Peripheral Intravenous Therapy: Incidence of and Factors for Complications in a Neonatal Intensive Care Unit Population

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INTRODUCTION

Neonates admitted to a neonatal intensive care unit (NICU) rely highly on intravenous (IV) therapy for administering fluids, nutrients, blood products and medication. Neonates, particularly preterm or critically ill newborn infants, are slow to tolerate the introduction of enteral feeds because of delayed gastric emptying and intestinal peristalsis (1). When central lines are no longer necessary, venous cannulation via peripheral intravenous (PIV) catheters is the simplest and frequently used method for administration of infusion in the severely ill and premature population in the NICU (2,3). However, in this population PIV therapy is not without risk and complications as leaking, clotting, infiltration, extravasation, phlebitis, infection and necrosis of (sub)cutaneous tissue are frequently observed (3). The incidence of complications in PIV therapy has remained relatively constant over the last 30 years (2) with no studies reporting on complication rates in neonates during the recent 10 years. In general, complications including infiltration, leaking and occlusion account for the removal of 95% of all PIVs (4). These complications increase morbidity and prolong hospital stay which leads to an increase of treatment costs. Infiltration is the administration of IV fluids outside the vein (5). Since the dorsum of the hand and food is most commonly used for cannulation in neonates, infiltration can cause permanent skin damage and cause nerve or tendon damage, which may lead to loss of movement over joints (6).

Placement of a PIV is a painful procedure and the American Academy of Paediatrics stresses that the number of painful disruptions in neonatal care must be minimized (7). It is therefore important to limit the number of painful procedures, and thus limit the number of attempts needed to insert a PIV. Unfortunately, in current practice often more attempts are necessary for successful placement of a PIV due to the particularly tiny veins of neonates. Furthermore, premature infants are particularly vulnerable to infections due to their compromised immune system (8). The repeated attempts for insertion break the skin barrier and predispose the neonate to infections (3). PIV lines are often left in situ in neonates until complications arise (3). Practice shows that due to complications, PIVs in neonates often need daily replacement. Replacing a PIV means yet another invasive and painful procedure with a risk for infections.

Before 2010, in The Netherlands, the limit of viability was set at 25 weeks gestational age (GA). Due to a change of the Dutch law in October 2010, in Dutch NICU's infants with a GA of 24 weeks and up are admitted. Because of this, the survival of the extremely premature infants has significantly increased. Due to this change in policy more extremely low birth weight (ELBW) infants are admitted to the NICU. These ELBW infants are even more prone to encounter complications in PIV therapy because they are longer in need for a PIV.

In order to reduce the incidence of complications, specially trained vascular access teams (VATs) have demonstrated effectiveness in reducing IV complications (8-13). The most important tasks of a VAT are insertion and maintenance of IVs, staff education on optimizing sterile techniques and trouble shooting of catheter problems (8,9).

PROBLEM STATEMENT, AIM AND RESEARCH QUESTIONS

Three months before this study a VAT was implemented in the Wilhelmina Children's Hospital (WKZ) in The Netherlands. This VAT was implemented to improve PIV management and aims to reduce PIV complications and lower the attempts at PIV placement before successful insertion. To improve PIV management a clear understanding of factors associated with complications in PIV management is required. The aim of this study is therefore to quantify the incidence and type of complications and to identify factors associated with these complications.

Research questions are: a) what is the incidence and type of complications related to PIV management in neonates admitted to the NICU of the WKZ in The Netherlands? b) which factors are associated with PIV complications in this population? c) how many attempts are needed for one successful PIV insertion and d) what is the relationship with the clinician's professional background?

METHOD

Data source and study population

A prospective observational design was used to examine PIVs in a NICU of a university medical center (UMC) situated in Utrecht, The Netherlands. A VAT operating within the NICU provides elective PIV placement for the admitted neonates. The study unit is primarily designated for critically ill neonates.

