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Short communication

Efficacy and safety of the EZ-IO™ intraosseous device: Out-of-hospital implementation of a management algorithm for difficult vascular access☆,☆☆

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ABSTRACT

Objective: Intraosseous access is a rapid and safe alternative when peripheral vascular access is difficult. Our aim was to assess the safety and efficacy of a semi-automatic intraosseous infusion device (EZ-IO) when using a management algorithm for difficult vascular access in an out-of-hospital setting.
Methods: This was a one-year prospective, observational study by mobile intensive care units. After staff training in the use of the EZ-IO device and provision of a management algorithm for difficult vascular access, all vehicles were equipped with the device. We determined device success rate and ease of use, resuscitation fluid volume and drugs administered by the intraosseous route, and complications at insertion site.
Results: A total of 4666 patients required vascular access. The EZ-IO device was used in 30 cardiac arrest patients (25 adults; 5 children) and 9 adults with spontaneous cardiac activity. The success rate for first insertion was 84%. Overall success rate (max. 2 attempts) was 97%. The device was used for fluid resuscitation in 16 patients (mean volume: 680 ml), adrenaline administration in 24 patients, and rapid sequence induction in 2 patients. There was only one local complication (transient local inflammation).
Conclusions: On implementation of an algorithm for the management of difficult vascular access, the EZ-IO device proved safe and highly effective in both adult and paediatric patients in an out-of-hospital emergency setting. It is a suitable device for consideration as a first-line option for difficult vascular access in this setting.

1. Introduction

In an out-of-hospital emergency setting, rapid vascular access is often needed to infuse fluids and administer drugs (e.g. analgesics, inotropes, or antibiotics). The conventional procedure is peripheral venous cannulation which can usually be performed rapidly even under difficult conditions.[1,2] However, in tricky or impossible cases, central venous access or intraosseous (IO) access may be used. Central access takes longer than peripheral access and can cause serious complications such as pneumothorax or arterial puncture. On the other hand, IO access is rapid and safe, and is widely used in emergency situations, especially in children.[3]

Recently, a new semi-automatic IO device with a battery-powered needle driver became available (EZ-IO) for use in both children and adults. Preliminary studies in cadavers, manikins and bone models have shown that it is easy to use and has a high success rate.[4,5] There are, however, few data on its use in an emergency and especially pre-hospital setting, whether in paediatric or adult patients.[6,7] A recent US army report described successful use under the hostile conditions of a tactically flying helicopter.[8]

Our aim was to test EZ-IO device efficiency when used as a rescue technique according to a predefined management algorithm in cases of impossible peripheral emergency vascular access in an out-of-hospital setting.

2. Methods

2.1. Design and setting

This was a prospective observational study conducted from February 2009 to February 2010 by the out-of-hospital emergency

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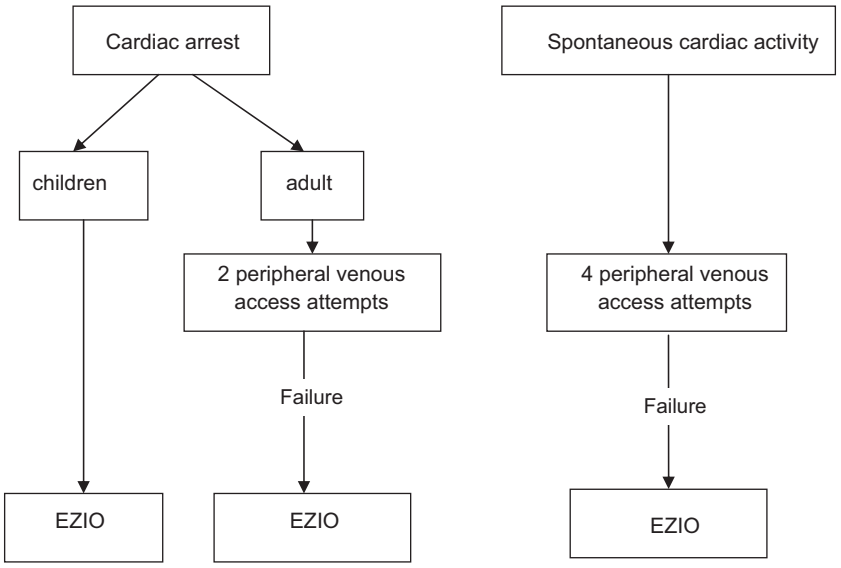

Fig. 1. Management algorithm for difficult vascular access.

medical services (SMUR) of a French university hospital (Henri Mondor Hospital, Créteil). The study was approved by the local ethics committee which waived the informed consent requirement on the grounds that the study was unrandomized and just assessed an algorithm for use in daily practice.

