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The effect of Intravenous House Ultra Dressing in reducing Phlebitis Associated with Peripheral Intravenous Cannulation in Pediatric patients: Randomized Controlled Trial (RCT)

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ABSTRACT

Background: Phlebitis is a common complication associated with peripheral intravenous (IV) cannulation in pediatric patients, often leading to discomfort, and it can result in pain, swelling, and complications that may prolong hospitalization.

Objective: to determine the effect of intravenous (I.V.) House Ultra Dressing in reducing phlebitis associated with peripheral intravenous cannulation in pediatric patients.

Methodology: It was a comparison and prospective randomised controlled trial (RCT). The study looked at 64 participants (2–34 months old) who were getting peripheral intravenous cannulation in paediatric wards. Randomly, 32 patients were put into the study group (Intravenous House Ultra Dressing) and 32 patients were put into the comparison group. Scores for phlebitis were kept for both groups. The Visual Infusion Phlebitis Scale (VIPS) was used to measure the severity of phlebitis, and scores were recorded every 8 to 12 hours from the start of intravenous treatment until the catheter was removed.

Results: The study showed a P-value of 0.000, which means that there were statistically significant differences between the study and control groups in terms of scores and signs of phlebitis. During the three days, there were big changes between the study group and the control group compared to both groups.

Conclusion: The statistically significant differences observed between the study and control groups across all three days (p-value = 0.000) indicate that this I.V. House Ultra Dressing significantly reduces the severity and scoring of phlebitis and improves intravenous site stability.

Key words: Intravenous House Ultra Dressing, Phlebitis, Peripheral intravenous Cannulation, Pediatric patients

1. INTRODUCTION

Peripheral Intravenous Cannulation (PIVC) is one of the frequently done nursing procedures, depending on the patient's medical condition, assessment, and treatment plan, which is usually accompanied by discomfort and agonizing (1). The management of pain in paediatric patients is complex, based on aspects such as age, cognitive and communication abilities,

past experiences in dealing with pain, and cultural insight (2). Over 25 million patients

in the US and billions from around the world have ever had cannulation from IV line. In addition, approximately 69 percent of all inpatients in healthcare institutions need IV cannulation (3).

Studies reveal that it is estimated that up to 90% of the patients who visit hospitals may need peripheral intravenous cannulation in order to receive medication or replace some fluid (4). Phlebitis is a local complication, related to peripheral intravenous (IV) therapy; it involves a technical intervention performed by the nursing staff that involves insertion of a (PIVC) (5). That procedure is vital in the management of treatment for the patient's condition, and thus being an essential part of the global systems of medical care (6). There are several risk factors that are associated with the occurrence of phlebitis, based on the duration of peripheral intravenous catheter (PIVC) use, gender, patient's characteristics, and chemical properties of the viewed drugs. Based on its primary cause, phlebitis may be mechanical, biological, chemical, or post-infusion (7). The Infusion Nurses Society requires a phlebitis rate of 5% or less in each community in order to realize harm reduction. This however varies significantly throughout the world, with the research from Brazilian institutions showing percentage of 5%, 25.8%, 31.6% and 55.6%, all above the safe range that is recommended (8).

Hospital-acquired infections (including bacteremia, thrombosis & hematoma) are the main sequelae of phlebitis. In addition, many guidelines have been developed for phlebitis for both assessment, diagnosis, and management (9). There may be several reasons for phlebitis, such as chemical, mechanical or biological when puncturing the spot (10). Mechanical phlebitis results from the size of the peripheral intravenous catheter being greater than the diameter of the venous lumen, or sudden change in the PIVC. Venous lumen itching, provoked either by drugs, intravenous fluids like potassium chloride or antibiotics, might result in occurrence of chemical phlebitis. Infrequent hygiene, or absence of PIVC insertion aseptic technique, leads to bacterial growth causing bacterial phlebitis (11).

