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Analiza porównawcza wybranych technik dostępów doszpikowych w warunkach medycyny ratunkowej

Rozprawa na stopień doktora nauk medycznych i nauk o zdrowiu w dyscyplinie nauki medyczne

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Obrona rozprawy doktorskiej przed Radą Dyscypliny Nauk Medycznych Warszawskiego Uniwersytetu Medycznego

Warszawa 2022

Słowa kluczowe: dostęp doszpikowy; dostęp dożylny; efektywność; medycyna ratunkowa; opieka przedszpitalna; symulacja medyczna.

Keywords: intraosseous access; intravenous access; efficiency; emergency medicine; prehospital cate; medical simulation.

Składam serdeczne podziękowania
promotorowi dr hab. n. med. Łukaszowi Szarpakowi
za opiekę merytoryczną, za cenne uwagi oraz sugestie
oraz za zaangażowanie, dzięki któremu możliwe było napisanie tej pracy.

Pracę dedykuję swoim Rodzicom.

Wykaz publikacji stanowiących pracę doktorską:

I. **Drozd A**, Wolska M, Szarpak L. Intraosseous vascular access in emergency and trauma settings: a comparison of the most universally used intraosseous devices. Expert Rev Med Devices. 2021; 18(9): 855-864. doi: 10.1080/17434440.2021.1962287.

(Punktacja MEiN: 70,0; Impact Factor: 3,166)

II. **Drozd A**, Smereka J, Filipiak KJ, Jaguszewski M, Ładny JR, Bielski K, Nadolny K, Ruetzler K, Szarpak Ł. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021;79(3):277-286. doi: 10.33963/KP.15741.

(Punktacja MEiN: 100,0; Impact Factor: 3,108)

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(Punktacja MEiN: -; Impact Factor: -)

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(Punktacja MEiN: 25,0; Impact Factor: 1,494)

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WYKAZ STOSOWANYCH SKRÓTÓW

AHA	Amerykańskie Towarzystwo Kardiologiczne *(ang. American Heart Association)*
CBRN	chemiczne, biologiczne, radiologiczne, jądrowe *(ang. Chemical, Bilogical, Radiological, Nuclear)*
CI	Przedział ufności *(ang. Confidence interval)*
ERC	Europejska Rada Resuscytacji *(ang. European Resuscitation Council)*
IO	Dostęp doszpikowy *(ang. Intraosseous)*
IV	Dostęp dożylny *(ang. Intravenous)*
OR	Iloraz szans *(ang. Odds ratio)*
PALS	Zaawansowane zabiegi resuscytacje u dzieci *(ang. Pediatric advanced life support)*
PPE	Kombinezony ochronne *(ang. Personal protective equipment)*

Streszczenie w języku polskim

Wstęp

Umiejętność uzyskiwania dostępu naczyniowego w medycynie ratunkowej stanowi jedną z kluczowych obligatoryjnych kompetencji personelu medycznego. W stanach nagłych takich jak zatrzymanie krążenia lub we wstrząsie, łożysko naczyniowe jest zapadnięte, co wiąże się z trudnym lub nawet niemożliwym uzyskaniem dostępu dożylnego. Wówczas alternatywę stanowią dostępy doszpikowe, które zapewniają porównywalną skuteczność w zakresie podaży płynów oraz prowadzonej farmakoterapii u pacjentów w stanach zagrożenia życia. W dobie pandemii COVID-19, kiedy to personel medyczny, a zwłaszcza personel wyjazdowych zespołów ratownictwa medycznego powinien traktować każdego pacjenta jako potencjalnie zakażonego wirusem SARS-CoV-2 i wykonywać procedury medyczne w środkach ochrony indywidualnej. Badania dotyczące intubacji dotchawiczej, jakość prowadzonej resuscytacji krążeniowo – oddechowej czy też uzyskiwania dostępów dożylnych pokazują, że wykonywanie procedur w środkach ochrony indywidualnej może zmniejszać skuteczność wykonywanych procedur. W związku z powyższym należy poszukiwać alternatywnych metod uzyskiwania dostępów naczyniowych, które mimo stosowania w środków ochrony indywidualnej cechować się będą wyższą skutecznością niż dostępy dożylne.

Cel pracy

Wspólnym celem artykułów wchodzących w skład spójnego tematycznie cyklu publikacji było porównanie różnych technik uzyskiwania dostępów doszpikowych w warunkach medycyny ratunkowej zarówno w aspekcie pacjentów pediatrycznych jak i osób dorosłych.

Materiał i Metoda

Pierwsze badanie było pracą poglądową, stanowiącą wprowadzenie do cyklu prac dotyczących stosowania wkłuć doszpikowych. Celem pracy było przybliżenie czytelnikowi wskazań, przeciwskazań oraz potencjalnych powikłań wkłuć doszpikowych – zastosowania wkłuć doszpikowych u osób dorosłych jak i pacjentów pediatrycznych.

Badanie drugie było prospektywnym, randomizowanym, przekrojowym badaniem symulacyjnym, w którym porównano umiejętność uzyskiwania dostępów doszpikowych (w tym NIO-P, EZ-IO, oraz igły Jamshidi) z umiejętnością uzyskiwania dostępów dożylnych wykonywanym za pomocą standardowej kaniuli dożylnej. Do badania włączono 65 pielęgniarek, które wykonywały dostęp donaczyniowy u symulowanego pacjenta pediatrycznego chorego na COVID-19. W związku z powyższym wszelkie procedury były wykonywane przez uczestników badania ubranych w środki ochrony indywidualnej. Analizie poddano takie parametry jak: skuteczność uzyskania dostępu naczyniowego, czas trwania procedury oraz łatwość jej wykonania. Dodatkowo oceniano subiektywne preferencje pielęgniarek dotyczące optymalnej metody uzyskiwania dostępu naczyniowego u pacjenta pediatrycznego z COVID-19.

Badanie trzecie również zostało zaprojektowane jako prospektywne, randomizowane, obserwacyjne przekrojowe badanie symulacyjne. Uzyskiwanie dostępów naczyniowych miało miejsce podczas symulowanej resuscytacji krążeniowo – oddechowej u osoby dorosłej. 40 ratowników medycznych wykonywało wkłucia doszpikowe stosując odpowiednio wkłucie B.I.G oraz NIO. Zarówno kolejność uczestników jak i metod uzyskania dostępu doszpikowego były losowe. Ocenie poddano parametry czasowe związane z wprowadzeniem igły do jamy doszpikowej, następnie jej stabilizację oraz czas do podłączenia linii infuzyjnej. Dodatkowo oceniano wiedzę z zakresu potencjalnych powikłań wkłuć doszpikowych jak również skuteczność uzyskania dostępu doszpikowego.

Badanie czwarte było zaprojektowane jako badanie randomizowane przekrojowe. W niniejszym badaniu 40 ratowników medycznych wykonywało dostęp doszpikowy za pomocą wkłucia B.I.G oraz igły Jamshidi z i ŚOI typu CBRN. Badanie było wykonywane w warunkach symulacyjnych. Ocenie poddano wpływ stosowania ŚOI na czas wykonania procedury poszczególnymi metodami. Zarówno kolejność uczestników, jak i metod badawczych były losowe.

Badanie piąte zostało zaprojektowane jako przegląd systematyczny i meta-analiza i zostało przeprowadzone zgodnie z wytycznymi PRISMA. Celem badania było porównanie efektywności i bezpieczeństwa stosowania wkłuć doszpikowych oraz dożylnych przez personel medyczny ubrany w ŚOI. Podczas przeglądu systematycznego dokonano analizy elektronicznych baz danych w tym PubMed, Scopus, EMBASE, Web of Science oraz bazy CENTRAL. W trakcie analizy wyżej wymienionych baz danych posłużono się

zdefiniowanymi uprzednio słowami kluczowym. Ostatnia analiza baz danych miała miejsce 10 kwietnia 2020 roku. Analiza baz danych na podstawie słów kluczowych wykazała 947 rekordów bibliograficznych, z których po usunięciu powtarzających się artykułów, wstępnej analizie prac na podstawie tytułów i streszczeń, a następnie analizie pełnych tekstów artykułów zakwalifikowano do meta-analizy 8 badań.

Wyniki

W badaniu oceniającym uzyskiwanie dostępu doszpikowego u pacjentów pediatrycznych (NIO-P, EZ-IO, Jamshidi) z dostępem dożylnym wykonywanym przez pielęgniarki ubrane w pełny ŚOI skuteczność wykonania procedury wyniosła odpowiednio 100% dla NIO-P oraz EZIO, 80% dla igły Jamshidi oraz 69,2% dla dostępu dożylnego. Czas wykonania procedury w poszczególnych metodach był zróżnicowany i wynosił odpowiednio: 33 ± 3s, 37 ± 6,7s, 43 ± 7s oraz 98,5 ± 10 s. Łatwość wykonania intubacji w 10 stopniowej skali, gdzie „1" oznaczało łatwą do wykonania procedurę – zaś „10" – procedurę trudną do wykonania – NIO-P oraz EZ-IO zostały ocenione na 2 ± 1 punkt, uzyskanie dostępu doszpikowego za pomocą igły Jamshidi na 5 ± 3 punktu, zaś wykonanie dostępu dożylnego na 7 ± 2 punktu. Najbardziej preferowaną metodą uzyskania dostępu naczyniowego, uczestnicy badania wskazali urządzenie NIO-P (78,5%).

W badaniu porównującym wkłucia NIO oraz B.I.G podczas symulowanej resuscytacji krążeniowo – oddechowej, skuteczność uzyskania dostępu doszpikowego wynosiła odpowiednio 100% i 95% dla NIO oraz B.I.G. Czas od wzięcia do ręki wkłucia doszpikowego do momentu wprowadzania igły do jamy szpikowej wynosił 5,4 ± 3,5s dla B.I.G oraz 3,5 ± 2,5s dla wkłucia NIO (p=0,014). Z kolei czas od wzięcia do ręki wkłucia doszpikowego do ręki uczestnika do momentu podłączenia linii infuzyjnej do igły doszpikowej był zróżnicowany i wynosił 25 ± 5,5s oraz 11,5 ± 5,2s odpowiednio dla B.I.G and NIO (p<0,001).

W badaniu porównującym uzyskanie dostępu doszpikowego wykazano, iż zastosowanie ŚOI typu CBRN wpływało istotnie na wydłużenie czasu trwania procedury w przypadku igły Jamshidi (69,5 ± 34,2 oraz 35 ± 8s; p<0,001). Zależność ta nie była natomiast obserwowana w przypadku wkłucia doszpikowego B.I.G (29,5 ± 13,2s oraz 22 ± 7s, odpowiednio z i ŚOI typu CBRN; p=0,063).

W meta-analizie porównującej efektywność uzyskiwania dostępów doszpikowych oraz dostępów dożylnych w przypadku stosowania pełnych kombinezonów ochronnych

wykazano, iż zastosowanie pełnej odzieży ochronnej wiązało się z wydłużeniem czasu trwania procedury uzyskania dostępu doszpikowego (MD = 11,69; 95%CI: 6,47 - 16,92; p<0,001) jak również zmniejszeniem skuteczności wykonania dostępu doszpikowego o 0,8% oraz dostępu dożylnego o 10,1%. W warunkach wykonywania procedury w kombinezonie ochronnym czas trwania procedury był istotnie krótszy w przypadku wkłuć doszpikowych w porównaniu z wkłuciem dożylnym (MD = -41,43; 95%CI: -62,36 to -24,47; p<0,001).

Wnioski

Przeprowadzone badania pozwalają na sformułowanie następujących wniosków:

- W warunkach wykonywania dostępu naczyniowego przez personel medyczny ubranego w środki ochrony indywidualnej - dostęp doszpikowy w porównaniu z dostępem dożylnym wiąże się z krótszym czasem trwania procedury, jak również zwiększeniem skuteczności procedury.
- Wykazano istotne statystyczne różnice w wkłuciach doszpikowych półautomatycznych i typu EZ-IO a igłą Jamshidi.
- Zastosowanie ŚOI wpływa na wydłużenie czasu trwania procedury uzyskania dostępu naczyniowego, jak również zmniejszenia pierwszej próby jej wykonania.

Streszczenie w języku angielskim

COMPARATIVE ANALYSIS OF SELECTED INTRAOSSEOUS ACCESS TECHNIQUES IN EMERGENCY MEDICINE CONDITIONS

Introduction

The ability to obtain intravascular access in emergency medicine is one of the obligatory critical competences of medical personnel. In emergencies, such as cardiac arrest or shock, the vascular bed is collapsed, proving intravenous access challenging or even impossible to obtain. In such cases, an alternative is intraosseous access, which warrants comparable effectiveness in terms of fluid and pharmacotherapy provision in life-threatening conditions.

Amidst the COVID-19 pandemic when medical personnel, especially emergency medicine teams, should treat each patient as potentially infected with the SARS-CoV-2 virus, medical procedures should be carried out wearing personal protective equipment (PPE). Studies on endotracheal intubation, however, show that the quality of CPR, obtaining intravenous access and performing procedures while wearing PPE may reduce the effectiveness of the performed procedure. It is, therefore, essential to pinpoint alternative methods of obtaining intravascular access, which, despite the use of PPE, will be more effective than intravenous line access.

Objectives

The aim of the research included in the thematically coherent series of publications was to compare various techniques of obtaining intraosseous access in the emergency medicine setting, both in the aspect of adult and pediatric patient populations.

Materials and Methods

The first study was a review paper that introduced a series of research on intraosseous lines. This work introduced the reader to the indications, contraindications, and potential complications of the intraosseous line access - using intraosseous lines in adults and pediatric patients.

The second study was a prospective, randomized, cross-simulation study comparing intraosseous (IO) access (including NIO-P, EZ-IO, and Jamshidi needles) to intravenous

access using a standard intravenous cannula. The study included 65 nurses who obtained intravascular access to a simulated COVID-19 pediatric patient. Consequently, all procedures were performed by participants wearing full PPE. The following parameters were analyzed: the effectiveness of obtaining intravascular access, the duration of the procedure, and the ease of its execution. Nurses' subjective preferences regarding the optimal method of obtaining the intravascular access in a COVID-19 pediatric patient were additionally assessed.

The third study was designed as a prospective, randomized, observational, crossover simulation study. 40 paramedics obtained intravascular access via IO access using B.I.G and NIO using simulated CPR on an adult patient. The order of participants and the mode of obtaining IO access were random. Time parameters related to the insertion of the needle into the intraosseous cavity, its stabilization, and the time to connect the infusion set were assessed. Additionally, the knowledge of potential complications of intra-IOs was assessed, and the overall effectiveness of obtaining IO.

The fourth study was also designed as a randomized crossover study. This study included 40 paramedics who performed IO using B.I.G and Jamshidi needles with and without CBRN protective wear. The test was performed under simulation conditions. PPE impact on the procedure's duration using each mode of IO access was assessed; the order of participants and mode of IO access was random.

The fifth study was designed as a systematic review and meta-analysis and was conducted under PRISMA guidelines. The study compared the effectiveness and safety of using intraosseous and intravenous lines by medical personnel wearing PPE. During the systematic review electronic databases were searched, including PubMed, Scopus, EMBASE, Web of Science, and the CENTRAL database. Predefined keywords were used to search the databases mentioned above. A search of databases based on keywords revealed 947 bibliographic records. After removing duplicate articles, preliminary analysis of papers based on titles and abstracts, followed by a comprehensive review of full texts of articles, 8 studies were qualified for meta-analysis. The last database search took place on April 10, 2020.

Results

In the study assessing intraosseous access in pediatric patients (NIO-P, EZ-IO, Jamshidi) with intravenous access performed by nurses wearing a full protective suit, the effectiveness of the procedure was 100% for NIO-P and EZ-IO, respectively, 80% for the Jamshidi needle

and 69.2% for intravenous access. The duration of the procedure per each mode varied and amounted to 33 ± 3s, 37 ± 6.7s, 43 ± 7s, and 98.5 ± 10s, respectively. Ease of intubation on a 10-point scale where "1" meant an easy-to-perform procedure while "10" equaled a complicated procedure to perform - NIO-P and EZ-IO were scored 2 ± 1 point, obtaining an intra-IO with a Jamshidi needle at 5 ± 3 points, and intravenous access at 7 ± 2 points. The study participants indicated the most preferred method of gaining access to the vascular system as the NIO-P device (78.5%).

In a study comparing NIO and B.I.G during simulated CPR, the IO access efficacy was 100% and 95%, respectively, for NIO and B.I.G. The time from the intraosseous device in hand to inserting the needle into the medullary canal was 5.4 ± 3.5 s for B.I.G. and 3.5 ± 2.5s for NIO puncture ($p = 0.014$). On the other hand, the time from taking the IO device to the participant's hand to the connection of the infusion set to the IO device was varied and amounted to 25 ± 5.5s and 11.5 ± 5.2s, respectively for B.I.G and NIO ($p < 0.001$).

In the study comparing the obtaining of the intraosseous access, it was shown that the use of the CBRN suit significantly prolonged the duration of the procedure in the case of the Jamshidi needle (69.5 ± 34.2 and 35 ± 8s; $p < 0.001$). However, this relationship was not observed in the case of the B.I.G (29.5 ± 13.2s and 22 ± 7s, with and without the CBRN suit, respectively; $p = 0.063$).

The meta-analysis comparing the effectiveness of IO access and IV access with full protective suits showed that the use of full protective clothing was associated with an increase in the duration of the IO access procedure (MD = 11.69; 95% CI: 6.47 - 16.92; $p < 0.001$) as well as a decrease in the effectiveness of the intra-IOs access by 0.8% and the intravenous access by 10.1%. Under the conditions of performing the procedure in a protective suit, the duration of the procedure was significantly shorter in the case of the intraosseous puncture compared to the intravenous puncture (MD = -41.43; 95% CI: -62.36 - -24.47; $p < 0.001$).

Conclusions

The conducted research allows for the following conclusions:

- Obtaining intravascular access by medical personnel wearing PPE, IO access compared to intravenous access is associated with a shorter duration of the procedure and an increase in the effectiveness.
- There are statistically significant differences between the semi-automatic IO access, the EZIO, and the Jamshidi needle.

- The use of full protective gear prolongs the duration of obtaining vascular access as well as reduces the first attempt at its execution.

1. Wprowadzenie i rys historyczny

Zapewnienie dostępu naczyniowego u pacjentów znajdujących się w stanie krytycznym, a w szczególności po urazach ma kluczowe znaczenie w praktyce klinicznej mającej na celu ratowanie życia. Umieszczenie cewnika dożylnego (IV) u chorego w stanie ciężkim może być jedną z najtrudniejszych i stanowiących największe wyzwanie procedur, do wykonania których może zostać wezwany personel medyczny. W przypadku niepowodzenia lub braku możliwości umieszczenia IV zastosowanie znajdują wkłucia doszpikowe (IO). Historia wkłuć doszpikowych sięga roku 1922, kiedy to po raz pierwszy wyjaśniono technikę jej użycia oraz zaczęto ją wykonywać [1]. Na początku lat trzydziestych Tocantins i wsp. ustalili, że jama szpikowa kości długich jest potencjalnym miejscem dostępu naczyniowego umożliwiającym podawanie płynów i krwi [2]. Następnie w 1934 roku Josefson jako pierwszy udowodnił terapeutyczne zastosowanie infuzji IO u ludzi [3]. Wkłucia doszpikowe były stosowane stosunkowo często w latach 30. i 40. XX wieku, a w trakcie II wojny światowej mamy informację o tysiącach doniesień dotyczących ich użycia do podawania krystaloidów, leków oraz krwi [4]. Pomimo wczesnego sukcesu wkłuć doszpikowych zastosowanie tej metody jako alternatywy dla tradycyjnego dostępu naczyniowego było znacząco ograniczone do lat 80. XX wieku. Kilka badań wśród pacjentów pediatrycznych odnowiło zainteresowanie kaniulacją doszpikową jako metodą podawania leków ratunkowych podczas resuscytacji. Zachęcające wyniki tych badań doprowadziły do większego docenienia użyteczności kaniulacji IO podczas resuscytacji pediatrycznej. W 1985 r. nowe wytyczne resuscytacji pediatrycznej wydane przez American Heart Association (AHA) uznały IO za bezpieczną alternatywę dla dostępu dożylnego. Aby odzwierciedlić rosnącą akceptację stosowania IO w celu ustanowienia dostępu naczyniowego, wytyczne AHA PALS z 2010 roku uaktualniły swoje zalecenia dotyczące zatrzymania krążenia utożsamiając dostęp IV i IO w celach resuscytacyjnych [5]. Chociaż początkowo stosowanie IO było zalecane tylko u dzieci w wieku poniżej 6 lat, najbardziej aktualne wytyczne dotyczące resuscytacji krążeniowo-oddechowej dorosłych i dzieci popierają stosowanie technik IO u pacjentów w każdym wieku.

1.1. Anatomia i Patofizjologia

Czerwony i żółty szpik kości długich człowieka zawiera bardzo bogatą sieć naczyń posiadających dynamiczne krążenie. Są one zdolne do przyjmowania dużych objętości płynów i szybkiego transportu ich lub leków do krążenia centralnego. Kość, podobnie jak większość narządów, jest zaopatrywana przez główną tętnicę (tętnicę odżywczą). Tętnica przebija korę i dzieli się na gałęzie wznoszące się i opadające, które dalej dzielą się na tętniczki, które przebijają śródkostną powierzchnię warstwy zwartej, stając się naczyniami włosowatymi. Naczynia włosowate spływają do zatok żylnych rdzenia w całej przestrzeni szpikowej, które z kolei spływają do centralnego kanału żylnego. Zatoki rdzeniowe przyjmują płyn i leki podczas wlewu doszpikowego i służą jako droga transportu do centralnego kanału żylnego, żył wyrzutowych i ostatecznie do centralnego krążenia. Pośrodku trzonu kości przebiega rozległa zatoka centralna, złożona z rozciągliwego śródbłonka. Ta zatoka może się rozciągnąć, aby pomieścić pięciokrotny wzrost objętości [6]. Naczynia krwionośne przestrzeni śródkostnej są połączone z krążeniem ogólnoustrojowym szeregiem podłużnych kanałów zarówno w płaszczyźnie pionowej (kanały Haversa), jak i poziomej (kanały Volkmanna). Kanały Haversa są połączone z systemem kanałów Volkmanna, które penetrują korę i kończą się połączeniami z drenażem kostno-żylnym [7]. Ta obfita sieć żylna może funkcjonować zatem jako sztywna, niezapadająca się droga dożylna, gdy zawiedzie obwodowy lub centralny dostęp żylny [8]. Jest to szczególnie ważne u pacjentów znajdujących się we wstrząsie lub zatrzymaniu krążenia, gdy żyły obwodowe mogą się zapaść, a krew jest przetoczona do rdzenia z powodu kompensacyjnego skurczu naczyń obwodowych. Dostęp doszpikowy (IO) umożliwia bezpośredni dostęp do szpiku kostnego rdzenia kostnego i drenaż żylny kości długich. Ustanowienie trasy IO dla dostępu naczyniowego pozwala lekom i płynom dostać się do centralnego krążenia w ciągu kilku sekund. Składowe te odgrywają bardzo istotną rolę u dzieci, ponieważ mają one małe naczynia obwodowe, które zapadają się podczas wstrząsu, a wyższy udział tkanki tłuszczowej w organizmie utrudnia wizualizację i badanie palpacyjne naczyń obwodowych. Czynniki te często skutkują przedłużającymi się próbami i wysokimi wskaźnikami niepowodzeń dostępu dożylnego.

