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The Effect of Topical Aloe Vera Gel Therapy on Phlebitis in Pediatric Patients

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Abstract

Introduction: Phlebitis, or inflammation of the veins, is a complication of intravenous (IV) therapy that can be caused by chemical substances, mechanical factors (such as IV equipment), or infections (due to microbial colonies from the catheter). It is characterized by pain, erythema, swelling, induration, and sometimes fever. Phlebitis can lead to further complications or worsen the patient's condition, potentially extending their hospital stay. Managing phlebitis can be achieved through both pharmacological and non-pharmacological therapies, such as the use of aloe vera gel.

Objective: This study aims to identify the effect of aloe vera gel therapy on reducing the level of phlebitis in pediatric patients.

Method: The research design used a quasi-experimental non-equivalent control group design or non-randomized control group pretest-posttest design. The population consists of pediatric patients with IV infusions. A purposive sampling technique was used to select 58 children as the research sample. Data collection was conducted using observation sheets and then processed and analyzed using data processing applications with open-source statistical computer software jamovi version 2.4.8. The analysis test used the Wilcoxon-W test.

Results: The study results showed a standard deviation average decrease in phlebitis levels among pediatric patients. The analysis test results revealed a P-value of 0.001 < 0.05 with an effect size of 1.00, indicating that aloe vera gel therapy significantly reduces phlebitis in children.

Conclusion: There is a significant effect of aloe vera gel therapy before and after administration in the intervention group, and a significant difference between the intervention and control groups after the administration of aloe vera gel. So aloe vera gel is effective in treating phlebitis in children

Keywords: aloe vera, pediatric, phlebitis

Introduction

Phlebitis, or vein inflammation, is a complication of intravenous (IV) therapy caused by chemical agents, mechanical factors (such as IV equipment), infections (due to microbial colonies from the catheter), and patient-specific factors such as age, gender, underlying conditions, and medications administered. IV therapy is an invasive procedure commonly administered to hospitalized patients. Up to 80% of hospitalized patients receive IV therapy, with approximately 20% to 70% developing phlebitis. The increasing number of hospitalized patients correlates with a higher risk of phlebitis incidence. Phlebitis can lead to severe complications such as deep vein thrombosis (DVT), pulmonary embolism, cellulitis, and skin nodules, causing significant pain and discomfort, prolonging hospital stays, and increasing healthcare costs. Various nursing interventions have been attempted to manage phlebitis, including the use of 75% alcohol compresses, 33-50% MgSO4, and 0.9% saline solution; however, none have proven consistently effective in alleviating phlebitis.

A study conducted in China by Zhang et al. in 2014 demonstrated that aloe vera is beneficial for the prevention and management of phlebitis. Another study reported that compressing aloe vera mixed with glycerin and magnesium sulfate could reduce the severity of phlebitis. The use of aloe vera offers several advantages: it is readily available and does not cause extravasation due to its low electrolyte concentration.³ Statistical tests on the application of pure aloe vera compresses showed a significant reduction in phlebitis severity, with a minimum degree of 1 and a maximum of 4.4 Research conducted at the General Hospital of Sembiring, Deli Tua District, Deli Serdang Regency, on 31 respondents with phlebitis before aloe vera compresses were applied found that nearly half of the respondents had grade 3 phlebitis (45.2%). Aloe vera contains about 75 potentially active components, including vitamins, enzymes, minerals, sugars, lignin, saponins, and salicylic acids, many of which have pharmacological actions. These include carboxypeptidase, which deactivates bradykinin, salicylates, and substances that inhibit local vasoconstriction.³ In the inflammatory response, aloe vera reduces bradykinin, which can lower pain levels. It contains luteol, beta-sitosterol, and campesterol, natural steroids with strong anti-inflammatory properties; salicylic acid, which inhibits prostaglandins in inflammatory reactions; and inhibits cyclooxygenase (COX2), an enzyme that causes inflammation through the arachidonic acid pathway.⁴ Moreover, aloe vera is less likely to cause allergic reactions on the sensitive skin of children. Aloe vera is considered safer for pediatric use because it does not contain electrolytes that could cause extravasation in blood vessels. Despite evidence supporting the effectiveness of aloe vera gel in reducing phlebitis, previous studies have included all age groups. Thus, it is essential to specifically evaluate the effectiveness of aloe vera gel in treating phlebitis in children. This study, in addition to being conducted in groups of children, also compared two groups given aloevera gel intervention and not given intervention with a considerable number of samples, namely 58 respondents.

