AO AL Azienda Ospedaliera di ALESSANDRIA Santi Antonio e Biagio e Cesare Arrigo
REGIONE PIEMONTE

Working Paper of Public Health 2023; volume 11:9684

Original Article

Economic analysis and time monitoring of pediatric venipuncture procedures; audio-visual distraction and Buzzy® device *versus* standard care: protocol of an interventional randomized controlled trial

Analisi economica e monitoraggio dei tempi delle procedure di veni puntura pediatrica; distrazione audiovisiva e dispositivo Buzzy® rispetto alle cure standard: protocollo di uno studio interventistico randomizzato e controllato

Roberta Di Matteo[1], Michela Gentile[2], Elena Grassi[3], Denise Gatti[1], Tatiana Bolgeo[1], Antonio Maconi[1]

[1]SC Research Training Innovation Infrastructure, Integrated Activities, Research, Innovation Department (DAIRI), SS Antonio e Biagio e Cesare Arrigo National Hospital Alessandria; [2]SC Paediatrics - SS Paediatric Emergency Department, SS Antonio e Biagio e Cesare Arrigo National Hospital, Alessandria; [3]SC Directorate of Health Professions, SS Antonio e Biagio e Cesare Arrigo National Hospital, Alessandria, Italy

Key words: venipuncture, pediatric, pain, comfort, non-pharmacological methods.

ABSTRACT

Background: reducing anxiety and pain during an invasive procedure like venipuncture is crucial for preventing the onset of stress and making the nurse's procedures faster and smoother. Distraction techniques appear to be a viable solution. The aim of this study is to compare the effectiveness of two different distraction methods in terms of cost-effectiveness and time to perform venipuncture in a hospital setting.
Materials and Methods: a randomized, controlled, interventional-blinded 3-arm parallel-group study with inpatients aged 3 to 18 years old, awake and conscious, at the first venipuncture attempt and only after children and parents signed informed consent. The pain rating scales Wong-Baker FACES, Numerical Rating Scale, and Children's Fear Scale will be used.
Conclusions: pediatric pain is a challenge for medical professionals as well as a health need that must be addressed rapidly. It is crucial to assess and apply the most effective methods for adequate analgesia in shorter periods, while also reducing healthcare costs.

Background: la riduzione dell'ansia e del dolore durante una procedura invasiva come la venipuntura è fondamentale al fine di prevenire l'insorgere di stress, oltre che per rendere più rapide e agevoli le procedure dell'infermiere. I metodi di distrazione sembrano rappresentare una valida soluzione. Scopo dello studio è quello di valutare l'efficacia di due diversi metodi di distrazione verso l'assistenza standard in termini di analisi economica e tempo di esecuzione della venipuntura in un contesto ospedaliero.
Materiali e Metodi: studio interventistico randomizzato, controllato in cieco a 3 braccia a gruppi paralleli con inclusione di pazienti di età compresa tra i 3 e i 18 anni ricoverati, vigili e coscienti, al primo tentativo di venipuntura e solo dopo sottoscrizione del consenso informato dei bambini e genitori. Verranno utilizzate la scala di valutazione del dolore Wong-Baker FACES, Numerical Rating Scale, Children's Fear Scale.
Conclusioni: il dolore pediatrico rappresenta una sfida per i professionisti sanitari ed un bisogno di salute che richiede la necessità di essere affrontato tempestivamente. Risulta fondamentale valutare e applicare nella pratica clinica i metodi più efficaci per un'adeguata analgesia in tempi più ristretti, riducendo anche i costi sanitari.

INTRODUCTION

Venipuncture is a technique for obtaining venous access in order to inject or infuse a therapy or draw blood.[1]

Obtaining a peripheral vein is a medium-to-high-complexity health act that requires the patient's cooperation, especially if the patient is a child. If the patient is uncooperative, there is a risk of procedural complications such as failure to find the vein and wasting the equipment, excessive pain while performing the procedure, accidental puncture of the adjacent peripheral artery or nerve, local or systemic infection, hematoma, venous extravasation with skin necrosis or thrombophlebitis.[2]

Pain, like in adults, is a very common symptom in pediatric care, compromising the child's psychological and physical well-being and distressing family members. During the course of their care, hospitalized children are frequently subjected to numerous painful diagnostic and therapeutic procedures. In particular, venipuncture appears to be among the most performed and, at the same time, feared procedures by children, with both short-term and long-term negative implications;[3,4] at a psychological level, venipuncture would seem to be associated with the pathological condition whilst negatively affecting the anxiety and fear of both the child and his parents.[5] In fact, there is evidence that in pediatric age, inadequately treated painful stimuli have significant effects on prognosis, with ramifications in the psycho-relational sphere, needle phobia that persists into adulthood, increased sensitivity to pain, avoidance behaviors or poor adherence to medical care, and higher levels of anxiety before a painful procedure.[6,7] Younger age, the absence of a parent during the invasive procedure, and cultural differences all have a negative impact on this fear in children.[8,9]

Furthermore, the child's restlessness caused by pain perception can make the procedure more difficult and time-consuming to perform, increasing the risk of failure and, as a result, increasing the stress of both the healthcare professional and the parent caring for the child.

