Practical session: Study designs I

Below you have three abstracts of three different study designs. Read carefully and complete the table using information provided.

Antiretroviral-Free HIV-1 Remission and Viral Rebound After Allogeneic Stem Cell Transplantation

Report of 2 Cases

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Background: It is unknown whether the reduction in HIV-1 reservoirs seen after allogeneic hematopoietic stem cell transplantation (HSCT) with susceptible donor cells is sufficient to achieve sustained HIV-1 remission.

Objective: To characterize HIV-1 reservoirs in blood and tissues and perform analytic antiretroviral treatment interruptions to determine the potential for allogeneic HSCT to lead to sustained, antiretroviral-free HIV-1 remission.

Design: Case report with characterization of HIV-1 reservoirs and immunity before and after antiretroviral interruption.

Setting: Tertiary care center.

Patients: Two men with HIV with undetectable HIV-1 after allogeneic HSCT for hematologic tumors.

Measurements: Quantification of HIV-1 in various tissues after HSCT and the duration of antiretroviral-free HIV-1 remission after treatment interruption.

Results: No HIV-1 was detected from peripheral blood or rectal mucosa before analytic treatment interruption. Plasma HIV-1 RNA and cell-associated HIV-1 DNA remained undetectable until 12 and 32 weeks after antiretroviral cessation. Both patients experienced rebound viremia within 2 weeks of the most recent negative viral load measurement and developed symptoms consistent with the acute retroviral syndrome. One patient developed new efavirenz resistance after reinitiation of antiretroviral therapy. Reinitiation of active therapy led to viral decay and resolution of symptoms in both patients.

Limitation: The study involved only 2 patients.

Conclusion: Allogeneic HSCT may lead to loss of detectable HIV-1 from blood and gut tissue and variable periods of antiretroviral-free HIV-1 remission, but viral rebound can occur despite a minimum 3-$\log_{10}$ reduction in reservoir size. Long-lived tissue reservoirs may have contributed to viral persistence. The definition of the nature and half-life of such reservoirs is essential to achieve durable antiretroviral-free HIV-1 remission.

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For author affiliations, see end of text.
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Social determinants of pulmonary tuberculosis in Brazil: an ecological study

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Abstract

Background: Social determinants may influence the incidence and control of tuberculosis (TB). The aim of this study was to evaluate the correlation between social determinants and pulmonary TB (PTB) incidence and treatment outcomes in different regions in Brazil.

Methods: In this ecological study, PTB incidence and treatment outcome rates as well as HIV incidence for all 5560 Brazilian cities as reported to the Brazilian Tuberculosis Program in 2010 were correlated with two social indicators, the Human Development Index (HDI) and Gini Index (GI). Cities were stratified into six groups based on location (metropolitan region or not) and size (small, medium, and large cities), and according to the regions of the country to which they belong. The Spearman correlation coefficient was used to assess the association between variables.

Results: In 2010, 68,729 new PTB cases were reported in Brazil, with an incidence rate of 36 cases per 100,000 inhabitants. Incidence rates and PTB mortality demonstrated a weak negative correlation with HDI and a positive correlation with GI. The correlation between HDI and GI with cure, relapse, and lost to follow-up of treatment greatly varied in the different groups of cities and regions of the country evaluated.

Conclusions: There is a weak correlation between HDI and GI and PTB incidence and mortality rate. However, there is great variation between the HDI and GI and cure, relapse, and lost to follow-up in the different groups of cities and regions of the country. This suggests that for TB determination, these outcome variables might be more related to the quality of healthcare provided by services than to social determinants in the general population.

Keywords: Tuberculosis, Income, Inequality, Social indicators

Binge Drinking and Blood Pressure: Cross-Sectional Results of the HAPIEE Study

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Abstract

Objectives: To investigate whether binge drinking pattern influences blood pressure independently from drinking volume or whether it modifies the effect of volume of drinking.

Methods: We used cross-sectional data from population samples of 7559 men and 7471 women aged 45–69 years in 2002-05, not on antihypertensive medication, from Russia, Poland and Czech Republic. Annual alcohol intake, drinking frequency and binge drinking (≥100 g in men and ≥60 g in women in one session at least once a month) were estimated from graduated frequency questionnaire. Blood pressure was analysed as continuous variables (systolic and diastolic pressure) and a binary outcome (≥140/90 mm Hg).

Results: In men, annual alcohol intake and drinking frequency were strongly associated with blood pressure. The odds ratio of high blood pressure for binge drinking in men was 1.62 (95% CI 1.45–1.82) after controlling for age, country, body mass index, education and smoking; additional adjustment for annual alcohol intake reduced it to 1.20 (1.03–1.39). In women, the fully adjusted odds ratio of high blood pressure for binge drinking was 1.31 (1.05–1.63). Binge drinking did not modify the effect of annual alcohol intake. Consuming alcohol as wine, beer or spirits had similar effects.

Conclusions: The results suggest that the independent long-term effect of binge drinking was modest, that binge drinking did not modify the effect of alcohol intake, and that different alcoholic beverages had similar effects on blood pressure.

TABLE 1	HIV study	Tuberculosis study	Hypertension study
Type of study			
Outcome variable			
Predictor variables			
Hypothesis / aim			
Population size (#)			
Sampling method			
Time, follow-up, duration			
Intervention (yes/no, what)			
Control/comparison group (yes/no, what)			
Statistical method			
Effect measurement			
Correlation or causation			

TABLE 2	HIV study	Tuberculosis study	Hypertension study
Alternative explanations for the associations			
Analytical or descriptive			
Generalize findings (yes/no)			
Rate the cost of the study from 1 (cheap) to 5 (very expensive)			
Is the outcome an acute or chronic disease?			
Is this study useful? Why?			
Sources of bias			
Rate the quality of evidence from 1(low) to 5 (high)			
Design a better study. How would you improve the design? (imagine you have unlimited money)			