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RESEARCH ARTICLE

COMPARISON OF HEPARINOID AND ICHTHAMMOL GLYCERINE APPLICATION ON PATIENTS WITH PHLEBITIS

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ABSTRACT

Background: Phlebitis is inflammation of the vein wall that is the most common complication of intravenous infusion therapy. The incidence of phlebitis in hospitalized patients receiving IV therapy has been reported to be as high as 80%.

Aim: To find out the most effective applicant for reduction of phlebitis in comparison of Heparinoid and Ichthammol glycerine.

Setting and Design: Christian Medical College and Hospital, Ludhiana, Punjab and Non-experimental comparative research design with quantitative approach.

Material and Methods: Total 60 subjects (30 with Heparinoid and 30 with Ichthammol Glycerine application-age, gender and type of disease condition- matched). The participants were selected from critical care areas of Christian Medical hospital, Ludhiana. Data was collected with using Modified Visual Infusion Scale and Standardized Numerical Pain Intensity assessment scale.

Result: In Heparinoid group mean phlebitis score before application was 10.14 and after 48 hours it decreased to 2.37 but on the other hand in Ichthammol glycerine application group mean phlebitis score was 10.51 which decreased to 1.50 after 48 hours of application. Before application, after 24 hours and after 48 hours of application 't' value between Heparinoid and Ichthammol application group was 0.71, 0.63 and 1.68 respectively, which were not significant at $p < 0.05$ level of significance. Conclusion: Both the applications were effective in reducing IV induced phlebitis.

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INTRODUCTION

Estimated 25 million patients enter the health service each year and receive infusion therapy via peripheral venous access (Angeles and Barbone, 1994). The incidence of phlebitis in hospitalized patients receiving IV therapy has been reported to be as high as 80% (Feldstein, 1987). Phlebitis associated with peripheral cannula is an inflammatory condition defined by the presence of at least two of the following symptoms: Local pain, Redness, Swelling, Palpable thrombosis of the catheterized vein (White, 2001). Phlebitis can be classified according to its etiology as chemical, mechanical or infectious. The initial treatment for any form of phlebitis is to stop infusion and remove the PVC. Moderate phlebitis will usually resolve itself. An affected limb should be elevated to minimize inflammation and anti-inflammatory cream or gel can be directly applied to the area (Webster *et al.*, 2013). Heparinoid- is cream/gel which is a novel form of heparin therapy for topical application.

Heparin also has an antiphlogistic and anti-exudative effect, thus alleviating pain and promoting tissue metabolism and the process of healing (Buck, ML). Ichthammol glycerine-Ammonium bituminosulfonate a thick reddish brown liquid, possessing a bituminous odor and taste and soluble in water and miscible with glycerine having It has anti-inflammatory, bactericidal and fungicidal properties used in 10-20% concentration in ointment (Buck, ML).

MATERIAL AND METHODS

The target population was the patients who were admitted to critical care area and had developed sign and symptoms of phlebitis due to peripheral IV cannulation in a selected hospital, Ludhiana, Punjab. Total sample for the study were 60 patients with IV induced phlebitis. Purposive sampling technique was used to select the subjects for the sample with Matching the variables age, Gender and type of condition. Data collection commenced from 9th of December 2013 to 22nd of December 2013. The samples were 60 patients who were admitted in various critical care units of Christian Medical College and Hospital, Ludhiana, Punjab.

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Inclusion Criteria: All Adult patients admitted in critical care area and had developed phlebitis as the result of intravenous therapy. Patients between 18-80 yrs of age, Conscious patients who had developed phlebitis only on the upper limb and had Visual infusion phlebitis score >2 .

Hypothesis: H₁-There will be significant reduction in phlebitis with Ichthammol Glycerine as compared to Heparinoid application at $p < 0.05$ level of significance.

H₀- There will be no significant difference between the effect of Heparinoid and Ichthammol Glycerine application in reducing phlebitis.

Description of tool

A Modified Infusion Phlebitis scale was developed by intensive review of literature, expert's opinion, suggestions of the research panel, researcher's professional experience. Tool consists of 3 main parts. Part -1: It includes variables- age, gender, type of illness, total amount of fluid infused in 24 hours, type of medication, subjects of IV medication, size of cannula, duration of cannula in vein and no of phlebitis occurred previously. Part -2: The Modified Visual Infusion Phlebitis Grading scale was used to assess the severity of phlebitis with maximum 8 and minimum 0 score. Part-3: Standardized Numerical Pain Assessment Scale was used to assess intensity of pain with maximum 10 and minimum 0 score. Pilot study was conducted in medical and surgical ward with 8 samples (4 samples with Heparinoid and 4 Ichthammol Glycerine applications) with matching age, gender and type of disease condition. The data was collected by using inter-rater method. Changes were made according to suggestion of panel members.

