Routine Preoperative Vascular Ultrasound Improves Patency and Use of Arteriovenous Fistulas for Hemodialysis: A Randomized Trial

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Background and objectives: Arteriovenous fistulas (AVFs) are the preferred vascular access for hemodialysis but have a considerable failure rate. This study investigated whether routine preoperative vascular ultrasound results in better AVF outcome than physical examination.

Design, setting, participants, & measurements: Patients with end-stage kidney disease referred for permanent access formation were assessed by independent examiners using physical examination and ultrasound. After random allocation, the ultrasound report was disclosed to the surgeon for patients in the ultrasound group but not for the clinical group. End points were AVF failure and survival rates, analyzed by intention to treat and by use for hemodialysis.

Results: AVFs were made in 208 of 218 randomized patients. Clinical and ultrasound groups were similar in terms of patient characteristics, allocation to individual surgeons, and proportion of forearm AVFs. The ultrasound group had a significantly lower rate of immediate failure (4% *versus* 11%, $P = 0.028$) and, among failed AVFs, less thrombosis (38% *versus* 67%, $P = 0.029$). Primary AVF survival at 1 year was not statistically different (ultrasound = 65%, clinical = 56%, $P = 0.081$). Assisted primary AVF survival at 1 year was significantly better for the ultrasound group (80% *versus* 65%, $P = 0.012$). The number of patients requiring preoperative ultrasound to prevent one AVF failure was 12.

Conclusions: Routine preoperative vascular ultrasound in addition to clinical assessment improves AVF outcomes in terms of patency and use for dialysis. National Research Register, United Kingdom, trial number N0046131432.

Clin J Am Soc Nephrol 5: 2236–2244, 2010. doi: 10.2215/CJN.02820310

The arteriovenous fistula (AVF) is the preferred vascular access for hemodialysis (1,2). However, AVF failure is a common problem, particularly for radiocephalic AVF, with a modest two-thirds survival by 1 year (3). AVF failure is often attributed to vascular comorbidity because an increasing number of elderly patients with diabetes and cardiovascular disease are accepted for hemodialysis treatment (4–9).

Physical examination has traditionally been used to identify a suitable artery and vein for AVF formation (10). Preoperative vascular mapping with ultrasound has recently been shown to predict AVF outcome (10–13). The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines recommend the use of routine ultrasound mapping for all patients but noted the lack of level one evidence to support this recommendation (1).

We conducted a randomized trial to evaluate the outcome of routine preoperative assessment with ultrasound in terms of patency and use of AVFs for hemodialysis.

Materials and Methods

Patients

The study was approved by the Local Ethics Committee of East Birmingham, United Kingdom; was registered with the U.K. National Research Register, trial number N0046131432; and adhered to the Declaration of Helsinki.

All patients with end-stage kidney disease at Heart of England Hospital (Birmingham, United Kingdom) who were referred for formation of AVF were invited to take part in the study. Included were all with either none or one previous AVF. Patients who had already participated in the study, who had more than one previous AVF, or had a previous upper-arm arteriovenous graft were excluded. Patients who gave informed written consent were recruited between August 31, 2004 and September 30, 2006 and were followed for up to 40 months. Clinical data were obtained from electronic patient and hemodialysis session records.

Preoperative Assessment

All patients were evaluated with physical and ultrasound examination by independent assessors blinded to each other. Physical examination was carried out by one of four vascular surgeons (one consultant, three trainees) with experience in AVF formation. Following a standardized protocol, the pulses at elbows and wrists and the superficial veins in the forearm and upper arm (with tourniquet) were assessed. Vessels were considered suitable if the artery had a good pulse and the vein was patent and of good caliber. The most distal possible site was chosen for AVF formation.

The ultrasound examination was carried out by a nephrology trainee

($n = 216$ scans) and a vascular access nurse specialist ($n = 36$ scans). Patients were assessed with a portable ultrasound scanner (SonoSite 180 plus, SonoSite, Inc., Bothell, WA) with a 5- to 10-MHz linear probe. A standardized scan protocol was used based on a technique described elsewhere, and the most distal site possible was recommended for AVF formation (14).

