Ginger in the management of chemotherapy-induced nausea and vomiting (CINV), in patients receiving high dose cisplatin: a multicenter, randomized, double-blind, placebo-controlled study

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Background: The activity of ginger in CINV has been suggested, but design inadequacies, heterogeneity of the population, poor quality of tested products, and lack of dose-finding studies limit the possibility to offer generalizable results.

Materials and methods: This was a randomized, double-blind, placebo-controlled, multicenter study in patients planned to receive ≥3 chemotherapy cycles with high dose (>50 mg/m²) cisplatin. Concomitant radiation was allowed. Patients received ginger (G) 160 mg/day (with standardized dose of bioactive compounds) or placebo (P) in addition to the standard antiemetic prophylaxis for CINV, starting from the day after cisplatin administration. CINV was assessed through daily visual analogue scale and FLIE questionnaires. The main objective was protection from delayed nausea; secondary endpoints included intercycle nausea, and nausea anticipatory symptoms.

Results: The trial enrolled 251 patients (125 G, 126 P), mainly with lung (49%) or head and neck cancer (HNC, 35%); 154 (61%) subjects completed the study treatment. No differences were reported in terms of safety profile or compliance. The incidence of delayed nausea did not differ between the 2 arms in the 1st cycle (67%G vs 66%P) and 2nd cycle (72% vs 66%). A benefit of ginger over placebo was observed in FLIE nausea score differences (day 6-day 1) in females (p = 0.048) and HNC patients (p = 0.038).

Conclusions: In patients treated with high dose cisplatin, the daily addition of ginger, even if safe, did not result in a significant protective effect on CINV. The favorable effect observed on nausea in subgroups at particular risk of nausea (females; HNC) deserves specific investigation.

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