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7 **Factors Affecting Early Maturation of Arteriovenous Fistulae Created at a**
8 **Tertiary Centre in Oman**

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15
16 **Abstract**

17 **Objectives:** An arteriovenous fistula is ideal for vascular access, the maturation of which is
18 vital for hemodialysis. Our aim was to determine the risk factors associated with failure of
19 maturation of arteriovenous fistulae. **Methods:** This retrospective cohort study, from January
20 2014 to December 2018 was conducted in a tertiary care hospital in Oman, Patients were
21 followed up for three months after surgery. Electronic medical records were accessed for
22 demographics and clinical data. Data was analyzed using SPSS package. Univariant analysis
23 was used to determine the risk factors associated with early maturation of AVF and multi
24 variant analysis used to determine the predictive risk factors. **Results:** There were a total of 269
25 patients in the study. Female gender was a significant factor affecting maturity (P= 0.027).
26 While factors not affecting maturation were age (P= 0.320), diabetes (P= 0.858), hypertension
27 (P= 0.215), dyslipidemia (P= 0.215), coronary artery disease (P= 0.433), cerebrovascular
28 accident (P= 0.864), congestive heart failure (P= 0.509), previous central venous catheter
29 creation (P= 0.11), fistula type (P= 0.863) and fistula side (P= 0.861). Binary logistic regression
30 showed that all risk factors were insignificant. Failure of early maturation was 11.5%.
31 **Conclusion:** Our research has shown that the early maturation proportion of arteriovenous
32 fistulae created at our hospital is at par with international literature. Failure of maturation was
33 significantly associated with the female gender. Results of this study can help nephrologists

34 and vascular surgeons prognosticate maturation rates of arteriovenous fistulae. However, a
35 larger study is needed for definitive conclusions.

36 **Keywords:** CKD; AVF; maturation; early; failure; Oman.

37

38 **Advances in knowledge**

39 1- The outcome of this study will provide a guide to the vascular access team concerning
40 proportion of early primary failure and its factors that predict it among Omani patients.

41

42 **Application to patient care**

43 1- Knowing the associated risk factors will help improve the outcome, increase success
44 rates of patency of AVF's and hence quality of life of end stage renal disease patients
45 in Oman.

46

47 **Introduction**

48 The incidence of end-stage renal disease (ESRD) in Oman in 2013 was 120 per million
49 population. It was more prevalent in males (57.1%) than females (42.9%). The leading risk
50 factor was diabetic nephropathy (46%), followed by hypertensive nephropathy (19%).¹

51

52 An arteriovenous fistula (AVF) is a surgically crafted anastomosis between an artery and a vein
53 at the level of the wrist, elbow, axilla or groin. This connection increases the blood flow through
54 the vein, enlarges it and over time makes it thicker, allowing the dialysis needles to be inserted
55 and hemodialysis [HD] to be performed. This change that the vein undergoes is called
56 maturation of the fistula when combined with the proportion of blood flow through the vein of
57 at least 300ml/min. This process normally take six weeks from this time the AVF was created.
58 AVF's are the commonest vascular access for HD, but are fraught with a high proportion of
59 failure to mature.^{2,3}

60

61 Literature defines "failure of maturation" when the fistula does not achieve at least one of these
62 targeted criteria 6 weeks after AVF creation: (1) Blood flow proportion is greater than 600
63 mL/minute; (2) Vein diameter is less than 6mm; and (3) It has a maximum of 6mm depth from
64 the skin surface.⁴

65

66 Multiple factors are involved in the functional maturation of AVFs, these factors can be
67 demographic factors including patient age, sex, race/ethnicity, clinical factors such as presence

68 of cardiac disease, peripheral arterial disease, pulmonary hypertension, diabetes mellitus,
69 obesity.⁵ Hemodynamic factors including vein size, feeding artery size, blood flow and
70 technical factors like training / experience of the surgeon in AVF creation, care and use of the
71 AV fistula. A study done in South Korea, showed that failure of maturation in their cohort of
72 60 patients was 15%.^{6,7}

73

74 This study aims to determine the proportion and risk factors associated with early failure of
75 maturation of arteriovenous fistulae created at our tertiary care hospital.

