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Research Article

Effectiveness of an Intravenous Protection Device in Pediatric Patients on Catheter Dwell Time and Phlebitis Score

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ABSTRACT

Purpose: The study aimed to examine the efficacy of the I.V. House UltraDressing for protecting peripheral intravenous catheters (PIVCs) in pediatric patients.
Methods: This randomized controlled trial comprised 60 pediatric patients (aged 2–24 months): 30 in the experimental group and 30 in the control group. The PIVC dwell time and phlebitis scores were also reported for both groups. The degree of phlebitis was determined using the Visual Infusion Phlebitis Scale (VIPS) and was recorded every 8 hours from the start of antibiotic therapy until catheter removal.
Results: The mean catheter dwell time in the experimental group (2.10 ± 1.55 days) was significantly longer than that in the control group (1.27 ± 0.45 days) ($p < .01$). However, there were no significant differences between the scores and signs of phlebitis in both groups ($p > .05$).
Conclusion: The I.V. House UltraDressing is a useful device that can be used to increase catheter dwell time and protect and stabilize PIVCs in pediatric patients.
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Introduction

Pediatric patients are frequently hospitalized for infections, chronic illnesses, or conditions, the causes of which are undetermined. Hospitalization is often required when intravenous (IV) cannulation for the parenteral supply of fluids, blood and blood components, medication, or nutritional support is necessary [1,2]. For ensuring medical treatment, IV therapy is probably the most common invasive acute care procedure [3]. It is estimated that ≥ 90% of hospital stays involve the use of infusion therapy and that 1.8 million peripheral IV catheterizations (PIVCs) are performed in pediatric patients annually [4]. Especially in pediatric patients, skillful procedure is essential because the vascular structures are not yet adequately developed and the extremities move excessively [3]. To prevent unnecessary repeated interventions, a suitable peripheral vein must be identified and stabilized before inserting a cannula, and the procedure must be skillfully performed. It is also important to use the PIVCs properly for an extended dwell time without the complications, after successful placement of a catheter. Jeong et al. [5] determined that the mean PIVC dwell time was 55.6 hours, mostly at 24–72 hours intervals, in 1596 pediatric patients.

The clinician must also be able to palpate and visualize the entire extremity to inspect complications such as swelling, skin breakdown, phlebitis, or infiltration. Besides, regular IV care is effective in reducing complications. Kleidon et al. [6] recommended that PIVCs should be monitored using the maintenance bundle (prompt removal, inspect hourly, vein patency by the intermittent flush of 0.9% sodium chloride flush, clean hands, scrub the hub with 2% chlorhexidine gluconate and 70% alcohol swab). Lim et al. [7] concluded that phlebitis is the most common complication. In the literature, it was determined that cumulative risk for complications (especially infiltration) rapidly increased after 24 hours (especially between 48th and 120th hours) [5]. To extend dwell time and to prevent complications, it is important to identify an appropriate vein and stabilize and protect the PIVC site in pediatric patients. The Infusion Nurse

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Society recommends that PIVCs in neonatal or pediatric patients should be protected and assessed frequently. Protection can be achieved using a manufactured catheter stabilization device [8,9], whereas regular assessments can be facilitated using a transparent device that permits frequent assessment without the need for apparatus removal [10].

