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Optical detection of infiltration during peripheral intravenous infusion in neonates

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Abstract

Background: Infiltration and extravasation are common complications during peripheral intravenous infusion in the neonatal intensive care unit, and diagnosis is usually clinical, by inspection and palpation. Delay in diagnosis due to poor surveillance or misinterpretation of clinical signs may carry serious damage to the tissues of the neonate. Recently, a novel technology based on optical detection of infiltration has become available.

Methods: We have studied two groups of term and preterm infants receiving non-vesicant intravenous infusions by the peripheral route (24G short peripheral cannulas), and we evaluated the incidence of infiltration. In the first group, we have compared the clinical detection of infiltration versus the detection obtained by a novel optical device, blinding the alarms of the device. In the second group, the comparison was carried out without blinding the alarms.

Results: Of the neonates included in this study, 60% were female, 86% had a gestational age <37 weeks (34 ± 2.5 weeks) and a mean birth weight of 2.08 ± 0.4 g. Total recorded monitoring time was 1318 h and average monitoring time for each short peripheral cannula was 26.4 h. The incidence of infiltration was 80%, most of them having a Millam score <2. The novel device showed an overall sensitivity of 88.9% in detecting infiltration. Specificity was 84.4%, as evaluated assuming as standard the clinical diagnosis. Interestingly, in cases of documented infiltration, the event was diagnosed by the optical device approximately 6 h before the clinical diagnosis.

Conclusions: Continuous monitoring of the insertion site, as automatically ensured by this novel optical device, may play a complementary role in early detection of infiltration, even if the percentage of false positives and false negatives suggests that periodic clinical assessment by expert nurses cannot be omitted.

Keywords

Short peripheral cannula, extravasation, neonates, near infrared light, intensive care, new devices, techniques and procedures

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Introduction

Short Peripheral Cannulas (SPCs) are the most common venous access devices used in hospitals, but they are prone to many complications (phlebitis, thrombosis, occlusion, dislodgment, infiltration, extravasation) which limit their duration.[1,2] In neonates, SPC failure often occurs because the infusate leaks out of the vein into surrounding tissue; this complication is called "infiltration" (if the leakage involves non-vesicant solutions) or "extravasation" (in case of vesicant solutions).[3,4] The reported incidence of infiltration in the neonatal intensive care unit (NICU) ranges from 23% to 78% and is associated with potential long-term sequelae.[5] NICU patients are at high-risk for

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infiltration due to their intrinsic characteristics: poor and fragile vein asset, frequent and uncontrolled movements,[6] need for prolonged intravenous administration of drugs and fluid. Early detection of infiltration implies periodic assessment of the insertion site of the SPC used for continuous infusions, so to identify swelling, pain, redness, warmth, or other signs suggesting fluid leakage inside the tissues. An early identification of such complications can minimize its consequences.

Recently, a new device has been developed—the iv Watch Model 400 (manufactured by the company iv Watch, LLC, VA, USA)—which is designed to assist health professionals in the early "automatic" detection of infiltration, by means of an optical sensor, roughly similar to a pulse oximeter. The model 400 of iv Watch supports a disposable electronic sensor (SmartTouch sensor) which should be able to detect even minimal, non-clinical infiltration; this has been tested in pediatric patients[7] and it may be potentially useful also in neonates.

The purpose of our study was to investigate whether the iv Watch SmartTouch sensor (ISTS) might be helpful in the early identification of SPC-associated infiltration, if compared with the current standards of clinical surveillance in neonates. As in our study all SPCs were used exclusively for non-vesicant solutions, the efficacy of ISTS in detecting extravasation was not considered.

Materials and methods

Study design and population

This was a prospective, interventional cohort study divided in two phases. In both phases of the study, we enrolled term and pre-term infants, with birth weight >1.5 kg, requiring 24G short peripheral catheters (SPC) for continuous intravenous non-vesicant infusions for >24 h. All infusions and drugs delivered via the peripheral route were non-vesicant, according to our hospital policies.

Exclusion criteria were: birth weight ⩽1.5 kg; discontinuous or short (⩽24 h) intravenous infusion; indication to infusions preferably requiring a central venous access; skin abnormalities which may interfere with the optical sensor and/or with the clinical detection of infiltration.

