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Evaluation of optical sensor technology for the early detection of peripheral intravenous infiltration in neonates: a retrospective cohort study

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ABSTRACT

Objective This study aimed to evaluate the utility of optical sensor-based technology in mitigating the frequency and severity of peripheral intravenous infiltration and/or extravasation (PIVIE) in neonates.

Design Single-centre, retrospective, observational cohort study.

Setting Tertiary-level neonatal intensive care unit (NICU) (112 cots) at the Women's Wellness and Research Centre (WWRC), Hamad Medical Corporation (HMC), Doha, Qatar, January 2019–December 2022.

Participants All neonates admitted to the NICU requiring intravenous therapy via a neonatal short peripheral intravenous catheter (n-SPC) were included. Participants were excluded if the insertion was unsuccessful, if they had incomplete data, or if they received intravenous therapy exclusively through alternative vascular access devices.

Interventions The study analysed two cohorts representing different clinical practices over two distinct periods. In the conventional cohort (Phase 1, 2019–2020), PIVIE detection relied solely on periodic 'Touch Look Compare (TLC)' assessments. In the ivWatch cohort (Phase 2, 2021–2022), continuous optical sensor-based monitoring using the ivWatch system was implemented alongside TLC assessments. This sequential design allowed for a comparison of outcomes between the two phases.

Outcome measurements The primary outcomes were the occurrence and severity of PIVIE. Secondary outcomes included the influence of patient demographics, vascular access characteristics, and management details on PIVIE incidence and severity.

Results Over the 4-year data collection period, 32 713 peripheral intravenous catheters were analysed across two cohorts. PIVIE was the most common reason for unplanned device removal. In the conventional cohort (Phase 1, 2019–2020), 4941 infiltration events were reported (29.9%), compared with 4872 events (30.1%) in the ivWatch cohort (Phase 2, 2021–2022). However, severity measures using the Intravenous Extravasation Grading Scale (IEGS) revealed a marked reduction in severe PIVIE cases, with severe events decreasing from 243 (4.9%) in the conventional cohort to 54 (1.1%) in the ivWatch cohort ($p<0.001$).

Conclusions PIVIE remains a frequent complication in neonatal vascular access. Continuous site monitoring with optical sensor technology was associated with earlier detection of PIVIE events and reduced IEGS severity scores. These findings highlight the potential of integrating sensor-based monitoring with traditional observational methods to improve patient outcomes in neonatal care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study analysed a large dataset of 32 713 successful neonatal peripheral intravenous catheter insertions.
⇒ A sequential design was used, comparing two distinct clinical practice periods with consistent standard care protocols.
⇒ Continuous optical monitoring was implemented alongside standard observational assessments in the Phase 2 study cohort.
⇒ The single-centre setting limits generalisability to other neonatal intensive care settings.
⇒ The retrospective, non-randomised design may be subject to confounding due to unmeasured clinical variables.

INTRODUCTION

Worldwide, neonatal short peripheral vascular catheter (n-SPC) use is commonplace, and its use has become a common component of contemporary care provision.[1–3] Infants in neonatal intensive care units (NICU) experience a considerable burden of vascular access-related complications.[4–7] The likelihood and severity of complications associated with n-SPC use are associated with a range of unmodifiable factors (such as patient age and underlying medical conditions) and potentially modifiable factors (such as insertion technique and the type of catheter).[8]

Peripheral intravenous device-related complications occur in more than 50% of all inserted n-SPCs.[4679] These complications can

lead to unplanned removal of the catheter, interruption of therapy and exposure of infants to additional painful procedures. The most frequently reported complication is peripheral intravenous infiltration and extravasation (PIVIE).[6 8–10] Infiltration is said to occur when a non-vesicant solution leaks from the blood vessel into the surrounding tissue. The term extravasation is used to describe a similar situation but one involving a vesicant solution. Both events can lead to serious harm regardless of the chemical nature of the leaking fluid and are commonly combined using the acronym PIVIE. In this article, we use the term PIVIE to describe any fluid leakage into surrounding tissue associated with n-SPC use. Known risk factors for this complication include birth weight, gestational age and catheter material.[7–11] PIVIE-related complications cause discomfort and pain and increase infection risk.[8 12] Depending on the nature, volume and location of the infiltrated fluid, sloughing, blistering of the skin, skin necrosis, tissue damage, nerve damage, tendon damage and scarring may occur. This can result in temporary or permanent damage and adverse long-term patient outcomes.[1] Infiltration may go unrecognised,[10] developing silently with few early obvious signs. However, as fluids accumulate, PIVIE eventually becomes fully established. Detecting this silent threat before serious harm develops requires high levels of vigilance by healthcare professionals.[10]

