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EZ-IO® intraosseous device implementation in a pre-hospital emergency service: a prospective study and review of the literature

THESE

Préparée sous la direction du Docteur Pierre-Nicolas Carron
(avec la co-direction du Professeur Bertrand Yersin)
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par

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Rapport de synthèse

Introduction : La prise en charge des patients critiques nécessite dans la majorité des situations l'obtention rapide d'un accès vasculaire, afin d'administrer des médicaments, des solutés de remplissage, ou des produits sanguins. La mise en place d'un accès vasculaire peut s'avérer difficile chez ces patients. En cas d'échec de pose d'une voie veineuse périphérique, des abords vasculaires alternatifs existent. Il s'agit essentiellement de la pose d'une voie veineuse centrale, la réalisation d'une dénudation veineuse, ou la pose d'une voie intra-osseuse. Depuis le développement de dispositifs d'insertion « semi-automatique » à la fin des années 90, la voie intra-osseuse, traditionnellement réservée aux cas pédiatriques, est de plus en plus fréquemment utilisée chez les patients adultes. Le Service des Urgences du CHUV a introduit en 2009 les dispositifs d'insertion d'aiguilles intra-osseuses de type EZ-IO® (perceuse électrique), en salle de réanimation des urgences vitales (déchoquage), ainsi qu'au sein du secteur préhospitalier pour les interventions du SMUR de Lausanne et de l'hélicoptère REGA de la base de Lausanne. Par cette étude, nous voulions mettre en évidence les aspects épidémiologiques des patients ayant dû être perfusés par cet abord dans un contexte préhospitalier, ainsi que les circonstances cliniques ayant justifié un tel usage, le taux de succès, les éventuelles complications, les médicaments perfusés et la mortalité des patients ayant bénéficié de ce dispositif.

Méthode: Chaque patient ayant bénéficié de la mise en place d'une voie intra-osseuse par EZ-IO® du 1er janvier 2009 au 31 décembre 2011 a été inclus. Les données récoltées étaient l'âge, le sexe, l'indication à la mise en place de l'intra-osseuse, la localisation, le taux de succès, les médicaments et fluides administrés, les complications, la mortalité à 48 heures et à la sortie de l'hôpital.
Tous les articles mentionnant l'utilisation de l'EZ-IO® dans des situations cliniques ont également été analysés par une revue de littérature structurée exhaustive, afin de comparer nos résultats avec les données de la littérature.

Résultats : Cinquante-huit patients, représentant 60 intra-osseuses EZ-IO®, ont été inclus. Leur âge moyen (47 ans), le taux de succès (90%), les indications, la localisation de l'aiguille (98% au niveau du tibia proximal) et le taux de complications (0%) correspondent aux valeurs trouvées dans la littérature. Le taux de survie de nos patients est de 38% à 48 heures et de 29% à la sortie de l'hôpital. De nombreux médicaments ou solutés de perfusion ont été administrés; l'adrénaline restant le médicament le plus fréquemment administré par cette voie. Dans 7 cas, les patients ont bénéficié d'une induction d'anesthésie par voie intra-osseuse. La revue de littérature a permis de compiler 30 études distinctes, représentant un total de 1603 accès vasculaires de type EZ-IO®.

Conclusion : La voie intra-osseuse s'avère fiable et rapide pour obtenir un accès vasculaire, avec un taux de complications très faible et permet l'administration d'un grand nombre de substances. D'autres études sont nécessaires pour évaluer l'impact de la voie intra osseuse, notamment en termes de mortalité, de complications tardives, ainsi que d'analyse coût/bénéfice de ce matériel.

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Clinical paper

EZ-IO® intraosseous device implementation in a pre-hospital emergency service: A prospective study and review of the literature☆

