



EFFECT OF TOPICAL HEPARIN ON THROMBOPHLEBITIS: A RANDOMIZED CONTROL STUDY

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Abstract:

Background: Intravenous cannulation usage is a vital component for the patient admitted at hospitals . PIC insertion associated with some complications ranging from minor pain to severe thrombophlebitis and catheter related infections .The prevalence of thrombophlebitis due to IV insertion ranges fro 50-70%.In the present setting this sort of study is not yet conducted.

Aims and Objective: To evaluate the effectiveness of application of topical heparin before peripheral venous cannulation with non application of heparin gel in prevention of thrombophlebitis at different intervals in patients undergoing intravenous cannulation in patients admitted in a tertiary hospital in Mumbai.

Materials & Methods : A prospective, randomized, parallel group, single centre, clinical study .Main study was conducted after pilot study after obtaining clearance from ethical committee and consent from individual participants. A total 60 patients undergoing intravenous cannulation that has been planned to remain in situ for at least 72 hours indoor period were enrolled & randomized using computer generated random number table. Patients were randomized into Control vs Experimental group and assessed using a Visual Infusion Phlebitis Scoring Tool. Heparin gel was applied 5 minute before the procedure of intravenous catheter insertion at catheter site. Patients were evaluated using standardized tool Visual Infusion Phlebitis Score Tool for incidences of infusion phlebitis, first signs of phlebitis and treatment emergent application site reactions at 0.12,24,72 hours. Findings were statistically analysed for statistical significance, p - value below 0.05 levels was considered to be significant.

Results: Application of topical heparin in the experimental group is effective in preventing and mitigating superficial thrombophlebitis compared to control group.At 72 hours the experimental group has a median superficial thrombophlebitis grade of 1 with an IQR of 1 whereas in control group has a median Superficial Thrombophlebitis grade of 4 with IQR of 1 indicating severe superficial thrombophlebitis at p value of < 0.001

Conclusion: Heparin gel application was effective in the prevention of infusion-associated phlebitis

Key words: Topical Heparin, Superficial thrombophlebitis, Venous cannulation

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Introduction:

A well-known standard procedure used in hospital wards and intensive care units to facilitate the timely and accurate delivery of medications is peripheral vein cannulation. Despite the benefits, the placement of an intravenous cannula may result in unintended adverse effects that could affect patient outcomes, and phlebitis, which can be mechanical, chemical, or bacterial in nature, is one of the most common local problems linked to peripheral intravenous treatment.¹ Between 5% and 70% of hospitalised individuals develop superficial thrombophlebitis. An intravenous catheter acts as a foreign object in the vein, damaging the endothelium. Endothelial damage is one of the components of Virchow's triad of thrombosis, which also includes blood flow stasis, endothelial damage, and hypercoagulability. Phlebitis is caused by inflammation of the tunica intima of the superficial veins. Infectious, chemical, or mechanical causes could be the source of this inflammation.²

The common problems associated with intravenous catheter insertion are mechanical phlebitis, chemical phlebitis & infective phlebitis^{3,4} In the present setting study on effectiveness of topical heparin on thrombophlebitis is not yet undertaken. So the study was undertaken to see the effectiveness of topical heparin in prevention of thrombophlebitis.

Materials & Methods:

The present study is a prospective, interventional study, conducted after getting clearance from Institutional Research and Committee and written consent from participants. A total of 60 patients admitted in different medical and surgical wards of tertiary care hospital, requiring a venous cannulation for >72 hours in the upper limb without any comorbidities like Type 2 DM, HTN, CAD stroke and not on antiplatelet medication were selected using computer generated random number table for the

study in the month of Jul & Aug 2024. The age group of participants limited between 21-60 years of age. Group I did not receive any intervention whereas Group II received topical heparin application before intravenous cannulation. The site was cleaned with surgical spirit and after alcohol dried 1 ml of topical heparin applied around 3 cm diameter of site. The amount of heparin measured using 1 ml syringe. Adequate care was ensured to see the site is not touched by any person or objects. The time was marked as 0 hour and 18 G intracath inserted into site and fixed with Elastoplast. The same site was examined at 12 hours, 48 hours & 72 hours and graded using Visual Infusion Phlebitis Score, Any score of 1 or greater was considered phlebitis. This regime was followed for 72 hours. Any adverse effect if present was noted.