76

77 **Methods**

78 This is a retrospective cohort study conducted in a tertiary hospital in Muscat, Oman following
79 ethical approval from the medical research ethics committee at the college of medicine and
80 health sciences in Sultan Qaboos University.

81

82 The study included all adult Omani patients who underwent AVF creation in the hospital from
83 January 2014 to December 2018 and primary patency assessed at three months. The exclusion
84 criteria included patients who hadn't used the AVF for HD or had succumbed within the 3-
85 month follow-up period.

86

87 For the purpose of the study, patients were divided into those below 65 years of age and those
88 65 and above, based on the WHO definition of "elderly".

89

90 Data was collected from the hospital's electronic medical record system and included patient
91 demographics such as age, gender, weight, height; history of previous tunneled neck central
92 venous catheter or failed AVF creation and comorbidities - hypertension (HTN), diabetes
93 (DM), dyslipidaemia (DLP), coronary artery disease (CAD), congestive heart failure (CHF),
94 cerebral vascular accident (CVA). All patients underwent a pre-op ultrasound mapping and a
95 venogram was performed if there was history of a tunnelled catheter. AVF's were created by a
96 group of 3 surgeons. Surgical details collected, included anatomical factors such as type of the
97 fistula- radio-cephalic AVF (RCAVF), brachio-cephalic AVF (BCAVF), brachio-basilic AVF
98 (BBAVF), and site of the fistula (left, right arm).

99 All patients were on 100 mg of aspirin pre and post operatively. An anticoagulant was used
100 only in patients with atrial fibrillation. Furthermore, information about the HD sessions like

101 blood flow through the dialyzer and outcomes of arteriovenous fistulas maturation were
102 obtained.

103

104 The collected data was recorded as numbers in Statistical Package for Social Sciences (SPSS)
105 program version 23. The fistulae were evaluated at 3 months post creation for success of HD
106 for minimum of 6 sessions with adequate flow rate/s and ease of cannulation. AVF was
107 considered mature based on these criteria. For the continuous variables, mean and standard
108 deviation were used. Body mass index (BMI) was calculated as body weight (Kgs.)/
109 height(meters)², obesity was defined as BMI > 29.9 kg/m² and overweight was defined as BMI
110 between 25-29.9 kg/m². Chi square test was used to find the association between the proportion
111 of failure of maturation of AVF and the studied variable. A "p" value <0.05 was considered
112 significant. Frequency tables were used to get the frequencies and percentages of demographic
113 variables as well as the prevalence of the disease. Multivariate analysis: Binary logistic
114 regression analysis has also been performed to identify the significant independent factors.

115

116 **Results**

117 Two hundred and eighty two patients underwent AVF creation during the study period. After
118 excluding patients who did not use the AVF for HD during the three month follow-up and those
119 who died before using the fistula, there was a cohort 269 patients in the study. (Figure 1).
120 Failure of early maturation occurred in 11.5% of patients at 3 months' post creation. There
121 were 161 (59.9%) males and 108 (40.1%) females. The mean age was 54.8 ±15.7 years (Age
122 range: 18-90). BCAVF was the most common type of AVF created (195; 72.5%) followed by
123 BBAVF (64; 23.8%) and RCAVF (10 patients; 3.7%). Further demographic distributions are
124 demonstrated in Table 1.

125

126 In the 269 patients, 13 out of 162 males (8%) and 18 out of 107 (16.7%) females had failure to
127 mature at 3 months (P = 0.049) showing a significant association between gender and failure
128 and a Relative Risk of 2.28. Binary logistic regressions analysis also concluded similarly.

129

130 Majority of the patients (72.1%) were elderly with an early failure of AVF maturation of 9.3%
131 and in the subset 65 years and below (27.9%) , the failure proportion was 12.4% (P= 0.626).

132

133 Obese patients were those with BMI > 29.9 kg/m² (27.1%) of the cohort; overweight patients
134 with BMI between 25-29.9 kg/m² (45.7%) and the remaining patients (27.1%) had BMI < 25

135 kg/m². The early failure proportion among obese, overweight and normal BMI patients was
136 13.7%, 11.4% and 9.6% respectively (P= 0.73).

