ANNEXES TO CHAPTER 1

Clinical Question IV. What risk factors have been shown to influence the development of limb ischaemia after arteriovenous fistula creation (patient's medical risk factors, presence or absence of distal trunks, diameter of anastomosis, location of the access, quantity and quality of exit veins)?

No systematic reviews or randomised clinical trials were found in the evidence. Evidence was based on Clinical Practice Guidelines (CPG) and prospective and retrospective observational studies, which are described below.

CPG:
Four CPG have been identified that deal with this question (ERBP 2007,[1] DOQI 2006,[2] Japanese 2005,[3] Spanish 2004[4])

ERBP[1] CPG (Tordoir 2007) These CPG do not grade the recommendations; they only clarify the grades of evidence.

Recommendations

1. Clinical evaluation and non-invasive ultrasonography of upper extremity arteries and veins should be performed before vascular access creation (level of evidence II).
2. Central vein imaging is indicated in patients with a history of previous central vein catheters (level of evidence IV).
3. The venous access (VA) should provide sufficient blood flow to perform adequate haemodialysis (level of evidence II).
4. The upper extremity arteriovenous fistula should be the preferred access and should be placed as distal as possible (level of evidence III).

DOQI CPG, 2006[2] These CPG base their clinical recommendations on a number of observational studies and group consensus.

Medical history. Background. Numerous associated circumstances may alter the adequate development of a Vascular Access and prior knowledge of all the potential influencing factors is therefore required. The following are some of the most common factors:

- Prior CVC that may cause stenosis
- History of pacemaker, that would act under similar conditions
- Congestive heart failure (CHF) that may be worsened by the practice of VA
- Valvular disease, especially from catheters;
- Anticoagulant therapy that would complicate cannulation of the AVF
- Previous trauma in arms, neck or chest which might alter the natural anatomy
- Diabetes that would predispose towards an associated vascular disease; peripheral arterial disease, etc.

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

1. The assessments to be made prior to placement of a permanent access include:

• Medical history and physical examination (B). • Duplex ultrasound of the arteries or veins of the arm (B). • Evaluation of a central vein in a patient with previous catheter or a pacemaker (A).	
JAPANESE CPG[3] (Seiji Ohira2005) The recommendations are not graded; they are only practice guidelines. **Recommendation:** 1. 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 CPG 2004[4] **Recommendations:** (B: observational studies; C: expert opinion; D: group consensus) 1. To select the appropriate type of VA, it is essential to take the patient's medical history, in order to have an understanding of the associated comorbidity and be able to estimate the risk factors for failure associated with the development of the VA (B) 2. Imaging studies are indicated in patients with arterial disease, obesity or other problems that make palpation of the vessels difficult (B) 3. Imaging studies must be performed in children weighing less than 15 kg and children with a history of pacemaker or central lines (B)	
Observational studies	
Rocha 2010.[5] Prospective observational study conducted in Portugal. The study analysed 324 AVF created in 309 patients between January 2008 and December 2009. Data are presented on age, gender, diabetes mellitus (DM), coronary artery disease or peripheral arterial disease, the date of initiation of renal replacement therapy, the date the VA was created, the location of the AVF (brachiocephalic, brachiobasilic or brachiomedian), the type of anastomosis (ETS or STS), previous interventions, and outcome of the AVF. They utilised two different procedures for resolving ischaemia:banding and the ligation of the access, although ligation only in cases of severe ischaemia. Each AVF created was an independent clinical event for the purposes of the study. The objective of this study was to review all cases of steal syndrome (stealing of blood, ischaemia or distal hypoperfusion) occurring after creation of an AVF in the proximal arm for haemodialysis and to define the independent predictors. Steal syndrome is usually a result of arterial disease proximal or distal to the fistula. The mean follow-up of the 324 fistulae was 18.6 ± 8.5 months.	
Monroy-Cuadros 2010.[6] A retrospective, observational study that included 831 adult patients with a mature AVF from January 2005 to June 2008 in Canada. Demographic data included age at the time the surgery was performed, gender and race. Clinical data included the aetiology of renal insufficiency (e.g. diabetes, glomerulonephritis [GN], ischaemia/hypertension, interstitial nephritis, polycystic kidney disease, or unknown/other) and specific comorbidities such as diabetes, hypertension, peripheral vascular disease, history of smoking (currently smoking or self-classified as a regular smoker within the past 5 years) and use of medications (aspirin, anticoagulants, angiotensin-converting enzyme inhibitor). Vascular access data included the side of the surgery (right or left) and anatomical location (forearm or upper arm fistula). The primary	

