A Comparative Study of Accuracy and Usability between Two Extravasation Injuries Assessment Tools

Thitiporn Pathomjaruwat, Wongchan Petpichetchian, Padcha Pongcharoen*

Abstract: Extravasation injury is the severe complication of infusion therapy and requires nurses to assess and manage it appropriately. This comparative study was aimed to determine the accuracy and usability of two extravasation injuries assessment tools. The participants were 50 nurses from a tertiary hospital in Central Thailand. Each nurse was asked to review two parallel sets of photos (72 photos/set) and assessed for the occurrence and the severity of extravasation injuries using the Extravasation Assessment Tool and the Extravasation Scale, both developed by the first author. Photos were taken from 72 patients who had a normal condition (no extravasation) and three severity levels: mild, moderate, and severe extravasation (18 photos/condition/set) were used. Using the known diagnosis of extravasation injury of these patients by trained dermatologists as a reference standard, the accuracy of these tools was determined when used by the nurses. There were 3600 observed data for each tool (50 nurses*72 photos/tool). It was revealed that use of the Extravasation Assessment Tool and the Extravasation Scale produced 2,898 (80.5%) and 3,386 (94.1%) accurate results, respectively with a significant difference in the number of defectives or inaccurate ratings. The sensitivity and specificity of the Extravasation Scale were 0.96 and 0.88, respectively. The usability of the tools was compared and it was found that the Extravasation Scale was more usable as indicated by more nurses being satisfied and very satisfied, with fewer nurses requiring consultation and it was less time-consuming. These results support that the Extravasation Scale can be used to accurately assess the occurrence and severity of extravasation injuries better than the Extravasation Assessment Tool. Nurses should use this tool to help identify extravasation occurrence and severity in clinical practice as quality care would involve early detection and prompt management of this.

Pacific Rim Int J Nurs Res 2021; 25(3) 437-451

Keywords: Assessment tools, Extravasation injuries, Infusion therapy, Instrument development Nursing, Peripheral extravasation

Received 1 February 2020; Revised 13 Novebmer 2020; Accepted 1 February 2021

Introduction

An extravasation injury is tissue damage caused by the leakage of concentrated solutions from a vessel into surrounding tissue spaces during intravenous infusion.[1,2] It is a serious complication that mostly

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occurs when vesicant drugs and non-vesicant drugs/solutions leak out of the vein and make contact with the tissue and subsequently cause serious injuries to the surrounding tissues, nerves, tendons, joints, and various organs.[1,3,4,5] The pH of drugs or vesicant solutions outside of the range of 5.5-8.5 may have an adverse effect on tissues.[3] Drugs with a high concentration greater than 290mOsm cause water leakage from the vascular and cellular compartment into the interstitial compartment which can compress and damage the underlying nerve and vascular structures.[6]

The signs and symptoms of extravasation injuries include pain, edema, changes of skin color (e.g., pale, erythema or redness of the skin, purple), blanched skin, superficial skin loss as well as tissue loss, and necrosis around subcutaneous tissue,[7] bone, and muscle.[3] The leakage of fluid can be seen from the puncture site. Changes in skin temperature, coldness, warmth, and hot, can be found.[1,4,5] The healing process of these symptoms can take months. A delay in treatment can cause severe tissue injuries such as blistering, necrosis,[1] and compartment syndrome which may require surgical debridement.[7,8] Some patients may require skin grafting[3] or the amputation of the injured organs.[6]

Immediate identification of characteristics of extravasation is important as this allows nurses to offer interventions to prevent further damage. However, this can be challenging because extravasation injuries do not occur immediately following peripheral infusion therapy or injection of drugs. The assessment of occurrence and severity of extravasation injuries is therefore critical so that nurses can plan and provide nursing interventions appropriately and notify doctors for timely medical and/or surgical treatment.

There are several tools and guidelines used for assessing the severity of extravasation. Most of them assess signs and symptoms of extravasation progressing from simple to complex but the distinction of these clinical presentations between extravasation and phlebitis or flare-up drug reactions can be confusing.[1] Extravasation injuries can be classified into 3, 4, or 5 levels. For a 3-level classification, levels of tissue injury, signs and symptoms are classified into mild, moderate, or severe extravasation.[3,9] For a 4-level classification, the characteristics of the lesion and symptoms are used. These include pain at the infusion site, difficulty flushing cannula, swelling, skin color, capillary refill time, and perfusion.[10] A 5-level classification is made skin appearances (color, integrity, temperature) and other signs and symptoms including edema, mobility, pain, fever.[11,12] Another 5-level classification uses the degree of tissue damage and whether surgical treatments are needed starting from asymptomatic; erythema with associated symptoms (e.g., edema, pain, induration, phlebitis); ulceration or necrosis; severe tissue damage and surgical intervention indicated, life-threatening consequences; and urgent intervention indicated, death.[13] Some guidelines guide clinical assessment but do not explicitly stage the severity of extravasation.[1,2] These tools and guidelines are useful but do not alert nurses to foresee the possibility of moving up to more severe levels.

