

ANNEXES TO CHAPTER 1

Clinical Question II. In patients with chronic kidney disease, what are the demographic, clinical and analytical parameters in order to determine when the arteriovenous fistula (either native or prosthetic) should be created?

Clinical Practice Guidelines (CPG)

We have identified six CPG that assess the appropriate timing for the creation of a VA (UK 2011¹, DOQI 2006², CANADA 2007³, JAPAN 2005⁴, ERBP 2007⁵, SPANISH 2004⁶)

The UK 2011 CPG are the most recent and the only ones to grade the recommendations with the GRADE system. All recommendations on this subject made by the above CPG are based on observational studies and expert opinion, as no randomised trials have been carried out to date.

For the patient with end-stage renal disease, it is very important to allow time for proper planning for a VA and to have a VA available for use at the time of starting haemodialysis, thus avoiding the use of temporary catheters.

In order to achieve this goal, the different CPG establish a range for decline in renal function that indicates the imminence of the need to start haemodialysis. They also stress the importance of using these validated test parameters according to age, gender and the patient's body surface area.

UK CPG¹ (Fluck R, Kumwenda 2011)

The factors to be taken into account for determining the exact timing of placement of vascular access are: rate of decline of renal function; comorbidities that may affect the VA's likelihood of success; and the whole logistical and planning process a patient requires.

Patients should be referred to the specialist as early as possible in order to start the evaluation process that their subsequent treatment requires. To successfully obtain a sufficiently mature arteriovenous fistula (AVF), it would be appropriate for it to be placed a minimum of three months and not more than one year prior to the commencement of haemodialysis.

The group stresses that there are very few data to determine the optimal timing for placement of VA. Further research is required to determine optimal *timing* for vascular access creation.

Recommendations: (1 strong, 2 weak, C low level of evidence)

1. We suggest that planning for access should commence when patients enter CKD stage 4 (2C).
2. We recommend that the exact timing of placement of vascular access will be determined by rate of decline of renal function, comorbidities and by the surgical pathway (1C).

ERBP² (Tordoir 2007)

Recommendations: These CPG do not grade the recommendations; they only clarify the grades of evidence on which they based the recommendations.

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<ol style="list-style-type: none"> 1. Every chronic renal failure patient who has opted for haemodialysis should start dialysis with a functioning vascular access (LEVEL OF EVIDENCE III). 2. Potential chronic haemodialysis (HD) patients should be ideally referred to the nephrologist and/or surgeon for preparing vascular access when they reach stage 4 CKD (glomerular filtration rate <30 ml/min/1.73 m²) or earlier in the case of rapid progression of nephropathy or specific clinical conditions, such as diabetes or severe peripheral vascular disease (LEVEL OF EVIDENCE III). 	
<p>DOQI CPG, 2006³ These CPG base their clinical recommendations on a number of observational studies and group consensus.</p> <p>Appropriate planning allows for the initiation of dialysis therapy at the appropriate time with a permanent access in place.</p> <p>Early referral of a patient with CKD to a nephrologist is needed to facilitate CKD therapy with medications and diets that preserve kidney function.</p> <p>Recommendations: (A: high impact; B: moderate impact)</p> <ol style="list-style-type: none"> 1. Patients with a glomerular filtration rate (GFR) less than 30 ml/min/1.73 m² (CKD stage 4) should receive education about all modalities and options for renal replacement therapy (RRT), including transplantation. They should be referred in good time for the placement of a permanent access for dialysis, if necessary. (A) 	
<p>Canadian⁴ (Culleton B2006)</p> <p>Recommendations Graded according to the scheme developed by the <i>Canadian Hypertension Education Program Guidelines</i>.</p> <ol style="list-style-type: none"> 1. An AVF should be created when the patient has a GFR of 15-20 ml/min and progressive renal disease (D). 	
<p>Japanese CPG⁵ (Seiji Ohira 2005)</p> <p>The recommendations are not graded; they are only practice guidelines.</p> <p>Experience shows that the timing of the construction of the AVF is often influenced by the timing of the referral to the VA surgeon.</p> <ol style="list-style-type: none"> 1. If a diagnosis of chronic renal failure has been made on the basis of the clinical course, serum creatinine (Cr) level of 2-3 mg/dl or above, the patient must be promptly referred to a nephrologist to improve the outcome. 2. If haemodialysis has been selected as a treatment for end-stage renal failure, the nephrologist should explain the role and importance of VA in this therapy and refer the patient to an access surgeon as promptly as possible. 3. Creating VA is usually considered when creatinine clearance (Ccr) reaches 10-20 ml/min or serum Cr level reaches 6-8 mg/ml. However, it should be noted that changes in Ccr and in serum Cr may be inconsistent. In patients with diabetic 	