Briefly, the arterial scan followed the vasculature from the brachial artery in the mid-upper arm to the radial artery at the wrist in B-mode. Internal diameters were measured of the radial artery at the wrist and in the distal forearm and of the brachial artery at the elbow and in the mid-upper arm. The average of two diameter measurements at each site was the diameter reported. Minimum arterial diameters suitable for AVF formation were 2 mm in the forearm and 3 mm in the upper arm (10,15). Color power and spectral duplex ultrasound were recorded in the brachial artery just above the elbow and in the radial artery just above the wrist. The spectral Doppler waveform was considered adequate if it was triphasic or biphasic in the antegrade direction but inadequate if retrograde, damped, or absent (16). The ulnar artery was assessed in the distal forearm with B-mode and duplex ultrasound. Complete or near occlusion of the ulnar artery was considered a contraindication to access formation in the same arm because of the increased risk of hand ischemia.

After application of a tourniquet, the superficial veins were followed in cross section with B-mode from wrist to mid-upper arm with intermittent vein compression. The cephalic vein was scanned from wrist to mid-upper arm. The basilic vein was scanned from the elbow level to its drainage into the deep brachial veins and in the forearm if the cephalic vein was unsuitable (17). Internal diameters and vein depth were measured at the wrist, in the distal forearm, in the proximal forearm, at the level of the elbow, and in the upper arm. The average of two diameter measurements at each site was the diameter reported. Suitable veins had to be fully compressible and morphologically normal, with minimum diameters of 2 mm in the forearm and 3 mm in the upper arm (10).

Random Allocation

An independent trial coordinator, unaware of the results of the assessments, stratified patients by age (<65 years *versus* older) and dialysis status (prehemodialysis *versus* on hemodialysis) into four strata and randomized to clinical and ultrasound groups using four sets of consecutively numbered sealed envelopes containing the assessment allocation on the basis of a predefined computer-generated random sequence in blocks of eight. The allocation was revealed to the main researcher after consent, recruitment, and preoperative assessments were complete.

For the clinical group, the ultrasound findings were not disclosed to the surgeon. For the ultrasound group, the ultrasound findings were disclosed to the surgeon; in case of discrepancy between the clinical and ultrasound assessments, the surgeon could decide but usually followed the ultrasound recommendation. In the either group, the surgeon had the option to request further imaging (ultrasound, angiography) if deemed necessary. Patients were unaware of the random allocation.
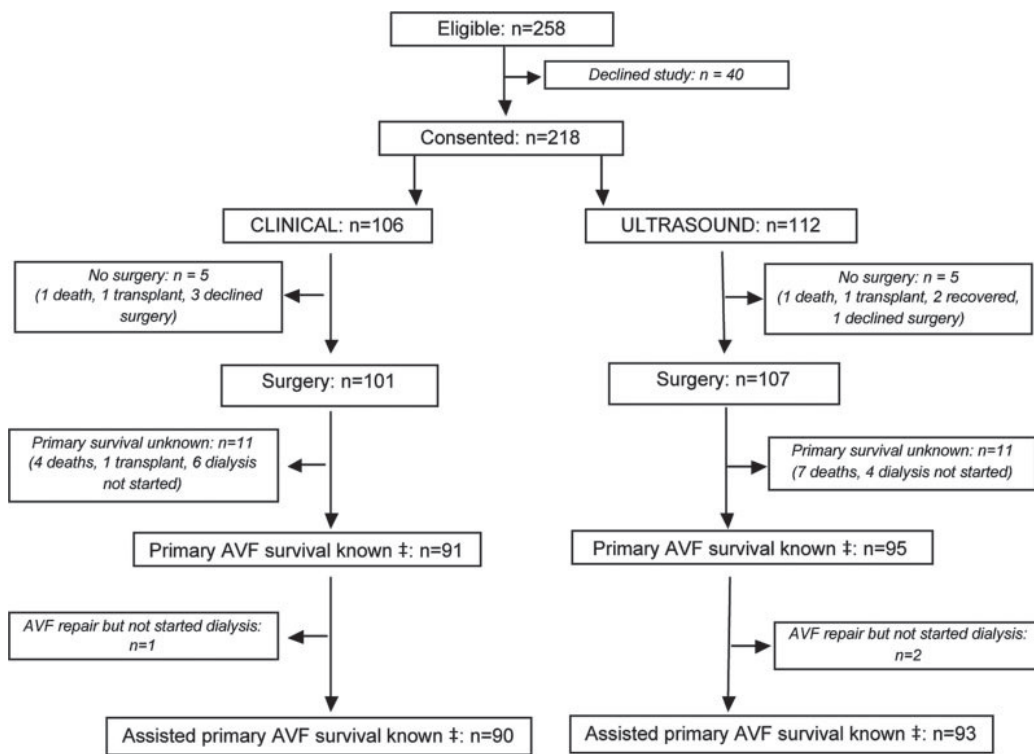
(‡) AVF survival known means that AVF usability for dialysis could be determined (as failure or being used for dialysis)

