Outcomes of primary arteriovenous fistulas in patients older than 70 years

Mingzheng Aaron Goh, MBChB, AFHEA, MRCS, Jason M. Ali, MA, MB BChir, FHEA, MRCS, PhD, Satheesh Iype, MBBS, MPhil, FRCS, and **Gavin J. Pettigrew, MBChB, MD,** *Cambridge, United Kingdom*

Background: **The population of elderly hemodialysis patients is increasing, yet the most suitable approach for providing permanent hemodialysis access remains unclear. Here we report outcomes using an approach aimed predominantly at creating radiocephalic (RC) fistulas.**

Methods: **A single-center retrospective cohort study was performed in which access outcomes for primary arteriovenous fistulas created between January 1, 2005, and December 31, 2012, in patients aged 70 years or older were compared.**

Results: **During the study period, 204 RC, 1 brachiobasilic, and 9 brachiocephalic (BC) primary fistulas were created initially for patients requiring dialysis. Immediate failure rates for RC fistulas were lower than for BC fistulas but not significantly so (12% vs 22%; Fisher's exact text, $P = .319$). One-year primary and secondary patency for RC fistulas was 54% and 66%, respectively, and similar for those created in patients between 70 and 80 years old and in those older than 80 years. The secondary patency rate at 1 year for RC fistulas using cephalic vein of diameter <2.5 mm was lower than for fistulas created with cephalic vein >2.5 mm (49% vs 72%; log-rank test, $P = .005$). Creation of a BC fistula was associated with a significantly higher incidence of steal syndrome than with an RC fistula (10% vs 2%; Fisher's exact text, $P = .009$).**

Conclusions: **RC fistulas formed in the elderly carry a lower risk of steal syndrome than BC fistulas and offer the potential for further revision surgery, such that acceptable secondary patency is achieved for RC fistulas formed using even small (<2.5 mm) cephalic veins. (J Vasc Surg 2016;63:1333-40.)**

As the population ages, the incidence of end-stage renal disease (ESRD) is increasing,[1] resulting in more elderly patients being considered for hemodialysis. In the United Kingdom, the median age of the incident hemodialysis population has increased from 61 years in 1997 to 66.9 years in 2012, and in 2000, 19% of hemodialysis patients were older than 70 years, whereas for 2012, that figure is 25%.[2,3]

Provision of vascular access in elderly hemodialysis patients is undoubtedly challenging, with relatively few data published to inform decision-making.[1,4-9] Current guidelines from the National Kidney Foundation Kidney Disease Outcomes Quality Initiative, the Society for Vascular Surgery, and the UK Renal Association[10-12] do not distinguish elderly hemodialysis patients as a separate cohort. All recommend that to preserve proximal sites for future access attempts, arteriovenous (AV) fistulas are sited as distally as possible in the upper extremity, with the implication that where possible, radiocephalic (RC) fistulas should be performed as first choice for dialysis access in the elderly. Nevertheless, on the basis that preservation of venous capital is less of a concern because of the limited life expectancy of elderly hemodialysis patients, allied to the consideration that patency rates for RC fistulas in this cohort may be lower,[4,8] several authors have advocated that antecubital (brachiocephalic [BC] and brachiobasilic [BB]) fistulas should instead be considered the first option.[4,13,14] Complication rates for antecubital fistulas are, however, higher than for wrist fistulas, and in particular, the incidence of hand ischemia from steal syndrome is approximately 10-fold higher for fistulas created in the antecubital fossa.[15-17] Similarly, survival rates for elderly dialysis patients are improving.[18] Hence, consensus as how to best provide hemodialysis access for elderly patients with ESRD has not been reached.[19]

On the basis that fistulas formed using small veins are less likely to mature,[20-22] many centers create RC fistulas only if the cephalic vein is at least 2.5 or 3 mm in diameter. However, this generally results in the majority of fistulas being sited in the antecubital fossa.[23-25] In comparison, our strategy for vascular access provision has focused on maximizing the numbers of RC fistulas created. Irrespective of vessel size, we create an RC fistula if the radial artery and cephalic vein at the wrist are judged clinically suitable.[26,27] Using this strategy, we fashion RC fistulas in >80% of patients, with 1-year patency rates of 77%.[26] We adopted the same approach for provision of permanent vascular access in elderly hemodialysis patients, principally because of concerns that antecubital fistulas would carry a higher risk for development of steal syndrome. Here we

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Correspondence: Mingzheng Aaron Goh, MBChB, AFHEA, MRCS, Department of Surgery, Addenbrooke's Hospital, Box 202, Cambridge CB2 0QQ, United Kingdom (e-mail: aaron.goh@nhs.net).