Wkłucie doszpikowe stanowi szybką i bezpieczną alternatywę dostępu do układu krwionośnego w sytuacji, gdy dostęp IV jest znacznie utrudniony bądź niemożliwy. Skuteczność uzyskiwania dostępu doszpikowego w różnych badaniach wacha się od 75%

do 100%, zaś czas od rozpoczęcia uzyskiwania dostępu doszpikowego do momentu podłączenia linii infuzyjnej zazwyczaj mieści się w zakresie 30-120s [9-11]. Dostępy doszpikowe stosowane są jako jedna z metod dostępu do łożyska naczyniowego zarówno w przypadku zatrzymania krążenia jak i wstrząsu. Zazwyczaj stosowane są one jako metoda umożliwiająca szybką stabilizację farmakologiczną i płynową pacjenta, stanowiąc swoisty pomost przed uzyskaniem dostępu dożylnego. Jednakże z uwagi na swoje właściwości i możliwość podania niemalże wszystkich leków znajdują zastosowanie również poza zespołami ratownictwa medycznego czy też szpitalnymi oddziałami ratunkowymi. Jak wskazują Krähling i wsp. [12] oraz Schindler i wsp. [13] za pomocą dostępu doszpikowego może być podawany kontrast podczas wykonywania tomografii komputerowej u pacjentów udarowych. Winkler i wsp. dodatkowo pokazali możliwość wykorzystania dostępu IO do podawania kontrastu przy badaniach angiografii tomograficznej aorty piersiowej [14]. Bjerkvig i wsp. wskazuje na możliwość transfuzji krwi pełnej za pomocą wkłucia doszpikowego [15]. Z kolei Mazaheri-Khameneh i wsp. prowadząc badanie eksperymentalne na modelu zwierzęcym wykazali, iż za pomocą wkłucia doszpikowego można podawać również leki anestetyczne, w tym propofol [16]. Kolejną zaletą dostępów doszpikowych jest możliwość pobierania tą metodą krwi na potrzeby badań laboratoryjnych, w tym oznaczania pH oraz PCO_2, czy też oznaczania układu AB0. Badania wykazały jednak, że wartości próbek pobranych z szpiku kostnego dla niektórych wartości laboratoryjnych mogą być niedokładne w porównaniu z próbkami z krwi żylnej. Dlatego należy zachować ostrożność podczas interpretacji następujących wartości laboratoryjnych takich jak: utlenowania krwi, potasu, glukozy, ciśnienia parcjalnego dwutlenku węgla (PCO_2), dehydrogenazy mleczanowej, liczby białych krwinek, liczby płytek krwi, a także poziomu aminotransferazy asparaginianowej, aminotransferaza alaninowa, fosfataza alkaliczna i zjonizowany wapń [17,18]. Natomiast wartości laboratoryjne uzyskane ze szpiku kostnego, które są w pełni zgodne z próbkami z dostępu żylnego, obejmują hemoglobinę, hematokryt, pH, nadmiar zasad, wodorowęglan w surowicy, sód, chlorki, magnez, fosfor, wapń całkowity, albuminę, azot mocznikowy we krwi, kreatyninę, bilirubinę, białko całkowite, kwas moczowy, typ i badanie przesiewowe, poziomy leków w surowicy i posiewy krwi np. kultury bakterii, wirusów czy też grzybów [19].

Niemożność uzyskania dostępu doszpikowego często podyktowana jest obraniem przez osobę wykonującą zabieg złych punktów orientacyjnych, możliwością śródkostnego zagięcia się igły doszpikowej, jak również zatkania igły przez szpik bądź odłamy kostne. Kolejnym powodem niepowodzenia zabiegu dostępu doszpikowego jest zsunięcie się igły po powierzchni kości. Warto w tym momencie podkreślić, iż aby prawidłowo wykonać dostęp doszpikowy i zmniejszyć ryzyko rozwarstwienia kości bądź wspomnianego uprzednio zsunięcia się igły po powierzchni kości jest odpowiednie przyłożenie wkłucia doszpikowego pod kątem prostym do powierzchni, w której ma być wykonane.

W przypadku poprawnie założonego dostępu doszpikowego niektórzy autorzy wskazują możliwość wystąpienia powikłań po wlewach doszpikowych, jednakże zgodnie z badaniami tych autorów powikłania tego typu są niezwykle rzadkie i dotyczą mniej niż 1% przypadków [20]. Rosetti i wsp. w swoim badaniu wskazują również na ryzyko zapalenia kości i szpiku, sięgające 0,6% przypadków [21]. Jednakże to wynaczynienie krwi, płynów i leków do tkanek miękkich jest uznawane za jedną z najczęstszych komplikacji dostępów doszpikowych [22-24]. W przypadku EZ-IO problemy z dostępem doszpikowym raportowane przez Helma i wsp. dotyczyły 1,6% prób wykonania procedury (w tym: 0,8% to dyslokacja igły, 0,4% krwawienie oraz 0,4% nieszczelność) [25]. Z kolei przegląd literatury przeprowadzony przez Greensteina i wsp. wykazał, iż poważne komplikacje związane z dostępem doszpikowym obserwowane były zaledwie w 0,3% przypadków [26]. Odnotowali oni przypadek wynaczynienia leków wazopresyjnych, który z uwagi na działanie obkurczające stanowił potencjalne zagrożenie dla tkanek otaczających wkłucie doszpikowe. Za pomocą wkłucia doszpikowego mogą być podawane nawet leki o krótkim okresie półtrwania, takie jak adenozyna. Przykład skutecznego zastosowania adenozyny doszpikowo w przypadku częstoskurczu nadkomorowaego u noworodka opisał Friedman [27].

Przeciwskazania do założenia dostępu doszpikowego są nieliczne i obejmują m.in. złamanie kości długie z urazem naczyniowym bądź infekcją skóry lub oparzeniem w miejscu planowego dostępu doszpikowego [21]. Szczególną ostrożność należy również zachować w odniesieniu do pacjentów z osteoporozą, którzy narażeni są na większe ryzyko złamań jatrogennych. Ponadto wkłucie doszpikowe nie powinno być umieszczane w kości, w której próbowano uprzednio wykonać dostęp doszpikowy –z uwagi na ryzyko

wynaczynienia podawanych płynów przez wcześniej wykonany przy próbie otwór w kości [5].

1.2. Rodzaje wkłuć doszpikowych

Igły doszpikowe w zależności od sposobu uzyskiwania dostępu doszpikowego można podzielić na trzy kategorie: igły manualne, igły z napędem sprężynowym oraz igły z napędem elektrycznym.

1.2.1. Igły ręczne

Dostępnych jest kilka dostępnych na rynku ręcznych igieł doszpikowych i wykazano, że można je łatwo stosować u pacjentów pediatrycznych i dorosłych [6,28], np. Igła do aspiracji/infuzji szpiku kostnego Jamshidi/Illinois, w rozmiarze 15 i 18 (G) (CareFusion, Vernon Hills, IL) [29] lub gwintowana igła infuzyjna Sur-Fast IO oraz zmodyfikowana igła infuzyjna Dieckmann IO (obie firmy Cook Critical Care, Bloomington, IN) [30]: Igły te mogą być stosowane w kości udowej, proksymalnej i dystalnej kości piszczelowej, w tym w kostkach, mostku, kości ramiennej głowy, dystalnej kości promieniowej i kości łokciowej oraz kości biodrowej. Uchwyt Near Needle Holder (Near Manufacturing, Camrose, Alberta, Canada) jest uchwytem wielokrotnego użytku, który umożliwia wprowadzenie standardowej pustej igły do przestrzeni śródkostnej. Grupa lekarzy i studentów medycyny w Gujanie próbowała symulować wprowadzenie obu rodzajów igieł po obejrzeniu krótkiego filmu szkoleniowego. Czasy wprowadzania dla obu typów były prawie identyczne (Near Needle Holder: 32 ± 13,2 s vs Cook: 32 ± 12,3 s), a większość użytkowników oceniła Near Needle Holder jako bezpieczną i łatwą w użyciu [31]. Uchwyt Near Needle Holder może być bezpieczną i niedrogą opcją w krajach rozwijających się. Techniki wprowadzania są podobne dla wszystkich typów igieł ręcznych. Igła jest ustawiona prostopadle do miejsca wprowadzenia i nacisk jest stosowany w połączeniu z ruchem skręcającym, aż do wyczucia „utraty oporu" podczas wprowadzania igły do jamy szpikowej. Zgłoszone wskaźniki powodzenia pierwszych prób z ręcznymi igłami są bardzo zróżnicowane. Jedno z badań wykazało ogólny wskaźnik sukcesu 67,7% z czterema rodzajami igieł (standardowa igła podskórna, igła do szpiku kostnego, igła do kręgosłupa i ręczna igła doszpikowa) wprowadzonych przez lekarzy rezydentów u znieczulonych

prosiąt [32]. W innym badaniu symulacyjnym studenci medycyny mieli 95% wskaźnik skuteczności wkłuwania igły SurFast ® (Cook Critical Care, Bloomington, IN) w kości zwierzęce. U pacjentów pediatrycznych (w wieku poniżej 5 lat) z przedszpitalnym zatrzymaniem krążenia odnotowano nawet 85% przypadków powodzenia [33.34]. Niedawno stwierdzono, że przy użyciu różnych igieł śródkostnych odsetek powodzeń przy pierwszej próbie w warunkach przedszpitalnych wyniósł 78% [35].

Rycina 1. Igła manualna Jamshidi. *Źródło: archiwum autora.*

1.2.2. Easy intraosseous access device- EZ-IO

System dostępu naczyniowego Arrow EZ-IO (Teleflex, Morrisville, NC) to łatwy w obsłudze i szkoleniu, zasilany baterią litową, wielorazowy IO [7,36], który jest dostarczany z zestawem trzech igieł do do użytku przez jednego pacjenta [37]:

- Igły 15-G o długości 15 mm (różowe) dla pacjentów o masie ciała 3–39 kg
- Igły 15-G o długości 25 mm (niebieskie) dla pacjentów o wadze 40 kg i cięższych
- Igły 15-G o długości 45 mm (żółte) dla pacjentów o wadze 40 kg i cięższych z nadmiarem tkanki/obrzękiem w miejscu wkłucia, które obejmuje proksymalną i dystalną kość piszczelową oraz głowę kości ramiennej (ale nie wskazane do stosowania do mostka; Rycina 2 i 3).

Wykazano, że urządzenie EZ-IO jest skuteczne w uzyskiwaniu dostępu naczyniowego w warunkach przedszpitalnych z 90% skutecznością [36].

Przeprowadzono szereg badań w celu sprawdzenia szybkości i dokładności wstawiania EZ-IO. Randomizowane badanie porównało wprowadzenie EZ-IO z ręczną techniką igłową

w zwłoki osób dorosłych. Chociaż czasy wprowadzania były podobne (EZ-IO: 32 ± 11 s w porównaniu z manualnym: 33 ± 28 s), EZ-IO miał wyższą ocenę „przyjazności dla użytkownika” i lepszy wskaźnik sukcesu przy pierwszej próbie (EZ-IO: 97,8% w porównaniu z instrukcją manualną: 79,5%) [38]. W porównaniu z metodą head-to-head z wkładaniem BIG, urządzenie EZ-IO ma wyższy wskaźnik powodzenia przy pierwszej próbie (EZ-IO: 90% w porównaniu z BIG: 80%) i krótszy czas wprowadzania (EZ-IO: 1,8 min vs. BIG: 2,2 min) w warunkach resuscytacji oddziału ratunkowego (pacjenci urazowi i zwykli) [39].

Rycina 2. Rozmiary igieł EZ-IO. Źródło: archiwum autora.

7-letnia retrospektywna analiza zakładania przedszpitalnego wykazała, że umieszczenie implantu EZ-IO ma znacznie wyższy wskaźnik powodzenia przy pierwszej próbie w porównaniu ze wskaźnikiem powodzenia pierwszej próby zarówno wszczepienia ręcznego, jak i BIG (EZ-IO: 96% w porównaniu z ręcznymi: 50% vs. BIG: 55 %) [40]. Urządzenie EZ-IO jest łatwe w obsłudze i wymaga minimalnego przeszkolenia. Grupie 99 lekarzy bez doświadczenia z EZ-IO przeprowadzono 5-minutową prezentację z jednym pokazem wprowadzania. Następnie każdy z nich wykonał trzy wszczepienia piszczeli na zwłokach. Wskaźniki powodzenia dla trzech prób wynosiły odpowiednio 96,9, 94,9 i 100%, przy medianie czasu wynoszącej zaledwie 6 sekund [41]. W innym badaniu studenci

ratownictwa medycznego przeszli szkolenie wideo na temat urządzeń EZ-IO i BIG. Uczestnicy mieli znacznie wyższy wskaźnik sukcesu przy pierwszej próbie (w kościach indyka) z EZ-IO (EZ-IO: 28 z 29 vs. BIG: 19 z 29) [42]. Badania te sugerują, że EZ-IO jest łatwym w użyciu i łatwym do nauczenia narzędziem, które można z powodzeniem stosować w scenariuszach resuscytacji przy minimalnym przeszkoleniu.

Rycina 3. Napęd EZ-IO do wkłuć doszpikowych. Źródło: archiwum autora.

1.2.3. FAST1, FASTX i FASTResponder

FAST1, FASTX i FASTResponder (Pyng Medical, spółka zależna Teleflex, Morrisville, NC) to jednorazowe urządzenia IO przeznaczone do umieszczenia w rękojeści mostka (Ryciana 4) [43]. Zawierają sterylną jednorazową sondę z wieloma igłami i są zazwyczaj używane wyłącznie u dorosłych lub dzieci powyżej 12 roku życia. Zgłaszane szybkości infuzji wynoszą od 30 do 80 ml/min w przypadku kroplówki grawitacyjnej, 120 ml/min w przypadku źródła pod ciśnieniem i 250 ml/min w przypadku wstrzyknięcia strzykawką [44].

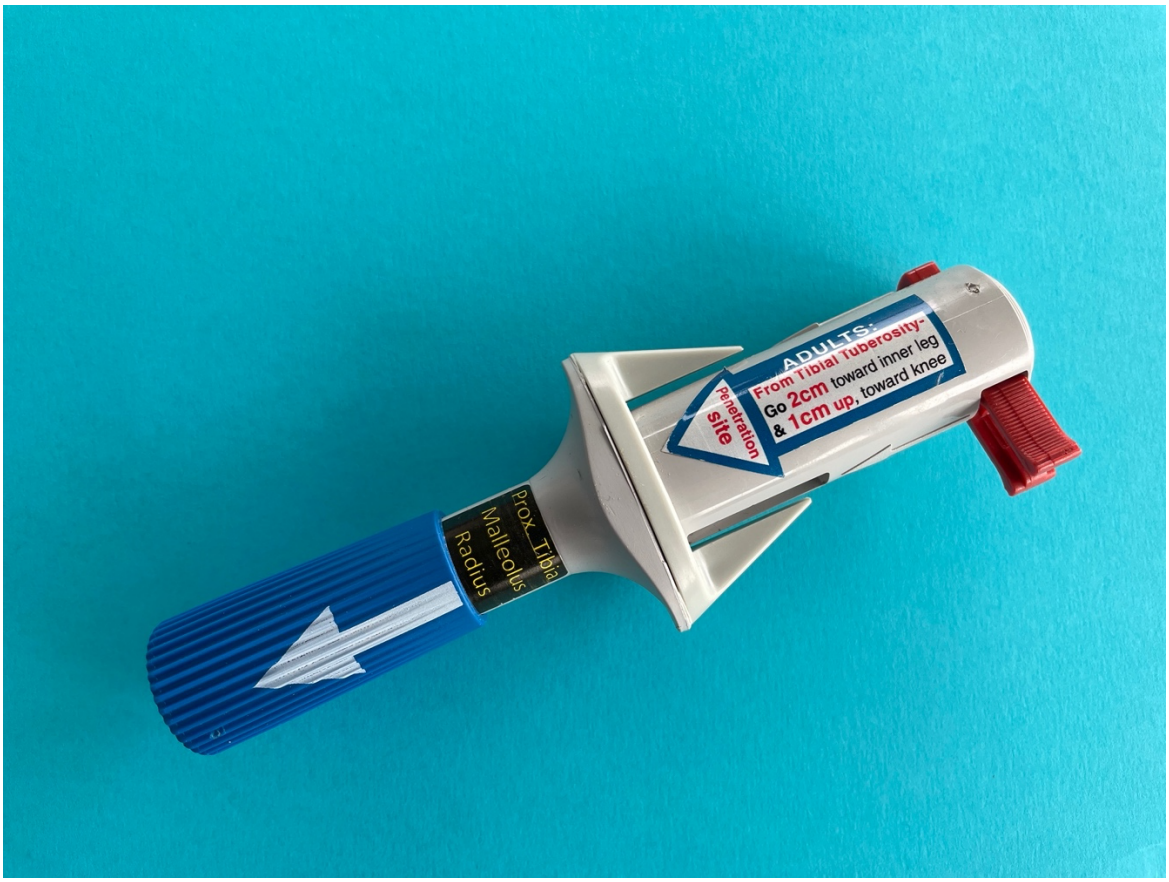
Rycina 4. Igła doszpikowa FAST1. Źródło: archiwum autora.

Pilotażowe badanie wskaźników sukcesu wykazało, że osoby, które po raz pierwszy użyły FAST1, miały 74% wskaźnik sukcesu. Już po jednym doświadczeniu z użyciem urządzenia, wskaźnik powodzenia wzrósł do 95% przy kolejnych próbach, przy czym mediana czasu wprowadzenia dla wszystkich badanych wynosiła 60 s (ustawienie przedszpitalne i oddział ratunkowy) [45]. Badanie symulacyjne wykazało, że po 2-godzinnym wykładzie 96,6% studentów techników ratownictwa medycznego prawidłowo zidentyfikowało anatomiczne punkty orientacyjne, a 100% prawidłowo umieściło naklejkę docelową. Ogólnie rzecz biorąc, uczniowie mieli 93,1% wskaźnika pomyślnego umieszczenia igły w manekinie [46]. Biorąc pod uwagę zastosowanie FAST1 urządzenia u pacjentów z amputacjami kończyn, przeprowadzono badanie w celu zbadania szkolenia wymaganego dla wojskowego personelu medycznego, aby uzyskać biegłość w jego obsłudze. Po 60-minutowym wykładzie, szkoleniowym filmie wideo i sesji symulacyjnej, badani prawidłowo umieścili FAST1 w zwłokach 29 razy 30 razy (94%) ze średnim czasem 114 ± 36 s [47]. Niektóre nieudane próby FAST1 w tych badaniach przypisuje się trudnościom technicznym wynikającym z otyłości pacjenta.

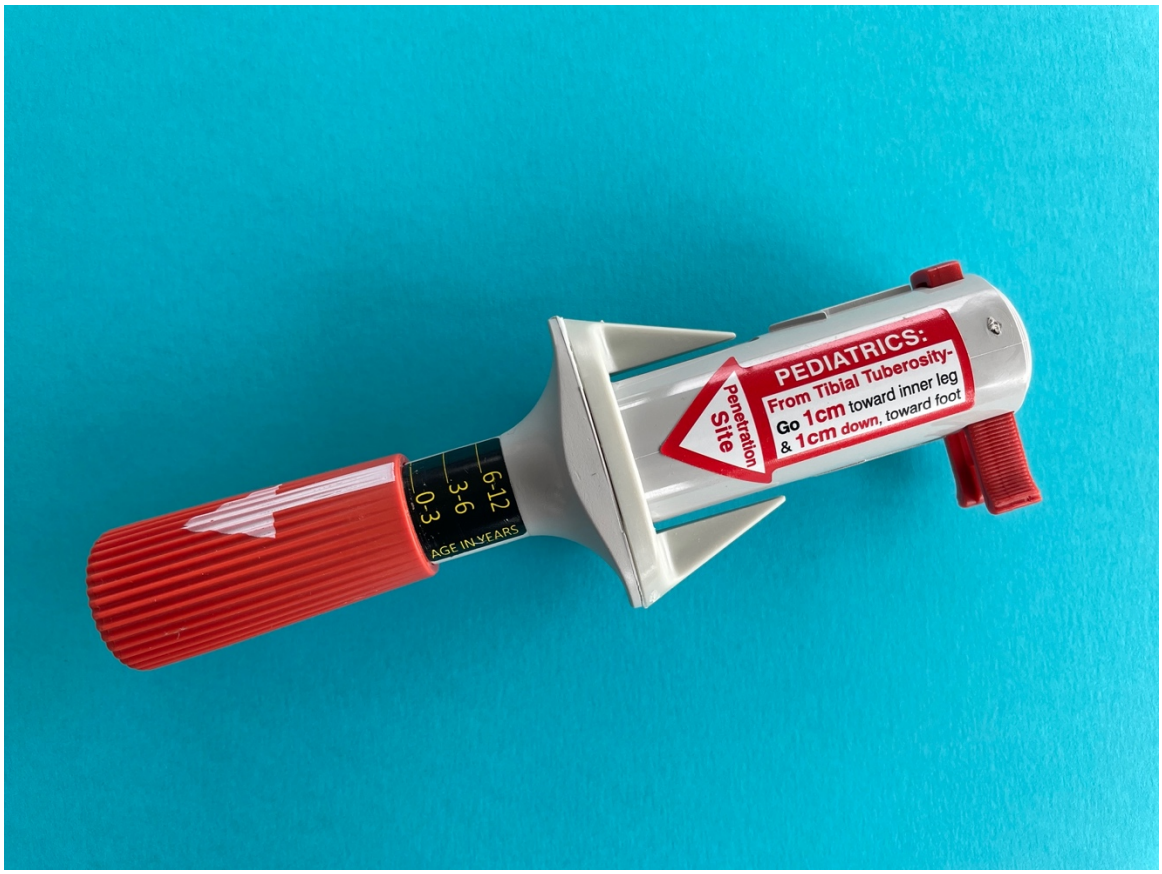
1.2.4. The Bone Injection Gun (BIG)

Pistolet do wstrzykiwań do kości (PerSys Medical) [48] jest dostępny jako urządzenia IO dla dorosłych i dzieci (Rycina 5 i 6). Te jednorazowe, sprężynowe urządzenia wprowadzające zostały zatwierdzone przez amerykańską Agencję ds. Żywności i Leków (FDA) do użytku w bliższej części kości piszczelowej i głowie kości ramiennej u dorosłych

[39]. Urządzenia te mają automatyczny jednorazowy wtryskiwacz IO z tworzywa sztucznego. Wersja dla dorosłych ma igłę 15G z wstępnie ustawioną głębokością wkłucia 2,5 cm lub 1 cal; wersja pediatryczna posiada igłę 18G z regulowaną głębokością wkłucia 0,5 cm i 1,5 cm. Zgłoszone wskaźniki powodzenia pierwszej próby wprowadzenia implantu BIG wahają się od 71 do 91% [49,50]. Badanie przedszpitalne oceniające użycie B.I.G. przez zespół ratownictwa medycznego transportującego helikopterem wykazało 71% ogólnego wskaźnika sukcesu (dorośli i dzieci) i nie wykazało żadnych powikłań [50]. W badaniu na psach wskaźniki powodzenia ręcznego wkłucia igły i wprowadzenia B.I.G. były podobne. Wprowadzenie urządzenia B.I.G. było jednak znacznie szybsze (B.I.G.: 22,4 ± 8,2 s vs. ręczne: 42,0 ± 28,1 s) [51]. Urządzenie B.I.G. jest łatwe do nauczenia i wymaga minimalnego przeszkolenia. Wojskowy personel medyczny bez wcześniejszego doświadczenia odniósł sukces w 29 z 31 prób wprowadzenia BIG (w zwłokach) po wykładzie i filmie szkoleniowym [47].



Rycina 5. Wkłucie doszpikowe B.I.G. w wersji dla pacjentów dorosłych. Źródło: archiwum autora.



Rycina 6. Wkłucie doszpikowe B.I.G. w wersji dla pacjentów pediatrycznych. *Źródło: archiwum autora.*

1.2.5. New Intraosseous (NIO) Device

Urządzenie New Intraosseous (NIO) to jednorazowe, automatyczne, sprężynowe urządzenie ze zintegrowanym stabilizatorem igły. NIO zawiera zestaw kaniuli z stałą głębokością wprowadzenia 35 mm dla dorosłych (Rycina 7) [52]. Zwykle, miejsca lokalizacji obejmują piszczel i głowę kości ramiennej. Shina i in. przeprowadzili badanie krzyżowe w celu porównania urządzenia NIO kontra EZ-IO na modelach zwierzęcych. Wskaźnik sukcesu pojedynczej próby z NIO wyniósł 92%, podczas gdy w przypadku EZ-IO było to 88%.

Powikłania NIO dotyczyła blokady zwalniania sprężyny z powodu złego położenia igły i fiksacja na kości, problemy z mocowaniem strzykawki i usuwania mandrynu. Z drugiej strony zdarzenia niepożądane związane z EZ-IO były: ze względu na przesuniętą igłę IO, zły kąt techniki, i odłączenie mandrynu wiertarskiego. Dodatkowo 46% uczestników wolało NIO, a 54% wybrało EZ-IO. Tak więc badanie nie wykazuje statystycznych różnic w wydajności i łatwości użytkowania te dwa urządzenia (EZ-IO vs. NIO) [53]. Z kolei Szarpak

i in. wskazał urządzenie NIO jako lepszy wybór dla dostępu IO podczas oceny NIO i EZ-IO urządzenia. Pomyślna procedura wprowadzania była znacznie szybsza w przypadku urządzenia NIO (16 s) niż EZ-IO (26 sek.).

