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# The Use of a Powered Device for Intraosseous Drug and Fluid Administration in a National EMS: A 4-Year Experience [Original Articles]

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## Abstract TOP

Background: Provide evidence of success rate and limitations of the prehospital use of a powered device for intraosseous (IO) bone infusion, the bone injection gun (BIG) for critical patients in whom peripheral intravenous (IV) access cannot be readily obtained.

Methods: This prospective study included all reports regarding the use of BIG in our national EMS during the study period. The BIG is a FDA and Israeli Health ministry approved device for IO cannulation. Starting April 2000, a new version was introduced to all ALS units. Simultaneously, our medical protocols were updated to include its use and mandatory reporting was initiated. Successful insertion was defined as obtaining a good fluid flow through the needle without evidence of extravasation. This article presents an analysis of the data collected during this period.

Results: From May 2000 to June 2004, 189 patient encounters in which the BIG was employed met inclusion criteria and comprised the study group. Successful insertion on first attempt was achieved in 172 patients (91.0%). In two additional patients, a second attempt was successful. Forty-seven of the patients were below the age of 18 years (24.9%). One hundred ten patients (58.2%) were over 60 years of age. One hundred thirty-three were found without a palpable pulse (70.4%), and only 18 were found with a Glasgow coma scale of 9 or above. The cause was traumatic in 34 patients (18.0%).

Conclusion: The BIG provides an effective alternative IV access for critical patients in whom a peripheral IV line cannot be readily obtained in the prehospital setting.



Obtaining rapid and reliable vascular access is crucial for the care of critically ill children and adults. The problem is even greater in the prehospital setting, where working conditions tend to be suboptimal and the insertion of a central venous catheter is usually unfeasible.[1] The venous cut-down technique is rarely practiced, even in the hospital setting, and tends to be time consuming and technically difficult.[2] The use of the intrapulmonary route for drug delivery, although relatively common in resuscitation scenarios, is limited by the need for endotracheal tube placement, by the limited number of medications that can be administered and by inconsistent absorption.[3] It has been discouraged in the latest update of the advanced cardiac life support (ACLS) by the American Heart Association.[4]

The intraosseous route is an alternative method for intravenous (IV) access. It was first described in 1922 by Drinker et al.,[5] who investigated blood circulation in the sternum of animals and proposed it as a site for transfusion. Intraosseous infusion (IOI) was first used in children in the 1940s for blood transfusion and antibiotics delivery.[6] Its use declined in the 1950s as a result of the introduction of plastic IV catheters.

IOI allows delivery of medications, fluids, and blood products. Studies of the pharmacokinetics of IOI show it to be comparable with IV administration both in maximal concentration and speed achieved after identical dosing.[3,7-14] The November 2005 AHA guidelines[4] even compare it with central venous administration stating that Intraosseous (IO) cannulation provides access to a noncollapsible venous plexus, enabling drug delivery similar to that achieved by central venous access.

IO access can also be used to draw blood samples for type and screen,[8] Chemistry,[15] blood gases,[16-18] and blood counts.[19,20]

Complication rates are reported to be minimal with rates of less then 1% for osteomyelytis, compartment syndrome, and bone fractures.[21,22] Today IOI is advocated for the care of both pediatric (Pediatric advanced life support, PALS) and adult patients (ACLS), if peripheral IV access cannot be easily obtained. Current guidelines further stress that efforts at obtaining peripheral IV access should not delay therapy in critical patients. In children, they even advocate the initial attempt to be at IOI if peripheral veins are not apparent. Recommended dosage for IOI is identical to that of IV.

### Sites for IOI TOP

Theoretically, IOI can be inserted to any bone with a marrow cavity. Commonly described sites of insertion include the femur, proximal tibia, ileac crest, sternum, and humerus.[23-27]

### Contraindications to IOI Use TOP

IOI should not be placed in a limb with vascular injury, compartment syndrome, significant soft tissue infection, or to a fractured bone.[28] Similarly, once a bone has been punctured by an IO attempt it cannot be used again.

