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INFORMATIVENESS OF BIOCHEMICAL INDICATORS IN THE DIAGNOSIS OF VIRAL HEPATITIS B AND C IN PREGNANT WOMEN

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The choice of the correct treatment tactics for HBV, HCV-infections is based on biochemical and immunological indicators. In this regard, the development of programs on a mathematical basis can be considered a rational and correct approach to solving the diagnostic problem. The aim of the research was to assess the informativeness of additional laboratory indicators in the diagnosis of viral hepatitis B and C in pregnant women. The investigation included 150 pregnant women: the main group – 100 pregnant women with hepatitis B and C, the control group – 50 practically healthy pregnant women. Were carried out serological studies, polymerase chain reaction, biochemical, immunological blood tests. The results of the study showed that, among the studied indicators, apolipoprotein A1 and IgG have the highest sensitivity and overall diagnostic value, IgG, IgM and microglobulin-b2 have the highest specificity, and the indicators of microglobulin-b2, IgG and IgM. Apolipoprotein A1 and IgG have the highest negative efficacy scores. The ratio of the accuracy of positive and negative results allows the use of indicators of total cholesterol, apolipoprotein A1, low-density lipoproteins, microglobulin-b2, iron, C-reactive protein, IgG, IgM as auxiliary diagnostic biomarkers of infection of pregnant women with hepatitis B and C.

Key words: pregnancy, HBV, HCV-infections, lipid metabolism indices, immunological biomarkers.

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ІНФОРМАТИВНІСТЬ БІОХІМІЧНИХ ПОКАЗНИКІВ У ДІАГНОСТИЦІ ВІРУСНИХ ГЕПАТИТІВ В ТА С У ВАГІТНИХ

Вибір правильної лікувальної тактики при HBV, HCV-інфекціях ґрунтується на біохімічних та імунологічних показниках. У зв'язку з цим розробку програм на математичній основі можна вважати раціональним та правильним підходом до вирішення діагностичного завдання. Мета дослідження – оцінити інформативність додаткових лабораторних показників у діагностиці вірусних гепатитів В та С у вагітних. До дослідження включено 150 вагітних: основна група – 100 вагітних із гепатитом В і С, контрольна група – 50 практично здорових вагітних. Було проведено серологічні дослідження, полімеразну ланцюгову реакцію, біохімічні, імунологічні аналізи крові. Результати дослідження показали, що серед досліджуваних показників найбільшу чутливість і загальну діагностичну цінність мають аполіпопротеїн А1 та ІgG, найбільшу специфічність мають ІgG, ІgM та мікроглобулін-в2, а також показники мікроглобулін – в2, ІgG та ІgM. Аполіпопротеїн А1 та ІgG мають найвищі негативні значення ефективності. Співвідношення точності позитивних та негативних результатів дозволяє використовувати показники загального холестерину, аполіпопротеїну А1, ліпопротеїдів низької щільності, мікроглобуліну-в2, заліза, С-реактивного білка, ІgG, ІgM як допоміжні діагностичні біомаркери інфекції вагітних при гепатитах.

Ключові слова: вагітність, ВГВ, ВГС-інфекції, показники ліпідного обміну, імунологічні біомаркери.

Hepatotropic infections, such as hepatitis B and C in pregnant women, often appear unapparent and do not appear as an increase in the activity of bilirubin and liver enzymes in the blood. Accordingly, it is impossible to assess the pathogenesis of these infections without using other serological methods.

Despite the fact, that hepatitis B and C during pregnancy are often asymptomatic, they can lead to the development of fibrosis in the liver. As the disease progresses, the elasticity of liver tissue decreases.

According to EASL (European Association for the Study of the Liver) guidelines (2017), screening for HBsAg in the first trimester of pregnancy is strictly recommended for all pregnant women [3].

With regard to the influence of pregnancy on HCV infection, it should be noted that most women with chronic hepatitis C virus do not show signs and symptoms of the disease during pregnancy, and in some cases, there is a normalization of serum ALT and AST levels.

During pregnancy, the level of aminotransferases in the mother's blood tends to decrease. This reflects a lower immunoreactive state of pregnancy. These changes are due to the action of immunosuppressive cytokines synthesized during pregnancy. There may be a slight increase in HCV RNA, especially in the second and third trimesters of pregnancy. The level of fibrosis is minimal in most pregnancies, but severe fibrosis can also be observed [7].

