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Turkish Validation of the Infiltration Scale in Infants

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ABSTRACT

Purpose: To test the validity and reliability of an infiltration scale in infants that was adapted for the pediatric population.
Design and methods: The present study is an observational prospective study. The study was conducted in a NICU of a training and research hospital in Istanbul. Data were obtained from131 infants who were <4 kg. Language validity of the scale was tested by expert linguists. The comments of fourteen experts were taken for content validity. For reliability testing, three observers independently evaluated the scale.
Results: Infiltration developed in 28.72% of infants who were examined and grade 2 infiltration was detected at rate of 58%. The content validity index of the scale was 0.93. The Cronbach's alpha was calculated as 0.96 in the agreement of the three observer nurses' evaluations. A highly significant association was detected between the coherence of Cohen's kappa values and Intra-Class Correlation coefficient (ICC) ($p < 0.01$).
Conclusions: The infiltration scale is a valid and reliable scale in infants. The validity and reliability of the scale has been verified and may be used in the identification of infiltration in infant gestational age between 24 and 39 weeks and weighing <4 kg.
Practice Implications: The infiltration scale for infants is a valid and reliable tool for monitoring catheter sites in the prevention of complications such as infiltration due to PIV therapy practices in neonatal intensive care units.

Introduction

One of the most common therapies in neonatal intensive care units (NICU) are peripheral intravenous therapies (PIV). Fluids, drugs, parenteral nutrition, and blood products are administered through PIV catheters (Franck, Hummel, Connell, Quinn, & Montgomery, 2001; Pettit, 2003). Infiltration is one of the most common complications of PIV infusion practices and is generally confused with extravasation. Physiopathologically, both infiltration and extravasation develop as a consequence of the transition of fluid or drugs out of the veins. Infiltration develops as a consequence of leakage of non-vesicant solutions/drugs (Infusion Nurses Society (INS), 2006; Machado, Pedreira, & Chaud, 2008; McCullen & Pieper, 2006, Thigpen, 2007; Vendramin, Pedreira, & Peterlini, 2007); however, extravasation develops as a consequence of leakage and diffusion of vesicant solutions/drugs into extravascular sites (Hadaway, 2007; INS, 2006).

The rate of infiltration ranges between 23% and 78% in infants (Beauman & Swanson, 2006; Danski, Mingorance, Johann, Vayego, & Lind, 2016; Legemaat et al., 2016; McCullen & Pieper, 2006; Pettit, 2003), and 43% of infiltrations cause damage to skin, tissues, muscles, and nerves in the body (Beauman & Swanson, 2006; Pettit, 2003). The use of PIV for drug and fluid administration has gradually been increasing in infants. It was reported that causes of infiltration in NICUs were intravenous administration of drugs such as ampicillin, gentamicin, cefazolin, flagyl, cefotaxime, acyclovir, vancomycin, vasopressor drugs, and fluids (Amjad, Murphy, Nylander-Housholder, & Ranft, 2011; Wagan, 2014).

Observable findings and symptoms of infiltration are cold or pale skin, local edema, pain, burning, and circulatory problems. Complications such as morbidity, increased health care costs, prolonged hospital stay, and the increase in stress of the child, family, and health team may be encountered as a result of the infiltration induced by the use of peripheral intravenous catheter (Vendramin et al., 2007).

Early detection of infiltration has great importance for enabling the required treatment and care in clinical practice fields. A common language and a standard scale must be used to measure infiltration for correct evaluation. This study was planned because a valid and reliable

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infiltration scale used in neonatal intensive care units was not found in the literature.

Design and Methods

Purpose

To test the validity and reliability of an infiltration scale in infants that was adapted for the pediatric population.

Design

The present study is an observational and prospective study.

