



COMPARISON OF EFFICACY, SAFETY AND PHARMACOECONOMIC EVALUATION OF 'ICHTHAMMOL GLYCERINE', 'HEPARINOID PREPARATION' AND 'MAGNESIUM SULPHATE GLYCERINE' APPLICATION ON THE REDUCTION OF POST CANNULATION PHLEBITIS: A RANDOMIZED OBSERVER BLIND CLINICAL STUDY

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Running title: Evaluation of 'Ichthammol glycerine', 'Heparinoid preparation' and 'Magnesium sulphate glycerine' on post cannulation phlebitis.

Abstract:

Phlebitis is the most common complication of peripheral intravenous cannulation. The current study was carried out to evaluate and compare the efficacy, safety and pharmacoeconomic of dressing with Ichthammol glycerine, Heparinoid preparation and Magnesium Sulphate-glycerine on phlebitis following peripheral intravenous cannulation. One hundred and twenty subjects were included in three groups by a computer generated block randomized (3:3:3) open list of numbers. First, all the subjects were screened and assessed for the grade of phlebitis as per 'Visual Infusion Phlebitis Scale (Jackson -1998)'. The subjects were given the code and divided in three treatment groups as per open list of random numbers by the investigator. The investigator did the intervention after checking the skin sensitivity with that particular drug for three days. The grade of phlebitis was assessed at baseline and then after every 24 hrs for 3 days by the observer. The total treatment cost in 72 hrs was calculated after completing the intervention. There was marked difference in pre and post phlebitis score in all the three groups ($p < 0.0001$). Amongst the three groups, Ichthammol glycerine group had shown the best result in reducing phlebitis score and was the most pharmacoeconomic followed by Magsulph glycerine. Heparinoid preparation was found to be the most costly drug among all the three interventions. None of the subjects had shown any adverse drug reaction.

Conclusions: Ichthammol glycerine was the best treatment in reducing phlebitis score without any adverse drug event and was the most cost-effective drug.

Introduction

Vascular access is an essential component of medical care for the hospitalized patients.¹ It is used for the administrations of intravenous medications, fluids, blood and blood products.² Infiltration, extravasations, and thrombophlebitis are the common associated complications.³ Pain, tenderness, redness, and bulging of the vein are common symptoms of phlebitis. Low grade fever may accompany superficial and deep phlebitis.^{4,5} The treatment of post cannulation phlebitis consists of discontinuing the IV line and restarting it at some another site; elevating the site; applying a warm, moist compresses to the affected site; and administering non-steroidal agents.⁶ Extra vascular injection of a drug may result in pain, delayed absorption and/or tissue damage.⁷

There are certain topical preparations such as Heparinoid preparation, Essaven gel, Magnesium Sulphate glycerine and diclofenac gel etc. which could be beneficial in these patients. Some recent trends in hospital care include the application of magnesium sulphate for reducing the oedema. It has an ability of absorbing or removing the water content through skin and hence reducing the oedema.⁸ Application of Magnesium sulphate alone may cause skin irritation. So, any of the skin softeners can be applied along with it. Usually glycerine is used. Glycerine is a thick liquid that has a variety of uses. It is capable of softening skin and helps to nourish the skin tissues.

Ichthammol is derived from marine sediments in Mesozoic era rock formations. It has a high hydrogen/ carbon ratio and is low in nitrogen. Ichthammol is generated from low temperature carbonisation of shale oil.^{9,10} Ichthammol and glycerine, the resultant preparation is called Ichthammol glycerine.¹¹ It has slight antiseptic and analgesic properties. Ichthammol is a weak antigen and has been proven to be successful in many skin disorders.^{12,13}

Heparinoid application contains heparin sodium,¹⁴ Benzyl nicotinate (preservative) and sorbic acid.^{14,15} It is a non uniform mixture of strait chain mucopolysaccharides. It reduces the

superficial thrombophlebitis. Heparin is moderately hygroscopic, inhibits thrombin formation, promotes fibrinolysis and helps in absorption of the more superficial microthrombi.^{16,17} Benzyl nicotinate, by vasodilatation enhances local heparin absorption.¹⁸ The process of healing is substantially promoted thereby and pain is rapidly alleviated.¹⁹

Heparinoid application accelerates absorption of haematoma, and other infiltrations like thrombophlebitis, superficial thrombosis, acute tendovaginitis, and superficial bruises etc.²⁰⁻²³

