

## რეზიუმე

HBV გენოტიპების განაწილება საქართველოს პაციენტებში სხვადასხვა ასაკობრივი ჯგუფების მიხედვით

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B ჰეპატიტის ვირუსული ინფექცია წარმოადგენს ჯანდაცვის ერთ-ერთ უმთავრეს პრობლემას საქართველოში, დაავადების 2.9%-იანი გავრცელებით ზრდასრულ მოსახლეობაში. სადღეისოდ სხვადასხვა ასაკობრივ კატეგორიებში B ჰეპატიტის ვირუსის გენოტიპების გავრცელების შესახებ მონაცემები არ მოიპოვება. კვლევის მიზანია გენოტიპების გავრცელების შესწავლა სხვადასხვა ასაკობრივი კატეგორიის B

ვირუსით ინფიცირებულ პაციენტებში საქართველოში. კვლევაში გამოყენებულია სამედიცინო ცენტრ მრჩეველის კლინიკური ბაზის მონაცემები. გენოტიპირება ჩატარებულია INNO-LiPA მეთოდოლოგიით. სტატისტიკური ანალიზი შესრულებულია სტატისტიკური პროგრამის SPSS 23.0 მეშვეობით. კვლევაში ჩართული იყო 84 პაციენტი, მათგან 52 (62.1%) იყო მამაკაცი. კვლევის მონაწილეები მეტწილად იყვნენ თბილისის მაცხოვრებლები - 53 (63.2%). კვლევის მონაწილეებში D გენოტიპი (57.1%, N=48) სჭარბობდა A გენოტიპს (42.9%, N=49). ასაკი იყო სარწმუნო კავშირში გენოტიპების გავრცელებასთან. კვლევის მონაწილეების უმეტესობა (58.3%, N=49) იყო 35 წლის ან უფრო ახალგაზრდა. D გენოტიპი ჭარბობდა 35 წლის და უფროს ასაკობრივ ჯგუფში (71.4%), მაშინ როცა 35 წლისა და უმცროს ასაკობრივ ჯგუფში მისი გავრცელება შეადგენდა 46.9% ( $p < 0.001$ ). A გენოტიპის გავრცელება  $< 35$  და  $\geq 35$  წლის ასაკობრივ ჯგუფში შეადგენდა 53.1% და 28.6%, შესაბამისად. მირებული მონაცემები მოწმობს, რომ B ჰეპატიტის ვირუსით ინფიცირებულ ასაკოვან პაციენტებში დომინირებს D გენოტიპი, ხოლო ახალგაზრდა (35 წელი და უმცროსი) პაციენტების ნახევარზე მეტს კი აქვს A გენოტიპი.

## ASSOCIATION OF QUALITY OF LIFE WITH LIVER FIBROSIS AMONG PATIENTS TREATED FOR HEPATITIS C IN GEORGIA

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It is estimated that 130 to 185 million people (2-3% of the global population) have a chronic hepatitis C infection [3]. The hepatitis C virus causes significant morbidity and mortality. It has been estimated that each year between 350,000 and 370,000 deaths are directly related to the HCV [2]. The majority (80%) of people infected with the hepatitis C virus live in low- and middle-income countries [10;8].

Seroprevalence survey was conducted in 2015 in Georgia among adults aged  $\geq 18$  years using a stratified, multi-stage cluster design [5]. National anti-HCV seroprevalence in Georgia was 7.7% and HCV RNA prevalence was 5.4% [6].

Georgia has launched hepatitis C elimination national program in 2015, which aims to sharply reduce the prevalence of HCV and prevent complications associated with the disease. It is also extremely important to improve the quality of life of infected people after recovery from the virus. The hepatitis C elimination program has made available access to the diagnostic tests and treatment of hepatitis C. Countrywide

free treatment program (with DAAs) made it possible for citizens to be treated for chronic hepatitis C infection. There are limited data on the role of successful antiviral treatment in changing the quality of life among patients in Georgia. According to different studies, which are mainly conducted among patients treated with interferon/ribavirin regimen, it has been found that curing for hepatitis C has a positive effect on the general health and improves quality of life among cured patients [1,7].

**Material and methods.** For data collection the questionnaire was developed to assess the quality of life of patients involved in the hepatitis C elimination program and evaluate the association of quality of life with the degree of liver fibrosis. The questionnaire was specifically developed for this study and piloted prior to administration. It included information on demographics (age, gender and residence) and health condition. Liver fibrosis level was measured by FIB4 score and liver elastography. FIB4 was computed based on age, as-

partate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count. The score was interpreted as follows: low (<1.45), equivocal (1.45-3.25) or advanced (>3.25) level of liver fibrosis. For those in the equivocal range, liver elastography was conducted and results were recorded.

