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# Mini-review

# Current advances in intraosseous infusion – A systematic review<sup>☆</sup>

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# ARTICLE INFO

# ABSTRACT

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Keywords: Intraosseous Infusion Needle Device Success rate Cardiac arrest *Objectives:* To describe the advancement of Intraosseous (IO) infusion in the spectrum of resuscitative protocols and to provide a systematic review on currently used semi-automatic IO infusion devices. The specific question addressed was: "In patients undergoing resuscitation, does the use of semi-automatic IO infusion devices compared to manual needles influence IO placement success rate, time for IO placement, and ease-of-use and user preference?"

*Methods:* The electronic databases PubMed and Embase were searched for articles published from 1997 to 2010 using the search terms ("intraosseous") AND ("needle" or "device" or "technique") AND ("infusion" or "injection" or "access"). The Internet search engine Google Scholar was searched using the search term "intraosseous infusion device" to identify articles published in electronic journals, books, and scientific websites. Articles were included only if they compared at least two types of semi-automatic devices, or compared one or more semi-automatic device with one or more manual needles. Reviews, editorials, surveys, and case reports were excluded.

*Results:* The search strategy yielded 179 papers. Ten studies met full criteria for further review. Of these, two were LOE 1 (randomized controlled trials), one was LOE 2 (non-randomized, concurrent controls), one was LOE 3 (retrospective controls), and six were LOE 5 (simulation-based study). One of the six LOE 5 studies was a non-peer reviewed article.

*Conclusions:* Only a few studies compared the performance of different types of IO infusion devices, most of them have a low level of evidence. These studies suggested a superiority of the battery-powered IO driver over manual needles, and other semi-automatic IO infuson devices.

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# 1. Introduction

Intraosseous (IO) infusion as a means of vascular access has been recognized for close to a century. The use of IO access in paediatric medical or trauma resuscitation is endorsed by the American Heart Association (AHA), the European Resuscitation Council (ERC), the American College of Emergency Physicians (ACEP), the American Academy of Paediatrics (AAP), the American College of Surgeons (ACS), the American College of Critical Care Medicine (ACCM), the U.S. National Association for Emergency Medical Service Physicians (NAEMSP), and the U.S. Army Committee on Tactical Combat Casualty Care (TCCC). These organizations recommend IO access as the immediate alternative route if intravenous (IV) access cannot be

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rapidly obtained.<sup>1–6</sup> Currently, there is sufficient evidence to recommend that this method of administering fluids and medications should also be used in any adult who is undergoing cardiac arrest, when rapid vascular access cannot be immediately achieved.<sup>3</sup> As an accepted standard of care treatment modality, IO infusion has now claimed its place as an important form of vascular access in trauma resuscitation in adults as well.<sup>4–6</sup> A large-caliber peripheral IV catheter is the preferable vascular route in trauma resuscitation in adults because they sometimes need a large volume of fluids.<sup>4</sup> However, IV access can be challenging, especially in the prehospital setting or in the setting of combat casualty resuscitation, where early IO infusion is currently recommended.<sup>5,6</sup>

# 2. Historical background and current recommendations for using IO access

IO infusion was first used in the 1920s when Drinker and colleagues demonstrated in an animal model that fluids administered into the marrow cavity did reach intravascular circulation.<sup>7</sup> The introduction of IO access for use in humans was reported in 1934 by Josefson.<sup>8</sup>



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#### 2.1. IO infusion in children

In the 1940s, two reports showed IO infusion to be an effective method of fluid and medication delivery in the paediatric population.<sup>9,10</sup> However, with the introduction of the plastic IV catheter, the IO route stopped being used as an important source for vascular access. This was due both to the ease and availability of IV cannulation as well as several reports of IO complications.<sup>11</sup> In the early 1980s, the first paediatric advanced life support (PALS) course was introduced, followed shortly by the original advanced paediatric life support (APLS) course.<sup>12</sup> These courses, based on the AHA, AAP, and ACEP recommendations were the first to reintroduce the option of IO access in children younger than 6 years of age, but only when IV access has failed.<sup>12</sup> The 1993 updated versions of the PALS courses recommended that the IO access be used after three attempts or 90 s, but still only in the younger population.<sup>13</sup> The 2005 AHA guidelines recommended that a more "liberal" approach could be used by allowing the PALS provider to decide how quickly the IO access should be performed ("if you cannot achieve reliable IV access guickly – establish IO access").<sup>14</sup> This recommendation is emphasized by the latest (2010) AHA guidelines.<sup>1,2</sup> IO infusion is also recommended in the out-of-hospital setting. In its 2007 statement, the NAEMSP published a formal recommendation to treat critically ill children with IO infusion.<sup>5</sup>

