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Coronal mode ultrasound guided hemodialysis cannulation: A pilot randomized comparison with standard cannulation technique

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Original Article

Access

Coronal mode ultrasound guided hemodialysis cannulation: A pilot randomized comparison with standard cannulation technique

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Abstract

Background: Infiltrations from cannulation result in significant morbidity including loss of hemodialysis (HD) vascular access (VA). Cannulation is dependent on personnel skill and VA characteristics. Surface marking of VA lacks real-time information and traditional ultrasound (US) devices are large, expensive, requiring skilled operators. Sonic Window© (Analogic Ultrasound, Peabody, MA, USA) is a coronal mode ultrasound device (CMUD) approved for VA cannulation.

Methods: Single center randomized, prospective pilot study comparing handheld US-guided cannulation of new arteriovenous fistula (AVF) to standard cannulation practices. Patients with end stage renal disease (ESRD) on in-center HD who had a new AVF cleared for cannulation and dialysis were enrolled. Patients with new AVF received either standard cannulation (control group) or image guidance using CMUD (study group) for 3 weeks. Ultrasound characteristics of VA, cannulation practices and complications end points were obtained.

Results: An infiltration rate of 9.7% was noted during the study. Slightly lower odds ratio (OR) of infiltration was observed in the study group (OR 0.94, 95% CI: 0.26–3.41, P value = 0.93). Study group yielded longer time for assessment (101.8 ± 80.2 vs. 22.3 ± 22.5 seconds, P = < 0.001), increased cannulation time (41.1 ± 70.6 vs. 25.0 ± 27.9 seconds, P = 0.04), and increased patient satisfaction (94.6% vs. 82%, P = 0.04) compared to control group. Number of cannulation attempts, needle size, arterial or venous needle insertion, and tourniquet usage between groups were not statistically different.

Conclusion: Handheld ultrasound is a safe and useful aid in cannulation of dialysis access.

Key words: Arteriovenous fistula, cannulation, handheld device, hemodialysis, infiltration, ultrasound guidance

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Conflict of Interest: On behalf of all co-authors and I being the corresponding author, I here by state that results presented in this paper have not been published previously in whole or part, except in abstract format.

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INTRODUCTION

The arteriovenous fistula (AVF) is the preferred form of vascular access (VA) for hemodialysis.[1] Transformation from "Fistula First Breakthrough Initiative" to "Fistula First Catheter Last Strategy" illustrates a dual front battle in obtaining a reliable dialysis access. AVF maturation failure has been indicated as a hindrance in achieving high fistula prevalence.[2] Secondary procedures to improve AVF maturation are growing.[3] Less than 10% of fistulae are successfully cannulated with two needles and reported infiltration rates are high (2.98 times more likely to have infiltration in an AVF of 6 months or less vintage).[4,5] Infiltration risk is highest in the early cannulation phase of a new AVF. Infiltration episodes lead to more diagnostic tests, costly interventions and prolongation of catheter use.

The method of access cannulation has not seen major changes in decades. The current techniques depend upon tactile sensation. Skin marking including tattoo or photographic image are frequently used to aid cannulators. Surface markings lack real-time information and are not well-studied.[6] A possible solution could be utilization of ultrasound guidance for AVF cannulation. In 2002, the Agency for Healthcare Research and Quality first proposed that ultrasound guidance for central line insertion as an evidence-based safety solution.[7] In 2011, the Centers for Disease Control and Prevention also listed the use of ultrasound as a safety solution to prevent catheter-related bloodstream infection.[8] Ultrasound guided access of both the artery and vein in other procedures has demonstrated superiority over physical examination.[9,10] Although usage of ultrasound-guidance for cannulation of veins is now well accepted in various procedures, its utilization data during cannulation of dialysis access is minimal.

Value of ultrasound assisted AVF cannulation is a function of quality and cost. Dialysis access cannulation encounters certain unique challenges. Dialysis technicians or nurses are frequently trained on-the job. Patients are dialyzed in shifts using special chairs with dialysis machines in close proximity. Any delay in patient care leads to ripple effects on work flow, patient care, and staff management. Infection control practices in hemodialysis centers are heavily regulated and closely scrutinized. Traditional ultrasound machines have a relatively large footprint making it clumsy to employ them routinely for access cannulation. It requires a certain level of staff competency to operate the device and can be a challenge in meeting regulatory requirements for infection control of devices. These and other factors have led to poor utilization of ultrasonography for in-center hemodialysis access care.

