

P8110: Applied Regression II
Homework #4 [15 points]

1. Read the NEJM paper “Long-term survival of participants in the prostate cancer prevention trial” and answer the following questions.

- (a) List three statistical analysis topics that are described in the paper and covered in our class. Copy the sentences used to describe each topic here. [3 points]

- e.g. 10-year survival rate: “Ten-year survival rates were 83.0% in the finasteride group and 80.9% in the placebo group for men with low-grade prostate cancer and 73.0% and 73.6%, respectively, for those with high-grade prostate cancer.”

1. **Survival rate:** *15-year survival rate was 78.0% in the finasteride group and 78.2% in the placebo group (similar statement made regarding 10-year survival rate under Results)*
2. **Hazard ratio:** *the unadjusted hazard ratio for death in the finasteride group was 1.02 (95% CI, 0.97 to 1.08; $P=0.46$); after adjustment for age, race, and a diagnosis of prostate cancer, the hazard ratio was 1.03 (95% CI, 0.98 to 1.09; $P=0.26$) (similar statements made about hazard ratios of death after diagnosis of prostate cancer under Results section to summarize Table 2) and also: a hazard ratio of less than 1 indicates a reduced risk of death (Table 2 footnote)*
3. **Cox model:** *A Cox model was used to estimate hazard ratios for death associated with the two treatments, after adjustment for risk factors. (One model for overall survival, another model for survival after a prostate cancer diagnosis.)*
4. **Kaplan-Meier curve:** *Figure 2 uses K-M curve to show the overall survival; Figure 3 shows overall survival for men with prostate cancer, stratified by treatment and cancer grade.*
5. **Proportional Hazard assumption:** *The proportional-hazards assumption for both models was tested within the PROC PHREG module.*
6. **Interaction:** *The covariates that were included in the model for survival after a prostate-cancer diagnosis were the age at diagnosis as a continuous variable, race (black vs. nonblack), a family history of prostate cancer (yes vs. no), the Gleason score (2 to 6 vs. 7 to 10), and a term for the interaction between treatment and Gleason score.*

7. **Time-dependent variable:** *Diagnosis of prostate cancer was added as a time-dependent covariate to account for the timing of the diagnosis (Table 2 footnote)*
8. **End point:** *The primary end point of the PCPT was histologically confirmed prostate cancer, including prostate cancer that was detected during the course of the 7-year treatment period and prostate cancer that was detected by means of an end-of-study prostate biopsy, as reported previously. (Methods Section p.605)*
9. **Data censoring:** *Data for all men who were last known to be alive or who had died after October 31, 2011, were censored on October 31, 2011. Data for men without a Social Security number were censored on the last date they were known to be alive, according to PCPT follow-up data. (Methods Section p.605)*
10. **Relative risk :** *the relative risk of prostate cancer in the finasteride group in current study, as compared with the placebo group, is 0.70; 95% confidence interval [CI], 0.65 to 0.76; $P < 0.001$ (similar statements made several times in similar fashion under Results to summarize Table 1)*
11. **Median:** *the median age of participants was 63.2 years (similar statements made several times in similar fashion under Results to summarize participant demographics)*
12. *Other potential topics mentioned in the paper that did not have much explanations attached:*
 - *randomization*
 - *post hoc analysis*
 - *at-risk analysis*
 - *two-sidedness*

(b) Comment on your answers in question (a). Was the provided description sufficient? Suggest improvement if not sufficient? [3 points]

- e.g. The description of the 10-year survival rate is clear, but can be improved by also providing 95% CI.
1. *Survival rate: Clear description. It could benefit from the inclusion of 95% confidence intervals for their measures.*
 2. *Hazard ratio: The adjusted and unadjusted hazard ratio for death in the finasteride group is clear and includes the 95%CI and the p-value.*
 3. *Cox model: Clearly specified the covariates in each model. In the model for survival after a prostate-cancer diagnosis, the treatment*

after diagnosis is an important variable as well, but not included in the model.

4. *Kaplan-Meier curve: Using K-M curves is a good way to visualize the survival data. It will be more clear if the y axis is re-sized.*
5. *Proportional Hazard assumption: The paper states that The proportional-hazards assumption for both models was tested, but did not provide the results of the test. It can be more clear with the test results.*
6. *Interaction: Clear description of the interaction in the model and corresponding p-value.*
10. *Relative risk: very clear and contains CI.*
11. *Median age: It could be helpful to add the 95% confidence interval of median age. (Median age should be median survival time)*