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Gastroenterologists Have Sub-Optimal Hepatitis B Virus Screening Rates in Patients Receiving Immunosuppressive Therapy

Sonali Paul,

Division of Gastroenterology and Hepatology, Massachusetts General Hospital, 55 Fruit Street, Blake 4, Boston, MA 02114, sonali.paul2@gmail.com

Asim Shuja, MD,

Department of Gastroenterology, University of Florida College of Medicine, 655 West 8th Street, Jacksonville, FL 23309, asimshuja@gmail.com

Idy Tam, MS,

Division of Gastroenterology and Hepatology, Tufts Medical Center, 800 Washington Street, Box #233, Boston, MA 02111, idyxtam@gmail.com

Eun Min Kim, MD,

Division of Gastroenterology and Hepatology, Tufts Medical Center, 800 Washington Street, Box #233, Boston, MA 02111, emk282@nyu.edu

Sandra Kang, BA,

Tufts University School of Medicine, 145 Harrison Street, Boston, MA 02111, smkang2012@gmail.com

Leonid Kapulsky, BS,

Tufts University School of Medicine, 145 Harrison Street, Boston, MA 02111, lkap13@gmail.com

Kathleen Viveiros, MD, and

Division of Gastroenterology and Hepatology, Tufts Medical Center, 800 Washington Street, Box #233 Boston, MA 02111, kviveiros@tuftsmedicalcenter.org

Hannah Lee, MD

Division of Gastroenterology and Hepatology, Virginia Commonwealth University Medical Center, 1101 East Marshall Street Richmond, Virginia 23298-0663, Hlee4445@gmail.com

Abstract

Background and Aims: Hepatitis B reactivation in patients undergoing immunosuppressive therapy can lead to liver failure and death. Prior studies have shown suboptimal hepatitis b screening rates, but few have compared screening rates across specialties or factors associated with screening.

Methods: A retrospective study was performed using a hospital based chemotherapy database and outpatient pharmacy records from January 1999 to December 2013. HBV screening rates prior

to initiation of immunosuppression were determined. Multivariate analysis was used to determine predictors of HBV screening.

Results: Of the 4,008 study patients, 47% were screened prior to receiving immunosuppressive therapy; only 48% on rituximab and 45% of those on anti-TNF therapy were screened. Transplant specialists screened most frequently (85%) while gastroenterologists screened the least (34%). Factors significantly associated with HBV screening were younger age, Asian race, use of anti-rejection therapy, and treatment by a transplant specialist ($p<0.001$).

Conclusion: HBV screening prior to immunosuppressive therapy is sub-optimal, especially among gastroenterologists. Efforts to improve screening rates in at risk populations are needed.

Keywords

hepatitis b; reactivation; screening; gastroenterologist; rituximab

Introduction

The hepatitis B virus (HBV) affects an estimated 350 million people worldwide, with approximately 1.25 million Americans [1]. Virus reactivation has been seen in the setting of a suppressed immune system and can lead to liver failure and death. Multiple studies have shown reactivation rates ranging from 30 to 80% in patients receiving treatment for cancer chemotherapy, organ transplantation, and autoimmune diseases [2].

While HBV prophylaxis can dramatically decrease reactivation rates in immunocompromised patients [3–8], prophylaxis can only be initiated if those with HBV infection are identified through appropriate screening. Current guidelines from the Centers for Disease Control (CDC) [9], American Association for the Study of Liver Diseases (AASLD) [10], Asian Pacific Association for the Study of the Liver [11], and the European Association for the Study of the Liver [12] recommends screening all those undergoing immunosuppressive therapy. The American Gastroenterological Association (AGA) also published guidelines in 2015 for HBV screening based on the type of immunosuppressive therapy [13]. The American Society of Clinical Oncology [14] recommends screening in those receiving “highly suppressive chemotherapy regimens” including bone marrow transplant and rituximab therapy in addition to any patients with a risk of hepatitis B infection.

Despite these recommendations for HBV screening, screening rates have been shown to be suboptimal in high-risk populations [2,15–19]. However, few studies have compared screening rates across specialties and treatment regimens. Therefore, the purpose of this study is to describe HBV screening rates across specialties and determine predictors of screening in patients receiving immunosuppressive therapy.

Methods

Study Design

We performed a retrospective cohort study at our institution (a tertiary care center) to examine rates of HBV screening prior to immunosuppressive treatment using a

comprehensive cancer chemotherapy database (from January 1999 to December 2011) and outpatient pharmacy database (from January 2007 to December 2013). The hospital electronic medical record for each patient was reviewed to obtain demographic information (patient age, sex, and self-reported race), primary disease, therapy type, specialty provider, and HBV serologies. Year of disease diagnosis was also obtained given that the CDC recommended universal screening prior to initiating immunosuppressive therapy in 2008 [9].

