

ANNEXES TO CHAPTER 1

Clinical Question III. What criteria are required for arteriovenous fistula planning (based on different types of fistula)?	
<p>An important condition for haemodialysis is to create an appropriate vascular access. The most desirable option for efficacy and safety for the patient is the arteriovenous fistula. Appropriate selection of the vessels where the vascular access is to be created substantially improves the success rate, and an important part of this assessment is a full physical examination and a detailed medical history (Reinhold 2011).</p> <p>A number of published studies were found that analyse different factors in cases of planning for fistulae, but only one on factors that may influence the success of a graft (Rosas 2003), and none on central venous catheters.</p>	
Physical examination alone vs ultrasound vascular mapping plus physical examination prior to fistula creation	
<p>Some authors and guidelines recommend that vascular mapping is performed in all patients for whom vascular access creation for haemodialysis is being considered, in order to assess the anatomy and arterial and venous functionality. Mapping involves measuring the diameter and quality of the arterial wall and the anatomy and patency of the superficial and deep venous system in the upper limb (Shenoy 2013).</p> <p>Other authors (Ferring 2008), in contrast, consider that physical examination should initially be used in all patients to assess an appropriate location for the AVF surgery and that preoperative ultrasound be used in certain patients only to improve the AVF outcome, such as in the following situations:</p> <ul style="list-style-type: none"> • insufficient clinical examination (obese, absence of pulses, multiple previous surgical interventions on limb), • patients with suspected arterial disease (elderly, diabetes, cardiovascular disease), • patients with suspected venous disease (previous cannulation). 	
<p>The systematic review by Wong (2013) located three RCT, with a total of 402 patients, which made this comparison (Mihmanli 2001; Nursal 2006; Ferring 2010). In one of the trials, patients randomised to ultrasound mapping had statistically significant better outcomes in terms of the success of the fistula for haemodialysis. However, this was not the case in the other two trials. A meta-analysis of the three studies found a difference, but not statistically significant (174/214 vs 130/188; OR 1.96, 95% CI 0.84 to 4.50; p=0.11).</p>	Low quality
Diameter of the artery or vein as a criterion for planning access by fistula	
<p>Internal vascular diameter is measured by ultrasound, but as we saw in the previous section, routine use is not justified, as the currently available evidence shows no statistically significant clinical benefit.</p>	
<p>A meta-analysis by Glass (2009) analysed the possible effect of the radial artery diameter and cephalic vein diameters on the success of a radiocephalic fistula, based on 20 observational studies with a total of 433 patients. The meta-analysis suggests cut-off points of 2.0 mm for both the radial artery and the cephalic vein. The success rate of the fistula (functional for at least 4-6 weeks after creation) was significantly better for radial arteries with a diameter greater than 2.0 mm (59%) than for those less than 2.0 mm (40%). The success rate of the fistula was also significantly better for cephalic veins with a diameter greater than 2.0 mm (71%) than for those less than 2.0 mm (29%).</p>	Low quality

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<p>In the case series by Lauvao (2009), with data from 185 arteriovenous fistulae, after multivariate logistic regression analysis, it was concluded that the only predictor of maturation of the fistula was the venous diameter (OR 0.15, 95% CI: 0.044 to 0.497; $p=0.002$).</p>	<p>Low quality</p>
<p>The case series by Zadeh (2012), with 96 fistulae, 62.5% in the distal radial artery in the wrist and 37.5% in the proximal radial artery in the antecubital area, found no relationship between the duration of maturation and vein or artery diameter ($p>0.05$). The maturation period showed a correlation with the diameter of the vein ($p=0.04$) in patients with distal radiocephalic fistula. The maturation of the fistula showed correlation with the diameter of the vein, but not with the diameter of the arteries.</p>	<p>Low quality</p>
<p>The Parmar (2007) case series, with 21 patients, compares the patency of the fistula according to the internal diameter of the radial artery (11 patients <1.5 mm and 10 patients >1.5). In the <1.5 mm-diameter group, 5 patients (45%) suffered immediate thrombosis of the access, while all those with a diameter >1.5 had a patent access at 12 weeks. The rate of blood inflow to the radial artery was consistently and significantly higher in the larger-diameter group for all measurements (at 1 day, 1 week, 4 weeks and 12 weeks) ($p<0.01$). In patients with small radial arteries, they suggest considering creating the fistula in the upper arm.</p>	<p>Low quality</p>
<p>The Korten case series (2009) retrospectively analysed 148 patients with fistula for associations between the diameter of the radial artery and the cephalic vein and primary failure at six weeks, primary patency and secondary patency at one year. No significant association was found between the diameter of the artery, whether or not the radial, or diameter of the dilated cephalic vein and primary failure. An association was found between the diameter of the radial artery primary patency ($p=0.042$). Men had a significantly larger mean radial artery diameter than women ($p=0.005$), but gender did not affect primary patency. They recommend the use of radial arteries with diameter ≥ 2.1 mm and ≤ 2.5 mm for fistula construction, as this was the category with the best patency at one year.</p>	<p>Low quality</p>
<p>The Hamish case series (2008) with 83 patients, 44 with radiocephalic and 39 brachiocephalic AVF, found a positive correlation between the size of the vein and access flow rate and access patency. Preoperative vein diameters of 1.5-3.9 mm showed a patency rate of 71.08% at follow-up at 13.8 months (range, 12-42 months). Although large vessels were correlated with long-term patency, smaller vein diameters (1.5-2 mm) were found to have an acceptable patency rate of 20% at 12 months. Furthermore, data indicated a positive correlation between access flow rate and access patency, with flow rates of above 700 ml/min being associated with a patency rate of 70% at 12-month follow-up.</p>	<p>Low quality</p>