Rycina 7. Wkłucie doszpikowe NIO dedykowane pacjentom dorosłym. *Źródło: archiwum autora.*

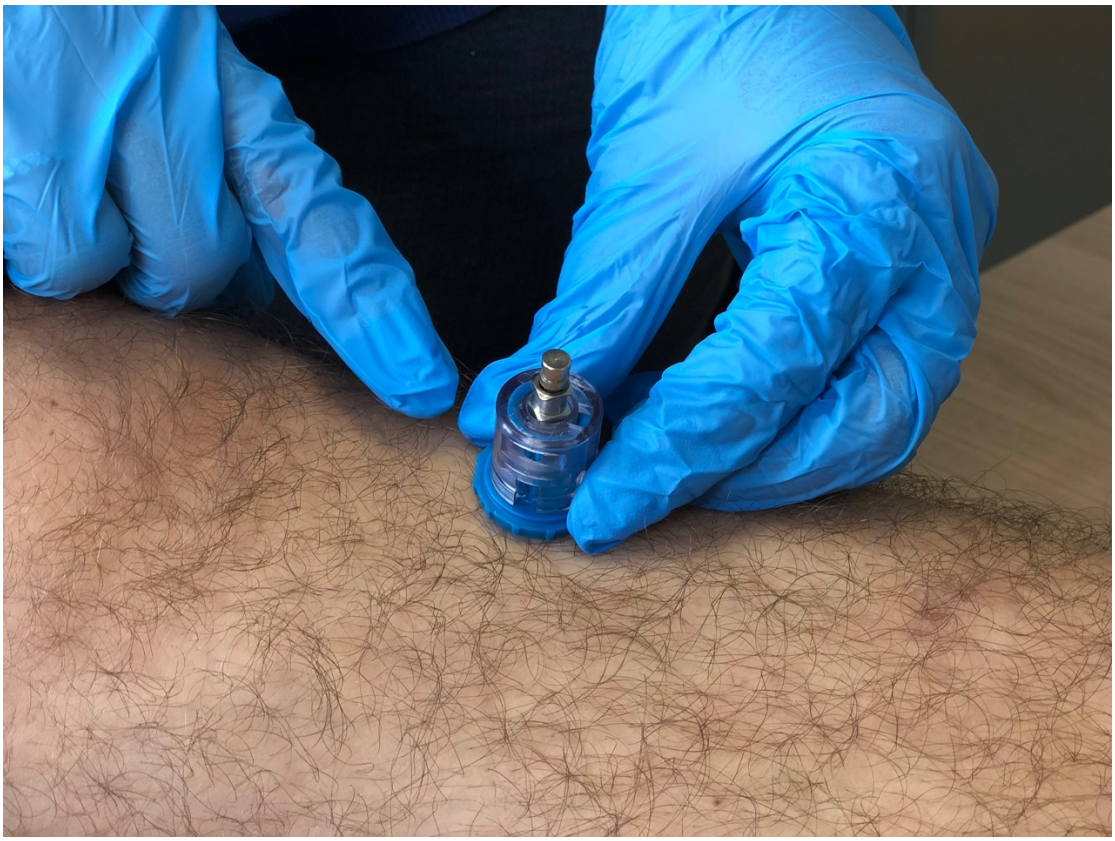
Ponadto ratownicy medyczni statystycznie częściej wskazał urządzenie NIO jako łatwiejsze w obsłudze [54]. Ci sami autorzy porównali te dwa urządzenia na zwłokach oceniając zdolność niedoświadczonych ratowników medycznych przy dostępie IO. Wskaźnik sukcesu pierwszej próby z obydwoma NIO i EZ-IO były bardzo wysokie (odpowiednio 97,4% vs. 100%) oraz nie było znaczącej różnicy między urządzeniami. Warto zauważyć, że dostęp do IO uzyskano znacznie szybciej dzięki NIO (16,8 s) w porównaniu z urządzeniem EZ-IO (42 s) [55]. Ponadto badanie Ramireza i wsp. również wskazało NIO jako bardziej efektywne, szybsze i znacznie łatwiejsze w użyciu urządzenie do IO niż BIG [56].

Uzyskanie dostępu doszpikowego z wykorzystaniem igły doszpikowej NIO jest niezwykle prostą procedurą, która obejmuje wyznaczenie potencjalnej lokalizacji wkłucia, ustawienie urządzenia pod kątem prostym do powierzchni kości, w którą będzie odbywało się wprowadzenie igły doszpikowej (Rycina 8). Zaletą wkłuć doszpikowych NIO jest fakt, iż posiadają one już podstawowy stabilizator igły, który jest jej nieodłącznym elementem

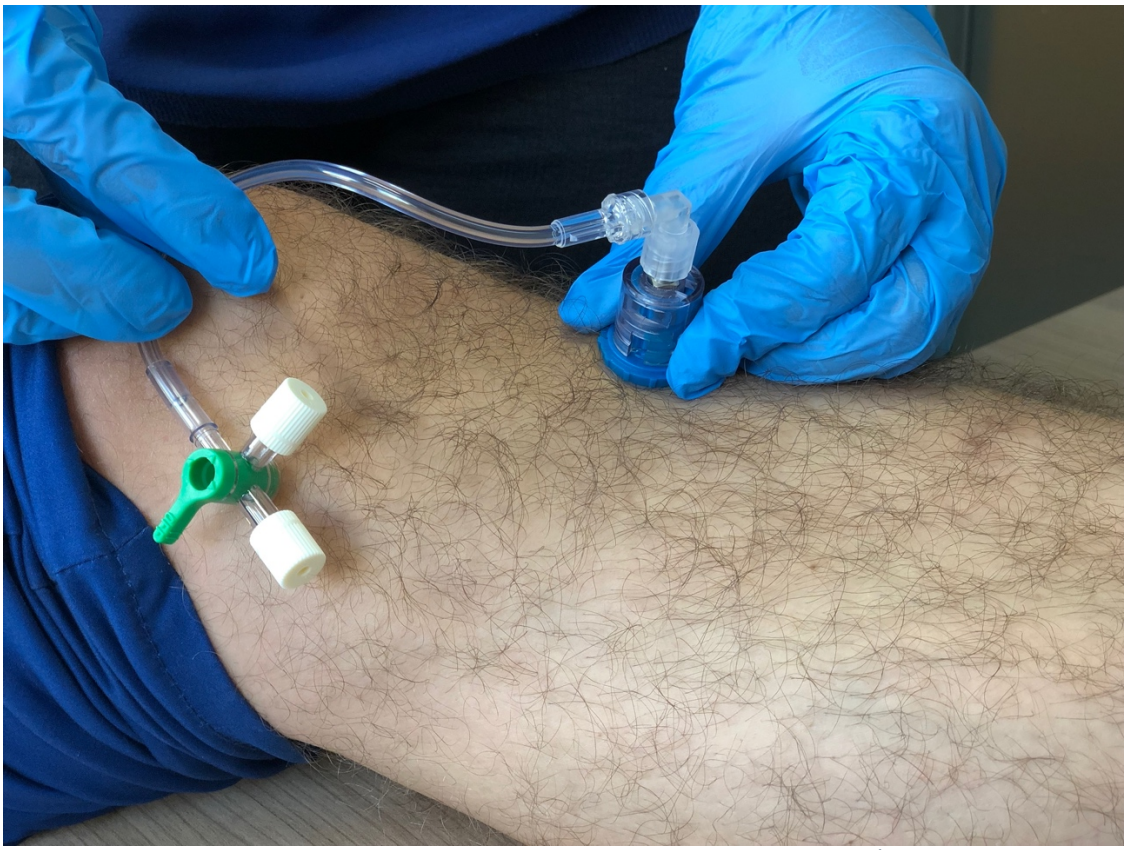
(Rycina 9). Następny krok to próba aspiracji za pomocą strzykawki (Rycina 10) oraz podłączenie przedłużacza infuzyjnego z kranikiem – który redukuje ryzyko rozszczelnienia igły podczas podłączania zestawów kroplowych bądź strzykawek.

Istnieje również dedykowana półautomatyczna wersja NIO dla pacjentów pediatrycznych (NIO-P) w wieku od 3 do 12 lat (Rycina 11). Mechanizm z NIO-P jest podobny do wersji dla dorosłych jednak różnice dotyczą igły 15G u dorosłego NIO w porównaniu z igłą o rozmiarze 18 dla dzieci.

Rycina 8. Uzyskiwanie dostępu doszpikowego w proksymalny odcinek kości piszczelowej. Źródło: archiwum autora.



Rycina 9. Igła doszpikowa NIO ze stabilizatorem. *Źródło: archiwum autora.*



Rycina 10. Kranik dwudrożny z wężykiem podłączony do dostępu doszpikowego. *Źródło: archiwum autora.*

Rycina 11. Wkłucie doszpikowe NIO dedykowane pacjentom pediatrycznym. Źródło: archiwum autora.

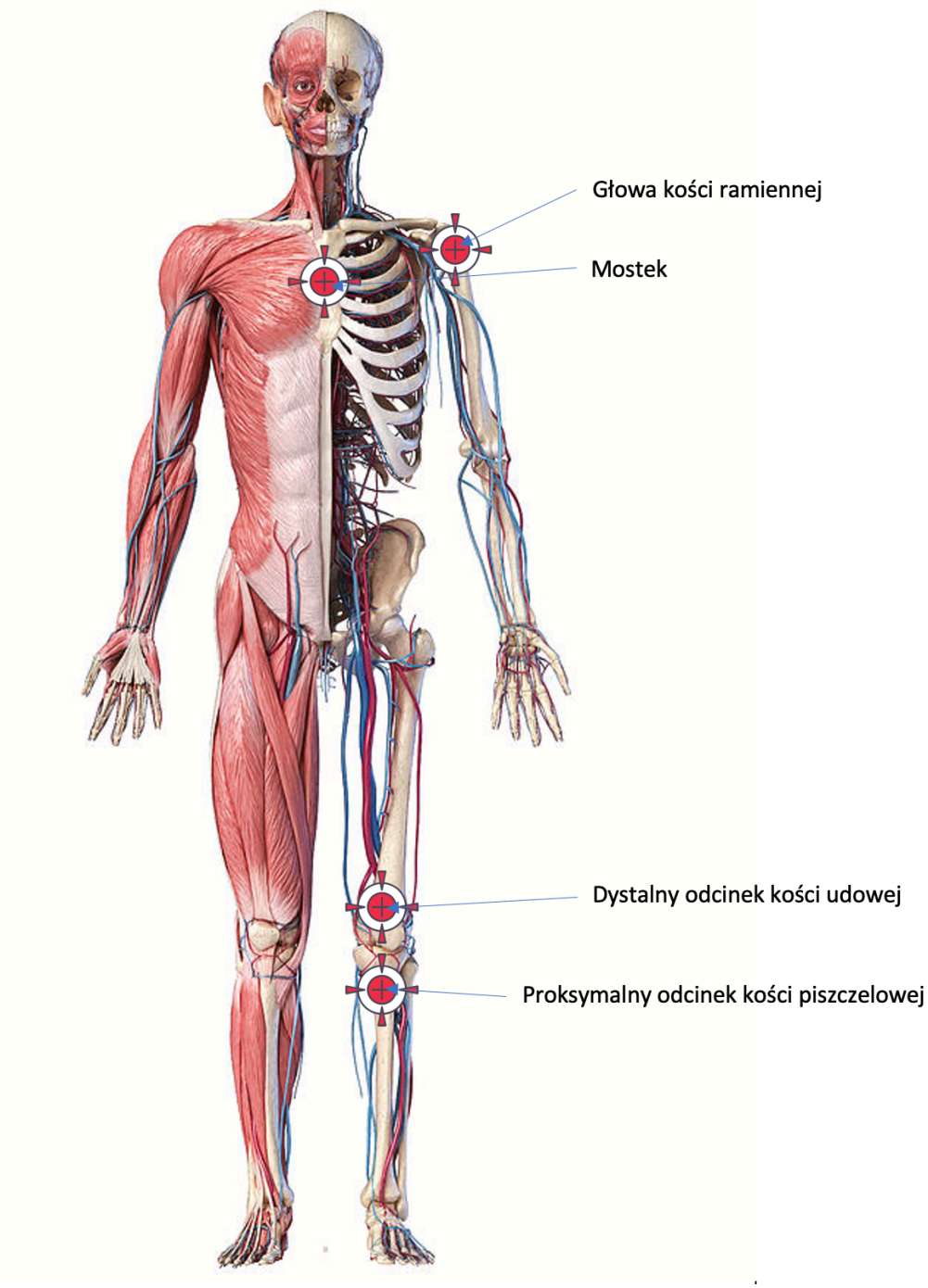
Głębokość wprowadzenia NIO-P można zmienić zgodnie z wiekiem pacjenta [57]. Wiele badań analizuje skuteczność urządzenia NIO u pacjentów pediatrycznych. Feldman i in. przeprowadzili badanie, w którym nie stwierdzono różnic we wskaźnikach powodzenia między pielęgniarkami ratunkowymi a ratownikami medycznymi (79,4% vs 83,3%). Wskaźniki sukcesu i niepowodzeń były podobne w obu przypadkach urządzenia. Ponadto obie grupy napotkały podobne komplikacje techniczne związane z tymi dwoma urządzeniami. Jednak 82,3% pielęgniarki i 73,3% ratowników medycznych wskazało EZ-IO jako urządzenie pierwszego wyboru [58]. Z drugiej strony, gdy porównano NIO-P do Jamshidi, BIG i EZ-IO, wskaźnik sukcesu wyniósł 100% dla NIO-P, natomiast 90% dla pozostałych urządzeń. Ponadto NIO-P był urządzenie pierwszego wyboru 91% użytkowników [59]. Podobnie, w innym badaniu wskaźnik sukcesu wyniósł 100% dla NIO-P, podczas gdy był gorszy dla trzech pozostałych urządzeń [60].

Warto w tym miejscu ponadto wspomnieć, iż została ponadto wypuszczona na rynek igła doszpikowa NIO dla niemowląt. Jednakże z uwagi na strukturę kostną tej grupy pacjentów jest to igła wprowadzana manualnie (Rycina 12).

Rycina 12. Wkłucie doszpikowe NIO dedykowane niemowlętom. *Źródło: archiwum autora.*

1.3. Lokalizacje wkłuć doszpikowych

Wkłucia doszpikowe w zależności od wskazań producenta może być założone w różnych lokalizacjach. Najczęstszymi lokalizacjami wybieranymi przez personel medyczny są: część proksymalna kości piszczelowej, głowa kości ramiennej czy też kostka przyśrodkowa (Rycina 13).



Rycina 13. Najczęściej wybierane lokalizacje do uzyskania dostępu doszpikowego. Źródło: opracowanie własne.

Zestawienie akceptowalnych przez poszczególnych producentów miejsc uzyskania dostępu doszpikowego prezentuje Tabela 1.

Tabela 1. Zalecane lokalizacje uzyskania dostępu doszpikowego zgodnie ze wskazaniami producentów.

Typ wkłucia	Pacjent dorosły	Pacjent pediatryczny	Lokalizacja
Igła manualna	✓	✓	Mostek, głowa kości ramiennej, dystalna część kości łokciowej, talerz biodrowy, kość udowa, proksymalna i dystalna część piszczeli, włączając kostkę przyśrodkową
FAST1	✓	✓	W przypadku domostkowego użycia jedynie u pacjentów w wieku ≥ lat
B.I.G.	✓	✓	Głowa kości ramiennej u dorosłych; Proksymalny i dystalny odcinek kości piszczelowej u dzieci i dorosłych
EZ-IO	✓	✓	Głowa kości ramiennej; Proksymalny i dystalny odcinek kości piszczelowej

Helm i wsp. wskazują, iż najczęściej preferowaną lokalizacją dostępu doszpikowego z wykorzystaniem EZ-IO była proksymalna część kości piszczelowej (87,2%), następnie część dystalna kości piszczelowej (7,5%) oraz kość ramienna (5,3%) [25].

1.4. Przepływy

Na przepływ przez igłę IO wpływa wiele różnych czynników w tym ciśnienie infuzji, szerokość i długość igły, lepkości płynu, opór hydrauliczny w obrębie szpik i układu żylnego, miejsce wprowadzenia, wielkość przestrzeni kostnej, obecność skrzepów i innych szczątków, obturacyjne oraz miejscowe napięcie naczyniowe w jamie szpikowej i tkankach ją otaczających. Ciśnienie krwi w przestrzeni kostnej jest zwykle utrzymywane na poziomie

od jednej trzeciej do jednej czwartej systemowego ciśnienia tętniczego krwi [61-63]. W konsekwencji, próby wlewu płynów do przestrzeni muszą najpierw pokonać wewnętrzny opór tego gradientu ciśnienia pomiędzy przestrzenią i systemem infuzyjnym. Można to osiągnąć za pomocą wlewu grawitacyjnego (wytwarzającego ciśnienie infuzji 100 mmHg zawieszonego na standardowej wysokości 100 cm nad igłą) lub przy użyciu standardowego worka ciśnieniowego, pompy infuzyjnej lub infuzji strzykawkowej. Ogólnie wlew ze strzykawki jest najszybszą techniką, ponieważ wytwarza najwyższe ciśnienie infuzyjne 760–1520 mmHg za pomocą strzykawki 50 ml [64,65]. Wyższe szybkości infuzji są ogólnie możliwe przy zwiększonym ciśnieniu infuzji we wszystkich miejscach wprowadzenia. Pod ciśnieniem strzykawki odnotowano szybkości przepływu 250 ml/min [66,67]. Ale ten wzrost natężenia przepływu ma swoją cenę. Rubal i wsp. [68] wykazali, że wysokie ciśnienia infuzji doszpikowej znacząco zwiększają ciśnienie śródszpikowe w sposób liniowy. Kompresja rdzeniowa i odkształcenie ścinające wzrastają dramatycznie między 30 a 60 ml/min. Fizjologiczne skutki zwiększonego ciśnienia wewnątrz kości podczas infuzji wysokociśnieniowej nie zostały całkowicie opisane. Zwiększone ciśnienie wewnątrz kości wiąże się z subiektywnym odczuwaniem bólu i wiąże się ze zwiększonym ryzykiem wynaczynienia płynów z wnętrza przestrzeni kostnej [6].

Kilku autorów sugerowało, że rozmiar igły IO nie wpływa znacząco na szybkość przepływu, co dowodzi, że aż 90% oporów przepływu w infuzji doszpikowej wynika z oporu hydraulicznego w szpiku kostnym [69,70]. Wydaje się to być poparte anegdotycznymi dowodami na to, że szybkość infuzji IO zmniejsza się automatycznie w miarę uzupełniania płynów ustrojowych. Gunz i wsp. [71] zauważył, że szybkości przepływu wydają się być związana z wagą dziecka i stopniem odwodnienia. Dalsze wsparcie dla tej teorii dostarcza Schoffstall i wsp. [72], którzy stwierdzili trzykrotną poprawę szybkości przepływu z 13-gauge IO w porównaniu z 18-gauge IO w dużych świniach, ale nie ma między nimi różnicy igły u mniejszych świń. Dotyczyło to zarówno infuzji grawitacyjnej (na wysokości 100 cm), jak i infuzja ciśnieniowej 300 mmHg.

Kilka badań wykazało, że kość ramienna jest miejscem zdolnym do wlewu znacznie większych objętości płynu niż miejsce piszczelowe w modelu świńskim pod wysokim ciśnieniem infuzji [73-75]. Wyniki z badań na ludziach porównujących kości ramiennej i miejsca piszczelowe są różne. W prospektywnym badaniu interwencyjnym porównano szybkości przepływu płynu przez igły EZ-IO umieszczone w kości ramiennej, piszczelowej

i udowej świni. Kość ramienna miała statystycznie istotnie ($p < 0,001$) wyższy przepływ (213 ml/min) w porównaniu z kością piszczelową (103 ml/min) lub kością udową (138 ml/min) podczas wlewu soli fizjologicznej przez worek ciśnieniowy [76]. Badania na ludziach porównujące szybkość przepływu kości ramiennej i piszczelowej dają mieszane wyniki. Badanie na 10 ludzkich ochotnikach wykazało znacznie wyższe średnie natężenie przepływu w kości ramiennej (kość ramienna: 5093 ± 2632 ml/h oraz piszczel 1048 ± 831 ml/h) we wlewie pod ciśnieniem [77]. Jednak prospektywne badanie obserwacyjne 24 krytycznie chorych pacjentów (ustawienie oddziału ratunkowego) porównujące szybkość przepływu EZ-IO w kości ramiennej i piszczelowej nie wykazało statystycznie istotnej różnicy między ośrodkami (kość ramienna: 153 ml/min vs. piszczelowa: 165 ml/min). Obydwa miejsca w tym badaniu charakteryzowały się znacznie większą szybkością przepływu w przypadku ciśnieniowego worka infuzyjnego niż w przypadku kroplówki grawitacyjnej [78]. Na podstawie tych małych badań na świniach i ludziach, miejsce w kości ramiennej może oferować większe prędkości przepływu niż w kości piszczelowej, ale konieczne są próby z większą liczebnością próbek, aby dokonać rozstrzygającego rozstrzygnięcia. Dla porównania, prospektywne badanie ochotników wykazało średnią szybkość infuzji 35,6 ml/min. przez cewnik dożylny o rozmiarze 18 (kroplówka grawitacyjna) [79]. Wyższe szybkości przepływu dożylnego (18 G: 205 ml/min; 16 G: 412 ml/min) wykazano przy użyciu systemu Rapid Infusion (Haemonetics Corp., Braintree, MA) [80]. Pasley i wsp. w jednych z najnowszych badań porównujących szybkość przepływu w trzech najczęściej stosowanych klinicznie miejscach wlewu doszpikowego u dorosłych w modelu zwłok człowieka dorosłego udowodnili, że miejsce na mostku dla dostępu IO zapewniało najbardziej spójny i najwyższy przepływ w porównaniu z miejscami wprowadzania implantów w kości ramiennej i piszczelowej. Średnie natężenie przepływu w mostku było 1,6 razy większe niż w kości ramiennej i 3,1 razy większe niż w kości piszczelowej [81]. Niedrożność igły przez skrzepy i resztki kości lub szpiku skłoniła niektórych autorów do odradzania aspiracji szpiku kostnego, aby potwierdzić prawidłowe umieszczenie przed infuzją IO. Inni stwierdzili, że przepłukiwanie lub wlewy heparynizowanej soli fizjologicznej przez igłę IO są skuteczne w poprawie przepływu, prawdopodobnie poprzez zapobieganie miejscowej aktywacji kaskady krzepnięcia [68,82].

1.5. Kosztochłonność

W wieloośrodkowym badaniu obserwacyjnym porównano koszty wprowadzenia cewnika do żyły centralnej z kosztem wprowadzenia śródkostnego u niestabilnych pacjentów zgłaszających się na oddział ratunkowy. Łącznie 105 pacjentów otrzymało dostęp doszpikowy (85% to pacjenci „medyczni", a 53% z zatrzymaniem krążenia lub oddechu), a koszty porównano z opublikowanymi danymi z linii centralnej. Stwierdzono, że oszczędności związane z umieszczeniem śródkostnym nad centralnym dostępem żylnym wyniosły 195 USD na zabieg [83]. Jednak to badanie ma ograniczenia, które należy wziąć pod uwagę. Skupiono się tylko na początkowych kosztach wkładania na oddziale ratunkowym i nie zajmowało się takimi kwestiami, jak codzienne koszty utrzymania linii centralnej lub odsetek pacjentów w grupie śródkostnej, którzy ostatecznie otrzymali linie centralne podczas przyjęcia do szpitala. Odsetek pacjentów, którzy później wymagają dostępu centralnego, nie był badany i musi zostać określony przed wyciągnięciem prawdziwych wniosków dotyczących „ogólnej" opłacalności.

2. CEL PRACY

Wspólnym celem artykułów wchodzących w skład spójnego tematycznie cyklu publikacji było porównanie różnych technik uzyskiwania dostępów doszpikowych w warunkach medycyny ratunkowej zarówno w aspekcie pacjentów pediatrycznych jak i osób dorosłych.

3. KOPIE OPUBLIKOWANYCH PRAC

EXPERT REVIEW OF MEDICAL DEVICES
2021, VOL. 18, NO. 9, 855–864
https://doi.org/10.1080/17434440.2021.1962287

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REVIEW

Intraosseous vascular access in emergency and trauma settings: a comparison of the most universally used intraosseous devices

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ABSTRACT

Introduction: Obtaining successful vascular access is an essential component of the emergency and trauma setting. The modern practice of medicine advocates IO access for patients in a critical condition, especially when IV access is problematic or unobtainable. Various medical devices allowing for IO access have been coined and used in the management of critical patients.