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<p>nephropathy with a tendency for overhydration, the construction of VA is often necessary at an even lower serum Cr of 4-6 mg/ml.</p>	
<p>Spanish 2004 CPG⁶</p> <p>The timing for creating the VA can vary depending on certain conditions. There are circumstances in which construction of VA should be considered as urgent and priority given over other patients.</p> <p>The following three situations come into this category:</p> <ol style="list-style-type: none"> 1. Cases where CKD progresses more rapidly than usual, with start of HD estimated in less than six weeks; 2. When patients have begun HD with a CVC and do not have a permanent VA, as it is advisable to keep the duration of the CVC to a minimum to reduce complications; and 3. In cases where after construction of the VA, technical or maturation failure occurs and a new VA has to be created. <p>Recommendations: (B: observational studies; C: expert opinion; D: consensus group)</p> <ol style="list-style-type: none"> 1. In patients with progressive CKD, creation of the AVF should be considered when the glomerular filtration rate (GFR) is less than 20 ml/min. 2. There is a demonstrated risk of having to start the HD via CVC if the surgical team delays the construction of the VA by more than four weeks (B evidence). 3. The VA should be constructed with urgency in patients with rapidly progressing CKD, in patients with failure of maturation, and in patients who have CVC without permanent VA (D evidence). 	
<p>Observational studies</p> <p>Nowadays, early referral to a nephrologist ensures full and accurate knowledge of the different aspects of renal replacement therapy. Various observational studies in recent years have presented data on the influence of the timing of referral to the nephrologist or surgeon on the appropriate timing for the construction of the VA.⁽¹⁻⁵⁾</p> <p>A prospective descriptive study (Farooq 2010)⁷ was conducted in patients with CKD who had undergone arteriovenous fistula (AVF) creation in Pakistan from 2006 to 2009. The objective was to determine the impact of the timing of AVF creation on subsequent AVF failure. Fistulae were allowed to mature for more than 4-6 weeks before use. It was considered that a fistula had failed when it did not mature adequately to be successfully used for dialysis. A total of 112 patients were included on whom 168 AVF, mostly radiocephalic, had been performed (no data are presented). Patients were divided into two groups depending on timing of fistula creation with respect to the start of haemodialysis (HD): early creation group (E-group; n=23), in which the fistula was created more than one month (>1 month) before the start of the HD; and late creation group (L-group; n=89), in which the fistula was created within one month before or even after the start of the HD. The outcome of the study was defined as a mature AVF that could be successfully used for starting haemodialysis.</p>	

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After comparison of demographic variables, the rate of failure was compared between two groups. The mean follow-up of the study was 14.05 ± 4.45 months.

A multicentre, retrospective, observational study (Inaguma 2011)⁸ conducted in Japan from January 2006 to September 2009 included 940 patients with CKD who underwent creation of a VA, whether AVF or AVG. The purpose of this study was to evaluate the effect of early referral (ER) to the nephrologists on the availability of a mature vascular access (VA) for use when haemodialysis (HD) was scheduled to start. The patients were divided into two groups according to the timing of referral to the nephrologist before HD: ER being 12 months or more; and LR, 3 to 12 months. The follow-up periods were 90 to 364 days (median of 210 days) in the LR group and 367 to 12,249 days (mean 1124 days) in the ER group.