In Thailand, the first author (TP) developed the Extravasation Assessment Tool[9,14] in her guidelines development work using Soukup's evidence-based practice model[15] with 12 pieces of evidence of support, including the Infusion Nursing Standard Practice,[16] the Peripheral Intravenous Cannulation Self Leaning Package for registered nurses,[17] and the Extravasation Guidelines 2007 (Guideline Implementation Toolkit).[18] The Extravasation Assessment Tool (A, Figure 1) was used to determine the occurrence and the severity of extravasation: normal, mild, moderate, and severe by assessing the following symptoms: skin color, skin integrity, skin temperature, edema, limb mobility, pain, and fever without other identified sources. Nurses involved in a previous study reported that it was not a user-friendly tool and it was often difficult to distinguish among the levels of severity.[9] This flagged a need for further refinement of the tool "A."

Subsequently, the tool "A" was modified to the "Extravasation Scale" (B, Figure 2) based on challenging issues found in the tool "A." In the Extravasation Scale, illustrations of signs and symptoms with photos at each severity levels were used in conjunction with textual descriptions. Photos lining up with each level of severity would be more helpful and were hypothesized to offer more accurate results when they were used to determine the severity of extravasation injuries. Additionally, the tool "B" contains nursing guidelines for each level so that nurses can use this information to guide their practice. Since the tool "B" is a newly-developed tool, it should be tested for accuracy (% of correctness, sensitivity and specificity) and usability (nurses' satisfaction, need for consultation, and time use) when compared to the tool "A" by testing against the reference standard, extravasation injuries diagnosed by the trained dermatologists.

<table>
<tr><th colspan="7">Extravasation Assessment Tool</th></tr>
<tr><th>Level</th><th>Normal</th><th colspan="2">Mild</th><th>Moderate</th><th colspan="2">Severe</th></tr>
<tr><td>Skin color</td><td>Normal</td><td>Pale</td><td>Pink</td><td>Redness/ erythema purple</td><td>Blanched area surrounded by red</td><td>Blackened</td></tr>
<tr><td>Skin integrity</td><td>Unbroken</td><td colspan="2">Not blistered</td><td>Superficial Skin loss</td><td>Severe Blistering, tissue loss and exposed subcutaneous tissue</td><td>Tissue loss and exposed bone/ muscle with necrosis</td></tr>
<tr><td>Skin Temperature</td><td>Normal</td><td>Cold</td><td>Warm</td><td>Hot</td><td colspan="2">Very Hot</td></tr>
<tr><td>Edema</td><td>Absent</td><td colspan="2">Edema/Non-pitting edema</td><td>Pitting edema</td><td colspan="2">Marked Swelling</td></tr>
<tr><td>Limb mobility</td><td>Full</td><td colspan="2">Slightly limited</td><td>Very limited</td><td colspan="2">Immobile</td></tr>
<tr><td>Pain (scale of 0-10)</td><td>0 = no pain</td><td>Pain 1-3 (Mild pain)</td><td>Pain 3-5 (Moderate pain)</td><td>Pain 5-10 (Pain at the position of medical procedure)</td><td>10 = worse pain</td><td>No Feeling</td></tr>
<tr><td>Fever without other source</td><td colspan="3">Normal 36.5-37.5 °c</td><td colspan="3">Elevated >37.5°c</td></tr>
</table>

Figure 1. Extravasation Assessment Tool

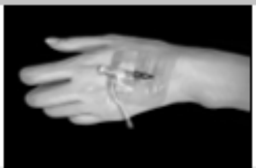
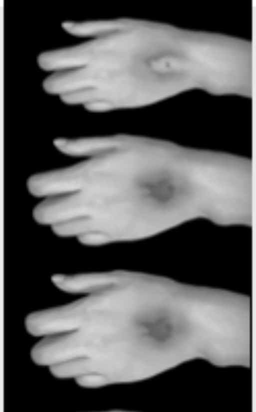
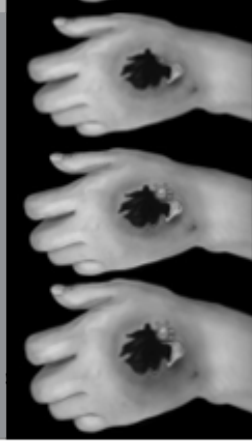
Extravasation Scale			
Level	**Signs**	**Photo**	**Nursing guidelines**
Normal	No pain Or Extravasation		* Assess the skin manifestations of the position receiving infusion therapy. * If the infusion is at risk, continuously assess every 1 hr.
Mild	Pale/pink skin No blisters, Skin Temperature is cold and warm. Non-pitting edema Limb mobility is slightly limited. Mild pain (Pain score of 1-3) Normal body temperature (36.5-37.5 °c)		* Assess skin manifestations: 1) Stop infusion therapy immediately. 2) Apply the suction to remove the drug leak as much as possible using syringe 5 ml. (Give Antidote). 3) Remove the needle, apply direct pressure to stop the bleeding. 4) Apply warm or cold compress according to the medication type. 5) Elevate the position of medication leak above the level of the heart in the first 24 hours. (Inform the doctor.) ** Monitor for symptoms every 8 hrs. for 2 days. The symptoms will gradually improve. (Take notes / photos.)
Moderate	Redness/ erythema or purple skin Color of epidermis changes to purple. / The skin is slightly blistered. The skin temperature is hot. Pitting edema Limb mobility is very limited. Moderate pain (Pain score of 3-5) Have a fever (BT >37.5°c)		* Assess skin manifestations Providing nursing care according to items 1-5 * * Monitor for symptoms every 8 hours for 48 hours (2 days). If the symptoms do not improve as expected or worsen, inform the doctor. After that, if the wound has not improved, follow the symptoms once a day for 1 week until the symptoms improve. (Make a note of the wide range of symptoms or take a photo.) * * * If the symptoms do not improve within one week, you should consult a surgery doctor.
Severe	Blanched area surrounded by red Severe blistered, Tissue loss exposed subcutaneous tissue. Tissue loss & exposed bone/muscle with necrosis The skin temperature is scorching. Marked Swelling resulting in the immobility. Severe pain (Pain score of 5-10) Pain at the position of medical procedure or no feeling Fever (BT >37.5°C)		* Assess skin manifestations Providing nursing care according to items 1-5. **Monitor for symptoms every 8 hours for 2 days. If the symptoms do not improve as expected or worsen, monitor for symptoms once a day. (For open wounds, use wet dressing with NSS 1-2 times a day.) * * * If symptoms do not improve within 2 days, should consult a surgical doctor to continue treatment by Excisional debridement of wound. (Make a note of the wide range of symptoms or take a photo.)