Figure 1. Consort diagram of patients in the study.

Table 1. Baseline characteristics

Characteristic	Clinical Group (n = 106)	Ultrasound Group (n = 112)	P
Age			0.760
median [range]	67 [20 to 89]	69 [26 to 88]	
25th percentile	55	60	
75th percentile	76	75	
Gender			0.496
male	70 (66.0%)	69 (61.6%)	
female	36 (34%)	43 (38.4%)	
Ethnicity			0.477
Caucasian	71 (67%)	80 (71.4%)	
Indo-Asian	21 (19.8%)	25 (22.3%)	
African	11 (10.4%)	4 (3.6%)	
other	3 (2.8%)	3 (2.7%)	
Body mass index[a]	26.9 ± 6.2	27.1 ± 6.31	0.471
Hypertension	79 (75.2%)	87 (78.4%)	0.584
Diabetes	36 (34.3%)	48 (43.2%)	0.177
Cardiac disease[b]	38 (36.2%)	33 (29.7%)	0.312
Vascular disease[c]	23 (21.9%)	16 (14.4%)	0.153
Antiplatelet agent[d]	55 (52.9%)	47 (42.3%)	0.122
Hemodialysis			0.955
not on hemodialysis[e]	82 (77.4%)	87 (77.7%)	
on hemodialysis	24 (22.6%)	25 (22.3%)	
Difficult access[f]	12 (11.3%)	12 (10.7%)	0.886
Surgical experience			0.549
surgical consultant alone	39 (39.8%)	47 (46.5%)	
surgical consultant + trainee	41 (41.8%)	35 (34.7%)	
surgical trainees alone	18 (18.4%)	19 (18.8%)	

ᵃBody mass index data only available for approximately 62% of patients (clinical 57%, ultrasound 67%).
ᵇCardiac disease was defined by a clinical history of previous angina, acute coronary syndrome, coronary artery bypass graft, or cardiac transplant.
ᶜVascular disease was defined by a clinical history of claudication, critical leg ischemia, and endovascular or surgical intervention for peripheral arterial disease.
ᵈAntiplatelet agent = aspirin or clopidogrel or both.
ᵉNot on hemodialysis included patients with advanced chronic kidney disease (majority), failing peritoneal dialysis or renal transplant with plan to transfer to hemodialysis, and patients having started hemodialysis for less than 90 days.
ᶠDifficult access was defined as patients in whom no suitable site for AVF formation could be identified by clinical examination alone.

Surgery

A team of 6 consultant vascular surgeons and 13 vascular surgical trainees shared the workload of AVF formation. Trainees generally operated with the consultant under direct supervision, but trainees with sufficient experience (n = 5) operated under indirect supervision.

AVF Use for Hemodialysis

After surgery, all AVFs were used by clinical need as defined by the attending nephrologist and by AVF maturity as assessed by an experienced hemodialysis nurse. When necessary, AVF salvage was undertaken by endovascular or surgical intervention for failed AVFs.

Study Objectives

We hypothesized that routine ultrasound use would result in (1) less AVF failure and (2) better AVF survival.

