# Trade-off between Type I error rate and statistical power: Requirement of a robust model for ordinal outcomes

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## Introduction

Clinical trials in traumatic brain injury (TBI) have a disappointing history, with a long track record of indecisive phase III trials of ordinal outcomes [1]. The conventional models applied for analyzing such trials have failed to detect slight improvements or deteriorations in the ordinal scales of outcome variables, specifically Glasgow Outcome Scale (GOS) in TBI. Sliding dichotomy model is considered as the best possible option over the standard logistic models.

## Research Questions

Two questions were addressed in this project:

- Is Type I error rate controlled by the classical models as well as sliding dichomy model?
- How power and Type I error rate react with varying sample size in the all models?

**Long term objective** - Develop an improved model balancing the power, sample size & Type I error rate for analyzing the ordinal outcomes of TBI or other clinical trials.

## Data & Methods

**Data Source:** CRASH (Corticosteroid Randomisation After Significant Head Injury) data, a baseline observed data set. 8 different case scenarios were created to fit 3 models by varying sample sizes, number of covariates, treatment effects and band sizes of sliding dichotomy model. Power & Type I error were quantified and compared from sample size 150 to 2700 for the 3 statistical models:

- Binary Regression Model (Base model)
- Proportional Odds Model
- Sliding Dichotomy Model

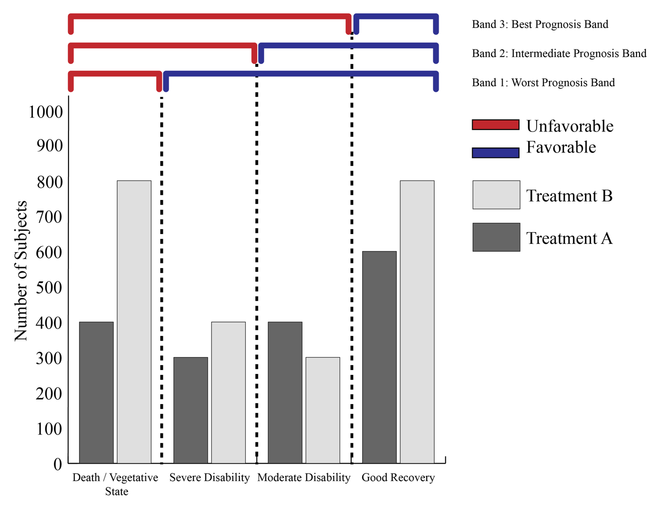


**Figure 1:** Sliding Dichotomy Model

## Results

The outcome of for 8 different case scenarios are displayed graphifacally:

