Prediction of Arteriovenous Fistula Clinical Maturation from Postoperative Ultrasound Measurements: Findings from the Hemodialysis Fistula Maturation Study

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ABSTRACT

Background The utility of early postoperative ultrasound measurements in predicting arteriovenous fistula (AVF) clinical maturation is uncertain.

Methods We investigated the relationships of ultrasound parameters with AVF clinical maturation in newly created AVF, measured at 1 day and 2 and 6 weeks, in 602 participants of a multicenter, observational cohort study. A backward elimination algorithm identified ultrasound measurements that independently predicted unassisted and overall AVF maturation. Candidate variables included AVF blood flow, diameter, and depth, upper arm arterial diameter, presence of stenosis, presence of accessory veins, seven case-mix factors (age, sex, black race, AVF location, diabetes, dialysis status, and body mass index), and clinical center. We evaluated the accuracy of the resulting models for clinical prediction.

Results At each ultrasound measurement time, AVF blood flow, diameter, and depth each predicted in a statistically significant manner both unassisted and overall clinical maturation. Moreover, neither the remaining ultrasound parameters nor case-mix factors were associated with clinical AVF maturation after accounting for blood flow, diameter, and depth, although maturation probabilities differed among clinical centers before and after accounting for these parameters. The crossvalidated area under the receiver operating characteristic curve for models constructed using these three ultrasound parameters was 0.69, 0.74, and 0.79 at 1 day and 2 and 6 weeks, respectively, for unassisted AVF clinical maturation and 0.69, 0.71, and 0.76, respectively, for overall AVF maturation.

Conclusions AVF blood flow, diameter, and depth moderately predicted unassisted and overall AVF clinical maturation. The other factors considered did not further improve AVF maturation prediction.

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Patients with ESRD undergoing maintenance hemodialysis require a functioning conduit to their bloodstream (vascular access). Although an arteriovenous fistula (AVF) is considered the preferred type of access,[1,2] 20%–60% of AVFs fail to mature for successful dialysis use.[3–6] For an AVF to mature sufficiently to support maintenance hemodialysis, both AVF

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diameter and blood flow must increase substantially.[7] An easily palpable AVF with a shallow depth from the skin can be cannulated more readily than a deeper one. Physical examination is commonly used to determine when an AVF can be cannulated and used for hemodialysis.[8,9] Physical examination by a skilled examiner predicts clinical maturation (*i.e.*, ability to use the AVF for dialysis) correctly in 72%–80% of patients,[10–12] but may vary substantially among dialysis staff and/or centers. An objective, reproducible, accurate, noninvasive, and inexpensive test is needed to improve the assessment of AVF progress toward clinical maturation.

Postoperative ultrasound measurements have been used to predict AVF clinical maturation in several small, single-center series,[10,11,13–21] using brachial or radial artery, or AVF vein inner diameter measurements, and blood flow measured in varying locations of these arteries or the AVF vein, limiting comparability. Early AVF clinical maturation criteria, proposed by a 2002 University of Alabama study, focused on AVF blood flow and diameter.[10] A subsequent Kidney Diseases Outcomes Quality Initiative (KDOQI) proposed ultrasound criteria for AVF maturation of 600 ml/min blood flow, 0.6 cm diameter, and ≤0.6 cm depth from the skin.[1] This "rule of sixes" is opinion-based and not validated, and the probability of AVF clinical maturation is unknown when the postoperative ultrasound meets only two of these three criteria. Moreover, the most predictive location to measure AVF blood flow (arterial versus AVF vein) is unknown. Therefore, the utility of early ultrasound measurements to predict AVF clinical maturation remains uncertain.

The Hemodialysis Fistula Maturation (HFM) study was a multicenter, prospective cohort study of 602 patients in the United States who received new single-stage AVFs.[22] Participants underwent standardized ultrasound examinations to map the upper extremity vessels preoperatively and to obtain multiple measurements postoperatively. We investigated the relationships of AVF blood flow, diameter, and depth, measured postoperatively at 1 day (0–3, targeting 1 day) and 2 and 6 weeks, with unassisted and overall (assisted and unassisted) AVF clinical maturation, and whether these ultrasound measurements could predict clinical maturation accurately enough for practical use.

Significance Statement

The utility of early postoperative ultrasound measurements in predicting arteriovenous fistula (AVF) clinical maturation is uncertain. This article describes associations of ultrasound AVF measurements at 1 day and 2 and 6 weeks with unassisted and assisted clinical maturation in 602 participants of the multicenter, prospective cohort of the Hemodialysis Fistula Maturation Study. Six-week ultrasound measurements of AVF blood flow, diameter, and depth moderately predicted unassisted and overall AVF clinical maturation (area under the receiver operating characteristic curve, 0.79 and 0.76, respectively). Ten demographic and clinical factors analyzed, including AVF location and upper arm arterial blood flow, did not further improve AVF clinical maturation prediction. The models quantify and confirm prior clinical beliefs and may assist prediction of AVF clinical maturation.

METHODS

The HFM study enrolled 602 patients with CKD, undergoing creation of a new single-stage, upper extremity AVF between March 2010 and August 2013, in a seven-center prospective cohort study, as detailed previously.[22] The study was institutional review board-approved and compliant with the Health Insurance Portability and Accountability Act at each participating institution. Written informed consent was obtained from all participants.

