The American Journal of Surgery 218 (2019) 590–596

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Reliability and accuracy of duplex ultrasound vein mapping for dialysis access☆

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ARTICLE INFO

Article history:
Received 24 September 2018
Received in revised form
19 October 2018
Accepted 12 December 2018

Keywords:
Duplex vein mapping
Dialysis access procedures
End stage renal disease
Arteriovenous fistula

ABSTRACT

Background: Duplex ultrasound vein mapping (DUVM) may increase autogenous dialysis access procedures but has not been universally adopted by surgeons.
Methods: We determined reliability and accuracy of arm vein measurements on physical examination (PE) and DUVM, compared to direct measurements in the operating room (OR, gold standard). Operative plans were developed from each set of measurements and we evaluated which approach identified more options for autogenous procedures.
Results: Vein diameters measured on DUVM correlated well with OR measurements but those made on PE did not. Autogenous access options were identified in 34.8% of patients based on PE and in 96.6% based on their DUVM. The 6-month primary-patency was 86.4%; assisted primary-patency was 89.8%.
Conclusions: Duplex ultrasound vein mapping is more reliable and accurate for assessing arm vein anatomy than physical examination. It identifies more autogenous options than physical-examination alone. It is essential for the preoperative evaluation for dialysis access.

Introduction

Hemodialysis is one of the mainstays of renal replacement therapy for patients with end-stage renal disease (ESRD). With the implementation of NKF KDOQI Vascular Access Guidelines and of the Fistula First Breakthrough Initiative (FFBI), autogenous dialysis access is the preferred access of choice for hemodialysis.[1,2] The US Renal Data System (USRDS), however, noted that 82.6% of primary hemodialysis access creations were hemodialysis catheters even though survival analysis at 1 and 5 years consistently favored autogenous accesses to hemodialysis catheters.[3] The Fistula First Breakthrough Initiative that targets an autogenous access prevalence of 66% has therefore yet to be met.[4] Furthermore, high access failures rates and the finite lifespan of dialysis accesses equate to ESRD patients enduring multiple access revisions and additional access procedures over their lifetime.

A major challenge in arteriovenous fistula (AVF) creation is assessment for a viable vein conduit. As patient populations becomes more complex, physical examination (PE) alone for dialysis access site assessment may be not provide adequate, reliable or accurate information. Various adjuncts have been proposed in order to increase the successful use of autogenous procedures for access options; Duplex ultrasound vein mapping (DUVM) being one of them. However, the accuracy of vein measurements made on ultrasound, and its impact on decision-making for dialysis access procedures have not been quantified. As a consequence, DUVM has not been universally adopted by all surgeons performing access procedures.

We therefore undertook this study with the aims of 1) measuring the reliability and accuracy of PE and that of DUVM when compared to direct anatomic vein measurements performed in the operating room; 2) evaluating whether DUVM identified more options for autogenous access procedures.

☆ Presented: American Venous Forum Annual Meeting 2016.

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https://doi.org/10.1016/j.amjsurg.2018.12.017
0002-9610/

Methods

Patient selection

Ninety-six patients undergoing evaluation for placement of dialysis access during a one year period were screened for potential participation in the study. Exclusion criteria included: history of intravenous drug abuse, prior dialysis access procedure on the ipsilateral upper extremity, prior injury to the ipsilateral upper extremity, history of contralateral hemispheric stroke, and body mass index (BMI) of $\geq$30 kg/m^2. Each patient was assessed by a vascular surgeon to determine eligibility in the study. A total of 92 limbs in 59 patients were enrolled in the study (Fig. 1). Pertinent clinical data that was recorded included: age, gender, BMI, smoking status, history of coronary artery disease, hypercholesterolemia, diabetes, and hypertension (Table 1).

Study design

Within one week prior to the scheduled procedure date, all patients underwent two sets of evaluations of their upper extremity arteries and veins. First, a physical examination of the upper extremity by a vascular surgeon (PE-1), second, a duplex ultrasound vein mapping (DUVM) study by a sonographer (DU). On the day of the procedure, a second physical examination was performed on all the patients by a different vascular surgeon (PE-2). To avoid ascertainment bias, all evaluators were blinded from other examiners' results and assessments. Each evaluator recorded his or her surgical plan based on their individual examination only. Finally, all patients underwent a third set of measurements in the operating room (OR) with their veins and arteries exposed within the surgical field (gold standard). The access procedure actually performed for the patient was recorded for comparison with preoperative findings. (Fig. 2). The study protocol was reviewed and approved by the Institutional Review Board and the protocol was granted exempt status for informed consent.

Table 1
Clinical characteristics of patients (n = 59).