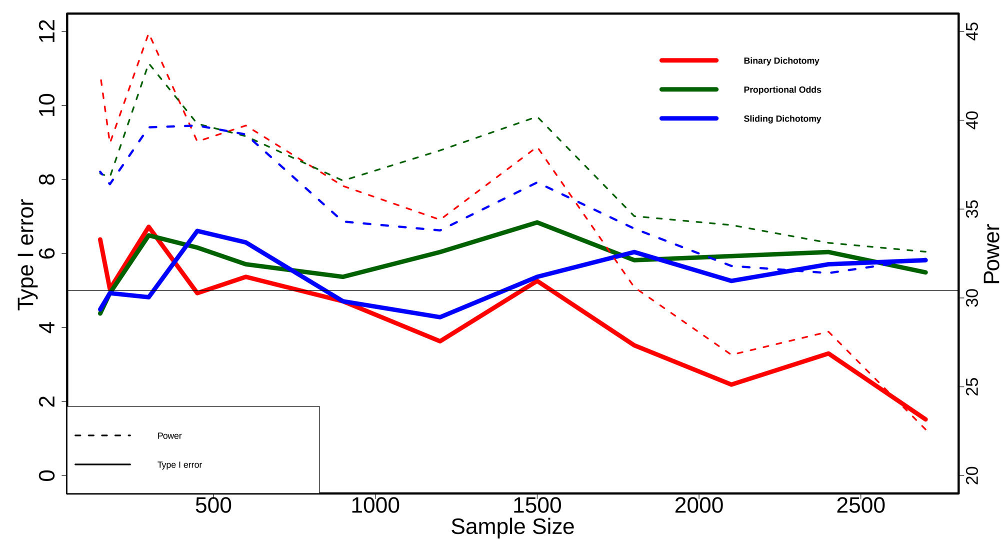


**Figure 2:** Case scenario 1 –> Three covariates - Equal Treatment - Equal Band

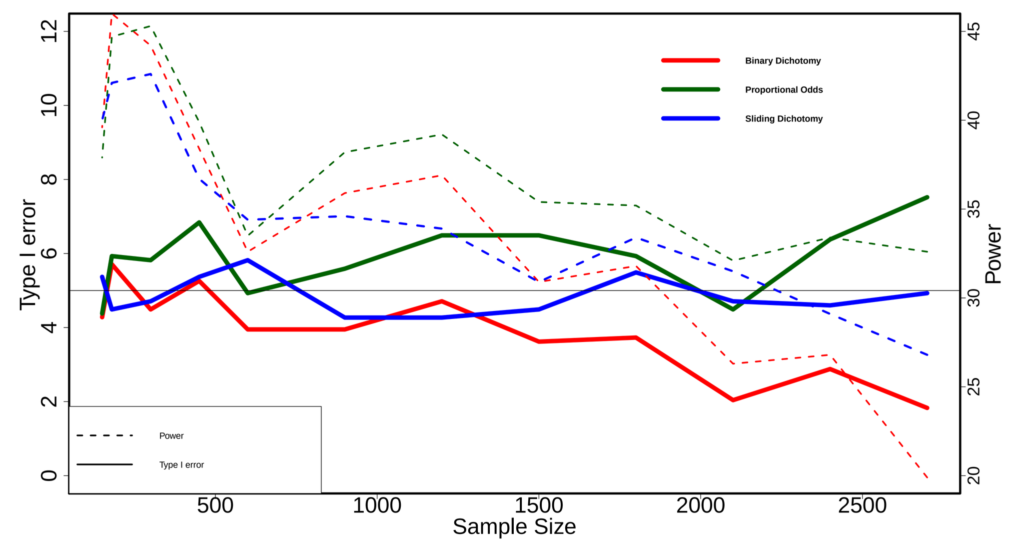


**Figure 3:** Case scenario 2 –> Three covariates - Equal Treatment - Unequal Band

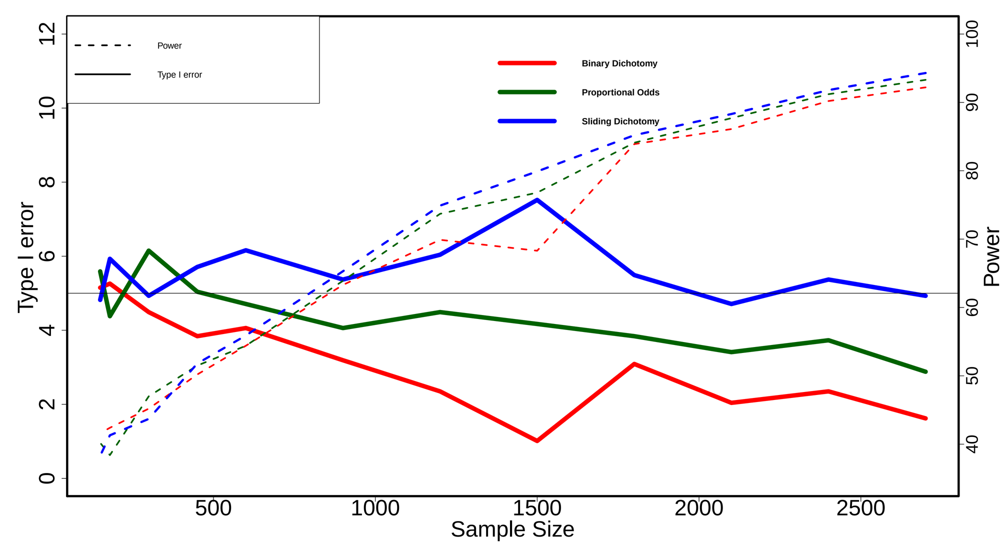


**Figure 4:** Case scenario 3 –> Three covariates - Unequal Treatment - Equal Band

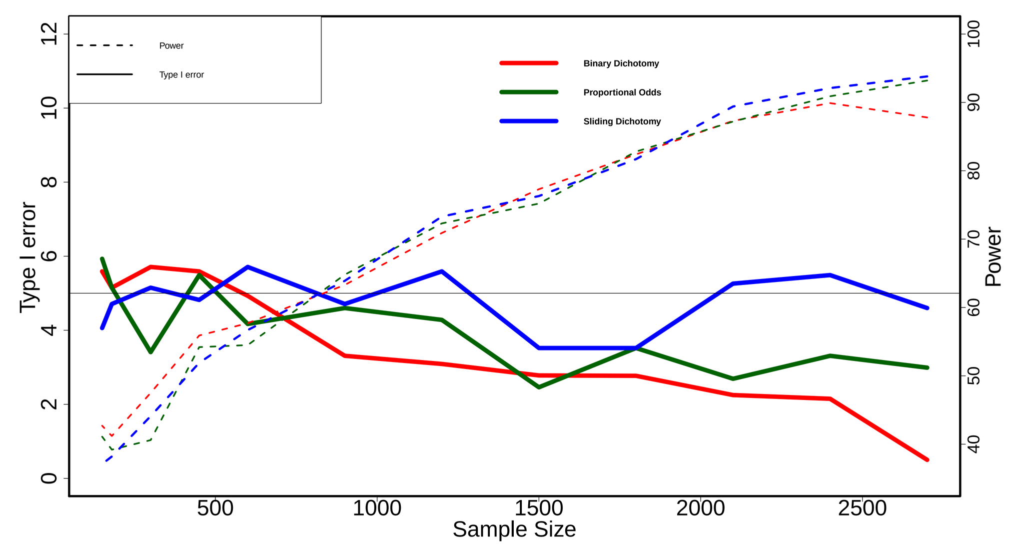


**Figure 5:** Case scenario 4 –> Three covariates - Unequal Treatment - Unequal Band

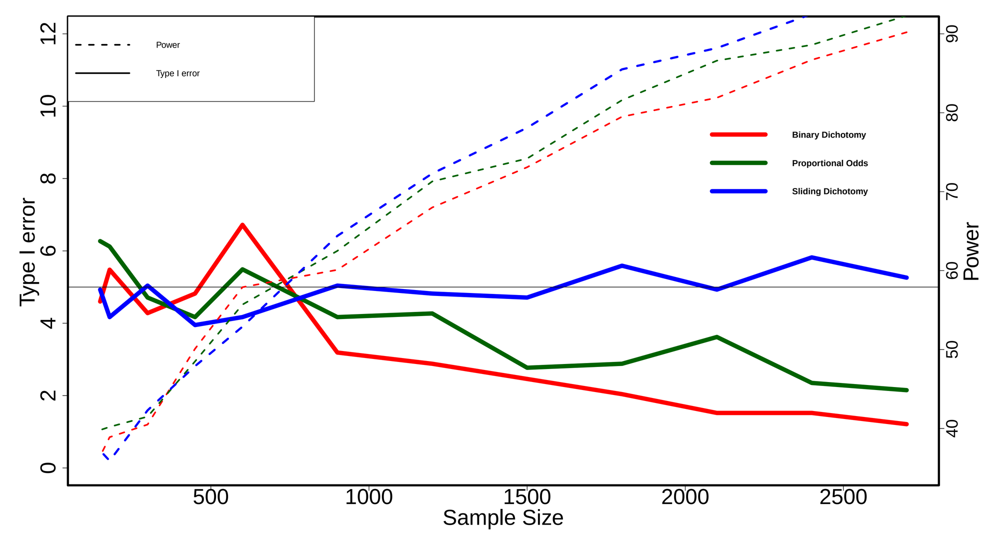


**Figure 6:** Case scenario 5 –> Treatment as covariate - Equal Treatment - Equal Band

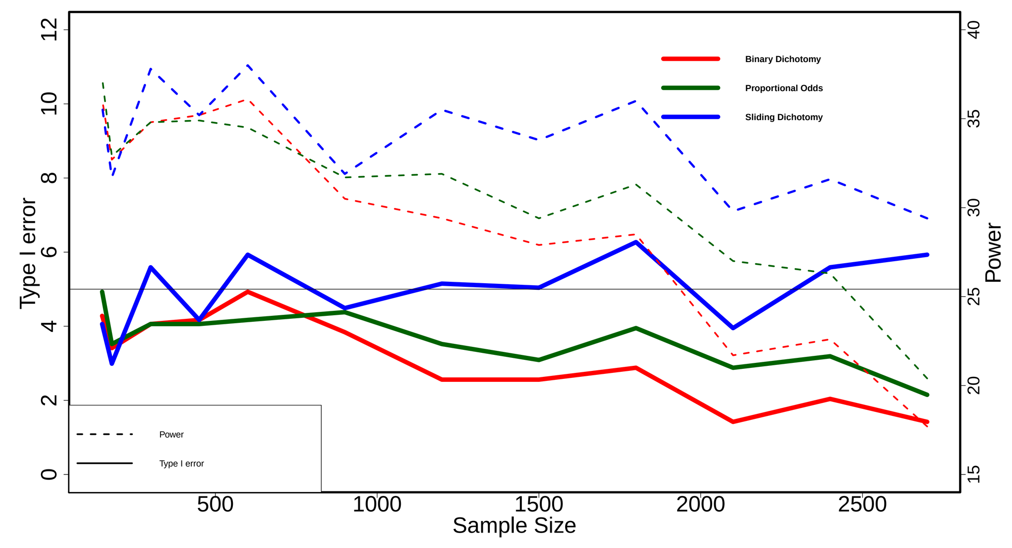


