Comparison of three intraosseous access devices for resuscitation of term neonates: a randomised simulation study

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ABSTRACT

Objectives To compare the success rates and ease of use of three intraosseous (IO) access devices used in term neonates.

Design A three-arm randomised controlled simulation study was conducted.

Setting A simulation laboratory.

Participants Seventy-two paediatric residents completing their emergency department rotation as part of their residency training, and 20 paediatric specialists.

Intervention Using an animal bone model, the one-attempt success rate of the EZ-IO drill, the NIO-I needle and the Jamshidi needle was compared. Uncooked Cornish Hen bones were used because of their similarity in length and diameter to the bones of neonates. Participants were asked to record the perceived ease of use of their assigned device using a 5-point Likert Scale.

Main outcome measure The main outcome was the visualisation of flow emerging from the distal end of the bone, and perceived ease of use of the three IO devices.

Results The EZ-IO, NIO-I and Jamshidi groups included 30, 31 and 31 participants, respectively, with median (IQR) years of experience of 3 (2–5), 3 (2–6) and 4 (3–5) years. Participants had significantly lower one-attempt success rates with the EZ-IO drill than with the NIO-I and the Jamshidi needles (14 of 30 (46.7%) vs 24 of 31 (77.4%); p=0.016, and 14 of 30 (46.7%) vs 25 of 31 (80.7%); p=0.007, respectively). The median (IQR) ease-of-use score of the EZ-IO drill was higher than that of the NIO-I and Jamshidi needles (5 (4–5) vs 4 (4–5); p=0.008, and 5 (4–5) vs 4 (3–4); p=0.0004, respectively).

Conclusions Although easier to use, the EZ-IO drill demonstrated lower success rates than the IO needles in establishing IO access on a neonatal bone model.

What is already known on this topic?

- Intraosseous access is an acceptable method for delivery of resuscitation medications in neonates, when umbilical venous catheterisation is not possible.
- Currently, there have been no randomised controlled trials that compared different intraosseous access devices in neonates.

What this study adds?

- The intraosseous drill demonstrated lower success rates than the intraosseous needles in establishing intraosseous access on a neonatal bone model.
- Study findings suggest that the intraosseous needles are more appropriate for use in neonates than the intraosseous drill.

INTRODUCTION

Intraosseous (IO) access is an acceptable method for delivery of resuscitation medications and volume expanders in all age groups, including neonates.[1 2] In newborns, umbilical venous catheterisation is a common practice extensively taught in resuscitation courses. This access method is not an available option in neonates who no longer have an umbilical cord access point.[2] A previous simulation study revealed that IO access is faster than umbilical venous catheterisation and has equal success rates.[3] The authors of this study concluded that IO access should be considered for use in neonatal resuscitation, especially by healthcare professionals who less routinely place umbilical venous lines.[3] The need for readily available IO devices in neonatal resuscitation has been suggested in a recently published systematic review, which emphasised the importance of further investigation into adequate device use in neonates.[2] Currently, there have been no randomised controlled trials comparing different IO access devices in neonates.

Among the most commonly used devices for IO access in term neonates in practice are the EZ-IO battery-powered drill (Teleflex) and the Jamshidi needle (Baxter HealthCare Corp).[2] In 2019, the NIO-I (Persys Medical), a new IO device specifically designed for use in neonates and young infants, was approved by the Food and Drug Administration.[4]

The objective of the current study was to compare the success rates and ease of use of the three devices.

MATERIALS AND METHODS

Study design

A three-arm randomised controlled simulation study was conducted. Using an animal bone model, the one-attempt success rate of the NIO-I needle, the EZ-IO drill and the Jamshidi needle was compared. The study was conducted in the simulation laboratory of a tertiary care centre in Israel.

