



Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation



Simulation and education

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

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ARTICLE INFO

Article history:

Received 13 March 2009

Received in revised form 15 May 2009

Accepted 28 May 2009

Available online xxx

Keywords:

Intraosseous

Intraosseous infusion device

Bone model

Success rate

Children

Paramedic

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.

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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 Jamshidi/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.

[☆] A Spanish translated version of the abstract of this article appears as Appendix in the final online version at doi:10.1016/j.resuscitation.2009.05.026.

^{☆☆} An abstract of this manuscript was presented at the Canadian Association of Emergency Physicians annual conference on June 8, 2009 in Calgary, AB, Canada.

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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.

2.5.2. Secondary outcome measures

Following the study procedure, participants were asked to complete a two-item questionnaire. In the first item, participants were asked to record the ease-of-use of the BIG and the EZ-IO using a five-point Likert Scale (“the device is easy to use”; 1—strongly disagree, 2—disagree, 3—neither agree nor disagree, 4—agree, 5—strongly agree). In the second item, they were asked to record their “first choice device” (BIG or EZ-IO). Data was collected anonymously.

2.6. Statistical analysis

As this was a crossover trial, pairing was taken into account in the statistical analysis. McNemer’s test was used for comparing the success rate of the BIG and the EZ-IO. A two-sided Wilcoxon signed-rank test was used for comparing the scoring of the ‘ease-of-use’. All statistics were calculated using the StatsDirect statistical software (v2.6.6, StatsDirect Limited, Cheshire, UK).

3. Results

All 29 paramedic students approached by the principal investigator (IS) participated in the study.

3.1. Demographic data

The BIG-first group consisted of 15 participants with a mean participant age of 20.3 years and a 6:15 female:male ratio. The EZ-IO-first group had 14 participants with a mean participant age of 19.8 years and a 4:14 female:male ratio.

3.2. Successful attempts (Table 1)

Participants had a significantly higher one-attempt success rate with the EZ-IO than with the BIG (28/29 vs 19/29, $p=0.016$).

3.3. Unsuccessful attempts and technical problems

In 6 of 10 unsuccessful attempts with the BIG, the stylet was stuck within the needle and could not be removed, in two attempts with the BIG participants failed to insert the needle, and in two attempts extravasation of fluid around the drilled hole occurred. In the one unsuccessful attempt with the EZ-IO extravasation of fluid around the drilled hole occurred. Two non-conclusive attempts were recorded with each device. All four repeated attempts were successful.

Bending or breaking of the needle, were not recorded with either device.

Table 1
Comparison of success rates, ease-of-use, and preference of the BIG and the EZ-IO.

	BIG	EZ-IO	P value
Success rates on one attempt (%)	19/29 (65.5)	28/29 (96.5)	0.016
Assessment of ‘ease-of-use’ (median)			
BIG-first	4	4	0.32
EZ-IO-first	3.5	5	0.0039
Preference for ‘device of choice’ (%)			
BIG-first	4/15	11/15	
EZ-IO-first	5/14	9/14	
Total	9/29 (31)	20/29 (69)	

3.4. Participant assessments (Table 1)

3.4.1. Assessment of ‘ease-of-use’

Participants of the EZ-IO-first group assessed the EZ-IO as easier to use than the BIG ($p=0.0039$). Subjects of the BIG-first group found no difference in the ease-of-use between the two devices ($p=0.32$).

3.4.2. Preference for ‘device of choice’

Participants of the two groups preferred the EZ-IO over the BIG as their device of choice.

4. Discussion

Success in establishing IO access on the first attempt is of major importance in the setting of resuscitation, because it is a rarely used emergency skill and thus might be difficult to perform.^{1–4,17} The traditional approach of establishing IO access using a manual IO needle has a long history and is considered to be safe and effective, especially in young children.³ However, this technique might be difficult to perform in the setting of resuscitation and has been shown to be associated with technical complications, such as bending or breaking of the needle during insertion.^{4,10,13,14} It is speculated that the new mechanical IO infusion devices (BIG and EZ-IO) make insertion easier and have fewer complications.³

Our pilot study is the first to compare the BIG with the EZ-IO. When the devices were tested on a turkey bone model, we demonstrated that:

1. The EZ-IO had a one-attempt success rate of 96.5% compared to only 65.5% for the BIG.
2. Nearly 70% of the study subjects chose the EZ-IO as their preferred device.
3. Participants of the EZ-IO-first group rated the EZ-IO as easier to use, while subjects of the BIG-first group found no difference in the ease-of-use between the two devices. It is statistically possible that more subjects from the EZ-IO-first group experienced technical problems with the BIG, which biased their rating. Consequently, we are unable to conclude that we found a difference between the two devices in terms of ‘ease-of use’.

Our study revealed a high success rate on one-attempt with the EZ-IO despite the fact that no participant had any prior clinical experience with it and received no hands-on training with the device prior to using it. The BIG success rate was significantly lower even though all participants had undergone hands-on training with it six months prior to the study.

