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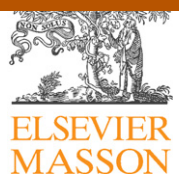

CLINICAL RESEARCH

Preventing acute decrease in renal function induced by coronary angiography (PRECORD): a prospective randomized trial

Prévention de la néphropathie de contraste au cours de la coronarographie (étude PRECORD)

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KEYWORDS
Acute renal insufficiency;
Contrast agent;
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Summary
Background. — Infusion of saline attenuates the decrease in renal function induced by radiographic contrast agents among patients with chronic renal insufficiency.
Aim. — The Preventing Renal alteration in Coronary Disease (PRECORD) trial was a randomized trial to assess the effect on renal function of saline infusion during and after coronary angiography in 201 patients without severe chronic renal insufficiency (serum creatinine < 140 μmol/L).
Methods. — All patients received standard oral hydration: 2000 mL of tap water within the 24 hours after coronary angiography. Patients were randomized before the procedure to intravenous hydration (1000 mL of 0.9% saline infusion) or no additional hydration. The infusion was started in the catheterization laboratory and continued for 24 hours. The primary endpoint was the change in calculated creatinine clearance between baseline and 24 hours after coronary

Abbreviations: CI, confidence interval; CIN, contrast-induced acute nephropathy; PTCA, percutaneous transluminal coronary angioplasty; SEM, standard error of the mean.

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angiography. The same ionic low osmolar radiographic contrast agent (ioxaglate) was used in all patients.
Results. — Both groups had similar baseline characteristics, including age, serum creatinine, volume of contrast and proportion of patients undergoing ad hoc coronary angioplasty. The overall decrease in serum creatinine clearance 24 hours after the procedure was −3.44 (0.68) mL/min. The change in serum creatinine clearance 24 hours after the procedure was −2.81 (1.07) mL/min in the infusion group vs −4.09 (0.91) mL/min in the control group ($p = 0.38$).
Conclusion. — Renal function is altered only slightly 24 hours after coronary angiography with standard oral hydration alone and is not affected by saline infusion started at the beginning of coronary angiography, even in patients with mild-to-moderate renal dysfunction.

MOTS CLÉS
Produit de contraste ;
Insuffisance rénale aiguë ;
Prévention ;
Coronarographie ;
Essai thérapeutique randomisé

Résumé
Prérequis. — La perfusion de sérum salé prévient la dégradation de la fonction rénale après injection de produit de contraste chez les insuffisants rénaux chroniques.
Objectif. — L'étude Preventing Renal alteration in Coronary Disease (PRECORD) est un essai thérapeutique randomisé évaluant l'effet protecteur de la perfusion de sérum salé au cours d'une coronarographie chez 201 patients non insuffisants rénaux sévères (créatininémie < 140 μmol/L).
Méthodes. — Tous les patients recevaient une hydratation orale de 2000 mL d'eau du robinet dans les 24 heures suivant la coronarographie. Les patients étaient randomisés avant l'examen en deux groupes : un groupe recevant une hydratation supplémentaire par sérum salé 0,9 % intraveineux 1000 mL débuté en salle de cathétérisme et poursuivi pendant 24 heures, et un groupe témoin sans hydratation supplémentaire. Le critère majeur était la diminution de la clairance de la créatininémie calculée à 24 heures. Pendant la coronarographie, tous les patients recevaient le même agent de contraste ionique à osmolarité basse (ioxaglate).
Résultats. — Les deux groupes étaient comparables à l'inclusion en ce qui concerne l'age, la créatininémie, la quantité de produit de contraste et le nombre d'angioplastie. La diminution moyenne de la clairance de la créatininémie observée à 24 heures était de −3,44 (0,68) mL/min. Dans le groupe recevant la perfusion de sérum salé elle était de −2,81 (1,07) mL/min et dans le groupe témoin de −4,09 (0,91) mL/min ($p = 0,38$).
Conclusion. — La fonction rénale n'est que modérément altérée après une coronarographie chez les patients recevant une hydratation préventive per os. L'ajout d'une hydratation intraveineuse en début de coronarographie n'entraîne pas de bénéfice significatif chez des patients n'ayant pas d'insuffisance rénale sévère.

Background

Contrast-induced acute nephropathy (CIN) is an important complication associated with the use of iodinated contrast media and accounts for a significant number of cases of hospital-acquired acute renal insufficiency [1]. CIN is typically defined as an increase in serum creatinine occurring within the first 24 hours after contrast exposure and peaking up to five days later [2]. CIN after percutaneous coronary intervention has been shown to increase the risk of death significantly, necessitating the evaluation of preventive strategies [3].

