ANNEXES TO CHAPTER 3

Clinical Question VII. What is the minimum maturation time required for a native or prosthetic arteriovenous fistula to be mature enough for needling?

Five CPG have been identified that assess the minimum maturation time before an AV fistula (AVF) should be cannulated (ERBP 2007,¹ CANADA 2007,² DOQI 2006,³ JAPAN 2005,⁴ SPANISH 2004⁵).

Maturation refers to the period from when the venous access (VA) is created until it is deemed "mature" or "usable" for effective haemodialysis. Although the ideal waiting period before the first cannulation of a VA remains under debate, it is accepted that attempting to cannulate too early can lead to complications resulting in failure of the VA.

Medical history and physical examination are of fundamental importance in preoperative care for an AVF. The physical examination may be carried out quickly with no additional cost or equipment. Unfortunately, it is not always of the greatest utility, especially in at-risk patients. With this type of patient, and whenever there is uncertainty about the results of the clinical examination, ultrasound is a useful additional diagnostic method for the fact that it is non-invasive, easy to apply and safe. A number of preoperative parameters which can be detected by ultrasound are associated with a higher risk of early failure and non-maturation of the vascular access route. To predict the best outcome for a vascular access route, a combination of arterial, venous and cardiac parameters should be used instead of one single parameter (Marlhow 2011).

CPG

EBPG CPG¹ (Tordoir 2007) These CPG do not grade the recommendations; they only clarify the grades of evidence.

The optimum time for cannulating VA has been reported in the Dialysis Outcomes and Practice Patterns Study (DOPPS; Saran 2004⁷). For grafts, the first cannulation was within 2-4 weeks in 62% of centres in the USA, 61% in Europe and 42% in Japan. For AVF, the first cannulation was within 2 months of creation in 36% of centres in the USA, 79% in Europe and 98% in Japan.

Early cannulation of AVF may be associated with failure of the fistula. Cannulation within two weeks of the creation of the AVF should be avoided while, in general, the minimum period of maturation should ideally be more than 4 weeks. The appropriate fistula flow rate (> 600 cm3/min) and diameter (> 5 mm) measured by ultrasound may improve maturation.

Recommendations:

- 1. An arteriovenous fistula should only be cannulated when sufficiently mature (level of evidence III).
- 2. Prior to placement of a VA, the veins and arteries of the arm should be assessed both clinically and by ultrasound scan (level of evidence II).

Canada.² (Culleton B 2006)

AVFs need time to mature before being cannulated (at least one month, preferably 3 months). DOPPS data (Saran 2004⁷) show great variation between countries in terms of when to first cannulate AVF. The majority of fistulae in Europe are cannulated early, within 8 weeks of creation. According to this study, early cannulation does not seem to be associated with subsequent failure of the fistula and it can reduce the time on central venous catheters. The maturation of the fistula depends on the size and the integrity of the artery and vein and on cardiac output. It is important to use clinical judgment to determine how long to wait before attempting to cannulate for the first time.

An arteriovenous graft (AGV) should not be cannulated until the swelling has gone down enough to allow it to be palpated, ideally 3 to 6 weeks after placement. No attempt should be made to cannulate a graft for at least 14 days after placement.

GPC DOQI, 2006.³ These CPG base their clinical recommendations on a number of observational studies and group consensus.

According to data presented by the DOPPS (Saran 2004⁷) an AVF may be successfully cannulated one month after creation. The previous KDOQI recommendation to wait 3 to 4 months after the creation of the VA is an opinion based on anecdotal reports of failure with early cannulations.

Consideration should be given to using ultrasound to help identify veins that are difficult to see and feel, accompanied by measurements of vein margins to prevent aspiration of clots when the needle is placed too close to the vein wall.

Recommendations: (A: high impact; B: moderate impact)

- 1. Patients should have a permanent vascular access when starting dialysis:
 - 1.1 An AVF should be created at least 6 months before the planned start of haemodialysis (HD). This synchronisation allows the access to be assessed and provides additional time for review to ensure that a mature fistula is available when dialysis treatment is scheduled to start. (B)
 - 1.2 In most cases, arteriovenous grafts (AVG) are placed at least 3 to 6 weeks prior to the scheduled start of HD. Some newer graft materials may be cannulated immediately after placement. (B)
 - 1.3 AVG should not generally be cannulated for at least 2 weeks after placement and not until swelling has gone down enough to allow the area to be palpated. Puncture-site rotation is necessary to prevent the formation of pseudoaneurysms. (B)
- 2. The assessment which should be carried out before creating a permanent VA for HD includes:
 - 2.1 Physical examination and medical history (B)
 - 2.2 Duplex ultrasound of arm arteries and veins (B)
 - 2.3 Evaluation of the central vein in a patient with previous catheter or pacemaker (A)

Japanese CPG⁴ (Seiji Ohira, 2005). The recommendations are not graded; they are only practice guidelines.