The Sonic Window (Analogic Ultrasound, Peabody, MA, USA) is a novel C mode handheld ultrasound device approved as a VA cannulation aid. It is portable with a small footprint and has smart touch technology for single hand use. The device has been predominantly used for peripheral intravenous line placement and has not yet been evaluated for guiding cannulation of dialysis access on a systematic basis in an in-center hemodialysis setting.

A theoretical concern would be the effect of ultrasound usage in dialysis centers on its workflow. Staff training and time involved in preparation, usage, and maintenance could impact the daily activities of dialysis units. Improper use of an US device can result in complications and loss of access. Anecdotal incidental usage of conventional US devices for patient with difficult access has been reported in the past, but continuation as a standard of practice for cannulation has not been evaluated. We propose that C mode ultrasonography can be utilized on a routine basis during cannulation of new AVFs at in-center hemodialysis units with no increased risk of complications.

SUBJECTS AND METHODS

Study design and eligibility criteria

We designed a randomized, prospective pilot study comparing handheld ultrasound guided cannulation of AVF to standard cannulation practices in patients with end stage renal disease (ESRD). A pilot study is performed to examine roles, feasibility, recruitment, retention, assessment, and implementation of a novel therapy or intervention. It is not intended to test a hypothesis.[11] Although, no set sample size has been recommended, literature suggests sample size of 10–30 to 10% of the intended sample.[12] This was a proof of concept study to demonstrate that a handheld ultrasound device can be used as a dialysis access cannulation aid. The study was not designed to show a noninferiority or superiority at this level. Cost effectiveness would require further studies to evaluate effect and cost associated with downstream complications arising from an infiltration.

Ten ESRD patients with new AVF cleared for cannulation were approached to participate in the study. We assumed 5 patients in each arm with maximum of 18 cannulations in 9 dialysis sessions (each dialysis requires two needle cannulations) will yield up-to 90 cannulations per study arm. New AVF were chosen as they are more prone to needle infiltration and significant consequent morbidity. Clearance for fistula use was provided by vascular surgery as per site specific practices (physical examination

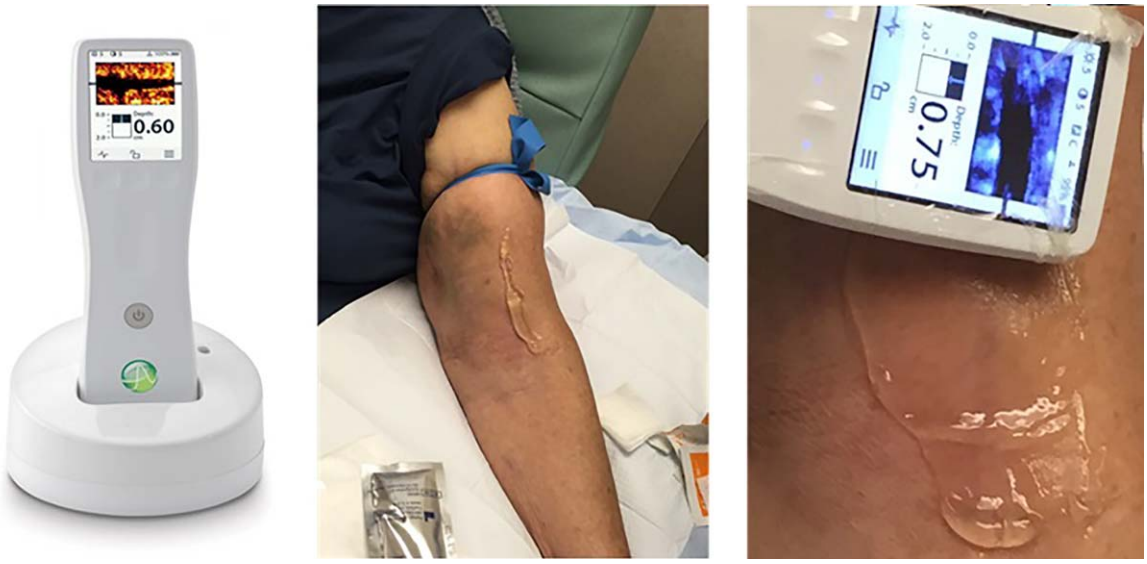

Figure 1 (a) Representational image of the device, (b) standard preparation for cannulation of fistula, and (c) image showing the fistula course and depth. [Color figure can be viewed at wileyonlinelibrary.com]

alone). Pre-clearance ultrasound evaluation of access was not the standard of practice. Two handheld ultrasound devices were provided by the sponsor for study. The patients were randomized to either the standard cannulation protocol (control group) or to the real-time ultrasound guided cannulation group (study group). The study period (fistula initiation phase) included 3 weeks from first cannulation or a total of 9 hemodialysis sessions per patient whichever occurred first, with a 3-month follow-up period. Four dialysis personnel were provided with up to 3 hours of simulated training in operation of the device followed by competency evaluation. The study protocol was approved by institutional review board and registered in clinicaltrials.gov (NCT02814721). Written informed consent was obtained from all patients at screening.

