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Original Article

The Incidence and Care Cascade of the Hepatitis C Virus in Korea

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Background/Aims: The 2030 hepatitis C virus (HCV) elimination targets of the World Health Organization are an 80% reduction in incidence and 65% reduction in mortality compared to the 2015 rates. However, information on the nationwide incidence and treatment rates of HCV infection are limited. We aimed to investigate the nationwide incidence and status of the care cascade for HCV infection in Korea.

Methods: This study used data from the Korea Disease Control and Prevention Agency linked with the data of the Korea National Health Insurance Service. Linkage to care was defined as visiting hospitals twice or more due to HCV infection within 1.5 years of the index date. The treatment rate was the number who had been prescribed antiviral medication within 1.5 years from the index date out of patients newly diagnosed with HCV.

Results: The new HCV infection rate was 17.2 per 100,000 person-years (n=8,810) in 2019. The number of new HCV infections was the highest in patients aged 50 to 59 years (n=2,480), and the new HCV infection rate significantly increased with age (p<0.001). Among newly infected patients with HCV, the linkage to care rate was 78.2% (78.2% men, 78.2% women) and the treatment rate was 58.1% (56.8% men, 59.3% women) within 1.5 years.

Conclusions: The new HCV infection rate was 17.2 per 100,000 person-years in Korea. It is necessary to continuously monitor the incidence and care cascade of HCV to establish proper strategies to reach the goal of HCV elimination by 2030. **(Gut Liver, Published online March 2, 2023)**

Key Words: Hepatitis C; Incidence; Korea; Linkage to care; Treatment rate

INTRODUCTION

Hepatitis C virus (HCV) infection is a leading cause of mortality in patients with advanced fibrosis and cirrhosis, resulting in various complications such as hepatic decompensation and hepatocellular carcinoma (HCC).[1,2] Approximately 180 million people worldwide are estimated to be affected by HCV,[3] and elimination of HCV is important to prevent liver-related complications resulting from disease progression. The World Health Organization aims to eliminate hepatitis C by 2030 and has developed a global hepatitis strategy since 2016.[4] Although one of the main challenges of HCV treatment is the difficulty in distributing effective antiviral treatment comprising direct-acting antivirals (DAAs)[5-7] owing to its high cost, another large hurdle for HCV elimination is the under-diagnosis and under-reporting of the disease.[8,9] Thus, accurate identification of HCV is a method for assessing how much progress has been made in achieving the World Health Organization 2030 HCV elimination plan, which will accordingly enable the establishment of subsequent plans.

Unfortunately, data for national HCV incidence is very limited worldwide. The National Notifiable Diseases Surveillance System reported the incidence of acute hepatitis C and newly reported chronic hepatitis C for a limited area in the United States.[10] The estimated incidence of acute hepatitis C and newly reported chronic hepatitis C in 2018 was 1.2 per 100,000 persons and 54.1 cases per 100,000

persons, respectively. However, reports on new cases of hepatitis C were only available for some regions because reporting was not obligatory. In Japan, a new case of hepatitis C has to be reported to the Infectious Disease Surveillance of the National Institute of Infectious Diseases as a type 5 infectious disease, but most data rely on the blood bank system; thus, the incidence of HCV infection in Japan (0.4 per 100,000 person-years) is likely to be under-reported.[11]

South Korea also has insufficient statistics to represent HCV infection. The anti-HCV positivity rate of 2015 to 2019 suggested by the Korea Disease Control and Prevention Agency (KDCA) is 0.6%. However, this is a sample survey and does not represent the number of new HCV cases diagnosed annually. HCV infection has only recently become a nationally controlled infectious disease in Korea and has been managed with a mandatory surveillance system by the KDCA since 2017.

Therefore, we investigated the incidence of hepatitis C infection in Korea. In addition, we evaluated the care cascade of HCV in terms of linkage to care and treatment rates in nearly all Korean patients with hepatitis C.

MATERIALS AND METHODS

1. Data source and study population

The incidence of HCV infection was determined using data from the KDCA, a control center for infectious diseases in Korea. Additional clinical data were obtained and analyzed by linking newly diagnosed subjects of the KDCA with data from the Korea National Health Insurance Service (KNHIS). Data were extracted and coded with an encrypted number in accordance with the disclosure principles of the KNHIS and KDCA. The Institutional Review Board of the National Evidence-based Healthcare Collaborating Agency approved this study (NECA-IRB number: NECAIRB20-028) and waived the requirement for informed consent.

