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International Journal of Current Research
Vol. 8, Issue, 10, pp.40522-40524, October, 2016

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

EARLY VIRAL RESPONSE IN CHRONIC HEPATITIS C PATIENTS TREATED WITH A POLYHERBAL UNANI FORMULATION – A CASE SERIES

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ARTICLE INFO

Article History:
Received 10th July, 2016
Received in revised form
24th August, 2016
Accepted 16th September, 2016
Published online 30th October, 2016

Key words:
Unani medicine,
Early Viral Response,
Arq Murakab Mussafi Khoon,
Hepatitis C.

ABSTRACT

In Unani medicine liver occupies prime importance and has been mentioned as the seat of humour production. Any derangement in the functioning of liver will certainly effect the functioning of whole body. A number of single and polyherbal formulations are being used in the management of hepatic disorders. The objective of the present study was to evaluate the therapeutic effect of Arq Murakab Mussafi Khoon (AMMK) in the chronic hepatitis C (CHC). We conducted a case series with five diagnosed treatment naïve cases of CHC. The diagnosis was reconfirmed by standard diagnostic procedures including Anti HCV antibody and HCV (RNA) quantitative. The constituents of AMMK possess antioxidant, hepatoprotective, anti-inflammatory, antiviral and immunomodulatory activity. Viral response was evaluated on the basis of Early Viral Response (EVR) after 12 weeks of treatment. Out of 5 patients partial EVR was observed in 2 patients, although the other 3 patients did show marked reduction in viral load but could not qualify for partial EVR, as the reduction in viral number was less than 2 log. We concluded that AMMK may have a therapeutic effect in CHC but further large scale randomized controlled trials should be carried out.

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Citation: Mohammad Akhtar Siddiqui and Amjad Waheed Yousuf, 2016. "Early viral response in chronic Hepatitis C patients treated with a Polyherbal unani formulation – A case series", *International Journal of Current Research*, 8, (10), 40522-40524.

INTRODUCTION

In 1989 Hepatitis C virus was proclaimed to be a major cause of non A, non B hepatitis transmitted parenterally. As reported by World Health Organization about 3% of the world's population is infected with HCV with more than 170 million chronically HCV-infected patients. Each year about 3–4 million persons acquire the infection for the first time (http://www.who.int/mediacentre/factsheets/fs164/en/. Accessed July 3, 2014; Patel *et al*., 2006; Hisham Shawkat, 2015). Seroprevalence of Hepatitis C has been reported to be 0.87% in Indian population while as it is 1.8-2.5 % among voluntary blood donors (Pal, 2005). About 80 % of the newly infected cases of Hepatitis C develop chronic infection with 10-20 % developing cirrhosis and 1%–5% developing Hepatocellular carcinoma (HCC) over a period of 20–30 years (Hisham Shawkat, 2015; Yakoot and Salem, 2012). Advanced liver disease due to HCV is now the leading indication for liver transplantation worldwide. The consequences and complications of chronic Hepatitis C (CHC) contribute a significant disease burden and, therefore, calls for effective management.

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Treatment of HCV with interferon (IFN)-based regimens can result in eradication of virus, thereby reducing incidence of hepatic decompensation and HCC leading to prolonged survival (Kanwal *et al*., 2011; Backus *et al*., 2011; Morgan *et al*., 2010). Sustained virological response (SVR), defined as undetectable levels of HCV RNA at least 24 weeks after completion of therapy, is the primary endpoint of successful therapy, and is associated with durable clearance of virus in more than 98 % of cases (George, 2009). Treatment with interferon (IFN) and antivirals is associated with many adverse effects, high cost, and inconvenience in administering injections.

Unani System of medicine has many formulations that have been claimed to possess haemo-purifying effect and are free of adverse effects, cost effective and easy to administer. Arq Murakab Mussafi Khoon (AMMK) is a polyherbal formulations that has been used in the management of disorders that are believed to occur due to impurities of blood and includes presence of infectious organisms in the blood (Qarabadeen-e Majeedi, 1986).

AMMK is a liquid preparation obtained by steam distillation of powdered drug material and contains Chiraita (*Swertiachiraita*), Shahtara (*Fumaria officinalis*), Neem (*Azardirachta indica*), Sandal surkh (*Pterocarpus santalinus*), Sarphooka (*Tephrosia purpurea*), Halelazard (*Terminalia*

belerica), Halela syah (*Terminalia belerica*), Gule mundi (*Sphaeranthus indicus*), Neel kanthi (*Gentiana kurroo*), Birhamdandi (*Echinops echinatus*), Sandal safaid (*Santalinum album*), Barghina (*Lawsonia inermis*), Burada abnoos (*Diospyros ebenum*), Burada sheesham (*Dalbergia sisso*), Unnab (*Szygigium zizyphus*), Gule neelofurr (*Nymphaea alba*) (Qarabadeen-e Majeedi, 1986). In experimental studies, constituents of AMMK have shown antioxidant, hepato protective, anti-inflammatory, antiviral and immunomodulatory activity (Ashish Turaskar, 2013). There is no clinical evidence for the use of AMMK in CHC, hence the current preliminary case series study is undertaken to evaluate the effect of AMMK on viral load in CHC patients.