Our SMUR serves a population of 1,300,000 inhabitants and responds to about 10,000 emergency calls a year. It has 5 Mobile Intensive Care Units (MICU). The minimum MICU team is an ambulance driver, a nurse anaesthetist, and a senior physician specialised in either emergency medicine (>90% of physicians) or anaesthesiology. France is divided into medical regions, each with a call centre which runs the MICUs based in the region's hospitals.

2.2. Training in device use

A senior physician with expertise in the use of the EZ-IO battery-powered needle driver (Vidacare, Shavano Park, TX) provided training in the IO technique to all the emergency physicians and nurses of our emergency medical services. Training included a 60-min lecture with slides and videos. This was followed by a 1-h practical session using a plastic bone model provided by the device manufacturer. When all staff members had completed their training, all 5 mobile units were equipped with the EZ-IO driver and needle set.

2.3. Algorithm for difficult vascular access

We invited all staff encountering a case of difficult peripheral vascular access to comply with the following algorithm (Fig. 1): (i) in paediatric cardiac arrest patients (age < 8 years), EZ-IO was to be used first-line; (ii) in adult cardiac arrest patients, EZ-IO was to be used after 2 failed attempts at peripheral venous access; (iii) in adult patients with spontaneous cardiac activity, EZ-IO was to be used after 4 failed attempts. The printed algorithm was handed out to all staff and the topic was regularly brought up at our daily staff meetings.

2.4. Outcome measures

For each patient in whom the device was used, the following data were recorded on a standard form: patient age, sex, estimated weight and height, clinical status (initial blood pressure and Glasgow coma score), factors potentially associated with difficult peripheral vascular access (obesity, any chemotherapy treatment, or drug abuse), indication for vascular access (cardiac arrest, coma, trauma, shock, etc.), number of venous cannulation attempts prior to EZ-IO use, success or failure of EZ-IO use, amount of fluid and drugs administered through the IO needle, and local complications on needle insertion. The needle was assumed to be correctly inserted if bone marrow could be aspirated easily and if 20 ml saline could be injected without extravasation. This was our definition of insertion success. EZ-IO-related complications were recorded until patient discharge from hospital.

2.5. Statistical analysis

Categorical data are reported as numbers (with percentages) and quantitative data as medians with 25th–75th percentiles.

3. Results

Forty-nine SMUR staff (26 emergency physicians, 3 anaesthesiologists and 20 nurses specialised in anaesthesia) participated in our one-year study. During this time, they managed 9876 patients, of whom 4666 required out-of-hospital vascular access. There was a need to resort to IO access in 34 adult and 5 paediatric patients. Demographic and clinical data for these 39 patients are given in Table 1. Twenty-five adults and all 5 children suffered from cardiac arrest. Central venous access was never required.

The success rate of the EZ-IO device on first insertion was 84% (33/39). The overall success rate after 1 or 2 attempts was 97% (38/39). The single failure occurred in an adult cardiac arrest patient in whom bone marrow could not be aspirated and injection through the needle was not possible. External jugular vein cannulation was performed instead.

The EZ-IO device was used for fluid resuscitation in 16 patients and adrenaline administration in 24 patients. The amount of fluid and drugs administered via the device needle are given in Table 2. The device was used for administration of drugs for rapid sequence intubation in 2 patients. Succinylcholine was administered about 1 min after hypnotic. Fasciculations were observed in both patients. Tracheal intubation conditions were good. All 5 conscious patients in whom the device was used reported pain on delivery of the first 20 ml of fluid.

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Table 1
Demographics and clinical data.