Outcome Definitions

Primary end point (early AVF outcomes):
1. Immediate AVF failure: AVF thrombosis on the day of surgery, defined as absence of a thrill or inadequate vein found at surgery (18,19)
2. Primary AVF failure: All AVF that were never adequate for hemodialysis after initial surgical formation, including immediate failure on the day of surgery, early thrombosis, and failure to mature (9,18).

Secondary end point (longer term AVF outcomes):

1. Primary AVF survival: Patency of all AVFs, defined by patency and usability for dialysis, from date of surgical formation to date of first access failure (20)
2. Assisted primary AVF survival: Patency of all AVFs, defined by patency and usability for dialysis, from date of surgical formation until the access was thrombosed, including time gained by successful salvage procedures (20).

AVF failure meant that AVFs were unusable for dialysis, requiring a salvage intervention, new access formation, or insertion of a hemodi-

Table 2. Site of AVF (in all patients who underwent surgery n = 208)

Site of AVF	Clinical (n = 101)	Ultrasound (n = 107)
All forearm	64 (63)	63 (59)
left radiocephalic	47 (47)	42 (39)
right radiocephalic	16 (16)	20 (19)
other forearm[a]	1 (1)	1 (1)
All upper arm	37 (37)	44 (41)
left braciocephalic	21 (21)	26 (24)
right brachiocephalic	12 (12)	10 (9)
left brachiobasilic	2 (2)	2 (2)
right brachiobasilic	1 (1)	5 (5)
other upper arm[b]	1 (1)	1 (1)
All AVF with superficialization/ transposition	5 (5)	11 (10)

Data presented as absolute number (%). Forearm *versus* upper-arm AVF: χ^2 0.266; P = 0.606. Superficialization/ transposition of vein *versus* none: χ^2 2.079; P = 0.149.
ᵃOther forearm AVF: left radiobasilic (ultrasound); left ulnobasilic (clinical).
ᵇOther upper-arm AVF: right upper-arm ulnocephalic (clinical); left upper-arm ulnocephalic (ultrasound).

aysis catheter (21). AVFs were considered usable for dialysis if they were used for at least six consecutive 4-hour dialysis sessions by two needle cannulation without assistance from a catheter, with a minimum blood pump rate of 200 ml/min after the third session.

Censoring occurred at the time of patient death, kidney transplantation, change to peritoneal dialysis, patient transfer to another unit, or the end of the follow-up period. Outcome assessment and data analysis were carried out without blinding to assessment groups using standard end points from the literature.

Statistical Analyses

Expecting primary AVF failure in 35%, we considered a reduction of failure with ultrasound by at least 15% as clinically important (9). At a significance level of 0.05 and a power level of 0.8, a minimum sample size of 280 patients (140 in each group) was required.

Univariate analysis of categorical variables was made with χ^2 square test. After cube transformation, age was tested by independent t test (22). Number needed to treat was calculated as 1/absolute risk reduction. Absolute risk reduction was calculated as the difference and relative risk was calculated as the ratio of failure risk in the clinical *versus* that in the ultrasound group (23). Primary and assisted primary AVF survival was examined by life-table analysis. Multivariate analysis

of AVF survival was examined by Cox regression. Predictor variables were excluded by a backward stepwise approach on the basis of the likelihood ratio (22). All analyses were by intention to treat and under the condition that AVF usability for hemodialysis was known. We used SPSS version 16 for statistical calculations. A P value of 0.05 or less was considered significant.

Results
Patients

Of 258 eligible patients, 218 consented to the study (Figure 1). All 208 patients undergoing surgery (clinical $n = 101$, ultrasound $n = 107$) received an AVF for which the immediate outcome was known. AVF usability for hemodialysis was known in 186 patients for primary survival and in 183 patients for assisted primary survival. Primary survival was unknown in 22 patients because of death or not having started dialysis by the end of follow-up. Assisted primary survival was unknown in a further three patients who had undergone AVF salvage but had not started dialysis (Figure 1). Thus, the number required by our power calculation was not reached.

