

Patient Outcomes for 2 Drug Combinations In Cerebral Palsy Patients

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Introduction

The data used in this analysis is synthetic data for corticosteroids and antiviral agents as treatment for Bell's Palsy. It was generated to simulate but obfuscate findings from the study *Early Treatment with Prednisolone or Acyclovir in Bell's Palsy* by Sullivan et al (2007).

The full journal can be found in the New England Journal of Medicine: <https://www.nejm.org/doi/full/10.1056/nejmoa072006#>

The Kaggle dataset can be found here: <https://www.kaggle.com/dillonmyrick/bells-palsy-clinical-trial?resource=download>

The scientific question we seek to answer is: How does early treatment of Bell's Palsy with a combination of Prednisolone, Acyclovir, and placebo effect outcomes over a 3 month period

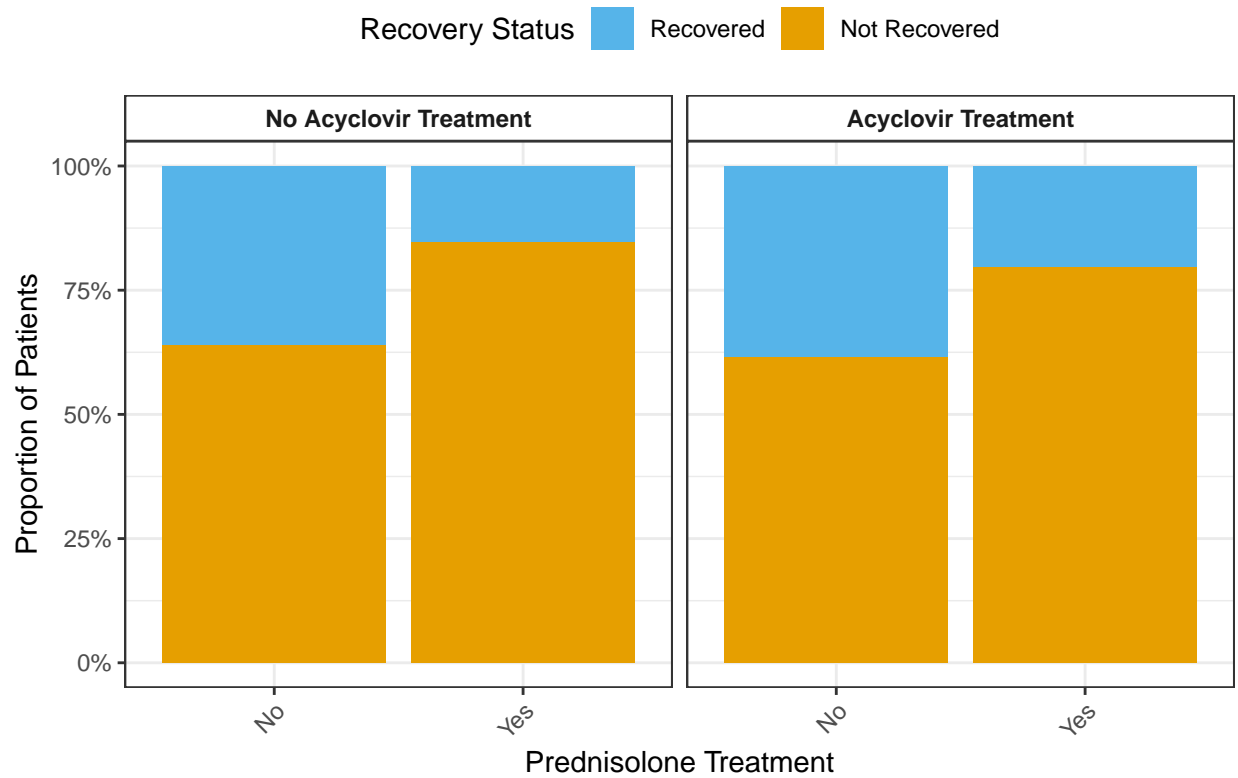
Data

The dataset contains 494 observations, with each row representing a patient. Each patient receives two pills, one being a steroid (Prednisolone) or placebo, and the other being an antiviral (Acyclovir) or placebo.

Table 1: Proportion of Full Recovery by Treatment Group Over 3 Month Period

Treatment Group	Subjects in Group	Number Recovered	Proportion	%
Prednisolone-Placebo	123	104	0.8455285	85%
Acyclovir-Prednisolone	127	101	0.7952756	80%
Placebo-Placebo	122	78	0.6393443	64%
Acyclovir-Placebo	122	75	0.6147541	61%

Full Recovery Rate by Treatment Group at 3 Months



From our data we observe that the group with the best 3 month outcome is the Prednisolone-Placebo group (84.4% Recovery), and the worst is the Acyclovir-Placebo group (61.4% Recovery). This suggests evidence that Prednisolone performs better than placebo, whereas Acyclovir performs worse than placebo, although more rigorous testing would need to be performed to conclude if these effects are significant.

