Ointment therapy and prevention of cannulation-induced superficial phlebitis

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Abstract

The primary aim of this prospective randomized trial is to determine the effect of clobetasol ointment with nitroglycerin ointment on the prevention of phlebitis caused by cannulation.

The target sample is 144 patients admitted to surgical ward, randomized to 3 groups. the data collection tools included demographic information, information about intravenous treatment and phlebitis measurement scale. In the intervention groups, after venipuncture, 1.5 cm of ointments (clobetasol and nitroglycerin) was applied n three time periods of 24, 48 and 72 hours from the time of venipuncture.

In the first 24 hours after cannulation, 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).

It is recommended to use clobetasol ointment and nitroglycerin ointment to prevent the occurrence of phlebitis in patients who need long-term use of cannula (more than 48 hours).

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.[1-3] cannulation is associated with many risks such as phlebitis.[4-6] 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.[7-9] 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.

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 eight-fold. The important point for nurses is that the best treatment for chemical, mechanical and bacterial phlebitis is to prevent its occurrence by frequent control of the cannulation site for any signs of redness, tenderness, and inflammation in order to change the location of the Angio catheter.[10]

Background

Studies to prevent superficial phlebitis have been performed for many years. 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.[12-14]

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.[15] 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.[16]

The study

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.

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Contributions: YR, conceptualization; methodology; software, validation; formal analysis; investigation; resources; data curation; writing - original draft preparation, review and editing, visualization. BSO, sample recruitment and procedure. All authors have read and agreed to the published version of the manuscript.

Conflict of interest: the authors declare no potential conflict of interests.

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

Availability of data and materials: the data presented in this study are available upon request from the corresponding author. The data are not publicly available due to privacy.

Ethics approval and consent to participate: the hospital and university Institutional Review Boards approved the study in March 2020; informed consent was obtained from all participants

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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.

Screening and enrolment - A convenience sample of 144 patients was enrolled within 72 hours of cannulation. Trained research staff was available for 24 hr each day for one week, to facilitate enrolment.

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.

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: i) '*Clobetasol ointment (intervention)*'; ii) '*nitroglycerin ointment (intervention)*'; and iii) '*routine (usual method)*'.

Data collection - Data collected at enrolment and at regular intervals including: demographic information, and checklist on the presence and severity of phlebitis. Demographic information included: age and type of disease. 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.

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. Patients were instructed how to take care of the inserted cannula. 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 4x2 cm from the inserting point, and with sterile hypoallergenic tape 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 cannulation, and each time the cannulation site were assessed in term of any sing of phlebitis.

Ethical considerations

The hospital and university Institutional Review Boards approved the study in March 2020; explaining the study, informed consent was obtained from all participants, within the designated enrolment period. The consent process is documented in both English and Persian, and all patients were given a copy of the consent form.

Results

The results of the study are summarized in Figure 1.

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.

Baseline data: the mean age of clobetasol group was 1/17±1/45 years, nitroglycerin group was 5/18±6/45years and control group was 3/18±6/50years. 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).

Outcomes: 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 oblivious (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).

In the first 24 hours after cannulation, frequency distribution of phlebitis severity

