

A Retrospective Study on the Effect of COA Mixture® on Viral Load in HIV and Hep B Patients

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Abstract

Background: Viruses are increasingly appreciated to cause a wide range of human diseases, ranging from acute self-resolving conditions to acute or chronic fatal diseases. However, treatment options for majority of viral infections are limited. The importance of herbal medicine for the treatment of viral infections cannot be overemphasized. Several medicinal plants are known to exhibit antiviral activities.

Aim: The present study evaluated clinical data at three different sites (Accra, Cape Coast and Kumasi) operated by the COA Research and Manufacturing Company Ltd with the aim of providing a background data on the outcome of the use of COA Mixture® for the management of HIV and Hep B infections.

Method: A total of 150 patient folders were screened over a period of three days with the aim of obtaining data that are fit-for-purpose i.e. individuals that have at least two test results and have been on the drug for at least one month. The baseline viral load (copies/ml) and the viral load at the time of the study were noted and entered in excel spreadsheet. The mean basal viral load was calculated and compared with the mean viral load at the time of the study. The percentage change in viral load were calculated. The duration of use of the COA Mixture® was also computed.

Results: The COA Mixture® caused significant reduction in viral load in all the Hep B infected individuals and some of the HIV infected individuals, with some HIV infected individuals reporting a complete clearance.

Conclusion: The COA Mixture® appears to have a positive effect in both HIV and Hep B patients by causing clearance in some individuals and producing a general decrease in the mean viral load among the patients.

Keywords: HIV, Hep B, Viral load and COA Mixture®.

Introduction

Viruses are increasingly appreciated to cause a wide range of human diseases, ranging from acute self-resolving conditions to acute or chronic fatal diseases [1]. The Human immunodeficiency virus (HIV), the cause of acquired immunodeficiency syndrome (AIDS) and Hepatitis viruses, the cause of viral hepatitis are common viral infections in Sub-Saharan Africa [2]. According to Global HIV and AIDS statistics, about 38 million people were living with HIV in 2019 [3]. Of this number, the sub-Saharan Africa was the most heavily affected region, accounting for over 59% of all infected cases, and the global rate of new HIV infections is not falling fast enough to reach the milestones set in place by 2020 [4].

Infectious viral hepatitis is an important challenge to health

worldwide. Hepatitis A virus (HAV) and hepatitis E virus (HEV) are endemic in many low-income countries [5]. They usually cause self-limiting hepatitis but occasionally lead to fulminant liver failure and, in rare cases of immunosuppression, chronic HEV infection. Hepatitis B virus (HBV) and hepatitis C virus (HCV) also cause acute illness but more commonly lead to progressive liver fibrosis, cirrhosis, and an increased risk of liver cancer (specifically hepatocellular carcinoma) [6-8].

Presently, there is no cure or vaccine for HIV with anti-retroviral treatment only slowing the progression of the disease [9]. In addition to the reported side effects of most of the anti-retroviral drugs, there have also been reports of the virus developing resistance to the current treatment regimens. The use of herbal

preparations for the management of HIV and HIV related morbidities is a common place [10,11].

Vaccination is still the most important strategy to protect healthy persons from becoming chronic HBV carriers [12]. On the other hand, the introduction of antiviral agents to people with chronic hepatitis B could attenuate or stop the fibrotic progression [13]. Because chronic hepatitis B is widely spread in Asia, Africa, southern Europe and Latin America, it is urgent to develop anti-HBV drugs in these countries. One possibility is to find useful therapeutic agents from herbs for treating chronic hepatitis B [14].

Medicinal plants have long been known as sources of drugs. The use of natural products with therapeutic properties is as ancient as human civilisation and, for a long time, minerals, plants and animal products were the main sources of drugs [15]. Of the 252 drugs considered as basic and essential by the World Health Organisation (WHO), 11% are exclusively of plant origin and a significant number are synthetic drugs obtained from natural precursors [16]. Recent developments in the field of traditional medicine have resulted in the production of improved herbal products using technologically advanced production processes. COA Mixture® (formerly sold under the trade name COA FS®) is an herbal supplement produced by the COA Research and Manufacturing Company Ltd. It is registered by the FDA, Ghana (FDA/DRID/HMD/HMU/16/0981, 2016) for use as an herbal mixture for general wellbeing. The present study evaluated clinical data at three different sites (Accra, Cape Coast and Kumasi) operated by the COA Research and Manufacturing Company Ltd with the aim of providing a background data on the outcome of the use of COA Mixture® for the management of HIV and Hep B infections.

Method

A total of 150 patient folders were obtained from the Accra, Cape Coast and Kumasi Herbal Units of COA Research and Manufacturing Company Ltd. The folders were screened over a period of three days with the aim of obtaining data that are fit-for-purpose, i.e. individuals that have at least two test results and have been on the drug for at least one month.

