

## A study to evaluate the effectiveness of topical interventions in two drug combination therapy versus mono drug therapy for the treatment of intravenous cannula related phlebitis of grade 3 or higher that is caused by the use of peripheral intravenous cannula

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### Abstract

Phlebitis—inflammation of the tunica intima of the venous wall—occurred in 13–56% of hospitalized patients <sup>1</sup>. It causes catheter site puss, palpable venous cord, erythema, oedema, and pain. Cannula-related bloodstream infection (CRBSI) complicates phlebitis <sup>2</sup>. Phlebitis can cause patient discomfort, a longer hospital stay, and higher medical costs. Topical treatment of phlebitis is highly recommended by the Centre for Disease Control (CDC) & The Infusion Nurses Society (INS) <sup>3</sup>. The aim of this study was to examine the efficacy of topical treatment with mono therapy versus Two drug combination therapy.

**Methodology:** Conducted a hospital-based prospective, observational study. 110 patients were enlisted using a procedure known as sequential sampling. All patients have been assigned to either a group receiving Two drug combination therapy or a group receiving mono therapy by using a lottery system. The Jackson's Visual Infusion Phlebitis <sup>3</sup> (VIP) Scoring System was used to determine the presence and severity of phlebitis. Numerical pain scale was used to identify the pain score.

**Result:** Phlebitis affected 41% of 50-64-year-olds. 62% of patients had mild to moderate pain. 75% pain relief and 89% Visual Infusion Phlebitis (VIP) score change after the Two drug combination therapy.

**Conclusion:** The results of the current study support the use of a Two drug combination of drugs for the topical treatment of intravenous cannula-induced phlebitis.

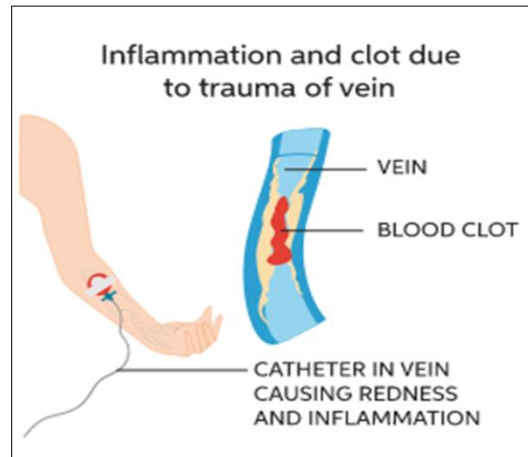
**Keywords:** Phlebitis; Intravenous cannula; Two drug combination therapy; Pain score; VIP scores

### 1. Introduction

Almost 80 to 90 percent of the patients admitted to hospitals receive some form of peripheral intravenous (IV) therapy as a part of the treatment. Intravenous catheters cause endothelial damage (Figure 01) and trauma, which can predispose to venous thrombosis. Peripheral vein infusion thrombophlebitis occurs in 25 - 35% of hospitalized patients with intravenous cannulas and has both patient-related implications (e.g., sepsis) and economic consequences (e.g., extra nursing time). The term phlebitis refers to the presence of inflammation within a vein, whereas thrombosis indicates the presence of clot within the vein. Superficial thrombophlebitis <sup>4</sup>(ST) is a common inflammatory thrombotic

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disorder in which a thrombus develops in a vein located near the surface of the skin (Figure 01). A study conducted in the emergency medical and surgical units of our hospital have reported the incidence of phlebitis associated with peripheral intravenous (IV) cannula to be 29.8%. However, the incidence can be as high as 75% and although the etiology is frequently obscure, it is speculated that IV catheters cause endothelial trauma and inflammation which then leads to venous thrombosis.



**Figure 1** Superficial thrombophlebitis is an inflammation of a vein just below the surface of the skin, which results from a blood clot

Peripheral vein infusion-related thrombophlebitis happens in 25–35% of hospitalized patients with intravenous cannulas. This condition has effects for both the patient and the hospital, such as sepsis and extra nursing time.