The American Association of Liver Diseases (AASLD, 2018) states that during HBV infection, antiviral therapy may reduce perinatal transmission of hepatitis B virus in women with positive HBsAg and DNA ≥ 2000 IU/ml [10].

It is known that accurate diagnosis of inflammatory or morphological changes (including fibrosis) of the liver is possible with liver biopsy, which is the "gold standard". However, the invasiveness of the method does not make it possible to use it during pregnancy. On the other hand, few scientific studies have been conducted outside of pregnancy.

Considering that we have not met scientific studies on biostatistical aspects, to study the sensitivity, specificity of the main and auxiliary indicators in the diagnosis of infection of pregnant women with viral hepatitis B and C, we set ourselves the task of studying these issues.

The purpose of the study was to assess the informativeness of clinical and laboratory parameters in the diagnosis of viral hepatitis B and C in pregnant women.

Materials and methods. The study material consisted of 150 pregnant women. The main group consisted of 100 pregnant women with viral hepatitis B and C, the control group consisted of 50 – practically healthy pregnant women.

The study was carried out in 2016–2018 at the clinical base of the Department of Obstetrics and Gynecology-2 AMU (Educational-Surgical Clinic).

At the beginning of the study, voluntary written consent was obtained from the patients. The compliance of the research with the requirements of biomedical ethics was discussed and approved by the Ethics Committee of the Azerbaijan Medical University (AMU, Ethics Committee, November 29, 2019, Protocol No. 10).

The inclusion criteria for the study were as follows: Pregnant women; 18–45 years old; HBV infection; HCV- infection.

The following were excluded from the study: Non-pregnant; Pregnant women with other intrauterine, genital, extragenital infections; Pregnant women under 18; 23 Pregnant women over 45 years old.

All pregnant women in the study groups were Azerbaijanians. The mean age in the HBV group was 28.3 ± 0.6 years (min – 19 years; max – 38 years); In the HCV group – 29.4 ± 0.8 years (min. – 19 years old; max – 42 years old). The mean age of pregnant women in the control group was 26.7 ± 0.6 years (min. – 21 years; max – 41 years).

Serological markers of viral hepatitis B and C in the blood were studied by electrochemiluminescence with a biochemical analyzer ECLIA Cobas 4000 e 411 (Roshe-Hitachi). Polymerase chain reaction (Real-Time PZR Detection Systems) "Bio-Rad"; CFX96, USA) was used in the virological diagnosis of HBV and HCV infections [2].

In the studied pregnant women, the level of biochemical parameters was determined: microglobulin-2, iron, ferritin, total cholesterol (TC), triglycerides (TG) in the blood, apolipoprotein A1 (ApoA1), low-density lipoproteins (LDL) and immunological parameters – C3, C4, CRP, IgA, IgM, IgG in the blood, a fully automated biochemical analyzer was used (Cobas 4000 c 311; Roshe-Hitachi).

The statistical calculations used the methods of variational (U-Mann-Whitney), variance (F-Fisher) and ROC analyzes. Statistical calculations were performed using the MS EXCEL 2019 [8] and IBM Statistics SPSS-26 [6] programs.

Results of the study and their discussion. Methods of biostatic analysis in binary classification were used as algorithms for solving diagnostic problems. First of all, analysis of variance was carried out for all quantitative indices in different groups. The statistical significance of the differences was additionally checked by the Mann-Whitney nonparametric U-rank test. Then a ROC analysis of all quantitative indices was carried out, with the definition of the "cut of point" studied and differentiated by groups. Then, using evidence-based medical methods the parameters were studied: the specificity (Sp), the sensitivity (Sn), the total diagnostic value (UDD) of clinical and laboratory data, the efficacy of evaluating a positive result

(pPV), the efficacy of evaluating a negative result (npV), the positive result (LR+) accuracy ratio, the negative result accuracy ratio (LR-), and the possibilities of practical application.

Statistical analyzes revealed a significant increase in microglobulin- ν 2 in the serum of infected pregnant women ($p < 0.001$).