137

138 Hypertension was the commonest co-morbidity (242 patients; 89.9%) followed by Diabetes
139 (181 patients; 67.2%); CAD (63 patients; 23.4%) and past history of CVA in 28 patients
140 (10.4%). 26 of the 31 patients with failed AVF were hypertensive (P= 0.215). Diabetic patients
141 constituted 179 (66.5%) of the cohort, 11.7% of them had a early failed AVF compared to the
142 non-diabetic patients (11.2%) (P= 0.858). Sixty-three patients (23.4%) in our study had CAD;
143 9 of them (29.0%) had early failure of AVF (P=0.433). (10.4%) had a history of CVA; 4 of
144 them who have failed AVF (P= 0.864).

145

146 Out of the 31 patients with failed AVF, 26 had hypertension (10.7% ; P= 0.378); 21 had DM
147 (11.7% : P= 0.954); 9 had CAD (14.3% : P= 0.576) : 4 had history of CVA (14.3% : P
148 =0.864);11 of them had a previous history of DLP (P=0.907) : 4 of them with a history of CHF
149 (P=0.685) and 26 patients (83.9%) had a previous CVC insertion (P=0.05).

150

151 The rate of failure of maturation in each type of fistula is as follows, RCAVF 1 (10%), BCAVF
152 21 (10.7%), BBAVF 9 (14%) (P =0.863).

153

154 In the 269 AVF's created, 220 were created in the left upper limb and 49 in the right. Twenty-
155 five (11.4%) of the left sided fistulas have failed to mature compared to 6 (12.2%) failed fistulas
156 in the right side (P=0.861).

157

158 Univariate analysis showed only gender as the significant risk factor to failure to mature,
159 females were found to have 2.277 times risk of failure to mature as compared to males. For
160 performing the binary logistic regression analysis BMI and HTN were also added as the risk
161 factors and the outcome of the analysis showed all the three risk factors as insignificant (Table
162 3).

163

164 The rate of early failure of AVF maturation was 11.5%. That means, 31 newly created AVF
165 considered primary failed AVF because it never develops adequately to support the dialysis or
166 fails to be needed within the first three months of its creation or impossibility to achieve more
167 than 300 mL/min that needed for successful dialysis treatment.

168

169 **Discussion**

170 This study was the first of its kind in the Sultanate of Oman as found in English literature. It
171 was done to find the prevalence of failure of early maturation of AVF in Omani adults and the
172 associated risk factors related to this key performance indicator (KPI).

173

174 This paper shows that the rate of maturation of AVF created at a single centre in Oman
175 determined at 3 months post creation was 88.5%. This study shows a lower proportion of early
176 AVF failure when compared with other single centre international studies from North America,
177 Korea and Netherlands.^{6,7,8} Previous studies used ultrasound to evaluate artery size, venous
178 dimensions, blood flow and subsequently predicted the AVF maturation.

179

180 This study depends on another definition for early failure AVF maturation. Non matured AVF
181 is the AVF that fails to be cannulated during the dialysis sessions or fails to achieve blood flow
182 ≥ 300 mL/min within 3 months of its creation. The reason behind the difference in the early
183 failure proportion of AVF between this study and previous research could be due to the relative
184 lower mean age of our cohort, higher proportion of BCAVF, variability of the definition that
185 was used to define failed AVF. Added to this is difference in number of centres involved,
186 surgeons experience, conduction of primary assisted/ secondary interventions and ethnicity that
187 affect the results. The higher proportion of BCAVF in our cohort reflects the effect of the pre-
188 operative vein mapping which led to appropriate avoidance of RCAVF which is known to
189 have higher proportion of failure. Hence, sparing the patient from undergoing a second surgery.

