

A comparison between the preventive effect of Nitroglycerin and Clobetasol on cannulation-induced phlebitis; A clinical trials study

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Yosra Raziani ¹

Abstract

Aim: The primary aim of this study is to determine the effect of clobetasol ointment with nitroglycerin ointment on the prevention of superficial phlebitis caused by Angio catheter. Secondary aim is to compare the effect of mentioned ointments on prevention of phlebitis.

Design: prospective randomized trial

Method: the study did not receive any funding. The target sample is 144 patients admitted to surgical ward, randomized to 3 groups. The intervention involves application of clobetasol and nitroglycerin ointment in the distal part of the cannula; while the usual care group did not receive any tropical ointment in cannulation site. the data collection tools included demographic information, information about intravenous treatment and phlebitis measurement scale. In the intervention groups, after venipuncture, 1.5 cm (about 2 g) of ointment was applied, and the site was dressed with sterile gauze. In three time periods of 24, 48 and 72 hours from the time of venipuncture.

Results: the age group of 18 to 30 years was the most common age group. The most common site of cannulation was the back of hand. In the first 24 hours after the placement of cannula, there was no significant difference between the three groups. But at 48 and 72 hours after placement, the difference between intervention and control groups was significant ($P < 0.0001$).

Conclusion: it is recommended to use clobetasol ointment and nitroglycerin ointment to prevent the occurrence of phlebitis in patients who need long-term use of Angio catheter (more than 48 hours).

Trial registration: NCT04685031 registered on <https://www.clinicaltrials.gov/>

Keywords: Patient, Clobetasol ointment, Nitroglycerin ointment, Phlebitis, Angio catheter

¹College of Medicine, Department of Nursing, Komar University of Science and Technology, Sulaymaniyah, Kurdistan Region, Iraq / Email: Yosra.anvar@komar.edu.iq

1/ introduction

Today, more than 80 to 90% of hospitalized patients receive intravenous treatment during their treatment, and more than 500 million peripheral venous catheters are placed annually. (Dandekar, Vidovich, & Shroff, 2012) (Jolly et al., 2011; Wang, Yang, Zhou, Xu, & Zhao, 2010)

. Intravascular is associated with many risks such as phlebitis. (Drake et al., 2009; Michael et al., 2013; Tewari et al., 2013) .Phlebitis, in addition to being dangerous on its own, leads to clot formation, thrombophlebitis, embolism, and shortened lifespan of cannulas. Research has shown that the main reason for removing peripheral catheters is phlebitis(Hibbert et al., 2012; Ibebuogu et al., 2012; Mason et al., 2018) .

The high prevalence of phlebitis increases economic costs, wastes nurses' time, increases patients' problems such as infection, patient discomfort, and ultimately leads to catheter removal and placement in a new location, which in turn makes access more difficult. The arteries become narrower and may lead to more invasive procedures, such as catheter insertion into central veins, which have far more complications. Intravenous medications may also be delayed and even the length of hospital stay may be increased.

In the presence of bacterial phlebitis, the risk of septicemia increases up to 18-fold. Phlebitis is a potentially dangerous source of systemic infections, so the chances of developing systemic infections in the presence of phlebitis increase eightfold. The important point for nurses is that the best treatment for chemical, mechanical and bacterial phlebitis is to prevent its occurrence. Frequent control of the Angio catheter placement area and, if the first

signs of redness, tenderness, and inflammation are observed, change the location of the Angio catheter (Balwanz et al., 2013).

BACKGROUND

Studies to prevent superficial phlebitis have been performed for many years. In several studies results showed that there is a significant relationship between the use of chlorhexidine solution. (Schussler, Vasudevan, Liana, Won, & McCullough, 2016).

the discussion about the effects of different types of dressings on the catheter entry site is still ongoing. On the other hand, studies have not yet been able to show the significant effect of using antiseptic ointment at the catheter entrance site on reducing the prevalence of phlebitis. For many years, the prevention of phlebitis caused by infusion and its relationship with the choice of dressing has been controversial(C, 2016 jun; Iwachow et al., 2017; L., November 19, 2012.) .