Patient Selection

Study inclusion criteria included those 18 years or older with a disease requiring immunosuppressive therapy and receiving their primary treatment at our institution (as defined by at least 2 hospital visits). Duplicate patients found in both databases were excluded.

Diseases include solid or hematologic malignancies (excluding liver and biliary tumors), kidney and heart transplantation, inflammatory bowel disease, rheumatologic conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis), other autoimmune diseases (e.g. idiopathic thrombocytopenia, autoimmune hemolytic anemia), and psoriasis. For patients with more than one medical condition, the first disease that was treated determined disease type and specialty provider.

Immunosuppressive medications included any chemotherapy regimen, monoclonal antibodies such as rituximab, anti-tumor necrosis factor (TNF) agents, anti-rejection medications (e.g. tacrolimus, mycophenolate mofetil, sirolimus, cyclosporine), and specific agents such as methotrexate, azathioprine, and 6-mercaptopurine. Corticosteroid use alone was not included. Patients needed only one course of immunosuppressive therapy in order to be included in the study cohort. Some patients received multiple treatments simultaneously. Treatments that included rituximab, systemic chemotherapy (without rituximab), or anti-TNF agents dictated therapy class.

Exclusion Criteria

Given the etiologic relationship between HBV and certain liver and biliary cancers, patients with a history of these cancers were excluded from this study. Patients with a history of liver transplantation were also excluded as these patients are always screened for HBV prior to transplant. In addition, those on clinical protocols were excluded, as HBV screening is usually required by study protocol.

HBV Screening and History of HBV

The primary outcome measure of this study was screening for HBV. A positive screen was defined by the presence of hepatitis b surface antigen and/or hepatitis b core antibody ordered 2 months before the first immunosuppressive therapy dose or up to 1 month after as defined previously [2]. If HBV serologies were not found in the hospital system, clinic notes were reviewed to determine if HBV screening had been documented prior to administration of immunosuppressive therapy. An ICD-9 billing code diagnosis of hepatitis B prior to the first screening test was determined to be positive for a history of HBV.

Statistical Analysis

Data were expressed as mean and standard deviation for discrete variables and counts and percentages for qualitative variables. Differences among the screened and unscreened groups were compared using a 2-sample t-test or Chi-Square test for continuous and categorical values respectively. Multivariable logistic regression was used to identify predictors of screening. Factors on univariate analysis that were significant with $p < 0.1$ were included in the final multivariable model. A two-tailed p-value of less than 0.05 was considered statistically significant. All data analyses were performed using R version 3.0.2 (The R Foundation for Statistical Computing).

Results

Total Study Population

Of the 5,342 patients identified in the database, 4,008 patients met our pre-defined inclusion criteria. Of the 1,334 patients excluded, 983 did not receive their primary treatment at our institution or had incomplete data, 184 underwent liver transplantation, 101 had hepatocellular carcinoma, 49 did not receive immunosuppressive therapy, and 17 had a biliary tract malignancy. Characteristics of the total study population are seen in Table 1. The mean age of the patients was 58.0 years with 51% males. Most patients were white (75%) and the majority of patients had a solid tumor (41%) and received chemotherapy for this condition (59%). The majority of patients were diagnosed after the year 2008. A history of HBV was found in 2.7% of the total study population.

HBV Screening

Among patients who underwent immunosuppressive therapy, 47% were screened prior to initiating treatment (Table 1). Of those screened ($n=1871$), 9.2% ($n=174$) tested positive for the hepatitis B virus (119 patients positive for surface antigen and core antibody, 31 patients positive for surface antigen alone, and 24 positive for only core antibody).

Screening rates increased significantly after the year 2008 (from 34 to 54%). Only 36% of patients receiving non-rituximab based therapy were screened for HBV as compared to 48% of patients receiving rituximab and 45% of patients on anti-TNF therapy. Of Asians, 56% were screened for HBV. Transplant specialists screened their patients most frequently (85%) followed by rheumatologists (54%). Oncologists and gastroenterologists screened the least (37% and 33% respectively). After excluding transplant specialists (as organ transplantation may require HBV screening), gastroenterologists continued to have the lowest screening rates (33%) followed by oncologists (37%). These trends remained when the dataset was limited to patients receiving only rituximab and disease diagnosis made after 2008.

We further analyzed the data with respect to anti-TNF screening and specialty. Of the 247 patients that received anti-TNF therapy, 123 (50%) were prescribed by a gastroenterologist, 72 by a rheumatologist (29%), and 51 by a dermatologist (21%). One patient received treatment with a hematologist. Even among anti-TNF agents, rheumatologists and dermatologists screened more frequently for HBV (64%, 61% respectively) than compared to gastroenterologists (28%).

