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Comparison of intravascular access methods applied by nurses wearing personal protective equipment in simulated COVID-19 resuscitation: A randomized crossover simulation trial

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ABSTRACT

Background: Prehospital emergency care of children is challenging. In the era of the COVID-19 pandemic, when medical personnel should use personal protective equipment against aerosol-generating procedures, the efficiency of medical procedures may decrease. The study objective was to evaluate the effectiveness of different intravascular access methods applied by nurses wearing biosafety Level-2 suits in simulated paediatric COVID-19 resuscitation.

Methods: A prospective, randomized, crossover, single-blinded simulation trial was performed. Nursing staff attending Advanced Cardiovascular Life Support courses accredited by the American Heart Association participated in the study. A total of 65 nurses were recruited and randomly assigned to different study groups. They received standard training on intravascular access methods employing distinct devices. The participants wore biosafety Level-2 suits and performed vascular access with the following intraosseous devices: NIO-P, EZ-IO, and Jamshidi needle; intravenous (IV) access was used as a reference method. Both the order of participants and the access methods were random. Each participant performed intravascular access with each of the four methods tested. The effectiveness of the first attempt to obtain intravascular access and the following time parameters were analysed: the time between grasping the intravascular device out of the original packing until infusion line connection. The ease of the procedure was measured with a visual analogue scale (1 – easy; 10 – difficult).

Results: The first attempt success rate of intravascular access by using NIO-P and EZ-IO equalled 100% and was statistically significantly higher than that with the Jamshidi needle (80.0%; $p = 0.02$) and with the IV method (69.2%; $p = 0.005$). The time required to connect the infusion line varied and amounted to 33 ± 4 s for NIO-P compared to 37 ± 6.7 s for EZ-IO ($p < 0.001$), 43 ± 7 s for Jamshidi ($p < 0.001$), and 98.5 ± 10 s for IV access ($p < 0.001$). The procedure was easiest in the case of NIO-P and EZ-IO (2 ± 1 points; $p = 1.0$) compared with Jamshidi (5 ± 3 points; $p < 0.001$) and IV access (7 ± 2 points; $p < 0.001$).

Conclusion: The study provides evidence that nurses wearing biosafety Level-2 suits were able to obtain intraosseous access faster and more effectively as compared with IV access during simulated COVID-19 paediatric resuscitation. The most effective method of intravascular access was the NIO-P intraosseous device. Further clinical trials are necessary to confirm the results.

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Abbreviations: AGP, Aerosol generating procedures; CI, Confidence interval; IO, Intraosseous access; IRB, Institutional Review Board; IV, Intravenous access; MD, Mean difference; OR, Odds ratio; PPE, Personal protective equipment.

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1. Introduction

The world is struggling with the COVID-19 pandemic. A total of 152,871,267 cases of COVID-19 were reported as of May 3rd, 2020, with a mortality rate of 2.1%. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to cause an international health crisis through the coronavirus disease named COVID-19. The safety of medical personnel in the time of the pandemic is extremely important owing to the risk of coronavirus transmission. Respiratory infections can be transmitted through droplets of different sizes: when the droplet particles are $>5\text{--}10\ \mu\text{m}$ in diameter, they are called respiratory droplets, and those $<5\ \mu\text{m}$ in diameter are referred to as droplet nuclei [1,2]. According to the existing evidence, COVID-19 virus is primarily transmitted between people through respiratory droplets and contact routes [3]. As a result, healthcare workers performing medical procedures with close contact with infected patients are particularly exposed. Current World Health Organization guidelines concerning personal protective equipment (PPE) and infection control are based on the assumption of the primary mechanism of transmission. A number of studies have shown an association between aerosol-generating procedures (AGP) and healthcare worker infection during the SARS-CoV-1 and SARS-CoV-2 epidemic [4–7]. Therefore, if cardiopulmonary resuscitation is undertaken, the medical personnel should wear PPE suitable for AGP because of the potential risk of infection [8,9].