Avaze et al. Conducted a clinical trial to investigate the effect of topical nitroglycerin on the incidence and severity of venous catheter phlebitis. The results showed that there was a significant difference between the frequency ($p = 0.001$) and severity of phlebitis ($p = 0.005$). The results also showed an increase in catheter lifespan in the case group compared to the control group ($p = 0.01$). there are some evidence that show use of sterile gauze dressing can be effective in preventing phlebitis (Samady et al., 2011) .Kohano et al. Conducted a study on the effect of corticosteroids on phlebitis caused by injecting chemotherapy drugs into rabbits; Histopathological results showed that dexamethasone injection significantly reduced phlebitis compared to the control group (Goff et al., 2014).

2 | THE STUDY

2.1 | Aims

Aim 1: The primary objective of this project is to assess the effect of ointment therapy in prevention of cannulation-induced phlebitis.

H1.1: the rate of phlebitis in intervention groups is significantly lower than control group

H1.2: the phlebitis in control group occurs more severe than intervention groups

Aim 2: the secondary objective of this project is to compare the efficiency of clobetasol and nitroglycerin ointment in prevention of cannulation-induced phlebitis

H2.1: the occurrence of phlebitis in clobetasol group is less than control group

H2.2: the occurrence of phlebitis in nitroglycerin group is less than control group

H2.3: the occurrence of phlebitis in clobetasol group is higher than nitroglycerin group

2.2 | Methodology

Trial design: This study is a single-blind, three-group clinical trial that was performed on all patients admitted to the surgical ward who met the inclusion criteria.

2.2.1 | Screening and enrolment— A convenience sample of 144 patients will be enrolled within 72 hours of cannulation. Trained research staff will be available for 24 hr each day, 7 days per week, to facilitate enrolment.

2.2.2 | Randomization and blinding—in this single-blind study only the researcher doing the study knows which treatment or intervention the participant is receiving

until the trial is over, that makes results of the study less likely to be biased.

2.2.3 | Study population— The study population were 144 patients selected from patients in surgical ward who were hospitalized for at least 3 days. The number of sample size in each group was calculated 48 people. Using simple random allocation method, the patients were placed in one of the groups of: A:"Clobetasol ointment (intervention)", B: "nitroglycerin ointment (intervention)", and C:"routine (usual method)".

2.2.4 | Data collection— Data collected at enrolment and at regular intervals including: demographic information, information on intravenous therapy, and checklist on the presence and severity of phlebitis. Demographic information included: age and type of disease. Information on intravenous therapy included: site of cannulation, type of serum received, amount of received serum over last 24 hours, and types of medications. according to the type of disease, type of serum, 24-hour serum intake and medications, Patients were divided into three groups. The Phlebitis Symptoms Checklist included the Phlebitis Visual Measurement Scale. This scale was introduced by Jackson in 1998 and was introduced to the Intravenous Injection Nursing Association in 1806 as a measure of phlebitis. Its reliability has been confirmed. The visual scale of phlebitis is as follows:

Grade 0: no clinical symptoms, Grade 1: pain or redness, Grade 2: pain, redness or edema at the site, unclear vein boundaries, no rope vein in touch, Grade 3: pain, redness or edema at the site, clear blood vessels, no rope vein in touch, Grade 4: the presence of pain and erythema or edema at the site, the clearness of the arteries and the rope vein in touch.