**Figure 7:** Case scenario 6 –> Treatment as covariate - Equal Treatment - Unequal Band

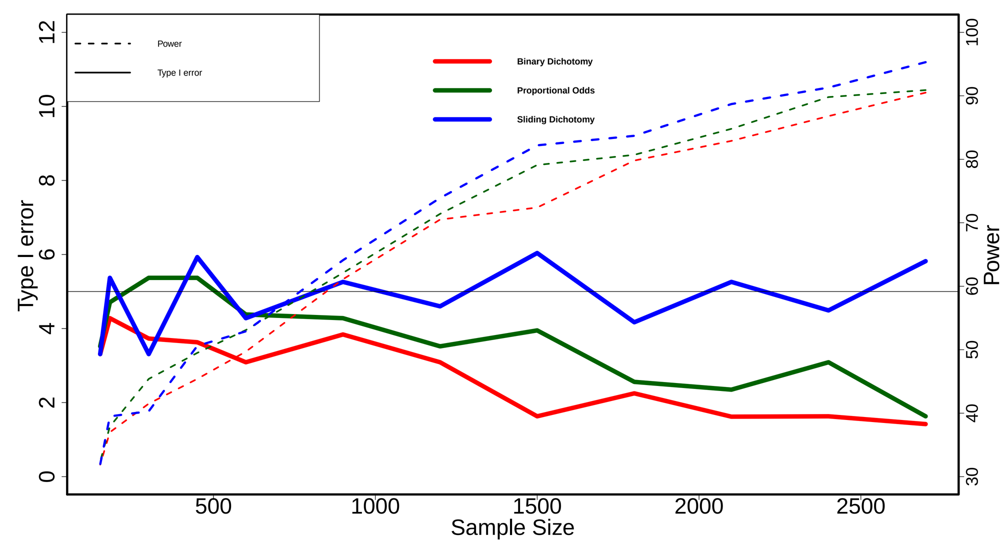


**Figure 8:** Case scenario 7 –> Treatment as covariate - Unequal Treatment - Equal Band

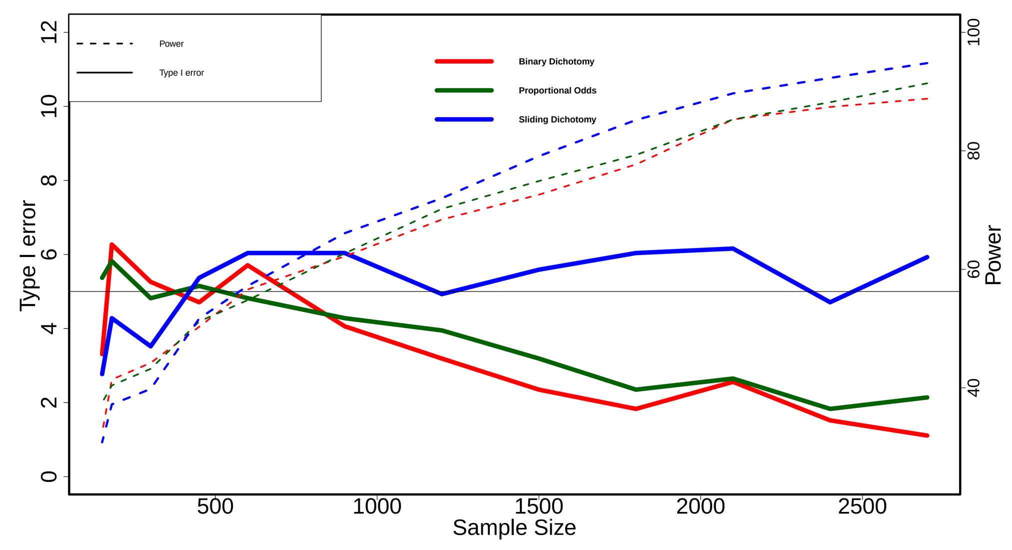


**Figure 9:** Case scenario 8 –> Treatment as covariate - Unequal Treatment - Unequal Band

## References

[1] Gillian S McHugh, Isabella Butcher, Ewout W Steyerberg, Anthony Marmarou, Juan Lu, Hester F Lingsma, James Weir, Andrew IR Maas, and Gordon D Murray. A simulation study evaluating approaches to the analysis of ordinal outcome data in randomized controlled trials in traumatic brain injury: results from the IMPACT project. *Clinical Trials*, 7(1):44–57, 2010.

## Contact

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## Outcome

The outcome from the results:

**Table 1:** Strength and weakness of the models

| Model | Type I error | Power |
|---|---|---|
| Binary Logistic | Stable | Weak |
| Proportional Odds | Stable | Strong |
| Sliding Dichotomy | Weak | Strong |

As sample size increases both binary logistic and proportional odds models maintain acceptable Type I error rates. In contrast, the sliding dichotomy model fails to maintain Type I error rates but performs better than the other two methods in terms of power. Unfortunately, the application of the proportional odds model is limited by the strict proportional odds assumption and the binary logistic model lacks sensitivity needed to fit ordinal scales.

**Future possibility:** Incorporating the error control mechanism of the binary logistic model with the sliding dichotomy model to achieve a model that maintains adequate statistical power and Type I error rates without any strict assumptions limiting application to ordinal data. Such a model would then be robust enough to confidently fit TBI outcomes.