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Clinical outcomes of flushing frequency in peripheral catheters of pediatric patients: randomized trial protocol*

HIGHLIGHTS

1. Evidence on flushing in pediatrics is still insufficient.
2. This research details the steps of a randomized trial.
3. A robust protocol favors the rigorous conduct of a definitive study.

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ABSTRACT

Objective: To verify the superiority of standardized flushing over usual flushing regarding dwell time and incidence of complications in short peripheral intravenous catheters inserted in hospitalized children. **Method:** Protocol of a randomized, controlled, open-label, superiority clinical trial in parallel groups. It will be conducted in a pediatric state hospital. Study participants will be allocated to the intervention group, consisting of children who undergo flushing before and after medication administration and every 12 hours, and to the control group, with participants undergoing flushing before and after medication administration. The primary outcome will be catheter dwell time. Data analysis will be descriptive and univariate, with estimation of the survival curve as a function of time. **Final considerations:** This protocol is a relevant instrument for presenting the different planning stages of a clinical trial. Brazilian registration number 9mtwh2j.

DESCRIPTORS: Pediatric Nursing; Child Health; Clinical Trial Protocol; Catheterization, Peripheral; Saline Solution.

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INTRODUCTION

Most pediatric patients have at least one short peripheral intravenous catheter (SPIC) insertion during hospitalization[1], as this is the most common vascular access device (VAD) used to administer fluids and medications in children[2,3].

Once the SPIC is inserted, it is desirable that its patency be maintained for as long as possible[4], ideally until the end of the prescribed intravenous therapy (IVT) and medication therapy.

However, sustained maintenance of SPIC patency is often difficult to achieve in the pediatric population[5], as study results show that the mean patency time of this VAD ranges from less than 30 hours to more than 72 hours, with most devices remaining in place for up to 24 hours[3,6].

Despite the important role of the SPIC in administering prescribed medications and solutions, failure and complication rates are widely reported[1], and these are among the reasons that lead to its non-elective and premature removal[1].

These unfavorable outcomes frequently lead to a new invasive procedure[7] and can significantly affect healthcare costs, reduce device dwell time[8,9], patient quality of life, morbidity, and mortality[10].

SPIC failures and complications are frequently associated with improper device use[11], medical diagnosis of respiratory or infectious disease, small-gauge catheter (24 gauge), history of complications, administration of non-irritant/vesicant medications and vesicant solutions[12] such as antibiotics[13], use of a controlled-volume burette[14], and longer IVT duration (7 or more days)[12].

Both failures and complications following SPIC insertion may occur due to inconsistent maintenance practices, such as flushing of this device[15].

The American Infusion Nursing Society (INS) recommends that flushing be performed to maintain VAD patency; 0.9% sodium chloride (NaCl), preservative-free[16], should be used with positive pressure and pulsatile technique16. It also recommends the use of single-dose systems (such as single-dose vials or labeled pre-filled syringes)[16].

Syringes with a 10 ml diameter should be used to check the patency and functionality of the peripheral intravenous catheter, avoiding increased pressure in the system and device rupture[4,16,17].

For flushing, a minimum volume equivalent to twice the internal volume of the catheter system (catheter plus complementary devices)[4,16] is recommended, as it can remove more fibrin deposits, drug precipitates, and other luminal residues[16].

Despite the INS recommendation on flushing, there is a lack of evidence regarding ideal volumes and adequate flushing frequency[18-20]. It is therefore necessary to develop studies capable of contributing to the reduction of this uncertainty. In this regard, this research aims to verify the superiority of standardized flushing over usual flushing regarding dwell time and incidence of complications in short peripheral intravenous catheters inserted in hospitalized children.

METHOD

This is a superiority randomized controlled clinical trial (RCT) protocol, in parallel groups and open-label. Registered in the Brazilian Registry of Clinical Trials under number RBR-9mtwh2j, following the recommendations proposed by the Standard

Protocol Items: Recommendations for Interventional Trials (SPIRIT)[21]. The study will take place in a state hospital in Feira de Santana, Bahia, Brazil, in a surgical inpatient unit (SIU). The estimated duration of data collection is approximately six months.

