Project Title

Randomized, Controlled Study of Ultrasound-Guided Peripheral Venous Access Using AccuCath Versus Ultrasound-Guided Conventional Intravenous Catheter in the Emergency Department

Principal Investigators

Gregg Helland, MD
Yong Suh, MD, MBA, MSc

Co-Investigators

Thomas Spiegel, MD, MBA, MS

Background & Significance

Peripheral venous cannulation is among the most common procedures performed in clinical settings and is a prerequisite for fluid resuscitation, administration of medications, and diagnostic testing[1,2]. In the United States, approximately 300 million peripheral intravenous catheters (PIV) are inserted annually[1], and more than 25% of all visits to the emergency department require intravenous catheters for parenteral fluid administration[3]. Providers in the emergency department have become adept at establishing peripheral venous access, but it is estimated that PIV insertion fails for 6 million patients annually[1].

Many factors are thought to be associated with difficult venous access, which is typically defined to be at least two failed attempts at establishing intravenous access[3]. Intravenous drug abuse, obesity, multiple hospitalizations, and chronic medical problems including diabetes, sickle cell disease, end-stage renal disease, and cancer are predisposing factors for difficult venous access[2-5]. Prior studies have reported prevalence of difficult venous access ranging from 8% to 23%[2-5]. Failure to establish peripheral venous access in the emergency department is a costly problem, leading to delays in diagnostics and treatment and requiring alternative sites for vascular access such as external jugular, intraosseous, or central venous access[3]. These alternative methods can lead to higher complications rates, decrease patient satisfaction, and increase utilization of nursing and physician time[6]. Central venous catheterization, which is often used when traditional venous cannulation methods fail, has an overall complication rate of 15%, and complications include arterial puncture, pneumothorax, deep vein thrombosis, and infection[7,8]. These complications pose a significant financial burden to the healthcare system, as the cost associated with a single central venous catheter related infection in 2002 was estimated to be $34,508 to $56,000 and the median payout for claims resulting from central venous catheter related injuries was $100,750[2].

In the past few decades, ultrasound guidance has greatly improved the process of localizing vessels for cannulation, especially in patients with abnormal vascular anatomy or difficult venous access, thereby providing many benefits over landmark-based techniques. Ultrasound guided venous cannulation dates back to 1984, when Legler and Nugent showed that the single pass success rate for internal jugular (IJ) cannulation could be improved to 77.3% using Doppler ultrasound versus 28.6% for the traditional landmark-based approach[9]. Since the report of real-time ultrasonographic guidance of IJ catheter placement by Yonei et al. in 1986[10], ultrasound guided central venous cannulation has repeatedly been shown to increase success rates, decrease complication rates, and improve patient satisfaction[1,2,11-15]. Based on the advantages offered by ultrasound guidance, the Agency for Healthcare Research and Quality now recommends real-time ultrasonographic guidance for all central venous access[13,16].

The ultrasound-guided approach was adapted for peripheral venous access in the emergency department by Keyes et al. in an uncontrolled study that demonstrated a 91% success rate for ultrasound-guided cannulation of brachial and basilica veins[17]. A subsequent controlled study validated a higher success rate in the ultrasonographic (97%) versus control (33%) group in patients identified to have difficult PIV access and also showed that the ultrasonographic group required less time to successful cannulation, fewer percutaneous punctures, and resulted in greater patient satisfaction than the traditional landmark-based approach[13]. Furthermore, ultrasound-guidance for peripheral venous cannulation has been shown to prevent the need for central venous catheterization in 85% of patients with difficult venous access[2] and used 40% fewer kits per patient than landmark-guided placement of catheters[11,18]. In a healthcare climate that is increasingly focused on outcomes and cost-effectiveness, ultrasound-guided peripheral venous cannulation has become not only a viable but often the preferred method in patients with difficult venous access.