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report a large single-center retrospective cohort study describing provision of vascular access surgery for hemodialysis patients older than 70 years. Contrasting previous reports,[8] RC fistulas were created successfully in the majority of patients, with acceptable maturation and patency rates and with a low incidence of complications.

METHODS

Patients. All consecutive patients aged 70 years and older who had a primary AV fistula created between January 1, 2005, and December 31, 2012, in Addenbrooke's Hospital were identified from our prospectively maintained vascular access database. All cases were retrospectively cross-referenced to theater records. Institutional Review Board approval was granted. All patients consented for their data to be stored in a database and analyzed in this manner. Incident hemodialysis patients who had a primary RC, BC, or BB fistula created as their first option for permanent hemodialysis access were included in the analysis. No prosthetic grafts were used as first-line vascular access in our cohort.

Case notes were examined for operative details. Data were analyzed until cessation of follow-up on June 30, 2013.

Preoperative assessment and initial AV fistula creation. Predialysis patients with a range of estimated glomerular filtration rates (eGFRs) are seen by the nephrologists at the low renal clearance clinic and are subsequently referred to the vascular access clinic. If it is believed that a patient is frail with a limited life expectancy, an AV fistula is thought not to be appropriate. Patients were assessed, and the decision to operate was made when the eGFR fell below 20 mL/min/1.73 m^2. During the study period, this threshold was revised downward to 12 mL/min/1.73 m^2. Our unit has previously demonstrated that clinical examination can suffice in certain instances.[26] Patients underwent preoperative clinical assessment, with Doppler ultrasound (FUJIFILM SonoSite, Bothell, Wash) vein mapping performed as an adjunct to clinical examination if required. In these cases, the diameters of the vessels of interest were recorded and the vein of interest was examined to ensure that no thrombus or stricture was present. In accord with our previous publication,[26] we did not employ a threshold value for the diameter of the wrist cephalic vein below which an RC fistula was not attempted and were prepared to create fistulas with cephalic vein diameter <2.5 mm if the vein was deemed clinically to be of good quality.[26] The patient was in a seated position with the forearm supported. A tourniquet was applied to the upper arm. A tap test was performed to elicit a transmitted impulse along the vein segment, which indicates that the vein segment is widely patent. Ultrasound was generally not used when the tap test result was positive. The radial and ulnar arteries were examined to determine the quality and character of the pulse. Allen test was performed.

Where clinically indicated, patients thought at risk of central venous stenosis were imaged preoperatively using magnetic resonance or computed tomography. Fistulas were created by a consultant surgeon with a special interest in vascular access and a team of transplant registrars. Both primary fistulas and proximal revisions were performed by the same team.

Description of surgical technique. Almost all fistulas were created under local anesthetic, with the exception of BB fistulas, which were created as a single-stage procedure under general anesthesia. Ultrasound was not routinely used perioperatively if the vein was of good quality and the artery had a good pulse and character. Heparinized saline was used to distend the vein before anastomosis, and an end-to-side anastomosis was created with 6-0 or 7-0 monofilament. Antiplatelet agents (generally aspirin) were continued in the postoperative phase. Radiologic salvage of a failed RC fistula was not available during the study period; secondary patency rates therefore reflect only operative salvage through formation of a proximal neoanastomosis,[27] which would still allow dialysis needles to be inserted in the forearm.

