SCIE DOI: 10.14744/scie.2022.92653
South. Clin. Ist. Euras.2022;33(2):136-141

Original Article

Diagnostic Reliability of Architect Anti-HCV Tests and Diagnostic Cost of False Positivity

Sinem Akkaya Işık,[1] Ersin Tural,[2] Ercan Yenilmez,[1] Riza Aytac Cetinkaya,[1] Orhan Baylan,[3] Levent Gorenek[1]

[1]Department of Infectious Diseases and Clinical Microbiology, University of Health Sciences, Sultan 2nd Abdulhamid Han Training and Research Hospital, İstanbul, Türkiye
[2]Department of Pediatrics, University of Health Sciences, Sultan 2nd Abdulhamid Han Training and Research Hospital, İstanbul, Türkiye
[3]Department of Microbiology, University of Health Sciences, Sultan 2nd Abdulhamid Han Training and Research Hospital, İstanbul, Türkiye

Submitted: 13.10.2021
Accepted: 02.02.2022

Correspondence: Sinem Akkaya Işık, Sağlık Bilimleri Üniversitesi, Sultan 2. Abdulhamid Han Eğitim ve Araştırma Hastanesi, Enfeksiyon Hastalıkları ve Klinik Mikrobiyoloji Kliniği, İstanbul, Türkiye
E-mail: drsinemakkaya@gmail.com

Keywords: Anti HCV; cost-effectivity; diagnostic virology; HCV antibody.

ABSTRACT

Objective: We aimed to determine the cutoff value of anti-hepatitis C virus (HCV) in the diagnosis of real positive patients based on the chemiluminescence immunoassay (CIA) test kit absorbance routinely used in our laboratory and to reveal the potential cost-effectiveness of confirmatory tests for false-positive samples.

Methods: All anti-HCV CIA test results between 2016 and 2019 were retrospectively screened and sample/cutoff (S/Co) values of the patients were recorded. Among these, the results that were confirmed with HCV RNA polymerase chain reaction (PCR) test were included.

Results: Of the 257 patients included in the study, 84 (32.68%) were positive for HCV RNA. The optimal S/Co value was 8.58 with sensitivity and specificity values being 95.24% and 85.55%, respectively. According to this 8.58 S/Co value, the anti-HCV test was reactive in 105 cases and 80 (76.2%) of these cases had active HCV infection. To prevent false negativity, the additional cost of using 1.0 S/Co value to our institution was 4114.64 USD. In our institution, approximately 6.25 working hours is spent to finalize the HCV RNA PCR test. The hours spent for S/Co of 1.0 and 8.58 was 1606.25 and 658.25, respectively.

Conclusion: False-positive anti-HCV results are an economic burden on countries. At least, different S/Co values might be used in accordance with the purpose of screening and prevalence of HCV infection in different laboratories and different populations.

INTRODUCTION

According to the World Health Organization, an estimated 58 million people have chronic hepatitis C virus (HCV) infection in the world. Globally, about 1.5 million new infections occur every year. The highest burden of disease is in the Eastern Mediterranean Region and European Region, with 12 million people chronically infected in each region. [1] Despite being located in the Eastern Mediterranean Region, the HCV prevalence is only 0.7% in Türkiye.[2]

The enzyme immunoassay (EIA) or chemiluminescence immunoassay (CIA) methods, which detect specific antibodies, are used to screen for HCV infection. Considering the development of EIA, only one HCV recombinant antigen derivative was used in first-generation tests. First-generation anti-HCV EIA tests have low sensitivity in high-prevalence populations, but they can lead to false positives in low-prevalence populations. Therefore, the sensitivity and specificity of second-generation anti-HCV EIA tests were increased by adding two protein derivatives to first-generation anti-HCV EIA tests. Third-generation anti-HCV EIA assays, which are commonly used today, are developed by adding a fourth protein derivative to second-generation assays. Although the sensitivity of third-generation anti-HCV EIA tests is high, false positivity is still observed.[3] Consequently, reactive anti-HCV test reagents should be confirmed by a recombinant immunoblot assay (RIBA) or nucleic acid amplification test (NAT).[4,5]

