



Published in final edited form as:

J Viral Hepat. 2025 April ; 32(4): e14022. doi:10.1111/jvh.14022.

Evaluation of Hepatitis C Virus Transmission Through Endoscopy Procedures in the Country of Georgia

Davit Baliashvili^{1,2}, Tsira Merabishvili³, Irina Tskhomelidze¹, Maia Tsereteli³, Lika Karichashvili³, Nazi Chitadze³, Paige A. Armstrong⁴, Maia Butsashvili⁵

¹The Task Force for Global Health, Tbilisi, Georgia

²Centers for Disease Control and Prevention, Georgia Country Office, Tbilisi, Georgia

³National Center for Disease Control and Public Health, Tbilisi, Georgia

⁴Centers for Disease Control and Prevention, Atlanta, Georgia, USA

⁵Health Research Union, Tbilisi, Georgia

Abstract

Exposure to healthcare procedures might be a source of hepatitis C virus (HCV) transmission in Georgia, one of the few countries currently on track to eliminate hepatitis C. While there has been a history of iatrogenic transmission of HCV, the risk of HCV transmission related to endoscopic procedures has not been previously assessed in Georgia. The goal of this study was to assess HCV seroconversion among individuals undergoing endoscopic procedures to estimate the relative role and incidence of HCV infection attributable to endoscopic procedures. A prospective cohort study was conducted in four endoscopy units in two cities (Tbilisi and Kutaisi) of Georgia during April–September, 2021. Recruitment of study participants was conducted using convenience sampling, and every eligible patient was approached and invited to participate in the study. Study population included adults (age ≥ 18 years) who received an endoscopic procedure (gastroscopy, colonoscopy and bronchoscopy) in inpatient or outpatient unit at the study sites. HCV antibody (anti-HCV) testing was conducted using rapid diagnostic test (RDT) on the same day they underwent the endoscopic procedure. Patients with a non-reactive anti-HCV baseline test were retested after 6 months. Patients with reactive baseline tests were excluded from the study and linked to further testing and care. Participants with a reactive result on follow-up RDTs were retested using a lab-based anti-HCV and HCV ribonucleic acid (RNA) test. A total of 981 HCV antibody non-reactive participants were enrolled; 590 (64.8%) of them were reached and retested after 6 months. At retesting, two out of 590 (0.3%) individuals had a reactive anti-HCV result on RDT and both were negative on laboratory-based anti-HCV and HCV RNA tests. Based on the results of this study, endoscopic procedures were not shown to contribute to HCV transmission in Georgia.

Correspondence: Davit Baliashvili (xot3@cdc.gov).

The findings and conclusions in this paper are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

Conflicts of Interest

The authors declare no conflicts of interest.

Keywords

endoscopy; HCV; hepatitis C; transmission

1 | Introduction

In 2015, Georgia launched an unprecedented Hepatitis C Elimination Program, aiming to decrease disease incidence and prevalence through comprehensive screening, diagnostic and treatment programmes [1]. One of the key priorities of the elimination programme is prevention of new hepatitis C virus (HCV) infections, including in the healthcare setting [2]. The incidence of HCV infection is a key indicator identified by the World Health Organization (WHO) to track progress towards elimination of hepatitis C [3]. Therefore, monitoring HCV transmission and identifying the settings where new cases occur is a priority. Despite a 67% reduction in HCV infection prevalence between 2015 and 2021 in Georgia [4, 5], incidence of hepatitis C in the general population is estimated to be substantially higher than the WHO target [6]. Healthcare-related HCV transmission is still a major problem in Georgia, with a history of blood transfusion, surgery and other invasive medical procedures previously found as factors significantly associated with HCV infection [4, 7, 8]. To further understand the sources of ongoing HCV transmission, assessment is needed across various healthcare settings.

Healthcare-related HCV transmission can occur via several mechanisms, such as unsterilised or inadequately sterilised medical equipment, unsafe injections or transfusion of infected blood or blood products. Georgia has made substantial progress in improving the safety of blood and blood products [9]. However, the risk of HCV transmission related to other medical procedures through medical equipment or unsafe injections has not been systematically evaluated in Georgia. It is not well documented which types of medical interventions contribute the most to the ongoing transmission of HCV. Endoscopic procedures, such as colonoscopy, gastroscopy and bronchoscopy, have been found to be a source of transmission of HCV in certain countries and less significantly in others [10, 11]. This suggests that unlike other factors, such as injection drug use, that are universally acknowledged as a major risk factor for HCV transmission, the risk of transmission associated with endoscopy procedures is more setting-specific and varies by country, likely reflective of infection prevention and control (IPC) practices. Decontamination techniques and maintenance of the decontamination system virtually eliminate the risk of transmitting HCV infection, but bad maintenance of this system can cause contamination of equipment and thus pose a risk of HCV transmission. Anecdotal data about suboptimal IPC practices at endoscopy units in Georgia prompted this study that aimed to assess HCV seroconversion among individuals undergoing endoscopic procedures in Georgia to estimate the relative role and attributable incidence.