Study participants

Study participants were paediatric specialists who work in a paediatric emergency department, and

Figure 1 (A) The Arrow EZ-IO power drill; (B) the NIO-I intraosseous infant access device; (C) the Jamshidi intraosseous infusion device (Jamshidi, Baxter HealthCare Corporation, Deerfield, Illinois, USA).

paediatric residents completing their emergency medicine rotation as part of their residency training. Using a computerised random-number generator, participants were randomly assigned to one of the three IO devices. Randomisation was performed in a stratified manner to ensure a similar distribution of paediatric residents and paediatric specialists. The random-allocation sequence was generated by the study statistician, and participants were enrolled and assigned to the study groups by the research coordinator (RD). Participants were informed of the objectives of the study.

Study instruments

1. The battery-powered IO infusion drill (Arrow EZ-IO, Teleflex, Morrisville, North Carolina, USA) is a semiautomatic system that consists of a multiple-use, battery-powered driver with an integrated hollow drill-tipped needle (figure 1). The operator has a choice of two different length 15-gauge needles. This study used the 15 mm long needle that is recommended for children from 3 to 39 kg (figure 1A).[5]
2. The new IO infusion device (New Intraosseous-Infant—NIO-I, Persys Medical, Houston, Texas, USA) is a stepped needle 14–18 gauge, manually inserted by use of pressure and rotation. Entry into the medullary space in indicated by loss of resistance (figure 1B).[4]
3. Jamshidi IO needle (Jamshidi, Baxter HealthCare Corporation, Deerfield, Illinois, USA), is a 15-gauge disposable bone marrow aspiration/IO infusion needle, manually inserted access by use of pressure and rotation. Entry into the medullary space is indicated by loss of resistance (figure 1C).[5]

IO model

Uncooked tibial bones of Cornish Hen chickens, readily available for commercial consumption, were used in this study because of their similarity in length and diameter to the bones of neonates. Based on measurements acquired by fetal ultrasound, the mean length of the fetal tibia at 40 weeks' gestation ranges between 6.0 and 7.0 cm.[6] The mean diaphyseal diameter of term neonatal tibias is approximately 6 mm, with an average medullary diameter of 4.0 (IQR 3.3–4.7) mm at the proximal tibia and a mean cortical thickness of 1.2 mm, measured by CT imaging.[7] The similarity in measurements was validated prior to study initiation by measuring eight sample tibial bones from four Cornish Hens with a mean total weight of 750 (IQR 685–782) g, mean tibial length of 7.1 (IQR 6.2–8.0) cm, while mean tibial diaphyseal diameter and mean tibial medullary diameter, both measured at the midshaft, were 6 (IQR 5.2–6.7) mm and 4 (IQR 3.3–4.7) mm, respectively.

To best visualise the flow of infused fluids inside the marrow cavity, we cut the bones prior to IO insertion at the distal end opposite to the intended location of the placed IO, proximally. In preparation, the bones were stripped of their overlying meat and tissues. Although leaving the meat on might provide a more realistic simulation given the subject's ability to palpate the bone within the extremity, possible micro fractures created during the butchering process might allow infused fluid to leak and potentially bias the results.[8] Thus, the absence of overlying soft tissue allowed us to best observe the flow and exit point of dyed fluid to make an accurate decision of a successful IO placement.[8] Since the study aimed to assess the IO devices themselves, rather than the participants' ability to identify anatomical markers on an animal model tibia, the approximate location for IO placement was marked with a visibly identifiable coloured dot using a surgical marker.[8]

Study procedure

Each participant was randomly allocated to one of three groups: Jamshidi needle, NIO-I needle and EZ-IO drill. On the day of the experiment, the participant received a 10-minute explanation on the device and the technique of IO access and, immediately after, practised the IO technique, manual insertion or drilling on a model. Practising was ended when the participant was satisfied with his/her understanding of the method of IO access. Thereafter, the participant was asked by a study investigator to perform a single IO insertion attempt independently, using the IO device (Jamshidi needle, EZ-IO drill or NIO-I needle) into the Cornish Hen chicken bone model. Participants were asked to subsequently connect and infuse dyed fluid from a prefilled 20 mL syringe once they believed IO insertion was successful. Immediately after performing the procedure, the participant answered a single-item questionnaire on the device's ease of use. The study investigators (AK, AB and RD) did not intervene with the procedure or provide any consultation or recommendation from procedure start to finish, and participants were not allowed to watch others perform the procedure.

