Analysing Survival Data from Clinical Trials and Observational Studies

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This book is intended to be a practical guide for medical researchers with limited statistical knowledge and experience as well as a useful reference for biostatisticians. These seemingly contradictory aims were achieved by non-technical, but in-depth, description of problems, rigorous outline of statistical principles, inclusion of many examples and practical advice.

Chapter 1 introduces the topic of survival data and presents some examples of data sets which are used throughout the book. Chapters 3 and 4 describe non-parametric methods of estimation of survival probabilities and comparison of survival curves, including the family of standard logrank tests but also the extension of Mantel–Haenzel test for stratification, Mantel–Byar procedure for time-dependent covariates and a method for comparing more than two groups. The next four chapters are concerned with the use of regression models. Chapter 5 gives an introduction, defining survival and hazard functions, maximum likelihood estimators and hypotheses testing. Chapters 6 and 7 are devoted to the proportional hazards model, discussing the basic Cox model, the stratified model and the model with time-dependent covariates. A thorough summary of model validation techniques is given, including tests on the proportional hazards assumption and checking model adequacy via graphical methods. The next chapter expands the topic further, considering non-exponential distributions of failure time and introducing parametric regression models. Problems related to studies of prognostic factors, such as adjustment of treatment effect, variable selection, predictive value of the model and definition of risk groups are discussed in Chapter 9. Another section of this chapter is devoted to the description of treatment effectiveness with a number of measures given. Finally, Chapter 10 introduces methods for the analysis in the presence of competing risks, including estimation of unbiased curves of cumulative incidence, comparison of such curves and regression analysis. Chapters 2 and 11 tackle the important general issues of randomized clinical trials and meta-analysis.

Overall, the book reads very easily. The non-technical style and placing of mathematical material in appendices help to a great extent. The topics discussed, both technical and more practical, are well illustrated in examples, as in the case of comparison of likelihood ratio, Wald and score tests, calculation of estimates in Cox model, model validation and meta-analysis. The authors give a lot of practical advice, often based on their own experience, on topics such as reporting of a survival curve, definition of end-points, sample size calculation, handling of continuous and categorical variables in Cox model, variable selection, just to mention few. The only information I did not find in the book was on the implementation of discussed methods in standard software but this information is widely available elsewhere. Instead, the authors give references to specifically developed software for more obscure tasks. These are available on request.

In summary, this is an excellent book which should find its way onto the shelf of both a medical researcher dealing with survival data and a medical statistician performing the survival analysis.

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