Outcome and statistical analysis. Patients who had an AV fistula created but did not proceed to require hemodialysis were excluded from further analysis. Categorical variables were compared using Fisher exact test. Kaplan-Meier survival analyses and log-rank tests were used for fistula survival and for patient mortality. Kaplan-Meier analysis was performed on an intention-to-treat basis, as outlined by Sidawy et al[28]; fistulas that failed within 72 hours were deemed to have failed at time zero. All analyses were performed with GraphPad Prism (v.5.03; GraphPad Software Inc, La Jolla, Calif). Patients were censored in the event of death or final measurement of patency. Percentages were reported to the nearest whole percentage or tenth if <1%. In accordance with the reporting standards, Kaplan-Meier graphs were truncated when the standard error exceeded 10%, unless otherwise indicated.

Definition of variables. Unless otherwise specified, all vascular access definitions were in accordance with the Society for Vascular Surgery/American Association for Vascular Surgery and North American Vascular Access Consortium.[28,29] Thus, immediate vascular access failure refers to an access that has a loss of bruit or thrill within 72 hours of creation; primary patency is defined as the interval from time of initial fistula placement until any intervention is performed to maintain or to re-establish patency; and secondary patency is defined as the time of access placement until access abandonment. However, in situations in which limited dialysis through a temporary catheter (one or two sessions) was required after sudden thrombosis of an established RC fistula, successful salvage of the fistula by formation of a proximal neoanastomosis was considered an operation to maintain secondary patency rather than formation of a new fistula.

Proximal revision of an RC fistula that had failed immediately was considered formation of a new primary fistula; proximal revision of an RC fistula in other circumstances was categorized as maintenance of secondary patency. A fistula that used a different arterial inflow was considered

Table I. Patient characteristics

	Hemodialysis cohort (N = 214)
Age at first operation, years, mean (SD)	77.8 (4.9)
Median follow-up, months (range)	46 (6-97)
Gender, male[a]	145 (68)
Anastomosis site	204 RC
	9 BC
	1 BB
Comorbidities	
Hypertension	145 (68)
Diabetes	52 (24)
Coronary artery disease	67 (31)
Predialysis[a]	71 (33)
Etiology of chronic kidney disease	
Idiopathic	35 (16)
Diabetic nephropathy	28 (13)
Renovascular disease	24 (11)
Glomerulonephritis	16 (8)
Hypertensive nephropathy	12 (6)
Myeloma	12 (6)
Adult polycystic kidney disease	7 (3)
Other	80 (37)

BB, Brachiobasilic; *BC,* brachiocephalic; *RC,* radiocephalic; *SD,* standard deviation.
Categorical variables are presented as number (%).
[a]Patients already established on dialysis were dialyzing through a central venous catheter.

to be a new primary fistula as opposed to a proximal revision. Revascularization using distal inflow procedure,[30-32] performed to ameliorate steal syndrome after creation of an antecubital fistula, was also considered an intervention to maintain secondary patency. A fistula was deemed matured if it sustained dialysis for at least three consecutive sessions.[27]

RESULTS

Patient cohort. Between January 1, 2005, and December 31, 2012, 304 patients older than 70 years were referred for creation of permanent hemodialysis vascular access. At referral, 52% of patients were predialysis; the remainder were dialyzing through a central venous catheter. Patient demographics of those who commenced hemodialysis during the study period are detailed in Table I; 68% of patients were male, 68% were receiving antihypertensive medication, and 24% were diabetic.

Provision and outcomes of hemodialysis access surgery. As detailed in Fig 1, of the 304 primary access procedures performed, 293 (96%) RC and 11 (4%) antecubital (10 BC and 1 BB) AV fistulas were created; no AV grafts were formed. Ninety patients (30%) remained predialysis and were excluded, leaving the remainder (204 RC, 9 BC, and 1 BB fistulas) as a cohort for further analysis. Patency rates for these fistulas are detailed in Table II, which shows that primary maturation rates and 1-year primary patency rates were similar for RC and BC fistulas, albeit formal comparison is not possible because of the small number of BC fistulas created as a primary procedure. Twenty-five RC and two BC fistulas experienced immediate failure (12% and 22%, respectively; Fisher's exact text, $P = .319$).