Participants

All infants aged 0–28 days, weighing <4 kg with intravenous catheters (excluding umbilical and percutaneous catheters) during the investigation, and who were treated in the NICU were included in the study. Infants receiving sedative drugs and mechanically ventilated infants and whose pain was difficult to determine by using the Neonatal Infant Pain Scale (NIPS) were excluded from the study. Sample size was determined as 129 based on the 16% incidence rate (Jacinto, Avelar, & Pedriana, 2011) with 0.05 reliability ($\alpha = 0.05$), and 0.95 power ($1\text{-}\beta = 0.95$) for significance verification. A total of 777 infants were hospitalized in the NICU during the study period. Parenteral intravenous catheterization was applied to 456 infants. Infiltration developed in 131 infants (Fig. 1).

Setting

The study was conducted between July 2015 and July 2016 in the NICU of an education and training hospital in Istanbul. There are 28 beds, nine of which were level II, and 19 were level III beds according to the criteria of the American Academy of Pediatrics (AAP) (Barfield et al., 2012).

Infant Identification Information Form

Gender, weights during the study, insertion site, catheter size, and administered fluids/drugs were recorded on the information forms of the infants. The administered fluids/drugs were categorized in different groups. The classification was performed as red (higher risk) (dextrose ≥12.5%, calcium, potassium ≥60 mEq/L, sodium chloride ≥3%, parenteral nutrition >900 mOsm, dobutamine, caffeine citrate); yellow (intermediate risk) (dextrose 10% to <12.5%, potassium <60 mEq/L, parenteral nutrition <900 mOsm/L, amikacin, vancomycin); and green (lower risk) (dextrose <10%, normal saline, ampicillin, gentamicin, meropenem, piperacillin, furosemide, cefotaxime) (Clark et al., 2013; Gorski et al., 2017).

Infiltration Scale

The Infusion Nurses Society (INS) developed an infiltration scale that could be used for all age groups (INS, 2006). The scale consists of 5 grades (0, 1, 2, 3, 4). The inter-rater reliability of the infiltration scale was statistically significant ($k = 0.393$, $p < 0.001$). It was reported that the evaluation of the baby with this scale took 1.3 min (Groll, Davies, Mac Donald, Nelson, & Virani, 2010). The infiltration scale was adapted for infants with the addition of criteria for edema size (Amjad et al., 2011). The scale consists of 3 grades (1, 2, 3). In this study, only the size of edema is considered, while the other findings of infiltration symptoms such as blanched, translucent, tight, leaking or blistering, discolored or bruised skin, swelling, circulatory impairment, and pain are not included (Amjad et al., 2011). The infiltration scale was revised for the pediatric population. The scale consists of 5 grades (0, 1, 2, 3, 4) divided into two parts, which are <4 kg and >4 kg (Tofani et al., 2012). At present, there is no available accepted infiltration scale that can be applied to infants. Therefore, there is a need for a comprehensive infiltration scale valid for infants.

Forward and Backward Translation

The study was conducted by 3 academic nurses, 3 clinical nurses who worked in the NICU, and a neonatology specialist. Of the academic nurses, one a professor of pediatrics, another was an assistant professor of pediatrics, and one was a research assistant of pediatric. Of the clinical