- 1. An AVF should be created at least 2-4 weeks before first cannulation by foreseeing the need to start haemodialysis from the laboratory test results and clinical symptoms. Ideally, first cannulation should be 3-4 weeks after placement of an AVG.
- 2. The surgeon creating the VA should carefully examine the patient by inspection, palpation and ultrasound of the arteries and veins in the forearm, recording the course of the vessels and devising a plan for creating the VA. Evaluation of the peripheral circulation and heart function is also required as part of this process.

Spanish 2004 CPG⁵

The ideal situation would be for an AVF to be created around six months prior to first cannulation. The waiting time before cannulation need not be so long when implanting a prosthesis, as grafts require shorter maturation time and have a lower primary patency rate than AVF.

Patient assessment should include a detailed medical history which identifies any risk factors for initial failure and non-maturation of the AVF. Preoperative assessment may at times need to be completed with imaging studies.

Recommendations: (B: observational studies; C: expert opinion; D: consensus group)

- 1. If the type of VA selected is a prosthesis, it is advisable to implant 4-6 weeks before commencing the HD (evidence D).
- 2. In patients with progressive CKD, AVF should be created 4-6 months prior to the start of the HD (evidence D).
- 3. All patients must be assessed by a surgical team specialised in implanting vascular access sites based on their medical history and associated comorbidity. A detailed physical examination facilitates the choice of VA and reduces the likelihood of complications (evidence B).
- 4. Imaging studies are indicated in patients with arterial disease, obesity or other problems that make palpation of the vessels difficult (evidence B).

Observational studies (OS)

Two Dialysis Outcomes and Practice Patterns Studies (DOPPS) (Saran 2004;⁶ Rayner 2003⁷) that three of the above CPG¹⁻³ include in their evidence are described below.

Saran 2004. ⁶ This DOPSS is a prospective, observational study conducted with data from adult patients (age >17 years) on HD in seven different countries (France, Germany, Italy, Japan, Spain, the UK and the USA). The sampling plan, the selection of representative samples and the study methods have been published previously (Young 2000). The study includes data from three continents, obtained from a sample of 309 HD sites (144 USA, 101 Europe and 64 Japan). On average, 30 adult patients on long-term haemodialysis were chosen at random at each site. Study subjects belonging to a particular centre were replaced periodically with new patients who started haemodialysis treatment at that site. The data were collected from July 1996 to May 2001 in the USA, from June 1998 to November 2000 in Europe, and from February 1999 to March 2001 in Japan. The longitudinal data were collected using identical questionnaires and included demographic characteristics, comorbidities and vascular access events. All new access routes for HD created over the course of the enrolment period were included in the sample. A total of 4884 VA were included belonging to 3686 patients (AVG = 2730 and AVF = 2154). The observation unit was the access, rather than the patient. The time of the first failure of a graft or fistula is defined as the time since the creation / surgical placement to the first thrombosis of the access or rescue procedure for such an occurrence. Patients were observed for an average of 4 months.	
Ragner 2003. ⁷ This DOPSS is a prospective, observational study conducted with data from adult patients (age >17 years) receiving in-hospital HD at 145 dialysis centres in the USA, 63 in Japan, 21 in Germany, and 20 each in France, Italy, Spain and the United Kingdom (UK). The data were collected from July 1996 to May 2001 in the USA, from June 1998 to November 2000 in Europe, and from February 1999 to March 2001 in Japan. Representative samples were obtained using a random selection of dialysis centres and their patients with ongoing longitudinal data collection, as described previously (Young 2000). Patient data (n=894) were obtained from the medical records. VA data (n=694) were collected on each patient at study entry and updated each time a new vascular access event occurred. The VA information includes type of access, location, date of creation, first use and failure.	
Saran 2004. ⁶ For grafts, the first cannulation took place within 2-4 weeks in 62% of centres in the USA, 61% in Europe and 42% in Japan. For fistulas, the first cannulation was within 2 months of creation in 36% of centres in the USA, 79% in Europe and 98% in Japan.	Low quality
Saran 2004. ⁶ In general, the relative risk (RR) of graft failure in Europe was lower than in the USA. (RR = 0.69, p= 0.04). The RR of graft failure (reference group = first cannulation in 2-3 weeks) was 0.84 with the first cannulation at <2 weeks (p=0.11), 0.94 with the first cannulation within 3-4 weeks (p=0.48) and 0.93 with first cannulation in > 4 weeks (p=0.48). The RR of fistula failure was 0.72 with the first cannulation in <4 weeks (p=0.08), 0.91 within 2-3 months (p=0.43) and 0.87 at > 3 months (p=0.31) (reference group = first cannulation at 1-2 months). The RR was adjusted for continent, age, race, body mass index, comorbidities, and the number of previous VA.	Low quality