The United States Centers for Disease Control and Prevention (CDC) have reported that anti-HCV signal

sample/cutoff (S/Co) values in EIA or CIA may be used to estimate the likely outcome before validation methods.[5]

During hepatitis C screening, a reactive or positive result may be reported by using different S/Co values based on different risk groups.[6] However, in Türkiye, only one S/Co value specified in the anti-HCV kit manual is being used. In this study, individuals without risk factors such as preoperative patients, blood donors, and marriage or job applicants were examined. The purpose of our study was to determine the S/Co value in true positive patients by taking the absorbance of the CIA test kit that is routinely used at our laboratory as a basis and to investigate the potential cost-effectiveness of applying the reflex test for false-positive samples based on this value. Another purpose of this study was to facilitate the access of more people to the test by reducing diagnostic costs in countries with limited economies like Middle Eastern and North African countries by using this determined value.

MATERIALS AND METHODS

This diagnostic accuracy study was conducted at the Department of Infectious Diseases and Clinical Microbiology of the Sultan II Abdulhamid Han Research and Training Hospital.

Patient groups

In this study, for screening purposes without risk factors, the results of 42 606 anti-HCV CIA tests, which were performed in the microbiology laboratory of our hospital between January 1, 2016, and January 1, 2019, were retrospectively screened, and the S/Co values of the patients were recorded. Patients who were previously diagnosed and treated with interferon or direct-acting agents were excluded. Among the remaining, the 257 results that were confirmed with HCV RNA NAT tests were included. Additionally, only one laboratory test result of each patient was included in the study to prevent bias. For this purpose, if the anti-HCV EIA test was repeated in patients with positive HCV RNA, the lowest S/Co value was recorded. The highest anti-HCV S/Co value among the repeated tests of the patients with negative HCV RNA was also included.

Anti-HCV assay

The anti-HCV test was performed by using the CIA method on the serum samples of the patients by using Architect i2000SR (Abbott Diagnostics®, Wiesbaden, Germany). HCV antibody levels were determined by the ratio of the signal (signal sample = S) measured by the device to the cutoff value of the test (Cutoff = Co) (S/Co = cutoff index). Based on the instructions of the kit's manual, those with values of S/Co <0.99 were accepted as reactive.

HCV RNA measurement

HCV RNA levels (viral loads) were determined by the real-time polymerase chain reaction (PCR) method. HCV RNA isolation was performed using a Magnesia® 2448 Nucleic Acid Extraction & PCR Setup Robot and Magnesia® 2448 Viral DNA/RNA Extraction Kit (Anatolia Geneworks, Türkiye). After isolation, the viral loads of the serum samples were determined by Applied Biosystems (ABI) 7500 Real-Time PCR using a Bosphore HCV Quantification Kit (Anatolia Geneworks, Türkiye). The dynamic range of the test was 25 IU/mL, and the linear range was 25 IU/mL and 1×10^8 IU/mL.

Laboratory-clinical test algorithm

In our hospital, the CDC 2013 manual is used as the laboratory-clinical approach.[7] According to this manual:

- Non-reactive anti-HCV results with CIA are reported as nonreactive, and no additional testing is performed.
- Reactive anti-HCV results are considered to be compatible with active HCV infection or previous HCV infection or false positivity. The HCV RNA NAT test is used to distinguish these three conditions. Cases with positive HCV RNA tests are considered active HCV infection and treated under follow-up.
- Most cases where anti-HCV is reactive and HCV RNA cannot be detected are considered as no current HCV infection, and no further procedures are required.

In our hospital, only NAT is used as a reflex test, and the RIBA test cannot be applied.