Characteristic	Distribution
Age (mean)	42.4 years
Gender (female)	64%
Body Mass Index (range)	24.9 (11.9–29.9) kg/m^2
Diabetes	49.2%
History of smoking	35.6%
Hypertension	61.0%
Hypercholesterolemia	45.8%
Coronary artery disease	25.4%

Vein measurement protocols

Patients were examined in a warm office. To ensure a uniform temperature across all examinations, a warm blanket was applied around the upper extremity for 1 min prior to each examination. On each patient, a mark was placed at the radial styloid, ante-cubital fossa crease, and the acromion process. A measuring ruler was then used to place three additional marks on the forearm (distal, mid and proximal) and three additional marks on the arm (distal, mid and proximal) (Fig. 2). The distance of each mark was recorded with respect to the radial styloid. These landmarks provided individualized sites in each patient for all evaluations and measurements (PE-1, PE-2, DU, and OR).

Physical examination (PE)

All patients underwent two independent physical examinations of their upper extremities conducted by two separate vascular surgeons (PE-1 and PE-2). First, visible lengths of the basilic and cephalic veins were measured over the forearm and arm. Next, basilic and cephalic vein diameters were measured with an electronic caliper at each of the 8 unique landmarks without a tourniquet. Thereafter, sequential tourniquets were applied at the elbow, and vein diameters were re-measured in the forearm and

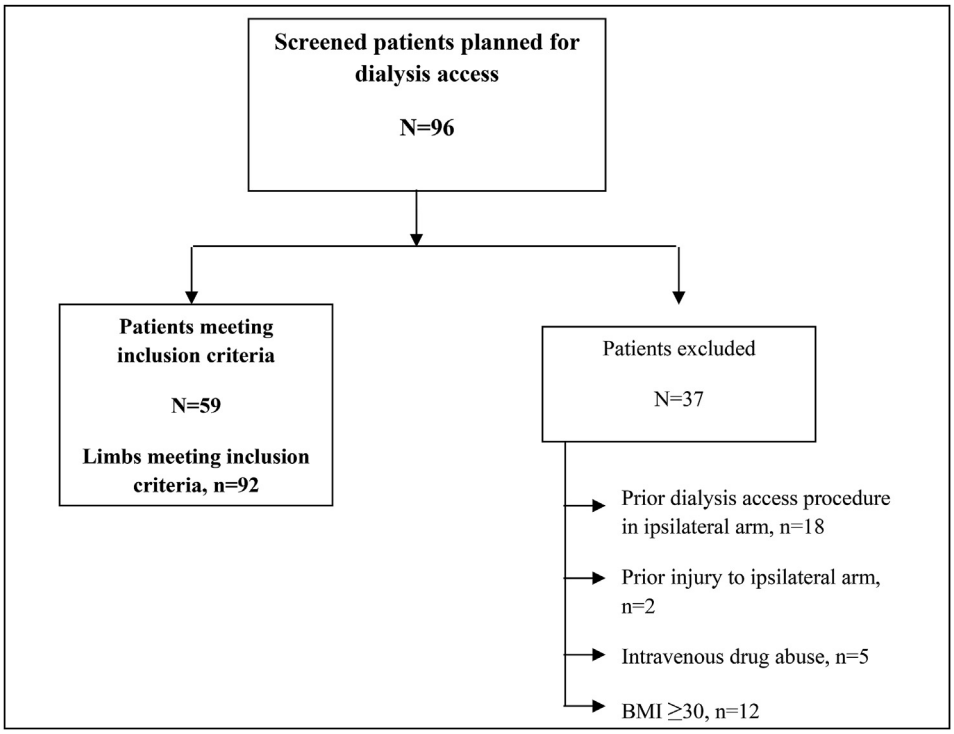

Fig. 1. Consort diagram for patient screening and enrollment.

Fig. 2. Method of standardized measurement of the distal, mid and proximal forearm and upper arm, basilic and cephalic vein diameters. An electronic caliper was used for measurements during physical examination. Duplex ultrasonography was used for measurements at the same locations where the veins were measured on physical examination (see methods section for details).

proximal portion of the arm. The shoulder and chest was examined to rule out any visible collateral vessels or edema suggestive of a central vein stenosis. The radial, ulnar and brachial arteries were palpated for presence or absence of a pulse, and an Allen test was performed to assess hand perfusion. Finally, a surgical plan for the optimal dialysis access procedure was proposed and recorded separately based on the findings of each examination (PE-1 and PE-2).