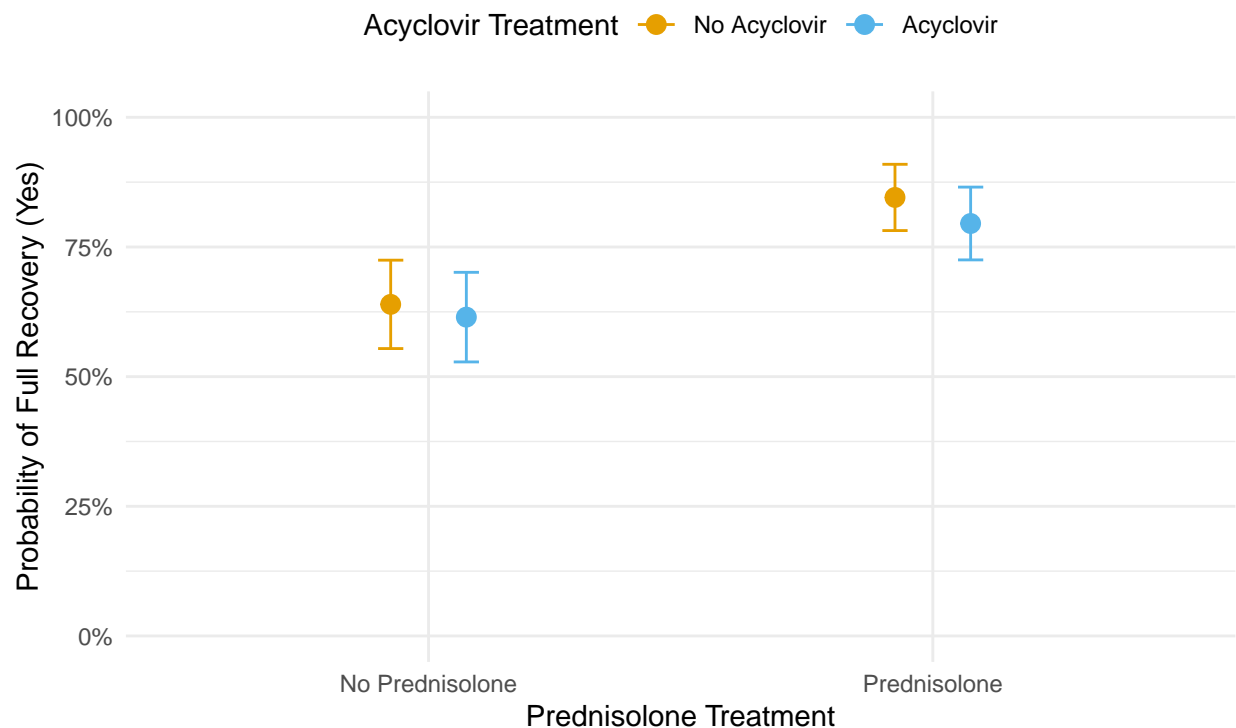
Results

Table 2: Odds Ratios (OR) with 95% CIs

	OR	2.5 %	97.5 %
(Intercept)	1.77	1.23	2.58
Received.PrednisoloneYes	3.09	1.69	5.80
Received.AcyclovirYes	0.90	0.53	1.51
Received.PrednisoloneYes:Received.AcyclovirYes	0.79	0.34	1.81

Predicted Recovery Probability by Treatment

With 95% Confidence Intervals



The model used is logistic regression using the interaction term between the two treatments. This model is used because the outcome is binary. The model is also highly interpretable and allows us to study how treatment effects recovery odds.

Findings

Prednisolone

- OR = 3.09 (95% CI: 1.69-5.8)
- Patients receiving Prednisolone had 3.1 times higher odds of recovery

Acyclovir

- OR = 0.9 (95% CI: 0.53-1.51)
- moderate increase in recovery odds

Interaction

- OR = 0.79 (95% CI: 0.34-1.81)
- No evidence of synergistic effects due to 1 being contained within the 95% confidence interval

Discussion

Summary The data for this analysis was obtained via Kaggle, and was simulated based on the findings of *Early Treatment with Prednisolone or Acyclovir in Bell's Palsy* by Sullivan et al (2007). We performed a logistic regression on our dataset due to the ease of explanation, which is extremely important in the healthcare field due to both ethical and legal concerns. We found that Prednisolone Monotherapy was the best treatment, and Acyclovir Monotherapy was the worst treatment.

Assumptions Independence: Independence was controlled for as this data was generated based on the results of a randomized double-blind experiment where assignments were done independently of one another.

Distributional Assumptions: The model assumes a binomial distribution of outcomes for recovery status after 3 months. Normality is required for sampling distribution of parameter estimates, which is achieved through central limit theorem ($n=494$).

Parameter Assumptions: Log-Odds of recovery are assumed to be linear in predictors, which is validated by the lack of significance in the interaction between drug treatments (Interaction OR = 0.79).

Generalizability and Causality This dataset can be generalized to a broader audience. The sample was taken from a variety of patients with early Bell's Palsy, 72 hours within presentation of symptoms with no pre-existing facial nerve damage. It is not generalizable to individuals who do not meet the inclusion criteria.

We are able to conclude a causal effect between treatment and outcome. This was a double-blind experiment, which is the gold standard for medical trials for establishing a causal relationship. The odds ratio can be interpreted as the causal effect for each treatment.