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Hepatitis C Cascade of Care among pregnant women on opioid agonist pharmacotherapy attending a comprehensive prenatal program

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Abstract

Background—Given the large increases in opioid use among pregnant women and associations with hepatitis C virus (HCV) infection, screening pregnant women who are on (opioid agonist) pharmacotherapy for HCV infection has potential to inform medical care for these mothers as well as their newborns. We investigated the HCV testing cascade among pregnant women on pharmacotherapy in order to describe exposure and infection rates and to identify opportunities that would improve care.

Methods—Secondary analyses of laboratory results were performed for HCV testing, including anti-HCV, viremia (RNA) and genotype. Information was abstracted from the medical records of women who were followed at a comprehensive prenatal care clinic for women with substance use disorders at the University of New Mexico.

Results—The sample included 190 pregnant women, of whom 188 were on pharmacotherapy (43.7% on buprenorphine and 55.3% on methadone); the remaining two had tested positive for heroin or prescription opioids. A total of 178 (93.7%) were tested for anti-HCV, 94 (98.9%) of whom were tested for RNA, and 41 (57.7%) were genotyped. Prevalence of exposure to HCV by anti-HCV results was 53.3%, and 37.3% were positive for HCV RNA indicating chronic infection.

Conclusions—The high prevalence of exposure and infection with HCV in pregnant women who involved in pharmacotherapy for a substance use disorder indicate a need for ongoing surveillance and testing for HCV. Identifying HCV during pregnancy is crucial because this identification would serve to enhance medical care and potentially prevent vertical transmission.

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Identifying HCS would also facilitate referrals to newly available curative HCV treatments following delivery.

Keywords

pregnancy; opioid-use disorder; opioid agonist pharmacotherapy; hepatitis C virus; prenatal care

INTRODUCTION

The opioid abuse epidemic, associated with both prescribed and non-prescribed drugs has highly impacted the United States (U.S.) population, including pregnant women. In the past 10 years the number of pregnant women using opioids has increased at least five-fold (Ailes et al., 2015; Martin, Longinaker, & Terplan, 2015; Mehta, Forbes, & Kuppala, 2013). Among Medicaid-enrolled pregnant women, 18.5% filled an opioid prescription in 2000, compared to 22.8% in 2007 (Desai, Hernandez-Diaz, Bateman, & Huybrechts, 2014). Injection drug use of opioids and heroin has increased in association with the prescription opioid epidemic as people have transitioned to injecting opioids and heroin after initiating prescription opioid use (Becker, Sullivan, Tetrault, Desai, & Fiellin, 2008; Grau et al., 2007; Muhuri, Gfroerer, & Davies), with concomitant increases in hepatitis C virus (HCV) infection (Suryaprasad et al., 2014). Two studies have estimated that between 10–17 of 100,000 pregnant women are chronically infected with HCV (Ellington, Flowers, Legardy-Williams, Jamieson, & Kourtis, 2015; Salihu et al., 2012). However, a recent retrospective study of inpatient pregnancies in the U.S. between 1998 and 2011, showed that HCV rates per 100,000 deliveries increased by over 5-fold, from 42 to 210 in those years, respectively (Salemi et al., 2016). Given this significant increase, it's evident that HCV infection is rising in pregnant women. Yet the burden of HCV in pregnant women with opioid dependence is not well characterized. The association between opioid and heroin injection and rapid contraction of HCV infection is established (Bruneau, Roy, Arruda, Zang, & Jutras-Aswad, 2012; Hagan, Pouget, Des Jarlais, & Lelutiu-Weinberger, 2008; Hahn et al., 2002). Therefore HCV screening of pregnant women with a history of opioid use disorder or who are on opioid-agonist pharmacotherapy provides a unique opportunity to optimize medical care for these patients as well as for their newborns. It will also render insight into a population that has not been well characterized.

In the prenatal care setting, HCV testing will help identify women with chronic infection, as well as identify the infants at risk of vertical transmission. Since 1998, the U.S. Centers for Disease Control and Prevention (CDC) has recommended risk-based HCV testing for anyone who has any history of injecting drugs (1998). In 2012 recommendations were updated to include testing persons born between 1945 and 1965 (the “baby boomers”) irrespective of injection exposures (Smith, Morgan, Beckett, & al., 2012). Testing guidelines further recommend that all people who are seropositive for HCV be tested for HCV RNA to detect viremia (Centers for Disease Control and Prevention). Despite these changes, the CDC recommendations do not support routine testing of pregnant women. However, it's important to note that both CDC and the American College of Obstetricians and Gynecologists (ACOG) are consistent regarding endorsing testing of high-risk women (American College of Obstetricians & Gynecologists, 2007). Nevertheless, several studies

have shown that pregnant women with HCV are not identified during care (Blasig et al., 2011; Giles, Hellard, & Sasadeusz, 2003; Prasad & Honegger, 2013) due to multiple patient and provider factors, notably misperceptions and reluctance to discuss risk factors (Delgado-Borrego et al., 2012; Kuncio, Newbern, Johnson, & Viner, 2016).