Areas covered: This study aims to review the literature regarding different intraosseous devices used to obtain vascular access (Bone Injection Gun (BIG), EZ-IO, NIO, Jamshidi, and First Access for Shock and Trauma (FAST-1) and discuss their clinical and experimental role in the emergency and trauma settings.

Expert opinion: The development of medical technology contributes to an increasing number of intraosseous devices facilitating vascular access in challenging scenarios, including cardiopulmonary resuscitation, anaphylactic, or hypovolemic shock. Each of these devices provides an effective route for fluid resuscitation, drug delivery, laboratory evaluation, and shortening the timeframe for established vascular access, provided that the person obtaining the access is acquainted with the use of the device.

ARTICLE HISTORY
Received 26 April 2021
Accepted 27 July 2021

KEYWORDS
Vascular access; intravascular; intraosseous device; emergency medicine; trauma setting

1. Introduction

The provision of vascular access for fluid and pharmacotherapy is a critical element of emergency medicine, particularly in trauma settings such as cardiopulmonary resuscitation (CPR) or life-threatening conditions. A delay in administering therapy because of prolonged attempts to establish vascular access in such emergency states may worsen patient prognosis or adversely affect the patient's state [1,2].

However, gaining vascular access via the intravenous (IV) route often proves unobtainable or delayed in emergency states. An abundant number of critical patients presenting during an emergency or trauma are in a state of shock where the body's natural defenses shut down peripheral circulation, making it difficult or impossible to access peripheral veins for the delivery of life-saving drugs and fluids [3]. In these patients, the collapse of the vascular bed with peripheral IV access (most commonly near the cuboidal fossa) proves challenging or even impossible, necessitating an alternative access site that may be achieved using an intraosseous (IO) device.

Although previously more common in critical care of pediatric patients or military settings, IO access has demonstrated to be an effective route for fluid resuscitation, drug delivery, and laboratory evaluation attained in all age groups and emergency scenarios with an acceptable safety profile [4]. Today, IO access is advocated for patients in a critical condition, especially in cases when IV access is problematic or unobtainable; a method approved by scientific circles at the European Resuscitation Council (ERC) and the American Heart Association (AHA) [5–7].

Innovative advances in medical device technology have prompted several devices that greatly facilitate the IO infusion of drugs and fluids in adults. Such devices penetrate the complex cortex of adult bone into the highly vascularized IO space through specially designed needles or needle sets – actions aiming to establish IO access consist of locating the tibial tuberosity [8]. IO access is the technique of choice for obtaining vascular access in pediatrics; however, it is only the recommended method for failed or prolonged attempts at IV access in adults. Advanced Trauma Life Support guidelines outline that IO access should be obtained after three unsuccessful attempts to access the peripheral vein or after 2 minutes of continued attempts [9].

As highlighted by experts, obtaining vascular access with an IO device can be deemed simple, fast, and safe, hence perhaps proving to be an integral part of rescue procedures [10,11]. Furthermore, research shows that obtaining IO access even after a relatively short training interval is not difficult for physicians, paramedics, or emergency nurses [8,12].

Establishing IO access requires an injection point located 2 cm medially and 1 cm cranially from the tibia's tuberosity in adults. In pediatrics, 1–2 cm medially and approximately 1 cm caudally from the tibial tuberosity on the bone's flat pane [12,13]. In adults, IO access can be performed in the sternum about 2 cm under the sternal notch, humous, tibial bone either proximal or distal after locating the medial malleolus, and two fingers width above the ankle's upper edge [4,12]. In children, the mark is one finger width over the upper edge of

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Article highlights

- Intraosseous access is an alternative method for pharmacotherapy or fluid administration and establishing vascular access in life-threatening conditions.
- Vascular access via an intraosseous device previously reserved for critical care conditions in pediatrics and the military is recommended for adult emergency and trauma conditions.
- Bone Injection Gun (BIG), its successor New Intraosseous Device (NIO), the Jamshidi, Easy Intraosseous Access Device (EZ-IO), or the FAST1 device are the most popular and widely used intraosseous devices for vascular access in emergency and trauma settings.
- Manual intraosseous devices (Jamshidi) are limited to the pediatric population in critical conditions or trauma.
- Semi-automatic intraosseous (BIG, NIO, and FAST-1) device systems are the most commonly used vascular access method due to their safety profile and ease of use.
- Drill intraosseous devices (EZ-IO) are user-friendly with limited training time.
- There are many types of intraosseous devices currently available on the market.
- Intraosseous devices may contribute to a decreased number of failed vascular access attempts, particularly during cardiopulmonary resuscitation or in life-threatening conditions.
- The learning curve for obtaining vascular access via an intraosseous device is shallow.

the ankle. A site conceivable to establish IO access is also the head of the humerus. The IO injection provides entry for resuscitation drugs and fluid resuscitation [14–16]. However, flow through the IO catheter must be initiated by an initial flush of at least 10 mL of saline and maintained using a pressure infusion bag inflated at 300 mmHg per the use instructions [17].

The advantage of IO access is that it is comparable to the central venous catheter achieved desired drug plasma concentrations. During massive fluid therapy through IO access with a quick transfusion cuff, it is possible to reach an average flow of 125 mL/min using one infusion site only [18]. However, IO access is an emergency solution for the impossibility of quickly obtaining peripheral IV access, ongoing cardiopulmonary resuscitation, and hypovolemia when emergency IV cannulation is difficult. Therefore, it is recommended to be maintained until the hemodynamic parameters, assessed non-instrumentally, are improved, and the time should not exceed 24 hours. Contraindications may include signs of soft tissue infection at the injection site, bone fracture, compartment syndrome, limb trauma with vascular bundle damage, and any attempt to establish IO access within the previous 24 hours [4].

To date, various medical devices allowing for IO access have been coined, some of which include devices through which the needle is kicked into the bone, such as the Bone Injection Gun (BIG) (WaisMed Ltd., Herzliya, Israel) and also the New Intraosseous Device (NIO) (WaisMed Ltd., Herzliya, Israel), the EZ-IO kit (Teleflex®, Morrisville, NC, USA) where the needle is twisted with a small drill, and FAST-1 system (Pyng Medical Corp. Richmond, Canada) which involves the attachment of a multi-needle injection system to the sternum. This article aims to review the most widely used IO devices for vascular access in emergency and trauma settings.

2. Semi-automatic spring devices

2.1. Big Bone Injection Gun (BIG)

The Bone Injection Gun (BIG) is a semi-automatic and disposable device (Figure 1) and one of the most commonly used for IO routes [19]. The mechanism involves a spring-loaded injector to fire an IO needle into the bone [20]. The most common insertion sites include the proximal tibia and humerus head due to its flat surface and shallow medullary canals [21]. Studies show that BIG allows for obtaining an effective route for quick and easy administration of medications and fluids in children and adults [19]. The injection success rate ranges from 73.0% to 92.3% in adults and remain at a steady 73.0% in children [22,23]. Notably, the preparation and insertion require a time of 17 seconds (s), while the procedure itself takes a surprisingly short time, with a maximum of 3 minutes (a mean procedure time of 2 minutes) [12,24]. The BIG device is commonly used by paramedics, physicians, and medical providers in advanced life support (ALS) procedures.

Depending on the persons' age, the characteristics of the BIG, such as small size, lightweight, and color-coded division, make it a good alternative for patients in life-threatening conditions and often in unfavorable environments. However, owing to technical parameters, the BIG device has limitations in its use. The data associated with the incidence of the complications is divergent, ranging from 7% to 27% [22], while some studies report even up to 40.9% [25]. The needle's wrong position, which missed the bone but entered the marrow, extravasation, or no flow in the cannula are among the most mentioned [25]. Nevertheless, Leidel et al. [26] underline that the bone cortex's missed penetration is probably due to the wrong insertion site and was only observed in tibial access [26].

Additionally, a commonly raised problem is the removal of the trocar needle. The stuck stylet within the cannula might reflect technical problems with the device. On the other hand, the effective administration of medications is still possible after removing the successful insertion [26].

Many researchers focused on comparing various IO access devices and their characteristics to identify the most suitable prehospital procedure for resuscitation in recent years. Demir et al. [24] conducted a study to compare the application of BIG and EZ-IO devices in 56 emergency adult patients. Among the three emergency physicians who performed the procedures, no significant difference was found in the first successful attempt rate, with 92.3% for BIG and 84.6% for EZ-IO, respectively. Furthermore, no substantial differences were identified in the patients' characteristics among the two successfully applied techniques. Notably, the time of insertion was significantly longer in the EZ-IO group, and BIG was assessed as a more comfortable device [24]. Even though BIG seems to be a more appropriate choice, the study involved three physicians, which is a significant limitation for extrapolating the results. Per the results of another analysis, Kurowski et al. [12] indicated a higher success rate for the first attempt for the BIG device (91.59%) compared to EZ-IO (82.66%) and Jamshidi (47.66%) in simulated resuscitation attempts

Figure 1. Bone Injection Gun (BIG).

performed by 107 paramedics. Moreover, the mean procedure time for BIG was 2.0 ± 0.7 (mean and standard deviation-SD) minutes compared to 3.1 ± 0.9 minutes for EZ-IO and 4.2 ± 1.0 minutes for Jamshidi [12].

On the other hand, Shavit et al. [27] reported a significantly higher success rate of the first attempt with the EZ-IO than the BIG device on simulated models. Twenty-nine paramedics students could use the EZ-IO before the BIG device assessed the EZ-IO as more comfortable to use. No difference was found in the ease of usage when BIG was used as the first device. The most common complication (6 out of 10) was associated with BIG, with which the stylet was unable to be removed as it was wedged in the needle. At the same time, in 2 other attempts, fluid extravasation was reported. In the case of EZ-IO, the only fluid extravasation around the insertion was observed [27]. Leidel et al. [26] achieved similar results when evaluating the two devices' effectiveness in 40 adult patients under resuscitation. They reported a higher success rate on the first attempt and shorter procedure time with EZ-IO than BIG devices. However, the differences were not statistically significant. In the study, the failed attempts in EZ-IO were due to extravasation, whereas complications with BIG usage involved the stylet being stuck in the bone and the missed penetration of the cortex [26].

Sunde et al. [28] examined the difference between BIG, EZ-IO, and manual needle devices in a helicopter emergency medical service. In the retrospective study, 78 IO insertion attempts were made on 70 patients, including adults (N = 47) and children (N = 23). The overall success rate was 50% with a manual needle, 55% with BIG, and 96% with the EZ-IO device. The adverse events related to the manual needle insertion included needle bending and extravasation. Misplacement and bending of the needles were also observed using BIG devices. Notably, one case of bone fracture and extravasation was reported with the BIG technique. No technical complications were noted with EZ-IO, except for one case of needle dislocation and extravasation [28].

Interestingly, Isayama et al. [19] evaluated BIG insertion's effectiveness among different age groups, including adult, pediatric and infant models, obtained a similar procedure time among all groups. 90% of the participants assessed BIG devices positively [19]. However, the success rate was significantly lower in the infant model (84%), compared to pediatric (94%) and adults (93%).

On the other hand, Ramirez et al. [29] compared the injections made by BIG and NIO during simulated cardiopulmonary resuscitation. The IO access was successfully achieved in 100% of NIO attempts while it showed 95% with the BIG device. The time-lapses to perform the IO injection, stabilize the needle, and connect it to the infusion were longer with BIG devices than NIO. Nonetheless, 90% of the paramedics assessed the NIO device as more comfortable to use [29].

Besides, Eisenkraft et al. [30] evaluated the efficacy of BIG in treating organophosphate poisoning in animal models. The study assessed three ways of midazolam administration – IV, intramuscular (IM), and IO in the effectiveness of terminating the seizures. Notably, the anticonvulsive effect of IO midazolam administration was observed during the injection compared to 5–10 minutes after administration by intramuscular access. Moreover, midazolam reached its peak in the blood sample after 2 minutes by the IO route, whereas after 10 minutes by IM route. Nevertheless, midazolam's bioavailability was 12% lower in IO access than IM, probably due to binding to IO components or metabolic biotransformation [30].

IO access is usually obtained in challenging, unfavorable conditions as a prehospital procedure, altering the provider's skills on stress. Nadler et al. [20] assessed the effectiveness of BIG use by military medical teams in the military environment. The first attempt included 30 trauma patients (adults and children); the success rate was only 53%, a significantly lower result than in the earlier discussed studies. The authors indicate the main challenge was the underestimated time of needle insertion under stress conditions [20]. Other factors included wearing personal protective equipment (PPE). We previously conducted a meta-analysis to investigate the effect of PPE on the success of obtaining IO and IV access during COVID-19. We found that the overall time to obtain IO access while wearing PPE was shorter than for IV, with IO's success

rate achieving 100% compared to IV access at 93%. Therefore, IO access could be obtained in a shorter time and with a higher success rate than an intravascular procedure by medical personal wearing PPE [31].

2.2. Adult New Intraosseous (NIO) Device

The New Intraosseous (NIO) device is a disposable, automatic, spring-loaded device with an integrated needle stabilizer (Figure 2). The NIO contains a set gauge cannula with a constant insertion depth of 35 mm for adults [8]. Usually, the location sites involve the tibia and humerus head.

Shina et al. [32] conducted a crossover study to compare the NIO versus EZ-IO devices on animal models. Fifty medical students were randomly allocated either to NIO or EZ-IO groups to begin the study. The single-attempt success rate with the NIO was 92%, while with the EZ-IO, it was 88%. The NIO complications involved the spring release blockade due to the device's wrong fixation on the bone, syringe attachment problems, and stylet removal. On the other hand, the adverse events with EZ-IO were due to dislodged IO needle, the wrong angle of the technique, and unplugging the driller stylet. Additionally, 46% of the students preferred NIO, whereas 54% chose EZ-IO. Thus, the study shows no statistical differences in efficiency and ease of using those two devices (EZ-IO vs. NIO) [32].

In turn, Szarpak et al. [15] indicated the NIO device as a better choice for IO access when evaluating NIO and EZ-IO devices. The randomized crossover trial involved 37 paramedics in simulated resuscitation. The successful insertion procedure was significantly faster with the NIO device (16 s) than EZ-IO (26 s). Moreover, paramedics statistically more often indicated the NIO device as easier to use [15]. The same authors compared these two devices in a randomized cadaver study to assess inexperienced paramedics' ability to perform the IO access [33]. The first attempt success rate with both NIO and EZ-IO were very high (97.4% vs. 100%, respectively), and there was no significant difference between the devices. Notably, the IO access was obtained significantly faster with the NIO (16.8 s) when compared to the EZ-IO device (42 s) [33]. Besides, the earlier mentioned study by Ramirez et al. [29] also indicated NIO as a more effective and faster device for IO insertion and significantly easier to use than BIG [29].

Interestingly, we previously compared the IO and IV accesses under conditions of simulated hypovolemic shock. The randomized crossover study involved 39 physicians who performed IV access and IO access with the NIO device. Three different time lapses from the beginning of the procedure were measured, including establishing the access, aspiration test, and infusion line connection. There was a significantly lower median time in establishing and confirming the IO access and connecting the infusion line when compared to the IV access. Moreover, 92.3% of the participants indicated the IO access as preferred in real medical situations [34].

2.2.1. NIO-Pediatric

There is also a dedicated semi-automatic version of the NIO for the pediatric group (NIO-P) aged 3 to 12. The IO access mechanism with NIO-P is similar to the adult version. The differences involve the 15-gauge needle in the NIO adult compared to the 18-gauge needle for children [8]. Moreover, the NIO-P insertion depth can be changed according to the patient's age [35].

Many studies analyze the effectiveness of the NIO device in pediatric patients. Feldman et al. [36] conducted a randomized crossover study to compare emergency nurses' and paramedics' effectiveness in obtaining IO access. The procedure involved insertions with the NIO and EZ-IO devices in animal models. No differences in success rates between the emergency nurses and paramedics were found (79.4% vs. 83.3%, respectively). The success and failure rates were similar in both devices. Moreover, both groups faced similar technical complications with these two devices. However, 82.3% of the nurses and 73.3% of the paramedics indicated EZ-IO as their first-choice device [36].

On the other hand, when NIO-P was compared to Jamshidi, BIG, and EZ-IO devices, the success rate was 100% for NIO-P, whereas 90% for the rest of the devices. Moreover, NIO-P was the first-choice device of 91% of the users [37]. Similarly, in another study, the success rate was 100% for NIO-P, whereas it was worse for the three other devices [38].

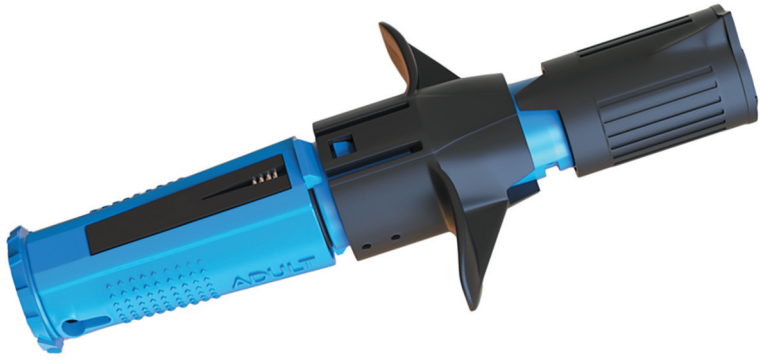

Figure 2. NIO adult intraosseous device.

2.3. First Access for Shock and Trauma 1 (FAST-1)

The First Access for Shock and Trauma (FAST-1) is a single self-contained device (Figure 3), activated by manual pressure and dedicated for sternal IO access, especially in prehospital and battlefield conditions [39]. The FAST-1 was the first FDA-approved device for mechanical sternal IO insertion [40]. It possesses a target zone, which indicates the optimal insertion site in the manubrium [21]. Moreover, after entering the marrow space, the introducer automatically releases the infusion tube. The FAST-1 access is a rapid, safe and effective alternative to the IV line [41].

FAST-1 is a commonly used device to obtain vascular access in emergency settings [41]. Byars et al. [40] evaluated the success rate and procedure time for IO access obtained with FAST-1 by paramedics in prehospital settings. The study subjects included adult patients in cardiac arrest. The researchers reported that of the 41 attempts of FAST-1 insertions, 73% were placed successfully. The mean time of the procedure of the recorded 28 attempts was 67s. Among the successful attempts, problems with adhesion, failure of needle retraction, delayed flow, and minor bleeding were reported. On the other hand, unsuccessful attempts were caused mainly by FAST-1 inability to deploy and infiltrate [40].

Findlay et al. [41] assessed the safety, speed of insertion, and ease of using the FAST-1 device by paramedics in simulated conditions. The mean procedure time was 96 ± 31s from the package's opening to the site stabilization, whereas 92 ± 32s to the beginning of the flow. Most participants assessed the FAST-1 device as safer than peripheral IV access and easier to use [41].

When FAST-1 is compared to the other IO devices, various researchers report divergent data. Pasley et al. [17] conducted a study to compare the IO infusion rates concerning different anatomic sites on the human cadaver model. The study involved 16 cadavers on which three IO accesses were obtained, including sternal location with FAST-1 and proximal tibia and humeral head with EZ-IO device (both 25-mm and 45-mm needle length according to the body habitus). The mean (SD) flow rate was 93.7 (37.9) mL/min in the sternum, 57.1 (43.5) mL/min in the humerus, and 30.7 (18.7) mL/min in tibia access. The total volume of the crystalloid infused during the 5 minutes was 469 (190) mL for the sternum, 286 (218) mL for the humerus, and 154 (94) mL for the tibia. Thus, the sternal site had a flow rate 1.6 times higher than in the humerus and 3.1 times higher than in the tibia [17].

Interestingly, in another cadaver study, researchers tried to verify the design criteria for adult IO infusion. The device was tested on 106 cadavers and excised sterna. It was reported that the FAST-1 device requires similar energy to insert the needle when compared to Cook Sur-Fast, Cook disposable needles, and a Sherwood 16-gauge Illinois [39]. Nevertheless, the other devices require higher caution to avoid over penetration and additional time to rotate the needle. When the optimal penetration depth was established between 5 to 6 mm, the FAST-1 portal was successfully inserted within this 1 mm space, which tended not to penetrate when displaced. The mean flow rate of normal and hypertonic saline with FAST-1 was similar to that with the Cook Sur-Fast device [39].

In turn, Frascone et al. [42] compared FAST-1 and EZ-IO's success rate in two field trials of prehospital provider use. Firstly, the researchers reported that of the 89 insertions with FAST-1 and 89 with EZ-IO, the overall success rate was higher for EZ-IO than FAST-1 (87% vs. 72%). Moreover, the time for fluid infusion was faster with EZ-IO than with FAST-1. No differences in the first and multiple attempts with the two devices were reported. Additionally, no differences in the comfort of usage or device effectiveness were noticed between EZ-IO and FAST-1 [42].

Sørgjerd et al. [43] compared the FAST-Responder (FAST-R) and EZ-IO in helicopter emergency medical services. Generally, among the 53 insertions done on 49 patients, 93.9% were successful on the first attempt. The median insertion procedure time was longer for FAST-R (20 s) than EZ-IO (15 s). On the other hand, 35.1% of the EZ-IO accesses presented poor flow, whereas, in FAST-R, the flow was assessed as good and very good at 85.7%. The adverse events associated with EZ-IO included extravasation (2.4%), aspiration failure (11.9%), and insertion time >30 s (4.8%), whereas, in FAST-R, the user failure (12.5%) and insertion time >30s (12.5%) were most commonly reported [43]. On the other hand, when FAST-1 was compared to other devices, including BIG and Jamshidi, the success rate was higher for FAST-1 (89.5%) when compared to the BIG (59.1%) and lower when compared to Jamshidi (91.7%) [25].

Vassallo et al. [44] conducted a prospective observational study to compare the FAST-1 and EZ-IO in the military operational setting. From the total number of 195 accesses obtained in 117 patients, 76% were done with EZ-IO, whereas 24% with FAST-1. Unfortunately, the only 111 insertions functioned properly, 58% for EZ-IO, and 52% for FAST-1. The overall success was

Figure 3. Fast Access for Shock and Trauma Device (FAST-1).

higher for EZ-IO (combined tibia and humeral access 86.2%) than FAST-1 (79.2%). Among the problems listed, the most commonly indicated with the FAST-1 was device failure, whereas EZ-IO's main problem was difficulty with flushing [44].

3. Semi-Automatic dual systems devices

3.1. Easy Intraosseous Access Device (EZ-IO)

Easy Intraosseous Access Device (EZ-IO) is a semi-automatic, battery-powered IO infusion drill with a needle set (Figure 4) [27]. There are three different sizes of the needle, which can be adjusted for the patients' weight and age. The successful procedure can be assessed by the 5 mm mark on the needle, visible when the needle is placed correctly. The insertion sites include proximal and distal tibia as well as the humerus. Although the device is often used in prehospital and military settings, it is significantly larger than the other devices [21].

Levitan et al. [45] conducted a study to assess acquired skills using EZ-IO in the cadaver model. 99 operators, including physicians, residents, and nonphysicians, attended short training and then performed 3 insertions. The overall rate of successful insertions was 97.3% (96.9% for the first insertion, 94.9% for the second, and 100% for the third, respectively). The median insertion time was 6s (interquartile range 5 to 8s). 99% of the participants indicated that they would use EZ-IO in real medical situations [45]. Notably, EZ-IO was assessed as an easy device for novice users.

Moreover, EZ-IO seems to be an easy and rapid alternative to intravascular access in prehospital settings. In the prospective, cross-sectional study, Torres et al [46]. showed that from 2 vascular accesses in 107 critical and severely injured patients, the first site of access was 100% with EZ-IO. In contrast, the second site was peripheral venous access in 79%. The insertion sites involved proximal tibia (49.4%), distal tibia (25.2%), radius (14.9%), and humerus (10.5%). Importantly, all of the EZ-IO insertions were obtained in less than 30s [46].

Comparingly, Byars, et al [47]. report an 86.5% success rate in EZ-IO (adult standard 15 G/25-mm needle) use among prehospital providers; this rate is slightly lower than other studies' results, as approximately 55% of insertions were carried out by novice users. Participating emergency medical service (EMS) providers rated the ease of use of the EZ-IO as 7.87 on a scale of 10 (meaning highest ease of use) with a convenience internal of 95% (7.22–8.52); insertion at the proximal tibia was most common (93.6%), followed by the distal femur (4.5%), and humeral head (1.8%). Overall, 111 EZ-IO insertions were made, 96 of which were successful, including 83 insertions (74.7%) in cardiac arrest cases and 13 insertions (11.7%) in multi-trauma patients [47].