A retrospective observational study conducted in Taiwan (Chen 2010)⁹ included 192 patients (mean age 63.6 ± 12.3 to, 87 male/105 female) with CKD receiving haemodialysis from January 1997 to December 2007. Patients were divided into groups according to time of referral to the nephrologist: ER, referred 6 months or longer before commencing HD (n=148); and LR, referred less than 6 months prior to starting HD (n=44). The endpoint of the study was overall mortality. Overall survival was analysed by Cox regression adjusted for their demographic and comorbid conditions. The mean follow-up was 92.0 to 113.8 months (range: 21.5 to 1329.4).

Astor (2003)¹⁰ conducted a prospective cohort study from October 1995 to June 1998 which included 762 patients using haemodialysis as their initial renal replacement modality. Patients were included a median of 45 days after start of therapy with chronic dialysis (98% within 4 months). Time to first referral to a nephrologist relative to the start of treatment with chronic haemodialysis was divided into four ranges (<1 month, 1-4 months, 4-12 months and >12 months). The Index of Coexistent Disease (ICED) score was rated as mild (0 or 1), moderate (2) or severe (3). The mean age of the 356 patients was 2 years less than that of their 350 counterparts with incomplete information (58 vs 60 years, $p=0.03$), but patients were similar in terms of gender, race, insurance cover at the time of starting treatment with haemodialysis, and the main cause of renal impairment. On commencing haemodialysis, 68% of patients used a dialysis catheter (49% tunnelled, 15% non-tunnelled, and 4% not specified) and 32% used an AV access (18% synthetic grafts and 14 AVF).

Laris Gonzalez (2011)¹¹ carried out a retrospective review of the records of all adult patients who started chronic haemodialysis from 2002 to 2006 in Mexico. Timing of referral was classified as early (>6 months), late (1-6 months) or very late (<6 months). Sociodemographic, clinical, laboratory and echocardiographic variables were compared according to timing of referral. They also compared the effects on hospitalisation, the first dialysis without permanent VA among those referred less than one month before the HD or within one month or more.

Farooq 2010. ⁷ Of the 168 fistulas created, 54 fistulas failed, with a larger proportion in the L-group at 83.3% (n=45), E-group 16.7% (n=9), ($p=0.005$).	Very low quality
Farooq 2010. ⁷ L-group patients were younger than the E-group. Both groups had more males (60% E-group, 67% L-group, $p=0.36$). Age, gender and DM had no significant effect on the failure rate of fistulae (statistical data not shown).	Very low quality
Farooq 2010. ⁷ Of the E-group, 91.4% consulted a nephrologist four months or more before starting the HD ($p<0.001$). In the L-group, 36% of patients consulted a nephrologist at 4 months and 46% one month before.	Very low quality
Inaguma 2011. ⁸ Mean age was significantly higher in the ER group than in the LR group ($p=0.004$). However, BMI (0.001), blood pressure (0.0008) and rates of diabetes mellitus (<0.0001) were significantly higher in the LR group than in the ER group.	Low quality

