## ORIGINAL RESEARCH PAPER

## PREVENTION OF SUPERFICIAL THROMBOPHLEBITIS IN PATIENTS COMING FOR SURGERY: COMPARISON OF TOPICAL QUICK PENETRATING SOLUTION(QPS) OF HEPARIN VERSUS HEPARIN GEL

### Anesthesiology

**KEY WORDS:** Topical Heparin, Thrombophlebitis , Intra Venous Catheters

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**ABSTRACT**

**Background:** Peripheral intravenous catheters (PIVCs) are a critical tool in the delivery of patient care but phlebitis is one of its commonest complications. Heparin reduces the superficial thrombophlebitis.

**Materials and methods:** This study was conducted at Yenepoya Medical College Hospital. The patients were divided into two groups, using closed envelope method. Group H1 included 70 patients who received QPS solution of topical heparin and Group H2 included 70 patients who received topical heparin gel. The patients were studied for the results on the basis of Phlebitic scale at the intervals of 0 hours, 12 hours, 24 hours, 48 hours and 72 hours.

**Results :** The mean age was calculated as 33.94 There was significantly lesser score in group H1 (receiving QPS topical heparin) in all time periods with p value of <0.001.and we concluded that prophylaxis with topical QPS heparin is more effective than thrombophobe gel in preventing thrombophlebitis..

### INTRODUCTION

In healthcare setting, peripheral intravenous catheters (PIVCs) are a critical tool in the delivery of patient care. Peripheral intravenous catheters are indispensable in patients coming for elective or emerency surgical procedures. IV access is essential for administration of anesthetic medications, resuscitation drugs, intravenous antibiotics, fluids, blood and blood products. Intravenous catheterization is a technique in which after taking strict aseptic precautions an intravenous catheter is placed inside a vein to allow venous access. Phlebitis is one of the most common complications of the PIVC and is defined as inflammation of a vein related to a mechanical or chemical irritation, or both. Maintaining a single indwelling intravenous (IV) cannula for long duration is limited by the development of superficial thrombophlebitis. Various literature have shown that the average thrombophlebitis incidence is more than 30% with peripheral intravenous therapy. Various treatment modalities are available for prevention of phlebitis, that include discontinuing intravenous catheter and restarting it in another site, applying a warm moist compress to the affected site , administration of analgesics and local application of heparinoid ointment. Heparin which is a non-uniform mixture of straight chain mucopolysaccharides reduces the superficial thrombophlebitis. Topical formulation of Heparin allows better penetration through the skin at the site of application with a lack of systemic exposure at clinically relevant doses, hence reducing the risk of adverse bleeding effects. Heparin gel(Thrombophobe) is a form of heparin therapy for topical application. Heparin is widely used as anticoagulant in clinical practice. A novel topical formulation of heparin sodium Quick Penetrating Solution (QPS) 1000 IU/ml, has been introduced.QPS contains non-aqueous and non-volatile solvents with added permeability enhancers to increase penetration of heparin across the skin, which may improve the efficacy compared to conventional heparin gel. Our study is to compare the prophylactic efficacy of Quick Penetrating Solution of heparin with heparin gel in the prevention of superficial thrombophlebitis.

### MATERIALS AND METHODS

This study was conducted by the Department of Anesthesiology at YENEPOYA MEDICAL College Hospital over a period of two months from February 2018 to April 2018 after getting ethical clearance from Yenepoya University Ethics Committee. A quasi experimental study was conducted on 140 patients of either sex, aged 18-60 years posted for elective and emergency surgery in whom IV antibiotics, IV analgesics and fluids were expected to be administered for more than 72 hours. They were randomly divided into two groups. In all the patients in the preoperative preparation area an 18 Gauge IV Cannula (BD venflon™) was inserted in a prominent vein in the fore arm. In Group H1, topical heparin 1000 IU/ml (Phlebotroy QPS, Troika Pharmaceuticals) 10 drops was applied to the said site along the length of the cannula. Then the site was covered by adhesive tape (3M micro pore) and that time was marked as 'O' hours. Every 12 hours the same site was examined using Visual Infusion Phlebotic scale and again 10 drops of 1000 IU of topical Heparin was applied and site was covered by adhesive tape for a total of 72 hours. In Group H2,thrombophobe gel was applied to the said site along the length of the cannula and that time was marked as 'O' hours. Every 12 hours the same site will be examined using Visual Infusion Phlebotic Scale and again thrombophobe gel was applied and site was covered by adhesive tape for a total of 72 hours. Statistical Analysis was based on Independent 't' test (or Mannwhitney non parametric test for two independent groups) with power 0.8, effect size 0.5. Sample size was calculated using the statistical software G\* power 3.0.10. The data collected was analysed statistically and validated by the research group based on the theory and guidelines on phlebitis. Phlebitis scale is proposed by the RCN 2010; and intravenous drugs, fluid therapy, antibiotic therapy, number of antibiotics, and drugs administered within 24 to 72 hours. Patients refusing to consent, those having an indwelling central venous catheter, with coagulation disorders or patients with hypersensitivity were excluded from the procedure.