All characteristics were summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and data were analyzed by Chi square test for association, and diagrammatic presentation. If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.27.0 and Microsoft Excel 365 based on the objectives of the study.

Result:

A total of 60 participants selected for the study in both control and experimental group in which both genders were equal in number. In experimental group majority (50.00%) of the participants were aged between 21-30 years whereas in control group majority (26.67%) of participants were between 41-50 years old. There was no statistically significant differences between the groups in all variables, age (p=0.112) gender (p=1) which suggests the group was homogeneous in nature.



Table No.1: Comparison of Superficial Thrombophlebitis over 72 Hours

Superficial Thrombophlebitis Grades at	Experimental (n=30)		Control (n=30)	
	Median	Interquartile Range	Median	Interquartile Range
00 Hrs	0	0	0	0
12 Hrs	0	0	1	1
24 Hrs	0	1	2	1
48 Hrs	1	1	3	1
72 Hrs	1	1	4	1

Table No .1 demonstrates that application of topical heparin in the experimental group is effective in preventing and mitigating superficial thrombophlebitis compared to the control group. The experimental group consistently shows lower median ST grades and less variability over time , while the control group experiences a significant increase in both the incidence and severity of ST.

At 00 hours both the experimental and control groups have median ST grade of 0 with an IQR of 0, indicating that superficial thrombophlebitis was not present in either group immediately after cannulation..At 12 hours, the experimental group maintains a median ST grade of 0 with an IQR of 0, showing that the application of topical heparin has effectively prevented ST. In contrast, the control group shows a median ST grade of 1 with an IQR of 1, suggesting that superficial thrombophlebitis has started to develop..In experimental group 86.67% of participants remain at Grade 0, while in the control group only 43.33% remain in grade 0.Additionally 13.33% of the participants in the experimental group develop Grade 1 phlebitis compared to 56.67 % in control group. At 24 hours, the experimental group's median ST grade rises to 0 with an IQR of 1, reflecting some mild ST cases but still significantly lower than in the control group. The control group, however, has a median ST grade of 2 with an IQR of 1, demonstrating a notable increase in ST severity. At 24 hours, the disparity grows further. 66.67% of

participants in the experimental group remain at Grade 0, while only 3.33% of the control group do. 33.33% of the experimental group progress to Grade 1, while 40.00% of the control group are in Grade 1, 50.00% in Grade 2, and 6.67% in Grade 3.At 48 hours, the median ST grade in the experimental group is 1 with an IQR of 1, indicating a moderate level of ST but still less severe than in the control group. The control group's median ST grade increases to 3 with an IQR of 1, showing a considerable escalation in ST severity over time. At 48 hours, only 30.00% of participants in the experimental group remain at Grade 0, compared to none in the control group. In the experimental group, 56.67% have reached Grade 1, and 13.33% have reached Grade 2. In contrast, 10.00% of the control group are at Grade 1, 33.33% at Grade 2, and 56.67% at Grade 3.At 72 hours the experimental group has a median ST grade of 1 with IQR of 1 suggesting that ST remains relatively mild .The control group however has a median ST grade of 4 with an IQR of 1 , indicating severe ST. By 72 hours, no participants in either group remain at Grade 0. In the experimental group, 60.00% of participants are at Grade 1, 33.33% at Grade 2, and 6.67% at Grade 3. In the control group, 36.67% of participants are at Grade 3, 50.00% at Grade 4, and 6.67% at Grade 5. The p value of <0.001 denotes a highly significant difference between the groups , reinforcing the benefit of topical heparin in preventing the progression of superficial thrombophlebitis.