outcome of interest was loss of primary functional patency, defined as thrombosis of the graft (including abandonment of the access site) or the need for surgical or percutaneous endovascular intervention. Demographic and initial clinical variables were included, and the blood flow within the access. (initial intra-access blood flow [IABF]). These variables were compared between VA with and without loss of primary functional patency. To determine the potential contribution of independent variables to the dependant variable of loss of primary functional patency, a multivariate analysis was performed using logistic regression.	
Bojakowski 2012.[7] Prospective, observational cohort study in Poland, including 68 patients with stage 5 chronic kidney disease with an AVF from June 2006 to September 2007. The study evaluated risk factors for dysfunction of native AVF. Follow-up lasted 24 months. The primary endpoint was the failure of the fistula. Patients' biochemical and histochemical parameters were measured.	
Diehm 2010.[8] Retrospective study conducted over two years in Switzerland in which 244 VA were evaluated; 127 were AVF and the rest different types of catheters (saphenous vein, bovine vein, central catheter). Clinical data, concomitant medications and surgical data were retrieved from files using a standardised data capture sheet. Outcome parameters were primary patency (PP) and secondary patency (SP) as well as freedom from repeated revascularisation. The minimum follow-up of the VA was 679 days.	
Monroy-Cuadros 2012.[9] This was a retrospective study of 359 patients on long-term haemodialysis with AVG in Canada from January 2005 to June 2008. Demographic and clinical variables and IABF were compared between those with and without loss of primary functional patency. To determine the contribution of the independent variables to the dependent variable for the loss of primary functional permeability, a multivariate analysis was performed using logistic regression.	
Field 2011.[10] Experience from one centre in the UK with 140 brachiobasilic fistulae over a five year period. Data were analysed to examine the factors significantly influencing the patency of the fistula at 12 months. Patients who had undergone creation of an AVF from January 2004 to January 2009 were identified. Details were collected on demographics, cause of renal failure, comorbidities (including diabetes, cardiac morbidity, hypertension, peripheral vascular disease) and dialysis status at the time of fistula creation. Haemoglobin, anticoagulation regimens, and complications from surgery were recorded.	
Rocha 2010.[5] The mean age of the patients was 66.7 ± 15.3 years, and the majority were male (53.7%). During follow-up, steal syndrome occurred in 26 AVF (8%). Most of these cases (22 AVF) underwent surgical correction by means of banding. The correction improved the blood flow, with return of ulnar pulse and relief of symptoms in 92.3% of patients. None of the patients required finger amputation. The mean length of the AVF anastomosis was 4.6 mm, with a mean flow rate of 1212 l/min.	**Low quality**
Rocha 2010.[5] Univariate analysis showed correlations between steal syndrome and DM (p=0.002), brachiomedian fistula (p=0.016), and STS anastomosis (p=0.003). Multivariate analysis found the presence of DM, STS anastomosis, and female gender to be independent risk factors. The strongest predictor was the DM (odds ratio: 6.7; 95% confidence interval: 2.5 to 17.9).	**Low quality**

