Volunteer Studies of Pain Management during Intraosseous Infusion

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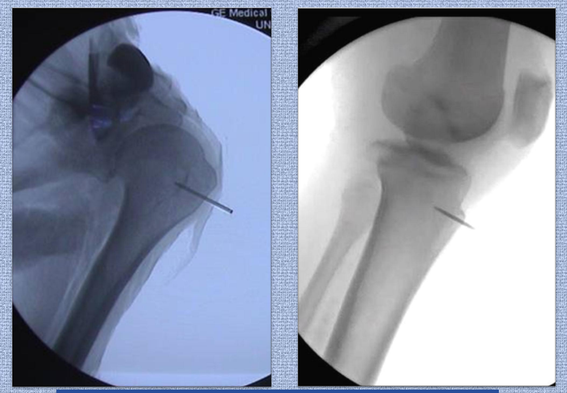
Introduction

Intraosseous (IO) access is an effective tool for vascular access when patients have emergent, urgent or medically necessary conditions and traditional intravenous access is difficult.[1–2] In the majority of cases, two actions are required for optimal IO infusions: a syringe flush after initial catheter insertion and use of a pressure device (pressure bag or infusion pump) for fluid administration. One study found mean pain levels reported by patients with a Glasgow Coma Score of >12 increased from 3,5 on insertion to 5.5 with pressurized infusion.[3] For alert patients, managing the pain associated with the pressure required for optimal IO infusions is imperative.

Two healthy human volunteer studies were designed to evaluate the effectiveness of 2% preservative-free lidocaine to mitigate the pain at two dose ranges (phase 1), various infusion flow pressures and interventions and to compare the level of pain experienced during IO infusion between the tibial and proximal humeral sites.



Images courtesy of the University of Texas Health Science Center at San Antonio

Materials and Methods

- Two non-randomized studies were approved by the IntegReview Institutional Review Board and conducted in a dedicated multi-specialty research facility.
- 10 healthy pain-free volunteers recruited as subjects for each study
- Visual Analog Scale (VAS) with 1-10 index was explained to subjects and used for pain assessments in both studies
- I5 gauge catheter placed (25mm or 45mm length depending on site and tissue depth) each site (EZ-IO, Vidacare Corporation, Shavano Park, TX)
- If pain reached level of 5 or greater at any time pressure was released and subject was given additional 20mg lidocaine

Phase 1: Tibial Study

- 10 subjects received 15g IO insertions in both tibia
- Left tibia received:
  - —40 mg lidocaine slow injection over ~ 2 minutes
  - —10 ml normal saline flush
  - —20 mg lidocaine injected over 30 seconds
- Right tibia received:
  - —80 mg of lidocaine slow injection over ~ 2 minutes
  - —10 ml normal saline flush
  - —20 mg lidocaine injected over 30 seconds
- Pressure infusion started @ 100 mmHg
- Pressure increased by 50 mmHg every 60 seconds up to 300 mmHg
- Pain scores recorded for each pressure interval

Observation period- Right tibia

- Pressure set to 200 mmHg for normal saline infusion
- Observed up to 90 minutes following 2nd lidocaine injection
- Pain assessed every 10 minutes
- Additional 20mg lidocaine given for pain scores ≥ 5

Phase 2: Humeral Study

- 10 subjects received 15g IO insertions in both proximal humeri
- Left humerus accessed for blood draw
  - —IO catheter removed
  - —Site dressed
- Right humerus received
  - —40 mg lidocaine slow injection over ~ 2 minutes
  - —10 ml normal saline flush
  - —20 mg lidocaine injected over 30 seconds
- Pressure infusion started @ 100 mmHg
- Pressure increased by 50 mmHg every 60 seconds up to 300 mmHg
- Pain scores recorded for each pressure interval

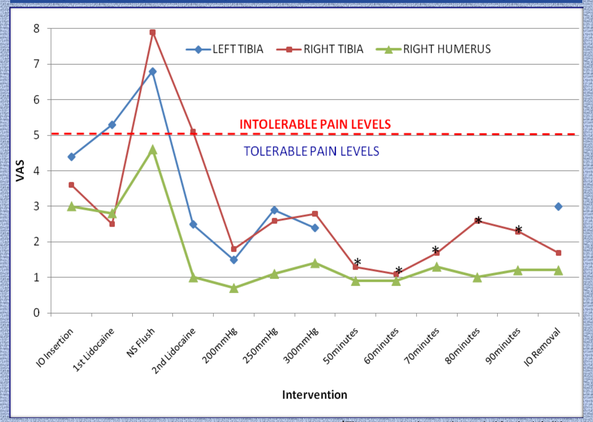
Observation period- Right humerus

- Pressure set to 200 mmHg for normal saline infusion
- Observed up to 90 minutes following 2nd lidocaine injection
- Pain assessed every 10 minutes
- Additional 20mg lidocaine given for pain scores ≥ 5

Results

- All IO insertions successful on first attempt.
- The mean IO insertion VAS pain scores:
  - –Left tibia: 4.4 ± 2.6
  - –Right tibia: 3.6 ± 2.3
  - –Right humerus:3.0 ± 1.5
- Highest mean VAS pain score for both studies during normal saline flush
  - –Left tibia: 6.8 ± 2.9
  - –Right tibia: 7.9 ± 2.8
  - –Right humerus: 4.6 ± 2.9
- Tibial observation period
  - –8 of 10 subjects required additional 20 mg lidocaine; subjects previously received 100 mg of lidocaine on initial insertion
  - –Mean elapsed time before additional dosing 39 ± 20 minutes.
- Humeral observation period:
  - –No subjects required additional lidocaine; subjects previously received 60 mg of lidocaine on initial insertion

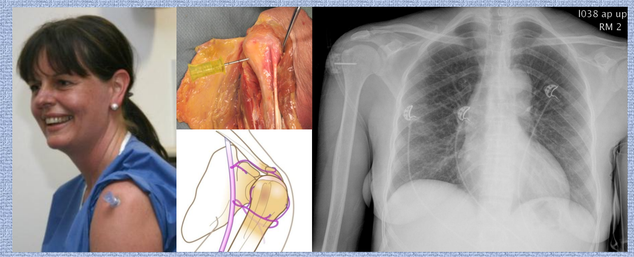
Mean participant pain levels (VAS) during various interventions and pressures



*There was no observation period for the left tibia

Conclusion

In conscious patients requiring IO infusion, the proximal humerus site should be strongly considered (if patient condition allows) over the tibial site for optimal pain control. A dose of 40 mg 2% lidocaine followed by a 10mL flush then additional 20mg provided for minimal pain during prolonged infusion in this study. Lower pain was reported in the humerus than in the tibia during the flush and all infusion pressures. settings.



Limitations

- Volunteer subjects rather than actual patients: investigators opted to use volunteers due to the difficulty studying pain in clinical, especially emergent, settings. Considerations included getting IRB approval; distracting physical and psychological stressors in emergency environment; difficulty obtaining consent and expecting caregivers to collect pain level data while performing multiple tasks.
- Small sample size

References

1. Hoskins S, Nascimento P, Espana J, et al. Pharmacokinetics of intraosseous drug delivery during CPR. *Shock*. 2005;23:35.
2. Paxton JH, Knuth TE, Klausner HA. Proximal humerus intraosseous infusion: A preferred emergency venous access. *J Trauma* 2009:67:606-611.
3. Fowler RL, Pierce A, Nazeer S et al. 1,199 c;23ase series: Powered: intraosseous insertion provides safe and effective vascular access for emergency patients. *Annals of Emergency Medicine* 2008;52(4):S152.