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Editorial

HCV Epidemic in Egypt: Thinking Outside the Box

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Editorial

Hepatitis C is a global, widespread public health problem where about 130 to 150 million people suffer from chronic Hepatitis C Virus (HCV) [1] which accounts for about 3% of the world's population [2]. It is reported that deaths related to HCV are estimated to be between 350,000 to 500,000 annually.

In Egypt, it is the most pressing public health challenge. According to World Health Organization (WHO), Egypt has the highest prevalence of HCV, A recently published Egypt Health Issues Survey (EHIS) in 2015 on a national level sample study reported that 10% of Egyptians between the ages of 15-59 have HCV infection, 7% of which are chronic active hepatitis C patients [3]. To add insult to injury, the high prevalence of HCV is accompanied by high incidence of HCV further exasperating the problem. Literature reported that the incidence ratio ranges from 2 to 6.9/1000 annually which means 160,000 to 500,000 new HCV infection occurs every year [4].

This huge number of newly infected cases worsens the situation especially with the limited capabilities of Egyptian Ministry of Health and Population (MOHP) of treating those patients and preventing new infections. In addition, the currently utilized treatment regimens for HCV are outdated and have a high cost and low efficacy.

This warrants the need to investigate the current and future burden of this disease not only from an epidemiological perspective, but also from an economic context. This knowledge is highly critical to evaluating the different scenarios of interventions in order to effectively manage this huge public health problem. Having this information would help policy makers in the health sectors decide on the most cost effective strategy to combat this disease at a national level.

Until recently, the standard treatment for HCV genotype 4 (HCV- G4) was a combination of Pegylated Interferon (PEG-INF) and Ribavirin (RBV) for 48 weeks [5]. The efficacy of this combination to treat a HCV-G4 patient was very poor.

With the discovery of Direct Acting Antivirals (DAAs) that target different sites in HCV replication system, a breakthrough in the efficacy of HCV treatment has occurred. There are two main classes of DAAs, but there are some drugs that are specific for HCV-G4 (e.g. Sofosbuvir , Simeprevir and Daclatasvir) , they differ from each other according to the drug target site [5].

The final cost of the course of PEG-INF/RBV 'old' treatment for 48 weeks in Egypt was about US$ 2,000. In comparison, the cost of the new DAAs drugs was very expensive in the US and Europe. For example, the initial cost of Sofosbuvir (SOF) for a 12-week course was US$84,000, and the cost of Simeprevir (SIM) for a 12-week course was US$ 60,000 [6], Fortunately, the Egyptian government managed in its negotiations with Gilead Science to secure a deal where the cost of a SOF 12-week course would b US$900 [6,7]. This price also became the standard for India and other developing countries [8]. Hence, the cost of the triple therapy (SOF+PEG-IFN/RBV) became US$ 1500 [5]. Recently, the head of National Committee for The Control of Viral Hepatitis (NCCVH) declared that the cost of the whole course of SOF + Daclatasvir (DCV) that has been approved for treatment of HCV patients in the last treatment protocol in December 2015 will be US$ 319.3 which is encouraging news [8].

Egypt is in urgent need to decrease its direct and indirect cost burden of HC infection treatment. The following analysis addresses the problem:

1- Three different scenarios in the treatment of HCV [9] were investigated to help estimate the financial burden of using the 'old' vs. new treatment regimens, where the scenario 1 assumes using the 'old' treatment regimen with 48% Sustained Virological Response (SVR) and the current rate of about 65,000 treated cases annually; scenario 2 assumes using the newly introduced drugs with 90% SVR while keeping the number of treated cases annually at 65,000; where scenario 3 assumes using the newly introduced drugs with 90% SVR while increasing the number of treated cases annually to 325,000. Applying regimen cost to the three scenarios above, shows that for scenario 1, the total cumulative cost burden (of continuing to use the old regimen) would be US$ 89.1 billion; in scenario 2, the financial burden would be lowered by a

decent 3.7%; scenario 3, however, reduces the financial burden by a whopping 35.4% bringing it down to US$57.6 billion [9].

2- Monitoring of DAAs treatment in order to determine whether it should be stopped or whether existing patients should continue the full treatment course until completion [10].This decision-making process requires frequent viral RNA testing. Despite the high specificity, sensitivity and reproducibility of HCV RNA quantification assays, their costs can constrain their utility in resource-limited countries. Furthermore, molecular assays performed in batches which may prolong the turn -around times that preclude the efficient HCV DAA treatment decisions [11]. Conversely, HCV core antigen (HCV c Ag) quantification assay [12] constitutes a rapid, more economical and easier-to-perform method, with good correlation to HCV RNA assays [13-15]. These advantages were previously investigated to assess the ability of antigen testing to replace molecular viral load testing for monitoring treatment of PEG-IFN/RBV therapy. The results showed the potential clinical utility of HCV c Ag at early stages in dual PEG-IFN/RBV therapy to predict treatment response as early as day 3 [16], week 1 [15,17] or week 2 [11,17-19].