Statistical analyses and economic evaluation

The statistical analyses were conducted by SPSS 15.0 and web-based computation (VassarStat: website for statistical computation)/MedCalc trial version. Mean and standard deviation values were used as descriptive statistics for the quantitative variables. Diagnostic accuracy was defined for the actual Co value estimated by receiver operating characteristic (ROC) analysis. A confidence interval of 0.95 was used for statistical significance. The mean and marginal costs were used for economic evaluation. The cost for the unit was estimated from a provider perspective. Reimbursement and currency rates published by local authorities (Social Security Institution and Central Bank) on the dates of February 1 and 4, 2018, were utilized. Sensitivity analysis was not conducted for the comparison of cost impacts.

Hamidiye Non-Interventional Research Ethics Committee.

RESULTS

A total of 42 606 anti-HCV tests were performed in our hospital within the study period. After excluding the duplicate anti-HCV test results of the same patients, 428 of the remaining 36 019 tests were found to be reactive. In 159 of these cases, although the anti-HCV test result was reactive, a confirmation test was not carried out. Additionally, 12 patients had already been diagnosed with chronic hepatitis C or were still receiving treatment for HCV infection. Finally, we had 257 naive cases among which anti-

HCV tests were reactive and HCV RNA PCR confirmation tests were performed. According to the confirmation test results by NAT, HCV RNA was not detected in 173 (67.32%) of the 257 anti-HCV reactive serum samples. For 84 (32.68%) cases with positive HCV RNA, the test results were defined as active HCV infection (Fig. 1).

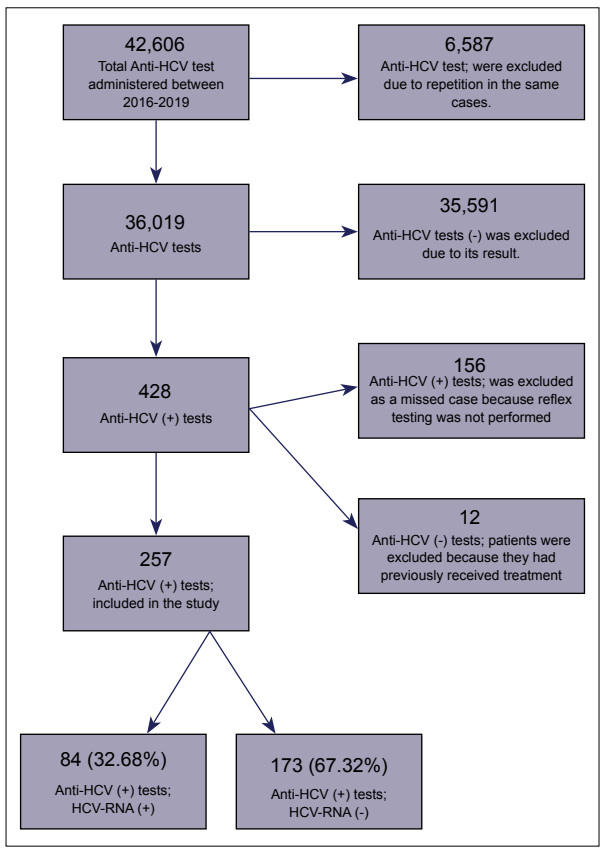

Figure 1. Hepatitis C virus infection diagnosis algorithm and distribution of patients.

