The magnetic resonance imaging 'rule of five': predicting the occurrence of relapse.

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Abstract

BACKGROUND: Clinical intuition suggests that a sharp increase in the number of enhancing lesions should signal an increased risk of relapse. The 'rule of five' recommends that subjects exhibiting at least five lesions over the baseline level be referred for closer monitoring. This rule has been used as an informal safety criterion with limited formal evaluation.

OBJECTIVE: The purpose of this study was to determine the best threshold for the rule and to demonstrate its predictive validity for risk of subsequent relapses for multiple sclerosis (MS) trials.

METHODS: We used logistic regression modeling to apply the rule to patient data from a phase II clinical trial. Predictive validity was ascertained using rate ratios and receiver operating characteristic (ROC) curves.

RESULTS: We found that, for these data, a threshold of five lesions over the baseline constituted the best definition of a threshold. Overall, 35% of subjects broke the rule at least once. Breaking the rule increased the odds of imminent relapse by a factor of 3.2 (95% confidence interval (CI): 1.8-5.5).

CONCLUSION: Breaking the rule of five was found to be a significant predictor of an imminent relapse. Length of follow-up and the number of lesions discovered via magnetic resonance imaging (MRI) were also significant predictors of relapse.