To date, IOI has been used mostly in children. Insertion of the IO needle to an adult is more difficult because of the thicker cortex of the bone and the smaller marrow cavity. Moreover, concerns were raised that because of the smaller relative diameter of the marrow and to the change in its composition, flow rates may be limited.

Multiple methods and devices are available for obtaining IO access. Those include the use of bone marrow aspiration needles, use IOI tailored manually inserted devices and powered devices.[29-37] One of the available spring activated devices for obtaining intra-osseous (IO) access is the bone injection gun (BIG). The BIG is capable of placing a 15-gauge trocar needle into the bone marrow of the tibia or radius of an adult or a 19-gauge trocar needle in to the proximal tibia the case of the pediatric device. This device has been used on animal models, cadavers, and human subjects.[37-39] The Food and Drug Administration (FDA) approved the device for marketing in the United States (FDA 510K No. K981853).

In Israel, a nationwide public EMS system exists (MDA) responding to over 90% of the prehospital emergencies.

## METHODS TOP

The BIG (adult and pediatric model by Waismed Ltd) (Fig. 1) was introduced to our EMS system in 1999. Prospective data collection was started in April 2000 with the introduction of a new version of the BIG. The device was introduced to all advanced life support (ALS) units. Before its introduction, all paramedics participated in theoretical and hands on classes regarding indications, contraindications, and proper use technique. Such classes are taught and practiced in all paramedic training facilities in Israel, having become an integral component of the curriculum since April 2000.

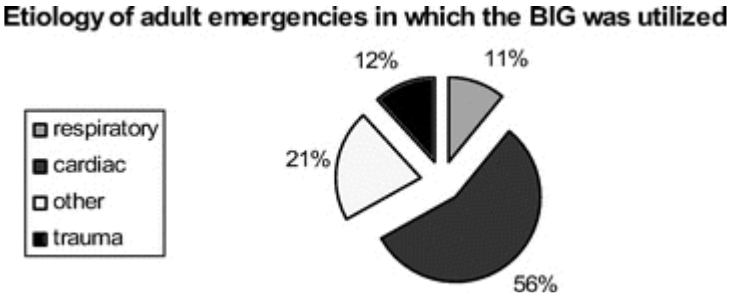


**Fig. 1.** *A pie chart showing the cause of adult emergencies in which the BIG was used.*

All MDA ALS units were equipped with the BIG device and uniform indications for its use and reporting were distributed. The use of the BIG was authorized for any life-threatening situation in which venous access was deemed necessary but no peripheral venous access could be readily established. Reporting was mandated for all attempts to use the BIG. Two types of BIG devices were used, a pediatric device for children assessed to be less then 8 years of age and the adult-type unit. ALS personnel were instructed to insert the BIG in the proximal tibial plateau. They were required to check that the needle was securely set in the bone and attempt to aspirate bone marrow. If both criteria were met, the IO was regarded as successfully placed. If the needle was secure but no marrow was aspirated, they were allowed to inject 20 mL of saline solution and evaluate for extravasation. If none was evident and good flow through the needle was accomplished, the IO was regarded as successfully placed. Once placement was confirmed, the lines were secured according to the manufacturer's instructions using the plastic safety pin of the device and securing it with tape. It was contraindicated to use BIG on any bone suspected as fractured or on any limb with significant swelling, vascular compromise, or infection.

The uniform reporting form included the following information: date of procedure, sex, and known or estimated age of patient, initial diagnosis, initial Glasgow coma scale (GCS), initial blood pressure (BP), number of attempts to insert a peripheral IV line, the use of sedation, the use of local infiltration with lidocaine, number of IO attempts, user assessment of reason for failed attempt (if initial IO insertion failed), effectiveness of flow through the IO and patient survival to hospital admission.