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Gender, diabetes mellitus, etc. as criterion for planning access by fistula	
<p>In the narrative review by Smith (2012), the authors maintain that the literature is limited, but suggest that some patient factors, such as age, diabetes, smoking, peripheral vascular disease, hypotension predialysis, and the characteristics of the blood vessel affect the patency of the fistula. They do not, however, consider there to be any link between gender or a high BMI and patency.</p> <p>They believe that small blood vessels (<2 mm) or vessels with limited distensibility are unlikely to be of use for creating a functional AVF.</p> <p>Nevertheless, they are of the opinion that there is a complex interaction of factors that may affect the patency of an individual AVF; factors that must be carefully considered when choosing the surgical site or the technique to be used.</p>	Low quality
<p>The case series by Lauvao (2009) analyses the role of different factors in predicting the maturation of the fistula in a series of 195 patients being assessed for the creation of a vascular access for haemodialysis. They studied the following factors: age, race, gender, body mass index (BMI), the site of the fistula, preoperative diameter of the vein, diabetes, hyperlipidaemia, hypertension, prior central catheter placement, HIV, and a history of intravenous drug abuse. AVF were created in 185 patients (95%) and adequate follow-up data were available for 158 patients, who they included in the analysis.</p> <p>Fistula location was posterior radiocephalic in 24 patients, wrist radiocephalic in 72 and brachiocephalic in 62. Maturation rates for these sites were 54%, 66% and 81% respectively. The differences were statistically significant when analysing site maturation rates separately (p=0.032), but not by multivariate logistic regression analysis.</p> <p>They found that neither age (65-99 years, OR 0.79, 95% CI: 0.263 to 2.366, p=0.672), or gender (OR 0.52, 95% CI: 0.166 to 1.605; p=0.254), or the existence of diabetes (OR 1.56, 95% CI: 0.447 to 5.501; p=0.482), or hypertension (OR 1.36, 95% CI: 0.210 to 8.762; p=0.749), or BMI had a significant effect on maturation of the fistula.</p>	Low quality
<p>The Zadeh study (2012) on a series of 96 fistulae, 62.5% with distal radial artery AVF in the wrist and 37.5% with antecubital proximal radial artery AVF, found no relationship between the duration of the maturation period and diabetes mellitus, gender, age or the diameter of the vein or artery (p>0.05). The median time for maturation was 38.60 days.</p> <p>A correlation was found between the maturation period and the diameter of the vein (p=0.04) in patients with distal radiocephalic fistulae. The maturation of the fistula showed correlation with the diameter of the vein, but not with the diameter of the arteries.</p>	Low quality
Age and location of the access	
<p>A meta-analysis by Lazarides (2006) included thirteen studies, all observational, 11 of them retrospective, comparing fistula outcomes in elderly and non-elderly adult patients, or patency rates of radiocephalic and proximal fistulae or grafts in elderly patients.</p> <p>The meta-analysis showed a significantly higher failure rate for the radiocephalic arteriovenous fistula in elderly compared to non-elderly adult patients: failure at 12 months (odds ratio (OR) 1.525, 95% CI: 1.189 to 1.957; p=0.001) and at 24 months (OR 1.357, 95% CI:</p>	Low quality

