RESEARCH ARTICLE

Saline-Lock Versus Continuous Infusion: Maintaining Peripheral Intravenous Catheter Access in Children

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ABSTRACT

OBJECTIVES: In children, peripheral intravenous catheters (PIVs) are maintained by either a continuous infusion of fluid "to keep vein open" (TKO) or a saline lock (SL). There is a widespread perception that TKO prolongs PIV patency, but there is a lack of evidence for this. We hypothesized that there would be no significant difference in duration of PIV patency between TKO and SL.

PATIENTS AND METHODS: This prospective, time-allocated study included patients from newborn to 17 years of age admitted to our pediatric ward. Patients enrolled in the first 3 months were assigned to TKO, and patients in the latter 3 months were assigned to SL. Primary outcome was duration of functional patency of the first PIV during the time of TKO or SL. Secondary outcomes included PIV-related complications and patient and caregiver satisfaction.

RESULTS: Complete PIV data were available on 172 ($n = 85$ TKO, $n = 87$ SL) of 194 enrolled patients. The mean (SD) duration of PIV patency was 41.68 (41.71) hours in the TKO group and 44.05 (41.46) hours in the SL group, which was not significantly different ($P = .71$). There were no significant differences in complication rates or overall patient and caregiver satisfaction. One patient in the TKO group had their PIV removed because of risk of strangulation from tubing.

CONCLUSION: There were no significant differences between TKO and SL in the duration of PIV patency, complication rates, and overall patient and caregiver satisfaction in our pediatric population. Overall, SL is a safe and reasonable alternative to TKO in maintaining PIV patency in children.

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Deidentified individual participant data (including data dictionaries) will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available on publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be submitted to sepideh.taheri@lhsc.on.ca.

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Peripheral intravenous catheter (PIV) insertion is a necessary yet painful and invasive procedure performed on most children admitted to hospital.[1,2] Unfortunately, failure rates of PIVs have been reported to be as high as 69%.[3] Currently, there is a lack of evidence on how best to maintain PIV patency in children.[4,5] One method is to run a continuous intravenous (IV) crystalloid infusion at a low rate "to keep the vein open" (TKO).[2,6–9] An alternate option is the saline lock (SL) and intermittent flush method.[2,6–9] There is a widespread perception that TKO prolongs the life of the PIV because a continuous infusion of fluid may decrease the risk of clot formation in the catheter.[7,10] However, evidence in the neonatal population has revealed that there is no significant difference in the duration of PIV patency between neonates with TKO and SL.[7–9,11] To our knowledge, similar studies have not been performed in a pediatric population.

Patient satisfaction and safety also need to be considered when choosing options for maintaining PIV patency in children. Because of the continuous connection to IV tubing, many caregivers and patients find that TKO limits mobility and return to normal activities.[2,6] Furthermore, there have been recent case reports of infant strangulation from IV tubing.[12,13]

Our primary objective with this study was to compare the duration of functional patency of PIVs that are running a continuous TKO infusion with those that are SL in hospitalized pediatric patients. Secondary objectives included assessing PIV-related complication rates and patient and caregiver satisfaction between TKO or SL. We hypothesized that there would be no significant difference in duration of PIV patency between TKO and SL.

METHODS

Study Design and Setting

This was a prospective, time-allocated study to compare TKO and SL in maintaining functional duration of PIV patency in children. We recruited patients from the 68-bed pediatric inpatient ward of our tertiary-care Children's Hospital. The ward admits ~1800 children per year under general pediatric medicine alone, in whom ≥80% require intravenous placement. The ward includes general, subspecialty medical, and surgical pediatric patients. Recruitment period was from September 2018 to February 2019. All eligible patients enrolled during the first 3 months of the study were allocated to the TKO group, and those enrolled in the last 3 months were allocated to the SL group. Ethics approval was obtained from our university's Health Sciences Research Ethics Board.

Participants

We included patients 0 to 17 years of age admitted to our pediatric inpatient ward with an 18- to 26-gauge PIV in place. Exclusion criteria included patients with known hypercoagulability or on anticoagulant therapy, patients admitted under the hematology and oncology service, patients with central venous access, and patients who were enrolled in any other research study involving drugs or devices. Patients who were previously enrolled in the study were not included on subsequent admissions during the study time frame.