Furthermore, EZ-IO use was evaluated in out-of-hospital management by mobile intensive care units in a study by Gazin et al. [48]. The staff received EZ-IO training; all vehicles were provided with the device. EZ-IO was utilized for administering fluids (16 patients), adrenaline (24 patients), and succinylcholine for intubation (5 patients). The insertion success rate was found to be at 84% (33/39), with an increase to 97% (38/39) after the first or second attempt. A failed attempt was noted in a cardiac arrest patient due to an unattainable bone marrow aspirate resulting in the insertion needle's impossible placement. The study results showcase the applicability of EZ-IO in emergency cases [48].

Ngo et al. [49] evaluated the use of EZ-IO within the emergency medicine department of an urban hospital, recruiting 24 patients. The study analyzed results from 35 IO insertions (tibial and humeral), finding that all carried out IO attempts were successful except for 3 attempted tibial insertions; all IO access was achieved within 20s. Furthermore, the study showed that obtaining IO access by residents vs. attending physicians is comparable with a 100% success rate for both groups. Nonetheless, more repeated insertion attempts were made by residents as compared to the attendings. Notably, 88.6% reported easier insertion with the EZ-IO than obtaining IV access [49].

Compared to NIO in simulated medical conditions, the successful IO access and infusion were significantly faster

Figure 4. Easy intraosseous access device (EZ-IO).

with NIO than the EZ-IO device (16s vs. 26s, respectively). EZ-IO was also assessed as significantly more challenging to use than the NIO device [15]. The procedure time was significantly longer with EZ-IO in the cadaver model, whereas the success rate was similar for both devices (97.4% with EZ-IO vs. 100% with NIO) [33]. Shina et al. [32] reported that both devices' success rate was similar [32].

In turn, when EZ-IO was compared to FAST-1 based on the success rate, the comfort of usage, 87% successfully obtained accesses were reported with EZ-IO, whereas 72% with FAST-1. No significant difference was found in the comfort of the procedure or device performance [42]. Sørgjerd et al. [43] reported that the median insertion time was shorter using EZ-IO than FAST-1 (15s vs. 20s, respectively). On the other hand, the flow was significantly lower with EZ-IO, while the flow with FAST-1 access was assessed as good and very good. Extravasation and aspiration failure were observed with the EZ-IO but not with FAST-1 [43].

EZ-IO was also compared to the BIG device, although the reports are divergent. Shavit et al. [27] tested both devices on the turkey bone model. They indicated that the paramedics had a significantly higher one attempt success rate with EZ-IO (96.5%) than with the BIG (65.5%). Moreover, EZ-IO was assessed as more straightforward than BIG and was the participants' first-choice device. The only complication concerning EZ-IO was extravasation [27]. Sunde et al [28]. also reported that EZ-IO is a more reliable device when compared to the BIG. The first attempt success rate with EZ-IO was 96% in the retrospective study, whereas only 55% with the BIG. Moreover, various technical problems were registered while using BIG, but none was associated with EZ-IO [28]. On the other hand, in the prospective, randomized clinical study with 56 adult patients, the first attempt at BIG was 92.3%, whereas with EZ-IO, 84.6%. The procedure was significantly longer with the EZ-IO (5.2 ± 2.2 s) than the BIG device (2.8 ± 1.2 s). BIG was assessed as easier to use [24]. In a similar randomized clinical study on adult patients, no significant difference was found in the first attempt success rate and procedure time between the EZ-IO and BIG devices [26].

Besides, when three IO devices were compared, including the EZ-IO, BIG, and Jamshidi needle on the manikin model, the highest success rate was reported with the BIG (91.59%), whereas the lowest with the Jamshidi needle (47.66%). The success rate with EZ-IO was 82.24%. EZ-IO was also in the middle between the three devices concerning the ease of usage. Moreover, within 2 minutes, 77.6% of the insertions with the BIG device were established, whereas only 38.3% with EZ-IO and 35.5% with Jamshidi [12]. Bielski et al. [37] compared EZ-IO, NIO, BIG, and Jamshidi devices in a randomized manikin trial. The first attempt success rate was the highest with NIO (100%), whereas the rest of the devices, including EZ-IO, were successfully inserted in 90% of attempts. A statistically significant difference in the procedure time was reported between NIO and EZ-IO and EZ-IO and Jamshidi. 91% of the participants chose NIO as their first-choice device, while only 7% preferred EZ-IO [37].

4. Manual devices

4.1. Jamshidi intraosseous device

Jamshidi IO device was primarily known as the bone marrow biopsy needle (Figure 5). It is a manual device that allows for adjusting the desired insertion depth [50]. The technique involves manual rotation and pressure. Loss of resistance during the insertion confirms entry into the medullary space [37]. The insertion site usually involves the proximal tibia and iliac crest [25].

Although IO access is a good alternative for IV routes in life-threatening conditions, the insertions with conventional manual devices are sometimes challenging to perform [51]. Thus, Halm et al. [52] compared the Cook and Jamshidi needles, two commonly known manual devices, on the turkey bone model. The study involved paramedics and pediatric residents who had earlier experience with those devices, either in humans or animals. It was shown that the time of insertion was shorter for Jamshidi devices (25.5 s) than for the Cook needle (56.2 s). Furthermore, Jamshidi was assessed as more comfortable to use, and only one complication associated with this technique was reported. On the other hand, the adverse events associated with Cook included 15 broken and 5 bent needles [52].

There are also reports that the procedure with Jamshidi manual devices might be shorter in the available literature compared to mechanical devices. Hartholt et al. [25] performed a randomized, controlled trial with 87 trauma patients, including adults and children, to compare Jamshidi, BIG and FAST-1 devices. They concluded that in both the adult and

Figure 5. Jamshidi intraosseous device.

pediatric groups, the Jamshidi had the shortest insertion time. No noteworthy differences were identified in the success rate, user-friendliness, and complication rate among the devices. Nevertheless, there seemed to be a trend in favor of the Jamshidi device, especially concerning adverse events. Only three of the 21 complications reported among adults were due to the Jamshidi manual device, whereas in the pediatric group, no adverse events associated with the manual device were reported [25].

Interestingly, Calkins et al. [50] evaluated the potential of manual and mechanical IO devices in the simulated Military Special Operations environment. All four devices, including Jamshidi, SurFast screw-tipped IO needle, FAST and BIG, were tested randomly by the 31 special operations medical providers. Although the success rate was similar among the four devices, the FAST insertion was significantly longer than other devices. The success rate did not improve with the number of devices tested. All of the devices were assessed as easy to learn and friendly to use, and there was no significant difference in the first-choice device indication [50].

In turn, Kurowski et al. [12] compared three devices, including BIG, EZ-IO, and Jamshidi, in simulated resuscitation. In the crossover study, 107 paramedics were randomly assigned to 3 groups. The success rate was 91.59% for BIG, 82.24% for EZ-IO, whereas only 47.66% for Jamshidi devices. The mean procedure time was the longest for Jamshidi (4.2 ± 1.0 minutes) when compared to BIG (2.0 ± 0.7 minutes) and EZ-IO (3.1 ± 0.9 minutes) devices. Moreover, Jamshidi was assessed as the most difficult to use [12]. We have previously obtained similar results when evaluating the effectiveness of BIG and Jamshidi usage in simulated conditions by 40 paramedics with special PPE. The time for obtaining IO access was shorter using BIG in the group with and without the PPE than the Jamshidi device [53]. Additionally, the success rate of IO access with PPE was higher than IV access [31].

Nowadays, all devices are also widely used in pediatric care, including NIO, BIG, EZ-IO, and Jamshidi, although NIO data is limited [37]. Thus, Bielski et al. [37] conducted a randomized crossover study to compare the effectiveness of NIO to the BIG, EZ-IO, and Jamshidi devices during simulated pediatric resuscitation. Regarding the Jamshidi device, significant differences in the procedure's success rate and time were observed compared to BIG, EZ-IO, and NIO. The success rate among the 87 paramedics was 100% for NIO and 90% for the rest of the devices. The time to obtain IO access ranged from 9s [8–12, mean and interquartile range] for NIO to 15s [13–19, mean and interquartile range] for the Jamshidi device. Significantly, 91% of the paramedics assessed NIO as the most comfortable device, whereas none would like to use the Jamshidi device [37]. Similarly, we have reported [38] that the effectiveness of Jamshidi usage was the worst. In this simulated study, 75 physicians used the devices on a pediatric manikin and turkey bone. The first attempt success rate was 43% for Jamshidi compared to 100% for NIO-P, 97% for EZ-IO, and 90% for BIG-P. The complications causing such disparity involved needle bent and chipped bone. Moreover, the procedure time was much longer with the Jamshidi device than NIO-P, EZ-IO, and BIG-P. Similarly, none of the participants indicated Jamshidi as a first-choice device [38].

5. Conclusions

Prompt intravascular access is crucial in the management of patients in the emergency and trauma setting. IO devices may be utilized in emergency settings such as patient resuscitation yielding high success rates in obtaining vascular access and low complication rates. However, IO devices use presents with the following challenges: i) insertion at the wrong site, ii) technical malfunction with the device stylet or catheter), or iii) leakage of fluid when the catheter is misplaced.

Notably, appointing one IO device as the best is challenging because of each device's effectiveness and application difficulties. For example, it was demonstrated that NIO-P was the most effective device compared to Jamshidi, BIG, and EZ-IO devices in pediatric settings, but harder to apply as the applicators assessed EZ-IO is easier to use [37,38]. On the other hand, in one study, the comparison between NIO and EZ-IO revealed that the successful IO access and infusion was significantly faster with NIO than the EZ-IO device, and NIO was also assessed as significantly more straightforward to use than the EZ-IO device [15]. The abovementioned, significantly higher number of paramedics assessed NIO as the most comfortable device (compared to EZ-IO, BIG, and Jamshidi), whereas none would like to use the Jamshidi device [37]. Moreover, the procedure time was much longer with the Jamshidi device than NIO-P, EZ-IO, and BIG-P [37,54]. This can be a result of the manual settings of the Jamshidi device. Thus, IO devices considered more technical present with fewer challenges in use and can be used by health professionals at different degrees of training, including beginners.

6. Expert opinion

Medical technology development contributes to an increasing number of intraosseous devices facilitating vascular access in challenging scenarios, including cardiopulmonary resuscitation, anaphylactic, or hypovolemic shock. Each of these devices may provide an effective route for fluid resuscitation, drug delivery, laboratory evaluation, and shortening the timeframe for established vascular access, provided that the person obtaining the access is acquainted with the use of the device.

Furthermore, use of IO devices should be explored in polytrauma cases, including pelvic and other bone injuries. As discussed by Meccariello et al. [55] and Grubor et al. [56], among the most complex trauma injuries are pelvic fractures and post-injury bone defects contingent on the management of related soft tissue injuries respectively. Meccariello et al., study of 98 patients with pelvic injury to design a new score system addressing the aftermath of such fractures, and Grubor et al., war trauma study on the methods of post gunshot fracture treatments, showed the criticality of considering the on-the-scene response and provision of vascular access for fluid and pharmacotherapy in such a life-threatening condition. Comparably, Rollo et al. [57] and Fortina et al. [58], in their studies, indirectly highlight the importance of IO devices in polytrauma requiring immediate response for which IO access would be suitable. Rollo et al. found that sport-related trauma sustained by Jockeys all too frequent with 96.1% of races resulting in at least one fall and in 28.6% of

the races, 50% or more jockeys falling with jockey taken to the emergency room in 43.3%; an incidence rate which only increases with *Palio* races, as discussed by the Rollo et al. [57].

6.1. Five-year review

IO devices used to obtain vascular access has been well known for many decades, particularly in pediatric emergency settings. Current medical techniques and materials allow various types of devices for adults, especially in trauma settings. IO devices' broad use in emergency and trauma environments would increase the number of successful first-attempt vascular access under challenging scenarios. Within the next few years, further development in and use of IO devices is expected. The most important is more significant clinical experience in the already available IO devices. All of the devices discussed in this review are currently used in prehospital and in-hospital emergency environments.

Acknowledgments

The paper was supported by the ERC Research Net and the Polish Society of Disaster Medicine.

Funding

This paper was not funded.

Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

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American Journal of Emergency Medicine 49 (2021) 189–194

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

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

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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ARTICLE INFO

Article history:
Received 28 February 2021
Received in revised form 3 May 2021
Accepted 29 May 2021

Keywords:
Intraosseous access
Intravascular access
Child
Cardiopulmonary resuscitation
Personal protective equipment
COVID-19
SARS-CoV-2
Coronavirus
Infection
Medical simulation

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.

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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https://doi.org/10.1016/j.ajem.2021.05.080
0735-6757/

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 >5–10 μm in diameter, they are called respiratory droplets, and those <5 μm 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].

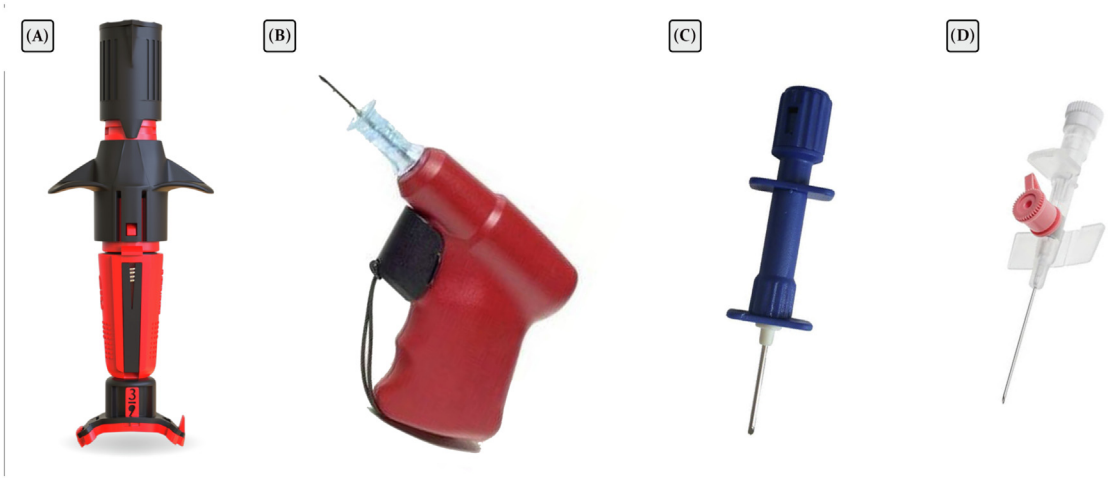

Fig. 1. Intraosseous access devices used in the trial: (A) NIO-Paediatric device; (B) EZ-IO device; (C) Jamshidi needle; (D) intravenous cannula.

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).

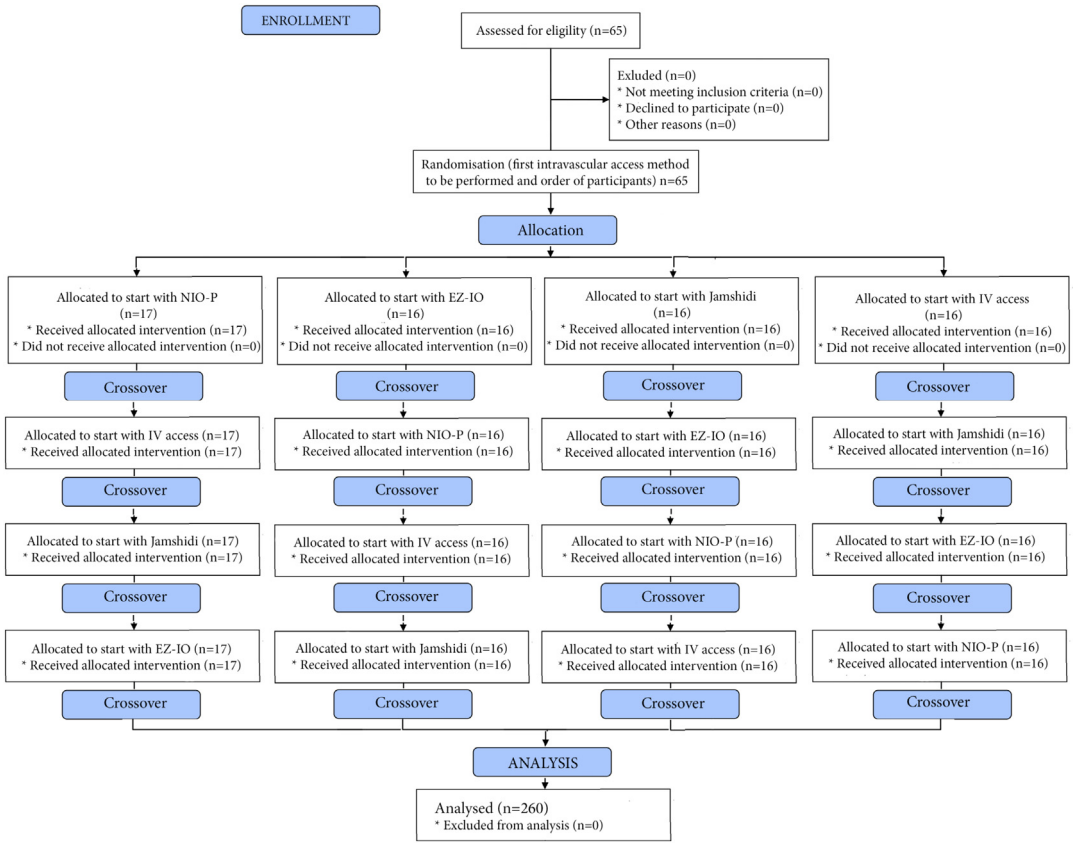

Fig. 2. Randomization flow chart in accordance with the CONSORT statement.

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)	*p*-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.

Acknowledgements

The study was supported by the ERC Research Net and by the Polish Society of Disaster Medicine.

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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VIA MEDICA

ORIGINAL PAPER

Disaster and Emergency Medicine Journal
2016, Vol. 1, No. 1, 24–29
DOI: 10.5603/DEMJ.2016.0004

ISSN 2451–4691

COMPARISON OF TWO INTRAOSSEOUS ACCESS DEVICES EMPLOYED DURING SIMULATED CARDIOPULMONARY RESUSCITATION. A PROSPECTIVE, RANDOMIZED, CROSSOVER, MANIKIN STUDY

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ABSTRACT

BACKGROUND: Intraosseous injection is an alternative method used regarding unsuccessful intravenous access during many emergency situations. The aim of the present study was to compare injections made by the Bone Injection Gun (BIG) with NIO Adult intraosseous access devices during simulated CPR performed by paramedics.

METHODS: 40 paramedics took part in this prospective, randomized, crossover, manikin study. The participants were chosen at random, while each paramedic performed an intraosseous injection with the Bone Injection Gun (BIG) or with the NIO Adult Intraosseous access device. The effectiveness of the intraosseous injection was analyzed as times T1, T2, and T3. Time T1 is defined as the time-lapse from placing the intraosseous device into one's hand to performing the intraosseous injection; Time T2 is the time-lapse from placing the intraosseous device into one's hand to the moment of stabilizing it at the injection site; while Time T3 is defined as the time-lapse from putting the intraosseous device into one's hand, attaching the syringe with a test aspiration, to connecting the infusion line. Attitudes toward the use of intraosseous access during resuscitation were also analyzed in the present study.

RESULTS: The efficacy of intraosseous access obtained with the use of NIO was at 100% where the efficacy of the use of BIG was at 95%. The average time of T1 was similar in the groups randomized to use BIG and NIO, represented as 5.4 ± 3.5 vs. 3.5 ± 2.5 s, respectively ($p = 0.014$); the average time of T2 was 17.5 ± 4.5 vs. 3.5 ± 2.5 s, respectively ($p < 0.001$); while the average time of T3 was 25 ± 5.5 vs. 11.5 ± 2.5 s, respectively ($p < 0.001$). Notably, 90% of the study's participating paramedics preferred to use the NIO during cardiopulmonary resuscitation ($p < 0.001$).

CONCLUSIONS: The present study shows that after a short period of training paramedics can perform an intraosseous injection with a high degree of efficiency. Thus, the authors stress the need for training medical personnel to have the skill to perform intraosseous injections along with knowledge and understanding of the indications and contraindication for IO access.

KEY WORDS: intraosseous access, paramedic, cardiopulmonary resuscitation, simulation, education.

Disaster Emerg Med J 2016; (1)1: 24–29

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INTRODUCTION

One of the basic skills that should be encompassed by medical personnel in the field of emergency medicine is performing an intravascular injection. An injection as such not only provides access to medication but provides access to fluid intake in order to expand the vascular bed and increase blood pressure [1, 2]. In emergency medicine, many cases occur requiring intravascular access that should be obtained as soon as possible [3–6]. Such emergency cases may include the onset of anaphylactic and hypovolemic shock and the necessity to initiate CPR. The importance of intravenous access during CPR is marked by the presence of a nonshockable rhythm described as pulseless electrical activity (PEA) or asystole during which the key step is the administration of adrenalin as outlined by the guidelines of the European Resuscitation Council (ERC) [7, 8], and the American Heart Association (AHA) [9, 10]. Intravascular access, however, may prove difficult as in the case of sudden cardiac arrest (SCA) in which there is a collapse of the vascular bed with which peripheral intravenous access (most commonly near the cuboidal fossa) may be not only difficult, but impossible. Moreover, while in departments of Emergency Medicine, Anaesthesiology and Intensive Care Units a trained anaesthesiologist may be able to obtain central line access, this is an impossible undertaking for paramedics. In their training, paramedics lack the qualified technique training, as well as access to the necessary instruments. Interosseous access (IO), therefore, serves as an alternative approach in the pre-hospital and hospital setting. This interosseous access may be obtained by devices such as the puncture Bone Injection Gun (BIG) and the NIO Adult Intraosseous device, both of which are compared in the present study.

Both intraosseous access devices provide intraosseous access with a semi-automatic technique in which by pressing the release trigger, the needle is ejected. This form of needle insertion proves useful in obtaining access into the intraosseous cavity. With this in mind, the aim of the current study was to compare the two types of devices under simulated CPR performed by paramedics.

METHODS

The present study was approved by the Institutional Review Board of the International Institute of Rescue Research and Education (approval no: 23.05.2016.01). After the presentation of the study's objectives, 44 paramedics participated in the study.

FIGURE 1. Intraosseous access devices used in the study: (**A**) Bone Injection Gun; (**B**) NIO Adult Intraosseous device

All of the participants before commencing the study completed a questionnaire concerning their knowledge and skill regarding intraosseous injection. Subsequently, all participants received appropriate training regarding the indications, contraindications, and techniques used in order to gain intraosseous access.

Once the theoretical training concluded, an instructor demonstrated the correct technique of performing intraosseous injection with both IO devices, namely; the Bone Injection Gun (BIG, WaisMed Ltd., Rosh Ha'Ayin, Israel) and the NIO Adult device (NIO; Persys Medical, Houston, TX, USA) (Fig. 1).

Participants in a randomized crossover order performed the intraosseous injection under conditions of simulated CPR. The ResearchRandomizer program (www.randomizer.org) was used to determine the order of participant participation, as well as which IO access devices each would use for the first then the second trial. The detailed randomized procedure is shown in Figure 2. At first, the first group performed intraosseous injections using the BIG intraosseous device while the other used the NIO device. Following a 30 minute break, the participants performed injections with the other IO devices. The intraosseous injections were performed using the Stat Adult ALS Manikin with the intraosseous Leg Trainer (Simulaids, Saugerties, NY, USA).