Figure 2. Extravasation Scale

Study Objective and Hypothesis

The primary objective of this study was to compare the accuracy (% of correctness, sensitivity, and specificity) of two extravasation injuries assessment tools: the Extravasation Assessment Tool (A) and the Extravasation Scale (B). We hypothesized that the Extravasation Scale would provide more accurate results than the Extravasation Assessment Tool. The secondary objective was to determine the usability of both tools.

Operational Definitions

In this study accuracy was defined as the number of times (observations) the nurses correctly rated the severity level of extravasation following the dermatologists' diagnosis (reference standard) which could be further used to determine sensitivity and specificity of tools A and B.

Sensitivity was defined as the ability of a tool to correctly identify those with extravasation. The formula used to compute sensitivity was: True positive/(True positive + False negative).[19] True positive was counted when the nurses' rating of mild, moderate, or severe extravasation injuries was similar to that of the dermatologists. A false negative was counted when the nurses' rating was not having extravasation but the dermatologists' rating of having it was mild, moderate, or severe.

Specificity was defined as the ability of the tool to correctly identify those without extravasation. The formula used to compute specificity was: True negative/(True negative + False positive).[19] True negative was counted when nurses' rating of not having extravasation injuries (normal condition) was similar to that of the dermatologists. A false positive was counted when there was a nurses' rating of mild, moderate, or severe extravasation but the dermatologists' rated no extravasation.

Usability was defined as nurses' satisfaction with the tool (dissatisfied to very satisfied), need for consultation (yes or no), and amount of time used for the tool (minutes).

Methods

This observational, comparative study was conducted at a university hospital in central Thailand from December 2018 to June 2020. Before data collection (December 2018-January 2020), 72 patients diagnosed by trained dermatologists of not having (normal condition) or having various degrees of extravasation injuries (mild, moderate, or severe) were asked to take pictures of his/her intravenous insertion sites twice, yielding two parallel sets of 72 photos. They were patients who received the following medications: norepinephrine (n = 49, 68.1%), amiodarone (n = 4, 5.6%), acyclovir (n = 3, 4.2%), ceftriaxone, ceftazidime, fosfomycin, piperacillin/tazobactam, sodium valproate (n = 2 , 2.8% for each medication), 10% calcium gluconate, hydrocortisone, phenytoin, meropenem, morphine, and vancomycin (n = 1, 1.4% for each medication). These photos with their known diagnoses as confirmed by at least 2 out of 3 trained dermatologists were used as a reference standard. Subsequently, data were collected by having nurse participants reviewing these photos with the use of the Extravasation Assessment Tool (A) and the Extravasation Scale (B) to determine the occurrence and the severity of extravasation injuries against the reference standard. With this, the accuracy of these two tools were determined.

Eligible Participants: This study involved two groups of participants: patients and nurses. Patients were adult patients admitted in the medical and surgical wards of the target hospital from December 2018 to January 2020. Patients were eligible if they received peripheral intravenous (IV) infusion with medication injection which was a high risk of producing extravasation injuries. Seventy-two patients who did not have extravasation (n = 18), and had mild, moderate, and severe level extravasation injuries (n = 18, each level) were purposively selected and granted permission to take pictures of his/her intravenous insertion site twice. Instead of using actual patients, their photos were used for this study to enhance reproducibility without disturbing more patients.

Nurses were conveniently recruited if they had worked during the data collection period (February to June 2020) in the wards that had a high number of patients receiving peripheral IV infusion with medications at high risk for producing extravasation injuries. These included the medical, surgical, and intensive care units. They had worked for at least one year of working experience with infusion therapy and willingly agreed to participate.