A single study conducted in Jordan identified Phlebitis related to peripheral intravenous catheters (PIVC) and its risk factors. Phlebitis was diagnosed in 164 (53.4%) out of 307 children in five government hospitals (12). The Centers for Disease Control and Prevention (CDC) recommends the removal of the cannula after 72-96 hours to minimize risks. However, none of the exact time has been mentioned for the patient (13). Furthermore, phlebitis rate in hospitalized clients with IV treatment with the PIVCs is also 3.2%-71.25% (14). A critical aspect is the high frequency of complications and the low durability of these catheters. In a study conducted at the University Hospital Rio Hortega's neonatal ward in Valladolid, the most common issues observed were phlebitis at 3.5% and extravasation at 48.3% out of 143 catheters placed in 68 neonates (15).

Current research explores various nursing interventions for preventing phlebitis, such as aseptic techniques and routine site assessments. However, studies specifically evaluating the effectiveness of advanced dressing devices in pediatric populations are notably absent. Most research tends to focus on standard nursing practices, overlooking how specific dressing techniques might influence the occurrence of phlebitis among pediatric patients (16) (17) .

Studies indicate that phlebitis rates in children receiving medical therapy can rise to 5.07%. Implementing protective covers, like the I.V. House Ultra Dressing, can extend catheter usage and reduce the incidence of phlebitis, potentially enhancing patient safety and overall quality of care treatment (18) .

2. METHODS:

Study Design and Setting

A prospective randomised controlled trial (RCT) with a single-blind strategy was used for this study. It took place from December 7, 2024, to February 1, 2025, and the patients who were in the paediatric wards of Tikrit Teaching Hospital and Balad General Hospital, both in Iraq and run by the Salah Al-Din Health Department, took part. These patients often need intravenous cannulation for long periods. A simple random picking method was used to put participants into either the study group or the control group. Use simple random sampling in this study to ensure that each participant has an equal chance of being assigned to any group, the possibility of comparison between the study and the control group, and to generalize the study results to the population (19). There have been (64) participants in the sample. Both the study group and the control group acquired an identical quantity of these subjects, as indicated in the Study Protocol Algorithm Section Figure (1).

Study Sample and Sampling

Children between the ages of 2 and 34 months who were brought to the paediatric ward, had an IV catheter stay of more than 48 hours, and were receiving the same antibiotic by IV infusion were included in the study. Patients who were allergic to or had bad reactions to the ultra-dressing materials, who were getting blood or blood products through a catheter, who had long-term vascular or immune system conditions that could make phlebitis more likely, or who already had phlebitis or skin infections were not allowed to take part. People who were more likely to bleed (like those with haemophilia or thrombocytopenia) or who had problems with how their blood clots were also not included.

Based on a 5% margin of error and an 85% confidence level, the minimum sample size needed for each group was 32, meaning that there were 64 participants in total for both groups. At first, 68 patients agreed to take part in the research.

Nevertheless, three patients chose not to take part in the intervention, and one patient was eliminated for failing to finish the assessment. In the end, the final data analysis contained 64 participants.

To choose their group assignment at random, each paediatric carer was given a sealed envelope with a card that was either red or yellow. Carers who chose a yellow card were assigned to the study group, which received the IV House Ultra Dressing intervention, whereas those who chose a red card were placed in the control group. The allocation process ensured a fair band of participants, as each individual had the same probability of being allocated to one of the groups. Given that the paediatric carers were aware of the intervention administered, the study was undertaken as an open-label trial.