2 | Materials and Methods

A prospective cohort study was conducted by the National Center for Disease Control and Public Health (NCDC) surveillance team and municipal epidemiologists. The study

sites included four endoscopy units in two large cities in Georgia. Three hospitals were selected in the capital city Tbilisi and one in Kutaisi. The enrolment took place during April–September, 2021. Selection criteria for the baseline testing included the following: (1) Age ≥ 18 years; (2) endoscopic procedure (gastroscopy, bronchoscopy or colonoscopy) in the inpatient or outpatient unit of the study sites; (3) no known history of chronic HCV infection or positive anti-HCV test reported by the potential study participant. The recruitment of study participants was conducted using convenience sampling. Patients were recruited during regular work hours of 9:00–17:00 from Monday to Friday. Every eligible patient was approached and invited to participate in the study. After invited patients provided consent, they were offered baseline HCV antibody (anti-HCV) testing using a rapid diagnostic test (RDT) (HEALGEN, HCV Hepatitis C virus Rapid test) that was purchased through the state programme at that time. Both sensitivity and specificity of the test were $> 99\%$ as reported by the manufacturer. Anti-HCV testing was done the same day they underwent an endoscopic procedure. Patients who tested positive and were not aware of their infection were excluded from the study and linked to hepatitis C care for further testing and treatment, as needed.

Given that the incubation period for HCV ranges between 2 weeks and 6 months, patients who were anti-HCV negative at the time of endoscopy procedure were followed up 6 months after the procedure and were retested for anti-HCV using RDT. Participants with a positive result on follow-up RDT were tested using laboratory-based HCV antibody and HCV RNA test to confirm the results at the national reference laboratory. HCV antibody testing was conducted using two assays: (1) Chemiluminescence assays ARCHITECT Anti-HCV Ab (Abbott Diagnostics, Wiesbaden, Germany) for the qualitative detection of anti-HCV antibodies in human serum/plasma; and (2) The INNO-LIA HCV Score (FUJIREBIO, Belgium) a Line Immuno Assay (LIA) for the detection of antibodies to human hepatitis C virus in human serum or plasma. HCV RNA testing was conducted using GeneXpert.

The study protocol was reviewed by NCDC Institutional Review Board which declared it exempt as it represented public health project designed to study, evaluate, improve or otherwise examine public benefit or service programmes. CDC's Human Subjects Research Office determined CDC's role did not constitute engagement in the research and deferred to the local IRB.

3 | Results

A total of 1109 patients undergoing endoscopic procedures (85% outpatient) were approached and screened for inclusion in the study. Of those, 128 (11.6%) did not meet the eligibility criteria. Of 981 patients with negative baseline anti-HCV tests who were eligible for follow-up testing in 6 months, 71 (7.2%) died before follow-up testing (Figure 1). Of the remaining 910 study participants, 590 (64.8%) were reached and tested. The most common reasons for not retesting the remaining participants were refusal (106, 11.6%), incorrect or changed contact information (67, 7.4%) and being abroad (35, 3.8%). Of the 590 participants who were retested, 304 (52%) were females, 238 (40%) were aged 18–45, 127 (22%) were aged 46–60 and 225 (38%) were aged ≥ 61.

At follow-up testing, 2 out of 590 (0.3%) individuals had an anti-HCV positive result on RDT. Samples from both participants were retested for HCV antibodies and RNA. Both were found negative on HCV antibody and viraemia testing, suggesting that the RDT results were false-positives.

4 | Discussion

In this cohort study conducted in four endoscopy units in the country of Georgia, none of the 590 patients who underwent endoscopy procedures and were retested were found to have evidence of exposure to HCV infection 6 months after the procedure. Our findings suggest that endoscopic procedures are not a source of HCV transmission in Georgia. This was the first study to assess the role of endoscopic medical procedures as a risk factor for HCV infection in the country.