Whether the CDC and ACOG recommendations are being followed in practice is unknown. We investigated HCV screening among pregnant women in treatment for opioid-use disorder. These women attended a comprehensive substance abuse prenatal care program that examined the cascade of HCV testing and assess opportunities for enhanced surveillance.

METHODS

We conducted secondary analyses of data obtained from pregnant women who were participants in one of two prospective cohort studies being conducted at the University of New Mexico Health Sciences Center's (UNM HSC) Milagro Clinic, which is a comprehensive prenatal care program for women with substance use disorders: Women participated in either the Biomarkers in Pregnancy study (BIPS) or the Ethanol, Neurodevelopment, Infant and Child Health (ENRICH) study. Pregnant women attending the Milagro clinic receive pharmacotherapy with buprenorphine or methadone. Detailed methodologies of both studies have been previously described (Bakhireva et al., 2012; Bakhireva, Lowe, Gutierrez, & Stephen, 2015). In brief, inclusion criteria included ability to give written informed consent in either English or Spanish, being 18 years old, singleton pregnancy, lack of prenatal diagnosis indicative of a major structural anomaly, and gestational age <32 weeks at enrollment. Participants were recruited during one of the first prenatal care visits and followed through labor and delivery. Substance use was ascertained at study visits by structured interviews based on the survey questions from the 2011 National Survey on Drug Use and Health (2011). Self-reported information was confirmed by medical record review, and clinic- and study-specific urine drug screening (Urine Drug Panel-7)(2016).

Patients in this analysis include women in the BIPS and ENRICH studies who either self-reported a history of opioid use, were on pharmacotherapy and/or had drug screens that were positive for opioids. Results of HCV testing, including anti-HCV, viremia (RNA), and genotype were obtained from medical records of eligible participants (HCV testing was not conducted as part of cohort research activities). The BIPS and ENRICH protocols were reviewed and approved by the UNM Human Research and Review Committee. All participants provided written informed consent to participate.

RESULTS

A total of 190 women were included: 75.7% were Hispanic, and at enrollment mean age was 26.9 ± 4.9 years, and mean gestational age was 21.6 ± 7.4 weeks (Table 1). More than half (62.1%) were not married, and 46.8% did not complete high school. Almost all (98.9%) were on pharmacotherapy: 105 (55.6%) with methadone maintenance and 83 (43.7%) with buprenorphine. Two non-pharmacotherapy participants screened positive for prescription opioids or heroin.

Figure 1 shows the HCV testing cascade among all 190 women. Almost all (n=178; 93.7%) of women had been tested for anti-HCV, of whom 95 (53.3%) were positive, and 94 (98.9%) were tested for HCV RNA. Seventy-one of 92 (77.1%) women tested for RNA were positive and 41 (57.7%) were further tested for infecting HCV genotype. Thus, among women with test results, prevalence of exposure was 53.3%, and of chronic infection, 37.3%. Among women genotyped, 58.5% were genotype 1, 31.7% genotype 3, 7.3% genotype 2, and 1 woman was infected with genotype 4 virus. A significantly higher proportion of women who received HCV testing at 20 or more weeks gestation were tested for HCV genotype testing (78.3%) than women who were tested in 20 weeks or less gestation (48%). No associations between gestational age and other testing cascade proportion (outcomes) were found.

DISCUSSION

In this sample of pregnant women on pharmacotherapy, almost all women had been tested for exposure to HCV (anti-HCV) and more than half were positive. Testing for viremia among women who screened anti-HCV positive was also high. If we assume similar infection patterns among the 12 women who had not been screened, another six would have been identified as anti-HCV positive, among whom at least four more would have been identified as chronically infected, totaling 75 or 39.5% women with chronic HCV infection.

The principal gap identified in this study was for HCV genotype testing: less than 50% of women with active infection were tested. The low proportion of women tested for genotype is likely associated with deferring testing until referral for HCV treatment. Until recently (2016), HCV infected pregnant in the Milagro Clinic did not get systematic referrals for HCV treatment during postpartum care unless they were abstinent, which may have also contributed to low genotype testing. Overall, the proportion tested, exposed, and infected with HCV in this cohort is similar to that seen in other studies of women with a history of opioid use disorder (Krans et al., 2016; Liu et al., 2009). A recent study of 791 pregnant women with a history of opioid use disorder in Pittsburgh found that a lower proportion were tested (77%) but showed similar anti-HCV prevalence (60.4%) and even lower rates of RNA and genotype testing (Krans et al., 2016). In 295 women attending methadone maintenance in Sydney, Australia, Liu et al., (Liu et al., 2009) found that 98% of pregnant women were tested for anti-HCV, of whom 84% were seropositive. However, only a fraction (18%) of women in that cohort were tested for RNA compared to almost all (96.8%) of women in our study.

