ANNEXES TO CHAPTER 2

Clinical Question V. Can an order of preference be recommended when performing the arteriovenous fistula?

Different guidelines and experts consider the fistula to be the best long-term vascular access, as after maturation it provides a sufficient flow volume and has a longer functional duration and lower rate of complications than other types of access (Sgroi 2013; Reinhold 2011; KDOQI 2006; Huber 2003). They also argue that the implantation of a graft or a central venous catheter should only be considered when creating a fistula is not possible.

The Kidney Disease Outcomes Quality Initiative (KDOQI 2006) guidelines state that radiocephalic and brachiocephalic arteriovenous fistulae are the first and second option respectively for creating a vascular access. If these options are not possible, they recommend considering the creation of a brachiobasilic fistula in the upper arm or a radial-antecubital graft in the forearm.

Fistula versus graft in the creation of the first haemodialysis vascular access

Only one recent RCT was identified that seems to directly compare fistula and graft (Gao 2013). However, it was published in Chinese and we only have the information provided in the abstract in English, which we present below. This RCT compared the outcomes of the brachiobasilic arteriovenous fistula and the graft in 61 patients on long-term haemodialysis. Patency rates at 3 months, 1 year, 2 years and 3 years: 100%, 96.8%, 90.3%, and 87.1% for fistulae and 96.7%, 50.0%, 36.7%, and 33.3% for grafts. Cumulative rate of infections after three years: 3.2% for fistulae and 26.7% for grafts ($p<0.05$). Cumulative rate of thrombosis after three years: 3.2% for fistulae and 33.3% for grafts ($p<0.05$).	**Moderate quality**
The systematic review with meta-analysis by Huber (2003) found thirty-four studies, the majority case series with one non-randomised controlled study, comparing the outcomes of fistulae and grafts in the upper limb. The primary patency rates for fistulae were 72% (95% CI: 70-74%) at 6 months and 51% (95% CI: 48-53%) at 18 months, and for grafts, 58% (95% CI: 56-61%) and 33% (95% CI: 31-36%) respectively. The secondary patency rates for fistulae were 86% (95% CI: 84-88%) at 6 months and 77% (95% CI: 74-79%) at 18 months, and for grafts, 76% (95% CI: 73-79%) and 55% (95% CI: 51-59%) respectively.	**Low quality**
Sgroi (2013) states that although fistulae generally provide higher patency rates and lower rates of complications than grafts, once access is mature, many patients do not have suitable arteriovenous anatomy for a fistula to mature. Sgroi (2013) lists the following clinical situations in which a graft would be the first option: - brachial-axillary graft when a patient does not have anatomically suitable veins in the forearm or upper arm.	**Low quality**

- forearm graft in a patient requiring urgent dialysis who cannot tolerate a central venous catheter for a prolonged period. - to avoid prolonged central venous catheterisation in a patient with ipsilateral axillary-subclavian vein thrombosis who needs urgent access. - if there is no site in the upper limb for creating a fistula for access. - in patients with end-stage renal disease with a limited life expectancy. - in a patient with clinical risk factors for failure of the AV fistula who meet the Lok criteria. In relation to the last point, this situation ceases to be as clear if we take into account the fact that the Lilly study (2012), based on data from 195,756 patients, 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 functioning fistula.	
Nonetheless, Lee (2012), who took a similar approach to Sgroi, suggests that the decision on whether to create the vascular access with a fistula or a graft should take into account a number of different variables: planning of the access depending on the desired/expected timing for starting haemodialysis; the patient's life expectancy in terms of age and comorbidities (recommending fistula first for patients whose life expectancy is greater than two years); if they have had failure in a previous vascular access; and the likelihood of fistula maturation (which they consider to be linked to the patient's age, less in the more elderly, and gender, less in women).	**Low quality**
Fistula in upper arm vs graft in cases where fistula in forearm is not possible or has failed	
The systematic review by Dukkipati (2011) analyses the outcomes of brachiobasilic fistulae, based on numerous observational studies and an RCT (Keuter 2008). They found a primary failure rates of approximately 15-20% (range 0-40%), a mean primary patency rate at one year of approximately 72% (range 23-90%), and a primary patency rate at two years of approximately 62% (range 11-86%).	
The RCT by Keuter (2008) compared the efficacy and safety of the brachiobasilic fistula in the upper arm to the radial-antecubital graft in the forearm, *in 105 patients in whom neither a brachiocephalic nor a radiocephalic fistula could be created*, either because of unsuitable arteries or veins, or because these types of access had already failed. The primary patency rate at one year was significantly higher in the fistula group than in the graft group: 46% ± 7.4% vs 22% ± 6.1% (p=0.005). The assisted primary patency rate at one year was significantly higher in the fistula group than in the graft group: 87% ± 5.0% vs 71% ± 6.7% (p=0.045). The secondary patency rate was similar in the two groups: 89% ± 4.6% vs 85% ± 5.2% for fistula and graft respectively. The incidence of complications was 1.6 per patient-year in the fistula group vs 2.7 in the graft group. The patients in the fistula group needed a total of 1.7 interventions per patient-year vs	**Moderate quality**

