IntraOsseous Devices – a Randomized Controlled Trial comparing three intraosseous devices

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Keywords: Intraosseous infusion, FAST1, Bone injection-gun, Jamshidi, RCT

Abstract

Access to the circulation is mandatory for adequate treatment in medical emergency situations. Intraosseous (IO) infusion is a safe, fast and effective alternative for gaining access to the circulation, if intravenous access fails. In the last decade, the IO method gained renewed interest. New devices have been developed, like the Bone Injection Gun 15G/18G (B.I.G.), and the First Access for Shock and Trauma 1 (F.A.S.T.1.).

Aim: To determine which IO needle can be used best for gaining IO access in patients requiring acute administration of fluids or medication in a prehospital setting.

Methods: In this single blinded prospective randomized trial, the IO needles were added to the equipment of the Helicopter Emergency Medical Service (HEMS). The HEMS nurses received training in proper use of all needles. Children (1-13 years) were randomized to the Jamshidi 15G or B.I.G. 18G, and adults (14 years or older) received the Jamshidi 15G, B.I.G. 15G or F.A.S.T.1.. All patients requiring acute administration of fluids or medication, without successful insertion of an i.v. catheter, were included. The intraosseous needles were compared in terms of insertion time, success rate, bone marrow aspiration, adverse events during placement, and user satisfaction.

Results: Sixty-five adult and 22 pediatric patients were included. The treatment groups were similar with respect to age, gender, mortality, and trauma mechanism ($p \geq 0.05$). The median insertion times ranged from 38 seconds for the Jamshidi 15G to 49 seconds for the B.I.G. 15G and 62 seconds for the F.A.S.T.1. ($p=0.004$). The devices did not differ with respect to success rates (adults overall 80% and children overall 86%), complication rates, and user satisfaction.

Conclusions: The Jamshidi 15G needle could be placed significantly faster than the F.A.S.T.1. The devices had similar success rates, complication rates, and user friendliness. Intra-osseous devices provide a safe, simple, and fast method for gaining access to the circulation in emergency situations.

Introduction

Access to the circulation is required for optimal treatment in emergency situations. The gold standard for vascular access is by use of an intravenous (i.v.) catheter. In certain (prehospital) emergency situations placement of an i.v. catheter is not feasible. It may for instance, be a challenge to establish i.v. access in patients with severe burn wounds, status epilepticus, major trauma, severe sepsis, or in hemodynamically unstable patients and in small children.[1-7] In addition, environmental factors may limit the success rate of gaining i.v. access.

Multiple animal and clinical studies have shown that intraosseous (IO) access is a safe, simple and effective technique for gaining vascular access in adults and children.[6, 8-16] An IO needle is a small hollow metal tube that can be inserted at different bone sites such as the distal and proximal tibia (Figure 1), femur, sternum, humerus, radius and clavicula.[17, 18] Even bones without medullary cavity such as the calcaneus may serve as insertion place.[13, 19-21]

Once the IO needle is properly inserted into the bone marrow, an infusion system can be connected to it. The IO route can be used for administering fluids, medication, crystalloids, colloids and blood products. Due to the unique and highly vascular trabecular network in the bone marrow, it is continuously being perfused, even during shock and hypotension. The administered compounds quickly enter the circulation from the intramedullary cavity. Medication administered intraosseously can be detected in the circulation almost as quickly as medication given intravenously.[13, 22-24] Bone marrow taken from an IO insertion location can be used to determine hemoglobin, sodium, potassium, magnesium, lactate, and calcium levels, blood group, and acid-base balance even during CPR.[13, 25-31]

IO infusion is an ancient technique and was widely used around 1940, but lost interest after the Second Wold War. In the last decade IO access gained renewed interest for use in emergency situations. This is reflected in the production of new intraosseous devices like the First Access for Shock and Trauma 1 (F.A.S.T.1.™)[32], Bone Injection Gun (B.I.G.) and, more recently, the EZ-IO (Vidacare, San Antonio, USA).