2. Reporting system for legal communicable diseases in Korea

HCV is a nationally controlled infectious disease in Korea. Since 2017, HCV infection has been managed with a mandatory surveillance system by the KDCA, which makes it mandatory to report HCV to a public health center without delay. When hepatitis C is confirmed or a patient is suspected, a doctor, dentist, or traditional Korean medicine doctor should use the Infectious Disease Web Report System (http://is.kdca.go.kr) or fax to fill out a report form and report it to the head of the public health center within 24 hours. Of these, only patients with HCV RNA positivity were considered to have confirmed hepatitis C and duplicate patients were removed.

3. Monitoring of linkage to care and antiviral treatment

Korea has a single national health insurance system that is mandatory for all citizens, and 97.2% of the Korean population have been enrolled in the system since 2018. Data of patients assigned with HCV infection codes are entered into the KNHIS database when Korean clinics or hospitals submit an insurance claim to the National Health Corporation for their medical services to be reimbursed. Patients assigned to an HCV infection code and receiving DAAs account for 30% of total medical expenses.

4. Definitions of main outcomes

The new HCV infection was defined as patients who were identified as HCV RNA positive by a hospital and whose records were newly incorporated into the KDCA database (index date) in 2019. Patients without any identification codes or those who were assigned the International Classification of Diseases (ICD) code for HCV infection (B18.2) within 3 years of the index date were excluded to filter out new infections. Linkage to care was defined as among patients newly diagnosed with hepatitis C in 2019, those who visited hospitals twice or more due to HCV infection (having HCV ICD code as main or secondary code) within 1.5 years from the index date. Treatment rate was defined as among patients newly diagnosed with hepatitis C in 2019, those who had been prescribed for antiviral treatment (DAAs or peg interferon) at least once within 1.5 years from the index date.

5. Identification of comorbid diseases

Liver cirrhosis, chronic kidney disease, HCC, other malignancies, cardiovascular diseases, and cerebrovascular

Table 1. Identification of Comorbid Conditions

Comorbid conditions	ICD code for diagnosis
Liver cirrhosis	Liver cirrhosis (K74, K70.2, or K70.3) or Cirrhosis-related complications (K76.6, I85, I86.4, K70.43, K71.11, K72.01, or K72.91)
Diabetes mellitus	E10, E11, E12, E13, E14, or E15
Hypertension	I10, I11, I12, or I13
Chronic kidney disease	N18 or N19
Other malignancies	All cancer codes beginning with C
Hepatocellular carcinoma	C22.0
Cardiovascular diseases	I20, I21, I22, I23, I24, or I25
Cerebrovascular diseases	I60, I61, I62, I63, I64, I65, I66, or I69

ICD, International Classification of Diseases.

diseases were identified as comorbidities if the relevant ICD codes were identified 3 years before or 6 months after the index date. Hypertension and diabetes mellitus were identified when patients had relevant ICD codes and were prescribed medication 3 years before or 6 months after the index date. The relevant ICD codes are listed in Table 1.

6. Statistical analyses

Data are presented as medians with 95% confidence intervals, numbers, rates per 100,000 person-years, or percentages. We used the chi-square test and *post-hoc* analysis with Bonferroni correction to analyze categorical variables. The Cochran-Armitage trend test was performed to identify trends according to age. Logistic regression analysis was applied, and a type 3 test was performed to confirm the statistical significance of the marginal distribution by sex and age. All statistical analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA) and R software (version 3.6.0, http://cran.r-project.org/). p-values <0.05 were considered statistically significant.

RESULTS

1. Newly identified HCV infection

In 2019, new HCV infection was identified in 8,810 patients (4,278 men and 4,532 women). The new HCV infection rate was 17.2 per 100,000 person-years. The new HCV infection rate was 16.7 per 100,000 person-years in men, and 17.6 per 100,000 person-years in women. The highest number of new HCV infections according to age group was in patients aged 50 to 59 years (n=2,480) (Fig. 1A). The new HCV infection rate significantly increased with age (p<0.001). The new HCV infection rate was 1.4 per 100,000 person-years in patients aged 20 to 29 years, 29.1 per 100,000 person-years in patients aged 50 to 59 years, and 43.1 per 100,000 person-years in patients aged 70 to 79 years (Fig. 1B). The numbers of new HCV infection according to age groups in each sex is depicted in Supplementary Fig. 1A, and the new HCV infection rate according to age group did not significantly differ between men and women (p=0.903) (Supplementary Fig. 1B). The new HCV infection rate did not differ among medical insur-