Predictors of HBV Screening

Age, sex, race, disease diagnosis, year of diagnosis, immunosuppression received, and provider specialty were found to be significant on univariate analysis. Provider specialty, type of immunosuppression, and disease type were found to be highly correlated predictors and only provider specialty was included in the final model. In the multivariable logistic regression model, the strongest predictors of HBV screening included younger age, male sex, Asian race, diagnosis made after 2008, and involvement of an organ transplant specialist (Table 2). The odds of undergoing HBV screening was nearly 20 times greater if a transplant specialist was involved as compared to a gastroenterologist and 5 times greater if a dermatologist was involved.

Discussion

The current study demonstrates low HBV screening rates prior to the initiation of immunosuppressive therapy. Specifically, 48% patients receiving rituximab-based therapy and 45% receiving anti-TNF treatments, therapies associated with high rates of HBV reactivation, were appropriately screened for HBV. Additionally, oncologists and gastroenterologists were the least likely to screen their patients while transplant specialists screened their patients most frequently. Asian patients who have a high pretest probability of HBV given their birthplace were also screened sub-optimally.

Previous reports have shown similar low HBV screening rates prior to the administration of immunosuppressive therapy [2,15–18,20]. However, these were mainly limited to one specialty and did not compare screening rates across disciplines. One study did show low screening rates among rheumatologists (27%), medical oncologists (6%), and hematologists (62%) but did not include gastroenterologists [19]. Our study highlights the lack of HBV screening performed by gastroenterologists prior to the administration of anti-TNF therapy with a screening rate of 28%. This has been shown in other studies that have cited HBV screening rates of 13 to 25% in patients with inflammatory bowel disease initiating anti-TNF therapy [17,18] with higher rates of screening from 2009 to 2010 (36 to 49%, [17]). Such low screening rates are surprising especially given that hepatitis b is under the purview of gastroenterology subspecialty training.

Overall screening rates increased after 2008. It is difficult to determine whether the release of the 2008 CDC guidelines was implicated in this change. Of note, all of the cases in this study prior to 2007 came from only the cancer chemotherapy database. In 2007, both the outpatient pharmacy database and chemotherapy database were used which may have biased the results. Although there was some improvement, further efforts at improving dissemination of new guidelines are warranted in order to increase actual screening rates.

We also show that 56% of Asian patients received appropriate screening, which is higher than previous reports [2]. A retrospective cohort study of those with newly diagnosed cancer showed that Asian race was not a significant predictor of screening while the current study did. One possible reason for this discrepancy could be the fact that our institution is located in Chinatown, introducing a screening bias, as providers are more aware of HBV in this patient population.

Recent narrative reviews in gastroenterology and hepatology journals have focused on the call for universal hepatitis B screening prior to immunosuppressive therapy [21,22]. However, there are likely several barriers to screening for HBV in these patient populations. Surveys exploring practitioner beliefs and knowledge of screening prior to chemotherapy have shown an underestimation of the risk of HBV reactivation in patients receiving chemotherapy and a lack of knowledge of risk factors leading to reactivation [19,23–27]. Similar results have been found in surveys of gastroenterologists prescribing anti-TNF therapy for inflammatory bowel disease and rheumatologists prescribing immunomodulatory therapy [28,29]. Screening recipients prior to organ transplantation is routine and transplant evaluations are often protocolized [30] which may explain why the rates of screening in this subgroup were so high. Recent studies have also shown improved screening rates with computer-assisted reminder systems [31].

Several societies including the CDC [9] and AASLD [10] have recommended HBV screening in any patient receiving immunosuppressive therapy. However, in 2015, the AGA published guidelines that stratified the risk of hepatitis B reactivation depending on the type of immunosuppressive therapy [13]. These guidelines currently recommend HBV screening in those receiving therapies that are of moderate or high-risk of reactivation. Such therapies include B-cell depleting agents (such as rituximab), anthracycline derivatives, anti-TNF agents, cytokine or integrin inhibitors, tyrosine kinase inhibitors, and those receiving long-term (greater than 4 weeks) of corticosteroids.

It is unclear how to interpret the results of the current study in the context of these AGA guidelines as our study reviewed data from 1993 to 2013, well before these 2015 recommendations. Additionally, we did not include long-term steroid use in the current study. However, although the current study included therapies other than those recommended by the AGA, screening rates were still suboptimal in patients receiving rituximab and anti-TNF agents.