Back in 2001, the American Academy of Pediatrics and the American Pain Society recommended minimizing pain and thus stress levels even during minor procedures such as venous blood sampling.[10] To reduce these negative experiences, the Association of British and Irish Anesthesiologists recommended in 2012 that both pharmacological and non-pharmacological methods be considered in pediatric care for effective management and prevention of acute pain in painful health care procedures.[11]

In the last decade, some researchers have demonstrated the efficacy of more cost-effective pain and anxiety control principles[5,12,13] that can be deployed flexibly and independently by nurses,[14] speeding up their procedures.[15]

Non-pharmacological approaches include cognitive or behavioral strategies,[16] which are broadly classified into two categories: physical comfort measures and distraction activities.[17]

Physical comfort measures are infant-specific interventions that refer to the early childhood era, whereas physical contact interventions associated with distraction activities are primarily used for preschool patients. The use of analgesic cryotherapy interventions, whether or not combined with distraction activities such as interactive games, is recommended for school age and adolescent patients.[17]

However, evidence suggests that the most common strategies are psychological distraction techniques, which can influence how children think or react prior to, during, or after the procedure.[16] Distraction activities are classified as either passive or interactive, and children of all ages and levels of maturity can use them.[18]

According to recent studies, Virtual Reality (VR) is a safe distraction method, as well as an effective and cost-effective 3D virtual environment used for painful procedures in children.[19] Conventional VR systems include a head-mounted device with 3D glasses and sensory input devices such as headphones and/or body tracking sensors, allowing for an experience that engages multiple senses at the same time (multisensory).[20] It appeals to a wide range of age groups and is simple to use in pediatric settings. It targets different age groups, is easily implemented in pediatric care units, and can also be used with cell phones;[19,21,22] it reduces pain and anxiety during health care procedures in children, resulting in better adaptation and adherence to treatment.[23]

Other scientific evidence has demonstrated how the patented Buzzy® device (MMJ Labs, Atlanta, USA) is simple to use, reusable, and designed to reduce injection pain in children.[24,25] It is a commercially available device shaped like an insect (bee or ladybird), with a central part (the body) and a removable peripheral part (the wings). The device's central part vibrates, while the peripheral parts deliver a concentrated cold to the child's skin at the injection site via contact.[26] Cold application and vibration begin a few seconds before the procedure and continue until the procedure is completed. Vibration causes numbness, paresthesia, and anesthesia, enabling pain reduction or elimination, whereas cold application (30-60 s) can slow the transmission of painful stimuli to the brain by blocking electrical signals in peripheral nerves and activating the gate-control mechanism with stimulation of tactile receptors and release of endogenous opioids, providing pain relief.[27]

There is a variety of evidence in the literature for the effectiveness of these methods in reducing pain and anxiety; however, it has not been evaluated whether these methods contribute to reducing venipuncture execution time and costs related to medications or tools used for venipuncture erroneously due to poor patient compliance.

The aim of this study is to compare the effectiveness of two different distraction methods (VR and Buzzy®) in terms of cost-effectiveness and venipuncture execution time in a sub-regional, multicultural hospital setting.

Objectives

The study's goal is to compare the efficacy of two different distraction methods (VR and Buzzy®) to standard care in terms of economic analysis and execution time from venipuncture in children aged 3 to 18 years admitted to the Paediatrics SC of the SS Antonio e Biagio e Cesare Arrigo National Hospital, Alessandria, Italy.

Furthermore, the study intends to detect pain and fear in patients treated with distraction methods versus those treated with standard venipuncture procedures.

MATERIALS AND METHODS

This is a three-arm, blinded, randomised, controlled interventional study with parallel groups. Patients aged 3 to 18 years admitted to the Paediatric SC of the SS Antonio e Biagio e Cesare Arrigo National Hospital, awake and conscious, at the first attempt of venipuncture and only after signing the informed consent form, will be included.

