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Vascular Access Outcomes in the Elderly Renal Failure Population: The VOERP Study

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Abstract

Background: A significant number of elderly patients (≥ 80 years) with end-stage renal disease require haemodialysis. We hypothesized that octogenarians would have poorer outcomes given the higher prevalence of comorbidities. The aim of our study was to analyze the outcome of Arteriovenous Fistula (AVF) creation in this group of patients.

Methods: A retrospective analysis of a prospectively collected renal access database between 2011 and 2014 was performed. Outcome measures included AVF usage, patency rates, re-intervention, and factors associated with failure to use the AVF. Cox regression survival analysis was used to compare patency rates.

Results: A total of 530 AVFs were created within the study period, of which 31 (5.8%) were created in octogenarians. From this population, 23 patients did not use their fistula within the follow-up period (AVF-not used group), with only 8 undergoing haemodialysis through their fistula (AVF-used group). Primary and cumulative patency rates were higher in the AVF-used group than in the AVF-not used group (49.4% *vs.* 10.4%, p=0.001 and 81.8% *vs.* 33.6%, p=0.02, respectively). On multivariate survival analysis, only diabetes mellitus was associated with non-use of the AVF (hazard ratio 0.14; 95% confidence interval 0.01-1.34).Within the first year of AVF creation, 9.7% of patients had died. No mortalities were observed within the study period in the AVF-used group.

Conclusion: Creation and maintenance of AVFs in octogenarians is time consuming and many AVFs created will not be utilized. AVFs should only be created in healthier patients with a longer life expectancy.

Keywords: Vascular surgery; Fistula; Haemodialysis; Renal failure

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Introduction

In today's aging population, the number of patients on Haemodialysis (HD) is increasing significantly [1]. The Australia and New Zealand Dialysis and Transplant Registry (ANZDATA; ANZDATA.org.au) record the proportion of patients receiving dialysis by age group. In 2010 there were 1,854 patients over the age of 75 receiving haemodialysis and 392 over 85 years old, a rise of 21% from 2009. This equates to patients over 75 years of age representing 27% of the total haemodialysis population in Australia. The rate of new cases of end stage kidney disease is projected to rise by 80% in the Australian population from 2009 to 2020, with patients over the age of 70 expected to account for the majority. Currently, Arterio Venous Fistula (AVF) remains the access of choice for HD worldwide. Studies on the outcomes of AVF placement in octogenarians have shown conflicting results, and maturation and functionality have been subjects of debate. A recent meta-analysis of 13 retrospective studies demonstrated that proximal autologous brachiocephalic AVFs had lower failure rates compared with radio cephalic fistulas [2]. Other retrospective studies have reported that age, in particular age over 65 years, did not affect primary or secondary patency, or usability [1,2]. However, some of these studies were based on single-centre experiences, with the proximal and distal AVFs included in the same study population. Octogenarians have significantly more comorbidities than the younger population. This represents a special challenge for vascular

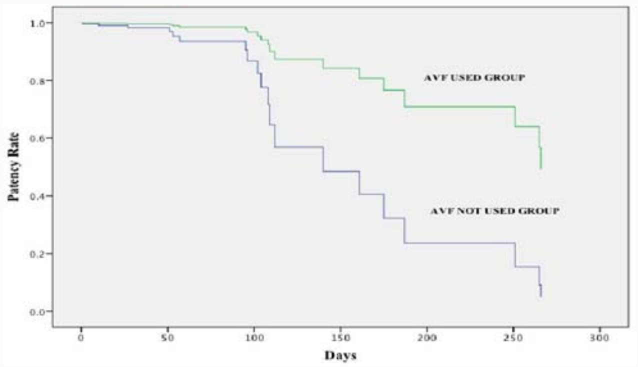

Figure 1: Primary patency rates of AVFs according to their usage.

