Comparison of 4 Pediatric Intraosseous Access Devices
A Randomized Simulation Study

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Background: Obtaining intravascular access can be challenging or even impossible in several clinical situations. As an alternative, medications and fluids can be administered via the intraosseous (IO) route, which is a well-tolerated and established alternative, especially in the emergency setting.

Methods: Seventy-five novice physicians participated in this randomized simulation study. After a single educational session and 6 months without any clinical application, participants were asked to identify the correct puncture site and obtain IO access using 3 widely used mechanical devices (BIG Pediatric, Arrow EZ-IO, NIO Pediatric) and a manual device (Jamshidi needle) on a pediatric manikin and turkey bone, respectively.

Results: Sixty-eight participants correctly identified the puncture site and performed IO cannulations. First placement attempt success rate was similar with mechanical devices (NIO Pediatric, 100%; Arrow EZ-IO, 97%; and BIG Pediatric, 90%), whereas was only 43% using the manual Jamshidi device. Also, procedure time was much faster using mechanical devices (ranging between 18 and 23 seconds) compared with the manual Jamshidi device (34 seconds).

Conclusions: Although the efficacy of devices was demonstrated in simulated environment in novice users, further studies are needed to assess the efficacy and safety of devices in clinical comparative settings. With more experienced users, the success rate may differ considerably as compared with naive users.

Key Words: intraosseous vascular access, vascular access, simulation study

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Establishment of early and effective vascular access for administration of pharmacological agents and fluid therapy is critically important in the emergency treatment of severely ill or injured patients.[1–3] Intraosseous (IO) route has already been introduced into clinical practice in the 1920s and has been widely used during the second world war, but its usage declined with the invention of intravenous catheters.[4,5] Intravenous catheters are reported to be easy to use, widely available, inexpensive, and devoid of any IO complications. In the 1980s, IO access was more commonly used again, as it was reported to be useful especially in several emergency scenarios.[6] Subsequently, IO administration of medications was incorporated as an alternative to intravascular administration by several international emergency guidelines.[7–11]

The bone marrow typically of long bones has a rich network of noncollapsible vessels, which ultimately drain into central circulation. These intramedullary vessels can be accessed directly by insertion of specially designed device (known as IO devices) into the network of veins of bone marrow, which can maintain a descent amount of infusion rate for a considerable period of time. The total concentration of drug infused and time to peak via IO route yields comparable results with the intravenous route.[12,13]

In principle, the IO technique can be used in all clinical situations and patients, but because of the potential of complications, the IO route is mostly used in the emergency setting. Intraosseous route provides rapid, efficient, and timely access in clinical scenarios when intravascular route cannot be established or is difficult to obtain.[14] The preferred site of access in infants and children is the anteromedial surface of the tibia, approximately 1 to 2 cm below the tibia tuberosity.[15]

Intraosseous access can be obtained with the help of 2 different techniques. The manual technique requires moderate to severe force applied by the provider, whereas the mechanical techniques depends on battery-powered or spring-loaded force. However, there are many different IO devices commercially available and the best device for pediatric IO device has not been established yet. Therefore, the aim of this study was to compare the success rate of 4 (mechanic: NIO Pediatric [NIO-P], BIG-P [BIG Pediatric], Arrow EZ-IO [EZ-IO], and the manual Jamshidi IO needle) widely used IO devices in a pediatric manikin study setting. Speed of insertion, ease of use, and complications served as secondary outcomes.

METHODS

Study Design and Participants

This was a simulation study with a randomized design. After obtaining institutional review board approval from the Polish Society of Disaster Medicine (approval number 25.12.2016.IRB), we recruited participants among novice physicians of the Polish Society of Disaster Medicine. The study was conducted between June 2016 and February 2017 at the Medical University of Warsaw, Poland, and all physicians participated voluntarily in this study. All participants were never trained on any IO access devices before the study.

Devices

Four IO access devices were investigated in this study (Fig. 1):

1. NIO-P (New Intraosseous PerSys Medical, Houston, Tex);
2. BIG-P (Bone Injection Gun PerSys Medical, Houston, Tex);
3. The intraosseous drill Arrow EZ-IO (Teleflex Medical Research Triangle Park, NC); and
4. Jamshidi IO needle 18G (Jamshidi, Baxter HealthCare Corporation, Deerfield, Ill).

