**Original Research Article**

# To Evaluate the Efficacy of Topical Quick Penetrating Solution of Heparin in Preventing Thrombophlebitis

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**Abstract**

**Background and Aim:** Thrombophlebitis is often linked to peripheral venous cannulation. Sometimes thrombophlebitis goes undiagnosed. Thrombophlebitis comes with major problems and unknown treatment, prevention is best. Prophylactic topical heparin helps minimize thrombophlebitis and its consequences, such as deep venous thrombosis and pulmonary embolism, which lengthen hospital stays. This study examined the efficacy of topical quick penetration solution (QPS) in preventing phlebitis in routine surgery patients who needed a 72-hour IV line.

**Material and Methods:** In this comparative prospective observational study, we observed 100 patients undergoing regular major surgery. We divided these patients in groups A and B of 50 patients in each group. In both the groups, 20G IV cannula was inserted and secured with a micropore. In group B patients, 10 drops of topical heparin 1000 IU/ml were applied along the vein. We used the Phlebitis Assessment Grading (PAG) scale to monitor the cannula site at 0, 12, 24, 48, and 72 hours.

**Results:** According to the PAG scale, at 12 hours, in Group A 48 patients had a score of 0 and two patients had a score of 1. While all 50 patients in Group B scored 0 (p<0.05). At 24 hours, in Group A, 14 patients had scored 0, 30 patients had scored 1 and 6 patients had scored 2. While in group B, 48 patients scored 0 and 2 patients scored 1 (P = 0.01). At 48 hours, in Group A, 18 patients scored 1 and 32 patients scored 2, while in Group B, 30 patients scored 0 and 20 patients scored 1 (P <0.05). At 72 hours, in Group A, 16 patients scored 1, 22 patients scored 2 and 12 patients scored. While in group B, 18 patients scored 0 and 24 patients scored 1 and 8 patients scored 2. Maximum score in group A was observed to be 3 which constituted 24% of the patients. In group B, the maximum score observed was 2 that too in only 8 patients which constituted 16% of the patients. This proves the efficacy of topical QPS of heparin.

**Conclusion:** Prophylactic application of QPS of heparin significantly decreases the incidence of thrombophlebitis. It may be of particular importance in high risk groups and in patients who require IVC for the long time.

**Keywords:** cannula, Heparin, Phlebitis Assessment Grading Scale, Thrombophlebitis.

## Introduction

Intravenous cannulation is one of the most commonly performed procedures in a hospital setting.[1] Superficial thrombophlebitis, defined as an acute inflammation of superficial veins due to presence of a blood clot within the veins, is one of the most common complications of peripheral intravenous cannulation.[2] Most hospitalized patients require IVC (intravenous cannulation) for drugs and fluids. However, 20%–80% of patients with IVC may develop superficial thrombophlebitis.[3,4] IVC, introduced in a vein, acts as a foreign body, which leads to endothelial damage. Endothelial damage is one of the components of Virchow's triad of thrombosis namely- stasis of blood flow, endothelial damage and hypercoagulability. Phlebitis is induced by the inflammation of the tunica intima of superficial veins. Factors leading to this inflammation can be

mechanical, chemical and infectious. Prevention of phlebitis is important because its development leads to acute inflammation causing redness, swelling, increased temperature in the surrounding area and also palpable venous cords.[5] If not treated in time, it may lead to deep venous thrombophlebitis which might lead to sudden pulmonary embolism, increasing the cost and hospital stay.[6] The incidence of superficial thrombophlebitis is around 5%-70% in hospitalized patients.

Topical heparin is widely used for the prevention and treatment of phlebitis. The topical formulation allows heparin to penetrate through the skin with no systemic absorption at clinical dose, thereby decreasing the risk of adverse bleeding effects. At present, heparin is also available as a topical quick penetrating solution (QPS) 1000 IU/mL which contains nonaqueous and nonvolatile solvents with added permeability enhancers to increase the penetration of heparin across the skin.[7] This study was conducted to evaluate the efficacy of topical QPS (quick penetrating solution) in prevention of phlebitis in patients undergoing routine surgery requiring postoperative IVC for 72 hrs.

**Material and Methods**

In our present comparative observational prospective study performed on 100 patients posted for routine major surgery. Patients belong to ASA grade I & II aged 18-60 years and of either sex.

Patients were divided into two groups of 50 each. The study was conducted after taking informed consent.