Nevertheless, studies to date on ultrasound-guided peripheral venous cannulation have revealed some shortcomings. Conventional IV catheters placed under ultrasound guidance have been prone to premature failure with failure rates of 8%[7,17] in the first hours after placement and 47% in the first 24 hours, most commonly due to infiltration[7]. These failure rates are significantly higher compared with 2% at 24 hours and 10% at day 4, which has been reported for standard peripheral IV catheters[7,19]. Moreover, while overall success rates range from 90% to 100% with multiple attempts[2,7,13,20], first attempt success rate has been less impressive, ranging from 46% to 71%[13,20]. Our study will assess whether the AccuCath catheter with its integrated guidewire can address these shortcomings and demonstrate superiority over conventional PIV catheters across clinical outcomes relevant to the emergency department setting.

While catheters with guidewires have long been used when placing central and arterial lines, they have largely been absent from PIV placement. The AccuCath catheter is differentiated from conventional IV catheter in two principal ways. The catheter material consists of polyether block amide, which is a thermoplastic elastomer with softness and flexibility designed to decrease vessel wall irritation and mechanical phlebitis[21]. In addition, the integrated guidewire facilitates catheter insertion and limits vessel damage[21]. A prospective, randomized, controlled study has shown a first attempt success rate of 89% for AccuCath versus 47% for conventional IV along with lower complication rates of 8% for AccuCath and 52% for conventional IVs[21]. This study was performed in an inpatient setting on patients receiving elective, non-emergent PIVs[21]. Our study will be important in determining whether AccuCath's superior first attempt success rate and lower complication rate can be replicated in emergent PIVs in the emergency department setting. These improvements could translate to cost savings from decreased utilization of physician and nursing time, fewer number of PIV catheters used, higher patient satisfaction from fewer percutaneous punctures, and less complications from infiltration and phlebitis.

Purpose & Hypotheses

The objectives of the study are to:

1. In patients who fail traditional non-ultrasound IV catheter placement, compare ultrasound-guided cannulation of AccuCath catheters versus ultrasound-guided cannulation of conventional IV catheters in ED patients across the following clinical parameters: first attempt success rate, procedure time from the point of first percutaneous puncture to successful cannulation, total number of percutaneous punctures required for successful cannulation, and total number of IV

catheters required for successful cannulation.
2. Assess patient and provider satisfaction with each catheter system on a 5-point Likert scale.
3. Check for clinical and demographic differences between patient groups that were successfully cannulated on first attempt versus those that required multiple attempts.

We hypothesize that:
1. Ultrasound-guided cannulation of AccuCath IV catheters will demonstrate a higher first attempt success rate, require less procedure time, require fewer percutaneous punctures, and utilize fewer catheters than ultrasound-guided cannulation of conventional IV catheters in ED patients.
2. Patients and providers will be more satisfied with AccuCath IV catheters versus conventional IV catheters in the ED setting.
3. There will be no statistically significant clinical and demographic differences between patient groups that are successfully cannulated on first attempt versus those that required multiple attempts.

Methods

I. Subject population (Patients)

a. Inclusion criteria
- English speaking patients, male or female, aged ≥18 years presenting to the UCMC Mitchell ED with Emergency Severity Index (ESI) from 1 to 5 anytime during Monday through Sunday.
- Capable and willing to provide informed consent
- Acceptable candidate for ultrasound-guided PIV per Mitchell ED protocol (i.e. 3 failed attempts by nurses- 2 by primary nurse, 1 by senior nurse)

b. Exclusion criteria
- Lack of decisional capacity (e.g., intoxication, dementia, delirium, developmental delay)
- Prior venous grafts or surgery at target IV site

II. Subject population (Providers)

UCMC emergency faculty and resident physicians.

III. Study implementation

1. Provider consent

We will obtain oral consent from UCMC emergency faculty and resident physicians, and nurses who have previously undergone ultrasound-guided PIV training, scheduled to work in the Mitchell Emergency Department during the study period. Typically, providers will be consented for participation in the study as group during academic conference hours or during ultrasound-guided PIV training sessions for nurses.

2. Patient recruitment and IV placement

We will use an unbiased mechanism for identifying a random cohort of ED patients. We will generate a randomization schedule for two treatment groups using 25 blocks of 20 patients. We expect to enroll a total of 500 patients in our study, 250 patients in each treatment arm.