Table 3. Primary outcome—AVF failure rates

Outcome	Clinical Group	Ultrasound Group	RR [95% CI][a]	P	ARR[b]	NNT [95% CI][c]
Immediate failure						
all AVF: n failures	12	4			8.1%	12 [6, 132]
ITT: $n = 218$[d]	11.3%	3.6%	0.315 [0.105, 0.944]	0.028		
surgery: $n = 208$[e]	11.9%	3.7%	0.315 [0.105, 0.944]	0.028		
forearm AVF: n failures	11	4			11.1%	9
ITT: $n = 131$	16.7%	6.2%	0.369 [0.124, 1.100]	0.054		
surgery: $n = 126$	17.5%	6.3%	0.364 [0.122, 1.081]	0.054		
Primary failure						
all AVF: n failures	33	24			11.0%	9
ITT: $n = 218$	31.1%	21.4%	0.688 [0.437, 1.084]	0.103		
dialysis use: $n = 186$[f]	36.3%	25.3%	0.697 [0.449, 1.082]	0.104		
forearm AVF: n failures	27	19			12.4%	8
ITT: $n = 131$	40.9%	29.2%	0.715 [0.444, 1.151]	0.139		
dialysis use: $n = 116$	45.8%	33.3%	0.728 [0.460, 1.154]	0.171		
Nonmaturation[g]						
all AVF: n failures	21	20			4.6%	22
ITT: $n = 218$	19.8%	17.9%	0.901 [0.519, 1.565]	0.712		
dialysis use: $n = 170$	26.6%	22.0%	0.827 [0.485, 1.409]	0.484		
forearm AVF: n failures	16	15			5.0%	20
ITT: $n = 126$	25.4%	23.8%	0.938 [0.509, 1.729]	0.836		
dialysis use: $n = 101$	33.3%	28.3%	0.849 [0.472, 1.526]	0.584		

AVF failures are shown for all patients, for the clinical and for the ultrasound group, respectively; n failures means absolute number of AVF failures; % failures means percentage of AVF failures to total number AVF.
[a]Relative risk of AVF failure with 95% CI [lower, upper limits].
[b]Absolute risk reduction of AVF failure.
[c]NNT [95% CI]: Number needed to treat (*i.e.*, the number of ultrasound scans needed to avoid one AVF failure; the 95% CI is shown for immediate failure but not for primary failure or the forearm subgroups because these are not statistically significant.
[d]ITT: analysis by intention to treat; i.e., for all patients randomized.
[e]Analysis restricted to patients who had surgery.
[f]Analysis restricted to AVF for which the outcome (dialysis use or failure) was known.
[g]Nonmaturation: primary failure excluding immediate failure.

Baseline Characteristics of Randomized Groups

Clinical and ultrasound groups were similar in terms of baseline patient characteristics, difficulty of access, or surgeon's experience (Table 1). Upper-arm or right-arm AVF location and the rate of vein transpositions were not significantly different, although the latter was more common in the ultrasound group (Table 2).

Early AVF Outcomes

Immediate failure was significantly worse in the clinical group (Table 3). Of all 16 immediate failures, 2 were due to an inadequate vein found at surgery (clinical $n = 2$, ultrasound $n = 0$).

Primary failure occurred less in the ultrasound group, but this was not statistically significant (Table 3). Primary failure after excluding immediate failure was similar (clinical $n = 21$, ultrasound $n = 20$). On univariate comparison, primary failure was significantly worse in forearm compared with upper-arm AVFs (39.7% *versus* 15.7%; $P = 0.001$). Further analysis of pri-

mary failure by thrombosis *versus* other causes showed significantly more early thrombosis in the clinical group (clinical $n = 22$ of 33 (67%); ultrasound $n = 9$ of 24 (38%); $P = 0.029$).

The number of ultrasound scans needed to avoid one immediate failure event was low (Table 3).

Longer Term AVF Outcomes

Primary AVF survival at 1 year was 56% for the clinical group and 65% for the ultrasound group, but this was not statistically significant ($P = 0.081$; Figure 2). The assisted primary survival at 1 year was significantly better for ultrasound (80% *versus* 65%, $P = 0.012$; Figure 3).