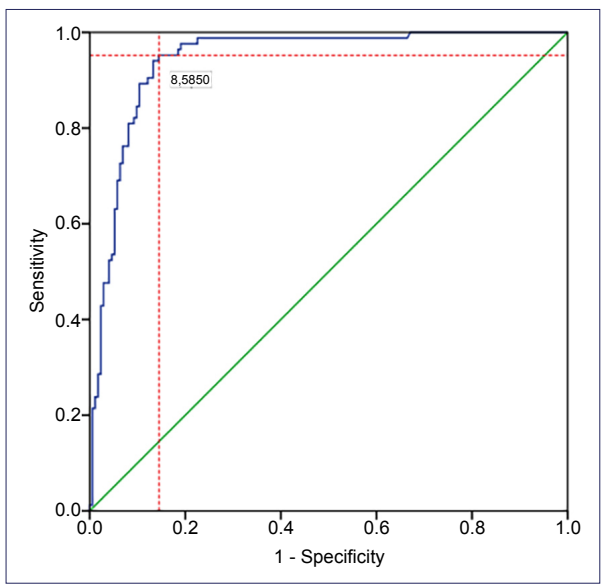

Figure 2. Receiver operating characteristic (ROC) analysis of anti-HCV S/Co values according to HCV RNA results. The area under the ROC curve was 0.942 for S/Co value of 8.58 (95% CI: 0.913–0.971).

We also performed a ROC analysis to determine the anti-HCV Co value. According to the analysis, the optimal S/Co value was 8.58 with sensitivity and specificity values of 95.24% and 85.55%, respectively. The area under the ROC curve was 0.942 (95% confidence interval, 0.913–0.971) (Fig. 2 and Table 1). According to this S/Co value (8.58), the anti-HCV test was reactive in 105 cases, and 80 (76.2%) of these cases had active HCV infection. However, when this S/Co value was applied, anti-HCV was nonreactive in 4 patients although they were diagnosed with active HCV infection. When these cases were examined, their anti-HCV S/Co titers were found to be 1.82, 6.05, 6.98, and 7.39. The patient who had an anti-HCV S/Co value of 1.82 was 73 years old, had normal transaminases, and had a low titer of HCV RNA (80 IU/mL). The subsequent follow-up revealed a spontaneous negative viral load with nonreactive anti-HCV, and the result was concluded as false-positive HCV RNA. When the other cases were examined, the transaminases were high, and they were concluded as active HCV infection.

According to the Health Application Communiqué published on February 4, 2018, in Türkiye, the unit cost of an HCV RNA PCR test was 27.07 USD.[8] When the S/Co value was evaluated as 1.0, the cost of the HCV RNA PCR assay studied for 257 subjects with an anti-HCV CIA test reagent was 6956.99 USD. However, if the S/Co value were determined as 8.58, the cost of 105 cases would be 2842.35 USD. Nevertheless, four cases with active HCV infection would be missing due to the increased S/Co value. To prevent false negativity, the additional cost of using the S/Co value of 1.0 in our institution was 4114.64 USD, meaning that we spent 1028.66 USD for diagnosis per true case of active HCV infection when using a S/Co value of 1.0 (Table 2a).

At our institution, approximately 6.25 working hours was spent to finalize an HCV RNA PCR test. The hours spent was 1606.25 with S/Co 1.0 and 658.25 with S/Co 8.58. Accordingly, the time spent for each case was 237.5 h (Table 2b).

DISCUSSION

HCV infection screening is performed by an anti-HCV test. HCV screening is required in many situations in Türkiye such as premarriage or preoperative screening, besides screening of blood donors and high-risk populations. In anti-HCV reactive cases, active infection is confirmed by an HCV RNA PCR test.[5,7] The false positivity rate of a screening test increases as the prevalence of the disease decreases in the community. As Türkiye is among countries with a low prevalence in terms of HCV infection, the false positivity rates of the test are high.[2] This is an important cause of an increase in medical costs and labor loss in Türkiye.

In a letter to the Abbott laboratories in 2007 by the CDC

Table 1. Diagnostic accuracy for Anti HCV ≥8.58 S/Co and Anti HCV ≥5.00 S/Co

Anti HCV	TP	P	TN	N	Sensitivity (95% CI)	Specificity (95% CI)
≥8.58 S/Co	80	84	148	173	0.9524 (0.876–0.985)	0.8555 (0.792–0.903)
≥5.00 S/Co	83	84	127	173	0.9881 (0.926–0.999)	0.7341 (0.661–0.797)

TP: Test Positive; P: Positive; TN: Test Negative; N: Negative.