Currently, several tools and scoring systems are available to aid in the early detection of infiltration and to grade the severity of the injury, such as the Infusion Nurses Society (INS) Scale, Extravasation Grading Scale (EGS) and the Intravenous Extravasation Grading Scale (IEGS).[12 13] In neonatal care settings, the Touch Look Compare (TLC) approach is a widely used observational tool for assessing the patency and integrity of n-SPCs.[9 10 14] While systematic, TLC assessments rely heavily on visual inspection and subjective interpretation, which can be challenging in high-acuity clinical environments. Detailed descriptions and visual guidance for both IEGS and TLC are available through the Vascular Access Service of Cincinnati Children's Hospital Medical Center, offering practical support for bedside implementation and training (https://www.cincinnatichildrens.org/service/v/vascular-access/hcp). In contrast, the optical sensor technology evaluated in this study offers continuous, real-time monitoring of peripheral intravenous catheter insertion sites. This is particularly beneficial in busy (neonatal) units, where clinicians may not always have the time for frequent visual inspections. The device's strengths include the ability to detect subtle changes at the intravenous site before overt clinical signs appear, potentially allowing for earlier intervention to prevent the progression of infiltration injuries.[15–19]

However, in clinical use, the technology can have drawbacks. For example, it may produce false-positive signals, which could lead to alarm fatigue and unnecessary interventions. Moreover, its sensitivity and specificity have not yet been robustly validated across diverse clinical settings, and integrating the device into established workflows may require additional training and consideration of cost-effectiveness. These potential drawbacks underscore the need for further research to optimise the device and confirm its clinical impact.[9 10 13 14 20]

METHODS

Design and setting

This study employed a single-centre retrospective observational cohort design. Data were collected from a 112-cot tertiary-level NICU at the Women's Wellness and Research Centre (WWRC), Hamad Medical Corporation (HMC) in Doha, Qatar, over 4 years from January 2019 to December 2022.

Participants and sample size

Over the 4-year study period, standard care protocols including catheter insertion techniques, site monitoring procedures and the management of intravenous therapy remained unchanged. The study population comprised all term and preterm neonates admitted to the NICU who required intravenous therapy via an n-SPC.

Data were collected from 1 January 2019 to 31 December 2022, during which two cohorts reflecting distinct clinical practices were established. In the conventional cohort (January 2019–December 2020), PIVIE detection relied solely on periodic 'Touch Look Compare (TLC)' assessments. In the ivWatch cohort (January 2021–December 2022), continuous optical sensor-based monitoring using the ivWatch system was implemented alongside TLC assessments. This sequential design enabled a direct comparison of outcomes between the two phases. Online supplemental figure 1 shows the Strengthening the Reporting of Observational Studies in Epidemiology participant flow diagram. This flow diagram outlines the number of potential participants identified, exclusions based on alternative vascular access or unsuccessful n-SPC insertions, and the final number of insertions analysed in each phase.

Procedures

The neonatal venous access team (NeoVAT) routinely manages peripheral intravenous cannulation. This team consists of a dedicated group of clinicians (16 nurses and 13 doctors) who provide 24-hour peripheral vascular access support across the NICU.

During pre-procedural assessment, the team routinely adheres to a locally developed mnemonic, the '5 Rights for Venous Access'.[8] This mnemonic stands for the Right device, for the Right vein, with the Right therapy, for the Right duration, by the Right healthcare professional. Venous cannulation is carried out in adherence to local hospital policies based on current international standards of practice (eg, [21–24]).

In our unit, n-SPCs are primarily used for the administration of isotonic fluids. Hyperosmolar fluids, which carry an increased risk of infiltration, are administered using central vascular access. Routine blood sampling is

typically performed at the time of n-SPC insertion, after which the catheter is used continuously for therapy. Transparent dressings are applied over the insertion site to facilitate ongoing visual inspection. Standard near infrared (NIR) technology is used for vein assessment and visualisation as an aid for vascular access cannulation. According to the INS guidelines, the smallest diameter catheter that meets therapeutic requirements should be selected to minimise vessel trauma and reduce complication risks.[24] We adhered to this recommendation by consistently using a 26G catheter in our NICU, which reliably provides adequate access for all our neonatal patients and delivers a maximum flow rate of 12 mL/min (720 mL/hour), meeting their clinical needs. Following hospital purchasing decisions, the study used a combination of 26G PTFE Neoflon (Becton Dickinson Infusion Therapy, Sandy, UT, USA), or 26G PUR Neoflon Pro (Becton Dickinson Infusion Therapy, Sandy, UT, USA), or 26G PUR SuperCath Safety (ICU Medical, San Clemente, CA, USA) n-SPCs.