Recruitment occurred through convenience sampling. Given that both TKO and SL are considered standards of care, an integrated consent model was used.[2,6–9] This consent model allowed for verbal consent for study enrollment to be obtained by the patient's own care team (See Supplemental Fig 3 and "Integrated Consent Model Instructions for Bedside Nurse for Patient Eligibility and Consent" in the Supplemental Information). After arrival on the pediatrics ward, patients were screened for eligibility by the bedside nurse or research coordinator. If patients were found to meet criteria, the bedside nurse or research coordinator approached the patient or caregiver to obtain and document verbal consent. After enrollment, each child was anonymized and assigned a unique identifier. Once the patient no longer required continuous IV fluids for hydration, the PIV was switched to TKO or SL according to the allocation period. TKO was defined as a continuous infusion of crystalloid fluid run at a rate of 3 to 5 mL/h for PIVs gauge 24 to 26 and 5 to 10 mL/h for PIVs gauge 18 to 22. Crystalloid fluid options included 0.9% normal saline, dextrose 5% with 0.9% normal saline, dextrose 5% with 0.45% saline, dextrose 10% with water, and Ringer's lactate. The choice of fluid was made by the medical team. Per hospital protocol, the PIV was visually assessed by the bedside nurse every hour for complications. SL was defined as flushing the PIV with 1 to 3 mL of 0.9% normal saline before and after each point of care access and then locking it, and/or at minimum every 12 hours. The PIV was also flushed before any intermittent medication administration. Hospital policy discouraged the use of PIVs to draw off blood work. Hospital and study protocols were reviewed with nurses before the start of the study.

Outcomes

The primary outcome was the mean duration (hours) of functional patency of the first PIV placed in children while the PIV was running TKO or SL. Secondary outcomes included PIV-related complications and patient/caregiver satisfaction. Data were collected by the bedside nurse, including patient demographics, location and gauge of the PIV, time the PIV was inserted, time the PIV was made TKO or SL, time and reason the PIV was removed, complications of the PIV, and medications or IV fluids administered. Where there were several different IV fluids administered, the fluid thought to be most caustic to the vein (in the order of dextrose 10% with water, dextrose 5% with 0.45% saline, dextrose 5% with 0.9% normal saline, and 0.9% normal saline and Ringer's lactate being equivalent) was documented according to literature from Pettit.[10] Data were collected for the first PIV only. Functional PIV patency was defined as the ability to infuse fluid into the PIV in the absence of any complications. The duration of patency was calculated as the time between the PIV being made TKO or SL to the time the PIV was removed because of complications or as decided by the medical care team. Complications were defined as phlebitis (erythema with or without pain, edema, and/or purulent discharge), infiltration and extravasation (leakage of intravenous fluid from the vein into the surrounding tissue), dislodgement (PIV having fallen out from the vein), occlusion (the inability of nursing to flush fluid into the PIV), and other. Presence of

complications was determined by the beside nurse. At the time of discharge, caregivers and/or patients 12 years or older were provided a 5-question paper satisfaction survey regarding their PIV experience by their bedside nurse. Questions addressed themes of patient mobility, ease of performing activities of daily living, comfort, disruption of rest, and overall experience. Satisfaction was rated on a 5-point Likert scale for level of agreement to each survey question (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree). See Supplemental Table 4 for survey questions. The survey was collected by the bedside nurse before the patient leaving.

Statistical Methods

A sample size of 77 patients per group was determined with a significant mean (SD) difference of 12 (24.15) hours, 80% power, and 5% significance level.[4] On the basis of consensus from nurses and physicians, as well as from previously published literature, a 12-hour effect size was considered to be clinically significant.[7,9] Allowing for a 10% attrition rate, enrollment of 85 patients per group was completed. An independent *t* test was used to examine the mean difference in patency hours between the 2 groups. A Cox regression survival analysis was conducted to examine differences between groups in time until PIV failure, controlling for significant baseline variables (sex and IV fluid type); right-censoring was used for patients whose IV never failed. Independent *t* tests (or Mann–Whitney *U* tests, as appropriate) and χ^2 tests were used to examine differences between groups for continuous and categorical variables, respectively. All inferential tests were 2-tailed, with *P* values $<.05$ considered statistically significant.