The use of the BIG was integrated into all relevant medical standing protocols for the ALS units. Those included the use of the BIG to administer vasoactive medications, antiarrhythmics, sedative medications, glucose, IV fluids, naloxone, and bicarbonate.

The principal investigator performed data collection. All report forms were reviewed. All patient encounter data that fulfilled inclusion criteria was collected and analyzed. The criteria for inclusion of the reports in the present study were complete data entry, and use of the updated version of the BIG. The institutional review board approved the study.

Statistical analysis was primarily descriptive. Data were entered on a spreadsheet and analyzed using commercially available software (MS Excel XP, Microsoft Corp, Redmond, WA).

## RESULTS TOP

Between April 2000 and June 2004, a total of 204 patients encounters in which the BIG was used were reported to MDA medical division. Of the 204 patient encounters, 189 (92.6%) met the inclusion criteria and thus constituted the study group. The mean age was 53.2 years (range 2 weeks to 100 years, SD 34.0 years). One hundred forty-two patients were over 18 years of age (75.1%) and 47 were below 18 years (24.9%). Ninety-nine of the patients were female (52.4%). One hundred seventy-one were found with a GCS of 8 or less (90.5%). Forty-one patients had spontaneous respiration (21.7%). Of the patients without spontaneous respirations, 15 (7.9%) had a detectable pulse. Ninety-four patients (49.7%) survived to hospital admission. In 166 patients (87.8%), prior attempts to obtain a peripheral IV access were made. In these patients, the average number of attempts was 2.0 (range, 1-6). Infiltration of the insertion site with lidocaine before BIG insertion (optional in the protocols) was performed on four patients. Injection of IO lidocaine (optional in the protocols) for local analgesia was performed on nine patients (4.8%).

### Type of Injury or Illness TOP

Thirty-four (18.0%) of the cases in which the BIG was deployed were trauma related. A primarily cardiac etiology was assessed to be the cause in 80 patients (42.3%). A primarily respiratory etiology was assessed to be the cause in 15 patients (7.9%).

### Success Rate TOP

In 172 of the patients, the BIG insertion resulted in good flow on the first attempt (91.0%) **Table 1**, in two additional patients, good flow was achieved on the second attempt. In one patient, the needle was dislodged during transport and a second needle was successfully inserted. In the 17 (9.0%) failed attempts, either the needle did not fire, was not securely placed in the bone, no flow was achieved, or there was extravasation.

**Table 1** Success Rate in the Different Age Groups and Causes

| Age Group/Cause | Number Successful | Number Unsuccessful | Percent Successful (%) |
|---|---|---|---|
| Total | 172 | 17 | 91.0 |
| Pediatric | 41 | 6 | 87.2 |
| >65 years old | 98 | 7 | 93.3 |
| Trauma | 27 | 4 | 87.1 |

**Table 1** Success Rate in the Different Age Groups and Causes

The causes in these cases were assessed by the caregivers to be device malfunction in six cases, technical insertion error in four cases, and remained unspecified in seven. In the 15 patients in which IO attempts (including repeat attempts when made) were unsuccessful, three were with traumatic injuries and five were in patients under 18 years (similar age and cause distribution as that of the entire group). Survival in this subgroup was 6 of 15 (40.0%) versus 50.6% in the patients in whom IO insertion was successful (not statistically significant).

## Use in Pediatric Patients TOP

Forty-seven of the patients were under 18 years of age. Fourteen had a palpable pulse, three had spontaneous respirations and only two were with a GCS of eight or higher. Thirteen pediatric patients were treated for trauma-related injuries (27.7%) (only one of them younger than 1 year of age), 10 patients below 1 year of age were found in cardiac arrest and in eight of them, medical personnel suspected SIDS as the cause (17.0%). Additional causes included drowning (n = 3), hanging (n = 1), and asphyxia from a foreign body (n = 1). Twenty-one patients were below the age of 1 year (44.7%), 23 between 1 and 8 years of age (48.9%) and 3 between 8 and 18 years (10.6%). An adult version of the BIG was used in the three pediatric patients who were more than 8 years of age.

