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Undiagnosed hepatitis C on the general medicine and trauma services of two urban hospitals★

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Summary

The inpatient medical service may be an important location to identify undiagnosed hepatitis C virus (HCV) infection. We conducted a cross-sectional HCV prevalence study in consecutive patients aged 18–65 admitted in a three-month period to two urban hospitals' general internal medicine and trauma services. Patient sera were anonymously screened for anti-HCV antibody with an enzyme-linked immunoassay and, when anti-HCV positive (+), for HIV. Health system records were examined for prior HCV testing or diagnosis or an HIV diagnosis then linked anonymously to test results. Multivariate logistic regression was used to examine associations of patient and health care factors with unknown HCV+ status. Of 786 unique patients tested (60.3% of all admitted patients), 62 (7.9%) were HCV+ without a prior HCV+ test or diagnosis while 61 patients (7.8%) tested HCV+ but had prior HCV+ test or diagnosis. Of 62 patients with unknown HCV+, 6 (9.7%) were HIV+ but only 3 had a prior HIV diagnosis; of 61 patients with known HCV+, all 9 (14.8%) HIV+ had been diagnosed. Among the 640 patients with prior unknown HCV status, an HCV+ test was strongly associated with age: 50–65 (adjusted odds ratio [AOR] 5.44, CI 2.20–13.48) and age 36–49 (AOR 4.65, CI 1.91–11.32) versus. 18–35. In this anonymous study, we could not obtain HCV risk factor data but the positive and negative predictive values of HCV testing all inpatients with an unknown HCV status were 99.3% and 99.0%, respectively. In similar urban general medicine and trauma services, broader efforts to test for HCV in inpatients aged 36–65 may be warranted.

Keywords

Seroprevalence; Epidemiology; HCV infections; Inpatients; Wounds and injuries

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Introduction

Of over four million Americans with antibodies to hepatitis C virus (anti-HCV) [1], approximately 80% become chronically infected [2]. After several decades of untreated HCV infection, 14–30% develop cirrhosis and/or hepatocellular carcinoma [3–5]. Because HCV infection is associated with non-specific or no symptoms, many chronically infected persons are unaware of having the disease [6–9]. Although the United States (U.S.) Preventive Services Task Force neither recommends nor advises against HCV screening [10], the prevalence of infection may be sufficiently high in some health care settings to warrant special screening programs. Once diagnosed with chronic HCV, patients can reduce their risk of liver damage through specific preventive measures such as immunizations; further, combination anti-viral therapy in appropriate candidates can eradicate the virus [11] and is cost-effective [12].

National U.S. data suggest that roughly half of all HCV-infected persons are or have been injection drug users [2]. Because drug users are frequently hospitalized [13], this may be an important site to diagnose HCV infection. Persons hospitalized with alcohol abuse or dependence have also been found to have high prevalence of HCV (15%)[14] as have psychiatric inpatients (20.3%) [15]. This study evaluated the prevalence of a positive anti-HCV antibody in hospitalized patients on two hospitals' general internal medicine or trauma services, using an anonymous testing methodology advocated by the Centers for Disease Control and Prevention (CDC) [16]. When patients had anti-HCV antibodies, we examined medical records for an HCV diagnosis or a prior positive test. Because HCV and HIV infections often co-occur [17], we also tested anti-HCV positive sera for HIV and, when positive, examined whether HIV infection had been previously diagnosed. Finally, we estimated the predictive value and likelihood ratios of testing selected patients for HCV in based on prevalence rates both lower and higher than observed in our setting.

Methods

Patient population

We sought residual serological samples during three-month time interval for consecutive admissions in 2002 of patients aged 18–65 years (inclusive) to the general medicine and trauma services of a 725 bed academic hospital or the general medicine service of an affiliated 324 bed tertiary-care community hospital. We allowed for one additional year on either side of the age cutoff because of the imprecision of birth dates and dates of admission. The academic hospital offers more specialty services but both hospitals serve the Philadelphia community.

