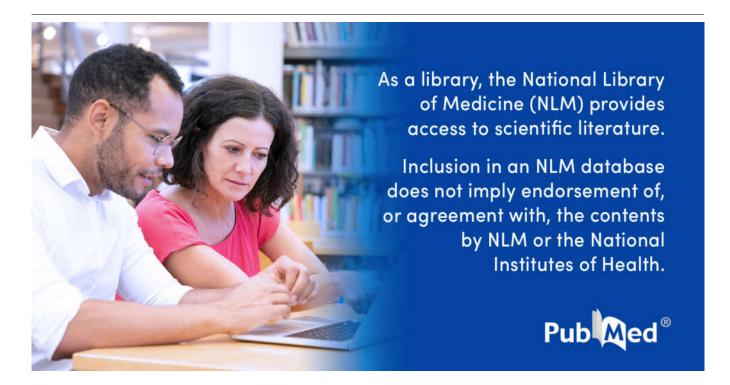
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Abstract

Systemic enzyme therapy was recently subjected to experimental investigations and to rigorous clinical studies in cancer patients. The designs of the relevant clinical cohort studies followed the guidelines of Good Epidemiological Practice and represent level IIB in evidence-based medicine (EBM). Scientifically sound experimental in vitro and in vivo investigations are far advanced and document promising immunological, anti-inflammatory, anti-infectious, and antitumor/antimetastatic activities of proteolytic enzyme mixtures (containing trypsin, chymotrypsin, and papain) or bromelain. EBM level II clinical studies, which are accepted by the European Union to show safety and efficacy of medical treatments, were performed to evaluate the benefit of complementary systemic enzyme therapy in cancer patients suffering from breast and colorectal cancers and plasmacytoma. These studies demonstrated that systemic enzyme therapy significantly decreased tumor-induced and therapy-induced side effects and complaints such as nausea, gastrointestinal complaints, fatigue, weight loss, and restlessness and obviously stabilized the quality of life. For plasmacytoma patients, complementary systemic enzyme therapy was shown to increase the response rates, the duration of remissions, and the overall survival times. These promising data resulted in an "orphan drug status" designation for a systemic enzyme product, which should motivate further studies on this complementary treatment.

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