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<p>1.062 to 1.751; p=0.019).</p> <p>The primary failure rate for the radiocephalic arteriovenous fistula was also higher in the elderly (OR: 1.79, 95% CI: 1.136 to 2.821; p=0.012).</p> <p>The secondary analysis showed better outcomes for brachiocephalic fistulae in the elbow than for radiocephalic fistulae in elderly patients (risk difference: -12.2, 95% CI: -20.6 to -4%; p=0.004), and the authors state that if confirmed by other prospective studies, these differences would have to be taken into account when planning creation of a vascular access in elderly patients.</p>	
Models/rules to predict the failure of the fistula	
<p>Based on data from 422 patients, Lok (2006) developed a prediction rule for risk of failure of the fistula, and found that the predictive factors were age ≥ 65 years (OR 2.23, 95% CI: 1.25 to 3.96), peripheral vascular disease (OR 2.97, 95% CI: 1.34 to 6.57), coronary artery disease (OR 2.83, 95% CI: 1.60 to 5.00) and Caucasian (OR 0.43, 95% CI: 0.24 to 0.75).</p> <p>However, based on data from 195,756 patients, the Lilly study (2012) found that the Lok criteria, together with other sociodemographic data, were of limited utility for identifying patients at high risk of fistula failure. They state that patients classified as at high risk of failure with the Lok prediction rule can achieve a fistula functioning.</p>	Low quality
<p>A prospective study by Feldman (2003) with 348 patients used multivariate logistic regression to develop explanatory models for the factors associated with AVF success and the models for predicting success based on sociodemographic characteristics and comorbidity. A total of 55.5% of the AVF matured successfully.</p> <p>They found that the following factors were associated with a lower likelihood of maturation: a history of cerebrovascular accident or transient ischaemic attacks; age; and dependence on dialysis at the time of access placement.</p> <p>Of the potentially modifiable variables, maturation was associated with higher doses of heparin intraoperatively, the use of large-diameter veins, and a mean arterial pressure of 85 mmHg or above.</p> <p>They considered that a predictive logistic regression model had moderate ability to predict the maturation of the AVF (area under the ROC curve 0.69).</p>	Low quality
<p>The Bojakowski study (2012) with 68 patients analysed patient characteristics and biochemical parameters associated with a higher risk of failure of the fistula performing a multivariate analysis.</p> <p>The independent predictors for fistula dysfunction were the number of white blood cells (HR 1.67; 95% CI: 1.24-2.25, p<0.001), the number of monocytes (HR 0.02, 95% CI: 0.00-0.21, p=0.001), and red cell distribution width (HR 1.44; 95% CI: 1.17-1.78, p<0.001).</p> <p>The red cell distribution width was the only important factor in the analysis of ROC curves (area under the curve 0.644; CI 0.51-0.76, p=0.046). A red cell distribution width greater than 16.2% was associated with a significant reduction in fistula patency at 24 months after surgery. They concluded that the red cell distribution width, an easily accessible laboratory value, was a new prognostic marker for AVF failure, although they stressed that further studies were needed to confirm the association.</p>	Low quality

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Determinants of a successful graft	
<p>A prospective study by Rosas (2003) analysed the results from 284 patients on haemodialysis who had undergone graft placement for vascular access and were followed up for four and a half years.</p> <p>A total of 172 (61%) had at least one graft-related event, such as temporary graft dysfunction or graft loss, during the follow-up period. A total of 54% of grafts were functional after three years (95% CI: 45-62%).</p> <p>Using the proportional hazards analysis, they found that the following variables were associated with shorter survival: history of claudication (RR 2.14, range: 0.97-4.73, p=0.06), the number of previous permanent grafts (1 graft: RR 1.49, range: 0.88-2.51; 2 or more grafts: RR 2.85, range: 1.43-5.69, p=0.01), dependence on dialysis at the time of surgery (RR 2.96, range: 1.23-7.12, p=0.02), and use of arterial clips in the construction of the graft (RR 2.32, range: 1.14-4.73, p=0.02), even taking the medical history into account.</p> <p>The following variables were associated with a lower risk of graft failure: the type of graft material, i.e. GORE-TEX compared to another material (RR, 0.28, range: 0.16-0.50, p<0.01), use of the axillary vein for the access site (RR 0.61, range: 0.36-1.02, p=0.06), acute arterial anastomosis, i.e. the arterial angle less than 90 degrees (RR 0.63, range: 0.45-0.91, p=0.01) and use of the brachial artery compared with the radial artery (RR 0.54, range: 0.33-0.54, p=0.01).</p>	Low quality
<p>The before-and-after design study by Flu (2008) compared previous practice at their site (historic control) with a new multidisciplinary treatment protocol (meetings analysing each case by a team including vascular surgeon, nephrologist, interventional radiologist, dialysis nurse and ultrasound technician) for planning the time, indication and type of access and logistics of the operation.</p> <p>In patients treated with the new protocol, there were significantly fewer episodes of revision surgery (p<0.019) and more endovascular angioplasties (p<0.001), as well as higher rates of primary and secondary patency in the accesses overall (p<0.001) and, in particular, in direct radiocephalic wrist fistulae (p<0.001) and brachiocephalic grafts in the forearm (p<0.001).</p>	Low quality
Summary of evidence	
<p>A meta-analysis of three RCT with 402 patients found a difference, although not statistically significant, in achieving a successful fistula for haemodialysis among patients who had been studied with ultrasound mapping in addition to physical examination.</p>	Low quality
<p>Evidence from clinical series is not sufficiently conclusive to recommend taking into account any isolated sociodemographic or clinical factor for planning vascular access, or any particular multivariate model for predicting the likelihood of vascular access success.</p>	Low quality
Patients' values and preferences	
<p>A study by Fissell (2013) used a cross-sectional sample of data from the Dialysis Outcomes and Practice Patterns Study (DOPPS 3, 2005-09), that included 3815 patients treated in 224 facilities in 12 countries. They found that patient preference for a catheter varied from country to country: 1% in Japan, 18% in the United States, and 42% to 44% in Belgium and Canada, suggesting that patient preference may be influenced by</p>	