Ultrasound

Standardized, preoperative mapping ultrasound was performed before surgery, and standardized, postoperative ultrasound AVF evaluations were performed at about 1 day and 2 and 6 weeks.[23–25] Briefly, ultrasound measurements of blood flow in the brachial artery (or radial and ulnar arteries in the upper arm if a high brachial artery bifurcation, a normal anatomic variant) and AVF vein were performed at specified locations using a standard protocol. Internal diameter measurements of the brachial artery and AVF draining vein, as well as depth of the anterior wall of the AVF vein to the skin surface, were performed at specified locations. AVF vein inner diameter and depth of the anterior AVF vein wall was measured at 2, 5, 10, and 15 cm, and averaged. Three blood flow measurements were performed at 10 cm in the AVF draining vein, and averaged.[23] Clinical center sonographers were trained at the HFM study Ultrasound Core Facility at the University of Alabama at Birmingham (UAB), with extensive vessel measurement and blood flow rate acquisition standardization to minimize errors during scanning. Ultrasound examination data were read by three radiologists specializing in ultrasound vascular studies at the Ultrasound Core Facility at UAB, with measurement correction if needed.

AVF Clinical Maturation

AVF maturation was defined as clinical use of the AVF with two needles for 75% of dialysis sessions over a continuous 4 week period, including either a mean dialysis machine blood pump speed of >300 ml/min over four consecutive sessions or a measured Kt/V>1.4 or a urea reduction ratio (URR) >70%. The first of the four qualifying sessions with pump speed >300 ml/min, or the date of the qualifying Kt/V or URR, had to occur by either 9 months after AVF creation surgery or 4 weeks after dialysis initiation. For patients receiving dialysis before AVF creation, the 4 week period of AVF use satisfying the HFM clinical maturation criteria had to commence within 9 months of AVF surgery. For patients not receiving dialysis at the time of AVF creation surgery, and initiating dialysis therapy >9 months later, the first dialysis session in the 4 week period meeting the stipulated pump flow, Kt/V, or URR criterion was required to be within 4 weeks of hemodialysis therapy initiation.[26] AVF clinical maturation was defined as unassisted when not preceded by a percutaneous or surgical intervention to promote maturation, and otherwise as assisted. Overall maturation was defined as AVF clinical maturation with or without a prior intervention.[22]

Statistical Analyses

Analyses of ultrasound parameters measured at 1 day and 2 and 6 weeks included 587, 570, and 556 patients. Our prognostic models evaluated the probabilities of AVF clinical maturation on the basis of ultrasound measurements at the designated assessment times, conditional on patient survival without AVF thrombosis before the assessment times. Additional missing data were multiple imputed. We used separate logistic regression analyses to relate unassisted AVF clinical maturation and overall AVF clinical maturation to individual ultrasound parameters at 1 day (0–3 days, targeting 1 day) and 2 and 6 weeks after AVF creation, as well as controlling for the seven case-mix variables (age, sex, race, AVF location, dialysis status, diabetic status, and body mass index). Ultrasound parameters evaluated were upper arm blood flow (brachial artery or summed radial and ulnar arteries for patients with a high brachial artery bifurcation, a normal anatomic variation), AVF blood flow, AVF diameter, AVF depth, arterial diameter, presence of stenosis, and presence of accessory veins. Natural cubic splines accounted for nonlinear relationships. Associations with AVF maturation were expressed as odds ratios comparing the odds of maturation between the 85th and 15th percentiles of each continuous ultrasound parameter. Separate backward elimination procedures identified ultrasound parameters that jointly and independently predicted unassisted and overall AVF clinical maturation (with $P<0.10$), after adjusting for clinical center and the seven case-mix factors. An additional backward elimination step considered additional removal of the case-mix variables and clinical center. The backward elimination procedure led to retention of clinical center and AVF blood flow, vein diameter and vein depth as independent predictors of unassisted and overall clinical maturation. The relationships between the AVF clinical maturation outcomes and the three ultrasound parameters retained in the final models were depicted with adjustment for clinical center by contour plots[27] and presentations of curves relating the estimated probability of maturation to AVF blood flow at the 5th, 50th, and 95th percentiles of each of the other ultrasound parameters.

Our final prognostic models for clinical maturation retained AVF blood flow, vein diameter, and vein depth, but excluded clinical center because it is not feasible to include clinical site in prognostic models intended for use in a general clinical practice setting. The accuracies of the final models were evaluated using crossvalidated receiver operating characteristics curves and estimates of the areas under the curves.[28] We also presented sensitivities and specificities provided by the KDOQI[1] and the UAB criteria for prediction of AVF clinical maturation.[10] Additional details on the data analyses are provided in the Supplemental Material.

RESULTS

Baseline Characteristics of Study Participants

Baseline clinical and demographic characteristics of the 602-participant HFM study cohort, enrolled from March 2010 to September 2013 and followed prospectively, have been previously described in detail.[29,30] A concise summary is provided in Table 1; at baseline, the mean age of participants was 55.1±13.4 (SD) years, 70% were men, 44% were black, 59% had diabetes, and 64% had already initiated maintenance hemodialysis.