The baseline viral load data for the HIV patients (copies/ml) and Hep B patients (IU/ml) were noted and recorded. The end-point viral load at the time of the study were also noted and recorded. The data were entered in excel spreadsheet and the mean viral load and percentage change in viral load were calculated. Comparison between means were done using simple student t-test to determine significant difference between the baseline and study point values.

Results and Discussion

The present study screened the clinical record of 150 patients from three (Accra, Cape Coast and Kumasi) Herbal Unit Sites operated by COA Research and Manufacturing Company Ltd. Out of the 150 folders screened, 74 were fit-for-purpose for HIV and 13 for Hep B. The age of the patients ranges between 12 to 60 years. The higher number of HIV patients recorded is expected since the COA Mixture® is usual marketed to HIV infected individuals. Additionally, the use of herbal products has been reported to be on the increase among this group of patients [10,11,17].

Duration of use of the Product

We found the duration of use to range from 1 month to 23 months among the HIV patients (Table 1). Majority (44) of the patients representing 57.9% were on the supplement for 1 to 5 months. Twenty-three (23) representing 30.3% were on it for 6 to 10 months, six (6) representing 7.9% were on it for 11 to 15 months and only one (1) representing 1.3% was on it for more than 15 months.

In the case of Hep B patients, the duration of use ranges from 1 month to 10 months (Table 2). Majority (8) of the patients representing 61.5% were on the supplement for 6 to 10 months, with the remaining 38.5% on it for 1 to 5 months. One (1) person was on it for just 1 month and only one was on it for 10 months. Six (6) of them were on it for 6 months.

The shorter duration of use among Hep B patients compared to HIV patients is expected and attributed to the debilitating and chronic nature of HIV infection. Additionally, the wide variation of duration of use was due to the fact that the study was retrospective and not prospective.

Table 1: Duration of use of the COA Mixture® among the 74 HIV patients.

Duration of use in months	Number of patients, N(%)
1-5	44(57.9)
6-10	23(30.3)
11-15	6(7.9)
>15	1(1.3)

Table 2: Duration of use of the COA Mixture® among the 13 Hep B patients.

Duration of use in months	Number of patients, N(%)
1-5	5(38.5)
6-10	8(61.5)

Effect on Viral Load

Out of the 74 HIV patients with the fit-for-purpose data, the COA Mixture® caused a decrease in the viral load when the mean baseline viral load was compared to the study point viral load in all the patients, although the decrease was not statistically significant ($p=0.083$). The mean viral loads were $233,728.1 \pm 98,459.42$ and $93,325.3 \pm 22,884.86$ before and after drug administration respectively (Figure 1). However, nineteen (19) patients representing 25.7% experienced a significant decrease ($p=0.04$) in viral load (Figure 2). Furthermore, when the effect of the COA Mixture® was analysed based on the duration of use, non-significant decrease in viral load was again observed in these two groups (at least 3 months, $p = 0.09$) (Figure 3) and (at least 6 months, $p = 0.16$) (Figure 4).

In terms of percentage decrease in viral load, out of the 74 patients (Figure 5), 7 representing 9.5% has a percent reduction of 1% to 20%, indicating up to 20% decrease, 6 representing 8.1% had percent reduction of 21% to 40%, a percent reduction of 41% to 60% were recorded in a further 6 representing 8.1%, another 6 representing 8.1% again recorded percent reduction of 61% to 80% and 19 representing 25.7% recorded a percent reduction of 81% to 100%. Six (6) representing 8.1% had their viral load completely cleared (100% reduction).

All the 13 Hep B patients with the fit-for-purpose data, representing 100% exhibited decrease in Hep B Viral DNA particles. The COA Mixture® caused a significant decrease in the viral DNA particles when the mean viral DNA particles at the baseline was compared to that at the study point in all the patients ($p=0.002$) (Figure 6). The mean HB viral DNA particles were $1125.2.1 \pm 251.0$ IU/ml and 412.7 ± 102.2 IU/ml for baseline and study point respectively.

The importance of herbal medicine for the treatment of viral infections cannot be overemphasized, as several herbs are known to exhibit antiviral activities with many medicinal plants and herbal products being reported to have effect on the HIV and the Hep B virus [18]. Sabde et al. have reported anti-HIV property of eight medicinal plants in India [19], Matsuse et al. reported moderate anti-HIV activity in seven medicinal plants from Panama [20]. In Africa, Wotson et al. highlighted the anti-HIV potential of four common medicinal plants including *Momordica charantia* [21]. A total of 30 plant species belonging to 24 families were reported by local practitioners for the treatment of jaundice and hepatitis [22].

