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Assess Phytochemical Properties & Effectiveness Of Alocen Gel On Thrombophlebitis Among Patients Under Intravenous Medications In Selected Hospital At Coimbatore

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ABSTRACT

The aim of the study to evaluate the phytochemical properties, shelf life, and clinical effectiveness of Alocen gel (a formulation of Aloe vera and Centella asiatica) in reducing intravenous (IV)-induced thrombophlebitis among hospitalized patients. A one-group pretest–post-test design was adopted. The effectiveness of Alocen gel was assessed using the Modified Phlebitis Assessment Scale. Phytochemical analysis (albumin denaturation and heat-induced hemolysis assays) and microbial testing were conducted to establish anti-inflammatory activity and safety, while shelf-life stability was observed over 30 days. Statistical analysis included paired t-test and chi-square test. Phytochemical assays confirmed significant anti-inflammatory activity with a dose- dependent increase in inhibition, and microbial testing revealed the absence of harmful organisms. Shelf-life testing demonstrated stability without Odor or colour changes for 30 days. Clinically, pretest findings showed 75% mild, 15% moderate, and 10% severe thrombophlebitis, with no symptom-free cases. Post-test assessment revealed 85% symptom- free, 11.6% mild, and 3.3% moderate cases, with no severe thrombophlebitis. The mean pretest score (Mean = 1.56, SD = 1.130) reduced to the post-test score (Mean = 0.20, SD = 0.541), with a mean difference of 1.36. The paired t value of 13.412 ($p < 0.0001$) confirmed high effectiveness. Chi-square analysis indicated significant associations with selected demographic and clinical variables. No adverse reactions were reported. Alocen gel is a safe, stable, and effective herbal preparation for reducing IV- induced thrombophlebitis. Its phytochemical richness and clinical efficacy support its integration as a complementary nursing intervention. Further large-scale and long-term studies are recommended to validate its broader application.

Keywords: Thrombophlebitis, Alocen gel, Aloe vera, Centella asiatica, phytotherapy, anti- inflammatory, intravenous therapy.

INTRODUCTION

The best possible balance and operation of a living being's mental and physical systems is known as health. It denotes a state of general well-being in humans, typically defined by the lack of pain, disease, or trauma. On the other hand, illness refers to a decline in health brought on by mental or physical issues. Any aberrant or pathological condition that interferes with the body's natural structure or function and compromises physiological systems is referred to as a disease. [1]

Applying therapies, such as prescribed drugs or other interventions under a doctor's supervision, is part of medical treatment. Intravenous (IV) devices are essential and widely used in modern healthcare, particularly for hospitalized patients. [2] To make it easier to administer fluids, drugs, and blood products, peripheral venous catheters are usually placed into the veins of the hands and forearm. [3]

One frequent side effect associated with intravenous treatment is thrombophilia. The National Standards of Practice (Australia) of the Infusion Nurses Society state that nurses who give intravenous fluids or drugs must be aware of any potential side effects and the steps that should be taken before the infusion begins.[4]

Alocen, a gel made from Centella asiatica and Aloe barbadensis miller, is gaining attention as a possible remedy. Because of their anti-inflammatory and antioxidant qualities, these plants may be used as adjunctive therapies to help patients undergoing intravenous therapy avoid thrombophlebitis. [5]

In order to improve patients' outcomes, this study intends to examine the phytochemical makeup of Alocen gel and assess how well it works to prevent thrombophlebitis in patients receiving intravenous medicine.

BACKGROUND OF THE STUDY

Scottish surgeon John Hunter was the first to identify phlebitis in 1784.[6] Up to 75% of hospitalized patients may experience infiltration and discomfort, two of the most serious side effects of intravenous therapy. An estimated 200,000 catheter- related infection cases are reported worldwide each year.[7]

Although there have been reports of one in 125,000 occurrences annually in the US, the true prevalence of spontaneous thrombophlebitis is still unknown. With a roughly 55- 70% ratio, the incidence is higher in men than in women. According to the incidence analysis, the average age at which thrombophlebitis develops is 54 for men and 58 for women. [8]

STATEMENT OF THE PROBLEM

"Assess phytochemical properties & effectiveness of Alocen gel on thrombophlebitis among patients under intravenous medications in selected hospital at Coimbatore".

OBJECTIVES

- To develop and assess the phytochemical properties of Alocen gel.
- To determine the shelf life of Alocen gel.
- To assess the pre-test and post-test thrombophlebitis scores among patients with thrombophlebitis

- To evaluate the effectiveness of Alocen gel in reducing thrombophlebitis.
- To associate the effectiveness of Alocen gel with selected demographic variables.