Protocol description

The standard cannulation protocol of the center was defined as using 17 gauge needles for the first 3 dialysis sessions, followed by 16 gauge for the next 3, and 15 gauge for subsequent sessions. Fistula initiation was considered as successful if fistula was used with two needles consecutively during the first three week. All new fistulae in the standard protocol were cannulated by personnel defined as members of the specialist cannulation team of the dialysis center. Needle direction could be in the direction of blood flow or in an opposing configuration.

The study protocol involved similar titration of needle size over a 3-week period, except that a pre-cannulation

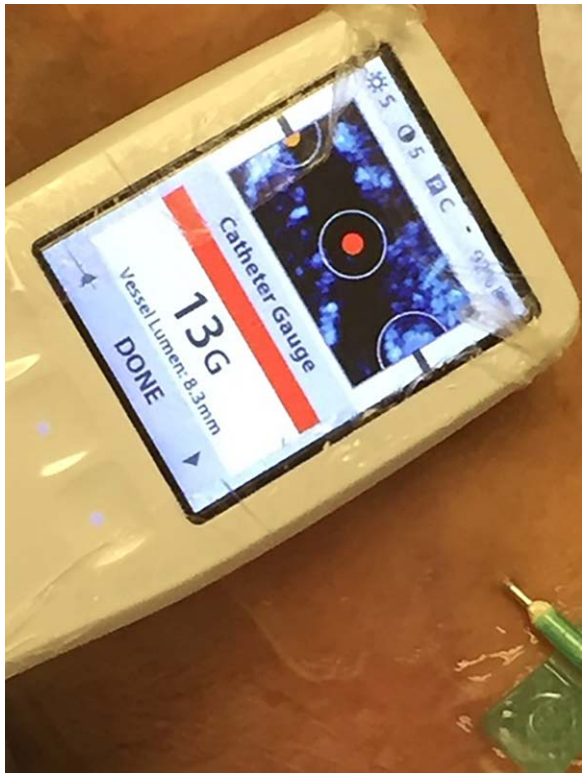

Figure 2 Image showing suggested needle size and vessel luminal diameter. [Color figure can be viewed at wileyonlinelibrary.com]

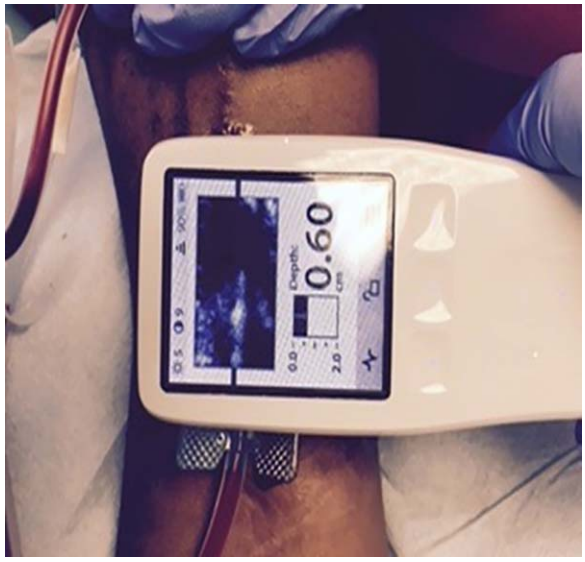

Figure 3 Image showing needle track while performing real time cannulation. [Color figure can be viewed at wileyonlinelibrary.com]

evaluation of the fistula was performed using the Sonic Window device. The device was used to evaluate and identify site of cannulation (Figure 1). Use of real-time guidance was at the discretion of cannulators (Figures 2 and 3). Four dialysis personnel trained in device use performed all cannulations in the study group. The device was disinfected between uses with hydrogen peroxide disinfectant wipes and covered with transparent adhesive film to avoid direct contact with the patient. Special sterile ultrasound gel packs were provided by the company for use with real-time guided cannulation. Device-trained cannulators were also allowed to perform cannulation in standard group using standard protocol if staffing requirements demanded.