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ABSTRACT

Introduction: Intraosseous access is increasingly recognised as an effective alternative vascular access to peripheral venous access. We aimed to prospectively study the patients receiving prehospital intraosseous access with the EZ-IO®, and to compare our results with those of the available literature.
Methods: Every patient who required an intraosseous access with the EZ-IO from January 1st, 2009 to December 31st, 2011 was included. The main data collected were: age, sex, indication for intraosseous access, localisation of insertion, success rate, drugs and fluids administered, and complications. All published studies concerning the EZ-IO device were systematically searched and reviewed for comparison.
Results: Fifty-eight patients representing 60 EZ-IO procedures were included. Mean age was 47 years (range 0.5–91), and the success rate was 90%. The main indications were cardiorespiratory arrest (74%), major trauma (12%), and shock (5%). The anterior tibia was the main route. The main drugs administered were adrenaline (epinephrine), atropine and amiodarone. No complications were reported. We identified 30 heterogeneous studies representing 1603 EZ-IO insertions. The patients' characteristics and success rate were similar to our study. Complications were reported in 13 cases (1.3%).
Conclusion: The EZ-IO provides an effective way to achieve vascular access in the pre-hospital setting. Our results were similar to the cumulative results of all studies involving the use of the EZ-IO, and that can be used for comparison for further studies.

1. Introduction

Rapid intravascular access is frequently required in order to administer emergency drugs or fluids in critical patients. Peripheral venous cannulation remains the standard of care, but may be altogether difficult to achieve and time-consuming in life-threatening situations. Intraosseous (IO) access is increasingly recognised as an effective alternative to peripheral venous cannulation. The IO access is characterised by a rapid learning curve and an effectiveness equivalent to peripheral venous cannulation in terms of pharmacokinetic and clinical efficacy.[1,2] Initially used in children, IO access has been implemented progressively with good results in the adult population, particularly since the development of the semi-automatic insertion devices in the late 90s, which may be more effective than manual IO techniques.[3] Since 2010, IO access became a standard of care in adult advanced life support and the first recommended alternative to peripheral venous cannulation in cardiac arrest patients.[4] Contraindications include orthopaedic hardware, infection at the site of insertion, traumatic extensive limb injuries, amputation of a limb and osseous pathologies such as osteogenesis imperfecta.[5]

The EZ-IO®, a new power drill semi-automatic device, has been introduced over the last ten years. To date, several articles about the EZ-IO device use have been published. They are mainly focused on the success rate and rapidity of insertion, but there is limited information about the complications and outcomes of patients in whom an intraosseous access has been attempted.

We prospectively studied the indications, localisations, medications administered and success rate of achieving intraosseous access with the EZ-IO in a physician-based pre-hospital setting. The complications and mortality rate of patients were also recorded. At the same time, all the published studies involving the EZ-IO device in the emergency setting were systematically reviewed in order to compare the results of our study, and to inventory all drugs and fluids administered by this route.

2. Methods

2.1. Study design and setting

This prospective study was conducted from January 1st, 2009 to December 31st, 2011, in the pre-hospital emergency medical

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service (EMS) of the Centre Hospitalier Universitaire Vaudois (CHUV). The CHUV is a 1000-bed university hospital located in Lausanne, Switzerland, and is the level 1 Trauma Centre and Burn Centre for a population of over one million people in the western part of the country. It is also the primary hospital for an immediate catchment area comprising about 300 000 persons. Road ambulances staffed with paramedics are the primary response of the pre-hospital emergency services. Emergency physicians may be sent on site by ground (emergency resuscitation vehicles) or by air (rescue helicopter) under specific indications such as airway obstruction, cardiac arrest, respiratory distress, shock, major trauma, severe burns, or by request from paramedics on site. Emergency physicians are engaged in about 3000 interventions annually; trauma-related emergencies represent 15% of all cases.

2.2. Study instrument and operators

The EZ-IO® (Vidacare Corp., Shavano Park, TX) is a battery-powered driver with a needle set. Three types of needles are available: one paediatric (15 G/15 mm) and two adult (15 G/25 mm and 15 G/45 mm) sizes. Since 2008, the EZ-IO has become a standard of care in our pre-hospital emergency resuscitation vehicles and in the rescue helicopter. The operators are pre-hospital emergency physicians trained in the use of the EZ-IO device during a 1-h theoretical and practical session.

2.3. Inclusion and exclusion criteria

An intraosseous EZ-IO access attempt was recommended after two unsuccessful peripheral intravenous catheter attempts in all critical patients requiring advanced resuscitation procedures. These procedures were defined as follows: cardiopulmonary resuscitation, fluid resuscitation, emergency drugs administration, anaesthesia induction, or major analgesia. All adult and paediatric patients who had undergone an intraosseous insertion were included. There were no exclusion criteria. Placement was considered successful if the needle was fixed firmly in the bone after insertion, along with the possibility of infusing a 5 ml saline bolus without resistance. The Institutional Review Board and the Ethics Committee of the Faculty of Medicine of the University of Lausanne approved the study.