Each needle was used on no more than one bone, and a new needle was used for each insertion attempt. For each insertion attempt with the EZ-IO, a new needle was connected to the driver, and for each insertion attempt with the Jamshidi needle or NIO-I needle, a new needled device was used.

Outcome measures and data collection

Primary outcome measure (test method)

Once the participant was ready to begin the procedure, a video recording was started, using an iPhone 11Pro. Only the participants' gloved hands, the device in use, the bone and the fluid-filled syringe were filmed. The recording was discontinued once the infusion of fluids had ended. In addition, after the participant left the room, the study investigator photographed the model with the IO needle left in its original placement. Still images of the models from various angles were captured to record any visually obvious technical failures in either IO placement or the bone model. Later, two study investigators reviewed the video films and still images independently, rating each procedure as successful or unsuccessful, and recorded any technical complications or failures observed. If there was a difference of opinion between the two evaluating investigators regarding a certain procedure's outcome, a third investigator was asked to review and assess. Visualisation of flow emerging from the distally cut end of the tibial bone was defined as *a successful attempt* because it reflects correct placement of the tip of the needle in the bone marrow (figure 2).[8] If fluid did not emerge from this distal end, but only extravasates from around the inserted device and/or

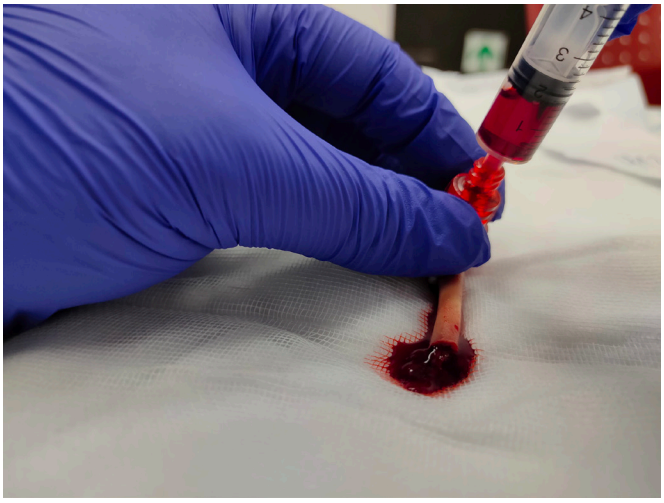

Figure 2 Demonstration of a successful attempt. Visualisation of flow emerging from the distally cut end of the tibial bone.

only from the porous proximal epiphysis, such an insertion was defined as *an unsuccessful attempt*.

Secondary outcome measures

Following the study procedure, participants were asked to complete a single-item questionnaire in which participants were asked to record their perceived ease of use of their assigned device using a 5-point Likert Scale ('the device is easy to use'; 1—strongly disagree, 2—disagree, 3—neither agree nor disagree, 4—agree, 5—strongly agree). Data were collected anonymously.

Power calculation and statistical analysis

The primary endpoint for the sample size calculation was the expected difference in one-attempt success rates between two devices. In a previous simulation study on a bone model in which the BIG and the EZ-IO were tested, the one-attempt success rates were 65.5% and 96.5%, respectively.[8] We regarded a difference of 30% in success rates as clinically meaningful. Assuming an alpha error of 0.05 and a power of 80%, a minimum of 29 participants in each group was required.[9]

Data were compared using descriptive statistics expressed as frequency, medians and IQR. Fisher's exact test was used for the comparison of success rates. The Mann-Whitney non-parametric test was used for comparison of the 'ease of use'. A two-sided p value of <0.05 was considered statistically significant. All statistics will be calculated using the StatsDirect statistical software (V.2.6.6, StatsDirect Limited, Cheshire, UK).