The intraosseous access success was defined as an attempt to introduce the intraosseous injection into the correct location, which proved to be a suc-

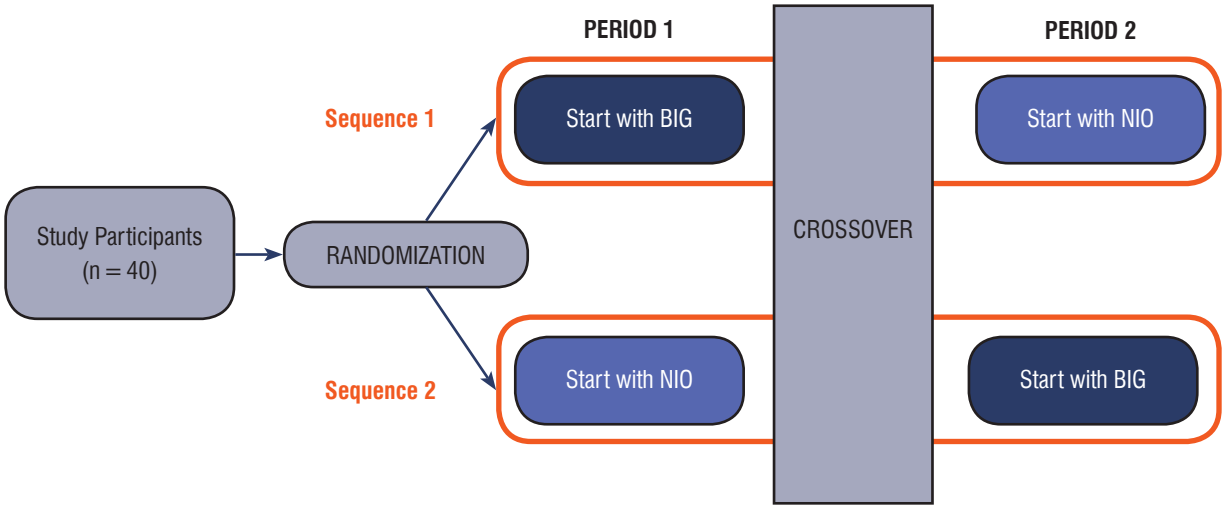

FIGURE 2. Randomization flow chart

cessful outcome. Furthermore, the study measured three time parameters as measures of the effectiveness of the intraosseous injection. Time T1 was the time lapse from placing the intraosseous device into one's hand and performing the intraosseous injection with the needle; Time T2 was measured as the time lapse from placing the intraosseous device into one's hand to the moment of stabilizing it at the injection site; while Time T3 was the time lapse from placing the intraosseous device into one's hand, attaching the syringe with a test aspiration, to connecting the infusion line. The participants were also asked to indicate the ease of intraosseous access using the given equipment and specify which IO device they would most likely use in real CPR conditions.

All the data collected was evaluated using the Statistica Package Software, version 12.5. Results were given as absolute values, percentages, medians, interquartile ranges (IQR) or means, and SD. To check for normal distribution, the Kolmogorov-Smirnov test was used. As a randomized crossover trial study, pairings were taken into consideration in the statistical analysis. McNemar's test was used to compare the cannulation success rates of the humeral head and the proximal tibia whereas the two-sided Wilcoxon signed-rank test allowed one 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

In the present study, 40 paramedics (12 females, equivalent to 30% of the participants) with an average age of 26.5 ± 3.7 years and work experience of 4.3 ± 2.5 years took part. Only 5 of the 40 participants (12.5%) stated that they had had previous experience with IO access. Amongst these, the average number of completed IO access devices uses was 3 ± 1. None of the study participants had previous experience with the use of the NIO Adult Intraosseous device.

To answer at which point during the resuscitation the participants believed an intraosseous injection would prove beneficial; 60% of the participants indicated that they would attempt IO access after two minutes of unsuccessful attempts at IV access, whereas, 40% of participants would attempt IO access after a single unsuccessful attempt at IV access. Furthermore, the participants described the contraindications to intraosseous injection as follows: fracture of limbs (100%); infection of the tissue at the site of planned injection (85%); extremity trauma with damage to the vascular bundle nerves (80%); and compartment syndrome (32.5%). In addition, 7.5% of the participants indicated that IO access needed to be obtained within the first 24 hours. The participants also reported the complications of IO access, namely: the dissection of bone (75%); bleeding (72.5%); osteomyelitis (52.5%); and infection at the injection site (10%). Moreover, 42.5% of participants indicated that medication administered via IO achieves the desired plasma concentration in a time which is comparable to those given via central line access, while 30% believed that the time compares to access obtained via the peripheral vein. Furthermore, 27.5% of participants indicated that the desired plasma level concentration is achieved at a longer time interval

when administered via IO access as compared to peripheral access.

The present study found that the efficacy for IO access using NIO was at 100% and 95% for the use of the BIG device. The lower efficacy with the use of BIG may be attributed to the too small setting of the depth of the puncture. All of the participants were able to correctly identify the place of IO access at the proximal tibia.

The average T1 time in the group using BIG and NIO device was comparable and amounted to 5.4 ± 3.5 vs. 3.5 ± 2.5 s, respectively ($p = 0.014$); the average T2 amounted to 17.5 ± 4.5 vs. 3.5 ± 2.5 s, respectively ($p < 0.001$); while the average T3 time was 25 ± 5.5 vs. 11.5 ± 5.2s, respectively ($p < 0.001$). Although not a statistically significant difference ($p = 0.534$), the participants did disclose that NIO was a simpler way to perform the intraosseous injection as compared to BIG. However, 90% of the study's participating paramedics, preferred to use the NIO during cardiopulmonary resuscitation ($p < 0.001$).

DISCUSSION

This study is, to our knowledge, the first that compares the efficacy of BIG and NIO intraosseous access devices during simulated cardiopulmonary resuscitation performed by paramedics.

Although in the standards of paediatric care intraosseous access is the technique of choice for intravascular access, in adults it is used in the event of failed vascular access, as in the case of an emergency scenario in which CPR is required. This is also true regarding the need to establish intravascular access in trauma patients (without arrest). In emergency situations, intraosseous access is becoming the recommended method with failed or prolonged attempts at intravenous access. Furthermore, the Advanced Trauma Life Support guidelines [11] outline that intraosseous access should be obtained after three unsuccessful attempts at access to the peripheral vein, or after 2 minutes of attempts.

Intraosseous injection provides entry for resuscitation drugs and fluid resuscitation [12–14]. However, flow through the IO catheter must be initiated by an initial flush of at least 10 mL of saline and maintained with the use of a pressure infusion bag inflated at 300 mmHg in accordance with the instructions of use [15]. Notably, the medication given via an intraosseous injection achieves the desired plasma concentration which compares to that by a central line catheter [16].

Undoubtedly, central vein cannulation is the superior method as compared with intraosseous access. However, as shown in the research, the effectiveness of access, the duration of the procedure, and the possible complications, suggest IO access to be the most accessible method. Several studies comparing the complications of IO access have reported complications such as iatrogenic bone fracture, osteomyelitis, and tissue necrosis [17–20]. Alternative studies, nonetheless, have reported no complications found as a result of IO access [21]. The research also explains that there are varying locations of IO access such as the tibia, the head of humerus [22–26] or the sternum [27] which may be used for IO access. In cardiopulmonary resuscitation, however, the research has demonstrated that the effectiveness of obtaining IO access to the proximal tibia (Fig. 3) is more likely than that to the humeral head [21, 23, 28]. This is especially significant regarding the present study, as it is, to the knowledge of its researchers, the first one to compare the efficacy of BIG and NIO intraosseous access devices employed during a simulated cardiopulmonary resuscitation performed by paramedics.

The results of this study further demonstrate that IO access is a rapid and simple way to obtain intravascular access in emergency scenarios. However, the present study does illustrate certain limitations as its data was collected under simulated conditions in order to avoid possible complications which could arise with human subjects. Although the study's participant pool only included paramedics, which may be presented as an another limitation, this was

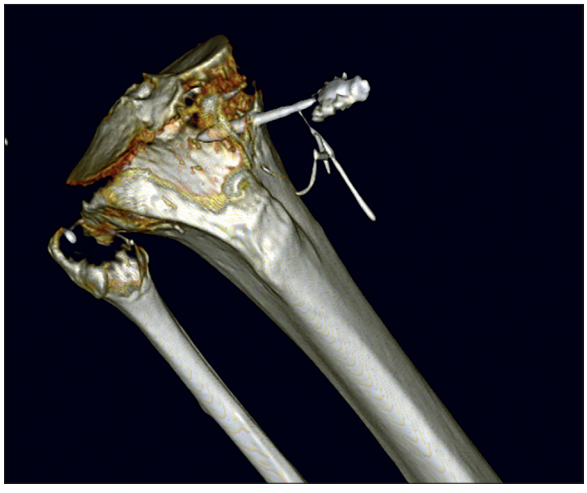

FIGURE 3. Intraosseous needle view in CT scan

deliberate considering it is paramedics which are most often in need of employing IO access in CPR emergency scenarios.

Even with such limitations present, it is also important to note that in order to mimic chest compression the study employed the Lifeline ARM (ARM, Defibtech, Guilford, CT, USA) which the research shows to be sufficient as compared with manual chest compressions [29, 30]. The use of the Lifeline ARM, as a result, caused a lower degree of error as unequal manual chest compression was avoided. The study's design, as one which was a randomized, crossover study, the researchers also believe to be an advantage.

CONCLUSIONS

The present study shows that after a short period of training paramedics can perform intraosseous injections with a high degree of efficiency. Thus, the authors stress the need for training medical personnel to have the skill to perform intraosseous injections along with knowledge and understanding of the indications and contraindication for IO access.

Conflict of interest statement

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

Role of funding source

The authors declare that they received no funding or any other kind of sponsorship regarding study design, data collection, and analysis as well as submitting the manuscript for publication. This study was only funded by Department of Emergency Medicine, Medical University of Warsaw funding.

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American Journal of Emergency Medicine xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

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Comparison of Bone Injection Gun and Jamshidi intraosseous access devices by paramedics with and without chemical-biological-radiological-nuclear personal protective equipment: a randomized, crossover, manikin trial☆

To the Editor,

We read with great interest the study by Kiefer et al entitled "Prospective Evaluation of Ultrasound-Guided Short Catheter Placement in Internal Jugular Veins of Difficult Venous Access Patients" [1]. Accessing intravenous access in patients in hypovolemic shock or during sudden cardiac arrest may be difficult or even impossible to perform [2,3]. As shown by scientific research, the use of ultrasonography to perform peripheral or central intravenous access is associated with prolonged execution time of the procedure [1,3].

The aim of this study was to compare the Bone Injection Gun (BIG) and Jamshidi intraosseous (IO) access devices by paramedics with/without chemical-biological-radiological-nuclear personal protective equipment (CBRN-PPE). This study was designed as a randomized, crossover, manikin trial and is a continuation of the research undertaken in previous studies [2,4]. After written informed consent was obtained, 40 paramedics from the Emergency Medical Service teams volunteered to participate in this trial. The study was performed in March 2016. Before the beginning, all participants received a 10-minute standardized demonstration of the different IO access devices available to make sure that the participants were familiar with their proper use. Practicing with the devices before the attempts was not allowed; moreover, to minimize bias and to increase difficulty, no assistant was available for the participant. Each participant performed IO access using each device while wearing either CBRN-PPE (CBRN group) or standard uniform (no-CBRN group). We use standardized CBRN-PPE (Respirex Internal Systems, Surrey, UK, and 3M, Bracknell, UK) which is a fully encapsulated suit incorporating a panoramic visor to improve vision; however, it retains the thick "rubber" gloves that can adversely affect fine motor skills [5]. The study was based using a Stat Adult ALS Manikin with an IO Leg Trainer (Simulaids, Saugerties, NY). IO access in proximal tibia was performed using 2 devices: BIG (Waismed Ltd, Herzliya, Israel) and Jamshidi device (CareFusion, San Diego, CA; Fig. 1). The Research Randomizer program was used (www.randomizer.com) to divide the volunteers into 4 groups and to determine the order in which to apply the different IO access devices within each group (Fig. 2). The first group attempted IO access using the BIG device with CBRN, the second using BIG without CBRN, the third using Jamshidi with CBRN, and the fourth using Jamshidi without CBRN. After completing the IO procedure, participants had a 10-minute break before performing IO access using another method. *Time to IO placement* was defined as time measured from the moment an IO access device was picked up until the intravenous line tubing was connected to the inserted IO needle.

All statistical analyses were performed with the use of the Statistica 12 PL for Windows software (StatSoft, Inc, Tulsa, OK). Time to IO placement was compared using Wilcoxon test for paired observations. The results were considered statistically significant at the value of $P < .05$.

Time was significantly increased in the CBRN group compared with the no-CBRN group for IO access using Jamshidi (69.5 ± 34.2 s vs 35 ± 8 seconds, $P < .001$). However, this correlation was not observed when participants use BIG device (29.5 ± 13.2 vs 22 ± 7 s, respectively; $P = .063$). Both for the CBRN group and no-CBRN group, time for IO access using BIG was significantly shorter as compared with IO access using Jamshidi ($P < .001$).

In conclusion, in this manikin trial, IO access using BIG was significantly faster than that using Jamshidi devices either with or without CBRN equipment. Further clinical investigations are required to evaluate the benefit of primary BIG device in emergency cases such as cardiac arrest.

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☆ Source of support: No sources of financial and material support to be declared.

http://dx.doi.org/10.1016/j.ajem.2016.04.032

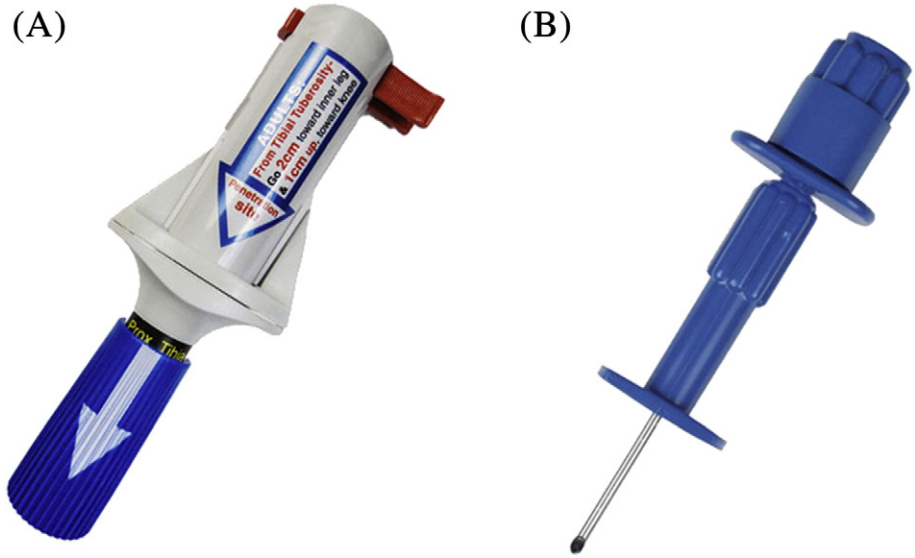

Fig. 1. Intraosseous access devices used in this study: (A) BIG and (B) Jamshidi device.

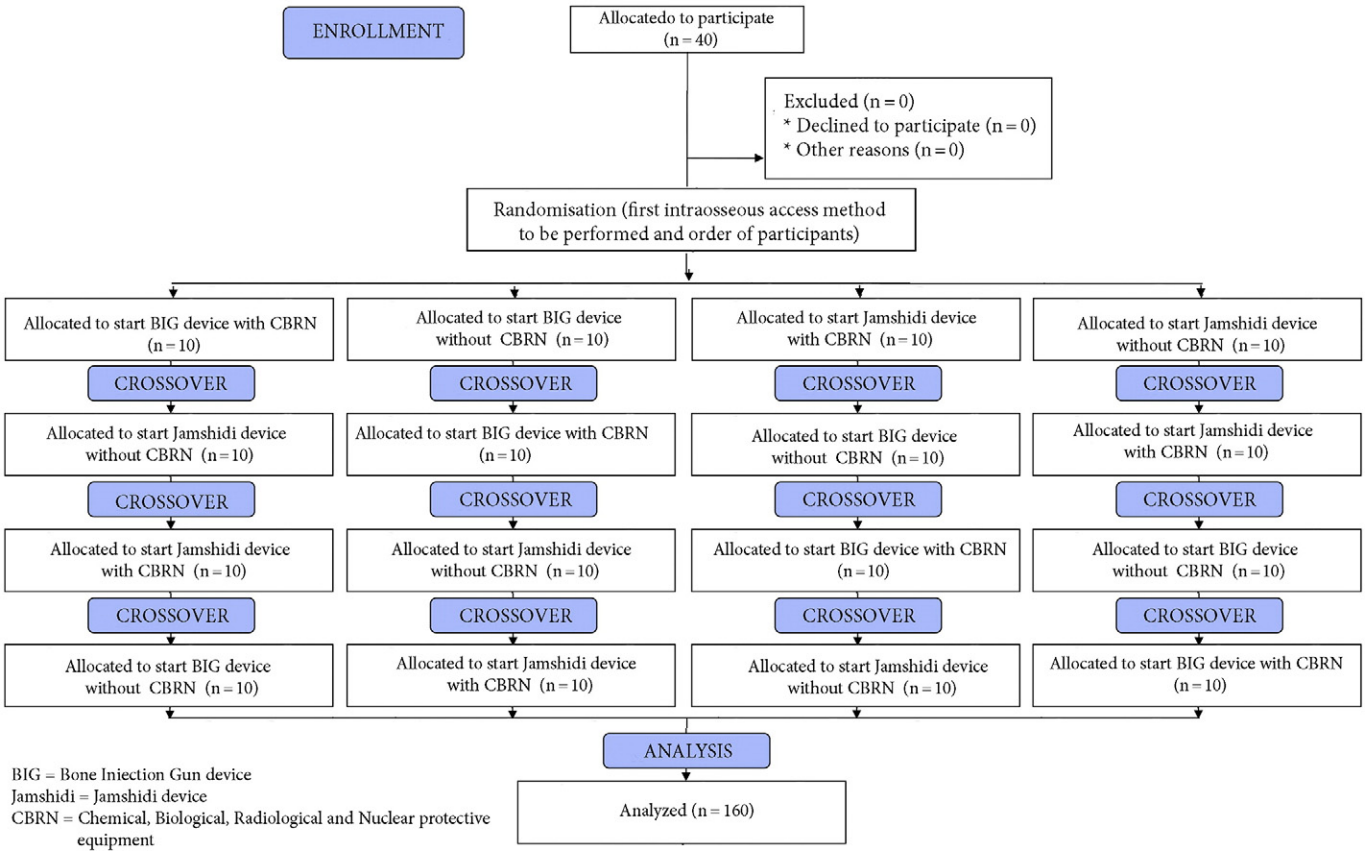

Fig. 2. Flowchart of design and recruitment of participants according to Consolidated Standards of Reporting Trials statement.

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ORIGINAL ARTICLE

Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19

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KEY WORDS
COVID-19, intravascular access, intraosseous, intravenous, meta-analysis

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by Paganini, Dalla Vecchia, and Franco, see p. 246

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Received: September 9, 2020.
Revision accepted: December 29, 2020.
Published online: January 7, 2021.
Kardiol Pol. 2021; 79 (3): 277-286
doi:10.33963/KP.15741

ABSTRACT

BACKGROUND Obtaining vascular access is one of the key procedures performed in patients in emergency settings.

AIMS The study was conducted as a meta-analysis and a systematic review and aimed to address the following question: which intravascular access method should be used in patients with COVID-19 when wearing full personal protective equipment (PPE)?

METHODS We performed a systematic search of PubMed, EMBASE, and CENTRAL databases for randomized controlled trials that compared intravascular access methods used by operators wearing full level C PPE. We evaluated procedure duration and the success rate of intraosseous and peripheral intravenous accesses.

RESULTS Eight randomized controlled trials were included in quantitative synthesis. The use of PPE during intravascular access procedures had an impact on procedure duration in the case of intraosseous access (mean difference [MD], 11.69; 95% CI, 6.47–16.92; *P* <0.001), as well as reduced the success rate of intraosseous access by 0.8% and intravenous access by 10.1%. Under PPE conditions, intraosseous access, compared with peripheral intravenous access, offered a shorter procedure time (MD, –41.43; 95% CI, –62.36 to –24.47; *P* <0.001).

CONCLUSION This comprehensive meta-analysis suggested that the use of PPE significantly extends the duration of intravascular procedures. However, under PPE conditions, operators were able to obtain intraosseous access in a shorter time and with a higher success rate than in the case of intravenous access.

INTRODUCTION Obtaining vascular access is one of the key components of critical care medicine including out-of-hospital emergency medicine and rescue operations. Vascular access enables the administration of drugs and infusions, including those used in sudden cardiac arrest, as well as catecholamines in various types of shock. The time to establish vascular access is crucial in emergency medicine, especially for critically ill patients. In numerous clinical situations, it is a major challenge for medical personnel, especially those with less experience.[1] Vascular access can be achieved either through peripheral or central venous access, or through intraosseous access. Intraosseous access was initially used mainly in pediatric patients, but it is now increasingly applied in adult patients as well.[2,3]

WHAT'S NEW?

This is the first meta-analysis to evaluate the effectiveness of intravascular access in personal protective equipment–restricted scenarios. The study was designed as a meta-analysis and a systematic review and aimed to determine which intravascular access method should be preferred when wearing full personal protective equipment to care for high-risk, infectious or contaminated patients, such as those with suspected or confirmed COVID-19.

SARS-CoV-2 is transmitted via the droplet route. Because of its relatively high infectivity and the need for long-term testing to confirm or rule out the infection, as well as the necessity of quarantining people who have had contact with an infected person, including medical personnel, the virus poses a serious risk to the functioning of healthcare systems.[4,5]

Although more than 80% of patients with COVID-19 have mild symptoms, some even being asymptomatic, about 5% to 15% of cases are severe. Some patients develop cytokine storm and consequently ARDS and multiorgan failure, which is the cause of death in a high percentage of critically ill patients with COVID-19.[6] The use of protective masks by medical personnel, including primarily masks with a suitable filter, and also of protective clothing and double gloves is essential.[7] According to the United States Centers for Disease Control and Prevention, medical personnel who interact with patients with known or suspected COVID-19 should adhere to standard precautions and use a respirator (or a facemask if a respirator is not available), a gown, gloves and eye protection. Some procedures, such as endotracheal intubation or bronchoscopy, could generate infectious aerosols. Consequently, medical personnel should wear an N95 or higher-level respirator such as disposable filtering facepiece respirators.

Numerous studies have compared the time of obtaining and the effectiveness of intravenous and intraosseous access.[8,9] The current SARS-CoV-2 pandemic forces medical personnel to use personal protective equipment (PPE) including double gloves, goggles, masks with appropriate filters, visors, and protective clothing. Such safety measures are particularly important in emergency medicine when the team is dispatched to a patient with suspected or confirmed COVID-19. Medical personnel may need to initiate emergency procedures, including vascular access. Personal protective equipment makes it difficult to carry out emergency procedures, among others, to obtain vascular access. It is reasonable to compare studies on the efficacy and timing of vascular access placement with different methods when using PPE, especially level C protection.[10]

This is the first meta-analysis to evaluate the effectiveness of intravascular access in PPE-restricted scenarios. The study was conducted as a meta-analysis and a systematic review. It aimed to answer the following question: which intravascular access method should be used when wearing full PPE to care for high-risk, infectious, or contaminated patients, such as those with suspected or confirmed COVID-19?

METHODS We conducted a systematic review of randomized controlled trials (RCTs) in accordance with the Cochrane Collaboration guidance. The presented review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[11] (Supplementary material). For this meta-analysis, neither ethics committee approval nor patient consent were required.

Eligibility criteria Studies were included if they met the following criteria: 1) RCT; 2) clinical, cadaver, or simulation trial; 3) provided data on intravascular access of in adult patient or a simulator; 4) compared intravascular access performed with and without level C PPE; and 5) reported procedure duration or success rates. Review articles and case studies were excluded. No language restrictions were placed on the search results.

Search strategy A comprehensive literature search was performed with PubMed, Scopus, EMBASE, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) databases, from the inception of each database up to April 10, 2020. The following terms were used: "intravascular" or "intravenous" or "intraosseous" or "iv" or "io" or "EZ-IO" or "B.I.G." or "NIO" or "FAST 1" or "Jamshidi" or "Cook" and "PPE" or "personal protective equipment" or "HazMat" or "Level C protective" or "CBRN" or "Chemical" or "toxic" or "infectious patient." The electronic database search was supplemented by searching Google Scholar and by back-searching the reference lists of the identified studies for suitable articles.

Study selection The references retrieved by electronic search were imported to and managed by the EndNote X7 software (Clarivate). Two independent investigators (JS and KL) screened both titles and abstracts to exclude inconsistent studies. Discrepancies were resolved by a third author (MJ). Relevant full-text articles were retrieved and analyzed for eligibility using the predefined inclusion criteria.