Phlebitis means that there is inflammation in a vein, while thrombosis means that there is a blood clot in the vein.

## 2. Literature survey

Yamber5 did a study on 30 ICU patients in Karnataka and found that Glycerin with Magnesium Sulphate is more effective than heparin-benzyl nicotinate (thrombophob) cream at the 0.05 level of significance ( $t = 2.301$ ) for treating cannula-induced thrombophlebitis<sup>6</sup>. Ravindra did a study on the Hospital of Vadodara to see how well magnesium sulphate with glycerin dressing helped patients with phlebitis who were getting peripheral intravenous infusions. He found that magnesium sulphate with glycerin dressing was very good at reducing the level of phlebitis in patients. Thomas<sup>7</sup> did a similar study to compare the effectiveness of Ichthammol glycerin and Heparinoid application on phlebitis in 90 patients at Christian Medical College, Vellore. He found that 26.07% of patients had phlebitis during the six-week study period, and that Ichthammol glycerin was more effective than Heparinoid application based on observations at 12 hours and 24 hours.

Several studies show that hospitals use a lot of Glycerin magnesium sulphate and heparin benzyl nicotinate cream. Magnesium Sulphate ointments was found to be the most effective treatment in reducing phlebitis. But the composition of Magnesium Sulphate ointment does not have vasodilator and anticoagulant properties. Same way in heparin benzyl nicotinate ointment does not have any properties like treat bacterial infection and to keep skin moisture. The VIP score was shown to be decreased more in the group that used Magnesium Sulphate ointment<sup>8</sup>. So, it is revealed that Magnesium Sulphate ointment is more effective than heparin benzyl nicotinate ointment in management of phlebitis. Anticoagulant heparin acts predominantly by inhibiting coagulation and further progression but has a very little effect on preformed clots. If prophylactic topical heparin treatment is begun on day one after an IV cannula has been inserted, it may be possible to prevent or delay the onset of thrombophlebitis with greater success.

### 2.1. Research question

Will this combined therapy of Heparin Benzyl Nicotinate and Magnesium Sulphate Ointment for the treatment of phlebitis related to intravenous cannulas be more effective than individual treatment?

#### *Objectives of the study*

##### 2.1 Hypothesis (H1)

The aim of this study is to evaluate the effectiveness of topical interventions in two drug combination drug therapy versus mono drug therapy for the treatment of intravenous cannula related phlebitis of grade 3 or higher that is caused by the use of peripheral intravenous cannula

### 2.1.1. Hypothesis ( $H_2$ )

To compare topical therapies in two drug combinations with drugs versus mono drug therapy for treating grade 3 or higher intravenous cannula-related phlebitis with selected socio-demographic variables.

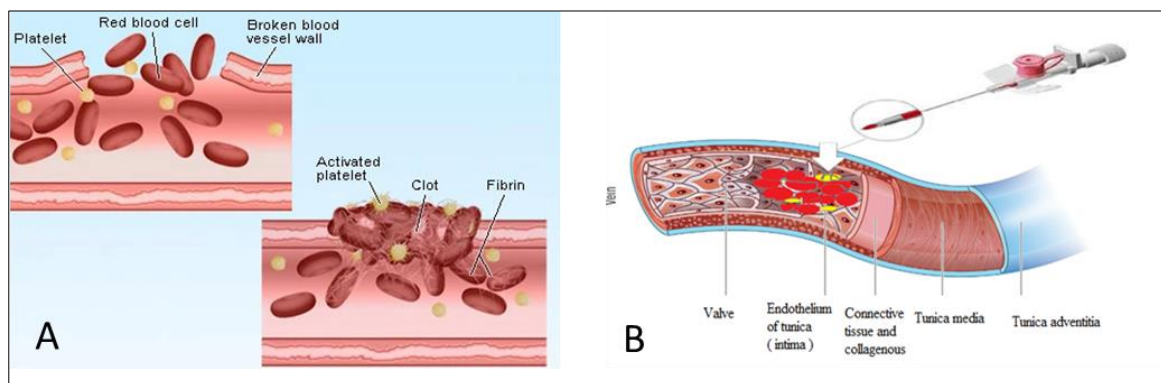
### 2.1.2. Null hypothesis ( $H_0$ )

There is no significant difference in effectiveness of two drug combination therapies as compared to single therapy on prevention of intravenous cannula related phlebitis.