The ivWatch system is intended to be used to detect infiltrations and extravasations of optically clear solutions, but this study was not limited to monitoring infusions with optically clear infusions only. The results include data from off-label use.

The study was carried out in the 16-bed NICU of a large University Hospital, after proper authorization of the local Ethics Committee (Prot. 811221; Trial registration number NCT05638971).

Intervention

All SPCs were inserted according to the local protocols and all of them were monitored by ISTS.

Figure 1. The ivWatch SmartTouch sensor is placed adjacent to the 24G short peripheral cannula.

The RaSuVA protocol[8] was adopted to select the most appropriate vein in terms of visibility, palpability, and linearity of course. The skin's condition above the vein was carefully evaluated to avoid areas with previous puncture-related or infusion-related complications (phlebitis, infiltration, etc.). When veins were difficult to visualize, a portable hands-free device using near-infrared light to identify superficial veins (Veinsite, Veutek, USA) was utilized.[9] Only 24G cannulas were used during the study. The skin was prepared with 2% chlorhexidine in 70% alcohol. SPCs were inserted by standard no-touch technique and sterile gloves. The insertion site was covered with a semi-permeable transparent membrane. The time of SPC insertion, as well as any difficulties in placing the catheter, were properly recorded in a computer database.

Immediately after SPC placement, the ISTS was placed adjacent to the vein, not to exceed 1 inch (25.4 mm) from the insertion site, without obstructing the inspection of the insertion site (Figure 1). The monitor was started just before starting the continuous intravenous infusion.

Photographs of the ISTS and of the insertion site were taken at this time. Once the ISTS was in place on the infant, the automatic collection of data was started immediately, according to the instructions for use of the device, and kept working for the whole duration of the dwelling time of the SPC.

The insertion site of the SPC was periodically assessed by the NICU nurses according to the local protocol: the site was classified using an adapted scale after Millam[10] and graded using Visual Infusion Phlebitis Score scale.[11] After each assessment, the nurse pressed a specific button on the ISTS monitor, so to record the assessment time in the memory of the ISTS. If infiltration or other infusion-related complications were identified during such assessment, the infusion was stopped, and the cannula was removed. If no complication occurred, the SPC was removed at the end of its use, after a small saline flush (to ensure that the tip of the catheter was still inside the vein). At the time of removal (either because of complication or because end of use), photographs were taken again, to

assess whether the ISTS had caused any skin irritation or disruption to the skin integrity (i.e. tearing or removal of skin layer).

The difference between the two phases of the study was based on the alarms-off or alarms-on of the ISTS monitor.

First phase of the study

Twenty-five neonates meeting the inclusion/exclusion criteria were consecutively enrolled in the first phase of the study.

All neonates had an SPC associated with an ISTS device. In this first phase of the study, the device was set up so to monitor the insertion site of the SPC, automatically collecting data, but without any alarm notification.

The goal of this first phase of the study was to investigate the incidence of infiltrations clinically detected during the study period and of the infiltrations automatically detected by ISTS, so to obtain a blind comparison between nurse-detected infiltrations and ISTS-detected infiltrations. The purpose was to quantify the accuracy of ISTS in terms of false positives and false negatives (thus considering clinical detection of infiltration as the current standard and regarding ISTS as the new methodology to be tested); also, we evaluated the time delay between ISTS detection and clinical detection.

Our endpoints were: (a) feasibility of ISTS-detection of infiltration, evaluated as the possibility of placing the device without errors and without early alarms during the first minutes of infusion; (b) sensitivity of ISTS, evaluated as a percentage of false positives (number of infiltrations detected by ISTS but not by the nurses), (c) specificity of ISTS, evaluated as percentage of false negatives (number of infiltrations detected by nurses but not by ISTS), (d) time delay between ISTS-detection and nurse-detection of the infiltration.

Second phase of the study

Twenty-five neonates meeting the inclusion/exclusion criteria were consecutively enrolled in the second phase of the study.