2.7 for the graft group. They concluded that the brachiobasilic fistula is a better option than the radial-antecubital forearm graft for the vascular access in these patients.	
The RCT by Morosetti (2011) compared the efficacy and safety of the brachiobasilic fistula to the prosthetic graft in 57 patients in whom an arteriovenous fistula in the arm was not possible, either because of unsuitable arteries or veins, or because these types of access had already failed. Mean primary patency was significantly better in the fistula group (455 ± 50 days) than in the graft group (223 ± 48 days) (log-rank test; p=0.001). The primary patency rates at 6, 12, and 24 months were higher in the fistula group (86%, 61% and 60%), than in the graft group (55%, 32% and 21%). Mean secondary patency was better in the fistula group but the difference was not statistically significant: 474 ± 49 days for fistula versus 223 ± 48 days for graft (log-rank test; p=0.08). The secondary patency rates at 6, 12, and 24 months were higher in the fistula group (86%, 76% and 66%), than in the graft group (72%, 52% and 34%). Overall mortality at 24 months was 21% for those treated with fistula and 28% in those treated with graft.	**Moderate quality**
Fistula and graft in elderly patients	
No RCT were found which compare fistula with graft in elderly patients.	
A retrospective study of a cohort of 82,202 patients aged 70 and older when starting dialysis whose data were entered into the United States Renal Data System (Desilva 2012), analysed overall mortality and survival in these patients, measured as time to death after the first haemodialysis session, according to the different types of vascular access, age subgroups (70 to ≤80, 81 to ≤90, and >90) and comorbidities. They did not make direct comparisons between fistula and graft, but between fistula and catheter and between graft and catheter. Patients who initiated haemodialysis with fistula had a lower mortality rate and better survival (hazard ratio [HR] 0.56, p<0.001), followed by those with graft (HR 0.74, p<0.001), compared to patients with a catheter, after adjusting for different possible confounding factors (age, gender, race, diabetes, comorbidity index, duration of nephrology care, cause of end-stage renal failure, albumin, BMI and haemoglobin). When comparing *fistula with catheter*, the use of fistula was better across all age groups (HR 0.56, p<0.001; HR 0.55, p<0.001; and HR 0.69, p=0.007 respectively), for each age group (70 to ≤80, 81 to ≤90, and >90). When comparing *graft with catheter*, the graft was better in patients in the 70 to ≤80 and 81 to ≤90 age groups (HR 0.73, p<0.001; and HR 0.74, p<0.001 respectively), and in the oldest age group, >90, although the difference was not statistically significant for this subgroup (HR 0.83, p=0.354). They performed a separate stratified analysis by individual comorbidities: diabetes, malignancies, and peripheral vascular disease.	**Low quality**

