

Peripheral intravenous cannulation: complication rates in the neonatal population: a multicenter observational study

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ABSTRACT

Introduction: Neonates admitted to a neonatal intensive care unit (NICU) rely highly on intravenous (IV) therapy, for which the peripheral intravenous cannula (PIVC) is the preferred device to allow such therapies to proceed. Placement of a PIVC is a painful procedure and repeated attempts for successful insertion should therefore be limited. We aimed to quantify the incidence, complications, and factors associated with these complications.

Methods: We conducted a prospective observational study to examine PIVC-related complications in level III NICUs of two university medical centers (UMC) in The Netherlands. We performed descriptive analyses and binary logistic regression analysis to identify factors associated with PIVC complications.

Results: A total of 518 catheters were inserted in 235 infants. The first-time success rate was 45%. The predominant reason for non-elective removal due to complications was infiltration (N = 193; 67%). No significant association was found between discipline of the inserter, vein visualization device and location of the PIVC and whether or not a catheter needed to be removed due to a complication.

Conclusions: In this study the majority of PIVCs were removed after the occurrence of a complication. The most common complication was infiltration. Strategies to identify and prevent infiltration in an NICU population are required. Future interventional studies should attempt to improve first-time insertion success and reduce PIVC failure from infiltration in the neonate. Based on the results of the present study, neonatologists and physician assistants are the preferential PIVC inserters. Advanced training of all members of vascular access specialist teams and ongoing monitoring of PIVC-related complications are recommended.

Keywords: Peripheral complications, Neonates, Insertion

Introduction

Neonates admitted to a neonatal intensive care unit (NICU) rely highly on vascular access for administering fluids,

nutrition, blood and blood products and medication. In particular, preterm or critically ill infants are slow to tolerate the introduction of enteral feeding because of immaturity of the gastrointestinal tract, delayed gastric emptying and intestinal peristalsis (1). Peripheral intravenous cannula (PIVC) is the most common method to administer medication in premature infants in the NICU (2). Although PIVC placement is one of the most routine procedures in pediatric and neonatal care, there are limited published data on this procedure in NICUs (3). PIVC therapy is not without risk. Complications such as clotting, occlusion, leakage, infiltration, extravasation, phlebitis and infection occur (2, 4). The incidence of these complications has remained relatively constant over the last 30 years (2) with no studies reporting on complication rates in neonates during the last decade. Infiltration, leaking, and occlusion account for the removal of 95% of all PIVCs (5). Infiltration is the unintended

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administration of non-vesicant intravenous (IV) fluid outside the vein (6). Infiltration can cause permanent skin damage of the hand, foot and scalp and cause nerve or tendon damage, which may lead to loss of movement over joints (7). These complications increase morbidity and prolong hospital stay, which may lead to higher treatment costs.

Placement of a PIVC is painful and the American Academy of Pediatrics stresses that the number of painful disruptions in neonatal care should be minimized (8).

In a recent study from The Netherlands (9), the mean number of painful procedures per neonate per day was 11.4 (SD 5.7). In an earlier Canadian study this number was even as high as 16 (10).

To limit the number of painful procedures it would be important to reduce the number of attempts needed to insert a PIVC. Successfully inserting a PIVC on the first attempt in premature infants is difficult and often the neonate is subjected to unsuccessful attempts.

Furthermore, premature infants are vulnerable to infections due to their compromised immune system (11). A high complication rate and thus decreased indwelling time as well as repeated attempts for PIVC (re-)placement consequently will damage the skin barrier and further predispose the infants to infections (12).

One intervention that may help reduce the number of attempts and the incidence of post-insertion complications is setting up a group of dedicated healthcare professionals, which the literature refers to as a vascular access specialist team (13, 14). With this approach the vascular access specialist team have clinical responsibility for vein assessment, PIVC insertion and maintenance, along with staff education and trouble-shooting of catheter problems (11, 15). In prospective studies, activities of such teams proved effective in reducing IV complications (11, 15-19).

In two NICUs in The Netherlands, a recent expansion of the role of the IV nurse in vascular access specialist teams was initiated at the Wilhelmina Children's Hospital (WKZ) and the Sophia Children's Hospital (SKZ). The IV nurses were implemented to improve PIVC management and thus reduce PIVC complications and the number of attempts at PIVC placement before successful insertion.

The aim of this study is (i) to quantify the incidence and type of complications in these two hospitals and (ii) to identify factors associated with these complications such as PIVC insertion by a discipline of the PIVC inserter: neonatologist, physician assistant, IV nurse, or resident. We hypothesized that a good understanding of PIVC complications in neonates will increase the quality and safety of IV management.