For those patients whose fistula failed to mature (49 RC and 2 BC fistulas; 24% and 22%, respectively), subsequent access interventions are detailed in Table III. Eight patients with RC fistulas declined further fistula creation and elected to dialyze through a central venous catheter. Operative salvage was attempted in 18 RC fistulas that had failed to mature by creating a more proximal neoanastomosis.[27] This proximal revision was successful in 15 patients. During the study period, another 33 RC fistulas that had achieved functional patency were salvaged successfully on failure by formation of a proximal neoanastomosis. As a consequence of early and late operative salvage of failed RC fistulas, 1-year secondary patency rates for RC fistulas were significantly higher than primary patency rates (Fig 2, *a*; 66% vs 54%; log-rank test, $P = .027$).

Effect of cephalic vein diameter on fistula patency. Our approach to hemodialysis provision differs from other centers in that we do not adopt a minimum cutoff value for the diameter of the cephalic vein below which an RC fistula is not attempted. Preoperative ultrasound measurements of the diameter of the cephalic vein were recorded for 166 of the 204 RC fistulas created (81%), and of these, 39 (24%) had RC fistulas formed using cephalic veins <2.5 mm in diameter. Although immediate failure rates of these fistulas were comparable to those of RC fistulas created using cephalic veins >2.5 mm in diameter (Fig 2, *b*; 15% vs 13%; Fisher's exact text, $P = .79$), 1-year primary patency was poorer (Fig 2, *b*; 41% vs 58%; log-rank test, $P = .015$). As a result of salvage through formation of a proximal neoanastomosis, secondary patency rates were greater, albeit still poorer than was achieved for fistulas created using cephalic veins ≥2.5 mm (Fig 2, *b*; 49% and 72%; log-rank test, $P = .005$).

Patient age and fistula patency. Although the immediate failure rate of RC fistulas formed in patients between 70 and 80 years old was lower than that of those formed in patients older than 80 years, this was not statistically significant (Fig 2, *c*; 10% vs 16%; Fisher's exact text, $P = .19$). Two-year secondary patency rates for these groups were also not statistically different (Fig 2, *c*; 57% vs 44%; log-rank test, $P = .114$).

Establishment of hemodialysis. As can be seen from Table IV, which reports the dialysis mode 1 year after creation of the first RC fistula, 69% of those patients who were dialyzing did so through an RC fistula, with a relatively low percentage (24%) dialyzing through a central line. Thus, despite an immediate failure rate of >30% for wrist fistulas in the elderly, the additional salvage operations required (mean, 1.38 per patient) do not appear to lead to delays that ultimately increase the reliance on dialysis through a central line. As additional support, of the 159 predialysis patients who underwent autogenous fistula formation, 69 (67 RC and 2 BC fistulas; 43%) proceeded to require hemodialysis during the study period. Of these,