Moreover, gaining IO access is also included in several guidelines for clinical practice. The European Resuscitation Council (ERC) prescribes that intraosseous vascular access should be established in both pediatric and adult emergency patients if it is difficult or impossible to establish peripheral venous access for cardiopulmonary resuscitation.[33, 34] It is also included in the curricula for Advanced Trauma Life Support (ATLS)[35] and Advanced Paediatric Life Support (APLS).[36] In the Netherlands, IO devices are frequently used by Helicopter Emergency Medical Services (HEMS) and Emergency Medical Services (EMS), as well as at Emergency Wards.

The aim of this prospective randomized controlled trial was to determine which IO needle can be used best for gaining acute IO access in patients requiring acute administration of fluids or medication in the prehospital setting. One manual system (Jamshidi 15G) and two semi-automatic IO systems (B.I.G. 15G/18G and F.A.S.T.1.) were compared in this study.

Materials and Methods

Study design

The study was designed as a single-centre, and single-blinded, prospective randomized clinical trial. Patients were randomized between Jamshidi 15G, B.I.G. 15G/18G and F.A.S.T.1. (see Table 1 for specifications of these devices). The study was performed at a level I trauma center, serving over 4 million inhabitants (Erasmus MC, Rotterdam, the Netherlands) with a physician staffed HEMS. The HEMS team consists of an anaesthesiologist or a trauma surgeon with a HEMS nurse and a pilot. The local ethics committee approved the study protocol. The study started on June 21, 2006 and ended on March 5, 2009.

The power analysis performed preliminary to this study, was based on a study of Calkins *et al*[32] and data provided of the manufacturers, to show a difference in insertion time of 30 seconds between the different IO needles to detect significant results with 80% power.

Patients and material

All patients in the prehospital setting in which the HEMS provided additional medical support, requiring immediate fluid resuscitation or drugs, were considered eligible for inclusion after the HEMS or EMS nurse failed to successfully insert an i.v. catheter on two consecutive attempts, or when cardiopulmonary resuscitation (CPR) was needed. The HEMS physician decided whether or not an IO device was needed, based on these inclusion criteria. Since F.A.S.T.1. placement required an intact sternum, patients with a sternal anomaly or (suspected) sternal fracture were excluded. Patients below 1 year of age were also excluded.

Pediatric patients, aged 1-13 years, were randomized between the Jamshidi 15G or B.I.G. 18G. Adult patients, aged 14 years and older, were randomized between the Jamshidi 15G, B.I.G. 15G or F.A.S.T.1..

All HEMS nurses received training in proper use and placement of the three intraosseous

devices, prior to the start of the study. Special instruction and training sets were placed at the helicopter station. The training was repeated after one year.

All devices were ready for direct use, and were applied following the manufacturer's instructions. The IO needles should not be placed in fractured bones. Each device was packed separately in a blinded plastic container that was sealed with an adhesive label in random order. Boxes for adult and pediatric patients differed in colour. Each box contained an IO device, two 10ml syringes, 10ml saline 0.9%, 10ml Lidocaine 1%, a stopwatch, an information brochure for in-hospital physicians, and a data entry form to be completed by the HEMS nurse that inserted the IO needle. An adult- as well as a pediatric randomization box was added to the regular HEMS equipment. Upon decision of the attending HEMS physician, the HEMS nurse opened the container containing the IO device if the patient met the inclusion criteria, thereby being unblinded for the IO device to be positioned. Time measurement started directly after opening of the sealed container and stopped after administration of 10ml of saline when bone marrow aspiration was attempted. Aspiration of bone marrow is a strong indicator of correct placement of an IO needle. Therefore, correct placement of all needles was verified by aspiration of bone marrow and flushing with saline. After placement the nurse completed the data form. The insertion time, success, aspiration of bone marrow, side effects, medication given, trauma mechanism and user satisfaction were recorded. The user satisfaction was scored on a visual analogue scale (VAS), in which 0 implied the device was not user-friendly at all, and 10 implied the highest user-friendliness possible.