Several evidence-based strategies are used to increase viable catheter dwell times and decrease the incidence rates of phlebitis, infiltration, and infection, as well as costs. Studies have reported that dressings [such as 3M Micropore and 3M Tegaderm (3M, Maplewood, MN, USA)] and securing devices [such as SorbaView SHIELD (Centurion, Williamston, MI, USA) and StatLock IV Ultra (Bard Access Systems, Inc., Salt Lake City, UT, USA)] can extend catheter dwell times by up to 96 h, reducing both patient discomfort and PIVC costs in the process [6,11,12]. In addition, Callaghan et al. [13] showed that a 3M Tegaderm 1633 dressing and splint were necessary to secure tubing and/or connections and immobilize a child's limb, when prolonged catheterization was anticipated. Hetzler et al. [14] also studied the use of an IV device created by pediatric nurses, suggesting that the use of an IV board was the best method for maintaining and preserving the PIVC. On the other hand, Laudenbach et al. [15] determined that the StatLock securement device was not effective in pointing the dwell time and complications rate. Weyers [16] designed a combinable transparent dressing and securement device [The Grip-Lok Arterial and splint (MED Alliance Group, Inc., Sycamore, IL, USA)]. Jeong et al. [5] determined that “adhesive breathable, transparent film dressing design” promoted better visibility, facilitating nurses to detect IV complications earlier. In addition, the new IV securement dressing brought about labor cost savings; enabling staff time directed to other patient care activities.

In the biomedical market, some devices have been developed to ensure patient safety and the effectiveness of IV therapy. One of these, splint [TLC UltraSplint (I.V. House, Inc., St. Louis, MO, USA)] is an ergonomically designed armboard that holds the joint in the ideal orientation for IV therapy to improve patient safety and increase nurse efficiency. In addition, a new device recommended for use with splint (especially TLC UltraSplint) for pediatric patients is a tape- and latex-free device [I.V. House UltraDressing (I.V. House, Inc., St. Louis, MO, USA)]. This device has been developed to protect, stabilize, and ensure the long-term safety of peripheral IV catheterization [17]. This tape-free protection and stabilization device is an innovative solution for safeguarding PIVC sites. This device, which was developed by pediatric nurses Lisa Vallino and Betty Rozier in 1991, is ventilated, has a transparent plastic dome that secures the catheter hub and loops of tubing, and has a soft foam pad under the outer dome edge to ensure patient comfort [17]. Its features ensure that the PIVC is kept safe and that the risks of thrombus formation, extravasation, leakage, and accidental displacement are minimized [9,18]. Based on the literature review, no reports on the evaluation of this device in pediatric cohorts were found.

Purpose of the study

The present study aimed to assess the effectiveness of I.V. House UltraDressing (I.V. House, Inc., St. Louis, MO, USA), an IV protection device in pediatric patients, in terms of catheter dwell time and phlebitis score.

The two research hypotheses were as follows:

1. The catheter dwell times in the pediatric patients in the experimental group (those using the I.V. House UltraDressing device) are longer than the dwell times in those in the control group.
2. The phlebitis scores obtained for pediatric patients who used the I.V. House UltraDressing device are lower than the scores for those in the control group.

Methods

Design

This randomized controlled trial aimed to examine the efficacy of the I.V. House UltraDressing for protecting PIVCs in pediatric patients. It was hypothesized that using the I.V. House UltraDressing would considerably improve clinical efficacy.

Setting and samples

This study included inpatients from the pediatric department of a public hospital in Turkey between February 2016 and March 2017. The patients were required to meet the following inclusion criteria: (a) being in the 2–24 months age range, (b) having been treated with the same antibiotic by IV infusion, and (c) having had an IV catheter in the metacarpal vein for the first time. The exclusion criteria were as follows: abnormalities of coagulation; hematological, oncological, and allergic diseases; incision or scar tissue in the metacarpal area; congenital, genetic, or neurological disease; feeding problems; problems with skin integrity or extremity movement at the PIVC site; abnormal hydration or receiving blood or blood products through the catheter.

Power analysis to estimate the sample size was performed based on previous research with a large cohort. A sensitivity power analysis to estimate the sample size was based on previous research involving a large effect size [7,13,15]. Assuming a power of 80% and an α risk of .05, a sample size of 60 was determined to be adequate. Pediatric patients ($N = 64$) were then assessed according to the inclusion criteria and invited to participate depending on their eligibility. A computer-based random number generator was used to assign the patients into groups. To conceal the random assignment of pediatric patients, a data collection form with a random number was kept in a sealed envelope which was opened by another research nurse only at the time of inserting the PIVC. According to the randomization result, the research nurse responsible for inserting the PIVC explained the study and demonstrated the device to be used to the parents before inserting the PIVCs. Four of the hospitalized pediatric patients' parents did not want to participate in the study (the I.V. House UltraDressing device group). Overall, the study sample comprised 60 pediatric patients: 30 in the experimental group and 30 in the control group. The flow diagram created by the researchers was based on the Consolidated Standards Of Reporting Trials (CONSORT) Statement [19] (Figure 1).