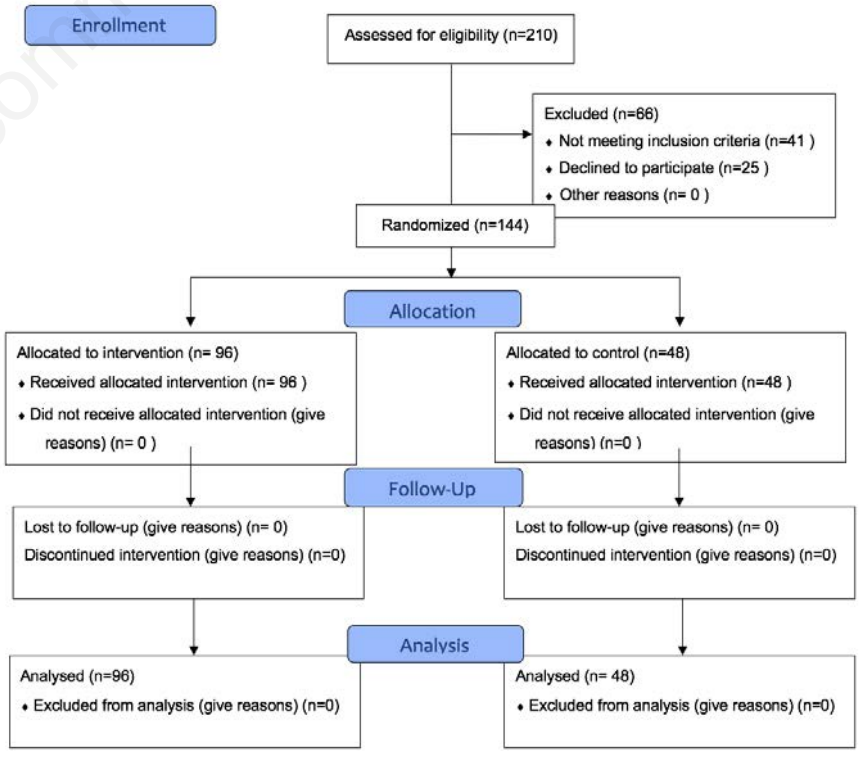

Figure 1. Participant flow

was examined and the difference was not significant (P=0.15). After 48 hours, 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 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) (Table 3).

Table 4 shows the frequency distribution of phlebitis in patients receiving clobetasol, and nitroglycerine at different times after cannulation by age. In both groups, there was not a significant difference in the incidence of phlebitis (P>0.05). Although in

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 (%)					
0/31	48 (100)	0 (0)	12 (25)	16 (33/3)	20 (41/7)	Clobetasol
	48 (100)	2 (4/3)	14 (27/7)	8 (17)	24 (51/1)	Nitroglycerin
	48 (100)	3 (6/1)	15 (30/6)	13 (28/6)	17 (34/7)	Control

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

P value	Control		Nitroglycerin		Clobetasol		Group and phlebitis / Time
	Does not have	Has it	Does not have	Has it	Does not have	Has it	
	Number (%)						
0/56 Accurate Fisher	46 (93/9)	3 (6/1)	46 (97/9)	1 (2/1)	45 (93/8)	3 (6/3)	24 hours
<0/001 Squared	26 (53/1)	23 (46/9)	39 (83)	8 (17)	40 (83/3)	8 (16/7)	48 hours
<0/0001 Squared	8 (16/3)	41 (83/7)	27 (57/4)	20 (42/6)	21 (43/8)	27 (56/3)	72 hours
	79 (54/4)	67 (46/6)	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 (%)					
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	

all three times the incidence of phlebitis in clobetasol group, 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.

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, at the both measuring times of 24 and 48, the most cases of phlebitis occurred in the wrist, but despite this, 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 72 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.

Discussion

Specific studies on the use of topical drugs in prevention of cannulation-induced phlebitis is limited. In the field of topical medicine, nitroglycerin ointment has been used in several studies, but clobetasol ointment has been used in 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

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		Group	Age and phlebitis / Time
	Does not have	Has it	Does not have	Has it	Does not have	Has it		
	Number (%)							
0/28 Fisher's test	11 (91/7)	1 (8/3)	14 (87/5)	2 (12/5)	18 (100)	0 (0)	Clobetasol	24 hours
0.44	12 (92/3)	1 (7/7)	8 (100)	0 (0)	118 (100)	0 (0)	Nitroglycerin	
0/79 Fisher's test	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 Squared	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	Does not have	Has it	Does not have	Has it	Does not have	Has it		
	Number (%)									
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	48 hours 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	

the control group, which is probably due to the late 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%.[17,18] While in the present study, the percentage of phlebitis in the clobetasol group was 26.43% and in nitroglycerin group was 20.56%, this reduction in our study is explained by fully observing sterile techniques in procedure, properly fixation of cannula, and also all procedures were performed by one trained staff.

Regarding the frequency distribution of phlebitis severity in the study groups by duration of cannulation, the results showed that, the severity of phlebitis occurred in the intervention groups in the first 24 and 48hours after cannulation compared to the control group was not obvious. the 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. The highest percentage of incidence of second-degree phlebitis was observed in the control group, that this could be due to the effect of ointment in the experimental groups. This result confirmed the findings of Saleh Moghadam *et al*.[19] Regarding third degree phlebitis, although the highest incidence was observed in the control group, 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. The use of clobetasol and nitroglycerin reduced the incidence and severity of phlebitis compared to the usual method used in the control group, and it was found that the effect of nitroglycerin ointment was more than clobetasol, which is in line with the results of a study conducted by Avaze *et al*. (2004).[20] 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.[19] No research has been done on clobetasol effect on the prevention of cannulation-induced phlebitis in human 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.[21,22] 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.[23] 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.[24] But some researchers believe that age can play an key role in the development of phlebitis.[25] 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*.[26] 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.[27-29]

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.

Conclusions

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.

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