TCT-258
Safe Limits of Contrast Vary with Hydration Volume:Prevention of Contrast-Induced Nephropathy after Coronary Angiography

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Background: There have been few studies of the prevention of contrast-induced nephropathy (CIN) on investigating the effect of intravenous hydration volume on relative safe maximum volume of contrast. This study investigated the effect of intravenous hydration volume on the safe maximum volume of contrast.

Methods: The ratios of contrast volume to creatinine clearance (V/CrCl) and hydration volume to body weight (HV/W) were determined in patients undergoing coronary angiography. Receiver-operator characteristic (ROC) curve analysis based on the maximum Youden index was used to identify the optimal cutoff for V/CrCl in all patients and in different hydration volume subgroups (HV/W < 12, > 12).

Results: Eighty-six of 3273 (2.63%) patients developed CIN. ROC curve analysis indicated that V/CrCl > 2.44 was a predictor for CIN in all patients (sensitivity = 71.6%, specificity = 70.5%, C-statistic = 0.780), and V/CrCl > 2.44 was significantly and independently related to the risk of CIN (adjusted OR: 4.157; 95% CI: 2.449-7.059, p < 0.001). Age > 75, diabetes, congestive heart failure, emergent coronary angiography, anemia, hypertension, intra-aortic balloon pump, hypotension, and the risk of 2 year death (adjusted HR: 2.629; 95% CI: 1.843-3.87, p < 0.001), even after including other clinical and procedural variables in multivariate logistic regression, the V/CrCl ratio for CIN was 1.87. In the insufficient hydration subgroup (HV/W < 12, sensitivity = 67.9%, specificity = 64.8%, C-statistic = 0.739, adjusted OR: 3.239; 95% CI: 1.312-7.995, p = 0.003) and ≥ 198 (HV/W > 12, sensitivity = 69.0%, specificity = 65.3%, C-statistic = 0.732, adjusted OR: 3.040; 95% CI: 1.640-5.633, p = 0.004).

Conclusions: Individual relative safe maximum volume of contrast during coronary angiography adjusted with different hydration volume may be more reliable even with the significant of long-term risk. We could moderately relax limits of contrast dose among patients with adequate hydration.

Table 1: Univariate Analysis and Multivariate Associations between CIN and V/CrCl for patients HV/W ≥ 12

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariate Analysis</th>
<th>Multivariate Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>V/CrCl &gt; 2.93</td>
<td>4.133 2.338-7.307</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Age ≥ 75 years</td>
<td>2.514 1.467-4.306</td>
<td>0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>3.745 2.187-6.411</td>
<td>0.0002</td>
</tr>
<tr>
<td>IABP</td>
<td>1.041 0.757-1.880</td>
<td>0.894</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8.527 4.471-16.264</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>CHF</td>
<td>5.294 1.910-14.673</td>
<td>0.001</td>
</tr>
<tr>
<td>Anemia</td>
<td>1.872 1.092-3.210</td>
<td>0.023</td>
</tr>
</tbody>
</table>

TCT-259
Prevention of Radio-Contrast Mediated Acute Renal Injury with Intravenous Sodium Bicarbonate - Results of the PRIMARY Trial

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Background: Radiocontrast-induced acute kidney injury (RAKI), is associated with increased short and long-term mortality, and poor renal outcomes. The usefulness of sodium bicarbonate (SB) compared with normal saline (NS) in preventing RAKI in patients undergoing coronary angiography with renal dysfunction is controversial. The goal of the PRIMARY study was to evaluate the 1-year and 5-year, clinical and renal outcomes of SB versus NS in preventing RAKI in patients with chronic kidney disease (CKD) stage III-IV undergoing coronary diagnostic and interventional procedures.