HYPOTHESES

All hypothesis will be tested at 0.05 level of significant

- **H_1:** There is a significant reduction in thrombophlebitis scores among patients following the application of Alocen gel.
- **H_2:** Alocen gel possesses significant phytochemical properties, including anti- inflammatory and antioxidant effects.
- **H_3:** There is a significant association between post-test level of thrombophlebitis among patients with IV Medications with their selected demographic variable
- **H_4:** Alocen gel has an adequate shelf life suitable for therapeutic use.

REVIEW OF LITERATURE

➢ Section A: Empirical Scientific Studies on the Rates of Intravenous Phlebitis Development and Prevalence

➢ Section B: Empirical Scientific Studies on the Benefits of Aloe Vera Gel Application in Reducing the Incidence and Severity of Intravenous Phlebitis

➢ Section C: Empirical Scientific Studies on the Phytochemical Analysis, Anti-inflammatory, and Antioxidant Activity of Centella asiatica Extracts in the Reduction of Thrombophlebitis

➢ Section D: Empirical Scientific Studies related to thrombophlebitis due to IV medications

➢ Section E: Empirical Scientific Studies related to 'Anti-inflammatory &wound healing activities of Centella Asiatica.

RESEARCH METHODOLOGY

RESEARCH APPROACH

Quantitative research approach was used as an appropriate research approach for the present study.

RESEARCH DESIGN

A Pre experimental one group pretest post-test research design was adopted for the present study.

VARIABLES

Dependent Variables

In this study, the dependent variable is Thrombophlebitis among patients with Intravenous Medications.

Independent Variables

In this study, independent variable includes application of Alocen gel on thrombophlebitis among patients under intravenous medications.

Clinical Variables

In this study, clinical variables are duration of hospital stays, site of IV cannulation, and size of IV cannula, duration of IV infusion, types of IV medications, frequency of changing IV cannula.

SETTING OF THE STUDY

The setting was chosen on the basis of availability of samples and cooperation from the management. The present study was conducted at Ganga Medical Centre& Hospitals Coimbatore, a 750-bedded super specialty hospital. The hospital is well equipped with modern facilities, advanced diagnostic services, and specialized departments. It provides comprehensive medical and surgical care and maintains an organized system with highly qualified professionals, making it suitable for conducting the study.

POPULATION

In this study population includes all patients who developed thrombophlebitis due to intravenous (IV) medications at Ganga Medical Centre & Hospitals.

TARGET POPULATION

In this study, the target population comprises patients who developed thrombophlebitis specifically due to intravenous (IV) medications across various healthcare settings in Coimbatore.

ACCESSIBLE POPULATION

In this study, the accessible population comprises patients diagnosed with IV drug-induced thrombophlebitis who are admitted in Ganga Medical Centre & Hospitals during the specified study period.

SAMPLE

In this study, the sample comprised selected patients with thrombophlebitis caused by Intravenous (IV) Medications at Ganga Medical Centre, Coimbatore.

SAMPLE SIZE

The sample size for study comprises of 60 patients with mild & moderate and symptoms of thrombophlebitis caused by IV medications in Ganga medical centre, Coimbatore.

SAMPLING TECHNIQUE

Participants of the study are selected by non-probability purposive sampling technique.

CRITERIA FOR SAMPLE SELECTION

Inclusion Criteria

The study included patients who were

- at the age group of 18 to 60 years
- able to read and write Tamil or English
- available during the data collection period
- willing to participate and provided written consent
- developing thrombophlebitis due do intravenous medications.

Exclusion Criteria

The study excluded patients who were

- who is unable to read and write Tamil or English
- Chronic Vascular disease
- allergic to Alocen
- mentally or physically unable to participate in the study procedures

DESCRIPTION OF DATA COLLECTION TOOL

The tool used in this study has 3 sections. SECTION 1: Assessment of demographic variables. SECTION 2: Assessment of clinical Variables.

SECTION 3: Modified Phlebitis Assessment scale.

SECTION 1:

Demographic variables consisted of items for obtaining information about selected socio demographic data such as age, gender, religion, residential area, marital status, educational status, income.

SECTION 2:

Clinical Variables consisted of 5 items for obtaining information about the clinical variables such duration of hospital stays, site of IV cannulation, and size of IV cannula, duration of IV infusion, types of IV medications, frequency of changing IV cannula, allergy to any medications.

