Evaluation of the effect of intravenous calcium and magnesium (CaMg) on chronic and acute neurotoxicity associated with oxaliplatin: Results from a placebo-controlled phase III trial.

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Abstract:

Background: Cumulative sNT is the dose-limiting toxicity of oxaliplatin which commonly leads to early discontinuation of oxaliplatin-based therapy in the palliative and adjuvant setting. We recently demonstrated the protective effect of CaMg against oxaliplatin-induced sNT as assessed by NCI-CTC (Nikcevich ASCO 2008). It is unclear, though, if CaMg reduced acute and/or chronic, cumulative sNT. Methods: 104 pts with colon cancer undergoing adjuvant therapy with FOLFOX were randomized to IV CaMg (1g calcium gluconate plus 1g magnesium sulfate pre- and post-oxaliplatin) or placebo (PL) in a double-blinded manner. NCI-CTC, an oxaliplatin-specific sNT scale and patient-reported outcome (PRO) questionnaires were used to differentially assess the effect of CaMg on acute (effect on sNT on days 1-4 after oxaliplatin) and chronic sNT (area between curves over whole course of therapy). Results: A total of 102 pts (50 CaMg, 52 PL; 96 mFOLFOX6, 6 FOLFOX4) were available for analysis. Apart from a strong reduction in muscle cramps with CaMg (p=0.002), no difference was found between CaMg and PL in PRO with regard to items reflecting acute sNT (e.g. sensitivity to cold, swallowing of cold liquids, throat discomfort) on days 1-4 after oxaliplatin and chronic sNT (area between curves over whole course of therapy). In contrast, CaMg was able to significantly reduce cumulative sNT in form of numbness in fingers (p=0.02), impaired ability to button shirts (p=0.05), tingling in fingers (p=0.06), and muscle cramps over the course of therapy (p=0.01). Conclusions: In our phase III, placebo-controlled trial, CaMg was able to significantly reduce chronic, cumulative sNT related to oxaliplatin as evaluated by specific PRO questionnaires. No effect was noted on phenomena associated with acute sNT. CaMg can be recommended as neuroprotectant against oxaliplatin-related chronic sNT, oxaliplatin’s dose-limiting toxicity.

Abstract Disclosures
Faculty and Discussant Disclosures
Annual Meeting Planning Committee Disclosures
2009 Annual Meeting Proceedings Part I Errata

Other Abstracts in this Sub-Category:
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