Methods: Three-hundred and ninety six patients (n = 396) (mean age: 67±12) (52% males) with a GFR < 60 mL/min/1.73m2, undergoing elective coronary angiography were included in the study using an iso-osmolar contrast agent. Patients were randomly randomized to receive either 154 mL/kg of intravenous (IV) SB (n = 192) or NaCl (n = 100) with 5% dextrose at 3 mL/kg for one hour before contrast administration followed by 1 mL/kg/hr for 6 hours post-procedure. Renal function was measured in all patients before, and 48 hours after contrast administration. Incidence of RAKI, hospital, 1 year and 5 year mortality and renal outcomes were compared between groups. RAKI was defined as increase in serum creatinine > 0.5 mg/dL or an increase from > 25% baseline within 48 hours after the administration of contrast.

Results: There were no statistically significant differences in each group regarding baseline demographics, medical therapy, renal function or co-morbidities, contrast volume used, hydration volume pre- and post-procedure, coronary artery severity, incidence of revascularization and ejection fraction. No significant differences between groups were noted in the incidence of RAKI [25 (13%) treated with SB vs. 31 (16%) with NS (p = 0.89)]. The in-hospital mortality, 1 or 5 year mortality or need for renal replacement therapy was not statistically different between groups.

Conclusions: In patients with stage III-IV CKD undergoing diagnostic and/or interventional coronary angiographic procedures, the use of SB as is effective as NS in preventing RAKI, with similar in-hospital, 1 and 5 year mortality and need for renal replacement therapy.

TCT-260
Abstract Withdrawn

TCT-261
Long-Term Prospective Outcome Analysis in High-Risk Patients for Contrast-Induced Acute Kidney Injury

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Background: Contrast-induced acute kidney injury (CI-AKI) is associated to increased morbidity, mortality, health costs and prolonged hospitalization. Common definitions of CI-AKI: a relative increase in Serum Creatinine (SCr) of at least 25% from the baseline values (definition 1), an absolute increase in SCr concentration of at least 0.5 mg/dL (definition 2), and an absolute increase in SCr of at least 0.3 mg/dL (definition 3), all presenting within 48-72 hours. This study has two main aims: a) to prospectively describe the long-term outcomes in a population at high-risk of CI-AKI development b) to clarify which definition of CI-AKI correlates best with long-term events.

Methods: Monocentric, prospective, observational registry enrolling patients undergoing coronary angiography with at least one of: age ≥ 75; diabetes; stages 2 or 3 chronic kidney disease (CKD); ST or STEMI. Biochemical determinations were assessed at baseline under preventive hydration and 12, 24, 48 and 72 hours thereafter. Blood examinations were repeated also at 1 month and subsequently every 6 months after discharge. Primary clinical end-point was a composite of death, MI and need for dialysis.

Results: We enrolled 216 patients (72% males; mean age 70 years) followed for a median of 1121 days. Thirty-nine patients (18.1%) developed CI-AKI by definition 2 and 37 (17.1%) by definition 3. 20% of patients had baseline mild/moderate renal dysfunction (GFR < 60 mL/min/1.73m2), while 46.7% were diabetics. At complete FU we observed 10 CV deaths (4.6%), 5 non-CV deaths (2.3%), 9 (4.2%) MI, 7 (3.2%) major strokes and 6 (2.8%) need for chronic dialysis. At Cox-regression only CI-AKI assessed by definition 3 predicted primary EPE (p = 0.04; HR: 2.168; 95% CI: 1.193-4.734). Renal impairment persisted at 30 days in 40.5% of CI-AKI patients and was associated with worst long-term outcome (p < 0.001; HR: 4.758; 95% CI: 2.039-11.100).

Conclusions: High-risk CI-AKI patients had 13.9% primary EPE at 3-years. An absolute increase in SCr of at least 0.3 mg/dL seems within 72s the most clinically useful CI-AKI definition. Persistent renal damage at 30 days correlates with poorer outcomes.