Sample size: According to Bujang and Adnan's paper entitled "Requirements for minimum sample size for sensitivity and specificity analysis,"[20] by assuming a prevalence of extravasation of 5% among patients receiving cytotoxic drug injection,[2,3] with an expected sensitivity of .80 (H_a) compared to a sensitivity of any conventional tool of .70 (H_0), a power of above .80 (.818), and a significant level of approximately .05 (p-value .044), this study required n = 3,100. Adding 15% to reduce sampling errors resulted in 3,565 observations, rounded up to be 3,600 observations needed for this study. The researchers used this number to indicate that at least 50 nurses would be needed to assess 72 photos representing 4 levels of extravasation occurrence and severity, totalled to be 3,600 observations (observed data) per set of photos or per tool being investigated.

Research instruments: There were two sets of instruments:

Set A: Nurses' self-reported questionnaires included (1) the nurse demographic questionnaire (age, gender, nursing experience in years, operating wards, experience in providing nursing care for patients receiving infusion therapy in years); (2) the nurses' satisfaction towards the use of the Extravasation Assessment (Tool A) and the Extravasation Scale (Tool B) questionnaire comprising six items (easiness and convenience, appropriateness, practical application, the desire to use, improving patient care, reducing errors) and using a 5-Likert scale ranging from dissatisfied (1) to very satisfied (5); and (3) the need for consultation, a single-item question asking if the nurse needs further consultation after using the Tools A and B (yes or no).

Set B: This comprised the tools nurse participants used for assessing the occurrence and the severity of extravasation injuries. These included: Tool A,[9,14] Tool B, and two parallel sets of 72 photos representing the occurrence and four conditions of extravasation injuries (normal condition, and mild, moderate and severe extravasation; 18 photos for each condition).

Content validation of the instruments involving examination by a panel of five experts (dermatologist, infusion nurse, head nurse, registered nurse, and pharmacist) yielded a content validity index (CVI) of 1.00 for all instruments after two rounds of validation. The validity of two sets of 72 photos was sought by having three dermatologists independently review them and two out of the three had the same diagnosis for each photo. The internal consistency reliability of Tool A and Tool B instruments based on actual nurse participants' responses yielded Cronbach's alpha coefficients of .87 and .91, respectively.

Time use (minutes/set of photo) for assessing the occurrence and severity level of extravasation injuries while the Tools A and B were utilized was collected by the first author (TP) using a time-stamp from (1) when each participant accessed the electronic files (the first set of photos file with descriptions and Tool A and the second set of photos file with descriptions and Tool B to (2) when each participant hit "submit" for their rating responses. This effort was to avoid measurement errors.

Ethical considerations: Approval for the study was obtained from the Ethics Review Sub-committee for the Research Involving Human Research Subjects of Thammasat University, No. 3, Faculty of Health Sciences and Science and Technology (No. 028-2561) in December 2018. The participants (patients and nurses) were informed about the study objectives and processes, confidentiality, risks, benefits, and their study rights. They had the right to ask questions and withdraw from the study at any time without penalty or loss of benefits. Written informed consent was obtained from the patient participants and their relatives and the nurse participants.

Data collection procedures: After preparing two parallel sets of 72 photos and recruiting nurse participants, the researchers formed small groups of 2-4 nurse participants and arranged meetings with them in their convenient time. The data were collected at two time-points, Day 1 and Day 14, for assessing the accuracy and usability of Tool A and Tool B, respectively. This 14-day elapsed time was considered to be a wash-out period to help lessen the familiarity of Tool A and the first set of photos that might contribute to the use of Tool B and the second set of photos. Details are described below:

Day 1: The nurse participants were instructed how to use Tool A using a PowerPoint presentation to show four pictures of normal condition, and mild, moderate and severe extravasations, and how to use the tool A to rate each picture. Questions and any queries were answered until they demonstrated full understanding. Subsequently, the researchers informed them the details of all electronic files and how to access the files using an electronic code (QR code). The electronic files included the first set of 72 photos, descriptions of each photo entailing data related to pain intensity, Tool A, and the self-reported questionnaires. Each nurse participant then independently accessed to the files via a computer or a tablet, assessed the occurrence and severity of extravasation of each photo using Tool A, and responded to the self-reported questionnaires. This took approximately one hour.

Day 14: The nurse participants were instructed how to use Tool B. The same procedures of Day 1 were repeated with the focus of the Tool B. The second set of photos was randomly rearranged by a computer-generated program to avoid remembrance of its order from the previous answers (Day 1).

Statistical Analysis: The Minitab version 17 statistical software was used to analyze the data. The demographic data were analyzed by using descriptive statistics: frequency and percentage, mean, and standard deviation.

To determine the accuracy of Tools A and B, the frequency (number) and percentage of times of correct responses (rating of severity levels of extravasation injuries in accordance with the reference standard) and two proportional statistics used for the diagnostic test, sensitivity, and specificity, were computed. For hypothesis testing, if Tool B would provide more accurate results than Tool A, the difference in the number of defectives (inaccurate ratings) was analyzed by using Z statistics for two proportions, with 99% confidence interval. Z statistics was used because our data were considered to have a normal approximation.