RESULTS

Participants

A total of 194 patients (n = 99 TKO, n = 95 SL) were enrolled, with data available on 172 patients (n = 85 TKO, n = 87 SL) (Fig 1). Patient characteristics are described in Table 1. There were more male patients in the SL group (n = 58/87, 67%) compared with the TKO group (n = 44/85, 52%). There was also a significant difference in type of IV fluids used before the PIV being made TKO or SL, with (1) the TKO group receiving more dextrose 5% with 0.45% saline (n = 14/85, 17%) compared with the SL group (n = 4/87, 5%), and (2) the SL group receiving more normal saline (n = 17/87, 20%) compared with the TKO group (n = 2/85, 2%). Top 8 admission diagnoses are described in Table 2, which demonstrated no significant difference between TKO and SL groups.

Duration of PIV Patency

The mean (SD) duration of functional PIV patency was 41.68 (41.71) hours in the TKO group, and 44.05 (41.46) hours in the SL group (P = .71). The proportion of surviving PIVs at any given time was not significantly different between TKO and SL (P = .87) (Fig 2.)

Complications and Satisfaction

As shown in Table 3, the overall prevalence of patients with a complication was 28% (24 of 85) in the TKO group and 26% (23 of 87) in the SL group, which was not significantly different (P = .79). Some patients had >1 complication. One patient in the TKO group had a PIV-related complication documented as "safety: patient getting tangled in tubing, found around neck and in mouth." The most common "other" complications in both groups were "pain" (TKO n = 1 of 85, 1%; SL n = 4 of 87, 5%) and "leaking" (TKO n = 8 of 85, 9%; SL n = 5 of 87, 6%). Of the patients who had their PIVs removed by physician preference or at discharge, the mean (SD) and median (interquartile range; IQR) duration of PIV patency were 34.95 (30.52) and 28.72 (14.76–47.44) hours in the TKO group; in the SL group, they were 47.01 (42.09) and 27.79 (18.57–69.71) hours (P = .18).

The satisfaction survey completion rate was 52% in the TKO group and 45% in the SL group. Significantly more patients in the SL group "agreed" (median response [IQR] = 4.0 [3–4]) that the PIV restricted their mobility, compared with patients in the TKO group who felt "neutral" (median response [IQR] = 3 [2–4], P = .01). There were no significant differences in the other satisfaction markers, including ease of activities of daily living, comfort, disruption of rest, and overall experience (P values >0.08). Several patients and caregivers provided qualitative statements about their PIV experience (See "Qualitative Comments Regarding Satisfaction With the PIV from Patients and Caregivers in TKO and SL Groups" in the Supplemental Information). Both TKO and SL groups had comments regarding discomfort and fear of pulling the PIV out. Caregivers in both groups had mixed opinions on whether the PIV prevented them from caring for their child. Specific comments in the SL group addressed how some patients and

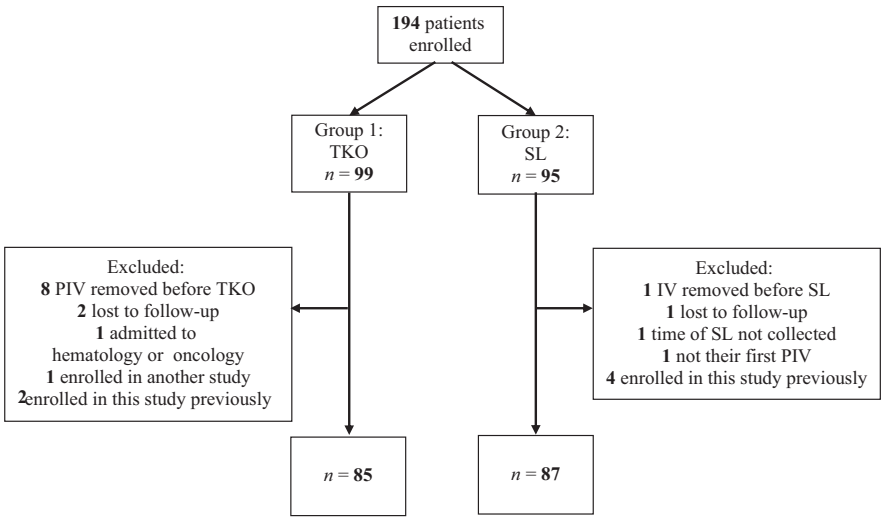

FIGURE 1 CONSORT diagram of patients included in the study.