Ethical considerations

The permission to conduct this randomized controlled trial was received from Selcuk University Clinical Ethical Board (Approval no. 2015/272). Before conducting the study, the parents were informed of the purpose of the research and were assured of their right to refuse to participate in the study or withdraw their consent at any stage.

Measurements and instruments

Two registered nurses were responsible for the procedure and data collection process. One of them, who had 19 years of experience in pediatric nursing, was responsible of all phlebotomy and applied devices. The other nurse, who had 10 years of experience in

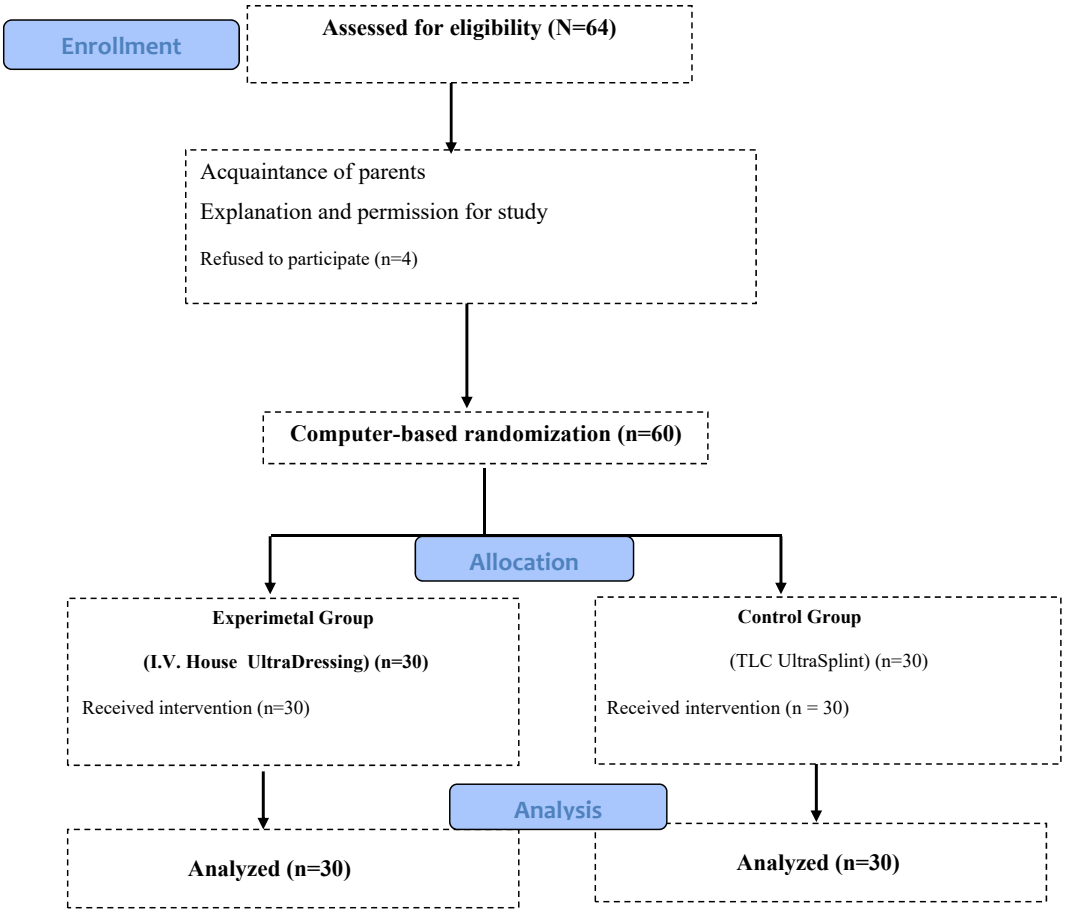


Figure 1. Allocation of participants.

clinical nursing, collected demographic information and determined pain intensity and anxiety levels.