COA Mixture® is produced by systematic distillation of fresh

leaves of *Azadirachta indica*, *Carica papaya*, *Spondias mombin*, *Ocimum viride* and *Persea americana*. *Azadirachta indica*, commonly called neem is a plant that has found varied use in ecological, medicinal and agricultural sectors. Biological and pharmacological activities attributed to different parts and extracts of these plants include antiplasmodial, antitrypanosomal, antioxidant, anticancer, antibacterial, antiviral, larvicidal and fungicidal activities. Polysaccharides obtained from *Azadirachta indica* acted against the poliovirus (PV-1) by inhibiting the initial stage of viral replication [23]. The extracts from the plant have been shown to have activities against Newcastle disease virus [24], dengue fever virus [25] and the Herpes Simplex Virus (HSV-1) [26].

The many benefits of *Carica papaya* are owed due to high content of vitamin A, B and C, proteolytic enzymes like papain and chymopapain which have antiviral, antifungal and antibacterial properties [27,28] and extracts from the plant had been shown to have activity against the dengue virus [29]. Extracts from *Spondias mombin* exhibited activity against the Herpes Simplex Virus (HSV) [30] and Geraniin from *Spondias mombin* had been shown in molecular docking experiment to be most promising inhibitor candidate for the Ebola Virus [31].

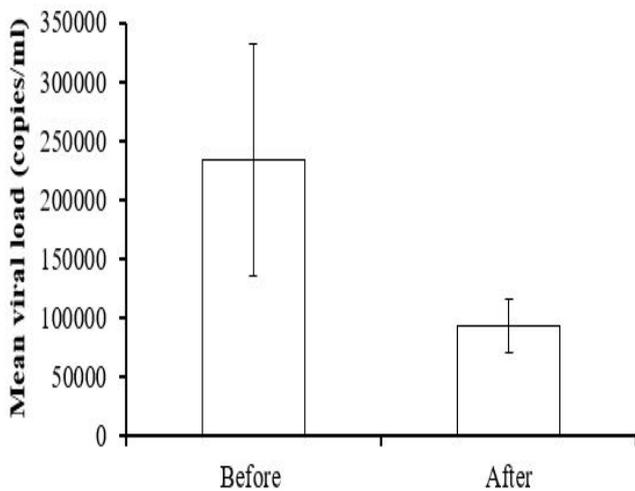


Figure 1: Non-significant decrease in mean viral load among the 74 HIV patients.

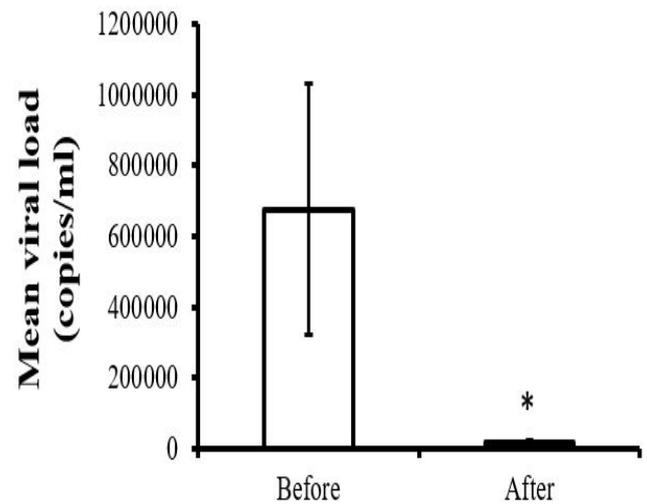


Figure 2: A significant decrease in viral load in 19 patients when the viral load prior to the beginning of treatment was compared to the viral load at the time of the study. ($p = 0.04$).

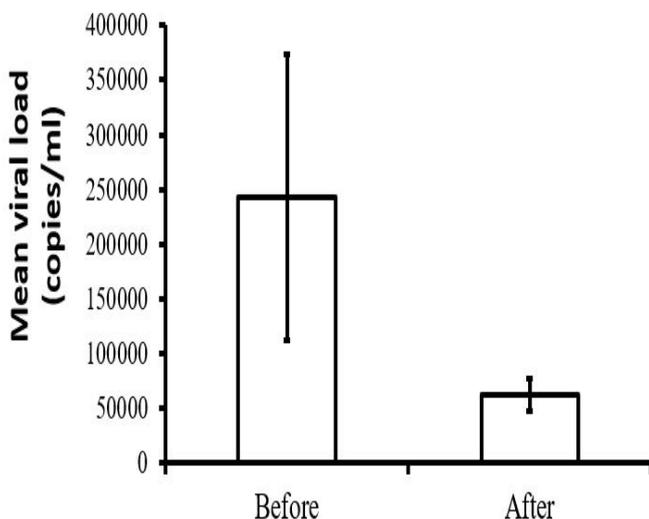


Figure 3: Non-significant decrease in mean viral load in HIV patients, who had been on the mixture for up to three months.