A written patient consent form will explain that patients will be randomized to receive either ultrasound-guided cannulation of an AccuCath catheter (Group A) or ultrasound-guided cannulation of a

conventional IV catheter (Group B). The consent form will also explain that anonymized records of their clinical and demographic information will be used for research purposes. Patients will be able to refuse to participate in our study.

If a patient agrees to participate in the study, he or she will undergo either ultrasound-guided cannulation of an AccuCath catheter or ultrasound-guided cannulation of a conventional PIV catheter, both of which are currently used in clinical practice. Following ultrasound-guided IV cannulation, patients will be asked to respond to survey questions that will assess patient satisfaction with the IV catheter received and will document past history of IV drug use, smoking, dialysis, difficult IV stick, diabetes, sickle cell disease, cancer chemotherapy, hypertension, and congestive heart failure.

3. Provider's assessment

Providers will be required to complete a standardized form documenting the ultrasound-guided IV cannulation procedure. The form will ask for: laterality of IV site, number of percutaneous punctures, procedure time, number of IV's used, overall satisfaction with IV catheter.

4. Data acquisition

All patients admitted to the ED at UC are identified using hospital and physician records, including patient age, gender, and race. Relevant demographic data along with emergency severity index, body mass index, blood pressure, and past history of IV drug use, smoking, dialysis, difficult IV stick, diabetes, sickle cell disease, cancer chemotherapy, hypertension, and congestive heart failure will be collected from the patients or extracted from EPIC and used to understand the demographic and clinical characteristics of our study participants, with PHI exclusions. The analysis of the data will help us understand the generalizability of our findings based on the characteristics of our study population.

Protocol Duration

2 years

Research Location(s)

UCMC (Mitchell Hospital, Emergency Department)

Special Precautions

Special precautions will be taken throughout the data collection process, including:

1. Performance results of AccuCath vs conventional IV catheters

In order to avoid influencing care decisions, all clinicians and patients will be blinded to aggregate performance results comparing AccuCath IV versus conventional IV catheters. Only study personnel will have access to aggregate results comparing AccuCath IV with conventional IV catheters.

2. MRN and Study ID

The study ID will be linked to the MRN in a password-protected database. No one besides the specified study personnel will have access to the records or data.

3. Clinical Data

Clinical data will be entered directly to a password-protected database. No one besides the specified study personnel will have access to the records or data.

4. Satisfaction survey data

Patient satisfaction survey data will be entered directly to a password-protected database. No one besides the specified study personnel will have access to the records or data.

5. Provider's assessment data

Providers will indicate their assessment of catheter performance on a form that will be collected and accessed only by the study personnel. The data will be transferred to a password-protected database, and the physical copies will be destroyed as soon as data transfer is completed.

Statistical Analysis

Our primary outcome will compare the first attempt success rate of ultrasound-guided AccuCath IV cannulation versus that of ultrasound-guided conventional IV cannulation in ED patients. Our sample size of 250 patients for each treatment group has been 80% powered to detect a difference of 10% (2-sided, α=0.05). Our secondary outcome measures include procedure time from the point of first percutaneous puncture to successful cannulation, total number of percutaneous punctures, total number of IV catheters used, and patient satisfaction.

We will also check for clinical and demographic differences that may have contributed to difficult venous access.

Potential Benefits and Risks to Subjects

The risks associated with the use of our experimental catheter are comparable to the anticipated risks of standard IV therapy, which include infection, infiltration, extravasation, phlebitis, dislodgement, bleeding, hematoma, and pain at IV site. There is possibility that the experimental catheter's guidewire could cause intimal damage, but the guidewire has been designed specifically to minimize this risk, which is shared by conventional IV catheters.