RESULTS

Overall, 92 participants, 72 paediatric residents and 20 paediatric specialists, with a median (IQR) age of 32 (30–36) years and a male/female ratio of 37:55, were randomly assigned to perform one IO insertion attempt with either the Jamshidi needle, the NIO-I needle or the EZ-IO drill (online supplemental appendix: Consort Diagram). The EZ-IO, NIO-I and Jamshidi groups included 30, 31, and 31 participants, respectively, with median (IQR) years of experience of 3 (2–5), 3 (2–6) and 4 (3–5) years. None of the paediatric residents or specialists had any clinical experience with the NIO-I needle or the Jamshidi needle; 15 of 72 (20.1%) paediatric residents and 11 of 20 (55.0%) paediatric specialists had clinical experience with the EZ-IO.

Success rates

The inter-rater agreement between the two evaluating investigators as calculated by percentage of agreement was 95.6%. Participants had significantly lower one-attempt success rates with the EZ-IO drill than with the NIO-I and the Jamshidi needles (14 of 30 (46.7%) vs 24 of 31 (77.4%); p=0.016, and 14 of 30 (46.7%) vs 25 of 31 (80.7%); p=0.007, respectively) (table 1).

Ease of use of the three IO devices

1. Overall (72 paediatric residents and 20 paediatric specialists)
   The median (IQR) ease-of-use score of the EZ-IO drill was higher than that of the NIO-I and Jamshidi needles (5 (4–5) vs 4 (4–5); p=0.008, and 5 (4–5) vs 4 (3–4); p=0.0004, respectively).
2. Participants who had clinical experience with the EZ-IO (15 paediatric residents and 11 paediatric specialists)
   The median (IQR) ease-of-use score of the EZ-IO drill was higher than that of the NIO-I and Jamshidi needles (5 (4–5) vs 4 (3–4); p=0.0004, and 5 (4–5) vs 4 (3–4); p=0.0004, respectively).

Unsuccessful attempts and technical problems

Among the 92 attempts made across the three devices, 27 attempts resulted from overinsertion of the IO needle through the bone cavity out the other side; 15 of 27 (55.6%) occurred with the EZ-IO drill, 7 of 27 (25.9%) with the NIO-I needle and 5 of 27 (18.5%) with the Jamshidi needle. One unsuccessful attempt with the Jamshidi needle was found to have been caused by a different mechanism: mishandling the IO needle after placement.

DISCUSSION

In this simulation study, we compared the success rates and perceived ease of use of the three IO devices used in term neonates. The major finding of this study is that the EZ-IO drill

Table 1 Comparison of success rates, and ease of use, of the EZ-IO drill, NIO-I needle and the Jamshidi needle

Success rate on one attempt (%)	EZ-IO drill (n=30)	NIO-I needle (n=31)	Jamshidi needle (n=31)	EZ-IO drill vs NIO-I needle	EZ-IO drill vs Jamshidi needle	NIO-I needle vs Jamshidi needle
Overall (n=92)	14/30 (46.7)	24/31 (77.4)	25/31 (80.7)	0.016	0.007	0.767
Paediatric residents (n=72)	11/24 (45.8)	19/25 (76)	18/23 (78.2)	0.036	0.027	0.863
Paediatric specialists (n=20)	3/6 (50)	5/6 (83.3)	7/8 (87.5)	0.303	0.189	0.857
Assessment of 'ease of use' (median, IQR)						
Overall	5 (4–5)	4 (4–5)	4 (3–4)	0.008	0.0004	0.384
Paediatric residents	5 (4–5)	4 (4–5)	4 (4–4)	0.024	0.0009	0.494
Paediatric specialists	5 (4–5)	4 (4–4)	3.5 (2–5)	0.365	0.266	0.741