Method

Patients and settings

A prospective observational design was used to examine two cohorts of neonates with PIVCs in level III NICUs of two university medical centers (UMC) in The Netherlands. Both study units are primarily designated for critically ill neonates.

We included all consecutive neonates in need of a PIVC and admitted to the NICUs between September 1st 2013 and March 31st 2014.

We excluded neonates with major congenital malformations of the veins and neonates requiring total body cooling for the management of hypoxic ischemic encephalopathy that obstructed intravenous access.

We calculated that a sample of at least 200 PIVCs was clinically pragmatic and sufficient to provide a heterogeneous sample that contains all important factors that contribute to complications and is large enough to deal with potential biases (20).

Data collection

PIVC data were collected on a case report form validated in SKZ, Rotterdam, The Netherlands. The following data were noted: insertion and removal dates and times, eight items concerning patient characteristics, reason for PIVC placement, discipline of the inserter, vein assessment, number of insertion attempts, location of the PIVC, PIVC device size and reason for PIVC removal. Elective PIVC removal is defined as removal in the absence of an indication for IV therapy or IV medication.

The inserter or remover of the PIVC entered the data on the case report form immediately after insertion and upon removal of the PIVC.

Ethics

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 analyzed in such a manner that individual patients cannot be identified directly.

Outcome measures

Outcomes of interest included (i) patient characteristics; (ii) skin color; (iii) diagnosis; (iv) characteristics of devices used; (v) type of the complications; (vi) number of insertion attempts in relation to the discipline of the inserter; (vii) indwelling time; (viii) factors related to complications.

Statistical analysis

Descriptive analyses were performed. The categorical variables skin color, diagnosis, PIVC brand, PIVC location, vein visualization device, discipline of the inserter and birth-weight group were compared between the two settings using Chi-square test or Fisher's exact tests.

Binary logistic regression analysis was used to determine a contribution to the occurrence of complications. The forced entry method was used to test all predictor variables in one block. The following variables were entered in the model: birth-weight group (i.e. <1000 g, >1000 g, ≤1500 g, >1500 g, discipline of the inserter, vein visualization device and location of the PIVC. In addition, binary logistic regression analysis was used to determine factors associated with insertion success. 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 inter-correlations between predictor variables was assessed by collinearity statistics. Cox

& Snell R squared and Nagelkerke R squared were used to test the usefulness of the model.

All statistics were performed using SPSS (version 20.0; SPSS Inc., Chicago, IL, USA) and $p < 0.05$ was considered statistically significant.

Results

Between September 1st 2013 and March 31st 2014, a total of 518 catheters were inserted in 235 infants (Tab. I). The mean birth-weight was 1709 g with a minimum of 365 g and maximum of 4540 g. The mean gestational age (GA) was 31 weeks and 4 days with a minimum of 23 weeks and 6 days and a maximum of 42 weeks and 2 days. The most common diagnosis for admission was prematurity (68%). In 69% of the study population the skin color was white. No insertion aids were used in 38% of all insertion attempts. The first-time success rate was 45% (N = 234).

Complication rate and catheter characteristics

Procedural and catheter information of successful insertions are presented in Table II. Removal of the catheter because of any type of complication occurred in 56% (N = 288) of patients. The predominant reason for non-elective removal due to complication was infiltration (N = 193 [67%]) followed by leakage of the connection of the PIVC hub to the IV administration set (N = 53 [18%]) (Tab. III).

In the WKZ, 20% of removals were elective on the grounds of end of IV therapy versus 7% in the SKZ.

The reason for removal was missing in 150 PIVCs (29%). The mean indwelling time was 47 hours \pm 43 (SD); it was

TABLE I - Patient characteristics (n = 235)

	n (%)	Mean (SD)
Total patients	235	
Patients from SKZ	134	
Patients from WKZ	101	
Total of inserted catheters	518	
Male gender	131 (56)	
Birth-weight (g)		1709 (940)
Birth-weight		
≤ 1000 g	61 (26)	
> 1000 and ≤ 1500 g	64 (27)	
> 1500 g	110 (47)	
Gestational age in weeks		31.4 (4.8)
Diagnosis		
Prematurity	159 (68)	
Pulmonology	27 (12)	
Gastrointestinal	12 (5)	
Infection	8 (3)	
Cardiac	6 (2)	
Other	23 (10)	

SKZ = Sophia Children's Hospital; WKZ = Wilhelmina Children's Hospital.