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<p>Inaguma 2011.⁸ On comparing the two groups (adjusted for age and gender) referral to the nephrologist was significantly associated with the availability of a permanent VA, whether arteriovenous fistula or arteriovenous graft, when starting HD (odds ratio [OR] = 1.705, p=0.001). The multivariate analysis (adjusted for age, gender, diabetes, heart failure, and biochemical parameters) also revealed the ER group to be significantly associated with the availability of a permanent VA (p=0.023).</p>	<p>Low quality</p>
<p>Chen 2010.⁹ Only 50% of LR patients had consultations with a nephrologist on three occasions in the pre-ESRD period compared to 97.3% of ER patients. It was also found that significantly fewer LR patients had a pre-established permanent vascular access than ER patients (13.6% versus 42.3%, p<0.001).</p>	<p>Low quality</p>
<p>Chen 2010.⁹ In the multivariate analysis, the LR group (hazard ratio: 2.827, p=0.049) and diabetes mellitus were independently associated with an increased risk of mortality. The survival benefits of ER seem to be originated from the period before initiation of renal replacement therapy.</p>	<p>Low quality</p>
<p>Astor 2003.¹⁰ The proportion of patients using an AV access at the start of haemodialysis therapy increased with time since referral to the nephrologist: from 10% of those referred at less than 1 month to 32% of those referred 1 to 4 months before, 28% of those referred 4 to 12 months before, and 46% of those referred more than 12 months before the initiation of haemodialysis therapy; all these data were adjusted for the different clinical characteristics of the patients and the VA (p<0.001). Earlier referral to the nephrologist was significantly associated with an increased likelihood of AV-access use at 6 months after initiation of haemodialysis (56% of those referred <1 month, 65% of those referred 1 to 4 months before, 63% of those referred 4 to 12 months before, and 82% of those referred >12 months prior to the start of haemodialysis; p<0.001).</p>	<p>Low quality</p>
<p>Astor 2003.¹⁰ One moderate or severe comorbidity, compared to mild, was associated with an approximately 50% lower likelihood of using an AV access at the start of haemodialysis (adjusted odds ratio [OR] = 0.48, 95% CI: 0.26 to 0.87), after the corresponding adjustment for the clinical characteristics of the patient and the VA.</p>	<p>Low quality</p>
<p>Laris Gonzalez 2011.¹¹ Of the 84 patients included, 56% were referred less than one month and an additional 15% between 1 and 6 months prior to the initiation of chronic haemodialysis. In univariate analysis, being referred by a relative or friend was associated with a higher risk (p=0.04), and being employed with a lower risk of late referral (p=0.05). Late referred patients (less than one month before HD) were more likely to require emergency dialysis and hospitalisation, and not to have a permanent vascular access for their first dialysis (p<0.001). They also had a higher prevalence of severe anaemia (haematocrit <28%), and an estimated glomerular filtration rate <5 ml/min/1.73 m² (p<0.008).</p>	<p>Very low quality</p>

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Summary of evidence	
Farooq 2010. ⁷ Timely referral to the nephrologists and early creation of permanent vascular access performed by an experienced team can improve the success rate of AV fistulae and thus improve the quality of life of patients with chronic kidney disease.	Very low quality
Inagama 2011. ⁸ The results suggest that a permanent VA is more likely to be available for the start of HD in subjects who have been under the care of nephrologists for 12 months or more compared to those under nephrology care for less time before starting HD.	Low quality
Chen 2010. ⁹ This study demonstrates that early referral is associated with lower loss of residual renal function and better survival. In addition, the study underlines the importance of early referral to improve clinical outcomes in patients undergoing haemodialysis.	Low quality
Astor 2003. ¹⁰ Patients referred early to a nephrologist have better preparation of vascular access than patients referred later. The duration of use of the dialysis catheter is associated with late referral to a nephrologist.	Low quality
Laris Gonzalez 2011. ¹¹ Late referral of patients with CKD to the nephrologist is a common problem and carries an increased risk of renal replacement therapy being commenced without a permanent VA, with parameters for poor prognosis.	Very low quality
<p>Patients' values and preferences <i>No relevant studies related to this aspect have been identified.</i></p>	
<p>Use of resources and costs <i>No relevant studies related to this aspect have been identified.</i></p>	
Recommendations [Proposal]	
Weak	<p>We suggest that the timing of creating vascular access is determined by the pace of decline in the patient's renal function (CKD stage 4: glomerular filtration rate <30 ml/min/1.73 m², validated by age, gender and body surface area), and any comorbidities, especially diabetes and peripheral vascular disease.</p> <p>Early referral to nephrologists is important for these patients, in order to prepare the VA and so improve clinical outcomes.</p>
References	
<ol style="list-style-type: none"> 1. Fluck R, Kumwenda M. Renal Association Clinical Practice Guideline on vascular access for haemodialysis. <i>Nephron ClinPract.</i> 2011;118 Suppl 1:c225-40. 2. GPC DOQI 2006 <i>Am J Kidney Dis.</i> 2006 Jul;48 Suppl 1:S248-73. Clinical practice guidelines for vascular access. Vascular Access Work Group 	