Duplex ultrasound vein mapping (DUVM)

All patients underwent a duplex ultrasound evaluation of their upper extremity veins and arteries according to a standardized vein mapping protocol (DU). The vein diameter measurements were performed at the same individualized landmarks where the PE measurements were performed. Veins were also assessed for compressibility and absence of stenosis, fibrosis or thrombosis. Ultrasound evaluation of the central veins was then performed to rule out the presence of a stenosis. Radial, ulnar and brachial artery diameters and blood-flow velocities were recorded, and an Allen test was performed to assess hand perfusion, both using ultrasonography. A surgical plan for the optimal dialysis access procedure that could be performed based on the DU findings was then recorded.

Operating room (OR)

During the dialysis access procedure, all patients were re-evaluated in the operating room, and vein diameter measurements were repeated at their appropriate landmarks. First, patient temperature, pulse rate, and blood pressure were recorded. Prior to vein dissection (with the vein in-situ), the surgeon measured the basilic and cephalic vein diameters using an electronic caliper at the landmarks visible in the operative field without a tourniquet. A second set of measurements were performed during proximal occlusion of the arm with vein distension attained by means of a syringe of heparinized saline to a mean pressure of 80 mm Hg.

Surgical protocol

The actual surgical procedure performed by the surgeon was based on a combination of preoperative duplex ultrasound vein mapping and intra-operative findings. The criteria used to determine suitability for an autogenous procedure were based on our previously published protocol[5] and included; 1a) a minimum venous diameter of 1 mm (without a tourniquet) and 2.5 mm (with a tourniquet), with 1b) the minimum venous diameter extending for at least a 15 cm length in the forearm or arm, with 1c) a minimum luminal diameter of the appropriate donor artery ($\geq$2 mm for the radial/ulnar arteries and $\geq$3 mm for the brachial artery), and 2) adequate hand collateral circulation (in case a forearm access was being contemplated), and finally, 3) no evidence of central vein stenosis. If all three of these criteria were not achieved in at least one segment of the cephalic or basilic vein in the arm or forearm, a prosthetic bridging graft was recommended. The actual procedure performed in each patient was recorded.

Follow up

Each patient returned for at least one follow-up evaluation within 4–12 months post-procedure. Clinical and ultrasound evaluations were performed at that time. The access was evaluated for anatomic patency. We also recorded whether the access was used successfully for dialysis, failed to mature, required additional procedures to maintain patency, or whether it thrombosed.

Statistical analysis

Statistical analysis was performed using GraphPad Prism 3.00 (GraphPad Software Inc., San Diego, CA) and SPSS (SPSS Inc., Chicago, IL). Patient characteristics were compared using the Chi square and Fisher's exact test as appropriate and $p \leq 0.05$ was considered significant. Variables analyzed included diabetes, age, sex, hypercholesterolemia, hypertension, CAD and smoking status. Measurements obtained by physical examination and duplex ultrasonography were compared to those obtained by direct measurements in the operating room using correlation coefficients and Bland Altman statistics to assess the repeatability (reliability) of physical examination and duplex ultrasound based measurements of vein diameters; and the accuracy of these approaches when compared to intra-operative measurements serving as the anatomic gold standard.

Results

Table 1 describes patient demographics and clinical characteristics. A total of 92 limbs were evaluated in the 59 patients. The mean age was 42.4 years (SD $\pm$ 6.3) and majority of patients (64%) were female. Patients demonstrated a high prevalence of cardiovascular and other co-morbidities such as hypercholesterolemia, diabetes, hypertension, coronary artery disease and smoking.

Most (74.6%) dialysis access procedures were performed on the non-dominant upper extremity. A majority (95%) of the procedures performed were autogenous. The radial artery was the inflow source in 40.7% of the autogenous procedures, while 54.2% used the

brachial artery for access. The remaining 5.1% of procedures utilized a prosthetic bridge graft. There were no loop forearm or upper arm prosthetic graft procedures performed.

The scatter-plots and Bland Altman plots in Fig. 3 illustrate the large variability (and correspondingly low reliability) in vein diameter measurements between the two separate physical examinations (PE-1 and PE-2) regardless of whether they were performed with a tourniquet ($r = 0.57$) or without one ($r = 0.52$). The scatter-plots and Bland Altman plots in Fig. 4 illustrate the low accuracy of vein diameter measurements obtained by a physical examination (PE-1) when compared to the true anatomical intra-operative (OR) measurements of the same vein segments. Physical examination-based measurements correlated poorly with intra-operative measurements, regardless of whether they were conducted with ($r = 0.3$) or without ($r = 0.15$) a tourniquet. Similarly, PE-2 correlated poorly with OR measurements when performed with ($r = 0.2$) or without ($r = 0.15$) a tourniquet.