Children who have received sedatives, analgesics, or narcotics in the 8 hours preceding the procedure, who have contact hypersensitivity to cryo-therapeutic applications, or who have been diagnosed with cognitive impairment, will be excluded; emergency venipunctures and haemato-chemical analyses of plasma protein, albumin, and transferrin levels will also be excluded.

Children in Group A 'VR' will undergo the pain management

procedure using Virtual Reality (VR). VR is a 360-degree audio-visual simulation that entertains the user in a three-dimensional world while allowing them to look around in all directions. Participants will be required to put on VR glasses and a headset approximately two minutes before the venipuncture and will be required to watch a 3D animation film for the duration of the procedure. The venipuncture will be performed with the Vacutainer® system and a butterfly needle. The VR device should be removed no later than 10 minutes after the procedure is completed, and the pain and anxiety rating scales should be explained and shown to the children and their parents.

Children in group B "Buzzy®" will use the Buzzy Bee method for pain management, following the instructions on the data sheet. The device's wings must be kept frozen until they are used. They must be disinfected and refrozen after each use. The entire device, wings on and vibration on, should be applied to the venipuncture site for 60 seconds prior to the procedure. After 60 seconds, the nurse should move the device upwards, 3-5 cm away from the venipuncture site, and immediately place the tourniquet, proximal to the device, before inserting the venipuncture needle. A butterfly needle will be used for venipuncture using the Vacutainer® system. Buzzy®.

The children in Group C 'Standard Care' will be subjected to the standard procedure used in the Paediatrics SC facility of the SS Antonio e Biagio e Cesare Arrigo National Hospital, while the pain and anxiety rating scales will be explained and shown to the children and their parents.

Tools

The Wong-Baker FACES pain rating scale (WB-FACES)[28] is used in children aged 3 to 18 years to diagnose pain. It consists of six facial expressions, each representing a different level of pain, rated on a scale of 0 to 5 from left to right (0=very happy/no pain, 5=worst pain imaginable). The first face has a happy expression that represents 'no pain' (0), while the last face has a crying expression and represents 'the worst pain imaginable' (5). The term "hurt" is generally used for children aged 3 to 5, while "pain" is used for children aged 6 to 7. Higher scores indicate a low level of pain tolerance. Participants are asked to select the best facial expression to represent their pain. In this study, the scale will be evaluated using self-assessment as well as reports from parents and the researcher.

The Numerical Rating Scale (NRS),[29] a one-dimensional quantitative 11-point pain rating scale, provides an adequate measure of pain intensity. The scale requires the practitioner to ask the patient to select the number that best describes the intensity of their pain at that precise moment, ranging from a score from 0 to 10.

The Children's Fear Scale (CFS)[30] is made up of five facial expressions that range from neutral (0) to extreme fear (4). The CFS can be used by both researchers and family members to assess children's fear and anxiety before and during procedures.

Data collection

Data from the study will be collected using rating scales that indicate the demographic and clinical variables of the participants, as well as scores from the rating scales for pain and anxiety expressed as fear. Furthermore, data will be collected on daily forms to survey the number of venipunctures performed, monitor the number of preps used, and track the venipuncture timing.

The data will then be entered into the computerized online platform "Electronic Data Capture" (REDCap), which is currently in use at the promoting canter and will be tailored to the specifics of the study.

Statistical analysis

The data will be analyzed descriptively by calculating the mean and standard deviation for normally distributed variables and median and interquartile range for non-normally distributed variables. Analysis of variance ANOVA will be used to compare treatment groups. The coefficients of Skewness and Kurtosis will be used to test for normality. Considering an effect size of 0.25, p=0.05, and a power of 0.80, a total of 159 patients were estimated, with 53 in each of the three groups. Statistical analyses will be carried out using SPSS v.25.

DISCUSSION

The aim of this study is to compare the effectiveness of two different distraction methods (VR and Buzzy®) versus standard care in terms of comfort, economic analysis, and time related to the venipuncture procedure in paediatric settings.