Patients aged between one and 14 years will be included, as this is the age range corresponding to the care profile of the institution where data will be collected; expected peripheral intravenous therapy for 48 hours or more; and use of SPIC for medication administration. Children on respiratory and contact precautions will not be included; those scheduled for transfer to other institutions; those with SPIC for single infusion of 0.9% NaCl for vascular access device maintenance; and those with fluid restriction. Children who request withdrawal of their assent or whose parents suspended their participation during follow-up will be excluded.

Participants allocated to the intervention group will undergo flushing before and after medication administration and every 12 hours, also referred to as standardized flushing, using BD PosiFlush™ pre-filled syringes (Becton, Dickinson and Company, Franklin Lakes, NJ, USA)[22].

For participants randomized to the control group, flushing will be performed before and after the administration of intermittent medications using the BD PosiFlush™ syringe, a technique also designated as usual flushing.

The primary outcome of the study is catheter dwell time, which will be measured from the difference between the removal date and the SPIC insertion date. The secondary outcomes of the research are the occurrence of local complications, the type of local complication, and the time to development of local complications. Sample size calculation will be performed after the pilot test, as there are no studies reporting possible differences between standardized and usual flushing on the dwell time of peripheral intravenous catheters.

Participants will be recruited by a team of experienced researchers who will be present daily at the data collection unit, initially contacting the sector's nursing professionals to identify children with an indication for SPIC insertion. For these participants, the researcher will verify the eligibility criteria. In the presence of eligible patients, the researcher will present to the children and their guardians the objectives, procedures, benefits, and risks of the study.

After presenting the study to the child/guardian, the researcher will request free and informed assent/consent; upon authorization, the research team will recruit the participant and allocate them to one of the study groups.

Participant allocation will occur by block randomization of 10 children, and the allocation sequence in the research will be generated by the *online* platform Random.

The table with the randomized allocation sequence will be generated by a researcher not affiliated with the project, and the randomization table will be used by a center constituted by external researchers.

It is noteworthy that, before initiating data collection, the nursing staff of the surgical inpatient unit will be trained in the use of BD *PosiFlush*™ pre-filled syringes[22] through a training program consisting of a theoretical and a practical stage. All nursing professionals will be invited to participate in the study; however, to be part of the team performing flushing in the research, it will be necessary to have one year of professional experience at the data collection site and to attend both stages of the training program.

The theoretical stage will last five hours and will be conducted through lecture and discussion in the institution's own auditorium. At this stage, the team will be guided regarding the research objective and method, and trained regarding the importance of performing flushing, being introduced to the pulsatile technique and the protocol for carrying out this intervention during the research.

The practical stage will take place after the theoretical classes and will last 10 hours, two of which in the institution's auditorium and eight at the bedside. Initially, the team will simulate the performance of pulsatile flushing using the pre-filled syringe, according to the research protocol, using a low-fidelity simulator. The syringes will be presented and handled by the team before being used on patients, in order to standardize the clinical intervention and address any questions that may arise.

Subsequently, each member of the nursing team will perform flushing in four hospitalized children, in order to identify difficulties and/or questions during the performance of the intervention *in vivo*.

After training the nursing professionals, data collection will begin. Data will be recorded in a form containing baseline characteristics, consisting of demographic, clinical, and IVT-related variables, and the outcome variables described above.

The demographic and clinical variables collected will be, respectively: age; sex; skin color and manual lateral dominance; medical diagnosis; length of hospitalization; weight; height/length; Body Mass Index (BMI) and nutritional status.

The body mass index will be calculated by dividing the child's weight by the square of their height/length according to age. Nutritional status will be obtained from the BMI and may be described as eutrophic, severe thinness, thinness, overweight risk, overweight, obesity, severe obesity.

The IVT-related variables collected will be: prior use of the blood vessel for current catheter insertion, gauge of the catheter used, and medications.

Subsequently, participants and their SPICs will be followed daily by the research team, which will perform assessment of the VAD insertion site.

VADs will be observed until removal, at which point the data collection team will record in the form the reason: end of IVT, accidental device removal, or local complications.

The collected data will be double-entered by independent researchers in the Statistical Package for the Social Sciences (SPSS) software version 22.0 and analyzed by the same program. The analysis of categorical variables will be described by frequencies and numerical variables summarized using measures of position and variability, according to adherence to normal distribution.

In the univariate analysis, Relative Risks and their respective 95% Confidence Intervals will be estimated, considering 5% as the level of statistical significance, using Pearson's Chi-square (X^2) or Fisher's Exact test for qualitative outcomes and Mann-Whitney or Student's t-test for quantitative outcomes.