### III. OBSERVATION AND RESULTS

In this study a total of 140 patients undergoing elective or emergency surgery in whom IV antibiotics, IV analgesics and fluids were expected to be administered for more than 72 hours were divided into two groups with 70 patients in each group. A total of 70 patients in H1 group (patients receiving QPS solution of topical heparin) and 70 patients in H2 group (patients receiving thrombophobe gel). The patients were studied for the results on the basis of Visual Phlebitic Scale at the intervals of 0 hours, 12 hours, 24 hours, 48 hours and 72 hours. The result was calculated by using Chi Square test at each time period as shown in tables 3. It was observed that there is significantly lesser Phlebitis score in Group H1 (patients receiving QPS solution topical heparin) as compared to Group H2 (patients receiving thrombophobe gel). Also we observed the frequency of incidence in different age groups as shown in tables1 and 2. In our study the mean age was calculated as 33.94 and it was seen that the incidence is more in the female group.
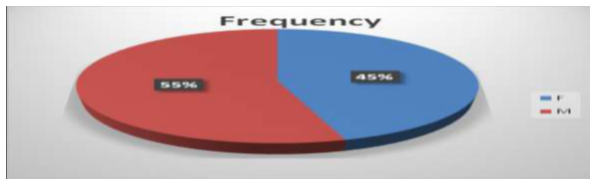
### TABLE 1: AGE DISTRIBUTION

| | GROUP | N | MEAN | Std.deviation | t | df | P value |
|---|---|---|---|---|---|---|---|
| AGE | GROUP H1 | 70 | 35.69 | 11.348 | 2.028 | 130.75 | 0.045 |
| | GROUP H2 | 70 | 32.19 | 8.927 | | | |

**GRAPH 1: AGE DISTRIBUTION IN THE STUDY GROUP**
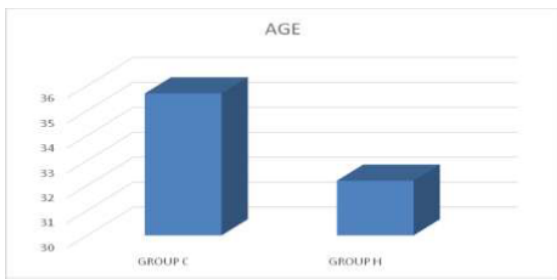


| GENDER | | FREQUENCY | PERCENT |
|---|---|---|---|
| **VALID** | **FEMALE** | **64** | **55%** |
| | **MALE** | **76** | **45%** |
| | **TOTAL** | **140** | **100%** |

**TABLE 2: GENDER DISTRIBUTION IN STUDY GROUP**



**GRAPH 2: GENDER DISTRIBUTION IN THE STUDY GROUP**

Table 3: Phlebitic scale at the intervals of 0 hours, 12 hours, 24 hours, 48 hours and 72 hours

| | | GROUP | | | | CHI SQUARE | P VALUE |
|---|---|---|---|---|---|---|---|
| | | GROUP C | | GROUP H | | | |
| | | Count | Column N % | Count | Column N % | | |
| 0 HRS | 0 | 70 | 100.0% | 70 | 100.0% | | |
| 12 HRS | 0 | 41 | 58.6% | 67 | 95.7% | 27.384 | <0.001 |
| | 1 | 29 | 41.4% | 3 | 4.3% | | |
| 24 | 0 | 4 | 5.7% | 60 | 85.7% | 90.88235 | <0.001 |

| HRS | 1 | 58 | 82.9% | 10 | 14.3% | | |
|---|---|---|---|---|---|---|---|
| | 2 | 8 | 11.4% | 0 | 0.0% | | |
| 48 HRS | 0 | 0 | 0.0% | 34 | 48.6% | 63.16571 | <0.001 |
| | 1 | 26 | 37.1% | 30 | 42.9% | | |
| | 2 | 44 | 62.9% | 6 | 8.6% | | |
| 72 HRS | 1 | 3 | 4.3% | 44 | 62.9% | 61.80705 | <0.001 |
| | 2 | 47 | 67.1% | 26 | 37.1% | | |
| | 3 | 20 | 28.6% | 0 | 0.0% | | |

