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[Efficacy and safety of long-term complementary treatment with standardized European mistletoe extract (*Viscum album L.*) in addition to the conventional adjuvant oncologic therapy in patients with primary non-metastasized mammary carcinoma. Results of a multi-center, comparative, epidemiological cohort study in Germany and Switzerland]

[Article in German]

Bock PR, Friedel WE, Hanisch J, Karasmann M, Schneider B.

Institut für Angewandte Gesundheitsforschung, IFAG Basel AG, Basel, Schweiz.

OBJECTIVES: The purpose of the study was to evaluate the therapeutic efficacy and safety of long-term complementary therapy in primary, non-metastatic mammary carcinoma patients in UICC stage I-III with a standardized European mistletoe extract (*Viscum album L.*, Iscador, "mistletoe extract") given in addition to conventional adjuvant oncologic therapy (i.e. chemo-, radio-, and hormonal therapy; "conventional therapy"). **METHODS:** The multicenter, comparative, retrospective, pharmaco-epidemiological cohort study with parallel groups design and randomly selected centers was carried out according to Good Epidemiological Practice (GEP) rules. The test group patients received subcutaneous mistletoe extract injections for at least three months in addition to the conventional therapy, while the control group was treated with conventional therapy only. The patients were followed up for at least three years or until death. The primary endpoint for efficacy was the overall incidence of adverse drug reactions (ADRs) attributed to the conventional therapy. Secondary endpoints were symptoms associated with disease and treatment, as well as the survival. All end-points were adjusted to baseline imbalance, therapy regimen and other confounders by the logistic regression or the Cox proportional hazard regression. Safety was assessed by the number of patients with ADRs attributed to the mistletoe extract treatment, the ADR severity and the evaluation of a possible tumor enhancement. **RESULTS:** 1442 patients (710 tests and 732 controls) were eligible for the "per protocol" analysis of efficacy and safety. At baseline, the mistletoe extract group had a more advanced disease and worse prognostic factors profile. After a median follow up

of 67 vs. 61 months, and a median mistletoe extract therapy duration of 52 months, significantly fewer test group patients (16.3%) than control patients (54.1%) developed one or more ADRs attributed to the conventional therapy (adjusted odds ratio (95% confidence interval, CI): OR = 0.47 (0.32-0.67), $p < 0.001$). In the mistletoe extract group, several symptoms more frequently disappeared, and the overall estimated survival was significantly longer (adjusted mortality hazard ratio (95% CI): HR = 0.46 (0.22-0.96), $p = 0.038$). Systemic ADRs attributed to the mistletoe extract treatment developed 0.8%, and local ADRs 17.3% of the patients. The ADR severity was mild to intermediate (WHO/CTC grade 1-2). Severe mistletoe extract therapy-related ADRs or tumor enhancement were not observed. **CONCLUSIONS:** The results of the present study confirmed the safety of the complementary therapy of patients with primary, non-metastatic mammary carcinoma with a standardized mistletoe extract and showed considerably fewer ADRs attributed to concurrent conventional therapy, as well as reduced disease and treatment-associated symptoms, and suggested a prolonged overall survival in the mistletoe extract group as compared with controls.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

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