2.2.5 | Overview of procedures—

Venipuncture and dressing in all patients, observing the principles mentioned in the reference books (washing hands before starting work and wearing disposable gloves, choosing the right place, choosing the right vein, cutting the hair at the injection site with scissors, Disinfect the area for at least 30 seconds with alcohol 70%) evenly with pink Angio catheter No. 18 produced by Haryana factory in India were performed. If the vein access was not successful within 2 times, a new location was chosen for the vein. Patients were instructed how to take care of the inserted cannula. According to the group in which the patients were located, after venipuncture, 1.5 cm (about 2 g) of the ointment was rubbed in the distal part of the Angio catheter in a width of 4×2cm and sterile gauze with anti-adhesive adhesive. Sensitivity was covered. Serum sets were changed equally every 48 hours

in both groups. To measure the occurrence and severity of phlebitis according to the Jackson scale, patients were evaluated at 24, 48 and 72 hours after venipuncture. topical drugs based on the type of patient group were used for 3 times, in the first hour of placement, 24 and 48 hours after Angio catheter placement.

2.3 | Ethical considerations

The hospital and university Institutional Review Boards approved the study in March 2020. The informed consent will be obtained from all participants, within the designated enrolment period. investigator will explain the study. A standardized script will be used. The consent process will be available in both English and Persian and an interpreter will be available. Consent will be documented. The patient will be given a copy of the consent form.

2.4 | Results:

2.4.1 | participant flow

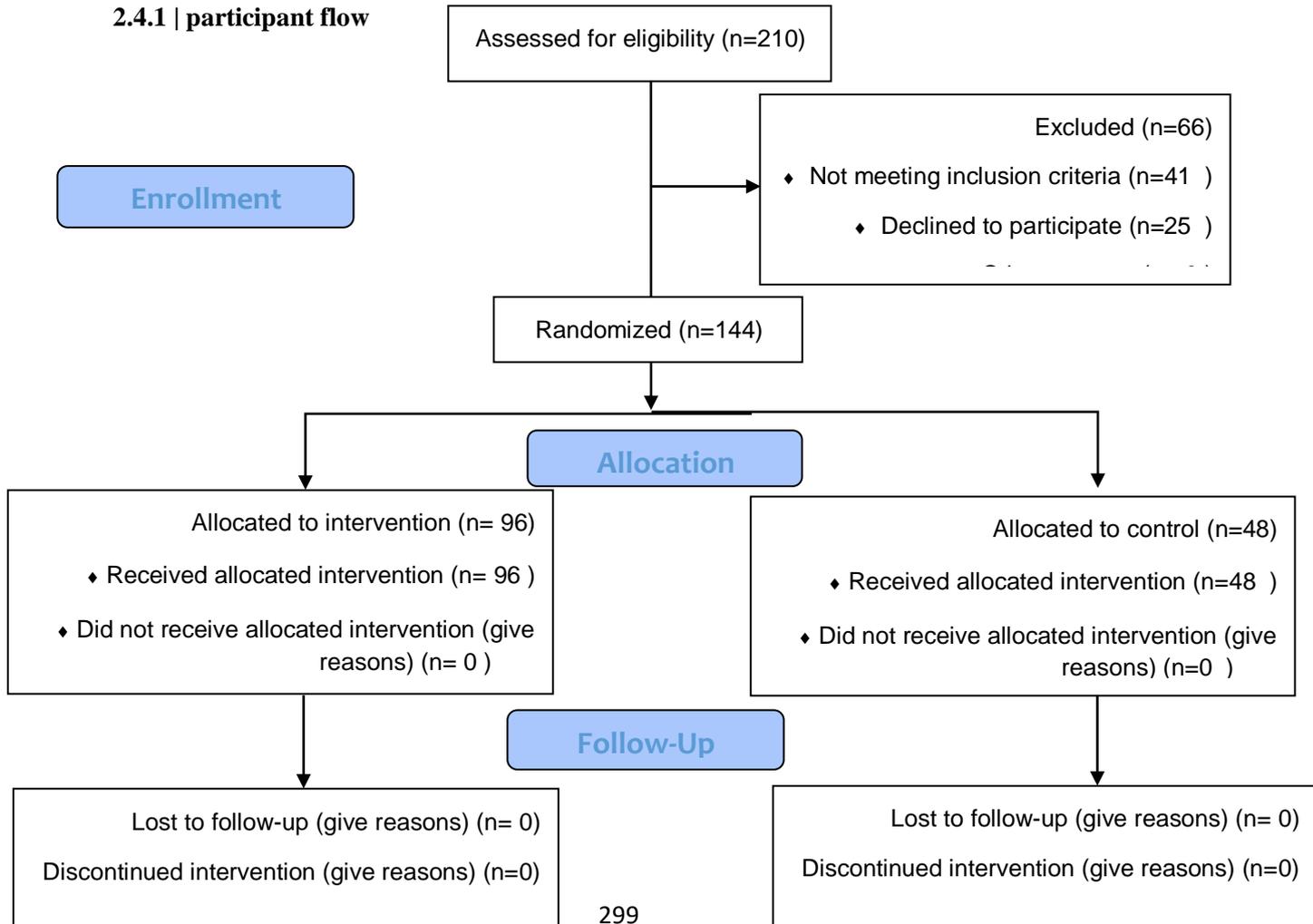


Table 1. Frequency distribution of different age groups in the studied patients by type of groups

P Value	Total	≥80	60-79	40-59	20-39	Age Group
	Number (Percent)	Number (Percent)	Number (Percent)	Number (Percent)	Number (Percent)	
0/31	48 (100)	0 (0)	12 (25)	16 (33/3)	20 (41/7)	Group Clobetasol
	84 (100)	2 (4/3)	41 (27/7)	8 (17)	24 (51/1)	group Nitroglycerin
	84 (100)	3 (6/1)	15 (30/6)	31 (28/6)	17 (34/7)	group Control

Table 2. Frequency distribution of phlebitis in the study groups by duration after cannulation

P Value	Control		Nitroglycerin		Clobetasol		Group and Phlebitis
	does not have	has it	does not have	has it	does not have	has it	
	Number (Percent)	Number (Percent)	Number (Percent)	Number (Percent)	Number (Percent)	Number (Percent)	Time
0/56 Accurate Fisher	46 (93/9)	3 (6/1)	46 (97/9)	1 (2/1)	45 (93/8)	3 (6/3)	hours 24
<0/001 Squared	26 (53/1)	23 (46/9)	93 (83)	8 (17)	40 (83/3)	8 (16/7)	hours 48
<0/0001 Squared	8 (16/3)	41 (83/7)	27 (57/4)	20 (42/6)	21 (43/8)	27 (56/3)	hours 72
	79 (54/4)	67 (45/6)	122 (79/44)	29 (18/56)	106 (73/63)	38 (26/43)	Total

Table 3. Frequency distribution of phlebitis severity in the study groups by duration after cannulation

P Value	Severity of phlebitis				group	Time
	Total	Grade three	grade two	Classy		
	Number (Percent)	Number (Percent)	Number (Percent)	Number (Percent)		
0/15	3 (100)	0 (0)	2 (66/7)	1 (33/3)	Clobetasol	24 hours
	1 (100)	0 (0)	0 (0)	1 (100)	Nitroglycerin	
	3 (100)	0 (0)	0 (0)	3 (100)	Control	
0/079	8 (100)	1 (12/5)	0 (0)	7 (87/5)	Clobetasol	48 hours
	8 (100)	1 (12/5)	2 (25)	5 (62/5)	Nitroglycerin	
	23 (100)	0 (0)	11 (47/8)	12 (52/3)	Control	
0/026	27 (100)	2 (7/4)	6 (22/3)	19 (70/4)	Clobetasol	72 hours
	18 (100)	1 (5)	2 (10)	17 (85)	Nitroglycerin	
	41 (100)	5 (12/2)	18 (43/9)	18 (43/9)	Control	

Table 4. Frequency distribution of phlebitis in patients receiving ointment at different times after cannulation by age

P Value	79-60		59-40		30-18		Age and phlebitis time
	does not have	has it	does not have	has it	does not have	has it	
	Number (Percent)						
0/28 Fisher's test	11 (91/7)	1 (8/3)	14 (87/5)	2 (12/5)	18 (100)	0 (0)	clobetasol