	Adult patients ($n = 34$)	Paediatric patients ($n = 5$)
Age (years, median, 25th–75th percentile)	57 (40–72)	0.45 (0.16–0.75)
Sex (M/F)	18/17	3/2
Estimated weight (kg, 25th–75th percentile)	82 (70–90)	5 (4–9)
Estimated height (cm, 25th–75th percentile)	169 (160–180)	54 (50–60)
Indication for EZ-IO (n)		
Cardiac arrest	25	5
Shock	4	0
Coma	2	0
Respiratory distress	3	0
Risk factors for difficult venous access		NA
Obesity (BMI > 30 kg m^{-2})	10	
History of IV drug abuse	2	
Chemotherapy	4	
Burns	1	

NA: not applicable.

Table 2
Use of the EZ-10 device for fluid resuscitation and drug administration.

	Number of patients[a]
Fluid resuscitation	16
Volume of fluid, ml (median, 25th–75th percentile)	680 (450–1000)
Drug administered	
Adrenaline (epinephrine)	24
Etomidate	2
Succinylcholine	2
Midazolam	3
Sufentanyl	5
Bicarbonates	4
Flumazenil	1
30% glucose solution	1
Hydroxocobalamin	1
Amiodarone	1

[a] Unless otherwise specified.

No immediate complications were observed. Transient local inflammation was observed at the EZ-IO puncture site 24 h after needle removal in one of 8 patients admitted to hospital.

4. Discussion

The success rate of the EZ-IO device was high (97%) on implementation of a predefined management algorithm for difficult peripheral vascular access in an out-of-hospital setting. To our knowledge, no algorithm has yet been proposed for management of difficult vascular access. The rationale of our algorithm was as follows: In accordance with recent guidelines, we used IO access as a first-line option in paediatric cardiac arrest patients as peripheral access is often difficult in these patients [9]. The decision to use IO access after 2 failed attempts at peripheral vascular access in adult patients or after 4 failed attempts in patients with spontaneous cardiac activity was based on our own clinical experience as published data are lacking. Four failed attempts at peripheral venous access may seem on the high side, but recent studies have reported a 99% success rate when up to 5 attempts were made in a pre-hospital setting.[1,2]

The EZ-IO device has several advantages. (i) It has a short learning curve. Cadaver and manikin studies have demonstrated that it can be successfully used by novice operators.[4] Our results have highlighted ease of use in an emergency setting. The success rate was 97% (1 or 2 attempts) after a very brief training period. (ii) Another advantage is the battery-operated drill which enables easy needle insertion even in adults with fairly thick cortical bone. Thirty-four of our patients were adults. The single failure we encountered was in an adult cardiac arrest patient. So far, few reports on IO access in out-of-hospital emergencies concern adults.[8,10] A 87% success rate was reported with the EZ-IO device in a field study in adults in which the operators were not provided with any training or standard protocol. In this study, operators spontaneously reported device use to a call centre. This may have led to under-reporting of failures.[6,11] (iii) A third advantage is rapid drug delivery from the medullary cavity within bone to the systemic circulation. We used the device to perform rapid sequence intubation in 2 patients and achieved tracheal intubation under good conditions. Fasciculations were observed in both patients confirming rapid drug delivery.[3,12,13] Most drugs can be administered by the IO route with pharmacokinetics and pharmacodynamics similar to those for the intravenous route.[13,14] (iv) IO access is preferable to central venous access because it is simpler, requires less training, and has fewer complications. In a recent small observational study carried out in adults in an emergency department, the EZ-IO device had a higher success rate and a shorter insertion time than central venous cannulation.[15] Several mechanical complications can occur on central venous puncture (e.g. arterial punctures, pneumothorax, and cannula malpositioning) whereas IO infusion-related complications are rare and mostly minor. We had only one complication, namely, a case of transient local inflammation.

In conclusion, we have established that the EZ-IO device is safe and has a high success rate of use in an out-of-hospital emergency setting and suggest that it could be the preferred vascular access option whenever intravenous injection or fluid resuscitation is needed in an emergency, whether in children or adults. Large-scale prospective randomized studies comparing IO and peripheral vascular access in resuscitation patients should be performed to obtain an evidence-base for drawing up guidelines on IO use.

Conflict of interest statement

None declared.

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