Ultrasound Measurements and Maturation: Descriptive Statistics

Supplemental Table 1 summarizes the 1 day (n=587), 2 week (n=570), and 6 week (n=566) ultrasound measurements obtained in participants who survived to the respective time point without AVF thrombosis. Unassisted AVF maturation (no intervention) was achieved in 46.9%, 48.2%, and 49.4% of patients undergoing the 1 day, 2 week, and 6 week ultrasound, respectively; the corresponding proportions of patients with overall AVF maturation (no intervention plus intervention, see Methods) were 71.9%, 73.2%, and 74.9%, respectively. These summary statistics are provided without imputation of missing measurements; all analyses described subsequently were performed after multiple imputation of missing data for participants surviving without AVF thrombosis before the pertinent ultrasound examination, and excluding those who died or thrombosed earlier.

Supplemental Figure 1 displays the distributions of AVF blood flow, diameter, and depth, stratified by AVF location (upper arm versus forearm), measured in patients within three categories of AVF outcomes: (*1*) unassisted clinical maturation, (*2*) assisted maturation (clinical maturation achieved after a percutaneous or surgical intervention), and (*3*) failed clinical maturation. AVF blood flow and diameter increased progressively from 1 day to 2–6 weeks for AVFs with all three outcomes. At each postoperative time point, the AVF blood flow and diameter were highest in patients with unassisted AVF maturation, intermediate in those with assisted maturation, and lowest in those with failed AVFs. Conversely, AVF depth decreased progressively over the 6 week postoperative period, with the depth being shallowest in patients with unassisted AVF maturation, intermediate in those with assisted AVF maturation, and deepest in those with failed maturation.

Association of Clinical Maturation with Individual Ultrasound Measurements

Table 2 displays the adjusted odds ratios from separate logistic regression analyses relating unassisted AVF clinical maturation individually to each of the seven ultrasound parameters (AVF blood flow, AVF diameter, AVF depth, upper arm arterial blood flow and diameter, presence of stenosis, and presence of accessory veins), with covariate adjustment for clinical center and case-mix (age, sex, black race, dialysis status, diabetic status, body mass index, AVF location [forearm versus upper arm]). Separate analyses were performed for each of the three postoperative ultrasound visits; the adjusted odds ratios in Table 2 compare the 85th and 15th percentiles for each continuous ultrasound parameter. Compared with the 15th percentile, the 85th percentiles in upper arm arterial flow, AVF blood flow, and AVF diameter were each associated .

Table 1. Baseline demographic and clinical characteristics of the study cohort (*n*=602)

Baseline Factor	*N* (%) or Median (Percentiles)
Age, yr, median (10th and 90th percentiles)	56.4 (35.8, 71.9)
Women, *n* (%)	180 (30)
Black[a], *n* (%)	264 (44)
Hemodialysis, *n* (%)	383 (64)
Diabetes, *n* (%)	353 (59)
Peripheral artery disease, *n* (%)	91 (15)
Coronary artery disease, *n* (%)	156 (26)
Upper arm fistula, *n* (%)	459 (76)
Body mass index, kg/m^2, median (15th–85th percentiles)	29.3 (21.7, 40.1)
Vascular calcification[b], *n* (%)	265 (44)

[a]Self-reported race was missing for eight participants, all with upper arm AVFs.
[b]Vascular calcification (on preoperative ultrasound) score ≥1 on 0–2 scale.

with four-fold or greater increases in odds of unassisted clinical maturation at each of the three ultrasound measurement time points. Conversely, compared with the 15th percentile, the 85th percentile of AVF depth was associated with half the odds or lower of unassisted clinical maturation at each of the three ultrasound measurement time points. The presence of AVF stenosis exhibited a somewhat weaker, but statistically significant, inverse association with unassisted clinical maturation for each of the three ultrasound visit assessments, consistent with a prior HFM study report.[31] Unassisted clinical maturation was not associated with either arterial diameter or the presence of accessory veins at any of the three ultrasound assessments. Arterial diameter was also associated with overall maturation at 2 and 6 weeks, but, otherwise qualitatively similar results were observed for the association of the ultrasound parameters with overall AVF clinical maturation (Table 3).

We measured both upper arm arterial flow and AVF vein blood flow to assess which blood flow measurement was more strongly associated with maturation. Upper arm brachial artery flow (or summed radial and ulnar artery blood flow in patients with a high brachial artery bifurcation anatomic variation) and AVF blood flow are closely linked physiologically, and were strongly correlated at each of the three ultrasound assessments, with Spearman correlation coefficients of 0.83, 0.81, and 0.83 at 1 day and 2 and 6 weeks, respectively. The adjusted odds ratios relating these parameters to the unassisted and assisted clinical maturation were similar to one another for the 1 day and 2 week assessments, but were stronger for AVF blood flow than for upper arm arterial flow at the 6 week assessment. Hence, we retained AVF blood flow but omitted upper arm arterial flow in subsequent multivariable analysis.