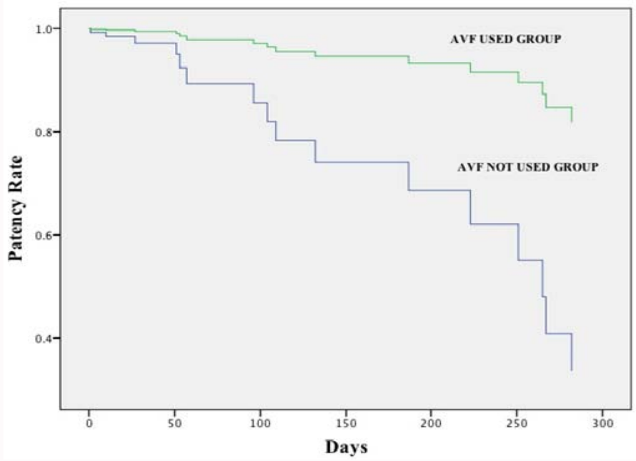

Figure 2: Cumulative patency rates of AVFs according to their usage.

surgeons and renal physicians, since factors such as diabetes, chronic pulmonary disease and cardiovascular disease lead to increased peri-operative risks. In addition, elderly patients will have often received more venepunctures and other vessel-related procedures, which may increase the risk of AVF failure [3]. Factors such as diabetes, female sex and previously undergoing HD are associated with non-use and loss of fistula patency [4]. We hypothesized that octogenarians would exhibit poorer outcomes given the higher prevalence of comorbidities. The aim of the VOERP study (Vascular access Outcomes in the Elderly Renal failure Population) was to analyze the outcome of AVF formation in this group of patients, whether they required more interventions, and if they ever utilize the fistula for HD. We specifically examined the factors associated with failure to use the newly created AVF.

Materials and Methods

Study Design

Since 2011, the details of all end stage renal failure patients have been prospectively entered into the Western Australian Nephrology Database. Utilising this database as well as other vascular and operating theatre databases, we retrospectively analyzed all the AVFs constructed in patients over the age of 80 years by our renal access service over a period of 3 years, from January 2011 to December 2014. Patients were categorized into two groups: patient's ≥ 80 years that had an AVF created and subsequently used for HD (AVF-used group) and those ≥ 80 years that had an AVF created but never used for HD (AVF-not used group).

Patients

All patients undergoing surgical and endovascular access procedures (first attempt primary fistula, revision and endovascular interventions) during the index period were identified. Information recorded included age (defined as age at time of fistula creation), ethnicity, smoking status (current smoker defined as smoking within 6 months of fistula creation), diabetic control (oral hypoglycemic, insulin, or both), hypertension (use of antihypertensive), history of malignancy, coronary artery disease, congestive heart failure, peripheral vascular disease, cerebrovascular disease, thromboembolic disease, timeliness of referral, and whether the patient had underwent HD before the primary access procedure using a temporary central venous dialysis catheter. Coronary artery disease was defined as coronary stenosis identified by angiography, history of myocardial infarction, or previous coronary revascularization. Peripheral vascular disease was defined by prior revascularization or amputation for ischemia or gangrene. Thromboembolic disease was defined as previous deep vein thrombosis or pulmonary embolus. Most importantly, we recorded if the fistula had been used for HD and the number of interventions performed on the fistula at any time. Data on fistula patency and suitability for dialysis was obtained by a combination of case note review, patient review, and consultation with nephrologists and dialysis nurses. The institutional ethics committee approved the study protocol. Informed consent was not sought as anonymised patient was used.