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<p>sociocultural factors and therefore could be modifiable.</p> <p>The preference for a catheter was associated positively with age (adjusted OR per 10 years 1.14; 95% CI: 1.2-1.26), female gender (OR 1.49; 95% CI: 1.15-1.93), and previous use (OR 2.61; 95% CI: 1.66-4.12) and/or current use of catheters (OR 60.3; 95% CI: 36.5-99.8). Also catheter preference was inversely associated with time on dialysis (OR per three years 0.90, 95% CI: 0.82-0.97).</p>	
<p>Use of resources and costs <i>No relevant studies related to this aspect have been identified.</i></p>	
<p>Recommendations [Proposal]</p>	
Weak	Routine vascular mapping by ultrasound for choosing arteriovenous fistula location is not recommended.
Weak	We do not recommend taking any isolated sociodemographic or clinical factor into account for planning vascular access, or any particular multivariate model for predicting the likelihood of vascular access success.
Weak	We recommend that in the planning of vascular access and in the choice of the location of the fistula, the decision is based on an overall assessment of the medical history and physical examination of the arteriovenous system of each patient, and on their individual preferences.
<p>References</p>	
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Table 1. STUDIES EXCLUDED

Study	Cause for exclusion
Ethier 2008	Descriptive study of use of various kinds of access in different countries, that does not analyse criteria for planning the vascular access.
Lampropoulos 2009	Clinical series about the utility of vascular mapping and venography, without comparator group.
Lin 2004	Old narrative review about the utility of vascular mapping. There is a more up-to-date systematic review that identifies three RCT.
Planken 2005	Study comparing use of pressure sleeve or tourniquet when measuring vein diameter.
Saggi 2012	Expert opinion that does not address the criteria for planning vascular access in detail.
Thalhammer 2013	Expert opinion that does not address the criteria for planning vascular access in detail.

GRADE TABLES

Date: 2013-12-17

Question: Should vascular mapping by ultrasound + physical examination be performed or only physical examination in the examination prior to choosing the site to create the arteriovenous fistula?

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Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ultrasonographic mapping + physical examination	Only physical examination	Relative (95% CI)	Absolute		
Success of the fistula for HD												
3	Randomised trials	serious ¹	serious ²	no serious indirectness	no serious imprecision	none	174/214 (81.3%)	130/188 (69.1%)	OR 1.96 (0.85 to 4.5)	123 more per 1000 (from 36 fewer to 218 more)	LOW	CRITICAL
								0%		-		

¹ Quote: "In all of the identified trials, operating surgeons were not blinded with respect to trial allocation". "... detection bias is invariably high risk in all three trials. Only one trial¹³ described allocation concealment as part of the method of randomization and therefore was graded as low risk in this domain."

² Quote: "In these trials, both arterial and venous mapping were used in evaluating outcomes of functioning successful AVF. There are no consistency inclusion criteria on ultrasonographic findings. Some authors assessed radial artery (RA) flow volumes, others use RA diameter, the minimum being 1.6 mm". "Two (trials) reported a significant benefit with duplex while the third demonstrated no effect. This inconsistency renders it difficult to recommend that duplex confers benefit".