SPSS (IBM) version 23 was used for data management and statistical analysis. Bivariate analysis was conducted to measure the association between the quality of life variables and the level of liver fibrosis.

Before enrollment, each study participant was provided with the information about the purpose, methods, procedures, risks and benefits of the study. Those individuals who agreed to participate in the survey were enrolled in the study after signing the consent form. The study protocol was approved by the Institu-

tional Review Board of Health Research Union (IRB00009520; IORG0005619).

**Results and discussion.** 378 randomly selected patients were involved in the study (out of 395 patients approached, refusal rate was 4.3%). Research site was one of the clinics providing services within the national HCV elimination program. We recruited study participants who were beneficiaries of the hepatitis C elimination program (HCV RNA positive patients) before the start of antiviral treatment. Majority of study participants - 280 (74.0%) were from Tbilisi and the rest of the participants were from other cities. The median age was 47 years (range 20 to 83). More than two-thirds of surveyed individuals - 283 (77.5%) were males and 85 (22.5%) were females. Almost 27.5% of participants had an advanced liver fibrosis ( $\geq$ F3 by Metavir or  $\geq$ 3.25 by FIB4 score) (Table 1).

Table 1. Socio-demographic and clinical characteristics

Characteristics	N	%
<b>Age (years)</b>		
≤45	170	45.0
≥46	208	55.0
<b>Gender</b>		
Male	293	77.5
Female	85	22.5
<b>Residence</b>		
Tbilisi	280	74.1
Other cities	98	22.5.5
<b>Level of fibrosis</b>		
≤Low liver fibrosis	274	72.5
≥Advanced liver fibrosis	104	27.5

Table 2. Frequency of reporting health problems (in the last two weeks)

Characteristics	Always		Often		Sometimes		Rare		Never	
	N	%	N	%	N	%	N	%	N	%
How often do you feel general weakness?	0	0	62	16.4	104	27.5	140	37.0	72	19.0
How often have you suffered from insomnia?	1	0.3	55	14.6	143	37.8	132	34.9	47	12.4
How often have you had a problem with lifting or carrying heavy objects?	8	2.1	37	9.8	50	13.2	67	17.7	216	57.1
How often have you had trouble breathing in your daily activities?	0	0	11	2.9	35	9.3	68	18.0	264	69.8
How often have you felt a lack of energy?	2	0.5	52	13.8	145	38.4	138	36.5	41	10.8
How often do you feel like you were blurred?	0	0	11	2.9	57	15.1	86	22.8	224	59.3
How often have you had muscle pain?	0	0	8	2.1	57	15.1	105	27.8	208	55.0
How often have you had abdominal pain?	0	0	5	1.3	54	14.3	118	31.2	201	53.2
How often have you been bothered by feeling bloated?	0	0	43	11.4	198	52.4	113	29.9	24	6.3
How often have you had the abdominal discomfort?	0	0	39	10.3	191	50.5	116	30.7	32	8.5

How often have you had dry mouth?	0	0	8	2.1	36	9.5	40	10.6	294	77.8
How often have you experienced itching?	0	0	0	0	18	4.8	28	7.4	332	87.8
How often have you been bothered by a restricted diet?	8	2.1	95	25.1	81	21.4	45	11.9	149	39.4
How often have you experienced mood swings?	0	0	27	7.1	190	50.3	129	34.1	32	8.5
How often have you felt unhappy?	0	0	6	1.6	30	7.9	58	15.3	284	75.1
How often have you been in an irritated state?	0	0	23	6.1	209	55.3	109	28.8	37	9.8
How often have you been depressed?	0	0	10	2.6	151	39.9	132	34.9	85	22.5
How often have you had a problem with concentration	0	0	7	1.9	16	4.2	49	13.0	306	81.0
How often have you been worried that your liver disease is affecting to your family?	0	0	11	2.9	53	14.0	71	18.8	243	64.3
How often have you complained that your symptoms are progressing and turning into major problems?	1	0.3	9	2.4	60	15.9	85	22.5	223	59.0
How often have you complained over that your condition is getting worse?	0	0	7	1.9	58	15.3	85	22.5	228	60.3