All neonates had an SPC associated with an ISTS device. In this second phase of the study, the device was set up so to monitor the insertion site of the SPC, collecting data but also sending visual and audible notifications in case of signs of infiltration.

The nurses inspected periodically the insertion site, as for the local policies, but they also checked the insertion site in case of alarm signals from the ISTS: if the visual inspection confirmed the suspect of infiltration, the SPC was removed; if not, the alarm was reset and the infusion was maintained.

The goal of this second phase of the study was to investigate the number of infiltrations detected during the study period, assessing the clinical usefulness of IVW in detecting infiltration, through a non-blind comparison between clinically detected infiltration and ISTS-detected infiltration, leaving the nurses free to agree or disagree with the ISTS-based diagnosis of infiltration.

Our endpoints were: (a) feasibility of ISTS-detection of infiltration, evaluated as the possibility of placing the device without errors and without early alarms during the first minutes of infusion; (b) sensitivity of ISTS, evaluated as percentage of false positives (number of infiltrations detected by ISTS but not confirmed by the nurses), (c) specificity of ISTS, evaluated as percentage of false negatives (number of infiltrations detected by nurses but not by ISTS), (d) time delay between ISTS-based diagnosis of infiltration and nurse-based diagnosis of infiltration.

Sample size and statistical planning

In a previous clinical study,[7] the ivWatch device has been estimated to detect approximately 80% of infiltrations before the clinician (difference between proportions, p1 = 90% vs p2 = 10%). Thus, an infiltration sample size of $n = 10$ was esteemed necessary to detect a significant difference between device and clinician in terms of sensitivity ($\alpha = 0.05$, power = 90%).

If infiltrations occur in 20% of SPIC in our NICU, approximately 50 SPCs were expected to be necessary to obtain 10 infiltrations. If 10 infiltrations would not have occurred within the first 50 enrolled cases studies, additional study subjects should have been enrolled.

Continuous data were described as mean and standard deviation or median and interquartile range, according to the distribution of data; categorical data were described as prevalence.

Results

Between August 2021 and May 2022, fifty neonates with SPCs were studied. Of the neonates included in this study, 60% were female, 86% had a gestational age smaller than 37 weeks (34 ± 2.5 weeks) and a mean birth weight of 2.08 ± 0.4 g. Details about the SPCs and the infusions are shown in Table 1. All patients were on continuous infusion with 10% glucose (46% of neonates) or with parenteral nutrition <800 mOsm/L (54%), but all of them received also boluses of drugs, as required. No abnormalities of the skin associated with the local application of the sensor were reported.

First phase of the study

Out of 25 consecutive cases, infiltration was clinically detected by nurses in 19 cases. In this subgroup of clinical infiltrations, the mean duration of the SPC was 21.8 h; in 13 cases, infiltration was detected both by ISTS and by

Table 1. Devices and infusions.

	50 patients	I phase	II phase
Insertion site			
Dorsum of the hand, *n* (%)	23 (46)	12 (48)	11 (44)
Forearm, *n* (%)	12 (24)	6 (24)	6 (24)
Foot, *n* (%)	13 (26)	6 (24)	7 (28)
Ankle, *n* (%)	2 (4)	1 (4)	1 (4)
Total monitoring time, h	1318	585	733
Mean monitoring time for each device, h	26.4	23.4	29.3
Infusate			
10% glucose, *n* (%)	23 (46)	10 (40)	13 (52)
Parenteral nutrition, *n* (%)	27 (54)	15 (60)	12 (48)
Infiltrations, *n* (%)	40 (80)	19 (76)	21 (84)
Millam score >2, *n* (%)	3 (7.5)	1 (4)	2 (8)

nurses, though ISTS detection occurred systematically earlier than clinical detection (with a mean time difference of 6.15 h and a median of 2.8 h); there were four false negatives (i.e. infiltration detected by nurses, but not by ISTS); in two cases, detection by ISTS was not considered reliable, since signs of infiltration were recorded few minutes after SPC insertion. Three of the four false negatives occurred in neonates receiving parenteral nutrition. In the subgroup of neonates who completed the IV treatment without clinical signs of infiltration (six cases), the mean duration of SPC was 28.5 h; there were four false positives (i.e. ISTS detected infiltrations that were not clinically evident).

