Effect of the AVERT Contrast Modulation System on Contrast Dose Reduction and Acute Kidney Injury After Coronary Angiography and PCI

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Background

Contrast-Induced acute kidney injury (CI-AKI) during coronary angiography is associated with increased morbidity and mortality. Minimizing contrast media volume (CMV) in patients at risk of AKI is a critical preventive measure. The AVERT™ system alters the coronary injection pressure profile resulting in a reduction in net contrast delivery. We performed a randomized trial to evaluate whether using the AVERT reduces CMV administration and the rate of CI-AKI without reducing image quality during angiographic procedures.

Methods

AVERT (NCT01976299) was a prospective, multicenter 1:1 randomized, clinical trial in 578 subjects at risk for CI-AKI undergoing coronary angiography with or without PCI. The treatment arm (n=292) included hydration + AVERT while the control arm (n=286) included hydration only. Primary objectives were 1) to assess total CMV used, and 2) to determine the incidence of CI-AKI defined as a 0.3 mg/dl increase in serum creatinine within 72 hours post-procedure.

Results

Subject demographics were well balanced between the 2 groups. Mean baseline serum creatinine (SCr) was 1.6 ± 0.4 mg/dL, and 64.9% of patients had diabetes mellitus. Of the 568 subjects evaluable for CIN, PCI was performed in 239 (42.2%). Use of AVERT resulted in a 15.5% relative reduction (RR) in CMV in all patients (86 ± 51 ml vs. 101 ± 71 ml, p=0.002), and a 22.8% RR in CMV for PCI patients (114 ml ± 55 vs 147 ± 81 ml, p=0.001). There were no significant differences in CI-AKI (27.0% vs 26.2%, p=0.72) or adverse event rates between the two groups. A post-hoc subgroup analysis of subjects (n= 470) with an eGFR between 40-60 ml/min who did not have significant protocol deviations related to hydration or renal function measurements, revealed a 49.5% RR in CI-AKI (21.5% vs 14%, P=0.020) in the AVERT arm.
when using a SCr increase of 0.5 ml/dl or 25% from baseline as the CI-AKI definition.

Conclusion

The AVERT System was safe and reduces CMV injection significantly during coronary angiography and PCI while maintaining adequate image quality. Use of this device did not result in a significant reduction of CI-AKI, however a post-hoc sub-group analysis shows a significant reduction in CI-AKI in patients with eGFR 40-60 ml/min.

Other Information

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