With Cox regression, we tested which baseline clinical variables were independent predictors of AVF survival. First, we included all variables (*i.e.,* means ultrasound, age, gender, ethnicity, diabetes, cardiac disease, vascular disease, antiplatelet medication, dialysis status, AVF site, or surgeon's experience) (Table 4). In the final analysis, after backward exclusion of
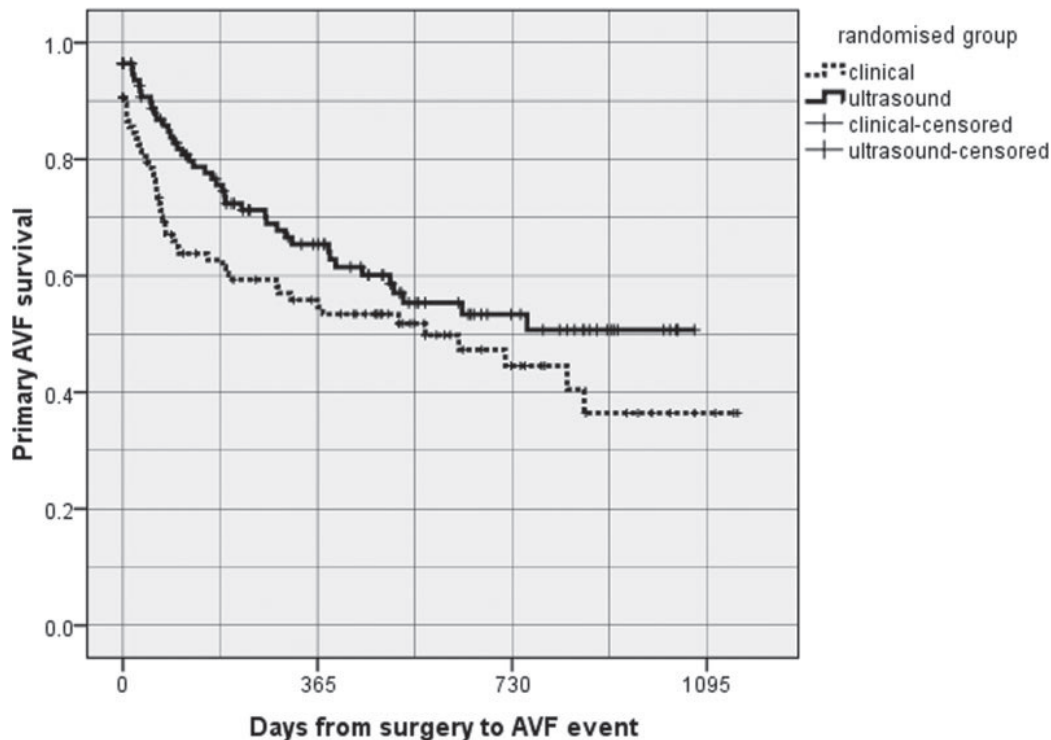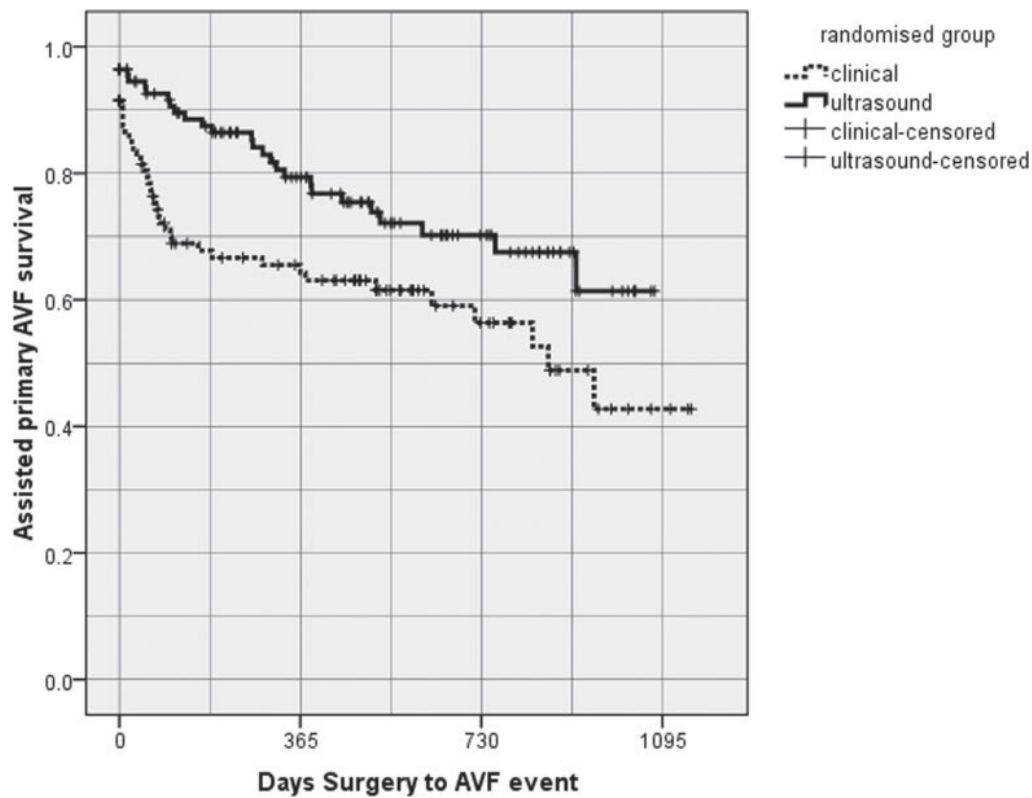

