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Research Article

THERAPEUTIC EFFECT OF A UNANI FORMULATION ON HEPATITIS B SURFACE ANTIGEN IN CHRONIC HEPATITIS B: A CASE SERIES

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ABSTRACT

Objectives: Chronic hepatitis B (CHB) is a major health concern in terms of its high prevalence, as well as restricted, and costly health care resources in India. The physicians of the Unani system of Medicine have been treating hepatitis since centuries. The purpose of our study was to assess the effect of Unani Formulation in the treatment naïve, CHB cases and to collect data to warrant further clinical trials.

Methods: We conducted a case series with five patient of CHB, subsequently treated with the Unani formulation. Cases were confirmed with standard hepatitis antigen and viral measurements. The patients were treated for 6 months with measurement of the hepatitis B surface antigen (HbsAg).

Results: Loss of surface antigen occurred in the patients and became HbsAg negative within an average 13 weeks of treatment.

Discussion: We reviewed the literature related to the Unani formulation used for the treatment in this study. Its constituents have exhibited antiviral, anti-inflammatory, immunomodulatory, hepatoprotective and antioxidant properties, suggesting possible mechanisms of action in the CHB.

Conclusion: The preliminary findings indicate the potential therapeutic role of the Unani formulation in the treatment of CHB. Clinical trials based on this Unani pharmacopeal formulation should be conducted to explore the therapeutic potential of this formulation in CHB.

Keywords: Chronic hepatitis B, Unani Medicine, Unani formulation, Complementary Medicine, Herbal antivirals, Hepatoprotective, *Warme jigar*, Viral hepatitis.

INTRODUCTION

Chronic hepatitis B (CHB) describes a spectrum of the disease usually characterized by the presence of detectable HbsAg in the blood or serum for longer than 6 months. The hepatitis B virus (HBV) causes chronic infection in 350 million people worldwide, 75% of whom are in the Asia-Pacific region [1]. HBV infection contracted early in life may lead to chronic hepatitis, then to cirrhosis, ascites, and finally to hepatocellular carcinoma, usually after a period of 30-50 years. Approximately, 15-40% patients infected with HBV will develop life-threatening liver consequences [2,3].

Every year over 100,000 Indians die due to illnesses related to HBV infection [2]. Due to the high prevalence of CHB, as well as restricted and costly healthcare resources in India, alternative approach in the treatment is the best way to combat such a global pandemic. Several antivirals are currently available for the treatment of HBV, which include interferon-α (IFN)-α, lamivudine, entecavir, telbivudine, tenofovir [4]. However, IFN therapy has limited efficacy and frequently cause adverse effects. IFN therapy is highly costly, and resistance develops in the case of prolonged therapy with antivirals [1,5].

The physicians of the Unani system of Medicine have been treating various forms of hepatitis since centuries. The entity "*Warme Jigar*" in Unani literature, mimic CHB and associated constellation of symptoms. A large number of single and compound drug preparation have been documented in the treatment of *Warme jigar*. Several mono and polyherbal preparations of Unani medicine have been proved for their efficacy in the management of CHB. These scientific studies have validated the antiviral, immunomodulatory, anti-inflammatory, and hepatoprotective nature of plant-based medicines, and their bioactive principle has been isolated and characterized. The Unani formulation is a polyherbal preparation of Unani medicine, mainly used as a purifier of morbid material from the blood. So present case series was performed, aimed to explore the effect of Unani formulation on HbsAg in CHB.

METHODS

Informed consent was taken from the patients. The human data's which are included in this case series were obtained in compliance with the declaration of Helsinki.

Intervention

Unani formulation used in this case series consisted of shahtara (*Fumaria officinalis*), sarphookah (*Tephrosia purpurea*), chiraita (*Swertia chiraita*), gule mundi (*Sphaeranthus indicus*), and sandal surkh (*Pterocarpus Santalinus*). A crude form of drugs, 5 g of each was advised to be soaked in 50 ml warm water overnight. The soaked drug was then advised to be heated for 10 minutes in the morning and to be ingested lukewarm empty stomach daily for 6 months.

