A New System for Sternal Intraosseous Infusion in Adults

Andrew Macnab, MD, Jim Christenson, MD, Judy Findlay, PEng, MASc, Bruce Horwood, MD, David Johnson, PhD, Lanny Jones, Kelly Phillips, Charles Pollack, Jr., MD, David J. Robinson, MD, Chris Rumball, MD, Tom Stair, MD, Brian Tiffany, MD, PhD, Max Whelan, MD

Abstract

Background. Intraosseous (IO) infusion provides an alternative route for the administration of fluids and medications when difficulty with peripheral or central lines is encountered during resuscitation of critically ill and injured patients. **Objective.** To report the first 50 uses of a new system for emergency IO infusion into the sternum in adults, the Pyng F.A.S.T.1 IO infusion system. **Methods.** Six emergency departments and five prehospital emergency medical services (EMS) sites in Canada and the United States provided clinical and/or research data on their use of the IO system in a pilot study of success rates, insertion times, and complications. Indications for use included adult patient, urgent need for fluids or medications, and unacceptable delay or inability to achieve standard vascular access. A basic data set was standardized for all sites, and some sites collected additional data. **Results.** The overall success rate for achieving vascular access with the system was 84%. Success rates were 74% for first-time users, and 95% for experienced users. Failure to achieve vascular access occurred most frequently in patients (5 of 9) described subjectively by the user as "very obese," in whom there was a thick layer of tissue overlying the sternum. Mean time to achieve vascular access was 77 seconds. Flow rates of up to 80 mL/min were reported for gravity drip, and more than 150 mL/min by syringe bolus. Pressure cuffs were also used successfully, although fluid rate was controlled by clamping the line. Further research on flow rates is needed. No complications or complaints were reported at two-month follow-up. **Conclusion.** These early data indicate that sternal IO infusion using the new F.A.S.T.1 IO system may provide rapid, safe vascular access and may be a useful technique for reducing unacceptable delays in the provision of emergency treatment. **Key words:** intraosseous infusion; sternum; adult; vascular access; intravenous; central line.

PREHOSPITAL EMERGENCY CARE 2000;4:173–177

There is controversy in the literature concerning the use of intravenous (IV) infusions by paramedics, particularly in trauma patients.[1,2] Resuscitation in the field is hampered by the time and difficulty associated with initiating IV therapy (reported to be as high as 12 minutes in one service),[3–5] the high access failure rate (10–40%),[6] and the small volumes of fluid that are typically administered.[7] In the urban setting, the long delays caused by often unsuccessful attempts to initiate IV therapy and stabilize the patient (25 minutes or more) result in higher morbidity and mortality than the "scoop and run" approach.[5,8] However, other centers have reported much shorter access times and higher success rates, and emphasize the need for physician supervision of paramedic care to ensure appropriate use of the technique.[1,6,9]

In the 1980s, alternatives to IV cannulation were investigated for situations in which peripheral IV access was unsuccessful, particularly the prehospital environment, and the pediatric population. Over the past two decades, intraosseous infusion (IOI) into the tibia has become a widely accepted procedure for the resuscitation of critically ill and injured children.[10–14] Intraosseous infuson is now considered to be "an effective, reliable and relatively simple technique both for obtaining rapid vascular access and for the administration of fluids and medications in the emergency setting," but is almost exclusively limited to the pediatric population.[15]

The only recent report of the use of IOI in the adult population[16] reported no difference between sternal IOI and peripheral vascular access in terms of blood pressure response, and no complications.