Table 2. Association of unassisted clinical maturation with individual ultrasound parameters

Ultrasound Assessment	Ultrasound Parameter	15th–85th Percentiles	Odds Ratio	95% Confidence Interval	*P* Value
Day 1	Upper arm arterial flow (ml/min)	357–1252	4.64	2.75 to 7.81	<0.001
	AVF blood flow (ml/min)	258–1105	4.95	2.81 to 8.70	<0.001
	Vein diameter (cm)	3.63–5.97	5.39	3.11 to 9.33	<0.001
	Vein depth (cm)	0.29–0.83	0.48	0.28 to 0.83	0.008
	Arterial diameter (cm)	2.90–5.40	1.77	0.86 to 3.62	0.12
	Presence of stenosis	—	0.59	0.34 to 1.00	0.05
	Presence of accessory veins	—	0.83	0.54 to 1.29	0.41
Week 2	Upper arm arterial flow (ml/min)	518–1473	4.39	2.63 to 7.33	<0.001
	AVF blood flow (ml/min)	414–1407	5.67	3.33 to 9.65	<0.001
	Vein diameter (cm)	4.48–7.15	8.13	4.40 to 15.03	<0.001
	Vein depth (cm)	0.27–0.78	0.24	0.13 to 0.43	<0.001
	Arterial diameter (cm)	3.30–5.60	1.68	0.91 to 3.09	0.10
	Presence of stenosis	—	0.63	0.41 to 0.97	0.04
	Presence of accessory veins	—	1.14	0.73 to 1.80	0.56
Week 6	Upper arm arterial flow (ml/min)	514–1656	8.20	4.13 to 16.27	<0.001
	AVF blood flow (ml/min)	419–1603	14.71	7.87 to 27.48	<0.001
	Vein diameter (cm)	4.85–8.03	6.20	3.41 to 11.27	<0.001
	Vein depth (cm)	0.25–0.67	0.22	0.12 to 0.40	<0.001
	Arterial diameter (cm)	3.40–5.90	1.57	0.83 to 2.95	0.16
	Presence of stenosis	—	0.46	0.29 to 0.74	0.002
	Presence of accessory veins	—	1.22	0.77 to 1.92	0.40

Shown are odds ratios relating unassisted clinical maturation to each of the indicated ultrasound parameters after statistical adjustment for the seven case-mix factors and clinical center. For continuous ultrasound parameters, the odds ratios compare the odds of maturation between the 85th and 15th percentiles in each ultrasound parameter. Cubic splines were used to account for possible nonlinear relationships in each of the continuous ultrasound parameters. The relationships of unassisted maturation with week 2 upper arm arterial flow (P=0.01), week 6 upper arm arterial flow (P<0.001), week 2 AVF blood flow (P=0.02), week 6 AVF blood flow (P<0.001), day 1 AVF blood flow (P=0.02), and day 1 vein diameter (P=0.01) were each significantly nonlinear on the logit scale at the 5% significance level.
—, not applicable.

Table 3. Association of overall clinical maturation with individual ultrasound parameters

Ultrasound Assessment	Ultrasound Variable	Odds Ratio	95% Confidence Interval	*P* Value
Day 1	Upper arm arterial flow (85th versus 15th)	5.56	2.94 to 10.51	<0.001
	AVF blood flow (85th versus 15th)	5.88	3.22 to 10.75	<0.001
	Vein diameter (85th versus 15th)	3.56	2.05 to 6.19	<0.001
	Vein depth (85th versus 15th)	0.56	0.31 to 1.02	0.06
	Arterial diameter (85th versus 15th)	1.64	0.76 to 3.58	0.21
	Presence of stenosis	0.47	0.26 to 0.83	0.01
	Presence of accessory veins	0.93	0.59 to 1.48	0.77
Week 2	Upper arm arterial flow (85th versus 15th)	4.45	2.39 to 8.29	<0.001
	AVF blood flow (85th versus 15th)	4.24	2.43 to 7.41	<0.001
	Vein diameter (85th versus 15th)	5.53	3.01 to 10.16	<0.001
	Vein depth (85th versus 15th)	0.37	0.19 to 0.72	0.004
	Arterial diameter (85th versus 15th)	2.66	1.36 to 5.23	0.005
	Presence of stenosis	0.57	0.36 to 0.91	0.02
	Presence of accessory veins	1.34	0.81 to 2.22	0.25
Week 6	Upper arm arterial flow (85th versus 15th)	6.24	3.23 to 12.06	<0.001
	AVF blood flow (85th versus 15th)	8.81	4.31 to 18.03	<0.001
	Vein diameter (85th versus 15th)	4.74	2.50 to 8.98	<0.001
	Vein depth (85th versus 15th)	0.38	0.19 to 0.75	0.006
	Arterial diameter (85th versus 15th)	3.21	1.56 to 6.60	0.002
	Presence of stenosis	0.47	0.29 to 0.75	0.002
	Presence of accessory veins	1.53	0.90 to 2.59	0.11

Shown are odds ratios relating overall clinical maturation to each of the indicated ultrasound parameters after statistical adjustment for the seven case-mix factors and clinical center. For continuous ultrasound parameters, the odds ratios compare the odds of overall clinical maturation between the 85th and 15th percentiles in the ultrasound parameter. Cubic splines were used to account for possible nonlinear relationships in each of the continuous ultrasound parameters. The relationships of overall clinical maturation with week 2 upper arm arterial flow (P=0.04), week 6 upper arm arterial flow (P=0.02) and week 6 AVF blood flow (P=0.009) were each significantly nonlinear on the logit scale at the 5% significance level.