Table 3. Association of liver fibrosis level with demographic and clinical data

Characteristics	Low liver fibrosis		Advanced liver fibrosis		Bivariate Prevalence Ratio (PR) and 95% CI
	N	%	N	%	
<b>Age (years)</b>					
≤45	154	56.2	16	15.4	1
≥46	120	43.8	88	84.6	7.05 (3.93,12.65)
<b>Gender</b>					
Male	208	75.9	85	81.7	1.29 (0.84,2.01)
Female	66	24.1	19	18.3	1
<b>Residence</b>					
Tbilisi	209	76.3	71	68.3	1
Other city	65	23.7	33	31.7	0.75 (0.53,1.06)
<b>Existence of general weakness</b>					
Yes	206	75.2	100	96.2	5.88 (2.23,15.45)
No	68	24.8	4	3.8	1
<b>Increased desire for daytime sleep</b>					
Yes	194	70.8	89	85.6	1.99 (1.21,3.26)
No	80	29.2	15	14.4	1
<b>Insomnia</b>					
Yes	231	84.3	4	96.2	3.55 (1.37,9.19)
No	43	15.7	104	3.8	1
<b>Problems with lifting or carrying heavy objects</b>					
Yes	96	35.0	66	63.5	2.31 (1.64,3.26)
No	178	65.0	38	36.5	1
<b>Lack of energy</b>					
Yes	235	85.8	102	98.1	6.20 (1.59,24.20)
No	39	14.2	2	4.9	1

<b>Feel exhausted</b>					
Yes	98	35.8	56	53.8	1.69 (1.22,2.35)
No	176	64.2	48	46.2	1
<b>Anxiety from muscle pain</b>					
Yes	98	35.8	72	69.2	2.75 (1.91,3.96)
No	176	64.2	32	30.8	1
<b>Abdominal pain</b>					
Yes	100	36.5	77	74.0	3.23 (2.19,4.77)
No	174	63.5	27	26.0	1
<b>Bothered by a restricted diet</b>					
Yes	146	53.3	83	79.8	2.57 (1.66,3.96)
No	128	46.7	21	20.2	1

33.3% of patients reported that they often or sometimes feel general weakness in the last two weeks. Majority of interviewed individuals (87.3%) suffered from insomnia. Based on our data 11.9% of study subjects always or often have a problem with lifting or carrying heavy objects. Almost 30% of patients have problems with daily activities. Only 90% of respondents felt lack of energy in the last two weeks. About half of study participants (52.4%) had the feeling of being bloated, nearly 80% of interviewed individuals reported that they often or sometimes have abdominal pain or discomfort. 40.7% of patients often feel drowsiness. 45% had at least one

episode of muscle pain in the last two weeks. 22.2% of the respondents reported having dry mouth and 12.2% - itching. One-quarter of the study participants noted that they often feel discomfort because of restricted diet. The majority of the respondents (91.5%) experienced mood swings, 24.9% reported feeling unhappy and 90.2% - irritated. 77.5% of patients are depressed, 35.7% are worried that their liver disease influences their families. Most of surveyed individuals (41%) reported that the symptoms are progressing and turning into significant problems and 40% complained that their health condition is getting worse (Table 2).

Table 4 Association of level of liver fibrosis with perception experienced in the last two weeks

Characteristics	Low liver fibrosis		Advanced liver fibrosis		Bivariate Prevalence Ratio (PR) and 95% CI
	N	%	N	%	
<b>Feeling unhappy</b>					
Yes	62	22.6	32	30.8	1.34 (0.95,1.89)
No	212	77.4	72	69.2	1
<b>Feeling irritated</b>					
Yes	249	90.9	92	88.5	1
No	25	9.1	12	11.5	0.8 (0.5,1.36)
<b>Have been depressed</b>					
Yes	211	77.0	82	78.8	1
No	63	23.0	22	21.2	1.08 (0.72,1.61)
<b>Problems with concentration</b>					
Yes	41	15.0	31	29.8	1.80 (1.29,2.15)
No	233	85.0	73	70.2	1
<b>Have been worried that liver disease is affecting to family</b>					
Yes	62	22.6	73	70.2	4.23 (2.94,6.098)
No	212	77.4	31	29.8	1
<b>Have been worried that symptoms are progressing and will turn into major problems</b>					
Yes	76	27.7	79	76.0	4.54 (3.04,6.78)
No	198	72.3	11.2	24.0	1
<b>Health condition is getting worse</b>					
Yes	77	28.1	73	70.2	3.57 (2.48,5.16)
No	197	71.9	31	29.8	1
<b>Feeling healthy</b>					
Yes	45	75.0	5	41.7	4.20 (1.15,15.22)
No	15	25	7	58.3	1

