

Original Article

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Clinical, Biochemical, Serological, Virological and Sonological Profile of Newly Diagnosed Patients of Chronic Hepatitis B Virus Infection – 422 Cases

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Abstract:

Introduction: This retrospective study was done to see biochemical, serological and sonological status of newly diagnosed hepatitis B virus infected patients.

Material and methods: Consecutive newly detected patients of chronic hepatitis B were included. Their epidemiological, clinical, biochemical, serological and sonographic findings were recorded. Data were analysed using (SPSS version20). Mean and percentage were calculated for continuous and categorical data respectively. Chi-square test was done and P value > 0.05 was taken as significant.

Result: Total 422 patients, age from 11 to 75 years (mean 33.4) were included. Of them 317 (75.1%) and 105 (24.9%) were male and female respectively. Of them 320 (75.8%) were from rural areas, 253 (60.0%) were poor. Among them 216(51.18%) were detected during medical checkup for foreign job. And 173 (40.88%) had history saloon shave. In this series 144 (34.12%) patients were below 25 years and 216(51.18%) patients were within 26 to 45 years age group. ALT of patients varied from 10 iu/dl to 715 iu/dl (mean 51.63±48.40). Around 50.5% (n=213) had ALT within normal range (up to 40 iu/dl). HBeAg was positive in 97 (23.4%) patients. Hepatitis DNA (PCR) was not detectable in 135(32%) patients while it was above 100,000 copies / dl in 107(24.4%) patients. In this study 175 (53.84%) of patients with HBeAg negative had normal ALT and 83(61.48%) of patients with undetectable HBV DNA had normal ALT. Sonological examination was normal in 221 (%). Chronic liver disease, Hepatocellular carcinoma, ascites, fatty liver disease were detected in 60, 06(1.4%), 14 & 75 cases respectively. In this series, significant difference was found in DNA level (P= 0.029), hypertension status (P=0.013), ALT levels (P=0.00) and HBeAg status (P=0.000) in between sexes. HBeAg also varied significantly with ALT levels (P=0.011). ALT level also varied significantly between sexes (p= 0.00).

Conclusion: Newly detected asymptomatic or symptomatic patients of chronic hepatitis B virus infected patients may have significant biochemical and serological viral activity requiring antiviral treatment. So mass screening and early detection of disease activity may improve outcome.

Key words: Chronic hepatitis B, Newlydiagnosed, Virological status

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Introduction:

Hepatitis B virus (HBV) infection is a major health problem (1).

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It is estimated that about 2.57 billion people are infected by HBV in the world, of them 250 million are having chronic infection with risk of developing cirrhosis and hepatocellular carcinoma (HCC) (2,3). In 2015 about 887,000 persons died due to HBV related diseases (2). Prevalence of chronic HBV infection is high in sub Saharan Africa and East Asia (4). In our country the (pooled data from 1995 to 2921) prevalence is 4.0% with female predominance (5) and show a decreasing trend in prevalence. A large number of patients with chronic HBV infection are detected incidentally during investigation for screening or medical checkup without prior history of hepatitis (6). One report

from India showed that rate of incidentally detected chronic HBV infection was 2.3% (7) and in another Indian report it was 3.9% (8). In Nepal prevalence of HBV infection is the lowest 0.9% (9). Srilankais a country of low endemicity and our another neighbor country, where prevalence of HBV infection is 2% (10). Our country is of intermediate endemicity with prevalence rate of 4%. In healthy donors in Mymensingh, Bangladesh prevalence of chronic HBV infection was 6.2% (11). Reports from semiurban area of Dhaka city showed a prevalence rate of chronic HBV infection approximately 5.8% (12). similar report was published from Dhaka by Mahtab et al. (13). Most of the patients with CHBV infection are asymptomatic and unaware of their disease. Indian report shows that asymptomatic patients of chronic HBV infection may have significant disease activity histologically (6). In spite of presence of a good number of asymptomatic patients of chronic HBV infection, there is paucity of their full disease activity evaluation. With this background this retrospective study was designed to see disease activity of incidentally detected chronic HBV infection in North East part of Bangladesh.

Material and methods:

Data was retrieved from records of consultation in private chamber. Consecutive newly detected patients of chronic HBV infection irrespective of age and sex were included. Patients having at least records of ALT, HBeAg, HBV DNA (PCR) and ultrasonogram of hepatobiliary system were included in this study. Patients with concomitant hepatitis C virus infection (HCV) were excluded from the study. Clinical records and laboratory investigation reports were retrieved and recorded in a data sheet.

