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Effects of High-Dose Pancreatic Enzyme Replacement Therapy on Body Weight, Nutritional Status, and Quality of Life after Pancreaticoduodenectomy

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Introduction : This study aimed to investigate the effects of pancreatic enzyme replacement therapy (PERT) on body weight, nutritional status and quality of life (QoL) in patients with acute-onset pancreatic exocrine insufficiency (PEI) after pancreaticoduodenectomy

Methods : In this randomized, double-blind, multicenter trial, pancreaticoduodenectomy patients with fecal elastase level ≤200 μg/g at preoperative or postoperative examination were randomly assigned. The PERT group received a single capsule of 40000 IU pancreatin (Norzyme®) thrice a day during meal for 3 months. Protocol completion was defined as taking more than two thirds of the total dose without taking other digestive enzymes. The primary endpoint was body weight change. The secondary endpoint was changes in bowel habits, nutritional parameters, and QoL.

Results : Among 304 patients, 151 and 153 were assigned to the PERT and placebo groups, respectively. From these groups, 71 and 93 patients completed the protocol, respectively. In the per-protocol set, the PERT and placebo groups achieved a weight gain of 1.09 kg and weight loss of 2.28 kg at 3 months, respectively, with significant difference in weight (3.37 kg) between both groups ($p<0.001$). However, no difference was observed in the intention-to-treat set. The prealbumin level showed significant difference (+10.9 mg/dL vs. +7.8 mg/dL, PERT vs. placebo, $p=0.002$). Poor compliance to PERT was a significant risk factor for weight loss ($p<0.001$). Furthermore, no difference in QoL scores according to PERT was noted.

Conclusions : As a nutritional support, PERT increases weight and nutritional parameters in postoperative patients with PEI. Active education and monitoring are important to maximize effectiveness.

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