The scatter-plots and Bland Altman plots in Fig. 5 illustrate the high accuracy of vein diameter measurements made during duplex ultrasonography (DU) when compared to the true anatomical intra-operative (OR) measurements of the same vein segments. The observations made by DU and in the OR consistently fell within ±2 standard deviations of each other. DU measurements correlated strongly with intra-operative measurements, regardless of whether they were conducted with ($r = 0.75$) or without ($r = 0.57$) a tourniquet.

The proportion of patients that were recommended an autogenous access based on a physical examination without a tourniquet was 22% (PE-1) and 20.3% (PE-2). When a tourniquet was added to the examination, recommendations for autogenous accesses

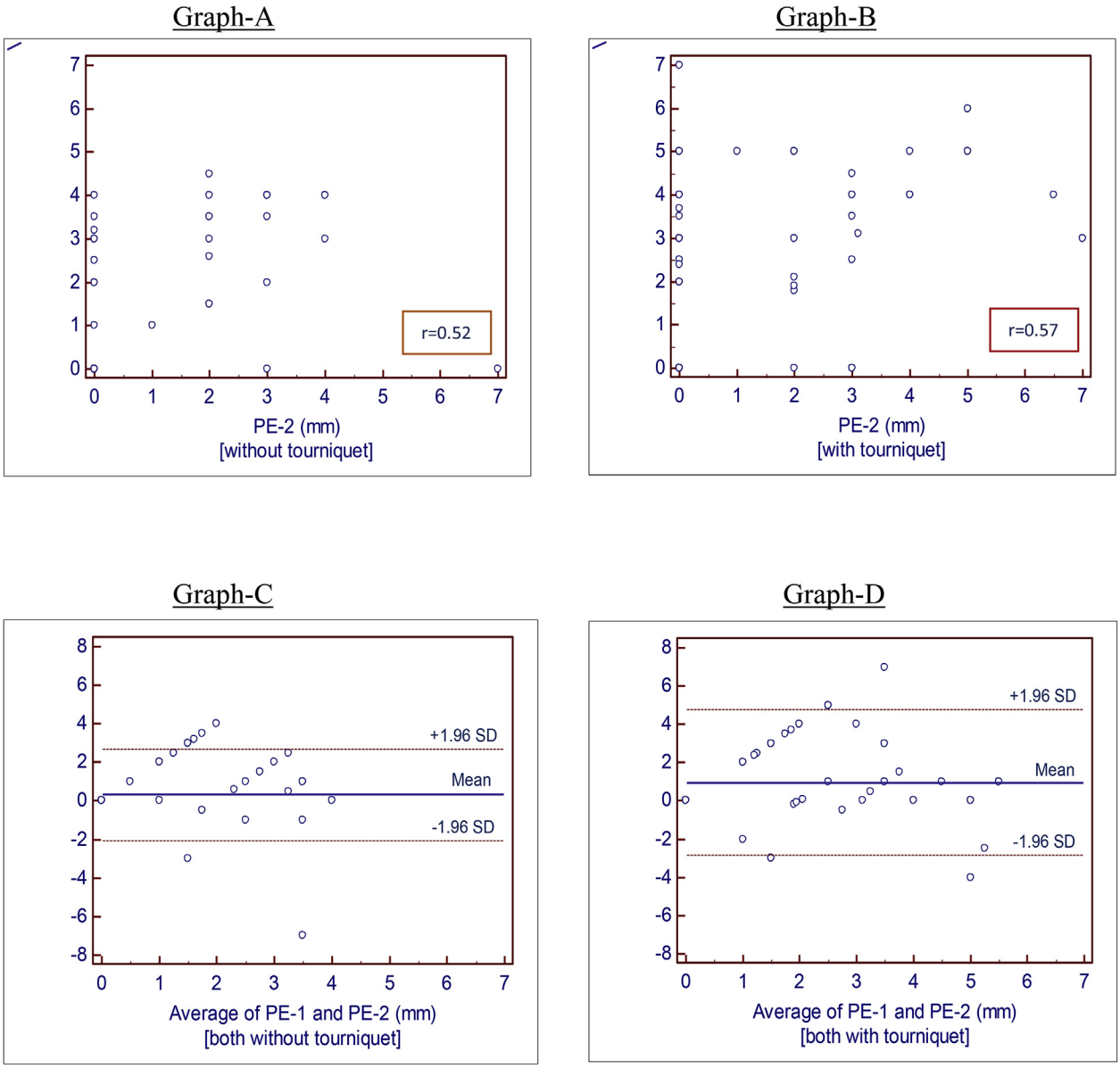

Fig. 3. Physical examination as a means of measuring vein diameter has low reliability (repeatability). Graph-A and Graph-B are scatter plots of measurements of vein diameters performed on the upper extremity based on physical examination using an electronic caliper. The X-axis displays measurements made by observer-2 (PE-2) and the Y-axis displays those made by observer-1 (PE-1). Graph-A displays the measurements made without a tourniquet and Graph-B shows those made with a tourniquet. Graph-C and Graph-D are Bland-Altman plots assessing agreement between vein diameter measurements obtained during PE-1 and PE-2 (conducted with and without a tourniquet). Graph-C compares measurements done without a tourniquet while Graph-D compares measurements done with a tourniquet.