Definitions and study end points

The primary end point was the functional outcome of a fistula, with a successful outcome defined as a fistula created in an octogenarian that was ultimately utilized for HD. Fistula failure was classified as primary or secondary, with primary failure referring to the failure of a fistula prior to cannulation. Secondary fistula failure was defined as fistula failure after a salvage procedure such as angioplasty, stenting, or surgical revision. All imaging studies of the fistulae or fistulae-at-risk were stored on the hospital imaging system and were reviewed by two vascular surgeons with a special interest in renal access surgery (BPM, VV). The secondary end points were related to fistula patency. Primary patency (intervention-free fistula survival) was defined as the interval between fistula creation and fistula failure or any intervention required to maintain or re-establish patency. Secondary or cumulative patency was defined as the time from AVF creation to the time of unsalvageable AVF failure. Complications and hospitalizations associated with AVF placement were also recorded. Complications recorded included bleeding, thrombosis, infection, arterial steal syndrome, nerve injury, seroma, and subclavian vein stenosis. AVF thrombosis was considered when determining patency and not included among these complications. An infection (surgical site-related cellulitis or abscess) was recorded if antibiotics were prescribed. Except for infections, a complication was only included if it led to AVF failure or required a procedure. Patients who underwent transplantation or died were tagged and censored for all survival analyses.

Statistical analysis

The baseline characteristics of the two groups were described using means and standard errors for continuous data and proportions for qualitative variables. Kaplan-Meier survival curves were used to calculate primary and cumulative patency rates, and Cox regression survival analysis was used to compare them. A paired sample T-test was used to compare all variables between the two subsets of patients.

Table 1: Patient's demographic data.

Variables	AVF-used (n=8)	AVF-not used (n=23)	P value
Age, years			
Mean (SD)	82.4 (3.2)	81.7 (1.03)	0.66
Range	80-89	80-88	
Sex (% female)	3 (37.5)	10 (43.5)	0.6
Co-morbidities			
Diabetes (%)	4 (50)	14 (60.9)	0.2
CCF (%)	2 (25)	4 (17.4)	0.6
IHD	3 (37.5)	12 (52.2)	1
Malignancy	2 (25)	8 (34.8)	1
Dementia (%)	1 (12.5)	1 (4.3)	0.35
Anaemia (%)	2 (25)	0 (0)	0.17
COPD (%)	2 (25)	3 (13)	1
Low albumin	2 (25)	6 (26.1)	0.68
Mobility with aid (%)	2 (25)	4 (17.4)	0.6
Social support			0.23
Home with services (%)	3 (37.5)	8 (34.8)	
Low level care hostel (%)	2 (25)	1 (4.3)	
Ethnicity (%)			0.98
Caucasian	5 (62.5)	20 (86.9)	
Asian	2 (25)	3 (13.1)	
Unclassified	1 (12.5)	0 (0)	
Anatomic site			
Radio cephalic	1 (12.5)	9 (39.1)	0.001
Brachiocephalic	5 (62.5)	9 (39.1)	0.28
Brachiobasilic	2 (25)	3 (13.1)	0.16

AVF: Arteriovenous Fistula; CCF: Chronic Congestive Failure; IHD: Ischemic Heart Disease; COPD: Chronic Obstructive Pulmonary Disease; eGFR: Estimated Glomerular Filtration Rate; SD: Standard Deviation

Continuous data are shown as mean ± standard deviation or median (range) and categorical data as number (%) A paired samples test was used. Unless otherwise noted, bootstrap results are based on 100 bootstrap samples.

Spearman and Pearson correlation coefficients were obtained for all potential predictor variables to look for confounding. Logistic regression analysis was performed with variables considered relevant to AVF patency. All variables with a p<0.05 were included in the multivariate analysis. Multivariate Cox proportional hazards models were used to determine factors associated with reduced AVF patency. Results are reported as Hazard Ratios (HR) or Odds Ratios (OR) with 95% Confidence Intervals (CI). All hypotheses tests were performed using two-sided tests, and the critical value for statistical significance was set at p<0.05. Analyses were conducted using PASW 18 (SPSS, Chicago, Il) and SAS 9.2 (SAS Institute Inc, Cary, NC) statistical software.