2.4. Measurements

The following data were collected: age, sex, indication for IO access, history of drug abuse (anamnestic or clinical), localisation of IO insertion and success of insertion. The drugs and fluids administered (types and doses) through the IO route were gathered. Immediate complications related to the insertion of the EZ-IO (fluid extravasation, dislodgements, fracture related to the IO procedure) were collected, as well as delayed complications (local infection, extensive soft tissue lesion) at 48 h or at discharge from hospital. Mortality during the first 48 h and mortality at hospital discharge were also evaluated.

2.5. Review of the literature

We searched the literature for all published studies and reports involving EZ-IO use in humans. All articles that described any administration of drugs, fluids or blood products through the IO route were also selected. The Medline and Cochrane Library databases were last consulted on October 25th, 2012, with no restriction to language. The following entry terms were used: intraosseous [Mesh] and EZ-IO. The selected articles where searched for additional references.

2.6. Statistical analysis

Descriptive statistics of the study sample and of the review of the literature were used to represent the mean and median with standard deviation or number and percentage as appropriate. Data analysis was done using Microsoft Excel (Microsoft Corp., Redmond, WA) and STATA (Stata Statistical Software 11.0, Stata Corporation, College Station, TX, USA).

3. Results

Among the 8378 patients who required an emergency physician intervention during the study period, 58 patients (0.7%) met the inclusion criteria, representing 60 EZ-IO insertion attempts (two patients each underwent two intraosseous insertion attempts).

3.1. Characteristics of study subjects

Forty patients were male (69%), with a mean age of 47 (range 0.5–91). Fourteen patients (24%) were aged 16 or under. In seven cases, the pre-hospital emergency physician placed the EZ-IO during transport to the hospital ($n = 7$).

Table 1
List of drugs and fluids administered through the EZ-IO.

Acteplase
Adrenaline[a] (epinephrine) (35)
Adenosine
Amiodarone[a] (6)
Atropine[a] (19)
Bicarbonate
Calcium
Cefazolin
Ceftriaxone
Cisatracurium
Cordarone
Cristalloids[a] (58)
Dopamine
Enoxaparin
Ephedrine[a] (3)
Etomidate[a] (5)
Factor VIIa
Fentanyl[a] (6)
Flumazenil
Furosemide[a] (1)
Glucose[a] (2)
Haloperidol
Heparin
Hydroxocobalamin
Ketamine[a] (2)
Labetalol
Lidocaine[a] (3)
Magnesium
Methylprednisolone
Midazolam[a] (6)
Morphine[a] (1)
Naloxone[a] (1)
Omeprazole
Packed red blood cells[a] (1)
Phenylephrine[a] (1)
Potassium chloride
Propofol
Rocuronium[a] (1)
Salycilic acid[a] (3)
Sodium bicarbonate
Sufentanyl
Suxametonium[a] (7)
Tenecteplase
Vecuronium[a] (2)

[a] Drugs given in our cohort (number of patients).

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3.2. Success rate and indication for intraosseous access

Intraosseous needle access was successful in 54 of the 60 insertion attempts (90%). The reasons for failure were impossibility to infuse in three patients, difficulty in inserting the needle in two, and one case of wrong location (IO placed in the tibial plateau). Indications for IO access were: cardiorespiratory arrest from presumed cardiac origin ($n = 36$, 62% of the 58 patients), traumatic cardiac arrest ($n = 7$, 12%), major trauma ($n = 7$, 12%), shock ($n = 3$, 5%), acute respiratory distress ($n = 2$, 3%), severe hypoglycemia ($n = 2$, 3%), and status epilepticus ($n = 1$, 2%). Four patients (7%) were IV drug abusers.

3.3. Site of puncture

Fifty-nine EZ-IO (98%) were placed in the anterior proximal tibia, including one that was inserted in the tibial plateau. One EZ-IO was placed in the humeral head (avalanche rescue situation).

