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医薬品情報データを理解するための統計モデルの活用

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Abstract

Researchers involved in biological or medical matters often regard statistics as a tool for detecting significant results based on experiment data. Actually, statistics provides various tools for extracting useful information from experiment or survey data. This article tries to show the usefulness of statistical models in the analysis of data related with medicinal products. The notion of the statistical model is introduced as a mathematical expression of the structure of observed measurements through a simple example of clinical trials. It is followed by two examples in literature that showed the validity of the statistical model. The one is concerned with a drug, Nipradilol, for glaucoma where the depression of intraocular pressure (IOP) is the principal target of therapy. A statistical model that incorporated a cosine function for representing the circadian variation of IOP was applied on the IOP data and successfully realized the efficacious feature of the drug. The other is concerned with an anti-cancer drug, TS-1, adverse events of which were observed through a post-marketing survey. A slip-mixed log-logistic model clearly explained the hazard feature of TS-1 captured by the survey data.

Key words: statistical model, case study, glaucoma, TS-1