All consecutive neonates in need of a PIV and admitted to the NICU of the WKZ in The Netherlands from January 1st 2014 until March 31th 2014 were eligible to the study. The exclusion criteria were neonates with major congenital malformations (of the veins) and neonates in need for total body cooling for the management of hypoxic ischaemic encephalopathy that result in hindered intra venous access.

To guarantee a representative sample of the NICU population we expected that a sample including 100 PIVs would be sufficient to provide a heterogeneous sample that contains all important factors that contribute to complications and is large enough to deal with potential biases. Based on previously collected data it was expected that in a three month period around 120 to 300 PIVs would be inserted.

The PIV data was collected on a PIV form that was developed and validated in the Sophia Children's hospital, Rotterdam, The Netherlands. The PIV-form is a customized data collecting form listing 8 items concerning patient characteristics, reason for PIV placement, discipline of the PIV inserter, PIV insertion attempts, location of the PIV, vein visualization device, PIV device and reason for PIV removal. The PIV-form was slightly altered by the coordinating investigator in cooperation with members of the VAT. Alteration consisted of adding the brand of the PIV devices and the vein visualization devices used in the hospital under research were added to the form. The adapted PIV form was discussed and assessed by specialists until consensus was reached. The adaptation did not influence the overall skill of the form. Immediately after insertion and upon removal of the PIV, data were collected with the PIV form by the inserter or remover of the PIV.
This study was approved by the Women and Baby division of the UMC Utrecht in The Netherlands. The study protocol (protocol number 14-031/C) was approved by the local Medical Ethics Committee. The study consisted of observations only and data were stored and analysed in such a manner that individual patients cannot be identified directly.

Outcome measures
Details of patient characteristics were collected. Outcome of interest was based on PIVs placed in neonates and included 1) patient characteristics, 2) characteristics of devices that were used, 3) type of the complications, 4) number of insertion attempts in relation to the profession of the inserter 5) indwelling time, 6) factors related to complications.
Rationale for the PIV insertion, insertion sites, catheter used, discipline of the inserter and insertion aid used were also documented.

Statistical analysis
Descriptive analyses were performed. Differences in each categorical variable were assessed using chi-square test. The outcome variable is a categorical variable and the predictor variables are continuous and categorical, therefore binary logistic regression analysis was used to determine the most significant contribution to complications. The forced entry method is used to test all predictor variables in one block. The following variables were entered in the model: birth weight, indwelling time, number of insertion attempts, diagnosis, reason for PIV placement, profession of the inserter, number of insertion attempts, PIV device, vein visualization device and location of the PIV. In this approach the predictive ability is assessed while controlling for the effect of the other variables in the model. The assumption that there are no high intercorrelations between predictor variables was assessed by collinearity statistics. Cox & Snell R Square and Nagelkerke R Square was

used to test the usefulness of the model. The Chi square test and non-parametric test were used for categorical data and Mann Whitney test was used for continuous variables. All statistics were performed using SPSS (version 20.0; SPSS Inc., Chicago, IL, USA) and $p < .05$ was considered statistically significant.

RESULTS

Population

Between January 1st 2014 and March 31nd 2014, a total of 242 catheters were successfully inserted in 103 infants (Table 1). Patient characteristics were reported on 103 infants and catheter characteristics, complication rates, associated factors for complications and insertion attempts per clinicians' professional background are reported on 242 catheters. Patients were eligible if they were admitted to the neonatal ward and underwent placement of a PIV. No patients were excluded. The mean birth weight was 1798 grams with a minimum of 560 grams and maximum of 4540 grams. The mean GA gestational age was 32 weeks with a minimum of 24.4 weeks and a maximum of 42.2 weeks. The most common diagnose for admission was prematurity (66%).