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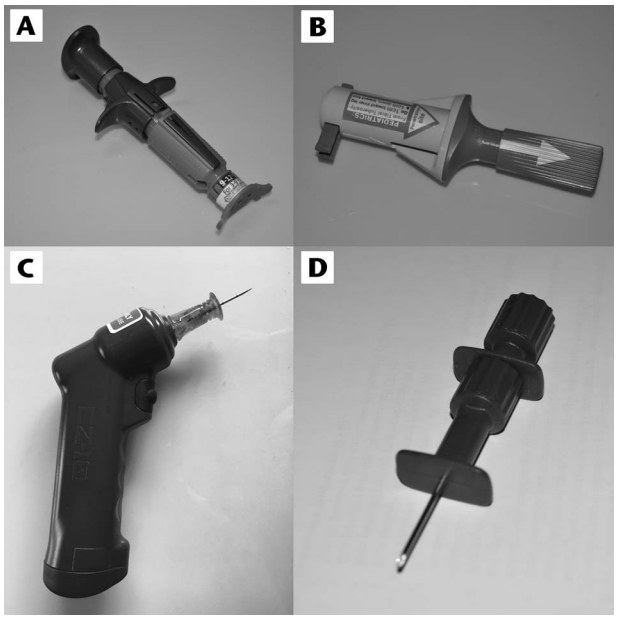

FIGURE 1. Intraosseous access devices used for this study were (A) NIO-P, (B) BIG-P, (C) EZ-IO, and (D) Jamshidi needle.

Study Procedure

All study participants attended at the Pre-Hospital Trauma Life Support course. After end of the course, all participants underwent a 20-minute lasting audiovisual lecture covering the principles of IO access and detailed demonstration of all devices used in this study. Afterwards, the participants were able to make themselves familiar with all devices. After 6 months, all participants were asked to participate in 2 subsequent practical study parts.

In the first study part, participants were asked to correctly identify the site of the IO access on a SimJunior advanced life simulator equipped with a pediatric IO leg (Laerdal, Stavanger, Norway), which represents a model of a 6-year-old child.

Afterwards, participants who correctly indicated the correct puncture site were asked to join the second practical study part and to perform an IO access with 4 IO devices in a randomized order. Randomization was performed using the Research Randomizer program (randomizer.org) and is reported in Figure 2.

Intraosseous access was performed on uncooked lower leg bones of a turkey, which nearly represents the anatomy of a human pediatric leg.[16] Any age adjustments of the IO devices were previously prepared by a researcher. Once the IO access was performed, the participants were asked to connect the IO device with an intravenous tubing system connected with a 20-mL syringe, which was filled with 20 mL of methylene blue-colored fluid. Successful and correct placement of the device was tested by pushing colored fluid within the IO device and observing flow of colored blue solution out of the bone, which was previously carved up about 5 to 6 cm distal to the expected IO device placement site by one of the researchers. During the IO device placement, the researchers did not intervene in any manner including helping or assisting the participants.

Each IO device was used in a single room only, and participants were asked to move from one to another room, as previously indicated by the randomization sequence. To avoid any teaching bias, none of the participants were allowed to watch any other participant. Each IO needle and turkey bone was only used once.