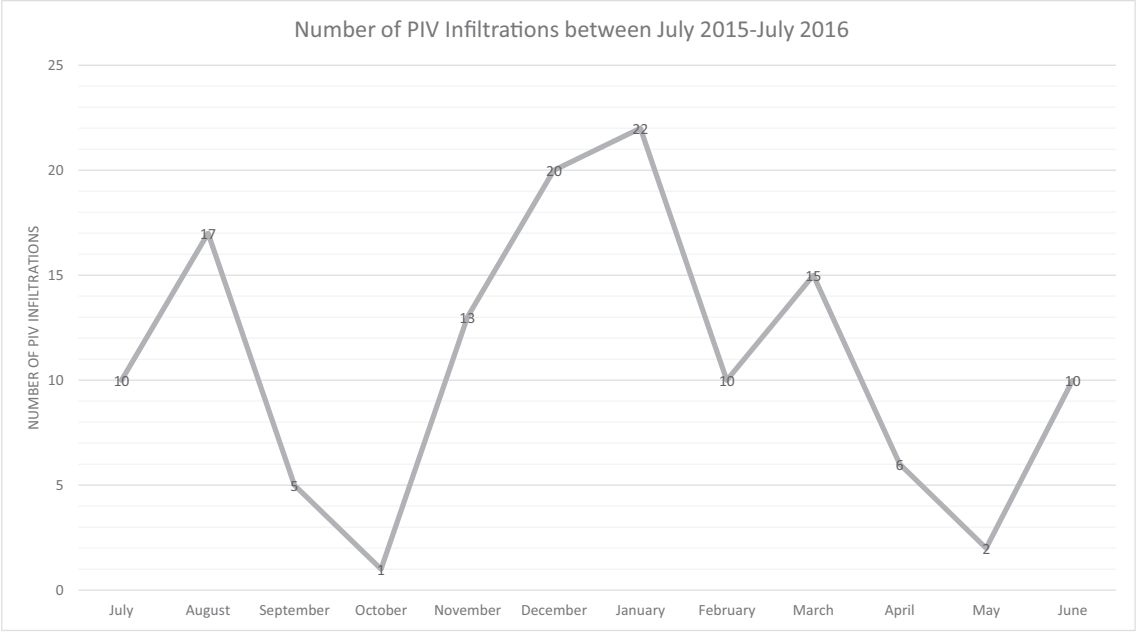

Fig. 1. Number of PIV infiltrations between July 2015-July 2016.

nurses, one was a unit charge nurse, another was a training nurse and one was a staff nurse in NICU. The neonatologist was both an associate professor and a clinic chief of the NICU.

The infiltration scale, which was adapted for pediatrics (Tofani et al., 2012), was translated into Turkish and the translated form was reviewed by an academic who was professor in pediatric nursing and familiar with both languages. The language validity of the scale was developed by 14 specialists including 10 pediatric nursing lecturers (5 assistant professors, 4 associate professors, 1 professor) and 4 neonatologists (2 specialist doctors, 2 associate professors). The scale translated into Turkish was sent to these 14 specialists. The final version of the Turkish version of the scale was created in line with the suggestions from these experts. The scale translated into Turkish was sent to a linguist working at Istanbul Technical University in order to be translated into English. The original version and the English translation of the scale were sent to another linguist working at Istanbul Technical University. It was concluded that the two versions had the same meaning. This determined language validity.

Content Validity

The content validity of the scale was evaluated by 14 specialists including 10 pediatric nursing lecturers (5 assistant professors, 4 associate professors, 1 professor) and 4 neonatologists (2 specialist doctors, 2 associate professors), who were living in different cities of Turkey. For the independent assessment of the scale, the research team was not included in the analysis of content validity. These specialists stated that body weight, edema, and pain parameters were appropriate and understandable for infants, and gave their recommendations for the neonatal group during the content validity phase of the scale. These suggestions resulted in re-determination of body weight, edema, and pain parameters. Edema and kilogram criteria were re-organized in the present study and were compatible with the literature. Infants were classified into two groups, infants weighing <2 kg, and those weighing 2–4 kg in accordance with body surface area. Pain evaluation was adapted by the inclusion of the NIPS score so as to provide more objective and tangible data. The pain parameter of the NIPS scale was evaluated as follows: 0,1,2 points = with or without pain; 3,4 points = mild to moderate pain; and 5,6,7 points = moderate to severe pain. The content validity index (CVI) of the scale was determined as 0.93 using the Davis technique (Grant & Davis, 1997). The original and new adapted version of the infiltration scale for infants is shown in Table 1. In the infiltration approach, the clinically applied algorithm is presented in Fig. 2.

