*Original research article*

JVA The Journal of Vascular Access

# Effect of peripheral intravenous catheter type and material on therapy failure in a neonatal population

The Journal of Vascular Access
1–9

DOI: 10.1177/11297298221080071
journals.sagepub.com/home/jva
SAGE

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## Abstract

**Background:** In neonatal settings vascular access devices are essential for treatment. However, their use is not without risks. The design and materials of peripheral vascular access devices have been evaluated amongst adult populations, but contemporary studies in neonatal settings are scant.

**Purpose/outcome measures:** This research describes the prevalence of peripheral intravenous catheter failure related to three different catheter types with the intent to identify modifiable risks that might be used to evaluate device efficacy, innovate neonatal practice, and support future policy developments.

**Method and setting:** This was a retrospective observational analysis of routinely collected anonymized intravenous therapy related data. The study was carried out at the tertiary neonatal intensive care unit (112 beds) of the Women's Wellness and Research Center of Hamad Medical Corporation, Doha, Qatar.

**Participants:** Neonates who were admitted to the unit requiring intravenous treatment wherefore peripheral intravenous cannulation was indicated, were included in this study.

**Results:** The use of different type of catheters resulted in significantly less therapy failures as phlebitis and increased dwell time, compared with the control groups. This remains significant after adjusting for age at insertion, gestational age, birth weight, and catheter type.

**Conclusions:** The study's findings are in accord with international literature concerning adult and pediatric patients concerning the superiority of PUR over PTFE catheters with respect to the risk of phlebitis and longer dwell times. However, the risk of failure of therapy did not differ between catheters. This finding is reassuring and supports practitioner judgment when selecting peripheral catheter devices.

## Keywords

Neonate, infusion therapy complications, peripheral vascular access devices

Date received: 24 September 2021; accepted: 24 January 2022

## Introduction

Intravenous (IV) therapy is one of the most commonplace interventions in neonatal intensive care units (NICU).[1] In most cases peripheral intravenous catheters (PIVC) provide the means for accessing the circulation. The preterm or sick neonate is more prone to complications caused by vascular access compared to other patient groups.[2–7] Risks associated with PIVC placement and use include pain, skin damage, sepsis, phlebitis, infiltration/extravasation, leakage, occlusion, dislodgement, and tissue necrosis.[2–7] The causes of this increased propensity for complications can

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be largely attributed to factors such as: immature skin structures, limited subcutaneous tissue, small veins, poor venous integrity, gender, chemical nature of the infusate, and pre-existing pathology.[6–9] Phlebitis is a complex complication of IV therapy and can be due to mechanical, infective, and chemical causes.[9] Though, often the exact causation is multifactorial in nature. Maki and Ringer[10] identified the critical importance of catheter material and design in contributing to the risk of PIVC related complications, including mechanical phlebitis. Indeed, Gaukroger et al.[11] have suggested that the cannulas chemical composition is the single most important factor in the determining the incidence and severity of infusion related thrombophlebitis.

### *Background*

The design of the modern (flexible catheter over a metal introducer stylet—"over the needle" configuration) PIVC can be traced to the work of DJ Massa and colleagues in the 1950s.[12,13] Initially, catheters were made from a synthetic plastic polymer, PVC (polyvinyl chloride). The arrival of polytetrafluorethylene (PTFE), a nontoxic, self-lubricating, kink resisting material, in 1969 and marketed as Teflon™ was associated with the first modern designs (e.g. BD Venflon™) becoming commonly used. However, designs compatible with small lumen neonatal blood vessels posed technical challenges and consequently took longer before been widely adopted into practice.

