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Simulation and education

Comparison of two mechanical intraosseous infusion devices: A pilot, randomized crossover trial☆,☆☆

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ABSTRACT

Introduction: Administration of medications via the intraosseous (IO) route has proven to be a lifesaving procedure in critically ill or injured children. Two mechanical IO infusion devices have been approved for use in children, the spring-loaded IO infusion device (Bone Injection Gun, BIG) and the battery-powered IO infusion drill (EZ-IO). The objective of this pilot study was to compare the success rates for insertion and the ease-of-use of the two devices.

Patients and methods: A randomized crossover study was conducted in a local paramedic training course with 29 paramedic students participating. Participants watched two videos describing the use of the two devices, followed by a demonstration on how to use each device on a turkey bone model. Then subjects were divided into two study groups: BIG-first or EZ-IO-first. Each participant performed one insertion attempt with each device independently. All attempts were filmed by a video camera. Successful placement was defined as the visualization of fluid flow from the marrow cavity. Following the study procedure, participants completed a two-item questionnaire recording their ranking of the ease-of-use of each device and their "first choice device".

Results: Participants had a significantly higher one-attempt success rate with the EZ-IO than with the BIG (28/29 vs 19/29, $p = 0.016$), and selected the EZ-IO as their first choice (20/29). Participants of the EZ-IO-first group assessed the EZ-IO as easier to use than the BIG ($p = 0.0039$). The subjects of the BIG-first group found no difference in the ease-of-use between the two devices ($p = 0.32$).

Conclusions: As tested by paramedic students on a turkey bone model, the EZ-IO demonstrated higher success rates than the BIG and was the preferred device. Future studies are planned to determine which of the two devices is more appropriate for obtaining IO access in the setting of paediatric emergencies.

1. Introduction

Fluid and drug administration via the intraosseous (IO) route has proven to be a lifesaving procedure in severely ill or injured children. The most recent edition of the International Liaison Committee on Resuscitation (ILCOR) states that establishing IO access is recommended if vascular access is not achieved rapidly in any infant or child for whom intravenous (IV) drugs or fluids are urgently required.[1] In 2005, the American Heart Association (AHA) and the European Resuscitation Council (ERC) revised their guidelines to include recommending IO access in critically ill adults as well, when IV access is not available.[2,3] IO access can be established manually using IO needles such as the Jamishidi/Illinois (Cardinal Health, McGraw Park, IL, USA), the threaded Sur-Fast needle, or the Dieckman modified needle (both by Cook Critical Care, Bloomington IN, USA). These needles are relatively similar, and the technique for their insertion is comparable.[4]

The recent development of mechanical IO infusion devices has increased the options available for IO access. The first mechanical IO infusion device, the FAST 1 system (Pyng Medical Corporation, Vancouver, Canada) was approved by the Food and Drug Administration (FDA) in 1997, but it was designed for the adult population and is not approved for use in children.[4,5] Two mechanical IO infusion devices have been approved by the FDA for use in the paediatric age group, the spring-loaded IO infusion device (Bone Injection Gun—BIG, Waismed Ltd., NY, USA) which was approved in 2000, and the battery-powered IO infusion drill (EZ-IO, Vidacare, San Anto-

Abbreviations: IO, intraosseous; BIG, Bone Injection Gun; EMS, emergency medical system.

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nio, TX, USA) which was approved in 2004.[4] A previous study that compared the BIG to an IO needle found no difference in the ease-of-use between the groups.[6] Another study found no difference in IO placement success rates between the BIG and an IO needle but the BIG was preferred by most users.[7] In Israel, the BIG is widely used by the national Emergency Medical System (EMS) and hospitals.[8] Although approved by the Israeli Ministry of Health, the EZ-IO has not been reported to be used in Israel. Two recently published studies examined the efficacy of the EZ-IO. A comparison of two field trials of EMS provider's use of the F.A.S.T. 1 and the EZ-IO reported more successful insertions with the EZ-IO than with the F.A.S.T. 1.[9] When the EZ-IO was compared to an IO needle (Cook Critical Care, Bloomington IN, USA) in an adult human cadaver model, the EZ-IO had a higher successful placement rate and was found to be more user-friendly.[10] A recently published study that prospectively recorded 95 EZ-IO insertions demonstrated its safety and efficacy in the paediatric age group.[11]

There have been no studies specifically comparing the two mechanical IO infusion devices approved by the FDA for use in children; the BIG and the EZ-IO. The objective of this pilot study was to compare the success rate of one-attempt and the ease-of-use of the BIG and the EZ-IO.