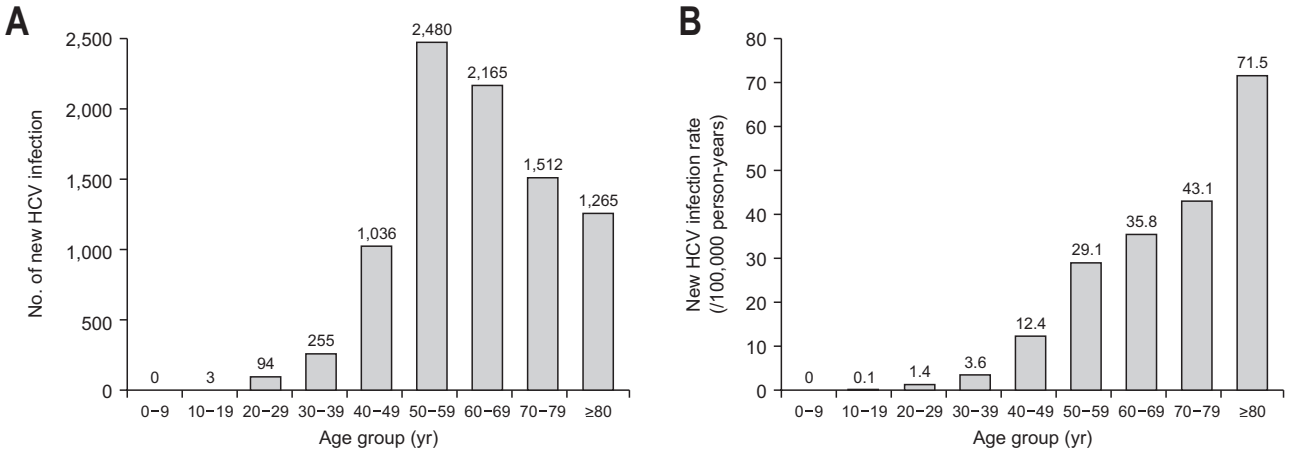

Fig. 1. Newly identified hepatitis C virus (HCV) infection. (A) Numbers of new HCV infections according to age groups. (B) New HCV infection rate according to age groups.

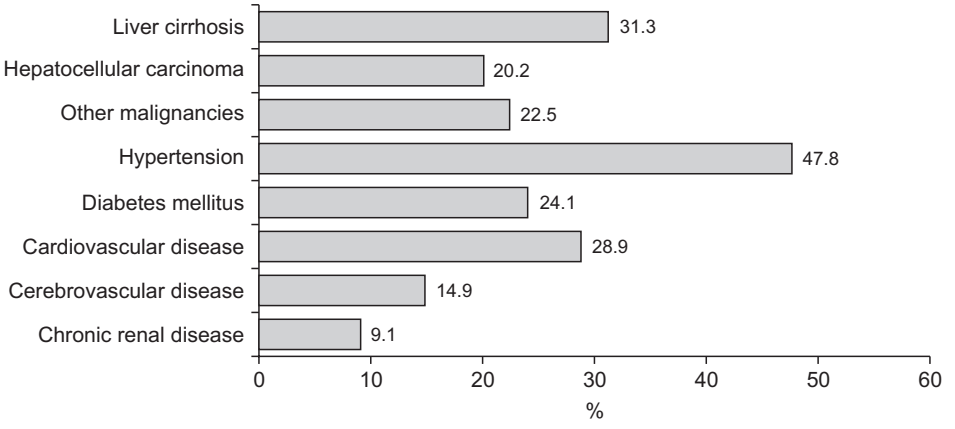

Fig. 2. Comorbid diseases in patients with hepatitis C virus infection.

ance groups (Q1–5, 21.9 per 100,000 person-years; Q6–10, 15.9 per 100,000 person-years; Q11–15, 16.9 per 100,000 person-years; and Q16–20; 13.9 per 100,000 person-years; p=0.569).