Monroy-Cuadros 2010.[6] Loss of AVF primary functional patency occurred in 81 patients (10% of all cases). The mean time from first cannulation to loss of primary functional patency was 48 days (interquartile range 12-95). Sixty-six of these patients (81%) had thrombosis as a cause.	**Low quality**
Monroy-Cuadros 2010.[6] The multivariate analysis found that older age (>65 years, odds ratio [OR] 3.6, p<0.001), history of diabetes (OR 2.3, p=0.007), history of smoking (OR 4.3, p<0.001), presence of forearm fistulas (OR 4.0, p<0.00), and low initial IABF (<500 ml/min, OR 29, p<0.001) were independently associated with loss of primary patency in the access.	**Low quality**
Bojakowski 2012.[7] In the multivariate analysis, independent predictors of AVF dysfunction were the number of leucocytes in the blood (hazard ratio [HR] 1.67, 95% CI: 1.24-2.25, p 0.001), the number of monocytes (HR 0.02, CI 0.00 to 0.21, p=0.001) and red blood cell distribution width (RDW) (HR 1.44; CI 1.17 to 1.78; p 0.001). The RDW was the only significant factor (area under the curve 0.644; 0.51 to 0.76; p=0.046). RDW greater than 16.2% was associated with a significantly reduced AVF patency frequency 24 months after surgery.	**Low quality**
Diehm 2010.[8] During the observation period, 244 patients (mean age 62.2 ± 0.9 years, 60.7% male) underwent vascular access procedures. The PP and SP were 35.6% and 45.6% respectively at 540 days. Diabetes mellitus was associated with decreased PP (OR: 0.6; 95% CI: 0.3 - 1.0) and SP (OR: 0.4; 95% CI: 0.2 - 0.7), whereas female gender was associated with lower SP (OR: 0.6; 95% CI: 0.3-0.9).	**Low quality**
Monroy 2012.[9] The incidence of primary failure was 30% (107/359). Multivariate analysis found that low initial IABF (<650 ml/min, odds ratio [OR] =31, p<0.001), presence of diabetes (OR 3.5, p=0.001), older age (>65 years, OR 3.2, p<0.001), and presence of peripheral vascular disease (OR 2.5, p<0.005) were independently associated with loss of primary patency.	**Low quality**
Field 2011.[10] The 140 brachiobasilic fistulae performed in 122 patients were created in single- or two-stage surgery: seven were created in a single stage, and the remainder in two stages with a mean interval of 146 days (range 38-455). Average age was 60.4 (18-85), 44% were male and 56% female. Of the fistulae created in one single stage, 26 failed, and in two stages, 11 failed. Patency (defined as the use of AVF for dialysis) was 83% at 3 months, 77% at 6 months, and 69% at 12 months. Length of patency ranged from 0 to 1918 days (at study cut-off) with a mean patency of 532 days. Factors found to significantly affect the patency of the fistula included age over 60 (p≤0.001) and presence of peripheral vascular disease (p=0.048).	**Low quality**
Summary of evidence	
Rocha 2010.[5] In the study population, the vast majority elderly, no association was found between steal syndrome and coronary artery disease and peripheral vascular disease. However, these are two significant comorbidities associated with diabetes, which was an independent predictor of steal syndrome. Diabetes was the principal risk factor for steal syndrome. Age, the type of AVF, the duration of renal replacement therapy and factors involved in endothelial damage were not	**Low quality**

significantly associated with steal syndrome. The results highlight the need for careful monitoring of the AVF, especially in women and patients with diabetes, and preferential use of end-to-side (ETS) anastomosis.	
Monroy-Cuadros 2010.[6] This study discovered a set of patient risk factors (age), clinical risk factors (diabetes, smoking), and vascular access characteristics (anatomical location, low initial IABF) which identify the patients who are at greatest risk of vascular access failure. Of all the above factors, low initial intra-access blood flow (IABF) is the most significant. These risk factors can be used to guide a targeted approach in a vascular access screening protocol.	**Low quality**
Bojakowski 2012.[7] Red blood cell distribution width (RDW), is a readily-available laboratory value that may be a novel prognostic marker for AVF. Further studies are needed to establish this relationship.	**Low quality**
Diehm 2010.[8] The prognosis for VA for haemodialysis is poorer in patients with diabetes mellitus and in women, as these factors adversely affect the patency of the VA and repeated revascularisation can sometimes be necessary.	**Low quality**
Monroy-Cuadros 2012.[9] Prosthetic arteriovenous grafts (AVG) are sometimes the best option for patients in whom time and the probability of successful maturation of the fistula may be a concern. Close monitoring of the AVG in patients with identified risk factors (low initial IABF, diabetes, advanced age and presence of peripheral vascular disease) in relation to the loss of primary patency can improve the life expectancy of the access.	**Low quality**
Field 2011.[10] Their brachiobasilic fistula patency rates are comparable to the existing literature and other fistulas. Within their population, patient variables including age over 60 and the presence of peripheral vascular disease are associated with worse patency. In spite of these factors, the brachiobasilic fistula is an excellent option for patients with more challenging access and should certainly be undertaken prior to the use of prosthetic grafts.	**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]	
It is suggested that a series of risk factors that may influence the development of ischaemia after creating a vascular access should be taken into account to prevent failure of the access site. These factors are associated with both patient characteristics (female gender, being elderly, diabetes, peripheral vascular disease) and characteristics of the vascular access (anatomical location, low initial blood flow).	