In this study, the authors investigated the effect of aloe vera gel therapy on phlebitis in pediatric patients. The aim was to determine whether aloe vera gel therapy could reduce the severity of phlebitis in hospitalized children. The findings are expected to demonstrate that aloe vera gel therapy effectively reduces phlebitis severity, providing a basis for implementing this non-pharmacological intervention in hospitals and potentially developing it into a standard operating procedure (SOP). So the treatment of pediatric patients with phlebitis in health facilities does not only use pharmacological therapy but can use non-pharmacological therapy (Aloe Vera Gel).

Methods

This study is quantitative research employing a quasi-experimental non-equivalent control group or non-randomized control group pretest-posttest design. The research was conducted with 58 respondents across several hospitals in Bogor City over two months, from December 2023 to January 2024. The variables in this study include the use of aloe vera gel, and respondent characteristics (age, gender, Body Mass Index (BMI), medical diagnosis, and IV catheter size). Aloe vera gel serves as the independent variable, while phlebitis is the dependent variable. PVC-associated phlebitis or thrombophlebitis is caused by inflammation of the tunica intima of superficial veins by chemical, or biological sources, these etiological factors are often combined, hence the origin of phlebitis is difficult to determine. The inflammatory process begins with sensitization of the vascular endothelium due to friction on the vein wall by the catheter itself, hyperosmolarity of the administered solution, or bacterial toxins. This causes the release of serotonin and histamine that promote platelet aggregation leading to the formation of palpable thrombotic cords that will be visible along the cannulated vein as the process progresses, resulting in localized heat.

The population of this study comprises pediatric patients aged 0.1 to 17 years who are hospitalized. The sample includes pediatric patients experiencing phlebitis. A purposive sampling technique was employed, adhering to the inclusion criteria: pediatric patients hospitalized in the pediatric ward, those receiving IV therapy, those experiencing phlebitis, and those willing to participate as respondents. The sample size for this study is 58 respondents, divided into 29 intervention group participants and 29 control group participants. Each respondent who entered the inclusion criteria was prepared a Phlebitis scale observation sheet, Visual Infusion Phlebitis (VIP). After that aloe vera gel therapy was given for 15 minutes on the phlebitis area (given for 2 days with a frequency of 3x in a day), then measured the pre and post-intervention phlebitis scale and recorded on the observation sheet. To ensure the representativeness of the sample, the minimum sample size was determined using the G Power program (version 3.1.9.4).

G Power is an open-source program designed for general analysis, used for conducting statistical tests, and includes an effect size calculator for t-tests. To determine the effect size for this study, researchers can use an online effect size calculator by entering the required data or mean values as prompted and then clicking calculate to obtain the effect size. For G Power, researchers input "means the difference between two independent means (two groups)" in the statistical test column, select "two" in the tails(s) field, enter the calculated effect size, and set the power $(1-\beta \text{ err prob})$ to 0.95 based on previous research. After entering all data into the input parameters, the calculate button generates the required sample size.

The research was conducted in two phases: the first phase involved screening for phlebitis using the Visual Infusion Phlebitis (VIP) score. The second phase involved implementing the intervention and data collection. Researchers administered the intervention, observed, and recorded the results using the established instruments. Aloe vera is the most important plant family of the alliance and belongs to the genus Aloe which consists of about 420 species and can be utilized in three basic forms: aloe vera gel, aloe vera sap, and whole leaf extract. Aloe vera has been described as an antibacterial agent, containing anthraquinones as active compounds which are structural analogs of tetracycline. Anthraquinones act like tetracyclines inhibiting bacterial protein synthesis by blocking the A site of ribososm (where the annealed tRNA enters). Therefore, bacteria cannot grow in media containing aloe vera extract. The intervention was applied for three days, during which aloe vera gel was administered, and the study was carried out over one month. The instrument used in this study included pre and post-test questionnaires about phlebitis in pediatric patients, employing the Visual Infusion Phlebitis (VIP) scale ranging from 0 to 5.

Data analysis involved univariate and bivariate analyses. The statistical analysis

application used in this study was JAMOVI 2.4.8, an open-source application available for free download from the official website. Univariate analysis employed descriptive analysis, while bivariate analysis used Wilcoxon-W to asses mean differences before and after treatment in both groups. his study passed the ethical protocol review conducted by the Ethics Committee of Universitas Indonesia Maju, with approval number: No.201/Sket/Ka-Dept/RE/UIMA/I/2024. All protocols and SOPs (standard operating procedures) were reviewed and revised based on feedback from the local Ethics Committee. Participation in the study was voluntary, and informed consent was obtained from all respondents to document their participation.