All study data were entered into an electronic database (Microsoft® Excel 2000). The IO devices were compared in terms of insertion times, success rates, adverse events during placement and user satisfaction. Also sex, age and trauma mechanism were recorded. Statistical analysis was performed by using the SPSS (Statistical Package for the Social Sciences) 16.0.1 statistical

software. Differences between groups were tested in terms of gender, mortality rate, trauma mechanism, success rate, bone marrow aspiration, and adverse events were analysed using the Chi square test. The Mann-Whitney U-test was used to assess differences between groups regarding user satisfaction, time for placement and age. For the adult patient group, Mann-Whitney U-test was performed for post-hoc pairwise comparisons upon a Kruskal-Wallis ANOVA. Correction for multiple comparison was performed where needed. A p-value <0.05 was considered statistically significant.

Results

During the study period 87 patients, 65 adult and 22 pediatric patients were included (Flowchart 1). In addition, five randomization boxes were opened by mistake for patients who did not meet the inclusion criteria; two patients with a clinical sternum fracture (F.A.S.T.1.), two adult randomization boxes for pediatric patients (Jamshidi and F.A.S.T.1.), one pediatric randomization box for an adult patient (B.I.G.). Tables 2 and 3 display patient demographic data. In both groups two-third of the patients was male. The adult patients had an average age of 43 years (P_{25}-P_{75} 25-59), the pediatric patients 7.5 years (P_{25}-P_{75} 2-11). Treatment groups showed no differences regarding these demographic characteristics. A high mortality rate of approximately 71% and 59% was seen in the adult and pediatric groups, respectively, during the resuscitation period prehospital or at the Emergency Department (ED). The main trauma mechanism was High Energetic Trauma (HET, all blunt trauma, were due to motor vehicle collisions 54.1%, fall from height 29.7%, person vs vehicle accidents 16.2% and non-specified 8.1%) (46% in adult patients versus 32% in pediatric patients) followed by Cardio Pulmonary Resuscitation (CPR, including medical and traumatic CPR) (20% versus 36%) and drowning (9% versus 9%). Convulsions (non-traumatic) and suicide attempts (including hanging, toxification and bloodletting) were infrequently seen. Also, isolated cases of severe burns, accidental strangulation, hypoglycaemia, carbon monoxide intoxication, stab injuries and electrocution were reported on a few occasions during this study.

All HEMS nurses participated and placed the randomly assigned IO needles. Each nurse performed 1-5 IO needle introduction procedures in the pediatric group and 3-19 in the adult group (p=0.4). The times needed for insertion are shown in Figure 2. The overall median insertion time was 50 (P_{25}-P_{75} 34-62) seconds. In the adult group, the Jamshidi 15G was placed fastest (median insertion time 37 seconds; P_{25}-P_{75} 30-49). This was significantly faster than placement of F.A.S.T.1. (median 62 seconds; P_{25}-P_{75} 50-131) (p=0.002). Time needed to insert the B.I.G. 15G (median 49 seconds; P_{25}-P_{75} 33-60) did not differ statistically significantly from

the other devices. In the pediatric group the median insertion time of the Jamshidi 15G was 43 (P_{25}-P_{75} 33-79) seconds versus 48 (P_{25}-P_{75} 28-65) seconds for the B.I.G. 18G (p=0.74).

Table 4 and 5 display the IO needle insertion characteristics such as success rate, bone marrow aspiration, adverse events and user satisfaction for the adult and pediatric group, respectively. No statistically significant difference was noted with respect to the rate of successful placement between the different types of IO needles in adults and in children. Successful placement of the IO needle was confirmed by bone marrow aspiration in over 80% both in the adult and the pediatric patient group. The overall score of user satisfaction was 9.8 (P_{25}-P_{75} 9.2-9.9) in both the adults and pediatric group. This was similar in all groups (p>0.05). The number of needles inserted during the study by each HEMS nurse did not correlate significantly with either the success rate or the rating of user satisfaction (data not shown).