The Neonatal Infant Pain Scale

The scale was developed in 1993, was used for pain assessment; the validity and reliability testing has been performed. Calculations are performed by evaluating five behavioral patterns (facial expression, crying, movements of arms and legs, wakefulness), and one physiologic parameter (respiration type). The total score ranges between 0 and 7 (Lawrence et al., 1993). Pain is assessed when the grades of infiltration are determined. The scale is included in our nurse observation form and routinely used in the clinic. The pain parameter of the NIPS scale was evaluated as follows: 0,1,2 points = with or without pain; 3,4 points = mild to moderate pain; and 5,6,7 points = moderate to severe pain.

Camera

A camera was used to take a photograph of the infant and the catheter site to assess scales. The camera's resolution was 12 MP.

Procedure

The study was conducted between 8:00 a.m. and 4:00 p.m. on weekdays. The reliability of the study was performed by three observers. The first observer was the NICU head nurse. The second observer was the research assistant of pediatric nursing. The third observer was the NICU training nurse. Clinical nurses were verbally informed about the infiltration scale by three observers before conducting the study. During the study, the catheter sites of all infants were monitored hourly by their own nurses. When the nurse thought that the infiltration developed, the nurse informed the first observer. The first observer assessed the infant and the catheter site. The first observer measured the edema at the catheter site of the infant with a measuring tape. The first observer determined the pain score according to the NIPS. The NIPS is routinely used in the unit and is available in the nurse observation form. The first observer photographed the infant and the catheter site. The first observer removed the catheter of the infant and provided care to the infant in accordance with the instructions in the algorithm prepared by the researchers (Fig. 2). The infant's follow-up according to the algorithm was made by his/her own nurse. The first observer took a photograph of the case and sent it to the other observers via the computer. The second and third observers evaluated the photographs unaware of each other scoring according to the scale.

Ethical Considerations

Ethics board approval (protocol no: 994/2015), and approval from the hospital management were granted, and written consent was given by the families. Permission was granted from INS (2006) for the use of the infiltration scale, from Tofani et al. (2012) for the use of infiltration scale, and Lawrence et al. (1993) for use of the NIPS scale.

Statistical analysis

The Number Cruncher Statistical System (NCSS) 2007 (Kaysville, Utah, USA) and SPSS Win (version 18.0) were used in the statistical analysis. Descriptive statistical methods (mean, standard deviation, frequency, minimum, maximum), content validity index (CVI) for validity, Cronbach's alpha and Intra-Class Correlation coefficient (ICC), Cohen's kappa values were used for reliability. Significance was evaluated between $p < 0.01$ and $p < 0.05$.

Results

The percentage of infiltration development was determined as 28.72% (Fig. 1). Demographic and clinical characteristics of infants are shown in Table 2. Infants were classified according to the infiltration scale criteria and the inter-rater reliability levels of these classifications are given in Table 3.

The infants included in the study were divided into subgroups of <2 kg and 2–4 kg according to their weight in kilograms. The data obtained from these two groups were analyzed using inter-rater reliability.

Infants Weighing Less Than Two Kilograms

Cronbach's alpha was detected as 96.9% and the ICC was 91.2%; significant coherence was found between the two indicators ($p < 0.01$). Cohen's kappa values were 89.5% between the first and second observer, 78.9% between the first and third observer and 86% between the second and third observer regarding the infiltration scale results, which was statistically significant ($p = 0.001$; $p < 0.01$).

Infants Weighing 2–4 kg

Cronbach's alpha coefficient was found as 95.8% and the ICC was 88.4% between the three observers; significant coherence was detected between the two indicators ($p < 0.01$). Statistically significant Cohen's kappa values were 84.7% between the first and second observers,

Table 1
The Infiltration scale: translations into Turkish of the items in the original version.

