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Evaluation of a new pediatric intraosseous needle insertion device for low-resource settings

Sara Kalechstein[a], Ahiliyia Permual[b], Blair M. Cameron[a], Julia Pemberton[a], Gwen Hollaar[c], Deirdre Duffy[d], Brian H. Cameron[a,*]

[a]McMaster International Surgery Desk, Hamilton, Canada L8N 3Z5
[b]Institute for Health Science Education, Georgetown, Guyana
[c]University of Calgary, Calgary, Canada T2N 1N4
[d]University of Alberta, Edmonton, Canada T5J 4P6

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Abstract

Background and Purpose: The Near Needle Holder (NNH) (Near Manufacturing, Camrose, Alberta, Canada) is a reusable tool to introduce a standard hollow needle for pediatric intraosseous (IO) infusion. We compared the NNH to the Cook Dieckmann (Cook Critical Care, Bloomington, IN) manual IO needle in a simulation setting.

Methods: Study subjects were 32 physicians, nurses, and medical students participating in a trauma course in Guyana. After watching a training video and practicing under supervision, subjects were observed inserting each device into a pediatric leg model using a randomized crossover design. Outcome measures were time to successful insertion, technical complications, ease of use, and safety of each device.

Results: The mean time for IO insertion (32 ± 13 seconds) was similar for both devices (P = .92). Subjects rated the NNH device equivalent in ease of use to the Cook IO needle but slightly lower in perceived safety to the user.

Conclusions: After training, all subjects successfully inserted the NNH IO device in a simulation environment, and most rated it as easy to use and safe. The NNH is a significant advance because IO needles are often not available in emergency departments in developing countries. Further studies are needed to evaluate clinical effectiveness of the NNH.

Rapid vascular access is an essential component of the management of children in shock. An intraosseous (IO) needle can be inserted within minutes for emergency vascular access when intravenous attempts have failed.

Mechanical and manual IO insertion devices are commercially available. Mechanical devices are not as well suited to low-resource settings because of their increased cost and reliance on battery power. For this reason, the Near Needle Holder (NNH) was developed as a low-cost and reusable method of introducing a standard hollow-bore needle into the marrow of the tibia (Fig. 1). It has been used in Southeast Asia, demonstrated at the Bethune Round Table on International Surgery (Calgary, 2010), and is now

* Corresponding author. McMaster University Medical Centre, Hamilton, ON, Canada L8N 3Z5. Tel.: +1 905 521 2100x75231; fax: +1 905 521 9992.
E-mail address: cameronb@mcmaster.ca (B.H. Cameron).

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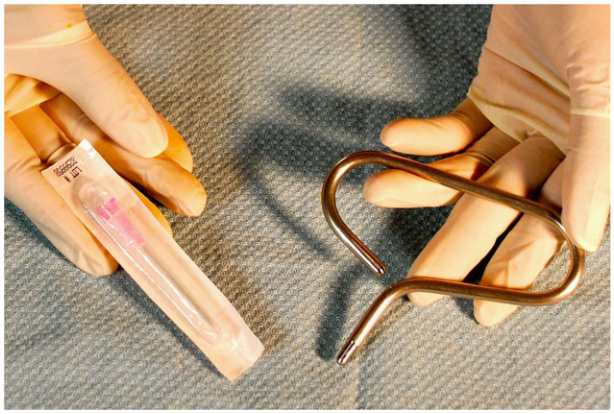

Fig. 1 Near Needle Holder.

commercially available (Near Manufacturing, Camrose, Alberta, Canada; www.nearperfection.com).

The primary objective of this study was to compare the insertion success and user's perceptions of the NNH to the single-use modified Dieckmann needle (Cook Critical Care, Bloomington, IN) [1]. A secondary objective was to evaluate the instructional video produced for the IO training module.

1. Methods

All participants, local and visiting faculty taking part in a Canadian Network for International Surgery Trauma Team Training update course in Georgetown, Guyana, in November 2010 were invited to take part in the study. Institutional Research Ethics Board approval was obtained in both Canada and Guyana. After obtaining written consent, each study subject completed a background data sheet detailing their type of medical training, specialty, postgraduate experience, number of IO lines placed, and IO device currently in use in their facility.

1.1. Instructional video

A 5-minute instructional video demonstrating the IO needle insertion technique with both devices was produced in Guyana. A compact, Canon FS300 video camera (Canon Canada Inc, Mississauga, Ontario) was used to film the simulated procedure, and footage was edited using iMovie '09 for Macintosh (Apple Inc., Cupertino, CA). Study participants watched the video twice before completing a 6-item, multiple-choice quiz to assess knowledge about IO insertion. Additional questions were asked to ascertain the participant's perceived value of the video as a training tool, using a 7-point Likert scale.

1.2. Intraosseous evaluation

The 2 devices compared in this study were the 18-gauge modified Dieckmann pediatric IO needle by Cook Critical Care (referred to as the Cook needle) and the NNH used with a 1-inch 18-gauge needle. After watching the instructional video twice, participants were given 5 minutes to practice inserting both devices on a plastic pediatric leg model. Feedback was provided on insertion technique by the primary investigators. Once subjects were comfortable and competent inserting both devices, participants were asked to demonstrate needle insertion using correct technique and confirm correct placement of the needle by aspirating simulated bone marrow. Because the purpose of the study was to evaluate the devices, participants were not evaluated on their insertion technique. A randomized crossover design was used. Computer-generated block randomization determined which device was used first by each participant. After inserting the first device, participants crossed over to insert the second device. Tape was applied across the proximal tibia of the leg model, and the desired needle insertion site was marked with a dot. This tape was replaced between subjects. The designated needle insertion site was used to prevent reinserting needles in the same hole, which would compromise the integrity of the model.

An independent observer recorded the time taken for successful insertion of each device, defined by aspiration of simulated bone marrow. Technical complications were noted. Participants then completed a written evaluation on the ease of use and safety of each needle using a 7-point Likert scale.

1.3. Data analysis

Descriptive statistics were calculated to summarize the participants' demographic data and quiz scores. A paired *t* test with 95% confidence intervals was used to compare mean time for successful insertion of each device. Fisher's Exact test was used to compare the rate of technical complications and Likert scores on the participant evaluations. Two-sided *P* values less than .05 were considered significant.

2. Results

Thirty-two subjects evaluated the IO devices and completed the instructional video evaluation. The group's type of medical training, medical subspecialty, and prior experience with IO devices are summarized in Table 1.

2.1. Intraosseous evaluation

All participants successfully inserted both IO needles on the first attempt. The mean time for successful insertion was the same for both devices (NNH, 32 ± 13.2 seconds; Cook, 32 ± 12.3 seconds), with a mean difference of 0.25 seconds ($P = .92$; 95% confidence interval, −4.97 to 5.57). The rate of technical complications was nearly identical for both devices (Cook, 11/32; NNH, 12/32; *P*, not significant; Fig. 2). Both