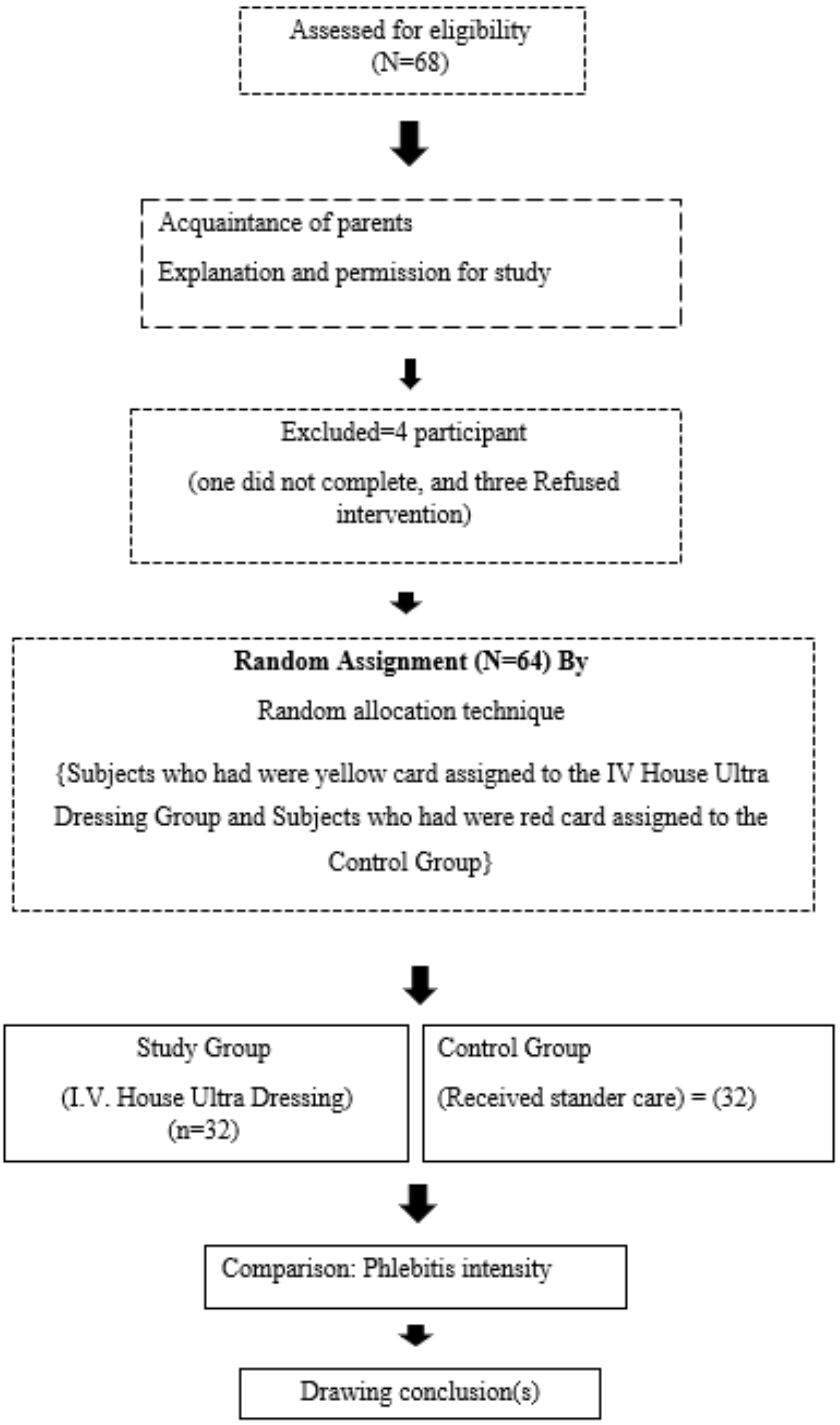

Figure 1: Study Protocol Algorithm

Data Collection Tool(s)

The data for the study was obtained from a questionnaire that had two parts: – demographic and clinical information; and – the Visual Infusion Phlebitis Scale (VIPS), which is a measure of the severity of phlebitis in paediatric patients who receive an intravenous catheter and require long-term output via intravenous therapy.

Demographic and clinical information

The section on demographic data was created for gathering the essential descriptive information concerning the patients who entered the scope of the study, for example, their age, sex, and residency, as well as clinical data, which included medical diagnosis and site of cannula insertion.