0.44	12 (92/3)	1 (7/7)	8 (100)	0 (0)	118 (100)	0 (0)	nitroglycerin	24 hours
0/79	9 (75)	3 (25)	13 (81/3)	3 (18/8)	18 (90)	2 (10)	clobetasol	48 hours
0.5	10 (76/9)	3 (23/1)	7 (87/5)	1 (12/5)	21 (87/5)	3 (12/5)	nitroglycerin	
0/12	3 (25)	9 (75)	6 (37/5)	10 (62/5)	12 (60)	8 (40)	clobetasol	72 hours
0.29	5 (38/5)	8 (61/5)	5 (62/5)	3 (37/5)	15 (62/5)	9 (5/37)	nitroglycerin	

Table 5. Frequency distribution of phlebitis in patients receiving ointment

P Value	behind hand		elbow		wrist		Forearm		Place of cannulation and phlebitis	time
	does not have	has it								
	Number (Percent)									
0/94	1 (100)	0 (0)	4 (100)	0 (0)	12 (92/3)	1 (7/7)	28 (93/3)	2 (6/7)	clobetasol	24 hours after Cannulation
0.17	2 (100)	0 (0)	9 (100)	0 (0)	7 (87/5)	1 (12/5)	18 (100)	0 (0)	nitroglycerin	
0/079	1 (100)	0 (0)	3 (75)	1 (25)	10 (76/9)	3 (23/1)	26 (86/7)	4 (13/3)	clobetasol	48hours after Cannulation
0.51	1 (50)	1 (50)	8 (88/9)	1 (11/1)	6 (75)	2 (25)	118 (85/7)	4 (14/3)	nitroglycerin	
0/068	0 (0)	1 (100)	2 (50)	2 (50)	2 (15/4)	11 (84/6)	17 (56/7)	13 (43/3)	clobetasol	72 hours after Cannulation
0.34	27 (57/4)	18 (42/6)	3 (33/3)	6 (66/7)	4 (50)	4 (50)	17 (60/7)	11 (30/3)	nitroglycerin	

2.4.2| Recruitment: the sample were enrolled in study from March 2020 to December 2020 .at the beginning of the study trained staff were educated in the term of inclusion criteria for enrollment of participant in each shift.

2.4.3| Baseline data:

The mean age of clobetasol group was 45/1±17/1 years, nitroglycerin group was 45/6±18/5years and control group was 50/6±18/3years.there was no significant difference in the mean age of the 3 groups (P = 0/28). (Table 1)

The back of hand was the most, and the elbow was the least used site of cannulation in all groups. ($P = 0.15$).

2.4.4| Outcomes:

Table 2 compares the frequency of phlebitis (with any degree) at different times after cannulation in the three groups. According to the obtained results there was not a significant difference in the occurrence of phlebitis in the first 24 hours ($P = 0.56$). after 48 hours the differences became more obvious ($P = 0.001$), and finally after 72 hours, in the clobetasol ointment group 56.3% , nitroglycerin ointment group 42.6%, and in the control group 83.7% phlebitis were seen with different degrees. ($P < 0.0001$). (Table 2)

the frequency distribution of phlebitis severity in the study groups is examined separately by the time elapsed since cannulation. In the first 24 hours after cannulation this difference was not significant ($P = 0.15$). 96 hours after cannulation, the majority of phlebitis (87.5%) in the clobetasol group were first degree and 12.5% third degree; in the nitroglycerin group 62.5% was first degree phlebitis and 25% was second degree and

12.5% was third degree. In the control group, 52.2% were first degree and 47.8% second degree, but according to Fisher's exact test, this difference was not significant ($P = 0.079$). In the evaluation performed at 72 hours after cannulation phlebitis degree 2 and 3 in the control group were less than the other two groups ($P = 0.026$). (Table 3)

Table 4 shows the frequency distribution of phlebitis in patients receiving clobetasol, and nitroglycerine at different times after cannulation by age. In clobetasol group, as the results of the table show, in none of the measuring times there was difference in the incidence of phlebitis. ($P > 0.05$). Although in all three times the incidence of phlebitis in the age groups of 40-59 and 60-79 was higher than the age group of 18-30 years, but this difference was not statistically significant. in nitroglycerin group, as the results of the table show, in none of the measuring times, there was no difference in the incidence of phlebitis.