Data collection

We collected administrative data on all persons admitted to the study inpatient services during the three-month period. To identify previously known HCV or HIV infection, electronic administrative records for all inpatient and outpatient services within the University of Pennsylvania Health System were examined for ICD-9-CM codes for infection with HCV or HIV up to five years prior to the study interval. We also examined longitudinal

laboratory data for anti-HCV tests and results. A prior anti-HCV positive test or an HCV diagnosis was considered to provide evidence that the patient was known to be HCV positive. An anti-HCV negative test was accepted as evidence that the patient was previously known to be HCV negative. Electronic administrative data files also offered demographic information and clinical data from the Diagnosis Related Group (DRG) assigned at each patient's discharge.

Specimen processing

Serological samples for persons admitted during the study period with at least 1 cc for testing were sought from the pathology laboratory for two days after the patient's admission. Administrative data and serologic specimens were linked by a unique study number. Sera were tested for anti-HCV by the ORTHO® HCV Version 3.0 ELISA Test System (Raritan, NJ) by an accredited outside laboratory (Princeton Laboratories). The specificity of this test system among blood donors is 99.95% [18] and 100% in other third generation antibody studies [19]. The sensitivity ranges from 88.1 to 98.9% in panels of sera [18,19]. All initially reactive specimens were retested and classified as HCV antibody positive only when confirmed by a second positive test. Anti-HCV positive sera were also tested for HIV-1 ELISA followed by confirmatory Western Blot. We followed procedures recommended by the CDC for anonymous unlinked seroprevalence studies [16]. After medical record data was abstracted but before HCV testing, the link between patients' record numbers and study identifiers was destroyed. Analyses of patient data were conducted in sufficiently large categories to obviate possible identification of a unique subject. For example, uncommon race/ethnicities (<10% of subjects) were grouped as "other". We examined only Major Diagnostic Categories (MDCs) that classify multiple DRGs by organ system or disease to prevent identifying a patient with an unusual disease (available from authors). However, we do not report this information because specific DRG data was not informative in our analyses.

HCV status categories

Patients were categorized into four mutually exclusive categories: 1) known anti-HCV positive with a prior HCV diagnosis or anti-HCV positive test (known anti-HCV positive); 2) known anti-HCV negative (known HCV negative); 3) anti-HCV positive from the anonymous test but no prior diagnosis or positive test (unknown anti-HCV positive); and 4) anti-HCV negative from the anonymous test without a prior test (unknown HCV negative).

Statistical analysis

Demographic and health care characteristics for patients with and without available sera were compared using a one-way analysis of variance with Bonferroni correction for multiple comparisons. Characteristics of patients previously known to be infected with HCV (known positive) were compared separately with those who had been previously tested and found to be HCV seronegative (known negative) as well as with those with previously unknown HCV serostatus.

Among patients with unknown anti-HCV status, our primary dependent variable was unknown anti-HCV positive status (unknown positive). We used chi-square and Wilcoxon

rank sum tests where appropriate. Multivariate logistic regression models were examined to evaluate adjusted associations with unknown anti-HCV positive status. All tests were interpreted using a 2-tailed significance level of less than 0.05. We examined effect modification using multiplicative interaction terms and likelihood ratio testing. Goodness-of-fit of the logistic model was evaluated by the Hosmer–Lemeshow test.

Positive and negative predictive values were calculated using observed prevalence and standard formulas. We used sensitivity and specificity estimates from the literature assuming the lower range of the estimates for these values (88.1% and 99.95, respectively) [19]. We calculated conventional positive and negative likelihood ratios as follows: positive likelihood ratio = sensitivity/(1-specificity) and negative likelihood ratio = (1-sensitivity)/specificity. We also calculated positive and negative likelihood ratios weighted for prevalence as follows: positive likelihood ratio weighted for prevalence equals (prevalence)(sensitivity)/(1-prevalence)(1-specificity) and negative likelihood ratio weighted for prevalence equals (prevalence)(1-sensitivity)/(1-prevalence)(specificity).

Statistical analyses were performed using the licensed software STATA (version 8.0). Prevalence rates were adjusted using a direct standardization method. This study was approved by the Institutional Review Board of the University of Pennsylvania, Philadelphia.