Results

The data analyzed in this study include the characteristics of respondents such as age, gender, Body Mass Index (BMI), admission diagnosis, and IV catheter size in pediatric patients.

Table 1. Characteristics of Respondents by Age, Gender, BMI, Admission Diagnosis, and IV Catheter Size (n=58)

Characteristics	Catalana	Intervention	Control	
Characteristics	Category	Mean (SD)/ n (%)	Mean (SD)/ n (%)	
Age, Mean (SD)	Age	5,76 (5,04)	3,34 (4,16)	
Gender, n (%)	Male	13 (22,4)	16 (27,6)	
	Female	16 (27,6)	13 (22,4)	
Body Mass Index / BMI, n	Normal	27 (46,6)	26 (44,8)	
(%)	Light	2 (3,4)	3 (5,2)	
	Heavy	0 (0,0)	0(0,0)	
Admission Diagnosis, n	Bronchopneumonia	9 (15,5)	9 (15,5)	
(%)	Dehydration	3 (5,2)	7 (12,1)	
	Diarrhea			
	Dengue Fever	3 (5,2)	2 (3,4)	
	Bacterial Infection	6 (10,3)	7 (12,1)	
	Other Diagnoses	8 (13,8)	4 (6,9)	
Ukuran IV Catheter	22	3 (5,2)	2 (3,4)	
	24	16 (27,6)	17 (29,3)	
	26	10 (17,2)	10 (17,2)	

Table 1 shows that of the 58 respondents, the average age of most respondents who experienced phlebitis was in the intervention group with a range of 5.76 years and in the control group with a range of 3.34 years. In gender, the highest number of respondents in the intervention group was female as many as 16, and in the control group male as many. In the Body Mass Index category, normal conditions showed more dominant results, namely 27 (46.6%) in the intervenes group and 26 (44.8) in the control group. The admission diagnosis of the respondents showed that Bronchopneumonia ranked the highest in children who experienced phlebitis in the same number, both in the intervention group and control group, namely 9 patients (15.5%). And in the size of the IV catheter used by respondents, most respondents were installed number 24 as many as 16 respondents (27.6%) in the intervention group and 17 respondents (29.3%) in the control group.

Table 2. Phlebitis Levels Before and After in the Intervention and Control Groups

Group	Mean (SD) Pre	Mean (SD) Post
Intervention	2.62 (1.08)	1.03 (1.02)
Control	2.52 (1.09)	1.97 (1.21)

Based on Table 2, the intervention group shows a mean phlebitis level of 2.62 with a standard deviation of 1.08 before the intervention (pre). After the intervention (post), the mean phlebitis level decreases to 1.03 with a standard deviation of 1.02. In the control group, the mean phlebitis level before the intervention (pre) is 2.52 with a standard deviation of 1.09, and it decreases to 1.97 with a standard deviation of 1.21 after the intervention (post).

Table 3. Phlebitis Levels in the Intervention and Control Groups

Group	N	Mean (SD)	P-value	Effect Size
Intervention				
Pre	229	2.62 (1.08)	0.001	1.00
Post	129	1.03 (1.02)	0.001	
Control				
Pre	229	2.52 (1.09)	0.001	0.889
Post	229	1.97 (1.21)	0.001	

Based on Table 3, the Wilcoxon-W test results for the intervention group indicate a P-value of 0.001, which is less than 0.05. This means that the null hypothesis (H0) is rejected, and the alternative hypothesis (Ha) is accepted, indicating a significant effect of the Aloe vera gel therapy on phlebitis levels before and after the intervention. The effect size for the intervention group is 1.00, suggesting a strong effect.

In contrast, the control group, which did not receive the Aloe vera gel therapy, also shows a P-value of 0.001, indicating a significant change in phlebitis levels before and after the period. However, the effect size for the control group is 0.889, which is smaller compared to the intervention group, indicating a moderate effect.

