PTU-051 ★

IS *TRITICUM MONOCOCCUM* A COELIAC-SAFE WHEAT? A PHASE II, SINGLE BLIND, CROSS-OVER STUDY ON THE EFFECT OF ACUTE ADMINISTRATION ON INTESTINAL PERMEABILITY

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Introduction Atoxic, widely available, unexpensive cereals retaining dough properties for production of palatable baked goods for gluten free diet (GFD) of CD patients are actively researched. *Triticum monococcum* ssp monococcum (Tm) is an ancient wheat with virtually absent toxicity in vitro[1] and ex vivo.[2] The aim of our study was to investigate the 'in vivo' effect of a single dose of gluten of Tm (cultivar Monlis), in patients with CD on GFD.

Methods We performed a phase II, single blind, cross-over study in CD patients on GFD for at least 12 months. Patient were randomly assigned to receive at day 0, 14 and 28 a single 2.5 g dose of rice, Tm and *Triticum aestivum* (Ta) flour mixed with gluten-free pudding. The primary end-point of the study was the change in intestinal permeability as assessed by changes of urinary lactulose/rhamnose ratio (L/R ratio) measured by HPLC. We also assessed the occurrence of adverse events graded for intensity and duration (WHO scale). Variables expressed as mean ± SEM; paired t test and χ^2 test used as appropriate.

Results 12 CD patients were enrolled in the study. The urinary L/R ratio was 0.058 ± 0.03 with rice flour, 0.048 ± 0.02 with Tm and 0.063 ± 0.015 with Ta. Differences did not reach statistical level of significance. Gastrointestinal adverse events were 11, 8 and 31 with rice, Tm and Ta, respectively. Eight gastrointestinal events occurred during Tm administration, a value similar to that observed with rice (n = 11). In all cases events were graded as 'mild' or 'moderate'. By contrast 31 adverse events were reported during Ta administration, a value significantly higher than that observed with Tm and with rice (table 1). In four cases events during Ta administration were graded 'severe' or 'disabling'. Among extraintestinal adverse events, headache was reported in 13 cases and malaise in 3 cases, equally distributed among the 3 flours.

Table 1 PTU-051 Gastrointestinal events during acute administration of rice, Triticum (T) monococcum and T aestivum

	Rice	T monococcum	T aestivum
Abdominal pain	1	2	7
Bloating	2	1	11
Diarrhoea	2	–	–
Taste impairing	1	–	2
Nausea	5	5	9
Vomiting	–	–	2
Total events	11	8	31*

*p <0.0001.

Conclusion Administration of a single 2.5 g dose of Tm to CD patients did not cause changes in urinary L/R ratio relative to that observed following administration of rice, the non toxic reference flour. Tm was well tolerated by all patients thus providing the rationale for further investigation on the safety of this cereal for CD patients. By contrast Ta caused a significant number of gastrointestinal side effects that in four cases were severe, but did not alter significantly urinary L/R ratio indicating that this method is not sensitive enough for acute toxicity studies.

Competing interests None.

Keywords COELIAC DISEASE, Gluten free diet, *Triticum monococcum*.

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