References

1. Adhikari S, Blaivas M, Morrison D, Lander L. Comparison of infection rates among ultrasound-guided versus traditionally placed peripheral intravenous lines. J Ultrasound Med. 2010;29(5):741-7.
2. Au AK, Rotte MJ, Grzybowski RJ, Ku BS, Fields JM. Decrease in central venous catheter placement due to use of ultrasound guidance for peripheral intravenous catheters. *Am J Emerg Med*. 2012;30(9):1950-4.
3. Fields JM, Piela NE, Au AK, Ku BS. Risk factors associated with difficult venous access in adult ED Patients. *Am J Emerg Med*. 2014;32(10):1179-82.
4. Elia F, Ferrari G, Molino P, et al. Standard-length catheters vs long catheters in ultrasound-guided peripheral vein cannulation. *Am J Emerg Med*. 2012;30(5):712–6.
5. Lapostolle F, Catineau J, Garrigue B, et al. Prospective evaluation of peripheral venous access difficulty in emergency care. *Intensive Care Med*. 2007;33(8):1452–7.
6. Mahler SA, Wang H, Lester C, Skinner J, Arnold TC, Conrad SA. Short- vs long-axis approach to ultrasound-guided peripheral intravenous access: a prospective randomized study. *Am J Emerg Med*. 2011;29(9):1194-7.
7. Dargin JM, Rebholz CM, Lowenstein RA, Mitchell PM, Feldman JA. Ultrasonography-guided peripheral intravenous catheter survival in ED patients with difficult access. *Am J Emerg Med*. 2010;28(1):1-7.
8. McGee DM, Gould MK. Preventing complications of central venous catheterization. *N Engl J*

Med. 2003;348(12):1123-33.
9. Legler D, Nugent M. Doppler localization of the internal jugular vein facilitates central venous cannulation. *Anesthesiology*. 1984;60(5):481-2.
10. Yonei A, Nonoue T, Sari A. Real-time ultrasonic guidance for percutaneous puncture of the internal jugular vein. *Anesthesiology*. 1986;64(6):830-1.
11. Miller AH, Roth BA, Mills TJ, Woody JR, Longmoor CE, Foster B. Ultrasound guidance versus the landmark technique for the placement of central venous catheters in the emergency department. *Acad Emerg Med*. 2002;9(8):800-5.
12. Denys BG, Reddy PS. Ultrasound-assisted cannulation of the internal jugular vein. *Circulation*. 1993; 87:1557–62.
13. Costantino TG, Parikh AK, Satz WA, Fojtik JP. Ultrasonography-guided peripheral intravenous access versus traditional approaches in patients with difficult intravenous access. *Ann Emerg Med*. 2005;46(5):456-61.
14. Randolph AG, Cook DJ, Gonzales CA, et al. Ultrasound guidance for placement of central venous catheters: a meta-analysis of the literature. *Crit Care Med*. 1996;24:2053-2058.
15. Mallory DL, Shawker TH. Ultrasound guidance improves the success rate of internal jugular vein cannulation. *Chest*. 1990;98:157-160.
16. Rothschild JM. Ultrasound guidance of central vein catheterization: making healthcare safer: a critical analysis of patient safety practices. Agency for Healthcare Research and Quality Publication No. 01-E058. http://www.ahrq.gov/clinic/ptsafety.
17. Keyes LE, Frazee BW, Snoey ER, Simon BC, Christy D. Ultrasound-guided brachial and basilic vein cannulation in emergency department patients with difficult intravenous access. *Ann Emerg Med*. 1999;34(6):711-4.
18. Thompson DR, Gualtiere E, Deppe S, et al. Greater success in subclavian vein cannulation using ultrasound for inexperienced operators. *Crit Care Med*. 1994;22:A189.
19. Catney MR, Hills S, Wakefield B, et al. Relationship between peripheral intravenous catheter dwell time and the development of phlebitis and infiltration. J Infus Nurs 2001;24(5):332-41.
20. Gregg SC, Murthi SB, Sisley AC, Stein DM, Scalea TM. Ultrasound-guided peripheral intravenous access in the intensive care unit. *J Crit Care*. 2010;25(3):514-9.
21. Idemoto BK, Rowbottom JR, Reynolds JD, Hickman Jr RL. The AccuCath Intravenous Catheter System With Retractable Coiled Tip Guidewire and Conventional Peripheral Intravenous Catheters: A Prospective, Randomized, Controlled Comparison. *The Journal of the Association for Vascular Access*. 2014;19(2):94-102.