Patients with known hypersensitivity to heparin, coagulation disorders, sepsis, deep-vein thrombosis, carcinoma, diabetes mellitus, and contraindication to heparin were excluded from the study. In addition, patients on anticoagulants, pregnant and lactating patients were also excluded. Good practice while inserting a cannula has been taken into account which includes - appropriate choice of site of vein, good hygiene -handwashing, skin preparation and using sterile equipment.

The patients were allocated to Group A (control group) and Group B(heparin QPS group) using a computer-generated sequence of random numbers. In group A patients 20G cannula was inserted and secured with micropore and patients in whom 10 drops of topical heparin 1000 IU/ml were applied along the length of the vein before securing the cannula were placed in group B. This time was taken as 0 hrs. Thereafter, every 12 hours, 10 drops of heparin were applied, and the site was covered with micropore. In both the groups the cannula site was observed using Phlebitis Assessment Grading Scale (PAG) [8] at 12, 24, 48, and 72hrs. Patients were advised to avoid hand washing.

Demographic data consisting of age, sex, and weight were recorded. The cannula site was examined using the Phlebitis Assessment Grading Scale at 12, 24, 48, and 72hrs.

**Table 1: Phlebitis Assessment Grading Scale**

| Site of observation | Score | Stage/action |
|---|---|---|
| Intravenous site appears healthy | 0 | No signs of phlebitis |
| One of the sign is evident<br>    Slight pain near cannulated site<br>    Slight tenderness | 1 | Possible first sign of phlebitis<br>    Observe cannula |
| Two of the signs are evident<br>    Pain<br>    Redness | 2 | Early stage of phlebitis<br>    Resite cannula |
| All of the following signs are evident<br>    Pain<br>    Redness<br>    Swelling | 3 | Medium stage of phlebitis<br>    Resite cannula<br>    Consider treatment |
| All of the signs are evident<br>    Pain<br>    Redness<br>    Swelling<br>    Palpable venous cord | 4 | Advanced stage<br>    Resite cannula<br>    Consider treatment |
| All of the signs are evident<br>    Pain<br>    Redness<br>    Swelling<br>    Palpable venous cord<br>    Pyrexia | 5 | Advanced stage<br>    Resite cannula<br>    Consider treatment |

**Statistical Analysis:** The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2019) and then exported to the data editor page of SPSS version 19 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were described as means and standard deviations or median and interquartile range based on their distribution. Qualitative variables were presented as count and percentages.

For all tests, confidence level and level of significance were set at 95% and 5% respectively.

**Results**

**Table 2: Demographic Comparison**

| Variables | GROUP A | GROUP B |
|---|---|---|
| | MEAN ± SD | MEAN ± SD |
| AGE (in years) | 42.50± 13.80 | 38.5± 10.50 |
| WEIGHT (in kgs) | 62.5± 9.69 | 60± 10.02 |
| P VALUE | AGE- 0.1061 | WEIGHT -0.312 |
| GENDER | M: F (16:34) | M: F(8:42) |

**Table 3: Consort Diagram**

| Enrolment | Assesses For Eligibility | |
|---|---|---|
| Allocation | N=100 (Total) Randomised ( N=100) | |
| | Control Group (A) 50 | Case Group (B) 50 |
| Analysis | Analyzed N-50 | Analyzed N-50 |

Demographic data of the patients including Age, weight, gender were comparable in both the groups. Table -3 shows the consort diagram.

**Table 4: Comparison between Two Groups**

| Group A | Number Of Patients | | | | |
|---|---|---|---|---|---|
| Scores | 0 Hrs | 12 Hrs | 24 Hrs | 48 Hrs | 72 Hrs |
| 0 | 50 | 48 | 14 | 0 | 0 |
| 1 | | 2 | 30 | 18 | 16 |
| 2 | | | 6 | 32 | 22 |
| 3 | | | | 0 | 12 |
| 4 | | | | | 0 |
| **Group B** | **Number Of Patients** | | | | |
| Scores | 0 Hrs | 12 Hrs | 24 Hrs | 48 Hrs | 72 Hrs |
| 0 | 50 | 50 | 48 | 30 | 18 |
| 1 | | | 2 | 20 | 24 |
| 2 | | | | 0 | 8 |
| 3 | | | | 0 | 0 |
| 4 | | | | 0 | 0 |
| P Value | | 0.04 | 0.01 | <0.05 | <0.05 |

According to the PAG scale, at 12 hours, in Group A 48 patients had a score of 0 and two patients had a score of 1. While all 50 patients in Group B scored 0 (p<0.05).