190

191 There is no significant difference in the early failure proportion of AVF between age groups.
192 This result is inconsistent with the meta-analysis conducted in the USA. It revealed a
193 statistically significantly higher proportion of failure to mature of AVF in elderly patients
194 compared with an odds ratio (OR) of 1.525. This significant difference is explained by the
195 presence of comorbidities like diabetes, DLP and cardiovascular disease in elderly patients that
196 show a stronger effect on AVF maturation, rather than age alone. Furthermore, elderly patients
197 exhibit problems including arteriosclerosis, poor-quality veins and thin skin that affect the
198 maturation process of the vascular access.⁹ The explanation for this conflict can be because of
199 relative significant lower mean of the age of our cohort. The disparity can also be due to the
200 exclusion of older patients who die before using AVF from the statistical analysis.

201

202 The study shows a significant difference in outcomes of early failure AVF maturation between
203 males and females. Female patients have a higher failure proportion of AVF compared to male
204 patients. This finding is consistent with a cohort study done in the USA. It found that fistula
205 adequacy for dialysis was lower in females compared to males (31 vs. 51%). In fact, increasing
206 blood flow through the arteriovenous connection and adequate dilation of the blood vessel are
207 essential variables required for AVF maturation.¹⁰ This significant difference in failure
208 proportion explained by smaller vessels of the female patients compared to males, so decrease
209 the chance for the new fistula to mature to adequate size. Another possible explanation between
210 male and female includes differences in vascular reactivity and platelet aggregation after
211 vascular injury. In addition to the difference in the ability of the veins to be dilated when
212 exposed to high pressure between genders as a result of AVF creation.¹¹

213

214 Our study shows no significant difference in the early failure proportion of AVF between
215 obese, overweight and normal BMI patients. This finding is inconsistent with a cohort study
216 done in the USA, which found that obese patients had a higher failure proportion compared to
217 non-obese patients with a relative risk (RR0 of 3.05. In fact, obese patients have higher levels
218 of C-reactive protein, which induce blood vessel intimal hyperplasia resulting in stenosis and
219 thrombosis. Obese patients also have a hypercoagulable state which increases the likelihood of
220 thrombus formation and subsequently, reduces the chance of AVF to be mature and usable. A
221 second potential explanation is that obesity makes it difficult for the surgeon to identify suitable
222 vessels for fistula creation. In addition, obese patients could have very deep arteriovenous
223 connections that can't successfully be cannulated by the dialysis needle. As a result, the fistula
224 must undergo transposition to be sufficiently superficial to offer anatomic landmarks and safe
225 cannulation.^{12,13} The difference in findings with the previous studies perhaps can be explained
226 by the small sample size and the relatively lower mean of BMI in our cohort.

227

228 Our research indicated that there is no relation between hypertension and failure of AVF
229 maturation. This result is supported by studies done by Kim et al, and another one conducted
230 in USA.^{14,15}

231

232 Diabetes mellitus has been considered as a significant predictor of AVF failure of maturation
233 in a study conducted in San Francisco (USA). It is explained by the fact that DM causes
234 metabolic changes that can cause endothelial changes and growth factors deregulation with
235 increased matrix deposition, all of these may lead to stenosis and thrombosis and thus failure

236 of maturation of AVF.¹⁶ Our study has shown that DM is not a significant risk factor for AVF
237 failure of maturation in agreement with a study was done by the University of Arizona Health
238 Sciences Center in Tucson (USA).¹⁵

239
240 Dyslipidemia has been considered as a non-significant factor affecting the AVF maturation.
241 The result conflict with a study was published in Canada that has indicated the DLP as a
242 significant risk factor explaining that by the role of dyslipidemia in forming calcified plaques,
243 leading to subintimal hyperplasia and decreasing the vessels diameter and that cause the failure
244 of maturation of AVF. The interference between the results can be due to the sample size and
245 the fact that the DLP percentage between the group with failure and those with non-failure is
246 very close; that is not making differences between each.

247
248 Coronary artery disease is considered as one of the main causes leading to atherothrombosis.
249 Which in sequence can cause thrombosis of connected vessels of AVF and thus failure of AVF
250 maturation.¹⁷ A prospective study was done on 422 patients has shown that CAD is a significant
251 factor affecting the failure of AVF maturation. This result conflict with ours, which has
252 indicated that CAD is not significant in determining the failure of AVF maturation. The conflict
253 between the two results can be explained by the difference in the sample size between the two
254 studies and the difference in the type of study itself.¹⁸

255
256 Cerebrovascular accident was considered as a non-significant factor in our study, which
257 coincided with the results of a study that was done in Canada.¹⁸ The agreement between the
258 results strongly indicates that there is no relation between CVA and failure of AV maturation.

