

To Study the Efficacy of Glycerol Magnesium Sulphate in Prevention of Superficial Thrombophlebitis

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Abstract

Background: Thrombophlebitis is vein inflammation associated with blood clot formation. Percutaneous venous Thrombophlebitis is the inflammation of a peripheral vein brought on by irritation to the vessel lining. In patients receiving intravenous therapy, peripheral venous thrombophlebitis is common.

Aim: The aim of the study was to study the efficacy of glycerol magnesium sulphate in prevention of superficial thrombophlebitis

Methods: This randomized controlled prospective study was carried out at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, within 2 years. 100 patients were randomly allocated in two groups, group H and group M.

Results: In group H, the majority of patients i.e., 32% were 41-50 years, the number of females (60%) was higher as compared to males. In group M, the majority of patients i.e., 42% were 19-30 years, the number of males (64%) was higher as compared to females. PR was highest at 48 hours, SBP at 24 hours, DBP at 36 hours and temperature at 60 hours for both groups.

Conclusion: We came to the conclusion that the QPS formulation of topical heparin was superior to the Glycerin Magnesium Sulphate in terms of preventing superficial thrombophlebitis

Keywords: Thrombophlebitis, Vein Inflammation, Blood Clot Formation, Intravenous, And Magnesium Sulphate.

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Introduction

Thrombophlebitis is vein inflammation associated with blood clot formation. Percutaneous venous Thrombophlebitis is the inflammation of a peripheral vein brought on by irritation to the vessel lining. In patients receiving intravenous therapy, peripheral venous thrombophlebitis is common.[1]Thrombophlebitis risk is increased by a number of variables. The duration of the catheter's stay at the location is the most crucial factor. A variety of infusates, including as certain antibiotics, potassium, parenteral nutrition, chemotherapeutic drugs, and blood products, may increase the risk of complications connected to intravenous catheters. Despite the use of plastic infusion sets and other kinds of presterilized plastic cannula, thrombophlebitis is still a frequent side effect of continuous intravenous infusion. When utilising an infusion pump, placing catheters close to the elbow, or administering medications using a catheter more

than four times per day, phlebitis is more likely to develop.[2]

Topical heparin administration for seven days is the currently recommended medical treatment for peripheral thrombophlebitis. Heparin works by inhibiting coagulation before lysing a formed clot. Heparin extends the period that a single intravenous cannula remains in place and can be extremely helpful in high risk groups that need intravenous cannulation, such as cancer patients receiving chemotherapy, ICU patients, and newborns. It improves patient compliance by reducing the need for frequent cannulations and related morbidity.[3] Additionally, it avoids complications from peripheral thrombophlebitis and accompanying hospital stays. Other pastes and ointments are also used for thrombophlebitis caused by infusions. The paste made of magnesium sulphate is one of them. With the chemical formula MgSO₄, magnesium sulphate is a substance that is frequently found in dry

form as magnesium sulphate-containing Epsom salts. Topical applications of magnesium sulphate have been recommended for relieving oedema and discomfort. Additionally, it is utilised to treat inflammatory skin disorders. According to a theory, magnesium sulphate paste may stop bacterial development by building up significant osmotic gradients that cause the germs to effectively dehydrate and die.[4] In addition to treating bronchial asthma and cardiovascular conditions such cardiac arrhythmia, hypertension, and tachycardia, magnesium sulphate has also been approved for use internally.[5]

The aim of the study was to study the efficacy of glycerol magnesium sulphate in prevention of superficial thrombophlebitis; To compare efficiency of glycerin magnesium sulphate with qps heparin in prevention of superficial thrombophlebitis and to look for any side effect related to superficial application of both drugs.[6]

Methods

This randomized controlled prospective study was carried out at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, within 2 years. 100 patients were randomly allocated in two groups, group H and group M (50 in each group) as per computer generated random number table. Demographic profile of patient like age, sex, BMI and ASA was recorded either in preop area or in operation theatre before operation. Sample size was estimated based on alpha error of 0.05 and power of 80%. 18G IV cannula was inserted and secured in prominent vein. We secured cannula in pre-operative area under strict aseptic and antiseptic precautions. The site of iv cannulation was also be recorded after securing the cannula.