Statistical analysis:

Patients having ALT, HBeAg, HBV DNA (PCR) and Ultrasonogram of abdominal organs with or without other relevant investigations were included for statistical analysis. All data were analyzed using SPSS version 20 (Statistical package for social science). Mean and SD were calculated for continuous data and percentage were calculated for categorical data.

Duration and place:

This retrospective study was done from January 2020 to December 2022 at Popular Medical Centre, Sylhet, Bangladesh.

Result:

A total of 422 patients, age ranging from 11 to 75 years (mean 33.4 ± 12.586) were included in this study (Table 1). Males (n=317, 75.1%) the females (n= 105 24.9%). Most of the study subjects (n=320, 75.8%) were from rural areas (Table 2). Of them 148(35.1%), 44(10.43%), 126(29.9%), had education of from class six to SSC, HSC and above HSC level respectively. Common occupations were housewife (n=83; 19.7%), businessman (n=79; 18.7%) and student (n=68; 16.1%). Most of patients of this series belong to poor and lower middle class economic status (n=253; 60.0%). In this study 37 (8.8%) and 49(11.6%) subjects were diabetic and hypertensive respectively. In our series 216 (51.18%), 30 (7.11), 49 (11.61%), 46(10.9%) and 81 (19.19%) participants were detected during medical checkup for job abroad, screening before vaccination, and blood donation, during pregnancy, during evaluation of overt liver disease and evaluation of fatty liver disease respectively (Table 2). In this study population 173(40.885%), 33 (7.82%), 22(5.21%) and 61 (12.45%) had history of saloon shave, dental procedure, surgical intervention and family history of liver disease respectively. No other definite history of risk factors or possible route of transmission were available in this study. In this series 216 (51.18%) patients were in 26 to 45 years age group followed by 144 (34.12%), who were in below or up to 25 years age group. Alanine aminotransferase (ALT) varied from 10 iu/dl to 715 iu/dl (mean 51.635 and SD 48.405) (Table 3) among the study population. And 213 (50.5%), 164 (38.9%) patients had ALT within normal range and up to two times normal respectively. Fourteen patients (3.32%) with markedly raised ALT underwent Anti-HBC IgM test and were found negative. Ninetyseven (23.4%) had HBeAg marker positive. HBeAg negativity is higher among females (80.1% vs 75.39%) (Table 4). In this series Hepatitis B virus DNA was not detected in 135 (32.0%) cases, in 128 (30.3%) cases HBV DNA was up to 10000 copies per ml, in 52 (12.3%) cases HBV

DNA was more than 1000 to 10,000 copies per ml and in 107(25.4%) cases, HBV DNA was more than 100000 copies per ml by polymerase reaction (PCR) (Table 5).

Of 325 patients with negative HBeAg175 (53.84%) had ALT within normal range. Again out of 135 patients with non-detectable DNA, 83 (61.48%) had normal ALT level.

In this series sonological examination revealed 221 (53.4%), 60(14.2%), 75 (17.8%), 14(3.3%), 41 (9.7%), four (0.9%), 6(1.4%) were normal, features suggestive of chronic liver disease with male predominance, fatty liver disease, ascites, splenomegaly, portal vein thrombosis and space occupying liver suggestive of hepatocellular carcinoma respectively (Table 6).

ALT level varied significantly between sexes ($p= 0.00$) and HBeAg status ($P=0.011$) (Table 4). In this series, significant difference was found in DNA level between sexes ($P= 0.029$), hypertension status ($P=0.013$), ALT levels ($P=0.00$) and HBeAg status ($P=0.000$) (Table 5).

Table-1: Patients' profile

| Patients | Number (%) | Age range (years) | Mean \pm SD |
|---------------|-------------|-------------------|--------------------------|
| Total Patient | 422 (100%) | 11 y - 75 y | mean 33.40 \pm 12.58 |
| Male | 317 (75.10) | 11y -75y | mean 32.769 \pm 12.017 |
| female | 105 (24.90) | 16y-75 y | 35.304 \pm 14.056 |