Demographic information [age, sex, weight (measured using a portable digital baby scale), and height (measured using a tape)] was obtained from all patients. The PIVC dwell time and phlebitis scores were reported every 8 hours for both groups. The registered nurse, who was responsible for data collection procedure, checked the PIVC before treatment to confirm catheter placement within a vessel. During assessment times, if the PIVC was occluded or phlebitis sign was determined on the PIVC site, the registered nurse removed the catheter. Before assessment times, if pediatric patients removed the PIVCs unconsciously, the nurses reported this situation. The degree of phlebitis was determined using the Visual Infusion Phlebitis Scale (VIPS) and was recorded every 8 hours from the start of antibiotic therapy until the catheter removal.

Visual Infusion Phlebitis Scale

The VIPS is a validated visual tool used to determine the phlebitis score in patients after IV infusion [20]. This scale provides a numerical rating based on observable phlebitis symptoms (e.g., pain, pallor, erythema, swelling, and induration). According to each rating score, this scale is recommended for specific actions for health-care providers. The standardized use of this scale eliminates catheter dwell time as a prominent variable when changing peripheral IV sites. The scores range from 0 (absence of phlebitis) to 5 (the presence of advanced thrombophlebitis) [21].

Procedure

All patients were hospitalized with their mothers, and the nurses and mothers provided basic care. The patients received IV penicillin by infusion in an isotonic solution over 30 min, three times daily, for lower respiratory tract infections as prescribed by the treating pediatrician. The PIVC insertion procedure was based on previously reported methods [1,22,23]. Briefly, the pediatric patients were placed in the supine position, maintaining verbal and visual contact with their mothers in the clinic's intervention room. A single registered nurse held the patients' hand to assess the metacarpal veins while another registered nurse focused on ensuring patient safety. The registered nurse assessing the metacarpal veins then cleansed the skin puncture site with an alcohol swab, allowed it to dry for 30 seconds, and inserted a 24-gauge Teflon Introcan Safety IV Catheter (B. Braun Medical Inc., Bethlehem, PA, USA).

After IV catheter insertion, the same registered nurse applied the fixation device to the patients' hands. The I.V. House UltraDressing in the experimental group was fitted according to the manufacturer's instructions and secured with a small adhesive strip on the dressing that prevented slipping; no other taping was necessary (Figure 2) [17,24]. The manufacturer recommends the use of the I.V. House UltraDressing with splint support (especially TLC UltraSplint). The same nurse applied splints (TLC UltraSplint) in the control group, after applying



Figure 2. Experimental group (I.V. House UltraDressing).



Figure 3. Control group (applying TLC UltraSplint).

transparent, self-adhesive, semipermeable dressings made of polyurethane film (3M Tegaderm) (Figure 3). The devices used in both the control and experimental groups were supplied by the same manufacturer. The PIVCs were not removed until at least 96 hours, unless contraindicated, in line with the recommendations in the literature [1,4,11,12,21]. Catheter occlusions are one of the most frequent, serious PIVC-related complications, and prevention by flushing and maintaining a secure dressing are key to maintaining patency. Flushing of PIVCs is thought to be essential in the prevention of occlusion. The clinical sign of occlusion is catheter malfunction, and saline flushing is effective in maintaining patency of IV lines [25,26]. In this study, the PIVC sites were flushed using a saline solution before and after antibiotic infusion to clean the catheter and protect the vessel line. In addition, all PIVC sites were taken care by the same procedure that included changing dressings daily and applying 2% chlorhexidine gluconate swabs. Furthermore, PIVCs were removed when signs of phlebitis start to develop and not opened by flushing.

