

Ultrasound-Guided Femoral Dialysis Access Placement: A Single-Center Randomized Trial

Mayoor V. Prabhu,* Deven Juneja,[†] Palepu B. Gopal,[†] Mohan Sathyanarayanan,[†] Sreepada Subhramanyam,* Sridhar Gandhe,* and K. Shivanand Nayak*

Departments of *Nephrology and [†]Anesthesiology and Critical Care, Global Hospitals, Hyderabad, Andhra Pradesh, India

Background and objectives: Insertion of dialysis catheters (DCs) is a prerequisite for successful initiation of hemodialysis. We attempted to determine if ultrasonography-guided (USG) insertion was superior and safer than the anatomical landmark-guided technique (ALT) for the femoral vein (FV).

Design, setting, participants, & measurements: This was a randomized prospective study on 110 patients requiring FV DCs in a tertiary care hospital. Patients were randomized into two groups: USG and ALT. Data were collected on demography, operator experience, and side of insertion. The USG group had their catheters inserted under USG guidance, whereas the ALT group had their DC inserted by ALT. Outcome measures included successful insertion of DC, number of attempts, and complications.

Results: Both groups were comparable regarding age and gender of patients, operator experience, and the side of catheterization. The overall success rate was 89.1%, with 80% using ALT and 98.2% under USG guidance ($P = 0.002$). First attempt success rate was 54.5% in the ALT group as compared with 85.5% in the USG group ($P = 0.000$). The complication rate was 18.2% in the ALT group and 5.5% in the USG group ($P = 0.039$). The odds ratio (OR) for complications with two or more attempts was 10.73 with a relative risk (RR) of 3.2. The OR for successful insertion using USG was 13.5 (95% CI: 1.7 to 108.7).

Conclusions: USG significantly improves success rate, reduces number of attempts, and decreases the incidence of complications related to FV DC insertion.

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Initiation of hemodialysis is an integral part of the management of patients with renal failure. This mandates the placement of a dialysis catheter (DC) in a central vein of sufficient caliber to permit the high blood flow rates required for successful dialysis. Common sites for DC insertion include the internal jugular vein (IJV), subclavian vein (SCV), and femoral vein (FV) (1). There is a higher incidence of thrombosis and higher rates of complications associated with SCV insertion, hence IJV and FV are generally preferred (2). The major deterrent to FV catheter placement was a high risk of infection, but recent data indicate that FV catheterization is not associated with any higher risk of infection than IJV catheterization (3).

Hence, FV catheterization, especially with tunneled catheters, may become a more preferred site for catheterization because of its comparative ease of insertion and lower risk of complications (4). Although there are numerous studies proving the superiority of the ultrasonography-guided (USG) technique over the anatomical landmark-guided technique (ALT) for IJV catheter insertion, the same has not been conclusively

demonstrated for FV catheterization. This prompted us to undertake this study.

Materials and Methods

Study Design and Setting

This was a prospective, randomized study performed in the medical and surgical intensive care units of a tertiary care hospital over a 7-month period.

Selection of Participants

All patients requiring FV DC insertion for initiation of dialysis as part of their management between April and November 2008 were enrolled for the study. Exclusion criteria included patients <18 years of age, those who had FV catheterizations done previously on the same side, and those who did not consent for the study. Patients were then randomized using a computer-generated randomization chart into two groups: in the first group the DC was inserted using ALT and in the second group USG was used for DC insertion. A total of 110 patients were included in the study, with 55 patients in each group.

Interventions

Operators were classified into two groups according to experience. Operators with <6 years experience were classified as “registrars” and the operators with >6 years of experience were classified as “consultants.” The right FV was catheterized as the first choice. DC insertion by ALT was performed per standard guidelines. The femoral artery was located manually below the inguinal ligament. A chorhexidine solution was used to cleanse the area, and local anesthesia was administered

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Correspondence: Dr. Mayoor V. Prabhu, Senior Registrar in Nephrology, Global Hospitals, Hyderabad-500004, Andhra Pradesh, India. Phone: +91-9908528207; Fax: +91-4023244455; E-mail: drprabhunephro@gmail.com

using 1% lidocaine. An introducer needle (16 gauge) was used to locate the vein by advancing it until venous blood was obtained. The guide wire was inserted, and after confirming free to-and-fro movement of the guide wire the introducer needle was removed and the uncuffed DC with a minimum length of 18 cm was inserted.

