MD CONFERENCE ONLINE
LECTURE ESSENTIALS

Lecture Notes

American College of Cardiology 60th Annual Scientific Session & i2 Summit

Renal Insufficiency Following Contrast Media Administration Trial II (REMEDIAL II): RenalGuard™ System In High-Risk Patients for Contrast-Induced Acute Kidney Injury

Sponsor: Clinica Mediterranea

Clinical Trial #: NCT01098032

Background

Contrast-induced acute kidney injury (CI-AKI) is strongly associated with unfavorable early and late clinical outcomes in patients. Maintaining a high urine flow mitigates risk. Forced diuretic regimens (typically with high-dose furosemide) may cause a harmful negative fluid balance.

Hypothesis

The RenalGuard™ hydration system would be noninferior to a control hydration strategy of prophylactic sodium bicarbonate plus N-acetylcysteine to prevent CI-AKI in high risk and very high risk patients with chronic kidney disease.

Study Design

- Randomized
- Multicenter
- Prospective

Subject Characteristics

- n=294
- Mean age 75 years
- Approximately 33% women
- 100% hypertensive
- 70% diabetic
- 50% on ACE inhibitors
- Mean eGFR 32 ml/min/1.73 m^2

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Primary Endpoint

- The rate of CI-AKI, defined as an increase of ≥0.3 mg/dL in serum creatinine (sCr) concentration 48 hours after the procedure

Secondary Endpoints

- Increase in serum creatinine (sCr) concentration ≥25% and ≥0.5 mg/dL at 48 hours post contrast exposure
- Changes in serum cystatin concentration at 24 an 48 hours post contrast exposure
- Rate of acute renal failure requiring dialysis
- Rate of in-hospital and 1-month major adverse events

Results

- The percentage primary endpoint occurred in 11% in the RenalGuard™ group and 20.5% in the control group (OR, 0.47; 95% CI, 0.24 to 0.92; p=0.025); translating into an absolute risk difference of 8.5%, or a number needed to treat of 12 to prevent 1 patient with a 10% rise in creatinine after contrast exposure
- Increase in sCr concentration at 48 hours occurred in 2.7% in the RenalGuard™ group versus 13% in the control group (p=0.001)
- Change in creatinine and cystatin C at 48 hours were significantly reduced
- At one month 0.7% of the RenalGuard™ group required dialysis versus 4.8% in the control group (p=0.013; number needed to treat of 25 to prevent 1 patient requiring dialysis

Conclusion

Data from REMEDIAL II demonstrate that among patients who are at high risk for contrast nephropathy, the aggressive hydration and matched fluid balance achieved with the RenalGuard™ system (in conjunction with NAC and furosemide) were superior to hydration with sodium bicarbonate plus NAC in preventing contrast-induced serum creatinine increases.

Further Reading

http://clinicaltrials.gov/ct2/show/NCT01098032?term=NCT01098032&rank=1