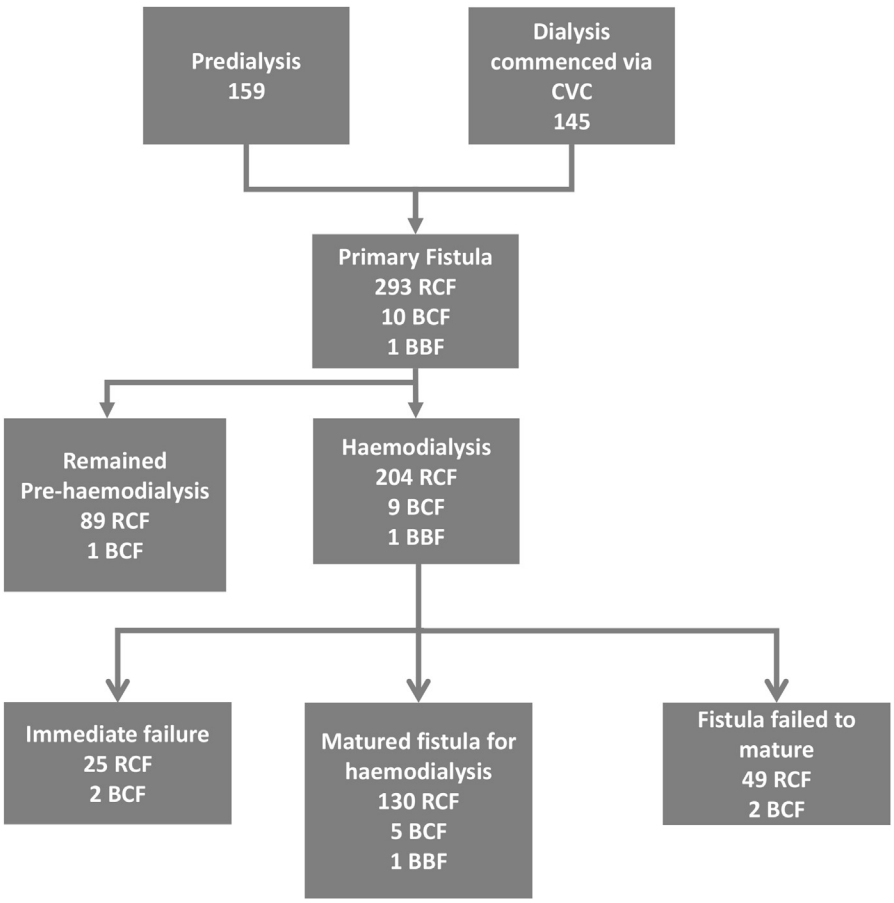


Fig 1. Outcome of patients older than 70 years referred for creation of permanent hemodialysis access. *BBF,* Brachiobasilic fistula; *BCF,* brachiocephalic fistula; *CVC,* central venous catheter; *RCF,* radiocephalic fistula.

Table II. Patency rates of patients who proceeded to hemodialysis

	Primary RC fistula (n = 204)	*Primary antecubital fossa fistula (n = 10)*	
		BC (n = 9)	*BB (n = 1)*
Achieved maturity and subsequently used for dialysis, %	130 (64)	5 (56)	1
Immediate failure, %	25 (12)	2 (22)	0
Median primary patency, months (range)	12.9 (0-97.4)	5.3 (0-47.1)	2.8
Median secondary patency, months (range)	33.4 (0-97.4)	6.7 (0-47.1)	2.8

BB, Brachiobasilic; *BC,* brachiocephalic; *RC,* radiocephalic.

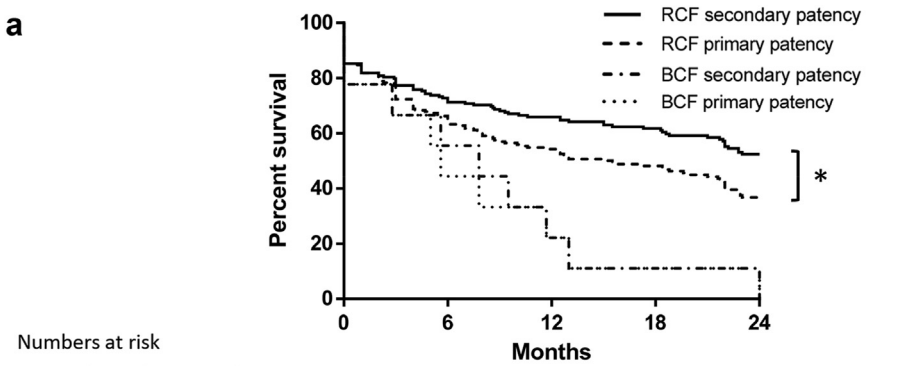
65 (94%) avoided central line catheterization and initiated hemodialysis through the fistula, with a median time of 8 months (range, 0-60 months) from referral to initiation of dialysis.

Table III. Outcome of fistulas that failed to achieve maturity

	Failed to achieve maturity, No.	
Subsequent access interventions	*RC fistulas (49 of 204)*	*BC fistulas (2 of 9)*
Proximal neoanastomosis	18	0
Refused further surgery	8	0
Further primary wrist fistula	12[a]	2[b]
Further primary BC fistula	11	0