Collected data included age, gender, body mass index, diabetes mellitus, hypertension, peripheral vascular disease, coronary artery disease, tunneled cuffed dialysis catheter insertion, removal, complications, VA creation, use, and interventions. Cannulation data included 1) pre-cannulation real-time ultrasound parameters in the study arm: depth from skin, needle size, and use of real-time vs. marking only ultrasound guidance; 2) pre-cannulation assessment time (recorded using a stop clock): classified as < 3 minutes, 3–5 minutes, 5–10 minutes, or > 10 minutes; 3) cannulation attempts; 4) reason for failure to cannulate; 5) dialysis at expected blood flow; 6) pain score per patient; 7) staff comfort; 8) cannulation time (measured from preparing the arm for ultrasound evaluation to actual cannulation): classified as under 5 minutes, 5–10 minutes, 10–15 minutes, or above 15 minutes; and 9) infiltration (during cannulation or ecchymosis over access at subsequent dialysis session): classified into major (cannulation abandoned for that dialysis session) or minor (further successful attempts in same session).

Access outcomes at the end of initiation phase and 3-month follow-up included 1) success of fistula initiation; 2) fistula rest due to major infiltration; 3) continued catheter use; 4) catheter removal date; 5) catheter-related complications; 6) access related hospitalizations and procedures; and 7) missed dialysis sessions.

Statistical methodology

We compared both baseline factors as well as 3-month follow-up data between the treatment and control arms using Mann-Whitney tests for continuous variables and Fisher's exact test for categorical variables. Fisher's exact test was chosen for categorical variables because the small number of recruited patients meant low expected counts and the assumptions of the chi-square test were not met. We assessed the number of days from first cannulation to catheter removal between the treated and control arms using a Mann-Whitney test. Due to the larger number of cannulations, we used Mann-Whitney tests to compare continuous variables and chi-square tests to compare categorical variables between the treatment and control arms. The ratio of total infiltrations between the treatment and control arms was modeled using generalized estimating equations modeling, and the results are displayed in terms of an odds ratio.

RESULTS

We began with 10 patients; however, 1 patient was excluded due to protocol violation. Final sample size was 9 patients: 5 patients in the study arm and 4 patients in the control arm. Nine of the AVF were created by a single vascular surgeon. Five patients in study arm had 74 cannulations and 4 patients in the control arm had data for 51 cannulations. The difference in cannulations arise from episodes of early infiltrations in the control group leading to fistula rest. Baseline characteristics of the randomized patients are shown in Table 1. No difference in baseline characteristics were noted. Three brachiobasilic transposed fistulae and two brachiocephalic fistulae were in the study group and the control group had all brachiobasilic fistulae. Left upper extremity was predominantly used for access in both groups with none of the patients had an ipsilateral catheter. All patients were using catheters prior to fistula initiation with no difference in catheter

Table 1 Baseline characteristics and access outcomes at initiation phase

	Study (N = 5)	Control (N = 4)	P value
Age (years)	66.0 (57.0–70.0)	52.5 (32.5–67.5)	0.64
Body mass index	23.5 (23.0–32.1)	23.7 (22.3–25.1)	0.90
Male	3 (60.0%)	2 (50.0%)	0.48
Diabetes mellitus	3 (60.0%)	2 (50.0%)	0.48
Hypertension	5 (100.0%)	4 (100.0%)	—
Coronary artery disease	1 (20.0%)	2 (50.0%)	0.52
Access laterality left	4 (80.0%)	3 (75.0%)	
Catheter days prior to fistula usage (days)	220	234.3	0.42
Fistula age prior to usage (days ± SD)	114.4 ± 49.7	64.5 ± 31	0.42
Successful fistula initiation	4 (80.0%)	2 (50.0%)	0.52
Fistula rested	1 (20.0%)	2 (50.0%)	0.34
Hospitalizations due to fistula complications	0 (0.0%)	1 (25.0%)	0.44

SD = standard deviation; TCC = tunnel cuffed catheter.

days (220 vs. 234 days). Fistulae in the study group had longer maturation days compared to the control group; however, the results were not statistically significant (114.4 ± 49.7 vs. 64.5 ± 31 days, P = 0.42).