Important risk factors are preexistent renal insufficiency (particularly when associated with diabetes), contrast volume and dehydration [4—6]. In an unselected population, the rate of acute decrease in renal function —defined as a 25% increase in serum creatinine concentration— was 14.5% after percutaneous coronary intervention [7]. In patients without preexistent chronic renal insufficiency, an acute decrease in renal function induced by the administration of radiographic contrast agents has been reported in up to 10% of patients [5,8—10].

Several prophylactic measures have been evaluated in patients at high risk [11—17]. Previous studies suggest that volume expansion using isotonic crystalloid, saline or bicarbonate solution is an effective means of preventing a further acute decrease in renal function induced by radiographic contrast agents in patients with chronic renal insufficiency [18—20].

No prospective randomized study has evaluated intravenous saline hydration in patients without preexistent chronic renal insufficiency. The Preventing Renal alteration in Coronary Disease (PRECORD) study was a prospective, randomized, controlled, open-label study that investigated the benefit on renal function of saline infusion during and after elective coronary angiography in patients without preexistent chronic renal insufficiency.

Methods

Patients

All consecutive patients between the ages of 18 and 80 years scheduled for elective coronary angiography, with or without percutaneous transluminal coronary angioplasty (PTCA), who had a baseline serum creatinine concentration below 140 μmol/L (1.58 mg/dL) between September 2000 and March 2001 were eligible for the study. Exclusion criteria included New York Heart Association class IV congestive heart failure, pregnancy, significant valvular heart disease, nonischaemic dilated cardiomyopathy, active cancer or any life-threatening disease. The study protocol was approved by the local ethics committee and all patients gave written informed consent.

Study protocol

According to our hospital guidelines, all patients received oral hydration with 2000 mL of tap water in the 24 hours after coronary angiography.

Patients were assigned treatment randomly upon arrival in the catheterization laboratory by means of computer-generated randomization. The randomization was stratified according to sex and baseline creatinine level by a minimization algorithm.

The infusion group received 1000 mL of 0.9% saline infusion, which was started at the beginning of the procedure and continued for the next 24 hours. The control group received no additional hydration.

Abdominal aortography was performed systematically after left ventriculography in the 20° left oblique anterior projection, to screen for the presence of renal artery stenosis. By convention, an angiographically significant lesion was defined as a greater than or equal to 50% luminal diameter narrowing of a major renal artery [21].

An ionic low osmolar radiographic contrast agent (sodium and meglumine ioxaglate; Hexabrix® 320 mg I/mL, Laboratoires Guerbet, Roissy CdG, France) was used for all patients.

The primary endpoint was the change in serum creatinine clearance between baseline and 24 hours after coronary angiography.

Serum creatinine was measured in our hospital laboratory 12 to 24 hours before, and 24 hours after, coronary angiography. After discharge, one additional determination of serum creatinine was performed in an external laboratory, three days after coronary angiography. Creatinine clearance was calculated with the Cockcroft and Gault formula from serum creatinine concentration, weight, age and sex [22].

Statistical analysis

Based on a between-subject standard deviation of 24-hour percentage change in creatinine clearance of 15%, a trial of 168 patients would have a power of more than 90% to

Table 1 Baseline clinical and biochemical characteristics of the study patients.

	Infusion ($n = 100$)	Control ($n = 101$)
Sex (male/female)	80/20	82/19
Age (years)	62 (1)	62 (1)
Baseline serum creatinine (μmol/L)[a]	86.7 (1.7)	85.6 (1.5)
Baseline creatinine clearance (mL/min)[b]	85.7 (2.6)	85.8 (2.7)
Current smoker	16 (16)	22 (21.78)
Body mass index	26.8 (0.4)	26.7 (0.4)
Concomitant medication		
Antihypertensive therapy	44 (44)	37 (36.6)
Antidiabetic therapy	16 (16)	12 (11.8)
Statin	45 (45)	43 (42.5)
Aspirin/clopidogrel	79 (79)	78 (77.2)
ACE inhibitor	29 (29)	29 (28.7)
Betablocker	60 (60)	59 (58.4)
Calcium channel antagonist	32 (32)	31 (30.7)
Diuretic agent	21 (21)	20 (19.8)
Peripheral artery disease	12 (12)	13 (12.8)
Indication for coronary angiography		
First diagnosis	65 (65)	80 (79.2)
Unstable angina or NSTEMI	9 (9)	5 (4.9)
Postmyocardial infarction	6 (6)	5 (4.9)
Other[c]	20 (20)	11 (10.9)

Values are number (%) or mean (standard error of the mean).
ACE: angiotensin-converting enzyme; NSTEMI: non-ST segment elevation myocardial infarction.
[a] To convert values for serum creatinine from μmol/L to mg/mL, multiply by 0.0113.
[b] Calculated with the Cockcroft and Gault formula from serum creatinine concentration, weight, age and sex.
[c] Postcoronary artery bypass graft control, postpercutaneous transluminal coronary angioplasty control, silent ischaemia.