## Use in Adult Patients TOP

One hundred forty-two of the patients were over 18 years of age. One hundred five of them were over the age of 65 years (77.5%) and 61 were over the age of 80 years (41.5%). In the above 80-year-old patient group, 59 of 61 insertion attempts were successful (96.7%). Seventeen patients were treated for trauma-related injuries (12.0%). In 80 patients, the cause was assessed to be of primarily cardiac origin (56.3%). Other causes included primarily respiratory etiologies, 16 patients (11.2%) (6 of them with suspected aspiration); sepsis, 7 patients; CVA, 3 patients; suspected overdose, 2 patients; and aortic dissection and DKA, 1 each, Figure 2.

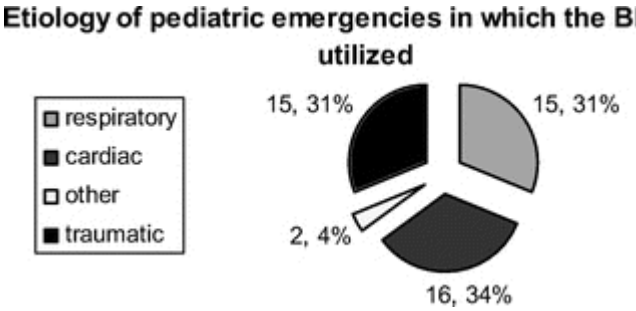


**Fig. 2.** *A pie chart showing the cause of pediatric emergencies in which the BIG was used.*

Hundred adult patients were found initially without a pulse. Thirty-one of them arrived at the hospital with a palpable pulse (31%). Forty-one adult patients were found initially with a palpable pulse, eight of them were pronounced dead on arrival to the hospital (25.8%).

## Use in Cardiac Arrest Nontrauma-Related Adult Patients TOP

Seventy-one of the patients were adult nontrauma-related cardiac arrest patients. The average age in this subgroup was 74.1 (SD 14.4). In 63 of them, good flow was achieved through the IO device (88.7%). Nineteen patients from this subgroup (26.8%) survived to hospital admission.

## DISCUSSION TOP

Obtaining vascular access in critically ill patients is of paramount importance. This is true both in the hospital and the prehospital setting. Such access is necessary for delivery of fluids and medications. Obtaining such access in a timely fashion is often difficult, resulting in delay or even inability to adequately treat critical patients. In the prehospital setting, care givers can be faced with additional obstacles, including inadequate light, a noisy and hostile environment, the need not to delay patient transport, and the inability in most EMS settings to insert a central venous line.

The use of IO injection has been widely advocated in life threatening situations both in the adult and pediatric population. The BIG inserts a metal needle into the bone marrow. Its main advantages are simplicity and minimal time requirements. Additionally, unlike hand-driven devices the BIG does not require the user to apply a large amount of force to penetrate the adult bone cortex.

The BIG in our study was used as part of protocol driven treatment algorithms in critical patients, when a peripheral vein was not accessible. The study describes our experience during a 4-year period (May 2000 to June 2004) in a nationwide EMS system. Data collection was performed prospectively, starting with the introduction of a new version of the BIG.

Most studies to date have reported the use of IOI in relatively small numbers of patients.[29,30,33,40,41] We report its use on 189 patients of all age groups and a wide variety of causes.

### Success Rate TOP

The success rate of the initial attempts was 91.0%. In two additional patients, a second attempt was successful raising the overall success rate to 92.1%. In at least four additional attempts, the failure was related to faulty operator technique. The high rate of success was apparent in all age groups and etiologies.

Since long term use of the device has not been evaluated it would seem prudent to limit the usage time of the BIG needle to 1 to 2 hours and to remove it as soon as alternative IV access has been secured.