Analysis of data

Analysis of data was done in accordance with the objectives. The data analysis was done using the descriptive and inferential statistics. Chi square test is used to assess homogeneity of population. The means of variables were compared by using t-test. The level of significance chosen was $p < 0.05$ & $p < 0.01$ levels. Results of the study were shown in the form of tables and bar graphs.

RESULTS

Findings related to demographic characteristics of samples

Majority of the patients were from 66-80 years of age group in Heparinoid (30.00%) as well as in Ichthammol glycerine application (33.33%). Majority of the subjects were male (56.67%). Majority of patients were having medical condition with (56.67%) and (53.33%) in HPA group and IGA group respectively. Hypertonic solution was being infused (53.34%) and (63.34%) in HPA group and IGA group respectively. Total amount infused in majority subjects was <1 liters with (43.34%) and (56.67%) in HPA and IGA group respectively. A combination of drugs was given in majority of subjects was (46.67%) and (36.67%) in HPA and IGA group respectively. Subjects of medication in majority of subjects was Q 8 hourly in both with (43.33%) and (53.33%) in HPA and IGA group

respectively. Majority the size of cannula being used was 22 G in both groups with (50.00%) in HPA group and (60.00%) in IGA group. Majority of subjects had 25-48 hours of duration of cannula in both groups with (50.00%) & (56.67%) in HPA group and IGA group respectively. Majority of subjects had 2 episodes phlebitis previously (46.66%) in HPA group whereas 3 episodes (33.33%) in IGA group.

Findings related to assess the effectiveness of Heparinoid and Ichthammol glycerine application and compare both

According to level of phlebitis in HPA maximum subjects (90.00%) had moderate phlebitis and after 48 hours of application no subject in severe phlebitis and maximum (63.34%) in mild phlebitis. On the other hand in IGA group maximum (76.66%) subjects had moderate phlebitis and after 48 hours of application no subject was in severe and moderate phlebitis. Thus it was concluded that both the applications were effective in reducing level of phlebitis. Before application the overall mean score of HPA was 10.14 which decreased to 5.90 after 24 hours of application and 2.37 after 48 hours of application. Whereas in IGA the overall mean score was 10.51 which decrease to 2.66 after 24 hours and 1.57 after 48 hours of application. The calculated 't' values were highly significant in between both the groups which shows that HPA and IGA were effective in reducing IV phlebitis. To compare the effect among HPA and IGA test of significance before, after 24 hours and after 48 hours were 0.71, 0.63 and 1.68 which were smaller than tabulated 't' values thus there was no significance difference in effectiveness of both.

To assess and compare the effectiveness of HPA and IGA in term of sign and symptoms of phlebitis i.e. redness, warmth, consistency, cord formation and pain test of significance was applied in between the group and between the group. It showed that there was statistically significance difference between in group after 24 and 48 hours of application but there was no significance difference between both the groups at $p < 0.05$ level of significance thus it was concluded that both the application were effective in reducing redness, warmth, consistency, cord formation and pain.

Findings related to compare the effectiveness of HPA and IGA with selected variables

According to age in years the maximum numbers of subjects were in the category of 66-80 years in both HPA as well as IGA group. It was concluded that there was no significance relationship of HPA and IGA with various categories of age groups in terms of effectiveness in reducing IV phlebitis. There is no significance relationship of HPA and IGA with other variables in term of effectiveness. A study topical heparin for treatment for the treatment of acute superficial phlebitis secondary to indwelling time intravenous catheter A double-blind, randomizes, placebo –controlled trial on 132 patients, thus it implies that topical heparin is safe and effective for the treatment of superficial phlebitis secondary to indwelling intravenous catheter (Polit and Hungler, 1999). Second objective of the study was to assess the effectiveness of Ichthammol glycerine on patients with phlebitis. The present study concluded that IG is effective in reducing sign and symptoms of phlebitis.