The high success rate on one-attempt using the EZ-IO that was recorded in our study is in line with three previous studies that reported high first-attempt success rates using this device.^{9–11} However, only one of these studies reported clinical use in children.¹⁰ It is worth noting that Frascone et al. reported technical problems related to drill power and battery failure, problems that did not result in failed attempts.⁹

We recorded a 65% (19/29) success rate with BIG. Draaisma et al. demonstrated a success rate of 73% (29/40) when the BIG was used by Dutch Helicopter-transported Emergency Medical personnel.¹⁸ This finding of a 65% success rate in our study was not the result of improper use by the study participants; all participants received proper instructions on how to adjust the penetration depth specifically in the turkey bone model, first by watching an educational video and then by watching a study investigator (YH) perform the procedure. The instructions which participants received were similar to the instructions given by Ben-Abraham et al. who also tested the BIG on turkey bones stripped of the overlying meat, and

recorded a success rate of 19/20 at first attempt.¹⁶ Furthermore, all participants underwent hands-on training with the BIG six months prior to the study and were familiar with its use.

The technical problem of difficulty in removing the stylet from the needle in six attempts was surprising. We believe that this problem of a 'stuck stylet', which was not recorded with the EZ-IO, is unique to the BIG and may reflect a potential problem with this device. Our search revealed three reports of this technical problem using the BIG. Draaisma et al. demonstrated that the problem of 'stuck stylet' occurred in 3/40 cases.¹⁸ Calkins et al. recorded this problem when the BIG was tested on a cadaver bone model,⁵ and this technical failure was also reported in an EMS newsletter.¹⁹ It is reasonable to assume that the problem of 'stuck stylet' would have been less apparent if we had used an adult cadaver model or a plastic leg model in our study. A possible explanation for the high rate of 'stuck stylet' in our study may be related to the bone model and the mechanism of operation of the BIG. The spring-loaded mechanism forcefully injects the needle into the bone at a relatively high speed. In all six cases of 'stuck stylet' recorded in our study, the needle was inserted deep into the bone and was placed in the distal cortex. We speculate that when the BIG is tested on a bone with a thin cortical thickness, the forceful injection of the needle increases the chance of inserting the needle into the distal cortex, which may result in difficulty in pulling the stylet out of the needle. Our search for other studies that tested the BIG on a turkey bone stripped of its overlying meat revealed only one study.¹⁶ This study demonstrated a high success rate at first attempt (19/20), and did not report any technical problems.¹⁶ However, the investigators defined successful IO placement as "needle anchored in a firm upright position". IO access should be confirmed by infusion of fluids into the marrow cavity without extravasation of fluids around the drilled hole. In our study, the flow of coloured fluid from the marrow cavity without extravasation, as observed on a video recording, represented successful placement. In the Ben-Abraham et al. study, there was no attempt to flush fluids into the marrow cavity and, therefore, a needle that was not located in the bone marrow might have yielded a positive result (fluids that would have been infused through this needle might not emerge from the marrow cavity). This could be a confounding factor in interpreting the success rate of IO access.

In Israel, the BIG has been used since 1999. Schwartz et al. analyzed all IO insertion attempts using the BIG by Israeli EMS personnel over a period of four years. Successful placements on first attempt were recorded in 91% of the total 172 cases and in 87% of the 41 paediatric cases. Only 17 (10%) failed attempts were reported, which included device malfunction, technical insertion errors, and unspecified failed attempts. The specific types of insertion errors and failed attempts were not described.⁸ It is worth noting that, according to this report, the BIG was considered 'standard of care' by the Israeli national EMS during the study period, and was the only device used for purposes of IO access. It is possible that some EMS personnel used the BIG on more than one patient; these providers may have had a higher rate of success than others.

Future studies are planned to determine which of the two devices is more appropriate for purposes of paediatric emergencies, a question that cannot be answered in this pilot study. We believe that achieving a high rate of success at first attempt is most important, but two other major parameters should also be investigated:

- The overall IO placement time with either device. The time elapsed from opening the original sterile packaging of the device until a successful IO placement is achieved; in cases of failed first-attempt, the total time needed for two–three more attempts until success.
- The retention of this critical skill. The success rates with either device when tested three, six and twelve months after training.

Our study has certain limitations. Firstly, we did not compare the BIG and the EZ-IO to manual IO needles. Secondly, our sample size in this pilot study was relatively small. Thirdly, since a non-human bone model was used, the applicability of this data to a real leg is unclear. Fourthly, we recorded the success rates of only one-attempt because we were limited in the number of needles supplied to us by the two manufacturers.

5. Conclusion

Despite these limitations, we believe that our pilot study clearly demonstrated that paramedic students instructed in how to insert two mechanical IO infusion devices into turkey bones had higher success rates using the battery-powered IO infusion drill (EZ-IO) than the spring-loaded IO infusion device (BIG), and indicated the EZ-IO as the preferred device. Further studies are needed to determine which of the two devices is more appropriate for obtaining IO access in the setting of paediatric emergency.

Conflict of interest statement

The authors declare that they have no conflict of interest regarding any financial or personal relationships with the manufacturers or with any other people or organizations that could inappropriately influence or bias their work.

Role of the funding source

Investigators received supplies from the manufacturers, but not funding. Waismed Ltd. (Persys Medical Division of PERSYS Group), and Vidacare provided the mechanical IO infusion devices and the needles, but had no role in the design of the study; in the collection, analysis, and interpretation of the data; in the writing of the report; or in the decision to submit the paper for publication.

Acknowledgments

We would like to thank the suppliers Waismed Ltd. (Persys Medical Division of PERSYS Group), and Vidacare corporation for providing us the IO infusion devices and the needles free of charge.

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