Phase 1: Conventional cohort, 2019–2020

Phase 1 used the TLC approach with hourly assessments for notification of n-SPC infusion infiltration and the IEGS for assessment of the severity of any suspected PIVIE event.[13 14 20] This group served as the baseline for assessing n-SPC integrity and detecting complications.

The TLC tool includes a continuous scale for estimating the volume of fluid extravasated, a three-category estimation of the potential local chemical and physical toxicity of the extravasated medication or agent, and a volume measurement that can be used for estimating the size of extravasation anywhere on the body. The IEGS[20] was used to estimate the size of PIVIE when apparent. Comparing the IEGS scores provided insights into whether the innovation was beneficial.[13 14]

Phase 2: ivWatch cohort, 2021–2022

Following the baseline period (Phase 1), a novel technology was introduced and used for the second period of data collection (Phase 2). During Phase 2, the ivWatch Model 400 Patient Monitoring System (ivWatch, LLC, Newport News, VA, USA) was used exclusively alongside the conventional method. The ivWatch system is the only infiltration and extravasation detection technology on the market that has received Food and Drug Administration clearance and the Conformité Européenne mark for use with all patient groups regardless of SPC location, skin tone or body mass.[25 26] This monitor and sensor combination uses an NIR and visible light sensor to deliver real-time continuous monitoring of n-SPC sites.[27] The mechanism involves the transmission of NIR light into the tissue surrounding the n-SPC insertion site. If fluid infiltrates into surrounding tissue, it alters its optical properties. This is detected as a change in the NIR light absorption and scattering pattern. Once detected, the ivWatch monitor alerts healthcare providers to a potential infiltration and prompts them to check the infusion site. Studies among neonatal and paediatric populations report high degrees of sensitivity and specificity.[15–17 27] Online supplemental figure 2 shows a typical n-SPC set-up with the ivWatch Sensor in Place. The image demonstrates the typical n-SPC set-up in our unit using cyanoacrylate glue, transparent dressing, and with the ivWatch SmartTouch Sensor in situ.

Measurements and data collection

An extensive database of routinely collected vascular access-related data was used. Demographic data parameters for this study consisted of gender, gestational age at birth (in weeks and days) and (birth) weight in grams. Data regarding the procedure for peripheral intravenous cannulation included: the date and time of insertion, date and time of device removal, total dwell time in hours, reason for removal and in cases of PIVIE, the IEGS where applicable were collected and validated.

Statistical analyses

The baseline characteristics of the participants were assessed for normality using the Kolmogorov-Smirnov test for continuous variables. Discrete variables were represented as absolute numbers and percentages. Differences between study groups were evaluated using the χ^2 test for categorical variables and either unpaired t-tests or Mann-Whitney U tests, depending on data distribution.

To assess the association between clinical variables and PIVIE occurrence, logistic regression analyses were applied. Univariable logistic regression was first conducted, with variables achieving statistical significance at $p<0.005$ included in the multivariable logistic regression model. ORs with 95% CI were calculated to quantify the strength of associations between clinical variables and PIVIE risk. Multivariable modelling used backwards elimination based on the Wald statistic with a removal threshold of $p<0.001$. This strict criterion aimed to reduce Type I errors and enhance model stability. While stepwise methods may exclude clinically relevant variables with weaker effects, this was mitigated by integrating both statistical and clinical judgement in variable selection.[28–30] Catheter survival, as influenced by PIVIE occurrence and ivWatch implementation, was analysed using Kaplan-Meier regression. Differences in survival distributions were assessed using the log-rank (Mantel-Cox) test. A p value <0.05 was considered statistically significant. All statistical analyses were conducted using MedCalc version 20.114 (MedCalc Software Ltd, Ostend, Belgium).

Sample size considerations

This was a retrospective observational cohort study that included all eligible cases over 4 years (n=32 713), and as such, no a priori sample size calculation was performed. However, the sample size was large, and the incidence of the primary outcome (PIVIE) was high across both cohorts. These conditions ensured that the study was adequately powered to detect statistically and clinically meaningful differences in outcome measures.

