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Title: *In vivo* evaluation of properties of a new medical device against intestinal commensals with uropathogenic potential

Maïwenn Olier, Soraya Sekkal, Cherryl Harkat, Hélène Eutamène, Vassilia Theodorou, Lionel Bueno[†].

UMR 1331 Toxalim, INRA/INPT/UPS, Neuro-Gastroenterology and Nutrition Group, Toulouse, France. [†] Deceased

Background: Based on protecting intestinal mucosa properties, a cross-linked protein compound, is a new medical device for the control and prevention of urinary tract infections. Considering that intestinal microbiota is a common immediate source of uropathogens, we evaluated the antagonistic activity of this product to limit the intestinal commensal bacterial communities with uropathogenic potential in feces of treated rats, decreasing their contact with the intestinal mucosa.

Methods: Female Wistar rats were orally fed for 4 days either with the product (7500 mg kg^{-1}, day^{-1}, p.o) or vehicle (water plus Na_2CO_3, p.o). *E. coli* population and other *Enterobacteriaceae* such as *Klebsiella spp., Enterobacter ssp., Serratia ssp., Citrobacter ssp.* (named collectively KESC), *Enterococcus ssp.* or *Proteeae ssp.* were enumerated from feces collected throughout the course of the experiment by using selective chromogenic agar plates. Monitoring of fecal *E. coli* levels was additionally performed in streptomycin-pre-treated rats highly colonized with a streptomycin-resistant human commensal O1:K1 *E. coli* strain sharing some common genetic traits of archetypal uropathogenic *E. coli* strains. **Results:** The treatment with the product resulted in a significant reduction of fecal endogenous *E. coli* (2.89+/-0.61 *vs.* 4.04+/-0.09 Log_{10} CFU/g feces, $p<0.05$) and *Enterococcus* spp. (3.77+/-0.29 *vs.* 5.24+/-0.12 Log_{10} CFU/g feces, $p<0.01$) levels without

affecting other detected fecal opportunistic uropathogens. Antagonistic property of the product was additionally confirmed in feces of rats highly colonized with the O1:K1 *E. coli* strain (5.09+/-0.25 *vs.* 6.56+/-0.33 Log_{10} CFU/g feces, $p<0.001$).

Conclusion: A cross linked protein product through its ability to reduce the risk of urinary tract infections by altering intestinal niche occupied by opportunistic uropathogens such as *E. coli* or *Enterococcus spp* may be a promising candidate in the management of urinary infections.