2. Patients and methods

2.1. Study design

We conducted a randomized crossover study comparing the use of BIG with EZ-IO in a paramedic training course. This two-day paediatric resuscitation course was conducted at Rambam Health Care Campus (RHCC) in Haifa, Israel, and the study was performed on the first of the two-day course. Participants were informed of the objectives of the study and the RHCC ethics committee approved the study with a consent waiver.

2.2. Study participants

Study subjects were emergency medical technicians undergoing initial training for paramedic status. Prior to the study, participants had completed courses in ACLS and in Pre-Hospital Trauma Life Support (PHTLS) as part of the standard paramedic curriculum. None of the study subjects had prior clinical experience with either the BIG or the EZ-IO. However, all had completed a 3 h workshop with the BIG during the PHTLS course six months before the study.

The sequence of device insertion was randomized to either BIG-first or EZ-IO-first. Using a computerized random-number generator, an allocation sequence was created and course participants were divided into two groups of the study: BIG-first and EZ-IO-first.

2.3. Materials for practice

2.3.1. Study instruments

- The spring-loaded IO infusion device (Bone Injection Gun—BIG, Waismed Ltd., NY, USA) is a small semi-automatic, disposable, spring-loaded device with a trigger. The paediatric version is indicated for children younger than 12 years of age, contains an 18 gauge needle, and has an adjustable insertion depth of between 0.5 cm and 1.5 cm.[4]
- The battery-powered IO infusion drill (EZ-IO, Vidacare, San Antonio, TX, USA) is a semi-automatic system that consists of a multiple-use, rechargeable, battery-powered driver with an integrated hollow drill-tipped needle. The operator has a choice of two different length 15 gauge needles. This study utilized the 15 mm long needle that is recommended for children from 3 to 39 kg.[4]

2.3.2. IO model

Uncooked bones of the lower leg of a turkey (drumsticks) were used in this study because of their similarity to the bones of children.[12] In order to visualize the flow of infused fluids inside the marrow cavity we used bones that were cut approximately 6 cm distal to the IO placement site. The bones were stripped of their overlying meat. Leaving the meat on might provide a more real simulation because of the ability to palpate the bone within the extremity.[12] However, when a turkey bone is removed from the animal, it may have small holes in it due to micro fractures. Fluid infused into the marrow cavity can leak out through these holes and may bias the results. The absence of overlying soft tissue allowed us to observe this flow and to make an accurate decision of proper IO placement.[13–16]

2.4. Study procedure

Participants received a 45-min general lecture on the treatment of paediatric shock, followed by two standardized educational videos on the use and the techniques of insertion of the BIG and the EZ-IO, and a 10-min demonstration on the IO model with each mechanical IO infusion device by a study investigator (YH). Thereafter, they were randomly divided into the two groups. Each participant was asked by a study investigator to perform *a single IO insertion attempt* independently, using a mechanical IO infusion device (BIG or EZ-IO) into a turkey drumstick. Participants were asked to connect intravenous (IV) line tubing to the needle when they believed insertion was successful and to infuse coloured water into the bone using a 20 ml syringe. Immediately after performing the first procedure, the participant entered a second room where a single insertion attempt was made using the other mechanical IO infusion device. The study investigators (IS and YH) did not intervene with the procedure or provide any consultation or recommendation, 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 paediatric needle was connected to the driver and, for each insertion attempt with the BIG a new needle was loaded to the spring of a multi-use device.

2.5. Outcome measures and data collection

2.5.1. Primary outcome measure (test method)

Once the IV line tubing was connected to the inserted IO needle, a video recording was started (Casio, EX-S770, Tokyo, Japan). The camera was fixed to a table and was located 30 cm from the bone. Only the bone and the IV line tubing were filmed, and recording discontinued when the infusion of colored water ended. For purposes of blinding, all video films were edited. The IO needle in each frame was blackened, making it unrecognizable on video (Video Edit Magic 4.47). The study investigators (IS, YH, YW), blinded to the group allocation, reviewed the video films independently, rated each procedure as successful or unsuccessful, and recorded any technical complication. Visualization of flow emerging from the IO cavity without extravasation of fluid around the drilled hole was defined as *a successful attempt*. If fluid did not emerge from the bone marrow or extravasated around the drilled hole, the insertion was defined as *an unsuccessful attempt*. If fluid emerged from other hole/s within the bone, the insertion attempt was defined as *a non-conclusive attempt* and the participant was asked to repeat the procedure using a new bone and a new needle.