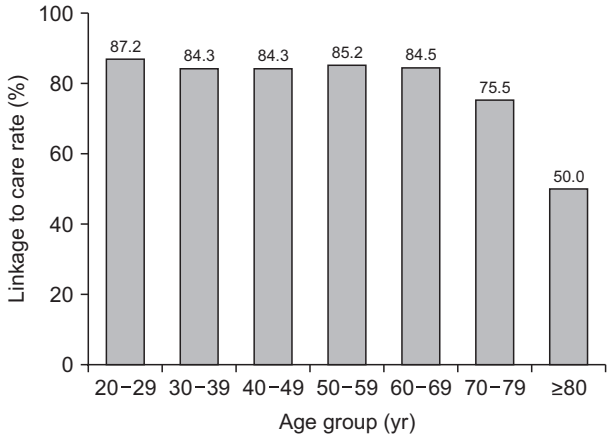

Fig. 3. Linkage to care rate according to age groups.

2. Comorbid diseases

Among 8,810 patients with HCV in 2019, 7,056 (80.1%) had comorbid diseases (Fig. 2). Liver cirrhosis was present in 31.3% of patients. Hypertension and diabetes mellitus were present in 47.8% and 24.1% of patients with HCV, respectively. A total of 20.2% and 22.5% of patients had a current or past diagnosis of HCC or other cancers, respectively, at the time of HCV diagnosis. The prevalence of cardiovascular disease, cerebrovascular disease, and chronic renal disease as a comorbid condition was 28.9%, 14.9%, and 9.1%, respectively.

3. Linkage to care

A total of 78.2% of new HCV patients visited hospitals more than two times with a main or secondary HCV ICD code within 1.5 years of HCV diagnosis. A total of 65.5% of

Table 2. Characteristics of Patients According to Linkage to Care and Treatment

Variable	Linkage to care			Treatment		
	Linked to care	Not linked to care	p-value	Treated	Not treated	p-value
Age group, yr						
0–19	3 (0.0)	0	<0.001	1 (0.0)	2 (0.1)	<0.001
20–29	82 (1.2)	12 (0.6)		57 (1.1)	37 (1.0)	
30–39	215 (3.1)	40 (2.1)		166 (3.2)	89 (2.4)	
40–49	873 (12.7)	163 (8.5)		655 (12.8)	381 (10.3)	
50–59	2,113 (30.7)	367 (19.1)		1,690 (33.0)	790 (21.4)	
60–69	1,829 (26.5)	336 (17.5)		1,410 (27.5)	755 (20.4)	
70–79	1,142 (16.6)	370 (19.3)		818 (16.0)	694 (18.8)	
≥80	633 (9.2)	632 (32.9)		321 (6.3)	944 (25.6)	
Men	3,346 (48.6)	932 (48.5)	0.987	2,431 (47.5)	1,847 (50.0)	0.019
Medical insurances						
Medicaid	774 (11.2)	267 (13.9)	<0.001	555 (10.8)	486 (13.2)	<0.001
Q1–5	1,659 (24.1)	468 (24.4)		1,225 (23.9)	902 (24.4)	
Q6–10	1,333 (19.3)	316 (16.5)		992 (19.4)	657 (17.8)	
Q11–15	1,699 (24.7)	421 (21.9)		1,289 (25.2)	831 (22.5)	
Q16–20	1,425 (20.7)	448 (23.3)		1,057 (20.7)	816 (22.1)	
Charlson Comorbidity Index			<0.001			<0.001
1	868 (12.6)	148 (7.7)		673 (13.1)	343 (9.3)	
2	1,022 (14.8)	207 (10.8)		800 (15.6)	429 (11.6)	
3	5,000 (72.6)	1,565 (81.5)		3,645 (71.2)	2,920 (79.1)	
Comorbid diseases						
Liver cirrhosis	4,853 (70.4)	1,250 (65.1)	<0.001	3,752 (73.3)	2,351 (63.7)	<0.001
Hepatocellular carcinoma	1,443 (20.9)	320 (16.7)	<0.001	976 (19.1)	787 (21.3)	0.009
Other malignancies	2,965 (43.0)	772 (40.2)	0.027	2,103 (41.1)	1,634 (44.3)	0.003
Hypertension	3,140 (45.6)	1,013 (52.8)	<0.001	2,209 (43.2)	1,944 (52.7)	<0.001
Diabetes mellitus	1,551 (22.5)	532 (27.7)	<0.001	1,059 (20.7)	1,024 (27.7)	<0.001
Cardiovascular diseases	1,699 (41.5)	796 (41.5)	<0.001	1,179 (23.0)	1,316 (35.6)	<0.001
Cerebrovascular diseases	824 (12.0)	440 (22.9)	<0.001	544 (10.6)	720 (19.5)	<0.001
Chronic renal disease	550 (8.0)	227 (11.8)	<0.001	360 (7.0)	417 (11.3)	<0.001