Data Analysis

Data were analyzed using Statistical Package for the Social Sciences for Windows, version 21.0, (IBM Corp., Armonk, NY, USA). The demographic and outcome variables (i.e., catheter dwell times and VIPS scores) were analyzed based on the frequency distributions for categorical variables and means and standard deviations for continuous variables in both groups. The Chi-square test was used to examine the differences between categorical variables, and independent sample *t* tests were used to assess the differences between continuous variables. A $p < .05$ was considered statistically significant.

Results

The final cohort included 60 patients (29 females and 31 males), 30 in the experimental group and 30 in the control group. The mean age, gestational weight, height, and weight were 8.66 ± 6.91 months, 3.20 ± 0.37 kg, 66.98 ± 10.47 cm, and 7.82 ± 2.54 kg, respectively. There were no statistically significant differences between the control and experimental groups regarding the demographic variables (Table 1).

Research hypothesis 1: catheter dwell time

The catheter dwell times of the two groups are summarized in Table 2. The mean catheter dwell time in the experimental group (2.10 ± 1.55 days) was significantly longer than that of the control group (1.27 ± 0.45 days) ($p = .001$).

Research hypothesis 2: catheter VIPS scores

The VIPS scores of both groups are summarized in Table 3. However, there were no significant differences between the groups ($p > .05$) (Table 3).

Table 1 *Demographic Characteristics of Pediatric Patients (N = 60).*

Characteristics	Experimental group, (n = 30)	Control group, (n = 30)	Total groups, (N = 60)	t *or* χ^2, *p*
	n (%) or M ± SD (Min-Max)	n (%) or M ± SD (Min-Max)	n (%) or M ± SD (Min-Max)	
Age (months)	9.03 ± 7.10 (2-24)	8.28 ± 6.81 (2-24)	8.66 ± 6.91 (2-24)	t = 0.42 $p = .678$
Gestational weight (kg)	3.16 ± 0.39 (2-4)	3.23 ± 0.35 (2-4)	3.20 ± 0.37 (2-4)	t = 0.79 $p = .432$
Gender				
Female	13 (43.3)	16 (53.3)	29 (48.3)	$\chi^2 = 0.61$
Male	17 (56.7)	14 (46.7)	31 (51.7)	$p = .303$
Length (cm)	68.27 ± 10.94 (50-86)	65.70 ± 9.98 (52-90)	66.98 ± 10.47 (50-90)	t = 0.95 $p = .347$
Weight (kg)	8.25 ± 2.56 (4-13)	7.39 ± 2.49 (4-12)	7.82 ± 2.54 (4-13)	t = 0.78 $p = .192$

Note. M = mean; Max = maximum; Min = minimum; SD = standard deviation.

Table 2 *Catheter Dwell Time (N = 60).*

Dwell time	Experimental group (n = 30)	Control group (n = 30)	
	M ± SD (Min-Max)	M ± SD (Min-Max)	t (*p*)
Average time (days)	2.10 ± 1.55 (1-4)	1.27 ± 0.45 (1-2)	3.68 (.001)*

Note. M = mean; Max = maximum; Min = minimum; SD = standard deviation. *$p<.001$.

Table 3 *Phlebitis Scores (N = 60).*

Visual Infusion Phlebitis Score (VIPS)	Experimental group (n = 30), M ± SD	Control group (n = 30), M ± SD	t (*p*)
1st day	0.00 ± 0.00	0.03 ± 0.18	−0.64 (.583)
2nd day	0.03 ± 0.18	0.07 ± 0.25	−0.78 (.541)
3rd day	0.07 ± 0.25	ND	–
4th day	0.10 ± 0.30	ND	–

Note. M = mean; ND = not defined; SD = standard deviation.