TABLE II - Procedural and catheter information

	n (%)	
Catheters	518	
Number of attempts per patient; mean (SD)	2.22 (± 1.58)	
Maximum attempt rate	10	
First time success rate	234	
Indwelling time in hours; median	34.1	
Inserting discipline		
Neonatologist	149 (28.8)	
Junior doctor	126 (24.3)	
Residents	121 (23.3)	
IV nurse	72 (13.9)	
Other	27 (5.2)	
Missing	23 (4.4)	
Vein visualization device		
Astodia®	204 (39)	
Wee Sight®	55 (11)	
Veinviewer	27 (5)	
None	194 (38)	
Unknown	38 (7)	
Catheters (caliber)	Material	
24 g BD Insyte – N®	Vialon	234 (45)
26 g Terumo/Versatus®	Teflon	208 (40)
24 g Braun®	Teflon	33 (7)
24 g Bioflow®	Teflon	18 (4)
24 g ABBO cath®	Teflon	7 (1)
Other		6 (1)
Missing		12 (2)
Location of the catheter		
Dorsum of the hand		197 (38)
Foot		118 (23)
Lower arm		78 (15)
Wrist		35 (7)
Elbow		32 (6)
Ankle		16 (3)
Head		15 (3)
Lower leg		10 (2)
Other		17 (3)
Reason for catheter placement		
Adverse event previous catheter		319 (62)
Blood transfusion		68 (13)
After CL removal		22 (4)
Sepsis work up		25 (5)
Other		62 (16)

CL = central line; IV = intravenous; SD = standard deviation.

TABLE III - Reasons for catheter removal (n = 518)

	n (%)
Successful completion/end of therapy	69 (13.3)
Complication	288 (55.6)
Infiltration	193 (67.0)
Leaking catheter	53 (18.4)
Catheter occlusion	15 (5.2)
Other	27 (9.3)
Reason unknown	150 (29.0)
Died or transferred	14 (2.7)

TABLE IV - Number of insertion attempts and indwelling time per discipline

	Number of total attempts	Successful attempts (%)	Failed attempts (%)	Indwelling time in hours (mean and SD)
Neonatologist	273	149 (55)	124 (45)	49 (45)
Physician assistant	241	126 (52)	115 (48)	49 (47)
Resident	354	121 (34)	233 (66)	37 (35)
IV nurse	176	72 (41)	104 (59)	53 (43)
Other	67	27 (40)	40 (60)	42 (42)
Total	1111	495 (45)	616 (55)	47 (43)

IV = intravenous; SD = standard deviation.

longest when inserted by a member of the vascular access specialist team (Tab. IV).

Factors associated with PIVC complications in this sample

There was a significant association between birth-weight group >1500 g and whether or not a catheter needed to be removed due to a complication. Chi-square 13.40, $p < 0.001$ (df2). No significant association was found between catheter removal due to a complication and discipline of the inserter, vein visualization device and location of the PIVC. No association was found between the studied variables and number of insertions.

Attempts needed for successful insertion of the PIVC

One to 10 attempts (median 2) were needed for successful insertion. There was a significant association between the discipline of the inserter and whether or not the PIVC was successfully inserted; Chi square (df4) 33.8; $p < 0.001$. The odds of a PIVC being inserted with success was 2.3 times higher if inserted by a neonatologist than by a resident; 2.11 for physician assistant versus resident; 1.7 for neonatologist versus IV nurse; 1.6 for physician assistant versus IV nurse; and 1.1 for neonatologist versus physician assistant (Tab. IV).

Discussion

In this study 56% of the PIVCs were removed on the grounds of a complication, predominantly infiltration (67%). The factor that was associated with complications is birth-weight. Furthermore, neonatologists had the highest success rate for PIVC insertion.

The complication rate of 56% in the study population is higher than that of a previous prospective study (50%) (21). This may be explained by a shift from premature to extremely premature in the neonatal populations of the two Dutch centers. A review on techniques for maintaining catheter security found a complication rate ranging from 0% to 78% in the various studies (2). The complication rate in our study may be biased by the high percentage of missing reasons for catheter removal: 29% (Tab. III). Infiltration accounted for two-thirds of all complications. Additionally, in one study infiltration was the major complication of PIVC therapy with reported incidences from 23% to 78% (2).

Regarding factors associated with PIVC complications, the strongest predictor for PIVC removal on the grounds of a complication was birth-weight >1500 g. Significantly more PIVCs were inserted by residents in the birth-weight group >1500 g. Residents are still in training and have less experience in inserting PIVCs than neonatologists with many years' working experience. Residents are recommended to practice inserting a PIVC in larger neonates, which is assumed to be easier.

