ADOLESCENTS IN KARACHI: A CLUSTER RANDOMIZED TRIAL

Among 14 (74%) women who completed the study, average daily alcohol consumption and health outcomes in women with HIV. Although enrollment of HIV-infected women into alcohol treatment trials can be challenging, we demonstrated that these challenges can be minimized by recruiting from previously established long term cohorts that directly address alcohol consumption. Health outcome, especially alcohol consumption reduction, reported in this study will provide valuable input for future decision making and evaluation of the cost-effectiveness of using pharmacotherapy targeting hazardous drinking among HIV patients.

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Drugs Associated with Adverse Drug Events in Children: Analysis of the United States FDA Adverse Event Reporting System Database

METHODS: Adverse drug events reported to the US FDA AERS Database between 1 January 2007 and 30 June 2012 and occurring in children and adolescent (<18 years old) were examined. Demographic characteristics of the patients and severity of the adverse drug events described by age, gender and reporter type. Additionally, the most commonly suspected drugs and the most frequently occurring adverse events in the AERS database were identified. RESULTS: We identified 46,655 drug-related reports (average 16,469 reports/year) of primary suspect medications in children, of which 60.8% were for individuals < 12 years old and 50.6% were males. Physicians (30.5%) and consumers (27.4%) reported the majority of pediatric adverse drug events. Methylerphedate was the most frequently reported drug with 3,755 (4.2%) reports, followed by inhaled (3.0%) and isosorbin (2.7%). Vomiting (1.3%), pyrexia (1.2%), convulsion (1.1%), drug ineffective (1.0%) and product quality issue (0.9%) were the top five reported adverse events. Pyrexia and hypogonadism became the fourth and fifth leading adverse events respectively when restricting our analysis to only severe events (i.e., resulting in hospitalization, life-threatening events, or death). CONCLUSIONS: Data from post-marketing surveillance of adverse events can add to our understanding of drug safety in children. A large proportion of events reported to the FDA are not considered severe and focusing solely on severe events is likely important to identify potential high risk medications. Subsequent analyses of the most commonly reported drug causes of severe adverse events may lead to important safety questions.

A Pilot Study of Pharmacotherapy (Naltrexone) for Hazardous Drinking Among Women Infected with HIV

OBJECTIVES: Pharmacological treatment is effective in reducing hazardous drinking in persons with alcohol dependence, while little is known whether it is effective in HIV patients. The purpose of this study was to examine feasibility and effectiveness of using pharmacotherapy (naltrexone) on women infected with HIV. METHODS: The NIAAA-sponsored pilot study was a double-blind, randomized controlled trial. Women with HIV who met criteria for NIAAA-defined past-year hazardous drinking were recruited from HIV clinical settings in Jacksonville (FL) and the Women’s Interagency HIV Study (WIHS) in Chicago (IL) and Washington DC. Participants were randomized 2:1 to oral naltrexone (50mg) or placebo for 4 months; outcomes were assessed 2, 4 and 7 months after enrollment. RESULTS: From December, 2010 to February, 2012, 19 women were enrolled (mean age 48.8 years, 95% African American). Approximately 70% of eligible women were successfully enrolled at two WIHS sites, compared with 12% at the clinical site in Jacksonville (FL). Almost all women reported prior use of other drugs (heroin, 3; methadone, 3; cocaine, 13; marijuana, 14; tobacco, 16). Among those who completed the study, average daily alcohol consumption dropped significantly from 7.13 standard drinking units (SDUs) at baseline to 0.46 SDUs at month 7. CONCLUSIONS: Although the sample is small, this pilot study demonstrates the feasibility of conducting a larger study to determine the impact of naltrexone on alcohol consumption and health outcomes in women with HIV. There is no safe range for Blood Lead Levels (BLL) in humans. Lead exposure is associated with many adverse health outcomes in children because of more susceptibility to environmental lead. We aimed to explore a convenient and cost-effective strategy for decreasing BLL among adolescent with the objective to assess the effect of Ascorbic-acid on BLL among school going adolescent of Karachi. METHODS: A cluster randomized trial was conducted in schools, consisting of Ascorbic acid 250mg or 500mg (in 6 clusters each) BLL was measured at baseline and after four weeks of intervention. Lead exposure was assessed through a questionnaire at baseline and dietary Vitamin-C through Food Frequent Questionnaire at follow-up. The difference between the groups calculated through independent t-test and within group difference through paired t-test. A multiple-linear-regression model was built for analyzing causal variable and factors that may affect the outcome. The overall mean BLL at baseline was 12.9mg/dl (95%CI; 12.2-13.8). For Ascorbic-acid 250mg and 500mg it was 13.4mg/dl (95%CI, 12.1-14.7) and 12.5mg/dl (95%CI; 11.7-13.4) respectively. The mean decline in BLL was 2.7mg/dl (p<0.002) and 3.2mg/dl (p<0.001) in 250mg and 500mg respectively. The mean difference in BLL decline between two group was 0.6mg/dl (p=0.824). On an average, for one mg/dl increase in baseline BLL, the decreased was 0.8mg/dl after adjusting for clustering and school of school point and intervention group (p<0.001). CONCLUSIONS: The overall mean baseline BLL of our sampled population was above the acceptable level recommended by CDC (10mg/dl). Oral supplementation of Ascorbic-acid in both 250mg & 500mg significantly decreased BLL. However, the drug-dependent decline in BLL was greater (3.2mg/dl) for participants who had initially elevated BLL showed greater decline at follow-up. Thus, using Ascorbic-acid 250mg or 500mg daily could be a cheap, safe and easily available strategy to lower BLL among adolescent particularly those living in highly exposed areas.

