Prevention of palmar-plantar erythrodysesthesia with an antiperspirant in breast cancer patients treated with pegylated liposomal doxorubicin (SAKK 92/08).

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BACKGROUND:
Elevated concentrations of doxorubicin are found in eccrine sweat glands of the palms and soles. We therefore evaluated an antiperspirant as preventive treatment for palmar-plantar erythrodysesthesia (hand-foot syndrome) in patients with metastatic breast cancer treated with pegylated liposomal doxorubicin.

PATIENTS AND METHODS:
An antiperspirant containing aluminum chlorohydrate or placebo cream was applied to the left or right hand and foot in a double-blinded manner (intra-patient randomization). The primary endpoint was the rate of grade 2 or 3 palmar-plantar erythrodysesthesia. A secondary endpoint was the patient-reported symptom burden (tingling, numbness, pain, or skin problems). Using McNemar's matched pairs design, 53 patients were needed to detect a 20% difference between the treatment and placebo sides with a significance level of 5% and power of 90%.

RESULTS:
Grade 2 or 3 PPE occurred in 30 (58%) of 52 evaluable patients; in six patients adverse effects occurred on the placebo side but not on the treatment side, whereas one patient developed palmar-plantar erythrodysesthesia on the treatment side only (P = 0.07). Four patients developed grade 2 or 3 palmar-plantar erythrodysesthesia on their foot on the placebo side but not on the treatment side (P = 0.05). In the cohort with grade 2 or 3 palmar-plantar erythrodysesthesia there was a trend towards fewer dermatologic symptomatologies with the active treatment (P = 0.05), and no difference for other adverse events.

CONCLUSION:
Using topical aluminum chlorohydrate as an antiperspirant appears to reduce the incidence of grade 2 or 3 palmar-plantar erythrodysesthesia following pegylated liposomal doxorubicin chemotherapy for metastatic breast cancer.