Our results imply that endoscopic procedures are unlikely to contribute to the ongoing transmission of HCV infection in Georgia. This might be a result of improved IPC practices and maintaining the adequate decontamination processes. Another important implication for future studies is that studies looking at incidence should consider laboratory-based tests to avoid false-positive results. Currently RDTs have high sensitivity and specificity [12]. Previous research in Georgia found false-positivity rate for anti-HCV RDTs ranging from 0.4% to 0.7% [13], which is comparable but slightly higher than in our study (0.3%). However, with rare outcomes like incident HCV infection, false-positivity poses a serious challenge since even sporadic false-positive results might largely overestimate the incidence, unless they are confirmed using lab-based testing. This issue is particularly relevant for Georgia and other countries on track to eliminate hepatitis C, considering that incidence is a key indicator for demonstrating hepatitis C elimination.

Despite these encouraging findings, the possibility of HCV transmission during endoscopy cannot be completely ruled out due to several limitations of our study. First, the risk of HCV transmission through endoscopy is generally considered low, and the sample size may have been too small to detect the incidence for endoscopic procedures. Second, we could not reach approximately a third of the study population who tested negative at baseline to conduct follow-up testing. Third, our study was conducted in only four medical facilities in two large cities in Georgia; thus, the findings may not be generalisable to the entire country. It is possible that these results represent larger cities and not smaller population centres that may have less optimal infection prevention and control practices. However, in national serosurveys conducted in 2015 and 2021, HCV infection prevalence was higher in urban settings [4, 5].

In conclusion, HCV transmission through endoscopy procedures is unlikely to be a substantial source of incident infections in Georgia. Infection prevention and control remains an important intervention to prevent transmission of HCV and additional investigation is needed to assess whether other elements of healthcare and what specific types of invasive procedures may be contributing to new infections. This will in turn help developing targeted interventions to prevent new infections and achieve hepatitis C elimination in Georgia.

Funding:

This study was supported by Cooperative Agreement Number, GH20-2130 funded by the Centers for Disease Control and Prevention.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

References

1. Mitruka K, Tsertsvadze T, Butsashvili M, et al. , “Launch of a Nationwide Hepatitis C Elimination Program—Georgia,” *Morbidity and Mortality Weekly Report* 64, no. 28 (2015): 753–757. [PubMed: 26203628]
2. Georgia Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health, and Social Affairs, “Strategic Plan for the Elimination of Hepatitis C Virus in Georgia, 2016–2020,” 2017, https://www.moh.gov.ge/uploads/files/2017/akordeoni/failebi/Georgia_HCV_Elimination_Strategy_2016-2020.pdf.
3. World Health Organization, *Guidance for Country Validation of Viral Hepatitis Elimination and Path to Elimination: Technical Report* (Geneva: World Health Organization, 2023), Licence: CC BY-NC-SA 3.0 IGO, <https://www.who.int/publications/i/item/9789240078635>.
4. Hagan LM, Kasradze A, Salyer SJ, et al. , “Hepatitis C Prevalence and Risk Factors in Georgia, 2015: Setting a Baseline for Elimination,” *BMC Public Health* 19, no. Suppl 3 (2019): 480, 10.1186/s12889-019-6784-3. [PubMed: 32326913]
5. Gamkrelidze A, Shadaker S, Tsereteli M, et al. , “Nationwide Hepatitis C Serosurvey and Progress Towards HCV Elimination in the Country of Georgia, 2021,” *Journal of Infectious Diseases* 228 (2023): 684–693, 10.1093/infdis/jiad064. [PubMed: 36932731]
6. Walker JG, Tskhomelidze I, Shadaker S, et al. , “Insights From a National Survey in 2021 and From Modelling on Progress Towards Hepatitis C Virus Elimination in the Country of Georgia Since 2015,” *Eurosurveillance* 28 (2023): 2200952, 10.2807/1560-7917.es.2023.28.30.2200952. [PubMed: 37498534]
7. Baliashvili D, Averhoff F, Kasradze A, et al. , “Risk Factors and Genotype Distribution of Hepatitis C Virus in Georgia: A Nationwide Population-Based Survey,” *PLoS One* 17, no. 1 (2022): e0262935, 10.1371/journal.pone.0262935. [PubMed: 35061841]
8. Kanchelashvili GBM, Galdavadze TM, Shadaker S, et al. , “Identifying Risk Factors for HCV Transmission in the Country of Georgia: A Case-Control Study,” 2022 Presented at: International Viral Hepatitis Elimination Meeting, Amsterdam.
9. Bloch EM, Kipiani E, Shadaker S, et al. , “Blood Transfusion Safety in the Country of Georgia: Collateral Benefit From a National Hepatitis C Elimination Program,” *Transfusion* 60 (2020): 1243–1252, 10.1111/trf.15815. [PubMed: 32542715]
10. Morris J, Duckworth GJ, and Ridgway GL, “Gastrointestinal Endoscopy Decontamination Failure and the Risk of Transmission of Blood-Borne Viruses: A Review,” *Journal of Hospital Infection* 63, no. 1 (2006): 1–13, 10.1016/j.jhin.2005.10.014. [PubMed: 16517005]
11. Van Remoortel H, Borra V, De Buck E, Compennolle V, and Vandekerckhove P, “Is an Endoscopic Examination Associated With Transfusion-Transmissible Infections? A Systematic Review and Meta-Analysis,” *Transfusion* 58, no. 2 (2018): 507–519, 10.1111/trf.14416. [PubMed: 29194668]
12. Vetter BN, Reipold EI, Ongarello S, et al. , “Sensitivity and Specificity of Rapid Diagnostic Tests for Hepatitis C Virus With or Without HIV Coinfection: A Multicentre Laboratory Evaluation Study,” *Journal of Infectious Diseases* 226, no. 3 (2022): 420–430, 10.1093/infdis/jiaa389. [PubMed: 32614451]
13. Vetter BN, Ongarello S, Tyshkovskiy A, et al. , “Sensitivity and Specificity of Rapid Hepatitis C Antibody Assays in Freshly Collected Whole Blood, Plasma and Serum Samples: A Multicentre