The Milagro clinic provides comprehensive health care for pregnant women with opioid use disorder, which may account for higher rates of testing than in other routine prenatal programs. With new guidelines for referral in place, additional analyses of follow-up and adherence to HCV testing and treatment protocols will further inform gaps and the need for universal HCV testing in this population. The low fidelity to HCV screening and testing protocols is shown here by low genotype testing, and future cascades should include linkage to care, treatment uptake and sustained viral response to fully characterize the continuum of care (Viner, Kuncio, Newbern, & Johnson, 2015). These results inform the larger public health community about the burden of HCV infection, and provide opportunities to optimize screening and diagnosis of HCV in the prenatal settings.

Several studies have found higher than expected HCV infection rates among pregnant women not involved in pharmacotherapy programs, including in Australia, England and the U.S. (Kuncio et al., 2015; Liu et al., 2009; Orkin, Jeffery-Smith, Foster, & Tong, 2016). This finding led proposals to adopt universal prenatal HCV screening, as was done in Australia and New Zealand (Wilson & Beckmann, 2015). In light of increasing opioid use among pregnant women in the U.S. (Desai et al., 2014), high probability of under ascertainment of risk, and poor access to pharmacotherapy programs (Martin et al., 2015), serious consideration should be given to universal screening. The primary argument against universal screening is the lack of effect on clinical care since current HCV treatments, direct acting antivirals (DAAs), several of which are classified by the FDA as Pregnancy Category B, are not generally used during pregnancy or breastfeeding (Spera, Eldin, Tosone, & Orlando, 2016). Likewise, consistent evidence for effective prevention of vertical transmission, which occurs in 5% to 7% of infants born to infected mothers, is also lacking (Cottrell, Chou, Wasson, Rahman, & Guise, 2013). However, knowledge of HCV RNA status has potential to inform modifications of delivery and postnatal care that may potentially reduce mother-to-child transmission of HCV including avoiding the use of fetal scalp monitors, episiotomies (Garcia-Tejedor et al., 2015), and breastfeeding when there is active bleeding from the nipples.

Limitations of this study include a modest sample size of women recruited from one clinic in New Mexico, and thus results may not be representative of all pregnant women with opioid use disorder in the state or elsewhere. While the analyses are secondary, and original data were gathered for other primary research questions, the cohort studies did have secondary goals of assessing multiple health outcomes. Despite these limitations, this study presents important results on HCV screening in a high-risk population of women attending a clinic that provides comprehensive care. Results are consistent with other studies showing that a high proportion of these women are infected with HCV and that screening and testing in this setting can be optimized.

Newly available and highly effective DAA treatments for HCV also change the dynamic of antenatal screening and testing for HCV in pregnant women. Screening of pregnant women, especially if they have a history of opioid use will inform prenatal health management as well as follow-up of infants born to pregnant women with HCV. Women should be treated for HCV after delivery, including women with opioid-use disorder or on pharmacotherapy (Dore et al., 2016; Grebely et al., 2015), not only for their postnatal health but also to avoid potential transmission in future pregnancies. Clinical trials using direct-acting antivirals in pediatric populations are currently underway, and have potential to further reduce the burden of infection and accompanying morbidity in children (Ohmer & Honegger, 2016). HCV elimination, a much discussed goal given the high efficacy of new treatments (National Academies of Sciences, 2017), remains a likely possibility if women and children are included in the continuum of testing and treatment.

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Figure 1.
HCV Testing Cascade and Results among 190 Pregnant Women attending the Milagro Clinic and enrolled in the BIPS and ENRICH cohorts

Table 1

Characteristics of Pregnant Women attending the Milagro Clinic and enrolled in BIPS and ENRICH Studies (N=190)

Characteristics	N (%)
Maternal Age at Enrollment (mean $\pm$ sd)	26.89 $\pm$ 4.88
Gestational Age (in weeks) at Enrollment	21.64 $\pm$ 7.43
Marital Status	
Single/Separated/Divorced/Widowed	118 (62.1)
Married/Cohabiting	72 (37.9)
Ethnicity: Hispanic/Latina	143 (75.7)
Race	
White	167 (87.9)
Black or African American	3 (1.6)
American Indian or Alaskan Native	10 (5.3)
More than one race/Prefer not to answer	10 (5.2)
Education Level	
Less than High School	89 (46.8)
High School	51 (26.8)
College or Higher	50 (26.3)
Insurance	
Medicaid	175 (92.1)
Employer Based	4 (2.1)
No Insurance	4 (2.1)
Other	7 (3.7)
Primigravida	28 (14.7)