## 2.2. Operational definition

Phlebitis<sup>9</sup>: Intravenous cannula-associated phlebitis is caused by inflammation to the vein at a cannula access site. It can have a mechanical, chemical or infectious cause. Phlebitis is characterized by inflammation of the vein wall and can be accompanied by symptoms such as edema, pain, and erythema near the catheter insertion site or along the affected vein, sometimes progressing to palpable venous cord, intense redness, tenderness, and fever.

This consists of acute inflammation of the wall of the blood vessels, with irritation of the venous endothelium in the section or segment cannulated by the catheter. Identification of phlebitis requires assessment of possible signs and symptoms present in the insertion area, such as erythema, tumefaction in the vein, pain, heat, and fever. In this sense, the use of rating scales such as the Visual Infusion Phlebitis (VIP) scale, the Phlebitis scale, and the Maddox scale may be useful.



**Figure 2** Cannula insertion injures the vein wall (A) causing endothelial damages. Blood flow in the vein is disrupting. A thrombus begins to form as the platelet aggregate at the site of injury (B)

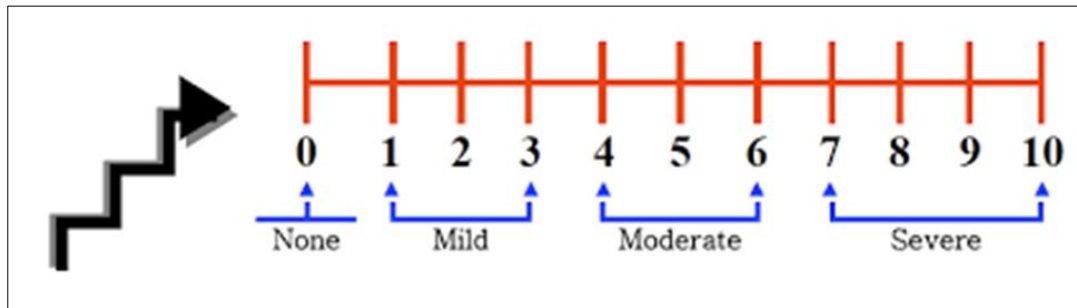
A characteristic inflammatory response is involved in the pathophysiology of phlebitis, which is characterized by a quick onset of symptoms. When the vascular endothelium becomes sensitized—which can happen as a result of friction created by the vascular apparatus against the vascular endothelium, hyperosmolarity in the solution that is supplied, or bacterial toxins—the inflammatory process can begin. This results in the production of inflammatory substances such as serotonin, bradykinin, and histamine, which can produce vasodilation. This further increases vascular permeability and promotes the extravasation of proteins and blood plasma towards the interstitial space, which is what will characterize the edema. In addition to the increase in platelet aggregation that is triggered by histamine, there is a thrombotic formation along the vein wall that extends all the way to the lumen of the vascular apparatus. This thrombotic formation is characterized by localized erythema and a palpable vascular cord that can be up to 3.5 centimeters in length.

- **MAGNESIUM SULPHATE TOPICAL OINTMENT** is a two-drug combination of three medicines Magnesium Sulphate, Sulphacetamide and Urea. Magnesium Sulphate is a natural exfoliant (Exfoliation is the process of removing dead skin cells from the outer layer of skin) and anti-inflammation remedy. Sulphacetamide is used to treat bacterial infections on the skin and urea is used as a moisturizer. SuMag does not have vasodilator and anticoagulant properties.

