

ASSIGNMENT 23

Cardiovascular Disease

A clinical trial was conducted to test the efficacy of nifedipine, a new drug for stopping chest pain in patients with angina severe enough to require hospitalization. The duration of the study was 14 days in the hospital unless the patient was withdrawn prematurely from therapy, was discharged from the hospital, or died prior to this time. Patients were randomly assigned to either nifedipine or placebo and were given the same dosage of each drug in identical capsules at level 1 of therapy. If pain did not cease at this level of therapy, or if pain recurred after a period of pain cessation, then the patient progressed to level 2, whereby the dosage of each drug was increased according to a prespecified schedule. Similarly, if pain continued or recurred at level 2, then the patient progressed to level 3, whereby the dosage of the anginal drug was increased again. Patients randomized to either group were allowed to receive nitrates in any amount that was deemed clinically appropriate to help control pain.

The main objective of the study was to compare the degree of pain relief with nifedipine and placebo. A secondary objective was to better understand the effects of these agents on other physiologic parameters including heart rate and blood pressure. Data on these latter parameters are given in the Data Set NIFED.DAT (on the data disk); the format of this file is given in Table 5.3.

The data have the following form:

Column	Variable	Code
1-2	ID	
4	Treatment group	N=nifedipine/P=placebo
6-8	Baseline heart rate*	beats/min
10-12	Level 1 heart rate+	beats/min
14-16	Level 2 heart rate	beats/min
18-20	Level 3 heart rate	beats/min
22-24	Baseline systolic bp*	mm Hg
26-28	Level 1 systolic bp	mm Hg
30-32	Level 2 systolic bp	mm Hg
34-36	Level 3 systolic bp	mm Hg

* Immediately prior to randomization.

+ Highest heart rate and systolic blood pressure at baseline and each level of therapy respectively.

Blank values indicate that either

- (a) the patient withdrew from the study prior to entering this level of therapy
- (b) the patient achieved pain relief prior to reaching this level or therapy,
- or (c) the patient encountered this level of therapy, but this particular piece of data was missing.

Construct a model in BUGS to assess if there are differences in the measurements of heart rate for the two treatment groups.