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4. Culleton B. Introduction to the Canadian Clinical Practice Guidelines. *J Am Soc Nephrol* 2006;17:S1-3.
5. GPC japon Seiji Ohira *Therapeutic Apheresis and Dialysis* 10(5):449-462, Japanese Society for Dialysis Therapy Guidelines for Vascular Access Construction and Repair for Chronic Hemodialysis GPC
6. Rodríguez Hernández JA, González Parra E, Julián Gutiérrez JM, Segarra Medrano A, Almirante B, Martínez MT, Arrieta J, Fernández Rivera C, Galera A, Gallego Beuter J, Górriz JL, Herrero JA, López Menchero R, Ochando A, Pérez Bañasco V, Polo JR, Pueyo J, Ruiz CI, Segura Iglesias R; Sociedad Española de Nefrología. [Vascular access guidelines for hemodialysis]. *Nefrologia*. 2005;25 Suppl 1:3-97
7. Farooq Z, Mehmood A, Saeed S, Raja KM, Khan MN, Murtaza B. Early versus late arterio-venous fistulae: impact on failure rate. *J Ayub Med Coll Abbottabad*. 2010 Jul-Sep;22(3):179-81.
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10. Astor BC, Eustace JA, Powe NR, Klag MJ, Sadler JH, Fink NE, Coresh J. Timing of nephrologist referral and arteriovenous access use: the CHOICE Study. *Am J Kidney Dis*. 2001 Sep;38(3):494-501.
11. Laris-González A, Madero-Rovalo M, Pérez-Grovas H, Franco-Guevara M, Obrador-Vera GT. [Prevalence, risk factors and consequences of late nephrology referral]. *Rev Invest Clin*. 2011 Jan-Feb;63(1):31-8. Spanish.

GRADE TABLES

Date: 2013-10-25

Question: Should early referral to nephrologist E-group vs late referral to nephrologist L-group be used for CKD?^{1,2}

Bibliography: Farooq Z, Mehmood A, Saeed S, Raja KM, Khan MN, Murtaza B. Early versus late arterio-venous fistulae: impact on failure rate. J Ayub Med Coll Abbottabad. 2010 Jul-Sep;22(3):179-81. PubMed PMID: 22338450

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Early referral to nephrologist E-group ¹	Late referral to nephrologist L-group ²	Relative (95% CI)	Absolute		
Failure of AVF (follow-up 18.50 ± 9.60 months)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ³	none	9/54 (16.7%)	45/54 (83.3%)	-	506 fewer per 1000 (from 506 more to 506 more)	VERY LOW	CRITICAL
								0%		-		

¹> 1 month before the HD

² 1 month before the HD or once started

³ No statistical data presented

Date: 2013-10-24

Question: Should early referral to nephrologist (ER) vs late referral to nephrologist (LR) be used for CKD with AVF or AVG?

Bibliography: Inaguma D, Ando R, Ikeda M, Joki N, Koiwa F, Komatsu Y, Sakaguchi T, Shinoda T, Yamaka T, Shigematsu T. Nephrologist care for 12 months or more increases hemodialysis initiation with permanent vascular access. ClinExpNephrol. 2011 Oct;15(5):738-44. doi: 10.1007/s10157-011-0472-7. Epub 2011 Jul 2. PubMed PMID: 21725658

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Early referral to nephrologist (ER) ¹	Late referral to nephrologist (LR) ¹	Relative (95% CI)	Absolute		
AVF or AVG mature for HD (follow-up mean: LR 210 days, ER 1,124 days)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	715/940 (76.1%)	225/940 (23.9%)	OR 1.509 (1.058 to 2.153) ²	83 more per 1000 (from 10 more to 165 more)	LOW	CRITICAL