References

1. WHO (2015) Hepatitis C.
2. NIH (2002) National Institutes of Health Consensus Development Conference Statement: Management of hepatitis C 2002 (June 10-12, 2002). Gastroenterology 123: 2082-2099.
3. El-Zanaty and Associates [Egypt] & ICF International (2015) Ministry of Health and Population [Egypt], Egypt Health Issues Survey 2015.
4. Breban R, Doss W, Esmat G, Elsayed M, Hellard M, et al. (2013) Towards realistic estimates of HCV incidence in Egypt. Journal of Viral Hepatitis 20: 294-296.
5. Abdel-Razek W and Waked I (2015) Optimal therapy in genotype 4 chronic hepatitis C: finally cured?. Liver International 35: 27-34.
6. Fick M and Hirschler B (2014) Gilead offers Egypt new hepatitis C drug at 99 percent discount. Reuters.
7. Wanis H (2014) HCV Treatment in Egypt, Why cost remains a challenge?.
8. Palmer E (2014) Gilead Sciences prices Sovaldi in India at a tiny fraction of U.S. cost.
9. Estes C, Abdel-Kareem M, Abdel-Razek W, Abdel-Sameea E, Abuzeid M, et al. (2015) Economic burden of hepatitis C in Egypt: the future impact of highly effective therapies. Alimentary Pharmacology & Therapeutics 42: 696-706.
10. European Association (2014) EASL Clinical Practice Guidelines: management of hepatitis C virus infection. Journal of hepatology 60: 392-420.
11. Loggi E, Cursaro C, Scuteri A, Grandini E, Panno AM, et al. (2013) Patterns of HCV-RNA and HCV core antigen in the early monitoring of standard treatment for chronic hepatitis C. Journal of Clinical Virology 56: 291-295.
12. Morota K, Fujinami R, Kinukawa H, Machida T, Ohno K, et al. (2009) A new sensitive and automated chemiluminescent microparticle immunoassay for quantitative determination of hepatitis C virus core antigen. Journal of virological methods 157: 8-14.
13. Loggi E, Cursaro C, Scuteri A, Grandini E, Panno AM, et al. (2013) Patterns of HCV-RNA and HCV core antigen in the early monitoring of standard treatment for chronic hepatitis C. Journal of clinical virology: the official publication of the Pan American Society for Clinical Virology 56: 207-211.
14. Veillon P, Payan C, Picchio G, Maniez-Montreuil M, Guntz P, et al. (2003) Comparative evaluation of the total hepatitis C virus core antigen, branched-DNA, and amplicor monitor assays in determining viremia for patients with chronic hepatitis C during interferon plus ribavirin combination therapy. Journal of clinical microbiology 41: 3212-3220.
15. Vermehren J, Susser S, Berger A, Perner D, Peiffer KH, et al. (2012) Clinical utility of the ARCHITECT HCV Ag assay for early treatment monitoring in patients with chronic hepatitis C genotype 1 infection. Journal of clinical virology: the official publication of the Pan American Society for Clinical Virology 55: 17-22.
16. Fujino T, Nakamuta M, Aoyagi Y, Fukuizumi K, Takemoto R, et al. (2009) Early decline of the HCV core antigen can predict SVR in patients with HCV treated by Pegylated interferon plus ribavirin combination therapy. Journal of digestive diseases 10: 21-25.
17. Wada Y, Tamai H, Uno A, Kawashima A, Shingaki N, et al. (2014) Prediction of efficacy to pegylated interferon-alpha-2b plus ribavirin in patients with genotype 2 hepatitis C virus using viral response within 2 weeks. Hepatology research: the official journal of the Japan Society of Hepatology 44: 179-186.
18. Tamai H, Shingaki N, Shiraki T, Tukuda H, Mori Y, et al. (2011) Prediction of sustained response to low-dose pegylated interferon alpha-2b plus ribavirin in patients with genotype 1b and high hepatitis C virus level using viral reduction within 2 weeks after therapy initiation. Hepatology research: the official journal of the Japan Society of Hepatology 41: 1137-1144.
19. Tedder RS, Tuke P, Wallis N, Wright M, Nicholson L, et al. (2013) Therapy-induced clearance of HCV core antigen from plasma predicts an end of treatment viral response. Journal of viral hepatitis 20: 65-71.