[Table 1 about here]

Complication rate and catheter characteristics

Removal of the catheter because of any type of complication occurred in 61 % (n = 148) and 49 catheters (20%) were elective removed because IV therapy ended. Procedural and catheter information of successful insertions are presented in Table 2. The predominant reason for non-elective removal due to complication was infiltration n = 106 (72%) followed by leakage of the catheter n = 22 (9%). (Table 3.).

A total of 40 PIVs had a missing on reason for removal (17%). The characteristics of the group with reported reasons for catheters removal did not significantly differ from the group with missings on catheter removal reasons on GA ($p < .09$) and birth weight ($p < .08$). The mean indwelling time was 47 hours ± 41 (SD).

[Table 2 about here]

[Table 3 about here]

Factors associated with PIV complications in this population

Skin color, GA, diagnosis, inserting discipline, insertion aid used, catheter used, location of the catheter and reason for catheter placement were tested for significant contribution to the model. The full model containing all predictors was statistically significant, Chi square 49,18

(11, *n* = 197), *p* <.001, indicating that the model was able to distinguish between PIVs that were removed due to a complication and PIVs that were electively removed.
The model as a whole explained between 22% (Cox and Snell R square) and 33% of the variance in complication status, and correctly classified 81% of the cases.
Four independent variables made a unique statistically significant contribution to the model: location of the PIV, PIV material, birth weight and reason for PIV placement (all *p* <.05). The strongest predictor for a PIV of being removed caused by a complication was the 24 g BD Insyte-N® PIV, recording an odds ratio of 6.50. This indicated that 24 g BD Insyte-N® PIVs were 6 times more likely to be removed caused by a complication than other PIVs, controlling for all factors in the model. In our logistic regression model the 24 g BD Insyte-N® PIV had an odds ratio of 6.50 which ranged from 1.801 to 23.485. The confidence interval in this case does not contain the value 1, therefore this result is statistically significant at *p* < .05. The odds ratio of 0.285 for 'location of the PIV on the dorsum of the hand' was less than 1, indicating that for every additional PIV placed at the dorsum of the hand, the PIV was 0.285 less likely to be removed caused by a complication, controlling for all factors in the model.

Attempts needed for successful insertion of the PIV

The infants under study acquired 1 to 10 attempts before successful insertion (mean 2.15, median 2.0).There was a significant association between the clinician's professional background and whether or not the PIV was successfully inserted; Chi square (df 4) 12.4, *p* = .015. This seems to represent the fact that, based on the odds ratio, the odds of a PIV being inserted with success were 2.12 times higher if they were inserted by a neonatologist than If they had been inserted by a medical student in residency. Physician assistant (PA) versus medical student in residency 1.81; neonatologist versus IV nurse 1.75; PA versus IV nurse 1.49; Neonatologist versus PA 1.17 (Table 4).

[Table 4 about here]

DISCUSSION

This study shows that 61% of the PIVs were removed because a complication occurred. The most frequent observed complication was infiltration (72%). Factors that are associated with complications are location of the PIV, reason for PIV insertion, birth weight and PIV material. Furthermore, this study shows that neonatologists have the highest success rate for PIV insertion.
The complication rate of 61% in the study population is 10% higher compared to the complication rate of a previous prospective study by Garland et al that found a complication

rate of 50% in a pediatric intensive care unit (14). Differences may be caused by the fact that our population consists of significant younger and more vulnerable infants. In addition, a review on techniques for maintaining catheter security found a complication rate ranging from 0% to 78% (2). The complication rate in our study may also be biased by a high number of missing data. Reasons for PIV removal was missing in 17% of the catheters. The main type of complication in the recent study was infiltration, accounted for 72% of all complications. Other studies also show that infiltration is the most commonly identified complication of PIV therapy with reported incidences between 23% and 78% (2).