Table-2: Epidemiological features of patients and mode of diagnosis

| Age | up to 25 y | | 26 to 45 y | | 46 to 60 y | | >60 y | |
|-------------------------|------------|---------|------------|---------|------------|--------|-------|-------|
| | N | % | N | % | N | % | N | % |
| Male (317) | 109 | (34.38) | 168 | 52.99) | 27 | (8.5) | 13 | (4.1) |
| Female (105) | 35) | (33.33 | 48 | (45.71) | 14 | (13.3) | 8 | 7.61) |
| Rural (320) | 112 | 35.0 | 161) | (50.31 | 30 | (9.37) | 17 | 5.30 |
| Urban(102) | 32 | 31.37 | 55 | 53.92 | 11 | 10.7 | 4 | 3.92 |
| Education | | | | | | | | |
| 0 to class five 27 | 1 | 3.7 | 5 | 18.51 | 10 | 37.03 | 11 | 40.74 |
| 6 to SSC (148) | 54 | 36.48 | 72 | 48.62 | 16 | 10.81 | 6 | 4.05 |
| HSC (44) | 7 | 15.90 | 33 | 75.0 | 3 | 6.81 | 1 | 2.27 |
| Above (126) | 53 | 42.06 | 66 | 54.1 | 6 | 4.92 | 1 | 0.82 |
| poor (15) | 8 | 53.33 | 4 | 26.66 | 3 | 20.0 | 0 | 0 |
| LMC (238) | 90 | 37.81 | 118 | 49.57 | 18 | 7.5 | 12 | 5.04 |
| MC 159 | 45 | 28.30 | 89 | 55.97 | 17 | 10.69 | 8 | 5.03 |
| High (10) | 1 | 10 | 5 | 50 | 3 | 30 | 1 | 10 |
| Occupation | | | | | | | | |
| dependent 1 | 1 | 100 | 0 | | 0 | | 0 | |
| Student 68 | 63 | 92.64 | 5 | 7.36 | 0 | | 0 | |
| service 36 | 2 | 5.55 | 28 | 77.77 | 3 | 8.33 | 3 | 8.33 |
| Business 79 | 11 | 13.92 | 61 | 77.21 | 6 | 7.5 | 1 | 1.26 |
| Housewife 83 | 23 | 27.71 | 39 | 46.98 | 13 | 15.66 | 8 | 9.63 |
| Farmer 33 | 11 | 33.33 | 10 | 30.30 | 6 | 18.18 | 6 | 18.18 |
| Day lab 5 | 2 | 40 | 2 | 40 | 1 | 20 | 0 | |
| Private service 37 | 9 | 24.32 | 25 | 67.56 | 2 | 5.40 | 1 | 2.70 |
| Abroad 25 | 6 | 24 | 14 | 56 | 6 | 24 | 0 | |
| Driver 18 | 6 | 33.33 | 12 | 66.66 | 0 | | 0 | |
| Unemployed 10 | 2 | 20 | 6 | 60 | 2 | 20 | 0 | |
| Others 26 | 8 | 30.76 | 14 | 53.84 | 2 | 7.69 | 2 | 7.69 |
| detection | | | | | | | | |
| Medical for job 216 | 93 | | 117 | | 6 | | 0 | |
| Blood donation 49 | 3 | | 19 | | 14 | | 13 | |
| Pregnancy 46 | 21 | | 25 | | 0 | | 0 | |
| FL and liver disease 81 | 16 | | 36 | | 21 | | 8 | |
| Vaccination 30 | 11 | | 19 | | 0 | | 0 | |

Table-3: Relation of age with other variables

| Variables | | Age | | | | P Value |
|------------|-----|-----------|-----------|----------|----------|---------|
| | | Up to 25 | 26-45 y | 46-60 y | >60 y | |
| HBeAg stat | N | N (%) | N 9%) | N (%) | N (%) | |
| Positive | 97 | 42 43.30 | 41 42.27 | 10 10.31 | 4 4.12 | 0.152 |
| Negative | 325 | 102 31.38 | 175 53.85 | 31 9.54 | 17 5.24 | |
| ALT status | | | | | | |
| Up to 40 | 213 | 76 35.68 | 108 50.70 | 23 10.8 | 6 2.816 | |
| 41-80 | 164 | 54 32.926 | 85 51.83 | 12 7.317 | 13 7.926 | 0.524 |
| 81-120 | 31 | 10 32.26 | 15 48.39 | 4 12.9 | 2 6.45 | |
| >120 | 14 | 4 28.57 | 8 57.14 | 2 14.285 | 0 | |

Table-4: Relation of ALT with other variables]

| Variables | | ALT level | | | | P value |
|------------|-----|-------------|-------------|------------|----------|---------|
| | | up to 40 | 41-80 | 81-120 | >120 | |
| Sex | N | N (%) | N (%) | N (%) | N (%) | |
| Male | 317 | 142 (44.79) | 133 (41.95) | 31(9.78) | 11 (3.4) | 0.000 |
| Female | 105 | 71 (67.61) | 31 (29.52) | 0 | 3 (2.86) | |
| HBeAg stat | | | | | | |
| Positive | 97 | 38 (39.17) | 42 (43.29) | 10 (10.30) | 7(7.21) | 0.011 |
| Negative | 325 | 175 (53.84) | 122 (37.53) | 21(6.46) | 7 (2.15) | |