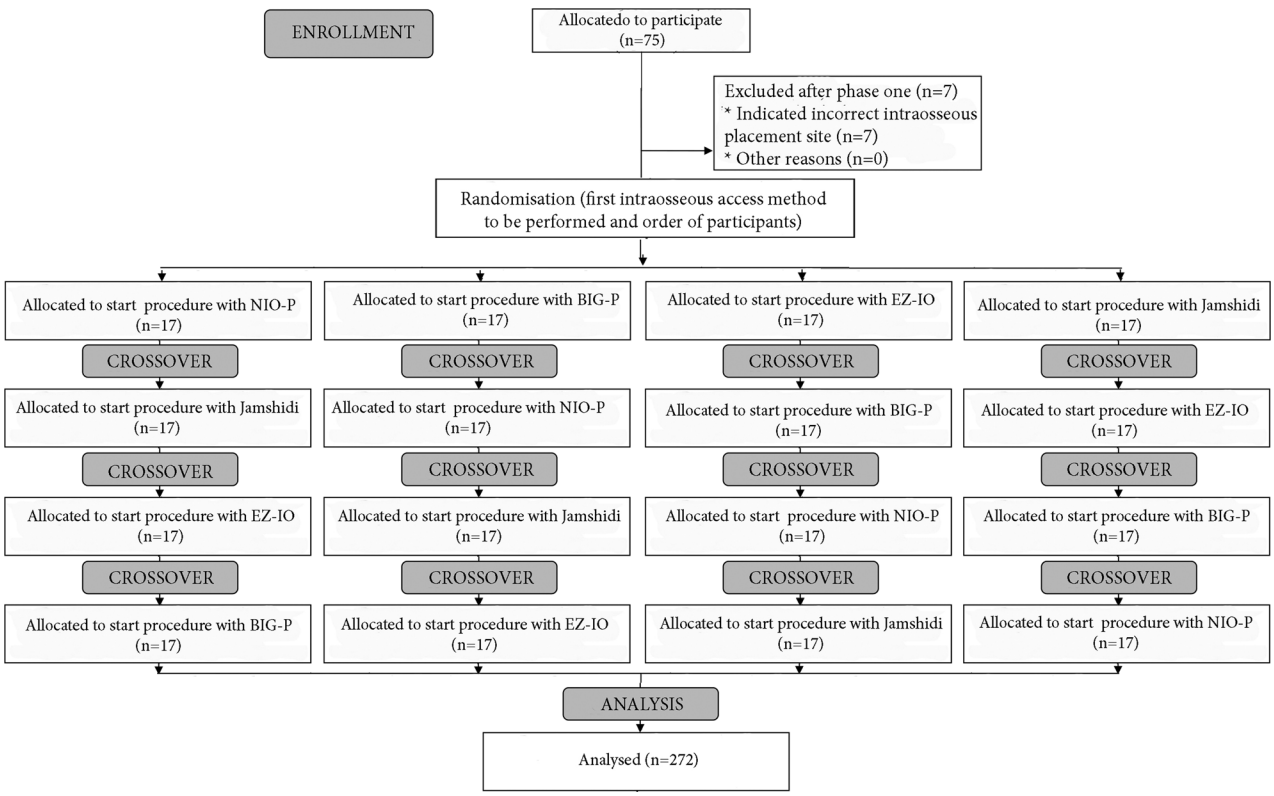

FIGURE 2. Flow chart of design and recruitment of participants according to Consolidated Standards of Reporting Trials statement.

Outcomes

In the first practical part of the study, correct location of IO site was evaluated. Identification of the correct puncture site was confirmed by one of the researcher.

During the second part, the following parameters were assessed:

- first placement attempt success rate;
- overall success rate after a maximum of three placements attempts;
- time to perform the procedure, defined as the time from grasping the device until the infusion of blue-colored liquid;
- identification of any technical problems;
- subjective ease of use, as indicated by the participants after finishing each placing procedure ranging from 1 (very easy) to 10 (impossible);
- subjective first choice device, as indicated by the participants after finishing all intradoses device placements.

Statistical Analysis

All statistical analyses were performed using Statistica version 13.1EN (StatSoft, Tulus, Okla). The results are presented as absolute values (percentages), medians (interquartile ranges [IQRs]), or means (±SD). Normal distribution was evaluated using the Kolmogorov-Smirnov test. Because this was a randomized simulation study, pairing was taken into account in the statistical analysis. McNemar test was used for comparing the cannulation success rates. The 2-sided Wilcoxon signed rank test allowed to compare the procedure time as well as "ease of use."

RESULTS

Demographic

Seventy-five novice physicians (37 female, 49%) participated in this study. None of the participant had any previous experience with any IO devices. The mean age of the participants was 24 years (IQR, 23.5–25 years).

Correct IO Location Placement

The correct IO placement site was identified by 68 participants (91%), whereas 7 participants (9%) failed. Out of these 7 participants, 2 indicated the location outside of the tibia, and 5 of them indicated the location of the medial tibia tuberosity 2 centimeters above the line of tuberosity. All of those participants who did not identify the correct location were excluded and did not participated in the second part of the study.

Successful IO Attempts

During the study, a total of 272 IO access procedures were performed, from which overall 224 (82%) were successful within one single placement attempt. First placement attempt success rate ranged between Jamshidi (43%), BIG-P (90%), EZ-IO (97%), and NIO-P (100%) (Table 1).

IO Access Procedure Time

The fastest median time to achieve IO access was performed with the NIO-P using 18 seconds (IQR, 16–21), followed by EZ-IO, 23 seconds (IQR, 18–24), and BIG-P, 23 seconds (20.5–29). Placement of the Jamshidi needle took 34 seconds (IQR, 29.5–45) and was therefore the most time-consuming device (Fig. 3, Table 1).