Life-table analysis:

by patency as intention to treat (n=218): log rank test 3.042, p = 0.081

by AVF use for haemodialysis (n=186): log rank test 3.237, p = 0.072

Figure 2. Primary AVF survival of clinical and ultrasound groups.

Number at risk

clinical	60	53	34	20	9	3
ultrasound	83	64	41	29	12	0

Life-table analysis:
by patency as intention to treat (n=218): log rank test 6.309, p=0.012
by AVF use for haemodialysis (n=183): log rank test 6.144, p=0.013

Figure 3. Assisted primary AVF survival for clinical and ultrasound groups.

nonsignificant variables, predialysis status, upper-arm AVF site, and male gender remained independent predictors of better primary survival; predialysis status, upper-arm AVF site, and ultrasound were independent predictors of better assisted primary survival (Table 4).

Discussion

Our randomized trial shows that routine preoperative ultrasound in addition to physical examination improves AVF patency and dialysis use in a patient population without complex access problems. Specifically, ultrasound results in less immediate failure, less early AVF thrombosis, and better assisted primary AVF survival. Ultrasound is effective with a small number of ultrasound scans needed to prevent failure.

Our finding that immediate failure is significantly reduced by preoperative ultrasound is consistent with another randomized trial, which showed significantly less failure (6% *versus* 25%) on the day of surgery in the ultrasound compared with the clinical group (19). Inadequate vessels can be identified by ultrasound, which reduces the rate of immediate failure (11,12,24).

Our data show no statistically significant difference between the clinical and ultrasound groups for primary failure or for primary survival of AVF. Particularly, we saw no difference when primary failure is counted without immediate failure. This could indicate that ultrasound improves AVF patency but not AVF maturation, in agreement with published experience that maturation failure remains an important problem, even when preoperative ultrasound is used (25–27). However, our study is underpowered and cannot give a definitive answer.

Our study shows a significantly better assisted primary AVF survival (*i.e.*, survival time gained by AVF salvage) in the ultrasound group. The clinical group had a significantly greater early AVF loss due to a higher rate of early thrombosis and thus had poorer potential for salvage.

We found that factors other than preoperative assessment affect AVF outcome, including gender, diabetes, and AVF site. This is in keeping with the literature (5,6,27,28). As noted by others, prior hemodialysis strongly predicted poorer outcome

Table 4. Secondary outcome—Cox regression for primary and assisted primary AVF survival