- BENZYL NICOTINATE TOPICAL OINTMENT is a vasodilator and Heparin is an anticoagulant. It dissolves the clots and also relieves pain and inflammation by increasing the blood flow. This improves the overall healing process.
- HEPARINOID APPLICATION: It refers to application of thrombophob ointment (containing heparin) by gentle massage, three times a day at the site of phlebitis continuously for two days which reduce inflammation, stiffness and, thus alleviate pain and promote tissue metabolism as well as the process of healing.

**2.3. In a numerical rating scale (NRS) 10**

The 11-point numeric scale ranges from '0' representing one pain extreme (e.g., “no pain”) to '10' representing the other pain extreme (e.g., “pain as bad as you can imagine” or “worst pain imaginable”).



**Figure 3** Numerical Rating Scale (NRS)

THE VISUAL INFUSION PHLEBITIS SCORE (VIP SCALE) The VIP scale provides a score from 0 to 5, in ascending order of severity of inflammation.

<b>Visual Infusion Phlebitis Score</b> IV site appears healthy	<b>0</b>	No signs of phlebitis <b>OBSERVE CANNULA</b>
One of the following is evident: • Slight pain at IV site • Redness near IV site	<b>1</b>	Possible first sign of phlebitis <b>OBSERVE CANNULA</b>
Two of the following are evident: • Pain • Erythema • Swelling	<b>2</b>	Early stage of phlebitis <b>RESITE THE CANNULA</b>
All of the following signs are evident: • Pain along the path of the cannula • Erythema • Induration	<b>3</b>	Medium stage of phlebitis <b>RESITE THE CANNULA CONSIDER TREATMENT</b>
All of the following signs evident and extensive: • Pain along the path of the cannula • Erythema • Induration • Palpable venous cord	<b>4</b>	Advanced stage of phlebitis or start of thrombophlebitis <b>RESITE THE CANNULA CONSIDER TREATMENT</b>
All of the following signs are evident and extensive: • Pain along the path of the cannula • Erythema • Induration • Palpable venous cord • Pyrexia	<b>5</b>	Advanced stage of thrombophlebitis <b>INITIATE TREATMENT RESITE THE CANNULA</b>

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**Figure 4** The visual infusion phlebitis score (VIP scale)

**2.4. Rationale for combination therapy**

Studies reveal that hospitals utilize glycerin magnesium sulphate and heparin benzyl nicotinate ointment for topical treatment of intravenous Cannula related Phlebitis. Magnesium Sulphate ointments reduced phlebitis best. However, Magnesium Sulphate ointment is not vasodilator or anticoagulant. Heparin benzyl nicotinate ointment has no antibacterial or moisturizing characteristics. Magnesium Sulphate ointment reduces VIP score more. Heparin is an

anticoagulant and dissolves the blood clot. It also prevents the formation of new blood clots. Benzyl nicotinate is a vasodilator. When patients with thrombophlebitis fail to reach therapeutic goals, including pain relief and a VIP score of zero, medication combinations with fewest adverse effects are an alternative.

#### 2.4.1. Design

The research was conducted using a quantitative method, an observational technique, and a quasi-experimental design.

### 2.5. Setting and population

#### 2.5.1. Setting

The study will be conducted in a Multispecialty Hospitals. Kolkata

#### 2.5.2. Population

All the patients admitted in Multispecialty Hospitals. Kolkata who all experienced phlebitis (VIP score 3 or more) having peripheral intravascular cannula (PIC) in situ constitute the population of the study. Simple random sampling technique was used to allocate the wards to each interventional group and purposive sampling technique to select samples where instruments baseline Performa and observation scale was used to collect data.

#### 2.5.3. Sampling

The subjects were randomly allocated to control and experimental group using Sequentially Numbered, Opaque Sealed envelopes (SNOSE) method. Subjects were observed for 72 hours with an interval of 24 hours. Visual infusion phlebitis scale and numeric pain intensity scale were used to collect data.

