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Management of chronic Hepatitis C at a primary health clinic in the high-burden Context of LAHORE, Pakistan

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ABSTRACT

BACKGROUND

The burden of hepatitis C (HCV) infection in Pakistan is among the highest in the world, with a reported national HCV prevalence of 6.7% in 2014.In specific populations ,such as in urban communities in LAHORE, the prevalence is suspected to be higher. Interferon-free treatment for chronic HCV infection (CHC) could allow scale up, simplification and decentralization of treatment to such communities.
We present an interim analysis over the course of February-December 2015 of an interferon-free, decentralized CHC program in the community clinic in Machar Colony, LAHORE, Pakistan.

DESIGN

A retrospective analysis of a relative cohart.

RESULTS

There were1,089 patients included in this analysis. Aspartate to platelet ratio index score was used to prioritize patients in terms of treatment initiation, with 242 patients
Placed in high priority for treatment and
202 starting treatment as scheduled.
169 patients started
HCV treatment with Sofosbuvir-Ribavirin regimen according to HCV genotype over the course of 2015: of these, 35% had Hemoglobin reductions below 11.0 g/dl during the treatment course. Among the153 patients (85%) with genotype 3 HCV infection,84% of patients achieved sustained virologic response at 12 weeks following treatment completion (SVR12).

CONCLUSION

Outcomes of HCV treatment with all oral combination in an integrated, decentralized model of care for CHC in a primary care setting, using simplified diagnostic and Treatment algorithms, are comparable to the outcomes achieved in clinical trial settings For Sofosbuvir based regimens. Our results suggest the feasibility and the pertinence if including interferon-free treatment regimens in the national programme , at both provincial and national levels.

INTRODUCTION

Hepatitis C Virus (HCV) infection is an urgent global health concern. The World Health Organization (WHO) estimates that more than 185 million people are infected with HCV. [1] Transmission is blood-borne, occurring through unsafe injection practices, inadequate sterilization of instruments, blood transfusion, sexual transmission, and mother-to-child transmission. [1] Chronic Hepatitis C can develop
Into cirrhosis and hepatocellular carcinoma, and ~350,000 people are estimated to Die from these complications annually. [2] The prevalence of HCV infection varies worldwide: the Middle East and North African regions, including Egypt and Pakistan, Register among the highest prevalence of HCV. [3] Pakistan is a lower middle income country with a population of approximately 180 million. [4] In 2014, an estimated adult HCV sero prevalence of 6.7% was reported in Pakistan. [4,5] The province of Punjab , where Lahore is situated, has a recorded seroprevalence of 5.5% among the general population. [6,7]
Most important risk factors for HCV transmission in Pakistan are health system-related, including a documented high frequency of therapeutic injections, [8]re use Of syringes, and unlicensed clinics conducting high volumes of blood transfusions, Dental surgeries, etc. [9] Most HCV Infections in Pakistan are genotype 3 (69.1%), Followed by genotypes1 (7.1%), 2 (4.2%) and 4 (2.2%). [5,7]
Interferon (IFN)-based treatment for HCV is recommended by the Chief minister's Programme for Hepatitis B and C, and a 67% end of treatment viral clearance for such regimens has been documented. [10] HCV treatment is conventionally offered Through specialized, tertiary care-level governmental hospitals. Given the high-burden of the disease, these centers are overwhelmed with patients.

METHOD:

This retrospective cohort study was done among CHC patients enrolled in the Hepatitis C programme at the local clinic in lahore, Pakistan.

RESULTS:

Characteristics at enrollment to the programme

For this study, records of 1089 patients were reviewed. Sixty two percent of patients were females, 52% belonged to the 25–44 years age group, and 70% originated from outside the clinic.
Ninety percent were treatment na ive patients, and 372 (34%) patients had no significant liver fibrosis based on their APRI score index.242 patients were considered high priority for treatment initiation.
Of these ,202 (83%) were ultimately placed on treatment, and 17% did not start Treatment as scheduled, signifying at least a 9-month delay in treatment initiation And possibly complete pre-treatment loss-to-follow-up. Reasons for failing to initiate Treatment included delayed family planning initiation (29 patients), patient's unwillingness to start treatment (8 patients) and absent/ incorrect phone numbers for Tracing (4 patients). Males, patients in the 25–44 years age group, and those with Genotype 1 infection were identified as being at higher risk for failing to initiate treatment as scheduled.
From the registration date to treatment initiation, there was a median delay of 72 days (IQR 37–100 days).

Treatment characteristics

One hundred sixty-nine patients were placed on treatment in 2015, and were followed up over their treatment course. Severe anemia was only observed in one patient over the 24-week treatment course, at week 20. Treatment was discontinued
For 2 weeks, folate supplementation was continued and the patient was monitored For symptomatic anemia. Moderate anemia peaked at week 8. For 53 patients (35%), the dose of Ribavirin was reduced as per recommendation, and patients were monitored for symptomatic anemia along with folate supplementation. Median Pretreatment ALT and AST for patients who initiated treatment was 77 and 84 IU/L, respectively.
At the end of treatment, repeat ALT and AST were taken with median levels at 18 and 24 IU/L.

DISCUSSION

The use of the Sofosbuvir-Ribavirin (SOF-RBV) treatment regimen in the Pakistani context is new, given that Sofosbuvir was only registered in Pakistan since November 2014. [20] Treatment outcomes for this setting have to our knowledge
Not yet been published. In this study, an integrated, decentralized model of care for HCV was effective, with loss-to-follow-up rates at 10%.
The outcomes and treatment characteristics are in line with published evidence from Other settings. The new all-oral treatment regimen, with the exception of GT1 (which Requires pegylated IFN on top of the SOF-RBV combination), is highly tolerable with Documented limited adverse events in clinical trials. [16–19] The VALENCE study, a multicenter Phase 3 trial in Europe showed that the SOF-RBV regimen for 24 weeks In GT3 patients had an SVR12 of 85%.[18] Conventional management relying on an

IFN-based treatment regimen over a prolonged time period [10] resulted in general SVR rates of 42–93% for all genotypes, showing only moderate efficacy for the combination of pegylated IFN with Ribavirin in multiple randomized control trials. [19]

CONCLUSION

Hepatitis C management in a programmatic approach using an integrated decentralized model of care in a primary healthcare setting, using direct-acting Antiviral, produces treatment outcomes comparable to clinical trials done for Sofosbuvir based treatment regimens.

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