Considering that in two cases ISTS was not reliable, the overall feasibility of IVW for detection of infiltration was 92% (23 cases out of 25). In the 23 cases studied in this first phase of the study, both the sensitivity of the method (total cases without the false negatives) and the specificity of the method (total cases without the false positives) were 83% (19 out of 23). The overall accuracy (defined as total cases without false positives and without false negatives) was 65% (15 out of 23).

Second phase of the study

Out of 25 consecutive cases, infiltration was detected in 21 cases. In this subgroup, the mean duration of the SPC was 28.2 h. In 17 cases, the infiltration was detected by ISTS: though, in all cases, the nurses did not remove the line at the time of the red alarm but waited until clinical signs of infiltration were evident so that there was a consistent delay between ISTS detection and SPC removal (a mean delay of 6.15 h and a median delay of 3.4 h). In one case, infiltration was clinically manifest, though ISTS did not detect it (one false negative); the neonate was receiving parenteral nutrition. In three cases, as in the first group of patients, detection by ISTS was not considered reliable since the alarm notification occurred few minutes after SPC insertion.

In the four cases without clinical evidence of infiltration, the mean duration of the SPC was 22.3 h. In all four cases, the ISTS device notified a red alert, but as no clinical signs of infiltration were evident, the SPC was left in place and the infusion treatment was completed (four false positives).

In this second phase of the study, the overall feasibility of ISTS for detection of infiltration was 88% (22 cases out of 25). In the 22 cases fully studied in this second phase of the study, the sensitivity of ISTS (total cases without the false negatives) was 95.4% (21 out of 22) and the specificity (total cases without the false positives) were 86.3% (19 out of 22). The overall accuracy (defined as total cases without false positives and without false negatives) was 77.3% (17 out of 22).

Combining the results of the two phases of the study, the applicability of the IVW method was 100%, its feasibility was 90%, its accuracy was 71.1%, its specificity 84.4%, and its sensitivity 88.9%.

The results are summarized in Table 2.

Discussion

In the 50 SPCs investigated in this study, the incidence of infiltration was 80.0%. This infiltration rate is very high but similar to the rate reported in a previous prospective study.[7] Infiltration is the most frequent complication associated with SPC in neonates, with a reported incidence between 23% and 78%.[12] The relationship between birth weight and incidence of infiltration/extravasation is controversial, as a significant association has been reported in some studies,[13] but not in others.[14,15]

Considering that the neonate is at risk for infiltration/extravasation for multiple reasons, early detection of such complication is of paramount importance in NICU, but it may be difficult to achieve because of inadequate staffing, high-acuity patients, or inability to visualize properly the insertion site. In this regard, a technology providing accurate early detection of infiltration/extravasation may be highly advantageous for the patient, for the clinician, and for the institution.

In a previous study,[7] the ISTS device demonstrated 80% sensitivity in detecting IV infiltration events, being capable of detecting infiltration before the clinician.

In our study, we have systematically investigated the applicability, the feasibility, and the overall accuracy of ISTS (including sensitivity and sensibility) in a group of 50 neonates requiring peripheral intravenous infusion for 24 h or more.

ISTS applicability was 100% since the monitoring device was easily applied to all neonates, without exception.

ISTS feasibility was 90%; though, actual feasibility may be close to 100%, considering that in our study we started the ISTS monitor before starting the intravenous infusion: this might have caused artifacts which could

Table 2. Clinical performance of ISTS.

	First phase (alarm off)	Second phase (alarm on)	Total cases
Feasibility	92% (23/25)	88% (22/25)	90%
Sensitivity	83% (19/23)	95.4% (21/22)	88.9%
Specificity	83% (19/23)	86.3% (19/22)	84.4%
Accuracy	65% (15/23)	77.3% (17/22)	71.1%
Earlier detection[a]	6.2 ± 3 (2.8)	6.1 ± 6 (3.4)	6.1 ± 5 (3.1)

[a]Value expressed as mean ± standard deviations (median), in hours.

account for the erroneous notifications of infiltration in the first minutes of SPC use (5 cases out of 50: 90%).