Table 4. Comparison of Phlebitis Levels Between the Intervention and Control Groups

Inte	ervention	(Control	P Value	Effect
N	Mean (SD)	N	Mean (SD)	1 value	size
29	1.03 (1.02)	29	1.97 (1.21)	0.002	0.833

Based on Table 4, the analysis shows a comparison of phlebitis levels between the intervention and control groups. The results of the analysis indicate a P-value of 0.002, which is less than 0.05. This signifies a significant difference in phlebitis levels before and after the administration of Aloe vera gel therapy.

The effect size is 0.833, indicating a large effect. The mean phlebitis level in the intervention group is 1.03 with a standard deviation of 1.02, whereas, in the control group, the mean phlebitis level is 1.97 with a standard deviation of 1.21.

Discussion

Description of age, gender characteristics. Body Mass Index (BMI), admission diagnosis, and IV size

Table 1, presents the research findings respondents had an average age ranging from 5.76 years, and the control group with a range of 3.34 years. The increased prevalence of phlebitis in this age group can be attributed to the frequent occurrence of

stress among young children. The distress faced by children encompasses emotional spectrums such as anxiety, fear, and pain, accompanied by various behaviors ranging from calm and controlled to wild thrashing. This condition is determined by various elements, including the child's age, gender, experience, temperament, anxiety, coping style, pain sensitivity, genotype, and level of preparation before treatment. The majority of children undergoing surgical procedures exhibit crying and excessive movements, indicating a loss of control possibly caused by fear or discomfort from surgery. Although age may have an impact on the occurrence of phlebitis, this study did not test the correlation between phlebitis and participant attributes.

The study shows that when detailed by gender, there is balanced data between males and females, with 29 (50%) each. Although some studies show a correlation between the incidence rate of phlebitis and gender. In the study by Puspita and Fadli (2023)¹⁵ a relationship was found between gender and the incidence of phlebitis in children (p-value 0.024) using the chi-square test. Strong child movements and improper fixation can also result in mechanical consequences, especially cannula displacement into blood vessels and subsequent irritation of the inner vessel layers. ¹² In a study by Hasanah et al. (2017)¹⁶ on Minimizing the Severity of Phlebitis, a Study of Intravenous Therapy in Children with Aloe vera Compresses showed that boys had a higher incidence of phlebitis, with a prevalence of 66.7%, compared to girls. Apart from gender, another aspect to consider is the nutritional status of the child.

Regarding Body Mass Index (BMI) characteristics, most children had normal nutritional status, accounting for 53 (91.4%). This is consistent with a study by Hartanto et al (2024)¹⁷ on the Relationship between Nutritional Status and the Incidence of Phlebitis in Adult Patients in the Flamboyan Room at RSUD Gambiran, Kediri. Findings showed no relationship between patient nutritional status and the occurrence of phlebitis. Similar venous inflammation risks exist for individuals with low and high body weights. In a study also conducted by Lalithambigai (2018)¹⁸, the majority of respondents experiencing phlebitis were children with normal nutritional conditions, totaling 21 respondents (70.00%). Therefore, the conclusion drawn is that there is no correlation between nutritional status measured by BMI and the occurrence of phlebitis in children.

Regarding respondent characteristics based on medical diagnosis, the diagnosis of Bronchopneumonia showed the highest data of respondents experiencing phlebitis, at 18 (31.0%). This was followed by the diagnosis of Dehydration Diarrhea with 13 respondents (22.4%). Medical diagnosis will affect the therapy provided by doctors, both medication and fluids. Phlebitis can be caused by vein injury during cannula insertion. infection, and irritation from chemicals. 19 The occurrence of phlebitis, or vein irritation, caused by medications and infusion fluids is greatly influenced by the pH and osmolarity of the fluids. These parameters have a significant impact on the likelihood of phlebitis development.²⁰ Antibiotics, due to their acidic nature, impact phlebitis. Parenteral nutrition solutions, including glucose, amino acids, and lipids, can also have the same effect.²¹ Based on the above, patients diagnosed with Bronchopneumonia always receive antibiotic therapy, and patients diagnosed with dehydration diarrhea will receive fluid therapy with high osmolarity (hypertonic) in significant amounts to address dehydration. This can lead to an increased risk of phlebitis in children. This assumption is supported by a study conducted by Lalithambigai (2018)¹⁸ where the number of patients with phlebitis receiving crystalloid fluids (hypertonic) was 26 respondents (86.6%), and those receiving antibiotics were 10 respondents (33.33%).

