

## Development and Validation of the Intravenous Infiltration and Extravasation Risk Assessment Tool (IIERAT) for Pediatric Patients

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**Objective:** To develop and validate a new tool viz., Intravenous Infiltration and Extravasation Risk Assessment Tool (IIEART) for assessing risk of fluid extravasation in children.

**Participants:** 120 children (aged 2-18 year) undergoing peripheral intravenous cannulation were recruited from four hospitals of Haryana to determine the IIEART scale's psychometric properties.

**Methods:** The tool was developed under four phases with Modified Delphi rounds among nine experts. After experts' confirmation of final draft, the reliability and validity of the tool was ascertained.

**Results:** The final IIERAT with 11 items showed good internal

consistency ( $\alpha=0.81$ ) with inter-rater reliability of ( $\kappa=0.88$ ). To calculate predictive validity, sensitivity and specificity were assessed for 3 consecutive days from the day of cannulation. At a score  $>21$ , the sensitivity was 100% and specificity was 100% with area under curve of 1.0 (95% CI 1.0, 1.0) on second day of cannulation.

**Conclusion:** The IIEART developed was found to be valid and reliable and can be used by healthcare personnel to predict pediatric patients at risk for intravenous infiltration and extravasation.

**Key words:** Risk assessment, Sensitivity, Specificity, Venous cannula.

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Peripheral venous cannulation is one of the most commonly performed invasive procedures in clinical practice [1]. Children are more at risk of an infiltration injury because of their small and weaker blood vessels, immature skin, lack of subcutaneous fat, and constant movement [2]. Infiltration is defined as an inadvertent delivery of non-vesicant fluid or medication into surrounding tissue with the potential to harm the patient. If a vesicant fluid or medication has been infused into the surrounding tissue space, it is called extravasation [3]. Certain fluids and drugs can easily cause venous rupture when the venous endothelium and blood vessel walls are irritated, leading to intravenous infiltration or extravasation.

Peripheral infiltration injury rates among pediatric patients receiving intravenous infusions can range from 10-30% [8], but may be as high as 58% [9]. We developed and validated an objective tool to identify the risk of developing infiltration and extravasation among pediatric patients.

### METHODS

A methodological research design was adopted to

develop and validate the Intravenous Infiltration and Extravasation Risk Assessment Tool (IIERAT) for pediatric patients undergoing peripheral intravenous cannulation. The IIERAT was developed by using a modified Delphi technique with four rounds. The psychometric properties of the IIERAT were assessed by applying Cronbach alpha and Cohen kappa for calculating the reliability. For validation, we calculated the predictive validity, sensitivity and specificity. Area under ROC curve was used as measure of the accuracy.

We identified 11 parameters that are associated with the risk of developing infiltration and extravasation in a child viz., site, vein condition, cannula size according to age, indwelling cannula time, type of medication, body mass index (BMI), splint, assessment of cannula site, securement of cannula, flushing in case of intermittent infusion, and dressing status. These parameters or risk factors were also identified and included in Visual infusion phlebitis (VIP) score developed by Ray-Barruel and Polit [10].

A preliminary draft of the IIERAT was developed by review of literature in order to determine various risk factors that cause infiltration and extravasation in pediatric

patients. Selected items were pooled together to generate the first version of IIERAT tool and categorized as Site-associated factors, Mechanical factors, Chemical factors, Disease-associated factors, Physical factors, Nursing care-related factors and Self-care related factors.

Modified Delphi rounds were conducted amongst nine experts in the field of pediatric medicine and nursing, and response was documented after each round to reach final consensus for relevance, comprehensiveness and clarity of items. Expert suggestions were incorporated and modifications were done, followed by re-review.

After four rounds of revision and reviews, 100% consensus among experts was achieved, and face validity was established. For scoring of the IIERAT for the three categories of mild, moderate and severe risk, the median value was calculated by subtracting the minimum score of 11 from maximum score of 33 and dividing it by 3, which was approximately 7. Then, this value was added into the minimum score to get the range of scores in each level-Low risk (11-18), Moderate risk (19-26) and Severe risk (27-33). Content validity index for each item in the tool was found to be 1. Sensitivity and specificity were assessed for three consecutive days from the day of cannulation.

Ethics clearance to conduct the study was taken from the institutional ethical committee. The children eligible to participate in the study were those who had undergone peripheral intravenous cannulation, were available at the time of data collection, were between the age group 2-18 years, and children and their parents were willing to participate in the study.