The principal outcome measure of infiltration episodes was not different between the groups. Overall, 12 infiltrations (9.7%) were noted. There were 112 (90.3%) cannulations without an infiltration. Data for one cannulation in control group was lacking. Overall, 7 out of 74 (9.5%) cannulations in the study group had an infiltration compared to 5 out of 50 cannulations (10.0%) in the control group (odds ratio 0.94, 95% CI: 0.26–3.41, P = 0.93). Lower odds of infiltration in the study group was noted without statistical significance. A higher percentage of major infiltration episodes in the study group (6.8%) were noted compared to the control group (4.0%) lacking statistical signficance (P = 0.70). Time to first infiltration varied from 0 to 14 days (median 7 days). Post-infiltration accesses were rested in two subjects in the control group and one in the study group.

Cannulation measures

Among US aided cannulations, the median fistula depth (skin to proximal wall of the fistula) was noted to be 5 mm ± 1.7 mm and with a suggested needle size of 13.6 gauge ± 1.7. Real-time guidance was used in 61% of cannulations in the study group with the rest using the device for needle site marking only. Cannulators in the study group were given latitude to choose between real time guided cannulation vs. using device to mark optimal cannulation site depending on their comfort level with the device. Two cannulations did not have data recorded for depth, mark only vs. real-time and three cannulations lacked suggested needle size. Predictably US guided cannulations took a longer time for assessment (101.8 ± 80.2 vs. 22.3 ± 22.5 seconds, P = < 0.001) and cannulation (41.1 ± 70.6 vs. 25.0 ± 27.9 seconds, P = 0.04) compared to standard cannulation practices. There was no statistical difference in the number of cannulation attempts, needle size, arterial, or venous needle insertion and tourniquet usage between the groups (Table 2). The study group had a higher average achieved blood pump speed (313.2 ± 73.7 vs. 264.2 ± 60.1 mL/min, P = 0.002), which lasted into the last 30 minutes of the dialysis session (314.4 ± 73.9 vs. 262.4 ± 59.0 mL/min, P = 0.001). Topical anesthetic cream usage was higher in the study group (88% vs. 47%, P = < 0.001), but the patient reported pain score was no different between the groups (2.6 ± 1.8 vs. 2.1 ± 2.0, P = 0.12). A greater proportion of patients in the study group reported being "very comfortable" with needle cannulation than those in control group (94.6% vs. 82%, P = 0.04). Similar percentages (96% each) of successful cannulations were noted between the groups.

Fistula outcome at initiation phase and at 3-month follow-up

At the end of initiation phase, 80% of fistulae in the study group were in use compared to 50% in the control group (P = 0.52). One fistula in the study group and two fistula in control group were rested due to infiltration. There were no catheter-related complications including infection, exchanges, or reinsertions during the initiation phase. One patient in the control group had non-fistula related hospitalization. At 3 months, 8 fistula were in use

Table 2 Cannulation variables and outcomes

	Study (N = 74)	Control (N = 51)	P value
Assessment time (seconds)	101.8 ± 80.2	22.3 ± 22.5	<0.001
Number of attempts	1.0 ± 0.1	1.0 ± 0.2	0.64
Average blood flow rate	313.2 ± 73.7	264.2 ± 60.1	0.002
Last recorded blood flow rate	314.4 ± 73.9	262.4 ± 59.0	0.001
Cannulation time	41.1 ± 70.6	25.0 ± 27.9	0.04
Pain score	2.6 ± 1.8	2.1 ± 2.0	0.12
Needle size 17 gauge	30 (40.5%)	25 (49.0%)	0.24
16 gauge	21 (28.4%)	17 (33.3%)	
15 gauge	23 (31.1%)	9 (17.7%)	
Topical anesthetic usage	60 (88.2%)	22 (46.8%)	<0.001
Successful cannulations	71 (96.0%)	48 (96.0%)	0.98
Tourniquet usage	74 (100.0%)	49 (98.0%)	0.40
Major infiltration	5 (6.8%)	2 (4.0%)	0.70
Minor infiltration	2 (2.7%)	3 (6.0%)	0.39
Catheter usage due to infiltration	5 (6.8%)	2 (3.9%)	0.70
Patient comfort			
Very comfortable	70 (94.6%)	41 (82.0%)	0.06
Somewhat comfortable	4 (5.4%)	5 (10.0%)	
Neutral	0 (0.0%)	3 (6.0%)	
Somewhat uncomfortable	0 (0.0%)	1 (2.0%)	

with no further infiltration episodes, 3 of them had subsequent procedures, with no hospitalizations or catheter-related complications. One patient from the study group had repeat infiltration post-fistula rest and subsequently the access was abandoned.