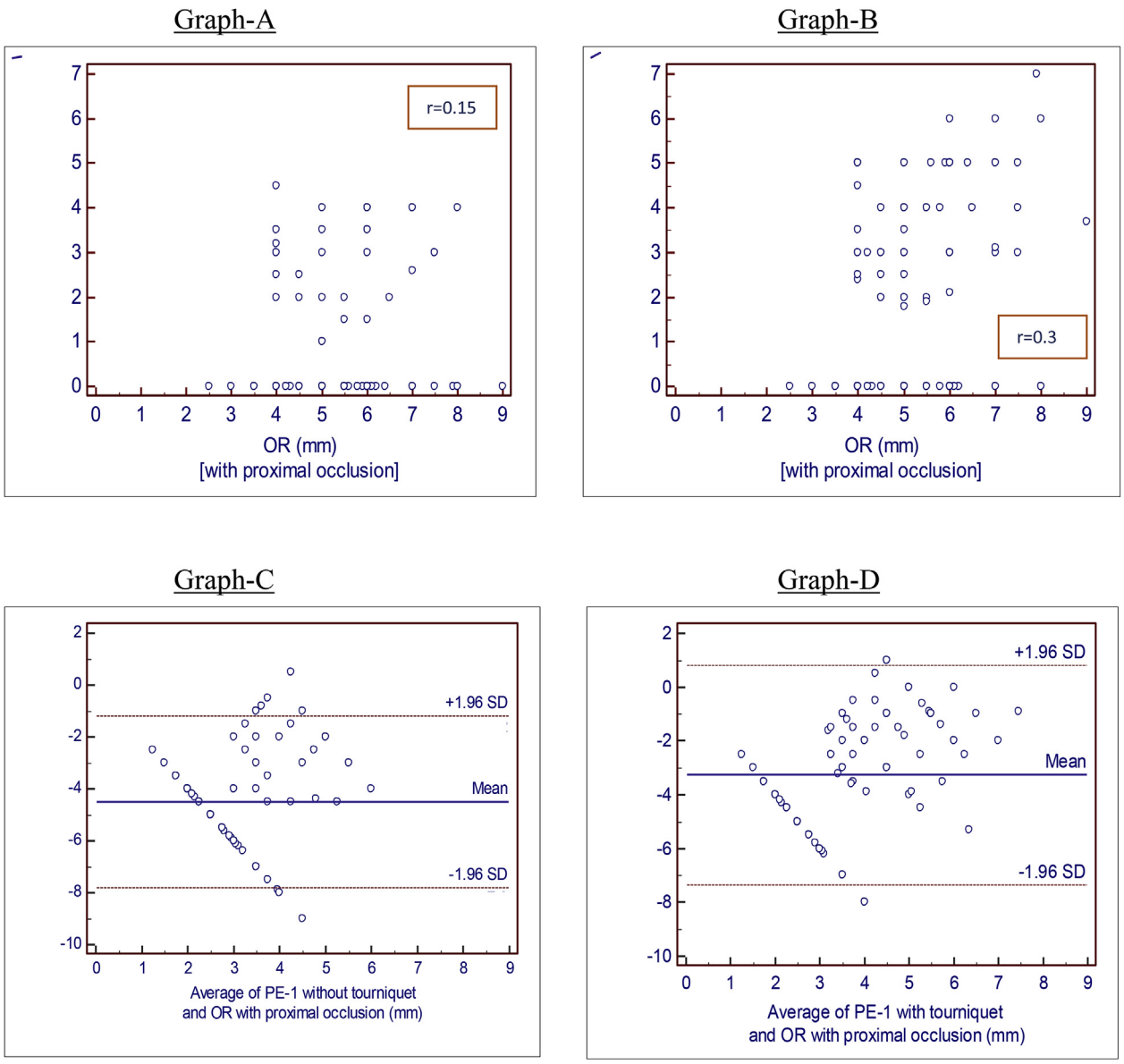

Fig. 4. Physical examination as a means of measuring vein diameter has low accuracy. Graph-A and Graph-B are scatter plots of measurements of vein diameters performed on the upper extremity during physical examination (PE-1) using an electronic caliper versus direct measurement of the vein in the operating room (OR) with proximal occlusion, as the gold standard. The X-axis displays measurements made in the OR and the Y-axis displays those made on PE-1. Graph-A displays the PE-1 measurements made without a tourniquet while Graph-B shows those made with a tourniquet. Graph-C and Graph-D are Bland-Altman plots assessing agreement between vein diameter measurements obtained during PE-1 (conducted with and without a tourniquet). Graph-C compares measurements done without a tourniquet while Graph-D compares measurements done with a tourniquet. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