Saran 2004. ⁶ The mean of the rate of blood flow in Europe was 300 ml/min and in Japan was 196.5 ml/min, compared to 412 ml/min in the USA. These values were significantly different from one another (p<0.0001). There was more failure of the AVG the higher the blood flow rate, although these data were not statistically significant (relative risk (RR)=1.14, p=0.28). In general, there were no statistically significant differences in the RR for graft or fistula failure between different categories of blood flow rate.	Low quality
Rayner 2003. ⁷ For new patients starting haemodialysis with an AVF, the following results were observed for the average time to first cannulation: Japan and Italy (25 and 27 days), Germany (42 days), Spain and France (80 and 86 days), UK and USA (96 and 98 days).	Low quality
Rayner 2003. ⁷ No association was found between cannulation at 28 days or more than 28 days and patient characteristics in terms of age, gender and fifteen different classes of comorbidities. The risk of failure of the AVF was higher in patients who had a previous temporary access (RR=1.81, p=0.01), or who were female (RR=1.52, p=0.02).	Low quality
Rayner 2003 . ⁷ A sensitivity analysis with additional categories of cannulation time suggested that the period of greatest risk was during the first 11 days (0- 11 days RR=2.75, p=0.004, n=57, 12-21 days RR=1.16, p=0.73; n=64, each compared to the reference group time of 43-84 days).	Low quality
Rayner 2003. ⁷ Cannulation 14 days after creation was associated with a 2.1-fold higher risk of fistula failure compared to fistulas cannulated after more than 14 days (RR=2.1; p=0.006; n=642).	Low quality
Rayner 2003. ⁷ A simple regression analysis adjusted for the effects of pooling across study sites indicated a non-significant relationship between the rate of blood flow and the time to first cannulation of the AVF (p=0.47, n=769). This relationship remained non-significant after adjustment for the patients' age, gender, comorbidity, early nephrology care, the previous use of a temporary access route and hospitalisation in the three months prior to entering the study (p=0.09).	Low quality
Summary of evidence	
Analysis of the DOPPS (Saran 2004, ⁶ Rayner 2003 ⁷) suggests that, while cannulation of a fistula would not be advisable within the first two weeks after it is created, a first cannulation after two to four weeks could be attempted if clinically indicated and considered feasible based on clinical assessment, without unnecessarily increasing the risk of fistula failure.	Low quality
Saran 2004. ⁶ First cannulation of grafts within 2 weeks and of fistulae within 4 weeks was not associated with a higher risk of access failure. These findings suggest that shortening the time necessary for the maturation of vascular access does not compromise the long-term survival of the access.	Low quality

Rayner 2003.⁷ AVF should be allowed to mature for at least 14 days prior to the first cannulation. The decision should be complemented by clinical assessment, supported by measurement of the AVF blood flow by ultrasound. Moreover, the training of personnel and their experience in cannulating AVF can also be important factors for the success of the cannulation programme and maintaining the viability of AVF.

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	It is suggested that the maturation time before an arteriovenous fistula is cannulated should be no less than four weeks, and it is preferable to wait four to six months.						
Weak	It is suggested that the maturation time before an arteriovenous graft is cannulated should be three to six weeks.						
Weak	It is suggested that a clinical assessment be performed based on a detailed physical examination and scrutiny of the patient's medical records to determine how long to wait before cannulating of an arteriovenous fistula or graft for the first time. If the results of physical examination are equivocal, an ultrasound scan should be performed to assess the arteries and veins of the arm.						

