Acute kidney injury in patients treated for symptomatic peripheral arterial disease

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The authors hypothesized that patient experiencing CIN would have greater annual mean renal decline following endovascular interventions, compared to patients that not develop CIN.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26709

Bron

NTR

Verkorte titel CIN in patients treated with PTA

Aandoening

PAD: Peripheral artery disease CRI: Chronic renal insufficiency IC: Intermittent claudication CLI: Critical limb ischemia GFR: Glomerular filtration rate PTA: Percutaneous transluminal angioplasty CIN: Contrast induced nephropathy PCI: Percutaneous coronary intervention CKD: Chronic kidney disease

Ondersteuning

Primaire sponsor: T.A. Sigterman MD, Resident general surgery Department of Surgery

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Acute kidney injury (contrast-induced nephropathy) CIN was determined as a >25% increase of baseline creatinine level day 5 post-procedural

Toelichting onderzoek

Achtergrond van het onderzoek

Comprehensive literature has been published regarding contrast-induced nephropathy (CIN) following percutaneous coronary intervention (PCI). However, limited data is known regarding CIN after percutaneous transluminal angioplasty (PTA) in patients with symptomatic peripheral arterial disease (PAD). CIN is defined as an increase in serum creatinine by more than 25% or 44umol/L during 3 days post-operative. Contrast-induced nephropathy characteristically manifests 3 days after administration of the contrast medium, with a peak in kidney function decline 3 to 5 days after contrast administration.

Acute kidney injury can occur frequently in vascular surgery patients. Though, the wide range of definitions available for acute renal injury makes comparisons of different studies difficult. Although, the overall incidence of CIN following PCI was recently reported 14.5% in a large epidemiologic study (defined as > 25% increase in serum creatinine levels over baseline in the first 5 days). Moreover, incidence of CIN varies from 0% to 90%, depending on the presence of risk factors, most notably chronic kidney disease (CKD), diabetes mellitus and administration of high contrast volume.

Contrast-induced nephropathy is after surgery and hypotension, the third most common cause of hospital-acquired acute kidney injury. Many studies have shown that patients developing CIN have a greater risk for prolonged hospitalization, cardiovascular events and death. Furthermore, when patients with acute kidney injury require dialysis, mortality is even

higher compared to those not requiring dialysis. For example, McCullough et al. show a hospital mortality of 7.1% in CIN and 35.7% in patients who required dialysis referentie.

To the best of the authors knowledge limited literature is available on CIN in symptomatic PAD patients treated with PTA. The aim of this study was to analyze the incidence of contrastinduced nephropathy in symptomatic PAD patients undergoing PTA. Secondly, identifying risk factors associated with the development of CIN. The authors hypothesized that patient experiencing CIN would have greater annual mean renal decline following endovascular interventions, compared to patients that not develop CIN.

Doel van het onderzoek

The authors hypothesized that patient experiencing CIN would have greater annual mean renal decline following endovascular interventions, compared to patients that not develop CIN.

Onderzoeksopzet

1 Creatinine pre-procedural: (maximum 6 months prior to intervention (PTA), 2 Creatinine Post-procedural: (5 days post intervention), 3 Creatinine 30 days. (According to local post-contrast administration protocol).

2: Pre-procedural estimated glomerular filtration rate (eGFR) and one year post-procedural eGFR difference were analysed. The estimated GFR was calculated from serum creatinine using the Modification of Diet in Renal Disease (MDRD) Study equation: MDRD GFR (mL/min/1.73 m2) = $30849 \times [\text{standardised serum creatinine (micromole/L)}]$ -1.154 × [age (years)]-0.203 × 1.212 (if African American) × 0.742 (if female)6. Vital sign data closest in time and before (but within 12 months of) the index date were used for analyses.

Onderzoeksproduct en/of interventie

Endovascular procedures for symptomatic peripheral artery disease

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients presenting at the department of vascular surgery between May 1st 2013 and February 15th 2014

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria were end-stage renal disease (ESRD), no renal function test, any CTangiography or percutaneous coronary intervention in the first year of follow-up

Onderzoeksopzet

Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	350
Туре:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	16-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4783
NTR-old	NTR4921
Ander register	:

Resultaten