When comparing *fistula with catheter,* in patients aged ≤90, the fistula was better than the catheter in all subgroups by different comorbidities. In patients >90, the survival benefit associated with the use of the fistula (compared to the catheter) was not statistically significant in patients with history of cancer (HR 0.45, p=0.182), peripheral vascular disease (HR 0.70, p=0.350) or diabetes (HR 0.67, p=0.146), but it did reach statistical significance in patients with no history of any of these conditions (HR 0.72, p=0.024; HR 0.70, p=0.019; and HR 0.69 p=0.026 respectively). When comparing *graft with catheter,* the graft showed better results but the differences were not statistically significant over the use of catheters in patients aged 70 to ≤80 and with a history of cancer (HR 0.79, p=0.079), or for patients of 81 to ≤90 with history of cancer or peripheral vascular disease (HR 0.88, p=0.423; and HR 0.85, p=0.221 respectively). However, those aged 81 to ≤90, with or without a history of diabetes showed a significant benefit from the use of grafts over catheters (HR 0.78, p=0.002; and HR 0.71, p<0.001 respectively). In the >90 age group, no significant differences were found between graft and catheter in any of the comparisons. The authors consider that the fistula-first option is, in general, also valid for the majority of elderly patients, even those with comorbidities.	
Order for creating successive vascular access sites by means of fistula	
The experts and guidelines all agree that vascular access placement should start with a fistula as distal as possible to preserve the option of more proximal access sites for the future in case necessary. However, no RCT have been found that compare the outcomes of different locations of the first haemodialysis fistula, whether between different forearm fistulae or forearm fistulae and brachial fistulae, in patients in whom any of these options seemed viable. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines state that radiocephalic and brachiocephalic arteriovenous fistulae are the first and second option respectively for vascular access. If these options are not possible, they recommend considering the creation of a native brachiobasilic fistula in the upper arm or a radial-antecubital graft in the forearm.	**Low quality**
At the same time, there is a general recommendation to create the first access via fistula in the non-dominant upper limb (left for left-handers and right for right-handers), probably based on the reasonable assumption that the patient will prefer to have the dominant hand less exposed to potential complications and have it free during dialysis, but no RCT have been found that specifically compare the options of starting in the dominant hand or on the other side. The authors of the Koksoy RCT (2009), designed to compare the efficacy and safety of brachiocephalic fistulae and brachiobasilic fistulae in patients whose forearm fistula had failed, performed a secondary multivariate analysis which found that the *use of the dominant arm* increased the risk of fistula failure (RR 5.61; 95% CI: 1.68-18.72; p=0.005). Moreover, no RCT have been identified that specifically compare whether it is more effective and/or safer to give priority to the criterion of the most distal location possible, alternating between non-dominant and dominant limb, or up to what point to continue in the same non-dominant limb, to exhaust the non-dominant forearm first, in case a fistula was necessary at a	**Low quality**

later date at another site due to failure of the previous one. In view of the lack of solid evidence clearly favouring one option over another, it seems logical to let the patient decide, with advice from the healthcare professionals, about whether the next fistula should be created at a more proximal location in the same limb or in the most distal possible in the other limb.	
Reinhold (2011) states that the first access should be placed as distally as possible. The main disadvantages of the distal radiocephalic AVF in the anatomical snuffbox or in the wrist are the relatively high rates of occlusion and non-maturation, which are influenced by patient's risk factors such as age, diabetes mellitus and cardiovascular disease. They point out that the rate of early occlusion for distal fistulae is 5-30% and that the long-term patency rates are 65-90% at one year and 60-80% at two years. The incidence of thrombosis (0.2 events per patient-year) and infection (2%) were low. A previous review with meta-analysis (Rooijens 2004), based on 38 observational studies, estimated a primary failure rate for the radiocephalic fistula in the wrist of 15.3% (95% CI: 12.7-18.3%) and primary and secondary patency rates of 62.5% (95% CI: 54.0-70.3%) and 66.0% (95% CI: 58.2-73.0%) respectively.	**Low quality**
Brachiocephalic elbow fistulae vs radiocephalic wrist fistulae in elderly patients	
The review with meta-analysis by Lazarides (2007), based on retrospective cohort studies, included studies providing separate information for elderly and younger patients, and found there was a higher risk of radiocephalic fistula failure in elderly patients than in younger patients (at 12 months: Odds Ratio 1.525, p=0.001; at 24 months: Odds Ratio 1.357, p=0.012). In the category of elderly patients, an analysis based on four studies with 640 patients compared results according to the location of the fistula and showed a lower failure rate with brachiocephalic fistulae in the elbow (75/214) than for radiocephalic fistulae in the wrist (75/426) (Risk Difference: -12.2%; 95% CI: -20.6% to -4%; p=0.004). The elbow fistulae also had better outcomes in terms of secondary patency (82%) than the wrist fistulae (66.1%). The authors considered that one of the advantages of creating an access with a fistula in the wrist is that it allows the construction of a more proximal access in the event that the distal access fails, but also pointed out that such preservation of proximal sites for possible future access is of minimal importance in patients with short life expectancy. They maintain that there are studies showing that over half of patients aged over 75 die within two years of starting dialysis, with mean survival being 31 months. The authors therefore consider that the brachiocephalic fistula should be the first choice in elderly patients with short life expectancy or with late-start haemodialysis (*late referrals*).	**Low quality**
Brachiocephalic fistulae vs brachiobasilic fistulae in cases of failed forearm fistula	
The Koksoy RCT (2009) compares the efficacy and safety of these two fistula locations in 100 patients in whom a previous more distal fistula had failed, followed-up for an average of 43.2 months. No significant differences were found between the two groups in relation to thirty-day mortality, wound complications, thrombosis at 24 hours, post-operative bleeding, maturation of the fistula and time to maturation.	**Moderate quality**