Results

During the three-month study period, 1305 unique patients had 1365 admissions. We obtained and tested sera for anti-HCV of 797 of all admitted 1305 patients (61.1%). We excluded 11 patients due to: age outside of our eligible range ($N = 3$), indeterminant results ($N = 1$), or unavailable administrative data ($N = 7$). Although we have no information about the anti-HCV status of the untested patients, tested and untested patients did not differ significantly on any study characteristic (not shown).

786 subjects underwent serologic testing for HCV and constituted our study population; 123 were found to be seropositive (15.6%, CI 13.2–18.4%). The overall prevalence of anti-HCV positive among study subjects admitted to the general medicine services was 19.1% for academic hospital and 18.6% for the community hospital versus 12.7% for the trauma service which was only at the academic hospital ($P < 0.05$, data not shown). Prior health system records showed that 61 (7.8%, CI 6.0–9.9%) of these patients were known to be anti-HCV positive while 62 were unknown with no prior positive test or HCV diagnosis (7.9%, CI 6.1–10.0%). Compared with all the patients who tested anti-HCV negative, those who were positive (either known and unknown) were more likely to be men, aged >35 , and insured through Medicaid (Table 1). In both groups, approximately one-third of the patients had no record of prior outpatient visits to our health care system.

Comparison between the patients with known anti-HCV positive status with those who were unknown to be positive showed that the latter group was less likely to reside nearby in West Philadelphia, where the majority of inhabitants are black, and had fewer outpatient visits in our health system (Table 2). Among the 62 patients with unknown anti-HCV positive status, 6 (9.7%, CI 3.6–19.9%) were co-infected with HIV and three of these had no previous

record of an HIV diagnosis; among the 61 patients with a known anti-HCV positive status, all 9 (14.8%) HIV co-infected patients had been diagnosed in prior records.

Among all 663 patients with negative anti-HCV test, 85 (12.8%) had prior records documenting a negative test. Therefore, 640 patients had previously unknown anti-HCV status (i.e., 62 positive and 578 negative) based on our health system record review. Of these, 62 (9.7% CI 7.5–12.2%) were unknown anti-HCV positive. Among patients with unknown HCV status, age was strongly associated being anti-HCV positive both before and after adjustment (Table 3). Patients aged 50–65 and those aged 36–45 had, respectively, over five-fold and four-fold greater adjusted odds of testing anti-HCV positive than those aged 18–35. Unmarried patients had nearly 90% higher adjusted odds of anti-HCV positive but the confidence intervals cross one. Patients admitted to both academic hospital services (trauma and general medicine) were two to three times more likely to be anti-HCV positive than the patients on the general medicine service at the affiliated hospital but this association was significant only for the trauma service. Having a greater number of visits to our health care system was negatively associated with unknown anti-HCV positive status. The estimated prevalence of unknown anti-HCV positive exceeded 8% among patients who had fewer than 2 previous visits in our health system in the past five years and these individuals were more likely to be aged 50–65, black, or unmarried.

Based on our observed anti-HCV positive prevalence of 9.7% in the 640 subjects with an unknown status and, assuming a sensitivity of 88.1% and a specificity of 99.95% for the third generation ELISA anti-HCV test, we calculated that both the positive and negative predictive values of our test results were 99%. As shown in Table 4, the positive predictive value would decrease slightly as the prevalence decreased. In our cohort, the adjusted positive likelihood ratio was calculated to be 1762.0 and the negative likelihood ratio as 0.12. The positive likelihood ratio was also sensitive to the prevalence of HCV but dropped to only 45 if an inpatient population had a prevalence rate of 2.5%.

Discussion

In a cohort of patients admitted to the general medicine services of two urban hospitals and the trauma service of one hospital, 8% tested anti-HCV positive without any prior record of a positive test or diagnosis based on our review of five years of health system records including the index hospitalization. An additional 8% of patients were previously known to be HCV positive. The overall anti-HCV prevalence of 16% in this inpatient cohort is roughly eight times greater than that of the general population (1.3–1.9%) [2]. It is slightly lower than the 17–20% prevalence reported in studies of universal screening among emergency department attendees and psychiatric inpatients [15,20] but substantially higher than the 3–5% range reported for sexually transmitted disease clinics [21–23].

