ABSTRACT

Crossover design is an important field in clinical trials. Majority of the works have been performed in cases of dichotomous or binary responses as well as continuous responses. This project emphasizes upon a crossover design of recurrence of any disease over two periods, considering two treatments, having carryover effects and involving count data responses. This project brings into limelight the creation of a statistical model for the crossover design and performing the necessary estimation and hypothesis testing to make some inferences about the effectiveness of our model upon implementation for the crossover design and draw some conclusions.

Keywords: Crossover design, Carryover effect, Statistical model, estimation, hypothesis testing, count data responses.

INTRODUCTION

A crossover design is a repeated measurements design such that each experimental unit (patient) receives different treatments during the different time periods, that is, the patients cross over from one treatment to another during the course of the trial. This is in contrast to a parallel design in which patients are randomized to a treatment and remain on that treatment throughout the duration of the trial. To clearly understand what a crossover design is, we have to know what actually happens in a crossover design. In a crossover design, each participant is randomized to a sequence of two or more treatments therefore the participant is used as his or her own control. Moreover, these subjects or participants receive these treatments over several study periods.

The reason to consider a crossover design when planning a clinical trial is that it could yield a more efficient comparison of treatments than a parallel design, that is, fewer patients might be required in the crossover design in order to attain the same level of statistical power or precision as a parallel design. Intuitively, this seems reasonable because each patient serves as their own matched control. Every patient receives both treatment A and B. Crossover designs are popular in medicine, agriculture, manufacturing, education, and many other disciplines.

There have been several works previously done in the area of crossover design, majority of which have been for dichotomous or binary responses. To name a few, works are done: - by U.Bandyopadhyay, A.Biswas, and S.Mukherjee (2007, 2009); by UttamBandyopadhyay, Atanu Biswas, Shirsendu Mukherjee (2011); among many others. Many of the works have also been for continuous responses. To name a few, they are: - by Uttam Bandyopadhyay &Shirsendu Mukherjee (2015); among many others. Moreover, there have been a few works in the area of crossover design for count data responses, namely, by M. W. J. Layard and J. N. Arvesen (1978); among few others. But statistical modeling of crossover design in count data response is very rare in past works. In this project, we are working upon building a statistical model for crossover design in count data responses since it is not unnatural or inapplicable even if it is rare and no past literature is present on modeling in crossover design for count data responses.

Thus, as suggested earlier, in our project, we develop a statistical model for crossover design of recurrence of any disease based on count data responses. The layout of our project is as follows: Section 2 deals with detail of the problem handled and the statistical modeling used. The inferential aspects, mainly estimation and hypothesis testing, are discussed elaborately in Section 3. Section 4 deals with detailed simulation study and display of related power curves. Finally, Section 5 concludes our project.

CONCLUSION

In our project, if we observe our simulation study, we have performed simulation work for known β. We tried the same for unknown β but could not complete it. So, we would eagerly want to venture the aspect of unknown β in our future work.

Moreover, in our project, we have assumed equal number of allocation of patients for application of both the treatments. So we would eagerly want to venture the aspect of random allocation of patients for application of both the treatments for our crossover design in the near future.

Similarly, we have considered the treatment combinations AB, BA after carryover to the second period. In the near future, we would want to take up the other possible combinations namely AA and BB and perform the similar tasks in the hope of getting better results.

Our proposed model can easily be generalized for more than two periods but its practical usefulness would much less than two period crossover design. So, at present, we do not discuss it in detail but we would definitely venture it in near future.

Moreover, we would also want to venture the possibility of more than two treatments in two or more periods in the near future.

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