

TITLE: Bayesian Survival Models for Real-World Evidence: Implementation in Assessing Treatment Duration and Mortality Risk

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ABSTRACT:

Real-world data is increasingly used to generate real-world evidence (RWE) for post-market studies. This study addresses a common challenge: assessing the impact of treatment duration on mortality in the presence of treatment switching.

As a case study, we focus on oral corticosteroids (OCS), a standard treatment for various inflammatory and autoimmune conditions. Prolonged use of OCS can lead to significant side effects, potentially increasing patient mortality. Traditional survival models often fail to accurately represent the complexity and variability in patient data, especially when treatment duration and adherence fluctuate over time, as is common with OCS.

To overcome this, we propose a Bayesian survival model to estimate the impact of OCS treatment duration on mortality risk. Our model employs a Bayesian piecewise exponential survival model, allowing for variation in the hazard rate across distinct time intervals. This approach offers a more flexible and precise representation of the data. We also explore spline functions to model the hazard rate flexibly over time.

The models are implemented using Markov Chain Monte Carlo methods, yielding posterior distributions of the parameters and providing a complete probabilistic characterization of the effect estimates. We illustrate our approach using simulation data and conduct out-of-sample validation exercises to evaluate the performance of our proposed model in the context of OCS treatment.

This study highlights the potential of Bayesian statistics in generating robust RWE for post-market studies. Importantly, it demonstrates the practical implications of these methods, from design to implementation to reporting.

Presentin Author Short Bio: Dr. Zhengfan Wang is a biostatistician with extensive experience in Bayesian methods and survival analysis. He earned his Ph.D. in Biostatistics from the University of Massachusetts Amherst and currently works at Genesis Research Group. Dr. Wang's work primarily revolves around the application of Bayesian modeling in real-world evidence and complex hierarchical models.