The Comparative Analyses of the PreS1-Ag and the Pattern of HBV Serum Marker in 1134 Patients with Hepatitis B Virus

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Abstract: To evaluate the clinical significance of detection of the preS1-Ag, the preS1-Ag and the pattern of HBV serum marker were analyzed retrospectively in 1134 patients with HBV. The results showed that six modes have been detected. The communal were HBsAg/Anti-HBe/Anti-HBc(+) (58.73%), HBsAg/HBeAg/anti-HBc(+) (21.43%) and HBsAg/Anti-HBc(+) (17.99%). Although HBsAg/HBeAg(+) was uncommon, but the positive rate of preS1-Ag was the highest(100%). The total positive rate of preS1-Ag was 76.90%, but the total positive rate of HBeAg was 18.87%. The Positive rate of PreS1 was higher significantly than that of HBeAg. Comparison of HBeAg (+)groups with HBeAg (-)groups, the positive rate of PreS1 had significiant differences(all P<0.05). In 214 cases with HBeAg (+), the PreS1 was 199 cases, accounting for 98.51%. In 920 cases with HBeAg (-), the PreS1 was 673 cases, accounting for 73.15%,which implied that the PreS1- Ag had good consistency with the HBeAg, and the preS1-Ag was more sensitive and meaningful than HBeAg at detecting the duplication of HBV. It can be used as observation indexes such as infection, replication, treatment and prognosis of HBV hepatitis. HBV preS1-Ag has very high value for the diagnosis, curing and observation of chronic hepatitis patients.

Key words: Hepatitis B virus; Serum markers; HBsAg; HBeAg; PreS1-Ag

1 Introduction
The capsid protein of Hepatitis B virus (HBV) is consisted of preS1Ag, preS2Ag and HBsAg. PreS1-Ag plays an important role in the infecting hepatic cells and the responding organism immune because there are live cell membrane receptors in it. PreS1-Ag can be detected in the serum with the prompting infection of HBV. It could be a new serum marker for detecting the infection, copy, treatment and prognosis of HBV (Minfu Yuan, 2004). Given these, the pattern of HBV serum marker and preS1-Ag were analyzed retrospectively in 1134 cases patients with HBsAg(+) to evaluate the clinical significance of detection of the preS1-Ag in patients with HBV. It will be illustrated as follows.

2. Material and Methods
2.1 Sources of specimens:
Specimens was collected from patients with HBsAg(+) in Huai’an First People’s Hospital from January 2012 to December 2012, 599 males and 535 females, their ages were from 0 to 83 years old , and average age was 47.6 years old.

2.2 Reagent and instrument:
Used 8ch automatic instrument of ELISA came from Hamilton Medical production, Swiss Confederation. Diagnostic reagent of HBV came from Shanghai Kehua. Diagnostic reagent of preS1-Ag came from Shanghai Alpha Biotechnology.

2.3 Methods:
Enzyme-linked Immunosorbent assay (ELISA) was used to determine serum markers of HBV and Serum PreS1 Ag. The judgment of results accorded to the requirements of kit. They were reported by S/CO value size.

2.4 Statistical analysis:
SPASS19 software for statistical analysis was used. Comparison between two groups used χ² test.

3. Results
The results of HBV serum marker and preS1-Ag: In the 1134 patients with HBV, HBeAg (+) was 214 cases, accounting for 18.87%, and the PreS1 (+) was 872 cases, accounting for 76.90%. The different combination models of HBV and the results of PreS1 are illustrated in Table 1.
Table 1 The different combination models of HBV and the results of PreS1 in the 1134 patients with Hepatitis B (%)

<table>
<thead>
<tr>
<th>Groups</th>
<th>HBV serum marker</th>
<th>preS1-Ag</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases</td>
<td>constituent ratio</td>
</tr>
<tr>
<td>HBsAg/ Anti-HBe /Anti-HBc (+)</td>
<td>666</td>
<td>58.73</td>
</tr>
<tr>
<td>HBsAg/ Anti-HBe (+)</td>
<td>243</td>
<td>21.43</td>
</tr>
<tr>
<td>HBsAg /HBeAg/ Anti-HBc (+)</td>
<td>204</td>
<td>17.99</td>
</tr>
<tr>
<td>HBsAg/ HBeAg (+)</td>
<td>10</td>
<td>0.88</td>
</tr>
<tr>
<td>HBsAg/ Anti-HBe (+)</td>
<td>9</td>
<td>0.79</td>
</tr>
<tr>
<td>HBsAg/ Anti-HBs / Anti-HBc (+)</td>
<td>2</td>
<td>0.18</td>
</tr>
</tbody>
</table>