Discussion

According to the Infusion Therapy Standards of Practice, the most important practice standards are protecting special patient populations (particularly pediatric patients) and managing and monitoring PIVCs, joint stabilization, and phlebitis [8,21]. To the best of our knowledge, this is the first study to demonstrate the effectiveness of the protection device (I.V. House UltraDressing) in securing the PIVC sites in pediatric patients.

According to the literature, long-term and safe use of PIVC (especially up to 72 hours) increases the safety of pediatric patients and reduces the frequency of repeated interventions. It also helps to control possible infections (phlebitis, infiltration, etc.), reduces hospital stay and care costs, and prevents physical injury to the pediatric patient [5,7]. Notably, this study showed that the catheter dwell time was longer in pediatric patients who received the PIVC protection device. According to this result, the researchers determined that the I.V. House UltraDressing is a useful device to increasing dwell time in pediatric patients. In the literature and according to the policy of the institution where the study was conducted, all PIVCs were not removed until at least 96 hours, unless contraindicated [5,9,12]. In an aspect of patient safety, the experimental group was provided with prolonged dwell time and minimized repeated intervention. The duration of IV cannulation is affected by numerous factors, including the intended use, vein accessibility in a given patient's position, the patient's age and comfort, and the urgency of the situation [1]. The Infusion Therapy Standards of Practice recommend using a manufactured catheter stabilization device to protect the PIVC [8,21].

Phlebitis scores are also an important measure of the quality of nursing care. Tofani et al. [27] and Park et al. [28] suggested that monitoring of PIVCs and the implementing of IV infiltration management program were effective procedures in reducing complications. In this study, all pediatric patients' PIVCs were managed by same procedures (monitoring, flushing, PIVC care). In addition, PIVCs were removed when signs of phlebitis start to develop (i.e., mild pain and a slight redness around the IV area). In the present study, the phlebitis scores obtained were very low ($\leq$1) in both groups at all measurement times. Considering the patients' safety, all scores is a positive outlook for pediatric patients. The low phlebitis score may be attributed to the fact that the same research nurse decided patients' veins and inserted PIVCs for both groups. In addition, using the same procedure (monitoring, flushing, PIVC care), the same phlebitis level was considered for both groups. However, the experimental group's measurement times were longer than those of the control group. The most important reason for the longer measurement times in the experimental group, having the longer catheter dwell time than the control group, is that the research nurse determined phlebitis scores using the VIPS and recorded every 8 hours from the start of antibiotic therapy until the catheter removal. Despite the prolonged catheter dwell time, PIVCs were stabilized and protected without any complications in the experimental group. The Infusion Therapy Standards of Practice also recommend that pediatric nurses provide individualized, collaborative, and age-appropriate care for PIVCs [8,29]. Lim et al. [7] determined that the use of an adhesive transparent dressing could lead to prevention and earlier detection of phlebitis and extravasation. In addition, the new IV securement dressing brought about labor cost savings, enabling staff time directed to other patient care activities [7].

Limitations

Only one registered nurse, who was also a researcher, assessed the VIPS scores of pediatric patients. In future studies, objective data should be collected and assessed by researchers blinded to group allocation. In addition, the satisfaction scores when using the I.V. House UltraDressing should be evaluated for pediatric patients, pediatric nurses, and parents.

Conclusion

The I.V. House UltraDressing is a useful device that can be used to increase catheter dwell time and protect and stabilize PIVCs in pediatric patients. This provides additional evidence-based support for the prolonged use of the I.V. House UltraDressing as a safe, easy-to-use, and effective device to protect or manage PIVCs in pediatric patients. This could be further improved by studying additional variables in the future (e.g., age, overweight/dehydrated, or different vein status) to provide more conclusive evidence about the efficacy of the I.V. House UltraDressing in a wider range of pediatric settings. In addition, it has been recommended that the efficacy of this device for protecting PIVCs should be assessed when pediatric nurses or parents deliver basic care (e.g., dressing and bathing). However, it is also important to assess the conditions such as the lack of access to each institution and the cost factor.

Declaration of competing interest

The authors declare no conflict of interest for this study.

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