Results

A total of 530 AVFs were created within the study period. Of these, 31 (5.8%) were created in patients ≥ 80 years. Among these, 23 patients did not use their fistula during follow-up (AVF-not used group) whilst the remaining 8 patients underwent HD through their fistula (AVF-used group). Table 1 demonstrates the demographic similarities between both groups, with the exception of a larger number of radio cephalic AVFs created in the non-used group than in the used group (9 patients *vs.* 1 patient, p=0.001).

Table 2: Types of intervention.

Procedure	AVF-used (%)	AVF-not used (%)	P value
Fistuloplasty	2(25)	9 (39.1)	0.29
Stent	1 (12.5)	0	N/A
Surgical revision	0	1 (4.4)	0.23
Total	3 (37.5)	10 (43.5)	0.83

AVF: Arteriovenous Fistula

Table 3: Logistic regression analysis of independent predictors of primary patency in the AVF-used group.

Variables	Odds Ratio	SE	95% CI	P value
Sex	0.75	14.25	0.04-14.97	0.42
Ethnicity	1.77	13.25	0.15-20.98	0.18
Age (years)	0.99	5.47	0.62-1.60	0.93
Creatinine	0.98	0.21	0.95-1.01	0.09
eGFR	0.81	0.25	0.49-1.33	0.19
Diabetes	4.84	0.76	20.01-22.87	0.02
CCF	0.07	0.83	0.01-1.01	0.01
IHD	0.04	0.81	0.01-1.03	0.01
Malignancy	2.01	1.66	0.08-51.59	0.25
Dementia	0.05	0.74	0.01-1.02	0.01
Low albumin	0.06	0.89	0.01-0.05	0.01
COPD	0.08	0.76	0.01-1.11	0.01

AVF: Arteriovenous Fistula; CI: Confidence Interval; SE: Standard Deviation; OR: Odds Ratio; eGFR: estimated Glomerular Filtration Rate; CCF: Congestive Cardiac Failure; IHD: Ischemic Heart Disease; COPD: Chronic Obstructive Pulmonary Disease

AVF outcomes

Primary and cumulative patency rates were higher in the AVF-used group compared to the AVF-not used group (49.4% *vs.* 10.4%, p=0.001 and 81.8% *vs.* 33.6%, p=0.02, respectively) (Figures 1 and 2). The reasons for censoring in the AVF-not used group were as follows: 4 (17.4%) cases of critical stenosis either of the anastomosis or the venous outflow of the AVF; 7(30.4%) AVF thromboses; 1 AVF failure within 30 days of creation due to a small, heavily calcified artery; and 3 (13%) deaths. The rate of fistula thrombosis was lower in the AVF-used group (12.5% *vs.* 30.4%%, p=0.02). The overall re-intervention rate was higher in the AVF-not used group (Table 2), however the difference was not statistically significant (43.5% *vs.* 37.5%, p=0.83). Interventions performed in the AVF-used and not used groups included fistuloplasty (25% *vs.* 39.1%, p=0.29), central vein stenting following failed angioplasty (12.5% *vs.* 0%), and surgical revision (0% *vs.* 4.4%, p=0.23). Two patients in the AVF-not used group required at least 2 interventions compared to only 1 patient in the AVF-used group.

Risk factors for loss of fistula patency

Table 3 represents the logistic regression analysis of independent predictors for primary patency in the AVF-used group. Diabetes mellitus was significantly associated with a loss of primary patency in the AVF-used group (p=0.02), as was congestive cardiac failure (p=0.01), dementia (p=0.01), ischemic heart disease (p=0.01), chronic obstructive pulmonary disease (COPD; p=0.01), and low serum albumin level (p=0.01). In the case of diabetes, the odds of loss of primary patency occurring were almost five-fold greater in the AVF-used group than for those who did not have diabetes (95% CI, 20.01-22.87). For cumulative patency in the AVF-used group, serum

Table 4: Logistic regression analysis of independent predictors of cumulative patency in the AVF-used group.

