A Randomized Cadaver Study Comparing First-Attempt Success Between Tibial and Humeral Intraosseous Insertions Using NIO Device by Paramedics

A Preliminary Investigation

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Abstract: Medical personnel may encounter difficulties in obtaining intravenous (IV) access during cardiac arrest. The 2015 American Heart Association guidelines and the 2015 European Resuscitation Council guidelines for cardiopulmonary resuscitation (CPR) suggest that rescuers establish intraosseous (IO) access if an IV line is not easily obtainable. The aim of the study was to compare the success rates of the IO proximal tibia and proximal humerus head access performed by paramedics using the New Intraosseous access device (NIO; Persys Medical, Houston, TX, USA) in an adult cadaver model during simulated CPR.

In an interventional, randomized, crossover, single-center cadaver study, a semi-automatic spring-load driven NIO access device was investigated. In total, 84 paramedics with less than 5-year experience in Emergency Medical Service participated in the study. The trial was performed on 42 adult cadavers. In each cadaver, 2 IO accesses to the humerus head, and 2 IO accesses to the proximal tibia were obtained. The success rate of the first IO attempt was 89.3% (75/84) for tibial access, and 73.8% (62/84) for humeral access (P = 0.017). The procedure times were significantly faster for tibial access [16.8 (interquartile range, IQR, 15.1–19.9) s] than humeral access [26.7 (IQR, 22.1–30.9) s] (P < 0.001).

Tibial IO access is easier and faster to put in place than humeral IO access. Humeral IO access can be an alternative method to tibial IO access.

Trial Registration: clinicaltrials.gov Identifier: NCT02700867.

INTRODUCTION

In the out-of-hospital emergency settings, rapid vascular access is often required in order to administer drugs and fluids in critical patients, and is particularly important during cardiopulmonary resuscitation (CPR). Medical personnel may encounter difficulties in obtaining intravenous (IV) access during cardiac arrest; the heart does not work as a pump, which causes veins to collapse. The average time needed for peripheral IV catheterization is reported to be between 2.5 and 16 minutes in patients with difficult IV access.1-2 The 2015 American Heart Association (AHA) guidelines and the 2015 European Resuscitation Council (ERC) guidelines for CPR suggest that rescuers establish intraosseous (IO) access if an IV line is not easily obtainable.3,4

The IO access is usually established in the proximal part of the tibia (near the tibial tuberosity), or in its distal part (near the medial ankle). Other penetration sites used for injection include the humeral bone head, radial bone, or femoral bone. The IO access allows the patient to be treated immediately by facilitating the administration of fluids and medications.5 All drugs and IV solutions may be administered through IO access6,7; however, it should not last longer than 24 hours and should be discontinued as soon as peripheral or central IV access has been established. The most frequent complications include hematoma, inflammation, and bone fractures.8

The aim of the study was to compare the success rates of the IO proximal tibia and proximal humerus head access performed by paramedics using the New Intraosseous access device (NIO; Persys Medical, Houston, TX, USA) in an adult cadaver model during simulated CPR.

METHODS

Study Design

The study was approved by the Bioethics Committee of the Medical University of Warsaw, Poland (approval No.: KB/22/2015), and registered in the ClinicalTrials database
A research randomizer program was used (www.randomizer.org) to divide the participants into 2 groups and to determine the order in which the participants would perform the IO access and the order of the anatomic sites (humeral head or proximal tibia) of performing the IO access (Figure 2). The first group attempted to perform the IO access in the tibia, and the second in the humerus (Figure 3). After completing each IO procedure, participants had a 5-minute break before performing IO access using NIO in the next location. The participants were allowed only 1 IO access attempt with each location. Each of them performed an IO cannulation in the humeral head and proximal tibia. They were reminded before each attempt that the “patient” needed emergency IV access as quickly as possible; this was to provide the feeling of time pressure that would be present in real emergency situations. Chest compression was performed with the use of Lifeline ARM chest compression system (ARM; Defibtech, Guilford).

