CASE REPORT

Successful Treatment of Chronic Viral Hepatitis With High-dilution Medicine

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ABSTRACT

Introduction: Two cases of viral hepatitis that had failed conventional therapy are presented. Both were subsequently treated with protocols using homeopathic medicines as detailed below. Both patients sustained remissions for 2 years after taking ultradilute natural medicines after their conventional treatment had been discontinued.

Methods: The treatment protocol included *Chelidonium majus* 6X and Thuja 30C as the main medicines. Other homeopathic medicines were used as detailed below. Cases were confirmed with standard hepatitis antibody and viral measurements. Patients were followed for more than 2 years with measurements of viral counts, liver enzymes, and other relevant biomarkers of liver disease.

Results: Both patients are alive and functioning normally in their home environments more than 2 years after treatment initiation.

Discussion: We review the literature related to the chief medicines used in these cases and find that they have known and demonstrated therapeutic effects suggesting plausible mechanisms of action in these cases.

Conclusions: Clinical trials of this homeopathic treatment protocol should be conducted to explore the therapeutic potential of these medicines for treatment of viral hepatitis.

摘要

序言：常规治疗失败的两例病毒性肝炎病例。这两个病例后来都使用顺势疗法药物进行治疗，详见下文。在中断常规治疗，并服用过度稀释的自然药物之后，两名患者都经历了2年的持续缓解期。

方法：白屈菜6X和金钟柏30C作为本治疗方案的主要药物。其他顺势疗法药物的使用，详见下文。通过标准肝炎抗体和病毒测量方法对两例病例的治疗效果进行确认。通过测量病毒计数、肝酶水平，以及肝病的其他相关生物标志物，对患者进行超过2年的后续跟踪。

结果：在启动治疗2年多之后，两名患者都健在，而且在各自的家庭环境下官能正常。

讨论：我们对这些病例中使用的主要药物的相关文献进行了审核，发现它们具有已知的、能够证明的疗效，因此可作出合理的推断，上述药物在这些病例中能够发挥积极作用。

结论：应该对该顺势疗法进行临床试验，以发掘这些药物对病毒性肝炎的潜在疗效。

RESUMEN

Introducción: Se presentan dos casos de hepatitis viral en los cuales la terapia convencional no fue efectiva. Ambos fueron tratados posteriormente según protocolos de uso de medicamentos homeopáticos, como se describe a continuación. Ambos pacientes registraron una remisión sostenida durante 2 años, luego de consumir medicamentos naturales ultradiluidos y de que se descontinuaran sus correspondientes tratamientos convencionales.

Métodos: El protocolo de tratamiento incluyó como medicamentos principales Chelidonium majus (Celidonia mayor) 6X y Thuja (Tuya) 30C. Se utilizaron otros medicamentos homeopáticos, como se indica a continuación. Se confirmaron casos de desarrollo de anticuerpos estándares contra la hepatitis y mediciones de carga viral. Se realizó un seguimiento de los pacientes durante más de 2 años con mediciones de carga viral, enzimas hepáticas y otros marcadores biológicos relevantes de enfermedades hepáticas.

Resultados: Ambos pacientes viven y se desenvuelven normalmente en sus hogares, luego de transcurridos más de 2 años desde el inicio del tratamiento.

Discusión: Analizamos la información relacionada con los medicamentos principales empleados en estos casos y descubrimos que tienen efectos terapéuticos conocidos y demostrados que sugerían mecanismos de acción convincentes aplicables a estos casos.

Conclusiones: Los ensayos clínicos de este protocolo de tratamiento homeopático se deben llevar a cabo para analizar los efectos terapéuticos potenciales de este tipo de medicamentos para el tratamiento de la hepatitis viral.

Ultradilute, serially agitated solutions behave quite differently than normal solutions; the principles of their behavior are being actively researched around the world.[1] Meanwhile, ultradilute solutions in the form of homeopathic medicines are widely sought and used clinically throughout the world. In 1999, the US National Cancer Institute's Office of Cancer Complementary and Alternative Medicine's rigorous Best Case Series validated the effectiveness of cancer treatment protocols in 14 cases of different varieties of the disease using homeopathic medicinal protocols developed at the Prasanta Banerji Homeopathic Research Foundation (PBHRF) in Kolkata, India, and identified studies in collaboration with PBHRF as a funding priority.[2] Published research reports also provide credible evidence of the mechanisms of action and effectiveness of some of the protocols used at PBHRF to treat cancer.[3-7]

In addition to cancer, virtually all diseases are treated at PBHRF with specific protocols using ultradilute medicines. In this article, we report on 2 well-documented cases of progressively worsening acute and chronic viral hepatitis that responded to treatment with these medicines per the Banerji Protocol.