demonstrated significantly lower success rates than the Jamshidi and NIO-I needles in establishing IO access on a neonatal bone model (approximately 50% vs 80%). Our findings are corroborated by the results of a previous simulation study on stillborns that verified correct positioning of the needle within the bone marrow cavity, using spectral CT. This study found a success rate of 39.7% using the EZ-IO drill vs 61.1% with a manual device.[7] Using postmortem CT, Maxien *et al* investigated the rates of malpositioning of IO needles in 22 infant cadavers who were treated via the IO access during resuscitation. Findings revealed a success rate of 52% for the EZ-IO drill.[10] In our study, all the unsuccessful attempts with the EZ-IO resulted from overinsertion of the needle to the other side of the cortex. This phenomenon occurred less frequently with the manual devices. The relative softness of the neonatal cortical bone makes it easier for penetration by a needle. We speculate that bone softness is an advantage when the procedure is performed manually, as the performer more easily feels the loss of resistance and can discontinue insertion pressure. When the drill is being used, however, it is probably more difficult to identify loss of resistance and to discontinue insertion pressure.

Though the NIO-I device is described to have been specifically designed for young infant and neonatal use,[4] our study found no significant difference when comparing the NIO-I and the Jamshidi needles' success rates, indicating neither device is superior to the other. Our findings suggest that the use of either manual devices, the NIO-I needle or the Jamshidi needle, would provide similarly successful results in the neonatal age group.

Another interesting finding of this study is the ease of use of the devices. Despite its lower success rates of IO insertion, participants found the EZ-IO drill easier to use than either the NIO-I or the Jamshidi needle (5 vs 4 on the Likert Scale). This result was found for participants who were familiar with the device, and for participants who were not familiar with it. This finding is likely a result of the semiautomatic drill mechanism versus the manual hand-twisted needle mechanism. While ease of use may seem to be a favourable quality for use during critical situations, it is reasonable to believe that a marginally higher degree of ease should not compromise the successful outcome in the real environment.

LIMITATIONS

This study has certain limitations. First, as this was a simulation study, it is uncertain how the results might apply to actual patient care. Second, although the non-human animal bone model replicated certain parameters of neonatal tibial bones, it may not replicate a human neonatal bone in terms of bone density and composition, and the overlying soft tissue. The bones were stripped of their overlying soft tissue. Leaving the soft tissue on might provide a more realistic model of the depth variation; however, when a bone is removed from the animal, it may have small holes in it due to small fractures. Fluid infused into the marrow cavity can leak out through these holes and may bias the results.[8] Third, the investigators evaluating the device attempts were not blinded to which device was used. Fourth, other manual devices, such as the Cook needle (Cook Medical, USA) or the Butterfly needle (not licensed for IO), were not tested in this study.

In summary, although easier to use, the EZ-IO drill demonstrated lower success rates than the Jamshidi and NIO-I needles in establishing IO access on a neonatal bone model. The findings of this simulation study suggest that the EZ-IO drill is more appropriate for use in neonates than the IO needles.

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Contributors AK conducted the intraosseous tests, collected the data, prepared a first draft, made an early data analysis and critically revised the article. AB conducted the intraosseous tests, collected the data, prepared a first draft, made an early data analysis and critically revised the article. AB has equal contribution as first author. OF designed the study and analysis plan, and critically revised the article. RD coordinated enrolment of study participants, collected the data and critically revised the manuscript. IS conceived the idea for the study, designed the study and the analysis plan, carried out the statistical analysis, drafted the manuscript, and analysed and interpreted the data. IS has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The Institutional Review Board waived the need for approval in view of the fact that the simulation study was not being performed on patients and the human subjects are physicians who were given the opportunity to decline participation (No. 1607-20).

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Appendix

CONSORT flow diagram