The results of the study show that the concentration of TC and LDL in pregnant women infected with HBV and HCV statistically significantly increased by 51 % ($p < 0.001$) and 47 % ($p < 0.001$), respectively, compared to the control group. The mean was 5.71 ± 0.18 mmol/L (range: 1.88–9.90 mmol/L) and 3.52 ± 0.18 mmol/L (range: 0.30–8.80 mmol/L compared with the control group). In pregnant women infected with HBV and HCV, the concentration of apolipoprotein A1 decreased by 2 times ($p < 0.001$) compared to the control group and amounted to 1.62 ± 0.07 g/L (range: 0.01–3.65 g/L). TG (2.78 ± 0.12 mmol/L; $p = 0.280$), iron (32.2 ± 6.0 mmol/L; $p = 0.278$) and ferritin (78.1 ± 13.2 mg/L; $p = 0.104$) did not change statistically significantly compared with the control group according to F-Fisher, but according to the results of the analysis of variance, the “0” hypothesis can be rejected ($pU = 0.017$).

The results of the study show that the concentration of CRP and IgG in pregnant women infected with HBV and HCV increased by 7.7 times ($p < 0.001$) and by 8 times ($p < 0.001$), respectively, compared to the control group. The mean was 33.0 ± 4.2 ng/ml (range: 0.08–221.86 ng/ml) and 10.5 ± 1.1 ng/ml (range: 3.9–112.0 ng/ml). The concentration of IgM in pregnant women infected with HBV and HCV decreased by 4.7 times ($p < 0.001$) compared to the control group and amounted to 1.53 ± 0.08 g/l (range: 0–4 g/l). Concentration of C3 (2.00 ± 0.16 g/L; $p = 0.788$), C4 (0.52 ± 0.07 g/L; $p = 0.884$) and IgA (1.85 ± 0.08 g/L; $p = 0.808$) was not statistically significant in comparison with the control group based on analysis of variance. However, based on the nonparametric analysis of Mann-Whitney a completely different result was obtained ($pu = 0.057$ for C3; $pu = 0.003$ for C4; $pu = 0.079$ for IgA), at the next stages these indices were analyzed in detail.

Thus, the indices of total TC, LDL, CRP, ν 2-microglobulin, IgG concentration in pregnant women infected with HBV and HCV are statistically significantly higher than in the control group, which included not infected women, and the concentration of albumin, apolipoprotein A1 and IgM, on the contrary, decreased. These indices can be considered informatively significant.

The study investigated the predictive informativeness of the level of the studied biochemical and immunological markers in pregnant women with HBV and HCV infection. By us were studied, the levels of the “cut of point”, specificity and sensitivity of the biochemical and immunological markers. For this purpose, the clinical and laboratory parameters of the patients included in the study groups were processed using the ROC analysis.

The results of ROC analysis for TC, TG, Apo A1 and LDL are shown in fig. 1.

ROC indices showed that lipid spectrum indices are highly specific and sensitive in assessing the clinical state of pregnant women with hepatitis. The area of the ROC curve of TC is 0.821 ± 0.034 ($p < 0.001$). In the range of 95 % CI, the reference values of this index were in the range from 0.755 to 0.887. According to ROC analysis, TG, apolipoprotein A1 and LDL had high specificity and information content of the lipid spectrum in pregnant women with hepatitis. The ROC area calculated on the basis of TG is 0.381 ± 0.045 ($p = 0.017$), the upper limit was 0.469, and the lower limit was 0.292 at 95 % CI. The ROC area of apolipoprotein A1 is 0.090 ± 0.026 ($p < 0.001$), and the reference values in the 95 % confidence interval were in the range from 0.039 to 0.141. The ROC area of LDL was 0.755 ± 0.039 (95 % CI: – 0.679–0.831), with $p < 0.001$).

Exceeding the TC cut off point of 4.5 mmol/L was of diagnostic value. The sensitivity of the index was 75.0 ± 4.3 %, the specificity of the index was 92.0 ± 3.8 %, the overall diagnostic significance is 80.7 ± 3.2 %; assessment of the positive result efficacy was 94.9 ± 2.5 ; negative efficacy score (npV) was 64.8 ± 5.7 due.

It was found that, the cut-off point for the TG value equaled to 2.8 mmol/L. The sensitivity and specificity of this index was 62.0 ± 4.9 % and 72.0 ± 6.3 %, respectively, the overall diagnostic significance is 65.3 ± 3.9 %, the assessment of the positive and negative results efficacy was 81.6 ± 4 , respectively, 4 % and 48.6 ± 5.8 %, respectively, which did not allow using this criterion in the diagnosis of hepatitis in pregnant women.

