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## Clinical impact of whey protein and nutritional counseling in gastrointestinal cancer patients

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**Background:** Malnutrition frequently affects gastrointestinal (GI) cancer patients. It is known how protein supplementation could prevent loss of lean body mass and sarco-penia. Therefore, we present a placebo-controlled study, to explore the effect and safety of whey proteins in GI cancer patients.

**Methods:** Patients with GI cancer referred for 5-fluorouracil based chemotherapy, without metabolic alteration, were considered eligible. After informed consent was obtained, they were blind-randomized 1:1 to whey protein (PROLYOTIN®) (arm A) vs placebo (arm B). Patients were assessed, before chemotherapy, after 3 and 6 months, on a physical-nutritional examination, Body Impedance Assessment, MNA® and MUST questionnaire. At the same time frames, tumor characteristics, dietary practices and laboratory values were collected by a specialist team of medical oncologists and dieticians.

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**Results:** Forty subjects with a median age of 65.53 years old were included in this preliminary analysis. Baseline patients characteristics were well balanced between the two arms (A and B) for age, sex, localization and stage of disease, clinical status, nutritional condition and laboratory values (Vitamin D proved to be insufficient in both groups:17,3 ng/ml in A and 15,4 ng/ml in B). After three months of chemotherapy, 32 patients were reevaluated. Overall, no patient was found underweight or malnourished, nor were any differences in blood analysis. Meanwhile, clinical and anthropometric parameters (PS ECOG= 0: 89% A vs 59% B; lean body mass 69,7 % to 71,8% A vs 67,6% to 63,6% B, p value=0,013), nutritional status (MNA>27=34% to 100% A vs 42% to 65% B, p value=0,001) and toxicity (hematological: no adverse effects 86% A vs 29% B, p value 0,005; gastrointestinal: 94% A vs 29% B, p value 0,001) resulted to be significantly different between the two groups.

**Conclusions:** The nutritional counselling and whey proteins intake during chemotherapy showed a significant benefit in nutrition, performance status and treatment tolerability in GI cancer patients. However, further studies are needed to improve the knowledge of whey protein protective role against chemotherapy toxicity and to select more accurately those patients who may benefit from a preventive whey protein supplements.

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