Group H: patients received topical 10drops of heparin qps (1000 IU/ml)

Group M: patients received topical glycerin magnesium sulphate.

Both heparin qps and glycerin magnesium sulphate were applied along the length of cannula and

covered with adhesive tape and this time was marked as '0' hour. Topical application of both study drug was repeated after every 12 h for total 72 h and site of iv cannulation was inspected for pain, oedema, streak formation and palpable veinous cord greater than 2.54 cm in length and scored as per infusion nursing society (INS) phlebitis score.

INS phlebitis score:

0 - no symptom's

1- Pain and erythema

2- Pain, erythema and oedema

3- Pain, erythema, oedema and streak formation

4- Pain, erythema, oedema, streak formation and palpable veinous cord greater than 2.54 cm in length.

Any score greater than 1 was considered as phlebitis this was followed till 72 hrs. Any adverse effects if present were noted. Application of study drug was done by independent nursing staff that was not the part of study. Patient and investigator both were blinded by the type of drug applied.

Inclusion criteria: Patients who were of age 18 to 55 years of either of sex, posted for elective surgery requiring Intra venous cannulation more than 72 h and patients of ASA physical status 1, 2, 3 were included in this study.

Exclusion criteria: Patients who were allergic to glycerin magnesium sulphate and heparin qps, who refused to participate, who were on IV chemotherapy, on central venous catheter on same side of limb, dermatological disorder, cardiac problem, had injury on same side of limb, or had coagulation disorder were excluded from this study.

Statistical analysis: All the data were analyzed using SPSS package (Stata, version 26.0 SPSS INC, Chicago, IL, USA) for windows. The data were presented as descriptive statistics for continuous variables and percentage for categorical variables and was subjected Chi-square test, ANOVA test and t test. Other values were represented in number, proportions (%) and mean \pm SD.

Results

Table 1: Frequency of Age Distribution

Age	Group H		Group M		P Value
	Number	%	Number	%	
19-30	12	24%	21	42%	1.000
31-40	12	24%	12	24%	
41-50	16	32%	13	26%	
51-55	10	20%	4	8%	

Table 1 depicts that in group H, the majority of patients i.e., 16 (32%) were 41-50 years, equal representation of patients 12 (24%) were in age groups 19-30 and 31-40, while 10 (20%) patients were 51-55 years. The Mean \pm SD was 40.18 \pm 10.51. In group M, the majority of patients i.e., 21 (42%) were 19-30 years, 13 patients (26%) belonged to 41-50 age group, 12 patients (24%) were of 31-40 years while 4 (8%) patients were of 51-55 years. The Mean \pm SD was 34.82 \pm 11.35.

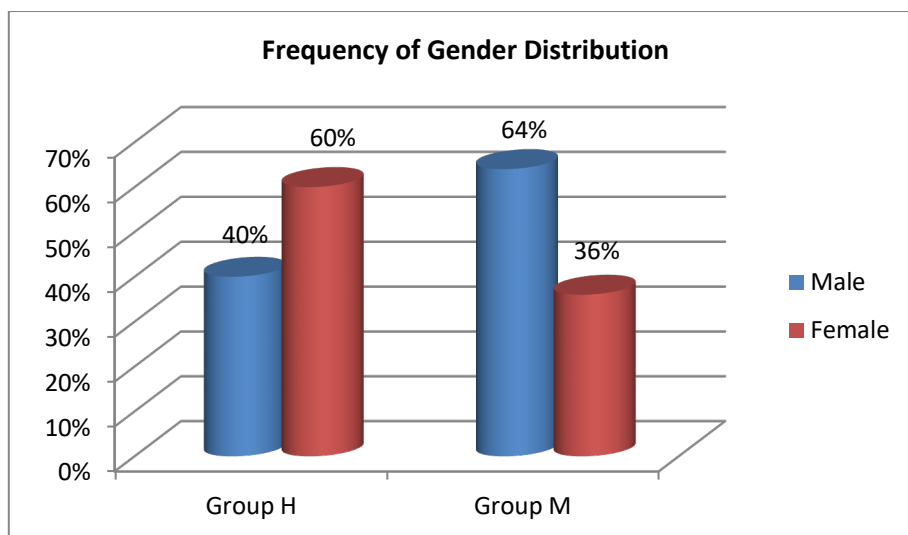


Figure 1: Frequency of Gender Distribution

According to Graph 1, the number of females [30 (60%)] was higher as compared to males [20 (40%)]. However, in group M, the number of males [32 (64%)] was higher as compared to females [18 (36%)].