259
260 Our results have shown that congestive heart failure is not a significant factor affecting the
261 AVF failure. The result is supported by three other studies which have been done in Portugal,
262 Canada and USA, respectively.^{18,19,20}

263
264 There was a discrepancy between studies about the relation of previous central venous catheter
265 creation with the failure of maturation of AVF. A study was done in USA has shown that Pre-
266 CVC is a significant risk factor that may affect the AVF maturation, explaining that by the
267 effect of Pre-CVC in forming stenosis thus affecting the vascular access outcomes.¹⁵ Our result
268 has shown that Pre-CVC is not a significant risk factor in this case which coincided with the
269 results of a study that was done in Tuscon (USA) from 2003-2007 among 298 patients.²⁰

270

271 Lauvao et al has shown that there is no relation between type/site of AVF (RCAVF, BCAVF,
272 BBAVF) with its maturation, and that agrees with our research results.²¹ However, this result
273 can be referred to the fact that AVF maturation depends more on the diameter of the vessels
274 used and how healthy are they.

275

276 It is preferred that the arteriovenous fistula be created on the non-dominant arm or the arm that
277 not used frequently. As a result, the patients will have a free dominant hand, allowing the
278 patient to complete the desired activities more easily during the dialysis session. However, if
279 the non-dominant arm is not suitable for AVF creation, the dominant arm will be used.²² This
280 study shows no significant variation in failure proportion of AVF whether the AVF is created
281 in the right or left arm of the patients. This finding is consistent with a single-centre cohort
282 study done in the United Kingdom (UK), which found no significant difference in failure
283 proportion of fistulas between dominant and non-dominant arms.²³

284

285 One of limitations of our study is its retrospective nature which can affect the results due to
286 lack of some data in the patients record. Secondly, it is a single-centre study, and although
287 SQUH is a large referral centre, it would not represent the results in other centres in Oman.
288 Third is that our cohort is small and duration of follow-up short.

289

290 **Conclusion**

291 The proportion of early failure of AVF maturation was 11.5% which is in the lower range of
292 reported international literature. We found that the female group of patients had a higher risk
293 for failure of AVF maturation. Preoperative ultrasound guided mapping is helpful to evaluate
294 and choose the appropriate vessel for AVF creation and for postoperative follow up of the
295 fistula to check AVF maturity or detect early complications. This group of patients should be
296 closely monitored as endovascular or surgical intervention can be offered to improve primary
297 patency of a fistula.

298

299 **Authors' Contribution**

300 DR conceptualized and designed the study. ES and KW contributed to methodology design.
301 SHa, SHu and HM collected the data under supervision of DR. All authors drafted the
302 manuscript and approved the final version of the manuscript.

303

304 **Conflict of interest**

305 The authors declare no conflict of interests.

306

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309

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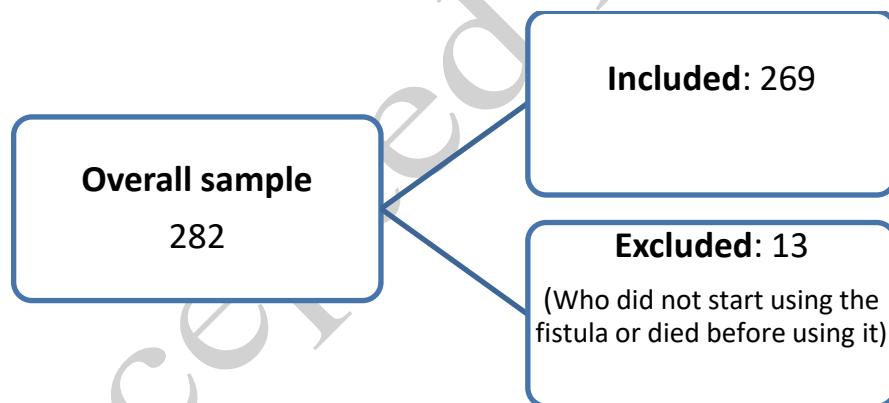
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386
 387 Figure 1: Sample recruitment flow