Multivariable Association of AVF Blood Flow, Diameter, and Depth with Clinical Maturation

Our backward elimination procedure (see Methods) identified AVF blood flow, AVF diameter, and AVF depth as independent predictors of both unassisted and overall AVF clinical maturation, after adjustment for clinical center and case-mix factors. The final models required nonlinear relationships of the clinical maturation outcomes with AVF blood flow, but simplified to linear relationships on the log odds scale for AVF diameter and AVF depth. Table 4 displays the mutually adjusted odds ratios, which jointly relate unassisted clinical maturation to AVF blood flow, AVF diameter, and AVF depth measured at either the 1 day, 2 week or 6 week assessments, with adjustment for case-mix and clinical center. Table 5 summarizes the relationships of 6 week ultrasound and unassisted clinical maturation with each of the case-mix variables considered individually, adjusting only for clinical center, then jointly with adjustment for clinical center and the case-mix variables, and then jointly with adjustment for clinical center, the case-mix factors, and the 6 week ultrasound parameters. Unassisted AVF clinical maturation was not associated with the case-mix factors, but was associated with clinical center (P<0.001 for each of the three ultrasound assessments), after adjustment for the three ultrasound variables and seven case-mix factors. Average ultrasound measures differed considerably across the seven clinical centers. The adjusted marginal mean probabilities of unassisted clinical maturation for the seven clinical centers, *i.e.*, maturation probability estimates computed as if each center shared the same study-wide case-mix and ultrasound profile, varied from 0.26 to 0.68, with a median of 0.53.

Supplemental Table 2 presents the adjusted odds ratios for the ultrasound parameters at the 1 day, 2 week or 6 week assessments from a similar multivariable analysis for overall clinical maturation. As with unassisted clinical maturation, overall clinical maturation was not associated with the case-mix factors but was associated with clinical center, after adjustment for the remaining variables in the model. The adjusted marginal mean probabilities of overall maturation for the seven clinical centers varied less than for unassisted clinical maturation, ranging from 0.61 to 0.88 with a median of 0.76. In a separate exploratory analysis, we found that the prior changes in AVF blood flow, vein diameter, and vein depth between 2 and 6 weeks or between 1 day and 6 weeks were not significantly associated with either of the clinical maturation outcomes after accounting for 6 week AVF blood flow, vein diameter, and vein depth (Supplemental Table 3, A and B).

For further model simplification, we continued the backward elimination procedure to omit case-mix factors while retaining clinical center, as these variables were not independently associated with either unassisted clinical maturation or with overall AVF clinical maturation for any of the three ultrasound assessments. On the basis of this model, Figure 1 displays the predicted probability of unassisted clinical

Table 4. Multivariable relationships of primary unassisted maturation with ultrasound and other predictor variables

Ultrasound Assessment	Predictor Variables	Odds Ratio	95% Confidence Interval	*P* Value
Day 1	AVF blood flow (85th versus 15th)	2.78	1.44 to 5.38	0.002
	Vein diameter (85th versus 15th)	2.95	1.71 to 5.10	<0.001
	Vein depth (85th versus 15th)	0.38	0.22 to 0.63	<0.001
	Clinical center	—	—	<0.001
Week 2	AVF blood flow (85th versus 15th)	2.81	1.49 to 5.29	0.001
	Vein diameter (85th versus 15th)	3.90	2.04 to 7.48	<0.001
	Vein depth (85th versus 15th)	0.31	0.18 to 0.54	<0.001
	Clinical center	—	—	<0.001
Week 6	AVF blood flow (85th versus 15th)[a]	11.70	5.29 to 25.89	<0.001
	Vein diameter (85th versus 15th)	2.14	1.08 to 4.23	0.03
	Vein depth (85th versus 15th)	0.18	0.10 to 0.32	<0.001
	Clinical center	—	—	<0.001

The table summarizes results from multivariable logistic regressions relating primary unassisted maturation to AVF blood flow, vein diameter, and vein depth after controlling for the seven case-mix variables and clinical center. *P* values for the seven case-mix variables considered as a group were 0.54, 0.81, and 0.94 at day 1, week 2, and week 6, respectively. *P* values for fistula location exceeded 0.10 at each of the three ultrasound assessments. Odds ratios comparing the seven clinical centers are intentionally omitted to simplify the presentation. —, not applicable.

[a]The *P* value for a nonlinear relationship between unassisted maturation and 6 week AVF blood flow on the log odds ratio scale was <0.001.

maturation as a function of AVF blood flow for three combinations of AVF vein diameter (5th, 50th, and 95th vein diameter percentiles) and three combinations of AVF depth (5th, 50th, and 95th percentiles), all assessed at the 6 week ultrasound visit. Blood flow ranges extend from the 5th to the 95th AVF blood flow percentiles for each combination of AVF vein diameter and vein depth. The predicted probabilities of unassisted clinical maturation range from <0.05 at the lowest extremes of AVF blood flow, diameter, and depth, to >0.90 at for the combination with the highest extremes of these three ultrasound parameters. We note that for each combination of AVF diameter and depth, a steep gradient exists between AVF blood flow and the probability of unassisted clinical maturation. However, beyond a blood flow of 1200 ml/min, there are no additional increases in the probabilities of clinical maturation. Supplemental Figure 2 displays the predicted probability of unassisted maturation in the upper arm versus forearm. Supplemental Figure 3 displays the predicted probability of overall AVF clinical maturation. For the 6 week ultrasound assessment, increases of 0.1 cm in vein diameter and vein depth, which were linearly related to the odds of maturation on the log scale, were respectively associated with a 16% (95% confidence interval [95% CI], 4% to 40%) increase and a 33% (95% CI, 26% to 41%) decrease in the odds of primary unassisted clinical maturation, and a 10% (95% CI, 10% to 34%) increase and a 24% (95% CI, 16% to 31%) decrease in the odds of overall clinical maturation.