Table 1 Participant demographics

	Phase 1 conventional cohort n=16 521	Phase 2 ivWatch cohort n=16 192	P value
Sex			
Male	9361 (56.7%)	9364 (57.8%)	p=0.039 (X^2=6.51, df=2)
Female	7143 (43.2%)	6803 (42.0%)	
DSD*	17 (0.1%)	25 (0.2%)	
Gestational age at birth (weeks)	34.6±4.7	34.7±4.8	p=0.050 (t=−1.96, F=25.94)
Post-natal age at insertion (days)	8.8±19.3	8.2±18.5	p=0.008 (t=2.65, F=11.00)
Birth weight (g)	2337±986	2368±963	p=0.004 (t=−2.89, F=21.12)
Weight at insertion (g)	2413±928	2434±900	p=0.042 (t=−2.04, F=11.99)

The assumption of normal distribution was tested with Kolmogorov-Smirnov testing.
χ^2 testing: nominal data.
Unpaired samples t-testing: continuous data with normal distribution.
*DSD: a disorder of sex differentiation.

While formal power calculations were not conducted in advance, the magnitude of observed differences in event severity (analysed post hoc) was substantial, indicating that the available data were sufficient to support the statistical inferences made.

Patient and public involvement

None.

RESULTS

Patient demographics

Over the 4-year study period, a total of 46 929 n-SPC insertion attempts were performed in 32 713 patients. Among these, 14 216 attempts were unsuccessful, requiring additional attempts before successful catheter placement. Ultimately, 94% of patients successfully received an n-SPC, though some required multiple attempts (ranging from 2 to 6) before a catheter was successfully placed. Every patient in the study had at least one successful n-SPC insertion, and a total of 32 713 successfully inserted n-SPCs were included in the final analysis. Notably, no patients had incomplete data.

Patient demographics, tested with Kolmogorov-Smirnov testing over the study period, show a normal distribution within the total cohort regarding n-SPC insertion data, with consistency in gestation, weight and day of insertion between both groups (table 1).

Phase 1 outcomes (conventional cohort, 2019–2020)

In the conventional cohort, PIVIE detection relied solely on periodic 'Touch Look Compare (TLC)' assessments. The mean number of n-SPC insertion attempts per patient was 1.34±0.69. The hand was the predominant insertion site, and the primary indications were intravenous fluids and medications, with increases in blood transfusions and blood extractions observed over time (table 2).

PIVIE was the most common complication. During Phase 1, 4941 cases (29.9%) of PIVIE were reported, and the mean catheter dwell time was 35:35 hours and minutes (table 3).

Phase 2 outcomes (ivWatch cohort, 2021–2022)

In Phase 2, continuous optical sensor-based monitoring using the ivWatch system was implemented alongside TLC assessments. The median number of insertion attempts per patient was 1 (range 1–6). A total of 14 409 insertions were recorded by hand. Although the overall number of PIVIE cases remained similar (4872 cases, 30.1%), the mean catheter dwell time decreased to 32:23 hours and minutes (p<0.001) (tables 2 and 3). Moreover, the severity of PIVIE, as measured by the IEGS, significantly decreased from a median score of 15 (range 2–830 during Phase 1 to 5 (range 0–57) in Phase 2 (p<0.001), with a sub-analysis showing a reduction in severe cases from 243 (4.9%) to 54 (1.1%) (p=0.008), (table 4). Figure 1 provides a visual comparison of this shift in severity distribution between cohorts, clearly illustrating the transition toward lower-grade events in the ivWatch group.

Variable analysis

Table 5 presents the results of the univariable and multivariable logistic regression analyses assessing factors associated with PIVIE occurrence. The analysis identified significant relationships between PIVIE risk and multiple clinical variables.

In the univariable analysis, shorter dwell time (OR=0.98, p<0.001) and higher current gestational age (OR=0.83, p<0.001) were both associated with a reduced likelihood of PIVIE. In contrast, the type of catheter (OR=1.03, p<0.001), reason for insertion (OR=1.54, p<0.001) and reason for removal (OR=1.21, p<0.001) were significantly associated with an increased PIVIE risk. Other significant correlations included age at insertion, birth weight and current weight, while extremity/site of insertion and side of cannulation were not significantly associated with PIVIE.