Among the respondents suffering from phlebitis, 33 individuals, accounting for 56.9% of the sample, used a size 24 catheter in the IV catheter univariate data. Sizes 24 and 26 are used to administer infusion fluids to neonates, children, and especially the elderly.²² Phlebitis can occur due to the displacement of foreign objects, such as infusion needles, into blood vessels. This displacement causes friction and subsequent vein inflammation. Needles that are too large can impede blood circulation and trigger

irritation of the blood vessel walls.¹⁹ This is consistent with a study by Sathya A (2020)²³ on the Efficacy of Aloe vera Gel Use in Phlebitis, particularly focusing on respondents with larger catheter sizes and their vulnerability to phlebitis at a ratio of 60:40. In a study by Lalithambigai (2018)¹⁸ similar conditions were found where size 24 catheters (53.33%) experienced more phlebitis compared to smaller catheter sizes. Thus, the researcher's assumption concludes that catheter size affects the occurrence of phlebitis.

The Influence of Aloe Vera Gel on Phlebitis in the Intervention and Control Groups

The research results show that before therapy was administered to pediatric patients with phlebitis, the intervention group exhibited phlebitis levels ranging from mild to severe, similar to the control group. After therapy was administered, the intervention group showed a significant decrease in phlebitis levels, with the degree of reduction varying depending on the initial phlebitis level before intervention. Meanwhile, the control group, which did not receive therapy, also showed varying decreases in phlebitis levels depending on the initial phlebitis level of the patients. From the conducted research, it was found that there was an effect both before and after the administration of Aloe Vera Gel therapy in the intervention group, and there was a difference between the intervention and control groups, as evidenced by the difference in mean values, with the intervention group being more dominant. The research results indicate that the average phlebitis level before aloe vera treatment was 1.82 with a standard deviation of 0.541. After treatment with aloe vera, the average phlebitis level decreased to 1.04 with a standard deviation of 0.499. Statistical analysis yielded a p-value of 0.000, which is smaller than the significance level of 0.05.

Difference in Phlebitis Levels Between the Intervention and Control Groups. The ttest results between the two groups also showed a p-value of 0.002 < 0.05 with an effect size of 0.83 (large effect), indicating a difference between the intervention and control groups before and after the administration of aloe vera gel therapy. This research also shows a decrease in phlebitis levels in both groups, but the decrease in phlebitis levels was more dominant in the intervention group that received aloe vera gel therapy. This difference can be seen from the level of decrease in phlebitis before and after the administration of aloe vera gel therapy, which showed a decrease in phlebitis levels to the mild range in the intervention group, while the control group, which did not receive therapy, also showed a decrease in phlebitis levels to the moderate range.

The researcher assumes that aloe vera gel is highly effective in treating phlebitis. An inflammatory agent because it contains anthraquinone as an active compound which is a structural analog of tetracycline. Anthraquinones act like tetracyclines inhibiting bacterial protein synthesis by blocking the A site of ribososm (where the annealed tRNA enters). Therefore, bacteria cannot grow in media containing aloe vera extract. Therefore, the implication of aloe vera gel therapy in this study can influence the decrease in phlebitis levels in the intervention group, although the control group, which did not receive aloe vera gel therapy, also experienced a decrease. However, in the intervention group receiving aloe vera gel therapy, a more dominant decrease in phlebitis levels was observed.

Implications and Limitations

The findings of this research indicate that pediatric patients with phlebitis can be administered aloe vera gel therapy, which can reduce or even heal phlebitis symptoms. However, the limitations of this study include the lack of time or duration of aloe vera gel application, potentially impacting the effectiveness of the therapy. Additionally, there were challenges in finding respondents with similar levels of phlebitis between the intervention and control groups, making it difficult to compare the effectiveness of aloe vera gel. Moreover, there was insufficient exploration of variables that could potentially influence phlebitis.

Conclusion

The findings of this study suggest that pediatric patients with phlebitis can benefit from aloe vera gel therapy, which has the potential to reduce and even heal phlebitis symptoms. However, there are limitations to consider. One limitation is the inadequate duration of aloe vera gel administration, which may impact the therapy's effectiveness. Longer therapy durations could potentially produce more favorable outcomes. Additionally, challenges were encountered in achieving comparability between the intervention and control groups in terms of phlebitis severity levels, complicating the assessment of aloe vera gel therapy effectiveness. Moreover, there was a lack of exploration into potential variables influencing phlebitis.

Conflict of Interest Declaration

There are no conflicts of interest in this study.

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