Table 1. Demographic Characteristics of Samples

Demographic Variables	HPA (n=30)		IGA (n=30)		N=60	
	Subjects (f)	Percentage (%)	Subjects (f)	Percentage (%)	df	χ^2
I. PATIENT RELATED VARIABLES						
Age in years						
20-35						
36-50	7	23.33	8	26.67		
51-65	6	20.00	5	16.67	3	0.28 ^{NS}
66-80	8	26.67	7	23.33		
	9	30.00	10	33.33		
Gender						
Male						
Female	17	56.67	17	56.67	1	0.00 ^{NS}
	13	43.33	13	43.33		
II. TREATMENT RELATED VARIABLES						
Type of illness						
Medical						
Surgical	17	56.67	16	53.34	1	0.07 ^{NS}
Infusion solution	13	43.33	14	46.63		
Isotonic						
Hypertonic						
Blood & blood products	6	20.00	8	26.67		
A combination of any of above	16	53.34	19	63.33	3	3.14 ^{NS}
Total amount of fluid infused per 24 hours in liters	1	3.34	-	-		
<1	7	23.32	3	10.00		
2-3						
3-4						
> 4						
Type of medication	13	43.34	17	56.67		
Antibiotics	13	43.33	7	23.33	2	2.73 ^{NS}
Electrolytes	4	13.33	6	20.00		
Antacids	-	-	-	-		
A combination of any of above						
Subjects of IV medication						
Q 6 hourly	6	20.00	10	33.33		
Q 8 hourly	1	3.33	1	3.33	3	1.42 ^{NS}
Q 12 hourly	9	30.00	8	26.67		
Q 24 hourly	14	46.67	11	36.67		
Size of cannula in Gauge						
18						
20						
22	2	6.67	2	6.67		
24	13	43.33	16	53.33	3	1.71 ^{NS}
	8	26.67	4	13.33		
Duration of cannula in vein	7	23.33	8	26.67		
< than 24 hrs						
25-48 hours						
49-72 hours						
> than 72 hours	1	3.33	-	0.00		
	13	43.33	11	36.67	3	1.44 ^{NS}
No of episodes phlebitis occurred	15	50.00	18	60.00		
1	1	3.34	1	3.33		
2						
3						
>3	6	20.00	3	10.00		
	15	50.00	17	56.67	3	1.19 ^{NS}
	8	26.67	9	30.00		
	1	3.33	1	3.33		
	4	13.32	6	20.00		
	14	46.66	7	23.34	3	5.37 ^{NS}
	4	13.33	10	33.33		
	8	26.66	7	23.33		

Table 2. Comparative Mean, Standard Deviation and ‘t’ Value of level of phlebitis among Heparinoid application (HPA) and Ichthammol Glycerine application (IGA)

Level of Phlebitis	Score	HPA (n=30)			IGA (n=30)			df	‘t’
		n	Mean	SD	n	Mean	SD		
BEFORE									
No	0	-	-	-	-	-	-	-	
Mild	1-6	1	5.00	0.00	2	5.00	1.41	1	2.88 ^{NS}
Moderate	7-12	27	9.78	1.85	23	10.48	1.38	48	1.50 ^{NS}
Severe	13-18	2	14.00	1.41	5	13.00	0.00	5	1.89 ^{NS}
AFTER 24									
No	0	2	0.00	0.00	1	0.00	0.00	-	-
Mild	1-6	15	4.33	1.50	12	4.33	1.72	25	0.00 ^{NS}
Moderate	7-12	13	8.69	1.65	17	8.17	1.29	28	0.96 ^{NS}
Severe	13-18	-	-	-	-	-	-	-	-
AFTER 48									
No	0	8	0.00	0.00	11	0.00	0.00	-	-
Mild	1-6	19	2.58	1.50	19	2.37	1.34	36	0.45 ^{NS}
Moderate	7-12	3	7.33	0.58	-	-	-	-	-
Severe	13-18	-	-	-	-	-	-	-	-

Table 3. Comparative Mean phlebitis score, Standard Deviation and ‘t’ Value of Heparinoid application (HPA) and Ichthammol glycerine application (IGA)

Level Of Phlebitis	n	HPA		n	IGA		df	‘t’	
		Mean	SD		Mean	SD			
BEFORE APPLICATION	a 30	10.14	10.13	a' 30	10.51	2.13	(a&a')	58	0.71 ^{NS}
AFTER 24 HOURS	b 30	5.90	3.04	b' 30	6.37	2.66	(b&b')	58	0.63 ^{NS}
AFTER 48 HOURS	c 30	2.37	2.36	c' 30	1.50	1.57	(c&c')	58	1.68 ^{NS}
		df	‘t’			df	‘t’		
	(a&b)	58	2.36*		(a'&b')	58	6.65****		
	(a&c)	58	4.02***		(a'&c')	58	18.65****		
	(b&c)	58	5.02***		(b'&c')	58	8.63***		

Table 4. Comparative Mean, standard deviation and ‘t’ Value between Heparinoid application (HPA) and Ichthammol Glycerine application (IGA) on patients with IV induced phlebitis with gender