In addition, we were interested to identify factors associated with PIV complications. The strongest predictor for a PIV being removed caused by a complication was the 24 g BD Insyte-N. The material of the BD catheter is Vialon®, whereas the material of the other four catheters under study is Teflon®. The results of this study suggest that catheters with Vialon® material are more prone to complications. On the contrary, a study that compares Teflon® and Vialon® catheters reported that Vialon catheter material reduced the risk of infiltration by 18% in a neonatal population, and by 35% in the ≤ 1500 grams subsample (15). Although an odds ratio of 6.50 indicated that the 24 g BD Insyte-N® were 6 times more likely to be removed caused by a complication, we can be 95% confident that the actual value of odds ratio in the population lies somewhere between 1.801 and 23.485, which is a wide range of values. This indicates that our sample was small. A subsequent study with a larger sample is warranted to explore a more precise effect of the catheter material. In the third week of the study a new needle with safety device to prevent needle stick injuries for healthcare workers was introduced (24g Braun®). This could influence outcome, however the results of this study suggest that there is no indication that the 24g Braun® contributes to the occurrence of complications.

The ratio of the numbers of events per variable analyzed in this study is small and therefore impedes further analysis. Problems can occur when a logistic model contains few events relative to the number of independent variables being evaluated (16). Therefore the significance of the location of the PIV (dorsum of the hand), reason for insertion (adverse event previous PIV) and birth weight (< 1000 grams) should also be interpreted with caution. The clinicians' professional background was not significantly associated with complications. This confirms the findings of a recent study which describes that a well-trained and dedicated VAT employing a high procedural volume can have beneficial patient- and device related outcomes that are not necessarily linked to the clinicians' professional background (17).

A total of 560 attempts resulted in a success rate of 242 insertions in 103 infants. A median attempt rate of 2.0 was found, ranging from 1 to 10 attempts. This is similar to the study of Franck et al. (4) who reported 1 to 12 attempts needed for successful insertion (median 2.2). Possibly the recently installed VAT at the NICU under research could increase the success rate over time since they will become more skilled after repeated insertions and education. Neonates are more sensitive for pain than older children and this hypersensitivity is exacerbated in preterm neonates (18,19). Unfortunately, these critically ill infants have to endure failed attempts. Less attempts means less painful interruptions and less multiple time consuming attempts before successful placement.
The results suggest that the number of attempts needed for successful insertion is linked to the clinician's professional background. The neonatologist in our study is the only professional that has more successful than failed attempts, i.e. the highest success rate for PIV insertions. The PA is second best in successful insertions, followed by the VAT-nurse. The medical student in residency needs the most attempts. This suggests that consistently and repeatedly performing PIV insertions neonatologists and PAs are likely to become more skilled compared to medical students in residency that perform these interventions less often (11). It is expected that the VAT nurses in the recently implemented VAT develop expertise in PIV insertion. This will lead to will increase successful insertions over time.

Strengths and weaknesses

Although PIV placement is one of the most routine procedures in pediatric and neonatal care, there are limited published data on this procedure (20). A strength of this study is that our results may help to fill the gap in knowledge. Another strength is that this study focuses on all important factors that may contribute to complications in PIV management. To our knowledge this is the first study reporting on insertion attempts per clinicians' professional background in a NICU setting.
Although we analyzed a cohort of 242 PIVs some limitations should be considered. First, the missing data of the reason for PIV removal was large. It is expected that due to hectic proceedings at the ward, the PIV form was not consequently filled in. Second, the sample was small and therefore the result of the logistic regression should be interpreted with caution. Third, the results reflect PIV complications of a NICU of a single university medical center.

Repeated and prolonged pain exposure alters the neonates pain processing, long-term development, and behaviour (18,19,21). Therefore, the aim is to decrease the number of attempts needed for successful insertions and decrease infection rates and complications.

Based on the results of the present study, the neonatologists and physician assistants should be the preferential PIV inserter. In addition, the VAT nurses of the recently installed VAT team will become more skilled in inserting the catheters and it is expected that their success rate will increase over time. When these dedicated IV-nurses have similar success rates as the neonatologists and physician assistants they can contribute to the well-being of the neonate and at the same time decrease the workload of the neonatologists and physician assistant.