Prevalence, Incidence, and Treatment Rates of Hypogonadism in Men Across Geographical Areas: A Systematic Literature Review

OBJECTIVES: To conduct a systematic literature review to assess the prevalence, incidence, and treatment rates of hypogonadism in men across geographies. METHODS: The literature search was undertaken within the PubMed/MEDLINE, Embase, and Cochrane databases for articles published between 1992 and 2012. Articles were excluded from this review if the sample size was less than 30. RESULTS: We reviewed 175 citations/abstracts and identified 109 relevant articles. Numerous cut-off points for testosterone level were used to define hypogonadism; however, the most widely used definitions were total testosterone <300 ng/dL (10.4 nmol/L) and free testosterone <5ng/dL (<0.174nmol/L). Few studies used the combination of symptoms and testosterone level cut-off points to define hypogonadism. The prevalence, incidence, and treatment rates of hypogonadism were described by generic names. The percentage of prescriptions with an injection(s) and antibiotic(s) were 85.9% and 68.6%, respectively. CONCLUSIONS: This study has provided real-time evidence that the prescribers in public teaching hospital were aware of the NLEM-2003. There are areas in addition to this, which require consolidation to promote rational drug therapy.

Effect of Ascorbic Acid on Blood Lead Levels Among School Going Adolescents in Karachi: A Cluster Randomized Trial

OBJECTIVES: There is no safe range for Blood Lead Levels (BLL) in humans. Lead exposure is associated with many adverse health outcomes in children because of more susceptibility to environmental lead. We aimed to explore a convenient and cost-effective strategy for decreasing BLL among adolescent with the objective to assess the effect of Ascorbic-acid on BLL among school going adolescent of Karachi. METHODS: A cluster randomized trial was conducted in schools, consisting of Ascorbic acid 250mg or 500mg (in 6 clusters each) BLL was measured at baseline and after four weeks of intervention. Lead exposure was assessed through a questionnaire at baseline and dietary Vitamin-C through Food Frequent Questionnaire at follow-up. The difference between the groups calculated through independent t-test and within group difference through paired t-test. A multiple-linear-regression model was built for analyzing causal variable and factors that may affect the outcome. The overall mean BLL at baseline was 12.9mg/dl (95%CI; 12.2-13.8). For Ascorbic-acid 250mg and 500mg it was 13.4mg/dl (95%CI, 12.1-14.7) and 12.5mg/dl (95%CI; 11.7-13.4) respectively. The mean decline in BLL was 2.7mg/dl (p<0.002) and 3.2mg/dl (p<0.001) in 250mg and 500mg respectively. The mean difference in BLL decline between two group was 0.6mg/dl (p=0.824). On an average, for one mg/dl increase in baseline BLL, the decreased was 0.8mg/dl after adjusting for clustering and school of school point and intervention group (p<0.001). CONCLUSIONS: The overall mean baseline BLL of our sampled population was above the acceptable level recommended by CDC (10mg/dl). Oral supplementation of Ascorbic-acid in both 250mg & 500mg significantly decreased BLL. However, the drug-dependent decline in BLL was greater (3.2mg/dl) for participants who had initially elevated BLL showed greater decline at follow-up. Thus, using Ascorbic-acid 250mg or 500mg daily could be a cheap, safe and easily available strategy to lower BLL among adolescent particularly those living in highly exposed areas.