CASE 1

On a routine health maintenance visit in 1994, a 37-year-old woman was found to have elevated liver enzymes. Her first liver biopsy in January 1998 showed grade 1 (of 4) inflammation and stage 1 to 2 (of 4) delicate bridging fibrosis. Subsequent hepatitis C antibody testing revealed chronic hepatitis C. Genotyping of the virus in 1998 revealed type 1b with a viral count of 33 000 000 IU/mL. She enrolled in a clinical trial of pegylated interferon (PEG-INF) subcutaneously 1.5 μg/kg once a week for 4 weeks followed by PEG-INF 0.5 μg/kg once a week for 44 weeks along with ribavirin 1000 mg orally daily, which was reduced to 600 mg daily due to anemia at treatment week 30. Serum levels of alanine aminotransferase reflected a response with relapse. Her virologic response using polymerase chain reaction (PCR)–based assay for hepatitis C virus RNA showed a temporary response. Posttreatment liver biopsy performed 6 months after completing treatment (in July 2000) was scored as grade 3 of 4 inflammation and stage 1 of 4 fibrosis with piecemeal necrosis consistent with relapse. Her viral count at that time was 16 000 000 IU/mL. A biopsy conducted in December 2003 showed inflammation grade 3 and fibrosis stage 3 of 4. She became increasingly symptomatic with nausea, fatigue, and loss of appetite. In April 2004, she started a second course of PEG-INF with ribavirin after undergoing whole-body hyperthermia. After 6 months, she was found to have no response to the interferon, and the drugs were discontinued. A biopsy in November 2005 showed stage 3 of 4 fibrosis and moderate (3 of 4) portal inflammation. Viral count in July 2006 was 14 250 000 IU/mL, and the patient was found to have persistent stage 3 of 4 fibrosis and grade 3 of 4 inflammation with bridging necrosis.

In August 2006, the patient initiated treatment prescribed by the PBHRF. The following protocol was used:

1. Chelidonium 6X twice a day,
2. Thuja 30C twice a day, and
3. Kalium muriaticum 3X and Ferrum phosphoricum 3X twice a day.

The 6X potency is the 6th decimal potency that is achieved by serial dilution and agitation of the mother tincture, or alcoholic extract, of the root of the plant *Chelidonium majus*. Thuja 30C is likewise the 30th centesimal serial dilution and agitated product; here, the alcoholic extract is from the fresh leaves and small twigs of the young *Thuja occidentalis* plant. The Kali muriaticum 3X and Ferrum phosphoricum 3X are triturations of the substances to the 3rd decimal potency. The medicine was procured from reputable homeopathic drug manufacturers and manufactured as per The Homeopathic Pharmacopoeia of India.

Chelidonium 6X and Thuja 30C are our standard protocol for cases of chronic viral hepatitis. Chelidonium has a strong body of research supporting its use for liver disease, and Thuja is effective in treating a wide variety of viral infections (see Discussion section). The combination of Kali muriaticum and Ferrum phosphoricum is our standard protocol for treatment of anemia, which this patient experienced as a side effect of interferon/ribavirin therapy.

The patient adhered to this protocol for 2 years and was rebiopsied in the United States in December 2008. Her inflammation was reduced to stage 1 of 4, and her fibrosis had regressed to stage 0-1a of 4. She used no other treatments during this time period. She no longer experiences daily nausea and has regained her normal body weight. Her viral count in December 2009 was 7 IU/mL. As of June 2011, she remained in remission and continued treatment with Chelidonium 6X twice a day. Table 1 provides a summary of the relevant biomarkers.

TABLE 1 Case 1: Chronic Active Hepatitis C[a]

Test	Reference Range	Date	Patient Value
HCV RNA	0-7 IU/mL	Jul 2006	14 250 000
		Dec 2009	7
Liver biopsy	Stage 0 inflammation; stage 0 fibrosis;	Nov 2005	Stage 3 inflammation; stage 3 fibrosis; bridging necrosis
		Dec 2008	Stage 1 inflammation; stage 0-1a fibrosis; no necrosis

[a] Homeopathic treatment initiated August 2006; as of June 2011, patient remained in remission.
Abbreviations: HCV, hepatitis C virus; RNA, ribonucleic acid; PCR, polymerase chain reaction.