DISCUSSION

We report for the first time incorporation of handheld ultrasound guided cannulation of new AVF by dialysis technicians is feasible in a busy outpatient hemodialysis. Preserving a functioning fistula is as important as a successful creation. An avoidable cause of fistula failure is cannulation error related infiltration. For a long time, the standard method for cannulating a fistula was the "feel and stick" method which has seen no major advances. Advances in portable and hand held ultrasound devices can aid in improving cannulation success and change the paradigm of access care in dialysis centers.

Utilization of real-time ultrasound guidance could aid in visualization of the fistula and minimize cannulation errors. The requirement of skilled personnel and device factors like size and cost have precluded widespread use of ultrasound technology in dialysis access cannulation on a routine basis. Knowledge of the size and depth of the target fistula would aid in the choice of needle length and angle of insertion. Real-time imaging guidance could potentially minimize cannulation errors. Utilization of a portable, handheld ultrasound device could provide this necessary safety practice in dialysis access cannulation. The Sonic Window device is able to provide the size, depth at cannulation site and real-time guidance for cannulators. Although time for assessment and cannulation time were significantly higher in study group, a trend for greater patient satisfcation with no significant difference in pain scores. This is likely a reflection of patient perception of safety, which is very valuable in the days of a value based payment structure. Notably patients in the study group completed dialysis sessions at higher blood flow rates possibly indicating optimal needle tip placement in relation to lumen of the vessel. Although subtle, its relevance needs to be seen in relation to needle tip mechanical injury, returning jet of blood shear stress on the endothelium and its impact on neointimal hyperplasia.

Infiltrations are less recognized complications of cannulation errors with significant morbidity. The definition of an "infiltration" related to cannulation is not clear. Lee et al. used the definition of subcutaneous hematoma from cannulation precluding fistula use until resolution of the hematoma.[4] The definition of infiltration in our study was any subcutaneous hematoma noted in access.

In practice, not all infiltrations are reported and frequently treated with transient resting of access. Prolongation of catheter use and delayed therapeutic interventions are common. Twelve infiltration episodes occurred in 125 cannulations giving an incidence of 9.7%, which is more than what has been reported in limited published literature. The control group had a fewer number of cannulation counts due to early infiltration despite shorter access maturation time. The number of subjects may not be adequate to show a significant decrease in infiltration rate. Availability of a point of care ultrasound device at dialysis units can also aid in different methods of cannulations. The two most common cannulations in use are "site rotation" or "rope ladder" and the "buttonhole" method. In the most widely used rope ladder method, puncture sites are successively rotated with the hope that rotation permits sufficient time for healing.[13] Twadorski described a method based on reuse of the "same" needle sites subsequently named the "buttonhole" technique.[14] Compared to rope ladder, buttonhole has been associated with significantly less cannulation pain, easier cannulation, and reduced cannulation attempts.[15] Widespread adaptation of the buttonhole technique has been limited due to difficulty in developing a needle track and frequent track-related infection. Limited availability of skilled cannulators adds to the complexity. Having a simple handheld ultrasound device with guidance for needle insertion will greatly enhance the ability to develop needle tracks. Further studies are needed to evaluate if utilization of a handheld ultrasound device would aid in buttonhole cannulation.

Our study has many limitations. Even though this is a pilot study, small number of subjects limits its potential. Crossover of cannulators between groups may have introduced bias although it's pragmatic considering dialysis units to have limited skilled cannulators. We also feel attentiveness of standard group cannulators improved in the presence of study personnel. Despite limitations in this study, we believe ultrasound guidance would greatly enhance the ability to identify fistula at risk for cannulation failure and minimize cannulation related complications.

Lack of infiltration data from larger databases impedes developing safer cannulation practices and evaluation of economic impact from preventable errors. A large prospective interventional trial evaluating cannulation practices is sorely needed.

In conclusion, our pilot study results show handheld ultrasound guidance is feasible without enhanced cannulation errors. Portable ultrasound devices like Sonic Window can be useful aids to incorporate within normal dialysis workflow.Larger randomized study with adequate power and sample size are needed to decisively demonstrate this intervention and will lead to improved VA outcomes.

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Contributions; Research idea: LK; study design and data acquisition: LK, VS, CBD, EA; statistical analysis and interpretation: LK, Patrick Karabon, MS, Biostatistician, Department of Public Health Sciences and Vattikuti Urology Institute, Henry Ford Health System; mentorship: JY. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. LK takes responsibility that this study has been reported honestly, accurately, and transparently; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained. In addition, we thank the two anonymous reviewers for their constructive feedback.

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