Beneficial Effects of Simvastatin and Pravastatin on Cardiac Allograft Rejection and Survival

In their study comparing beneficial effects of simvastatin and pravastatin on cardiac allograft rejection and survival, Mehra et al. (1) concluded both statins to be equivalent and superior to no-statin treatment. Clinical trials whose purpose are to show equivalence/noninferiority of two or more treatments commonly apply methods to demonstrate superiority and, if no statistical differences are found, treatments are assumed to be equivalent. The correct approach, however, would be to calculate sample sizes using bio-equivalence formulae (2). Although the findings of the statin trial are reassuring, the study could have been underpowered. Could the investigators comment on power-size calculation prior to this study and whether the concept of equivalence testing was adhered to?

REFERENCES