increased to 35.5% (PE-1) and 33.9% (PE-2). The percent of patients identified for autogenous access was higher when decisions were made based on duplex ultrasonography without a tourniquet (76.3%), and even higher with a tourniquet (96.6%). This compared favorably with the 94.9% rate of autogenous accesses ultimately performed by the operating surgeons. The primary functional patency at 6 months was 86.4% and the primary assisted functional patency at 6 months was 89.8%

Discussion

Functioning autogenous fistulae are the preferred mode of providing dialysis to patients with renal failure.[6,7] The quality of venous conduits are an important determinant of functional patency for these fistulae.[8] Our study demonstrated that venous conduit assessments based on a pre-operative physical examination (PE) have low reliability, and accuracy. Duplex ultrasound vein mapping (DUVM) was highly reliable, and accurate when compared to intra-operative measurements, particularly when a tourniquet was used to perform the measurements. As a result, surgical recommendations proposed on the basis of a PE alone would have resulted in fewer autogenous access procedures being performed. Decisions made on the basis of DUVM resulted in higher rates of autogenous procedure recommendations and this rate was similar to the actual procedures performed based on operating room (OR) measurements.

NFK-KDOQI recommends preoperative ultrasound for the evaluation of arm veins to increase the percentage of autogenous fistulae, and to select patients more likely to mature their access.[1] This is based on retrospective and prospective studies comparing