IO infusion may be gradually expanding into other conditions in paediatric emergencies in which urgent vascular access is needed. In paediatric septic shock, early aggressive fluids management is crucial to improve survival. In 2009, the ACCM updated their guidelines on haemodynamic support of paediatric and neonatal septic shock. The old guidelines (from 2002) recommended aggressive fluids treatment via peripheral line or central vein catheter (CVC) in critically ill infants or children. The ACCM currently recommends that aggressive fluids management should be provided via the IO route if peripheral IV access cannot be rapidly obtained.<sup>15</sup>

# 2.2. IO infusion in adults with cardiac arrest

In 2005, the AHA and the ERC revised their guidelines to include recommending IO access in adults with cardiac arrest when IV access is not available.<sup>16</sup> These recommendations were reemphasized in the AHA 2010 guidelines which recommended that only an appropriately trained provider should place a CVC (internal jugular or subclavian).<sup>3</sup>

#### 2.3. IO infusion in trauma

The American College of Surgeons Committee on Trauma, in its 2008 Advanced Trauma Life Support (ATLS) course, discouraged using IO access in adults. However, it recommended using IO infusion in children in whom venous access was impossible or difficult (when two attempts for placing intravenous cannula failed).<sup>4</sup> In the military field, establishing IV access for resuscitation of critically injured casualties remains a persistent challenge. During the military engagements of the U.S. and the U.K. armies in Iraq and Afghanistan, and the Israeli army in the Second Lebanon War, IO access emerged as a viable alternative to IV.<sup>17–19</sup> The U.S. Army Committee on the TCCC guidelines currently (2010) recommends using IO infusion in any resuscitation scenario in which IV access is not obtainable.<sup>6</sup>

## 3. IO infusion devices

#### 3.1. Manual needles

The first devices to be introduced were the manual needles which are still widely used by many practitioners. There are currently several different manual IO needles commercially avail-



Fig. 1. The FAST 1. Pyng Medical Corporation, Vancouver, Canada.

able. These are all basically modified steel needles with central removable trocars that prevent plugging during insertion. The Jamshidi/Illinois (Cardinal Health, McGaw Park, IL), the threaded Sur-Fast needle, and the Dieckman modified needle (both from Cook Critical Care, Bloomington, IN) are the most commonly used manual IO needles. These needles are all relatively similar, and their success rate, time for insertion, and ease-of-use seem to be comparable.<sup>20–22</sup> Previous studies and case reports showed that manual needles can be easily used in young paediatric patients, but are considered technically more difficult in older patients.<sup>23,24</sup>

Over the last 14 years, three mechanical semi-automatic IO devices designed for use both in children and adults were approved by the Food and Drug Administration (FDA). The IO device, the FAST 1 (Pyng Medical Corporation, Vancouver, Canada), was approved by the FDA in 1997. The spring-loaded IO device (bone injection gun – BIG, Waismed Ltd., New York, NY, USA), was approved in 2000, and the battery-powered IO drill (EZ-IO, Vidacare, San Antonio TX, USA) was approved in 2004.<sup>25–28</sup> The development of these IO devices has increased the options available for IO access.

# 3.2. The FAST 1

The FAST 1 (Fig. 1) is a sternal IO infusion device that creates a port through which fluids can be introduced via the sternum. The FAST 1 is a sterile disposable system which uses a probe composed of multiple needles that properly align the device with the patient's sternum. A guide is placed on the upper part of the sternum to mark placement, and the device uses a bed of needles to control the depth. With manual pressure, the IO device is inserted into the sternum and the infusion tube is left in place. The device requires the use of a specialized tool to remove it from the sternum.<sup>25</sup> Although the FAST 1 can be used in older children and adolescents. current literature indicates that this device has been used almost exclusively in adult patients.<sup>23</sup> A new generation of the device, the FAST X (Fig. 2) was approved by the FDA in September 2010. The device has been re-engineered and, according to the manufacturer, is faster and easier to use than the FAST 1. In this latest version, a removal tool is no longer needed.<sup>26</sup>