The content of apolipoprotein A1 less than 2.8 g/l has a practical diagnostic value, the sensitivity of the index is 97.0 ± 1.7 %, the specificity is 72.0 ± 6.3 %, the overall diagnostic value is 88.7 ± 2.6 %; 87.4 ± 3.2 assessment of the positive result efficacy (pPV) the assessment of the negative result efficacy (npV) was 92.3 ± 4.3 .

The cut-off point in the ROC analysis of the LDL index was higher than 2.7 mmol/L. The sensitivity and specificity of this index was 70.0 ± 4.6 % and 82.0 ± 5.4 %, respectively, the overall diagnostic

significance was $74.0 \pm 3.6\%$, the assessment of the positive and negative results efficacy was $88.6 \pm 3.6\%$ respectively and $57.7 \pm 5.9\%$, respectively. Iron less than 15.4 mmol/L had a diagnostic value, the sensitivity of the index was $57.0 \pm 5.0\%$, the specificity of the index was $92.0 \pm 3.8\%$, the overall diagnostic value was $68.7 \pm 3.8\%$; the score for evaluating the effect for evaluating the efficacy of a positive result was 93.4 ± 3.2 ; evaluation of the efficacy of a negative result was 51.7 ± 5.3 .

The cut-off point in the ROC analysis of the ferritin index was less than 17.5 mg/L . The sensitivity and specificity of this index was $35.0 \pm 4.8\%$ and $96.0 \pm 2.8\%$, respectively, the overall diagnostic significance was $55.3 \pm 4.1\%$, the assessment of the positive and negative results efficacy was 94.6 ± 3 , respectively, 7 and 42.5 ± 4.7 .

ROC analysis showed that the immunological parameters of CRP, IgG and IgM are indices of high performance and sensitivity in assessing the immune status of pregnant women infected with hepatitis B and C (fig. 2).

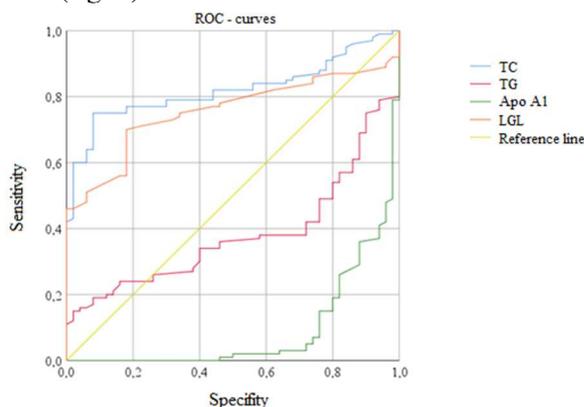


Fig. 1. ROC analysis for TC, TG, Apo A1 and LDL.

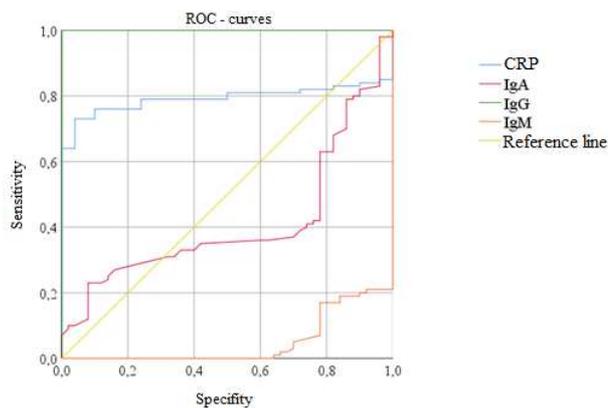


Fig. 2. ROC analysis for CRP, IgA, IgG, IgG and IgM

The range of sensitivity and specificity of CRP values is 0.792 ± 0.038 ($p < 0.001$). With a 95% confidence interval was from 0.717 to 0.867. ROC analysis of IgG, as expected, gave an ideal result of 1.000 ± 0.000 . The area of the ROC curve for IgM was 0.048 ± 0.015 ($p = 0.015$), and the 95% confidence interval values were from 0.019 to 0.078. According to the ROC, IgA was assessed as a test with low specificity and sensitivity in assessing the immunological status of pregnant women with hepatitis. The ROC area of IgA was 0.442 ± 0.048 (95% CI – 0.318–0.505) and statistical significance was calculated at $p = 0.079$.

