

## PRACE ORYGINALNE • ORIGINAL PAPERS

## Prevalence of anti-HCV antibodies in adult patient population of primary care clinic in Warsaw

### Ocena częstości występowania przeciwciał wirusowego zapalenia wątroby typu C w populacji dorosłych pacjentów lekarzy rodzinnych w Warszawie

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**A** – Study Design, **B** – Data Collection, **C** – Statistical Analysis, **D** – Data Interpretation, **E** – Manuscript Preparation, **F** – Literature Search, **G** – Funds Collection

**Summary Background.** Hepatitis C carries a huge disease burden worldwide. HCV (hepatitis C virus) is a blood-borne virus and its major risk factors are: illicit drugs use, hemodialysis, HCV-infected sexual partner, medical procedures, body piercing and tattoos. The majority of hepatitis C cases have asymptomatic course for a long time.

**Objectives.** To evaluate prevalence of hepatitis C virus antibodies among adult patients of primary care facilities in Warsaw and to determine the risk factors for anti-HCV antibody presence.

**Material and methods.** The study population ( $N = 1114$ ) consisted of adult patients of clinic from Warsaw. Between November 2009 and January 2010 we offered anti-HCV antibody testing to all adult patients who were referred to blood tests for other reasons. Patients were asked to fill out a 16-points questionnaire. All blood samples were tested in one laboratory using ECLIA test. Each positive anti-HCV antibody test result was confirmed with viral RNA testing. Multivariate logistic regression model was used to investigate the association between independent co-variables and the presence of anti-HCV antibody. Stepwise selection procedure was applied with 10% inclusion level for staying in the model. All tests were two-sided and 5% significance level was used.

**Results.** 1114 adults (727 women and 387 men) were included in the study, with a mean age of 50.65 years (18 to 88 years). 25 patients were positive for anti-HCV antibodies (2.24%; 95% CI, 1.37–3.11%), of whom 9 were positive for HCV RNA. Patients who underwent surgical procedures had a threefold increase in anti-HCV seropositivity risk (OR 3.03; 95% CI, 1.0–9.07;  $p = 0.048$ ).

**Conclusions.** The only statistically significant risk factor that correlated with anti-HCV seropositivity was history of major surgery. Family doctors should have provisions within national healthcare provider system to perform anti-HCV antibody tests in patients with history of surgical procedure.

**Key words:** anti-HCV antibodies, primary health care, risk factor.

**Streszczenie Wstęp.** Zapalenie wątroby typu C stanowi ogromny problem na świecie. Wirus HCV rozprzestrzenia się drogą krwiopochodną, stąd najważniejszymi czynnikami ryzyka są: używanie narkotyków, przetoczenia krwi, seks z osobą zakażoną, procedury medyczne oraz okaleczanie się w związku z noszeniem kolczyków lub tatuaży. Większość przypadków zakażenia przez długi czas ma przebieg bezobjawowy.

**Cel pracy.** Ocena częstości występowania przeciwciał anti-HCV wśród dorosłej populacji pacjentów lekarzy rodzinnych w Warszawie oraz oszacowanie czynników ryzyka zakażenia HCV.

**Materiał i metody.** Badanie przeprowadzono wśród dorosłych pacjentów poradni lekarzy rodzinnych z Warszawy. Zbadana grupa liczyła 1114 pacjentów, którzy w okresie od listopada 2009 do stycznia 2010 r. wyrazili zgodę na dodatkowe oznaczenie w trakcie realizowania zleconych testów laboratoryjnych. Pacjenci wypełnili 16-punktowy kwestionariusz. Wszystkie próbki krwi były badane w jednym laboratorium przy zastosowaniu testu ECLIA. W przypadku dodatniego wyniku na obecność przeciwciał anti-HCV oznaczano RNA wirusa. Czynniki ryzyka zakażenia wirusem HCV określono za pomocą wieloczynnikowego modelu regresji logitowej.