TCT-262
Comparison of Target Lesion Revascularization in Patients with Renal Insufficiency after Sirolimus-eluting Stent and Everolimus-eluting Stent Implantation: Three-year Outcomes from Single-center Retrospective Study

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Background: Everolimus-eluting stent (EES) is one of the most commonly used newer generation drug-eluting stent (DES) in clinical practice. However, the relative merits of EES against the previous gold-standard sirolimus-eluting stent (SES) for patients with renal insufficiency (RI) have been less extensively assessed. We aimed to evaluate the three-year outcomes after SES and EES implantation for patients with RI.

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Methods: A total of 1926 patients underwent the first SES implantation between November 2002 and December 2006 and 651 patients underwent the first EES implantation between January 2010 and December 2010, whose target lesion revascularization (TLR) were investigated by telephone follow-up, examining medical records, and asking family physicians. The patients were stratified into 4 groups according to their estimated glomerular filtration rate (eGFR): Group I, eGFR < 60 ml/min/1.73m² (mild-moderate RI); Group II, eGFR < 60 and ≥ 30 ml/min/1.73m² (mild-moderate RI); Group III, eGFR < 30 ml/min/1.73m² and not on hemodialysis (HD) (severe RI without HD); and Group IV, renal failure treated with HD (severe RI with HD).

Results: The figure shows the cumulative incidence of TLR at 3 years in all cases and group IV. Complete 3-year follow-up was achieved in 99.6% of SES (1919/1926) and 96.2% of EES (626/651). The cumulative incidence of TLR after EES implantation tended to be lower than that after SES implantation in group I (log rank p < 0.001), II (log rank p < 0.001) and III (log rank p = 0.073).

Conclusions: EES might reduce the cumulative incidence of TLR at long term follow up, except for the patients with HD.

TCT-263
Not Early Change in Serum Level Cystatin C, but Baseline Serum Cystatin C Level Predicted Contrast Induced Nephropathy and Cardiovascular Mortality
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Background: Cystatin C has emerged as a sensitive biomarker of renal function. Early change in cystatin C based glomerular filtration rate (CysC-GFR) has been reported to predict contrast induced nephropathy (CIN). We evaluated whether baseline and 24-h change in CysC-GFR after percutaneous cardiovascular intervention using contrast medium (CM) can serve as a prognostic marker of CIN and cardiovascular mortality.

Methods: We evaluated 597 patients who underwent elective coronary (n=240) and peripheral (n=240) intervention from 2010 September to 2013 August at Severance Cardiovascular Hospital, Seoul, Korea. CIN was defined as increased > 25% and/or ≥ 0.5 mg/dl in serum creatinine at 48-h after intervention compared from baseline. Cystatin C and serum creatinine levels were measured before and at 24-h after the procedure. Receiver operating characteristic (ROC) curve with area under the curve (AUC) value was calculated for prediction of CM related mortality.

Analysis and Cox proportional hazards regression analysis were used to find risk factors of cardiovascular mortality.

Results: Increment of cystatin C level at 24-h from baseline was not able to predict CIN. AUC value of 10.20, and 30% increment of Cystatin C levels were 0.51, 0.53, and 0.50, respectively. However, baseline CysC-GFR < 60 ml/min showed highest superior prediction of CIN (AUC 0.68, 95% Confidence Interval 0.65 – 0.72, P < 0.0001) followed by contrast amount > 200cc (AUC 0.64, P = 0.0003), baseline modification of diet in renal disease (MDRD) GFR < 60 ml/min (AUC 0.63, P = 0.0005). Although 24-h change in CIN CysC-GFR was not associated with cardiovascular mortality, baseline Cystatin C-GFR < 60 ml/min, baseline MDRD-GFR < 60 ml/min, age ≥ 75 years were associated with increased cardiovascular mortality by Kaplan-Meier survival curve analysis. In multivariate Cox regression analysis, only baseline CysC-GFR < 60 was a significant predictor of cardiovascular mortality (hazard ratio 4.1, 95% CI 1.54 – 15.65, P = 0.0075).