To examine the usability of the tools, descriptive statistics were used to describe the number of nurses being satisfied and requiring consultation and the average of time they used to assess each set of photos using Tools A and B. Subsequently, the mean satisfaction scores and the mean completion time in minutes for each tool were compared by using Mann-Whitney U test. The number of nurses who needed further consultation was also compared using the chi-square test.

Additional analyses were conducted to confirm if Tool B was practical for use in real-world clinical practice settings. First, a tool is considered practical if it provides accurate and precise results without the experience of an assessor.[21] With this, the rating scores of randomly selected 5 assessors representing 5 groups of nurses varying in their working experience (years): 1, 2, 3-5, 6-10 and >10 years were used to examine the number of correct responses they produced compared with the reference standard. For controlling of potential artefacts as a result of 12 not so clear photos, only ratings of 60 photos were analyzed. Second, Fleiss's Kappa statistic was also computed to seek for inter-rater agreement among these 5 assessors and the reference standard at each severity level of extravasation injuries. The Fleiss's Kappa coefficients of >.80 were satisfactory.[21]

Results

The study collected 3,600 observations for each tool (Tools A, B), totaling 7,200 observations. The nurse participants had an average age of 27.96 years (S.D. = 5.89) and 98% of them were female. Regarding their experience working in nursing and providing infusion therapy, the highest number of nurses had >9 years of experience (*n* = 16, 32%) and the lowest number of them had one year experience (*n* = 6, 12%). Two-thirds of them (*n* = 33, 66%) were working in intensive care-related fields (i.e., medical ICU, surgical ICU, coronary care unit, cardio-vascular-thoracic ICU) or sub-intensive care-related fields (i.e., medical sub-ICU, surgical sub-ICU). Among these nurse participants, 10 (20%) were specialized in intravenous (IV) care and were appointed to act as IV nurses.

Accuracy of the Extravasation Injuries Assessment Tools

It was found that using Tool A produced 2,898 accurate results (80.5%) whereas using Tool B produced 3,386 accurate results (94.1%). In other words, use of Tool B resulted in a significantly smaller number of defectives or inaccurate results as indicated by the difference of defectives at a 99% interval of <11.77% ($p < .001$) (**Table 1**)

Table 1. A Comparative analysis of number of accuracy, number of defectives, and the difference in number of defectives using Z-statistics of two proportions

Factors	Total Number Tested	Number of Accuracy n (%)	Number of Defectives n (%)	99% Upper Bound	Z-value	*p*-value
Extravasation Assessment Tool (A)	3,600	2,898 (80.5)	702 (19.5)	21.08		
Extravasation Scale (B)	3,600	3,386 (94.1)	214 (5.9)	6.92		
*Difference			488 (13.6)	11.77		<.001
Normal approximation					-17.63	0.000
Fisher's exact						0.000

*Difference = Extravasation Assessment Tool – Extravasation Scale (A-B)

The sensitivity and specificity estimates of both tools were computed. Table 2 showed the true positive, false positive, false negative and true negative findings of the nurse participants' responses to Tools and Tool B when compared with the reference standard and the respective sensitivity and specificity estimates of the tools. Tool B had higher values of both sensitivity and specificity (0.96 and 0.88) than Tool A (0.88 and 0.52). Also, Tool B had a higher probability of patients being assessed to have extravasation injuries when Tool B indicated to them to have a Positive Predictive Value: PPV, and the probability of patients being assessed as not having extravasation injuries when the Tool B indicated them not having a negative predictive value: (NPV) higher than that of Tool A (PPV/NPV of Tool B and Tool A = 96.4%/86.5% and 86.8%/56%, respectively).

Table 2. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the Extravasation Assessment Tool (A) and the Extravasation Scale (B)

Test Results	Reference Standard	
	Extravasation present n (%)	Extravasation absent n (%)
Extravasation Assessment Tool (A)		
Test positive	2,484 (69.0) (True positive)	377 (10.5) (False positive)
Test negative	325 (9.0) (False negative)	414 (11.5) (True negative)
	Sensitivity: 2,484/ (2,484+325) = 0.88 **PPV:** 2,484/ (2,484+377) = 0.868 = 86.8%	**Specificity:** 414/ (414+377) = 0.52 **NPV:** 414/(325+414) = 0.560 = 56%
Extravasation Scale (B)		
Test positive	2,642 (73.4) (True positive)	98 (2.7) (False positive)
Test negative	116 (3.2) (False negative)	744 (20.7) (True negative)
	Sensitivity: 2,642/(2,642+116) = 0.96 **PPV:** 2,642/ (2,642+98) = 0.964 = 96.4%	**Specificity:** 744/(744+98)= 0.88 **NPV:** 744/ (116+744) = 0.865 = 86.5%

Usability of the Extravasation Injuries Assessment Tools

Usability of Tools A and B was determined by nurses' satisfaction, their need for further consultation and time use. **Table 3** shows that the nurse participants indicated significantly higher satisfaction towards Tool B (M $\pm$ SD = 4.37 $\pm$ 0.46) than Tool A (M $\pm$ SD = 3.82 $\pm$ 0.63) with a mean rank of 62.78 and 38.22, respectively ($p < .001$). Item analysis revealed that the nurses rated the highest satisfaction score on "practical application" of the Tool B (M $\pm$ SD = 4.48 $\pm$ 0.54). For the Tool A, they indicated their "desire of use" at the lowest level (M $\pm$ SD = 3.62 $\pm$ 0.98), followed by "easiness and convenience (M $\pm$ SD = 3.64 $\pm$ 0.74)."