Intravascular access is a key procedure performed in life-threatening situations and an essential element of cardiopulmonary resuscitation [10]. Obtaining vascular access under emergency conditions, including cardiopulmonary resuscitation, may be difficult owing to the collapsed vascular bed or time pressure and patient movements caused by chest compressions. Numerous studies indicate that achieving peripheral intravenous (IV) access in children is generally more difficult than in adults [11,12]. Intraosseous access constitutes an alternative to IV access. In a study by Reades et al. [13], tibial intraosseous access was characterized by a higher first-attempt success rate and more rapid time for vascular access in adults during out-of-hospital cardiac arrest compared with peripheral IV access. The superiority of intraosseous access over IV access in the conditions of simulated cardiopulmonary resuscitation of children was demonstrated by Bielski et al. [14], however, this study was conducted under conditions where participants were not wearing protective suits. Bielski et al. demonstrated in their study the advantage of NIO-P intraosseous access device over BIG®, EZ-IO®, and Jamshidi devices. This advantage concerned both the reduction of the procedure duration, with the simultaneous highest first attempt success rate and easiest procedure to operate even by novice users.

However, none of the above-mentioned studies was conducted under simulated COVID-19 patient resuscitation conditions. Due to the prevailing pandemic, when emergency medical service personnel should treat any patient as potentially infected, procedures should be performed wearing PPE-AGP. Providing vascular access when using protective suits may reduce the effectiveness of the intravascular access, as well as extend the duration of the procedure. The meta-analysis published by Drozd et al. confirms this [15], in which the authors confirmed that the use of PPE significantly prolongs the duration of endovascular procedures in adults.

In this prospective, randomized, crossover study, we sought to determine if wearing a biosafety Level 2 suit had an impact on the time to obtain successful intravascular access and the first-pass success rates with different intravascular access methods in a paediatric model. Secondary objectives were to determine the preferred intravascular access modality with PPE and the barriers associated with intravascular access with PPE.

2. Material and methods

2.1. Study design and participants

The trial protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (No. 11.01.20.IRB). Study was designed as a prospective, randomized, crossover, single-blinded trial. The study was performed between January and August 2020 among nursing staff, in a medical simulation setting.

Overall, 65 nurses participating in Advanced Cardiovascular Life Support courses accredited by the American Heart Association were involved in the study after providing their voluntary written informed consent. The usage of all study devices was explained to them. The participants received no compensation for the enrolment. No participant was excluded during the study process.

2.2. Devices

The devices used in the study were the following (Fig. 1):

- The NIO-Paediatric (NIO-P; New Intraosseous PerSys Medical, Houston, TX, USA), which is a spring-loaded automatic intraosseous access device designed for patients aged 3–12 years. This single-package device contains an 18-gauge needle, a stylet, and a needle stabilizer. The location arrows on the device assist in finding the correct intraosseous tibial position in paediatric patients [14].
- The IO drill Arrow® EZ-IO® (EZ-IO; Teleflex Medical, Research Triangle Park, NC, USA), a device composed of a battery-powered vascular access driver with an integrated driller stylet-tipped 15-gauge needle. In the current study, a 15-mm-long needle was used, recommended for placement in the proximal tibia in 3–39-kg patients.
- Jamshidi intraosseous needle (Jamshidi; Baxter HealthCare Corporation, Deerfield, IL, USA), which is a 15-gauge device inserted manually with the use of pressure and rotation. An adjustable guard helps control the needle insertion depth.

As a reference method, a standard IV access was used. A peripheral IV catheter with an injection port was applied (20G size, Vasofix® Braunüle®, B. Braun Melsungen, Melsungen, Germany) [16] and the participants performed IV access within the cubital fossa.

2.3. Study procedure

Prior to the study, all participants took part in a 30-min theoretical training on the use of intraosseous accesses during cardiopulmonary resuscitation. At the end of the training, they received instructions on obtaining correct vascular access with particular devices. Next, the nurses took part in a practical session during which they had an opportunity to perform intraosseous access with the tested devices in an adult manikin under normal conditions.

The proper study was conducted on the following day. A Pedi HAL® S3005 simulator, designed as a 5-year-old patient, was used to simulate a child with suspected/confirmed COVID-19 requiring cardiopulmonary resuscitation with vascular access (Supplementary Fig. 1). The simulator was placed on a stretcher (Stryker, Kalamazoo, MI, USA). Chest compressions were performed with the LUCAS 3 mechanical chest compression system (Stryker, Kalamazoo, MI, USA) to standardize the difficulties resulting from the patient movement during the procedure.

As PPE, biosafety Level 2 suits were used, which comprise boot covers, protective overalls, inner nitrile gloves, a hood, an FFP3 mask, panoramic and self-ventilated protective goggles, and outer nitrile gloves [17].