MATERIALS AND METHODS

This prospective, preliminary study is being conducted in the Majeedia Unani Hospital (MUH), Jamia Hamdard, New Delhi. CHC patients aged 18–50 years, of either sex, are included in the study. Patients were not included if they had a history of treatment with conventional INF, pegylated INF or ribavirin (RBV) less than 6 months prior to enrolment. Patients with impaired kidney function, as cites, encephalopathy, decompensated liver disease, active co-infection with HBV, history of any systemic anticancer or immune modulatory treatment 6 months prior to enrolment were excluded. Pregnant women, lactating women, patients having history of hepatic, renal, or other major organ transplantation were also excluded from the study. AMMK 100 ml daily in two divided doses of 50 ml each before breakfast and before dinner was given to enrolled patients. (Qarabadeen-e-Majeedi, 1986) Duration of treatment is 48 weeks in all the patients of either genotype**.** Complete blood count (CBC), liver function test, prothrombin time (PT) and HCV (RNA) quantitative (RT-PCR) were done at baseline and repeated at around 12 weeks in all the patients.

Effect of treatment on viral load was determined by estimating the early virological response (EVR) and after the completion of treatment period will be determined by End of treatment response (ETR) and Sustained virological response (SVR). Partial EVR is >2 log reduction in HCV (RNA) level as compared to the baseline by 12 weeks and complete EVR is HCV (RNA) not detectable at treatment week 12 (Helen, 2012). Each patient was informed before enrolment in the study and the study was conducted in accordance to the Helsenki declaration.

Case 1

A twenty year Indian male with diagnosed treatment naïve CHC was admitted in the male general ward of MUH with chief complaints of general weakness, constipation, flatulence and pain upper abdomen. All routine hematological investigations were conducted. The base line HCV (RNA) was 7414261 IU/ml (RT-PCR) on 20 Jan 2014 which reduced to 65525 IU/ml (RT-PCR) on 09 April, 2014 12 weeks after initiation of treatment.

Case 2

Eighteen years Indian male diagnosed as CHC was registered in the OPD of MUH on 13 June, 2014 with complaints of loss of appetite, pain right hypochondrium and nausea. Viral load at the beginning of treatment was 67214 IU/ml (RT-PCR) which reduced to 2712 after 12 weeks of treatment.

Case 3

Fifty year Indian male registered for the first time on 26 July, 2015 as a case of CHC and presenting with chief complaints of pain in right hypochondrium and general weakness. Base line HCV (RNA) was 21448225 IU/ml (RT-PCRT) on 26 July, 2015. After the treatment for 14 weeks HCV (RNA) dropped to 8939 IU/ml (RT-PCR).

Case 4

A thirty five year Indian male, who was a known case of CHC was registered in the OPD of MUH on 24 Oct, 2015. Baseline HCV (RNA) was 8199700 IU/ml (RT-PCR) as on 24 Oct, 2015. After taking treatment for 12 weeks the viral load came down to 396538 IU/ml (RT-PCR) on 14 Nov, 2015.

Case 5

Treatment naïve thirty five year Indian female was registered in the OPD of MUH on 10 Dec, 2015 for the management of already diagnosed CHC. Baseline HCV (RNA) was 1044895 IU/ml (RT-PCR) as on 11 Dec, 2015 which declined to 575763 after 12 weeks of treatment.

RESULTS AND DISCUSSION

Out of the total 5 patients 4 (80%) were male while 1 (20%) was female with a mean age of 31.6 years. Assessment of effect on the viral load was evaluated on the basis of EVR at the end of 12 weeks. Over all partial EVR was obtained in 2 cases (40%), complete EVR was not recoded in any of the patients while 3 (60%) patients had a significant decrease in viral load but could not qualify as partial EVR and were non-EVR (Table 1). Viral load in all the five cases reduced from a mean of 7634859 IU/ml (Log 10) to a mean of 209895.4 IU/ml (Log 10) after a treatment of 12 weeks. The percentage decrease in mean viral load was 97.25 %.