Table 2 Baseline cardiac catheterization, angiographic and procedural details.

	Infusion ($n = 100$)	Control ($n = 101$)	p
Haemodynamic findings			
Left ventricular end-diastolic pressure (mmHg)	16.8 (1.3)	13.9 (0.7)	0.05
Left ventricular ejection fraction (%)	61 (1.8)	59.8 (1.3)	0.58
Left ventricular end-diastolic volume (mL)	99.7 (3.8)	100.2 (3.2)	0.91
Coronary artery disease			
No coronary artery disease	18 (18)	20 (19.8)	0.82
Atherosclerosis	15 (15)	13 (12.9)	0.78
One vessel	25 (25)	26 (25.7)	0.92
Two vessels	22 (22)	22 (21.8)	0.97
Three vessels	11 (11)	13 (12.9)	0.81
Left main coronary artery	9 (9)	6 (5.9)	0.69
Renal artery stenosis > 50%	9 (9)	4 (3.9)	0.60
PTCA performed during the procedure	34 (34)	31 (30.7)	0.67
Contrast agent dose (mL)	231.4 (7.8)	242.7 (8.6)	0.33
Patients without PTCA (mL)	207.8 (7.4)	215.8 (9.4)	0.51
Patients with PTCA (mL)	277.1 (15.1)	303.3 (12.9)	0.19
Dose of iodine (g/kg body weight)	0.99 (0.04)	1 (0.04)	0.85

Values are number (%) or mean (standard error of the mean).
PTCA: percutaneous transluminal coronary angioplasty.

detect, as significant at the 5% level, an average difference of 7.5% between the two treatments. We aimed to recruit 200 patients to allow for withdrawals and noncompliance.

All analyses were done according to a prespecified statistical analysis plan by intention to treat. The analysis compared creatinine clearance value at 24 hours between the two treatments, with adjustment for the baseline values by analysis of covariance. Analyses were performed on R software. Statistical analyses ignoring these baseline results produced similar results. All p-values were two-tailed; 95% confidence intervals (CIs) were calculated for differences within and between treatment groups. All results are reported as means (SEM).

Results

Between September 2000 and March 2001, 201 patients were assigned randomly to the infusion group (100 patients) or the control group (101 patients) in our department; their baseline characteristics are shown in Table 1. The two groups were similar with respect to age, baseline creatinine clearance, body mass index and concomitant medication. Cardiac catheterization, angiographic and procedural details before any oral or intravenous hydration are shown in Table 2.

Serum creatinine 24 hours after the procedure was measured in 97 patients from the infusion group and 96 patients from the control group. Serum creatinine three days after the procedure was measured in 74 patients from the infusion group and 85 patients from the control group. In the infusion group, mean serum creatinine clearance varied from 85.7 (2.58) mL/min at baseline to 82.5 (2.62) mL/min 24 hours after coronary angiography. Corresponding values in the control group were 85.8 (2.65) mL/min and 82 (2.72) mL/min. Serum creatinine clearance values for both groups are presented in Fig. 1.

The mean overall decrease in serum creatinine clearance 24 hours after the procedure was −3.44 (0.68) mL/min. Changes in serum creatinine clearance 24 hours and three days after coronary angiography in both groups are presented in Table 3.

The mean change in serum creatinine clearance 24 hours after angiography in patients receiving antihypertensive therapy was −1.98 (1.13) mL/min in the infusion group

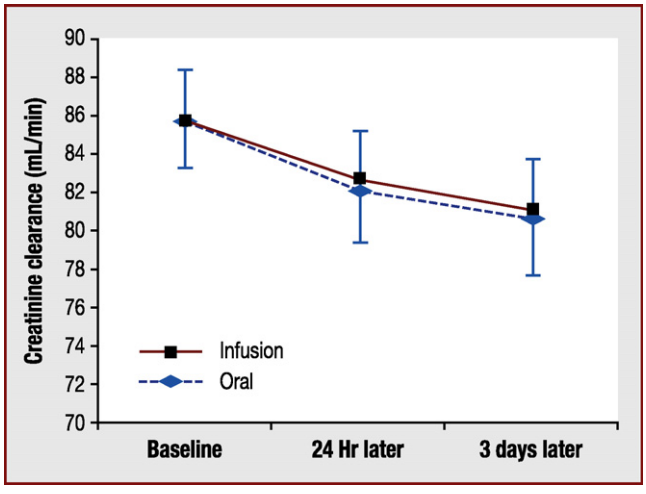

Figure 1. Serum creatinine clearance at baseline, 24 hours and three days after angiography. Error bars are the standard error of the mean.