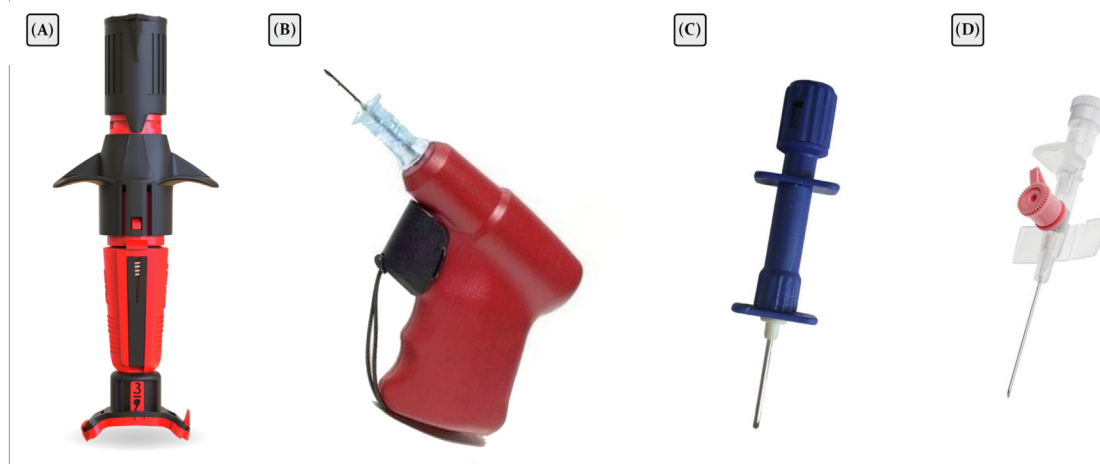


Fig. 1. Intravascular access devices used in the trial: (A) NIO-Paediatric device; (B) EZ-IO device; (C) Jamshidi needle; (D) intravenous cannula.

Both the order of participants and the methods of obtaining vascular access were random. The Research Randomizer system (randomizer.org) was used for this purpose. We divided the study participants into four groups, the first of which started intravascular access with the NIO-P device, the second with the EZ-IO, the third with the Jamshidi needle, and the fourth with intravascular access with standard intravenous cannula. The participants had one attempt to gain vascular access for each of the methods. After completing the vascular access, the nurse had a 5-min break and then performed vascular access with another method. The randomization procedure is described in detail in Fig. 2.

2.4. Outcome measures

The primary outcome of the study was the success rate of the first intravascular access attempt in the paediatric resuscitation model. The secondary outcomes were the procedure time defined as a time between grasping the intravascular device out of the original packing until infusion line connection. We also investigated preferences regarding intravascular access modalities with PPE and the barriers associated with intravascular access with PPE. The ease of the procedure was measured with a visual analogue scale (1 – easy; 10 – difficult).