USG catheters were inserted using the portable, software-controlled SonoSite MicroMaxx ultrasound system with a 13- to 6-MHz, 38-mm linear array transducer (Sonosite Inc., Bothell, WA). To maintain sterility, the lead and probe were cleaned with antiseptic solution and the probe was covered with a sterile sheath and gel. After the area was cleaned and draped, the transducer was placed in the transverse plane 1 cm below the inguinal ligament. The vein was identified by its large size and relation to artery and was confirmed by checking its easy compressibility and visualizing nonpulsatile continuous flow using color Doppler. The probe was placed so that the vein was visualized in the center of ultrasound screen. The procedure was performed in real time. The introducer needle was directly inserted at the center of the probe after giving local anesthesia toward the vein under USG. Once puncture of the vein occurred, Seldinger's technique was followed.

The procedure was considered a failure if the operator was unable to perform venous catheterization after three attempts, an attempt being defined as the introducer needle's entry into the skin and its removal from the skin. If the initial method was unsuccessful after a maximum of three attempts, USG was used if the insertion was being done by ALT technique, help was taken from a more experienced operator, or an alternative site was chosen.

At the end of the procedure, all data including patient characteristics, level of operator experience, method and side of insertion, number of attempts, and complications were recorded on a proforma.

Outcome Measures

The main outcome measure was the successful insertion of a DC. Secondary outcome measures included the number of attempts and complications such as hematoma or arterial puncture.

Statistical Analyses

We used SPSS version 16.0 for the statistical analysis. The means of continuous variables were compared using the *t* test and categorical variables were compared using the χ^2 test and the Fishers Exact test. We estimated the relative risk (RR) for complications between the two procedures and the 95% confidence intervals (CI) around the point estimates. A *P* value of <0.05 was considered statistically significant for this analysis.

Results

A total of 110 patients underwent FV insertion of a DC. Fifty-five patients were in each group. A comparison of the baseline demographics and characteristics is described in Table 1. Both groups were comparable with respect to age, gender,

operator experience, and the side of DC insertion (Table 1). Comparison of primary and secondary outcome measures between the ALT and USG groups is given in Table 2. The ALT group had six arterial punctures and four patients developed hematomas, whereas in the USG group there was one arterial puncture and two patients developed hematomas.

The odds ratio (OR) for developing complications with two or more attempts was 10.73 (95% CI: 2.7 to 42.3) with RR for developing complications with two or more attempts being 3.2 (95% CI: 2 to 5.2). The RR for developing complications with ALT was 1.66 (95% CI: 1.15 to 2.39). The OR for successful insertion using USG was 13.5 (95% CI: 1.7 to 108.7).

On comparing the outcome measures according to operator experience, there was a significant reduction in the number of attempts when DCs were inserted by consultants in the ALT group (Table 3). In addition, the failure and complication rates were also less when consultants were inserting the catheters in the ALT group, but it was not statistically significant. There was no statistically significant difference in any outcome measure in the USG group.

In all 11 patients in whom the initial ALT failed, the catheter could be successfully inserted on the same side with the use of USG, indicating that placement of a catheter under USG guidance is technically easier because the procedure is performed under direct vision. In one patient from the USG group in whom initial cannulation failed, catheterization had to be done on the other side because the guide wire could not be passed after successful needle puncture under USG guidance.

Discussion

Central venous access, although usually easily obtained by the traditional external landmark techniques, can often present difficult situations (5). Obesity, anatomical variations, venous insufficiency, edema, and clinical instability all pose unique problems. The risk of complications increases with each attempt, making a successful first attempt very important (6).

