

UMDNJ Biocomputing I Fall 2004

Project #2

Due: December 07, 2004

A 12-month, double-blinded, randomized, placebo-controlled clinical study was conducted to determine the efficacy of an active drug on bone density in postmenopausal women treated for osteoporosis. The statistical analyses were based on data from 237 patients who complete the study. Lumbar spine bone mineral density (BMD) was used to assess the efficacy of the active drug. The data set you were given contains the following variables: PATID = patient ID, TRT = treatment assignment (0=placebo, 1= active drug), RACE=race of patient (0=non-white, 1=white), WEIGHT=weight of patient at the beginning of trial (in pound), MONTH= month of measurement was conducted, BSLNBMD=baseline lumbar spine BMD, BMD=lumbar spine BMD.

You can download the data “spinbmd.sas7bdat” from our class’ web site. In this project, you are asked to

1. Create a format for treatment so that 0=Placebo, 1=Drug X, 2=All
2. Using PROC UNIVARIATE to create a data set for summary statistics of AGE, WEIGHT and BSLNBMD by treatment group and a data set for summary statistics of AGE, WEIGHT and BSLNBMD for all patients.
3. Concatenate the two data sets created in Step 2 and assign the treatment value to 2 for observation from the data set for all patients.
4. Using the data set from Step 3 and PROC REPORT to create the summary statistics Table 1. Save the table in RTF format for report later.
5. The following PROC GLM statements can be used to test the difference of baseline BMD between two treatment groups and provide tables for ANOVA, MEANS and LSMEANS,

```
proc glm data=bsln;  
class trt;  
model bslnbmd=trt;  
means trt;  
lsmeans trt/pdiff stderr tdiff;  
run; quit;
```

Using ODS to find the names of tables for ANOVA, MEANS, and LS MEANS.

6. Select only the tables for ANOVA, MEANS, and LS MEANS and save the result in RTF format to a file.
7. Create a variable PCHG for percent change from baseline from the original data.
8. Test treatment differences of PCHG by MONTH using PROC GLM and as in Step 5 and 6 select only tables for ANOVA, MEANS and LS MEANS and save the results to an RTF file.
9. Use an ODS statement to save MEANS and LS MEANS’ tables to SAS data sets.
10. Keep only the variables MONTH, TRT and N from the data set for MEANS, and merge the data set for LS MEANS and the data set for MEANS by MONTH and TRT.
11. Create the analysis table as in Table 2 using the data set from Step 10 and PROC REPORT. Save the table in RTF format to a file named ‘analysis.rtf’.
12. Write a simple report of your findings in an MS word document. Your report will include the tables as in Table 1, Table 2 and the ANOVA tables from PROC GLM. You can use copy and paste from tables you created to write the report.

Guidelines for the project:

- You may work in a group of up to 3 people and submit the results as a group. Everybody in the group will get the same score. You may work alone if you prefer.
- You are expected to submit the program, the related outputs and the report through email and to hand in a hard copy of the program and report in class.
- Feel free to ask questions if the problems are not clear to you through email or in person.

Table 1. Summary Statistics for Age, Weight and Baseline Spine BMD

TREATMENT	AGE (Year)					WEIGHT (Pound)					BASELINE BMD (gm/cm ²)				
	N	Mean	STD	Min	Max	N	Mean	STD	Min	Max	N	Mean	STD	Min	Max
Placebo	97	59.5	5.1	50.4	69.8	97	115	28.8	48.9	186.0	97	0.87	0.15	0.54	1.23
Drug X	140	59.5	6.1	50.1	69.7	140	119	30.0	46.8	198.7	140	0.86	0.14	0.42	1.25
All	237	59.5	5.7	50.1	69.8	237	118	29.5	46.8	198.7	237	0.86	0.15	0.42	1.25

Table 2. Analyses of treatment difference in percent change of Spine BMD from baseline by month

Month	Treatment	N	LS Mean	Standard Error	P-value for testing lsmean=0	P-value for testing treatment difference
3	Placebo	97	2.26	3.46	0.514	0.036
	Drug X	137	11.79	2.91	<.001	.
6	Placebo	97	-0.22	4.52	0.962	<.001
	Drug X	136	22.66	3.82	<.001	.
9	Placebo	97	2.63	3.77	0.487	0.006
	Drug X	138	16.24	3.16	<.001	.
12	Placebo	97	-0.15	4.08	0.971	<.001
	Drug X	135	18.69	3.46	<.001	.