CONCLUSION

This study reveals that the majority of PIVs were removed after the occurrence of a complication. The most common complication in PIV therapy is infiltration. Factors for complications are location of the PIV, reason for PIV insertion, birth weight and PIV material. Neonatologists have the highest success rate for PIV insertions.

RECOMMENDATIONS

An ongoing effort is still needed to reduce complication rates and insertion attempts in the NICU population. A well designed prospective multicentre study with a large sample size focussing on PIV material and PIV location could further explore the risk factors. Moreover, to prevent missing data, future studies in the Wilhelmina Children's hospital could benefit from a data collecting form that is part of the electronic patient file.

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TABLES

Table 1. Patient characteristics.

	n (%)	Mean (SD)
Total patient	103	
Male gender	55 (53)	
Birth weight in grams		1798 (± 980)
Birth weight		
≤ 1000 gram	22 (21)	
> 1000 and ≤ 1500 gram	29 (28)	
> 1500 gram	52 (51)	
Gestational age in weeks		31.9 (± 4.8)
Diagnosis		
Prematurity	68 (66)	
Gastrointestinal	10 (10)	
Pulmonology	8 (8)	
Cardiac	3 (3)	
Other	14 (13)	

Table 2. Procedural and catheter information of successful insertions.

	n (%)	Mean (SD)
Successful insertions	242	
Number of attempts per patient		2.15 (± 1.56)
Indwelling time in hours		47.3 (± 41.1)
Inserting discipline		
Physisician assistant	67 (28)	
Neonatologist	65 (27)	
IV-nurse	57 (24)	
Medical student in residency	45 (19)	
Other	8 (3)	
Insertion aid used		
Astodia®	120 (50)	
Wee Sight®	34 (14)	
None	81 (34)	
Unknown	7 (3)	
Catheters used		
24 g BD Insyte – N®	100 (41)	
26 g Terumo / Versatus®	79 (33)	
24 g Braun®	32 (13)	
24 g Bioflow®	17 (7)	
24 g ABBO cath®	7 (3)	
Other	7 (3)	
Location of the catheter		
Dorsum of the hand	88 (36)	
Foot	50 (21)	
Under arm	40 (17)	
Elbow	21 (9)	
Wrist	13 (5)	
Ankle	10 (4)	
Head	6 (3)	
Lower leg	6 (2)	
Other	8 (3)	
Reason for catheter placement		
Adverse event previous catheter	147 (61)	
Blood transfusion	42 (17)	
After CL removal	15 (6)	
Medication/fluid administration	17 (7)	
Sepsis work up	5 (2)	
Preoperative	7 (3)	
Other	9 (4)	

CL = central line; IV = intravenous

Table 3. Reasons for catheter removal.

	n (%)
Total catheters	242
Successful completion/end of therapy	49 (20)
Reasons for early catheter removal	148 (61)
Infiltration	106 (72)
Leaking catheter	22 (15)
Catheter occlusion	6 (4)
Phlebitis	4 (3)
Catheter dislodgement	2 (1)
Other	8 (5)
Reason unknown	40 (17)
Transfer	5 (2)

Table 4. Number of insertion attempts per clinicians professional background.

	Successful attempt	Failed attempt *n* (%)	Total	Best inserters
Total	242	318 (57)	560	
Neonatologist	65	58 (47)	123	1
Physician assistant	67	70 (51)	137	2
IV nurse	57	89 (61)	146	3
Medical student in residency	45	85 (65)	130	
Fellow	6	13(68)	19	
Anesthesiologist	1	2 (67)	3	
Unknown	1	1 (50)	2	

IV= intravenous

Nederlandse samenvatting (299 woorden)

Titel: Perifere infusen: de incidentie en factoren voor complicaties in een neonatale intensive care unit populatie.