In bivariate analysis older age (PR=7.05; 95% CI:3.93-12.65), general weakness (PR=5.88; CI:2.23-15.45), insomnia (PR=3.5, CI:1.37-9.19) and drowsiness was associated with advanced liver fibroses (Table 3). Patients with the degree of liver fibrosis  $\geq$ F3 by elastography or  $\geq$ 3.25 FIB4 score have twice more problems with lifting or carrying heavy objects, compared to the patients with low level of liver fibrosis (PR=2.31; CI:1.64-3.26). Feeling exhausted (PR=1.69; CI:1.22-2.35), having muscle pain (PR=2.75, CI:1.91-3.96) and abdominal pain (PR=3.23, CI:2.19-4.77) was higher among study participants with high liver fibrosis level. Problem with concentration (PR=1.8, CI:1.29-2.51) was also associated with stage 3 or higher fibrosis. Patients with high fibrosis level were more likely to think that liver disease is affecting their family (PR=4.23, CI:2.94-6.09). Gender, residence, having abdominal discomfort (meteorism), complains of itching, feeling unhappy or irritated and depressed was not statistically associated with level of liver fibrosis.

Findings of this study are consistent with the data from the studies conducted among the populations of the other European countries. Studies conducted in Spain, showed a significant improvement in the quality of life of patients cured by direct-acting antiviral drugs (DAAs) after completion of treatment, regardless of the degree of liver fibrosis [4,9].

Our study is one of the first, which was conducted in order to determine association of quality of life with liver fibrosis among patients treat for hepatitis C in Georgia, which is the strengths of the study, while the disadvantage is that the study covered just one period – start of the treatment and we did not have an opportunity to follow up the patients. In conclusion: chronic hepatitis C and liver fibrosis has a major negative impact on both physical and mental health, reducing quality of life among our patients. The most common complaints include symptoms such as fatigue, lack of energy and insomnia.

**Acknowledgements:** The study was supported by the Shota Rustaveli National Science Foundation of Georgia (SRNSF) grants # FR17\_371.

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## SUMMARY

### ASSOCIATION OF QUALITY OF LIFE WITH LIVER FIBROSIS AMONG PATIENTS TREATED FOR HEPATITIS C IN GEORGIA

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A seroprevalence survey was conducted in 2015 in Georgia among adults aged  $\geq$ 18 years. This survey data was used to estimate anti-HCV seroprevalence in Georgia at 7.7% and HCV RNA prevalence at 5.4%. Treatment adherence, recovery and quality of life are interrelated, however, there are limited data on the role of successful antiviral treatments in changing the quality of life (QOL) of patients in Georgia.

A questionnaire assessed the QOL for patients involved in the hepatitis C elimination program. Patient responses were analyzed to estimate the magnitude of any association between quality of life with the degree of liver fibrosis and various laboratory parameters. Liver fibrosis status was measured by the FIB4 score and liver elastography.

We recruited 378 eligible adult participants who were beneficiaries of the hepatitis C elimination program (HCV RNA-positive) before the start of antiviral treatment. Of the surveyed

individuals, 283 (77.5%) were males; the median age was 47 years (range 20 to 83). Almost 30% of participants had advanced liver fibrosis. The following factors were associated with advanced liver fibrosis: older age (PR=7.05; 95% CI:3.93-12.65), general weakness (PR=5.88; CI:2.23-15.45) and insomnia (PR=3.5, CI:1.37-9.19). Muscle pain (PR=2.75, CI:1.91-3.96) and abdominal pain (PR=3.23, CI:2.19-4.77) were more common among participants with a high FIB4 score; these patients were also more likely to report that liver disease affects family life (PR=4.23, CI:2.94-6.09).

This study suggests that advanced liver fibrosis is associated with poorer QOL, an association that has been noted by research elsewhere in Europe. Given that the Georgian experience appears to be similar to other European countries, public health interventions to improve QOL may be expedited by collaboration with regional neighbors.

**Keywords:** Quality of life (QOL), Hepatitis C, liver fibrosis.

## РЕЗЮМЕ

### АССОЦИАЦИЯ КАЧЕСТВА ЖИЗНИ С ФИБРОЗОМ ПЕЧЕНИ У ПАЦИЕНТОВ, ЛЕЧЕННЫХ ОТ ГЕПАТИТА С В ГРУЗИИ

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На основании проведенного в 2015 году в Грузии исследования серологической распространенности среди взрослых в возрасте  $\geq 18$  лет выявлено, что распространенность анти-HCV в Грузии составила 7,7%, а HCV RNA - 5,4%. В 2015 году Грузия запустила национальную программу элиминации гепатита С, которая направлена на резкое снижение распространенности HCV и предотвращение осложнений, связанных с этим заболеванием. Целью исследования явилась оценка качества жизни пациентов с гепатитом С и установление его ассоциации со степенью тяжести поражения печени.