On the other hand, the accuracy of ISTS was relatively low (65% in the first phase of the study and 77.3% in the second phase of the study), due to a relevant incidence of false negatives (5 out of 50 cases) and false positives (8 out of 50).

Most of the false negatives (4 out of 5) occurred in neonates on parenteral nutrition, suggesting that the device might not be accurate in detecting infiltration when the infiltrated fluid is not a clear fluid. Indeed, the IFU state that the device "may have reduced sensitivity when used with dark, colored or cloudy fluids." This may be regarded as a relevant limitation in the actual applicability of the device, considering the high percentage of neonates receiving parenteral nutrition by the peripheral route.

On the other hand, false positives might be considered not as errors of detection but as real events of subclinical infiltration; though, it may be postulated that such subclinical events have little or no clinical relevance since in all eight cases of "false positive" the peripheral infusion was carried on and the intravenous treatment completed without any harm to the neonate.

More interestingly, in all cases of infiltration detected by ISTS, but also confirmed clinically, ISTS detection occurred earlier than clinical detection (approximately 6 h in advance). This might be a relevant advantage of ISTS, though it may be questioned whether such a limited period represents an actual benefit in terms of cost-effectiveness. The issue of cost-effectiveness has not been specifically addressed in our study. Though in terms of diagnosis of infiltration the accuracy of the device is apparently inferior to the accuracy of clinical surveillance, the earlier automatic detection of infiltration if compared to clinical detection may be an interesting advantage of the device. This time difference (approximately 6 h) is obviously related also to the policies of the NICU and its staffing. In our NICU, the nurse/neonate ratio is 1:2 or 1:3; in other NICUs with different nurse/neonate ratio, the time delay might be different. It may be postulated that ISTS detection of infiltration may become useful and cost-effective in NICUs where there is a shortage of nurses and relatively less attention to be dedicated to monitoring each IV line.

Last, the device was completely safe since the local application of the sensor was not associated with any skin alteration.

To the best of our knowledge, this is the second clinical study investigating the potential use of ISTS in premature newborns. A previous pilot study[14] on 23 SPCs in 15 preterm infants have suggested a sensitivity of 93.3% in detecting infiltration (only one false negative out of 15 infiltrations), quite to the sensitivity observed in our study (88.9%). Interestingly, all neonates in the study were receiving parental nutrition, but this apparently did not affect the sensitivity of the device. The number of false positives were not reported. Though, this pilot study, just like our study, is somehow biased by the high occurrence of infiltrations (65.2%).

Study limitations

One of the limitations is the choice of selecting neonates with birth weight >1.5 kg. The decision was taken because the sensor of the device may have been too large for very small babies.

The number of false-negative may be due to infusions with not clear fluids, such as parenteral nutrition with low osmolarity. This is a limitation of both the study and the device.

Another limitation is that all SPCs were inserted and monitored by a selected group of nurses highly skilled in neonatal vascular access, so our results in terms of clinical outcome and clinical diagnosis of infiltration cannot be extended to any NICU.

Last, in this group of neonates, the occurrence of infiltration was quite high (80%), and this may have affected the interpretation of the actual sensitivity and specificity of the device.

Conclusions

Our study evaluated the use of infrared technology for noninvasive, continuous monitoring of the insertion site of SPC in the preterm and term neonatal population. As prevention and early detection of complications are the goal of all healthcare providers, technology which allows continuous automatic monitoring is to be pursued. As regards

infiltration, clinical surveillance may not be sufficient, especially in large settings with high numbers of critically ill neonates. Continuous monitoring of the insertion site of SPCs, as automatically ensured by ISTS, may play a complementary role in early detection of infiltration, even if the limited accuracy of the device suggests that periodic clinical assessment by expert nurses cannot be omitted.

Abbreviations

short peripheral cannula: SPC; neonatal intensive care unit: NICU; ivWatch SmartTouch sensor: ISTS.

Data sharing statement

Deidentified individual participant data will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. Proposals should be submitted to vito.dandrea@policlinicogemelli.it

Declaration of conflicting interests

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