Infiltration scale						
	Original version (Tofani et al., 2012)	Turkish version	Adapted to Turkish version in English language		Adapted to Turkish version	
Grade	Clinical criteria <4 kg weight	Klinik Kriter <4 kg	Clinical criteria <2 kg weight	Clinical criteria 2–4 kg weight	Klinik Kriter <2 kg	Klinik Kriter 2–4 kg
0 1	No symptoms -Skin blanched -Edema <1 cm in any direction -Cool to touch -With or without pain	*Semptom yok* *-Deri beyazlaşmış* *-Her yönde 1 cm'den az ödem* *-Dokunulduğunda bölge soğuk* *-Ağrılı veya ağrısız*	No symptoms -Skin blanched -Edema <0.5 cm in any direction -Cool to touch -With or without pain[a]	No symptoms -Skin blanched -Edema <1 cm in any direction -Cool to touch -With or without pain[a]	*Semptom yok* *-Deri beyazlaşmış* *-Her yönde 0,5 cm'den az ödem* *-Dokunulduğunda bölge soğuk* *-Ağrılı veya ağrısız*[a]	*Semptom yok* *-Deri beyazlaşmış* *-Her yönde 1 cm'den az ödem* *-Dokunulduğunda bölge soğuk* *-Ağrılı veya ağrısız*[a]
2	-Skin blanched -Edema 1–4 cm in any direction -Cool to touch -With or without pain	*-Deri beyazlaşmış* *-Her yönde 1–4 cm ödem* *-Dokunulduğunda bölge soğuk* *-Ağrılı veya ağrısız*	-Skin blanched -Edema 0.5–2 cm in any direction -Cool to touch -With or without pain[a]	-Skin blanched -Edema 1–4 cm in any direction -Cool to touch -With or without pain[a]	*-Deri beyazlaşmış* *-Her yönde 0,5–2 cm ödem* *-Dokunulduğunda bölge soğuk* *-Ağrılı veya ağrısız*[a]	*-Deri beyazlaşmış* *-Her yönde 1–4 cm ödem* *-Dokunulduğunda bölge soğuk* *-Ağrılı veya ağrısız*[a]
3	-Skin blanched, translucent -Edema >4 cm in any direction -Cool to touch -Mild to moderate pain	*-Beyazlamış, yarı saydam deri* *-Her yönde 4 cm'den büyük ödem* *-Dokunulduğunda bölge soğuk* *-Hafif-orta şiddette ağrı*	-Skin blanched, translucent -Edema >2 cm in any direction -Cool to touch -Mild to moderate pain[b]	-Skin blanched, translucent -Edema >4 cm in any direction -Cool to touch -Mild to moderate pain[b]	*-Beyazlamış, yarı saydam deri* *-Her yönde 2 cm'den büyük ödem* *-Dokunulduğunda bölge soğuk* *-Hafif-orta şiddette ağrı*[b]	*-Beyazlamış, yarı saydam deri* *-Her yönde 4 cm'den büyük ödem* *-Dokunulduğunda bölge soğuk* *-Hafif-orta şiddette ağrı*[b]
4	-Skin blanched, translucent, tight, leaking, or with blistering, discolored bruised, swollen -Edema >4 cm in any direction, deep pitting tissue edema -Circulatory impairment -Moderate to severe pain -Infiltration of any blood product, irritant, or vesicant	*-Beyazlamış, yarı saydam deri* *-Sızıntı ile şişmiş gerilmiş deri* *-Soluk, yaralı, şişkin deri* *-Her yönde 4 cm'den büyük ödem* *-Gode bırakan ödem* *-Dolaşım bozukluğu* *-Orta şiddette/ciddi ağrı*	-Skin blanched, translucent, tight, leaking, or with blistering, discolored bruised, swollen -Edema >2 cm in any direction, deep pitting tissue edema -Circulatory impairment -Moderate to severe pain[c] -Infiltration of any blood product, irritant, or vesicant	-Skin blanched, translucent, tight, leaking, or with blistering, discolored bruised, swollen -Edema >4 cm in any direction, deep pitting tissue edema -Circulatory impairment -Moderate to severe pain[c] -Infiltration of any blood product, irritant, or vesicant	*-Beyazlamış, yarı saydam deri* *-Sızıntı ile şişmiş gerilmiş deri* *-Soluk, yaralı, şişkin deri* *-Her yönde 2 cm'den büyük ödem* *-Gode bırakan ödem* *-Dolaşım bozukluğu* *-Orta şiddette-ciddi ağrı*[c]	*-Beyazlamış, yarı saydam deri* *-Sızıntı ile şişmiş gerilmiş deri* *-Soluk, yaralı, şişkin deri* *-Her yönde 4 cm'den büyük ödem* *-Gode bırakan ödem* *-Dolaşım bozukluğu* *-Orta şiddette-ciddi ağrı*[c]