#### 3.3. The bone injection gun (BIG)

The BIG is a small automatic plastic disposable IO injector. It includes a spring-loaded device with a trigger. Once the safety pin is



Fig. 2. The FAST X. Pyng Medical Corporation, Vancouver, Canada.

removed from the device and the trigger is pressed, a spring shoots the IO needle through the cortex. The BIG has an adjustable insertion depth of between 0.5 and 1.5 cm. The adult version (Fig. 3, in blue) has a 15-gauge needle, while the needle of the paediatric version (Fig. 3, in red) is of 18-gauge. The paediatric version is indicated for use in children younger than 12 years of age.<sup>27</sup> In the U.S., the BIG has been approved for use in the proximal tibia.

# 3.4. The EZIO

The EZIO is a battery-powered IO driver with a needle set.<sup>28</sup> The power driver is a reusable, hand-held, lithium-battery medical drill, capable of producing 1000 human insertions (Fig. 4). The new version of the device, EZIO G3, is smaller and is capable of producing 500 insertions (Fig. 5). The driver drills the hollow IO needle into the bone. The instructions recommend not pushing the driver, but instead allowing the driver to do the work. The operator should gently guide the needle and feel for the give that indicates penetration into the medullary space. The paediatric version uses the same driver as the adult one and is approved for children lighter than 39 kg. Fifteen gauge needles that are 15-mm long are available for children lighter than 39 kg, while 15-gauge 25-mm long needles are used for patients 40 kg or heavier, and 15-gauge 45-mm long needles are used for patients who have excess tissue over



Fig. 4. The EZIO. Vidacare, San Antonio, TX, USA.

the insertion site (excess tissue from edema, large musculature or obesity). In the United States, the EZIO has been approved for use at two anatomical sites, the proximal tibia and the humeral head.<sup>28</sup>

## 4. Methods

This review was conducted in accordance with the International Liaison Committee on Resuscitation (ILCOR) 2010 evidence evaluation process.<sup>29</sup> Review of the search strategy and findings were conducted by the four authors of the article.

# 4.1. PICO question

The review sought to identify evidence to address the following PICO (Patient/population, Intervention, Comparator, Outcome) question:

"In patients undergoing resuscitation, does the use of semiautomatic IO infusion devices compared to manual needles influence IO placement success rate, time for IO placement, and ease-of-use and user preference?"

# 4.2. Search strategy

The electronic databases PubMed and Embase were searched for articles published from 1997 to 2010 using the search terms ("intraosseous") AND ("needle" or "device" or "technique") AND ("infusion" or "injection" or "access"). The Internet search engine Google Scholar was searched using the search term "intraosseous infusion device" to identify articles published in electronic journals, books, and scientific websites. Articles were included only if



**Fig. 3.** The bone injection gun. Adult version (blue) and Paediatric version (red). Waismed Ltd., New York, NY, USA. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)



# Table 1 ILCOR level of evidence for therapeutic interventions.

- LOE 1: Randomized controlled trials (or meta-analyses of RCTs)
- LOE 2: Studies using concurrent controls without true randomization
- (e.g. "pseudo"-randomized) or meta-analyses of such studies)
- LOE 3: Studies using retrospective controls
- LOE 4: Studies without a control group (e.g. cases series)
- LOE 5: Studies not directly related to the specific patient/population (e.g.
- different patient/population, animal models, mechanical models, etc.)

they compared at least two types of semi-automatic devices, or compared one or more semi-automatic device with one or more manual needles. Reviews, editorials, surveys, and case reports were excluded. The references of the included articles were reviewed to ensure no relevant articles had been missed.

#### 4.3. Evidence appraisal

The studies were reviewed in detail and classified by level of evidence (LOE) for studies of therapeutic interventions (Table 1).

## 4.4. Review process

The review process had three steps. First, all the articles that the search yielded were cross-checked independently by two authors (GW, IS), and studies that met with the criteria for further review were sent to the other two authors. The four authors were then asked to prepare independent drafts examining the two PICO questions. Once this step had been completed, the four authors were met (via the Internet), reviewed the drafts together and decided on the final version.