Design innovations of first-generation devices sought to improve functionality or patient and user safety, these included the addition of winged and non-winged options, flash back visualization chambers, and shrouded /safety needles. Catheter material innovations have included catheters manufactured from fluorinated ethylene propylene (FEP) (e.g. Smiths Medical Jelco®) and polyurethane (PUR) polymers, of varying proprietary chemical formulations (e.g. Braun Introcan Safety® 3, BD Vialon biomaterial™). These materials have been chemically engineered to improve patient experience, reduce complications, and increase dwell time. For example, PURs combine rigidity and high resistance to kinking during insertion whilst afterwards softening when exposed to intra lumen body temperatures. These thermoplastic properties are argued to combine ease of insertion, lowering the risk of mechanical phlebitis, and thus increase dwell times. Evidence for the superiority of PTFE over PVC and metal cannula and PUR over PTFE with regard to phlebitis risk and dwell time comes largely from small scale controlled studies with adult volunteers and real-world clinical studies.[11,14–19]

There is limited contemporary research evidence from large scale studies in neonatal populations regarding how factors like PIVC material affect IV therapy related outcomes. Currently there is limited standardization of practice and an absence of guidance on the optimal catheter material or design of PIVC for use with neonates. PIVC selection is largely based upon practitioner familiarity/preference or health economics (hospital purchasing decision) rather than empirical evidence about the best suited material. Therefore, the current study aims to evaluate the effects of PIVC material on neonatal peripheral IV complications, resulting in premature removal (failure).

## Methods

### *Design and setting*

This retrospective observational study used routinely collected existing anonymized IV data compiled between January 2019 and July 2020. The study was carried out on the NICU (112 beds) of the Women's Wellness and Research Centre (WWRC) of Hamad Medical Corporation (HMC), Doha, Qatar. The study protocol (MRC-01-20-594) was reviewed by the local institution review body (IRB) who approved the study and designated it as a "chart review."

### *Study outcome*

The outcome of interest was the occurrence of therapy failure in relation to PIVC device and material. Complications included: peripheral IV infiltration or extravasation (PIVIE), phlebitis, occlusion, dislodgement, and or accidental removal.

### *Participants and sample size*

Neonates who were admitted to the NICU requiring IV treatment using a 26G cannula were included in this study. Data on participants were excluded from the sample if: a PIVC exceeded 26G, or insertion was ultimately unsuccessful, or other vascular access devices were used for example, umbilical catheters, epicutaneo-caval catheters (ECCs), or the data was incomplete. An open inclusion of review charts was used during the study period to create a maximal set of data.

### *Procedure*

In our practice, 26G PIVCs are inserted if IV therapy is predicted to be required for up to 2 days. In situations where IV therapy is expected to be longer or involve non peripherally compatible fluids extended PIVCs or central venous access is preferred (Figure 1). During every patient assessment phase, the team followed a locally developed mnemonic the "5 Rights for Vascular Access," based upon a similar concept reported by Steere et al.[20] The mnemonic consists of ensuring: the right device, for the right vein, with the right therapy, for the right duration, and selected for the right patient.

As part of the insertion procedure a mandatory vascular assessment for the selection of suitable veins for PIVC placement is performed using the VeinViewer® (Christie