Gender	HPA (n=30)			IGA (n=30)			df	‘t’
	n	Mean	SD	n	Mean	SD		
BEFORE APPLICATION								
Male	17	9.59	2.09	17	10.35	1.73	32	1.16 ^{NS}
Female	13	10.85	1.95	13	10.77	2.68	24	0.08 ^{NS}
AFTER 24 HOURS								
Male	17	5.65	3.69	17	6.06	2.22	32	0.39 ^{NS}
Female	13	6.23	2.00	13	6.77	3.19	24	0.52 ^{NS}
AFTER 48 HOURS								
Male	17	2.24	2.44	17	1.18	1.33	32	1.57 ^{NS}
Female	13	2.31	2.43	13	1.92	1.80	24	0.46 ^{NS}

This objective is being supported by Biwas D who conducted a study among four modalities to treat phlebitis that were used by nurses ie ichthamol belladonna, ichthamol belladonna with hot fomentation, glycerine magnesium sulphate and glycerine magnesium sulphate with hot fomentation and concluded that all the four modalities were effective with variables but ichthamol belladonna with hot fomentation was the most effective (Biswas, 2006). Third objective of the study was to compare the effectiveness of Heparinoid and Ichthammol glycerine on patients with phlebitis. In current study researcher found that the two applications were effective in reducing the sign and symptoms of phlebitis but it was not statistically proved that which one more effective or it can be concluded that there was no statistically significant difference between the Heparinoid and Ichthammol Glycerine application or both were equally effective. A study to compare the effectiveness of hot fomentation, thrombophob and Ichthammol glycerine on patients with phlebitis related to peripheral intravenous infusion and found that three modalities Ichthammol glycerine was the most effective in reducing sign and symptoms of phlebitis and this study is contradictory to my study (Jency, 2009). Bergqvist D, Brunjwall J, Jensen N, Persson NH conducted a trial on treatment of superficial thrombophlebitis has been performed in 68 patients randomized to either Hirudoid cream, piroxicam gel or placebo treatment effect was evaluated using the status of thrombophlebitis, the thrombophlebitis area, pain intensity with visual analogue scale and side effects registered. The result shows that both in the treatment groups and the placebo group there was significant decrease of sign and symptoms during treatment period (Bergqvist *et al.*, 1990). Chuanping H, Junying W, Yuling J conducted a study on the curative effects of notoginseny cream versus Hirudoid (heparin) cream in the treatment of postinfusion phlebitis and found that actual time of disappearance of the signs and symptoms of phlebitis also were significantly shorter in patients treated with notoginseny cream than with Heparinoid cream (Chuanping *et al.*, 2000). In the present study Heparinoid and Ichthammol glycerine application group the mean swelling score was 2.10 and 2.17 respectively. After 48 hours it decreases to 0.90 and 0.60 respectively. But there was no significance difference among the both in reducing swelling thus it was concluded that both the applications were effective in reducing swelling in IV induced phlebitis. Czarnetzki BM conducted study on inhibitory effect of shale oils (Ichthyols) on the secretion of Chemotactic Leukotrienes from Human Leukocytes and on Leukocytes migration and found that Ichthyols are shale oils with well known anti-inflammatory effects in dermatological diseases^[15]. In present study mean pain score in Heparinoid group was 4.10 and after 48 hours of application it was decreased to 0.50 whereas in Ichthammol glycerine group before application mean pain score was 4.47 and after 48 hours it reduces to 0.64 thus it indicates that both the applications are effective in reducing pain but statistically there was no significant difference in reducing pain thus both the applications are effective in decreasing pain in IV induced phlebitis. Purungala AA conducted a quasi experimental study on the effectiveness of hot fomentation in reducing sign and symptoms of thrombophlebitis caused by intravenous infusion and medications. The average pain level in the experimental group was 2.86 and reduced to no pain at the end of intervention (Purungala, 2009). Hastings, Tolsma MT and Tompkins

conducted a study on effect of cold and warm application on resolution of IV phlebitis. The findings revealed that application of warmth to sites of IV phlebitis produced faster resolution of extravasations than did cold application at a significant difference (Hastings-Tolsma *et al.*, 1993). 4th objective of the study is to ascertain the relationship of effectiveness of Heparinoid and Ichthammol glycerine with selected variables. In present study 56.67% are males and 43.34% are females. The risk developing mechanical phlebitis was higher in women as their veins are smaller and Maki GJ and Ringer M found that female gender to be an associated risk factor for the development of these complications (Maki *et al.*, 1981). In conclusion though Heparinoid is easy method of application but Ichthammol glycerine is one of the old method of application by using touch results in more patient satisfaction, is equally effective.

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