Molecular Pharmaceutics & Organic Process Research

ISSN: 2329-9053

Extended Abstracts Vol 7, Iss4

Development of a High-sensitivity Detection Device for Hepatitis B Virus Surface Antigen in Saliva

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ABSTRACT

According to the World Health Organization (WHO), two billion people are infected with hepatitis B virus (HBV). Among infectious diseases, viral hepatitis has been proposed as a target for global elimination. Currently, although blood-based examination is common, an alternate assay using saliva has attracted attention as an easy diagnostic method. However, many issues need to be overcome to facilitate the use of this method, such as sensitivity of the diagnostic method and stability of the sample. Therefore, we've developed a replacement testing method for HBV surface layer (HBs) antigen using immunochromatography, and have evaluated its effectiveness.

Comparison of the detection sensitivity of the traditional immunochromatography method thereupon of the newly developed immunochromatography method revealed that the latter showed a way higher sensitivity. Therefore, we collected blood and saliva samples from 70 HBs antigen-positive subjects and 100 HBs antigen-negative subjects in hospital and examined these samples using the newly developed immunochromatographic test. The positive and negative rates of blood and saliva of the 70 HBs antigen-positive subjects and therefore the 100 HBs antigen-negative subjects were found to be completely consistent.

Thus, the high sensitivity of the newly developed immunochromatographic test strongly suggests the clinical applicability of saliva as a clinical sample. In the near future, we plan to clarify the feasibility of this new method for implementation in various medical facilities and survey applications, with the goal of developing a wide range of clinical tests to detect HBV.Despite the availability of vaccines against HBV infection, HBV's prevalence remains high all over the world . According to the WHO, there are 2 billion HBV-infected individuals and around 378 million chronic carriers worldwide. 80 million such carriers reportedly reside in Southeast Asia . Over 50% of liver cancer cases result from HBV infection, with the main routes of transmission being sexual intercourse, parenteral contact, and vertical transmission. Other sources of infection include surgery, dental care, contaminated surgical instruments, and donor organs. Centers for Disease Control and Prevention , HBV is an extremely powerful virus that is present in blood, exudate, saliva, semen, vaginal secretions, urine, sweat, and breast milk. The virus can survive outside of the body and can easily be transmitted via contact with the infected body fluids In the present study, we developed an immunochromatographic HBs antigen testing method that utilizes saliva as the sample. Saliva collection, unlike venipuncture, does not involve pain when puncturing a vein, thereby reducing the distress for the patient. The convenience and safety of saliva collection are the major advantages of this technique. Furthermore, saliva samples can be collected more quickly than blood can . Since there are a large number of HBV carriers at the global level, the implementation of a survey investigation that uses saliva as the sample is expected to permit the accurate measurement of the true HBV infection rate. In turn, this information is expected to facilitate determination of the effectiveness of vaccination measures.The purpose of this study was to guage the sensitivity and specificity of HBs antigen detection in saliva using our new diagnostic method.This study was conducted with the approval of the Kyushu Dental University Ethics Committee (No. 14-18) and consent was obtained from the subjects after informing them about HBs antigen testing using saliva. Unstimulated saliva samples, collected according to a standard protocol, were obtained from 170 patients being seen at the Steel Memorial Yawata Hospital, including 70 patients who had tested positive for HBs antigen, and 100 patients who had tested negative for HBs antigen. The average age, the male to female ratio were 64.9 years, 45/25, respectively. The average HBV DNA level at 70 patients was 2.8 ± 1.3 IU/ml. The HBV genotype of 40 patients belonged to genotype C, 5 patients belonged to genotype B and no patient belonged to genotype A. The HBV genotype in 25 patients was unknown. 11 patients (15.7%) were positive for HBe antigen (HBeAg). Saliva was collected employing a sponge and tube developed for saliva collection. After the sponge was left in the mouth of the subject for 60 s, the saliva was collected in the tube and centrifuged. Approximately 2 ml of saliva was collected from each

Thisworkispartlypresentedat 10th World Congress on Pharmacology August 02-03,2018 Barcelona,Spain

patient and stored at -20°C until analysis . Saliva samples were confirmed HBs antigen (HBsAg) using chemiluminescent enzyme immunoassay (CLEIA).

In the present study, we developed a replacement diagnostic device and evaluated the sensitivity and specificity of HBs antigen detection in saliva using our new diagnostic method. In summary, we have developed a salivary HBV antigen measurement method that is extremely easy to use and does not require much testing time. The sensitivity and specificity of this immunochromatography method exceed those of conventional immunochromatography, providing a more reliable diagnosis. The newly developed salivary immunochromatographic method is expected to serve as an effective device for diagnosing HBV infection.

Keywords: HBV; surface antigen; saliva; immunochromatography