The femoral route is considered the easiest method of obtaining quick central venous access, because the IJV or SCV route are not only more technically demanding but also carry a higher possibility of life-threatening complications (7). These routes are also more difficult to access in bedridden patients. Although anatomical variations of the FV are rare, iatrogenic complications such as hematomas make it difficult to locate the vein with precision by the landmark technique (8). Thus USG guidance should ideally make FV catheterization far more sim-

Table 1. Demographics and baseline characteristics of the patient groups

Characteristic	Overall (<i>n</i> = 110)	ALT Group (<i>n</i> = 55)	USG Group (<i>n</i> = 55)	<i>P</i> Value ^a
Mean age (years; mean \pm SD)	49.5 \pm 14.7	48.3 \pm 14	50.8 \pm 15.2	0.377
Gender, male (%)	79 (71.8%)	38 (69.1%)	41 (74.5%)	0.672
Operators, residents (%)	79 (71.8%)	45 (67.3%)	42 (76.4%)	0.639
Side, right (%)	104 (96.4%)	52 (96.4%)	52 (96.4%)	1.0

^a*P* < 0.05 is considered statistically significant.

Table 2. Comparison of primary and secondary outcomes measures between ALT and USG groups

Characteristic	Overall (n = 110)	ALT Group (n = 55)	USG Group (n = 55)	P Value ^a
Success rate (%)	98 (89.1%)	44 (80%)	54 (98.2%)	0.002
Successful first attempt (%)	77 (70%)	30 (54.5%)	47 (85.5%)	0.000
Number of attempts (mean ± SD)	1.34 ± 0.55	1.51 ± 0.6	1.16 ± 0.42	0.001
Complications (%)	13 (11.8%)	10 (18.2%)	3 (5.5%)	0.039

^aP < 0.05 is considered statistically significant.

Table 3. Comparison of outcomes by operator experience

Outcome Measure	ALT			USG		
	Residents (n = 45)	Consultants (n = 10)	P Value ^a	Residents (n = 42)	Consultants (n = 13)	P Value ^a
Success rate (%)	34 (75.56%)	10 (100%)	0.19	41 (97.62%)	13 (100%)	1.00
Number of attempts (mean ± SD)	1.6 ± 0.62	1.1 ± 0.32	0.017	1.19 ± 0.46	1.08 ± 0.28	0.4
Complications (%)	9 (20%)	1 (10%)	0.77	2 (4.76%)	1 (7.69%)	1.00

^aP < 0.05 is considered statistically significant.

Table 4. Review of literature comparing previous studies using USG guidance for FV DC insertion

Author	Nature of Study	Sample Size (ALT/USG)	Results (ALT/USG)
Farrell (16)	Retrospective	16/14	Successful cannulation: 100%/100% Successful first attempt: 56.3%/85.7% Number of attempts: 1.5 ± 0.6/1.1 ± 0.4 Femoral arterial puncture: 6.3%/0%
Kwon (15)	Prospective with historical controls	38/28	Success rate: 89.5%/100% Successful first attempt: 55.3%/92.9% Femoral arterial puncture: 15.8%/7.1% Hematoma: 2.6%/0%
Zollo (4)	Retrospective	230/38	Success rate: 87%/100% Femoral arterial puncture: 11.2%/2.6% Hematoma: 3.9%/0%
This study	Prospective randomized controlled trial	55/55	Success rate: 80%/98.2% Successful first attempt: 54.5%/85.5% Number of attempts: 1.5 ± 0.6/1.2 ± 0.4 Femoral arterial puncture: 10.9%/1.8% Hematoma: 7.2%/3.6%

ple and safe than the landmark technique, especially in the emergency setting.

Although there are abundant data regarding the role of USG in improving outcomes with central venous catheter (CVC) insertion, the same has not yet been examined in sufficient detail for FV DC insertion. Two meta-analyses reviewed the available literature assessing the efficacy of USG guidance in obtaining central venous access (6,9). They included central venous access for hemodynamic monitoring, hemodialysis, fluid management, and for total parenteral nutrition. Although both of these meta-analyses were emphatic in their conclusions

that USG was overall superior to the landmark technique in CVC insertion, there were a few caveats. Both of these meta-analyses concluded that there was adequate evidence to support the use of USG for IJV catheterization in adults and children, but for infants there was no difference between either procedure. Furthermore, there were differences between Doppler USG and two-dimensional USG guidance for CVC access as per the literature reviewed in these meta-analyses. The landmark technique was found to be superior to Doppler-guided USG for SCV procedures. An indirect comparison of RRs indicated that two-dimensional USG would be more successful