3.4. Medications

Resuscitation drugs were the most frequently administered drugs through the intraosseous route: adrenaline (epinephrine) in 35 cases (60%, median dose 2.3 mg, range 0.15–10), atropine in 19 cases (32%), and amiodarone in 6 cases (10%). Crystalloids were administered to all patients, with a mean volume of 503 ml (SD 276.29). Seven rapid-sequence inductions were performed (all with etomidate and succinylcholine), as well as four major analgesias using either fentanyl or ketamine. The intraosseous access was used only once to administer red blood packed cells. All medications used are listed in Table 1. In seven cases, nothing other than fluids was administered through the EZ-IO.

3.5. Morbidity/mortality

No immediate complications occurred. Twenty-two patients survived at 48 h (38%) and 17 were discharged from the hospital (29%). Five (11%) of the 43 patients who had had cardiac arrest were discharged from the hospital. No complications were reported at hospital discharge in the 17 survivors.

3.6. Results of the literature review

The literature review identified 30 studies reporting the use of the EZ-IO device (Fig. 1). These studies were heterogeneous in their design and consisted of 12 case reports, 12 prospective studies, three retrospective studies, and three randomised controlled trials (Table 2).[6–35] Overall, 1585 intraosseous needles were inserted in 1603 patients. Needles were inserted by paramedics, nurses or physicians, both in the pre-hospital and in-hospital setting and both in civilian and warfare contexts. In most European studies, EZ-IO insertion was performed by physicians, whereas in most

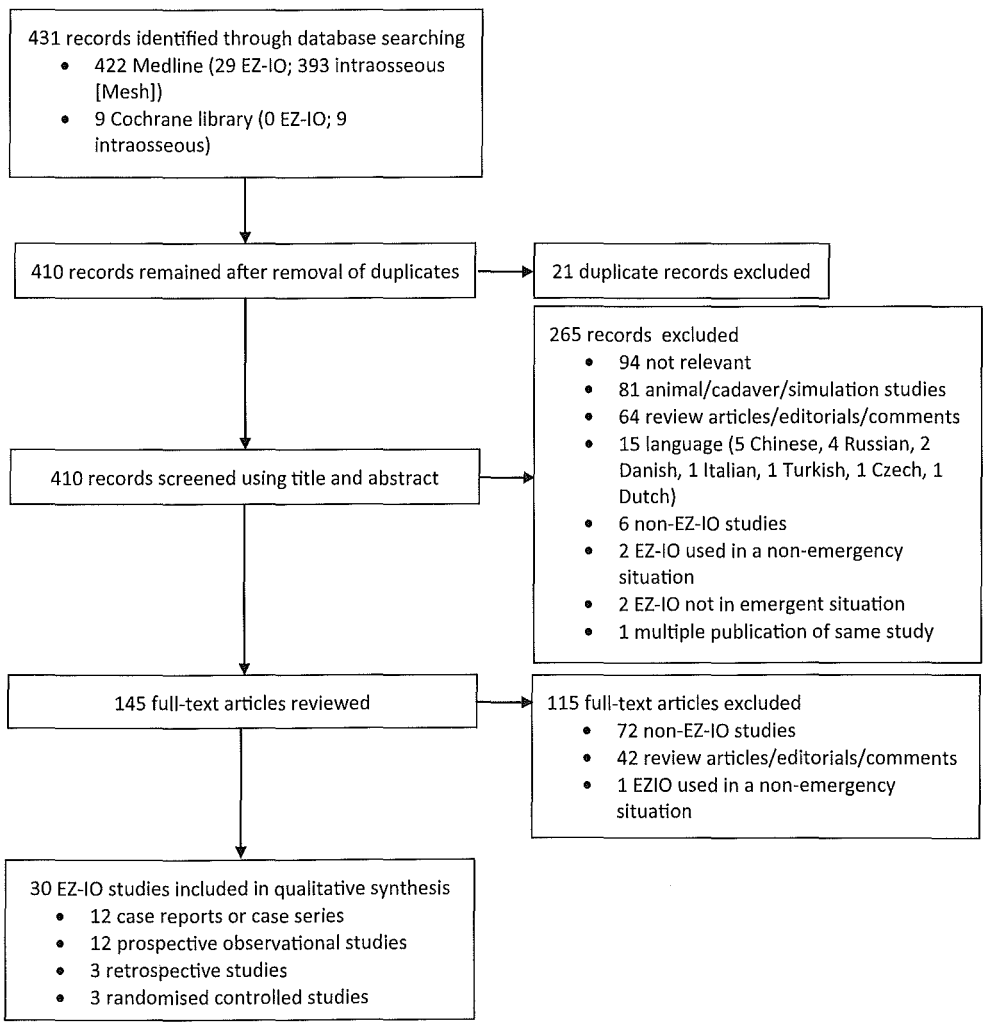

Fig. 1. Literature review flow diagram.