Table 2a. Cost analysis†

Anti-HCV cutoff	True positive	Total positive (USD)	Cost for unit (USD)	Total cost (USD)	Average cost (USD)	Marginal cost
≥1.00 S/Co	84	257	27.07	6956.99	82.82	1028.66
≥5.00 S/Co	83	129	27.07	3492.03	42.07	216.56
≥8.58 S/Co	80	105	27.07	2842.35	35.53	0

The cost for unit, that is, the cost per HCV RNA test was 27.07 USD.[8]

Table 2b. Workload analysis

Anti-HCV	True positive	Total positive	Workload unit (h)	Total cost (h)	Average workload (h)	Marginal workload (h)
≥1.00 S/Co	84	257	6.25	1606.25	19.12	237.50
≥5.00 S/Co	83	129	6.25	806.25	9.71	50.00
≥8.58 S/Co	80	105	6.25	656.25	8.20	0

The workload unit, that is, the workload per HCV RNA test was 6.25 h.

including the results of a study among low-prevalence and high-prevalence populations, the proportion of RIBA positivity was 97% among samples with a mean S/Co ratio of 5. In this letter, it was suggested that no confirmation test should be performed at <5 S/Co values in the laboratories running in vitro diagnostic anti-HCV tests, and positivity should be reported after confirmation testing at ≥5 S/Co values.[9] When a ≥1 S/Co value was applied for positive anti-HCV results according to the user manual of the kit in our laboratory, the true positivity rate in our study was 32.68%. However, when the S/Co value had been applied as ≥5 based on the CDC recommendation, 129 patients would have been found to have reactive anti-HCV test results, and 83 (64.3%) of them would have had active HCV infection. One undiagnosed case in our study was a 73-year-old patient with normal transaminases and a viral load below 100 IU/mL. Additionally, HCV RNA decreased to an undetectable level with nonreactive anti-HCV in that patient during follow-up.

According to the results of a study published in 2012 by Ecemiş et al.,[10] which had a total of 387 patients for HCV RNA PCR testing, 197 of whom were anti-HCV reactive and 190 were nonreactive. The PCR tests resulted positive in 79 cases, while 308 cases had negative PCR results. In that study, when the reactivity threshold (S/Co) of anti-HCV was considered 1, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the test were 94.9%, 60%, 38.1%, and 97.9%, respectively. Ecemiş et al.[10] found the optimal S/Co value as 5.06 in their ROC analysis, and they determined that the sensitivity and specificity of the test were 92.4% and 76.6%, respectively. In our study, the optimal S/Co value was 8.58, and the sensitivity and specificity values for this value were 95.24% and 85.55%, respectively. The S/Co, sensitivity, and specificity values were high in our study. We also found that HCV RNA PCR was positive in 4 of the anti-HCV nonreactive cases (4/190) when the S/Co ratio was applied as ≥1. However, this unit of data contradicted the literature in Türkiye because Türkiye is a low-endemic country for HCV infection. According to the data of the Turkish Red Crescent, the estimated HCV infection window period (anti-HCV nonreactive, NAT positive) risk ratios for blood donors tested for the first time were reported as 2.97, 4.37, 3.4, and 3.6 per million donations for 2015, 2016, 2017, and 2018, respectively.[11] In comparison to this information, the HCV infection window period (anti-HCV nonreactive, NAT positive) risk ratio was very high in the study of Ecemiş et al.,[10] and the optimal cutoff value in the study was also lower than ours. The study of Ecemiş et al. could be conducted on high-risk populations including patients with hemodialysis or IV drug users. As the criteria for inclusion of reactive and nonreactive cases in the study and the S/Co values of 4 false-negative cases were not given in detail, we could not comment on the reason for the high rate.

In another study carried out in Türkiye in 2016, HCV RNA PCR tests were performed for confirmation in 658 anti-HCV reactive cases, and the optimal value was found

to be 5.0 S/Co with the sensitivity and specificity values of respectively 95.6% and 52.7% by ROC analysis.[12] The confirmation tests, just in the same way as our study, were performed only in the anti-HCV reactive cases in their study, and an HCV RNA PCR test was not performed in the nonreactive cases.