Conclusions: Baseline CysC-GFR < 60 was a significant predictor of CIN and cardiac mortality after cardiovascular intervention and early change of cystatin C showed no benefit for CIN prediction or cardiac mortality.

TCT-264
Impact of different definitions on prevalence of contrast induced nephropathy in patients undergoing transcatheter aortic valve implantation
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Background: Recentely the Valve Academic Research Consortium (VARC) adopted the Acute Kidney Injury (AKIN) system in the place of the Risk, Injury, and Failure, Loss and End-stage kidney disease (RIFLE) system to define acute kidney injury (AKI) following transcatheter aortic valve implantation (TAVI). In this study, we sought to assess different definitions in prognostic accuracy between the two systems in our real-world retrospective population of patients undergoing TAVI.

Methods: In the present study, 239 consecutive patients undergoing transfemoral TAVI were prospectively enrolled. AKI was defined: (1) according to the AKIN system as a post-procedural creatinine increase of ≥ 0.3 mg/dl; or (2) according to the RIFLE system as a post-procedural decrease of the creatinine clearance of at least 25%.

Results: Both AKIN and RIFLE system definitions were significantly associated to one-year mortality (binary logistic regression, respectively: (1) OR 3.2, 95%CI 1.5-6.9, P = 0.003; and (2) OR 8.5, 95%CI 3.9-18.4, P < 0.001). However, the prognostic accuracy of RIFLE was higher (AUC 0.704; P = 0.001) as with respect to AKIN (AUC 0.602; P = 0.037) for the primary end-point of one-year mortality.

Conclusions: In a non-selected patient population undergoing TAVI, the RIFLE system had a higher prognostic accuracy in comparison to the currently proposed AKIN system.

TCT-265
Contrast induced acute kidney injury in patients undergoing transcatheter aortic valve implantation – interaction with left ventricular ejection fraction
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Background: The prognostic relevance of direct contrast toxicity in patients undergoing transcatheter aortic valve implantation (TAVI) remains unclear, due to the confounding hemodynamic effect of acute left ventricular ejection fraction (LVEF) impairment on kidney function estimation.

Methods: In the present study, 239 consecutive patients undergoing transfemoral TAVI were prospectively enrolled. Contrast induced acute kidney injury (CI-AKI) was defined according to the VARC-2 criteria as a post-procedural creatinine increase of ≥0.3 mg/dl.

Results: While LVEF and creatinine values at admission were not significantly associated to CI-AKI, their interaction term significantly defined CI-AKI (P = 0.033). The long-term survival (1.7±1.4 years) was significantly lower in the CI-AKI patient group (log-rank 5.1, p = 0.025). In the Cox-regression multivariate model analysis CI-AKI was an independent predictor of mortality (HR 2.2, 95%CI 1.1-4.7, P = 0.034), along with LVEF (HR 0.97, 95%CI 0.95-0.99, P = 0.012).

Conclusions: In a non-selected patient population undergoing TAVI, CI-AKI was confirmed as an independent predictor of clinical outcome. Interestingly, only the interaction between LVEF and baseline creatinine values was found to determine CI-AKI.

Drug-Eluting Balloons and Local Drug Delivery
Washington Convention Center, Lower Level, Hall A
Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 266-289

TCT-266
PEPCAD-DES: A randomized, multicenter, single blinded trial comparing paclitaxel coated balloon angioplasty with plain balloon angioplasty in drug-eluting stent restenosis – 3 year results
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Background: We evaluated the impact of paclitaxel-coated balloon angioplasty for treatment of drug-eluting stent restenosis compared with uncotted balloon angioplasty alone.

Methods: In this prospective, single-blind, multicenter, trial we randomly assigned 110 patients with In-stent Restenosis of drug eluting stents to undergo treatment either with paclitaxel coated balloon (SeQuest Pleaze, B.Braun, Melsungen) or balloon angioplasty alone. Primary endpoint was in-stent late lumen loss at 6 months.