¹ LR 3-12 month referral, ER 12 months or more

² p=0.023 multivariate analysis (adjusted by age and gender, diabetes, heart failure and biochemical parameters)

Date: 2013-10-24

Question: Should early referral to nephrologist (ER) vs late referral to nephrologist (LR) be used for CKD?^{1,2}

Bibliography: Chen SC, Hwang SJ, Tsai JC, Liu WC, Hwang SC, Chou MC, Lin MY, Chang JM, Chen HC. Early nephrology referral is associated with prolonged survival in hemodialysis patients even after exclusion of lead-time bias. Am J Med Sci. 2010 Feb;339(2):123-6. doi: 10.1097/MAJ.0b013e3181c0678a. PubMed PMID: 20145431.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Early referral to nephrologist ER ¹	Late referral to nephrologist LR ²	Relative (95% CI)	Absolute		
mortality (follow-up 92.0 to 113.8 months) assessed with: overall survival cox)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	148/192 (77.1%)	44/192 (22.9%)	HR 2.827 (1.005 to 7.951) ³	292 more per 1000 (from 1 more to 645 more)	⊕⊕⊕⊕	LOW
								0%		-		

¹ ER 6 months or more before HD

²LR less than 6 months before HD

³multivariate analysis p= 0.049

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Date: 2013-10-24

Question: Should timing of nephrologist referral (TNR) < 1 month, 1-4 months vs timing of nephrologist referral 4-12 months more than 12 months be used for CKD?

Bibliography: Astor BC, Eustace JA, Powe NR, Klag MJ, Sadler JH, Fink NE, Coresh J. Timing of nephrologist referral and arteriovenous access use: the CHOICE Study. Am J Kidney Dis. 2001 Sep;38(3):494-501. PubMed PMID: 11532680

Quality assessment							No of patients(n358)				Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TNR < 1 m	TNR 1-4 m	TNR 4-12 m	TNR > 12 m	Relative (95% CI)	Absolute		
VA permanent at the start of the HD														
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	10%	32%	28%	32%	Adjusted*OR (95% CI) ¹ TRM < 1m 1.00(referent) TRM 1-4m 5.14 (1.99-13.26) TRM 4-12m 3.22 (1.24-8.37) TRM >12m 8.88 (3.90-20.23)	p<0,001	LOW	CRITICAL

¹p<0.001

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Date: 2013-10-24

Question: Should severe or moderate comorbidity vs mild comorbidity be used for CKD?

Bibliography: Astor BC, Eustace JA, Powe NR, Klag MJ, Sadler JH, Fink NE, Coresh J. Timing of nephrologist referral and arteriovenous access use: the CHOICE Study. Am J Kidney Dis. 2001 Sep;38(3):494-501. PubMed PMID: 11532680

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Severe and moderate comorbidity	Mild comorbidity	Relative (95% CI)	Absolute		
VA permanent at the start of the dialysis												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	247/356 (69.4%)	109/356 (30.6%)	OR 0.48 (0.26 to 0.87)	131 fewer per 1000 (from 29 fewer to 203 fewer)	LOW	CRITICAL
								0%		-		

Date: 2013-10-24

Question: Should timing of nephrologist referral < 1 month vs timing of nephrologist referral ≥ 1 month be used for?

Bibliography: Laris-González A, Madero-Rovalo M, Pérez-Grovas H, Franco-Guevara M, Obrador-Vera GT. [Prevalence, risk factors and consequences of late nephrology referral]. Rev Invest Clin. 2011 Jan-Feb;63(1):31-8. Spanish. PubMed PMID:21585008.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Timing of nephrologist referral < 1 month	Timing of nephrologist referral ≥ 1 month	Relative (95% CI)	Absolute		
VA permanent on the first HD												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	none	1/47 (2.1%)	11/37 (29.7%)	-	297 fewer per 1000 (from 297 fewer to 297 fewer) ²	⊕⊕⊕⊕ VERY LOW	CRITICAL
								0%		-		

¹very few patients

²p<0.001