In India, no study could be retrieved regarding the together comparative effect of application of Heparinoid preparation, Ichthammol Glycerine and Magnesium Sulphate-glycerine in peripheral venous access induced phlebitis. The incidence of phlebitis has been reported to be 29.8% in the study setting.²⁴ It has been observed that there is no standard practice in treating the peripheral venous access induced phlebitis. So, the present study was undertaken to find out the comparative efficacy, safety and pharmaco-economic evaluation of dressing with 'Ichthammol glycerine', 'Heparinoid preparation' and 'Magnesium Sulphate-glycerine' on phlebitis following peripheral intravenous cannulation.

Material and Methods

The study was conducted at Advanced Cardiac Centre (ACC) of Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. A block randomized (3:3:3), double blinded (observer and investigator), parallel group, multiple arm trial design was employed in the study.

The study population included all the patients admitted in ACC, PGIMER, Chandigarh during the study period of two months and developed phlebitis only in the upper limb as the result of peripheral post cannulation. Another criterion to include the study population were patients with infusion related phlebitis (**Visual Infusion Phlebitis Score of two or more as per 'Jacksons scale-1998'**) and had not received any form of phlebitis reducing intervention by the staff. The exclusion criteria included the patient who were not willing to participate in the study; patients who were receiving chemotherapeutic agents; central venous catheter on the same limb; with dermatological disorders; any bleeding disorders; any injury on the same limb; pre-existing lymphatic obstruction and the patients who were allergic to Ichthammol glycerine or Heparinoid preparation or Magnesium Sulphate- glycerine.

The tools used for the data collection were demographic profile sheet; clinical data sheet; Visual Infusion Phlebitis scale (**Jackson (1998)**). The scale score ranges from 0 indicating no symptoms of phlebitis to 5 with all of the signs and symptoms including pain along path of cannula, redness around site and swelling, palpable venous cord and pyrexia.

Safety of the used drugs refers to the no adverse drug reaction and no adverse drug event.

Pharmacoeconomic evaluation included a Digital weighing Scale and calculator to calculate the total treatment cost in 72 hours. Protocol for the application of all the three agents was developed.

The data was collected daily from 6 AM to 11 PM during the study period. Every day the researcher and the observer used to take round in the all wards of the ACC to identify the new

cases of phlebitis. The observer used to assess the level of phlebitis and used to note the grade of phlebitis into the observation sheet. A code number was given to each patient by the observer. The investigator was blinded to that number. The intervention was applied in the respective group of patients twice in a day for three days.

The sample size was calculated as per incidence rate of post cannulation phlebitis in PGIMER, Chandigarh.²⁴ The α -error was kept at 0.05 and final calculated sample size was 120. So, 40 patients in each interventional group were included.

Ethical approval for the study was obtained from Institute Ethical Committee (IEC), PGIMER, Chandigarh. The Informed written consent was taken from each subject prior to the intervention. The trial was registered with Clinical Trial Registry of India (CTRI). [CTRI/2013/12/004245]

Statistics: Both descriptive and inferential statistics was applied to analyze the data. Intra group comparison was done using 't' test. ANOVA- Post Hoc Bonferroni test was applied for the intergroup comparison.

Results

Out of total 120 study subjects, 75.83% subjects were from cardiology wards and rest of the subjects were from cardiothoracic-vascular surgery wards.

Socio demographic profile of the subjects

Table 1 shows the distribution of subjects as per the socio demographic profile. The subjects were in range of 4 to 88 years with mean age of 52.22 yrs \pm 19.52 SD in Ichthammol Glycerine intervention group (Group I), 53.22 yrs \pm 18.84 SD in Heparinoid preparation intervention group (Group II), and 53.22 yrs \pm 18.84 SD in Magnesium Sulphate Glycerine intervention (Group III). As per the gender, 65%, 60% and 75% of the subjects were male in Group I, Group II and Group III respectively. Most of the study subjects in three groups were married. All the three groups were homogeneous and comparable as per socio-demographic profile of the subjects ($p > 0.05$).

Distribution of study subjects as per the cannulation practices

Table 2 depicts distribution of study subjects as per cannulation practices. In nearly more than half of the subjects (62.5%) in group II, hand was used as anatomic site for cannulation next to ventral side of forearm (35%) in group III, dorsal side of forearm (15%) in group I and III of the study subjects.