A written informed consent was obtained from the parents and assent from children (verbal assent for the children aged 7-12 year and written assent for the children aged >12-18 year) before including them as research participants. The tool was administered to 50 pediatric patients undergoing peripheral intravenous cannulation admitted in pediatric medicine and surgical wards of our institution. A single researcher physically collected the data by scoring on the IIERAT from the day of cannulation till the occurrence of infiltration and extravasation. One patient was included only once for data collection.

To establish the reliability and validity of the tool, it was administered to 120 patients (aged 2-18 year) undergoing peripheral intravenous cannulation, available at the time of data collection and selected conveniently, admitted in four hospitals in Haryana viz., Pediatric Medicine and Surgical wards of MMIMS&R Hospital, Mullana, Ambala; AVS Ravi Hospital, Model Town, Yamuna Nagar; Madan Memorial Hospital, Madan chowk, Yamuna Nagar; and Civil Hospital, Ambala; between November, 2019 and

January, 2020. Patients who were critically ill and admitted in pediatric intensive care units of hospitals were excluded from the study.

*Statistical analysis:* The data were analyzed by SPSS Statistical software Version 20.0 (SPSS Inc). The psychometric properties of the tool were assessed by applying Cronbach alpha and Cohen Kappa for calculating the reliability. For predictive validity, sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV) were calculated for three consecutive days of hospitalization. Area under ROC curve was used as measure of the accuracy.

## RESULTS

The overall internal consistency of the tool was high ( $\alpha = 0.810$ ). The total correlation was applied on 11 items in the tool and found that all IIERAT items had item score to total score correlation in between 0.32-0.81. To check the individual contribution of items, each item was deleted one by one to analyze the changes in the value of alpha, but no item showed increase in the value of alpha coefficient rather the value remained the same or it decreased, which indicated that all the items were equally contributing to the reliability of the IIERAT tool (**Web Table I**) [19].

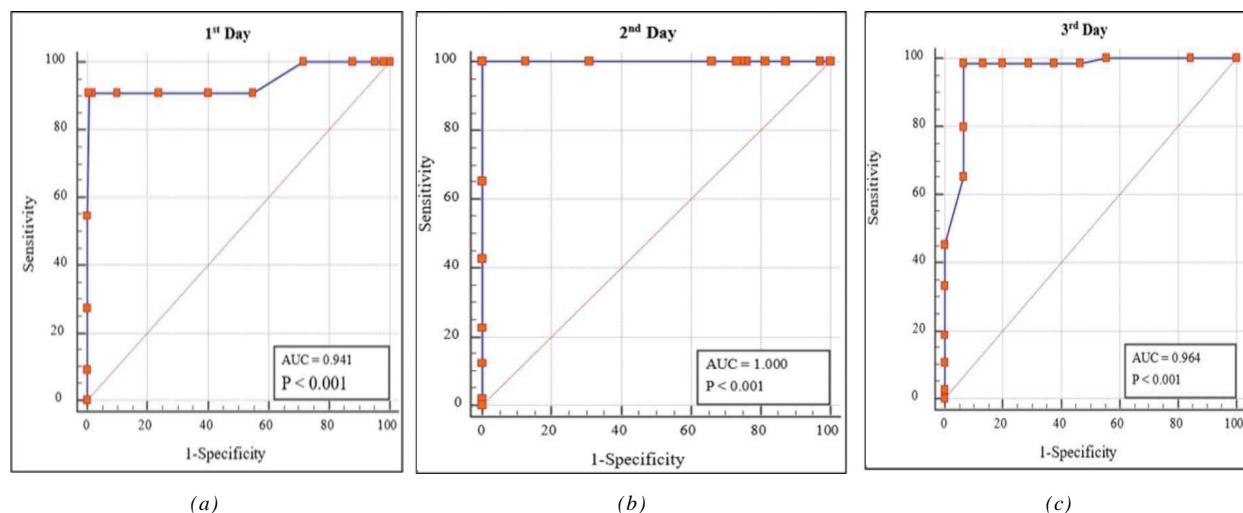
The inter-rater reliability was calculated by Cohen kappa and found to be 0.81. The items with perfect agreement were site, vein, cannula size, type of medication, BMI, splint, securement of cannula, and dressing status. Only two items demonstrated an agreement of <80%, viz., assessment of cannula, and flushing in case of intermittent infusion.

Predictive validity calculation shows that for day 1 of cannulation, at a cut-off point of 21, the best balance between the sensitivity (90.48%) and specificity (99.08%) was achieved with PPV of 90.9% and NPV of 99.1%. For day 2, the optimum cut-off score was 21, with sensitivity (100%) and specificity (100%); while on day 3, a cut-off score of 20 was the optimum score with sensitivity and specificity of 98.67% and 86.67%, respectively.