Table-5: Distribution of DNA levels with different variables

| Variables | N | Hepatitis B virus DNA level per cumm (HBV DNA) | | | | P value |
|---------------|-----|--|--------------|-----------|------------------|---------|
| | | 1 to 10000(%) | 10001-100000 | > 100000 | notdetectable(%) | |
| Age | | N (%) | N (%) | N (%) | N (%) | |
| up to 25y | 144 | 45 31.25 | 17 11.80 | 45 45.31 | 37 25.69 | |
| 26-45 y | 216 | 71 32.87 | 29 13.425 | 42 19.444 | 74 34.26 | 0.088 |
| 46-60 | 41 | 10 24.39 | 4 9.756 | 11 26.83 | 16 39.02 | |
| >60 | 21 | 2 9.52 | 2 9.52 | 9 42.857 | 8 38.095 | |
| Sex | | | | | | |
| Male | 317 | 95 29.968 | 44 13.88 | 37 11.67 | 91 28.706 | 0.029 |
| female | 105 | 33 31.428 | 8 7.619 | 20 19.047 | 44 41.904 | |
| Residence | | | | | | |
| rural | 320 | 9329.06 | 42 13.12 | 89 27.81 | 96 30.0 | 0.103 |
| Urban | 102 | 35 34.31 | 10 9.80 | 18 17.647 | 39 38.23 | |
| Education | | | | | | |
| no inst edu | 27 | 4 14.81 | 3 11.11 | 10 37.04 | 10 37.04 | |
| Class 1 to 8 | 148 | 46 31.08 | 18 12.16 | 41 27.70 | 43 29.05 | 0.615 |
| SSC | 44 | 12 27.27 | 6 13.636 | 12 27.27 | 14 31.82 | |
| HSC | 77 | 27 35.06 | 8 10.39 | 12 15.84 | 30 38.96 | |
| Above | 126 | 39 30.95 | 17 13.49 | 32 25.40 | 38 30.16 | |
| Economic sta | | | | | | |
| poor | 15 | 6 40.0 | 2 13.333 | 3 20.00 | 4 26.66 | |
| Lower Middl | 238 | 7330.67 | 32 13.445 | 68 28.57 | 65 27.31 | |
| Middle class | 159 | 44 27.67 | 18 11.32 | 33 20.75 | 64 40.25 | 0.220 |
| Higher | 10 | 5 50.0 | 0 | 3 30.00 | 2 2.00 | |
| DM status | | | | | | |
| Present | 38 | 6 15.79 | 5 13.16 | 10 26.31 | 17 44.73 | 0.15 |
| Absent | 384 | 122 31.77 | 47 12.24 | 97 25.26 | 118 30.73 | |
| HTN status | | | | | | |
| Present | 50 | 9 18.0 | 3 6.0 | 14 28.0 | 24 48.0 | 0.013 |
| Absent | 372 | 119 31.99 | 49 13.17 | 93 25.0 | 111 29.84 | |
| ALT status | | | | | | |
| 0 to 40 iu/dl | 213 | 75 35.21 | 25 11.74 | 30 14.08 | 83 38.97 | |
| 41 - 80 | 164 | 49 29.88 | 21 12.80 | 50 30.49 | 44 26.83 | 0.000 |
| 81-120 | 31 | 4 12.90 | 516.13 | 15 48.39 | 7 22.58 | |
| >120 | 14 | 0 | 1 7.14 | 12 85.71 | 1 7.14 | |
| HBeAg status | | | | | | |
| Positive | 97 | 42 43.30 | 41 42.27 | 10 10.31 | 4 4.13 | 0.000 |
| Negative | 325 | 11836.31 | 37 11.38 | 49 15.076 | 121 37.30 | |