Variables	Odds Ratio	SE	95% CI	P value
Sex	0.12	1.66	0.01-3.22	0.12
Ethnicity	0.01	4.91	20.79-42.41	0.74
Age (years)	1.01	0.54	0.01-2.01	0.08
Creatinine	0.98	0.02	0.94-1.02	0.02
GFR	0.9	0.26	0.54-1.51	0.22
Diabetes	2.38	11.79	0.28-20.32	0.4
CCF	0.01	0.11	0.01-1.03	0.99
IHD	0.03	0.99	0.02-2.04	0.33
Malignancy	1.01	0.98	0.01-1.08	0.05
Dementia	4.01	0.97	0.03-3.07	0.05
Low albumin	0.59	20.81	0.02-18.64	0.34
COPD	0.59	23.78	0.02-18.64	0.31

Cumulative patency (equivalent to secondary patency or intervention-assisted patency) was defined as the time from AVF creation to the time of unsalvageable AVF failure.
AVF: Arteriovenous Fistula; CI: Confidence Interval; SE: Standard Deviation; OR: Odds Ratio; eGFR, estimated Glomerular Filtration Rate; CCF: Congestive Cardiac Failure; IHD: Ischemic Heart Disease; COPD: Chronic Obstructive Pulmonary Disease

Table 5: Logistic regression analysis of independent predictors of cumulative patency loss in the AVF-not used group.

Variables	OR	SE	95% CI	P value
Sex	2.23	3.73	0.40-12.38	0.38
Ethnicity	0.82	13.65	0.06 -11.15	0.55
Age (years)	0.71	1.74	0.44-1.17	0.11
Creatinine	0.99	2.15	0.98-1.00	0.08
GFR	0.9	6.01	0.76-1.07	0.25
Diabetes	2.38	11.79	0.28-20.32	0.4
CCF	0.47	12.9	0.03-5.33	0.2
IHD	0.43	9.52	0.30-17.37	0.36
Malignancy	1.81	11.77	0.18-17.68	0.47
Dementia	1	0.56	0.01-4.22	0.02
Low albumin	1.01	6.41	0.01-4.45	0.02
COPD	1.04	12.35	0.01-5.23	0.02
Fistula type	0.31	1.11	0.24-1.58	0.28
Maturation	0.11	4.2	0.75-19.10	0.08

Cumulative patency (equivalent to secondary patency or intervention-assisted patency) was defined as the time from AVF creation to the time of unsalvageable AVF failure. AVF: Arteriovenous Fistula; CI: Confidence Interval; SE: Standard Deviation; OR: Odds Ratio; eGFR: estimated Glomerular Filtration Rate; CCF: Congestive Cardiac Failure; IHD: Ischemic Heart Disease; COPD: Chronic Obstructive Pulmonary Disease

creatinine (OR 0.98; 95% CI 0.94 to 1.02, p=0.02), malignancy (OR 1.01; 95% CI 0.01 to 1.08, p=0.05), and dementia (OR 4.01; 95% CI 0.03 to 3.07, p=0.05) were significantly associated with cumulative patency loss (Table 4). In the AVF-not used group, dementia (OR 1.00; 95% CI 0.01 to 4.22, p=0.02), low serum albumin level (OR 1.01; 95% CI 0.01 to 4.45, p=0.02), and COPD (OR 1.04; 95% CI 0.01 to 5.23, p=0.02) were associated with loss of cumulative patency (Table 5). On multivariate survival analysis, diabetes (HR 0.14; 95% CI 0.01 to 1.34) was associated with non-use of the AVF, while dementia (OR 1.86; 95% CI 0.03 to 10.91), anemia (HR 1.74; 95% CI 0.16 to 19.39),

Table 6: Multivariate analysis of predictors of fistula usage.