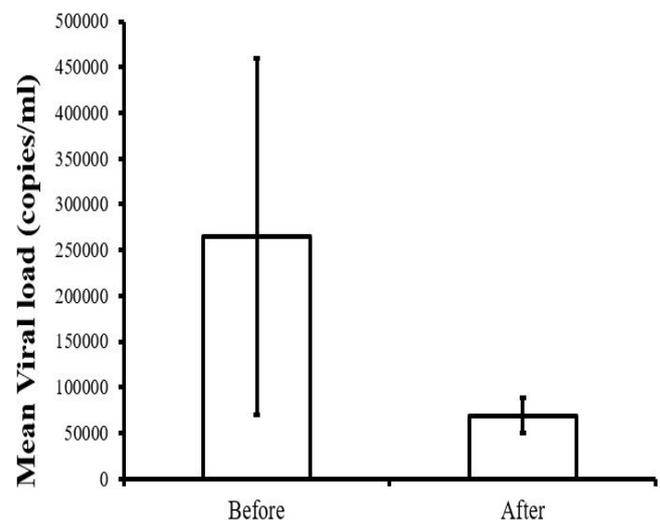


Figure 4: Non-significant decrease in mean viral load in HIV patients, who had been on the mixture for up to six months.

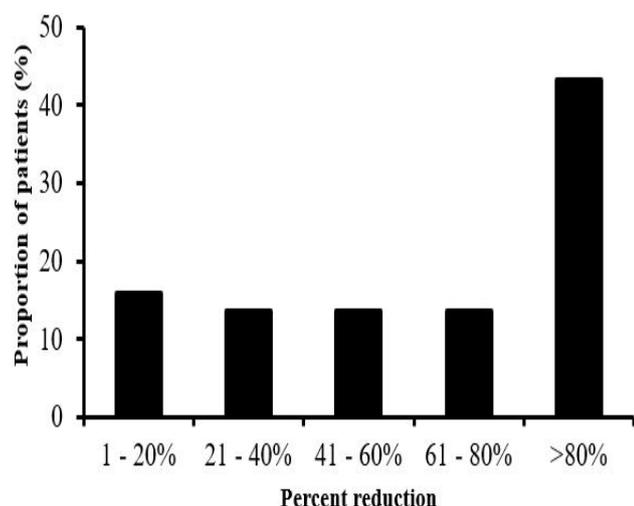


Figure 5: Percentage reduction of viral load from the basal to the study point.

Ocimum basilicum L., known as sweet basil, has been studied for its various potent effects including, antimicrobial, antifungal, insecticidal, antiparasitic, antioxidant, immunomodulatory, anti-inflammatory, hepatoprotective, anti-osteoporotic, cardioprotective, neuroprotective, anti-cancer, and other beneficial health effects [32,33]. Extracts from *Persea Americana* commonly known as Avocado pear had been shown to have anti-viral activity against a wide range of virus including anti-HIV activity [34], anti-HSV activity [35].

Conclusion

The COA Mixture® appears to have a positive effect in both HIV and Hep B patients by causing clearance in some individuals and producing a general decrease in the mean viral load among the patients. We recommend that a properly structured prospective study be carried out on the COA Mixture® as an herbal preparation for the management of HIV and Hep B infections.

Authorship Criteria

OQ and SA reviewed folders and put together the raw data. AO analysed the data and wrote the manuscript. All authors reviewed the manuscript.

Conflicts of Interest/ Competing Interests

Authors have no conflict of interest.

Grant Information

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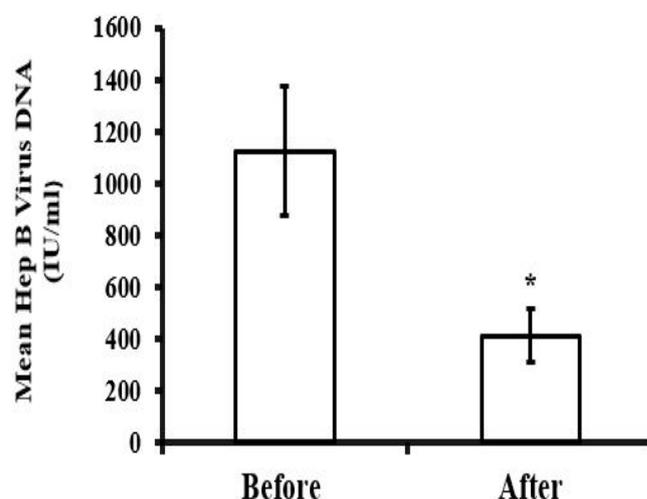


Figure 6: Significant decrease in mean Hep B viral DNA among the 13 Hep B patients.

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