According to a recent report by Halvorsen et al.,[17] the best anatomic site for performing IOI has not yet been determined. There have been reports of the successful use of the adult tibia as a site for IOI,[18] but it is not considered to be an ideal site because of the phys-

Received August 7, 1999, from the University of British Columbia (AM, JC, CR, MW), Vancouver, British Columbia, Canada; the Division of Critical Care, Children's and Women's Health Centre of British Columbia (AM), Vancouver, British Columbia, Canada; the Emergency Department, St. Paul's Hospital (JC), Vancouver, British Columbia, Canada; Pyng Medical Corp. (JF, DJ), Vancouver, British Columbia, Canada; the Emergency Department, Maricopa Medical Center and Arizona Heart Hospital (BH, CP, BT), Phoenix, Arizona; Rural/Metro Ambulance (BH, BT), Phoenix, Arizona; EMS Med Flight One (LJ), Richmond, Virginia; Bates County Hospital (KP), Butler, Missouri; the Emergency Department, University of Maryland Medical Center, VA Hospital (DJR, TS), Baltimore, Maryland; the Emergency Department, Royal Columbian Hospital (CR), New Westminster, British Columbia, Canada; and Erways Ambulance Service (MW), Elmira, New York. Revision received December 8, 1999; accepted for publication December 8, 1999.

Supported in part by the Science Council of British Columbia's Technology BC Program. Equipment and training were provided by Pyng Medical Corp. Some authors (JF, DJ) are shareholders in Pyng Medical Corp., a publicly traded company.

Address correspondence and reprint requests to: Andrew J. Macnab, MD, Room 2L5, ICU Physician's Office, Children's and Women's Health Centre of British Columbia, 4480 Oak Street, Vancouver, British Columbia, V6H 3V4, Canada. e-mail: <amacnab@wpog.childhosp.bc.ca>.

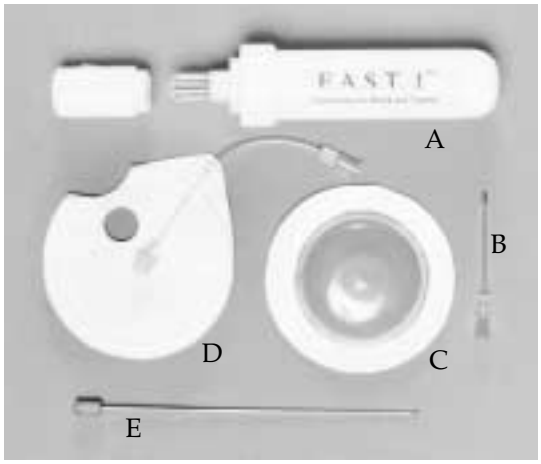

FIGURE 1. The F.A.S.T.1 intraosseous infusion system introducer and target/strain relief patch. **A** = introducer; **B** = infusion tube; **C** = protector dome; **D** = target/strain relief patch; **E** = remover.

iologic replacement of the red marrow in the tibia by less vascular yellow marrow or fat by the fifth year of life.[7,17] In addition, adult multiple trauma victims often suffer fractures of the peripheral long bones and vascular compromise of the extremities.[17]

The pelvis is an alternative site, but its marrow space has a complex shape, and a predomination of yellow marrow has been reported in 22% of cadavers studied.[7] Although the marrow space in the pelvis is large, it is covered by a thick layer of cortical bone (2.8–6 mm) and a highly variable layer of skin and subcutaneous adipose tissue.

The sternum is likely the site of choice in adults for a number of reasons: 1) the sternal body is large, is relatively flat, and can be readily located by unskilled practitioners; 2) the sternum retains a high proportion of red marrow; 3) it has a thinner, more uniform cortical bone covering (1.5–2.5 mm) overlying a relatively uniform marrow space (6–11 mm anteroposterior)[7,19]; 4) it is less likely to be fractured than the extremities, particularly at the level of the manubrium; and 5) there is no appreciable time lag between central infusion and IOI of most substances.[7,17]

Intraosseous infusion into the adult sternum is now possible with the use of the F.A.S.T.1 IOI system (First Access for Shock and Trauma, Pyng Medical Corp., Vancouver, BC, Canada). The system was developed to provide rapid, safe, reliable IO access for fluid and drug administration in adults for first responders and other emergency care providers; and to do so without the requirement for high levels of training or sophisticated skills. We report the first 50 uses of the F.A.S.T.1 system for emergency IOI into the sternum in adults.