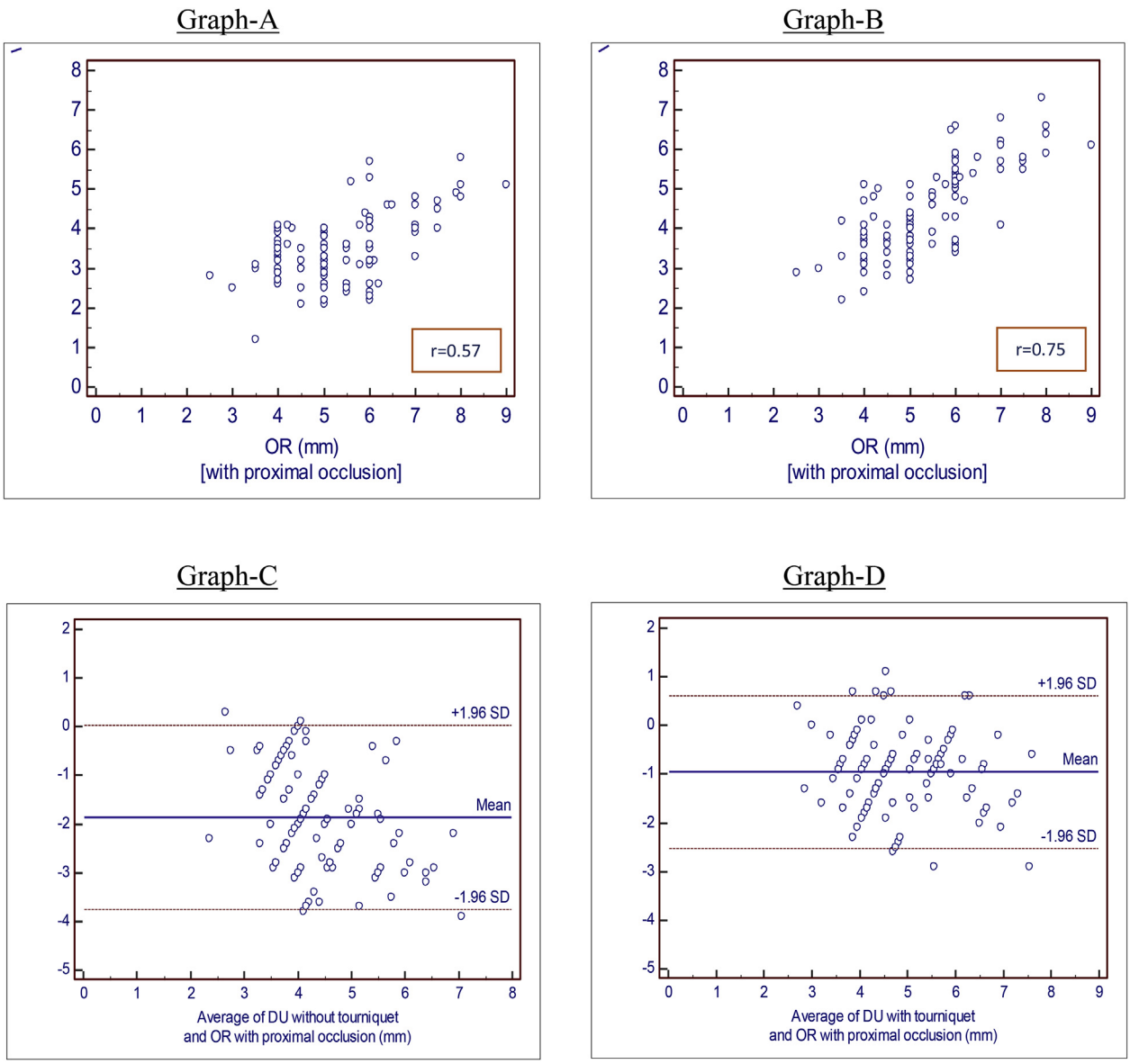

Fig. 5. Duplex ultrasound vein mapping (DUVM) as a means of measuring vein diameter has high accuracy. Graph-A and Graph-B are scatter plots of measurements of vein diameters performed on the upper extremity during DUVM (DU) versus direct measurement of the vein in the operating room (OR) with proximal occlusion, as the gold standard. The X-axis displays measurements made in the OR and the Y-axis displays those made by DU. Graph-A displays the DU measurements made without a tourniquet while Graph-B shows those made with a tourniquet. Graph-C and Graph-D are Bland-Altman plots assessing agreement between vein diameter measurements obtained during DU (conducted with and without a tourniquet). Graph-C compares measurements done without a tourniquet while Graph-D compares measurements done with a tourniquet. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

outcomes of DUVM-directed AVF surgery with historical controls from the same or other centers. These reports have documented various degrees of success using DUVM for this purpose, especially in obese patients and in patients with unsuitable vessels.[9–11] Silva et al.,[5] demonstrated that implementing a standardized DUVM protocol to measure venous anatomy increased the proportion of patients that could receive an autogenous dialysis access procedure. They proposed criteria for vein diameter ($\geq$2.5 mm) that would predict future successful maturation of the fistulae. Using duplex ultrasonography they were able to create autogenous hemodialysis access in 64% of their patients compared to 14% in a historical control population where accesses were presumably determined based on PE alone. Despite these and similar reports, DUVM has not gained universal acceptance due to an absence of objective quantitative information on the lack of accuracy and reliability of physical examination.[12,13] Our study demonstrates potential reasons why DUVM increases the performance of autogenous access procedures. The study design permits quantification of the reliability and accuracy of traditionally utilized physical examination and the extent to which DUVM-based measurements improve reliability and accuracy of vein measurements. Surgical recommendations based on PE would only allow for approximately 20–30% of patients to receive an autogenous fistula, quite similar to the proportion noted by Silva et al.[5]

In a randomized trial, Nursal et al.,[10] found that preoperative DUVM did not offer an advantage for AVF function over PE alone in patients with favorable forearm anatomy. However, patients with end-stage renal disease tend to have multiple co-morbidities, sedentary lifestyles, multiple prior venous punctures for blood-sampling, and multiple access procedures for dialysis, thereby

making physical examination difficult and potentially less reliable in the real world. The altered volume status in these renal failure patients may also contribute to over- or under-filled veins resulting in variable reliability. Furthermore, we excluded patients with a BMI $\geq$30 kg/m^2, prior procedures or trauma to the arm, intravenous drug use and stroke; yet the reliability of PE measurements remained low compared to DUVM.

In another randomized controlled trial by Ferring et al.,[11] the ultrasound group had a lower rate of immediate AVF failure in accesses created based on DUVM compared to those created based on PE alone (4% vs 11%, p = 0.028). Early thrombosis of AVF was more common in the clinical assessment group (67% vs 38% in the DUVM, p = 0.029). They postulated that ultrasound assessments can identify inadequate vessels, which reduces the risk of early thrombosis of the AVF. They did not find a difference in primary patency between the two groups at 1 year of follow up, though assisted primary patency was better in the ultrasound group (80% vs 65% in the PE group, $p = 0.012$). They concluded that preoperative DUVM improved immediate AVF patency but played no role in maturation. The improved assisted primary patency in the DUVM group could be attributed to a superior conduit selection by vein mapping; thereby, increasing the potential for fistula salvage. Our study with DUVM-directed access creation resulted in an even better primary patency rate of 86.4%. Consistent with the findings reported by Ferring et al.,[11] our assisted primary patency rates further improved to 89.8%. Therefore, conduit selection by DUVM has fewer immediate complication rates and provides improved outcomes in accesses needing revisions.