Primary patency after one and three years of follow-up was 87% and 81% for brachiocephalic fistulae and 86% and 73% for brachiobasilic fistulae (p=0.7). Secondary patency after one and three years of follow-up was 87% and 70% for fistulae brachiocephalic and 88% and 71% for brachiobasilic fistulae (p=0.8). During the follow-up period 18 patients with brachiocephalic fistulae and 10 patients with brachiobasilic fistulae died, with the difference not being statistically significant (p=0.18). A multivariate analysis found that the use of the dominant arm increased the risk of fistula failure (RR 5.61; 95% CI: 1.68-18.72; p=0.005). The mean duration of the operation was significantly less for brachiocephalic fistulae (44.7 minutes) than for brachiobasilic fistulae (86 minutes) (p<0.001).	
Grafts in the lower limb	
Creating a graft in the lower limb is an option when all possible areas for creating access sites in the upper limb have been exhausted. Two observational studies conducted in the same centre compared graft outcomes in lower limbs and upper limbs. Miller (2003) compared outcomes for 63 leg grafts with 346 upper limb grafts. The rate of technical failure was approximately two-fold higher for the grafts in the thigh (12.7% vs 5.8%; p=0.046). Intervention-free survival (median, 3.9 vs 3.5 months; p=0.55), thrombosis-free survival (median, 5.7 vs 5.5 months; p=0.94), and cumulative survival (time to permanent failure) (median, 14.8 versus 20.8 months; p=0.62) were all similar. Loss of access as a result of an infection tended to be higher for thigh grafts (11.1% vs 5.2%; p=0.07). Harish (2011) compared the clinical presentation, complications and outcomes of infections in thigh grafts and upper limb grafts in 132 patients with graft infections requiring surgical resection (40 in the thigh and 92 in the upper limb). Thigh graft infections were more likely to be caused by Gram-negative organisms (31% vs 4%; p=0.003) and were more likely to lead to systemic infection (15% vs 3%; p=0.02). Duration of hospitalisation associated with graft infection was similar (10.8 vs 8.7 days; p=0.09). The median time of catheter dependence after graft was higher for grafts in the thigh (319 vs 237 days; p=0.04).	**Low quality**
Summary of evidence	
Fistula versus graft A number of RCT in the literature show better outcomes for fistulae than for grafts in terms of longer functional duration and lower complication rates.	**Moderate quality**
Order for creating first and subsequent vascular access sites There were no comparative studies, randomised or otherwise, comparing the efficacy and safety of different orders in the creation of successive vascular access sites for haemodialysis.	**Low quality**

Patients' values and preferences
No relevant studies related to this aspect have been identified.

Use of resources and costs
No relevant studies related to this aspect have been identified.

Recommendations [Proposal]	
Weak	We recommend creating a fistula as distal as possible in the non-dominant upper limb as a first vascular access for haemodialysis.
Weak	We recommend that grafts in the upper limb should be limited to the following situations: - patients without anatomically suitable veins in the forearm or upper arm. - if there is no site in the upper limb for creating a fistula for access. - patients requiring urgent dialysis who cannot tolerate a central venous catheter for a prolonged period. - patients with end-stage renal disease with a limited life expectancy.
Weak	Where there has been a failure of a previous fistula, we recommend that the decision about the anatomical site for creating each new fistula be made with the participation of the patient, informed by the healthcare professionals, in order to decide whether to give priority in each particular situation to the criterion of "the more distal the better" or the criterion of "non-dominant limb first".