Данные о роли успешного противовирусного лечения в изменении качества жизни пациентов в Грузии ограничены. Для сбора информации использовалась анкета оценки качества жизни пациентов, участвующих в программе элиминации гепатита С, и его связи со степенью фиброза печени и различными лабораторными параметрами. Уровень фиброза печени измеряли по шкале FIB4 и эластографией печени. Методом случайной выборки в исследование включены 378 пациентов, из них 283 (77,5%) мужчин и 85 (22,5%) - женщин. У 30% участников выявлен выраженный фиброз печени  $\geq F3$  по метавиру и  $\geq 3,25$  по шкале FIB4. 30% пациентов имели проблемы с повседневной деятельностью, а 90% респондентов отмечали недостаток энергии. Пожилой возраст (PR=7,05; 95% CI: 3,93-12,65), общая слабость (PR=5,88; CI: 2,23-15,45) и бессонница (PR=3,5, CI: 1,37-9,19) связаны с развитым фиброзом печени. Наличие мышечной боли (PR=2,75, CI: 1,91-3,96) и боли в животе (PR=3,23, CI: 2,19-4,77) было выше среди участников исследования с высоким уровнем фиброза печени.

Данные проведенного исследования показали, что выраженный фиброз печени находится в корреляции с качеством жизни. Полученные результаты согласуются с данными исследований, проведенных среди населения других европейских стран.

## რეზიუმე

სიცოცხლის ხარისხის ასოციაცია ღვიძლის დაზიანების ხარისხთან, C ჰეპატიტის მკურნალობაზე მყოფ პაციენტებში საქართველოში

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2015 წელს საქართველოში ჩატარებული სეროპრევალენტური კვლევის შედეგად გამოვლინდა C ჰეპატიტის საწინააღმდეგო ანტისხეულების გავრცელება 7,7%-ში, ხოლო C ჰეპატიტის რნმ-ის პრევალენტობა კი 5,4%-ში. 2015 წლიდან ქვეყანაში მიმდინარეობს C ჰეპატიტის ელიმინაციის პროგრამა, რომლის ფარგლებშიც პაციენტებს ეძლევათ შესაძლებლობა ჩაიტარონ მკურნალობა, ამის მიუხედავად ძალზედ მნიშვნელოვანია გამოვლენილი უმჯობესების ხარისხი. სამწუხაროდ, ქვეყანაში მწირია მონაცემები წარმატებული ანტივირუსული მკურნალობის როლის შესახებ პაციენტების ცხოვრების ხარისხის ცვლილებაში. კვლევის მიზანს წარმოადგენდა C ჰეპატიტით დაავადებულ პაციენტებში ცხოვრების ხარისხის შეფასება და მისი ასოციაციის დადგენა ღვიძლის დაზიანების ხარისხთან. მონაცემთა შეგროვების მიზნით გამოყენებული იყო კითხვარი, რომლის მეშვეობითაც მოპოვებულია ინფორმაცია სიცოცხლის ხარისხის შესაფასებლად და მისი ღვიძლის ფიბროზის ხარისხთან ასოციაციის დასადგენად. ღვიძლის ფიბროზის დონის შეფასება განხორციელდა FIB4-ისა და ღვიძლის ელასტოგრაფიის გამოყენებით. კვლევაში მონაწილეობა მიიღო 378 ალბათობის პრინციპით შერჩეულმა პაციენტმა, მათგან 283 (77,5%) იყო მამაკაცი, ხოლო 85 (22,5%) ქალი. მონაწილეთა თითქმის 30%-ს აღენიშნა ღვიძლის მაღალი დაზიანება ( $\geq F3$  მეტავირით და  $\geq 3,25$  ქულა FIB4 სკალით). პაციენტთა 30%-ს აღენიშნა პრობლემები ყოველდღიური აქტივობის დროს, ხოლო 90% - ენერჯის ნაკლებობა. ხანდაზმული ასაკი (PR=7,05; 95% CI: 3,93-12,65), ზოგადი სისუსტე (PR=5,88; CI: 2,23-15,45) და უძილობა (PR=3,5, CI: 1,37-9,19) ასოცირებული იყო ღვიძლის მაღალი ფიბროზის ხარისხთან. კუნთების (PR=2,75, CI: 1,91-3,96) და მუცლის ტკივილი (PR=3,23, CI: 2,19-4,77) მეტად გამოხატული იყო პაციენტებს ღვიძლის ფიბროზის მაღალი ხარისხით. კვლევის შედეგების მიხედვით დადგინდა, რომ ღვიძლის გამოხატული ფიბროზი ასოცირებულია ცხოვრების ხარისხთან, რაც შეესაბამება სხვა ქვეყნებში ჩატარებული კვლევების მონაცემებს.