### Pediatric Population TOP

Until recent years, the use of the IO route was mostly limited to the pediatric population. In the study population, the 47 pediatric patients constituted only 24.9%. Reflecting the mortality trends in children, most of the patients needing IOI at less than 1 year of age, were found pulse-less without apparent cause and most probably died as a result of SIDS. In the group of children over 1 year of age, the most common cause was trauma. Given that in our EMS system, over 90% of the cardiac arrest and prearrest situations involve adults, the relative frequency of use of IOI in pediatric patients is much higher.

### Adult Population TOP

Widespread use of IOI for adults has only been recommended in recent years. In this subpopulation, there is an even greater advantage for powered devices because of the difficulty in penetrating the adult bone cortex. The BIG had excellent success rates for young adults (mainly trauma related) and for the elderly (mainly cardiac). In the subgroup of patients above 80 years, success rate was over 96% (possibly as a result of an osteoporetic cortex allowing for easier needle penetration).

### Limitations TOP

The main limitation of our study is the lack of comprehensive patient follow-up after hospital admission. Additional limitations include a relatively small study group and the lack of control groups. The BIG in our setting was considered standard of care, precluding us from designing a control group in which an IO device would not be used. It would however be desirable to compare the BIG with other IO devices, such as the FAST or hand-driven devices, in patient care settings. Minor complications such as slight bleeding or hematoma formation might have seemed insignificant to the reporting paramedics and was therefore omitted from their reports.

As for infectious complications since mandatory reporting was required only regarding the prehospital course, some such complications may have occurred without being reported.

Additionally, although reporting was mandatory, it may have been omitted in some instances of BIG use.

## CONCLUSION TOP

Obtaining IV access in a timely fashion for critically ill patients is crucial in all treatment settings. Failure to obtain such access can be a major obstacle to adequate treatment, especially in prehospital settings. In our EMS system, the BIG has been successfully used as a salvage method in critical patients on whom an IV access is needed and a peripheral venous cannula could not be readily inserted. The use of the BIG was not limited by the patient's age or the cause of their condition. Our patient population included all age groups and a large number of elderly patients. The advantages of the BIG for our system include ease of use and short insertion time. The BIG is a potential life saving device. Our crews have used it to deliver vasoactive medications in arrest or prearrest patients, to deliver sedative medications in trauma patients, to facilitate endotracheal intubation, for delivery of IV fluids and in other treatment settings.

We think that the BIG or a similar I.O. device has a place in all EMS systems and possibly in emergency departments and other inhospital settings for use as a backup method for IV access in life-threatening situations when other methods of IV access fail or are unlikely to succeed.

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## EDITORIAL COMMENT TOP

This prospective study by Dr. Schwartz and colleagues represents the first large-scale description of an intraosseous infusion device. This bone injection gun is a fascinating and potentially useful device for a variety of clinical settings including the prehospital care of traumatically and nontraumatically ill and injured patients. Importantly, this device is Food and Drug Administration-approved in the United States as a resuscitation device for adults. In their study, these authors have wisely promulgated guidelines for the use of this product and have recommended that the device be used for only up to 1 1/2 hours and only for use as a backup method for IV access in life-threatening situations when other methods of IV access fail or are unlikely to succeed. This study demonstrates that the device can be successfully employed in the setting described in the authors' recommendations.

However, further studies will have to be performed in large groups of patients of all ages to document the complication rates of the device in regards to hematoma, local infection, bone injury (most notably in osteoporotic patients), and dislodgment. Also, although the device appears fairly straightforward to insert, the authors offer no range of insertion times or details of any

learning curves for trainees. Additionally, other studies will have to be performed (most likely in animal models) to determine the degree of success of resuscitation using this product compared with existing large-bore venous access before its true merits will be known. A final caveat about this device surrounds its popularity: if it becomes too utilized and not as a backup as the authors recommend, will experience with current venous access techniques wane or will more complications with the device dampen enthusiasm for its use? Only time and attention to prudence will establish the bone injection gun as a true advance in medical care.

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**Keywords:**

Intraosseous; Bone injection gun; Vascular access; EMS