Table-6: Sonological findings

| USG | up to 25 | 26 to 45 | 46 to 60 | >60 | male | female |
|----------------------|------------|-------------|------------|-----------|-------------|------------|
| | N (%) | N (%) | N (%) | N (%) | N (%) | N (%) |
| Normal 221 | 98 (44.34) | 107 (48.41) | 13 (5.88) | 3 (1.36) | 166 (75.11) | 55 (24.89) |
| CLD 60 | 17 (8.33) | 26 (33) | 14 (23.33) | 3 (5.0) | 52 (86.67) | 8 (13.33) |
| Fatty liver 75 | 12 (16.0) | 51 (68.0) | 10 (13.33) | 2 (2.67) | 52 (69.33) | 23 (30.67) |
| Ascites 14 | 0 | 5 (35.71) | 7 (50.0) | 2 (14.28) | 12 (85.71) | 2 (14.29) |
| Splenomegaly 41 | 8 (19.51) | 19 (46.34) | 8 (19.51) | 6 (14.63) | 34 (82.93) | 7 (17.07) |
| P-V thrombosis 4 | 0 | 3 (75.0) | 1 (25.0) | 0 | 4 (100.0) | 0 |
| SOL / HCC 6 | 0 | 3 (50.0) | 1 (16.67) | 2 (33.33) | 6 (100.0) | 0 |
| GB sludge / stone 17 | 3 (17.65) | 9 (52.94) | 3 (17.65) | 2 (11.76) | 10 (58.82) | 7 (41.18) |

Discussion:

Like other developing countries of Asia and Africa, Bangladesh has significant number of patients of HBV related chronic hepatitis who are unaware of their disease (13). The mean age of patients of this series was 33 years. One previous report from our country found similar mean age (32.4 years) of chronic hepatitis patients (14) and one report from our country (15) and one reports from Pakistan (16, 17) showed lower mean age 29 and 30, 29.86 years respectively. But it is lower than Reports from Sudan (18,19), Nepal (20). Report from India showed mean age of patients 28 years (21). These variations may be due to difference in sample size, sample population and study design. In our country since 2003, vaccination for HBV was included in EPI vaccination schedule which will reduce burden of HBV related disease among new generations in near future.

More than half of patients in this study were in 26 to 45 years age group which is consistent with report from India (22), but it is higher than one previous report from our country (14). One report from India showed that most of the patients were in 35 to 44 years age group (8). Again in Nepal one study showed common age group 6-15 (9) years and another found common

age patients 30 to 60 years (20). These variations may be due to differences in sample size, study population, regional culture and study design. Majority of our patient are in main working age group which may have negative effect on national economy.

Male are predominantly affected in our country which is consistent with previous reports from our country (14), Sudan (18), Nepal (20), India (22) Egypt (23) and Pakistan (24). Male are more involved in outdoor works that may cause viral transmission. Males have option of saloon shave. In our villages people get shaving at temporary saloon in Hat where proper hygiene is not maintained. In our series, about 40% of patients had history of saloon shave which might be a risk factors for acquiring infection (25). In this series, more than 50% patients were detected during medical checkup for foreign job. Others were detected during blood donation, pregnancy, presenting with liver disease, evaluation for fatty liver and prevaccination screening. But one study from India (26) showed that majority of cases were detected during routine examination.

Most of the patients (about three fourth) in our series are HBeAg negative which is consistent with reports from our country (14), Nepal (20), Pakistan (24), India (7, 22), and Egypt (23). But one previous report from our country found higher HBeAg positivity (13) which may be due to difference in sample size and study population. Rate of normal ALT in HBeAg negative patients is higher than that in HBeAg positive patients in our study which is consistent report from Pakistan (16). In our series ALT was within 41 to 80 iu/dl in 39% patients and it was higher than reports from Sudan (18) and India (26), but lower than another report from India (7). Hepatitis viral DNA was not detectable in about one third patient which was higher than report from Egypt (16) but lower than report from India (7) and Sudan (18). In comparison to HBeAg positive patients HBeAg negative patients in our study had higher rate of HBV DNA negativity (37.23% vs 14.43%). Only 15% of our patients with HBeAg negativity had high level of DNA. One previous study (14) showed the rate is about 12%.

In our series 60 (14.22%) and 6 (1.42%) patients had features of chronic liver disease and Hepatocellular carcinoma respectively at sonological examination. Sonology is very common, cheap and acceptable method aiding diagnosis of liver disease which can also be adopted for follow up our patients. These patients developed complications of HBV infection before knowing the cause of their illness. Routine screening of people specially in older group could detect asymptomatic infection and give chance for evaluation and early treatment to ensure better outcome.

Limitations:

Liver stiffness or liver biopsy with histopathology was not done. As it a retrospective study, there is chance of biases.

Conclusion:

A good number of incidentally newly detected but unaware of disease chronic hepatitis B virus infected patients have significant viral activity and advance liver disease. Mass screening may detect them early and may bring them under anti-viral treatment and follow up according to present treatment guideline with better outcome. So mass population screening may be advocated in vulnerable population.

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