

Treatment with IMOD™ as a Novel Immune Modulator in HIV Positive Patients

SeyedAhmad SeyedAlinaghi¹, Koosha Paydary^{1,2}, Sahra Emamzadeh-Fard^{1,2} and Minoo Mohraz^{1*}

¹Iranian Research Center for HIV/AIDS (IRCHA), Tehran University of Medical Sciences, Tehran, Iran

²Students Scientific Research Center (SSRC), Tehran University of Medical Sciences, Tehran, Iran

Although, Highly Active Anti-retroviral Therapy (HAART) has significantly reduced the mortality and morbidity of HIV positive patient, its failure has been regarded as an important challenge in countries with prevalent HIV infection. In fact, HAART failure is extensively attributed to adverse effects, toxicities, psychological problems and development of resistance which are substantially observed in developing countries [1,2]. Immune-based therapies consist of different types of interleukins, cytokines, interferons and hormones have been discussed as valuable therapeutic alternatives throughout literature [3-5].

Setarud (IMOD™) which is composed of a mixture of herbal extracts, selenium, carotene and flavonoids, is a safe and effective drug among immune-based therapies [6-12]. It has anti-inflammatory properties and immune system stimulating effects such as increasing Interferon- γ and Interleukin-2. No specific adverse effects or dose-limiting toxicity have been mentioned till now [13,14].

We performed a study to assess the patients' and doctors' satisfaction from taking IMOD™ in different cities in Iran. A total of 198 HIV-positive patients were enrolled in our study. We surveyed patients and doctors' satisfaction from taking IMOD™ in 11 cities in Iran including Arak, Bandar Abbas, Bushehr, Isfahan, Gorgan, Kerman, Khoramabad, Mashhad, Shiraz, Tehran and Zahedan. Patients' and physicians' satisfactions were measured via using a questionnaire including the overall satisfaction based on a 10 point likert scale. Ethical approval was obtained from Ethics Committee of Tehran University of Medical Sciences. Before study registration, goals and objectives of the study such as the right to withdraw from participation in the study were thoroughly explained for patients. A hundred and sixty seven patients (84.3%) were male and 31 patients (15.7%) were female. Majority of the patients (50%) were 31-40 years old. Ninety three point one percent of patients were satisfied from the treatment. Doctor's satisfaction was also reported in 72.9%. After all, the overall patient's and doctor's satisfaction was adequately high in this study regarding the 11 cities in Iran. Such high patients' and doctors' satisfaction could also be attributed to the low prevalence of adverse effects in combine with acceptable clinical outcomes [10,12].

It has been shown that 50-70% of patients with HIV/AIDS who were taking HAART experienced problems with adverse effects which affected their adherence rate to the medications [15]. Subsequently, low adherence to HAART regimen may cause CD₄ decline and poor health condition [16]. Thereby, development of novel drugs with less adverse effects and higher tolerability has been announced as an imperative necessity worldwide. Among the newly introduced medications, IMOD™ is a safe immunomodulator drug with no reported serious side effects in previous trials [10-12].

Results of our studies present a potentially effective treatment for HIV patients with minimal side effects, especially among patients who had experienced adverse effects, consequent resistance or treatment failure associated with HAART regimen. For the most part, IMOD™ seems to be beneficial particularly in developing countries. Regarding

the high levels of patient and physician's satisfaction in combination with its safety and effectiveness [6-12], we propose IMOD™ for the treatment of HIV patients either alone or in combination with HAART, especially in developing nations.