Table 2 n-SPC insertion

	Phase 1 conventional cohort n=16 521	Phase 2 ivWatch cohort n=16 192	P value
Total n-SPC insertion attempts	25 665	21 264	
PIVC insertion attempts (median, min-max)	1 (1–6)	1 (1–6)	p<0.001 (U=65 898 418, Z=−6.03)
Catheter type			p<0.001 (X^2=17 184.02, df=2)
26G Neoflon	4317 (26.1%)	23 (0.1%)	
26G Neoflon PRO	7179 (43.5%)	27 (0.2%)	
26G SuperCath	5025 (30.4%)	16 142 (99.7%)	
Location of insertion			p<0.001 (X^2=252.06, df=10)
Ankle	9 (0.1%)	1 (<0.1%)	
Elbow	20 (0.1%)	6 (<0.1%)	
Foot	1912 (11.6%)	1174 (7.3%)	
Hand	13 990 (84.7%)	14 409 (89.0%)	
Knee	1 (<0.1%)	0 (0%)	
Lower arm	452 (2.7%)	538 (3.3%)	
Lower leg	13 (0.1%)	19 (0.1%)	
Scalp	5 (<0.1%)	1 (<0.1%)	
Upper arm	20 (0.1%)	19 (0.1%)	
Upper leg	5 (<0.1%)	4 (<0.1%)	
Wrist	94 (0.6%)	21 (0.1%)	
Side of insertion			p=0.009 (X^2=9.35, df=2)
Right	7411 (44.9%)	7034 (43.4%)	
Left	9105 (55.1%)	9157 (56.6%)	
Midline	5 (<0.1%)	1 (<0.1%)	
Reason for insertion			p<0.001 (X^2=146.12, df=3)
Blood sampling	1131 (6.8%)	1672 (10.3%)	
Blood transfusion	669 (4.0%)	780 (4.8%)	
Intravenous fluids/medication	14 488 (87.7%)	13 488 (83.3%)	
Procedure	233 (1.4%)	252 (1.6%)	

The assumption for normal distribution was tested with Kolmogorov-Smirnov testing.
χ^2 testing: nominal data.
Mann-Whitney U testing: continuous data without normal distribution.
n-SPC, neonatal short peripheral intravenous catheter; PIVC, peripheral intravenous catheter.

In the multivariable model shown in table 6, shorter dwell time (OR=0.99, p<0.001) remained a significant factor, indicating that catheters with shorter dwell durations were more likely to develop PIVIE. Additionally, lower current gestational age (OR=0.79, p<0.001) was an independent predictor, reinforcing that less mature neonates are at higher risk of infiltration events. These findings suggest that both catheter longevity and patient maturity play a crucial role in PIVIE risk, underscoring the need for careful catheter selection and continuous monitoring in this vulnerable population.

Survival analysis

Cox regression survival analyses demonstrated that catheter survival was significantly impacted by PIVIE occurrence. Catheters experiencing PIVIE had shorter survival times compared with those without PIVIE, reinforcing the importance of early detection and intervention.

Although longer dwell times were observed in the conventional cohort, this was associated with delayed detection of infiltration and higher severity grades. In contrast, the ivWatch system enabled earlier recognition of infiltration events, leading to improved catheter survival and reduced severity of PIVIE cases (figure 2).

This suggests that continuous site monitoring not only facilitates early detection of PIVIE but may also contribute to prolonged vascular functionality by preventing severe complications and harm to the vasculature. Further

Table 3 Reasons for removal of n-SPC

	Phase 1 conventional cohort n=16 521	Phase 2 ivWatch cohort n=16 192	P value
Reason for removal			<0.001 (χ^2=412.47, df=7)
Administrative censoring*	183 (1.1%)	237 (1.5%)	
Accidental removal	409 (2.5%)	435 (2.7%)	
Discolouration	88 (0.5%)	105 (0.6%)	
Leaking	1856 (11.2%)	2234 (13.8%)	
Occlusion	696 (4.2%)	721 (4.5%)	
Phlebitis	1532 (9.3%)	637 (3.9%)	
PIVIE	4941 (29.9%)	4872 (30.1%)	
Therapy completed	6816 (41.3%)	6951 (42.9%)	
Dwell time (hours:minutes) (mean±SD)	35:35±31:50	32:23±34:58	<0.001 (t=8.67, F=50.61)

P values are calculated with χ^2 testing or t-testing, as appropriate.
*Administrative censoring: infants transferred out to another facility or who died.
n-SPC, neonatal short peripheral intravenous catheter; PIVIE, peripheral intravenous infiltration and/or extravasation.

research should explore strategies to optimise catheter dwell time while minimising PIVIE risk.

DISCUSSION

This study found that over 42.6% of neonates who had peripheral intravenous therapy with a n-SPC developed a complication, with infiltration being the most common (53.0%). This happened despite strictly adhering to the principle of using n-SPCs only for fluids with osmolarity <600 mOsm/L and medications with pH 5.0–9.0. This finding aligns with previously reported results,[2 4 5 7–10] and confirms the intractability of vascular access-related complications in this patient population.