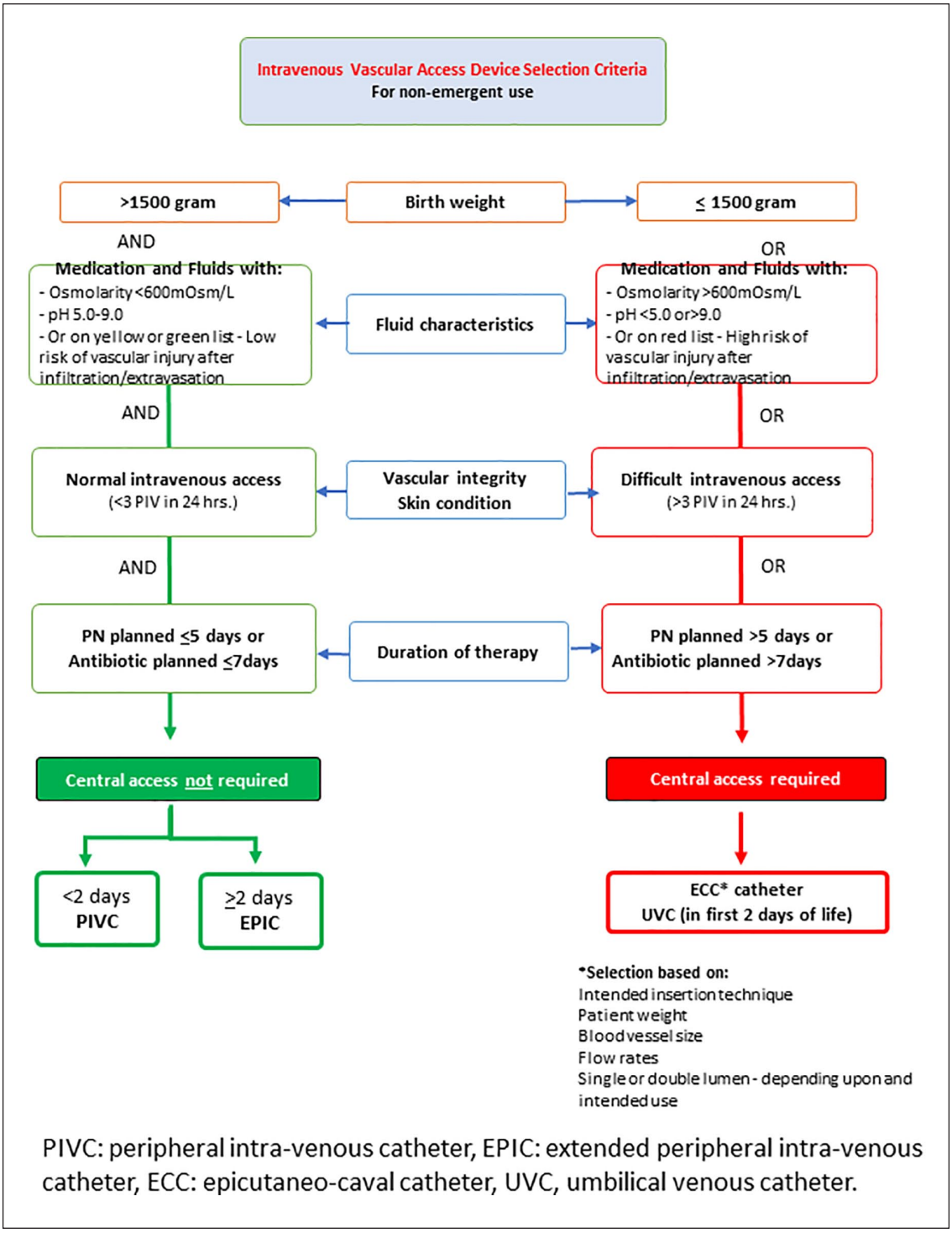


**Figure 1.** Vascular access device decisional algorithm (2020 version).

Medical Holdings Inc., Lake Mary, FL, USA). Vein length, potential valves, and potential for the vein to fill and empty itself are prior assessed during a standardized appraisal of the potential cannulation site. Proactive choices to prevent patients from running out of veins and being labeled as a difficult vascular access patient are key in the selection of cannulation site and intravenous catheter.[20] For that reason, saphenous and elbow veins are generally avoided for PIVC cannulation, being reserved for ECC placement.[21] Subsequently PIVC cannulation, securement, and use was performed according to hospital policy and international guidelines on infusion therapy.[21] In the study setting peripheral IV cannulation and securement (at the time using transparent

dressing, cyanoacrylate tissue adhesive, and flexible universal IV supports—UN27700, 365 Healthcare) is routinely performed by a dedicated nurse led neonatal vascular access team (NeoVAT).

In the study NICU, and in accord with hospital purchasing decisions the 26G PTFE Neoflon™ (Becton Dickinson Infusion Therapy, Sandy, UT, USA) catheters were used till the end of June 2019. After an extensive training program, the new type 26G PUR Neoflon™ Pro (Becton Dickinson Infusion Therapy, Sandy, UT, USA) catheters were introduced into the clinical setting and used between first of July 2019 and December 2019. From January 2020 onward the 26G PU SuperCath™ Safety (ICU Medical, San Clemente, CA, USA) was used. Standard aseptic techniques, preparation-, and insertion procedures were identical for all three types of PIVC.

### *Measurements and data collection*

Patients' demographics and baseline data included sex, gestational age at birth in weeks and days, age in days when the PIVC was inserted, birth weight and weight at time of insertion (current weight) both in grams. Relevant study data regarding the insertion procedure of peripheral intravenous cannulation included date and time of cannulation used type of vascular access device (VAD), for example, Neoflon™ 26G, Neoflon™ Pro 26G or SuperCath™ Safety 26G, side of the cannulation (left, right, midline), extremity of cannulation, as well as the number of attempts needed to achieve successful cannulation.