Twenty-one adverse events occurred (i.e., 18 in the adult patients, 3 in pediatric patients), however at similar rates in each treatment group (p>0.05). In the adult group; two Jamshidi 15G needles bent during insertion, in one case the needle was malpositioned. In 5 cases, a hemostat was needed to remove the trocar of the B.I.G. 15G. In two cases the B.I.G. 15G needle did not penetrate the cortex and in two cases the B.I.G. 15G was wrongly positioned next to the bone. After insertion of the F.A.S.T.1. the infusion tube was pulled out during withdrawal of the introducer in one case. In one case there was reasonable blood loss at the location of the 'bone-cluster'. Also, the needle was malpositioned in one case, and in one case it was not possible to remove the safety cap from the infusion tube. One procedural error was reported in case of a F.A.S.T.1.; the removal tool got lost during transport to the Intensive Care Unit (ICU) and the HEMS nurses had to bring a new removal tool. In the pedriatric group, three adverse events occurred with the B.I.G. 18G. In one case extravasation was reported and in one case the needle was wrongly positioned next to the bone. In one case the nurse could not remove the trocar.

Discussion

The aim of this study was to investigate which IO needle could be used best for gaining acute IO access in patients requiring immediate fluids or drug therapy, in cases where gaining i.v. access failed. On average, the median insertion times showed that the Jamshidi needles were placed faster as compared to the F.A.S.T.1.. The devices (adult and pediatric) did not differ statistically significantly with respect to success rate, complication rates and user satisfaction.

Although there were no significant differences in complication rates, all needles showed different types of complications possibly coherent to the insertion method. Insufficient perforation of the cortex or misplacement may be caused by the mechanical mechanism in both devices, which replaces the manual pressure that is needed for placement of the Jamshidi needle. Tactile references may be important to assure correct positioning.

All three IO devices tested were considered user friendly. Medical personnel are able to use the different types of IO devices after appropriate training.[37] Depending on circumstances a rational decision should be made in favor of a particular IO device. For example, military medics have to carry all their medical equipment. In this situation it can be better to use a light and small IO needle like the Jamshidi or B.I.G., but the sternum is a preferred insertion location since it is well protected in a bullet-proof vest and the sternum is easy reachable in a helicopter or ambulance (F.A.S.T.1.).

Clinical and practical disadvantages of the F.A.S.T.1. include the complexity of the device and the number of different parts. All parts are supplied in one pack, which is quite bulky. Care should be taken to prevent separate parts from getting lost. This may be a potential problem when using the device at the accident scene, particularly in windy and dark situations, but also when the patient is transported to a different department or ward within the hospital. During the current study, there was one case in which the infusion tube was removed without using the removal tool and the metal tip was left behind in the sternum. This did not have consequences for this patient. After this incident the nurses were instructed to tape the removal tool to the

patient. In this study, we used a F.A.S.T.1., which required the use of a specialized removal tool. Pyng has adapted their model of the F.A.S.T.1., and in the latest released version a removal tool is no longer needed. Although a F.A.S.T.1. for use in pediatric patients is under development, the current device is indicated for use in adult patients only.

Apart from differences in complexity there are also considerable differences in prices of the different IO needles. The newer, more sophisticated, IO devices are much more expensive than the simple and easy to use manual IO needles.

All IO needles tested should be applied in less than 60 seconds according to the different manufacturers. This was observed in our study only on several occasions, more often longer time was needed for identification of the correct site, insertion, aspiration, and flushing.