It is important to address the sensitivity and specificity of the ivWatch system, as these are key indicators of the device's effectiveness. Previous studies, including a pilot evaluation in a neonatal population, reported that the ivWatch system demonstrated a sensitivity of 93.3% for detecting infiltration events, with all detections occurring before clinical identification by staff.[15] A more recent study further confirmed the system's performance, achieving a sensitivity of 100% in detecting PIVIEs before clinician confirmation.[16] In contrast, D'Andrea *et al*,[17] while reporting similar sensitivity when using clear fluids, suggested that the sensor may be less sensitive in detecting infiltration when infusing opaque solutions like lipids. These findings suggest that the ivWatch system is highly reliable in identifying early-stage infiltration events, particularly during clear fluid infusions, as used in this study's NICU. This observation could partly explain the increase in the detection of PIVIE events in our study during Phase 2. However, the device's capability to provide earlier alerts—often before overt visual or tactile signs appear—likely also played a role in reducing the severity of PIVIEs observed in this study and reported by others.[15–17]

A key consideration in continuous optical sensor monitoring is the interpretation of alerts, particularly false positives. While alarm fatigue is a concern, studies in healthy volunteers demonstrated high sensitivity (99.0%) and a

Table 4 Infiltration/extravasation severity

	Phase 1 conventional cohort n=4941	Phase 2 ivWatch cohort n=4872	P value
PIVIE severity grade:			p<0.001 (χ^2=6943.09, df=3)
<7	208 (4.2%)	4265 (87.5%)	
7–<15	2120 (42.9%)	427 (8.8%)	
15–<30	2370 (48.0%)	126 (2.6%)	
≥30	243 (4.9%)	54 (1.1%)	
IEGS score (median, min-max)	15 (2–83)	5 (0–57)	p<0.001 (U=1 214 695, Z=−77.33)

P values are calculated with χ^2 testing or Mann-Whitney U testing, as appropriate.
IEGS, Intravenous Extravasation Grading Scale; PIVIE, peripheral intravenous infiltration and/or extravasation.

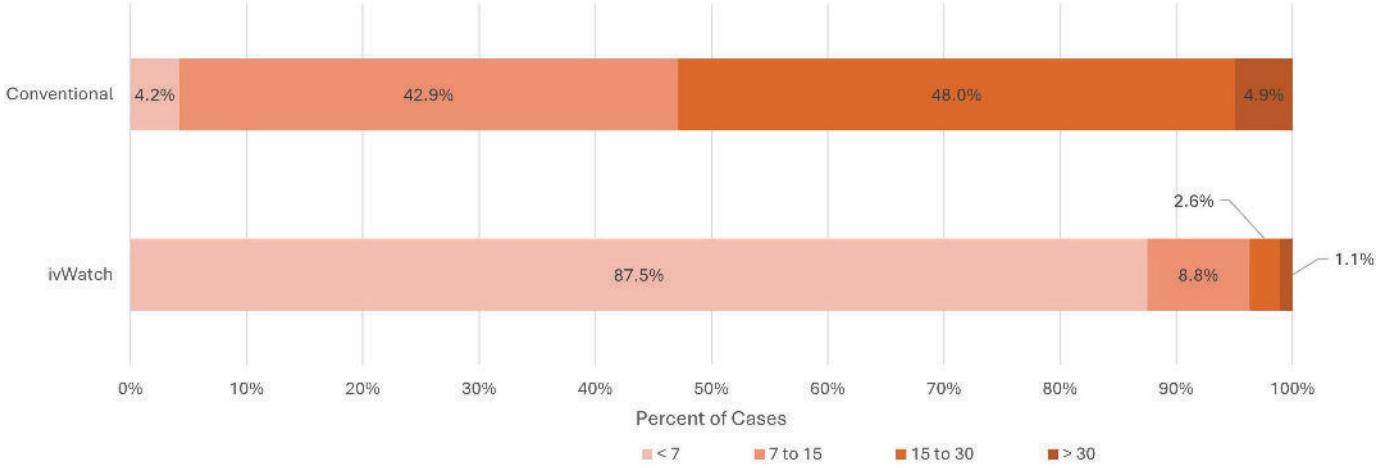

Figure 1 Intravenous extravasation severity.

low false positive rate (one event every 6.3 days) when subcutaneous saline injections simulated infiltration.[18 19] In clinical practice, however, some alerts classified as false positives may indicate early, subclinical tissue changes, offering an opportunity for proactive intervention. Additionally, improper sensor placement, such as over a vein or an air bubble, may affect detection accuracy.

A noteworthy finding in this study is the association between increased numbers of early infiltration notifications by the ivWatch system and PIVIE severity outcomes. Notifications of PIVIE increased with the use of continuous site monitoring via the ivWatch system. The increased detection of PIVIE events is indicative of the ivWatch system's sensitivity and its capability to detect both clinically significant and non-significant infiltrations, even with minimal fluid volumes.[17 27] Earlier notifications of possible PIVIE events could enable actions to be taken more promptly before they escalate in severity. In this study, the integration of this technology with existing TLC observations led to a significant decline, by around 90% in the most serious grades of PIVIE as measured by the IEGS. The decrease in PIVIE severity is a novel finding and might represent an opportunity for a critical advancement in neonatal care.