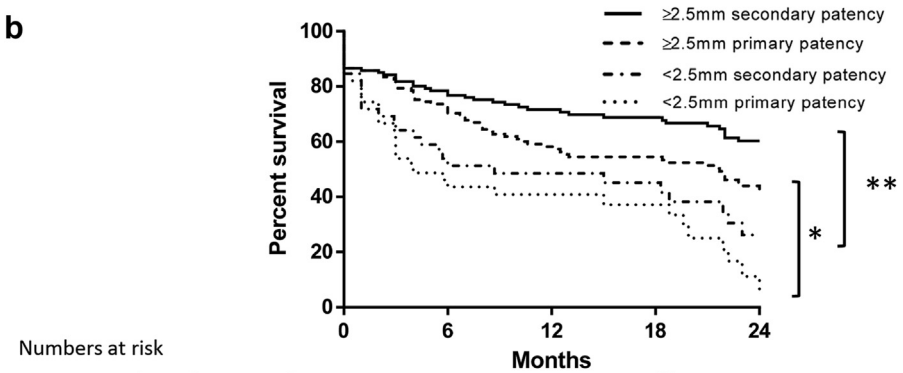
BC, Brachiocephalic; *RC,* radiocephalic.
[a]Seven contralateral radiocephalic fistulas, three ipsilateral ulnar-basilic fistulas, and two ulnar-cephalic fistulas.
[b]Two ipsilateral radiocephalic fistulas.

Complications and patient mortality. One of the major concerns underlying our strategy of focusing on the creation of distal (RC) fistulas was the potential for development of steal syndrome after formation of antecubital (BC and BB) AV fistulas in the elderly. A total of 298 vascular access procedures were performed on



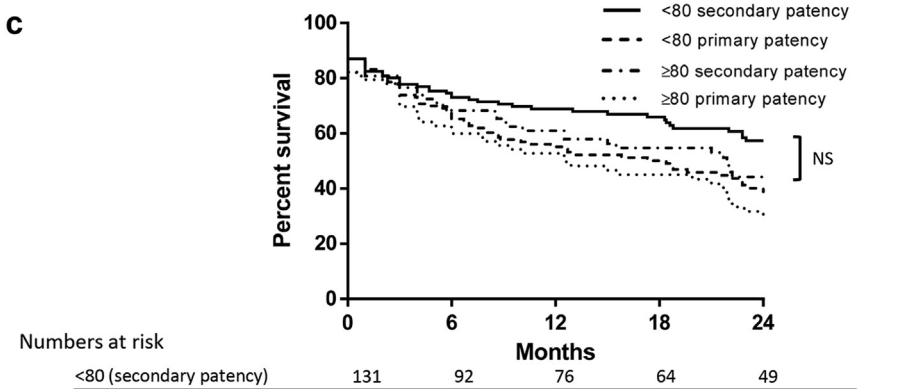
Numbers at risk

RCF (secondary patency)	204	141	116	96	73
RCF (primary patency)	204	126	95	75	52
BCF (secondary patency)	9	5	2	1	1
BCF (primary patency)	9	4	2	1	1



Numbers at risk

≥ 2.5mm (secondary patency)	127	93	78	66	52
≥ 2.5mm (primary patency)	127	85	63	53	40
< 2.5mm (secondary patency)	39	20	15	13	6
< 2.5mm (primary patency)	39	17	12	10	2



Numbers at risk

<80 (secondary patency)	131	92	76	64	49
<80 (primary patency)	131	82	60	48	33
≥80 (secondary patency)	73	49	40	32	24
≥80 (primary patency)	73	44	35	27	19

Fig 2. Primary and secondary patency rates of arteriovenous (AV) fistulas. **a,** Survival of radiocephalic fistulas (*RCFs*) and brachiocephalic fistulas (*BCFs*). *For RC fistulas, 1-year secondary patency rates were higher than primary patency rates (log-rank test, $P = .027$). Standard error exceeds 10% for both primary and secondary patency curves of the BC fistula cohort, which is likely a reflection of the small number of patients. **b,** Patency of RC fistulas stratified according to cephalic vein size. *Primary patency at 1 year was poorer in RC fistulas using cephalic vein <2.5 mm compared with those with cephalic vein >2.5 mm (log-rank test, $P = .015$). **Secondary patency rate of RC fistulas created with cephalic vein <2.5 mm was poorer than that of those using cephalic vein >2.5 mm (log-rank test, $P = .005$). **c,** Primary and secondary patency of RC fistulas stratified according to age. Two-year secondary patency rates for these groups were not statistically different (log-rank test, $P = .066$). *NS,* Not significant.