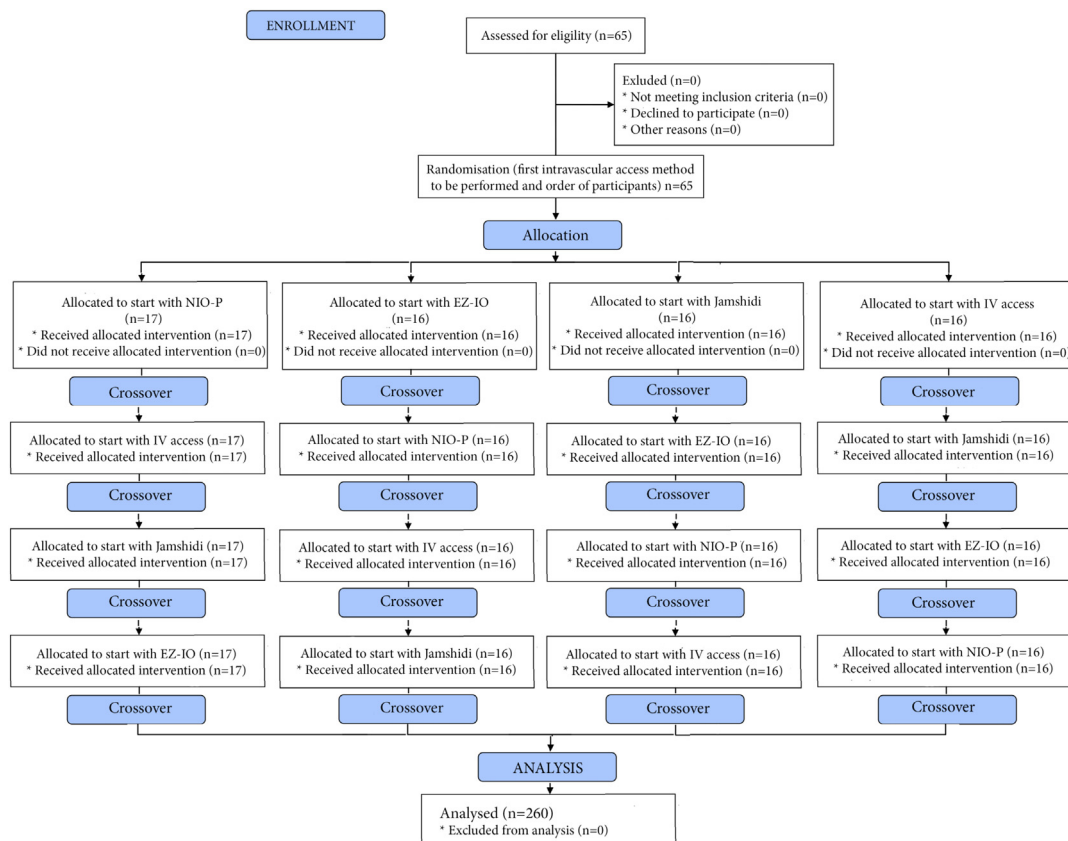


Fig. 2. Randomization flow chart in accordance with the CONSORT statement.

Table 1
Effectiveness of intravenous access

Parameter	Intravascular access type			
	NIO	EZ-IO	Jamshidi	IV
Success rate %	65 (100%)	65 (100%)	52 (80.0%)	45 (69.2%)
Procedure time, s	33 ± 4	37 ± 6.7	43 ± 7	98.5 ± 10
Ease of use	2 ± 1	2 ± 1	5 ± 3	7 ± 2
Preferences of use	51 (78.5%)	14 (21.5%)	0 (0.0%)	0 (0.0%)

2.5. Statistical analysis

The sample size was calculated with the G*Power 3.1 software (Cohen's *d*: 0.8; alpha error: 0.05; power: 0.95). The calculation implied a minimum of 53 necessary participants. To ensure a safety margin, we recruited 65 participants in the study.

All study data were entered into an electronic database (Microsoft Excel 2015, Microsoft Corp., Redmond, WA, USA) and then statistical analyses were performed by using Statistica 13.4EN software (Tibco Inc., Tulsa, OK, USA). At the stage of the statistical analysis, the data were blinded. Descriptive statistics are reported as numbers and percentages for categorical data and means and standard deviations or medians and interquartile ranges for continuous variables. The intravascular access devices were compared in terms of insertion times, success rates, adverse events that occurred during placement, ease of use, and user satisfaction. The Kolmogorov-Smirnov test was applied to test the data for normality. We compared qualitative variables by Fisher exact test and Kruskal-Wallis test. Continuous data, including time to obtain successful intravascular access, underwent testing with the analysis of variance (ANOVA). A two-tailed *p* value of 0.05 was considered significant.

3. Results

3.1. Participants

Overall, 65 nurses (57 females, 87.7%) participated in the study, and none of them had previous experience with intravascular access with biosafety Level 2 or higher suit. The subjects' mean age was 42.5 ± 16.3 years, and the mean work experience equalled 21.5 ± 13.7 years.

3.2. Primary outcomes

The first attempt success rate of intraosseous access by using NIO-P and EZ-IO equalled 100% and was statistically significantly higher than that with Jamshidi (80.0%; *p* = 0.02) and with the IV method (69.2%; *p* < 0.001).

3.3. Secondary outcomes

Detailed statistical analyses are presented in Tables 1 and 2. The time required to obtain intravascular access for NIO-P was 33 ± 4 s and turned out statistically significantly shorter than that for EZ-IO (37 ± 6.7 s; *p* < 0.001), Jamshidi (43 ± 7 s; *p* < 0.001) and IV access (98.5 ± 10 s; *p* < 0.001). There was also a statistically significant reduction in the time of intravascular access between EZ-IO vs. Jamshidi (*p* < 0.001) and EZ-IO vs. IV access (*p* < 0.001).