Case presentation

Case 1: A 40 years Indian male admitted to the in-patient department of Majeedia Unani Hospital (MUH) on November 13, 2013 with the chief

Table 1: Effect of treatment on HbsAg

Case no	HbsAg		Week at which HbsAg loss
	Pre-treatment (positive)	Post-treatment (negative)	
Case 1	15.59 IU/ml on 24/01/14	<0.04 IU/ml on 16/06/14	20 weeks
Case 2	05/09/13	<0.01 IU/ml on 08/01/14	17 weeks
Case 3	10/02/14	<0.01 IU/ml on 16/06/14	18 weeks
Case 4	10/09/14	<0.01 IU/ml on 16/10/14	5 weeks
Case 5	16.41 IU/ml on 10/11/14	<0.01 IU/ml on 02/01/14	8 weeks

HbsAg: Hepatitis B surface antigen

Table 2: Effect of Unani formulation on subjective parameters

Case no	Jaundice		Pain in abdomen		Loss of appetite		Fever		Flatulence		General weakness	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Case 1	2	0	2	0	3	0	2	0	2	0	2	0
Case 2	1	0	1	0	2	0	0	0	1	0	2	0
Case 3	1	0	1	0	1	0	0	0	0	0	1	0
Case 4	0	0	1	0	2	0	1	0	1	0	1	0
Case 5	0	0	1	0	2	0	0	0	2	0	1	0

Were analyzed and graded on a scale 0-3 (Likert scale); 0-Nil, 1-Mild, 2-Moderate and 3-Severe

complains of (1) jaundice (2) constipation (3) headache (4) body ache (5) fullness in abdomen and (6) loss of appetite since 2 years. He was a known case of CHB since 10 months. Pre-treatment, Australia antigen (HbsAg) titer value through minividas was 15.59 IU/ml on 24th January 2014 which turned out negative (<0.04 IU/ml) on 16th June 2014 post-treatment with the Unani formulation.

Case 2: A 20 years Indian male came to the outpatient department of MUH on September 30, 2013 with chief complains of (1) jaundice (2) appetite loss (3) mild pain in right hypochondriac region (4) flatulence (5) General weakness and (6) pain in legs while walking from 2 years. Viral testing revealed a positive HbsAg (5th September 2013) pre-treatment. HbsAg became negative on 8th January 2014 after treatment.

Case 3: A 30 years Indian male came to MUH on February 10, 2014 with chief complains of mild jaundice and associated symptoms. Pre-treatment, Australia antigen (HbsAg) was positive on 10th February 2014 which became negative (<0.01 IU/ml) on 16th June 2014 post-treatment.

Case 4: A 25 years Indian Male came to MUH on September 10, 2014 with chief complains of (1) ulceration of mouth (2) loss of appetite (3) general weakness (4) pain in abdomen. He was a chronic case of hepatitis B since 5 years. Pre-treatment, Australia antigen was positive (10th September 2014) which turned out negative (<0.01 IU/ml) on 16th October 2014, 1-month post-treatment.

Case 5: A 22 years Indian Male came to the outpatient department of MUH on November 10, 2014 with chief complains of (1) Retrosternal burning (2) appetite loss (3) general weakness with history of renal calculi. Pre-treatment, HbsAg titer value through minividas was 16.41 IU/ml on 10th November 2014 which became negative (<0.01 IU/ml) on 2nd January 2015, approx. 2 months post-treatment. Symptomatic improvement was also achieved post-treatment.

Outcome measures

Patients were evaluated with measurement of their HbsAg quantitative value at basal and every 2 months. Improvement in symptoms was also recorded every fortnightly.

RESULTS

HbsAg in these patients became negative at an average of 13 weeks post-treatment. The HbsAg loss in these five cases during the course of Unani treatment is shown in Table 1. Complete relief in symptoms of our patients such as loss appetite, jaundice, fever, general weakness, pain in abdomen, flatulence were also observed after 1 and 2 weeks of treatment with this Unani formulation Table 2.