388 Table 1: Distribution of the study participants among different variabilities

Characteristics		Value (%)
Age	Mean \pm SD	54.8 \pm 15.7
	Min	18
	max	90
Gender	Male	161 (59.9%)
	Female	108 (40.1%)
Body mass index	Mean \pm SD	28.0 \pm 6.3
	Minimum	13.9
	Maximum	54.9
Side of AVF	Right	49 (18.2%)
	Left	220 (81.8%)
Type of AVF	Radio-cephalic	10 (3.7%)
	Brachiocephalic	195 (72.5%)
	Transposed Brachio-basilic	64 (23.8%)
Comorbidities	HTN	242 (89.9%)
	DM	181 (67.2%)
	Dyslipidemia	99 (36.8%)
	CAD	63 (23.4%)
	CHF	46 (17.1%)
	CVA	28 (10.4%)
	PVD	13 (4.8%)

389 Standard deviation (SD), arteriovenous fistula (AVF), hypertension (HTN), diabetes (DM), dyslipidaemia (DLP), coronary
 390 artery disease (CAD), congestive heart failure (CHF), cerebral vascular accident (CVA)

391 Table 2: Analysis of risk factors associated with failure of AVF maturation

Characteristic	Total	n (%)		p-value
		Failed AVF (n = 31)	Mature AVF (n = 238)	
Gender				
Male	161	13 (8.1)	148 (91.9)	P= 0.049 RR= 2.277
Female	108	18 (16.7)	89 (83.3)	
BMI				
Normal BMI	73	7 (9.6)	66 (90.4)	P= 0.737
Overweight	123	14 (11.4)	109 (88.6)	
Obese	73	10 (13.7)	63 (86.3)	
Age				
< 65	194	24 (12.4)	170 (87.6)	P= 0.626
≥ 65	75	7 (9.3)	68 (90.7)	
Previous catheter				
Yes	249	26 (10.4)	223 (89.5)	P= 0.05
no	20	5 (25.0)	15 (75.0)	
Anatomical site				
RCAVF	10	1 (10.0)	9 (90.0)	P=0.863
BCAVF	195	21 (10.7)	174 (89.3)	
BBAVF	64	9 (14.0)	55 (86.0)	
Side of AVF				
Left	220	25 (11.4)	195 (88.6)	P=0.861
Right	49	6 (12.2)	43 (87.8)	
Hypertension				
Yes	242	26 (10.7)	216 (89.3)	P= 0.378
No	27	5 (18.5)	22 (81.5)	
Diabetes Mellitus				
Yes	181	21 (11.7)	159 (88.3)	P= 0.954
No	88	10 (11.2)	79 (88.8)	
Dyslipidaemia				
Yes	98	11 (11.2)	87 (88.8)	P= 0.907
No	171	20 (11.7)	151 (88.3)	
CAD				
Yes	63	9 (14.3)	54 (85.7)	P = 0.576
No	206	22 (10.7)	184 (89.3)	
CHF				
Yes	46	4 (8.7)	42 (91.3)	P= 0.685
No	223	27 (12.1)	196 (87.9)	
CVA				
Yes	28	4 (14.3)	24 (85.7)	P= 0.864
No	241	27 (11.2)	214 (88.8)	

392 Number (n), percentage (%), AVF: arteriovenous fistula, body mass index (BMI), P value (P), Radio cephalic AVF (RVAVF),
 393 brachio cephalic AVF (BCAVF), Brachio basilic AVF (BBAVF), coronary artery disease (CAD), congestive heart failure (CHF),
 394 cerebellar vascular accident (CVA).

396 Table 3: Risk and 95% Confidence interval using univariate and multivariate (logistic
397 regression) analysis

Characteristic	Univariate		Multivariate	
	Risk	95% CI	Risk	95% CI
Gender	2.277	1.065 - 4.869	1.860	.782 – 4.425
Hypertension	0.530	0.158 – 1.518	0.606	.153 – 2.409
BMI	1.544	0.650 – 3.668	1.526	.604 – 3.854

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