A limitation of the current study is the lack of patient follow-up, therefore the number of complications encountered might be slightly underestimated. Not much is known about complication rates after IO infusion. Only a few complications of IO infusion have been reported, but some can have devastating results. Complications reported include myonecrosis, osteomyelitis, epiphysiolysis, fat/air embolism and fractures do occur.[38-43] No cases of osteomyelitis or myonecrosis was brought to our attention during the course of the current study. However, it should be noted the in the current study patients were transported to 16 different hospitals spread over the Soutwestern part of the Netherlands, and accurate collection of follow-up data concerning complications was not successful. Due to the high injury severity of the study population, a high mortality rate at the ED was observed. An accurate assessment of complication rates requires additional research in a larger study population, with a longer follow up period

A post hoc power analysis showed that groups of at least 300 IO needles would have been needed to detect significant results with a power of 90% between all IO needles. During the study period IO access was used on 92 occasions. We expected to place 60 IO needles a year, based on the registration of IO infusion during the year prior to the study. During the study

period a new IO needle, the EZ-IO, a battery-powered electric drill, was introduced in the Netherlands. The EZ-IO was not included in this study, as it was not approved for use on the Dutch market at the time the trial started. Many EMS started using the EZ-IO and often an IO needle was inserted before arrival of the HEMS. The EZ-IO is at this moment becoming more and more popular in North America and Europe, and should be compared to other IO devices in further research.

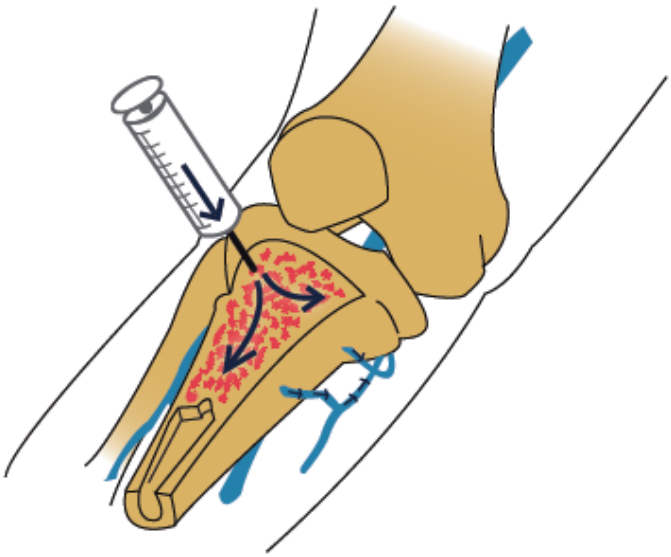
Conclusion

Creating vascular access is crucial, during the initial treatment of patients in life threatening situations. I.v. access remains the gold standard and should not be replaced, but the IO technique is a good alternative if i.v. catheter placement is not possible. The Jamshidi needle was placed significantly faster, compared with the F.A.S.T.1. in the adult group and had a success percentage of 91%. The devices, Jamshidi, B.I.G. and F.A.S.T.1. did not differ statistically significant with respect to success rate, complication rate and user friendliness in both the adult and the pediatric group. However, the Jamshidi did not statistically differs from the B.I.G., there seems to be a trend in favor towardsthe use of the Jamshidi needle, the least costly of the three devices tested, in terms of placement time, success rate, and adverse events may be noted. These differences may become statistically significant in larger patients group.

Acknowledgements

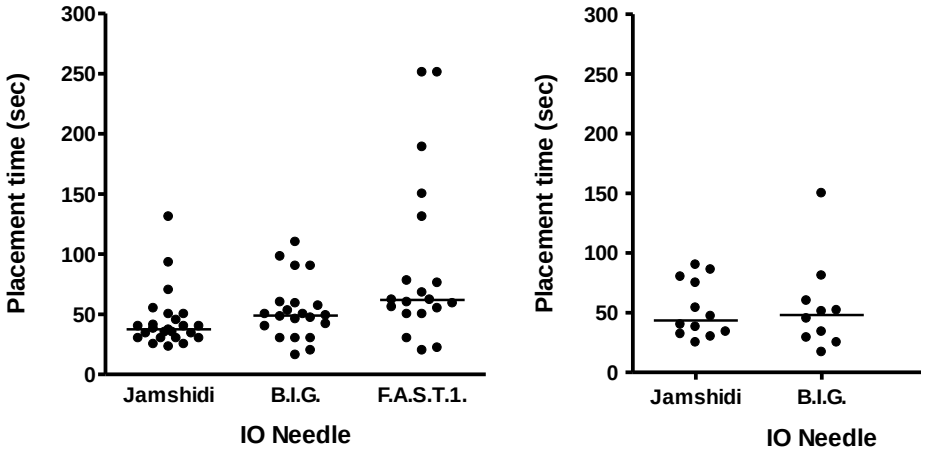
We like to thank the personnel of the HEMS, Lifeliner 2, for their participation and support for this study. We also like to thank manufacturers, Waismed for donating the Bone Injection Guns and Pyng Medical Corporation for donating F.A.S.T.1. devices. The Dutch liability insurance company for medical personnel Medirisk financially supported this study.