In the study of Wu et al.[13] in which four different antibody-screening tests (InTec, CHB, Wantai, Architect) were used, 336 of 22,626 clinical samples resulted as anti-HCV reactive. Among the anti-HCV reactive samples, 205 (61%) were found to be positive when confirmed by HCV NAT, and the anti-HCV S/Co values in these samples were revealed to be high. More than 95% of the samples had S/Co values of >8.00 (InTec), 6.00 (KHB), 12.00 (Wantai) and 8.00 (Architect). Additionally, the optimal S/Co ratio was 5 for those with 95% PPV when the Architect kits were analyzed separately for S/Co values of <1, 1–5, and >5.

In a study published in Korea by Seo et al.,[14] it was revealed that the most appropriate anti-HCV S/Co value was 10.9 by ROC curve analysis (sensitivity, 94.4%; specificity, 97.3%), and the area under the ROC curve was 0.989 (95% CI, 0.981–0.998). In another study by Fletcher et al.,[15] sensitivity and specificity values for S/Co 6.28 were found to be 94% and 91.1%, respectively. The area under the ROC curve was 0.9499 (95% CI: 0.9273–0.9724). In our study, the optimal S/Co value was 8.58 (sensitivity, 95.24%; specificity 85.55%), and the area under the ROC curve was 0.942 (95% CI: 0.913–0.971).

In the literature, there are not many studies about the optimal S/Co ratio in EIA tests used in HCV screening and the cost analysis of the confirmation tests and false-positive results of anti-HCV tests. The only publication in this regard was the one by Granados-García et al.,[16] which was a cost-effective study of seven HCV test strategies performed on blood donors in a low-prevalence population. Three of the seven strategies were based on the HCV diagnosis-reporting guide in Mexico, and four were based on the CDC recommendations. In these strategies, RIBA and HCV RNA NAT tests were used to determine antibody levels according to the S/Co value and confirm true positive cases. In the CDC 1, 2, and 3 strategies, the S/Co values were ≥1, ≥1, and ≥8, respectively. RIBA and HCV RNA NAT were performed together in different sequences (e.g., NAT first, then RIBA, or vice versa). In the CDC 4 strategy, S/Co ≥1, only HCV RNA NAT was performed. In the Mexico strategies, there were three different groups (M1, M2, and M3), and three different antibody levels were determined for each group. These levels were very low (1 ≤ S/Co <4.5), low (4.5 ≤ S/Co <20), and high (≥20). As with the CDC strategies, RIBA and HCV RNA NAT were performed concurrently, but in different sequences. In their study, confirmation tests at very low S/Co levels were not performed in the Mexico 1 (M1) strategy. As a result, the M1 strategy was found to have the lowest cost when compared in accordance with the cost of true positivity per patient, and it was stated that this strategy had the lowest diagnostic power. The strategies M2, M3, and CDC3 were revealed to be cost-effective, and their costs were 197, 185, and 195 USD, respectively. In our laboratory, a strategy similar to CDC4 was applied, and the cost was 245 USD, while the cost of confirmation (PCR test only) was approximately 82 USD. If the S/Co value of 5 recommended by the CDC were applied, the cost would be 42 USD. However, the cost would be 35 USD when the S/Co value of 8.58, which was revealed as the optimal value in the current study, was applied.

Study limitations

As NAT, RIBA, or PCR has not been performed on the anti-HCV nonreactive samples at our institution in clinical practice and our study was conducted retrospectively, we cannot comment on the PPV and NPV in our study. This may be considered one of the limitations of the study, and there is a need for prospective studies to reveal the rate of anti-HCV nonreactive but HCV RNA-positive patients.

