THE SAFETY AND TOLERABILITY OF REGADENOSON IN PATIENTS WITH END-STAGE RENAL DISEASE: THE FIRST PROSPECTIVE EVALUATION

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Background: Regadenoson (REG) appears to be safe in patients with end-stage renal disease (ESRD) on the basis of two retrospective studies. A prospective, placebo-controlled clinical trial by Palani et al found REG to be safe in chronic kidney disease (CKD) stage III-IV. However, there has not been a prospective study addressing the safety and tolerability of REG in ESRD.

Methods: The ASSUAGE and ASSUAGE-CKD trials are randomized, double-blinded, placebo-controlled clinical trials comparing the use of 75mg IV aminophylline vs. placebo administered 2 minutes post-REG in subjects undergoing myocardial perfusion imaging. Both studies are identically designed, except that ASSUAGE-CKD is limited to subjects with severe CKD while ASSUAGE was not limited to CKD. We pooled the placebo arms (rather than aminophylline) from both trials to study the safety and tolerability of REG in subjects with ESRD [hemodialysis, peritoneal dialysis, or GFR<15] vs. those with GFR ≥ 30.

Results: From both trials we identified 243 subjects who underwent standard REG stress; among those 145 with ESRD and 98 with GFR ≥ 30. ESRD subjects were younger (57 vs. 63, p < 0.05). Those with GFR ≥ 30 had a mean GFR of 92 (±44) ml/min. Diarrhea was more frequent in the ESRD group (24% vs. 9%, p < 0.05). There was no difference in the incidence of any other REG side effects (p > 0.05). ESRD subjects had higher baseline systolic blood pressures (SBP) (151 vs. 143, p<0.05). Compared to baseline, there was no difference in SBP, DBP or heart rate change at 30 seconds and at 3 minutes post REG (all p > 0.05). There was no difference in the incidence of hypotension (1.5% vs. 3%, p > 0.05) or supraventricular tachyarrhythmias. The ESRD group had higher incidence of transient 1st and 2nd degree AV block (13% vs. 3%, p< 0.05). There were no events of 3rd degree AV block, ventricular tachycardia, cardiac arrest or bronchospasm in either study group.

Conclusion: This study is the first prospective investigation confirming the safety and tolerability of REG in patients with ESRD. Except for an increase in the incidence of diarrhea and low-grade AV block, there were no significant differences in the incidence of adverse effects in subjects with ESRD vs. those with GFR ≥ 30.