DEVICE DESIGN

The F.A.S.T.1 system (Figs. 1 and 2) includes a handheld introducer that allows a caregiver to insert a flexible infusion tube with a stainless-steel tip to a predetermined depth in the sternal manubrium (Fig. 3). Fluids or drugs are delivered through the infusion tube to the marrow space and then flow out the emissary veins, where they rapidly enter the central circulation. Several design features prevent overpenetration of the sternum. A bone probe detects the anterior surface of the bone, allowing the user to place the infusion tube tip a preset distance into the marrow space, and a mechanism releases the handle from the stylet and infusion tube to prevent the user from pushing the infusion tube beyond the preset depth. The system also includes an adhesive patch that is applied to the skin in alignment with the suprasternal notch. The only site preparation that is required is standard aseptic technique. An opening in the patch indicates the optimal insertion site, and anchored connector tubing protects the infusion tube from external forces transmitted from the IV tubing. A clear, rigid plastic dome attaches to the patch with Velcro tape to protect the insertion site. The push–pull insertion action minimizes insertion time. The system includes a small flexible stylet that fits inside the infusion tube and threads into the portal for removal. The system is approved by the U.S. Food and Drug Administration and the Canadian Health Protection Branch.

The purpose of this pilot study was to determine the efficacy of the device in terms of success rates, insertion times, flow rates, and complications.

METHODS

Six emergency departments and five prehospital emergency medical services (EMS) sites in Canada and the United States provided medical and/or research data on their use of the IO system in a pilot study of success rates, insertion times, and complications. The EMS sites included a large urban EMS serv-

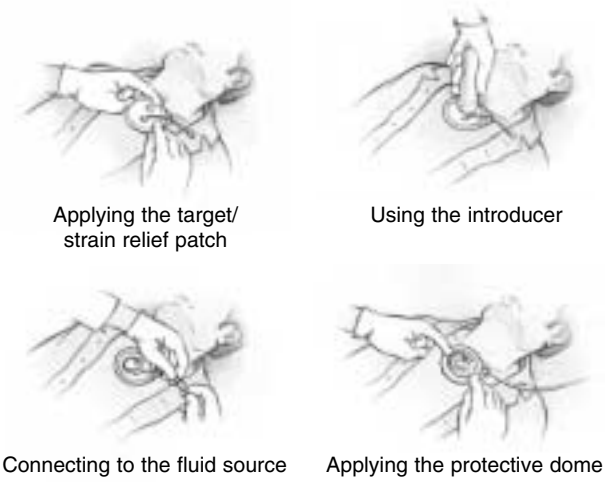

FIGURE 2. Vascular access using the F.A.S.T.1 intraosseous infusion system.

ice operated by a major international EMS service provider, a leading state police air ambulance service, a small rural public EMS service in the midwest, and a smal, rural private EMS service in upstate New York. All participants had the approval of their local ethics and/or protocol approval boards. None of the EMS service providers required institutional review board (IRB) clearance or waiver of IRB clearance, as all were operating on locally-approved medical protocols rather than research protocols. Informed consent was obtained at some sites when possible. If consistent with the urgency of the need for vascular access, lidocaine with epinephrine was injected at the insertion site for conscious patients.

Indications for use include adult patient, urgent need for fluids or medications, and unacceptable delay or inability to achieve standard vascular access. An exception to these indications were those patients enrolled in a study of flow rates and insertion times conducted in consenting, anesthetized patients undergoing coronary artery bypass surgery. Recommended exclusion criteria are small patient size (theoretically, sternum thickness less than 6.5 mm, but in practice achieved by excluding those aged less than 16 years, and those not appearing to be of "adult" size); previous sternotomy; evidence of severe skin compromise such as trauma, infection, or burns over the insertion site; fracture or vascular injury that would compromise the integrity of the manubrium or its vascularization; and very severe osteoporosis or other obvious bone pathology. In addition, the manufacturer advised that success rates are likely to be lower in obese patients who have a very thick layer of tissue overlying the sternum.