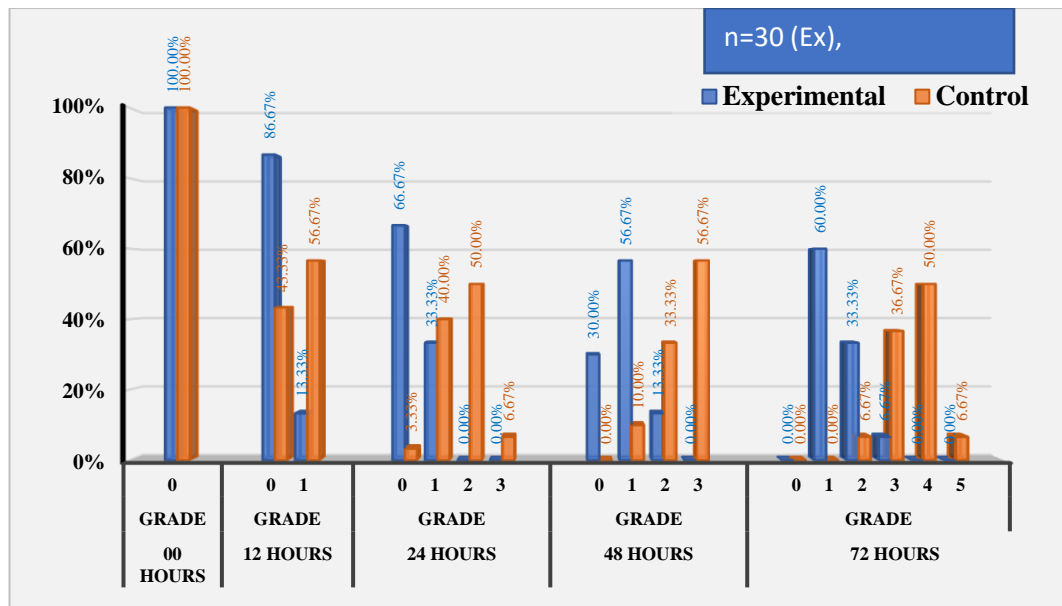


Fig No 1: Multiple bar chart depicting the Superficial Thrombophlebitis Grades Between Experimental and Control Groups Post Peripheral Venous Cannulation.

Fig No. 1 demonstrates the difference in level of thrombophlebitis over different duration like 0 hours, 12 hours, 24 hours, 48 hours and 72 hours. The bar chart clearly indicates that the development of thrombophlebitis was high among the control group.

There is no significant association observed between age and gender with severity of thrombophlebitis. However, in the control group a significant association emerges starting at 12 hours, with females consistently showing higher ST grades than males through 72 hours. This suggests that in the absence of an intervention, females may be more prone to developing higher grades of superficial thrombophlebitis compared to males following peripheral venous cannulation.

Discussion:

One of the most frequent side effects of intravenous cannulation, which is used to deliver medications, fluids, blood, and other infusions, is superficial thrombophlebitis. Despite being harmless and self-limiting, superficial thrombophlebitis can, if left

untreated, result in deep vein thrombosis and pulmonary embolism. Important risk factors include the length of cannulation, the material, the size, the type of infusate utilized, and the presence of superficial skin infections.

The present study is congruent with the study conducted by Sinjini A et al (2020) which has assessed the efficacy of topical heparin in prevention of superficial thrombophlebitis before peripheral venous cannulation that shows overall incidence of thrombophlebitis was 40% in the heparin groups as compared to 95.6% in the control group.⁵

Teena B et al (2019) conducted a study to evaluate the efficacy of topical quick penetrating solution of heparin in preventing thrombophlebitis shows that the application of QPS solution prophylactically significantly decreased the incidence of thrombophlebitis as observed in our study.⁶

Harsha Somavarapu et al (2024) conducted a multicentre, prospective, observational, single-arm registry study to assess the clinical safety and



effectiveness of thrombophob ointment (Heparin Sodium+ Benzyl Nicotinate) in Indian patients. Compared to baseline, patients experienced significantly reduced severity of phlebitis, shorter venous lesion lengths, and lower pain and tenderness scores. Treatment effectiveness was excellent in 72% of patients, and treatment safety was excellent in 93% of patients as observed in our study⁷

Conclusion:

The study reveals that application of topical heparin is effective in preventing superficial thrombophlebitis compared to control group. The effective use of heparin gel before intravenous insertion will lead to reduction in severity of thrombophlebitis. It is recommended to conduct study in bigger setting with mor sample size as well using other methods in prevention of thrombophlebitis.

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