

Acute kidney injury in patients treated for symptomatic peripheral arterial disease

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26709

Source

NTR

Brief title

CIN in patients treated with PTA

Health condition

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

Sponsors and support

Primary sponsor: T.A. Sigterman MD, Resident general surgery

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Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Renal decline 1 year after endovascular interventions

Study description

Background summary

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 44 μ mol/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 contrast-induced 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.

Study objective

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

Study design

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: $\text{MDRD GFR (mL/min/1.73 m}^2\text{)} = 30849 \times [\text{standardised serum creatinine (micromole/L)}]^{-1.154} \times [\text{age (years)}]^{-0.203} \times 1.212 \text{ (if African American)} \times 0.742 \text{ (if female)}$ ⁶. Vital sign data closest in time and before (but within 12 months of) the index date were used for analyses.

Intervention

Endovascular procedures for symptomatic peripheral artery disease

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-05-2013

Enrollment: 350
Type: Unknown

Ethics review

Positive opinion
Date: 16-12-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4783
NTR-old	NTR4921
Other	:

Study results