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Full Length Article

Risk assessment of hepatotoxicity among tuberculosis and human immunodeficiency virus/AIDS-coinfected patients under tuberculosis treatment

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ABSTRACT

Objective/background: Tuberculosis (TB) is a worldwide public health problem. It is a contagious and grave disease caused by *Mycobacterium tuberculosis*. Current drugs such as isoniazid, pyrazinamide, and rifampicin used for the treatment of tuberculosis are potentially hepatotoxic and can lead to drug hepatitis. In order to improve the follow-up of TB patients in Cameroon, we carried out a study which aimed to evaluate the hepatotoxicity risk factors associated with anti-TB drugs.

Methods: The studies were performed on 75 participants who had visited the Loum District Hospital located in the littoral region of Cameroon for their routine consultation. Participants have been selected based on pre-established criteria of inclusion and exclusion. Prior to the informed consent signature, patients were given compelling information about the objective and the result output of the study. They were questioned about antioxidant food and alcohol consumption as well as some clinical signs of hepatotoxicity such as fever, nausea, vomiting, and tiredness. The collected blood was tested for the determination of biochemical markers (transaminases and C-reactive protein) using standard spectrophotometric methods.

Results: Biochemical analysis of samples showed a significant increase ($p < .05$) of aspartate aminotransferase and alanine aminotransferase values in TB patients coinfecting with human immunodeficiency virus/AIDS (33.28 ± 16.58 UI/L and 30.84 ± 17.17 UI/L, respectively) compared with the respective values of the controls (16.35 ± 5.31 UI/L and 16.45 ± 4.83 UI/L). Taking individually, the liver injury patient percentage of TB patients was significant compared to TBC when considering alanine aminotransferase and aspartate aminotransferase parameters. When considering risk factors, antioxidant food

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consumption significantly reduced the liver injury patient percentage for the above parameters, whereas an opposite situation was observed with alcohol consumption between TB-coinfection and TB patients. Regarding the C-reactive protein results, the percentage of positive tests was very high among coinfecting patients (40%) compared with the control (15%). The interactions between parameters related to alcohol consumption and intake of antioxidant foods showed a slight decrease in activity compared with interactions without food.

Conclusion: The results showed that human immunodeficiency virus status and alcohol consumption constitutes aggravating factors for the occurrence of hepatic toxicity. In addition, the consumption of antioxidant foods simultaneously with TB drugs help in reducing the hepatotoxic effects of these drugs.

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Introduction

Tuberculosis (TB) is an infectious disease caused by the bacterium called *Mycobacterium tuberculosis*. It usually affects the lungs (pulmonary TB) but can affect other organs, such as bones and lymph nodes (extrapulmonary TB). The disease is spread through air when TB patients expel the bacteria, by coughing for example [1]. TB remains a major global health problem in Africa and Asia. It affects the health of millions of people annually throughout the world and ranks as the second disease leading to death among infectious diseases worldwide after human immunodeficiency virus (HIV)/AIDS [2]. The World Health Organization estimated in 2012 that there were up to 8,600,000 new TB cases and 1.3 million deaths. Just under the 1.0 million people who died were HIV-negative and 0.3 million deaths were people coinfecting with HIV [3]. Most TB cases and deaths occur in men, but the burden of disease in women is also high. In Cameroon, approximately 35,000 of TB cases are recorded every year and 40% of these patients are also diagnosed HIV-positive/AIDS. Between 2009 and 2013, among the 100,000 habitants hospitalized in Cameroon, 238 were suffering from TB, including 83 cases of pulmonary TB, with a mortality rate of 30.94% [4]. The recommended treatment regimen for new cases of TB includes four drugs (isoniazid [I], rifampicin [R], ethambutol [E], and pyrazinamide [Z]) for 6 months. Three of these drugs (I, Z, and R) are potentially hepatotoxic and can lead to drug-induced hepatitis [3]. A study carry out in India on the use of different schemes of TB regimen in adults demonstrated 2.6% liver toxicity with I coadministered with R and 1.1% and 1.6% with R and I alone, respectively [5]. Similar studies conducted in Turkey and Singapore showed that the reintroduction of Z was more likely to lead to a recurrence of hepatotoxicity [6]. As hepatotoxicity caused by these drugs is related to the administration of higher doses of drugs, a lower daily dose is recommended or a reduction in the frequency of the drugs to three times weekly [7].

In Cameroon very few studies have been conducted regarding the potential hepatotoxicity risks of TB treatment either in TB patients or in coinfecting TB/HIV patients. Therefore, it was important to carry out this study to identify and understand the hepatotoxic risks of TB drugs in order to manage the treatment.

Material and methods

Ethical consideration

This study was approved by the Ethics Research Committee of the Cameroon Bioethics Initiative (CAMBIN) located in Yaounde – Cameroon and the ethical clearance was obtained under the reference number CBI/317/CARE/CAMBIN. This approval helped receive authorization from the hospital center under the reference number 176/L/MSP/DRSPL/DSL/HDL. Patient gave “informed consent” in order to give details relating to the understanding of the purpose, any profit if involved in the study, as well as their right to be included or not in the study.

Patients and drug consumption

Descriptive and analytical retrospective and prospective studies were conducted in TB patients with ages ranging from 15 years to 65 years, under anti-TB drugs under Directly Observed Treatment, Short course, visiting Loum District Hospital. The study was conducted from June 2014 to February 2015. Composed of some voluntary participants without TB or/and HIV infection (control), both TB patients coinfecting with HIV/AIDS or not coinfecting were included in the study. The patients fulfilled the following criteria: (1) they were on anti-TB drugs at least 2 months; (2) were not receiving any other hepatotoxic drugs parallel with anti-TB treatment as well as without hepatitis B or C; and (3) had normal findings of liver function parameters at the beginning of the treatment. TB patients were given a 6-month regimen of four first-line drugs: I, R, E, and Z divided into two phases: 2 months of RIEZ and 4 months of RI. Coinfecting patients with HIV/AIDS received 9 months divided into two phases: 2 months of I/R/Z ± E and 7 months of I/R. Some hepatotoxicity clinical signs such as fever, nausea, vomiting, and tiredness were monitored. Patients were given a questionnaire about some antioxidant foods and alcohol consumption levels. Antioxidant food was well explained to the patients in relation to their physio-pathological situation, to help them understand that this type of food plays a big role in the elimination of excess of free radicals that can sometimes mediate hepatotoxicity according to Yew and Leung [8]. Ambreen et al.

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