A basic data set was standardized for all sites. Some sites collect additional data. Timing of insertion was performed by the user's partner using a stopwatch or sweep second-hand watch. Data were collected using a questionnaire either administered by telephone by third-party research project assistants or completed by the user. Whenever possible, questionnaires were completed within 24 hours of system use. Data were entered into an Excel spreadsheet (Microsoft, Redmond, WA), and descriptive statistics were used to analyze the data.

RESULTS

Of the first 50 uses of the IO system, 21 were by physicians in hospital and 29 were by paramedics in prehospital settings. There were 36 unconscious patients, 13 conscious patients, and one whose level of consciousness was unrecorded. Seven of the conscious patients were consenting IV drug users. Four of the unconscious patients were anesthetized for surgery. The ages of patients ranged from 14 to 84 years. Diagnoses included cardiac arrest (n = 15), trauma (n = 9), surgery for cardiac bypass grafting (n = 4), status epilepticus (n = 1), IV drug abuse with complications (n = 4), cancer (n = 1), diabetes (n = 2), and hypovolemia/hypothermia (n = 1). Diagnosis was unknown in 13 prehospital patients for whom follow-up data were not collected. In 15 patients, peripheral and/or central lines were attempted unsuccessfully prior to the use of the IO system.

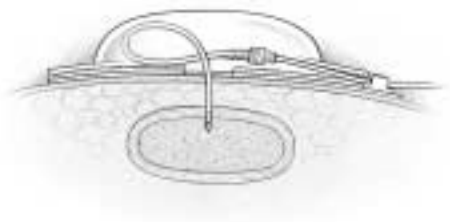

FIGURE 3. Anatomic placement of the F.A.S.T.1 bone portal in the manubrium.

Vascular access, defined as fluid flow into the patient, was achieved in 42 of the 50 patients (84%). Vascular access was achieved in 39 patients on the first attempt, two on the second attempt, and one on the third attempt. Repeat insertion attempts were performed only if there was no penetration of the bone on previous attempts. The success rate of vascular access for users with training but no previous clinical experience with the IO system was 74% (n = 27); for those with at least one previous IO device use, 95% (n = 22); and for one, IO experience was unknown. Vascular access was achieved in four of nine (44%) "very obese" patients. In two of the other three cases in which vascular access was not achieved, there was failure to penetrate the bone. The third of these patients had had three previous sternotomies (an exclusion criterion), but insertion was attempted as a lifesaving measure.

Mean access time, defined as length of time from opening the package to commencement of fluid flow, is reported in Table 1. One patient, for whom a 15-minute lapse between decision to insert to time of insertion was unexplained, was deemed to be an outlier and excluded. Access times were not reported for conscious IV drug users, because patient comfort rather than rapid vascular access was the priority.

A variety of fluids, blood products, and medications were delivered through the system. Reported open-line flow rates with a drip set ranged from 15 mL/min to 80 mL/min and "fast streaming in the drip chamber." Inadequate flow rate was reported for one patient. Initially sluggish flow rates in some patients were improved by flushing the line with a small bolus of saline (10 mL) from a syringe. Delivery of fluid using a pressure cuff was reported in three cases, with desired flow rates of up to 70 mL/min achieved.

Conscious patients who had IO insertion following the lidocaine protocol (n = 9) reported little or no pain during the insertion. All IV drug users at one site who

TABLE 1. Vascular Access Time (in Seconds) Using the F.A.S.T.1 Intraosseous Infusion System on Patients for Whom Access Times Were Recorded (n = 31)

Users	Mean Access Time	Median Access Time	Range	Number of Uses	Standard Deviation
All users	77	60	30–300	31	51
First-time users	79	60	30–300	19	59
Experienced users	73	60	30–180	12	39
Physicians	88	66	30–300	14	72
Paramedics	68	60	30–120	17	24

had previous experience with central lines (n = 6) preferred IOI to a central line. Rate of fluid boluses in these patients was titrated to subjective reports of chest discomfort, but maintenance infusions were not associated with pain.

Infusion tubes were left in place for an average of 7.5 hours (range 15 minutes to 24 hours, n = 15). Follow-up data are limited due to the low survival rate of this patient population and the lack of access to follow-up data for patients in the prehospital arm of the study. There were no complications or complaints at two-week, one-month, or two-month follow-up (n = 11, including all seven conscious IV drug users).