DISCUSSION

According to a recent estimate, more than 700 single and compound herbal preparations in the form of syrup decoction, tincture, majoon, tablets and capsules from more than 100 plants are under usage for liver disorders [6]. In our series, treatment was given of a Unani formulation, consisted of decoction of six plants, shahtara (*F. officinalis*), sarphookah (*T. purpurea*), chiraita (*S. chiraita*), gule mundi (*S. indicus*), and sandal surkh (*P. Santalinus*) which have been used as systemic purifier since decades in the Unani system of medicine.

In our patients of CHB, we prescribed above mentioned Unani formulation daily for 6 months to evaluate its effect on serum HbsAg. HbsAg became negative at an average of 13 weeks of treatment in these cases. The ideal aim of any therapy is to eradicate HbsAg and the virus from the body [1] which was achieved with this Unani formulation. Treatment with nucleoside analogue in CHB such as tenofovir which produces HbsAg loss in only 5% of the patient after 1-year of therapy [7] while with our drug HbsAg loss occurred very rapidly (maximum 20 weeks) along with improvement in their symptoms.

The suppressive effect on these viral marker, possibly could be due to constituents of the preparation, which have been proved for their potential antiviral activity in various animal models [8-12].

CONCLUSION

This case report provides a novel direction in which above mentioned Unani formulation can be used in the treatment of CHB. Therefore, further studies should be performed to warrant the antiviral effect and mechanism of action of this Unani formulation in CHB.

REFERENCES

1. National Clinical Guideline Centre (NICE), 2013. Hepatitis B (chronic): Diagnosis and management of chronic hepatitis B in children, young people and adult. p. 13-15, 20. Available from http://www.nice.org.uk/guidance/cg165/resources/cg165-hepatitis-b-chronic-full-guideline3. [Last accessed on Jan 2014].
2. Anand AC, Pankaj P. Indian Guidelines and Protocols: Hepatitis B. 2012. Ch. 53. Gastroenterology. Available from: http://www.apiindia.org/medicine_update_2013/chap53.pdf.
3. WHO. Hepatitis B (2014). In section Global Alert and Response (GAR). Available from: http://www.who.int/mediacentre/factsheets.fs204/en/print.html. [Last accessed on Jan 2014].
4. Grimm D, Thimme R, Blum HE. HBV life cycle and novel drug target. Hepatol Int 2011;5(2):644-53.
5. Schalm SW, Janssen HL. Treatment of HBeAg-positive chronic hepatitis B with conventional or pegylated interferon. Conference on Management of viral hepatitis, Paris. 2004. p. 246, 251, 254.
6. Ansari S, Siddiqui MA, Khan AA, Ahmad MA, Jabeen A, Asif M, *et al*. Experimental` models and hepatotoxic agents used to study hepatoprotective effect of traditional drugs. Int J Adv Pharm Med Bioallied Sci 2014;2:67-74.
7. Chang TT, Gish RG, de Man R, Gadano A, Sollano J, Chao YC, *et al*. A comparison of entecavir and lamivudine for HBeAg-positive chronic hepatitis B. N Engl J Med. 2006;354:1001-10.
8. Vimalanathan S, Ignacimuthu S, Hudson JB. Medicinal plants of Tamil Nadu (Southern India) are a rich source of antiviral activities. Pharm Biol 2009;47(5):4229.
9. Verma H, Patil PR, Kolhapure RM, Gopalkrishna V. Antiviral activity of the Indian medicinal plant extract, *Swertia chirata* against herpes simplex viruses: A study by *in-vitro* and molecular approach. Indian J Med Microbiol 2008;26(4):322-6.
10. Tiwari BK, Khosa RL. Hepatoprotective and antioxidant effect of *Sphaeranthus indicus* against acetaminopheninduced hepatotoxicity in rats. J Pharm Sci Res 2009;1:2630.

11. Parmar KA, Patel AN. Preliminary phytochemical screening and study of antiviral activity and antibacterial activity of *T. purpurea* flower. Life Sci Leaf 2010;1:7-13.

12. Orhan I, Ozcelik B, Karaoglu T, Sener B. Antiviral and antimicrobial profiles of selected isoquinoline alkaloids from *Fumaria* and *Corydalis* species. Z Naturforsch 2007;62(1-2):19-26.