As per the vein used for cannulation was concerned, the dorsal metacarpal vein was used in maximum subjects; in group II (62.5%), group I (57.5%) and group III (50%). The cephalic vein was used in group I (17.5%), group II (12.5%), and group III (15%). The basilic vein and median ante brachial vein were used almost equally.

As per the size of the cannula is concerned, 20G cannula was most commonly used in three groups (80% in group II, 77.5% in III and 75% in group I). Whereas 18 G cannula was used

in 17.5% subjects of both group I and III; and 15% in group II. The 16 G and 22 G cannulas were rarely used in rest of the subjects.

In more than 80% of the subjects the cannula were inserted in first attempted. All the three groups were homogenous as per the cannulation practices. ($p>0.0$)

Intra group comparison of phlebitis score between baseline and day 3 of intervention

Table 3 shows intra group comparison of Phlebitis score between baseline and Day 3 in all the three groups. There were significant changes in score of phlebitis, in baseline score and day 3 score ($p<0.0001$) in all the three groups. All the three groups differ significantly amongst themselves ($t=36.18, 25.48, 29.19, p<0.05$).

Intergroup comparison of effect of different drugs on status of phlebitis on day 3

Fig 2 depicts the comparison of the effect of three drugs on status of phlebitis on the third day of the study. ANOVA- Post Hoc Bonferroni test was applied. Group I (Ichthammol Glycerine) subjects had shown the maximum improvement in phlebitis score (Mean \pm SD- 0.125 ± 0.334) followed by Group III (Magnesium Sulphate glycerine) and group II (Heparinoid preparation).

Intergroup comparison of pharmacoeconomic among three drugs

Fig 3 depicts intergroup comparison of total treatment cost among the three drugs. ANOVA- Post Hoc Bonferroni test was applied. The Ichthammol glycerine found to be the cheapest treatment (Mean \pm SD: 18.51 ± 3.65) as compare to Magnesium Sulphate glycerine (Mean \pm SD: 37.74 ± 6.80) and Heparinoid preparation (Mean \pm SD: 56.06 ± 8.19) in treatment of post cannulation phlebitis.

Discussion

Phlebitis and thrombophlebitis occur frequently among the cannulated patients. It causes pain, sepsis, additional diagnostic investigations and treatments and may even lead to the increased duration of hospitalization, stress level amongst the patients and the caregivers and the financial burden as well. Eventually it may lead to increased workload amongst the health care personnel.²⁵ So, to improve the patients' outcome and reduce health care costs, sound management practices of phlebitis should be explored and implemented. Many pharmacological and non pharmacological interventions are available for its management.

The current study was carried out to evaluate the effect of dressing using 'Ichthammol glycerine', 'Heparinoid preparation' and 'Magnesium Sulphate-glycerine' on phlebitis following peripheral intravenous cannulation as per efficacy, safety and pharmaco-economic. Amongst the three interventions, Ichthammol glycerine had shown the best result in reducing phlebitis score. In Indian scenario, for the management of post cannulation phlebitis, Heparinoid preparation is commonly used as compare to Magnesium Sulphate glycerine and Ichthammol glycerine. But in present study, Ichthammol had shown the best result in comparison to the other two types of dressings.

None of the study showing the comparative effect of all the three interventions together could be retrieved. However, the effectiveness of all these three agents has been evaluated separately with other interventions. A study was carried out to see the effect of Ichthammol glycerine, thrombophob, hot fomentation on patients with phlebitis related to peripheral intravenous infusion. It was concluded that Ichthammol glycerine dressing was most effective as compared to the other two interventions.²⁶ Another study evaluated the effectiveness of four modalities i.e. hot fomentation, glycerine magnesium sulphate application, Ichthammol magnesium sulphate and Ichthammol belladonna. The results again went in favour of Ichthammol belladonna of all the 4 interventions.²⁷ In fact, Ichthammol has

been used in wound healing since 1880s,²⁸ though currently it is not much in practice. It has many properties viz antibacterial, antiphlogistine, anti-inflammatory, antiseborrhic, antieczematous, antimycotic, antiprurinous and blood stimulating effects.²⁹