**Outcome Measures and Data Collection**

The main outcome was the time of IO cannulation. It was measured in seconds, and defined as the time interval between taking the IO device out of the original packaging to the actual insertion of the needle into the bone and problem-free IO administration of 10 mL saline solution as a test dose directly through the needle. The secondary outcome was the success rate of IO cannulation on the first attempt. An insertion was labeled successful if it had a stable position on the bone and allowed the infusion of fluid (10 mL) without extravasation. Failure was defined as extravasation or unsuccessful (first) effort of IO insertion. In addition, the IO insertion was confirmed by ultrasonography with the application of a linear 6 MHz probe. Furthermore, complications of the IO cannulation were recorded.

After the procedure completion, each participant filled a questionnaire in which they subjectively rated the ease of NIO use (1–5; 1 = very difficult, 5 = very easy), the ease of NIO use versus a peripheral IV line (easier, the same, harder), the speed versus a peripheral IV line (slower, the same, faster), as well as the willingness to use the device in future sudden cardiac arrest (SCA) scenarios (no, maybe, yes).

**Statistical Analysis**

All study data were entered into an electronic database (Microsoft Excel 2010; Poland) and evaluated with the use of Statistica Package Software, version 12.5.

The results were presented as absolute values, percentages, medians and interquartile ranges (IQRs), or means and SDs. The Kolmogorov–Smirnov test was applied to check for normal distribution. As this was a randomized crossover trial, pairing was taken into account in the statistical analysis. McNemar test was used for comparing the cannulation success rates of the humeral head and proximal tibia. The 2-sided Wilcoxon signed-rank test allowed to compare the procedure time. The participants’ subjective opinions were compared with the use of the Stuart–Maxwell test. The value of $P < 0.05$ was considered statistically significant.

**RESULTS**

The study was carried out between February and March 2016. In total, 84 paramedics (27 women and 57 men aged 27.6 ± 4.2 years) participated in the study.

The success rate of the first IO attempt was 89.3% (75/84) for tibial access and 73.8% (62/84) for humeral access ($P = 0.017$). All unsuccessful attempts to the tibia IO access were bound with a
poor relief angle between the device and the bone, and with inserting the needle at the wrong angle. The reason for all unsuccessful attempts to the humerus IO access was an incorrect locating of the humeral head.

The procedure times were significantly faster for tibial access [16.8 (IQR, 15.1–19.9) s] than humeral access [26.7 (22.1–30.9) s] ($P < 0.001$). The time needed to perform the procedure is presented in Figure 4.

The participants assessed the IO access into proximal tibia as easier to obtain than the IO access into proximal humerus ($P < 0.001$; Table 1). As many as 81 of the 84 (96.4%) participants stated that they would use the NIO device in a future SCA scenario; 3 participants were hesitant. All participants (100%) perceived the IO access with the use of the NIO device as faster in their hands than placing a peripheral IV line, and all of them rated the NIO device easier than inserting a peripheral IV line, which applies to the IO access both in proximal tibia and in proximal humerus.

**DISCUSSION**

In the trial described, the authors compared the necessary procedure times and success rates of the first attempt to obtain IO access in proximal tibia and humerus head in adult cadavers under simulated resuscitation. To our knowledge, this was the first randomized crossover trial to assess the frequency of the

![FIGURE 2. A flow chart presenting the study design and participants recruitment according to CONSORT statement.](image)

![FIGURE 3. Intraosseous access founded by the NIO device: (A) into proximal tibia; (B) into humerus head.](image)
first-attempt success between humeral and tibial IO access. There are no randomized crossover trials presented in literature that would compare the tibial and humeral IO access obtained with the NIO device. Results demonstrated that the tibial IO route was the most effective method of gaining vascular access during simulated CPR.