Table 3 Changes in serum creatinine clearance 24 hours and 3 days after angiography, according to treatment group.

	Change in creatinine clearance (mL/min)[a]		Treatment effect (95% CI)	*p*
	Infusion	Control		
24 hours after angiography	−2.81 (1.07)	−4.09 (0.91)	1.28 (−1.49, 4.05)	0.38
3 days after angiography	−4.76 (1.25)	−4.73 (1.21)	−0.03 (−3.46, 3.39)	0.93

CI: confidence interval.
[a] Values are mean (standard error of the mean).

Table 4 Comparison of serum creatinine clearance before and 24 hours after angiography in the different quartiles, according to treatment group.

	Creatinine clearance (mL/min)		*p*
	Infusion	Control	
1st quartile	(*n* = 24)	(*n* = 24)	
Before angiography	54.7 (1.8)	57.2 (1.4)	
24 hours after angiography	54.4 (2.5)	54.6 (1.3)	
Change	−0.4 (1.4)	−2.6 (1.2)	0.23
2nd quartile	(*n* = 24)	(*n* = 24)	
Before angiography	73.9 (0.8)	73.5 (1.0)	
24 hours after angiography	72.2 (1.4)	71 (1.7)	
Change	−1.7 (1.0)	−2.5 (1.3)	0.62
3rd quartile	(*n* = 24)	(*n* = 24)	
Before angiography	91.2 (1.6)	89.8 (1.3)	
24 hours after angiography	89 (2.7)	86.5 (2.5)	
Change	−2.1 (2.3)	−3.3 (2.0)	0.70
4th quartile	(*n* = 25)	(*n* = 24)	
Before angiography	120.2 (2.8)	123.7 (4.0)	
24 hours after angiography	113.3 (3.9)	115.8 (4.8)	
Change	−6.9 (3.0)	−7.9 (2.4)	0.79

Values are mean (standard error of the mean).

(*n* = 44) vs −4.12 (1.58) mL/min in the control group (*n* = 37). The mean change in serum creatinine clearance 24 hours after angiography in patients receiving antidiabetic therapy was −3.31 (3.2) mL/min in the infusion group (*n* = 16) vs 0.88 (3.88) mL/min in the control group (*n* = 12).

A comparison of serum creatinine clearance before and 24 hours after angiography in the different quartiles is shown in Table 4. Twenty-four hours after the procedure, an increase in serum creatinine of more than 25% occurred in six patients (6%) in the infusion group and four patients (3.9%) in the control group. Three days after the procedure, an increase in serum creatinine of more than 25% occurred in five patients (5%) in the infusion group and seven patients (6.9%) in the control group.

Angiographically significant renal artery stenosis was found in 13 patients (nine in the infusion group and four in the control group); their mean baseline creatinine clearance of 79.05 (7.04) mL/min did not differ significantly from that of the overall population (85.76 [1.84] mL/min; *p* = 0.38). No patient required dialysis or died within 30 days after the procedure.

Discussion

Changes in serum creatinine clearance 24 hours after coronary angiography were moderate with standard oral hydration in patients without severe renal dysfunction. We found no benefit of additional intravenous hydration started at the beginning of coronary angiography in our population.

The PRECORD study is the first prospective, randomized trial evaluating intravenous hydration in patients scheduled for elective coronary angiography without preexistent chronic renal insufficiency. It is also the first study using standardized oral hydration for all patients. As expected from studies reported previously, the incidence of acute decrease in renal function was low in our population [23]. In previous studies an acute decline in renal function was generally defined as a rise in serum creatinine of more than 25% within three days of administration of radiographic contrast agents. We used calculated creatinine clearance from the formula of Cockcroft and Gault, which is a more accurate means of estimating glomerular filtration rate than

using serum creatinine concentration alone [4,24]. On inclusion, all patients had serum creatinine concentrations below 140 μmol/L (1.58 mg/dL), which was considered to reflect normal renal function. The second quartile had a serum creatinine clearance below 90 mL/min, which indicates mild renal dysfunction, and the first quartile had a serum creatinine clearance below 60 mL/min, which indicates moderate renal insufficiency. In these quartiles, the change in serum creatinine clearance 24 hours after coronary angiography did not differ significantly between groups. In accordance with previous studies we found a 5% incidence of significant acute decline in renal function (defined as a rise in serum creatinine greater than 25% above the baseline) at 24 hours and a 6% incidence at three days, with no difference between infusion and control groups.