SECTION 3:

Table 3.1 Modified Phlebitis Assessment scale

S.NO.	DEGREES OF PHLEBITIS	SYMPTOMS	LEVEL OF GRADING
1	NONE	NO SYMPTOMS	0
2	MILD	Slight Pain, tenderness near iv site, or slight redness near the iv site, warmth along the affected vein	1
3	MODERATE	Pain, erythema, induration	2
		warmth along the affected vein, with a palpable cord, low grade fever	3
4	SEVERE	Severe pain, erythema, induration, palpable venous cord, high grade Fever	4 5

PROCEDURE OF DATA COLLECTION

Data collection refers to the systematic gathering of information required to address a research problem.

In this study, data were collected from patients diagnosed with thrombophlebitis who were treated during the months of January and February at Ganga Medical Centre and Hospital, Coimbatore. Initially, rapport was established with the patients, and the purpose of the study was clearly explained to them. They were assured that all collected data would be kept strictly confidential and used solely for research purposes. After obtaining both verbal and written informed consent, the investigator collected demographic information from each participant. The intervention was carried out by the investigator. Freshly prepared 50 grams of Alocen gel was used, and a small amount was topically applied to the affected site. The post-test level of thrombophlebitis was assessed by the investigator using the Modified Phlebitis Assessment Scale.

PLAN FOR DATA ANALYSIS

The data were analyzed according to the objectives and hypothesis of the study. Data was analyzed, tabulated and interpreted using descriptive and inferential statistics.

Results

Demographic variables revealed that among 60 patients, most (33.3%) were aged 31 –40 years, followed by 51–60 years (28.3%) and 41–50 years (25%). Males comprised 66.7% and 90% were married. Educationally, 23.3% were graduates, and 10% were illiterate. A majority (66.6%) were manual workers, with 50% earning Rs. 10,001–20,000 monthly. Nearly half (48.3%) lived in urban areas, and 66.6% reported regular exercise, while 16.6% had smoking and alcohol habits. Overall, the typical profile was a middle-aged, married male graduate, working as a manual laborer, with moderate income, urban residence, and regular exercise habits.

Table 1: Pretest and Posttest Level of Thrombophlebitis Patients Caused by IV Medications n=60

Level of Thrombophlebitis	**Pre test**		**Post test**	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
No symptoms	0	0	51	85%
Mild	45	75%	7	11.6%
Moderate	9	15%	2	3.33%
Severe	6	10%	0	0

Table 2– Comparison of Mean, SD and Mean% of Pre and Post Test Level of Thrombophlebitis among patients caused by IV medications

n=60

	Range	**Mean**	**SD**	**Mean Difference**	**Paired 't' Test p-value**
Pre Test	5 – 1	1.56	1.130	1.36	t=13.412** p < 0.0001
Post Test	3-0	0.2	0.541		

**Significant at P<0.01 level.

Table 3: Association Between Posttest Level of Thrombophlebitis Among Patients with Their Selected Demographic Variables **n=60**

Variables	Post test level of Thrombophlebitis						F	Chi square test (x^2) & p- value
	No symptoms		Mild		Moderate			
	N	%	N	%	N	%		
Age in years								x^2 = 5.968 df = 6 **p=0.4268 NS**
a)18 – 30	5	8.33	2	3.33	1	1.66	8	
b)31 – 40	18	135	2	3.33	0	0	20	
c)41 – 50	13	21.66	1	1.66	1	1.66	15	
51 – 60	15	25	2	3.33	0	0	17	
Gender								x^2 = 0.613 df = 2 **p=0.7360 NS**
a) Male	35	58.33	4	6.66	1	1.66	40	
b) Female	16	26.66	3	5	1	1.66	20	
c) Others	0	0	0	0	0	0	0	
Marital status								x^2 =15.96 df = 6 **p=0.0140 S**
a) Unmarried	2	3.33	1	1.66	1	1.66	4	
b) Married	48	80	5	8.33	1	1.66	54	
c) Divorced	0	0	1	1.66	0	0	1	
d) Widowed	1	1.66	0	0	0	0	1	
Educational status								x^2 = 8.784 df = 6 **p=0.1861 NS**
a) Illiterate	13	21.66	1	1.66	0	0	14	
b) Primary education	11	18.33	0	0	0	0	11	
c)Secondary education	10	16.66	1	1.66	1	1.66	12	
d) Higher secondary education	6	10	3	5	0	0	9	
e) Graduate and above	11	18.33	2	3.33	1	1.66	14	
Occupation								x^2 = 20.431 df =10 **p=0.0254 S**
a) Manual laborer	36	60	3	5	1	1.66	40	
b) Home maker	10	16.66	2	3.33	0	0	12	
c) Business	1	1.66	1	1.66	1	1.66	3	
d) Professional	0	0	1	1.66	0	0	1	
e) Retired	1	1.66	0	0	0	0	1	
f) Student	3	5	0	0	0	0	3	
Family monthly Income								x^2 = 3.131 df = 4 **p=0.5361**
a) Below Rs.10,000	0	0	0	0	0	0	0	