The IO access was first described in 1922 and was used in a systematic manner during World War II. Over the 9 decades, it has been applied as a safe alternative to peripheral venous access (PVA). According to the ERC and AHA guidelines for CPR, since 2010, the IO access has become a standard of care in adult emergency scenarios,9–11 especially in shock, obese, IV drug users, following chemotherapy, or under CPR, especially in nondefibrillation rhythms, allowing administration of epinephrine or other drugs or fluids. However, in emergency patients, PVA might be difficult or impossible to obtain, especially in dehydrated patients, those in hypovolemic shock, obese, IV drug users, following chemotherapy, or under SCA. As reported in many studies, failure rates of PVA in emergency conditions equal around 10% to 40%.12–15 Of course, there are many alternative vascular access techniques under CPR with difficult PVA access, such as central venous cannulation (CVC) or ultrasound-guided PVA.

Rapid intravascular access is an essential component of CPR, especially in nondefibrillation rhythms, allowing administration of epinephrine or other drugs or fluids. However, in emergency patients, PVA might be difficult or impossible to obtain, especially in dehydrated patients, those in hypovolemic shock, obese, IV drug users, following chemotherapy, or under SCA. As reported in many studies, failure rates of PVA in emergency conditions equal around 10% to 40%.12–15 Of course, there are many alternative vascular access techniques under CPR with difficult PVA access, such as central venous cannulation (CVC) or ultrasound-guided PVA.

### TABLE 1. Comparison of the Ease of Using the New Intraosseous Access Device for the Proximal Humerus and Proximal Tibia Access

| Outcome | Proximal Tibia | Proximal Humerus | P |
|---------|----------------|------------------|---|
| 1 = very difficult | — | 24 (28.6%) | <0.001 |
| 2 = difficult | 13 (15.5%) | 37 (44.0%) |
| 3 = normal | 28 (33.3%) | 23 (27.4%) |
| 4 = easy | 43 (51.2%) | — |
| 5 = very easy | — | — |
the IV route at 30 seconds, which may constitute a survival advantage. Neufeld et al. indicated that drugs and fluids infused through IO access quickly reached the central venous circulation at concentrations comparable with the CVC.

The technical problem indicated by other authors, difficulty in removing the stylet from the needle, was not observed in the present study. Draisma et al. demonstrated that the problem of the ‘‘stuck stylet’’ occurred in 3 of 40 cases. In the authors’ study, ineffective IO injections in the humeral head stemmed from an improper location of the injection site. It seems reasonable, therefore, to increase the emphasis on the correct puncture site location during the IO access training.

EMS personnel have to decide which alternative for IV access should be chosen. There are several possibilities for IO access to be performed in clinical practice. The simulated CPR settings for IO insertion are very similar to real practice settings even in cadavers there are fixed tissues and there is no circulation. The same dilemma and the same time for insertion should be spent in real practice and simulated cadaver CPR settings. In the authors’ opinion, the results can be directly translated into human studies and clinical practice.

LIMITATIONS AND STRENGTHS

There are several potential limitations to the study. First, it was conducted on cadavers during simulated CPR. The cadavers were chosen intentionally, as according to the International Liaison Committee on Resuscitation, randomized clinical trials with cardiac arrest cases are unethical and cannot determine the expected CPR benefits. Moreover, the authors realize that studies on cadavers, in contrast to those among living subjects, are characterized by typical limitations, such as fixed tissues or no existing circulation. Bone marrow aspiration tests to verify the correct needle placement can be difficult or even impossible in cadavers; however, these difficulties can also be observed in living humans. To eliminate this limitation, only fresh cadavers were included in the study, and the ultrasound test was applied in order to finally confirm the IO location. Another limitation of the study is the fact that the research group constituted only of paramedics; they are, however, the ones in the EMS teams who most frequently face the urgent necessity of establishing an intravascular access during CPR.

The strengths of the study include the randomized crossover procedure and the usage of a mechanical chest compression machine to simulate chest compressions.

CONCLUSIONS

Tibial IO access is easier and faster to put in place than humeral IO access. Humeral IO access can be an alternative method to tibial IO access.

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