Collapsed vein segments due to hypovolemia or antihypertensive medications, or edema due to fluid overload, could have limited the repeatability and accuracy of vein measurements on PE. We tried to maximize the accuracy of PE by using a tourniquet, which did improve the findings somewhat, but they still remained inferior to DUVM. Furthermore, these conditions would adversely affect DUVM measurements also. Successful DUVM depends on operator technique, and requires vascular laboratory infrastructure with its associated cost. Arterial anatomy was not evaluated in our study. However, arterial occlusive disease in the upper extremity is less prevalent compared to the lower extremity, and this was further confirmed by the follow up patency rates and absence of pre- and post-operative hand ischemia. We did not randomize patients to DUVM versus PE and compare functional autogenous fistula rates thereafter because our focus in this study was to compare the accuracy and reliability of both approaches to assess venous anatomy. Our results support the use of DUVM to plan dialysis accesses in patients with ESRD.[5,9–11]

Surgeries performed on the basis of DUVM would have achieved a much higher rate of autogenous access creation than the national average. Our findings confirm that the increased reliability and accuracy of DUVM has the potential to augment utilization of autogenous procedures. It also quantifies, for the first time, the high reliability and accuracy of assessing venous anatomy using DUVM versus a simple physical evaluation for access procedures. DUVM contributes an incremental improvement in the assessment of vein characteristics that reduce early fistula failure and improve functional primary and assisted primary patency rates.

Conflicts of interest

No conflicts of interest declared for any authors.

Acknowledgements

Sources of funding: Dr. Brajesh K. Lal: NIH awards NS080168, NS097876and AG000513and VA Merit awards RX000995and CX001621.

For the remaining authors none were declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2018.12.017.

References

1. National Kidney Foundation. KDOQI clinical practice Guidelines and clinical practice recommendations for 2006 updates: hemodialysis adequacy, peritoneal dialysis adequacy and vascular access. *Am J Kidney Dis*. 2006;48(suppl 1): S1–S322.
2. Vassalotti JA, Jennings WC, Beathard, et al. Fistula first Breakthrough initiative: targeting catheter last in fistula first. *Semin Dial*. 2012;25:303–310. https://doi.org/10.1111/j.1525-139X.2012.01069.x.
3. Malas MB, Canner JK, Hicks CW, et al. Trends in incident hemodialysis access and mortality. *JAMA Surg*. 2015;150(5):441–448. https://doi.org/10.1001/jamasurg.2014.3484.
4. Saran R, Li Y, Robinson B, et al. US renal data System 2015 annual data report: epidemiology of kidney disease in the United States. *Am J Kidney Dis*. 2016;67: S1–S434 (3)(suppl 1).
5. Silva Jr MB, Hobson II RW, Pappas PJ, et al. A strategy for increasing use of autogenous hemodialysis access procedures: impact of preoperative noninvasive evaluation. *J Vasc Surg*. 1998;27:302–308.
6. Gibson KD, Gillen DL, Caps MT, et al. Vascular access survival and incidence of revisions: a comparison of prosthetic grafts, simple autogenous fistulas and venous transposition fistulas from the United States Renal Data System Dialysis Morbidity and Mortality Study. *J Vasc Surg*. 2001;34:694–700.
7. Basaran O, Karakayali H, Emiroglu R, et al. Complications and long-term follow-up of 4416 vascular access procedures. *Transplant Proc*. 2003;35:2578–2579.
8. Smith GE, Gohil R, Chetter IC. Factors affecting the patency of arteriovenous fistulas for dialysis access. *J Vasc Surg*. 2012 Mar;55(3):849–855.
9. Wong CS, McNicholas N, Healy D, et al. A systematic review of preoperative duplex ultrasonography and arteriovenous fistula formation. *J Vasc Surg*. 2013;57:1129–1133.
10. Nursal TZ, Oguzkurt L, Tercan F, et al. Is routine preoperative ultrasonographic mapping for arteriove- nous fistula creation necessary in patients with favorable physical examination findings? Results of a randomized controlled trial. *World J Surg*. 2006;30:1100–1107.
11. Ferring M, Claridge M, Smith SA, et al. Routine preoperative vascular ultrasound improves patency and use of arteriovenous fistulas for hemodialysis: a randomized trial. *Clin J Am Soc Nephrol*. 2010;5:2236–2244.
12. Dumaine C, Kiaii M, Miller L, et al. Vascular access practice patterns in Canada: a national survey. *Can J of Kidney Health Dis*. 2018;5, 2054358118759675.
13. Wells AC, Fernando B, Butler A, et al. Selective use of ultrasonographic vascular mapping in the assessment of patients before haemodialysis access surgery. *Br J Surg*. 2005;92:1439–1443.