References

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6. Monroy-Cuadros M, Yilmaz S, Salazar-Bañuelos A, Doig C. Risk factors associated with patency loss of hemodialysis vascular access within 6 months. Clin J Am Soc Nephrol. 2010 Oct;5(10):1787-92.
7. Bojakowski K, Dzabic M, Kurzejamska E, Styczynski G, Andziak P, Gaciong Z, Söderberg-Nauclér C, Religa P. A high red blood cell distribution width predicts failure of arteriovenous fistula. PLoS One. 2012;7(5):e36482.
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GRADE TABLES

Date: 2013-10-24
Question: Should AVF with steal syndrome (ischaemia) or AVF without steal syndrome (ischaemia) be used for CKD?
Bibliography: Rocha A, Silva F, Queirós J, Malheiro J, Cabrita A. Predictors of steal syndrome in hemodialysis patients. Hemodial Int. 2012 Oct;16(4):539-44. doi: 10.1111/j.1542-4758.2012.00684.x. Epub 2012 Apr 17. PubMed PMID: 22510166.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**AVF with steal syndrome (ischaemia)**	**AVF without steal syndrome (ischaemia)**	**Relative (95% CI)**	**Absolute**		
Diabetes mellitus (follow-up of 18.6 ± 8.5 months)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	16/26 (61,57%)	94/298 (31,5%)	OR 6.724 (2.523 to 17.916)[1]	395 more per 1000 (from 223 more to 484 more) -	⨁⨁⨁⨁ LOW	
STS anastomosis (follow-up of 18.6 ± 8.5 months)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	18/26 (69.2%)	118/298 (39.6%)	OR 3.270 (1.013 to 10.559)[2]	286 more per 1000 (from 3 more to 478 more) -	⨁⨁⨁⨁ LOW	
Female gender (follow-up of 18.6 ± 8.5 months)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	15/26 (57.7%)	135/298 (45.3%)	OR 3.080 (1.158 to 8.190)[3]	265 more per 1000 (from 37 more to 418 more)-	⨁⨁⨁⨁ LOW	

[1] p<0,001[2] p=0.048[3] p= 0,024

Date: 2013-10-24
Question: Should AVF with patency loss (AVF PL) or AVF without patency loss (AVF WL) be used for ?
Bibliography: Monroy-Cuadros M, Yilmaz S, Salazar-Bañuelos A, Doig C. Risk factors associated with patency loss of hemodialysis vascular access within 6 months. Clin J Am SocNephrol. 2010 Oct;5(10):1787-92. doi: 10.2215/CJN.09441209. Epub 2010 Jun 24. PubMed PMID: 20576823; PubMed Central PMCID: PMC2974378.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	AVF PL n 81	AVF WL n 750	Relative (95% CI)	Absolute		
Aged over 65												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	66/81 (81.5%)	471/750 (62.8%)	OR 3.6 (1.7 to 7.7)[1]	85 more per 1000 (from 47 more to 105 more)	⨁⨁⨁⨁ LOW	CRITICAL
Diabetes												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	57/81 (70.3%)	347/750 (46.2%)	OR 2.3 (1.3 to 4.5)[2]	74 more per 1000 (from 29 more to 106 more)	⨁⨁⨁⨁ LOW	CRITICAL
Smoker												
1	Observational studies	no serious risk of bias	no serious indirectness	no serious indirectness	no serious imprecision	none	61/81 (75.3 %)	317/750 (42.3%)	OR 4.3 (2.2 to 8.3)[3]	119 more per 1000 (from 81 more to 139 more)	⨁⨁⨁⨁ LOW	CRITICAL
Initial patency < 500 ml												

1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	51/81 (63%)	57/750 (7.6%)	OR 29 (15 to 52)[4]	474 more per 1000 (from 444 more to 489 more)	⨁⨁⨁⨁ LOW	CRITICAL
AVF located in forearm												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	48/81 (59.3%)	207/750 (27.6%)	OR 4 (2.1 to 7.4)[5]	133 more per 1000 (from 89 more to 158 more)	⨁⨁⨁⨁ LOW	CRITICAL

[1] p 0,001[2] p 0,007[3] p<0,001[4] p<0,001[5] p<0,001

Date: 2013-10-24
Question: Should AVG with primary patency loss (AVG PL) or AVG without primary patency loss (AVG WL) be used for CRD?
Bibliography: Monroy-Cuadros M, Yilmaz S, Salazar-Bañuelos A, Doig C. Independent prediction factors for primary patency loss in arteriovenous grafts within six months. J Vasc Access. 2012 Jan-Mar;13(1):29-35. doi: 10.5301/JVA.2011.8425. PubMed PMID: 21688243

