

**ABSTRACTS**

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### **Crofelemer Improves Acute Infectious Diarrhea Symptoms**

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**Background:** Crofelemer (C) a novel antidiarrheal drug inhibits CFTR-mediated Cl<sup>-</sup> secretion from intestinal epithelial cells. In prior studies C was well tolerated, with improvement in travelers' diarrhea, and diarrhea in AIDS patients. We report results using C in adult patients (pts) with acute diarrhea (AD). **Methods:** A prospective, randomized, double-blind, placebo (P)-controlled study in hospitalized adults with AD defined as  $\geq 3$  unformed stools the day preceding enrollment was conducted. Exclusions: chronic or bloody diarrhea, fever  $> 39^{\circ}\text{C}$ , dehydration requiring i.v. fluids, need for antimicrobial, antidiarrheal drugs. Pts received oral C 250mg q6h or P until recovery or 3 days, and oral rehydration solution. Primary endpoints: stool weight, frequency, consistency, duration of diarrhea. Secondary endpoints: clinical symptoms scored as total of 7-item GI index. Clinical success = no diarrhea within 48 hrs from study start. Treatment failure = no improvement/worsening of symptoms after 24 hrs, fever, bloody stools or dehydration. **Results:** 98 pts (51C, 47P) enrolled; 16 pts (4C, 12P) used antibiotics and were excluded from per protocol efficacy analysis. Groups were similar in age, weight, vital signs, stool frequency, consistency, dehydration, GI index. C group had improvement over

baseline and compared to P at day 3: stool weight (38% vs 13%), frequency (70% vs 28%), % pts with watery stools (4% vs 46%), improved GI index (72% C vs 48% P), all  $p < 0.05$ .

C was well tolerated with no related serious adverse events or concerning changes in lab values. Progression to dehydration and report of fecal incontinence was more common in P group ( $p < 0.05$ ). **Conclusions:** Clinical success (no diarrhea within 48 hrs of 1<sup>st</sup> dose) was 79% C and 28% P ( $p < 0.05$ ). Crofelemer demonstrated improvements from baseline and compared to P for stool weight, frequency, watery stools, dehydration, and total GIS (all  $p < 0.05$ ).