Patients on the trauma service have been reported to be less likely to be tested for blood-borne pathogens than non-trauma patients [24], even though the seroprevalence of HCV on trauma services ranges from 2.8 to 13.8% in blinded seroprevalence studies [24–26]. In our cohort, the overall prevalence of anti-HCV positive on the trauma service was 12.7%, most of whom were unknown based on our record review. Because patients admitted to trauma

services in the U.S. are often uninsured [27,28] or receive limited longitudinal care [29], this setting may offer an important opportunity to assess HCV status and link positive patients into care.

To our knowledge, this is the first anonymous HCV seroprevalence study conducted on inpatient general medicine services. The overall seroprevalence of anti-HCV (both known and unknown) on the academic and the community-based general medicine services was similar (19.1 and 18.6%, respectively). However, among the general medicine patients whose seroprevalence was not known, 7.7% of the academic hospital patients versus only 2.7% of community hospital patients were anti-HCV positive. Although most anti-HCV positive patients on the general medicine service received ambulatory care in affiliated practices with accessible electronic medical record data, it is possible that some patients hospitalized in an academic referral center may have been tested in settings that are not affiliated. However, prior studies in outpatient primary care practices have found that few physicians assess their patients' HCV status [30]. Therefore, as is the case for HIV infection [31], anti-HCV positive patients are unlikely to be identified during routine health care contacts.

Because roughly three-quarters of persons who test anti-HCV positive are chronically infected [2], we estimate that 45 (5.6%) of the roughly 800 patients in our cohort had apparently undiagnosed chronic HCV infection. The highest prevalence of unknown HCV was in persons aged 36–65. These results are consistent with national survey data reporting the highest HCV prevalence in persons aged 40–49 [2]. Current guidelines for the prevention and control of HCV call for targeted testing based on risk factors [32]. According to national survey data, 85% of persons aged 20–59 with a positive anti-HCV test can be identified by an abnormal ALT, a history of injection drug use, or a blood transfusion before 2002 [2]. Although asking patients about risk factors can improve the yield of testing, screening for risk factors has its limitations. Physicians must remember to ask about both current and previous injection drug use because over 80% of HCV-infected patients with this risk factor have not used injection drugs in the past year [2]. Even when physicians do ask, the actual prevalence of drug use has been reported to be two times greater than that acknowledged by patient self-report [33]. A Philadelphia-based study in an ambulatory general medicine practice reported a 1.5% prevalence rate of HCV and suggested a 72 item questionnaire could help identify these patients [34]. However, a less cumbersome screening method would be necessary for the inpatient service.

We found that the performance characteristics of our third generation anti-HCV test were excellent, yielding very high positive and negative predictive values (99%) as well as positive and negative likelihood ratios that far exceed guidelines for well performing tests (i.e., above 10 and below 0.1 respectively) [35]. Clearly, cost is an important factor when deciding on targeted versus universal screening for anti-HCV in inpatients who do not know their status. However, it should also be recognized that anti-HCV testing may also identify persons who have a greater risk of undiagnosed HIV infection. In our study, 4.8% of co-infected persons with unknown positive anti-HCV also had no documentation of HIV infection. In a prior anonymous HIV seroprevalence study conducted by our group on these services, we found that the seroprevalence of undiagnosed HIV infection ranged from 1.4 to

3.7%, depending on season [36]. Given the increased focus on identifying all undiagnosed HIV infection [37], the higher prevalence of apparently undiagnosed HIV in anti-HCV positive persons whose status is previously unknown also supports screening.