Figure 1. Insertion of an IO needle at the proximal tibia



The IO needle is positioned in the highly vascular intramedullary cavity.

Figure 2. Time needed for insertion of IO needles



Adult group Pediatric group

Dots represent insertion times for individual patients. Lines represent the median insertion time per type of device. Adult group: Jamshidi 15G versus B.I.G.15G p=0.091, Jamshidi 15G versus F.A.S.T.1. p=0.002, F.A.S.T.1. versus B.I.G. 15G p=0.053, Pediatric group Jamshidi 15G verus B.I.G. 18G p=0.74 B.I.G., Bone Injection Gun; F.A.S.T.1.. One insertion time is missing in the B.I.G. (adult) group.

Table 1. Characteristics of IO devices

	Jamshidi 15G	**B.I.G. 15G and 18G**	**F.A.S.T.1.**
Manufacturer	Cardinal Health, Ohio, USA	WaisMed Ltd, New York, USA	PYNG Medical Corporation, British Columbia, Canada
Insertion method	Manual rotation and pressure	Preloaded spring	Manual pressure
Insertion location	Long bones	Long bones	Sternum only
Insertion depth adjustable	Yes	Yes	No
Removal tool needed	No	No	Yes
Weight in grams	18	99	160
Package dimensions l x w x h cm	22.8 x 8.7 x 1.2	16.5 x 7.5 x 3.0	20.5 x 20.0 x 4.1
Package	Soft	Hard	Soft
Price (Euros)	€ 26.90	€ 58.20	€ 140.00
Reusable	No	No	No

Table 2. Patient characteristics for the adult group

	Overall	**Jamshidi 15G**	**B.I.G. 15G**	**F.A.S.T.1.**	***p*-value**
N	65	24	22	19	
Males[1]	42 (64.6%)	11 (45.8%)	15 (68.2%)	16 (84.2%)	0.030[+]
Age[2]	43 (25-59)	45 (38-62)	40 (28-67)	26 (20-49)	N.S.[*]
Mortality[1]	46 (70.8%)	16 (66.7%)	16 (72.7%)	14 (73.7%)	N.S.[+]
Trauma mechanism[1]					N.S.[+]
- HET	30 (46.2%)	9 (37.5%)	9 (40.9%)	12 (63.2%)	
- CPR	13 (20.0%)	7 (29.2%)	3 (13.6%)	3 (15.8%)	
- Drowning	6 (9.2%)	2 (8.3%)	1 (4.5%)	3 (15.8%)	
- Epilepsy	2 (3.1%)	1 (4.2%)	1 (4.5%)	0 (0.0%)	
- Attempted Suicide	3 (4.6%)	2 (8.3%)	1 (4.5%)	0 (0.0%)	
- Other	11 (16.9%)	3 (12.5%)	7 (31.8%)	1 (5.2%)	

Data are shown as [1]numbers with percentage within brackets or as [2] median with P_{25}-P_{75} within brackets. 'Other' includes for the Jamshidi electrocution, hypoglycaemia, severe burns, for the B.I.G. septic shock, explosion, severe burns, stab injuries, CVA, status epilepticus and a plasma deficiency, for the F.A.S.T.1. a collaps. [+]Chi square test, [*] Kruskal Wallis Anova. P-values <0.05 were considered statistically significant. B.I.G., Bone Injection Gun; F.A.S.T.1., First Access for Shock and Trauma; N.S., Not Significant; HET, High Energy Trauma; CPR, Cardiopulmonary Resuscitation.

