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Effect of a Contrast Modulation System on Contrast Media Use and the Rate of Acute Kidney Injury After Coronary Angiography

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ABSTRACT

OBJECTIVES The aim of the AVERT (AVERT Clinical Trial for Contrast Media Volume Reduction and Incidence of CIN) trial was to test the efficacy of the AVERT system to reduce the contrast media volume (CMV) used during coronary angiographic procedures without impairing image quality and to prevent contrast-induced acute kidney injury (CI-AKI) in patients at risk for CI-AKI.

BACKGROUND CI-AKI is a common complication of percutaneous coronary procedures, associated with increased morbidity and mortality. The AVERT system alters the coronary injection pressure profile by diverting contrast away from the patient during coronary injection.

METHODS The AVERT trial was a prospective, multicenter, 1:1 randomized clinical trial in 578 subjects with either baseline estimated glomerular filtration rate 20 to 30 ml/min/1.73 m^2 or estimated glomerular filtration rate 30 to 60 ml/min/1.73 m^2 and at least 2 additional risk factors for CI-AKI. Patients undergoing coronary angiography with planned or possible percutaneous coronary intervention (PCI) were randomized to hydration plus the AVERT system ($n = 292$) or hydration only ($n = 286$). The primary effectiveness endpoints were: 1) the total CMV used; and 2) the incidence of CI-AKI, defined as a ≥0.3 mg/dl increase in serum creatinine within 5 days post-procedure.

RESULTS Patient demographics were well balanced between the groups, with mean baseline serum creatinine of 1.6 ± 0.4 mg/dl and 64.9% patients with diabetes mellitus. PCI was performed in 42.2% of procedures, with coronary angiography in the remainder. Use of AVERT resulted in a 15.5% relative reduction in CMV overall (85.6 ± 50.5 ml vs. 101.3 ± 71.1 ml; $p = 0.02$) and a 22.8% relative reduction in CMV among PCI patients (114 ± 55 ml vs. 147 ± 81 ml; $p = 0.001$). The maximum relative reduction in CMV was 46% (124 ± 48 ml vs. 232 ± 97 ml; $p = 0.01$) when ≥3 lesions were treated. There were no differences in the rates of CI-AKI (27.0% vs. 26.6%; $p = 0.70$) between the study groups.

CONCLUSIONS Use of the AVERT system was feasible and safe, with acceptable image quality during coronary angiography and PCI. AVERT significantly reduced CMV, with the extent of CMV reduction correlating with procedural complexity. No significant differences in CI-AKI were observed with AVERT in this trial. (AVERT Clinical Trial for Contrast Media Volume Reduction and Incidence of CIN [AVERT]; NCT01976299) (J Am Coll Cardiol Intv 2018;11:1601–10)

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ABBREVIATIONS AND ACRONYMS

CI-AKI = contrast-induced acute kidney injury

CKD = chronic kidney disease

CMV = contrast media volume

eGFR = estimated glomerular filtration rate

PCI = percutaneous coronary intervention

RR = relative reduction

sCr = serum creatinine

Contrast-induced acute kidney injury (CI-AKI) is the most common cause of iatrogenic renal failure in patients undergoing percutaneous coronary intervention (PCI) (1). The prevalence of CI-AKI in the general population after PCI is approximately 10% to 12% but can reach 20% to 30% in patients with prior chronic kidney disease (CKD) (2,3), with the rate depending in part on the definition used for CI-AKI (4,5). Treatment of CI-AKI is limited to supportive measures and usually results in prolonged hospitalization and higher health care costs (6). In addition, development of CI-AKI is associated with increased short- and long-term morbidity and mortality (7). Models have been developed to stratify the risk for CI-AKI on the basis of baseline and procedural characteristics such as prior CKD, diabetes, age, hypotensive state, heart failure, anemia, and contrast media volume (CMV) used (8). In patients at moderate or high risk for CI-AKI, every effort should be made to remove modifiable risk factors and implement preventive strategies to avoid renal damage.

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Prophylactic measures for CI-AKI include periprocedural hydration, use of low osmolar contrast medium, and reducing the CMV used during the procedure (9,10). The CMV used is an independent predictor of CI-AKI, and there is no specific threshold of contrast medium exposure below which the risk is eliminated (8). The AVERT system (Osprey Medical, Minnetonka, Minnesota) consists of a contrast modulator for manual contrast medium injections that adapts the coronary injection pressure profile to minimize CMV. The AVERT (AVERT Clinical Trial for Contrast Media Volume Reduction and Incidence of CIN) trial tested the efficacy of the AVERT system to reduce the CMV used during coronary angiographic procedures without impairing image quality and to prevent CI-AKI in patients at risk for CI-AKI.

METHODS

The AVERT trial was a prospective, randomized, parallel group, multicenter clinical study that compared periprocedural hydration alone with periprocedural hydration plus procedural use of the AVERT system in patients at risk for CI-AKI undergoing coronary angiography with or without PCI (NCT01976299). The trial was designed by the principal investigator and executive committee and was sponsored by Osprey Medical. The study was reviewed and approved by Institutional Review Boards at all participating sites, and all patients provided informed written consent.

STUDY POPULATION. Consecutive patients ≥18 years of age who were undergoing coronary angiography with or without PCI and who were at increased risk for CI-AKI were considered for enrollment. Patients were enrolled with non–ST-segment elevation myocardial infarction, unstable angina, stable angina with positive stress test results, and silent ischemia. Patients were considered at risk for CI-AKI if baseline estimated glomerular filtration rate (eGFR) was between 20 and 30 ml/min (stage IV CKD) or if eGFR was between 30 and 60 ml/min (stage III) and 2 or more of the following CI-AKI risk predictors were present: New York Heart Association functional class III or IV criteria for heart failure, insulin-treated diabetes or type 2 diabetes on oral medications, albuminuria (≥2+ on urine dipstick), anemia (hemoglobin <12 g/dl in women and <13 g/dl in men), hypertension, and age ≥75 years. Principal exclusion criteria included acute renal failure or unstable renal function as evidenced by a change in serum creatinine (SCr) of >0.5 mg/dl or >25% within 7 days; contrast medium exposure within 7 days with change in SCr ≥0.1 mg/dl on 2 SCr measures ≥24 h apart; inability to receive periprocedural hydration; dialysis; use of nephrotoxic agents (aminoglycoside antibiotics, sulfonamides, amphotericin B, or pentamidine); need for >10 ml of iodinated contrast medium in any location other than the coronary arteries (e.g., ventriculography, aortography, renal angiography) during the procedure or within a period of 30 days after

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