Data extraction Raw data were extracted using a standardized, premade form. Two authors (KL and JS) independently assessed each article to determine whether or not it met the criteria for inclusion. Disagreements between the authors regarding values or analysis assignments were resolved through discussion with a third researcher (LS), and the decision was taken by the majority of the researchers. The agreement with respect to study inclusion was assessed by using the Cohen

TABLE 1 Comparison of intraosseous access times with and without personal protective equipment

Variable		Trials, n	MD or RR (95% CI)	*P* value	I^2 statistics, %
Operator specialty	Physicians	1	10 (8.42–11.58)	<0.001	N/A
	Paramedics	3	11.46 (3.62–19.31)	0.004	94
	Mixed staff	4	15.44 (11.13–19.75)	<0.001	47
Intraosseous access device type	EZ-IO	6	11.32 (3.84–18.79)	0.003	97
	BIG	2	9.78 (8.27–11.29)	<0.001	0
	Jamshidi	1	34.5 (23.62–45.38)	<0.001	NA

Abbreviations: BIG, bone injection gun; MD, mean difference; NA, not applicable; RR, risk ratio

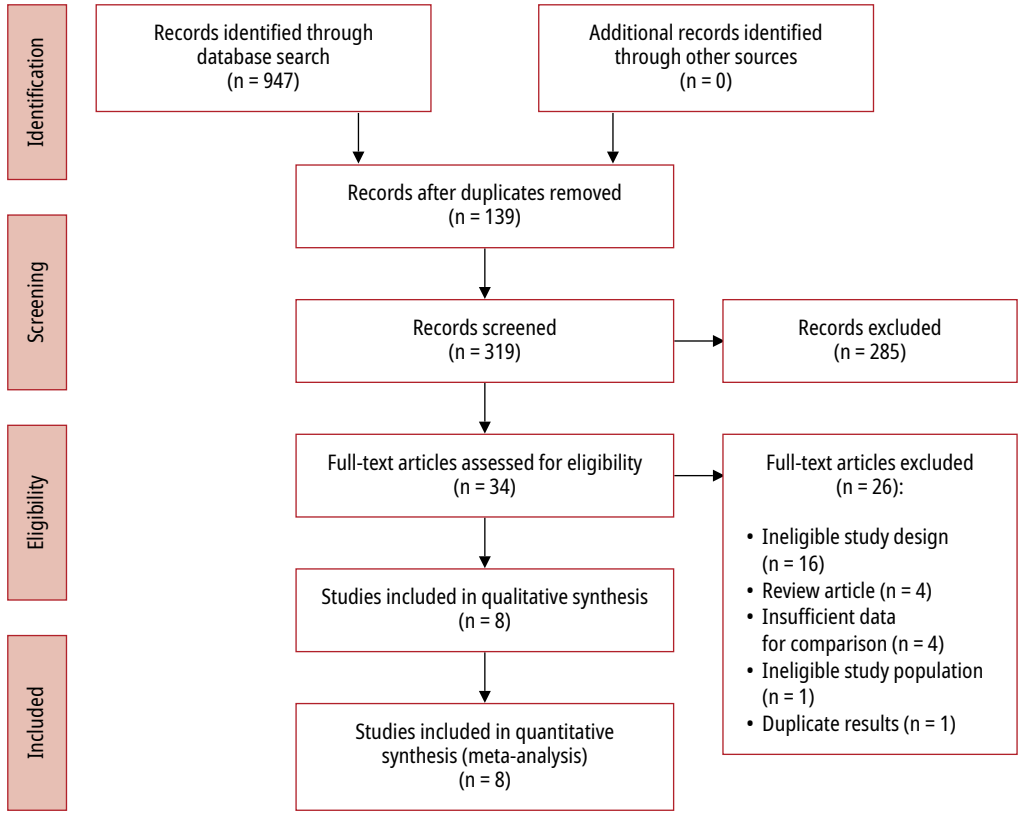

FIGURE 1 Flow diagram showing the stages of database search and study selection as per the PRISMA guidelines. Modified from Moher et al[11]

κ statistics.[12] We were careful to avoid inclusion of data from duplicate publications. In any case of suspected data discrepancies, we contacted the relevant author directly. Data extracted from eligible studies included the following characteristics: study and year, country, participants, number of participants, types of devices applied for intravascular access, procedure with or without PPE, procedure duration (measured in seconds), and success of intravascular access.

Statistical analysis Individual study data for intravascular access success rates and procedure duration were analyzed. We used Mantel-Haenszel models for all dichotomous outcomes and the inverse variance method for continuous outcomes. For continuous variables (procedure duration), mean differences (MD) were calculated. A random effect model was applied to analyze the data. Results are presented as risk ratios (RRs) with 95% CIs for dichotomous variables. The meta-analysis was carried out with the Review Manager (RevMan) software for Mac; version 5.3 (Cochrane Collaboration, Oxford, United Kingdom). When the continuous variable was reported in a study as median, range, and interquartile range, we estimated means and SDs using the formula described by Hozo et al.[13] We quantified heterogeneity in each analysis using the T^2 and I^2 statistics. Studies were subgrouped

TABLE 2 Characteristics of the included studies

Study	Patients, n	Study design	PPE level	Study object	Study device	Procedural conditions	Operators	Definition of injection time	Injection success rate
Ben--Abraham et al[19]	20	RCT	C	Turkey femurs	BIG	With and without PPE	Emergency care physicians previously inexperienced with BIG	From the moment the BIG was attached to the bone until the successful placement of the needle was achieved	A bare needle anchored in a firm upright position in the bone
Borron et al[14]	16	RCT	A, B, C, and D	Goats	EZ-IO	With and without PPE	12 ED physicians, physician assistants, and nurses	From the moment participants touched either the EZ-IO needle cover or the driver throughout needle placement and bone marrow aspiration (where possible) and until they completed the injection of a 5-ml bolus of isotonic sodium chloride solution	Noted by aspiration of bone marrow and / or facile injection of 5 ml of isotonic sodium chloride solution
Castle et al[8]	64	RCT	C	Manikin	IV and EZ-IO	With and without PPE	4 prehospital care doctors (ALS-trained general practitioners activated by the ambulance service), 6 resuscitation officers, 14 paramedics, 15 anesthetists, and 25 emergency physicians	From when the EZ-IO drill was picked up until the IO needle was placed into a training bone and a 3-way extension attached	Not specified
Collins[15]	8	RCT CP	C	Cadaver	EZ-IO	With and without PPE	Paramedics	Not specified	Not specified
Lamhaut et al[16]	25	RCT	C	Manikin	IV and EZ-IO	With and without PPE	9 nurses and 16 physicians	From the moment the device was attached to the bone until the successful placement of the needle was achieved	Successful fluid infusion
Suyama et al[17]	22	RCT	C	Manikin	IV and EZ-IO	With and without PPE	Paramedics	Not specified	Not specified
Szarpak et al[18]	40	RCT	C	Manikin	BIG and Jamshidi	With and without PPE	Paramedics	From the moment the device was touched to successful fluid infusion	Not specified
Szarpak et al[20]	35	RCT	C	Manikin	IV and NIO	With PPE	Paramedics with a minimum 2-year experience in emergency medical service	From touching the device to successful fluid infusion	Successful fluid infusion

Abbreviations: ALS, advanced life support; CP, conference paper; IV, intravenous access; PPE, personal protective equipment; RCT, randomized controlled trial; others, see TABLE 1

by the type of intravascular access devices. Heterogeneity was detected with the χ^2 test with n - 1 degrees of freedom, which was expressed as I^2. Values of I^2 greater than 50% and greater than 75% were considered to indicate moderate and significant heterogeneity among studies, respectively.[13] All *P* values were 2-tailed and considered significant if less than 0.05.

Quality assessment of the included studies The methodological quality of the included RCTs was assessed using the "risk of bias"

tool in accordance with the RevMan software. The following domains were evaluated for RCTs: random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias.[12] To assess the risk of bias, we only relied on the information presented in the publications. Two researchers (LS and JRL) estimated the risk of bias in each domain as "yes," "no," or "unclear," which reflected a high, low, and uncertain risk of bias, respectively (TABLE 1). The review authors' judgments about each risk of bias item are provided in Supplementary material, *Table S2*.

RESULTS **Study selection** The search strategy used in this study produced 947 potential titles and abstracts from database search (FIGURE 1). After removing duplicates (n = 319) and screening titles and abstracts, we were left with 34 articles. These were screened against the inclusion and exclusion criteria. A total of 26 articles were excluded, because they represented ineligible study design (n = 16), were review articles (n = 4), applied ineligible devices (n = 4), concerned pediatric population (n = 1), and presented duplicate results (n = 1). Ultimately, 8 studies that met the inclusion criteria and contained the necessary data for the planned comparison were identified.

Study characteristics The characteristics of the included studies are presented in TABLE 2. Intraosseous access was attempted with the EZ-IO device by 160 operators,[8,14-17] with a bone injection gun by 60 operators,[18,19] with the Jamshidi device by 40 operators,[18] and with the NIO device by 35 operators.[20] A single study was conducted on goats,[15] another one on turkey femurs,[14] and others on manikins.[8,16-18,20] Five articles were original full papers,[8,14,16,17,19] 2 were research letters,[18,20] and a single one was a conference paper.[15]

Influence of personal protective equipment on intravascular access Seven studies evaluated the duration of an intraosseous access procedure performed with and without PPE.[5,14-19] The time to complete the procedures was presented in seconds. Obtaining intraosseous access while wearing PPE in comparison with the same procedure without PPE was associated with longer procedure duration (MD, 11.69; 95% CI, 6.47–16.92; *P* <0.001) (FIGURE 2). The intraosseous access success rate with and without PPE was reported in 4 studies[14,16,19] and was 98.4% and 99.2%, respectively (RR, 1; 95% CI, 0.97–1.03; *P* = 0.93) (FIGURE 3).

An additional subanalysis by operator's specialty showed that physicians (MD, 10; 95% CI, 8.42–11.58; *P* <0.001), paramedics (MD, 11.46; 95% CI, 3.62–19.31; *P* = 0.004), as well as a mixed staff group (MD, 15.44; 95% CI, 11.13–19.75; *P* <0.001) performed intraosseous access procedures longer when using PPE (TABLE 1).

The subanalysis regarding the type of intraosseous device used also revealed shorter time to obtain intraosseous access with EZ-IO (RR, 11.32; 95% CI, 3.84–18.79; *P* = 0.003), bone injection gun (RR, 9.78; 95% CI, 8.27–11.29; *P* <0.001), and Jamshidi (RR, 34.5; 95% CI, 23.62–45.38; *P* <0.001) devices as compared with peripheral intravenous access.

Three studies evaluated the time of peripheral intravenous access obtained with and without PPE.[8,16,17] Intravascular access time with and without PPE was presented in FIGURE 4. The effectiveness of obtaining peripheral intravenous access with and without PPE was reported in 2 studies and equaled 89.9% versus 100% (RR, 0.93; 95% CI, 0.78–1.12; *P* = 0.44) (FIGURE 5).

Intraosseous and intravenous access procedure duration under personal protective equipment–restricted conditions Five studies presented a comparison of intraosseous and peripheral intravenous accesses performed by an operator wearing PPE.[8,16-18] The overall analysis showed shorter duration of an intraosseous access procedure compared with peripheral intravenous access (MD, –41.43; 95% CI, –62.36 to –24.47; *P* <0.001) (FIGURE 6A and 6B).

Subgroup analysis revealed a shorter time to obtain intraosseous access compared with peripheral intravenous access in research letters (MD, –26.3; 95% CI, –29.57 to –23.03; *P* <0.001). In original articles, the above finding was not observed (MD, –49.93; 95% CI, –99.86 to 0; *P* = 0.05). Subgroup analysis by operator's profession demonstrated shorter duration of the intraosseous versus peripheral intravenous procedure when performed by paramedics (MD, –21.79; 95% CI, –29.56 to –23.04; *P* <0.001), as well as by mixed staff (MD, –26.3; 95% CI, –29.56 to –23.04; *P* = 0.008) (TABLE 3).

Success rates of intraosseous and intravenous access under personal protective equipment–restricted conditions Three studies reported the success rate of intraosseous versus peripheral intravenous access under PPE-restricted conditions.[8,16,20] The efficacy of intraosseous access was 100% compared with 90.3% for peripheral intravenous access (RR, 1.08; 95% CI, 0.97–1.2; *P* = 0.18) (FIGURE 7A and 7B).

The effectiveness of intravascular access amounted to 100% for intraosseous compared with 89.9% for peripheral intravenous access in the subanalysis of original articles (RR, 1.08; 95% CI, 0.9–1.29; *P* = 0.44), and to 100% and 91.4%, respectively, in the subanalysis of research letters (RR, 1.09; 95% CI, 0.97–1.22; *P* = 0.13). The subanalysis showed that the effectiveness of intraosseous versus peripheral

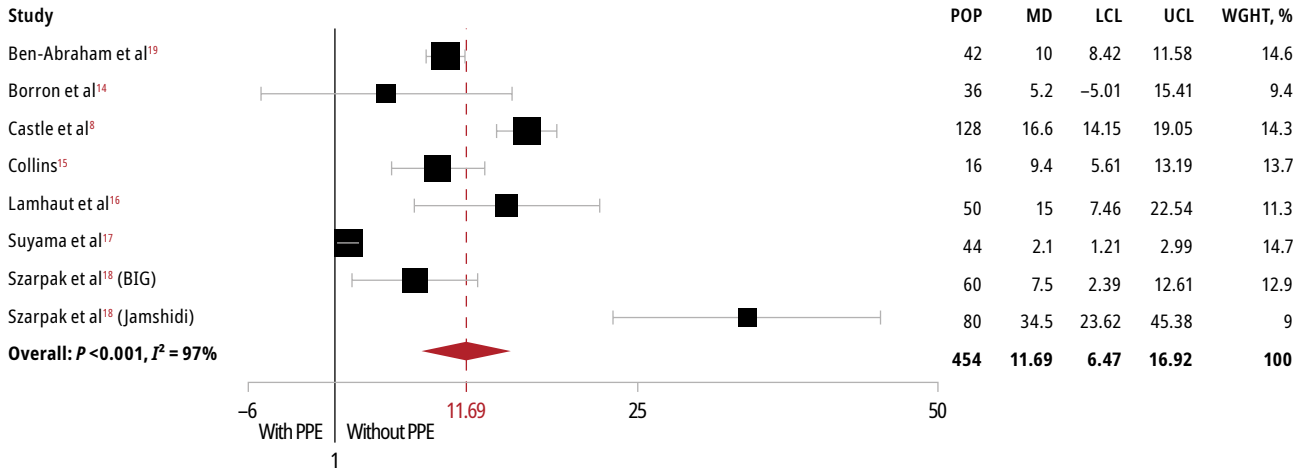

FIGURE 2 Forest plot of intraosseous access procedure duration while using level C personal protective equipment (PPE) versus standard clothing. The center of each square represents the weighted mean difference for individual trials, and the corresponding horizontal line stands for 95% CI. The diamond represents pooled results. Procedure time was presented in seconds.

Abbreviations: LCL, 95% lower confidence limit; POP, probability of precipitation; UCL, 95% upper confidence limit; WGHT, weight; others, see TABLE 1

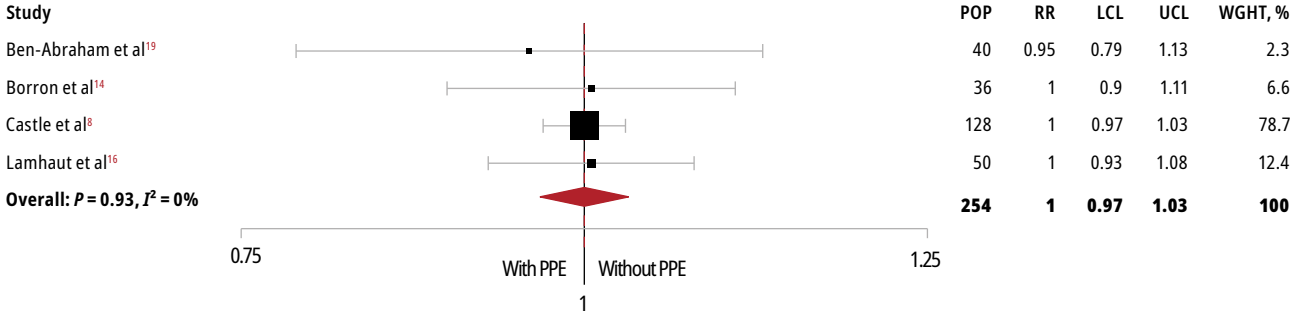

FIGURE 3 Forest plot of intraosseous access success rate while using level C personal protective equipment (PPE) versus standard clothing. The center of each square represents the weighted risk ratio for individual trials, and the corresponding horizontal line stands for 95% CI. The diamond represents pooled results.

Abbreviations: see TABLE 1 and FIGURE 2

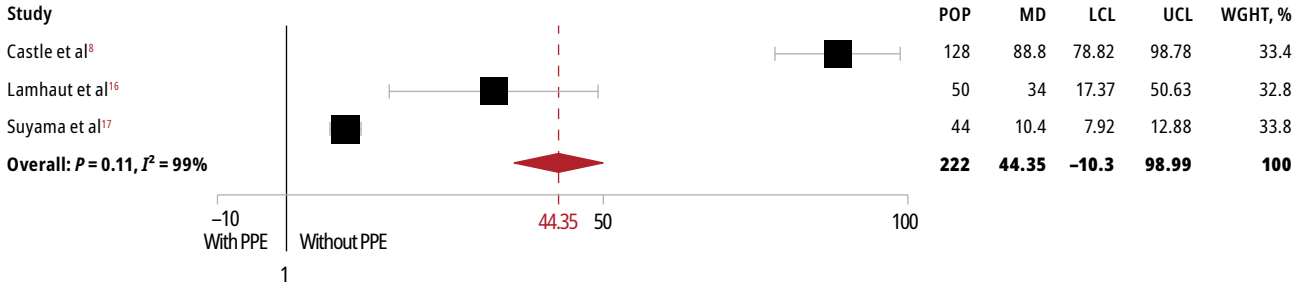

FIGURE 4 Forest plot of peripheral intravenous access procedure duration while using level C personal protective equipment (PPE) versus standard clothing. The center of each square represents the weighted mean difference for individual trials, and the corresponding horizontal line stands for 95% CI. The diamond represents pooled results. Procedure time was presented in seconds.

Abbreviations: see TABLE 1 and FIGURE 2

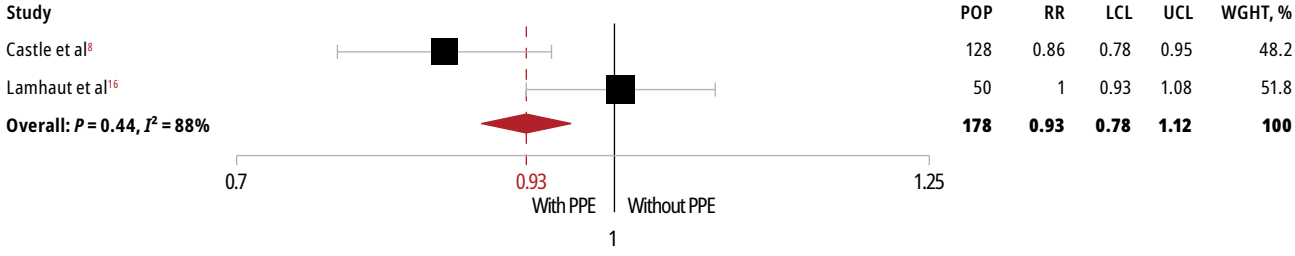

FIGURE 5 Forest plot of peripheral intravenous access success rates while using level C personal protective equipment (PPE) versus standard clothing. The center of each square represents the weighted risk ratio for individual trials, and the corresponding horizontal line stands for 95% CI. The diamond represents pooled results.

Abbreviations: see TABLE 1 and FIGURE 2

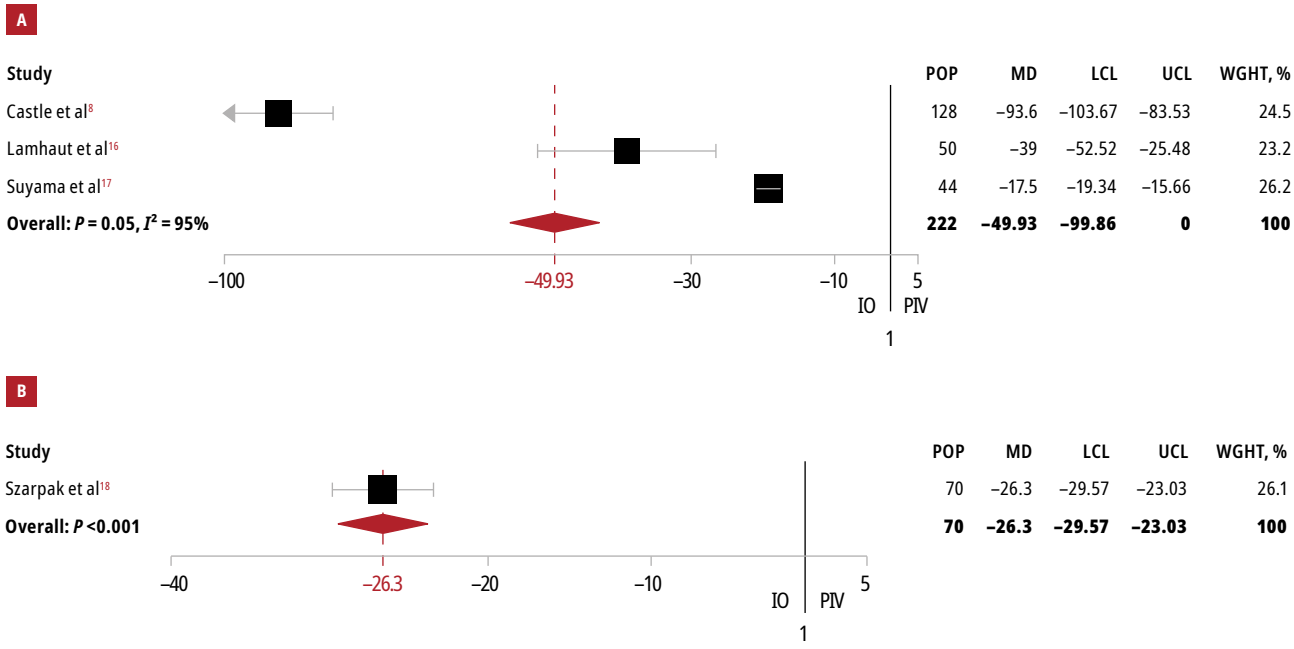

FIGURE 6 Forest plot of intraosseous versus peripheral intravenous access procedure duration while using level C personal protective equipment in original articles (**A**) and research letters (**B**). The center of each square represents the weighted mean difference for individual trials, and the corresponding horizontal line stands for 95% confidence interval. The diamonds represent pooled results.
Abbreviations: see TABLE 1 and FIGURE 2

TABLE 3 Comparison of intraosseous and peripheral intravenous access times under personal protective equipment–restricted conditions

Variable		Trials, n	IO efficacy, %	PIV efficacy, %	RR or MD (95% CI)	*P* value	I^2 statistics, %
Procedure duration	Paramedics	2	NA	NA	−21.79 (−29.56 to −23.04)	<0.001	95
	Mixed staff	3	NA	NA	−26.3 (−29.56 to −23.04)	0.008	97
Success rate	Paramedics	1	100	91.4	1.09 (0.97–1.22)	0.13	NA
	Mixed staff	3	100	89.9	1.09 (0.9–1.29)	0.44	88

Abbreviations: IO, intraosseous access; PIV, peripheral intravenous access; others, see TABLE 1

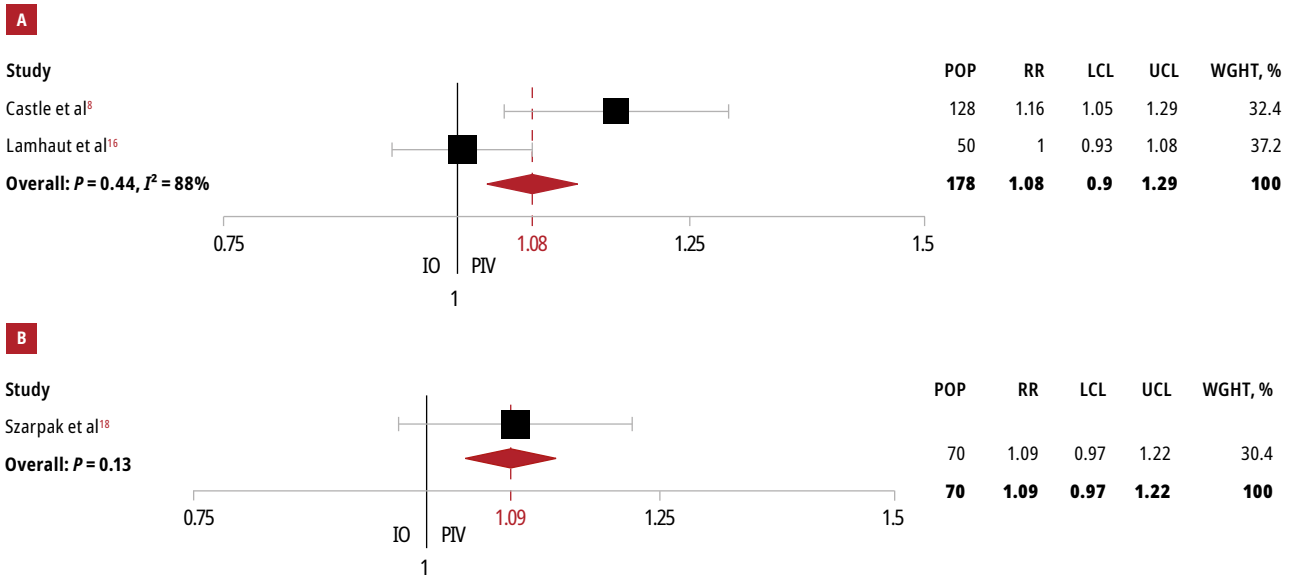

FIGURE 7 Forest plot of intraosseous versus peripheral intravenous access success rates while using level C personal protective equipment in original articles (**A**) and research letters (**B**). The center of each square represents the weighted risk ratio for individual trials, and the corresponding horizontal line stands for 95% CI. The diamonds represent pooled results.
Abbreviations: see FIGURE 2 and TABLE 3

intravenous access varied and amounted to 100% and 91.4%, respectively, in the paramedics group (RR, 1.09; 95% CI, 0.97–1.22; P = 0.13) and to 100% and 89.9%, respectively, among mixed staff (RR, 1.09; 95% CI, 0.9–1.29; P = 0.44) (TABLE 3).