Table 2: PR and SBP in different group at different time interval

Time intervals	Group H		Group M	
	PR	SBP	PR	SBP
	Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD
0hr	77.2 \pm 5.24	121.44 \pm 10.29	77.92 \pm 5.39	120.94 \pm 9.86
12hr	76.12 \pm 6.04	124.26 \pm 9.39	78.08 \pm 6.12	123.96 \pm 9.21
24hr	79.54 \pm 4.57	124.38 \pm 9.83	80.1 \pm 3.94	124.04 \pm 7.78
36hr	79.62 \pm 5.15	119.62 \pm 12.11	84.26 \pm 3.33	121.28 \pm 9.32
48hr	81.26 \pm 4.79	121.6 \pm 9.15	86.54 \pm 3.48	121.64 \pm 8.33
60hr	80.54 \pm 5.31	121.7 \pm 10.0	83.66 \pm 4.58	122.44 \pm 9.03
72hr	79.22 \pm 5.62	123.4 \pm 8.57	81.46 \pm 5.81	123.74 \pm 8.52

Table 2 depicts the PR and SBP of the patients and the mean differences between both groups at different time intervals. The highest mean values in group H were seen at 48 hours for PR (81.26 \pm 4.79) and at 24 hours for SBP (124.38 \pm 9.83). However, the highest mean values in group M were seen at 48 hours for PR (86.54 \pm 3.48) and at 24 hours for SBP (124.04 \pm 7.78).

Table 3: DBP and temperature in different groups at different time interval

Time Intervals	Group H		Group M	
	DBP	Temperature	DBP	Temperature
	Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD
0hr	74.82 \pm 4.84	98.52 \pm 0.57	75.14 \pm 10.04	98.21 \pm 0.62
12hr	79.26 \pm 3.31	98.48 \pm 0.69	79.74 \pm 4.52	98.48 \pm 0.58
24hr	78.36 \pm 4.31	98.73 \pm 0.46	78.74 \pm 5.1	98.32 \pm 0.77
36hr	81.28 \pm 2.79	98.60 \pm 0.57	81.54 \pm 3.32	98.81 \pm 0.60
48hr	76.98 \pm 11.69	98.81 \pm 0.52	79.50 \pm 4.63	99.02 \pm 0.41
60hr	77.52 \pm 4.66	99.02 \pm 0.44	79.56 \pm 5.45	99.20 \pm 0.19
72hr	79.58 \pm 5.27	98.70 \pm 0.63	80.70 \pm 5.06	98.81 \pm 0.67

Table 3 depicts the DBP and Temperature of the patients and the mean differences between both groups at different time intervals. The highest mean values in group H were seen at 36 hours for DBP (81.28 \pm 2.79) and at 60 hours for Temperature (99.02 \pm 0.44). However, the highest mean values in group M were seen at 36 hours for DBP (81.54 \pm 3.32) and at 60 hours for Temperature (99.20 \pm 0.19).