We acknowledge several limitations to our study. First, these data come from two large urban hospitals earlier in this decade and are likely to be generalizeable to tertiary care hospitals in regions with higher prevalence of injection drug users such as moderate- and large-size cities of the Northeast, Mid-Atlantic, California and Pacific Northwest [38]. Second, we were able to obtain left over sera for only 60% of unique patients admitted during the study timeframe but tested and untested subjects did not differ on any demographic or clinical characteristic. Third, as noted, we lacked access to patient records outside of our system. Fourth, this anonymous study did not allow us to interview patients for HCV risk factors. However, if we had tried to interview patients we would have likely achieved a smaller sample that would likely have been less generalizeable.

If these results are confirmed, this unique study has important policy implications concerning inpatient screening for HCV infection for the U.S. and possibly other countries. In addition to recommendations to perform targeted anti-HCV testing in incarcerated persons in the U.S. due to their high HCV prevalence (12 to 31%) [39], we would suggest that routine HCV screening on general medicine and trauma inpatients aged 36–65 in urban areas with higher HCV prevalence such as Philadelphia. In addition to benefits for the patient, identifying and educating chronically HCV-infected persons may reduce risky behaviors that can infect others. Drug users have been found to be often unaware of HCV risk factors such as sharing injecting paraphernalia [40]. The absence of special efforts to diagnose HCV infection on inpatient services such as ours represents a missed opportunity for both treatment of the individual and the health of the public.

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Table 1

Comparison of demographics of patients admitted to study services with and without anti-hepatitis C virus (anti-HCV).

Characteristic	Positive anti-HCV	Negative anti-HCV	<i>P</i> value*
	<i>N</i> = 123	<i>N</i> = 663	
	Column percent		
Gender			
Men	60.2	48.6	0.018
Women	39.8	51.4	
Age (years)			
18–35	8.1	29.4	<0.001
36–49	48.8	33.8	
50–65	43.1	36.8	
Race			
White/other/unknown	30.1	34.5	0.338
Black	69.9	65.5	
Marital status			
Married	22.0	25.9	0.350
Unmarried	78.0	74.1	
Region of residence			
West Philadelphia	34.2	31.4	0.366
Other areas of Philadelphia	49.6	44.5	
Outside Philadelphia	15.5	23.8	
Not reported	0.8	0.3	
Service			
General medicine – affiliated tertiary care hospital	25.2	20.5	0.102
General medicine – academic hospital	58.5	56.9	
Trauma – academic hospital	16.3	21.6	
Not reported	0.0	2.0	
Arrived health system office visits (<i>N</i>)			
0	35.8	32.7	0.319
1–2	22.8	18.6	
3–5	12.2	14.5	
6–13	14.6	17.7	
>14	14.6	16.6	
Insurance status			
Medicaid	44.7	33.5	0.010
Medicare/HMO/PPO	48.8	55.4	
Other/none	6.5	11.2	

* *P* value from one-way analysis of variance with Bonferroni adjustment for multiple comparisons.

Table 2

Comparison of patients admitted to study services with known versus unknown HCV positive antibody status.

Characteristic	Known anti-HCV positive <i>N</i> = 61	Unknown anti-HCV positive <i>N</i> = 62	<i>P</i> value*
Column percent			
Gender			
Men	60.7	59.7	0.913
Women	39.3	40.3	
Age (years)			
18–35	4.9	11.3	0.926
36–49	55.7	41.9	
50–65	39.3	46.7	
Race			
White/Other	26.2	33.9	0.360
Black	73.8	66.1	
Marital status			
Married	27.9	16.1	0.118
Unmarried	72.1	83.9	
Service			
General medicine – affiliated tertiary care hospital	39.3	11.3	0.086
General medicine – academic hospital	57.4	59.7	
Trauma – academic hospital	3.3	29.0	
Not reported	0.0	0.0	
Region of residence			
West Philadelphia	39.3	29.0	0.022
Other areas of Philadelphia	54.1	46.8	
Outside Philadelphia	6.6	24.2	
Not reported	0.0	0.0	
Arrived health system office visits (<i>N</i>)			
0	27.9	43.6	<0.001
1–2	18.0	27.4	
3–5	11.5	12.9	
6–13	18.0	11.3	
>14	24.6	4.8	
Insurance status			
Medicaid	49.2	40.3	0.091
Medicare/HMO/PPO	49.2	48.4	
Other/none	1.6	11.3	

* *P* value from one-way analysis of variance with Bonferroni adjustment for multiple comparisons.

