

## **Pycnogenol may alleviate adverse effects in oncologic treatment.**

### **Clinical Trial**

Belcaro G, et al. Panminerva Med. 2008.

### **Abstract**

**AIM:** A large variety of adverse reactions are well known to frequently occur during chemotherapy and radiotherapy in oncology. Specific medications exist to target individual side effects. The aim of this study was to explore in a pilot trial whether supplementation with French maritime pine bark extract Pycnogenol could alleviate side effects and improve patient's quality of life.

**METHODS:** Cancer patients who previously underwent surgery and who were in view of their pathology in relatively good condition, both physically and psychologically, were recruited for this study and divided into two groups. These patients received their first cycle of radiotherapy or chemotherapy, which lasted from 10 days up to 1 month. Then one group of patients received 150 mg Pycnogenol, the control group comparable placebo in a single-blinded fashion. The authors studied the occurrence of side effects and made attempts to judge their severity on a semi-quantitative visual analogue scale over a 2 months period starting after patients completed their first cycle of chemo- or radiotherapy, respectively.

**RESULTS:** Twenty five radiotherapy patients receiving Pycnogenol showed a decreased frequency of essentially all investigated side-effects as compared to 21 patients receiving placebo, though in many categories the difference was limited. The most apparent improvements of acute side effects related to decreased soreness and ulceration in the mouth and throat as well as less dryness of the mouth and the eyes. A decreased incidence of nausea /vomiting, diarrhoea, edema and weakness was noticed, which was reflected by semi-quantitative evaluation suggesting that severity was only half or even less pronounced than in the control group. Only one case of deep vein thrombosis occurred in the Pycnogenol group whereas 2 cases of superficial vein thromboses and one case of deep vein thrombosis occurred in the control group (2.9% vs 10%). Thirty four chemotherapy patients were supplemented with Pycnogenol and another 30 patients were in the control group. For all patients this was the first chemotherapy treatment period. The Pycnogenol group presented with a lowered incidence of all investigated side effects as compared to the control group, though in many cases to a limited extent. The most prominent improvements were found for nausea, vomiting, diarrhoea and weight loss. Semi-quantitative evaluation showed that here again symptom severity was half or less pronounced than in the control group. Various further symptoms improved such as cognitive impairment and also cardiotoxicity and neutropenia. Effects on anemia could not be investigated as several patients received erythrocyte transfusion. In the Pycnogenol group one case of superficial vein thrombosis was indentified while 3 cases of superficial vein thromboses and one deep vein thrombosis were detected in the control group (4% vs 19%). In both chemotherapy

and radiotherapy patients Pycnogenol lowered the requirement for medication to address side effects. This was reflected by less days of hospitalisation the patients required. The authors did not investigate a possible interference with the anti-neoplastic efficacy of chemo- and radiotherapy. This possibility requires attention in future studies with Pycnogenol. From their previous clinical experience the authors suggest that alleviation of side effects described in this study results from Pycnogenol activities related to endothelial protection, and anti-inflammatory anti-edema activities.

**CONCLUSION:** The results of this pilot trial warrant further prospective studies with larger number of patients to validate benefits more specifically with regard to type of malignancy and treatment regimen.

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