References

1. Fellay J, Boubaker K, Ledergerber B, Bernasconi E, Furrer H, et al. (2001) Prevalence of adverse events associated with potent antiretroviral treatment: Swiss HIV Cohort Study. *Lancet* 358: 1322-1327.
2. Murphy RA, Sunpath H, Kuritzkes DR, Venter F, Gandhi RT (2007) Antiretroviral Therapy-Associated Toxicities in the Resource-Poor World: the Challenge of a Limited Formulary. *J Infect Dis* 196: S449- S456.
3. Novitsky YA, Madani H, Gharibdoust F, Farhadi M, Farzamfar B, et al. (2007) EU Patent Application 087825.
4. Hunt PW, Deeks SG (2006) Immune-based therapy for HIV infection: are acute and chronic HIV infection different diseases? *J Infect Dis* 194:1632-1634.
5. Rizzardi GP, Harari A, Capiluppi B, Tambussi G, Ellefsen K, et al. (2002) Treatment of primary HIV-1 infection with cyclosporin A coupled with highly active antiretroviral therapy. *J Clin Invest* 109: 681- 688.
6. Kanter M, Coskun O, Budancamanak M (2005) Hepatoprotective effects of *Nigella sativa L* and *Urtica dioica L* on lipid peroxidation, antioxidant enzyme systems and liver enzymes in carbon tetrachloride-treated rats. *World J Gastroenterol* 11: 6684- 6688.
7. Schinella GR, Giner RM, Mordujovich BP, Rhos JL (1998) Anti-inflammatory effects of South American *Tanacetum vulgare*. *J Pharm Pharmacol* 50: 1069-1074.
8. Ninomiya K, Matsuda H, Kubo M, Morikawa T, Nishida N, et al. (2007) Potent anti-obese principle from *Rosa canina*: structural requirements and mode of action of trans-tiliroside. *Bioorg Med Chem Lett* 17: 3059-3064.
9. Chrubasik JE, Roufogalis BD, Wagner H, Chrubasik S (2007) A comprehensive review on the stinging nettle effect and efficacy profiles. Part II: *urticae radix*. *Phytomedicine* 14: 568-579.
10. Mohraz M, Kheirandish P, Kazerooni PA, Davarpanah MA, Shahhosseini MH, et al. (2009) A clinical trial on the efficacy of IMOD in AIDS patients. *Daru* 17: 277-284.
11. Kheirandish P, Mohraz M, Farzamfar B, Abdollahi M, Shahhosseini MH, et al. (2009) Preclinical and phase 1 clinical safety of Setarud (IMOD), a novel immunomodulator. *Daru* 17: 148-156.
12. Mohraz M, Sedaghat A, SeyedAlinaghi SA, Asheri H, Mohammaddoust S, et al. (2012) Post marketing surveillance on safety and efficacy of IMOD™ in Iranian patients with HIV/AIDS. *Infectious Disorders -Drug Targets*: In press.

*Corresponding author: Minoo Mohraz, Iranian Research Center for HIV/AIDS (IRCHA), Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran, Tel: +98-021-66947984; E-mail: minoomohraz@ams.ac.ir

Received November 01, 2012; Accepted November 14, 2012; Published November 21, 2012

Citation: Alinaghi SAS, Paydary K, Emamzadeh-Fard S, Mohraz M (2012) Treatment with IMOD™ as a Novel Immune Modulator in HIV Positive Patients. *J AIDS Clinic Res* 3:180. doi:10.4172/2155-6113.1000180

Copyright: © 2012 Alinaghi SAS, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

13. Khorram Khorshid HR, Abdollahi M, Novitsky YA, Shahhosseiny MH, Sadeghi B, et al. (2008) Studies on potential Mutagenic and Genotoxic activity of Setarud. Daru 16: 223-228.
14. Khorshid HR, Azonov JA, Novitsky Y, Farzamfar B (2008) Hepatoprotective effects of setarud against carbon tetrachloride-induced liver injury in rats. Indian J Gastroenterol 27: 110-112.
15. Roca B, Gómez CJ, Arnedo A (1999) Stavudine, lamivudine and indinavir in drug abusing and non-drug abusing HIV-infected patients: adherence, side effects and efficacy. J Infect 39: 141-145.
16. Gifford AL, Collins R, Timberlake D, Schuster MA, Shapiro MF, et al. (2000) Propensity of HIV patients to seek urgent and emergent care. HIV Cost and Services Utilization Study Consortium. J Gen Intern Med 15: 833-840.