

Errata: Correction of Figure 9 in FDA Executive Summary

Version of Figure 9 appearing in FDA's Executive Summary

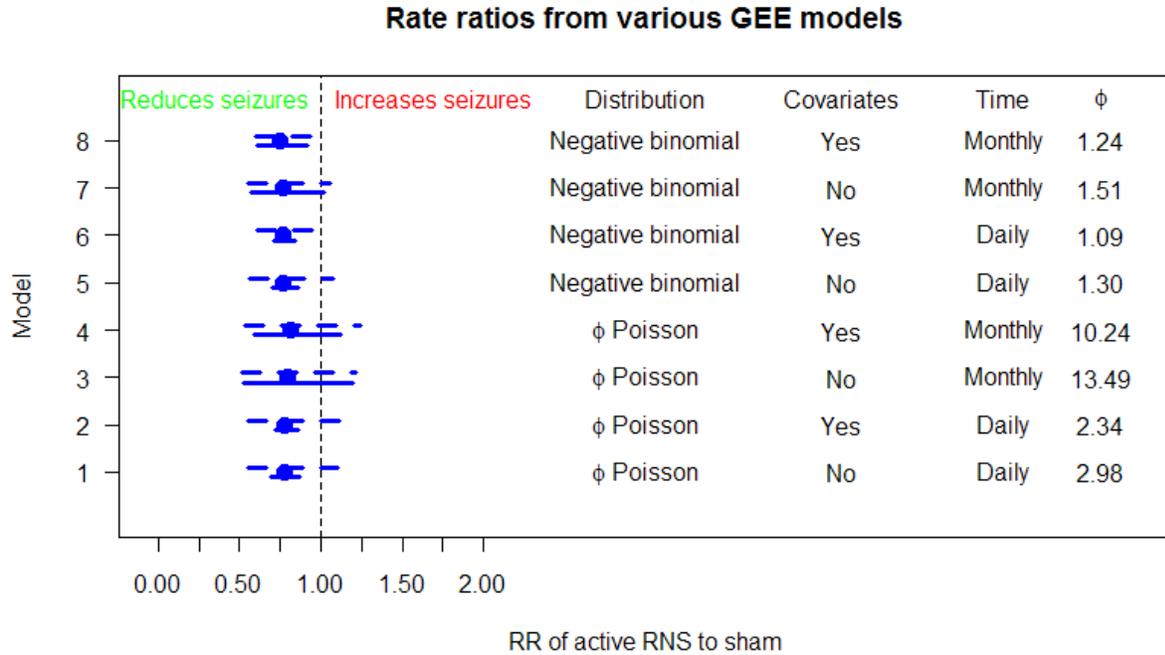


Figure 9. "Forest plot" Comparison of Alternative GEE Models

Circles denote relative risk reduction for active treatment relative to Sham; 95% confidence intervals are presented for model-based (solid) and empirical (dashed) horizontal lines. The relative risk reduction corresponds to the additional reduction in seizure frequency attributable to active stimulation relative to Sham stimulation; a value of 1 would suggest there is no additional benefit from active stimulation, while a value less than 1 or greater than 1 would indicate that active stimulation reduces or increases seizures relative to Sham stimulation. Model 1 represents the pre-specified analysis model, while model 8 represents the final post hoc analysis model.

Amended version of Figure 9

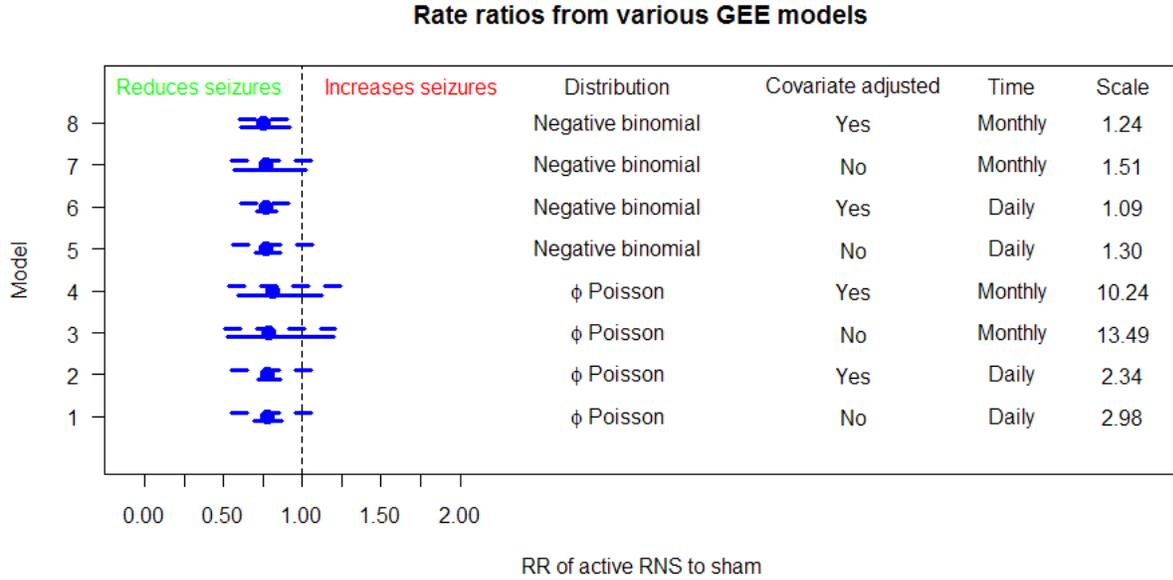


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Explanation of change

In the version of Figure 9 in the Executive Summary, the right-most column (entitled ϕ), is mislabeled. It should be entitled "Scale" as in the amended version of the Figure. In over-dispersed models, ϕ denotes the overdispersion parameter, while the scale parameter (Scale) is the square root of ϕ . The scale parameter is used to adjust the standard error estimate obtained from a model assuming no over-dispersion.