The nurse participants responded to the query about if they needed further consultation when the tool being investigated was used. It was found that when Tool A was used, there was a significantly higher number of nurses reporting this need as opposed to the Tool B (n = 42, 84% VS n = 14, 28%, respectively, $p < .001$). In addition, time use when they utilized these two tools also revealed a significant difference. Tool A required more time to assess a set of 72 photos (M $\pm$ SD = 13.94 minutes $\pm$ 6.26) than that of the Tool B (M $\pm$ SD = 8.56 minutes $\pm$ 3.44) ($p < .001$) with an average time/photo of 11.61 seconds and 7.13 seconds, respectively (**Table 3**).

Table 3. Responses of nurses regarding nurses' satisfaction, time use, and need for consultation compared between when they used the Extravasation Assessment Tool (A) and the Extravasation Scale (B)

Usability	Extravasation Assessment Tool (A)		Extravasation Scale (B)		*p*-value
	M	**SD**	**M**	**SD**	
Nurses' Satisfaction (Total Score) [a]	3.82	0.63	4.37	0.46	.000
Mean Rank	38.22		62.78		
Sum of Ranks	1911.00		3139.00		
Each item of Nurses' Satisfaction					
Easiness and convenience	3.64	0.74	4.38	0.56	
Appropriateness	3.80	0.80	4.38	0.56	
Practical application	3.86	0.77	4.48	0.54	
Desire of use	3.62	0.98	4.28	0.53	
Improving patient care	4.12	0.82	4.38	0.56	
Reducing errors	3.90	0.67	4.32	0.51	
Total time use (minutes) [b]	13.94	6.26	8.56	3.44	.000
Mean Rank	65.87		35.13		
Sum of Ranks	3293.50		1756.50		
Average time use/photo (seconds)	11.61	5.21	7.13	2.87	
	n	**%**	**n**	**%**	
Need for Consultation [c]					.000
Yes	42	84	14	28	
No	8	16	36	72	

[a] Mann-Whitney U test: U = 636.00, Z = -4.293, Asymptomatic sig. (2-sided test)
[b] Mann-Whitney U test: U = 481.50, Z = 5.321, Asymptomatic sig. (2-sided test)
[c] Chi-square test: χ^2 = 31.818, df = 1

Additional Analyses

The findings above indicated that the Tool B was superior to the Tool A, but additional analyses were conducted to determine its practicality regarding whether it could provide 1) accurate and precise results regardless of the experience of an assessor and 2) an acceptable level of interrater agreement. Table 4 shows that when Tool B was used, each assessor produced >88% accuracy with precision between 77.43% to 98.96%. This finding confirmed that experienced or inexperienced nurses should be able to use the Tool B although some experienced nurses (i.e., Assessor 5) might have produced a little higher number of accurate results than less experienced ones (i.e., Assessors 1-4).

Table 4. Accuracy (number of accuracy) and precision (95% confidence interval: CI) among five assessors different in years of working experience (total number observations = 60)

Assessors	Years of Working Experience	Number of Accuracy n (%)	95% CI
Assessor 1	1	56 (93.33)	(83.80, 98.15)
Assessor 2	2	53 (88.33)	(77.43, 95.18)
Assessor 3	3-5	55 (91.67)	(81.61, 97.24)
Assessor 4	6-10	56 (93.33)	(83.80, 98.15)
Assessor 5	>10	57 (95.00)	(86.08, 98.96)

Regarding inter-rater agreement at each condition of extravasation injuries (normal, mild, moderate, and severe extravasation), Table 5 shows that the agreement estimates (Fleiss's Kappa coefficients) of Assessors 1-5 and the reference standard were satisfactorily accepted with an overall coefficient of .92 and a range of coefficients from .89 to .96 ($p < .001$).

Table 5. Interrater agreement among five assessors and the reference standard analyzed by using Fleiss' Kappa Statistics

Responses	Kappa	SE Kappa	Z	p-value
Normal	.923	0.0408	22.602	.000
Mild	.905	0.0408	22.162	.000
Moderate	.894	0.0408	21.897	.000
Severe	.962	0.0408	23.557	.000
Overall	.920	0.0245	37.534	.000

Discussion

This study provides research-based evidence regarding two clinical assessment tools used to assess extravasation injuries among adult patients receiving peripheral intravenous infusion together with medications high risk of extravasation. The two clinical assessment tools, the Extravasation Assessment Tool (A) and the Extravasation Scale (B) were tested for accuracy and usability with an additional test of practicality.