TABLE 1 Patient Characteristics in TKO and SL Groups

	TKO (n = 85)	SL (n = 87)	P
Sex, *n* (%)			.05
Male	44 (52)	58 (67)	
Female	41 (48)	29 (33)	
Age, mo, mean (SD)	59.42 (63.76)	61.91 (69.74)	.81
Age group, *n* (%)			.36
<30 d	12 (14)	12 (14)	
1–11 mo	20 (24)	16 (18)	
1–4 y	17 (20)	27 (31)	
5–10 y	21 (25)	14 (16)	
>10 y	15 (18)	18 (21)	
Weight, kg, mean (SD)	22.18 (21.74)	23.09 (24.66)	.80
Location of PIV, *n* (%)			.85
Hand	46 (54)	43 (49)	
Antecubital	26 (31)	28 (32)	
Forearm	8 (9)	7 (8)	
Foot	4 (5)	8 (9)	
Scalp	1 (1)	1 (1)	
PIV gauge, *n* (%)			.67
18	2 (3)	1 (1)	
20	5 (8)	4 (5)	
22	23 (35)	38 (47)	
24	33 (51)	36 (44)	
26	2 (3)	2 (3)	
Hours IV was in use before TKO or SL, mean (SD)	22.07 (23.78)	27.13 (24.16)	.17
IV fluid administered through PIV before TKO or SL, *n* (%)			<.001
NS	2 (2)	17 (20)	
D5NS	60 (71)	59 (68)	
D5 0.45S	14 (17)	4 (5)	
D10W	2 (2)	1 (1)	
RL	6 (7)	1 (1)	
Other	1 (1)	5 (6)	
Use of IV antibiotics or IV antiviral agents, *n* (%)	43 (51)	38 (44)	.36

D5 0.45S, dextrose 5% with 0.45% saline; D5NS, dextrose 5% with 0.9% normal saline; D10W, dextrose 10% with water; NS, 0.9% normal saline; RL, Ringer's lactate.

caregivers preferred not to be "tethered" to the IV pole. One caregiver commented that her daughter had previous admissions to hospital, and that SL was "perfect" and "felt normal."

DISCUSSION

In this study, we demonstrated no significant difference in duration of functional PIV patency between a continuous TKO infusion and SL in our pediatric population. Moreover, complication rates were not significantly different between the 2 groups. We also focused on the novel aspect of patient and caregiver satisfaction and found overall PIV satisfaction was not significantly different between TKO and SL.

Authors of similar studies have compared SL and TKO in neonates in the NICU or special care nursery settings.[2,6–9] Our findings were consistent with 2 neonatal cohort studies by Flint et al[2] and Stok et al,[7] and a randomized control trial by Kalyn et al,[9] that SL is not significantly different from TKO in maintaining duration of PIV patency. Interestingly, in a prospective cohort study, Perez et al[8] found that SL had a significantly longer duration of PIV patency compared with TKO in neonates in an intermediate care nursery. This study was different from ours in that their SL protocol was defined as SL with intermittent saline flushes at minimum every 24 hours, which was longer than our minimum of 12 hours and much longer than the minimum of 4 to 6 hours in the 3 previously mentioned studies.[2,7,9] It is possible that our more frequent handling of the PIV for flushes may have allowed for greater risk of PIV mechanical irritation or dislodgement, thus leading to early failure. Second, the lack of statistical significance in PIV patency between our TKO and SL groups could reflect the experience of our nurses with the SL and flush technique. Before the introduction of our study, the use of SL was rare in our institution. Although nursing education was done before the start of the study, there was likely still a learning period involved with SL. Given how important proper SL technique is to the success of PIV patency, it is possible that this learning period may have biased the duration of PIV patency in our SL group.[9,10]