Directly after removal study data collected were date and time of removal of the PIVC, total dwell time of the PIVC in hours (calculated as the removal date and time minus the insertion date and time), and the reason for removal of the PIVC (elective removal, accidental removal, leaking, occlusion, phlebitis, PIVIE and patient transferred or died (administrative censoring)). Furthermore, additional data registrations included standardized PIVIE severity scoring in percentages.[22,23]

### *Statistical analyses*

Descriptive statistics were used to summarize the outcomes with a mean and its standard deviation or median and its minimum and maximum for continuous variables regarding its normal distribution, and absolute numbers with percentage for discrete variables. Chi squared, one-way ANOVA, Kruskal-Wallis, and unpaired *t*-testing were used to identify differences between study outcomes as appropriate. Any relation between independent variables with the outcome of interest was identified using univariate logistic regression analysis. Variables with significancy in the univariate analysis ($p < 0.05$) were used for multivariate logistic regression analyses. Using a backward elimination process based on the highest Wald score and lowest *p* value, the smallest set of factors with a significant relation which the occurrence of complications was identified. Survival analyses with Kaplan–Meijer curves and Mantel–Cox Log Rank Chi squared testing was used to look for differences between study groups regarding catheter dwell times. SPSS version 27.0 was used for statistical analyses, a $p$ value $<0.05$ was denoted as statistically significant.

## Results

During the study period data from a total of 12,713 neonates was collected, of which data on 1810 attempts to insert a PIVC resulted in a failure (Figure 2). These failures were excluded from follow up and further data analyses, because patients subsequently had alternative IV access. Therefore, data from 10,903 patients were included in this study and analyzed. Demographical and baseline data regarding the analyzed cohort are summarized in Table 1.

Throughout the study there were 13,744 insertion attempts performed to create peripheral intravenous access. The overall first attempt success rate during the study period for all catheter types was 77.9%. The number of attempts required to acquire IV access was lowest in the 26G Neoflon group, with a success rate of 81.4% ($p < 0.001$, $\chi^2 = 146.79$, df = 10). Detailed data regarding the procedure of peripheral intravenous cannulation is represented in Table 2, which is comparable between the three study groups.

Failure of therapy resulting in premature removal of the device, occurred in 6387 (59%) of participants. The highest failure rate was observed in the 26G Neoflon Pro group (63%), when compared to either 26G Neoflon (59%) and 26G SuperCath (52%) groups ($p < 0.001$, $\chi^2 = 93.34$, df = 2), as shown in Table 3. A mean PIVC dwell time of $36 \pm 24$ h was recorded in participants with no complications, whereas the mean dwell time was $29 \pm 22$ h in participants with an indication for therapy failure ($p < 0.001$, $t = 15.52$). The highest overall dwell time was recorded in the 26G SuperCath group when compared to the other study groups, with Log Rank (Mantel-Cox) $\chi^2 = 118.48$ ($p < 0.001$), as represented in Figure 3. Regarding the reason for removal of the IV device, these were comparable between al study groups. Only the incidence of phlebitis differed and was lower in the 26G SuperCath group (3%) when compared to the 26G Neoflon (12%) and 26G Neoflon Pro (13%) groups ($p < 0.001$, $\chi^2 = 212.20$, df = 2). The overall PIVC complication rate was 28 per 1000 device days.

Subgroup analyses were performed regarding a patient's body weight. Dwell time of the device did not differ between neonates with a body weight $<1500$ or $>1500$ g, with dwell time being $34 \pm 26$ h and $33 \pm 24$ h respectively ($p = 0.254$, $t = 1.14$). Despite, the incidence of complications was 52%