Mangesium sulphate which was second best in the current study has also been proven to be effective on phlebitis. A study was conducted to assess the effectiveness of cold application, Heparinoid application and magnesium-sulphate application on superficial thrombophlebitis. It was concluded that magnesium sulphate application was most effective intervention in reducing the superficial thrombophlebitis.³⁰ Another study was done to observe the clinical effects of glycerine magnesium sulphate emulsion and 50% magnesium sulphate solution on the treatment of peripheral phlebitis. It was concluded that glycerine Magnesium Sulphate emulsion was safe, simple and effective method with many advantages.³¹ However, heparin was found to be better in another study.³²

The present study shows that as per the pharmacoeconomic evaluation also amongst all the three interventions, Ichthammol glycerine was the most cost effective followed by Magnesium Sulphate glycerine and Heparinoid preparation. The Heparinoid preparation was found to be the most costly drug among three interventions.

As such all the three drugs were quite safe in application as none of the patients didn't develop any adverse drug reaction.

Conclusion: Ichthammol glycerine was found to be the most effective as per efficacy, safety, and pharmaco economic evaluation. The study is first of its kind in India. It has provided us with an evidence of a cost effective agent for one of the most commonly occurring problem amongst the admitted patients.

However, single cantered study and small sample size are the two limitations of the study. Further studies keeping in mind these two limitations are recommended.

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Table 1: Distribution of subjects as per Socio-demographic profile**N= 120**

Variables		Ichthammol Glycerine N= 40 n (%)	Heparinoid Preparation N=40 n (%)	Magsulph Glycerine N=40 n (%)	χ^2 , df, p Value (95%CI)
Age (Yrs)	1-20	04 (10)	03 (7.5)	03 (7.5)	2.35, 6, 0.88*
	21- 40	05 (12.5)	08 (20)	04 (10)	
	41- 70	26 (65)	23 (57.5)	28 (70)	
	>71	05 (12.5)	06 (15)	05 (12.5)	
Mean age (yrs) \pm SD		52.22 \pm 19.52	53.22 \pm 18.84	53.22 \pm 18.84	
Gender	Male	26 (65)	24 (60)	30 (75)	2.10, 2, 0.35*
	Female	14 (35)	16 (40)	10 (25)	
Educational Status	Illiterate	09 (22.5)	12 (30)	12 (30)	5.70, 8, 0.68*
	Primary	11 (27.5)	06 (15)	11 (27.5)	
	Secondary	07 (17.5)	05 (12.5)	08 (20)	
	Senior	06 (15)	09 (22.5)	05 (12.5)	
	Secondary Graduate & above	07 (17.5)	08 (20)	04 (10)	
Marital Status	Married	31 (77.5)	35 (87.5)	35 (87.5)	3.84, 2, 0.15*
	Unmarried +Widow	09 (22.5)	05 (12.5)	05 (12.5)	
Religion	Hindu	19 (47.5)	21 (52.5)	20 (50)	0.45, 4, 0.98*
	Sikh	17 (42.5)	15 (37.5)	17 (42.5)	
	Muslim	04 (10)	04 (10)	03 (7.5)	
Occupation	Retired + Not working	12 (30)	12 (30)	09 (22.5)	4.23, 8, 0.84*
	Agriculture + Labourer	11 (27.5)	05 (12.5)	13 (32.5)	
	Housewife	09 (22.5)	12 (30)	07 (17.5)	
	Student	04 (10)	03 (7.5)	04 (10)	
	Service + Business	03 (7.5)	06 (15)	06 (15)	
	Professional	01 (2.5)	02 (5)	01 (2.5)	
Group (Income/ month inRs.)	≤ 2000	04 (10)	01 (2.5)	04 (10)	4.23, 8, 0.84*
	2001- 5000	11 (27.5)	11 (27.5)	15 (37.5)	
	5001- 10000	10 (25)	12 (30)	08 (20)	
	10001- 30000	11 (27.5)	11 (27.5)	10 (25)	
	≥ 30001	04 (10)	05 (12.5)	03 (7.5)	
Habitat	Rural	24 (60)	18 (45)	28 (70)	5.21, 2,

	Urban	16 (40)	22 (55)	12 (30)	0.07*
Dietary	Vegetarian	19 (47.5)	21 (52.5)	20 (50)	0.20, 2,
Habits	Non-vegetarian	21 (52.5)	19 (47.5)	20 (50)	0.95*
Addiction	Alcoholic	23 (57.5)	17 (42.5)	25 (62.5)	2.955, 2,
	Smoker	17 (42.5)	13 (32.5)	15 (37.5)	0.23*
	Any other substance	Nil	Nil	Nil	0.917, 2,
					0.63*