[a] NIPS score = 0,1,2.
[b] NIPS score = 3,4.
[c] NIPS score = 5,6,7.

84.8% between the first and third observer and 84.8% between the second and third observer ($p = 0.001$; $p < 0.01$).

All Infants

The Cronbach's alpha coefficient was 96.7% and the ICC was 90.6% between the three observers; significant coherence was detected between the two indicators ($p < 0.01$). Statistically significant Cohen's kappa values were 87.3% between the first and second observers, 83.1% between the first and third observer and 86% between the second and third observer ($p = 0.001$; $p < 0.01$).

Discussion

Amjad et al. (2011), who evaluated the INS scale in the neonatal and infancy period, reported only the edema criteria; however, they did not test the validity and reliability. The infiltration scale adapted healing strategies to reduce PIV-related infiltration and extravasation injuries using the adapted infiltration scale for the pediatric population (Amjad et al., 2011). A significant decrease in infiltration was noted as a result of hourly evaluations using the touch-look-compare method in children who were administered PIV treatment. However, validity and reliability testing of the adapted infiltration scale was not performed (Tofani et al., 2012).

No publication that investigated validity and reliability in infants weighing <4 kg was found in the literature. The present study revealed that most infiltration cases were grade 2 infiltrations (Table 3). Tofani et al. (2012) found that they decreased Grades 2–3 infiltration rate from 4.2 to 1.8 per day over 1000 catheters based upon hourly observations. In the study by Simona (2012) it was reported that Grade 1 infiltration developed in 44% of 100 pediatric patients based on IV team nurse values. When the literature was examined, it was observed that both scale development studies were performed in the pediatric population. The reason behind why Grade 2 infiltration developed most frequently in this study may be that vascular structures of infants <4 kg are more fragile. In parallel with the literature (Simona, 2012), it can be also considered that the rate of infiltration in these infants is affected significantly by the type of intravenous fluid, the rate of infusion, and the duration of exposure to infusion fluid. In addition, the characteristic of the intravenous fluid is also very important for the development of infiltration. In particular, the administration of red-colored drugs would increase the rate of infiltration. It is recommended that infants receiving