than Doppler guidance for SCV catheters. Both of these meta-analyses did not analyze the data for hemodialysis catheters separately and also found literature regarding the use of USG for SCV and FV catheterization to be sparse. This is where we feel our study could add to existing literature. Ours was a randomized study with a fairly large sample size, and we specifically addressed the issue of DC placement for hemodialysis access, comparing USG with landmark technique. We also addressed issues such as operator experience, first attempt success rates, number of attempts, and complication rates.

The possibility of the patient receiving a renal transplant in the future and the need for long-term accesses such as arteriovenous grafts or arteriovenous fistulae should always be considered when the placement of a CVC for hemodialysis is contemplated.

Complications at the time of catheter placement could jeopardize the possibility of creation of a successful arteriovenous graft or arteriovenous fistulae at a later date. The SCV route is generally avoided because the rate of central vein stenosis is high, precluding the use of the entire arm for access (10). The FV has been explored as a route of long-term access placement (grafts or catheters) by a few researchers (11,12). The current weight of evidence supports the use of shared governance in making this decision (13,14). Thus, it is important to establish evidence-based guidelines and safe techniques for placement of a FV DC.

We found a paucity of studies comparing USG with landmark technique for femoral DC catheterization. Kwon and colleagues reported significant reduction in complications, procedure time, and number of attempts with the use of USG, which also had a 100% success rate compared with 89.5% in the landmark technique (15). Our study mirrored these findings. Only experienced operators with >4 years of experience performed the catheterizations in their study; hence, operator experience was not a factor in comparing outcomes between the landmark and the USG groups. We did look into operator experience as a factor, with a direct comparison between registrars (<6 years experience) and consultants (>6 years experience). According to operator experience, there was no statistically significant difference in any of the measured outcomes in the USG group. The mean number of attempts was significantly less when consultants were inserting DCs in the ALT group. This may reflect that operator experience is of lesser significance when the veins are cannulated under direct vision using USG guidance. In all 11 patients of the ALT group in which initial catheterization failed in our study, USG helped to successfully achieve venous access. This was similar to the findings of Kwon *et al.*'s study and clearly helps to prove that the use of USG can reduce the number of catheterization failures. We did not analyze the total procedure time because we believe it may not be exactly representative with the procedures being done by different operators in different clinical situations. Other studies also reported similar findings (16,17). Farrell *et al.* (16) compared outcomes such as success rates, successful first attempts, number of passes, and complications in USG and ALT groups. They were able to demonstrate higher first attempt success rates with no arterial punctures in the USG group for

IJV and FV catheterization. However, this study had a major limitation in being a retrospective analysis. Farrell *et al.* believed that USG would more likely be used in patients in whom the doctors thought cannulation would be more difficult, thus leading to bias. To avoid such bias, we randomized patients to the ALT and USG groups using a computer-generated algorithm, eliminating the doctors' opinion as a factor. We were also able to confirm the early findings of Hartle *et al.* (17) that USG guidance significantly improves outcomes with FV catheterization. We believe our study was well representative because we had a larger sample size than most of the mentioned studies.

In our center we followed the guidelines recommended by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative Working Group for FV catheters (14). Because we did not have a control arm (IJV or SCV groups) we could not examine issues related to infection in comparison to these groups. Another potential limitation is that this was a single-center study. However, we believe that the prospective, randomized nature of the study and the substantial sample size could offset these limitations.

In conclusion, we believe that USG guidance improves success rates, decreases complications and decreases the number of attempts related to femoral DC catheterization and should become the standard of care in regular clinical practice. However, we do endorse the observation made by the National Institute for Clinical Excellence (18) (of the United Kingdom) that it is important to ensure that operators remain well trained and competent in using ALT because this skill may be invaluable in an emergency setting in which ultrasound may not be available. Nephrology and critical care fellows should continue to train themselves in both techniques.

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Disclosures

None.

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