Supplemental Figure 4 provides an additional perspective on the association of the ultrasound measures with unassisted clinical maturation by displaying contour plots of predicted

Table 5. Association of unassisted clinical maturation with case-mix variables, before and after adjusting for AVF blood flow, vein diameter, and vein depth

Factor	Maturation versus Individual Case-Mix Factors			Maturation versus Case-Mix Factors in Multivariable Model[a]			Maturation versus Case-Mix Factors in Multivariable Model Adjusting for 6-wk Fistula Blood Flow, Vein Diameter, and Vein Depth[a]		
	OR	95% CI	*P* Value	OR	95% CI	*P* Value	OR	95% CI	*P* Value
Age (85th versus 15th percentile)	0.72	(0.50 to 1.05)	0.08	0.72	(0.48 to 1.07)	0.10	0.94	(0.58 to 1.52)	0.80
Women	0.57	(0.39 to 0.85)	0.006	0.58	(0.39 to 0.88)	0.01	1.12	(0.67 to 1.89)	0.66
Black race	0.92	(0.62 to 1.36)	0.68	0.86	(0.57 to 1.29)	0.47	0.90	(0.55 to 1.47)	0.67
Dialysis	1.16	(0.79 to 1.69)	0.46	0.98	(0.66 to 1.47)	0.94	1.06	(0.63 to 1.76)	0.84
Diabetes	0.58	(0.41 to 0.84)	0.004	0.70	(0.47 to 1.05)	0.08	1.09	(0.67 to 1.79)	0.72
BMI, per 5 kg/m^2	0.81	(0.72 to 0.92)	0.001	0.86	(0.75 to 0.98)	0.02	0.96	(0.81 to 1.14)	0.65
Upper arm fistula location	1.29	(0.83 to 2.01)	0.25	1.51	(0.95 to 2.41)	0.08	0.60	(0.32 to 1.14)	0.12

Each analysis included clinical center as a covariate. OR, odds ratio; BMI, body mass index.

[a]*P* values for joint association of primary unassisted maturation with all seven case-mix factors were 0.002 without adjustment for 6 week ultrasound variables and 0.94 after adjustment for the ultrasound variables.

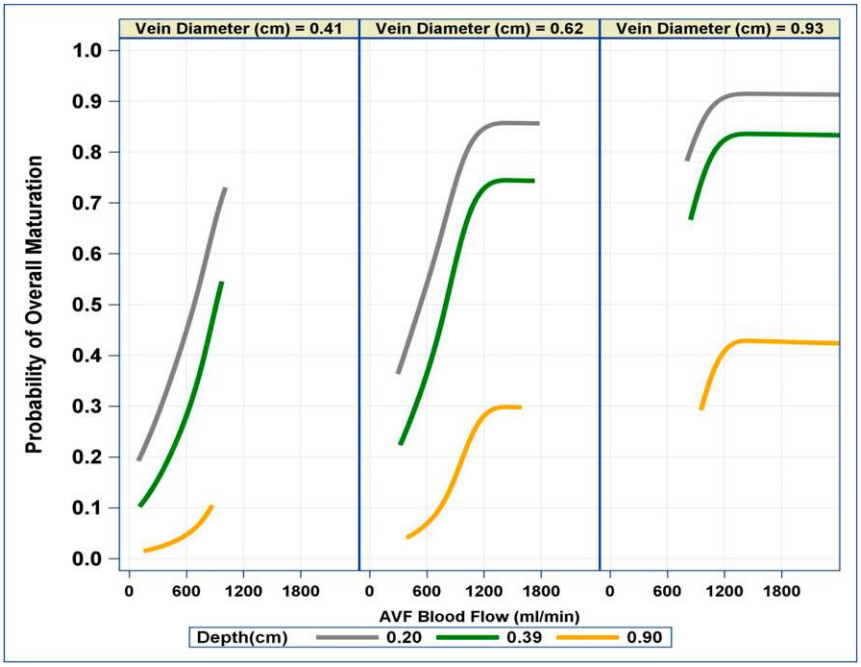

Figure 1. The figure displays how the probability of overall maturation increases at higher AVF blood flow and at higher vein diameter, but decreases at higher vein depth. A cubic spline in AVF blood flow was used to account for nonlinear association. The depicted levels of vein diameter and vein depth represent the 5th, 50th, and 95th percentiles.

probabilities of unassisted clinical maturation across different combinations of 6 week AVF blood flow, and diameter for four levels of vein depth. Combinations of AVF blood flow, vein diameter, and vein depth with predicted maturation probabilities $\leq$0.25 represent AVFs with a low probability of maturing without intervention, whereas combinations with predicted maturation probabilities $>$0.75 represent combinations with a high probability of achieving unassisted clinical maturation. For example, if a AVF has an average vein depth of 0.2 cm, an average vein diameter of 0.65 cm, and an average blood flow of 900 cc/min, the predicted probability of achieving unassisted maturation is approximately 75%. If the vein depth increases to 0.4 cm, the same AVF has a predicted unassisted maturation probability of approximately 55%, and approximately 40% when the vein depth increases to 0.6 cm. Supplemental Figure 5 provides a similar contour plot for overall clinical maturation.

