13. The effect of ginkgo biloba and panax ginseng on driving ability: A pilot study

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Background: Driving under the influence of xenobiotics is an important national safety issue. Panax ginseng and Gingko biloba are commonly used supplements in the United States whose use has been reported to increase alertness and cognitive function. The objective of this study was to investigate the effects of these specific herbals on driving ability.
Methods: Twelve volunteers were tested using the STISIM3® Driving Simulator (Systems Technology Inc., Hawthorne, CA) in this double-blind, placebo-controlled study. The subjects were randomized into 3 groups of 4 subjects per group. After 10-minutes of simulated driving, subjects received either ginseng (1200 mg), gingko (240 mg), or placebo administered orally. The test herbals and placebo were randomized and administered by a research assistant outside of the study to maintain blinding. One hour following administration of the blinded herbals or placebo, the subjects completed an additional 10-minutes of simulated driving. Standard driving parameters were studied including reaction time (RT), standard deviation of lateral positioning (SDLP), and divided attention (DA). Data collected for the DA parameter included time to response and number of correct responses. The data was analyzed with repeated-measures analysis of variance (ANOVA) using SPSS 20 (IBM, Armonk, NY).
Results: The results are shown in Table 1. Improvement in RT was demonstrated in the ginseng group however, the results were not statistically significant ($p = 0.251$). There was no improvement in SDLP within the three groups. Improvement was demonstrated in DA in all three groups with regard to time to response and number of correct responses. The ginseng group demonstrated the greatest improvement with regard to time to response and number of correct responses. However, the intergroup differences were not statistically significant ($p = 0.197$ and $p = 0.059$ respectively).
Conclusion: The data suggests that ginseng and ginkgo may improve certain parameters of driving ability without negatively impacting overall driving performance. However, the results reported herein do not rise to statistical significance. We postulate this is due to the relatively small numbers in our pilot study. Further study with a larger sample size is planned in order to elucidate more fully the effects of ginkgo and ginseng on driving ability.
Keywords: Herbals, Driving, Public health

Table 1.

	Reaction Time (seconds)		Standard Deviation of Lateral Positioning (feet)		Divided Attention Time to Response (seconds)		Divided Attention Number of Correct Responses	
Group	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Placebo	0.96	0.91	0.92	1.93	3.17	2.46	6.25	7.50
Ginseng	1.41	1.22	0.58	0.75	3.45	2.17	6.00	9.25
Gingko	1.67	1.81	0.53	0.66	2.71	2.12	7.75	8.25

14. Impact of ethanol on integrity of the sustained release properties of Avinza®

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Background: Sustained-release medications allow for once- or twice-daily dosing of selected drugs that would otherwise require more frequent dosing. Several years ago the Food and Drug Administration (FDA) issued a warning that ethanol enhances the release of morphine from the sustained-release capsules Avinza®. To the best of our knowledge, the data demonstrating this effect have not been published. As a preliminary aspect of a larger study examining the potential impact of polyethylene glycol solutions on the integrity of sustained-release morphine products and given the absence of published data we first undertook a confirmation of the FDA–based warning.
Methods: Simulated gastric fluid was prepared. 100 mL of simulated gastric fluid was mixed with either 100 mL of water (control) or 100 mL of 40% ethanol (final solution 20% ethanol) and placed in an agitated heated water bath to 37° C. One Avinza® 90 mg tablet was added to each flask and 1 mL samples were obtained at 30, 60 and 90 minutes. A total of five duplicate comparisons (control and ethanol) were utilized. Specimens were stored @ - 70° C until assay. After solid phase extraction, morphine concentrations were measured with a triple quadrupole GC/MS/MS operated in the Multiple Reaction Monitoring (MRM) mode. Comparative analyses were conducted by two separate statisticians to assure results confirmation.
Results: Ethanol dramatically increased the rate of release of morphine from this proprietary tablet over the time frame studied. Within 30 minutes there was over a 100% increase in free morphine in the presence of 20% ethanol compared to control ($p < 0.01$). At 90 minutes nearly 50% of the available morphine had been released into the gastric/ethanol solution compared to less than 12% in the control solution ($p < 0.0001$).
Conclusions: These results vividly confirm the FDA's warning of loss of sustained-release properties when Avinza® is taken with ethanol. The potential impact of ethanol (and possibly other solvents like PEG) on the sustained-release properties of medications-particularly the impact on time related alterations of concentration curves- needs to be considered when managing an overdosed patient. Further investigation into the effect of polyethylene glycol solution on the integrity of sustained release morphine products is being investigated to determine whether this therapeutic intervention alters the tmax of sustained-release opioids.
Keywords: Pharmacokinetics, Alcohol, Opioid

15. Epidemiology of patients in whom levamisole was detected in comprehensive urine drug screens

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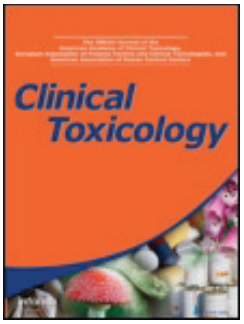

Clinical Toxicology

ISSN: 1556-3650 (Print) 1556-9519 (Online) Journal homepage: http://www.tandfonline.com/loi/ictx20

2014 Annual Meeting of the North American Congress of Clinical Toxicology (NACCT)

To cite this article: (2014) 2014 Annual Meeting of the North American Congress of Clinical Toxicology (NACCT), Clinical Toxicology, 52:7, 682-818, DOI: 10.3109/15563650.2014.940163

To link to this article: https://doi.org/10.3109/15563650.2014.940163

Published online: 04 Aug 2014.

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