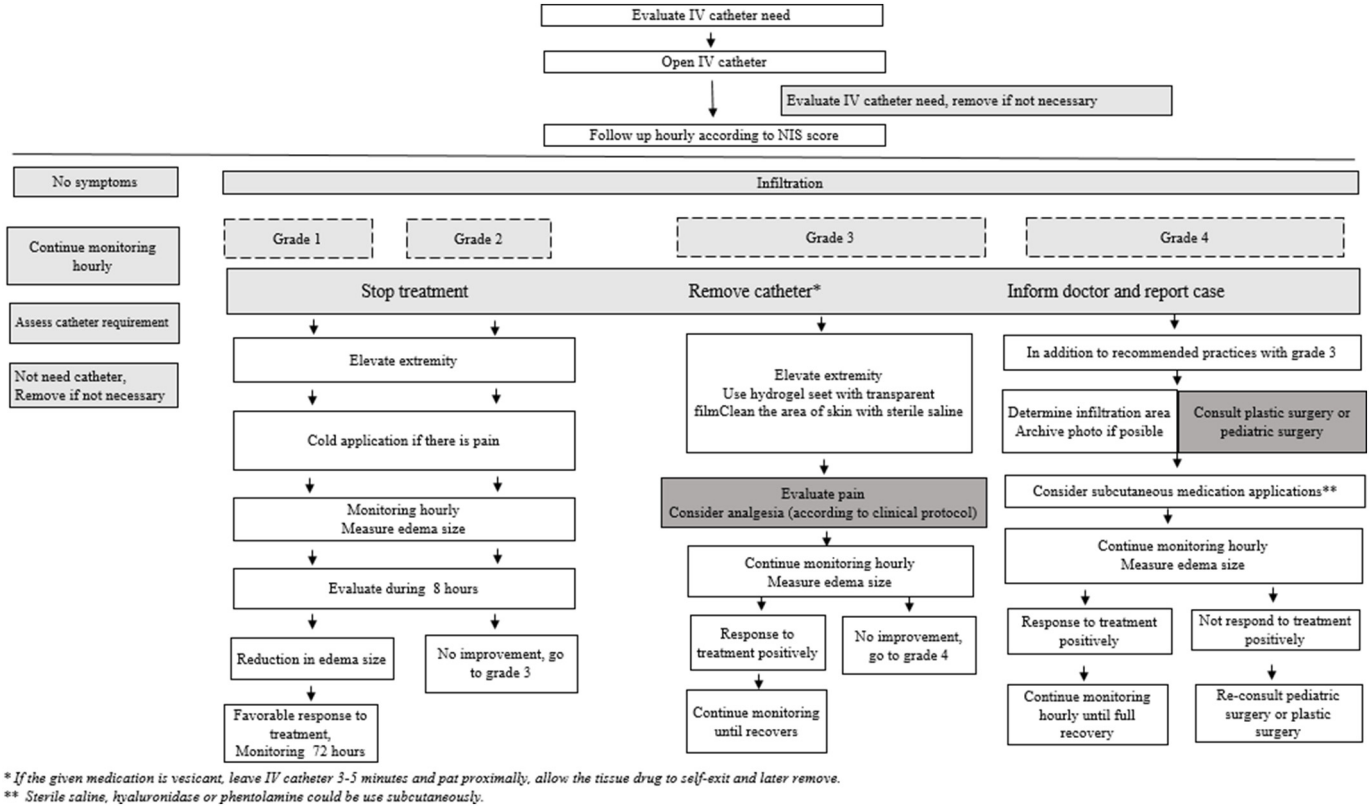

Fig. 2. Infiltration approach algoritm.

such drugs should be evaluated for infiltration at shorter intervals rather than hourly intervals. Because of there were no studies about infiltration involving only neonatal period the results of our study were not comparable. It may be recommended to determine the infiltration grades according to similar age groups in future studies.

Practice Implications

PIV complications are frequently seen in the neonatal intensive care units due to the critical population of the infants. To reduce or prevent PIV complications, nurses working in the unit should monitor the infant's catheter area on an hourly basis. The use of a valid and reliable scale during this observation is important in providing evidence-based standardization in care. The practice implications of these findings suggest that infiltration can be prevented or decreased in infants by following the catheter regions using this valid and reliable scale.

Limitations

Since the three observers were not in the clinic in each case at the same time and the first observer always was in the clinic study at the time and dates of the study, the item “cool to touch” of the scale was assessed only by the first observer. The size of the edematous area was measured by the first observer using a measuring tape. Observations were conducted at selected times as indicated previously; therefore, other infiltration circumstances were not recorded per the study protocol and may have been caused by other individual differences

Table 2
Demographic and clinical characteristics of infants (N = 131).