Risk of bias in the included trials The risk of bias in the included studies is outlined in TABLES 1 and 2. All the 8 studies clearly described random sequence generation.[8,14-20] The risk of bias in the RCTs was assessed as either low or moderate across all domains, apart from the blinding of participants and personnel, where blinding was clearly not possible.

DISCUSSION

Quick intravascular access is the key to the successful management of patients with shock, trauma, or cardiac arrest. The major finding of this meta-analysis is that when an operator is wearing level C PPE, intraosseous access offers advantages over peripheral intravenous access in terms of procedure duration and success rates. Moreover, the use of PPE increases the duration and significantly reduces the effectiveness of peripheral intravenous access. In the case of intraosseous access, the use of PPE increases the duration of the procedure, however, the effectiveness decreases by only 0.8% compared with the procedure performed without a protective suit.

The conducted meta-analysis showed a significantly shorter time of obtaining intraosseous access in comparison with peripheral intravenous access, as well as an advantage regarding the effectiveness of intraosseous over peripheral intravenous access. The American Heart Association indicates in its guidelines for advanced resuscitation that it is reasonable to establish intraosseous access if intravenous access is not readily available.[21] However, extraordinary situations (including caring for patients with suspected or confirmed COVID-19, when medics are wearing level C PPE) require extraordinary measures. Consequently, a different vascular access technique may be advised to increase patient safety, at least as a bridging procedure during ongoing resuscitation efforts, until the patient is in a more stable condition. It would therefore be appropriate to prioritize obtaining intraosseous access when using PPE suits.

The use of full level C PPE undoubtedly affects the quality of the performed procedures by making movement difficult. Additionally, applying double gloves during procedures is more protective than using a single pair as far as percutaneous needle injuries during intravenous cannulation are considered,[22,23] especially in the case of highly infectious patients. At the same time, this practice impairs comfort, sensitivity, and dexterity[24] reducing the effectiveness and increasing the duration of numerous medical procedures.[8] However, owing to the increased protective effect against needle-stick injuries, double gloves should be used routinely in contact with infected patients.

As indicated by Iskrzycki et al,[25] the risk of potential complications is one of the main concerns about the use of intraosseous access among physicians. Complications of intraosseous access were reported as rare and mostly minor.[26,27] Their majority occurs when aseptic and antiseptic rules are not followed, as well as when intraosseous access is kept too long.[28] The most significant issue for conscious patients with an intraosseous device in situ was their experience of pain. Ong et al[29] recommended the administration of 20 to 50 mg of 2% lidocaine to all conscious patients, although the effectiveness of this strategy has not been evaluated.

Another factor in favor of the routine use of intraosseous access in suspected or confirmed COVID-19 patients with cardiovascular and/or respiratory failure is that most drugs can be administered via intraosseous access in equivalent dosage and with the same time effect compared with peripheral intravenous access. The pharmacodynamics and pharmacokinetic effects of intraosseously applied drugs and infusions are well described in the literature.[30-32]

Alternative vascular access techniques in adult patients undergoing resuscitation with impossible peripheral intravenous catheterization include central venous catheterization or ultrasound-guided catheterization of peripheral veins. The presented analysis did not include studies on the comparison of intraosseous versus central venous catheterization, as the latter should not be used as the primary method of obtaining vascular access under emergency medicine conditions, especially in patients with cardiovascular and/or respiratory failure. As shown by Leidel et al,[33] in the emergency department, in adults undergoing cardiopulmonary resuscitation with inaccessible peripheral veins, the efficacy of the first attempt to obtain vascular access with the intraosseous method equaled 85% and was higher than the 60% for central venous catheterization (P = 0.024). In addition, the procedure for obtaining central access should be carried out under ultrasound guidance[34,35] and is relatively time-consuming and associated with relevant risks for the patient, especially in the emergency setting. Furthermore, central venous catheterization or ultrasound-guided catheterization of peripheral veins require the ultrasound device and an experienced operator and are more time-consuming compared with obtaining intraosseous or peripheral intravenous access.[36]

Current Infection and Control recommendations for Healthcare Personnel endorsed by Centers for Disease Control and Prevention suggest that all healthcare personnel working in healthcare facilities should wear a facemask at all times.

If working in facilities located n the region of moderate-to-substantial community transmission, healthcare personnel should additionally wear eye protection. If performing any aerosol-generating or surgical procedures, an N95 or higher-level respirator, gloves, and a gown should be used.

Limitations As a limitation, all of the included studies in our meta-analysis were small in size and were at high risk of bias, because neither the operator nor the outcome assessor were blinded for obvious technical reasons. We found a significant heterogeneity regarding procedure duration, as well as procedure success rates, most likely secondary to the varied experience levels of study participants. As the number of studies was small, it was not possible to conduct a meta-regression analysis to identify potential causes of heterogeneity. Another limitation is that all research was experimental and was not carried out on humans, but it is difficult and sometimes even impossible to do such research in a group of highly infectious patients, as it would potentially delay the therapeutic procedure. We focused on level C PPE in this meta-analysis, because this might be most commonly used in emergency medicine, but the level of PPE used in the included studies might vary. While the level of PPE is standardized in the United States, it might differ among various hospitals and healthcare settings around the globe.

Conclusions This comprehensive meta-analysis suggests that the use of PPE significantly extends the duration of intravascular access procedures. Moreover, it was observed that, under PPE-restricted conditions, operators were able to obtain intraosseous access in a shorter time and with a higher success rate compared with peripheral intravenous access. As the overall quality of evidence is universally low and limited to experimental, mostly simulation, trials, an RCT of human patients is warranted.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

ACKNOWLEDGMENTS This study was supported by the ERC Research NET and the Polish Society of Disaster Medicine.

CONTRIBUTION STATEMENT All authors confirm that they had full access to data, contributed to drafting the paper, analyzed the data, edited the paper, and approved the final version of the manuscript. AD and ŁS designed and coordinated the study.

CONFLICT OF INTEREST None declared.

HOW TO CITE Drozd A, Smereka J, Filipiak KJ, et al. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021; 79: 277-286. doi:10.33963/KP.15741

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Supplementary material

Drozd A, Smereka J, Filipiak KJ, et al. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021; 79: 277-286. doi:10.33963/KP.15741

Supplementary Table S1. Comparison of intraosseous access times with and without personal protective equipment

	Number of trials	**MD or RR (95%CI)**	***P* value**	**I^2 statistic, %**
Operator type				
Physicians	1	10(8.42, 11.58)	<0.001	N/A
Paramedics	3	11.46(3.62, 19.31)	0.004	94%
Mixed staff	4	15.44(11.13, 19.75)	<0.001	47%
Intraosseous device type				
EZ-IO	6	11.32(3.84, 18.79)	0.003	97%
BIG	2	9.78(8.27, 11.29)	<0.001	0%
Jamshidi	1	34.50(23.62, 45.38)	<0.001	N/A

Abbreviations: N/A, Not applicable; IO, intraosseous access; BIG, Bone Injection Gun.

Supplementary Table S2. Comparison of intraosseous access times with peripheral intravenous access times under personal protective equipment.

	Number of trials	Efficacy IO	Efficacy PIV	RR or MD (95%CI)	*P* value	I^2 statistic, %
Procedure time						
Paramedics	2	N/A	NA	-21.79(-29.56, -23.04)	<0.001	95%
Mixed staff	3	N/A	NA	-26.30(-29.56, -23.04)	0.008	97%
Success rate						
Paramedics	1	100%	91.4%	1.09(0.97, 1.22)	0.13	N/A
Mixed staff	3	100%	89.9%	1.09 (0.90, 1.29)	0.44	88%

Abbreviations: N/A, Not applicable; IO, intraosseous access; PIV, Peripheral intravenous access.

4. PODSUMOWANIE I WNIOSKI

Monotematyczny zbiór prac dotyczących zastosowania dostępów doszpikowych w warunkach medycyny ratunkowej składa się z pięciu publikacji [84-88]. Jedno badanie było pracą poglądową [84], trzy badania zostały przeprowadzone w warunkach symulacji medycznej [86-88], zaś jedna była przeglądem systematycznym i meta-analizą [85].

Pierwsze badanie było pracą poglądową, która stanowiła swoiste wprowadzenie do cyklu prac dotyczących stosowania wkłuć doszpikowych [84]. Niniejsza praca miała na celu przybliżenie czytelnikowi wskazań, przeciwskazań oraz potencjalnych powikłań wkłuć doszpikowych.

Celem drugiej pracy była analiza efektywności stosowania wkłuć doszpikowych (NIO-P, EZ-IO, oraz igły Jamshidi) w odniesieniu do symulowanego pacjenta pediatrycznego z podejrzeniem COVID-19 [86]. Jako metodę referencyjną uzyskania dostępu donaczyniowego wykorzystano dostęp dożylny. Badanie zostało zaprojektowane i przeprowadzone jako prospektywne, obserwacyjne, randomizowane, krzyżowe badanie symulacyjne. Do badania włączono 65 pielęgniarek, które wykonywały dostęp doszpikowy w odniesieniu do symulowanego pacjenta pediatrycznego chorego na COVID-19. W związku z powyższym wszelkie procedury były wykonywane przez uczestników badania ubranych w pełne kombinezony ochronne. Jako metodę kontrolną wykorzystano dostęp dożylny. Analizie poddano takie parametry jak: skuteczność uzyskania dostępu doszpikowy, czas trwania procedury oraz łatwość jej wykonania. Dodatkowo oceniano subiektywne preferencje pielęgniarek dotyczące optymalnej metody uzyskiwania dostępu donaczyniowego u pacjenta pediatrycznego z COVID-19.

Celem trzeciej pracy było porównanie dwóch wkłuć doszpiowych (NIO oraz B.I.G.) podczas symulowanej resuscytacji krążeniowej [87]. Badanie – podobnie jak badanie powyżej – zostało zaprojektowane jako prospektywne, randomizowane, obserwacyjne krzyżowe badanie symulacyjne. Uzyskiwanie dostępów doszpikowych miało miejsce podczas symulowanej resuscytacji krążeniowo – oddechowej osoby dorosłej. 40 ratowników medycznych wykonywało uzyskiwanie dostępów doszpikowych stosując odpowiednio wkłucie B.I.G. oraz NIO. Zarówno kolejność uczestników jak i metod uzyskania dostępu doszpikowego były losowe. Ocenie poddano parametry czasowe związane z wprowadzeniem igły do jamy doszpikowej, następnie jej stabilizację oraz czas

do podłączenia linii infuzyjnej. Dodatkowo oceniano wiedzę z zakresu potencjalnych powikłań wkłuć doszpikowych jak również skuteczność uzyskania dostępu doszpikowego.

Celem czwartej pracy była analiza efektywności uzyskiwania dostępów doszpikowych (B.I.G. oraz igły Jamshidi) przez ratowników medycznych [88]. Badanie czwarte również było zaprojektowane jako badanie randomizowane krzyżowe zaś uczestnicy badania wykonywali procedurę wkłucia doszpikowego z i bez kombinezonu CBRN. Badanie było wykonywane w warunkach symulacyjnych. Ocenie poddano wpływ stosowania kombinezonów ochronnych na czas wykonania procedury poszczególnymi metodami. Zarówno kolejność uczestników jak i metod badawczych były losowe.

Celem piątej pracy było porównanie efektywności stosowania wkłuć doszpikowych oraz dożylnych w przypadku pacjentów z podejrzeniem bądź potwierdzeniem choroby zakaźnej [85]. Badanie zostało zaprojektowane jako przegląd systematyczny i meta-analiza, oraz zostało przeprowadzone zgodnie z wytycznymi PRISMA. Badanie miało na porównanie efektywności i bezpieczeństwa stosowania wkłuć doszpikowych oraz dożylnych przez personel medyczny ubrany w kombinezony ochronne. Podczas przeglądu systematycznego dokonano przeszukania elektronicznych baz danych w tym PubMed, Scopus, EMBASE, Web of Science oraz bazy CENTRAL. W celu przeszukiwania w/w baz danych posłużono się predefiniowanymi słowami kluczowym. Ostatnie przeszukanie baz danych miało miejsce 10 kwietnia 2020 roku. Przeszukanie baz danych na podstawie słów kluczowych wykazało 947 rekordów bibliograficznych, z których po usunięciu powtarzających się artykułów, wstępnej analizie prac na podstawie tytułów i streszczeń a następnie analizie pełnych tekstów artykułów zakwalifikowano do meta-analizy 8 badań [88-95].

Uzyskanie dostępu donaczyniowego stanowi kluczową procedurę wykonywaną zarówno w warunkach przedszpitalnych jak i szpitalnych. U pacjentów z zatrzymaniem krążenia jest to metoda z wyboru podaży leków resuscytacyjnych, podobnie jak w przypadku pacjentów we wstrząsie – metoda do uzupełniania płynów podczas resuscytacji płynowej [96,97]. W przypadku pacjentów, u których obserwowane jest zapadnięcie łożyska naczyniowego uzyskanie dostępu dożylnego jest niejednokrotnie wydłużone w czasie z uwagi na liczne próby wykonania procedury – bądź czasami całkowicie niemożliwe do wykonania [98]. W takich przypadkach pomocne mogą być

wkłucia doszpikowe, które niejednokrotnie zapewniają najszybszy sposób uzyskania dostępu do układu krążenia, szybkiego podawania leków i płynów w stanach nagłych [99].

Już w 2000 roku wytyczne Emergency Cardiovascular Care zalecały wykorzystanie dostępu doszpikowego u wszystkich pacjentów pediatrycznych we wstrząsie, gdy pierwsze dwie próby uzyskania dostępu dożylnego były nieskuteczne [100]. W 2010 roku wytyczne Amerykańskiego Towarzystwa Kardiologicznego wskazywało dostępy doszpikowe jako metodę uzyskiwania dostępu donaczyniowego w przypadku, gdy nie można uzyskać dostępu dożylnego [5]. Obecnie dostęp doszpikowy jest rekomendowaną techniką uzyskania dostępu do układu naczyniowego podczas zatrzymania krążenia zarówno u pacjentów pediatrycznych jak i osób dorosłych [101,102]. Z kolei w przypadku zdekompensowanego wstrząsu wkłucie doszpikowe powinno być wykorzystane, gdy próba dostępu dożylnego zakończy się niepowodzeniem. Wyjątkiem w tym aspekcie są noworodki, gdzie metodą z wyboru w celu podaży leków i płynów jest kaniulacja żyły pępowinowej [103], jednakże jak wskazuje Scrivens i wsp. Jeżeli dostęp doszpikowy będzie szybszą metodą uzyskania dostępu donaczyniowego powinien być również stosowany w aspekcie noworodków [104].

Jak wskazują Sørgjerd i wsp. wkłucia doszpikowe znajdują również zastosowanie w warunkach transportu pacjentów za pomocą śmigłowców ratunkowych [105]. Sørgjerd i wsp. porównując dwa rodzaje wkłuć: wkłucie EZ-IO oraz wkłucie FAST-Responder wykazali, iż EZ-IO w porównaniu z FAST-Responder była szybszą metoda uzyskania dostępu doszpikowego, jednakże w przypadku FAST-Responder możliwe było zastosowanie wyższych przepływywów płynów infuzyjnych. Z kolei Helm i wsp. analizując zastosowanie EZ-IO w niemieckim lotniczym pogotowiu ratunkowym wykazali całkowitą skuteczność tego typu urządzenia na poziomie 99,6% przy jednoczesnej skuteczności pierwszej próby uzyskania dostępu doszpikowego na poziomie 85,9% [25]. Jednocześnie Helm i wsp. wskazują, iż najczęściej preferowaną lokalizacją dostępu doszpikowego była proksymalna część kości piszczelowej (87,2%), następnie część dystalna kości piszczelowej (7,5%) oraz kość ramienna (5,3%). Ponadto Helm i wsp. wykazali, iż dostęp doszpikowy stanowił postępowanie z wyboru u 64% pacjentów pediatrycznych. Skuteczność EZ-IO w warunkach zespołów naziemnych ratownictwa medycznego wskazywana przez Santosa i wsp. wynosiła 90% [36].

Jak już wspomniano powyżej uzyskiwanie dostępu dożylnego w niektórych sytuacjach może być utrudnione [106]. Wpływ na zmniejszenie efektywności procedury uzyskiwania dostępu donaczyniowego może mieć również wykonywanie niniejszej procedury w kombinezonach ochronnych, które są stosowane w przypadku wykonywania interwencji wobec pacjentów z podejrzeniem bądź potwierdzeniem COVID-19 [107,108]. Wykonywanie procedur medycznych w pełnych ubraniach ochronnych jak wskazują doniesienia literaturowe wpływają na zmniejszenie efektywności wykonywanych procedur medycznych prezentujące się w postaci wydłużenia czasu trwania poszczególnych procedur czy też zmniejszeniem stateczności ich wykonywania. Powyższa zależność obserwowana jest zarówno w aspekcie jakości kompresji klatki piersiowej [109-111], zabezpieczania drożności dróg oddechowych [112,113] jak również wobec omawianego zakresu procedur – czyli uzyskiwania dostępów donaczyniowych [114,115]. W badaniu Lamhaut i wsp. zastosowanie kombinezonu CBRN wpłynęło na wydłużenie czasu trwania procedury uzyskania dostępu dożylnego z 70±30s do 104±30s [108].

Jak wskazuje Lamhaut i wsp. [108] zastosowanie wkłucia doszpikowego w porównaniu z dostępem dożylnym wiązało się z krótszym czasem trwania procedury (odpowiednio 50±9s oraz 70±30s). Podobna zależność była również obserwowana podczas wykonywania procedury w kombinezonach CBRN (odpowiednio 65±17s oraz 104±30s). W badaniu porównującym efektywność uzyskania dostępu doszpikowego z wykorzystaniem urządzenia B.I.G. oraz igły Jamshidi wykazano istotną równicę w czasie trwania procedury (odpowiednio 22±7s oraz 35±8s). Z kolei w przypadku wykonywania dostępu doszpikowego w scenariuszu, gdy uczestnicy badania byli ubrani w kombinezony ochronne CBRN (29,5±13,2 s oraz 69,5±34,2s). Dodatkowa analiza wykazała, iż wykonywanie procedury uzyskania dostępu doszpikowego w pełnym kombinezonie ochronnym wiązało się z istotnym wydłużeniem czasu trwania procedury w przypadku igły Jamshidi ($p<0,001$), jednakże nie było obserwowane w przypadku zastosowania wkłucia doszpikowego B.I.G. ($p=0,063$).

Uzyskiwanie dostępu donaczyniowego w kombinezonach CBRN może być problematyczne również w odniesieniu do pacjentów pediatrycznych. Jak wykazano w przeprowadzonym autorskim badaniu, skuteczność uzyskiwania dostępu dożylnego za pomocą standardowej kaniuli dożylnej wynosiła zaledwie 69,2%, zaś w przypadku wkłuć doszpikowych wynosiła od 80% do 100% w zależności od typu wkłucia doszpikowego [86].

Podobna zależność była obserwowana również przez El-Nawawy i wsp. w przypadku pacjentów pediatrycznych prezentujących objawy wstrząsu septycznego [116]. El-Nawawy wykazali wówczas, iż w przypadkach nagłych podobnie jak ma to miejsce w przypadku wstrząsu, w celu uzyskania szybkiego dostępu donaczyniowego zalecaną metodą jest dostęp doszpikowy. Obniżenie efektywności procedur medycznych wykonywanych w kombinezonach ochronnych wynika z faktu, iż personel medyczny ma założone podwójne rękawiczki, które ograniczają czucie i zdolności manipulacyjne [117], jak również problemy z widocznością w przypadku nadmiernego zaparowywania okularów ochronnych i przyłbic. Dodatkowo w przypadku długiego czasu stosowania kombinezonu ochronnego dochodzi do przegrzania organizmu – zwłaszcza podczas aktywnego prowadzenia akcji reanimacyjnej [118].

Przeprowadzone badania pozwalają na sformułowanie następujących wniosków:

- W warunkach wykonywania dostępu donaczyniowego przez personel medyczny ubrany w pełne kombinezony ochronne dostęp doszpikowy w porównaniu z dostępem dożylnym wiąże się z krótszym czasem trwania procedury jak również zwiększeniem skuteczności procedury.
- Istnieją istotne statystycznie różnice pomiędzy wkłuciami doszpikowymi półautomatycznymi i EZIO a igłą Jamshidi.
- Zastosowanie pełnych kombinezonów ochronnych wpływa na wydłużenie czasu trwania procedury uzyskania dostępu donaczyniowego jak również zmniejszenia pierwszej próby jej wykonania.

5. OŚWIADCZENIA AUTORÓW PUBLIKACJI

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OŚWIADCZENIE

Jako współautor pracy:

Drozd A, Wolska M, Szarpak L. Interosseous vascular access in emergency and trauma settings: a comparison of the most universally used intraosseous devices. Expert Rev Med Devices. 2021 Sep; 18(9):855-864. doi: 10.1080/17434440.2021.1962287.

oświadczam, iż mój własny wkład merytoryczny w przygotowaniu, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji stanowi współudział w: analizie piśmiennictwa oraz opracowaniu pierwotnej oraz końcowej wersji manuskryptu. Mój udział procentowy w przygotowaniu publikacji określam jako 20%.

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Jako współautor pracy:

Drozd A, Smereka J, Filipiak KJ, Jaguszewski M, Ładny JR, Bielski K, Nadolny K, Ruetzler K, Szarpak Ł. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021; 79(3):277-286. doi: 10.33963/KP.15741

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Drozd A, Smereka J, Filipiak KJ, Jaguszewski M, Ładny JR, Bielski K, Nadolny K, Ruetzler K, Szarpak Ł. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021; 79(3):277-286. doi: 10.33963/KP.15741

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OŚWIADCZENIE

Jako współautor pracy:

Drozd A, Smereka J, Filipiak KJ, Jaguszewski M, Ładny JR, Bielski K, Nadolny K, Ruetzler K, Szarpak Ł. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021; 79(3):277-286. doi: 10.33963/KP.15741

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Drozd A, Smereka J, Filipiak KJ, Jaguszewski M, Ładny JR, Bielski K, Nadolny K, Ruetzler K, Szarpak Ł. Intraosseous versus intravenous access while wearing personal protective equipment: a meta-analysis in the era of COVID-19. Kardiol Pol. 2021; 79(3):277-286. doi: 10.33963/KP.15741

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7. SPIS TABEL

Tabela 1. Zalecane lokalizacje uzyskania dostępu doszpikowego zgodnie ze wskazaniami producentów. 36

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