#### 5. Results and discussion

The search yielded 179 articles. After cross-checking of these articles, ten studies met with the criteria for further review.<sup>30-39</sup> Of these, two were LOE 1 (randomized controlled trials)<sup>31,36</sup>; one was LOE 2 (non-randomized, concurrent controls)<sup>35</sup>; one was LOE 3 (retrospective controls)<sup>37</sup>; and six were LOE 5 (simulation-based study).<sup>30,32-34,38,39</sup> One of the six LOE 5 studies was a non-peer reviewed article.<sup>33</sup>

#### 5.1. FDA-approved semi-automatic IO devices vs. manual needles

#### 5.1.1. FAST 1 vs. manual needles

Calkins et al. compared the FAST 1 with two types of needles, the hand-driven threaded-needle SurFast (cook critical care) and the straight-needle Jamshidi needle (Baxter). They reported that the FAST 1 and the two needles had similar success rates for establishing IO access (29/31 for the FAST1, 30/31 for the needles), but the FAST 1 required a longer placement time (114 s vs. 90 s).<sup>30</sup> Longer IO placement time (compared with manual needles) was also reported by Hartholt et al.<sup>31</sup>

#### 5.2. BIG vs. manual needles

When the BIG was compared with the Jamshidi needle using a paediatric leg mannequin, the IO placement time was found to be faster, but no difference in ease-of-use was reported.<sup>32</sup> Calkins et al. also showed that the BIG was faster than manual needles.<sup>30</sup> Gilman et al. compared placement of traditional IO needles with the BIG in a swine model and found similar placement times and success rates, however the BIG was preferred by most users.<sup>33</sup>

#### 5.3. EZIO vs. manual needles

Brenner et al. used an adult human cadaver model to test the EZIO vs. a manual needle (Cook Med. Inc., Bloomington, USA).<sup>34</sup> The two IO devices were compared in terms of insertion times, success rates and user friendliness. Correct placement was defined as a provider report of sudden loss of resistance (a clue for bone marrow penetration), stable needle hold after releasing the stylet, and free flush of saline via the needle with no soft tissue swelling around the drilling canal. Eighty-four emergency technicians were randomly divided into two groups; 39 performed IO insertion using the manual needle, and 45 preferred the EZIO. Mean insertion time was similar for both groups ( $33 \pm 28$  s for the manual needle vs.  $32 \pm 11$  s for the EZIO), however the EZIO had a higher first attempt success rate than the manual needle (97.8% vs. 79.5%; p < 0.01).<sup>34</sup>

# 5.4. Head-to-head comparison of the semi-automatic IO infusion devices

Our search strategy revealed four clinical studies and three simulation-based studies that compared the different types of semi-automatic devices with each other.

#### 5.5. Clinical studies (Table 2)

Our literature search revealed no paediatric studies that performed a comparison between the semi-automatic IO devices, but four adult studies were found (Table 1). These studies differ significantly in their assessment of the effectiveness of each device and the research methodology terms. Two of the four clinical studies were LOE 1, one was LOE 2, and one was LOE 3. One study revealed superiority of the FAST 1 over the BIG and another showed the superiority of the EZIO over the FAST  $1.^{31,35}$  The EZIO was found superior to the BIG in one study,<sup>37</sup> but the difference in performance between the two was statistically nonsignificant in another study.<sup>36</sup>

Hartholt et al. compared the Jamshidi 15G needle, the FAST 1 and the BIG in a helicopter emergency service system.<sup>31</sup> In this randomized controlled trial, correct placement of all IO needles was verified by aspiration of bone marrow and flushing with saline. Of the 65 patients, 24 were treated by the Jamshidi needle, 22 by the BIG, and 19 by the FAST 1, with success rates of 91.7%, 59.1% and 89.5%, respectively. The Jamshidi needle and the FAST 1 had similar success rates, complication rates, and user-friendliness rates, but the Jamshidi needle was placed significantly faster than the FAST1 (median insertion time of 37 s vs. 62 s). Eighteen technical complications were recorded during the study; nine related to the BIG, five to the FAST 1, and three to the Jamshidi needle.<sup>31</sup>

Frascone et al. conducted two sequential prospective nonrandomized trials to compare the FAST 1 with the EZIO in the prehospital setting.<sup>35</sup> Correct placement was determined by aspiration of bone marrow and flushing in the usual fashion. The investigators recorded 178 IO insertions over five years: 64 of the 89 FAST 1 insertions were successful, as were 78 of the 89 EZIO insertions (72% vs. 87%). During the 5-year study period, 11 technical complications were recorded with the EZIO and 25 with the FAST 1. There were no differences in provider comfort or provider assessed device performance between the two devices.<sup>35</sup>