Visual Infusion Phlebitis Scale

A validated visual instrument called VIPS is used to assess the score of a patient's phlebitis, after being given an IV infusion (20). For healthcare practitioners, this scale provides specific advice. The Visual Infusion Phlebitis (VIP) Scale formulated by Jackson: Six elements constitute this standardised tool, 0 means no phlebitis and 5 severe phlebitis.

Intervention(s)

Children between 2 and less than 34 months old who required intra venous (IV) cannulation and who were taken to paediatric wards were involved in this study. In order to ensure ethical and professional research standards were observed, the researcher ensured those that eligible patients understood the objectives, techniques, and duration of the study of the carers. The carers were then asked to give written as well as verbal informed consent prior to participation.

64 of all the participants who qualified for the study and had had the full clinical assessment of the child by the paediatrician to ensure that there is a need for IV cannulation were enrolled into the research. Having been granted permission, the subjects were assigned into one of two groups randomly. Random selection was done in order to ensure that all of them were placed in the same group, and each had an equal opportunity to be amongst the two groups. The process also ensured the study's integrity from selection bias and ensured comparability between the intervention and control groups.

Interventional Procedure

All patients were admitted to the hospital with their mothers after obtaining consent from the patient's caregiver. The mothers and nurses provided basic care. In the clinic's intervention room, the pediatric patients were positioned supine while maintaining verbal and visual communication with their parents. The first step in this research process was administering intravenous cannulations to patients who received IV therapy by infusion solution over 30 minutes, three times a day.

In order to examine the veins and guarantee patient safety, the nurse or researcher held the pediatric youngster in either the foot, elbow, or wrist. After using an alcohol swab to clean the skin puncture site and letting it dry for 30 seconds and inserted a 24-gauge novocath Safety IV catheter. Following the implantation of an IV catheter, the researcher used following the insertion of IV catheter; placed the fixation device on the patient's foot, elbow, or wrist. The study group's I.V. House Ultra Dressing was then fitted in accordance with the manufacturer's instructions; no further taping was required (21). Using the I.V. House Ultra Dressing with support—particularly the TLC Ultra Splint is advised by the manufacturer (Figure 2)

. However, in the control group after insertion IV catheter secure it with traditional dressing (zinc oxide adhesive plaster) only and monitoring signs phlebitis (Figure 3). Throughout the catheterization time, the researcher will gather data and check participant every 8 to 12 hours for symptoms of phlebitis. A visual infusion phlebitis scale (0–5 score) will be used for observation assessment. To ensure uniform data collection across all participant assessments will continue for 72 hours (three days)

Figure 2.Study group (I.V. House Ultra Dressing).

