





Among patients with measurable assays the youngest was 1 year old and the oldest 83 years, with an average age of 33.2 years. Mean assay level was  $3.5 \times 10^6$  IU/ml while the highest was  $1.5 \times 10^8$  IU/ml and the lowest 20 IU/ml. The modal class was 31–40 years [Table 4].

## Discussion

There is a preponderance of males among HBV-infected persons with detectable VL as seen in this study. Although the reason is not clear, similar finding has been documented in previous studies.<sup>[30,31]</sup> Okwurawe *et al.*<sup>[11]</sup> had similar finding in Lagos and suggested it could be due to increased financial resources available to males to go for tests as against women. In contrast, Onwuliri *et al.*<sup>[31]</sup> and Okonko *et al.*<sup>[32]</sup> found more females with HBV infection among HIV patients and blood donors, respectively. A well-designed study may be needed to determine whether women abort the infection better than men.

The modal age range for measurable VL was 31–40 years, similar to 30–39 years obtained in Lagos<sup>[11]</sup> and 36–50 years in Bangladesh.<sup>[33]</sup> This may be related to the higher incidence of activities associated with HBV acquisition or reactivation of existing infections in this age group.<sup>[34,35]</sup> The highest mean was in the 1–10 year group, and was possibly associated with high perinatal transmission and a less competent immune status.<sup>[36]</sup> The net effect of this is that there were significantly higher VLs among subjects < 30 years, notwithstanding that the modal age for detection was in the 31–40 years modal group.

Effective management of HBV infection requires HBV DNA VL assay in accordance with existing treatment guidelines. A current guideline developed by the Society for Gastroenterology and Hepatology in Nigeria (SOGHIN) considers HBeAg status a major factor but discounts age.<sup>[13]</sup> In HBeAg-positive cases, the critical VL level is  $2.0 \times 10^4$  IU/ml. VL above this level with abnormal liver enzymes is an indication for chemotherapy, while

VL <  $2.0 \times 10^4$  IU/ml with abnormal liver enzymes needs liver biopsy before chemotherapy can be considered. If patient is HBeAg negative, the critical VL level is  $2.0 \times 10^3$  IU/ml. A VL greater than this in combination with abnormal liver enzymes supports therapy, but if VL <  $2.0 \times 10^3$  IU/ml a liver histology is needed. Only in the presence of moderate to severe fibrosis is chemotherapy indicated.

Under the SOGHIN guidelines, assuming all patients were HBeAg-positive with an abnormal alanine aminotransferase (ALT) level, 74.0% who have VL <  $2.0 \times 10^4$  IU/ml would need a liver biopsy for further assessment while 16.7% would qualify for chemotherapy based on their DNA and abnormal ALT alone. On the other hand if it is taken that all the patients were HBeAg negative with abnormal ALT levels, then 33.1% would qualify for chemotherapy while 57.6% would need a liver biopsy for determination of appropriate therapy. Therefore, it follows that a large number of patients would be subjected to liver biopsy with its attendant risk.<sup>[37]</sup> This would appear to be a challenge in using the SOGHIN guidelines despite its advantage that a single VL and liver function tests could be used to determine therapy.

The National Institute for Health and Care Excellence (NICE) guidelines recognize VL values of  $2.0 \times 10^3$ – $2.0 \times 10^4$  IU/ml as critical cutoff points when considering therapy, in conjunction with age, ALT levels, pregnancy/breastfeeding, and liver histology.<sup>[22]</sup> In patients aged  $\geq 30$  years, with VL >  $2.0 \times 10^3$  IU/ml and ALT > 30 IU/l (male) or > 19 IU/l (females) on two consecutive occasions at least 3 months apart chemotherapy is indicated. However, when the patient is < 30 years with similar findings, an abnormal liver biopsy is needed before considering chemotherapy. In cases where VL >  $2.0 \times 10^4$  IU/ml with abnormal ALT levels, then chemotherapy is indicated. Cases of active liver disease with VL >  $2.0 \times 10^3$  IU/ml or cirrhosis with any VL level also require therapy.

The slightly different approach followed by the NICE guidelines means that if all patients' ALT levels are taken as abnormal, then 23.3% would be placed on chemotherapy among those aged  $\geq 30$  years while 13.0% of those aged < 30 years would need a liver biopsy for further assessment and subsequent management. 20.3% would be eligible regardless of age for chemotherapy since their VL is >  $2.0 \times 10^4$  IU/ml. In effect the NICE guidelines may be associated with fewer liver biopsies.

The highest measurable VL load range was recorded in the 1–10 years age group. This is where the widest variation

**Table 3: Profile of hepatitis B viral load results**

VL range	Number (%)
ND	62 (9.3)
<20	72 (10.8)
$20-2 \times 10^3$	312 (46.8)
$2001-2 \times 10^4$	109 (16.4)
$>2 \times 10^4 - >1.7 \times 10^8$	111 (16.7)
Total	666 (100)

ND: HBV DNA not detected in sample, HBV: Hepatitis B virus, VL: Viral load

**Table 4: Distribution of measurable viral load parameters by age groups (n=276)**

Mean VL	Age groups						
	1-10	11-20	21-30	31-40	41-50	51-60	>60
	$3.6 \times 10^7$	$1.7 \times 10^7$	$2.4 \times 10^6$	$2.1 \times 10^6$	$6.2 \times 10^6$	$2.8 \times 10^5$	632
Viral load range	$48-1.5 \times 10^8$	$20-1.3 \times 10^8$	$26-6.8 \times 10^7$	$28-7.4 \times 10^7$	$21-5.6 \times 10^7$	$124-3.9 \times 10^6$	$63-2.1 \times 10^3$
Number of patients	15	38	65	79	58	15	6

VL: Viral load

occurred. This can be explained by the relatively naïve immune system in children and the different clinical course of the infection in this age group.<sup>[33,36,38]</sup> This emphasizes the need for both maternal and childhood vaccination against HBV infection.<sup>[10,27,36,38]</sup> The retrospective nature of this work is a major limitation, however the information to the scientific community is very relevant to patient management.

## Conclusion

VL testing is important in making management decisions in HBV infection. It will help to avoid unnecessary therapies, commence treatment as appropriate, and save cost. More research is needed to further fine-tune the local guidelines. Access to HBV DNA assay needs to be increased through some kind of support to enhance quality of care and research.

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## Conflicts of interest

There are no conflicts of interest.

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