JL05. Efficacy and Safety of the Granisetron Transdermal System (GTS) in Elderly Patients Receiving Multiday Chemotherapy Regimens

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Background: Chemotherapy-induced nausea and vomiting (CINV) is a common side effect of multiday chemotherapy that can lead to poor adherence, decreased quality of life, and compromised functional status. Commonly used routes of administration of antiemetics, such as oral and intravenous, are accompanied by a number of challenges. Elderly patients compound challenges with oral agents due to the added risk of nonadherence owing to dementia or impaired vision. This analysis examined the impact of age on the efficacy and safety of a transdermal antiemetic, the Granisetron Transdermal System (GTS), in elderly cancer patients receiving multiday chemotherapy. A published, randomized phase III trial (N = 641) demonstrated the noninferiority of GTS vs. oral granisetron in complete CINV control in adult patients receiving multiday chemotherapy and served as the basis of its FDA approval in the prevention of CINV in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration. *Methods*: This post-hoc analysis divided patients from the previously reported phase III study into three age categories: < 50 years of age, 50–64 years of age, or ≥ 65 years of age (defined as elderly). The primary endpoint was the percentage of patients achieving complete control of CINV (no vomiting and/or retching, no more than mild nausea, and no use of rescue medication) from the first administration until 24 hours after final administration of chemotherapy. Additional endpoints were the use of rescue medication; the percentage of patients achieving complete response (no vomiting and/or retching, no rescue medication); patients' global satisfaction with antiemetic therapy (assessed using a 10-cm visual analog scale (VAS) at the time of patch removal); and safety. *Results*: A total of 621 patients were included, 142 of whom were elderly. There were no statistically significant differences in baseline characteristics between treatment groups. No significant differences were found in complete control rates, complete response, use of rescue medication, or patients' global satisfaction with antiemetic treatment between the GTS and oral granisetron treatment groups regardless of age. GTS was well tolerated with mild side effects; gastrointestinal disorders were the most common study drug-related treatment-emergent adverse events in each age subgroup of the GTS-treated population. *Conclusion*: This post-hoc analysis showed the efficacy and safety of GTS were maintained in all age subgroups, suggesting that GTS is an appropriate antiemetic agent for a wide range of ages including the elderly.