Table 5 shows the frequency distribution of phlebitis in patients receiving ointment at different times after cannulation by site of cannulation. As shown in the table, in

the first 118 hours, the most cases of phlebitis according to the location of cannulation in the wrist was 7.7% and the lowest was 0% in the elbow area ($P = 0 / 94$). In the first 96 hours after cannulation, the most cases of phlebitis in the wrist area were 23.1% and the lowest in the back area was 0%, but despite this difference, the difference in the frequency distribution of phlebitis according to the site of cannulation was not statistically significant. ($P = 0/079$). Also, in the first 118 hours after cannulation, the highest number of cases of phlebitis was 100% in the back of the hand, followed by 84.6% in the wrist, and the lowest was in the forearm ($P = 0.068$). the frequency distribution of phlebitis in patients receiving nitroglycerin at different times after cannulation by site of cannulation, was not statistically significant based on the results of Fisher's exact test.

2.5 | Discussion:

Specific studies on the use of topical drugs in prevention Phlebitis due to cannulation is limited. In the field of topical medicine, nitroglycerin ointment has been used in several studies in Iran and abroad, but

clobetasol ointment has been used in only a few studies with animal samples.

In this regard, this study was conducted to compare the effect of clobetasol ointment with nitroglycerin ointment on the prevention of superficial phlebitis caused by cannulation.

the results showed that the frequency of phlebitis in the intervention groups in the first 24 hours after cannulation was not statistically significant compared to the control group.

The frequency of phlebitis in the first 24 hours in the clobetasol group was equal to the control group, which is probably due to the long-lasting effect of clobetasol ointment. Comparison of control group, and two intervention groups at the measuring times of 48 and 72 hours, showed that there is a statistically significant difference between the two intervention groups and the control group.

In a study conducted by Glineur(2011) , the incidence of phlebitis following applying nitroglycerin ointment reduced by 30.8%(Glineur et al., 2011). While in the present study, the amount of phlebitis in the clobetasol ointment group was

26.43% and in the nitroglycerin ointment group was 20.56%, which is probably due to the cannulation performed by one researcher and the use of sterile gas for dressing.

Regarding the frequency distribution of phlebitis severity in the study groups by duration of cannulation, the results showed that statistically, the severity of phlebitis occurred in the intervention groups in the first 24 and 48 hours after cannulation compared to the control group was not obvious. However, severity of phlebitis in the intervention groups in the first 72 hours after cannulation compared to the control group, showed that there is a statistically significant difference between the two intervention groups and the control group, meaning that second-degree, and Three-degree phlebitis in the control group in the first 72 hours after cannulation were more than the two intervention groups.

In the intervention groups, the severity of phlebitis in the nitroglycerin ointment group was lower than clobetasol ointment group. Regarding the severity of first-degree phlebitis, the highest rate of phlebitis was observed in the two groups

of Clobetasol ointment and control. However, chi-square test did not show a significant difference between the three groups from the first 24 hours to the first 72 hours after catheter placement. In connection with the incidence of second-degree phlebitis between the experimental and control groups, the highest percentage of incidence of second-degree phlebitis was observed in the control group, that this could be due to the effect of nitroglycerin ointment and clobetasol ointment in the two experimental groups. This result confirmed the findings of Saleh Moghadam et al. regarding the highest incidence of second-degree phlebitis from 24 hours to the first 72 hours (SALEH MOGHADAM, VAHEDIAN AZIMI, & REZAEI ADRIANI, 2009). Regarding third degree phlebitis, although the highest incidence was observed in the control group from 24 hours to the first 72 hours, but there was no statistically significant difference. In both experimental groups, the incidence of phlebitis with any degree in nitroglycerin ointment group was lower than clobetasol ointment group. Based on the results of the study and comparing it

with the research hypotheses, the research hypothesis was confirmed.