Prospective Study,” PLoS One 15, no. 12 (2020): e0243040, 10.1371/journal.pone.0243040.
[PubMed: 33270716]

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

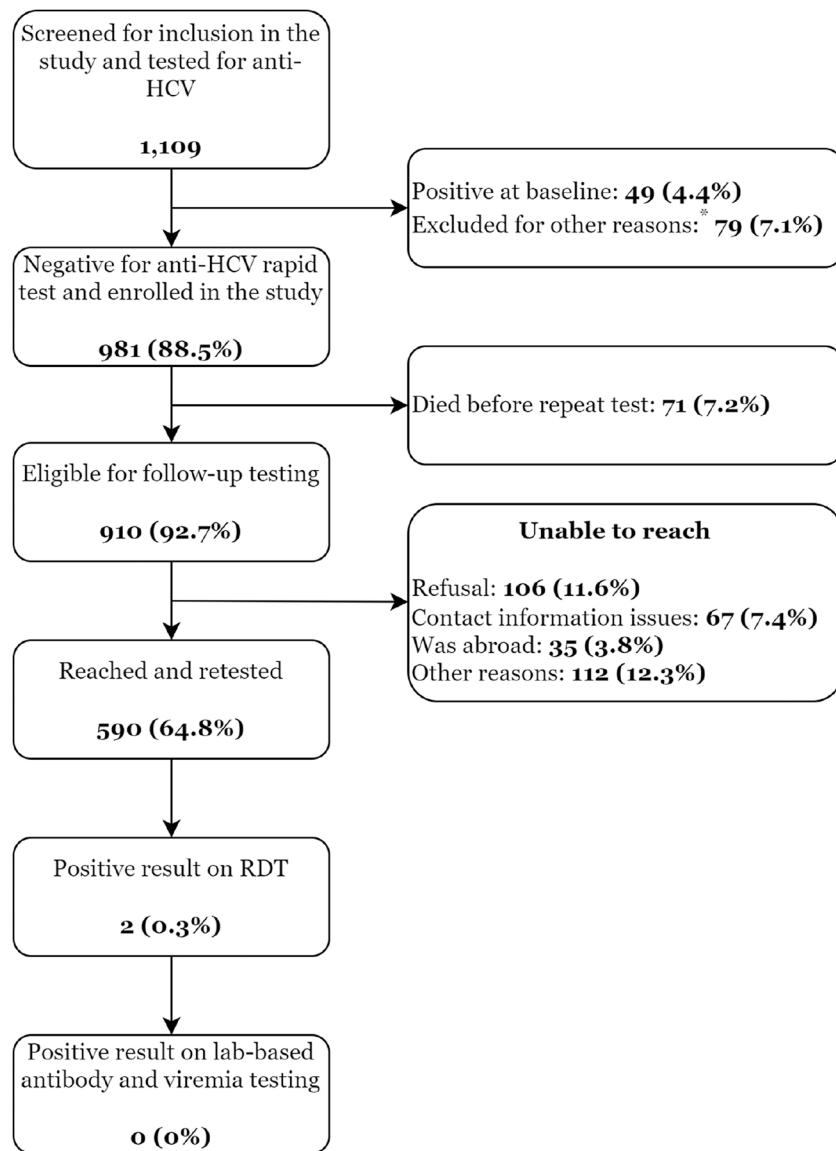


FIGURE 1 |

Flow chart of the study population. *Reasons for exclusion: Previously tested positive, already on hepatitis C treatment, previously treated for hepatitis C, planned emigration and residence in territories occupied by Russia.