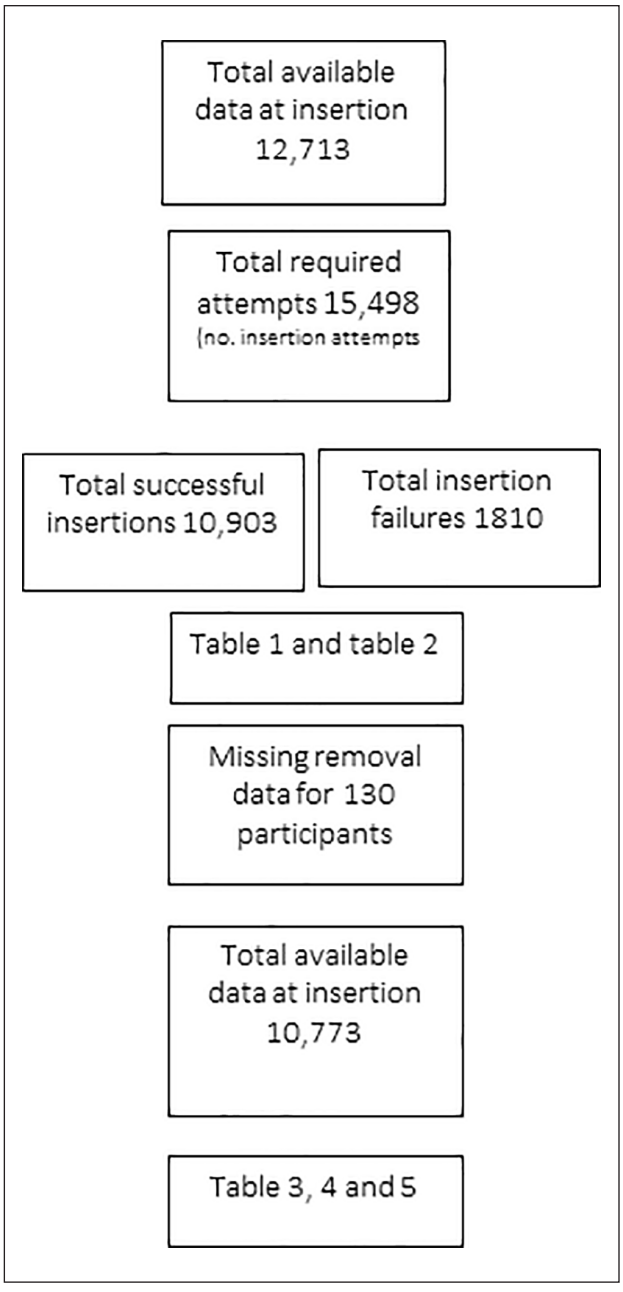


**Figure 2.** Participant flowchart.

in neonates with a body weight <1500 g and 60% in the group with a body weight >1500 g ($p < 0.001$, $\chi^2 = 42.41$, df = 1). Regarding prematurity, dwell times were significantly lower in patients with a gestational age at birth <36 weeks (31 ± 23 h) when compared to patients with a gestational age at birth >36 weeks (36 ± 25 h), with $p < 0.001$ ($t = 8.76$). This also applies to the incidence for complications, which was 62% with a gestational age at birth <36 weeks and was 53% in patients with a gestational age at birth >36 weeks ($p < 0.001$, $\chi^2 = 84.91$, df = 1).

**Table 1.** Baseline and demographic data.

| | |
|---|---|
| Gender | |
| Male | 6317 (58%) |
| Female | 4573 (42%) |
| Ambiguous | 13 (<0.12%) |
| Gestational age at birth | |
| Weeks | 34.5 ± 4.6 |
| Age from birth | |
| Days | 9.6 ± 19.5 |
| Weight at birth | |
| Grams | 2311 ± 985 |
| Current weight | |
| Grams | 2392 ± 925 |

Data is presented as mean ± standard deviation, or as absolute number (percentages).

Eleven factors (gender, gestational age at birth, birthweight, current weight, catheter type, catheter material, number of attempts, side and site of access, dwell time, reason for removal) were included in a univariate logistic regression analysis to determine which factors led to premature removal of the device. Four factors were identified as statistically significant with the outcome of interest and were included in further analysis. Table 4 presents the results of a multivariate logistic regression analysis using these factors. This analysis identified three factors with statistical significance in relation to the occurrence of a complication related to the PIVC. Specifically, these were: the type of catheter inserted ($p < 0.001$, OR = 0.85 [0.79–0.90]), the reason for removal of the device ($p < 0.001$, OR = 0.11 [0.10–0.12]), and the dwell time of the catheter ($p < 0.001$, OR = 0.97 [0.96–0.99]).

