Evaluation of efficacy and safety of Sofosbuvir and Daclatasvir with or without Ribavirin for the treatment of hepatitis C in Hospital Melaka

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ABSTRACT

Introduction: The Sofosbuvir (SOF) and Daclatasvir (DCV) combination therapy (SOF/DCV) with or without (±) Ribavirin (RBV) have shown efficacy in patients with chronic hepatitis C in clinical trials. However, clinical data comparing both regimens among the Malaysian population are sparse. **Materials and Methods:** Our objective is to explore the efficacy and safety of SOF/DCV compared to SOF/DCV/RBV in chronic Hepatitis C patients in Hospital Melaka. Our study method is a retrospective study conducted among hepatitis C patients within the Medication Therapy Adherence Clinic (MTAC) programme in Hospital Melaka. The inclusion criteria involved patients who received SOF/DCV ± RBV regimens from 1st January 2020 until 31st December 2022. Sustained virological response (SVR) level was evaluated at week 12 post-treatment (SVR-12). Pre- and post-counselling assessments as well as adverse effects were also being reviewed and evaluated during the MTAC session. **Results:** A high overall SVR-12 rate of 97.8% was observed in this study. The comparison between SVR-12 rates in patients receiving SOF/DCV alone versus those receiving SOF/DCV/RBV suggests that the addition of Ribavirin may contribute to slightly higher treatment success rates (100% vs. 97.7%). However, the difference in SVR-12 rates between the two regimens is minimal. Approximately one-third (33%) of all patients had reported tolerable adverse effects, which were fatigue (11%), headache (5%) and dizziness (3%). An increase in mean knowledge scores post-MTAC session compared to pre-session scores was also observed (7.99 vs 6.76-point score). **Conclusions:** As a conclusion, these findings provide valuable real-world evidence supporting the efficacy and tolerability of SOF/DCV-based regimens in treating Hepatitis C, particularly when integrated with pharmacist-led MTAC programs.