In interpreting the outcomes of this study, it is important to consider the impacts of statistical modelling and clinical confounding variables such as catheter material alongside the introduction of sensor technology. It is notable that some ORs reported as statistically significant ($p<0.05$) in the uni and multivariable modelling analysis are very close to 1.0. This indicates a minimal effect size and raises questions about the clinical relevance of

Table 5 Univariable logistic regression analysis for PIVIE

Factor	B	SE	P value	OR	95% CI
Sex	0.018	0.024	0.447	1.02	0.97 to 1.07
Gestational age at birth	−0.039	0.012	<0.001	0.96	0.94 to 0.98
Current gestational age	−0.183	0.015	<0.001	0.83	0.81 to 0.86
Age at insertion	−0.011	0.001	<0.001	0.98	0.98 to 0.99
Weight at birth	0.009	0.012	0.479	1.01	0.98 to 1.03
Current weight	−0.102	0.014	<0.001	0.90	0.87 to 0.93
Reason of insertion	0.432	0.024	<0.001	1.54	1.47 to 1.61
Type of catheter	0.029	0.008	<0.001	1.03	1.01 to 1.05
Number of attempts	0.022	0.024	0.353	1.02	0.98 to 1.07
Insertion site—extremity	−0.011	0.018	0.562	0.99	0.96 to 1.03
Insertion site—side of insertion	−0.020	0.024	0.413	0.98	0.94 to 1.03
Reason for removal	0.188	0.008	<0.001	1.21	1.19 to 1.23
Dwell time	−0.011	0.001	<0.001	0.98	0.98 to 0.99
Year of insertion	0.009	0.024	0.720	1.01	0.96 to 1.06

Factors from the univariable analysis were included if $p<0.005$. Variables were removed from this model using a backward elimination process based on the Wald value, with the removal criteria set at $p<0.001$. Constant B=−2.306, SE=0.105, $p<0.001$, OR=1.00. Nagelkerke R^2=0.081.
PIVIE, peripheral intravenous infiltration and/or extravasation.

Table 6 Multivariable logistic regression analysis for PIVIE

Factor	B	SE	P value	OR	95% CI
Age at insertion	−0.010	0.001	<0.001	0.99	0.98 to 0.99
Current gestational age	−0.241	0.016	<0.001	0.79	0.76 to 0.81
Reason of insertion	0.456	0.025	<0.001	1.58	1.50 to 1.66
Reason for removal	0.208	0.008	<0.001	1.23	1.21 to 1.25
Dwell time	−0.012	0.001	<0.001	0.99	0.98 to 0.99

PIVIE, peripheral intravenous infiltration and/or extravasation.

these findings. In this study, the large sample size plays an important role in negating this concern. With large samples, statistical power increases substantially and even very small differences are more easily detected. As a result, the p value becomes sensitive to trivial differences, which can lead to findings that are statistically significant but clinically negligible. Consequently, clinicians should avoid relying solely on p values when interpreting results and attention to the clinical relevance of the findings should be given.

Stepwise procedures, such as backwards elimination using an arbitrary statistical threshold (eg, p<0.001) as a removal criterion, have been criticised for potentially generating unstable models.[28] A strict p value cut-off may result in the exclusion of clinically important variables that exhibit only modest statistical effects but are necessary for adjusting bias in the relationship between independent and dependent variables.[28 29] To mitigate this, combining statistically grounded and knowledge-based confounder selection can yield more robust and interpretable models.[30] While this approach improves conceptual validity, using a stringent threshold like p<0.001 can also reduce the inclusion of variables that are only coincidentally associated with the outcome (ie, Type I errors). Focusing on variables that meet both statistical and clinical relevance criteria offers a pragmatic compromise between model complexity and stability, particularly in contexts where the primary aim is prediction rather than causal explanation.