At 24 hours, in Group A, 14 patients had scored 0, 30 patients had scored 1 and 6 patients had scored 2. While in group B, 48 patients scored 0 and 2 patients scored 1 (P = 0.01). At 48 hours, in Group A, 18 patients scored 1 and 32 patients scored 2, while in Group B, 30 patients scored 0 and 20 patients scored 1 (P <0.05).

At 72 hours, in Group A, 16 patients scored 1, 22 patients scored 2 and 12 patients scored. While in group B, 18 patients scored 0 and 24 patients scored 1 and 8 patients scored 2. The postoperative infusions were largely the same in both the groups,

including Ringer's lactate, paracetamol, and cephalosporin.[9]

**Discussion**

Intravenous cannulation is one of the most common components of hospital management to administer drugs, fluids, blood, other infusates etc. and superficial thrombophlebitis is one of its most common complications. [1,2] Although superficial thrombophlebitis is benign and self-limiting, can lead to deep venous thrombophlebitis and pulmonary embolism if not prevented. [6] The duration of cannulation, material, size, type of infusate used and existing superficial skin infections are important risk factors.

Incidences of thrombophlebitis get influenced by the location of the cannula also. Catheters placed

near the joints, bony prominences or venous valves carry more risk of thrombophlebitis. Also, the catheters placed on the upper limb have lower rates of developing into thrombophlebitis than those placed on the lower limb.

In this current study it was observed that according to the PAG scale, at 12 hours, in Group A 48 patients had a score of 0 and two patients had a score of 1. While all 50 patients in Group B scored 0 (p<0.05). At 24 hours, in Group A, 14 patients had scored 0, 30 patients had scored 1 and 6 patients had scored 2. While in group B, 48 patients scored 0 and 2 patients scored 1 (P = 0.01). At 48 hours, in Group A, 18 patients scored 1 and 32 patients scored 2, while in Group B, 30 patients scored 0 and 20 patients scored 1 (P <0.05).

At 72 hours, in Group A, 16 patients scored 1, 22 patients scored 2 and 12 patients scored. While in group B, 18 patients scored 0 and 24 patients scored 1 and 8 patients scored 2.

The results of the present study are in agreement with a study which evaluated the efficacy of QPS heparin in preventing the incidence of thrombophlebitis after peripheral intravenous cannulation.[10] The study included 140 patients of the age group 14-55 years posted for surgery (70 patients in each group heparin and control). It was observed significantly lesser phlebitis score in heparin group as compared to the control group.

Our study also agrees with yet another study which compared the efficacy of topical heparin QPS and diclofenac QPS for prevention of superficial thrombophlebitis. This study observed that heparin QPS was 100% effective in the prevention of peripheral intravenous cannulation induced superficial thrombophlebitis, proving diclofenac QPS inferior as 23% of patients developed grade I thrombophlebitis in this group.[11] Heparin-based topical formulations showed a trend of better outcomes at a lesser cost as compared to diclofenac topical preparation in preventing the incidence of thrombophlebitis in surgical patients.

Another study compared the efficacy of topical QPS heparin (1000 IU/ml) versus heparin gel (200 IU/g) in the management of developed thrombophlebitis in 202 patients of early, medium, and advanced stage of thrombophlebitis.[12] Changes at the cannulation site from baseline and proportion of patients with complete healing were recorded, and it was observed that 90% of patients in the heparin QPS group got healed as compared to 65.7% patients in the heparin gel group. In the present study, heparin was used prophylactically while these authors used heparin QPS for the management of phlebitis. Superficial thrombophlebitis is a serious consequence in response to cannula itself or injected drugs. The

basic mechanism responsible is a foreign body reaction due to indwelling cannula or the injected drugs resulting in inflammation and formation of clot. The predominant action of heparin occurs by inhibiting coagulation and with a very little effect on preformed clots.

The low cost and easy application of QPS topical heparin solution without any adverse effects makes it an ideal prophylaxis in prevention of superficial thrombophlebitis. Because of these properties, it also saves the hassles of frequent changing of the I.V. cannulas, thus reducing the cost and hospital stay.

### Conclusion

Prophylactic application of QPS of heparin significantly decreases the incidence of thrombophlebitis. It may be of particular importance in high-risk groups and in patients who require IVC for the long time.

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