No significant differences in complications were found between the TKO and SL groups. However, we had relatively fewer complications compared with previous literature and, as a result, were not fully powered to detect this difference.[7–9] Previous literature regarding complication rates between TKO and SL has been inconsistent. Perez et al[8] demonstrated no significant difference in complications, whereas Stok et al[7] found that the occurrence of complications with SL was significantly lower than with TKO. Kalyn et al[9] found significantly more infiltration and phlebitis in the TKO group, whereas there was significantly more occlusion in the SL group. All 3 studies had higher total complication rates compared with ours, ranging from 31% to 76%. This could reflect overall differences in their strictly neonatal population, compared with our heterogenous pediatric population.

One complication in the TKO group was documented as a safety concern, involving IV tubing wrapped around an infant's neck

TABLE 2 Admission Diagnosis in TKO and SL Groups

Most Responsible Diagnosis, *n* (%)	TKO (*n* = 85)	SL (*n* = 87)	*P*
Bronchiolitis or viral respiratory tract infection	5 (6)	12 (14)	.08
Asthma	5 (6)	3 (3)	.49
Seizures	7 (8)	3 (3)	.21
Feed intolerance or emesis	7 (8)	6 (7)	.74
Viral meningitis	2 (2)[a]	1 (1)	.62
Bacterial infection, medical and surgical	25 (29)	27 (31)	.82
Other medical diagnosis	19 (22)	23 (26)	.53
Other surgical procedure	15 (18)	12 (14)	.49

[a] One patient had varicella zoster meningitis.

and in his mouth. In 2 other recent case reports, authors have described infants who were found apneic from accidental strangulation with their own PIV tubing.[12,13] Although the prevalence appears to be low, given the high morbidity and mortality associated with accidental strangulation, the significance of this complication cannot be overlooked.

The finding that SL was felt by patients and caregivers to be more restrictive than TKO contradicts the observations made in previous literature that SL allowed patients to be more mobile.[2,6,9] This was specifically observed in a study by Flint et al,[2] where they found easier access for mothers to initiate feeding and enhanced maternal–infant bonding in infants with SL. Qualitatively, we had specific comments in the SL group that not being attached to the IV pole was helpful for bathroom breaks and sleeping. In addition, 1 caregiver noted that her child had previous admissions and that SL was "perfect" and felt "normal." It is possible that we did not see similar results in our quantitative satisfaction scores because patients and caregivers were not able to compare TKO and SL directly. Furthermore, the results of the quantitative satisfaction should be interpreted with caution, because the overall number of completed surveys was small, and this survey was not previously validated. Collection of completed surveys was challenging because surveys were handed out at the time of patient discharge and were sometimes misplaced or forgotten.