Identification features of infant		<2 kg (n = 42)		2–4 kg (n = 89)	
		Min-max	Mean ± sd	Min-max	Mean ± sd
Current body weight (kg)		800–1976	1675.9 ± 265.6	2020–3968	2800.2–488.6
		n	%	n	%
Gender	Male	27	64.3	32	36.0
	Female	15	35.7	57	64.0
Catheter size	24	14	33.3	34	38.2
	26	28	66.7	55	61.8
Insertion site	Dorsum of hand	20	47.6	59	66.3
	Ankle	10	23.8	15	16.9
	Forearm	10	23.8	9	10.1
	Head	2	4.8	5	5.6
	Leg	0	0.0	1	1.1
Medications/solutions	Red (higher risk)	24	37.5	20	29.8
	Yellow (intermediate risk)	38	59.3	44	65.6
	Green (lower risk)	2	3.1	3	4.4
Medications/solutions	TPN with or without medication	39	92.9	60	67.4
	Only medication	3	7.1	29	32.6

Table 3
The distribution of observers to assess the infiltration scale for infants.

		1. Observer n, %	2. Observer n, %	3. Observer n, %	Cronbach alpha (95% CI)	ICC (95% CI)	p	1.–2. Observer Agreement (k)	1.–3. Observer Agreement (k)	2.–3. Observer Agreement (k)
<2 kg (n = 42)	Grade 1	7(16.7)	8(19)	7(16.7)	0.969 (0.948–0.982)	0.912 (0.859–0.94)	***0.001*****	0.895	0.789	0.860
	Grade 2	16(38.1)	16(38.1)	16(38.1)						
	Grade 3	16(38.1)	15(35.7)	16(38.1)						
	Grade 4	3(7.1)	3(7.1)	3(7.1)						
2–4 kg (n = 89)	Grade 1	20(22.5)	24(27)	18(20.2)	0.958 (0.841–0.919)	0.884 (0.841–0.919)	***0.001*****	0.847	0.840	0.848
	Grade 2	60(67.4)	55(61.8)	60(67.4)						
	Grade 3	6(6.7)	9(10.1)	11(12.4)						
	Grade 4	3(3.4)	1(1.1)	0(0)						
All infants (n = 131)	Grade 1	27(20.6)	32(24.4)	25(19.1)	0.967 (0.955–0.975)	*0.906* (0.877–0.930)	***0.001*****	*0.873*	*0.831*	*0.860*
	Grade 2	76(58)	71(54.2)	76(58)						
	Grade 3	22(16.8)	24(18.3)	27(20.6)						
	Grade 4	6(4.6)	4(3.1)	3(2.3)						

ICC: Intra-Class Correlation coefficient; CI: Confidence Interval; k: Cohen's kappa values.
** $p < 0.01$.

and factors not captured in this investigation. The results of the research were limited with this sample population and this hospital.

Conclusion

Prior to this study, a valid and reliable infiltration scale for use in the NICU to detect PIV infiltrations in neonates. A scale developed by INS and adapted to pediatrics by Tofani et al. was adapted and tested for this study of PIV infiltration in neonates. The validity and reliability tests of the newly developed scale were performed and we found that the newly developed scale could be used to detect PIV infiltrations with infants between <2 kg and 2–4 kg in neonatal intensive care units.

Contributions

Study design: MCI, SY, MS, SB, AB; Data collection: MCI, MS, VK, FGT; Data analysis: MCI, statistician; Manuscript preparation: MCI, SY, SB, AB. All authors approved the final version for submission.

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Conflict of Interest

There are no conflicts of interests.

CRediT authorship contribution statement

Mujde Calikusu Incekar: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Resources, Writing – Original draft, Writing – Review & editing, Visualization, Supervision, Project administration, Funding acquisition. **Suzan Yildiz:** Conceptualization, Methodology, Validation, Writing – Original draft, Writing – Review & editing, Funding acquisition. **Melek Selalmaz:** Methodology, Validation, Investigation, Resources, Funding acquisition. **Vesile Kantas:** Validation, Investigation, Resources, Funding acquisition. **Serap Balci:** Conceptualization, Methodology, Validation, Writing – Original draft, Funding Acquisition. **Fatma Gul Tamer:** Validation, Investigation, Resources, Funding acquisition. **Ali Bulbul:** Methodology, Validation, Investigation, Resources, Writing – Original draft, Writing – Review & editing, Funding acquisition.

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