CONCLUSION

Low S/Co levels may cause false-positive results in countries with a low prevalence of HCV infection like Türkiye. The high rate of false-positive anti-HCV test results causes psychological stress in patients, labor loss in health workers, and additional burden on the health economics of countries. To prevent this, we recommend classifying or increasing the S/Co level in the screening procedure according to the risk population. At least different S/Co values might be used in accordance with the purpose of the screening, such as blood donors or preoperative screening, and the prevalence of HCV infection in different laboratories, different situations, and different populations.

Ethics Committee Approval

This study approved by the Hamidiye Non-Interventional Research Ethics Committee. (Date: 29.03.2019, Decision No: 19/41).

Informed Consent

Retrospective study.

Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: S.A.I., R.A.C., O.B.; Design: S.A.I., E.Y., L.G.; Supervision: S.A.I., E.Y., E.T.; Fundings: S.A.I., E.T.; Materials: S.A.I., E.Y.; Data: S.A.I., L.G.; Analysis: S.A.I., R.A.C., O.B.; Literature search: S.A.I., R.A.C., O.B.; Writing: S.A.I., E.T.; Critical revision: S.A.I., L.G.

Conflict of Interest

None declared.

REFERENCES

1. WHO Hepatitis C. Available at: https://www.who.int/news-room/fact-sheets/detail/hepatitis-c. Accessed Oct 9, 2022.
2. T.C. Sağlık Bakanlığı. Türkiye viral hepatit önleme ve kontrol pro-

gramı 2018-2023. Ankara: Department of Health; 2018. Available at: https://hsgm.saglik.gov.tr/depo/birimler/Bulasici-hastaliklar-db/duyurular/Turkiye_Viral_Hepatit_Onleme_ve_Kontrol_Programi/Turkiye_Viral_Hepatit_Onleme_ve_Kontrol_Programi_TR.pdf. Accessed May 9, 2022.

3. Kim S, Kim JH, Yoon S, Park YH, Kim HS. Clinical performance evaluation of four automated chemiluminescence immunoassays for hepatitis C virus antibody detection. J Clin Microbiol 2008;46:3919–23.
4. Kim B, Ahn HJ, Choi MH, Park Y. Retrospective analysis on the diagnostic performances and signal-to-cut-off ratios of the Elecsys Anti-HCV II assay. J Clin Lab Anal 2018;32:e22165. [CrossRef]
5. Alter MJ, Kuhnert WL, Finelli L; Centers for Disease Control and Prevention. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. Centers for Disease Control and Prevention. MMWR Recomm Rep 2003;52:1–13, 15; quiz CE1–4.
6. Contreras AM, Ochoa-Jiménez RJ, Celis A, Méndez C, Olivares L, Rebolledo CE, et al. High antibody level: an accurate serologic marker of viremia in asymptomatic people with hepatitis C infection. Transfusion 2010;50:1335–43. [CrossRef]
7. Centers for Disease Control and Prevention (CDC). Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR Morb Mortal Wkly Rep 2013;62:362–5.
8. Sosyal Güvenlik Kurumu Başkanlığı. 5.4- Fatura, incelemeye esas belgelerin teslimi ve ödeme işlemleri. Sosyal Guvenlik Kurumu sağlık uygulama tebliğinde degişiklik yapılmasına dair tebliğ. Ankara: Sosyal Güvenlik Kurumu Başkanlığı; 2018. Available at: https://www.resmigazete.gov.tr/eskiler/2018/02/20180204-11.htm. Accessed May 9, 2022.
9. Kuhnert WL. Department of Health and Human Services. 2007. Available at: https://www.cdc.gov/hepatitis/hcv/pdfs/architectletter_5-24-07.pdf. Accessed Jul 4, 2019.
10. Ecemiş T, Akçalı S, Dündar PE, Şanlıdağ T. The threshold value of Anti-HCV test in the diagnosis of HCV infection. Turkiye Klinikleri J Med Sci 2012;32:1648–52. [CrossRef]
11. Saygan MB. Transfuzyonla bulaşan enfeksiyon verileri (Türk Kızılayı 2015-2018). In: Uluhan R, Emekdas G, Heper Y, Bayik M, editors. XII. National Blood Centers and Transfusion Medical Congress Book; 2019 March 10-14; Antalya, Türkiye. Istanbul; 2019. p. 65–81.
12. Şanlıdağ T, Akçalı S, Ecemiş T, Süer K, Erbay Dündar P, Arıkan A, et al. Investigation of the correlation between anti-HCV levels (S/Co) with HCV-RNA in the diagnosis of hepatitis C virus (HCV) infection. Mikrobiyol Bul 2016;50:508–10. [CrossRef]
13. Wu S, Liu Y, Cheng L, Yin B, Peng J, Sun Z. Clinical evaluation of the signal-to-cutoff ratios of hepatitis C virus antibody screening tests used in China. J Med Virol 2011;83:1930–7. [CrossRef]
14. Seo YS, Jung ES, Kim JH, Jung YK, Kim JH, An H, et al. Significance of anti-HCV signal-to-cutoff ratio in predicting hepatitis C viremia. Korean J Intern Med 2009;24:302–8. [CrossRef]
15. Fletcher GJ, Raghavendran A, Sivakumar J, Samuel P, Abraham P. Diagnostic reliability of Architect anti-HCV assay: Experience of a tertiary care hospital in India. J Clin Lab Anal 2018;32:e22245.
16. Granados-García V, Contreras AM, García-Peña C, Salinas-Escudero G, Thein HH, Flores YN. Cost-effectiveness analysis of different testing strategies that use antibody levels to detect chronic hepatitis C in blood donors. PLoS One 2016;11:e0154625. [CrossRef]