In the analysis of time variables, the survival curve will be calculated using the Kaplan-Meier method with a significance level of 0.05.

This research complied with Resolution No. 466 of December 12, 2012 of the Brazilian National Health Council, having been approved by the Ethics Committee of the Universidade Estadual de Feira de Santana, under opinion number: 6.270.077.

FINAL CONSIDERATIONS

The protocol developed for this research represents a relevant instrument for presenting in detail the different planning stages of an RCT and can be used in a complementary manner by researchers in the field for the design of related studies.

REFERENCES

1. Indarwati F, Mathew S, Munday J, Keogh S. Incidence of peripheral intravenous catheter failure and complications in paediatric patients: systematic review and meta analysis. Int J Nurs Stud [Internet]. 2020 [cited 2025 Jun 5];102:103488. Available from: https://doi.org/10.1016/j.ijnurstu.2019.103488

2. Heydinger G, Shafy SZ, O'Connor C, Nafiu O, Tobias JD, Beltran RJ. Characterization of the difficult peripheral iv in the perioperative setting: a prospective, observational study of intravenous access for pediatric patients undergoing anesthesia. Pediatric Health Med Ther [Internet]. 2022 [cited 2025 Jun 5];13:155-63. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC9081190/

3. Ullman AJ, Takashima M, Kleidon T, Ray-Barruel G, Alexandrou E, Rickard CM. Global pediatric peripheral intravenous catheter practice and performance: a secondary analysis of 4206 catheters. J Pediatr Nurs [Internet]. 2020 [cited 2025 Jun 5];50:e18-e25. Available from: https://doi.org/10.1016/j.pedn.2019.09.023

4. Infusion Nurses Society (INS). Policies and Procedures for Infusion Therapy: Neonate to Adolescent. 4th ed. Massachusetts: Infusion Nurses Society; 2024. 367 p.

5. Tseng JH, Elaine Chen YFE, Chang SP, Wang HC, Kuo YT. Factors affecting the patency and complications of peripheral intravenous catheters in newborns. Pediatr Neonatol [Internet]. 2023 [cited 2025 Jun 5];64(3):239-46. Available from: https://doi.org/10.1016/j.pedneo.2022.07.011

6. Tripathi S, Gladfelter T. Peripheral intravenous catheters in hospitalized patients: Practice, Dwell times, and factors impacting the dwell times: A single center retrospective study. J Vasc Access [Internet]. 2021 [cited 2025 Jun 5];23(4):581-8. Available from: https://doi.org/10.1177/11297298211000874

7. Saliba P, Cuervo G, Hornero A, De Carli de G, Marani A, Puro V, et al. The impact of flushing with pre-filled saline syringes on the incidence of peripheral venous catheter failure: A quasi-experimental study. J Vasc Access [Internet]. 2019 [cited 2025 Jun 13];21(4):490-6. Available from: https://doi.org/10.1177/1129729819888423

8. Liu C, Chen L, Kong D, Lyu F, Luan L, Yang L. Incidence, risk factors and medical cost of peripheral intravenous catheter-related complications in hospitalised adult patients. J Vasc Access [Internet]. 2022 [cited 2025 Jun 13];23(1):57-66. Available from: https://doi.org/10.1177/1129729820978124

9.van Loon FHJ, Leggett T, Bouwman ARA, Daele ATMDV. Cost-utilization of peripheral intravenous cannulation in hospitalized adults: an observational study J Vasc Access [Internet]. 2020 [cited 2025 Jun 13];21(5):687-93. Available from: https://doi.org/10.1177/1129729820901653

10. de la Vieja-Soriano M, Blanco-Daza M, Macip-Belmonte S, Dominguez-Muñoz M, López-Sánchez E, Pérez-Pérez E. Difficult intravenous access in a paediatric intensive care unit. Enferm Intensiva [Internet]. 2021 Jul 7 [cited 2025 Aug 28];33(2):67-76. Available from: https://doi.org/10.1016/j.enfie.2021.03.006

11. Marsh N, Rickard CM. Peripheral intravenous catheter failure-is it us or is it them? Lancet Haematol [Internet]. 2021 [cited 2025 Jun 13];8(9):e615-e7. Available from: https://doi.org/10.1016/S2352-3026(21)00234-9