## Discussion

The incidence of PIVC failure impacts clinical practices, patient experience, wellbeing, and outcomes and hospital economics. Prolonging dwell times, maintaining patency, and avoiding therapy failure are important concerns given the limited number of useful veins for catheter insertions in most neonates. PIVC dwell time is highly variable and often cited in duration hours and maximally reported anywhere between 15 and 54 h. However, these figures are influenced by numerous confounding variables and are often highly contextual.[2–6,9,19–24–26] Consequently, claims for improved dwell times must be viewed in light of local circumstances.

Participants in this study sample were more mature and weighed more at birth than the unit profile. This observation reflects the selective use of PIVCs, based upon the decisional algorithm (Figure 1) used in this unit and might affect generalization of findings to other units with less

**Table 2.** Data related to the type of catheter inserted.

| | 26G Neoflon ($n = 3877$) | 26G Neoflon Pro ($n = 3936$) | 26G SuperCath 5 Safety ($n = 3090$) |
|---|---|---|---|
| Gender* | | | |
| Male | 2388 (62%) | 2280 (58%) | 1649 (53%) |
| Female | 1488 (38%) | 1650 (42%) | 1435 (47%) |
| Ambiguous | 1 (<1%) | 6 (<1%) | 6 (<1%) |
| Gestational age at birth** | | | |
| Weeks | 34.3 ± 4.6 | 34.9 ± 4.4 | 34.3 ± 5.0 |
| Weight at birth** | | | |
| Grams | 2283 ± 978 | 2344 ± 972 | 2305 ± 1012 |
| Current weight** | | | |
| Grams | 2331 ± 924 | 2441 ± 927 | 2405 ± 920 |
| Side of cannulation* | | | |
| Left | 2080 (54%) | 2135 (54%) | 1728 (56%) |
| Right | 1796 (46%) | 1801 (46%) | 1362 (44%) |
| Midline | 1 (<1%) | 0 (0%) | 0 (0%) |
| Site of cannulation* | | | |
| Ankle | 45 (1%) | 31 (<1%) | 12 (1%) |
| Elbow | 11 (<1%) | 3 (<1%) | 0 (0%) |
| Foot | 481 (12%) | 545 (14%) | 281 (9%) |
| Hand | 3221 (83%) | 3237 (82%) | 2694 (87%) |
| Lower arm | 97 (3%) | 112 (3%) | 90 (3%) |
| Lower leg | 8 (<1%) | 4 (<1%) | 7 (<1%) |
| Scalp | 1 (<1%) | 0 (0%) | 0 (0%) |
| Upper arm | 11 (<1%) | 4 (<1%) | 4 (<1%) |
| Upper leg | 2 (<1%) | 0 (0%) | 2 (<1%) |
| Insertion attempts*** | | | |
| Number of attempts | 1 (1–6) | 1 (1–3) | 1 (1–5) |

*Data is presented as absolute number (percentages), **mean ± standard deviation, ***median (minimum–maximum), as appropriate.

**Table 3.** Data related to removal based on material of the inserted catheter.

| | 26G Neoflon ($n = 3877$) | 26G Neoflon Pro ($n = 3936$) | 26G SuperCath 5 Safety ($n = 3090$) |
|---|---|---|---|
| Dwell time | | | |
| Hours | 34 ± 25 | 31 ± 23 | 35 ± 24 |
| Reason for removal | | | |
| Elective removal | 1538 (40%) | 1408 (36%) | 1331 (43%) |
| Administrative censoring | 44 (1%) | 38 (<1%) | 27 (<1%) |
| Failure of therapy: | | | |
| Accidental removal | 66 (2%) | 123 (3%) | 76 (2%) |
| Leaking | 476 (12%) | 376 (10%) | 413 (13%) |
| Occlusion | 113 (3%) | 201 (5%) | 117 (4%) |
| Phlebitis | 476 (12%) | 504 (13%) | 102 (3%) |
| PIVIE | 1163 (30%) | 1286 (33%) | 895 (29%) |
| No data/ missing | 1 (<1%) | 0 (0%) | 129 (4%) |
| Failure of therapy | | | |
| Yes | 2294 (59%) | 2490 (63%) | 1603 (52%) |
| No | 1583 (41%) | 1446 (37%) | 1487 (48%) |