The ease of intravascular access by using NIO-P, as well as EZ-IO was assessed at 2 ± 1 points in the visual analogue scale score. In the case of Jamshidi, the procedure ease was determined at 5 ± 3 points (*p* < 0.001), while the most difficult procedure to obtain intravascular access was the IV method (7 ± 2 points; *p* < 0.001).

Table 2
Statistical analysis of study results.

Parameter	Comparison	OR / MD (95%CI)	<i>p</i> -Value
Success rate	NIO vs. EZ-IO	OR = 0.00 (−0.03, 0.03)	1.0
	NIO vs. Jamshidi	OR = 33.69 (1.96, 579.98)	0.02
	NIO vs. IV	OR = 59.02 (3.48, 1000.95)	0.005
	EZ-IO vs. Jamshidi	OR = 33.69 (1.96, 579.98)	0.02
	EZ-IO vs. IV	OR = 59.02 (3.48, 1000.95)	0.005
	Jamshidi vs. IV	OR = 1.78 (0.80, 3.97)	0.16
Procedure time	NIO vs. EZ-IO	MD = −4.00 (−5.90, −2.10)	<0.001
	NIO vs. Jamshidi	MD = −10.00 (−11.96, −8.04)	<0.001
	NIO vs. IV	MD = −65.50 (−68.12, −62.88)	<0.001
	EZ-IO vs. Jamshidi	MD = −6.00 (−8.36, −3.64)	<0.001
	EZ-IO vs. IV	MD = −61.50 (−64.43, −58.57)	<0.001
	Jamshidi vs. IV	MD = −55.50 (−58.47, −52.53)	<0.001
Ease of use	NIO vs. EZ-IO	MD = 0.00 (−0.34, 0.34)	1.0
	NIO vs. Jamshidi	MD = −3.00 (−3.77, −2.23)	<0.001
	NIO vs. IV	MD = −5.00 (−5.54, −4.46)	<0.001
	EZ-IO vs. Jamshidi	MD = −3.00 (−3.77, −2.23)	<0.001
	EZ-IO vs. IV	MD = −5.00 (−5.54, −4.46)	<0.001
	Jamshidi vs. IV	MD = −2.00 (−2.88, −1.12)	<0.001
Preferences of use	NIO vs. EZ-IO	OR = 13.27 (5.75, 30.63)	<0.001
	NIO vs. Jamshidi	OR = 465.28 (27.11, 7985.28)	<0.001
	NIO vs. IV	OR = 465.28 (27.11, 7985.28)	<0.001
	EZ-IO vs. Jamshidi	OR = 36.88 (2.15, 633.01)	0.01
	EZ-IO vs. IV	OR = 36.88 (2.15, 633.01)	0.01
	Jamshidi vs. IV	NA	NA

Legend: NA = Not applicable; MD = Mean Difference; OR = Odds Ratio; CI = Confidence Interval. A two-tailed *p* value of 0.05 was considered significant.

The study participants indicated NIO-P in 78.5% of cases and EZ-IO in 21.5% ($p < 0.001$) of cases as the method they preferred in terms of clinical practice use. None of the subjects pointed at Jamshidi or IV access as their method of choice.

4. Discussion

The aim of this study was to evaluate various techniques for obtaining vascular access by nurses with PPE for AGP during simulated paediatric COVID-19 resuscitation. To our knowledge, it was the first comparison of NIO-P, EZ-IO, and Jamshidi devices under such conditions.

Prehospital emergency care of children is challenging. During cardiopulmonary resuscitation, it is extremely important that individual medical procedures are performed quickly and efficiently; this also refers to obtaining vascular access [10,14]. Rapid establishment of vascular access as indicated by the European Resuscitation Council and the American Heart Association guidelines is all the more essential in the context of non-shockable rhythms, where epinephrine should be administered as soon as possible. Hansen et al. [18] indicated that each minute of delay in epinephrine administration was associated with decreased survival and unfavourable neurological outcomes. Numerous studies also point to comparable pharmacokinetics and pharmacodynamics of drugs administered by IV and intraosseous access [19,20].

The use of protective suits increases the safety of medical personnel in the context of potential infection. However, the mobility constraints associated with wearing aprons or overalls and double gloves may reduce the effectiveness of medical procedures by increasing their duration and lowering the performance efficiency [21–25].