It was found that in the majority of pregnant women with hepatitis, the amount of CRP exceeds 7 g/l , while in the vast majority of pregnant women without hepatitis, this index was below the cut-off point. The sensitivity and specificity of this index was $73.0 \pm 4.4\%$ and $96.0 \pm 2.8\%$, respectively, the overall diagnostic significance was $80.7 \pm 3.2\%$, assessment of the positive and negative results efficacy was 97.3 ± 1.9 respectively and 64.0 ± 5.5 , respectively. The use of the criterion for the content of the amount in the blood of less than 1.8 g/l of component C_3 for the diagnosis of hepatitis in pregnant women was tested. The sensitivity of this index was $61.0 \pm 4.9\%$, the informativeness content is $76.0 \pm 6.0\%$, and the overall diagnostic significance was $66.0 \pm 3.9\%$. Were determined evaluations of the positive and negative results efficacy, respectively, 83.6 ± 4.3 and 49.4 ± 5.7 , which denies the possibility of practical application of this indicator. Component C_4 less than 0.32 g/l had a diagnostic value – the sensitivity of the index was $61.0 \pm 4.9\%$, the specificity of the index was $72.0 \pm 6.3\%$, the overall diagnostic value was $64.7 \pm 3.9\%$; 81.3 ± 4.5 – an assessment of the positive result efficacy (pPV) 48.0 ± 5.8 – an assessment of the negative result (nPV), efficacy which denied the possibility of a practical application of diagnostics of the C_4 indicator. The cut-off point for IgA ($n = 100$) was less than 1.78 g/L . The sensitivity and specificity of this index were $58.0 \pm 4.9\%$ and $78.0 \pm 5.9\%$, respectively, the overall diagnostic significance was $64.7 \pm 3.9\%$, the assessment of the positive and negative results efficacy was 84.1 ± 4 , respectively, 4 and 48.1 ± 5.6 . As expected, the ROC analysis of the index gave a 100% result in the binary classification. At the cut-off point (3 g/L), the sensitivity and specificity of this index was equal to 100.0%.

Statistical analyzes showed that the cut-off point of the IgM index was determined at the level of 2 g/l . This index can be used to diagnose hepatitis B and C infection in pregnant women. The sensitivity of this index is $79.0 \pm 4.1\%$, the specificity is $100.0 \pm 0.0\%$, the overall diagnostic significance is $86.0 \pm 2.8\%$, the assessment of the positive and negative results efficacy is 100.0 and 70.4 ± 5.4 , respectively.

The results of the ROC analysis for microglobulin-B2 are shown in fig. 3.

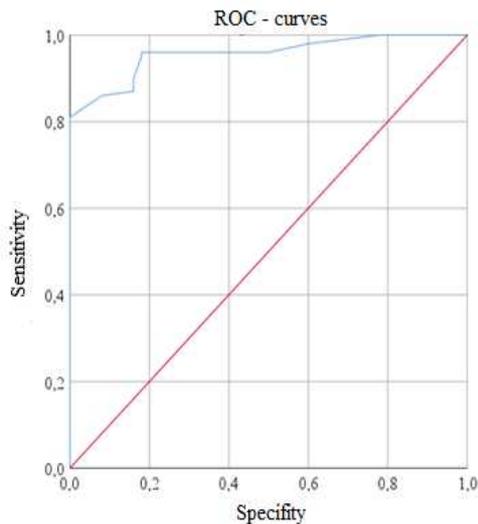


Fig. 3. ROC analysis for microglobulin-2.

accuracy of positive and negative results allows the use of indices of albumin, TH, apolipoprotein A1, LDL, microglobulin-B2, iron, CRP, IgG, IgM and fibrosis as diagnostic criteria for infection in pregnant women with hepatitis B and C.

At the previous stages of our study, we identified the main laboratory parameters that can be taken as additional diagnostic biomarkers of infection of pregnant women with hepatitis B and C [9].

The results of our statistical analysis confirmed the high specificity of immunological parameters – IgG and CRP in the diagnosis of HBV, HCV infections in pregnant women. According to Semenov AV (2017) in chronic viral hepatitis, immunological markers reflect the intensity of inflammatory processes in the liver and permit predicting liver fibrosis. As a result, together with molecular biological markers, they can predict the course of the disease [1].

It is known that, during normal pregnancy, due to increased production of estrogens from the placenta, the level of low density lipids (LDL) in the blood decreases [4]. Our scientific work revealed that the level of TC, TG, low-density lipids increased and the level of high-density lipids (Apo A1) decreased in the blood of infected pregnant women with hepatitis B, C.