Data is presented as mean ± standard deviation, or as absolute number (percentages), as appropriate.

selective PIVC protocols. For example, elective removal (i.e. completion of therapy) in this study was around 41%. This figure, though slightly higher is similar with contemporary figures published for adults,[8] children,[5] and

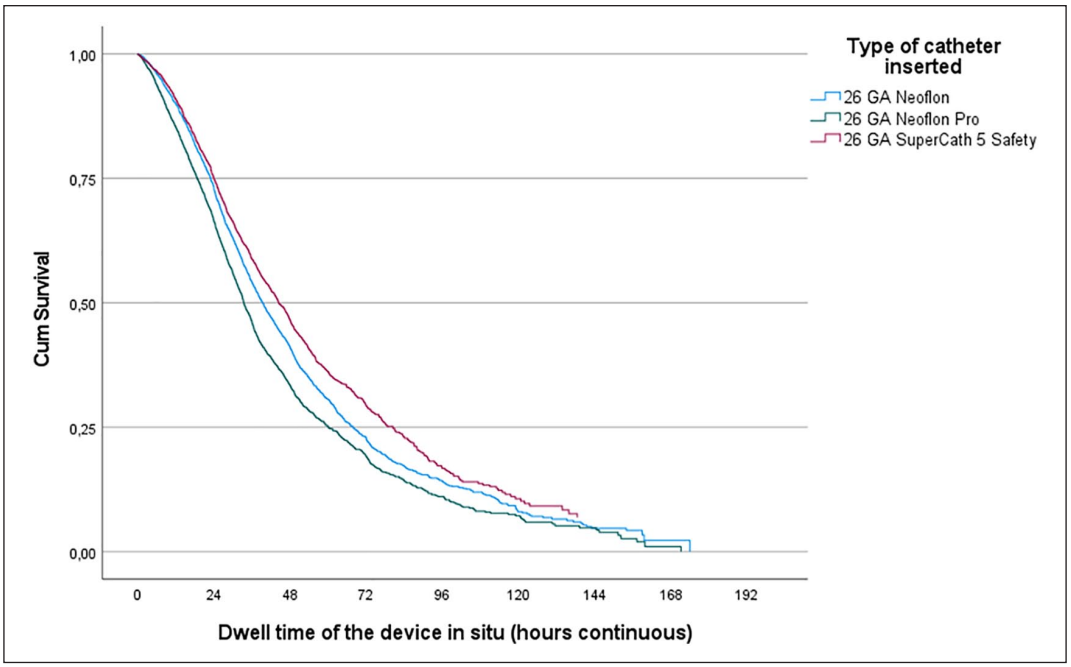


**Figure 3.** Survival analyses for a complication based on the type of catheter inserted.

**Table 4.** Multivariate logistic regression analyses for complications leading to premature removal of the device.

| Factor | *B* | SE | Odds | *p*-Value | 95% CI |
|---|---|---|---|---|---|
| Type of catheter inserted | 0.167 | 0.034 | 0.85 | <0.001 | 0.79–0.90 |
| Reason for removal | 2.210 | 0.047 | 0.11 | <0.001 | 0.10–0.12 |
| Dwell time | 0.012 | 0.001 | 0.97 | <0.001 | 0.96–0.99 |
| (Constant) | 4.607 | 0.307 | 2.21 | <0.001 | |

Model fit $R^2 = 71\%$.

neonates.[2,4] However, this finding is not comparable with older neonatal studies,[15,19,25] reflecting the effects of different study population demographics and IV access procedures.