As the results showed, the use of clobetasol and nitroglycerin reduced the incidence and severity of phlebitis compared to the usual method used in the control group. Then, by comparing the effect of the two interventions with each other, it was found that the effect of nitroglycerin ointment was more than clobetasol ointment. The results of present study confirm the results of a study conducted by Avaze et al. (2004) (Avazeh, Azar & Elahi, 2004). In another study conducted by Saleh Moghadam et al. (2008), they concluded that the incidence of phlebitis in the experimental group (nitroglycerin ointment) was lower than the control group ($P < 0.001$) and second-degree phlebitis in the control group, was significantly higher than the experimental group ($P < 0.05$), which results are consistent with our finding in the present study (second-degree phlebitis in the control group was more than the two intervention groups). (SALEH MOGHADAM et al., 2009) Also, in a study conducted by Tajon et al. (2000),

the results showed that the use of topical nitroglycerin ointment is effective when intravenous administration is required for more than 50 hours (Tjon & Ansani, 2000).

The results of these studies are consistent with the results of the present study. No research has been done on clobetasol ointment and its effect on the prevention of phlebitis due to catheter placement in human specimens and only in some cases in animal specimens; the researcher states that although an animal study cannot be a basis for human studies, this study guarantees the positive effect of clobetasol on phlebitis in the human sample, and if the use of topical corticosteroids in humans is proven, it can replace heparin, and other non-steroidal anti-inflammatory drugs (Dvir, Russo, Meshorer, Duvdevani, & Rosenberg, 2009) In the present study, clobetasol ointment reduced the incidence of phlebitis and the severity of phlebitis throughout the treatment compared to the control group, which was in line with the results of the study by Doyer et al. Kahno et al. (2019) the prophylactic effect of intravenous dexamethasone on chemotherapy-induced phlebitis was

investigated; Histopathological results showed that dexamethasone injection significantly reduced drug-induced phlebitis compared to the control group(Kohno, Murase, Matsuyama, & Okamura, 2009).

Finally, by examining the frequency distribution of phlebitis in patients in the intervention groups (clobetasol and nitroglycerin) at different times after cannulation by age and location of cannulation, the results showed that there was not a statistically significant difference between the frequency of phlebitis and age and place of cannulation.

in this study, most of the samples were between 18 and 30 years old, Aslani (2017) in his research did not find a significant relationship between the occurrence of phlebitis and age(Aslani, 1999) . But some researchers believe that age can play an key role in the development of phlebitis(Macklin, 2003).

In the present study, the highest incidence of phlebitis occurred in the back of the hand and then the wrist. These results are similar to the results of Avaze et al.(Avazeh, Elahi, Asadizaker, Rasekh, &

HAJI, 2004) According to the results of the present study, it was found that the most important factor in the incidence of phlebitis is time and the incidence of phlebitis increases over time. This result confirmed the findings of Rahmani et al. And Ghadami in 2000 and Kardak et al. (1800) that the incidence of phlebitis increased with increasing catheter placement hours.(GHADAMI, 2001; Karadag & Görgülü, 2000; Raziani & Raziani)

2.6 | Limitations

Environmental stimulators, the patients hand mobility and activity, individuals body tolerance in response to intravenous medications, were some limitations that we faced in our study; we propose that new studies control these variables in order to obtain more accurate results.

3| Conclusion

According to the positive effect of using clobetasol ointment and nitroglycerin ointment on the prevention of phlebitis caused by Angio catheter, it is recommended to use that clobetasol and nitroglycerin drugs to prevent phlebitis in patients who need long-term use of Angio

catheter. Considering that, cannulation can be expressed as one of the first measures in the face of most of the patients, and according to the results of this study, it is recommended that, in nursing and other treatment-related professions, there should be more discussion about establishing a venous route, and its obvious complications.

Conflict of interest: There is no conflict

Funding information: No funding was received

Resources

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