The explained variance in the logistic regression model, the Nagelkerke R^2 of 0.081, is low. At first inspection, this figure suggests a model with limited explanatory power (only 8.1% of the variance in the dependent variable is explained). However, the interpretation of this metric should be more nuanced in the context of logistic regression. Unlike in linear regression, where R^2 represents a direct proportion of explained variance, the Nagelkerke R^2 does not have the same intuitive meaning and is not linearly interpretable. In models where the dependent variable involves binary or rare outcomes, such as the occurrence of a clinical event (eg, PIVIE), or disease, or an accident, low R^2 values are common, even when the predictors are clinically relevant and statistically significant. This is because much of the unexplained variance is often due to chance, measurement error, biological variability, or unknown factors that are not included in

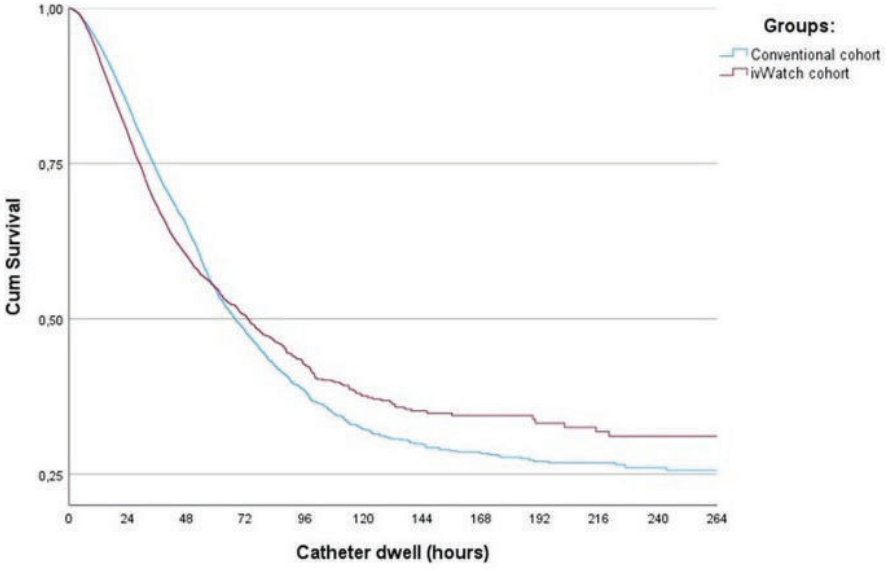

Figure 2 Kaplan-Meier analysis for PIVIE on catheter dwell. Log rank (Mantel-Cox) x2= 931.20, 0= 3, p<0.001. The HR for the year of inclusion on the event PIVIE = 0.62 (95% CI = 0.60 to 0.65). PIVIE, peripheral intravenous infiltration and/or extravasation.

the model. Nonetheless, despite these constraints, the identified associations provide important insight into potential risk factors for PIVIE and should be interpreted accordingly.

The study spanned 4 years, with 2 years (Phase 1) without sensor technology (conventional) and 2 years (Phase 2) with sensor technology (ivWatch) as an adjunct. During the first year (2019), PTFE-based Neoflon catheters were predominantly used. From the second year (2020) onward, there was a transition to catheters made from PUR, including Neoflon Pro and SuperCath. This change in materials may have influenced the incidence and severity of PIVIE independently of the sensor technology, although no significant effect was found in the analysis. PUR catheters are known for their flexibility and biocompatibility, which might reduce the risk of infiltration and extravasation compared with PTFE catheters.[31–35] Therefore, the observed reduction in PIVIE severity after the introduction of sensor technology may be partially attributable to the concurrent switch to PUR catheters. Further research is warranted to disentangle the effects of catheter material from those of continuous monitoring technology on PIVIE outcomes.

Our study is not without other limitations. The single-centre setting limits generalisability to other neonatal intensive care settings, while the retrospective, non-randomised design may be subject to confounding due to unmeasured clinical variables.

Irrespective, the reduction in PIVIE severity is particularly noteworthy. Results from this study suggest that the ivWatch system can improve early detection, simplifying the management of PIVIE and confirming those reported previously.[15–17 27] By identifying infiltration events at a much earlier stage, healthcare providers can intervene sooner and thereby reduce patient harm. This finding positions the ivWatch system as a potentially transformative tool in neonatal vascular access care. The ability to detect PIVIEs early before they lead to severe harm could significantly improve patient outcomes and set a new standard for vascular access care. However, further study is required across different practice settings using research designs that can account for all confounding variables and demonstrate the superiority of this combined approach to infusion site monitoring.

CONCLUSION

The findings from this study confirm the high incidence of PIVIE in neonatal populations reported in other studies and the need to develop preventative strategies. Less severe PIVIEs require simpler management and are more likely to have fewer long-term sequelae. This study uniquely highlights the positive impact of integrating advanced optical sensor monitoring technologies like ivWatch with systematic healthcare staff observation tools (TLC) on the severity of PIVIEs. While further research is required to confirm this finding, routine use of this technology has the potential to lead to better patient and family experience from less exposure to complications.

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