Prognostic Model for Clinical Maturation

Each relationship of AVF blood flow, vein diameter, and vein depth with unassisted and overall clinical maturation was qualitatively similar in the multivariable models from the backward elimination procedure, with and without including adjustment for clinical center (Supplemental Table 4, A and B). We evaluated accuracies of our final multivariable prognostic models for clinical maturation after dropping clinical center, because center would not be appropriate for inclusion in a prognostic model intended for general use. The cross-validated areas under the curves for the final prognostic models on the basis of the three ultrasound parameters were 0.69, 0.74, and 0.79 for the 1 day, 2 week, and 6 week assessments for unassisted clinical maturation, and 0.69, 0.71, and 0.76 for overall clinical maturation, respectively. Expressions for the prognostic models are provided in the Supplemental Material. The corresponding crossvalidated receiver operating characteristics curves for unassisted clinical maturation and overall clinical maturation are displayed in Figure 2 and Supplemental Figure 6, with the combinations of sensitivity and 1– specificity of the KDOQI and UAB maturation criteria superimposed.

DISCUSSION

We examined the associations of 1 day, 2 week, and 6 week AVF ultrasound blood flow, diameter, and depth with unassisted and assisted AVF clinical maturation in a large multicenter cohort of patients undergoing new AVF creation, with and without adjustment for seven clinical and demographic characteristics. We found that these three ultrasound measurements fully accounted for the associations of both unassisted and overall clinical maturation with the case-mix variables (age, sex, black race, AVF location [forearm versus upper arm], dialysis status, diabetic status, and body mass index). Interestingly, any effect of AVF location appears to have been mediated by its relationships with blood flow and diameter, which tended to be smaller in forearm AVF. Thus, the three ultrasound variables were sufficient for maturation prediction. Moreover, changes in AVF blood flow and diameter from 1 day to 2 and 6 weeks were not independently associated with the unassisted or overall clinical maturation outcomes, after accounting for the 6 week ultrasound measurements. Hence, as long as 6 week ultrasound measurements are available, it does not appear necessary to account for prior trajectories in the ultrasound parameters when predicting future clinical maturation.

In a previous analysis of anatomic AVF development, we found that ultrasound-measured AVF blood flow at 1 day usually exceeded 50% of the 6 week blood flow rate, and that 2 week measurements were more predictive than 1 day measurements for the 6 week AVF diameter and blood flow.[23] Further analyzing this cohort by clinical maturation, we now find that the greatest increases in AVF blood flow were observed in patients who later achieved unassisted AVF maturation, intermediate increases were observed in those who achieved assisted AVF maturation, and lowest increases were seen in those whose AVFs subsequently failed. AVF diameter showed similar but

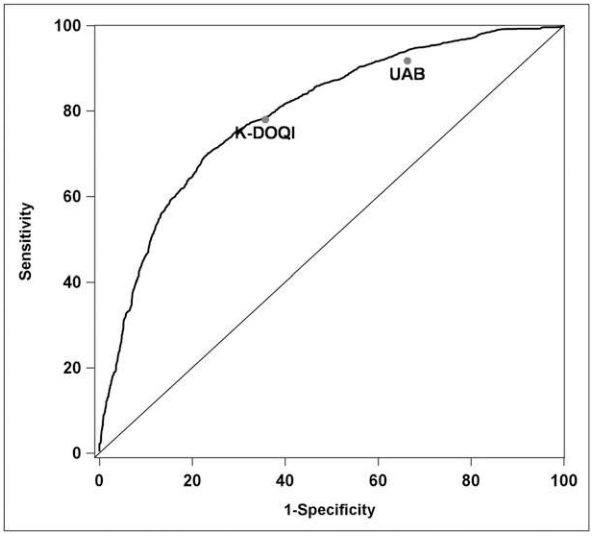

Figure 2. The cross-validated receiver operating characteristic curve displayed in the figure shows that the multivariable model based on 6-week AVF blood flow, diameter, and depth provides moderately accurate prediction of unassisted clinical maturation. The sensitivities and specificities of prediction of clinical maturation using the KDOQI and UAB criteria are also displayed. Crossvalidated areas under the receiver operating characteristic curves for prognostic models on the basis of only the three ultrasound parameters increased from 0.69 at 1 day to 0.74 and 0.79 at 2 and 6 weeks. KDOQI criteria: AVF blood flow ≥600 ml/min, vein diameter ≥0.6 cm, and vein depth ≤0.6 cm; UAB criteria: AVF blood flow ≥500 ml/min and vein diameter ≥0.4 cm.

smaller relative increases over the 6 week postoperative period, as flow is proportional to vessel radius to the fourth power.[32] Although the upper arm brachial artery flow was correlated with AVF maturation, this association was stronger for AVF blood flow at the 6 week assessment, and thus AVF blood flow was used in the final modeling.

Although AVF vein depth is critical to AVF cannulation and, as a result, affects fistula usability, there has been little investigation of the contribution of AVF depth to maturation to date. Interestingly, the overall median vein depth decreased by approximately 0.1 cm from 1 day to 6 weeks ($P<0.001$, Wilcoxon sign rank test), suggesting remodeling of the overlying soft tissues. We found that accounting for vein depth in addition to AVF blood flow and vein diameter significantly improved prediction of subsequent clinical maturation.