**Graph 3: Phlebitic scale at the intervals of 0 hours, 12 hours, 24 hours, 48 hours and 72 hours**
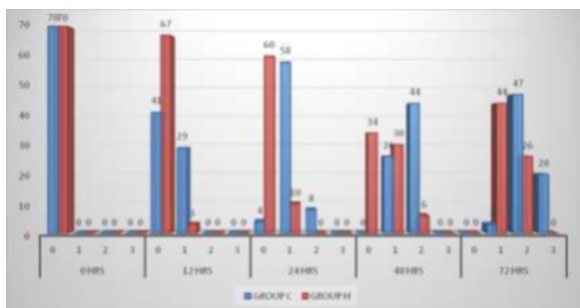


## IV. Discussion

Superficial thrombophlebitis is a common complication of continuous intra-venous infusion. It is a pathological condition characterized by presence of a thrombus in the lumen of a superficial vein, followed by inflammatory reaction of its wall and adjacent tissues. Phlebitis is the most common complication of IV therapy and several factors have been implicated in its pathogenesis. Chemical factors such as irritant drugs and physical factors such as duration of cannulation are few of the identified risk factors for the development of phlebitis The peripheral vein is traumatized during insertion of peripheral venous catheter. The catheter is also a foreign body to the human body. This initial

trauma and presence of foreign body in the vein stimulates an inflammatory response which predisposes the development of thrombus and subsequent phlebitis. Catheters that are left for a longer time have higher rate of thrombophlebitis because of their longer duration of insertion.

The goals of treatment of superficial thrombophlebitis are to reduce pain and other symptoms and also to prevent complications. Effective treatment of superficial thrombophlebitis is important not only for resolution of local symptoms but also for preventing the development of systemic conditions such as deep vein thrombosis where topical heparin was found to be quite effective.

For difference in risk and incidence of thrombophlebitis in different age groups, it was found that the incidence of thrombophlebitis was similar throughout all age groups of patients. The age of a patient did not influence the development of thrombophlebitis among our patients. This observation has also been reported in other studies. Both genders are identified as a significant risk factor to the development of thrombophlebitis secondary to peripheral venous catheterization.

In our study, we graded phlebitis observed, using a scale adapted from the clinical grading of phlebitis by Visual Infusion Phlebitis Scale. Mild grades of phlebitis was the commonest, comprising approximately two thirds of the observed incidence. Moderate and severe phlebitis were uncommon. Both the study groups were effective and safe in preventing superficial thrombophlebitis. However, heparin QPS was more effective than heparin gel as heparin QPS showed a significantly less scale on Visual Infusion Phlebitic Scale. These favorable results were found may be due to novel patented QPS technology used in the formulation which allows higher penetration of heparin through the skin. Our finding was consistent with the line of evidences which suggest that this heparin 1000 IU/g topical formulation is more effective than other topical preparations of heparin in preventing superficial thrombophlebitis, possibly because of the relatively high heparin levels in such formulation..

A catheter that is used for infusion has double the risk of developing thrombophlebitis compared to a catheter that has not been used. This may be due to the type of solution infused through the catheter. Certain infusates such as antibiotics, chemotherapeutic drugs, solutions of low pH and high osmolarity are associated with an increased risk of thrombophlebitis. We tried to look for an increased incidence of thrombophlebitis when infusate are used in patients. However, there was no significant difference between type of infusate and the development of thrombophlebitis among the sample population in this study. This may be due to the inadequate size of the study sample and the fact that most of the patients received different infusate through the same peripheral catheter. A further study using only one infusate per catheter may be helpful in confirming the risk of different infusates on development of thrombophlebitis.

The duration a catheter is left in the vein was found to significantly influence the incidence of thrombophlebitis. Patients who have a catheter for more than 3 days are more likely to have an increased risk of developing thrombophlebitis. Similar findings have previously been reported by Uslusoy and Barker. The duration of catheterization is the only modifiable risk factor identified. The results of many studies have shown that the risk of thrombophlebitis increases with increased duration of catheterization. It is recommended that prophylactic resiting of catheter should be practiced in all patients. The catheter should be removed or replaced in a different site.

Moreover, no case of any adverse events was recorded with either study drug. Safety results suggested that, while improving the efficacy of heparin through quick penetrating solution, safety of the patients was not vitiated. In safety endpoint, our result was consistent with the several clinical studies which have shown that

heparin 1000 IU gel was well tolerated.

## V. CONCLUSION

In our study we concluded that QPS formulation of topical heparin was more effective in preventing superficial thrombophlebitis than the thrombophobe gel It was found to be useful in managing a patient with intravenous cannula in order to reduce the high incidence of thrombophlebitis associated with intravenous cannula. the duration of an indwelling intravenous catheter was found to be the major risk factor for developing superficial thrombophlebitis.

## VI. ACKNOWLEDGEMENT

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