Because of the lack of literature data on intraosseous access performed in children by rescuers wearing PPE, the discussion was developed in relation to the results concerning vascular access obtained without a protective suit. In addition, the results of our own study were presented with respect to intraosseous access in adults when the medical personnel were dressed in PPE for AGP.

In our study, the first attempt success rate of intravascular access was 100% for NIO-P and EZ-IO, 80% for Jamshidi, and 69.2% for IV access. El-Nawawy et al. [25] in a study analysing intravascular access in paediatric septic shock patients indicated that the success rate of the first attempt of IV and intraosseous access was varied and amounted to 50% and 100%, respectively. As implied by Feldman et al. [26], paramedics presented a slightly higher insertion success rates in intraosseous access compared with emergency department nurses in a paediatric bone model (83.3% vs. 79.4%); the effectiveness of obtaining access equalled 80% vs. 70.6% for the NIO-P intraosseous access device and 86.7% vs. 88.2% for EZ-IO. Szarpak et al. [27] observed the effectiveness of NIO-P, EZ-IO, and Jamshidi at the level of 100%, 97%, and 43%, respectively.

Another important parameter related to intraosseous access during resuscitation is the time of the procedure execution. Owing to personal limitations and the necessity to perform many medical procedures during cardiopulmonary resuscitation, the access should be obtained as soon as possible. In our study, the shortest time was achieved for the intravascular access with NIO-P (33 ± 4 s) and the longest for IV access (98.5 ± 10 s; $p < 0.001$). In a study by Suyama et al. [28], 22 paramedics established anterior tibial intraosseous access in an adult patient using the EZ-IO system and routine antecubital IV access with and without PPE. The authors revealed a statistically significantly shorter fluid infusion time in the case of intraosseous access (28.33 s) compared with IV access (46.28 s; $p < 0.001$). Also, other authors, including Castle et al. [29], Lamhaut et al. [30], and Szarpak et al. [31], reported a significantly shorter time of performing the intraosseous access procedure while using PPE for AGP.

It is worth emphasizing that the use of NIO-P or EZ-IO, in the subjective opinion of the study participants, was associated with a much easier procedure to get intravascular access, compared to the Jamshidi needle or the intravenous cannula. The ease of performing the procedure may

shorten the duration of the procedure as well as increase the efficiency of its performance. However, although NIO-P and EZ-IO were similarly easy to perform, NIO-P was the preferred method of IO access compared to EZ-IO (78.5% vs. 21.5%; $p < 0.001$). The differences observed between NIO-P and EZ-IO in “procedure time” and “ease of use” make NIO-P more effective than EZ-IO, therefore, NIO-P should be considered as the first intravascular access option. However, EZ-IO shows more positive results than the other techniques and should be used as a second option to gain intraosseous access.

4.1. Strengths and limitations

The present study has several limitations. Firstly, it was conducted under the conditions of medical simulation and not those of real medical actions. This was, however, intentional and dictated by the fact that medical simulation allows to fully standardize the performed medical procedures, without any risk for a potential patient or the personnel involved in particular procedures [32,33]. This is even more important in the era of a pandemic, when the risk of potential infection is extremely real owing to the high virulence of SARS-CoV-2 [2,34]. The second limitation was the participation of nurses only. Nevertheless, in a hospital setting, it is relatively often nurses who are required to perform cardiopulmonary resuscitation and to obtain vascular access. Another limitation is the use of an adult mannequin during the training session, in which the participants of the study exercised both intraosseous and intravenous access. They carried the exercises out without the use of PPE-AGP. Such action was deliberate and was aimed at mastering the technique of obtaining intraosseous access using various methods - without causing distortions of the results in the proper examination.

The study also has its strengths, which include, among others, the randomized, cross-over design, as well as result blinding at the stage of statistical analysis. An additional advantage is the use of three different methods for establishing intraosseous access. Additionally, the obtained results have clinical implications. Medical personnel, especially emergency medical service personnel wearing PPE-AGP - where each patient should be treated as potentially infectious, and every minute is critical - we should consider the use of intraosseous access as the primary method of obtaining intravascular access.

5. Conclusions

The study provides evidence that nurses wearing biosafety Level 2 suits were able to obtain intraosseous access faster and more effectively as compared with IV access during simulated COVID-19 paediatric resuscitation. The most effective method of intravascular access was the NIO-P intraosseous device. Further clinical trials are necessary to confirm the results.

Declaration of Competing Interest

Authors don't declare any conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ajem.2021.05.080>.

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