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**Generic versus brand sofosbuvir-based therapy: Safety and efficacy- Real life data****Moutaz F Derbala, Elham Elsayad, Omr Hajelssedig, Aliaa Amer, Nazeeh Eldweik, Saad R Alkaabi, fuad I Pasic and Mohammed E Elbadri**  
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**Background & Aim:** Since the launch of the Qatar plan for HCV control by 2020, the expatriate HCV is a challenge, because of reduced access to innovative treatment caused by restrictions on drug reimbursement. The cost effective analysis, recognizes budget limitations for health care spending and seeks to maximize public health benefits within those budget constraints. In APASL 2016, we reported our preliminary analysis, which showed that low-cost generic antiviral drugs are as effective and safe as the more expensive brand-name drugs, in treating HCV. The aim is to assess the effectiveness and safety of generic versus brand medication, in 399 patients treated with sofosbuvir (SOF) based therapy.

**Method:** This study is a single-centered cohort, retrospective, observational study, including 399 cases. All patients, who started Sof-based regimens, whether brand provided by Hamad center, Qatar, or generic brought by the patients, were included: 24 weeks of SOF/ribavirin (RBV) (22.3%), or 12 weeks of either, SOF/daclatasvir (DCV) (15.9%), SOF/simeprevir (SMV) (29.1%), or SOF/PegIFN/RBV (32.8%).

**Results:** 33.1% were treated with brand and 66.9% were with the generic. GT1/GT4, were 57/399 (14.3%)/342/399 (85.7%). The overall response was 72% for generic compared to 87% for brand. In G4, the generic group had a lower response, both in cirrhotic and non-cirrhotic compared to the original, where SVR in non-cirrhotic was 80% and 88.5%, while in cirrhotic, 67.2% and 75%, respectively. In G1, SVR achieved 88.2% in cirrhotic and 94.1% in non-cirrhotic, with brand, compared to 75.0% and 100%, with generic. There was a significant increase in serotonin level in patients treated with generic compared to brand by weeks 2 and 24 ( $P = 0.029$  and  $0.025$ ), but still within normal. The low response rate was seen in Sof/Rib group, 60.3%. Patients having Sof/Sim or Sof/Dac, are 4.46 and 5.32 times, more likely to achieve SVR-12 than other regimen. The patients received generic medication were more prone to adverse effects ( $P=0.29$ ). 13.6% experienced adverse effects, including: 2 deaths have been reported on SOF/PR due to cardiac arrest and MI, HCC in 5 cases, decompensation in 2, other include anaemia and hyperbilirubemia.

**Conclusion:** Although response in generic is lower than brand, but still comparable, especially in Sof/Sim and Sof/Dac, regimens, with similar safety and tolerability. Generic drugs competition can dramatically reduce the price, but further study of long term safety, is needed. We suggest that Sof/Rib is not a proper option. The low price generic DAAS, ensures access to the new drugs, in low or moderate economic countries, and can afford an opportunity to join the initiative to achieve the ultimate elimination of HCV.

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