Poster 73

STATCREAT Trial - Randomized controlled trial of point of care creatinine / eGFR versus standard care to reduce Contrast Induced Nephropathy (CIN) in Primary Percutaneous Coronary Intervention (PPCI) for ST elevation Myocardial Infarction (STEMI).

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Introduction

Contrast-induced nephropathy (CIN) occurs in approximately 15-20% of patients who are treated with primary percutaneous coronary intervention (PPCI) for acute ST elevation myocardial infarction (STEMI heart attack). Onset is usually within 3 days of contrast administration and creatinine usually peaks at 3 - 5 days post contrast exposure, generally normalizing within 10-21 days; however permanent damage is possible. Where there is pre-existing renal disease the effects are generally greater. It has been shown that the volume of contrast agent used is a factor in determining likelihood of CIN. CIN is associated with longer hospital stay, increased number of ITU admissions and greater mortality. Pre-PCI eGFR<60 is a good predictor of CIN. Serum Creatinine is inversely related to eGFR and can be measured at the point of care (PoC).

Study design

We aim to establish in a STEMI population under-going PPCI whether knowing the pre-procedural serum creatinine / eGFR (using a PoC analysis) leads to a decrease contrast volume use (ml) and potentially in the incidence of CIN and consequent morbidity and mortality. This will be a pilot study of 250 patients at the Essex Cardiothoracic Centre to get early data and allow us to power correctly a larger multi-centre study. 250 consecutive patients who are admitted acutely with STEMI for PPCI will be will be recruited to the study and randomized in a one-to-one fashion to the operator knowing or not knowing the renal function prior to PPCI using a PoC Creatinine / eGFR device (STATSENSOR, Nova Biomedical). Operators will be informed of the level and then proceed to perform PPCI without further input from the investigators. This sample will be taken from the initial arterial sheath sample used for baseline bloods and will not require extra venepuncture. Creatinine / eGFR will be measured as with standard care in the laboratory at 0, 24 and 72 hours. Decisions about ongoing management including that of any renal impairment will be left to the discretion of the attending doctors, and not the study team.

Primary study end points will be:

i) Volume of contrast used during the PPCI case, ii) Incidence of CIN defined as an increase of >25% or 44 μmol/L in pre-PCI serum creatinine at 72 h after PCI.

Secondary Study End Points will be:

i)Number of vessels treated, ii) need for Renal Replacement Therapy (RRT), iii) need for ITU admission, iv) Length of hospital stay, v) mortality a) in hospital b) 30 day, vi) Angiography / PCI / neither, vii) Acute pulmonary oedema or cardiogenic shock,viii) volume of IV fluids given in first 48 hours, ix) Peak troponin level during stay, x) ejection fraction as measured by inpatient echocardiogram.

Conclusion

The StatCreat AMI study will give an early indication of whether a simple point of care measurement of serum creatinine can have an impact on nephropathy associated with acute STEMI and its treatment. If improvements in 72-hour renal function and other study end points were found this would help to power a larger multicenter study to decide whether the practice should be part of the first-line management of acute STEMI. During the CPOCT conference we will present our interim data analysis.