The findings suggested that Tool B provided better accuracy than Tool A as it produced more accurate results and fewer defectives ($p < .001$). Also, Tool B showed higher sensitivity and specificity estimates (0.96 and 0.88, respectively) compared to Tool A (0.88 and 0.52, respectively). Moreover, the nurse participants were more satisfied when using Tool B especially due to its practical application, lower need for consultation, and less time needed for assessing extravasation injuries than that of Tool A.

Patients with peripheral intravenous lines should be assessed regularly to detect an occurrence of extravasation and its severity. A site assessment should be conducted hourly when there are fluids or medications running through the line. If nothing is being infused, the site should be assessed before accessing the line and at least every eight hours.[10] To do so, an insertion site must be seen clearly and nurses should be able to easily assess the site. An adhesive transparent dressing material should be used to help improve visibility and security of the IV line and reduce the occurrence of phlebitis and extravasation.[22] In the current practice of the study setting, adhesive transparent dressing has been used routinely.

To assess any clinical condition, nurses use clinical judgement to make decisions but this requires an advanced level of expertise. In Bochaton *et al.*'s study,[23] they demonstrated that using clinical judgement alone was worse than using a "standardized measure of extravasation" (the Pediatric Peripheral Intravenous Infiltration Scale: PIV scale). Their study evidenced that clinical extravasation assessment tools were necessary to provide more accurate results (sensitivity of PIV scale and clinical judgement alone = 69% and 60%, respectively, $p < .001$). In our study, both Tools A and B are clinical assessment tools that predominately use both clinical signs and symptoms in cases of extravasation to help nurses identify the occurrence and severity of an injury. However, Tools A and Tool B were distinctively different. In the Tool B photo line-up were 10 photos, (**Figure 2**), arranged in a user-friendly fashion, starting from normal (one photo) to mild, moderate, and severe extravasations (3 photos, each). The contribution of visual aids may help assessors easily recognize and differentiate the severity levels. Using photo line-ups to help assess the severity of other clinical conditions has been reported. For example, the TABBY (Tongue-tie and Breastfed Baby) tool was developed to assess the severity of ankyloglossia or "tongue-tie" in breastfed babies.[24] In their study, Ingram *et al.*[24] compared the TABBY (provided with pictures of different degrees of ankyloglossia) with the previous Bristol Tongue Assessment Tool (BTAT) (had only objective wording indicators). They found that the TABBY was easy to use and provided assessors with information to be clear about the crucial features of a tongue-tie. With this regard, the Extravasation Scale (Tool B) is an evidence-based extravasation assessment tool that will be helpful internationally for early detection and prompt management of extravasation injuries.

Moreover, the additional analyses findings supported the strength of Tool B regarding its practicality. It was revealed that nurses with any levels of working experience could use it easily after a short training, for it is quick to use and simple to score. However, it can be argued that clinical assessment tools lack objectivity and reliability. This current study has proved that this may not always be the case. The Extravasation Scale demonstrated its satisfactorily valid and reliable estimates as indicated by sensitivity 0.96, specificity 0.88, PPV 96.4% and NPV 86.5%. These findings are promisingly attractive. Even though the more objectivity measure, such as thermography, was found to offer impressive results with sensitivity, specificity, PPV and NPV of 84.6%, 94.8%, 64.7%, and 98.2%, respectively,[25] thermography may not be available in many clinical settings, especially in those in under-resourced countries.

Limitations and Recommendations

Methodological strengths of this study are identified. First, this study was similar to diagnostic test studies. For this type of study to be valid, it is important to include samples with and without a disease,[26] so photos of patients with and without extravasation were used. Second, the use of photos instead of actual patients enhances reproducibility, an ability of the tools under this investigation when repeated under the same conditions. Third, with the use of photos, all nurse participants were blinded from the primary doctor or dermatologist's diagnosis so that nurses may come to know if the actual patients were used. With these three methodological characteristics, the study findings were considered valid.

However, this study has some certain limitations. Although it seems that 3,600 observed data per each tool were considered a very large size (a total of 7,200 observed data), it was conducted at one university hospital and included only adult patients with 14 types of medications identified as causative agents of extravasation. Use of medication high risk for extravasation injuries may vary from one institution to another and some medications produce different degree of extravasation. This may limit the generalizability of the findings. A multicenter, extended replication study is recommended. Next, even though the use of photos seems optimistic, some photos may be distorted as a result of surrounding ward environment (e.g., lighting) and shooting effects. Future studies should use high-quality photos as much as possible, to clearly depict the various conditions of extravasation and normal situations.

Conclusions and Implications for Nursing Practice

This study found that the accuracy and usability of the Extravasation Scale (B) were superior to the Extravasation Assessment Tool (A). When the Tool B was used, the nurses were able to produce more accurate results (% of correctness), higher sensitivity and specificity estimates than when they used Tool A. They reported to have more satisfaction, lower number of the need for consultation and time use when the Tool B was utilized. In addition, the Tool B also showed its practicality in which it could be used regardless of the nurses' working experience. Therefore, nurses working with adult patients who are at high risk of developing extravasation injuries while receiving medications via peripheral intravenous infusions should use the Extravasation Scale to help identify its occurrence and severity in their daily clinical practice. We recommend providing training to nurses about how to use Tool B with actual patients and performing standardized tests with experts (physicians, dermatologists) is recommended.