Minor complications include localized bleeding at the time of insertion, and bruising, swelling, redness, or tenderness at the site at the time of device removal. Kinking of the infusion tube was reported for 11 of the first 30 uses (37%) and four of the remaining 20 uses (20%). Difficulty with use of the removal tool, primarily with threading the tool into the bone portal, was reported by users in 12 cases. Two devices required removal using a small incision and two stitches.

All of the users reported their intentions to continue using the IO system in their practices.

DISCUSSION

Intraosseous infusion is an established concept and is recommended in resuscitation guidelines such as Basic Trauma Life Support for adults and Pediatric Advanced Life Support. Historically, reluctance on the part of physicians to incorporate IOI in their practices has been partly attributable to the lack of an ideal device, concerns about complications, and lack of experience with or exposure to the technology. In addition, the role of the paramedic in prehospital resuscitation is expanding, and the IO route lends itself well to this environment. The present device was the subject of extensive scientific development to address many of these issues.

The success rate in this study for first-time users with minimal training (74%) demonstrates the ease and accuracy with which the device can be inserted. With even limited experience, the success rate increased to 95%, for an overall success rate of 84%. This indicates that the device is well designed for its intended use, and has the potential for successful use in resuscitation in a variety of emergency settings.

Failure to achieve vascular access occurred most frequently in patients described subjectively by the user as "very obese," in whom there was a thick layer of tissue overlying the sternum. However, 44% of insertions in these patients were successful, suggesting that although caution should be exercised in this group, the use of the device is not precluded.

Mean time to achieve vascular access was 77 seconds. This is well within acceptable limits in the clinical setting, and better than is frequently achieved for

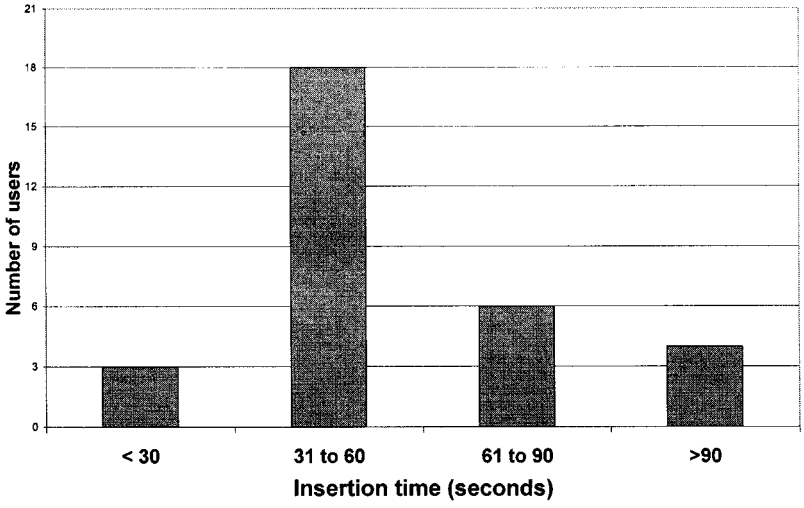

FIGURE 4. F.A.S.T.1 insertion time, all users.

peripheral intravenous access in the prehospital setting.

Flow rates of up to 80 mL/min were reported for gravity drip and more than 150 mL/min by syringe bolus. This flow rate is in excess of the flow rate required on a sustained basis in the majority of resuscitations. Delivery of fluid at 10–80 mL/min was achieved using a pressure cuff on the fluid bag in three cases, but in two of these cases fluid flow rate was controlled by line clamping. In general, information about flow rates was limited, and further research on flow rates is needed.

No complications or complaints were reported at two-month follow-up. This addresses one of the main concerns expressed by participating physicians—the risk of complications such as infection or overpenetration.

Areas for design improvement identified by study participants included kinking of the tubing and difficulties with removing the device. Kinking is being addressed through changes in the length and shape of the infusion tubing and the type of luer connection. The manufacturer made subsequent design changes to improve the removal tool, and is currently developing an infusion tube that does not require a removal tool.