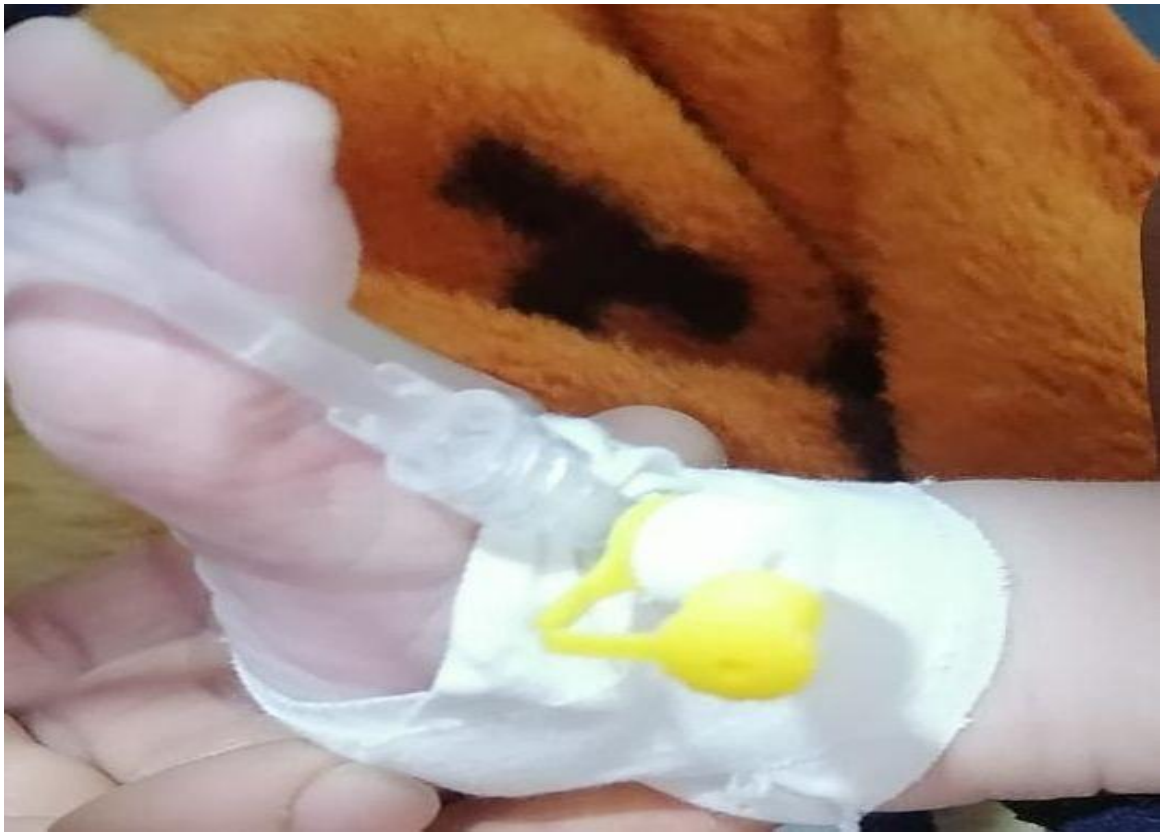

Figure3. Control group (applying standard care).

Data Analysis Methods:

The data in this study was analysed using SPSS version 26. The data was analysed using inferential analysis, the Pearson correlation coefficient, the T-test, and descriptive data analysis, which included frequencies, percentages, and the arithmetic mean.

Ethical Considerations

This research was validated by the Committee of Scientific Research at the College of Nursing, University of Baghdad, on November 6, 2024. Following the endorsement from the Ministry of Planning (Central Statistical Organization) on November 12, 2024, formal approvals were secured to commence operations with the Salah Al-Din Health Department. Approval from the designated hospitals was obtained on November 26, 2024, for the collection of samples. The patients were informed that participation in the study was voluntary and would entail no financial or legal repercussions and that their information would be maintained in strict confidentiality.

Clinical Registry

As an integral part of the initial RCT, we obtained approval for the registration of the trial from the Iranian Registry of Clinical Trials (IRCT) on 15th December 2024. The registration reference is IRCT20241123063810N1

3. RESULTS:

Table 1: Statistical Results of the Demographic Variables and Health History for the Sample (Study and Control Groups) in the Study

Demographic	Estimate	Study Group		Control Group	
		Freq	%	Freq	%
Sex	Male	20	62.5	22	68.8
	Female	12	37.5	10	31.3
Age	(2-12) months	28	87.5	28	87.5
	(13- 23) months	2	6.3	2	6.3
	(24-34) months	2	6.3	2	6.3
Residency	Rural	23	71.9	26	81.3
	Urban	9	28.1	6	18.8
Diagnosis	Respiratory diseases	12	37.5	18	56.3
	Urinary diseases	2	6.3	2	6.3
	Digestive diseases	18	56.3	12	37.5
Cannula Insertion Site	Wrist	15	46.9	21	65.6
	Forearm	8	25.0	5	15.6
	foot	9	28.1	6	18.8

***F*=Frequency, *%*= Percentage**

Table (1) Demographic analysis revealed that 62.5% of the study group and 68.8% of the control group were male. Most participants (87.5%) were aged 2–12 months. Regarding residency, 71.9% of the study group and 81.3% of the control group resided in rural areas. In terms of diagnoses, 56.3% of the study group had digestive diseases, while an equal proportion (56.3%) of the control group had respiratory diseases. For cannula insertion sites, 46.9% of the study group and 65.6% of the control group had wrist insertions.