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Table 2
Literature review.

Publication	Trial type	Cases (*n*)	Age (mean)	Cardio respiratory arrest (%(*n*))	Major trauma (%(*n*))	Paediatrics (%(*n*))	Tibial localisation (%(*n*))	Success (%(*n*))	Complications IO (%(*n*))	Induction of anaesthesia
Torres et al.[18]	Prospective observational	107 (114 IO)	56.5	67 (72)	40 (43)	NM	74 (85)	100 (114)	0	0
Landy et al.[6]	Case report	1	53	100 (1)	0	0	100 (1)	100 (1)	100 (1)	0
Tan et al.[19]	Prospective observational	42	NM	NM	50 (21)	0	47 (20)	93(39)	NM	0
Leidel et al.[33]	Randomised controlled	40 (BIG + EZ-IO)	48	NM	73 (29)	0	45 (18)	85(34)	0	NM
Wampler et al.[30]	Retrospective	244	63	100 (244)	NM	NM	0 (244)	93(227)	NM	NM
Myers et al.[31]	Retrospective	60 (62 IO)	0.98	70 (42)	5 (3)	100 (60)	NM	87 (54)	0	NM
Cotte et al.[7]	Case report	1	57	0	0	0	100 (1)	100 (1)	100 (1)	0
Schalk et al.[20]	Prospective observational	77	66	56 (41)	20 (15)	7 (5)	100 (77)	97 (75)	NM	0
Reades et al.[34]	Randomised controlled	115	64	100 (115)	0	0	55 (64)	71 (82)	NM	0
Knuth et al.[8]	Case report	1	48	0	100 (1)	0	0	100 (1)	0	1
Ruiz-Hornillos et al.[9]	Case report	1	64	100 (1)	0	0	100 (1)	100 (1)	0	0
Chatterjee et al.[10]	Case report	1	38	0	0	0	0	100 (1)	0	0
Gazin et al.[21]	Prospective observational	39	57	76 (30)	0	12 (5)	NM	85 (33)	0	2
Reades et al.[22]	Prospective observational	88	63	100 (88)	0	0	66 (58)	69 (61)	0	0
Sunde et al.[32]	Retrospective	49	NM	NM	NM	NM	NM	96 (47)	4 (1 displacement 1 extravasation)	0
Werner et al.[11]	Case report	1	76	0	0	0	100 (1)	100 (1)	0	0
Leidel et al.[35]	Randomised controlled	20	43	NM	70 (14)	0	45 (9)	90 (18)	10 (2 extravasations)	0
Truhlar et al.[12]	Case series	22	NM	32 (7)	40 (9)	40 (9)	NM	95 (21)	0	0
Burgert[13]	Case report	1	79	0	0	0	100 (1)	100 (1)	0	1
Paxton et al.[23]	Prospective observational	30	46.9	6 (2)	33 (10)	0	100 (30)	97 (29)	NM	4
Tsung et al.[14]	Case series	3	29.4	100 (3)	0	33 (1)	NM	67 (2)	0	0
Sarkar et al.[15]	Case report	1 (3 IO)	19	0	100 (1)	0	33 (1)	67 (2)	0	0
Frascone et al.[24]	Prospective observational	19	1.5	52 (10)	16 (3)	100 (19)	100 (19)	95 (18)	26 (2 extravasation, 2 impossibility to infuse 1 dislodgment)	0
Ong et al.[25]	Prospective observational	35	NM	NM	23 (8)	0	69 (24)	100 (35)	0	NM
Langley et al.[16]	Case report	2	48	0	50 (1)	0	100 (2)	100 (2)	0	1
Horton et al.[26]	Prospective observational	95	5.5	NM	31 (30)	100 (95)	NM	94 (89)	0	NM
Cooper et al.[17]	Case series	26 (33 IO)	NM	NM	96 (25)	30 (10)	NM	94 (31)	0	4
Frascone et al.[27]	Prospective observational	89	55.1	NM	NM	0	100 (89)	88 (78)	NM	0
Davidoff et al.[28]	Prospective observational	250	NM	NM	24 (60)	0	100 (250)	97 (242)	0.8 (2 displacements)	NM
Gillum et al.[29]	Prospective observational	125	61	82 (102)	10 (13)	0	100 (125)	94 (118)	0	NM
Overall		1585 patients (1603 IO)	51.3	758/939 = 81%	286/1203 = 24%	204/1185 = 17%	1120/1298 = 86%	1458/1603 = 91%	13/995 = 1.3%	13
Santos et al.	Prospective observational	58 (60 IO)	47.2	74 (43)	26 (15)	24 (14)	98 (58)	90 (54)	0	7

NM = not mentioned.