LIMITATIONS AND FUTURE STUDIES

Limitations of the study are recognized. Data were collected from both study sites and early field use. A basic data set was collected from all sites, but additional data were not available from every site for every use. This was a pilot study, and further research will be needed to confirm these early findings. Suggested areas for study include flow rate measurements in the clinical setting using both gravity and pressure flow, follow-up for complications, and outcome studies comparing the system with other methods of vascular access in the prehospital and critical care settings.

CONCLUSION

These early data indicate that sternal IOI using the new F.A.S.T.1 IO system may provide rapid, safe, and effective vascular access and may be a useful technique to reduce unacceptable delays in the provision of emergency treatment.

The authors thank Susak Management Associates for their assistance with project management and manuscript preparation.

References

1. Border JR, Lewis FR, Aprahamian C, Haller JA, Lenworth MJ, Luterman A. Panel: prehospital trauma care—stabilize or scoop and run? J Trauma. 1983;23:708–11.
2. Stapczynski JS. Fluid resuscitation in traumatic hemorrhagic shock: challenges, controversies and current clinical guidelines. Emerg Med Rep. 1994;1515(25):241–50.
3. McSwain GR, Garrison WB, Artz CP. Evaluation of resuscitation from cardiopulmonary arrest by paramedics. Ann Emerg Med. 1980;9:341–5.
4. Rosetti V, Thompson BM, Aprahamian C, et al. Difficulty and delay in intravenous access in pediatric arrests [abstract]. Ann Emerg Med. 1984;13:406.
5. Smith JP, Bodai BI, Hill AS, Frey CF. Prehospital stabilization of critically injured patients: a failed concept. J Trauma. 1985;25:65–70.
6. Lewis FR. Prehospital intravenous fluid therapy: physiologic computer modelling. J Trauma. 1986;26:804–11.
7. Kramer GC. Intraosseous resuscitation progress report. Davis, CA: Department of Human Physiology, University of California, Davis, Mar 1990.
8. Gervin AS, Fischer RP. The importance of prompt transport in salvage of patients with penetrating heart wounds. J Trauma. 1982;22:443–8.
9. Jones SE, Nesper T, Alcouloumre E. Prehospital intravenous line placement: a prospective study. Ann Emerg Med. 1989;18:244–6.
10. Fiser DH. Intraosseous infusion. Curr Concepts. 1990;322: 1579–81.
11. Glaeser PW, Hellmich TR, Szewczuga D, Losek JD, Smith DS. Five-year experience in prehospital intraosseous infusions in children and adults. Ann Emerg Med. 1993;22(7):1119–24.
12. Guy J, Haley K, Zuspan SJ. Use of intraosseous infusion in the pediatric trauma patient. J Pediatr Surg. 1993;28:158–61.
13. Hodge L. Intraosseous infusions: a review. Pediatr Emerg Care. 1985;1:215–8.
14. Miccolo MA. Intraosseous infusion. Crit Care Nurse. 1990;10(10):35–47.
15. Cameron JL, Fontanarosa PB, Passalaqua AM. A comparative study of peripheral to central circulation delivery times between intraosseous and intravenous injection using a radionuclide technique in normovolemic and hypovolemic canines. J Emerg Med. 1989;7:123–7.
16. Chavez-Negrete A, Cruz SM, Munari AF, Perches A, Arguero R. Treatment of hemorrhagic shock with intraosseous infusion or intravenous infusion of hypertonic saline dextran solution. Eur Surg Res. 1991;23:123–9.
17. Halvorsen L, Bay BK, Perron PR, et al. Evaluation of an intraosseous infusion device for the resuscitation of hypovolemic shock. J Trauma. 1990;30:652–9.
18. Valdes MM. Intraosseous fluid administration in emergencies. Lancet. 1977;i:1235–6.
19. Morozov IA, et al. Morphological foundation for determining the site and technique of obtaining bone marrow from the sternum. Arkhiv Anatomii Gistologii I Embriologii [Russia]. 1973;65(11):103–8.