Acknowledgements

We express our gratitude to the Faculty of Nursing, Thammasat University for granting research funding, and to all patients and nurses for their great contributions, and Thammasat University Hospital for facilitating the field study.

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การศึกษาเปรียบเทียบความแม่นยำ และความสามารถใช้งานเครื่องมือสำหรับการประเมินระดับความรุนแรงของการเกิดภาวะการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาหรือสารน้ำทางหลอดเลือดสองชนิด

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บทคัดย่อ: การบาดเจ็บของเนื้อเยื่อจากการรั่วของยาหรือสารน้ำออกนอกหลอดเลือดดำส่วนปลาย เป็นภาวะแทรกซ้อนที่รุนแรงของการให้ยาหรือสารน้ำทางหลอดเลือดดำ พยาบาลต้องประเมินระดับความรุนแรงของภาวะการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือดและให้การพยาบาลอย่างเหมาะสม วัตถุประสงค์ของการศึกษาเปรียบเทียบนี้เพื่อตรวจสอบความแม่นยำและความสามารถใช้งานของเครื่องมือสำหรับการประเมินระดับความรุนแรงของการเกิดภาวะการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาหรือสารน้ำทางหลอดเลือดดำสองชนิด โดยอาสาสมัครวิจัยเป็นพยาบาลจากโรงพยาบาลตติยภูมิแห่งหนึ่งจำนวน 50 คน พยาบาลแต่ละคนประเมินภาพภาวะการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือดจำนวน 2 ชุด (ชุดละ 72 ภาพ) ว่ามีการเกิดการบาดเจ็บหรือไม่ และประเมินระดับความรุนแรงของการบาดเจ็บโดยใช้เครื่องมือ (A) Extravasation Assessment Tool และ (B) Extravasation Scale ซึ่งภาพที่ใช้ประเมินได้จากผู้ป่วย 72 คนซึ่งได้รับยาทางหลอดเลือดดำแล้วไม่เกิดการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือด (ปกติ) และเกิดการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือด 3 ระดับ ตั้งแต่น้อย ปานกลาง มาก (ระดับความรุนแรงอย่างละ 18 ภาพของแต่ละชุดภาพ) ภาพที่ใช้ได้รับการวินิจฉัยระดับความรุนแรงจากแพทย์เฉพาะอาสาสมัครพยาบาล ผลรวมการประเมินภาพทั้งหมด 3,600 ครั้งต่อการใช้เครื่องมือ (พยาบาล 50 คน*72 ภาพ) พบว่า เมื่อใช้เครื่องมือ (A) Extravasation Assessment Tools และ (B) Extravasation Scale ได้ผลลัพธ์ตรงกับทางด้านผิวหนังซึ่งถูกใช้เป็นมาตรฐานตรวจสอบความถูกต้อง (reference standard) กับผลการประเมินโดยการวินิจฉัยของแพทย์ทั้งหมด 2,898 ครั้ง (ร้อยละ 80.5) และ 3,386 ครั้ง (ร้อยละ 94.1) ตามลำดับ และพบความแตกต่างอย่างมีนัยสำคัญของจำนวนที่ผิดพลาด (ร้อยละ 13.6, แตกต่างกันอย่างน้อยร้อยละ 11.77 ที่ระดับความเชื่อมั่นร้อยละ 99 ที่ระดับนัยสำคัญ < 0.01) ทดสอบค่าความไวและความจำเพาะของเครื่องมือ Extravasation Scale ได้ 0.96 และ 0.88 ตามลำดับ เมื่อเปรียบเทียบความสามารถใช้งานของเครื่องมือทั้งสองชนิด พบว่า Extravasation Scale สามารถใช้งานได้ดีกว่า โดยพยาบาลส่วนใหญ่พึงพอใจถึงพึงพอใจมาก มีความต้องการคำปรึกษาและระยะเวลาที่ใช้ในการประเมินน้อยกว่า ผลการวิจัยสนับสนุนว่า Extravasation Scale สามารถใช้ในการประเมินระดับความรุนแรงของภาวะการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือดได้แม่นยำและดีกว่า Extravasation Assessment Tool พยาบาลควรใช้เครื่องมือนี้ในการประเมินการเกิดและความรุนแรงของการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือดดำ ทำให้สามารถประเมินการบาดเจ็บได้เร็วขึ้นและสามารถให้พยาบาลได้อย่างเหมาะสม

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คำสำคัญ: แบบประเมิน การบาดเจ็บของเนื้อเยื่อจากการรั่วของยาหรือสารน้ำ การให้สารน้ำทางหลอดเลือดดำ การพัฒนาเครื่องมือ การพยาบาล ภาวะการบาดเจ็บของเนื้อเยื่อจากการรั่วของยาออกนอกหลอดเลือดดำส่วนปลาย

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