References

- 1. Tordoir J, Canaud B, Haage P, Konner K, Basci A, Fouque D, Kooman J, Martin-Malo A, Pedrini L, Pizzarelli F, Tattersall J, Vennegoor M, Wanner C, ter Wee P, Vanholder R. EBPG on Vascular Access. Nephrol Dial Transplant. 2007 May;22 Suppl 2:ii88-117.
- 2. Culleton B. Introduction to the Canadian Clinical Practice Guidelines. J Am Soc Nephrol 2006;17:S1-3.
- 3. GPC DOQI 2006 Am J Kidney Dis. 2006 Jul;48 Suppl 1:S248-73. Clinical practice guidelines for vascular access. Vascular Access Work Group.
- 4. 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
- 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
- 6. Saran R, Dykstra DM, Pisoni RL et al. Timing of first cannulation and vascular access failure in haemodialysis: an analysis of practice patterns at dialysis facilities in the DOPPS. Nephrol Dial Transplant 2004; 19: 2334–2340

- Rayner HC, Pisoni RL, Gillespie BW, Goodkin DA, Akiba T, Akizawa T, Saito A, Young EW, Port FK; Dialysis Outcomes and Practice Patterns Study. Creation, cannulation and survival of arteriovenous fistulae: data from the Dialysis Outcomes and Practice Patterns Study. Kidney Int. 2003 Jan;63(1):323-30.
- 8. Nursal TZ, Oguzkurt L, Tercan F, Torer N, Noyan T, Karakayali H, et al. Is routine preoperative ultrasonographic mapping for arteriovenous fistula creation necessary in patients with favorable physical examination findings? Results of a randomized controlled trial. World J Surg 2006;30:1100-7
- 9. Ferring M, Claridge M, Smith SA, Wilmink T. Routine preoperative vascular ultrasound improves patency and use of arteriovenous fistulas for hemodialysis: a randomized trial. Clin J Am Soc Nephrol 2010;5: 2236-44.
- 10. Mihmanli I, Besirli K, Kurugoglu S, Atakir K, Haider S, Ogut G, et al. Cephalic vein and hemodialysis fistula: surgeon's observation versus color Doppler ultrasonographic findings. J Ultrasound Med 2001;20:217-22

GRADE TABLES

Date: 2013-11-06

Question: Should 1st AVF puncture ≤ 4 weeks or > 4 weeks be used for CRD with AVF?

Bibliography: Saran R, Dykstra DM, Pisoni RL et al. Timing of first cannulation and vascular access failure in haemodialysis: an analysis of practice patterns at dialysis facilities in the DOPPS. Nephrol Dial Transplant 2004; 19: 2334–2340

Quality assessment								No of patients N=2154			Ouality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	1st AVF puncture ≤ 4 weeks	1st AVF puncture > 4 weeks	Relative (95% CI)	Absolute		
AVF failure (4-month follow-up)												
1	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none			RR 0.72 (0 to 0)		???? LOW	CRITICAL

Date: 2013-11-06

Question: Should 1st AVG puncture ≤ 2 weeks or > 2 weeks be used for CRD with AVG?

Bibliography: Saran R, Dykstra DM, Pisoni RL et al. Timing of first cannulation and vascular access failure in haemodialysis: an analysis of practice patterns at dialysis facilities in the DOPPS. Nephrol Dial Transplant 2004; 19: 2334–2340

Quality assessment								No of patients N=2730			Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	1st AVG puncture ≤ 2 weeks	1st AVG puncture > 2 weeks	Relative (95% CI)	Absolute		
AVG failure (4-month follow-up)												
1	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none			RR 0.84 (0 to 0)		2222 LOW	CRITICAL

Date: 2013-11-06

Question: Should 1st puncture ≤ 14 days or > 14 days be used for CRD with AVF? Bibliography: Rayner HC, Pisoni RL, Gillespie BW, Goodkin DA, Akiba T, Akizawa T, Saito A, Young EW, Port FK; Dialysis Outcomes and Practice Patterns Study. Creation, cannulation and survival of arteriovenous fistulae: data from the Dialysis Outcomes and Practice Patterns Study. Kidney Int. 2003 Jan;63(1):323-30.

Quality assessment								No of patients		Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	1st puncture ≤ 14 days n=72	1st puncture > 14 days n=570	Relative (95% CI)	ntive % CI) Absolute		Importance
AVF failure (4-month follow-up)												
1	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none			RR 1.2 (0 to 0)	178 more per 1000 (from 888 fewer to 888 fewer)	2222 LOW	CRITICAL