**Wyniki.** W badaniu wzięło udział 1114 pacjentów (727 kobiet i 387 mężczyzn). Średnia wieku grupy badanej wyniosła 50,65 lat (18 do 88 lat). Obecność przeciwciał anti-HCV wykazano u 25 osób, co stanowi 2,24% grupy badanej (95% CI, 1,37–3,11%), RNA wirusa stwierdzono u 9 osób. Pacjenci poddani zabiegowi operacyjnemu mieli 3-krotnie większe ryzyko obecności przeciwciał anti-HCV w porównaniu z pacjentami nieoperowanymi (OR 3,03; 95% CI, 1,0–9,07;  $p = 0,048$ ).

**Wnioski.** Jedynym istotnym statystycznie czynnikiem ryzyka obecności przeciwciał anti-HCV okazało się poddanie zabiegowi operacyjnemu. Lekarze rodzinni powinni mieć możliwość badania obecności przeciwciał anti-HCV u pacjentów, którzy byli operowani.

**Słowa kluczowe:** przeciwciała anti-HCV, podstawowa opieka zdrowotna, czynnik ryzyka.

## Background

Hepatitis C imposes a significant disease burden worldwide. According to WHO, 7.3 million of EU citizens are infected with HCV [1]. Morbidity rate in Poland is estimated at 7–8/100 000 per year, with greater prevalence of genotype 1b infection, which is known to be more drug-resistant [2, 3]. HCV is a bloodborne virus and its major risk factors are: illicit drugs use, hemodialysis, HCV-infected sexual partner, medical procedures, body piercing and tattoos [4].

The majority of hepatitis C cases present an asymptomatic course for a long time. In 15 to 50% of infected patients the elimination of virus is observed, mainly in case of a symptomatic acute hepatitis C. The remainder of patients develops a chronic hepatitis C which progresses to a liver cirrhosis in 5–20% of cases within 20–25 years [2]. Despite the majority of cases spreads via parenteral route, in approximately 10% of cases no risk factors are identified [3].

There are no known preventive measures, such as vaccines or immunoglobulins. Therefore, it is vital to follow and promote practices of bloodborne infections control and to raise hepatitis C awareness.

Under current regulations anti-HCV antibody testing is not financed by Polish National Health Fund in primary healthcare facilities, it is available only in infectious diseases clinics. Patients are referred to HCV testing only after clinical symptoms of hepatitis (i.e. elevated serum transaminases) have occurred. Thus, there is no way to screen asymptomatic patients within public healthcare system.

## Objectives

1. To assess the anti-HCV antibody prevalence in adult patients population of family medicine clinics in Warsaw.
2. To determine HCV infection risk factors.

## Material and methods

Every adult patient of the Postgraduate Training Centre for Family Medicine in Warsaw, who was referred to blood tests for any reason and gave consent to participate was eligible for the study. All participants completed a questionnaire on demographical data and risk factors concerning HCV infection (Table 1). Patients who had documented prior HCV seropositivity were not included.

All blood samples were tested in a single laboratory. In case of the positive chemiluminescence immunoassay (ECLIA) result, the same sample was tested for HCV RNA presence. The cohort was

**Table 1. HCV infection risk factors**

Ordinal number	Risk factor
1.	Co-habitation with HCV-positive individual
2.	Minor medical procedures
3.	Healthcare professional
4.	Tattoo/body-piercing
5.	Blood product transfusion prior to 1992
6.	Injections
7.	Illicit drug use
8.	Endoscopic studies
9.	Acupuncture
10.	Major surgery
11.	Correctional facility

planned for a minimum of 1000 patients. Using the multivariable logit regression risk factors associated with anti-HCV seropositivity were determined.

## Results

The total number of patients tested in this study was 1114, with 65.2% of women [ $N = 727$ ] and 34.7% [ $N = 387$ ] of men (Table 2). The median age of the group was 50.6 [SD 16.7] years. Anti-HCV antibodies were detected in 25 people – 2.24% of the cohort [CI 95%, 1.37–3.11%] (Table 3). HCV RNA was present in 36% of HCV – seropositive patients ( $N = 9$ ), what made up 0.8% of all tested patients.