To reduce pain and anxiety during painful invasive procedures such as venipuncture, both pharmacological and non-pharmacological methods are used.[31] Pharmacological treatment is widely used, but given the high cost, the long wait for therapeutic efficacy, and the fact that it only prevents pain but not the anxiety and fear caused by the procedure, this type of treatment should be used only in special cases characterized by a high level of pain in the child.[32]

The most significant benefit of non-pharmacological methods is that they reduce the use of analgesics while improving the patient's quality of life.[33] The distraction technique is one of the non-pharmacological methods for reducing pain by encouraging the patient to focus on something else. Although distraction is widely accepted as an effective acute pain management strategy for children undergoing painful medical procedures, some research suggests that certain types of distraction tasks may be more effective than others. Some studies, for example, have found that active distraction is more effective than passive distraction.[31] According to a systematic review, these techniques can be made more effective if they are used appropriately in relation to the child's age and mental and physical condition.[34] In a national context, a study conducted in 2012 at the Gaslini Hospital in Genoa demonstrated how audio-visual distractions improved procedural pain management during venipuncture, with increased confidence and cooperation from children.[35] To plan, it is necessary to assess the efficacy of various techniques.

CONCLUSIONS

Invasive procedures cause significant pain and anxiety in both children and parents.

Distraction techniques are simple, inexpensive, and easy to implement; they could be used in clinical practice to promote the comfort and cooperation of pediatric patients by making the nurse's procedures faster and easier.

Correspondence: Denise Gatti, via Venezia 16, 15121 Alessandria, Italy.
Tel. +39 0131206309.
E-mail: dgatti@ospedale.al.it

Authors' contributions: DG, MG: interpretation of data for the work, drafting the work and revising it critically for important intellectual content; MG, EG: acquisition, analysis and interpretation of data for the work, drafting the work and revising it critically for important intellectual content; RDM, TB, AM: substantial contributions to the conception, design of the work, acquisition, analysis and interpretation of data for the work, drafting the work and revising it critically for important intellectual content. All the authors have read and approved the final version of the manuscript, and agreed to be held accountable for all aspects of the work.

Conflict of interest: the authors declare no potential conflict of interest.

Funding: none.

Availability of data and materials: the data used to support the findings of this study are available from the corresponding author upon request.

Received: 10 February 2023.
Accepted: 22 March 2023.

Publisher's note: all claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article or claim that may be made by its manufacturer is not guaranteed or endorsed by the publisher.

Licensee PAGEPress, Italy
Working Paper of Public Health 2023;11:9684
doi:10.4081/wpph.2023.9684

BIBLIOGRAFIA

1. Chen Y, Min C, Wang Q, et al. Procedural Pain in Hospitalized Children in a Chinese Children's Hospital. Pain Manag Nurs Off J Am Soc Pain Manag Nurses. 2021;22:414–22.
2. Boussicault G, Ollivier M, Allard L, Ringuier B. Accessi venosi nel neonato, nel lattante e nel bambino. EMC - Anest-Rianim. 2018;23:1–24.
3. Inan G, Inal S. The Impact of 3 Different Distraction Techniques on the Pain and Anxiety Levels of Children During Venipuncture: A Clinical Trial. Clin J Pain. 2019;35:140–7.
4. Schinkel MG, Boerner KE, Chambers CT, McMurtry CM. Adult judgments of children's pain and fear during venipuncture: The impact of adult and child sex. Can J Pain. 2018;2:292–301.
5. Arıkan A, Esenay FI. Active and Passive Distraction Interventions in a Pediatric Emergency Department to Reduce the Pain and Anxiety During Venous Blood Sampling: A Randomized Clinical Trial. J Emerg Nurs. 2020;46:779–90.
6. Mahoney L, Ayers S, Seddon P. The Association Between Parent's and Healthcare Professional's Behavior and Children's Coping and Distress During Venipuncture. J Pediatr Psychol. 2010;35:985–95.
7. Taddio A, Appleton M, Bortolussi R, et al. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline (summary). Can Med Assoc J. 2010;182:1989–95.
8. McCarthy AM, Kleiber C. A Conceptual Model of Factors Influencing Children's Responses to a Painful Procedure When Parents are Distraction Coaches. J Pediatr Nurs. 2006;21:88–98.
9. Pedro H, Barros L, Moleiro C. Brief Report: Parents and Nurses' Behaviors Associated with Child Distress during Routine Immunization in a Portuguese Population. J Pediatr Psychol. 2010;35:602–10.
10. American Pain Society Task Force. The assessment and management of acute pain in infants, children, and adolescents. Pediatr-Springf-. 2001;108:793-7.
11. Paediatric Association of Anaesthetists of Great Britain and Ireland. Good Practice in Postoperative and Procedural Pain Management, 2nd Edition. Pediatr Anesth. 2012;22:1–79.
12. Ali S, Manaloor R, Ma K, et al. A randomized trial of robot-based distraction to reduce children's distress and pain during intravenous insertion in the emergency department. Can J Emerg Med. 2021;23:85–93.
13. Ryu JH, Han SH, Hwang SM, et al. Effects of Virtual Reality Education on Procedural Pain and Anxiety During Venipuncture in Children: A Randomized Clinical Trial. Front Med. 2022;9:849541.
14. Wente SJK. Nonpharmacologic Pediatric Pain Management in Emergency Departments: A Systematic Review of the Literature. J Emerg Nurs. 2013;39:140–50.
15. Canares TL, Parrish C, Santos C, et al. Resource Use During Pediatric Venipuncture With Virtual Reality: Secondary Analysis of a Randomized Controlled Pilot Trial. Hosp Pediatr. 2021;11:775–8.
16. Birnie KA, Noel M, Chambers CT, et al. Psychological interventions for needle-related procedural pain and distress in children and adolescents. Cochrane Pain, Palliative and Supportive Care Group, editor. Cochrane Database Syst Rev. 2018;10:CD005179.
17. Krauss BS, Calligaris L, Green SM, Barbi E. Current concepts in management of pain in children in the emergency department. The Lancet. 2016;387:83–92.
18. Krauss BS, Calligaris L, Green SM, Barbi E. Current concepts in management of pain in children in the emergency department. The Lancet. 2016;387:83–92.
19. Arane K, Behboudi A, Goldman RD. Virtual reality for pain and anxiety management in children. Can Fam Physician. 2017;63:932–4.
20. Pourmand A, Davis S, Marchak A, et al. Virtual Reality as a Clinical Tool for Pain Management. Curr Pain Headache Rep. 2018;22:53.
21. Gerçeker GO, Ayar D, Özdemir EZ, et al. Effects of virtual reality on pain, fear and anxiety during blood draw in children aged 5–12 years old: A randomised controlled study. J Clin Nurs. 2020;29:1151–61.
22. Gupta A, Scott K, Dukewich M. Innovative Technology Using Virtual Reality in the Treatment of Pain: Does It Reduce Pain via Distraction, or Is There More to It? Pain Med. 2018;19:151–9.
23. Gold JI, Mahrer NE. Is Virtual Reality Ready for Prime Time in the Medical Space? A Randomized Control Trial of Pediatric Virtual Reality for Acute Procedural Pain Management. J Pediatr Psychol. 2018;43:266–75.

