had no effect on their treatment process. In addition, the researcher was available throughout the research process to answer the possible questions raised by the patients. Moreover, written informed consent was obtained from the participants prior to the study.

2.6. Statistical analysis

The data were analyzed using descriptive statistics. In addition, the Chi-square test was employed to compare the difference between the groups in terms of demographic characteristics. The comparison of the changes in the severity of phlebitis between the pre- and post-intervention stages was performed by means of repeated measures ANOVA. Moreover, the one-way ANOVA was run to compare the mean age and severity of phlebitis among the study groups. All data analysis was performed in SPSS version 22.

3. Results

The demographic characteristics of the participants are presented in Table 2, according to which no statistically significant difference was observed between the groups in terms of the evaluated variables. After the intervention, a significant reduction was observed in the mean phlebitis scores of the compress (P=0.006) and Calendula groups (P=0.002). According to the results of the one-way ANOVA, a significant difference was found among the three groups on the second (P=0.003) and third (P<0.001) days of the intervention regarding the severity of phlebitis (Table 3). Moreover, the result of the Scheffe test was indicative of significant intragroup changes in this regard (P≤0.005).

Table 2. Demographic and clinical characteristics of warm moist compress, Calendula ointment, and control groups

Variables	Groups	Warm moist compress	Calendula ointment	Control	P-value
		N(%)	N(%)	N(%)	
Gender	Female	11(34.4)	13(40.6)	12(37.5)	0.7*
	Male	21(65.6)	19(59.4)	20(62.5)	
Type of disease	Esophageal cancer	18(56.25)	18(56.2)	12(37.5)	0.2*
	Gastric cancer	7(21.9)	8(25)	16(50)	
	Insulinemia	5(15.6)	5(15.6)	3(9.3)	
	Rectal mass	2(6.25)	1(3.2)	1(3.2)	
Gauge number	20	19(59.4)	20(62.5)	21(65.6)	0.3*
	22	13(40.6)	12(37.5)	11(34.4)	
Catheter site	Forearm	17(53.2)	15(46.9)	3(9.4)	0.5*
	Cubital fossa	10(31.2)	5(15.6)	4(12.5)	
	Wrist	5(15.6)	2(6.25)	7(21.9)	
	Hand	0(0)	10(31.25)	18(56.2)	
Injection times of dextrose per day	Three times	21(65.6)	10(31.25)	9(28.1)	0.1*
	Two times	11(34.4)	22(68.75)	23(71.9)	
Age	Mean±SD	59±0.68	60±0.70	64±0.82	0.2**

*Chi-square; **One-way ANOVA

Table 3. Comparison of the mean severity of phlebitis at the pre- and post-intervention stages among the three study groups

Time / Group	Pre-intervention	First day	Second day	Third day	*P-value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Calendula ointment	2.48±0.62	3.46±0.96	1.3±0.417	1±0.12	0.002
Warm moist compress	2.48±0.50	3±0.95	1.64±0.64	1.2±0.86	0.006
Control	2.40±0.64	3.02±0.90	2.7±0.91	2.9±0.64	0.07
****P-value**	0.1	0.13	0.003	0.001	

*Repeated measures ANOVA, **One-way ANOVA

4. Discussion

As the findings of the present study indicated, after the intervention, the Calendula group showed a higher reduction in the severity of phlebitis, compared to the compress group. In the review of the literature, we could find no study directly evaluating the effect of Calendula ointment or even its derivatives on the severity of phlebitis. However, there are various studies investigating the anti-

inflammatory effect of this plant on different body parts. In this regard, Nicolaus et al. (2015) recommended the use of Calendula extract to treat the minor inflammation of the skin and wounds.[26] In addition, Kaur et al. reported that Calendula plant has analgesic and anti-inflammatory effects, which can be used to treat wounds.[27] In another study conducted by Dawid-Pać (2013), the effect of high concentrations of Calendula extract was reported to be comparable to that of synthetic anti-inflammatory medications.[28] Additionally, in an empirical study carried out by Parente et al. (2012), C. officinalis was demonstrated to have anti-inflammatory and antibacterial effects, marking that its angiogenic and fibroplastic properties can have positive impact on the inflammatory and proliferative stages of the recovery process.[21] Furthermore, Preethi et al. (2009) introduced the strong anti-inflammatory response of C. officinalis as the inhibition of anti-inflammatory cytokines and Cox-2, followed by the synthesis of prostaglandins.[29] The results obtained by Khaimar et al. (2013) indicated that the use of Calendula mouthwash could significantly reduce the widespread inflammation of the mouth caused by gingivitis.[22] In another study performed by Fotouhi et al. (2007), it was reported that although Calendula has anti-inflammatory effect similar to corticosteroids, it has none of their complications and is safe to use.[30] The results of all the mentioned studies are in line with our findings, demonstrating that C. officinalis can be the cause of reduced phlebitis due to the inflammatory nature of phlebitis caused by damage to vascular wall.

One of the major drawbacks of this study was the fact that the hospitalized patients had no separate vein for 50% dextrose infusion, and the same vein was used to infuse antibiotics or other medications, which might have affected the final results. However, this factor could not be controlled by the researcher due to some limitations.

5. Conclusion

According to the results of the current study, the application of Calendula ointment decreased the severity of phlebitis in a shorter period, compared to the use of moist warm compress. Therefore, it is recommended that this method be applied immediately after the occurrence of phlebitis and repeated every 8 h. In addition, it is suggested to prioritize the application of Calendula ointment for the reduction of phlebitis severity.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Neda Jourabloo: study design, data collection, editing the article, Tahereh Nasrabadi: study design, editing and final approval of the article, Ebrahim Ebrahimi Abyaneh: data analysis, participation in the editing of the article.

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