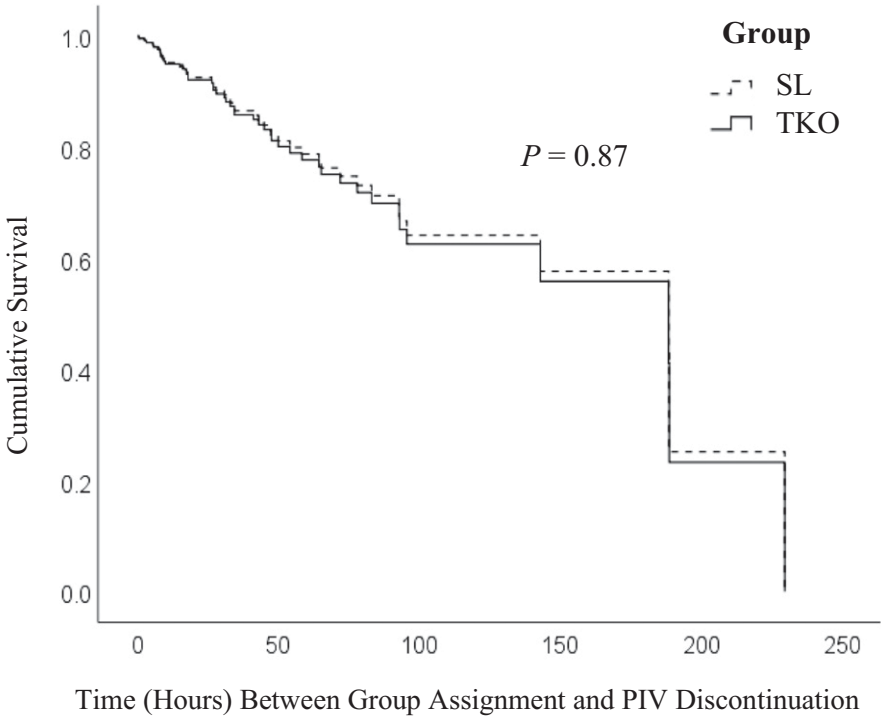

FIGURE 2 Cox regression survival analysis for duration of PIV patency in TKO and SL groups in hours.

Given many inherent differences between TKO and SL, there are other considerations to be stated. One major difference is that TKO requires hourly nursing visual assessments of the PIV, whereas SL requires PIV assessments with each medication administration and at minimum every 12 hours. Less-frequent assessments with SL could theoretically have the unintended consequence of nurses missing patient problems if they are in the room less frequently. However, in discussion with nursing colleagues, it was felt that hourly PIV assessments could also interfere with nursing care by taking away time from other patients who require greater attention. Furthermore, the hourly assessments for TKO can be disruptive for the sleeping child and caregiver.

Limitations of our study included the convenience sampling method and lack of randomization, which allows for the possibility of sample bias. Some patient characteristics were significantly different between the 2 groups (sex and IV fluid), but analyses were appropriately adjusted to control for these differences. Regarding IV fluid differences, the Canadian Pediatric Society updated their hyponatremic practice point in December 2018 that discourages use of 0.45% saline and encourages isotonic fluids, including normal saline. It is possible that our study results reflect general uptake of this new guideline, although there was no formal training done during the study period. As well, this was a single-center study, and there may have been institution-specific factors that impacted our results, such as nursing training in PIV patency and historical institutional practice on PIV handling. Our study was also not powered to identify rare, but more serious, PIV

TABLE 3 Complication Rates in TKO and SL

Complication, *n* (%)	TKO (*n* = 85)	SL (*n* = 87)	*P*
Phlebitis	2 (2)	3 (3)	>.994
Infiltration or extravasation	9 (11)	7 (8)	.57
Dislodgement	6 (7)	6 (7)	.97
Obstruction	2 (2)	6 (7)	.28
Other[a]	10 (12)	6 (7)	.27
Any complication	24 (28)	23 (26)	.79
Removed at discharge or physician preference	61 (72)	64 (74)	.79

[a] Other refers to leaking, pain, concern for strangulation, or parent interference of pump.

complications, including severe extravasation injuries or significant PIV site infections. Finally, our study population was heterogeneous, with a wide range of ages, diagnoses, and indications for PIV use that may have impacted the duration of PIV patency. However, this population allowed for strong external validity, therefore making the results applicable to many general pediatric inpatient settings.

Future directions for research would include a large multicenter randomized approach in comparing duration of PIV patency between TKO and SL. Furthermore, a cost-analysis between TKO and SL would be prudent when considering health care resources. The TKO method has previously been found to pose extra costs to the health care system in the form of more nursing time for monitoring, IV fluids and IV tubing.[2,7] Regarding patient and caregiver satisfaction, a validated survey should be used. It would also be interesting to assess satisfaction in a subset of patients who receive multiple PIVs and can experience both TKO and SL, so a direct comparison can be made.

CONCLUSIONS

In this study, we demonstrated that there was no significant difference in the duration of functional PIV patency between (1) SL with intermittent flushing at minimum 12-hour intervals and (2) continuous TKO infusion of a crystalloid fluid in a pediatric inpatient population at a diverse, single-center Children's Hospital. There were also no significant differences in complications rates and satisfaction with the overall PIV experience between the 2 groups. Importantly, SL confers additional safety benefits, including avoidance of strangulation risk. This study also serves as a reminder to continuously challenge our historical perceptions and methods in our collective goal to practice evidence-based medicine. Overall, SL is a safe and reasonable alternative to TKO in maintaining PIV patency in children.

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