Statistical analyzes of our study proved the high specificity and sensitivity of the β 2-microglobulin index in the diagnosis of infection in these pregnant women. In the literature, we have not found data on studies during pregnancy in this aspect.

We believe that clinicians in their practice can choose those non-invasive tests for diagnosing hepatitis B, C infection in pregnant women that are available in this clinic. In conditions of limited resources, it is preferable to use biochemical or immunological tests (separately or in combination).

It should be noted that, in the WHO guidelines, attention is paid to the characteristics of diagnostic tests for hepatitis B (positive predictive value (PPV), negative predictive value (NPV), specificity of the test, true negative results, true positive results). Since, on the basis of false positive results, it is possible to prescribe an optional or premature treatment to the patient. This can cause inconvenience to patients due to the duration of treatment, accompanied by the possibility of developing drug resistance, as well as toxic effects of drugs. Conversely, a false negative result means that a person with cirrhosis will not be identified by non-invasive tests (NIT) and, therefore, will not receive urgent antiviral treatment, which can prevent the transition of the disease to the stage of decompensation or reduce the risk of developing hepatocellular carcinoma (HCC) [5].

Conclusion

Total cholesterol, Apo A1, serum albumin, LDL, β 2-microglobulin, CRP, iron, IgG and IgM can be used as additional diagnostic biomarkers in the diagnosis of HBV, HCV infections in pregnant women due to their high specificity and sensitivity.

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INDICATORS OF THE LEVEL OF SUBJECTIVE CONTROL IN MALE PATIENTS WITH MILD OR SEVERE PSORIASIS WITHOUT TAKING INTO ACCOUNT SOMATOTYPE AND WITH TAKING INTO ACCOUNT SOMATOTYPE

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In men with mild or severe psoriasis, compared with healthy subjects without division into somatotypes, the level of subjective control showed a significant decrease in the value of interpersonal relationships and the ability to influence their own health. Significantly lower levels of general internality in patients with severe psoriasis were found in the distribution by body type in men of mesomorphic somatotype as well as the indicator of the level of subjective control in the field of failures, educational and interpersonal relationships in patients with mild and severe disease compared with the control group of a similar somatotype.

Keywords: psoriasis, severity, men, level of subjective control, body type.

О.А. Серебреннікова, О.Б.А-Р. Аль-Каралех, І.В. Дзевульська, Т.Г. Кривоніс, І.В. Пролигіна ОСОБЛИВОСТІ ПОКАЗНИКІВ РІВНЯ СУБ'ЄКТИВНОГО КОНТРОЛЮ У ХВОРИХ НА ПСОРИАЗ ЛЕГКОГО АБО ТЯЖКОГО ПЕРЕБІГУ ЧОЛОВІКІВ БЕЗ ТА З УРАХУВАННЯМ СОМАТОТИПУ

У хворих на псоріаз чоловіків легкого або тяжкого перебігу, порівняно зі здоровими досліджуваними без розподілу на соматотипи, за показниками рівня суб'єктивного контролю виявлено достовірне зниження цінності міжособистісних відносин і можливості впливати на власне здоров'я. При розподілі за типом тілобудови у чоловіків мезоморфного соматотипу встановлено достовірно нижчі рівні загальної інтернальності у хворих із тяжким перебігом псоріазу, а також показника рівня суб'єктивного контролю в галузі невдач, навчальних і міжособистісних відносин у хворих із легким і тяжким перебігом захворювання порівняно із групою контролю аналогічного соматотипу.

Ключові слова: псоріаз, тяжкість перебігу, чоловіки, рівень суб'єктивного контролю, тип тілобудови.

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The idea of psoriasis origin under the influence of both internal and external environmental factors is widespread and recognized in the scientific community [14]. The genetic basis of psoriasis is polymorphism and increased expression of IL-22, which makes common the pathological basis of the psoriasis process together with atopic dermatitis [10]. In favour of the genetic component is evidenced by data on the high incidence of psoriasis among monozygotic twins (65–72 %) compared to dizygotic (15–30 %). The PSORS1 gene accounts for about 35–50 % of the hereditary burden of psoriasis [3].

However, new studies indicate overexpression of filaggrin, loricrin and involucrin in psoriasis-affected skin. If normally, the last protein is found in the granular layer, then in psoriasis it is found in the spinous layer [10].