### 2.6. Inclusion and exclusion criteria

#### Inclusion criteria

- Patients who developed phlebitis only in the upper limb with visual infusion phlebitis score of three or more.
- Patients who are 18 to 65 years old.
- Patients with infusion related phlebitis and not received any form of intervention by staff nurse

#### Exclusion criteria

- Patients who are not willing to participate.
- Patients who are having skin disorder and abscess seen at the puncture site.
- Patients receiving total parenteral nutrition (TPN).
- Patients who are allergic to Glycerin Magnesium Sulphate paste or Heparinoid (Thrombophob) ointment.

### 2.7. Ethical consideration

Institutional Ethics Committee of Apollo Multispecialty Hospitals Limited IEC Reference Number IEC/BR/2022/09/21.

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## 3. Methodology

50 patients were assigned to the Group A treatment, which consisted of applying a single therapy of magnesium sulphate ointment. 50 participants were assigned to the Group B application of the combined therapy of heparin benzyl nicotinate ointment and glycerin magnesium sulphate ointments. Participation in the trial was permitted for a patient who had peripheral intravenous cannula-induced phlebitis of the upper arm with VIP score 3 or more.

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## 4. Results

### 4.1. Descriptive and Inferential statistic was applied

Table1 shown that 36.4 % the age group 50 to 64 years accounted for 65.5% of the male patients and 34.5% of the female patients who received topical monotherapy medication treatment for phlebitis grade 3 or above. More members in this group have college degrees, and their socioeconomic status is somewhat middle-class. A marital status is held by

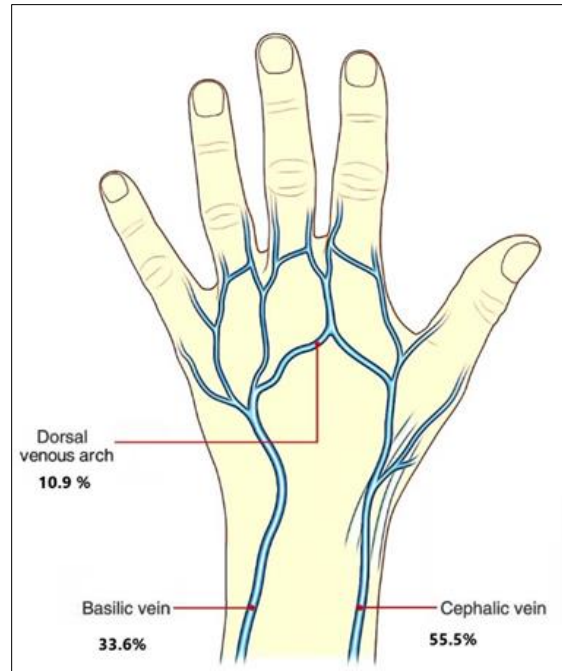
36% of the population. Occurrence happened in both the Intensive Care Unit and the Ward. 43.67% of the population was between the ages of 50 and 64, and 16% were older than 80 years old, and they all received topical combination therapy for patients with phlebitis 3 or more. Phlebitis is more common in the wards than in the intensive care unit and oncology.

**Table 1** Descriptive Statistics for Demographic (N=110 patients)

Criteria	Monotherapy		Combination therapy	
	Frequency	Percent	Frequency	Percent
1. Age group in years				
18 - 34	6	10.9	4	7.3
35 - 49	9	16.4	4	7.3
50 - 64	20	36.4	26	47.3
65 - 79	16	29.1	12	21.8
≥ 80	4	7.3	9	16.4
2. Sex				
Female	19	34.5	30	54.5
Male	36	65.5	25	45.5
3. Educational status				
Graduate	26	47.3	12	21.8
Post Graduate and above	8	14.5	20	36.4
Under graduate	21	38.2	23	41.8
4. Socio Economic Status				
High	18	32.7	30	54.5
Low	10	18.2	2	3.6
Medium	27	49.1	23	41.8
5. Marital Status				
Married	36	65.5	5	9.1
unmarried	19	34.5	27	49.1
6. Type of Family				
Joint	27	20.0	15	27.3
Nuclear	28	29.1	40	72.7
7. Unit Location				
Emergency	1	1.8		
ICU	23	41.8	8	14.5
Oncology	9	16.4	21	38.2
Ward	22	40.0	26	47.3

**Table 2** Cannula insertion site

Cannula insertion site	n=110	Frequency	Percent
The Basilic vein		37	33.6
The Cephalic vein in the lateral forearm		61	55.5
The Dorsal venous arch		12	10.9



**Figure 5** IV cannulation sites on hand. Percentage of insertions of cannulas in this study (Table 2)

The image (Figure 05) depicted that 10.9% of intravenous cannulas were placed in the Dorsal Venous arch, 33.6% in the Basilic vein, and 55.5% in the Cephalic vein.