* Non significant

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Table 2: Distribution of study subjects as per the cannulation practices

N=120

Variables		Ichthammol Glycerine N= 40 n (%)	Heparinoid Preparation N=40 n (%)	Magsulph Glycerine N=40 n (%)	χ^2 , df, p Value (95%CI)
Anatomic Site	Dorsal side forearm	06 (15)	05 (12.5)	06 (15)	1.42, 4, 0.42*
	Ventral side forearm	11 (27.5)	10 (25)	14 (35)	
	Hand	23 (57.5)	25 (62.5)	20 (50)	
vein used for Cannulation	Cephalic	07 ((17.5)	05 (12.5)	06 (15)	2.54, 6, 0.86*
	Basilic Vein	06 (15)	04 (10)	07 (17.5)	
	Median antebrachial vein	04 (10)	06 (15)	07 (17.5)	
	Dorsal Metacarpal	23 (57.5)	25 (62.5)	20 (50)	
Cannula Size	16 G	02 (05)	01 (2.5)	01 (2.5)	0.66, 6, 0.99*
	18 G	07 (17.5)	06 (15)	07 (17.5)	
	20 G	30 (75)	32 (80)	31 (77.5)	
	22 G	01 (2.5)	01 (2.5)	01 (2.5)	
Number of attempt	Once	35 (87.5)	32 (82%)	33 (82.5)	2.12, 2, 0.37*
	Twice or more	05 (12.5)	08 (20%)	07 (17.5)	

*Non significant

Table.3: Intra group comparison of phlebitis score between baseline and day 3 result

Interventional Group	Patient (N)	(Phlebitis; baseline Score)	(Phlebitis;Day3 Score)	t	P
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		Mean \pm SD	Mean \pm SD		
Ichthammol glycerine	40	3.90 \pm 0.59	0.12 \pm 0.33	36.18	<0.0001
Heparinoid preparation	40	3.60 \pm 0.55	1.14 \pm 0.50	25.48	<0.0001
Magnesium Sulphate glycerine	40	3.65 \pm 0.58	1.10 \pm 0.63	29.19	<0.0001