Two recently published studies compared the BIG with the EZIO in the adult population.<sup>36,37</sup> Leidel et al. conducted a randomized controlled trial on Emergency Department patients.<sup>36</sup> Success rate was defined as successful administration of drugs or infusion of solutions via the IO access. Failure was defined as extravasation or unsuccessful (first) IO insertion. Twenty patients were treated with the BIG and 20 with the EZIO, with success rates in the first attempt of 85% and 90%, respectively (differences were

#### Table 2

#### Results from clinical studies.

	Devices compared	Methodology and level of evidence (LOE)	Population	Verification of correct placement	No. of patients/participants	Success rate	Technical complications
Hartholt et al. [31]	MN <sup>a</sup>	RCT	Helicopter	Aspiration of bone marrow,	MN <sup>a</sup> – 24	MN <sup>a</sup> – 91.7	MN <sup>a</sup> – 2
	BIG <sup>d</sup>	(LOE 1)	EMS personnel	flushing with saline	BIG – 22	BIG – 59.1	BIG – 5
	FAST 1 <sup>c</sup>		-	Ū.	FAST1 – 19	FAST1 – 89.5	FAST1 – 2
Frascone et al. [35]	FAST 1	Prospective nonrandomized trial	EMS personnel	Aspiration of bone marrow, flushing with saline	FAST 1 – 89	FAST 1 – 73	FAST1 – 17
	EZIO <sup>e</sup>	(LOE 2)		Ū.	EZIO – 89	EZIO – 85	EZIO – 5
Leidel et al. [36]	BIG	RCT	Emergency Department physicians	Successful administration of drugs or infusion of solutions	BIG – 20	BIG - 80	BIG – 5
	EZIO	(LOE 1)			EZIO – 20	EZIO – 90	EZIO – 0
Sunde et al. [37]	MN <sup>b</sup>	Retrospective analysis of	Helicopter	Not mentioned	MN <sup>b</sup> – 5	MN <sup>b</sup> – 40	MN <sup>b</sup> – 1
	BIG	medical records (47 adults,	EMS personnel		BIG – 18	BIG – 56	BIG – 3
	EZIO	23 children) (LOE 3)	·		EZIO – 49	EZIO – 96	EZIO – 0

<sup>a</sup> MN = manual needle. Jamshidi (Cardinal Health, Dublin OH, USA).

<sup>b</sup> MN = manual needle. Bone marrow aspiration needle (Inter V, Medical Device Technologies Inc., Denmark).

<sup>c</sup> FAST 1 (Pyng Medical Corp., Richmond, BC, Canada).

<sup>d</sup> BIG, bone injection gun (Waismed Ltd., New York NY, USA).

<sup>e</sup> EZIO (Vidacare, San Antonio TX, USA).

#### Table 3

#### Results from simulation-based studies.

Study	Devices compared	Simulation model	Participants	Verification of correct placement	Sample size	Success rate (%)	Technical complications
Calkins et al. [30]	MN <sup>b</sup> MN <sup>c</sup> FAST 1 <sup>f</sup> BIG	Human cadaver; randomized cross-over trial	Air force para-rescuemen, army special forces, ranger medics	Aspiration of bone marrow, flushing with saline, extavasation	31 per device	MN <sup>b</sup> – 97 MN <sup>c</sup> – 97 FAST 1 – 94 BIG – 94	MN <sup>b</sup> - 0 MN <sup>c</sup> - 1 FAST 1 - 2 BIG - 1
Shavit et al. [38]	BIG EZIO	Turkey thigh bone; randomized cross-over	Paramedics in training	Saline flushed from marrow	29 per device	BIG - 65.5 EZIO - 96.5	BIG – 6 EZIO – 0
Bukoski et al. [39]	BIG <sup>d</sup> EZIO <sup>e</sup> MN <sup>a</sup>	<b>fiabl</b> cadaver; prospective controlled study	Veterinarians	Flushing with minimal resistance; CT image of medullary cavity	24 attempts per device (12 tibial, 12 humeral)	BIG – 75 EZIO – 96 MN <sup>a</sup> – 88	Not reported

<sup>a</sup> MN = manual needle. Jamshidi (Cardinal Health, Dublin OH, USA).