Table IV. Outcome and dialysis mode 1 year after creation of primary radiocephalic (*RC*) fistula

Disposition	*No.*	*%*
RC fistula	82	40
Tunneled central line	36	18
Predialysis[a]	29	14
Proximal RC fistula	20	10
Death	18	9
BC fistula	9	4
No longer required dialysis	8	4
Ulnar-cephalic fistula	1	0.5
Dialysis discontinued (subsequent death)	1	0.5

BC, Brachiocephalic.
[a]These patients had not initiated dialysis at 1 year as renal function was adequate; dialysis was initiated subsequently.

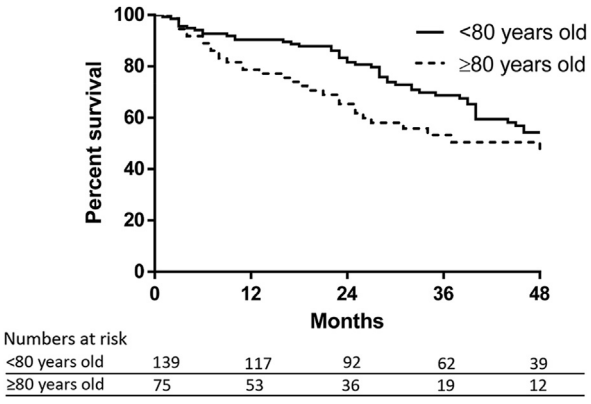


Fig 3. Kaplan-Meier analysis for patient survival according to age from commencement of dialysis.

the elderly dialysis cohort during the study period; 214 primary fistulas initially and another 43 wrist and 41 antecubital (BC and BB) primary fistulas were created subsequent to failure of the original primary access. Only nine patients developed steal syndrome; in eight, this required either ligation of the fistula or a revision using a distal inflow procedure.[30,32] Another patient described marked hand claudication, associated with a systolic digital blood pressure of 54 mm Hg; this was treated conservatively. In agreement with published literature,[15,33] steal syndrome developed much less frequently after formation of a wrist than an antecubital fistula (5 of 51 [10%] for antecubital [BC and BB] fistulas and 4 of 247 [2%] for wrist fistulas; Fisher's exact text, $P = .009$; odds ratio, 6.60).

An additional consideration influencing the decision to site an AV fistula more proximally is the anticipated improved immediate patency rates in a dialysis population with limited life expectancy. Only three patients from our study population received a transplant. For the rest of the study population, in keeping with recent UK Renal Association data,[34] survival was perhaps better than anticipated (Fig 3); at commencement of dialysis, of the patients aged 70 to 80 years and those older than 80 years, 54% and 46%, respectively, were alive 4 years later.

DISCUSSION

The best choice of permanent access procedure for elderly hemodialysis patients remains controversial.[1,4,7-9] Selection is based on a number of competing factors, such as the patient's life expectancy, expected immediate patency rates, and risk of complications.[7,35,36] In this study, one of the largest series to date reporting outcomes for hemodialysis patients older than 70 years, we highlight that successful access placement can be achieved using an approach predominantly focused on creation of RC fistulas. Creation of wrist fistulas in the elderly is not a novel concept, but perhaps the most important aspect of our study is that approximately 70% of our elderly patients successfully dialyze through an RC fistula. This represents a much higher proportion than reported in other publications detailing outcomes for elderly hemodialysis patients[35,37] and indeed is higher than is typically reported by centers for their entire hemodialysis population.[25,38,39]

Nationally, unadjusted 4-year survival for incident hemodialysis patients aged ≥65 years as reported in 2012 was 41%,[34] and historically the median survival for very elderly patients (>75 years) is <2 years from initiation of dialysis. Nevertheless, the current UK Renal Registry analysis confirms that survival for the incident elderly dialysis population is gradually increasing.[34] Our elderly hemodialysis cohort aged ≥70 years had a better survival than the overall elderly dialysis population in the United Kingdom, with 51% alive at 4 years. Thus, survival of the elderly dialysis population appears to be improving, suggesting that greater emphasis should be placed on conserving proximal access sites for future access provision. We acknowledge that for centers serving elderly hemodialysis populations with shorter life expectancies, such an aggressive strategy for RC fistula creation is perhaps not warranted.