24. McNair C, Campbell-Yeo M, Johnston C, Taddio A. Nonpharmacologic Management of Pain During Common Needle Puncture Procedures in Infants. Clin Perinatol. 2019;46:709–30.
25. Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. Int J Nurs Stud. 2021;113:103803.
26. Ballard A, Khadra C, Adler S, et al. Efficacy of the Buzzy® device for pain management of children during needle-related procedures: a systematic review protocol. Syst Rev. 2018;7:78.
27. Su HC, Hsieh CW, Lai NM, et al. Using Vibrating and Cold Device for Pain Relieves in Children: A Systematic Review and Meta-analysis of Randomized Controlled Trials. J Pediatr Nurs. 2021;61:23–33.
28. Wong DL, Baker CM. Pain in children: comparison of assessment scales. Pediatr Nurse. 1988;14:9–17.
29. Downie WW, Leatham PA, Rhind VM, et al. Studies with pain rating scales. Ann Rheum Dis. 1978;37:378–81.
30. McMurtry CM, Noel M, Chambers CT, McGrath PJ. Children's fear during procedural pain: Preliminary investigation of the Children's Fear Scale. Health Psychol. 2011;30:780–8.
31. Hussein HA. Effect of active and passive distraction on decreasing pain associated with painful medical procedures among school aged children. World J Nurs Sci 12 13-23. 2015;1:13–23.
32. Lessi E. Il dolore da venipuntura nel bambino: il beneficio della distrazione con audiovisivi. Edizioni Accademiche Italiane. 2016. 108 pp.
33. Viggiano MP, Giganti F, Rossi A, et al. Impact of Psychological Interventions on Reducing Anxiety, Fear and the Need for Sedation in Children Undergoing Magnetic Resonance Imaging. Pediatr Rep. 2015;7:5682.
34. Rezai MS, Goudarzian AH, Jafari-Koulaee A, Bagheri-Nesami M. The Effect of Distraction Techniques on the Pain of Venipuncture in Children: A Systematic Review. J Pediatr Rev. 2017;5:26-37.
35. Bagnasco A, Pezzi E, Rosa F, et al. Distraction Techniques in Children during Venipuncture: An Italian Experience. J Prev Med Hyg. 2012;53:44–8.