The strengths of this study include its large heterogeneous sample size of over 4,000 patients with varying HBV risk factors. We also acknowledge several limitations. First, as a single-center study, this does not capture global practice variations. Additionally, given the retrospective and manual chart review of patient records, ascertainment of complete risk factors for HBV were not possible. Third, although our definition of HBV screening was based on a previous study [2], it is possible that testing done 1 month after initiation of therapy (or testing in general) was done because of abnormal liver tests or imaging and not HBV screening. Consequently, our findings may be an overestimation of the true HBV screening rate in this patient cohort.

In conclusion, HBV screening prior to immunosuppressive therapy is sub-optimal. Organ transplant specialists have the highest rates of screening while gastroenterologists have the lowest. The lack of knowledge and awareness of screening guidelines remains a challenge for healthcare providers. Future studies looking at the utility and cost-effectiveness of hepatitis B screening in these patient populations and examining strategies to disseminate guidelines are warranted.

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Table 1.

Characteristics of total study population and by HBV screening status.

Characteristic (n, %)	Total (n=4,008)	Screened for HBV		P value
		No (n=2137, 53.3%)	Yes (n=1871, 46.7%)	
Age, yrs, mean (SD)	58 (18.4)	62.07 (18.2)	53.36 (17.6)	< 0.001
Male	2047 (51)	1018 (49.7)	1029 (50.3)	< 0.001
History of HBV	107 (2.7)	12 (11.2)	95 (88.8)	< 0.001
Race				< 0.001
White	3001 (74.9)	1686 (56.2)	1315 (43.8)	
Hispanic	198 (4.9)	84 (42.4)	114 (57.6)	
Black	285 (7.1)	123 (43.2)	162 (56.8)	
Asian	410 (10.2)	181 (44.1)	229 (55.9)	
Other	114 (2.8)	63 (55.3)	51 (44.7)	
Primary disease				< 0.001
Solid Tumor	1649 (41.1)	1218 (73.9)	431 (26.1)	
Liquid Tumor	1045 (26.1)	475 (45.5)	570 (54.5)	
IBD	233 (5.8)	155 (66.5)	78 (33.5)	
Rheumatologic	267 (6.7)	124 (46.4)	143 (53.6)	
Psoriasis	73 (1.8)	28 (38.4)	45 (61.6)	
Organ Transplant	678 (16.9)	100 (14.8)	578 (85.3)	
Other [‡]	63 (1.6)	37 (58.7)	26 (41.3)	
Diagnosis Year				< 0.001
Before 2008	1,445 (36.1)	948 (65.6)	497 (34.4)	
2008 or After	2,563 (63.9)	1189 (46.4)	1374 (53.6)	
Type of therapy				< 0.001
Chemotherapy (non-Rituximab)	2382 (59.4)	1531 (64.3)	851 (35.7)	
Rituximab-based Therapy	348 (8.7)	180 (51.7)	168 (48.3)	
Anti-TNF	247 (6.2)	136 (55.1)	111 (44.9)	
Anti-Rejection	678 (16.9)	100 (14.7)	578 (85.3)	
Other [‡]	353 (8.8)	190 (53.8)	163 (46.2)	
Specialty provider				< 0.001
Oncologist	2695 (67.2)	1693 (62.8)	1002 (37.2)	
Gastroenterologist	233 (5.8)	155 (66.5)	78 (33.5)	
Rheumatologist	267 (6.7)	124 (46.4)	143 (53.6)	
Dermatologist	73 (1.8)	28 (38.4)	45 (61.6)	
Transplant	678 (16.9)	100 (14.8)	578 (85.2)	
Neurologist or Hematologist	63 (1.6)	37 (58.7)	26 (41.3)	

[‡]Idiopathic thrombocytopenia, autoimmune hemolytic anemia[‡]Methotrexate, 6-mercaptopurine, azathioprine, plaquenil.

Table 2.

Multivariable logistic regression model for predictors of HBV screening.

Predictor	Odds Ratio	95% CI	p-value
Age	0.97	0.97 – 0.98	< 0.001
Sex			
Female	0.80	0.70 – 0.92	0.003
Male	Reference		
Race			
Hispanic	1.13	0.82 – 1.58	0.49
Black	1.33	1.01 – 1.76	0.05
Asian	1.79	1.41 – 2.26	< 0.001
Other	0.89	0.58 – 1.36	0.59
White	Reference		
Diagnosis Year			
2008 or After	1.28	1.08 – 1.66	0.003
Before 2008	Reference		
Specialty provider			
Transplant	20.37	14.14 – 29.61	< 0.001
Rheumatologist	3.94	2.67 – 5.85	< 0.001
Dermatologist	5.02	2.87 – 8.94	< 0.001
Oncologist	2.56	1.87 – 3.55	< 0.001
Neurologist or Hematologist	2.86	1.54 – 5.25	< 0.001
Gastroenterologist	Reference		