

Homework #2
BSTA 519 - Fall 2021
Applied Longitudinal Data Analysis
Due - Monday 10/18/2021 by midnight

The Toenail Data

A randomized, double-blinded parallel group study was conducted for the comparison of two oral treatments (group A: Lamisil; group B: Itraconazol) for toenail dermatophyte onychomycosis (TDO). TDO is a common toenail infection and difficult to treat. The aim of the present study was to compare the efficacy and safety of 3 months of continuous therapy for the two treatments.

In total, 2×189 patients were randomized and subjects were followed up to a total of 12 months. Measurements were taken at baseline, every month during treatment, and every 3 months afterward, resulting in a maximum of seven measurements per subject. For the purpose of this homework, we will consider one of the secondary outcomes, unaffected nail length as our outcome variable of interest.

You have obtained the dataset from Homework 1. Using the same dataset, do the following:

Response profile Analysis

- a) Test the hypothesis whether the changes in the mean unaffected nail length are the same for the two treatment groups.
 - 1) Write down your model for testing this hypothesis, perform the test and interpret your results.
 - 2) Calculate group differences at each time point after subtracting the baseline response and interpret your results.
 - 3) Calculate the overall (average) group difference after subtracting the baseline response and interpret your results.
- b) Test the hypothesis whether there is a time effect and interpret your results.
- c) What are the differences in assumptions between models used in this problem and a regular linear regression model?
- d) How does the covariance structure play a role in the estimation and inference of the model coefficients?
- e) How might the study design (observational studies vs. randomized clinical trials) affect the choice of the hypothesis tests in response profile analysis?