CASE 2

In late November 2007, a 28-year-old male was admitted to the premier Indian medical institution, the All India Institute of Medical Science (AIIMS) in Delhi, for a case of hepatitis B virus (HBV)–related chronic

liver disease decompensated by acute hepatitis E virus (HEV) infection. He also had developed spontaneous bacterial peritonitis. His clinical history included a rapidly progressing jaundice followed by pedal edema, ascites, fever, and abdominal tenderness. Viral antibody testing revealed a positive Australia antigen (hepatitis B surface antigen), negative immunoglobulin M for hepatitis B core antigen, HBV DNA 1300 copies/mL, and positive immunoglobulin M antibody for HEV. At AIIMS, he was treated with intravenous glycyrrhizin (0.2%) 60 mL daily for 6 weeks, and then the dose was reduced to 3 times a week. Additionally, he received daily diuretic treatment with spironolactone/furosemide (Lasilactone, Sanofi-Aventis) 50 to 75 mg per day, 20% albumin 100 mL intravenously daily for the first 2 months of hospitalization, cefuroxime axetil (Ceftum, GlaxoSmithKline) 500 mg twice a day for 4 weeks, and lamivudine-HBV 100 mg daily.

After 6 weeks of hospitalization and treatment at AIIMS, the patient's serum bilirubin continued to be markedly elevated and alanine transaminase was continuously 75 times normal, indicating failure of conservative treatment. Endoscopy revealed esophageal varices. The cancer antigen 19-9 and carcinoembryonic antigen were negative. The patient and his parents were advised of the need for a liver transplant. They refused to have him placed on the transplant list, and he was discharged in January 2008 and returned to Kolkata. After repeated episodes of spontaneous bacterial peritonitis requiring multiple hospitalizations in Kolkata, he developed right hepatic hydrothorax.

At this point, the patient sought treatment at PBHRF. On first presenting at PBHRF on August 22, 2008, he had severe ascites, dyspnea without exertion, abdominal pain, and 4+ pitting edema in the lower extremities. Treatment was initiated with the following protocol:

1. Chelidonium 6X 3 drops alternating 3 times a day with
2. *Carduus marianus* (milk thistle) mother tincture 10 drops,
3. Thuja 30C 2 pills once every evening,
4. *Lycopodium clavatum* 30C 3 drops 3 times a day, and
5. Belladonna 3C alternating with *Carduus marianus* mother tincture every 10 minutes as needed for pain.

In addition to our first-line agent, Chelidonium, we added *Carduus marianus*, as it has a long history of use in traditional herbal medicine for support of liver problems. Thuja again was prescribed as an antiviral agent. Lycopodium is our first-line agent for treatment of edema or fluid retention of any kind. Belladonna is one of our first-line agents for pain, particularly pain of visceral origin.

When the patient's condition did not improve, on September 15, 2008, Myrica (bayberry) mother tincture was added, alternating every 3 hours with Chelidonium 6X, and Carduus was discontinued. On September 27, acetic acid 30C, another of our prime medicines for water retention and effusions, 3 drops 3 times a day replaced the Lycopodium for management of the ascites. By December 13, 2008, the patient's pleural effusion was clearing, ascites had decreased substantially, and urine output improved significantly. Clinic notes from January 7, 2009, reported worsening of the pleural effusion and ascites, and treatment exclusively by PBHRF continued with the expectation that improvement was likely to recur. By March 2009, the patient was reporting a sustained improvement in symptoms, and the pleural effusion and ascites had almost completely subsided. On June 3, 2009, the HBV DNA count was 5.82 copies, and the patient was feeling well. Blood work done on May 9, 2009, revealed liver function tests generally near the normal range, as indicated in Table 2. Table 2 also shows the continued improvement in liver function tests when retested in December 2009. As of June 2011, the patient continued to feel well, having been in remission for 2 years.