Unsuccessful Attempts/Technical Problems

None of our participants had any unsuccessful attempts or technical problems using the NIO-P, resulting in an overall success rate of 100%. With BIG-P device, 7 attempts failed. In 5 of 7 unsuccessful attempts, the bone was chipped and in 2 cases extravasation

TABLE 1. Intraosseous Access Parameters

Parameter	NIO-P	BIG-P	EZ-IO	Jamshidi	*P*
IO success rate on first attempt	68/68 (100%)	61/68 (90%)	66/68 (97%)	29/68 (43%)	0.044, NIO-P vs BIG-P <0.001, NIO-P vs Jamshidi <0.001, BIG-P vs Jamshidi <0.001, EZ-IO vs Jamshidi Others: not significant
Procedure time, s	18 (IQR, 16–21)	23 (IQR, 20.5–29)	23 (IQR, 18–24)	34 (IQR, 29.5–45)	0.034, NIO-P vs BIG-P 0.048, NIO-P vs EZ-IO <0.001, NIO-P vs Jamshidi <0.001, BIG-P vs Jamshidi <0.001, EZ-IO vs Jamshidi Others: not significant
"Ease of use"	1.5 (IQR, 1.0–1.9)	3.0 (IQR, 2.2–3.9)	2.7 (IQR, 2.4–3.8)	6.5 (IQR, 5.3–7.3)	<0.001, NIO-P vs BIG-P <0.001, NIO-P vs EZ-IO <0.001, NIO-P vs Jamshidi <0.001, BIG-P vs Jamshidi <0.001, EZ-IO vs Jamshidi Others: not significant
First choice device	39/68	11/68	18/68	0/68	<0.001, NIO-P vs BIG-P <0.001, NIO-P vs EZ-IO <0.001, NIO-P vs Jamshidi 0.031, BIG-P vs EZ-IO <0.001, BIG-P vs Jamshidi <0.001, EZ-IO vs Jamshidi

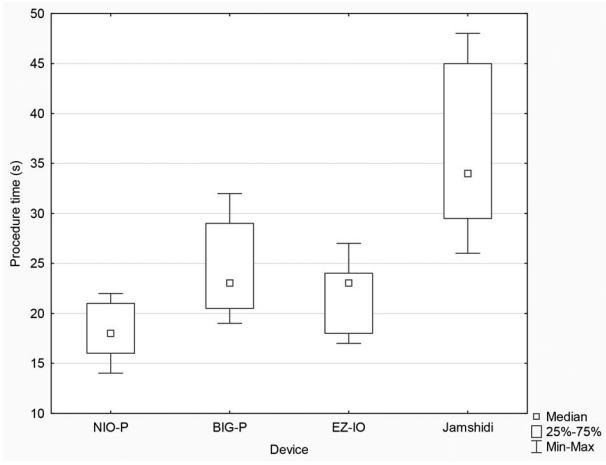

FIGURE 3. Median IO access placement time.

of fluid at the hub of the needle was observed (overall success rate, 90%). With EZ-IO, 2 participants observed to have fluid leakage (overall success rate, 97%). In 39 of 68 placement, procedures using the Jamshidi needle were unsuccessful resulting in an overall success rate of 43%. Needle bent was observed in 21 attempts, and the bone was chipped in another 18 attempts.

Ease of Use

The ease of use, as rated by the participants, varied significantly throughout the devices and are reported to be 1.5 (IQR, 1.0–1.9) in NIO-P, 2.7 (IQR, 2.4–3.8) in EZ-IO, 3.0 (IQR, 2.2–3.9) in BIG-P, and 6.5 (IQR, 5.3–7.3) in Jamshidi (Table 1).

Participant Preferences

Thirty-nine of all participants preferred NIO-P as first choice device, followed by EZ-IO (18 of 68) and BIG-P (11 of 68). None of the participants preferred Jamshidi (Table 1).

DISCUSSION

This randomized simulation study aimed to investigate the clinical performance of 4 different needles in a pediatric simulation setting. Although the performance of 3 mechanical devices (NIO-P, BIG-P, and EZ-IO) was comparable, the use of the manual device Jamshidi was associated with low overall and first attempt success rate, as well as prolonged time to perform the procedure.