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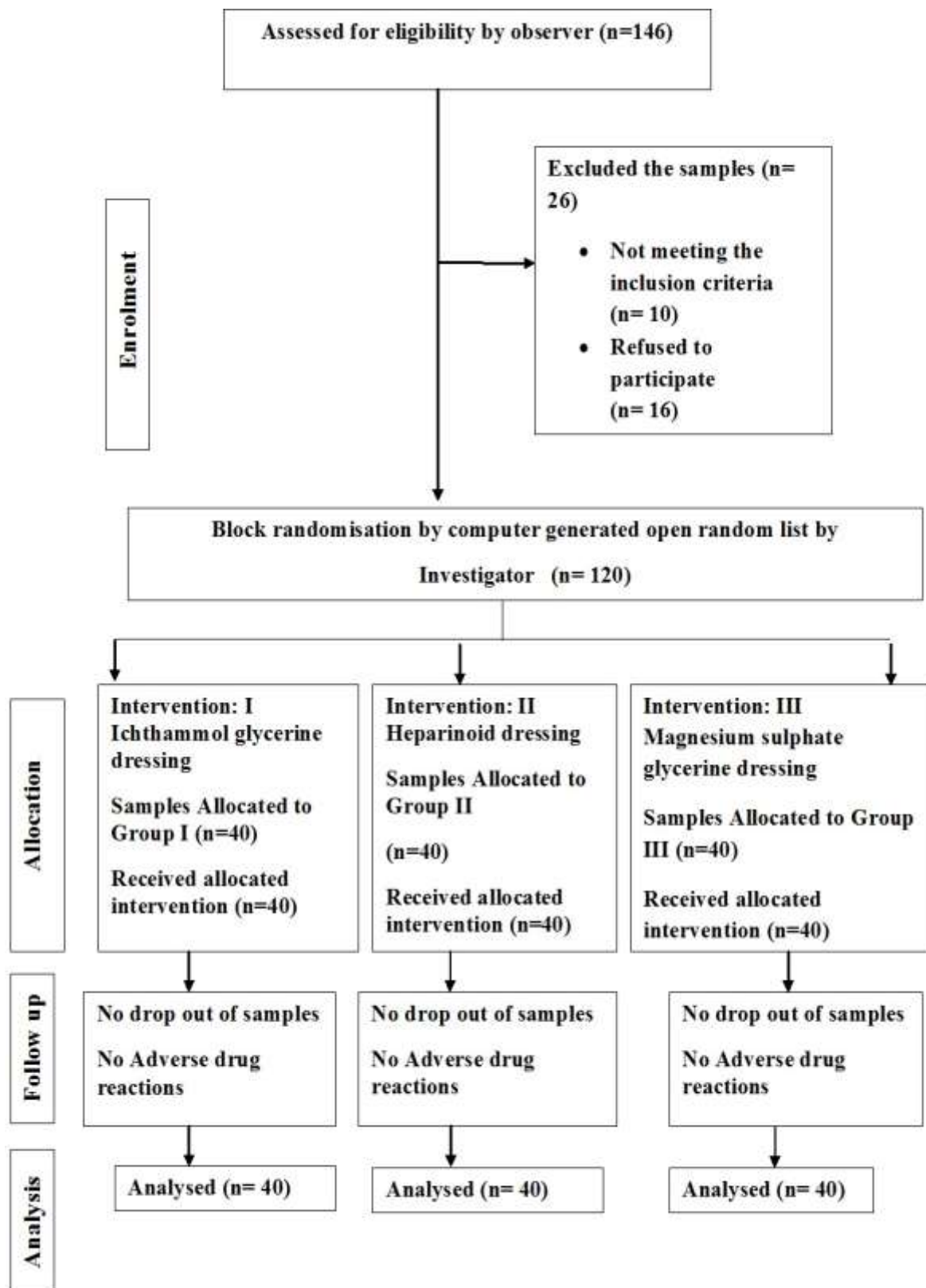
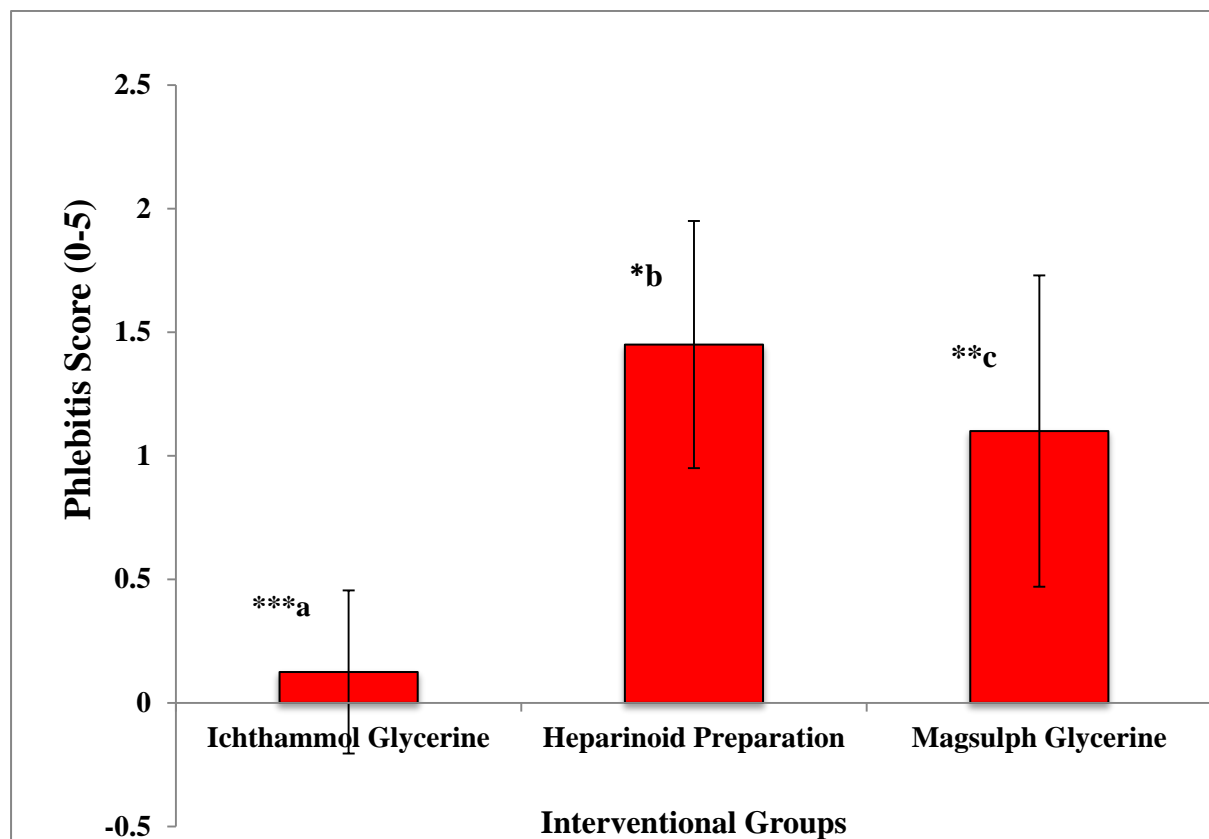