A subsequent study with a larger sample is warranted to explore a more precise effect of the other factors associated with PIVC complications.

The number of neonates with white skin color was larger at the WKZ than the SKZ. Inserting in a lighter skin is considered easier. However, in the SKZ fewer inserting aids were used; 43% of PIVC inserters at the SKZ did not use an inserting aid versus 32% in the WKZ. Despite the differences in skin color between institutions no difference in number of attempts needed for successful insertion was found.

Professional discipline was not significantly associated with complications. This confirms the findings of a recent study which describes that a well-trained and dedicated vascular access specialist team employing a high procedural volume can have beneficial patient- and device-related outcomes that are not necessarily linked to the clinicians' professional background (22).

A total of 1151 attempts resulted in 518 inserted PIVCs in 235 infants. The median attempt rate of 2.0 (range 1-10) compares well with the study reported by Franck et al (5), i.e. median 2.2 (1-12). Possibly a vascular access specialist team could increase the success rate over time since members will become more skilled after repeated insertions and education (14). Neonates are more sensitive to pain than older children and this hypersensitivity is exacerbated in preterm neonates (10, 23). Unfortunately, these critically ill infants endure failed attempts.

The results suggest that the number of attempts needed for successful insertion is linked to the professional background. We did not record the experience or procedure volume per inserter and therefore we cannot draw conclusions with regard to experience of the inserter. However,

the neonatologists and the physician assistants in our study had the highest success rate but have amassed more clinical exposure to PIVC insertion in the neonatal population. The residents needed the most attempts. This could suggest that consistently and repeatedly performing PIVC insertions makes neonatologists and physician assistants more skilled than residents, who perform these interventions less often (19). However, to have 'experience' is not enough. Appropriate training is also required for peripheral vein cannulation in neonates. This training should include knowledge of appropriate materials and the most appropriate methodology. Healthcare professionals who insert PIVCs as in our study (i.e. neonatologist, physician assistants, residents and IV nurses) should be appropriately trained in specific neonatal PIVC procedures during their academic and employment training period. Additionally, revalidation should occur to ensure this clinical skill is contemporaneous and reflective of empirical guidelines and policy.

All complications detected in this study could be a way to measure outcomes of a standardized appropriate training. A dedicated vascular access specialist team is mandatory in cases of predicted difficult peripheral vein access in which ultrasound or near-infrared technology may be useful.

It is expected that when the vascular access specialist team nurses, who are trained and have appropriate knowledge of the materials, develop expertise in PIVC insertion, this will lead to an increase in successful insertions over time. However, PIVCs placed by an IV nurse had the longest indwelling time. We did not record the experience or procedure volume per inserter and therefore we cannot draw conclusions with regard to experience of the inserter.

Strengths and limitations

A strength of this study is a focus on all potential factors that may contribute to complications in PIVC management. To our knowledge this is the first study reporting on insertion attempts per clinicians' professional background in an NICU setting.

Although we analyzed a cohort of 518 PIVCs, a limitation should be considered. A large number of reasons for PIVC removal were missing, probably due to hectic proceedings at the ward, and lack of time to complete the case record form.

Repeated and prolonged pain exposure alters a neonate's pain process, long-term development, and behavior (10, 23, 24). Clinicians therefore should aim to limit the number of attempts needed for successful insertions and decrease infection rates and complications.

Conclusion

This study reveals that the majority of PIVCs were removed after the occurrence of a complication with the most frequent of these being infiltration. Based on the results of the present study, neonatologists and physician assistants should be the preferred PIVC inserters. Additionally, we expect that the nurses who recently joined the installed vascular access specialist team will become more skilled in inserting PIVCs as they increase their procedural hours and first-time insertion successes. As a result, they will likely develop expertise in

neonatal PIVC insertion resulting in improved and sustained success rate. We believe this model of care will allow vascular access specialist teams to provide PIVC insertion and maintenance in the neonate population. Furthermore, this could decrease the workload of the neonatologists and physician assistants with regard to PIVC insertion, and allow them attend to other clinical duties.

Recommendations

An ongoing effort is still needed to reduce complication rates and insertion attempts in the NICU population. Targeted strategies to identify and prevent infiltration in a NICU population are required. The use of a vascular access specialist team is clinically reasonable and justifiable, however, future interventional studies should attempt to improve first time insertion success and reduce PIVC failure from infiltration in the neonate population. These clinical outcomes should take into account the influence of clinician factors, patient factors, along with materials and products used.

Moreover, a case record form integrated in the electronic patient file is recommended as a feasible instrument to prevent missing data in future studies and to continuously monitor PIVC-related complications in clinical practice.

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