In our cohort, almost 60% of patients who had a fistula created did not proceed to require hemodialysis, which is a particular issue in this age group.[40,41] Timing of access placement is particularly difficult in the elderly population as older individuals exhibit a slower rate of eGFR decline and possess limited life expectancy compared with younger individuals.[7] Where previously a fistula was created when the eGFR fell below 20 mL/min/1.73 m^2, we now consider the rate of eGFR decline and routinely create a fistula only when the eGFR falls below 12 mL/min/1.73 m^2. Thus, the relatively high percentage of patients who remained predialysis after fistula creation likely reflects our earlier practice of creating fistulas at a relatively early stage in progression of ESRD. Nevertheless, early referral certainly has a direct bearing on initiation of dialysis through an autogenous fistula,[19,42] allowing adequate time for maturation and repeated interventions; conversely, patients who start dialysis with lines are more likely to decline fistula creation.[7]

Our results suggest that for elderly patients with wrist cephalic veins >2.5 mm, creation of an RC fistula should

be the first option, assuming suitable arterial inflow. Such an approach would be anticipated to achieve reasonable patency rates and to be associated with minimal complications and in particular to carry a low risk for development of steal syndrome. This strategy provides the additional advantage of successful salvage and preservation of venous capital; in our series, the formation of a neovascular anastomosis improved 1-year patency rates by 12%.

The most appropriate choice for fistula placement in those patients with small cephalic veins (<2.5 mm) who are nevertheless believed to have reasonable vein quality is more contentious. The immediate failure and primary patency rates for RC fistulas created in these conditions were undoubtedly poor, with less than half achieving primary patency at 1 year. Nevertheless, secondary patency rates were acceptable and substantially better than the secondary patency rates for BC fistulas created. However, very few BC fistulas were performed as a primary procedure, and direct comparison between outcomes for BC and RC fistulas is therefore difficult. Patients in our study designated for a BC fistula as the first option for hemodialysis provision were generally considered to have poor-quality radial artery or cephalic vein at the wrist and are perhaps a cohort selected to have inherently poor results for hemodialysis access provision. Nevertheless, it is undoubtedly more difficult to surgically salvage failed BC than RC fistulas,[14] which may partly explain why 1-year secondary patency rates were relatively poor for BC fistulas, despite the immediate patency rates being similar to those achieved for RC fistula. We do not routinely attempt radiologic salvage of a failed BC fistula because our experience mirrors reports from other centers[43-46] in that improvements in fistula patency are achieved only by intensive and repeated radiologic interventions.

Accepting these limitations with the analysis of outcomes for BC fistulas in our study, our findings, at the very least, raise questions as to the merits of an approach in elderly patients centered predominantly on creation of BC fistulas. Indeed, it would be difficult, given the high incidence of steal associated with BC fistulas in our series, to justify such a change in our practice without performing a prospective trial in which elderly patients with small (<2.5 mm) wrist cephalic veins that are deemed clinically usable are randomized to either RC or BC fistulas. End points would include immediate failure rates, 1- and 2-year patency, and development of clinically relevant steal.

Finally, it is surprising that formation of proximal neoanastomosis was reasonably successful in salvaging RC fistulas that failed to mature, supporting the contention that the radial artery and cephalic vein at the wrist were of sufficient quality to attempt RC fistula creation but that there are perhaps stochastic events that influence successful maturation. The neoanastomosis was routinely performed just proximal to the initial anastomosis, and it is therefore unlikely that the arterial and venous caliber differed significantly at the second anastomotic site. We are, however, careful to counsel patients about the relatively high risk of primary failure and that a secondary procedure may be required.

CONCLUSIONS

RC fistulas created in the elderly carry a lower risk of steal syndrome than BC fistulas and offer the potential for further revision surgery, such that acceptable secondary patency is achieved for RC fistulas formed using even small (<2.5 mm) cephalic veins. Given the increasing life expectancy of the elderly cohort, preservation of venous capital should still be a consideration when access sites are planned.

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AUTHOR CONTRIBUTIONS

Conception and design: MG, SI
Analysis and interpretation: MG, GP
Data collection: MG, SI
Writing the article: MG, JA, GP
Critical revision of the article: MG, JA, GP
Final approval of the article: MG, JA, SI, GP
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