

## **Biotherapy with the pineal immunomodulating hormone melatonin versus melatonin plus aloe vera in untreatable advanced solid neoplasms.**

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The possibility of natural cancer therapy has been recently suggested by advances in the knowledge of tumor immunobiology. Either cytokines such as IL-2, or neurohormones, such as the pineal indole melatonin (MLT), may activate anticancer immunity. In addition, immunomodulating substances have also been isolated from plants, particularly from Aloe vera. Preliminary clinical studies had already shown that MLT may induce some benefits in untreatable metastatic solid tumor patients, whereas, for the time being, no clinical trial has been performed with aloe products. We have carried out a clinical study to evaluate whether the concomitant administration of aloe may enhance the therapeutic results of MLT in patients with advanced solid tumors for whom no effective standard anticancer therapies are available. The study included 50 patients suffering from lung cancer, gastrointestinal tract tumors, breast cancer or brain glioblastoma, who were treated with MLT alone (20 mg/day orally in the dark period) or MLT plus A. vera tincture (1 ml twice/day). A partial response (PR) was achieved in 2/24 patients treated with MLT plus aloe and in none of the patients treated with MLT alone. Stable disease (SD) was achieved in 12/24 and in 7/26 patients treated with MLT plus aloe or MLT alone, respectively. Therefore, the percentage of nonprogressing patients (PR + SD) was significantly higher in the group treated with MLT plus aloe than in the MLT group (14/24 vs. 7/26,  $p < 0.05$ ). The percent 1-year survival was significantly higher in patients treated with MLT plus aloe (9/24 vs. 4/26,  $p < 0.05$ ). Both treatments were well tolerated. This preliminary study would suggest that natural cancer therapy with MLT plus A. vera extracts may produce some therapeutic benefits, at least in terms of stabilization of disease and survival, in patients with advanced solid tumors, for whom no other standard effective therapy is available.

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