AN INVESTIGATION OF CEREBELLAR TOXICITY (TOXICITY)

Study question

A chemotherapeutic agent is manufactured by two companies, Smith Inc. and Jones Inc. This drug is used to treat adults with leukemia and lymphoma in both relapse and remission. With the best of hospital care, this drug is associated with a serious form of cerebellar toxicity that occurs approximately 8% of the time.

A tertiary care hospital has recently switched its source of this drug from the Smith Co. to the Jones Co. It now appears to the clinicians at this hospital that more toxicity is being seen after administration of the Jones product. To address this issue, you have completed a chart review in which you have collected information on several patients and treatment characteristics that the literature suggests may place patients at greater risk for this toxic reaction. These variables include age, sex, diagnosis, disease stage, dose and serum creatinine.

The hospital asks you to determine whether there is a higher incidence of toxicity among patients treated with the Jones product compared to the Smith product (i.e., relative risk > 1?). Additionally, they wish to know whether differences in characteristics of the patients may explain any observed difference. (For example, are the patients treated with the Jones product older?, do they have poorer renal function as indicated by elevated creatinine?, etc.).

Data set and code book

TOXICITY.REC TOXIC.SAV

Variable	Type	Codes	Comment
AGE	numeric	in years	
SEX	numeric	1=male, 2=female	
MANUF	character	Smith or Jones	manufacturer
DIAG	numeric	1=leukemia 2=lymphoma	diagnosis
STAGE	numeric	1=relapse 2=remission	disease stage
TOX	numeric	1=yes 2=no	drug toxicity
DOSE	numeric	(gms/M²)	dose
SCR	numeric	mg/100 ml	serum creatinine
WEIGHT	numeric	kilograms	body weight

HW

1. Comparison the two drug groups (i.e., Smith vs. Jones) - categorical variables SPSS ANALYZE > DESCRIPTIVE > CROSSTABS

   Compare the two groups for comparability of sex, diagnosis, and stage of disease. Report descriptive statistics and hypothesis test conclusions.

2. Comparison of drug use groups - continuous variables

   Compare the mean age, dose, and serum creatinine of the two groups. Report descriptive statistics and hypothesis test conclusions.

   SPSS > ANALYZE > COMPARE MEANS > INDEPENDENT SAMPLES

3. Rates of toxicity

   Calculate the rate of toxicity associated with drugs from the two manufactures. Calculate a crude relative risk of toxicity between the two manu-

   CROSSTABS

facturers. Report a 95% confidence interval and an appropriate *p* value. Briefly, interpret your results.

4. Age-adjusted relative risk (1) USE TRANSFORM > RECODE TO GROUP DATA

Stratify the sample into two age groups. Let the younger group encompass all study subject less than 35 years of age. Those greater than or equal to 35-years of age will be the other age group. Do you notice anything interesting? Does controlling for age make a difference in interpreting the results in part 3? (2) USE CROSSTABS & STRATIFY (LAYER) BY AGEGRP

5. Relationship between age and serum creatinine

Assess whether there is a significant relationship between age and serum creatinine levels among these cancer patients. Report your results and briefly interpret your findings.

AGE IS QUANTITATIVE
SCR IS QUANTITATIVE
} CORRELATION & REGRESSION
LAB 6 (WAIT)