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Comparison of GI Toxicity Associated with AA Formulations Co-Infused With PRRT: Commercial Parenteral Nutrition Formula versus Compounded L-Lysine/L-Arginine

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BACKGROUND: Renal reabsorption of radiolabeled somatostatin analogs can be decreased by co-infusion of positively charged amino acids (AA). Different AA solutions have been used with Peptide receptor radionuclide therapy (PRRT) for that purpose. We hypothesized that AA infusion containing only the essential L-Lysine and L-Arginine would be significantly less toxic than the AA-containing solutions used for parenteral nutrition.

METHODS: Retrospective study of two cohorts of patients with metastatic GEP-NETs treated at our center with PRRT using 177Lu-DOTATATE: one cohort receiving treatment on an early access program (EAP) using Clinisol® 15% sulfite AA 2 L (9 essential and 8 non-essential AA) and another cohort treated subsequent to FDA approval who received the compounded formulation Aminoprotect® containing only L-Lysine HCl 2.5%/L-Arginine HCl 2.5%, 1L. Clinical information related to gastrointestinal symptoms during administration of AA infusion and MAR were reviewed to identify adverse reactions and PRN medications given. Chi Squared tests were used to compare AEs.

RESULTS: 20 patients treated on the EAP program with Clinisol® 15% were compared to the first 29 consecutively treated patients who received Aminoprotect®. There were 69 infusions in the Clinisol group and 115 infusions

in the Aminoprotect group. Most common GI side effect during AA infusion in each group was nausea. In the Clinisol group, 75.4% (52/69) of infusions caused nausea, 69.6% (48/69) requiring antiemetics, while in the Aminoprotect group 5.2% (6/115) of AA infusions caused nausea, 2.6% (3/115) requiring antiemetics ($p<0.05$). All 20 patients in Clinisol group experienced nausea during at least one of their AA infusions. In the Aminoprotect group, 20.7% (6/29) of patients had nausea during any AA infusion with 10.3% (3/29) needing medication.

CONCLUSION: AA infusion containing L-lysine/L-arginine has significantly better GI tolerance than commercial parenteral nutrition formulas containing numerous AA. We recommend the use of L-lysine/L-arginine infusions during PRRT in order to decrease acute GI toxicity.