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The very rapid virologic response and the early HCV response kinetics, as quick outcome measures to compare efficacy and as qualifiers for a personalized response-guided therapy

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Background: This study was designed to compare two generic sofosbuvir products for the degree and speed of virologic response to a dual all-oral, anti-hepatitis C virus (HCV) treatment protocol. We aimed to test the applicability of the early virus response kinetics and the very rapid virologic response (vRVR) rate as quick outcome measures for accelerated comparative efficacy studies and as a foundation for a personalized response-guided therapy.

Methods: Fifty eligible chronic HCV patients were randomized to either one of two generic sofosbuvir products (Gratisovir or Grateziano) at a daily dose of one 400 mg tablet plus a weight-based ribavirin dose. Data were compared between the groups for early virus response kinetics and vRVR rates in relation to the rates of final sustained virologic response at week 12 post-treatment (SVR12).

Results: The Log10 transformed virus load (Log PCR) curves showed fairly similar rapid decline during the first 2 weeks, with no significant difference between the groups at four analysis points throughout the study by repeated-measures factorial ANOVA test (P=0.48). The SVR12 rates were 96% (95% confidence interval, 79.6%–99.9%) in Gratisovir group (24/25) and 95.7% (95% confidence interval, 78%–99.9%) in Grateziano group (22/23). There was no statistically significant difference found by exact test (P>0.999). There was a significant association between the vRVR and the SVR12, with 100% positive predictive value (38/38 of those who had vRVR, achieved a final SVR12) and 82.6% sensitivity (among the total 46 with SVR12, 38 were having vRVR).

Conclusion: We can conclude from our study that the early HCV response kinetics and the vRVR rates could be used as sensitive quick markers for efficacy (with a very high positive predictive value for SVR12), based on our accelerated comparative efficacy research model. This might open the way for new models of accelerated equivalence efficacy studies along with the bioequivalence kinetics studies to test a generic drug against a reference. Also, the early response kinetics and the vRVR might be used as qualifiers for a personalized course of treatment. This could shorten unnecessarily long treatment courses in rapid responders and might help to avoid relapses in slow responders.

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