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Table 1. STUDIES EXCLUDED

Study	Cause for exclusion
Davidson 2007	Expert opinion not based on a systematic review.
Dix 2006	Non-systematic review of series of patients with brachiobasilic fistula as vascular access for haemodialysis; with no group comparison and no search date expressly defined. There is a more up-to-date review (Dukkipati 2011).
Kakkos 2008	This is a non-randomised study. There are two published RCT, Morosetti (2011) and Keuter (2008), which provide a better level of evidence, analysing the same comparison of brachial-basilic fistula and graft.
Kalman 1999	Observational study comparing clinical series that is included in the review with meta-analysis by Huber (2003).
Niyyar 2009	Non-systematic review about the contribution of vascular mapping; it does not provide useful evidence for the question of fistula vs graft or about the order for creating fistulae. The contribution of vascular mapping has been addressed in Chapter 1.
Shenoy 2009	Explanation by an expert of the anatomy of the vessels for the planning of initial and secondary vascular access sites for fistulae, but it does not provide useful evidence for the question of fistula vs graft or about the order for creating fistulae.

GRADE TABLES

Date: 2014-01-14
Question: Should fistula vs synthetic graft be used in patients on haemodialysis?
Bibliography: Gao 2013

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Fistula**	**Synthetic graft**	**Relative (95% CI)**	**Absolute**		
Patency rate at 1 year												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	30/31 (96.8%)	15/30 (50%)	difference 46.8 (0 to 0)	1000 more per 1000 (from 500 fewer to 500 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Patency rate at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	28/31 (90.3%)	11/30 (36.7%)	difference 53.6 (0 to 0)	1000 more per 1000 (from 367 fewer to 367 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Patency rate at 3 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	27/31 (87.1%)	10/30 (33.3%)	difference 53.8 (0 to 0)	1000 more per 1000 (from 333 fewer to 333 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL

								0%		-		
Accumulated rate of infections at three years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/31 (3.2%)	8/30 (26.7%)	difference - 22.5 (0 to 0)	1000 fewer per 1000 (from 267 fewer to 267 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Accumulated rate of thrombosis at three years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/31 (3.2%)	10/30 (33.3%)	difference - 30.1 (0 to 0)	1000 fewer per 1000 (from 333 fewer to 333 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		

[1] The bias risk could not be evaluated as the article is in Chinese , and only the information in the abstract which is in English could be extracted.

Date: 2014-01-14
Question: Should brachiobasilic fistula vs radial-antecubital graft be used in cases in which the fistula of the forearm is not possible or has failed?
Settings: outpatients
Bibliography: Keuter 2008

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Brachiobasilic fistula**	**radial-antecubital graft**	**Relative (95% CI)**	**Absolute**		
Primary patency at 1 year												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24/52 (46.2%)	12/53 (22.6%)	difference 23.6 (0 to 0)	1000 more per 1000 (from 226 fewer to 226 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Incidence rate of complications per patient-year (Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	53	52	-	difference 1.1 lower (0 to 0 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Incidence rate of additional interventions per patient-year (Copy) (Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	53	52	-	difference 1.0 lower (0 to 0 higher)	⨁⨁⨁◯ MODERATE	CRITICAL

[1] They do not report on the randomisation procedures, allocation concealment or blinding

Date: 2014-01-14
Question: Should brachiobasilic Fistula vs prosthetic graft be used in cases in which the forearm fistula is not possible or has failed?
Bibliography: Morosetti 2011

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Brachiobasilic fistula	prosthetic graft	Relative (95% CI)	Absolute		
Overall mortality at 24 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	6/30 (20%)	8/28 (28.6%)	difference 8.6 (0 to 0)	1000 more per 1000 (from 286 fewer to 286 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Mean primary patency in days (Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	30	27	-	MD 232 higher (0 to 0 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Primary patency rate at 12 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	18/30 (60%)	9/28 (32.1%)	difference 29 (0 to 0)	1000 more per 1000 (from 321 fewer to 321 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		

[1] They do not report on the randomisation procedures, allocation concealment or blinding.

Date: 2014-01-14
Question: Should brachiocephalic fistulas vs brachiobasilic fistulas be used in cases in which the forearm fistula has failed?
Bibliography: Koksoy 2009

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Brachiocephalic fistulas**	**Brachiobasilic fistulas**	**Relative (95% CI)**	**Absolute**		
Primary patency rate at 1 year												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	44/50 (88%)	43/50 (86%)	difference 1 (0 to 0)	0 fewer per 1000 (from 860 fewer to 860 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		
Mortality												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	18/50 (36%)	10/50 (20%)	difference 16 (0 to 0)	1000 more per 1000 (from 200 fewer to 200 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
								0%		-		

[1] They do not report on the randomisation procedures, allocation concealment or blinding.