Table 2 Case 2: Hepatitis B Virus and Hepatitis E Virus[a]

Test	Reference Range	Date	Patient Value
INR	0.9-1.1	May 2009	1.9
		Dec 2009	1.2
tBili	<1.0 mg/dL	Dec 2007	31.9
		May 2009	1.37
		Dec 2009	1.21
AST	10-60 IU/L	Dec 2007	324
		May 2009	65
		Dec 2009	36
ALT	10-60 IU/L	Dec 2007	241
		May 2009	41
		Dec2009	25
Alk phos	40-120 IU/L	May 2009	275
		Dec 2009	
GGT	0-60 IU/L	May 2009	56
		Dec 2009	42

[a] Homeopathic treatment initiated August 2008; as of June 2011, the patient remained in remission.
Abbreviations: Alk phos, alkaline phosphatase; ALT, alanine transaminase; AST, aspartate transaminase; GGT, gamma-glutamyl transferase; INR, international normalized ratio; tBili, total bilirubin.

DISCUSSION

The protocols used in these cases were developed based on the extensive experience of the physicians at PBHRF, which spans several generations, as well as the known actions of its specific component medicines. We will briefly review the research literature that is available on these medicinal substances.

Chelidonium majus (greater celandine) is an herb with documented hepatotoxic properties in its undiluted tincture or herbal form,[8-10] but it has also been shown to have hepatoprotective, antitumor, and immunostimulatory actions.[11] *Thuja occidentalis* has been reported to have similar hepatoprotective and antitumor effects.[4,12-17] Thuja and its related species also have been reported to have antiviral[13,18] and antimetastatic[4] properties. Myrica, or bayberry, is a common herb that is high in tannins; there is virtually no research documenting its effectiveness in treatment of liver disease, but standard

homeopathic references all list jaundice as one of its principle indications.[19] *Carduus marianus* (milk thistle) was reviewed recently in the Cochrane database. The conclusion of this rigorous review was that

> *milk thistle could potentially affect alcoholic and/or hepatitis B or C virus liver diseases. Therefore, large-scale randomized clinical trials on milk thistle for alcoholic and/or hepatitis B or C liver diseases versus placebo are needed.* [20]

The larger issue is how ultradilute, serially agitated preparations of these biologically active substances are able to exert therapeutic effects even when the dilutions exceed Avogadro's number, which is the case for the dilutions of 30C used in the Banerji Protocol for hepatitis. The preparations of Chelidonium are diluted to a factor of 1/1000000; this explains the lack of toxicity observed in the normally hepatotoxic Chelidonium when in its crude form but does not explain its effectiveness as a hepatoprotectant. The emerging disciplines of complexity, nanoscience, and materials science offer some hypotheses on how these ultradilute medicines may still maintain biological activity.[21] One research team advocated the hypothesis based on available scientific evidence and logic that one major pathway of ultradilute homeopathic drugs could possibly be through regulation of expression of relevant genes.[1] A recent study by Frenkel et al provided solid support for this hypothesis.[3] The medicines used by PBHRF for treatment of breast cancer were tested in vitro at the University of Texas MD Anderson Cancer Center, Houston. The remedies exerted preferential cytotoxic effects against 2 breast cancer cell lines, causing cell cycle delay/arrest and apoptosis. The researchers demonstrated a clear biological activity of the tested natural products (Phytolacca, Carcinosin, Conium, and Thuja) when present at ultradiluted doses.

Despite the lack of a proven explanation for how these ultradilute medicines exert their effects, there is significant laboratory evidence that highly dilute toxins can paradoxically protect the very tissues they harm in macrodoses. There are several reports of liver damage reversal in mice with ultradilutions of arsenic trioxide after exposure to toxic doses of the same substance.[5,22] One randomized double-blind placebo-controlled human study documented favorable improvements in multiple markers of arsenic toxicity after 2 months of treatment with a serially agitated dilution (1:100 dilution 30 times) of arsenic,[23] or the 30th centesimal potency. A recent review of the in vitro research on serially diluted and agitated solutions concluded that even the studies with high methodological standards demonstrated an effect of these solutions.[24]

A number of articles has been published in medical journals denouncing categorically the use of homeopathic medicine, claiming that there is no evidence to support any further research into their therapeutic effects. Clearly, even in this very brief research review and in these case reports, there is enough to suggest that this is an area that should be further explored. The era of nanomedicine is upon us and requires a fresh look at medicines that are ultradiluted. A major advantage of treating disease with ultradilute solutions is that adverse effects are virtually eliminated. The case reports in this article will, hopefully, inspire a fresh interest and further research in this fascinating and controversial area of therapeutics.

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