Inleiding: Neonaten op een neonatale intensive care unit (NICU) zijn afhankelijk van perifere infusen (PIV) voor het toedienen van voeding, vocht en medicatie. PIVs leiden vaak tot complicaties met een verhoogde morbiditeit, mortaliteit, verlengde opnameduur en verhoogde ziektekosten. Het plaatsen van een PIV is een pijnlijke procedure en het aantal prikpogingen moet tot een minimum worden beperkt.

Strategieën om PIV management te verbeteren vragen om een duidelijk beeld over factoren die van invloed zijn op complicaties en het aantal prikpogingen.

Doel en onderzoeksvragen: Doel van deze studie is het kwantificeren van de incidentie en soort complicaties en het identificeren van beïnvloedende factoren om PIV management te verbeteren. Onderzoeksvragen zijn: a) wat is de incidentie van complicaties en welke soort complicaties komen voor in de NICU populatie? b) welke factoren zijn van invloed op het ontstaan van complicaties? c) hoeveel prikpogingen zijn nodig voor het inbrengen van een PIV? en d) is er een relatie met de discipline van de PIV inbrenger?

Methode: Prospectief observationeel design voor analyse van PIVs bij neonaten opgenomen op de NICU van het Wilhelmina kinderziekenhuis in Utrecht.

Resultaten: Bij 103 neonaten werden 242 PIVs ingebracht. Dit resulteerde in complicaties bij 61% van de PIVs met infiltratie als meest voorkomend. Factoren van invloed op het ontstaan van complicaties: PIV indicatie, locatie van de PIV, PIV materiaal en geboortegewicht. Er waren 2.15 prikpogingen nodig om een PIV succesvol in te brengen. De neonatoloog had de minste prikpogingen nodig.

Conclusie: Bij de meerderheid van de PIVs trad een complicatie op waarbij infiltratie het meest voorkwam. Neonatologen hebben het minst aantal prikpogingen nodig.

Aanbeveling: Een verder gaande inspanning is nodig om in de toekomst complicaties te voorkomen en het aantal prikpogingen te verminderen.

Trefwoorden: Complicaties, Neonaten, NICU, Perifeer infuus.

ABSTRACT (299 words)

Title: Peripheral Intravenous Therapy: Incidence of and Factors for Complications in a NICU population.

Background: Neonates admitted to a neonatal intensive care unit (NICU) rely highly on intravenous (IV) therapy. Peripheral IV (PIV) catheters are frequently used vascular access devices. In this population PIV complications are frequently observed. These complications increase morbidity, prolong hospital stay and increase treatment costs. Placement of a PIV is a painful procedure and repeated attempts for successful insertion should therefore be limited. Strategies to improve PIV management require a clear understanding of associated factors of PIV complications and repeated attempts.

Aim and research questions: The aim of this study is to quantify the incidence and type of complications and to identify associated factors in order to improve PIV management. Research questions are: a) what is the incidence and type of complications related to PIV management in neonates? b) which factors are associated with PIV complications in this population? c) how many attempts are needed for one successful PIV insertion and d) what is the relationship with the clinician's professional background?

Method: A prospective observational design was used to examine PIVs of neonates admitted to the NICU of the Wilhelmina Children's Hospital, The Netherlands.

Results: There were 244 PIVs inserted into 103 infants. Removal of the PIVs due to complications occurred in 61%. Predominant complication was infiltration (72%). Reason for PIV placement, location of the PIV, PIV material and birth weight appeared to be statistically associated with complications. A mean insertion attempt rate of 2.15 was found with neonatologists showing the lowest number of attempts.

Conclusion: The majority of PIVs were removed after the occurrence of infiltration with neonatologists showing the highest success rate for PIV insertions.

Recommendation: An ongoing effort is still needed to reduce complication rates and insertion attempts in the NICU population.

Keywords: Complications, Neonates, NICU, peripheral IV.