Fig. 1: CONSORT diagram of the trial



***= Mean score 0.125; **= Mean score 1.100; *= Mean score 1.145; a= SD 0.334; b= SD 0.503; c= SD 0.632 (ANOVA- Post Hoc Bonferroni)

Fig. 2: Intergroup comparison of different drugs effects on status of phlebitis on day 3

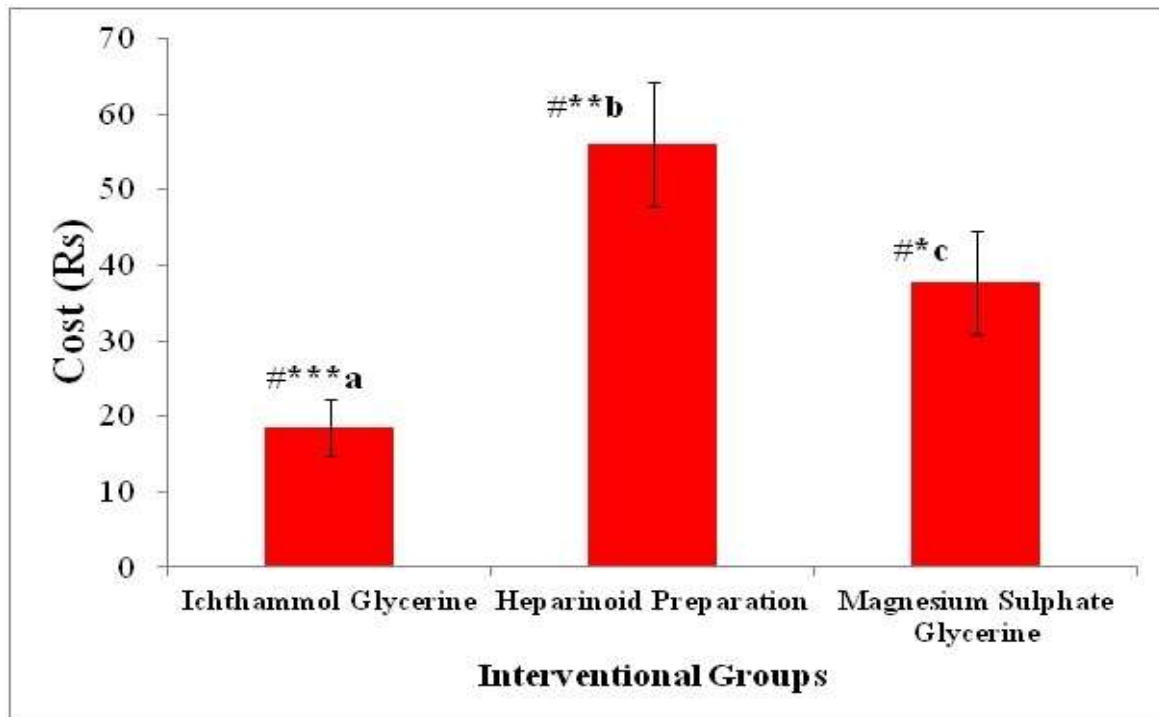


Fig 3: Intergroup comparison of pharmacoeconomic among three drugs

***Mean cost: 18.51; **= Mean cost: 56.06; *Mean cost: 37.74

a= SD 3.65; b= SD 8.19; c= SD 6.80 #= $p < 0.05$ (ANOVA- Post Hoc Bonferroni)