In neonates, early studies were concerned with exploring the clinical and economic advantages of PTFE (Teflon™) devices over the then ubiquitous use of steel needles for IV access (e.g. Tobin,[15] Gupta et al.,[24] and Batton et al.[27]). Tobin,[15] examining the use of Teflon™ versus steel devices ($n = 72$) reported improved mean dwell (up to 30.1 h), less infiltration (57% in PTFE vs 100% with steel needles), and less phlebitis. Considering newer materials Stanley[28] showed that Vialon™ (PUR) catheters reduced the risk of infiltration by 18% (95% CI, 1%–32% reduction) in the total sample and by 35% (95% CI, 15%–50% reduction) in the higher risk low-weight (less than or equal to 1500 g) subsample compared to Teflon™ catheters. However, the pertinency of these findings, from comparatively small-scale studies to contemporary neonatal populations and IV practices should be considered with caution. Over recent decades potentially modifiable and unmodifiable risks factors in IV therapy have changed. For example, improved survival of smaller, more preterm infants has increased the complexity of technical challenges in obtaining and maintaining IV access. Newer device or securement options which were not previously available (e.g. Extended dwell catheters, securement glues, engineered IV stabilization devices) also likely influence outcomes. Furthermore, it might be that circumstances where PIVCs were used in the past are no longer considered preferable practices, making applicability to current clinical practice outcomes difficult.

The most frequently reported complication was PIVIE, leaking and phlebitis like other neonatal studies,[3,4] this was similar regardless of which PIVC material group the patient was in. Phlebitis was higher in participants with the PTFE Neoflon catheter and lower in the PUR groups. This finding concerning the superiority of PUR versus PTFE catheters for phlebitis risk is in accord with the literature.[14–18,28] The finding that, irrespective of phlebitis incidence the risk of therapy failure did not differ based on the material (PTFE or PUR) is interesting and requires further investigation to examine the impacts of additional confounding variables on modelling for IV therapy failure/success before a definitive statement can be made. Nevertheless, these findings are reassuring to practitioners making real-world decisions about which PIVC to use.

## Strength and limitations

To the authors knowledge, this is the only recent study to examine the effects of different PIVC materials in a neonatal population in this geographical region. All eligible neonates were included, the sample size was large and representative of the neonatal PIVC population. This increased the statistical power of the study's findings, helping to minimize selection bias, and increase the generalizability of the findings to similar settings.

Despite these strengths, there are limitations to this research. This study was a single center, retrospectively collected dataset. Inserter variability may have affected the results, however, the facility's use of a standardized education program and limiting vascular access procedures to members of a dedicated vascular access team (NeoVAT) may possibly have reduced data variability. Data outcomes that were not available for neonates (death or transferred out of the facility) were deemed as administrative censoring (in Table 3). Although this group was small ($n = 130$), patients lost to follow-up may have a differing outcome than those who completed the study.

## Conclusion

Recent evidence about the effects of catheter material in neonatal populations is limited. This large study has confirmed findings from studies in other patient groups and older small neonatal studies about the benefits of PUR over other materials in relation to some IV therapy related complications. Whilst the risk of complication is ever present in neonatal IV therapy and no choices are risk free these findings can inform discussions, and aid decisions about catheter selection and optimizing peripheral IV therapy in this vulnerable patient group.

In this study several variables demonstrated benefit from the use of a different catheter types and materials These included phlebitis, number of attempted insertions, and dwell time. The risk for developing phlebitis decreased significantly if the PUR SuperCath 5 was used. Furthermore, this study's findings tentatively support a view that catheter design/type and the material they are constructed from, rather than the catheter material alone is more predictive of some IV related complications. However, further study of the impacts of additional factors and confounding variables and how they are affected by catheter material is essential before definitive statements about optimal PIVC design and material can be made.

### Acknowledgements

The authors would like to thank the neonatal vascular access team and all our other colleagues in the NICU of the Women's Wellness and Research Center (WWRC). A special thank you for Ms. Lourthu Cecily Arul Raj, Ms. Ashamol Yohannankutty and Ms. Christina Keziah Taduran Amorado for their part in data collection and clearing and to Ms. Binsy Padinharayil for her administrative support in data preparation and initial graphical visualization.

### Author contributions

Matheus FPT van Rens was the main investigator, conceptualized and designed the study, coordinated, and supervised data collection, drafted the initial manuscript, and reviewed and revised the manuscript. Mohammad Adnan Mahmah and Kevin Hugill critically reviewed and revised the manuscript for important intellectual content. Airene LV Francia designed the data collection instruments, collected data, and reviewed and revised the manuscript. Fredericus HJ van Loon carried out the overall analyses, and critically reviewed the manuscript for important intellectual content and revised the manuscript. All authors approved the final manuscript as submitted.

### Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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