**Table 3** Time of phlebitis development

		Group		Total
		A Monotherapy	B Combination therapy	
24–48 hours	N	38	28	66
	Col %	69.10%	50.90%	60.00%
	N	17	27	44
48–72 hours	Col %	30.90%	49.10%	40.00%
Total	N	55	55	110
	Col %	100.00%	100.00%	100.00%

Table 03 demonstrated that participants in Group A developed phlebitis with a VIP score of three or above 69.1% of the time during the first 24 - 48 hours, and 30.9% of the time within the first 48 - 72 hours. The same way, the people who belonged to group B and had a VIP score of three or more developed phlebitis 50.9% between 24 to 48 hours and 49.1% within 48 - 72 hours.

**Table 4** Before interventions the pain in numeric rating scale (NRS) 0–10 scale

<b>Numeric rating scale (NRS) 0–10 scale</b>		<b>Group</b>		<b>Total</b>
		<b>A Monotherapy</b>	<b>B Combination therapy</b>	
<i>0 No pain</i>	N	1	1	2
	Col %	1.8%	1.8%	1.8%
<i>1-3 Mild pain</i>	N	34	35	69
	Col %	61.8%	63.6%	62.7%
<i>4- 6 Moderate</i>	N	20	19	39
	Col %	36.4%	34.5%	35.5%
<i>Total</i>	N	55	55	110
	Col %	100.0%	100.0%	100.0%

Before receiving any treatment for their phlebitis, the participants in group A reported moderate pain at a rate of 34.5%, as shown in Table 04; participants in group B had moderate pain at a rate of 36.4%.

**Table 5** VIP scale changed after 48 hours of topical drug Intervention

<b>VIP scale changed after 48 hours of Intervention</b>	<b>Group</b>		<b>P value</b>
	<b>A Monotherapy</b>	<b>B Combination therapy</b>	
Improved	20	49	Value 32.701
	36.40%	89.10%	
No change	35	6	P value < 0.0001
	63.60%	10.90%	

Table 05 and Graph 02 demonstrated that there was a significant improvement in 20 (36.04%) of the participants' VIP scores, while there was no change in 35 (63.60%) of the participants who had received topical medication monotherapy. It also demonstrated that all subjects who were given combination medication therapy to treat phlebitis and had a VIP score of three or above had shown signs of improvement 49 participants (89.10 % among the population).

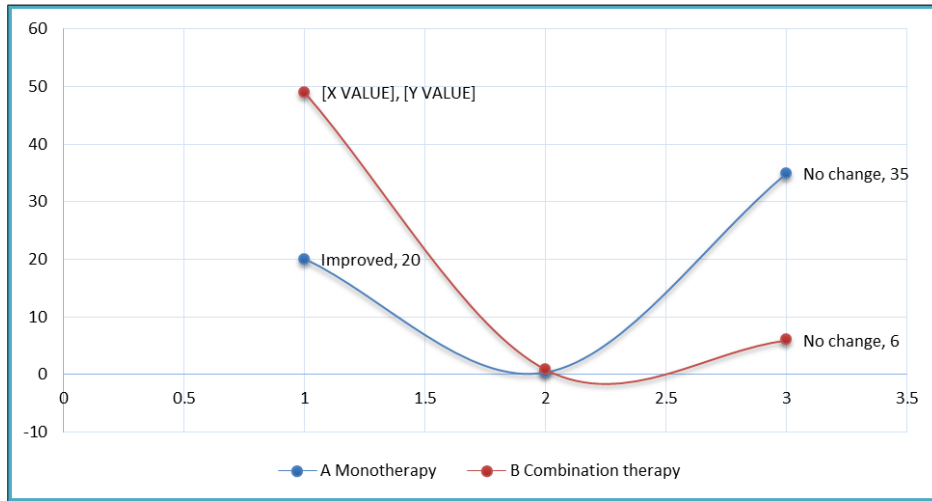
**Table 6** NRS score changed after 48 hours of Intervention. The numeric rating scale (NRS) 0–10 scale