In emergency situation, obtaining prompt and reliable vascular access is imperative.[17,18] Intraosseous access techniques are rarely used, but successful placement in a timely manner is essential. Our study demonstrated success rates of 100%, 90%, and 97% with NIO-P, BIG-P, and EZ-IO, respectively, as compared with 43% with the Jamshidi device. Our results are in line with previous findings by several studies reporting successful first attempts with EZ-IO ranging from 82% and 98%.[19–21] Another study compared the NIO-P with the EZ-IO device and reported 92% versus 88% successful placement.[22] The BIG-P needle was previously reported to be successful in about 91%.[21,23]

The performance of the Jamshidi device was only 43% in our study, which is clinically unacceptable low. However, our findings confirm previous findings, reporting a success rate of the Jamshidi device of 48%.[21] Therefore, mechanical devices (NIO-P, BIG-P, and the EZ-IO) clearly outperformed the manual device (Jamshidi) regarding success rates. The reason can be attributed to higher rate of complications,[24] technical problems, and overall nature of manual procedures. Our study population included novice and unexperienced physicians without any previous exposure or familiarity with IO devices and techniques. Hence, owing to lack of experience with manual insertion, an undue amount of force may be applied, causing needle to distort its shape[25,26] or bend, which was observed by 57% with Jamshidi needle as compared with less than 10% with mechanical devices. Majority of complications with Jamshidi were limited to needle bent (54%) and bone stratification (35%). Fluid extravasation around the drill site (2/7, 30%) and failure to insert needle (5/7, 70%) were noted with BIG-P needle. No complications were reported with NIO-P device, and fewer (3%) reported with EZ-IO were limited to extravasation of fluid. Problems with "threading the stylet out" or "stuck stylet" were not reported with any of the device, although previously reported in the literature.[26] However, technical difficulties are usually reduced by increasing familiarity with the procedure.[27]

Excess time spent in prolonged intravenous access attempts is not necessary and is associated with negative outcomes, especially in emergency situations. The procedure time was similar in NIO-P, EZ-IO, and BIG-P, ranging between 18 and 23 seconds, whereas the procedure time for the Jamshidi was 34 seconds. Our study confirms previous findings that manual needle placement is much more time-consuming compared with mechanical needle placement. The reason for this finding is obviously based on the individual physical effort. Mechanical devices usually require only minimal force, whereas manual devices require high level of force applied.[21]

Based on subjective evaluations by the physicians included in our study, our participants preferred the mechanical devices instead of the manual device, which is in line with previous findings in a swine model.[24]

Direct costs of the devices vary between about US $20 and 120, the Jamshidi being the cheapest and the NIO-P being the most expensive devices. Direct costs vary enormously from one country to another and among hospitals. Consequently, obtaining local information's is critical before making any cost-benefit decisions. However, decisions for any medical devices should be based on clinical performance instead of any cost saving arguments.

Establishing a vascular access is of critical importance, especially during emergency situations like cardiopulmonary resuscitation. Luckily, cardiopulmonary resuscitation situations in pediatrics are relatively rare. As a consequence, health care providers are relatively inexperienced in these situations and even establishing a vascular access is challenging. To test a realistic clinical environment, we decided to enroll novice (and inexperienced) physicians and performed assessment after a period of 6 months instead of immediately after the training.

There are several IO devices commercially available, both manual and mechanical. We included 4 of the most commonly used devices in the out-of-hospital emergency setting in Poland. Consequently, results of this study are reliably applicable to the devices tested in this study. Any other device might have their own (dis)-advantages, although results of this study might also be suitable to comparable devices.

The results of our study must be interpreted with the pinch of limitations. First, time to perform cannulation is faster in a simulated model as compared with actual chaotic emergency settings. Second, the turkey bone used in the study lacks some of the clinical aspects of confirming location of insertion like aspiration of bone marrow. Third, microfractures caused while preparation of bone may lead to extravasation from other site can cause bias. Fourth, it is almost impossible to blind the physicians to different devices. Fifth, turkey bones morphology may favor IO insertion to one device over others.

Although the efficacy of devices was demonstrated in simulated environment in novice users, further studies are needed to assess the efficacy and safety of devices in clinical comparative settings. With more experienced users, the success rate may differ considerably as compared with naive users.

CONCLUSIONS

Obtaining IO access using mechanical devices like the NIO-P, BIG-P, and EZ-IO were much more successful, faster, associated with lower complications rate, and more user-friendly as compared with the manual device Jamshidi. Although this study provides significant evidence, further clinical trials are indicated.

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