Table 3

Association of patient characteristics with HCV positive antibody among 640 patients with unknown antibody status.

Characteristic	Unadjusted odds ratio (95% CI)*	Adjusted odds ratio (95% CI)	Adjusted anti-HCV positive prevalence % (95% CI)
Gender			
Men	1.0 (ref)	1.0 (ref)	7.8 (6.6–9.0)
Women	0.69 (0.43–1.12)	0.75 (0.42–1.36)	5.3 (4.1–6.6)
Age (years)			
18–35	1.0 (ref)	1.0 (ref)	3.8 (3.5–4.0)
36–49	3.14 (1.40–7.07) ‡	4.65 (1.91–11.32) ‡	7.5 (5.6–9.4)
50–65	3.10 (1.39–6.92) ‡	5.44 (2.20–13.48) ‡	8.7 (6.8–10.6)
Race			
White/other/unknown	1.0	1.0 (ref)	5.8 (4.6–7.1)
Black	1.57 (0.99–2.50) †	1.07 (0.53–2.16)	8.2 (6.8–9.7)
Marital status			
Married	1.0 (ref)	1.0 (ref)	2.1 (1.4–2.9)
Unmarried	1.68 (0.87–3.22)	1.86 (0.87–3.97)	8.7 (7.4–10.0)
Service			
General medicine – affiliated tertiary care hospital	1.0 (ref)	1.0 (ref)	2.6 (1.9–3.2)
General medicine – academic hospital	1.80 (0.82–3.92)	2.23 (0.90–5.53)	7.7 (6.1–9.3)
Trauma – academic hospital	2.11 (0.91–4.88)	3.00 (1.02–8.89)	5.0 (4.2–5.8)
Not reported	0.0	0.0	0.0
Philadelphia region			
West	1.0 (ref)	1.0 (ref)	4.3 (2.9–5.7)
Other regions within city	1.10 (0.62–1.93)	1.03 (0.52–2.04)	7.6 (6.2–9.1)
Outside	1.09 (0.57–2.09)	1.19 (0.46–3.08)	3.5 (2.9–4.2)
Not reported	3.70 (0.70–19.48)	3.02 (0.19–48.2)	0.3 (0.30–0.3)
Arrived visits in the health system (N)			
0	1.0 (ref)	1.0 (ref)	9.6 (7.1–12.1)
1–2	1.11 (0.63–1.96)	1.10 (0.55–2.17)	8.7 (6.8–10.6)
3–5	0.76 (0.36–1.60)	0.64 (0.27–1.52)	3.4 (1.7–5.2)
6–13	0.63 (0.28–1.39)	0.63 (0.25–1.54)	3.1 (1.5–4.7)
>14	0.31 (0.10–1.01) †	0.28 (0.08–0.98) †	0.8 (0.1–1.4)
Insurance status			
Medicaid	1.0 (ref)	1.0 (ref)	7.7 (6.5–9.0)
Medicare/HMO/PPO	0.78 (0.47–1.30)	0.76 (0.41–1.41)	6.1 (4.8–4.4)
Other/None	0.79 (0.36–1.77)	0.57 (0.21–1.54)	3.8 (3.1–4.4)

* P values calculated from χ^2 test or Wilcoxon rank-sum test.

† P value < 0.05;

[‡]*P* value < 0.01.

Table 4

Estimated test characteristics of an anti-HCV result by prevalence of unknown HCV status.

Prevalence of positive anti-HCV	Positive predictive value (%)	Negative predictive value (%)	Positive likelihood ratio ^a	Negative likelihood ratio ^a
2.5%	97.83	99.69	45.2	0.003
5.0%	98.93	99.38	92.74	0.006
7.5%	99.30	99.04	142.86	0.010
10.0%	99.49	98.69	195.78	0.013
12.5%	99.60	98.32	251.71	0.017
15.0%	99.68	97.94	310.94	0.021

^aWeighted for prevalence.