Table 2: Statistical t-test Differences Results between Study and Control Groups for three-time Days regarding Intravenous House Ultra Dressing

Days	Mean	Std. D.	t-test	P.value	Sign

Day 1	Study Group	0.000	0.00	- 7.048	.000	HS
	Control Group	0.677	0.84			
Day 2	Study Group	0.336	0.13	- 17.529	.000	HS
	Control Group	0.772	2.72			
Day 3	Study Group	0.499	0.41	- 22.718	.000	HS
	Control Group	0.716	3.94			

Std. D. = Standard Deviation, *S + Sign*=Significant at *P*.value ≤ 0.05 level, *HS*= High Significant

Table 2: shows the statistical t-tests demonstrated statistically significant differences in intravenous house ultra-dressing between the two groups for day 1 at t-test (- 7.048) and p.value (.000). There were high significant differences between two groups for day 2 at t-test (- 17.529) and p.value (.000). In addition, there was high significant differences between two groups for day 3 at t-test (- 22.718) and p.value (.000).

Table 3: Statistical Consequences ANOVA between Study and Control Groups for three-time Day regarding Intravenous House Ultra Dressing

Days		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Day 1	Between Groups	11.391	1	11.391	49.668	.000
	Within Groups	14.219	62	0.229		
	Total	25.609	63			
Day 2	Between Groups	107.641	1	107.641	303.782	.000
	Within Groups	21.969	62	0.354		
	Total	129.609	63			
Day 3	Between Groups	199.516	1	199.516	524.290	.000
	Within Groups	23.594	62	0.381		
	Total	223.109	63			

df= degree of freedom, *F*= Calculator F. *Sign*. =Significant at *P*.value ≤ 0.05 level, *HS*= High Significant

Table 3: Using ANOVA for the statistical analysis showed that the effects of intravenous house ultra-dressing, which was used for three days, were very different between the study group and the control group. With a p-value of less than 0.001, the change on Day one was very important. On Days two ($p < 0.001$) and three ($p < 0.001$), there were also statistically significant differences.

4. DISCUSSION:

The first section is designed to present and discuss the socio-demographic characteristics and medical history of study participants from the two covered groups. Tables (1) were created to describe a given population's demographics, including frequencies and percentages.

Regarding sex, the two groups have a larger proportion of males than females. Males made up the majority of the control group participants. Similarly, in the study group, the majority of participants were males (22).

Regarding age, the majority of the control and study groups are between the ages of 2 - 12 months. More than half of the participants in both groups ranged in age from two to twelve months. This result is consistent with a study by Suliman, Mohammad, et al. (2020), which found the majority of our sample was newborns (19.5%), infants (38.1%), and toddlers (24.8%)(12).On the other hand, this result determined that a total of 57.8% of the children who were included in the study were 1-36 months old (23). This result is not consistent with a study by Al-Musawi, Khatam M., et al. (2020), which found that the majority (53.3%) of neonates were at the age 16-30 days (24).

Regarding residency, most of them lived in rural areas for both groups. This result is agree with Khalel, M., & Shawq, A. H. (2024). Who found (52.6%) children lived in rural areas (25). In terms of the diagnosis for hospitalization, digestive and respiratory disorders were the main causes. This result is consistent with Bitencourt, Elessandra Souza, et al. (2018), which found that the majority of participants were respiratory diseases(17). On the other hand, this result is consistent with a study by Baye, Nega Dagnew et al. (2023); the common disease cause for admissions was respiratory diseases followed by gastrointestinal problems (26).