<b>The numeric rating scale (NRS) 0–10 scale</b>		<b>Group</b>		<b>Total</b>
		<b>A. Monotherapy</b>	<b>B. Combination therapy</b>	
1-3 Mild pain	N	38	14	52
	Col %	69.1%	25.5%	47.3%
4- 6 Moderate	N	17	0	17
	Col %	30.9%	0.0%	15.5%
No pain	N	0	41	41
	Col %	0.0%	74.5%	37.3%
Total	N	55	55	110
	Col %	100.0%	100.0%	100.0%



Chi-Square Tests	Value	p value
Pearson Chi-Square	69.077	< 0.00001

Table 06 displayed how the NRS score changed after an intervention with a topical medication for 48 hours. After receiving topical medication monotherapy to treat peripheral cannula related phlebitis with a VIP score of three or more, 69.1% of participants reported feeling mild pain (1-3), 30.9% reported having moderate pain (4-6), and no one indicated that they had no pain. In contrast, the tropical drug combination therapy (two drugs) showed very good outcomes in participant pain control. There was a reduction in participants' reports of pain on the NRS scale; 74.5 % of individuals reported having no pain, and only 25.5 percent reported having mild discomfort.



**Figure 6** VIP score changed after 48 hours of topical Intervention for treating Peripheral cannula related phlebitis



**Figure 7** A Cannula present on hands. B Thrombophlebitis VIP score 3 or More. C Combination therapy D VIP score improved after combination therapy.

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## 5. Discussion

The aim of this study is to evaluate the effectiveness of topical interventions in two drug combination drug therapy versus mono drug therapy for the treatment of intravenous cannula related thrombophlebitis of grade 3 or higher. The table 05 and 06 illustrated that the combination medication therapy to treat the peripheral cannula related thrombophlebitis with VIP score 3 or more were very effective. This study revealed that the 89.10% individuals were benefited with this medication. Both VIP score has been improved and the pain also lowered greatly. It is estimated that around 74.5% of participants' pain has been improved. They discovered that after 48 hours of receiving this combined treatment, there was absolutely no pain.

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## 6. Conclusion

A study done by Amuda K.C. in 2019 at the B.P. Koirala Institute of Health Sciences (BPKIHS) <sup>11</sup> found that both magnesium sulphate with glycerin dressing and heparinoid ointment application were helpful at treating peripheral cannula-induced phlebitis (p 0.001). But magnesium sulphate with glycerin dressing had a higher mean VIP score than heparinoid cream, which means it worked better. According to the findings of the present study, combination topical drug therapy both magnesium sulphate with glycerin dressing and heparinoid ointment application were effective in the management of peripheral cannula-induced phlebitis (p value 0.0001), but only magnesium sulphate with glycerin ointment application was not effective because the VIP score and pain was higher in the monotherapy. Nurses are very important when it comes to finding, treating, and stopping phlebitis and its consequences. If phlebitis is found in a patient, the best way to treat it is with an application of Glycerin Magnesium Sulphate paste and heparinoid ointment. Since phlebitis getting worse affects general care more than treatment, it is important to focus on prevention.

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## Compliance with ethical standards

### *Acknowledgments*

I want to thank all of the teachers who helped me finish this study from the bottom of my heart. It is my pleasure to send my heartfelt thanks and gratitude to and the people who took part in this study.

### *Disclosure of conflict of interest*

The authors have no any conflict of interest for publishing this article.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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