Table 3. Patient characteristics for the pediatric group

	Overall	**Jamshidi 15G**	**B.I.G. 18G**	***p*-value**
N	22	12	10	
Males[1]	15 (68.2%)	10 (83.3%)	4 (44.4%)	N.S. [+]
Age[2]	7.5 (2.0-11.0)	9.5 (2.5-12.5)	6.5 (2.0-8.7)	N.S.[*]
Mortality[1]	13 (59.1%)	7 (58.3%)	6 (60.0%)	N.S.[+]
Trauma mechanism[1]				N.S.[+]
- HET	7 (31.8%)	4 (33.3%)	3 (30.0%)	
- CPR	8 (36.4%)	5 (41.7%)	3 (30.0%)	
- Drowning	2 (9.1%)	1 (8.3%)	1 (10.0%)	
- Epilepsy	1 (4.5%)	0 (0.0%)	1 (10.0%)	
- Attempted Suicide	-	-	-	
- Other	4 (18.2%)	1 (16.7%)	2 (20.0%)	

Data are shown as [1]numbers with percentage within brackets or as [2] median with P_{25}-P_{75} within brackets. 'Other' includes for the Jamshidi CO-intoxication and electrocution, for the B.I.G. severe burns and strangulation. [+]Chi square test, [*] Kruskal Wallis Anova. P-values <0.05 were considered statistically significant. B.I.G., Bone Injection Gun; N.S., Not Significant; HET, High Energy Trauma; CPR, Cardiopulmonary Resuscitation.

Table 4. IO needle placement characteristics in the adult group

Device	**Overall**	**Jamshidi 15G**	**B.I.G. 15G**	**F.A.S.T.1.**	***p*-value**
N	65	24	22	19	
Success rate[1]	52 (80.0%)	22 (91.7%)	13 (59.1%)	17 (89.5%)	0.010[+]
Bone Marrow aspiration[1]	43 (66.2%)	21 (87.5%)	11 (50.0%)	11 (57.9%)	0.018[+]
Insertion location					
- Proximal tibia	45 (69.2%)	23 (95.8%)	22 (100%)	0 (0.0%)	
- Iliac crest	1 (1.5%)	1 (4.2%)	0 (0.0%)	0 (0.0%)	
- Sternum	19 (30.2%)	0 (0.0%)	0 (0.0%)	19 (100%)	
Adverse events[1]	18 (26.1%)	3 (12.5%)	9 (40.9%)	5 (26.3%)	N.S.[+]
VAS user satisfaction[2]	9.8 (9.2-9.9)	9.8 (8.8-9.8)	9.8 (9.3-9.9)	9.7 (9.3-9.9)	N.S.[*]