Discussion

Continuous intravenous infusion can result in a common complication called superficial

thrombophlebitis. It is a pathological condition marked by the presence of a thrombus in a superficial vein's lumen, followed by an

inflammatory response in the vein's wall and surrounding tissues.[7] The most frequent IV therapy side effect is phlebitis, and a number of factors have been linked to its pathogenesis. A few of the physical and chemical risk factors for the development of phlebitis include the length of cannulation and irritant drug use. When the peripheral venous catheter is inserted, the peripheral vein is traumatized. Another foreign object in the human body is the catheter. The initial injury and the presence of the foreign body in the vein trigger an inflammatory response that increases the risk of developing a thrombus and phlebitis later on. Because of their longer duration of insertion, catheters that are left in place for a longer period of time have a higher rate of thrombophlebitis.[8]

The purpose of treating superficial thrombophlebitis is to alleviate pain and other symptoms, as well as to prevent complications. Effective treatment of superficial thrombophlebitis is crucial not only for the resolution of local symptoms, but also for preventing the development of systemic conditions such as deep vein thrombosis, for which topical heparin has been shown to be quite effective.[9]

The occurrence of thrombophlebitis was found to be comparable across all age groups of patients, despite differences in risk and incidence between age groups. Our patients' thrombophlebitis did not develop as a result of their age. Other studies have also reported this observation. Significant risk factors for the development of thrombophlebitis following peripheral venous catheterization include both genders.[10]

In our study, we used a scale that was adapted from the clinical grading of phlebitis by the Visual Infusion Phlebitis Scale to grade observed phlebitis. The most prevalent type of phlebitis, accounting for about two thirds of cases, was the mild variety. Phlebitis that was moderate or severe was rare.[11] In preventing superficial thrombophlebitis, both study groups were successful and secure. Heparin QPS, however, performed better than glycerol magnesium sulphate. The novel, patented QPS technology used in the formulation, which allows for greater heparin penetration through the skin, may be the cause of these encouraging results. Our results were in line with the body of research suggesting that this topical heparin formulation, 1000 IU/g, is superior to other topical heparin preparations in preventing superficial thrombophlebitis.[12]

This superiority may be attributable to the formulation's relatively high heparin levels. Comparing a catheter that has been used for infusion to one that has not increased the risk of thrombophlebitis by twofold.[13] The type of solution infused through the catheter may be to blame for this. An increased risk of thrombophlebitis is linked to specific infusate, such as antibiotics,

chemotherapeutic medications, solutions of low pH, and high osmolarity. When infusate is used in patients, we tried to look for an increased prevalence of thrombophlebitis.[14] But among the study's sample population, there was no discernible relationship between the type of infusate and the onset of thrombophlebitis. This might be as a result of the study sample being too small and the majority of patients receiving various infusions via the same peripheral catheter. In order to confirm the impact of various infusates on the development of thrombophlebitis, further research using just one infusate per catheter might be useful.

It was discovered that thrombophlebitis incidence is significantly influenced by how long a catheter is left in a vein. A patient's risk of developing thrombophlebitis increases if they use a catheter for longer than three days.[15] Uslu soy and Barker have previously reported findings of a similar nature. The only risk factor that can be altered is the length of catheterization. Numerous studies' findings have demonstrated that as duration of catheterization increases, so does the risk of thrombophlebitis. All patients should practice prophylactic catheter care, according to recommendations. The catheter needs to be taken out or changed to a different location.

Additionally, no instances of any negative side effects were reported with either study drug. According to safety results, patients' safety was compromised while heparin's effectiveness was increased by using a quick-penetrating solution. Our results for the safety endpoint were in line with the findings of numerous clinical studies that demonstrated the safety and tolerability of topical heparin delivered as a 1000 IU/ml quick penetrating solution.

This study was conducted to compare the effectiveness of Magnesium Sulphate compress Vs Heparin quick penetrating solution (qps), Pain, Erythema and Oedema among patients with Thrombophlebitis at IGIMS, Patna. The subjects in both groups received Magnesium Sulphate compress and Heparin quick penetrating solution for three consecutive days. The study proved that there is an insignificant difference in Pain between patients.

Conclusion

In our study, we came to the conclusion that the QPS formulation of topical heparin was superior to the Glycerin Magnesium Sulphate in terms of preventing superficial thrombophlebitis. In order to lower the high incidence of thrombophlebitis connected to intravenous cannula, it was discovered to be helpful in managing a patient with one. The main risk factor for developing superficial thrombophlebitis was found to be the length of an indwelling intravenous catheter.

Conflict of Interest: The authors state that they have no conflicts of interest.

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