12. dos Santos LM, Silva CSG, Machado ES, Almeida AHV, da Silva CAL, Silva BSM, et al. Risk factors for site complications of intravenous therapy in children and adolescents with cancer. Rev Bras Enferm [Internet]. 2020 [cited 2025 Jun 13];73(4):e20190471. Available from: https://doi.org/10.1590/0034-7167-2019-0471

13. Marsh N, Larsen EN, Takashima M, Kleidon T, Keogh S, Ullman AJ et al. Peripheral intravenous catheter failure: a secondary analysis of risks from 11,830 catheters. Int J Nurs Stud [Internet]. 2021 [cited 2025 Jun 13];124:104095. Available from: https://doi.org/10.1016/J.IJNURSTU.2021.104095

14. Abdelaziz RB, Hafsi H, Hajji H, Boudabous H, Chehida AB, Mrabet A, et al. Peripheral venous catheter complications in children: predisposing factors in a multicenter prospective cohort study. BMC Pediatr [Internet]. 2017 [cited 2025 Jun 13];17:208. Available from: https://doi.org/10.1186/S12887-017-0965-Y

15. Keogh S, Shelverton C, Flynn J, Mihala G, Mathew S, Davies KM, et al. Implementation and evaluation

of short peripheral intravenous catheter flushing guidelines: a stepped wedge cluster randomised trial. BMC Med [Internet]. 2020 [cited 2025 Jun 24];18:252. Available from: https://doi.org/10.1186/S12916-020-01728-1

16. Nickel B, Gorski L, Kleidon T, Kyes A, Devries M, Keogh S et al. Infusion therapy standards of practice, J Infus Nurs [Internet]. 2024 [cited 2025 Jun 28];47(15). 285 p. Available from: https://doi.org/10.1097/NAN.0000000000000532

17. Brasil. Agência Nacional de Vigilância Sanitária [Internet]. Nota técnica no 04/2022. Práticas seguras para a prevenção de incidentes envolvendo cateter intravenoso periférico em serviços de saúde. Brasília, DF: ANVISA; 2022 [cited 2025 oct 01]; 22 p. Available from: https://portaldeboaspraticas.iff.fiocruz.br/atencao-recem-nascido/nt4-cateter-intravenoso-anvisa-2022/

18. Zhu L, Liu H, Wang R, Yu Y, Zheng F, Yin J. Mechanism of pulsatile flushing technique for saline injection via a peripheral intravenous catheter. Clin Biomech [Internet]. 2020 [cited 2025 Jun 28];80:105103. Available from: https://doi.org/10.1016/J.CLINBIOMECH.2020.105103

19. Sotnikova C, Fasoi G, Efstathiou F, Kaba E, Bourazani M, Kelesi M. The efficacy of normal saline (N/S 0.9%) versus heparin solution in maintaining patency of peripheral venous catheter and avoiding complications: a systematic review. Mater Sociomed [Internet]. 2020 [cited 2025 Jun 28];32(1):29-34. Available from: https://pubmed.ncbi.nlm.nih.gov/32410888/

20. Schreiber S, Zanchi C, Ronfani L, Delise A, Corbelli AA, Bortoluzzi R et al. Normal saline flushes performed once daily maintain peripheral intravenous catheter patency: a randomised controlled trial. Arch Dis Child [Internet]. 2015 [cited 2025 Jun 28];100(7):700-3. Available from: https://doi.org/10.1136/ARCHDISCHILD-2014-307478

21. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: Defining standard protocol items for clinical trials. Ann Intern Med [Internet]. 2013 [cited 2025 Jun 28];158(3):200-7. Available from: https://doi.org/10.7326%2F0003-4819-158-3-201302050-00583

22. Becton Dickinson (BD). BD® PosiFlush™ Prefilled Flush Syringes [Internet]. São Paulo:BD; 2024 [cited 2024 jun 24];[about 5 screens]. Available from: https://www.bd.com/en-us/products-and-solutions/products/product-families/bd-posiflush-pre-filled-saline-syringe

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Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work - **de Souza ÉR, Silva BSM, Kusahara DM, Bittencourt IS, Rocha PK, de Camargo MC, dos Santos LM.** Drafting the work or revising it critically for important intellectual content - **de Souza ÉR, Silva BSM, Kusahara DM, Bittencourt IS, Rocha PK, de Camargo MC, dos Santos LM.** Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - **de Souza ÉR, dos Santos LM.** All authors approved the final version of the text.

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