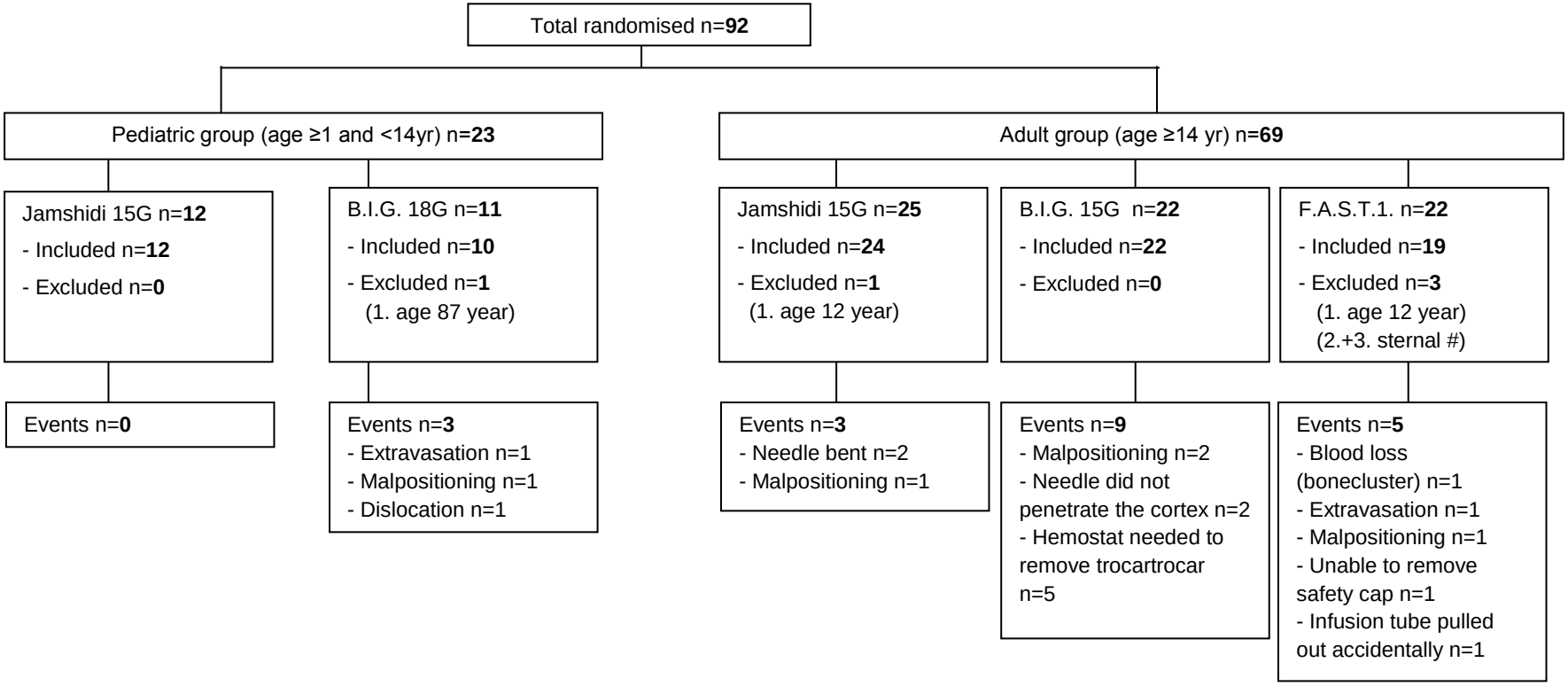
Data are shown as [1]numbers with percentage within brackets or as [2] median with P_{25}-P_{75} within brackets. [+]Chi square test, [*] Kruskal Wallis Anova. P-values <0.05 were considered statistically significant. B.I.G., Bone Injection Gun; F.A.S.T.1., First Access for Shock and Trauma; N.S., Not Significant; VAS, Visual Analogue Scale

Table 5. IO needle placement characteristics in the pediatric group

Device	**Overall**	**Jamshidi 15G**	**B.I.G. 18G**	***p*-value**
N	22	12	10	
Success rate[1]	19 (86.4%)	12 (100%)	7 (70.0%)	N.S. [+]
Bone Marrow aspiration[1]	17 (77.3%)	10 (83.3%)	7 (70.0%)	N.S. [+]
Adverse events[1]	3 (13.6%)	0 (0.0%)	3 (30.0%)	N.S. [+]
VAS user satisfaction[2]	9.8 (9.3-9.9)	9.8 (9.3-9.9)	9.8 (5.8-9.9)	N.S.[*]

Data are shown as [1]numbers with percentage within brackets or as [2] median with P_{25}-P_{75} within brackets. VAS, Visual Analogue Scale; [+] Chi square test, [*] Mann-Whitney U-test. P-values <0.05 were considered statistically significant; B.I.G., Bone Injection Gun; N.S., Not Significant.

Flowchart 1.



Flowchart of patients included and excluded for adults and children and events during the study period. Sternal #, sternal fracture.

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