Architect Anti-HCV Testlerinin Teşhis Güvenilirliği ve Yanlış Pozitifliğin Teşhis Maliyeti

Amaç: Laboratuvarımızda rutin olarak kullanılan kemilüminesans immunoassayn (CIA) test kiti absorbansını esas alarak gerçek pozitif hastaların tanısında anti-HCV'nin cut-off değerini belirlemeyi ve yalancı pozitif örnekler için refleks tamamlayıcı test uygulamasının potansiyel maliyet etkinliğini araştırmayı planladık.

Gereç ve Yöntem: Hastanemizde 2016–2019 yılları arasında yapılan tüm anti-HCV CIA test sonuçları geriye dönük olarak tarandı ve hastaların S/Co değerleri kaydedildi. Bunlar arasında HCV-RNA real-time PCR testi ile doğrulanan sonuçlar çalışmaya dâhil edildi.

Bulgular: Dahil edilen 257 hastanın 84'ü (%32.68) HCV-RNA pozitifti. Anti-HCV değerlerinin ROC analizine göre, en uygun S/Co değeri 8.58 olup, duyarlılık ve özgüllük değerleri sırasıyla %95.24 ve %85.55'di. Bu değere göre 105 olguda anti-HCV testi reaktifti ve bu olguların 80'inde (%76.2) aktif HCV enfeksiyonu vardı. Yanlış negatifliği önlemek için, kurumumuzda 1.0 S/Co değeri kullanmanın ek maliyeti 4114.64 USD idi. Kurumumuzda, HCV-RNA PCR testini tamamlamak için yaklaşık 6.25 çalışma saati gerekmektedir. S/Co değeri 1.0 ve 8.58 alındığında gereken iş saati sırasıyla 1606.25 ve 658.25 idi.

Sonuç: Yanlış pozitif anti-HCV sonuçları ülkelerin sağlık ekonomisi üzerinde önemli bir yüktür. En azından, taramanın amacına (kan donörleri veya ameliyat öncesi tarama gibi) ve farklı laboratuvarlarda, farklı durumlarda ve farklı popülasyonlarda HCV enfeksiyonu yaygınlığına göre farklı S/Co değerleri kullanılabilir.

Anahtar Sözcükler: Anti-HCV; architec; tanı maliyeti; yanlış pozitif.