The AUC shows the accuracy of the IIERAT at best cut-off point of 21 for first day with value 0.941 (95% CI: 0.833, 1.00) (**Fig. 1a**); at cut-off-point of 21 for second day, AUC was 1.00 (95% CI: 1.00, 1.00) (**Fig. 1b**); and at cut-off point of 20 on third day AUC 1.00 (95% CI: 1.00, 1.00) (**Fig. 1c**).

## DISCUSSION

The IIERAT was developed with an aim to assess the risk of infiltration and extravasation among children receiving intravenous fluids/drugs. The final IIERAT was developed with 11 items that showed good internal consistency



a) The optimal cut-off point was 21, with sensitivity- 90.48% and specificity- 99.08 %; b) The optimal cut-off point was 21, with sensitivity-100% and specificity-100%.; c) The optimal cut-off point was 20, with sensitivity-98.67% and specificity-86.67%.

**Fig. 1** Receiver operating characteristics curve for the IIEART from Day 1 to Day 3 of cannulation.

( $\alpha=0.81$ ) and inter-rater reliability ( $\kappa=0.88$ ). On the second day of cannulation, the sensitivity and specificity were found to be 100%.

Simin, et al. [21] reported that cannula involvement within joint area ( $P=0.03$ ), use of elbow joint (0.018), age ( $P=0.011$ ), diseases condition ( $P=0.016$ ), cannula insertion site ( $P=0.02$ ), presence of soiled securement device ( $P=0.001$ ), cannula inserted by nursing staff and students ( $P=0.53$ ), were the common risk factors for the development of infiltration and phlebitis in pediatric patients. Current guidelines also recommend cannulation limited to use of upper extremities [22], avoiding the wrist, and preferring distal areas for IV cannulation [23]. According to updated guidelines on infiltration and extravasation: prevention and management, healthcare personnel must choose a vein that feels smooth and resilient, not one that is hard or cordlike [24]. Site of venous puncture and cannula length were added as the parameters in detecting risk of developing infiltration and extravasation in pediatric patients. Kagel and Rayan [25] also found that selection of catheter insertion site had effect on infiltration development. This is because small and or fragile veins are more prone to cause infiltration [26].

Similar to our results, Schulmeister [27] also found that sterile, transparent dressings should be used by clinicians to protect the site from extrinsic contamination, and visual assessment in pediatric patients for redness, tenderness, swelling, numbness, or tingling on a regular basis.

In contrast to other assessment tools, the IIERAT provides a better way to assess the risk of infiltration and extravasation in pediatric patients. A higher score on the

IIERAT indicates a higher risk of developing infiltration and extravasation. Though the IIERAT could not be done in a large number of pediatric patients, the results of statistical analysis suggest that this is a valid and reliable tool to assess risk of infiltration and extravasation.

Healthcare researchers may conduct further research studies to investigate patient care strategies according to the levels of risks (mild, moderate and high) of developing infiltration and extravasation among patients.

The IIERAT demonstrated adequate validity and reliability. It can be used by all health professionals, especially nursing officers, to identify the pediatric patients at risk for developing intravenous complications such as infiltration and extravasation.

*Ethics clearance:* IEC, MM Deemed University; No. 1513, dated July 19, 2019.

*Note:* Additional material related to this study is available with the online version at [www.indianpediatrics.net](http://www.indianpediatrics.net)

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**WHAT IS ALREADY KNOWN?**

- Many infiltration/extravasation tools have been developed that can assess the grades of these complications after the occurrence.

**WHAT THIS STUDY ADDS?**

- The IIERAT is specifically designed for assessing the risk of developing infiltration/extravasation complications before their occurrence in children.

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**Web Table I Baseline Characteristics of Children Undergoing Intravenous Cannulation (N=120)**

| <i>Patient Characteristics</i> | <b>No. (%)</b> |
|--------------------------------|----------------|
| <i>Age (Y)</i>                 |                |
| 2-6                            | 61 (50.8)      |
| 7-12                           | 36 (30)        |
| 13-18                          | 23 (19.2)      |
| Female gender                  | 71 (59.1)      |
| <i>Affected system</i>         |                |
| Gastrointestinal               | 64 (53.3)      |
| Respiratory                    | 32 (26.6)      |
| Renal                          | 11 (9.2)       |
| Neurological                   | 8 (6.7)        |
| Cardiovascular                 | 5 (4.2)        |
| <i>Inpatient ward</i>          |                |
| Pediatric medicine             | 79 (65.8)      |
| Pediatric surgery              | 26 (21.6)      |
| PICU                           | 15 (12.6)      |
| <i>Cannula Inserted By</i>     |                |
| Staff nurses                   | 98 (81.6)      |
| Doctor                         | 22 (18.4)      |