* : HBeAg(+)groups, # : HBeAg(-)groups

Comparison of HBeAg(+) groups with HBeAg(-) groups, the positive rates of PreS1 had significant differences (all P<0.05)

4. Discussion

Although the content of HBV- DNA can estimate the replication, action and infection of HBV, and can directly represent the level of viremia (Chen Gang, 1999), but because of the high test requirement, it can't be tested in general laboratory; The detection requirements of PreS1 is not high and it can be detected in the general laboratory, and the positive rate of PreS1 is highly correlated with HBV- DNA (Hou Xiaojing, 2007). So as a new serological symbol of HBV, PreS1-Ag has shown higher clinical value, which has been used widely in clinical.

In table 1, HBeAg (+) was 214 cases, in which the PreS1-Ag (+) was 199 cases, accounted for 98.51%, which implied that both methods have good consistency. Of all the 1134 patients with HBsAg (+), HBeAg (+) was 214 cases, accounting for 18.87%; and the PreS1-Ag (+) was 872 cases, accounting for 76.90%. The positive rate of PreS1-Ag was higher significantly than that of HBeAg in patients with HBsAg (+), and comparison of HBeAg (+)groups with HBeAg (-)groups, the positive rates of PreS1 had significant differences(all P<0.05), which implied that the PreS1-Ag was more sensitive than HBeAg at detecting the duplication of HBV. In mode of HBsAg /HBeAg (+), the positive rate of PreS1-Ag was 100%; In HBsAg /HBeAg /Anti- HBe (+), the positive rate of PreS1-Ag was 92.65%, and in HBsAg/ anti-HBe /anti-HBc (+), it was 72.07%, which implied that PreS1 could be used as early diagnostic indicators. Studies have found the PreS1-Ag (+) indicated the early acute infection of Hepatitis B, and could be detected with rising transaminase early, so it can be used as early diagnosis of HBV (Mary, 2006). In the process of antiviral treatment, if PreS1-Ag turns from positive to negative, it will imply the effectiveness of interferon (Shuaijun Chen, 2008).

In 920 cases with HBeAg (-), the PreS1 was 673 cases, accounting for 73.15%, which implied, although the HBeAg was negative, HBV could still duplicate possibly, and the infection could not be ruled out. These may be related to the area C gene variants, not expressing HBeAg, or stopping its synthesis, or affecting its antigenicity and immunity, and making it possible that HBeAg turns from positive to negative, but do not affect HBV to replicate and transfer. However, the PreS1-Ag has not this phenomenon and can avoid the virus mutating and producing false negative results (Huang YH, 2006). HBeAg (-) or Anti-HBe(+) or Anti-HBc(+) cannot fully represent that the level of HBV is downing or better. So it has some shortcomings that only according to HBeAg to judge whether infection or not. The PreS1-Ag is a supplement and strengthened of HBeAg, and the PreS1-Ag is more meaningful than HBeAg at detecting the duplication of HBV. HBsAg, HBeAg and PreS1-Ag were reported by S/CO value size, the size could also explain the virus concentration (Ding Jin, 2006). In table 1, there was a kind of uncommon mode which was HBsAg/anti-HBs (+), accounting for 0.18%. It was slightly lower than reported of Tan Zhixi (2.7%) (Tan Zhixi, 2006). In addition to the test error, it is generally believed as early subclinical type HBV infection or different subtypes simultaneously or successively secondary infection, or high variability of HBV, and it also may be believed as coming better, pattern transformation process.

So PreS1-Ag can be used as observation indexes such as infection, replication, treatment and prognosis of HBV hepatitis. The clinical should concern the changes of PreS1-Ag, so that they can cure it better.
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