The spectrum of liver disease in patients infected with hepatitis C virus (HCV) ranges from minimal lesions in HCV asymptomatic carriers to chronic hepatitis of variable severity, cirrhosis, and HCC. Different host and viral factors have been postulated to influence the clinical outcome of the disease. (De Moliner, 1998) Eradication of virus in CHC is possible with interferon and antiviral regimens but involve a high cost. Unani system of medicine has an array of single and polyherbal formulations that are implicated in hepatic disorders. AMMK is one such formulation used in current case series (Qarabadeen-e Majeedi, 1986).

Table 1. Changes in the viral load at the end of 12 weeks (EVR)

Case No.	HCV (RNA) IU/ml (Log 10) (RT-PCR)		Log reduction	Virological Response
	Base line	12 + 1weeks		
1	7414261	65525	2.1	Partial EVR
2	67214	2712	1.4	Non EVR
3	21448225	8939	3.4	Partial EVR
4	81,99,700	3,96,538	1.3	Non EVR
5	1044895	575763	0.3	Non EVR

In the present case series we observed that with the use of AMMK out of 5 patients partial EVR was achieved in 2 cases with a reduction of more than 2 log in the viral numbers. In the remaining cases a mean of 1 log reduction was observed in the viral load and were therefore categorized as non EVR response. The aim of management in CHC is elimination of the virus thereby reducing the possibilities of complications including cirrhosis and HCC. Interferon and antivirals are ideal therapy for chronic hepatitis C, however, in India a major chunk of cases being below poverty line turn towards traditional medicines for treatment. Treatment with AMMK has shown a significant effect on the viral load and therefore, can be evaluated as an alternative to conventional treatment or adjuvant to potentiate its effect. Patients of the current series will be followed further till completion of the treatment and the results will be evaluated.

Conclusion

AMMK has shown a therapeutic effect in chronic hepatitis C by markedly reducing the viral load. Although we may not suggest use of AMMK as an alternative to conventional treatment, however, further large sample size studies with AMMK should be carried out to evaluate its effect in the treatment of chronic hepatitis C.

Conflict of Interest: Non declared

Source of funding: Nil

Acknowledgement

We are indebted to the patients for their co-operation during the study.

REFERENCES

Ashish Turaskar *et al*. 2013. Antianaemic potential of Swertia chirata on phenylhydrazine induced reticulocytosis in rats: *AJPCTI*, (1) 037-041.

Backus, L.I., Boothroyd, D.B., Phillips, B.R. *et al.* 2011. A sustained virologic responsereduces risk of all-cause mortality in patients with hepatitis C. *Clin Gastroenterol Hepatol.,* 9: 509 – 516.e1

De Moliner, L 1998. Serum and liver HCV RNA levels in patients with chronic hepatitis C: correlation with clinical and histological features: Gut 42:856–860

George, S.L., Bacon, B.R., Brunt, E.M. *et al.* 2009. Clinical, virologic, histologic, and biochemical outcomes after successful HCV therapy: A 5-year follow-up of 150 patients. *Hepatology* 49: 729 – 38.

Helen, S. Yee, *et al*. 2012. Update on the Management and Treatment of Hepatitis C Virus Infection: Recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office, *Am J Gastroenterol* advance online publication, 24 April 2012; doi: 10.1038/ajg.2012.48

Hisham Shawkat *et al*. 2015. Efficacy and safety of a herbal mixture (Virontablets) in the treatment of patients with chronic hepatitis C virus infection: A prospective, randomized, open-label, proof-of-concept study. Drug Design, *Development and Therapy*, 9; 799-804

Kanwal, F., Hoang, T., Kramer, J.R. *et al.* 2011. Increasing prevalence of HCC and cirrhosis in patients with chronic hepatitis C virus infection. *Gastroenterology,* 140 : 1182 – 1188.e1 .

Morgan, T.R., Ghany, M.G., Kim, H.Y. *et al.* 2010. Outcome of sustained virological responders with histologically advanced chronic hepatitis C. Hepatology; 52 : 833 – 44 .

Pal, S.K., Choudhuri, G. 2005. Hepatitis C: The Indian scenario. *Physicians Dig*., 14:46–53.

Patel, K., Muir, A.J., McHutchison, J.G. 2006. Diagnosis and treatment of chronic hepatitis C infection. *BMJ*, 332:1013–1017.

Qarabadeen-e Majeedi, 1986. Hamdard Dawakhana, Delhi, Ajanta offset and publication limited. P, 253

World Health Organization. Hepatitis C. Fact sheet 164. Available from: http://www.who.int/mediacentre/factsheets/fs164/en/ Accessed July 3, 2014.

Yakoot, M., Salem, A. 2012. *Spirulina platensis* versus silymarin in the treatment of chronic hepatitis C virus infection. A pilot randomized, comparative clinical trial. *BMC Gastroenterol*., 2:32.

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