Variable	Hazard ratio	95 % CI	P value
Dementia	1.86	0.03-10.91	0.76
Anaemia	1.74	0.16-19.39	0.65
Diabetes	0.14	0.01-1.34	0.09
COPD	2.76	0.22-34.49	0.43

COPD: Chronic Obstructive Pulmonary Disease, Cox proportional hazards regression analysis of the association of four variables (dementia, anaemia, diabetes, chronic obstructive pulmonary disease) and usage of the fistula.

Table 7: Potential causes of AVF non-use.

Cause	Number (%)
AVF-related problem	8 (25.8)
Stable creatinine	2 (6.5)
Death	5 (16.1)
Fear of needling	1 (3.2)
New cancer	1 (3.2)
Other*	6 (19.4)

*Others causes are stroke, family and patient refusal of haemodialysis, and deterioration of general condition.

and COPD (OR 2.76; 95% CI 0.22 to 34.49) were associated with successful use of the AVF for HD (Table 6), however none of these interactions were statistically significant.

Complications

At the end of the follow-up period, thrombosis rates in the AVF-not used group were twice as high as in the AVF-used group (30.4% *vs.* 12.5%, p=0.02). One patient in the AVF-not used group had a fistula that failed within 24 hours of creation. The main reasons for AVF non-use were fistula-related problems (25.8%) such as maturation, failure, and thrombosis. Other reasons included stabilization of creatinine and estimated glomerular filtrations levels (6.5%) and death (n=5 patients, 16.1%) (Table 7).