Prognostic Model for Ultrasound AVF Maturation Evaluation

Potential etiologies for AVF nonmaturation include stenosis, lack of vein and artery dilation due to intimal hyperplasia, vein scarring, and atherosclerotic disease, large accessory veins, AVF vein too deep to cannulate, and other factors.[7,33–37] The presence of physiologically significant stenosis may result in smaller diameters and decreased blood flows. Therefore, although the presence of stenosis was significant in our initial models, the final prognostic model only contains AVF blood flow, diameter, and depth. We did not find a significant association of AVF nonmaturation with the presence of accessory veins, and did not investigate the category further, although clearly a large accessory vein can divert blood flow sufficient to warrant correction in an individual patient.[17]

The slopes of the prediction curves of the model attenuated at larger blood flows, which is not surprising and correlates with clinical experience. Maturation rates varied across clinical centers, more than readily explainable by sampling variation, ultrasound measures, or the seven case-mix characteristics examined. Other measured and unmeasured patient characteristics, surgical selection and intraoperative factors, and postoperative processes of care may contribute to this variation.

Final Model and Potential Use

Our final AVF maturation predictive models included AVF blood flow, diameter, and depth at each of the three time points studied (1 day, 2 weeks, and 6 weeks). A prediction of the likelihood of maturation could therefore be obtained from input of the ultrasound values from any of these time points into the model. In contrast to the KDOQI[1] and UAB[10] recommendations that use discrete criteria, this model offers a major advantage in that it provides probabilities of maturation, as depicted in Supplemental Figures 4 and 5, using the averaged AVF depth, diameter, and flow. Such probabilities could facilitate decisions by the clinician as to the course of action, such as surgical interventions or abandonment of the AVF. The richness of the present data will also be highly valuable for practice guideline workgroups to formulate recommendations, taking into account other factors such as invasiveness of the remedial procedures, burden to the patient, costs, and differences in process of care in individual centers.

Strengths of this study include its multicenter, prospective cohort design, large diverse patient population, few AVFs that thrombosed early, and few AVF interventions before 6 weeks.[29] Moreover, the AVFs studied included a large percentage of upper arm AVFs, commonly placed in the United States but less well studied than forearm AVFs in the literature. Additional study strengths were critical to reliable ultrasound measurements, including a uniform preoperative mapping and postoperative AVF evaluation ultrasound protocol, central training and certification of the study centers' sonographers, and centralized core read of all of the ultrasounds.

Limitations of the study include the restriction of the study cohort to single-stage AVFs, as a planned two-stage basilic vein transposition with a second operation to promote AVF maturity would have introduced significant complexity into AVF maturation follow-up and interpretation. Second, AVF maturation fractions varied across centers. Because our model predictions are not calibrated to any specific center, they may consistently underestimate or overestimate the chances of AVF maturation at an individual practice setting. The prognostic models developed within this study reflect the relationships between ultrasound AVF and maturation at the seven participating sites, and may need external validation at additional facilities.

In conclusion, statistical models from the large HFM Study, multicenter cohort permit prediction of AVF outcomes on the basis of an individual AVF's ultrasound blood flow, diameter, and depth at 1 day, 2 weeks, and 6 weeks after AVF creation. Ultrasound may be useful as a quantitative imaging study in assessing likelihood of AVF maturation; future research evaluating this tool in maturation studies may be warranted. Regardless of other factors, 6 week ultrasound AVF blood flow, diameter, and depth are moderately predictive of AVF clinical maturation.

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All authors designed the study and participated in conducting the trial; T.G., P.B.I., M.K.R., and G.J.B. analyzed the data; T.G., P.B.I., and M.K.R. made the figures; M.L.R., T.G., and P.B.I. drafted the paper; all authors participated in data interpretation, edited the manuscript, and approved the final version of the manuscript.

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DISCLOSURES

M.A. is a Consultant for CorMedix. A.K.C. is a member of the Data and Safety Monitoring Board for a trial on vascular graft cosponsored by Humacyte, Inc. and the National Heart, Lung, and Blood Institute, as well as a member of the Clinical Events Committee and Data Safety and Monitoring Board for the Novel Endovascular Access Trial sponsored by TVA Medical, Inc. L.M.D. is a member of the Data Monitoring Committee for vascular access trials sponsored by Proteon Therapeutics. J.S.K. is consultant and member of the Data Monitoring Committee for vascular access trials sponsored by Proteon Therapeutics. P.R.-C. is a Consultant/Advisory Board Member for WL Gore, Bard Peripheral Vascular (Lutonix), Medtronic, TVA, Cormedix, and Proteon. M.A.V. was a member of the Managing Committee for the University of Texas Southwestern Health Systems-DaVita Dialysis Joint Venture. C.A., L.A., H.I.F., J.H., T.G., P.B.I., J.W.K., M.L.R., Y.-T.S., and H.R.U. have no disclosures.

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See related editorial, "The Science of Fistula Maturation," on pages 2607–2609.

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Erratum

CORRECTION

Robbin ML, Green T, Allon M, Dember LM, Imrey PB, Cheung AK, et al.: Prediction of arteriovenous fistula clinical maturation from postoperative ultrasound measurements: findings from the hemodialysis fistula maturation study. *J Am Soc Nephrol* 29: 2735—2744, 2018.

In Table 2, vein and arterial diameter are labeled as cm, but the 15th and 85th percentiles are actually reported in mm for Day 1, Week 2 and Week 6.

In Supplemental Tables 3A and B, vein diameter was previously labeled as per cm, but the results were actually expressed per mm.

Also in the Equations Appendix of the Supplemental Material, the units used were ml/min for flow, mm for diameter, and cm for depth, similar to Table 2.