<sup>b</sup> MN = manual needle. Hand-driven SurFast (Cook Critical Care, Bloomington IN, USA).

<sup>c</sup> MN = manual needle. Jamshidi (Baxter Allegiance, McGaw Park III, USA).

<sup>d</sup> BIG, bone injection gun (Waismed Ltd., New York NY, USA).

<sup>e</sup> EZIO (Vidacare, San Antonio TX, USA).

<sup>f</sup> FAST 1 (Pyng Medical Corp., Richmond, BC, Canada).

statistically not significant). Mean procedure time was 2.2 min  $\pm$  1.0 for the BIG vs. 1.8 min  $\pm$  0.9 for the EZIO. Five technical problems were reported with the BIG, none with the EZIO. In five patients who were treated with the BIG, the stylet stuck within the cannula and could only be removed with a clamp, after which the administration of drugs and fluids through the cannula was possible without further complications and the IO insertion was deemed successful. Sunde et al. retrospectively reviewed all IO placement attempts between the years 2003 and 2010 in a Helicopter Emergency Medical Service.<sup>37</sup> Data collection was based on patient medical records and included demographic data as well as insertion site, insertion success rates, insertion-related problems and complications. Three IO devices used during the study period were analyzed: manual needles (bone marrow aspiration needle, Inter-V, Medical Device Technologies Inc., Denmark), BIG, and EZIO. During the seven-year study period, 78 IO insertion attempts were made on 70 patients, 47 older than 18 years of age. Rates of success on first attempt were significantly higher with the EZIO compared with the manual needle and the BIG. Overall success rates were 50% with the manual needle, 55% with the Bone Injection Gun, and 96% with the EZIO. Eighteen patients were younger than two years of age. The authors, however, did not provide any information on the IO success rate in the paediatric group (vs. the adult group). One technical problem was reported with the manual needle, three with the BIG, and none with the EZIO.37

## 5.6. Simulation-based studies (Table 3)

Our literature search revealed three studies that compared the semi-automatic IO infusion devices in simulation-based models (LOE 5). In two of these studies, the EZIO was found superior to the BIC.<sup>38,39</sup>

Calkins et al. compared four IO devices, the FAST 1, the BIG, the hand-driven threaded SurFast needle and the Jamshidi needle.<sup>30</sup> Air Force para-rescuemen, Army Special Forces, and Ranger medics were tested on a cadaver model in a prospective, randomly assigned cross-over study. Correct placement was determined by using aspiration of bone marrow, flow of fluid with flushing of the syringe used for aspiration, flow of crystalloid under high pressure, and security of the needle after placement. High success rates were recorded for all four devices (94–97%), but the BIG had the fastest placement time. The authors concluded that all four devices can be appropriately used in a special operations environment and are reasonable alternatives when intravenous access cannot be gained.<sup>30</sup>

Shavit et al. performed a randomized cross-over study and tested the BIG and the EZIO on a turkey bone model.<sup>38</sup> Study results showed that the EZIO had a one-attempt success rate of 96.5% (28/29) compared to 65.5% (19/29) for the BIG, and that nearly 70% of the study subjects chose the EZIO as their preferred device.<sup>38</sup> Six technical complications were reported with BIG, none with the EZIO.

A recent work by Bukoski et al. compared the EZIO, the BIG and the Jamshidi manual needle in cat cadavers.<sup>39</sup> This study showed a higher success rate with the EZIO than the other two devices (96% vs. 75% and 88%, respectively). The authors concluded that the EZIO was inserted quicker and was assessed as easier to use than the other two devices. No technical difficulties were mentioned in this article.<sup>39</sup>

#### Conclusions

Most of the studies reported in this systematic review have a low level of evidence.

Only a few studies compared the performance of different types of semi-automatic IO infusion devices. These studies suggested a superiority of the battery-powered IO driver over manual needles, and over the other semi-automatic IO infusion devices.

#### Contributions

G.W. conceived the idea for the study, reviewed the literature, prepared the first draft, and reviewed the manuscript. Y.H. reviewed the literature, prepared the first draft, and reviewed the manuscript. R.G. critically reviewed the article and the literature. I.S. prepared the tables, and critically reviewed the article and the literature. I.S. has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

#### **Conflict of interest statement**

None declared.

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