b) Rs.10001 – Rs.20,000	26	43.33	3	5	1	1.66	30	**NS**
c)Rs.20,001 – Rs.30,000	18	30	2	3.33	0	0	20	
d) Above Rs. 30,000	7	11.66	2	3.33	1	1.66	10	
Residential area								$x^2 = 2.583$ df = 4 **p=0.6298** **NS**
a) Urban	26	43.33	3	5	0	0	29	
b) Semi Urban	16	26.66	2	3.33	1	1.66	19	
c)Rural	9	15	2	3.33	1	1.66	12	
Life style habits								$x^2 = 21.79$ df = 4 **p=0.00022 S**
a) Smoking	6	10	3	5	1	1.66	10	
b) Alcohol	5	8.33	4	6.66	1	1.66	10	
c) Exercise	40	66.66	0	0	0	0	40	

Table 5: Association Between Posttest Level of Thrombophlebitis Among Patients with Their Selected Clinical Variables.

n=60

Variables	**Posttest level of Thrombophlebitis**							**F**	**Chi square test (x^2) p Value**
	Mild		**Moderate**		**Severe**				
	N	**%**	**N**	**%**	**N**	**%**			
Reason for Hospitalization									$x^2 = 16.74$ df = 2 **p=0.001 S**
a) Medical condition	0	0	0	0	0	0		0	
b) Surgical procedure	48	80	3	5	1	1.66		52	
c)Trauma	3	5	4	6.66	1	1.66		8	
d)Others (Specify)	0	0	0	0	0	0		0	
Duration of intravenous infusion therapy									$x^2= 19.902$ df=4 **p=0.001 S**
a) < 24 hours	1	1.66	3	5	1	1.66		5	
b)– 48 hours	40	66.66	2	3.33	1	1.66		43	
c)> 48 hours	10	16.66	2	3.33	0	0		12	
Types of IV medications									$x^2= 43.409$ df=4 **p=0.00001 S**
a) Single dose	1	1.66	0	0	1	1.66		2	
b) Multiple doses	48	80	2	3.33	0	0		50	
c)Boles	2	3.33	5	8.33	1	1.66		8	

Cannula size used									x^2 = 3.822
a)18G	**5**	**8.33**	**1**	**1.66**	**1**	**1.66**		7	df=4 **p=0.400**
b)20G	14	23.33	1	1.66	0	0		15	**NS**
c)22G	32	53.33	5	8.33	1	1.66		38	
d)24G	0	0	0	0	0	0		0	
Iv site									x^2 = 10.839
a) Hand	26	43.33	3	5	1	1.66		30	df=6
b) Forearm	**14**	**23.33**	**3**	**5**	**1**	**1.66**		18	**p=0.09**
c)Elbow	11	18.33	0	0	0	0		11	
d)Others (Specify)	0	0	1	1.66	0	0		1	**NS**
Frequency of Iv site rotation									x^2 = 10.49 df=4 **p=0.033 S**
a) <24 hours	1	1.66	2	3.33	1	1.66		4	
24 – 48 hours	38	63.33	3	5	1	1.66		42	
>48 hours	12	20	2	3.33	0	0		14	
Pre-existing medical condition									x^2 =19.479 df=6 **p=0.004 S**
a) Diabetes	7	11.66	1	1.66	0	0		8	
b) Hypertension	2	3.33	2	3.33	1	1.66		5	
c) Varicose vein	0	0	1	1.66	0	0		1	
d)Peripheral vascular disease	42	70	3	5	1	1.66		46	
e) None	**0**	**0**	**0**	**0**	**0**	**0**		0	

CONCLUSION

Alocen gel demonstrated strong anti-inflammatory and antioxidant properties, with stability and clinical effectiveness in reducing thrombophlebitis among IV therapy patients. Its application significantly reduced severity levels and showed associations with selected demographic and clinical variables. These findings confirm its therapeutic efficacy and highlight the role of Kolcaba's Comfort Theory in improving patient comfort and recovery.

Recommendations

- Integrate Alocen gel into clinical protocols as a preventive and therapeutic measure.
- Conduct larger, comparative, and molecular-level studies to strengthen evidence.
- Promote educational and training initiatives on herbal-based therapies for nurses.
- Establish standardized policies on evidence-based herbal practices in IV therapy care

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