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American studies, paramedics inserted the device. The reported drugs, electrolytes or blood products administered through the EZ-IO needle are presented in Table 1. The most frequent drug administered was adrenaline. Only one study reports survival at discharge; 13 patients (or 5.4% of all patients) survived among a cohort of patients with cardio-respiratory arrest on which the EZ-IO had been inserted in the humerus by paramedics.[30]

4. Discussion

The predominance of males among our study subjects is consistent with the findings of other studies, and is most likely explained by the large proportion of cardio-respiratory arrests and major trauma situations. The 90% success rate of EZ-IO insertion in our study is similar to the pooled data of the available studies (Table 2).[6–35] The failure to achieve IO access in our study was related to technical difficulties or erroneous location in half of the cases, indicating a need for improvement with additional training.

Although humeral access is a recommended alternative in our EMS, proximal tibial access was used in all but one patient. The ideal site of insertion of the IO device remains a matter of debate. Nevertheless, tibial access is frequently considered easier and faster, with less unsuccessful attempts and fewer dislodgements than with humeral access.[22,34] It also minimises interference with resuscitation efforts in case of CPR or airway management.[19] On the other hand, the humeral site may be of great value in case of trauma, especially lower limb entrapment, injuries or burns. Our results are consistent with the high percentage of proximal tibial access described in the literature, although the humerus, distal radius and distal tibia are also occasionally described as insertion sites.

A wide variety of medications was administered through the EZ-IO (Table 1). The high proportion of patients (60%) that received adrenaline in our study is consistent with the high proportion of patients (90%) with cardio-respiratory arrest. General anaesthesia induction was successfully performed in seven patients, a relatively high rate that may be explained by our physician-based setting. The seven cases where only fluids but no medication was administered through the EZ-IO included five cardiac arrest patients in which a rapid decision to discontinue the resuscitation was made; one patient had severe sepsis, and one had a severe traumatic brain injury. The literature review confirmed that the IO route can be used to administer a wide variety of drugs or fluids (Table 1).

The survival rates at 48 h and at discharge from the hospital were 38% and 29%, respectively. No comparison with the available literature can be made, given the heterogeneous cohort and small patient numbers. Those rates were nevertheless collected and reported to allow a more precise interpretation of the complication rate.

We did not identify any short-term complications of the IO access in our patients, or complications at discharge from the hospital in the survivors. Extravasation is the most commonly described immediate complication, but is generally inconsequential.[32,36] Osteomyelitis is a potential severe delayed complication, but its overall incidence remains low (0.6%).[37] In the literature, osteomyelitis in children was correlated to high doses of adrenaline.[38] Other complications include compartment syndrome and fractures, particularly with the semi-automatic devices.[6,39,40] Less frequent complications include gaseous embolism and fat embolism.[41,42]

The main limitation of our study is its specific, pre-hospital setting, which may not reflect the reality of other pre-hospital emergency medical services. This limitation is, however, inherent in all pre-hospital studies. As our intraosseous indication protocol partially relies on a subjective assessment of the patient, a selection bias cannot be ruled out. Finally, the small size of the cohort and the non-randomised trial design do not permit the evaluation of the impact of the IO route on the patient's survival.

5. Conclusion

The EZ-IO device was shown to be effective in achieving vascular access in the pre-hospital setting. The 90% success rate, the localisation of insertion and the reasons for inserting an intraosseous device were similar to what is described in the literature. The intraosseous route can be used to administer a wide range of drugs and fluids.

Further studies are needed to evaluate the impact of the intraosseous route, particularly on the patient's survival, and on the occurrence of delayed complications.

Conflict of interest statement

None to declare. The EZ-IO devices were the property of the Emergency Service and the study was conducted independently of the manufacturer.

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