According to of the Cannula Insertion Site, the results indicate that peripheral IV cannulas were placed in the wrist of most study and control group participants. However, peripheral IV cannulas were inserted in the foot and forearm of less than half of both groups. This result is consistent with a study by Suliman, Mohammad, et al. (2020), which found the majority of catheters were inserted into different sites; the main insertion site was the wrist (12).

Regarding Table (2) (3). The results demonstrated that the intravenous house ultra-dressing significantly decreased the occurrence of pediatric phlebitis in comparison to the control group, which received traditional dressing as the intervention. The control group was used as a baseline for comparison, and it showed a greater incidence of phlebitis. Conversely, patients administered the intravenous house ultra-dressing showed a significant reduction in phlebitis, demonstrating its efficacy in alleviating complications associated with intravenous therapy in pediatric populations.

This result is not consistent with a study by Büyükyılmaz, Funda, et al.(2019) who found that a randomized controlled trial design investigating the efficiency of intravenous house ultra-dressing in the pediatric population found no significant differences in phlebitis scores between experimental and control groups(27). This result is supported by a study Cho, Yen-Hua, et al. (2015). Who found that study, implemented a modified catheter care bundle, including 2% chlorhexidine sterilization and improved fixation techniques, which reduced phlebitis incidence from 5.07% to 2.08% in children (28).

This result is in line with a study, Tay, S., & Yilmaz Kurt, F. (2020) . The study used a transparent film dressing for peripheral intravenous catheters, which was associated with longer dwell time and reduced incidence of complications(29). This finding is supported by a study Aziz A (2022). Study the use of Transparent Dressing minimized the phlebitis rate compared to conventional dressings as proven by the use of transparent dressing, the phlebitis rate was 2.7%, and the use of conventional fixation resulted in a 6.8% phlebitis rate(30).

This result is in line with a study by Ravindra HN, Patel K. (2015). Who found that study, Glycerin magnesium sulphate dressing was found to be highly effective in decreasing phlebitis levels compared to a control group (31).

This result agrees with a study, Anggraeni R, Suryati Y, Nurjanah N(2021). This study found that Aloe Vera could significantly reduce the degree of phlebitis compared to 70% alcohol (32). The literature indicates that prolonged and secure utilization of PIVC, particularly for up to 72 hours, enhances the safety of pediatric patients and decreases the incidence of repeated interventions. It assists in managing potential infections (phlebitis, infiltration, etc.), decreases hospital duration and care expenses, and safeguards against physical harm to the pediatric patient (33, 34).

5. LIMITATIONS

There were some challenges with the study, especially since it was a first-of-its-kind attempt in the Iraqi healthcare system. The I.V. House Ultra Dressing was not sold in local stores, so it had to be bought through foreign electronic procurement, which was a big problem. This limitation could make it harder to use in settings that are more clinical unless rules and procedures for buying things are changed to make it easier for people in those areas to get them. Additionally, the study was

limited to just two hospitals- Tikrit Teaching Hospital and Balad General Hospital so the results may not apply to other groups of people or hospitals in Iraq.

6. CONCLUSION:

The I.V. House Ultra Dressing significantly lowers phlebitis scoring and symptoms and enhances intravenous site stability, according to statistically significant differences between the study and control groups within a period of three days (p-value = 0.000).

7. RECOMMENDATIONS:

Future studies should explore the long-term effects of the I.V. House Ultra Dressing in diverse pediatric populations, including neonates and critically ill children. Larger multicenter trials could validate these findings and assess additional outcomes such as cost-effectiveness, nurse satisfaction, and parental feedback. It is essential to recommend that nurses and other healthcare professionals receive comprehensive training on the proper application and maintenance of the I.V. House Ultra Dressing. This includes adherence to manufacturer guidelines and best practices for ensuring optimal patient comfort and catheter dwell time. The author recommended Procurement and Implementation by the Iraqi Ministry of Health. Since the I.V. House Ultra Dressing is currently unavailable in Iraq, the Ministry of Health should prioritize its importation and distribution to healthcare facilities, particularly pediatric wards.

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