

## #60 - EFFECT OF AN-PEP PROTEASE ON INVOLUNTARY GLUTEN INTAKE AND SYMPTOMS IN THE REAL-LIFE OF PATIENTS WITH CELIAC DISEASE ON A GLUTEN-FREE.

<https://doi.org/10.46613/congastro2023-60>

Stefanolo J<sup>1</sup>, Segura V<sup>2</sup>, Grizzutti M<sup>1</sup>, Heredia A<sup>2</sup>, Comino I<sup>2</sup>, Costa A<sup>1</sup>, Puebla R<sup>1</sup>, Temprano M<sup>1</sup>, Niveloni S<sup>1</sup>, de Diego G<sup>3</sup>, Oregui M<sup>1</sup>, SMECUOL E<sup>1</sup>, De Marzi M<sup>3</sup>, Verdú E<sup>4</sup>, Bai J<sup>5</sup>

<sup>1</sup>Hospital de Gastroenterología "Dr. C. Bonorino Udaondo", Buenos Aires, Argentina <sup>2</sup>University of Seville, Sevilla, España <sup>3</sup>National University of Lujan, Luján, Argentina <sup>4</sup>Mc Master University, Hamilton, Canadá <sup>5</sup>Del Salvador University, Buenos Aires, Argentina

**Background/Aim:** To examine the effects of orally administered *Aspergillus niger* endopeptidase (AN-PEP) on inadvertent gluten exposure and symptom prevention in real-life patients with celiac disease (CeD) consuming a gluten-free diet (GFD).

**Methods:** This exploratory, double-blind, randomized, placebo-controlled trial enrolled patients with CeD. After four-week run-in period, patients were randomized to 4-week treatment with 2 AN-PEP capsules at each of 3 meals/day, or placebo. AN-PEP capsule contained 325 mg of 70% AN-PEP (GliadinX. AVI Research LLC; USA). Outcome endpoints were the changes in 1- the stool gluten immunogenic peptides (GIP) concentrations; 2- the Celiac Symptom Index (CSI); 3- CeD-specific serology and, 4- the quality of life. During run-ins and treatments, samples were collected for GIP measurement by ELISA (Biomedal S.L., Seville, Spain) every Tuesday and Friday.

**Results:** 40 patients were randomized to the intention-to-treat analysis. Overall, 628/640 (98.1%) possible stool samples were collected. GIP was undetectable (<0.08 µg/g) in 65.6% of samples without differing arms. Only 0.5% of samples had isolated stool GIP concentrations sufficiently high (>0.32µg/g) to cause mucosal damage potentially. Compared with the run-in period, the median GIP concentration in the AN-PEP arm was 44.7% lower after treatment. Furthermore, 35.6% of patients in AN-PEP had an average stool GIP >0.180 µg/g reduced (>50% of run-in concentrations) or exhibited undetectable GIP after treatment. The AN-PEP significantly reduced the proportion of patients with a CSI >38 (severe symptoms) compared to the run-in (*McNemar*: p<0.03). Treatments did not detect changes in the specific serology.

**Conclusions:** This exploratory study, conducted in a real-life setting, revealed that patients exhibited high adherence to the GFD. Specifically, patients with an average stool GIP >180 µg/g during the run-in period experienced reduced gluten exposure when consuming AN-PEP and a significantly lower prevalence of more severe symptomatic cases by AN-PEP treatment.