Predictor Variables	Primary AVF Survival		Assisted Primary AVF Survival	
	HR	95% CI: Lower, Upper	HR	95% CI: Lower, Upper
Randomization to ultrasound	0.669	0.436, 1.027	0.573	0.348, 0.945
Age[a]	1.001	0.986, 1.015	0.999	0.983, 1.016
Gender[b]	0.672	0.426, 1.060	0.857	0.504, 1.458
Ethnicity[c]	0.951	0.579, 1.564	1.364	0.782, 2.380
Diabetes	1.659	1.002, 2.747	1.648	0.922, 2.945
Cardiac disease	1.033	0.597, 1.788	1.037	0.555, 1.936
Vascular disease	1.105	0.605, 2.018	1.434	0.735, 2.794
Antiplatelet drug	0.733	0.422, 1.273	0.609	0.324, 1.145
Dialysis status[d]	2.060	1.217, 3.487	2.668	1.451, 4.907
Surgical experience[e]				
trainee alone	0.912	0.487, 1.708	1.419	0.731, 2.756
consultant + trainee	0.945	0.580, 1.540	0.751	0.418, 1.349
AVF site[f]	0.449	0.273, 0.741	0.460	0.257, 0.823

Cox regression for AVF survival by intention to treat (for primary and assisted primary patency, respectively) with AVF survival as the dependent variable; the initial regression model with all predictor variables is shown in the table above with HR for AVF failure and 95% CIs.

[a]Age was transformed to $[(age^3)/10,000]$ to correct for skew.
[b]Female gender as baseline hazard.
[c]Caucasian as baseline hazard *versus* non-Caucasian.
[d]"Not yet on hemodialysis" as baseline hazard *versus* "on hemodialysis."
[e]Consultant operating alone as baseline hazard, compared to trainee alone and to consultant with trainee operating.
[f]Forearm AVF as baseline hazard *versus* upper-arm AVF.

Primary AVF Survival: For the initial model with all predictor variables shown in the table above, χ^2 was 25.312 with 12 degrees of freedom and $P = 0.013$. The final model after backward stepwise exclusion of nonsignificant variables included only dialysis status (hazard ratio [HR] 2.196; 95% confidence interval [CI] [1.323, 3.644]), AVF site (HR 0.448; 95% CI [0.277, 0.724]), gender (HR 0.637; 95% CI [0.412, 0.985]), randomization to ultrasound (HR 0.691; 95% CI [0.453, 1.054]), and diabetes (HR 1.504; 95% CI [0.965, 2.344]). The final model χ^2 was 23.263 with 5 degrees of freedom and $P = 0.000$.

Assisted Primary AVF Survival: For the initial model with all predictor variables shown in the table above, χ^2 was 26.759 with 12 degrees of freedom and $P = 0.008$. The final model after backward stepwise exclusion of nonsignificant variables included only dialysis status (HR 2.601; 95% CI [1.473, 4.594]), AVF site (HR 0.491; 95% CI [0.284, 0.849]), randomization to ultrasound (HR 0.594 95% CI [0.364, 0.969]), and diabetes (HR 1.657; 95% CI [0.989, 2.777]). The final model χ^2 was 19.613 with 4 degrees of freedom and $P = 0.001$.

(28). Our stratified randomization produced equal allocation of patients with prior hemodialysis.

Our study supports the recommendation by KDOQI and European guidelines for routine preoperative ultrasound (1,2). However, a recent trial, which preselected only patients with normal preoperative physical findings and then randomized some to additional ultrasound mapping, found no advantage for ultrasound in terms of immediate patency or early AVF survival (29). In comparison, our patients were considerably older and not preselected, and our data show that such patients generally benefit from ultrasound. In our experience, ultrasound is unlikely to add information in the small subgroup of young nondiabetic men with normal physical findings.

Potential strengths of our study are its randomized design, the strict end point definition for functional AVF patency by use on dialysis, a real-life setting including the option of selective imaging for the clinical group, and a low dropout rate in terms of surgery not being done ($n = 10$). A potential weakness is that the operating surgeons were not blinded to the randomization group because it was necessary to justify the decision

for AVF formation on the basis of the details of the preoperative assessment.

In conclusion, our randomized clinical trial demonstrates a benefit of routine preoperative ultrasound in AVF outcomes with a small number needed to treat to save one fistula. Although nonmaturation may remain an important problem, preoperative ultrasound combined with appropriate AVF salvage leads to better long-term AVF use in hemodialysis.

Acknowledgments

Disclosures

None.

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