Discussion

It is not uncommon in current clinical practice to encounter patients over 80 years of age needing renal replacement therapy. In these patients, clinicians face a challenge in not only determining the appropriate time to initiate dialysis, but also in deciding the most appropriate approach for vascular access and the mode of dialysis. NKF DOQI currently recommends the creation of a native fistula as the optimal access site for HD [5]. However, our study has shown that the majority of fistulae created in octogenarians were not used, and as such this recommendation may not be a pragmatic treatment for this population. The Institute of Medicine published guidelines in 1991 that identified three groups of patients that should not be dialysed: (1) patients with irreversible, profound neurologic impairment, (2) terminally ill patients from a non-renal cause, and (3) patients with a medical condition that precludes the technical process of dialysis [6]. The guidelines further state that, in such patients, palliative care and/or a time-limited trial of dialysis may offer the best recourse [7]. Age was not considered as a factor influencing the commencement of HD and its effect on AVF patency remains a controversial issue. However, Lazaridis and colleagues reported that age is significantly associated with failure of autogenous access [2,8]. In their study, every additional year in the age of a patient increased the risk of failure by 0.8%. A similar association was not found with prosthetic grafts. None of the variables tested in the present study were found to be associated with poor primary patency. The two groups were similar for age, sex, and all other risk factors. In the current study, 5.8% of patients who underwent primary AVF creation were octogenarians. Within the first year of fistula creation, 9.7% of our octogenarian patients had died. There were no mortalities in the AVF-used group within the study period [9,10]. Munshi et al. [11] reported 1 and 5-year mortality rates of 46.5% and 97.6% respectively, in HD patients aged over 75 years. Similarly, Vachharajani et al. [12] reported a mortality rate of up to 40% in the first year of dialysis in veterans over 70 years of age. In our study, whilst dementia was not a characteristic significant between the groups at baseline, it was significantly associated with a loss of primary patency in the AVF-used group and a loss of cumulative patency in both groups. Similarly, Vachharajani et al. [12] describe a higher rate of dementia (25.6%) amongst their patients in their series of octogenarians on dialysis, one of much comorbidity suggesting an alternative to AVF creation is considered. Diabetes was present in 58% of our patient population [13]. It is well known that these patients have poorer outcomes and increased mortality, likely secondary to the increased incidence of cardiovascular disease in diabetics [10]. Our study certainly showed that cardiovascular disease, coronary heart disease, and cerebrovascular disease were significantly more prevalent in diabetics ($p<0.001$). It is therefore prudent to employ a holistic approach to the assessment of elderly CKD patients, including comorbidities, life expectancy, and social support structures, before any decision on the initiation of renal replacement therapy [14]. Kurella et al. [15], reported that survival after dialysis initiation in the extremely elderly was often poor and substantially lower than that of the age-matched population, with only 54% surviving at 1 year. Additionally, very elderly CKD patients are at a significantly increased risk of decline in cognitive function [16,17]. In our study, 25.8% of the created fistulas were eventually used for dialysis. Extrapolating from this, we would have to create an additional 3AVFs for every AVF to be created and used for dialysis. This is compounded by the high reintervention rates of 43.5% in the AVF-not used group and 37.5% in the AVF-used group. Despite a diligent approach to reintervention, 1-year primary patency rates were low in both the AVF-used and not used groups (49.4% *vs.* 10.4% respectively, $p=0.001$).Similarly, secondary 1-year patency rates were worse in the AVF-not used group (81.6% *vs.* 33.6%, $p<0.02$). Previous studies regarding the effect of age on AVF patency have produced conflicting results. Wedye et al. [18] reported that successful AVFs were created in 81.6% of patients older than 70 years that survived for more than 3 years, while Lazarides et al. [2] reported that for every additional year of patient age there was an increase in the risk of failure by 0.8%.Our opinion is that maturation and patency of fistulae are significant problems in AVFs created in the elderly population due to the presence of extensive arterial disease and comorbidities. The site of fistula creation appears to be an important consideration, especially in octogenarian patients. In our series, 39.1% of patients in the AVF-not used group had a radio cephalic AVF compared to 12.5% in the AVF-used group ($p=0.001$). Brachiocephalic AVFs were constructed in 62.5% of the AVF-used group and 39.1% of the AVF-not used group ($p=0.28$). This finding is in agreement with a meta-analysis by Lazarides et al. [2] which revealed a significantly higher rate of radio cephalic AVF failure in elderly patients compared with non-elderly adults at 12 and 24 months (OR, 1.525 and 1.357, respectively. Therefore, if a fistula is to be created in an octogenarian patient, a more proximal position is recommended to increase the probability of fistula maturation, and thus suitability, for effective dialysis. The time needed for maturation of an AVF in the elderly is significantly longer and this plays an important role in the consideration of fistula creation [19]. In a series by Garcia Cortes et al. [20], patient's older than75 years that were started on dialysis without permanent vascular access were divided into AVF creation or Temporary Central Catheter (TCC) placement groups. The authors found that the AVF group needed a longer time to achieve a functioning permanent vascular access compared to the TCC group (3.0 ± 1.9 months vs. 1.3 ± 1.7months, $p<0.05$). Furthermore, due to the higher number and longer usage of temporary catheters, complications such as infection and central venous thrombosis were higher in the AVF group. It has been suggested that AVF should only be created in elderly patients with end-stage renal failure that have a life expectancy of more than 180 days [13]. Nephrologists need to perform a careful screening process when referring this elderly population for renal access creation. Life expectancy and comorbidities should be evaluated. A multidisciplinary approach involving nephrologists and vascular surgeons is imperative in ensuring optimal renal access planning to achieve the best outcomes for elderly patients over the age of 80 who may require HD. The major limitation of this study is the small sample size. This hindered our ability to draw conclusions and determine the predictors of AVF non-use after creation. In addition, since some of the data was collected retrospectively, we could not assess the true functional age and status of the patient, which should be performed as part of the decision-making process when treating elderly patients with CKD. A larger multicentre cohort study would be useful to validate the observations from this single centre study.

Conclusion

Octogenarian patients with end-stage renal failure have limited life expectancy and quality of life. Creation and maintenance of AVFs in these patients is time consuming and many of the AVFs created will not be utilized. AVFs should only be created in healthier patients with a longer life expectancy. Alternative viable options that should be considered in octogenarians include arteriovenous grafts, TCCs, and peritoneal dialysis.

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