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**AVG PL N 107**	**AVG WL N 252**	**Relative (95% CI)**	**Absolute**		
Primary patency < 650 ml/min												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	98/107 (91.6 %)	57/252 (22.6%)	OR 31 (14 to 68)[1]	580 more per 1000 (from 523 more to 608 more)	⨁⨁⨁⨁ LOW	CRITICAL
										-		
Patients aged over 65												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	97/107 (91%)	160/252 (63.5%)	OR 31 (14 to 68)[2]	358 more per 1000 (from 336 more to 369 more)	⨁⨁⨁⨁ LOW	CRITICAL
										-		
Patients with diabetes												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	84/107 (78.5%)	114/252 (45.2%)	OR 3.5 (1.8 to 7)[3]	250 more per 1000 (from 134 more to 329 more)	⨁⨁⨁⨁ LOW	CRITICAL
Patients with peripheral vascular disease												
1	Observational	no serious risk of	no serious	no serious	no serious	none	60/107	96/252	OR 2.5 (1.3 to	-	⨁⨁⨁⨁	

	studies	bias	inconsistency	indirectness	imprecision		(56.1%)	(38.1%)	4.8)[4]		LOW	

[1] p<0,001[2] p<0,001[3] p<0,001[4] p 0,005

Date: 2013-10-24
Question: Should decreased patency at 12 months or preserved patency at 12 months be used for?
Bibliography: Field M, Van Dellen D, Mak D, Winter H, Hamsho A, Mellor S, Inston N The brachiobasilic arteriovenous fistula: effect of patient variables. . PMID: 21607922 [PubMed - indexed for MEDLINE]

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Preserved patency at 12 months	Decreased patency at 12 months	Relative (95% CI)	Absolute		
Patients aged over 60												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	25/73 (34.2%)	48/73 (65.8%)	p< 0.001 (0 to 0)	657 fewer per 1000 (from 658 fewer to 658 fewer)	⨁⨁⨁⨁ LOW	CRITICAL
								0%		-		
Patients with peripheral vascular disease (PVD)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/8 (37.5%)	5/8 (62.5%)	P 0.048 (0 to 0)	595 fewer per 1000 (from 625 fewer to 625 fewer)	⨁⨁⨁⨁ LOW	CRITICAL
								0%		-		

Date: 2013-10-24
Question: Should primary patency (PP) or secondary patency (SP)?
Bibliography: Diehm N, van den Berg JC, Schnyder V, Bühler J, Willenberg T, Widmer M, Mohaupt MG, Baumgartner I. Determinants of haemodialysis access survival. Vasa. 2010 May;39(2):133-9. doi: 10.1024/0301-1526/a000018. PubMed PMID: 20464668.

Quality assessment							No of patients	Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**SP**	**Relative (95% CI)**	**Absolute**		
Patients with diabetes											
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	77/244 (31,6%)	OR 0.4 (0.2 to 0.7)		⨁⨁⨁◯ LOW	CRITICAL
Female gender											
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	96/244 (39.3%)	OR 0.6 (0.3 to 0.9)	-	⨁⨁⨁◯ LOW	CRITICAL

Quality assessment							No of patients	Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PP	Relative (95% CI)	Absolute		
Patients with diabetes											
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	77/244 (31,6%)	OR 0.6 (0.3 to 1)		⨁⨁◯◯ LOW	CRITICAL
Female gender											
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	96/244 (39.3%)	OR 0.6 (0.3 to 1.1)	-	⨁⨁◯◯ LOW	CRITICAL

Date: 2013-10-25
Question: Should RDW > 16.2% or RDW ≤ 16,2% be used for?
Bibliography: Bojakowski K, Dzabic M, Kurzejamska E, Styczynski G, Andziak P, Gaciong Z, Söderberg-Nauclér C, Religa P. A high red blood cell distribution width predicts failure of arteriovenous fistula. PLoS One. 2012;7(5):e36482. doi: 10.1371/journal.pone.0036482. Epub 2012 May 4. PubMed PMID: 22574168; P

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**RDW > 16.2%**	**RDW ≤ 16.2%**	**Relative (95% CI)**	**Absolute**		
VA patency (mean follow-up of 24 months)												
1	Observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	68 patients		0.644 (9.51 to 0.76)[1]	-	⨁⨁⨁◯ LOW	CRITICAL
										-		

[1] P<0.046 multivariate Roc curve analysis