**Table 2. Study cohort – gender**

Gender	No of participants	Percentage of participants (%)
Male	387	34.77
Female	727	65.23
Total	1114	100.00

**Table 3. Anti-HCV antibody presence**

Anti-HCV antibody	No. of individuals	%
Negative	1089	97.76
Positive	25	2.24
Total	1114	100.00

Multivariate analysis of correlation of risk factors listed in Table 3 with anti-HCV antibody presence was performed for 939 cases. Patients on hemodialysis and former prisoners (19 cases) were excluded from the study since there were no anti-HCV antibody positive test results noted in any of two groups; patients with incomplete data (156) were excluded as well.

Those 175 patients were concluded to have immeasurable incident risk. Using stepwise logistic regression method, variants associated with statistical significance of 5% with anti-HCV antibody detection were determined. The only risk factor showing a statistically significant relation to anti-HCV antibody positivity was a history of major surgery. Patients who underwent a major surgery had a three-fold increase in risk of being HCV seropositive than patients who had no history of surgical procedures (OR 3.03; 95% CI, 1.0–9.07;  $p = 0.048$ ).

## Discussion

Hepatitis C imposes an important disease burden worldwide as well as in Poland [5–8]. Infection is often asymptomatic, there is neither a screening program nor any HCV transmission surveillance, all of which result in progression to chronic disease and liver cirrhosis. Early detection is associated with possibility of sustained serum virus clearance in half of the patients [9]. In our study we assessed HCV status in adults whose blood samples were obtained for any medical reason and who gave consent to an additional HCV testing.

Amongst 1114 ( $N = 1114$ ) patients in our study, 25 were positive for HCV antibodies (2.24%). RNA test confirmed HCV-positive status in 9 patients – 36% of anti-HCV positive and 0.8% of all patients. Official estimates of world prevalence suggest that 3.1% of the population is chronically infected with HCV, amounting to around 170 million cases [10]. Polish national surveillance data accounts only for symptomatic cases of hepatitis C: there were 2353 new cases identified in 2008 what translates to morbidity rate of 6.17/100 000 per year [11]. In spite of the reduction of morbidity rate by 48% in comparison to 2007, the scale of virus spread is probably underestimated due to lack of routine screening program and underprovision of infectious diseases

clinics, where HCV testing is provided. The majority of hepatitis C diagnoses are made accidentally, resulting from mostly an asymptomatic course of HCV infections and prompting clinicians to determine the risk factors and the target prevention groups. In our project patients filled out the 16-points self-administrated questionnaire on demographic data and blood borne pathogens exposure risk factors. When multivariate analysis was applied, undergoing a surgery was the only statistically significant risk factor. The triple-fold risk increase was noted in comparison to patients with no history of any surgery. In other similarly designed studies a prior surgical procedure is a major risk factor for HCV infection [8, 12] or ranks third following blood transfusions or illicit drug use [7, 13, 14]. Blood donors in Poland are routinely screened for HCV since 1992, thus significance of this risk factor is declining, which is in line with our study results. According to data on illicit drugs use in Europe, its prevalence at a level of 0.3% in Poland is relatively low in comparison to some other European states – i.e. Spain 5.5%, United Kingdom 4.5%, Denmark 3.4%, Ireland and Italy 3.1% [15]. The standard of medical care in Poland is lower than in the above-mentioned countries, thus it comes as no surprise that in our country the major risk factor for HCV infection is a prior surgery.

It seems vital for the public health to implement HCV infection screening – particularly, of asymptomatic individuals, in order to enable early treatment and avoid virus transmission among unaware carriers [16].

In Poland HCV screening should target patients with history of major surgeries. In that group an anti-HCV antibody testing provided by family physicians seems to be justified, cost-effective and simple solution, also from the National Health Fund's point of view.

## Conclusions

Family physicians should be able to perform routinely the anti-HCV screening in patients who underwent a surgery since an early diagnosis allows higher treatment efficacy and closer monitoring of asymptomatic individuals. Currently, the anti-HCV antibody testing is not reimbursed in primary healthcare settings by the National Health Fund.

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