Diagnosis of hepatitis C virus infection in pregnant women in the healthcare system in Poland

Is it worth the effort?

Bozena Walewska-Zielecka, PhD, Urszula Religioni, PhD, Grzegorz Jusczyk, PhD, Aleksandra Czerw, PhD, Zbigniew Wawrzyniak, PhD, Piotr Soszyński, PhD

Abstract
The hepatitis C virus (HCV) is globally recognized as a serious public health concern. Current statistics indicate that approximately 2% of people worldwide and 1.9% of people in Poland suffer from HCV infection.

This study was conducted to assess the anti-HCV seroprevalence in pregnant women in Poland and subsequently provide recommendations on the rationale for obligatory screening.

A total of 42,274 women participated in our study, of which 16,130 were pregnant. We were granted access to their health data stored in the form of electronic medical records kept by the network of outpatient clinics throughout Poland.

The lowest rate of positive anti-HCV test results was found in women ages 25 to 34 (0.73%); however, younger and older age groups had similar rates (15–24 = 0.86%; 35–44 = 0.84%). Additional analysis of data from the period between 2011 and 2014 revealed a downward trend in the proportion of positive anti-HCV tests among pregnant women (mean positive anti-HCV = −0.001 x year + 1.9451; R² = 0.7274). Regardless of the gradual increase in the number of female patients undergoing screening between 2004 and 2015, there has been a constant decrease in the rate of positive cases. The rate of pregnant women potentially infected with HCV was twice as low as that in a control group of women undergoing tests for other medical circumstances: 0.76% vs 1.67% (P < 0.0001).

Analysis of real-world data of female patients in Poland provides evidence that screening based on an individual’s medical history and behavioral risk factors in clinical circumstances would be more effective than obligatory testing of all pregnant women.

Abbreviations: anti-HCV = antibodies to HCV, CDC = US Center for Disease Control and Prevention, HCV = hepatitis C virus, HIV = human immunodeficiency virus, WHO = World Health Organization.

Keywords: hepatitis C virus, obligatory screening, pregnant women

1. Introduction

Hepatitis C virus (HCV) infection is considered to be a serious public health concern by the World Health Organization (WHO) and one of the major public health priorities. The most common available marker of HCV infection consists of the antibodies to HCV (anti-HCV). The prevalence of HCV infection ranges from 1.2% to 3.8% in different regions of the world. The highest prevalence of HCV is noted in Central Asia (3.8%), East Asia (3.7%), and North Africa/Middle East (3.6%).[1,2]

The antenatal prevalence of infection varies from 1.0% to 2.5% in Europe to more than 10.0% in some sub-Saharan countries, and mother-to-child HCV transmission risk ranges from 3.0% to 10.0%. Vertical transmission of HCV is considered the primary route of HCV infection in children.[3,4] The presence of maternal HCV RNA at the time of delivery and maternal co-infection with HCV and human immunodeficiency virus (HIV) are the most important factors for the increased risk of perinatal HCV transmission.[4]

So far, the research on HCV infection in Poland has mostly focused on the prevalence of HCV infection in specific risk groups, possible diagnostic methods, or descriptions of clinical cases. However, available data may not accurately reflect the actual prevalence of HCV infection due to different methods of data collection. Therefore, our study is based upon a wide range of patient data obtained from medical records of countrywide outpatient clinics. It is important to point out that in 2012, the Polish Government introduced the obligatory anti-HCV test for all pregnant women in Poland in order to reduce the risk of vertical infection to their children.

2. Objective

The objective of the study is to estimate the anti-HCV seroprevalence in pregnant women in Poland and formulate recommendations on the rationale of such a screening accordingly.
3. Patient and methods

Data were obtained in February 2015 from electronic medical records of a large countrywide outpatient managed care clinic’s network operating mainly in large cities. De-identified, aggregate data used for this study were publicly accessible and therefore ethical approval was not required. The data contained medical information of patients who had been tested for anti-HCV at least once. Only the test latest result was included in the study pool, which finally comprised 42,274 women in the period of 2004 to 2014 (Table 1, Fig. 1). The studied group included a population representative of the working age, 15 to 64 years. The working age population was defined according to the WHO definition. The average age of the women was 33.4 years with a standard deviation of 7.9 (Table 2). The results of the pregnant women were compared to the corresponding age groups of nonpregnant women and with all women in the study sample. Data were analyzed using the data analysis software system STATISTICA version 12 (StatSoft, Inc., Warsaw, Poland; www.statsoft.com) to calculate prevalence estimates. The independent-sample t test was used for normally distributed variables, and the nonparametric Mann–Whitney U test was used for not normally distributed parameters. Significance level was set at $P < 0.05$. Using linear regression analysis, the trend of the number of positive women as a function of time (years) was calculated and the $R^2$ value evaluated the goodness of fit of the regression (Fig. 1, Tables 1 and 2).