Our study compared oral hydration with a combination of oral and intravenous hydration. Previous studies used 0.45% saline infusion at a rate of 1 mL per kilogram of body weight per hour, beginning 12 hours before angiography. In a randomized trial, hydration using 0.9% saline infusion has been shown to be more effective than 0.45% saline infusion in the prevention of acute decline in renal function after coronary angiography, even without precatheterization hydration [23]. The combination of oral and intravenous hydration has been shown to be effective in preventing acute changes in renal function in patients with mild-to-moderate renal dysfunction in a prospective, randomized trial [25]. Adequate intravenous volume expansion with isotonic crystalloid (1—1.5 mL/kg per hour) for 3—12 hours before the administration of iodinated contrast media and continued for 6—24 hours afterwards is a well established and recommended method for reducing the risk of CIN in patients with chronic renal failure [26]. In the present study, saline infusion was started only at the beginning of the procedure, and not several hours before, which decreases the potential protective effect of intravenous hydration on CIN. Therefore we cannot exclude a benefit of intravenous hydration started 3—12 hours before the procedure in our population. The volume of saline infusion and water intake was not adjusted to body weight or clinical conditions. All patients received 2000 mL of tap water after coronary angiography and the infusion group received 1000 mL of 0.9% saline infusion started at the beginning of coronary angiography. We did not observe any hydration-induced pulmonary oedema even in patients with impaired left ventricular function.

In our population, baseline-calculated serum creatinine clearance was at the 75th percentile according to population age- and sex-based standards [27]. We measured serum creatinine 24 hours and three days after coronary angiography to avoid underestimating the occurrence of radiocontrast-induced decrease in renal function [28]. Most patients were discharged within 48 hours after coronary angiography. The change in serum creatinine clearance 24 hours after coronary angiography was our major endpoint because serum creatinine was measured in the same hospital laboratory as baseline serum creatinine. Serum creatinine clearance three days after coronary angiography would have been more sensitive but it was measured in various external laboratories, leading to greater measurement variability. Absolute changes in creatinine clearance three days after coronary angiography were similar in both groups.

Our study excluded patients with preexistent chronic renal insufficiency diagnosed on the basis of baseline serum creatinine and/or past medical history. We screened for the presence of renal artery stenosis to evaluate the incidence of potential ischaemic renal disease and its influence on renal function after coronary angiography. We found a 6.5% incidence of angiographically significant renal artery stenosis in our population, which is in keeping with previously reported studies [21,29]; baseline creatinine clearance and change in creatinine clearance 24 hours after coronary angiography did not differ significantly between these patients and the rest of our population.

All patients received the same low osmolar ionic radiocontrast media that is preferred over nonionic contrast media in coronary angiography [30]. The volume of radiocontrast media and the iodine dose administered were moderate and similar to those in a recent study in comparable patient cohorts [23]. Previous studies have shown that the use of ionic radiographic contrast agent is not associated with a higher incidence of acute decrease in renal function compared with nonionic contrast agent [31].

Renal protection in coronary patients is a major concern because altered renal function in essential hypertension, advanced heart failure and after a myocardial infarction is associated with higher cardiovascular morbidity and mortality [32—34]. The expanding use of diagnostic and therapeutic coronary angiography makes it important to establish recommendations for nephroprotection, even in patients without preexistent chronic renal insufficiency. Acute radiocontrast nephropathy is not the only potential cause of renal impairment after coronary angiography. Cholesterol embolization induced by the introduction of catheters is probably underreported, but generally presents with a progressive decline in renal function a few weeks rather than a few days after the procedure [35]. There is no reason to expect that oral or intravenous hydration would prevent this late complication of coronary angiography.

Conclusion

We found no evidence of a benefit of intravenous hydration with 0.9% saline started at the beginning of coronary angiography over standard oral hydration with tap water after coronary angiography on renal function in patients with normal or mild-to-moderate renal dysfunction.

Conflicts of interest

None.

Acknowledgements

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