4. Results

Table 3 shows the numbers and percentages of positive women per age group. In the group of tested women, the percentage of those with positive anti-HCV test results was similar across age groups; it was the lowest among women ages 25 to 34 (0.73%) and 35 to 44 (0.84%), which was similar to that of the youngest group, 15 to 24 years (0.86%). An analysis of the data of pregnant women for the years 2011 to 2014 shows a downward trend of the proportion of positive anti-HCV results (linear trend for number of positive anti-HCV pregnant females $= -0.001 \times \text{year} + 1.9451; R^2 = 0.7274; P < 0.001$; Fig. 1). With the systematic growth in the number of tested women in the years 2004 to 2015, a decrease in the percentage of positive anti-HCV test results was observed. The prevalence of potential HCV infection was almost 2 times lower in pregnant women (0.76%) than in the other cases, which were patient requests or doctor referrals (1.67%; $P < 0.0001$). For the pregnant women of all 3 age groups (15–24, 25–34, and 35–44 years) the percentage of positive test results was 0.86% or lower, which is still far less than the lowest value of 1.39% for the group of 25- to 34-year-old nonpregnant women ($P < 0.0001$).

5. Discussion

WHO data show that the prevalence of HCV infection in European countries is estimated at 2.4% for Central Europe, 2.9% for Eastern Europe, and 2.4% for Western Europe. Over half of the cases of HCV infection in Europe occur in the age

Table 1

| Gender                  | Age, y   | n (%)       |
|-------------------------|----------|-------------|
| Total females           | 33.4 ± 7.9 | 42,274 (100) |
| Positive pregnant females | 30.6 ± 3.9 | 122 (21.9)   |
| Positive nonpregnant females | 37.5 ± 10.4 | 436 (78.1)   |
| Positive females         | 36.0 ± 9.8 | 558 (1.32 ∗) |

Values of age (y) expressed as mean ± standard deviation. Anti-HCV = antibodies to hepatitis C virus. ∗% Number of positive females/total number of females.
Table 3

Results of anti-HCV tests for the different age groups in the study population.

| Anti-HCV result | Pregnant females | Nonpregnant females | P |
|-----------------|------------------|---------------------|---|
| Females         | Total Positive % | Positive Total %   |   |
| Total           | 38,309 1.17%     | 16,120 0.76%       |   |
| 15-24           | 2234 1.48%      | 579 0.86%          |   |
| 25-34           | 26,631 1.07%    | 12,926 0.73%       |   |
| 35-44           | 9444 1.40%      | 2615 0.84%         |   |

| Anti-HCV result | Pregnant females | Nonpregnant females | P |
|-----------------|------------------|---------------------|---|
| Females         | Total Positive % | Positive Total %   |   |
| Total           | 22,189 1.48%     | 1655 1.69%         |   |
| 15-24           | 328 1.48%       | 28          |   |
| 25-34           | 13,705 1.39%    | 190         |   |
| 35-44           | 6829 1.61%      | 110         |   |

Anti-HCV = antibodies to hepatitis C virus.

6. Conclusion

According to our research, we recommend that screening for HCV should be done mainly in individuals over 45 years old. Examining healthy and young people should not be carried out as a regular screening test. However, such tests may be recommended for individuals who have been exposed to risk factors, as established through a thorough interview by a physician. Obligatory screening in pregnancy according to the results on a large group of women in Poland has proven less effective that screening in other clinical circumstances based on individual medical history and behavioral risk factors. Thus, as a recommendation, healthcare providers and payers should consider developing internal guidelines and standards for anti-HCV screening with definitions of suspected cases, instead of relying on such general characteristic like pregnancy.

The results of evaluating anti-HCV prevalence in the real-world daily patient flow may be helpful for public health authorities and policy makers. These results may be used in estimating the potential costs of treatment for HCV infection, as well as treating complications resulting from the infection.

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