Data are presented as number (%).

new HCV patients visited hospitals more than four times with an HCV ICD code within 1.5 years of HCV diagnosis. Approximately 23.2% of patients did not visit the hospital or visited once after HCV diagnosis (Supplementary Fig. 2). The linkage to care rate in 2019 was reported to be 78.2% in all patients (78.2% in men and 78.2% in women). The linkage to care rate was significantly lower in patients aged 80 years or older than in other age groups in both sexes (all p<0.001) (Fig. 3). There was no significant difference in the linkage to care rate between men and women according to age groups (p=0.758) (Supplementary Fig. 3). There was also no difference in the linkage to care rate between urban areas (Seoul and other metropolitan cities) and rural areas (p=0.618). The linkage to care rate was significantly lower in the Medicaid group than in other insurance groups (Medicaid, 74.4%; Q1–5, 78.0%; Q6–10, 80.5%; Q11–15, 80.1%; and Q16–20, 76.1%; all p<0.001). Characteristics of patients according to linkage to care are depicted in Table 2. Patients who were linked to care were younger, belonged to higher medical insurance groups, and had lower Charlson Comorbidity Index (Table 2).

4. Treatment rate

Among 8,810 patients diagnosed with hepatitis C in 2019, 320 patients were treated (58.1%) within 1.5 years of HCV diagnosis. The treatment rates in men and women were 56.8% and 59.3%, respectively. The treatment rate was higher in the middle-aged group (30 to 69 years), and it was significantly lower in patients aged 80 years or older than in other age groups (all p<0.001) (Fig. 4). The treatment rate was 60.6% in patients aged 20 to 29 years, 65.1% in patients aged 30 to 39 years, 63.2% in patients aged 40 to 49 years, 68.1% in patients aged 50 to 59 years, 65.1% in patients aged 60 to 69 years, 54.1% in patients aged 70 to 79 years, and 25.4% in patients aged 80 years or older. In most age groups, the treatment rate was significantly higher in women than in men (p=0.034) (Supplementary Fig. 4). The treatment rate did not significantly differ among various regions (p=0.130), and it was significantly lower in the Medicaid group than in the other insurance groups (Medicaid, 53.3%; Q1–5, 57.6%; Q6–10, 60.2%; Q11–15, 60.8%; and Q16–20, 56.4%; all p<0.001). Patients who were treated included more women, and they were younger, belonged to higher medical insurance groups, and had lower Charlson Comorbidity Index (Table 2).

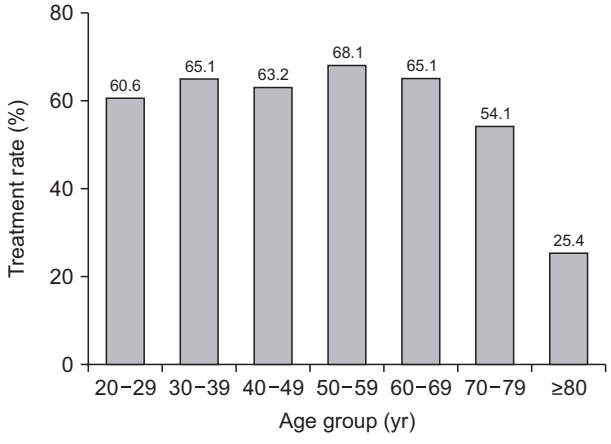

Fig. 4. Treatment rate according to age groups.

DISCUSSION

In 2019 in Korea, new HCV infection was identified in 8,810 patients, with new HCV infection rate of 17.2 per 100,000 person-years. Among 8,810 patients diagnosed with hepatitis C in 2019, 78.2% were linked to care and 58.1% were treated. To the best of our knowledge, this is the first study to show the prevalence, linkage to care, and treatment rates using a national database in Korea. This study aimed to analyze Korea's progress in reaching the 2030 HCV elimination target specified by the World Health Organization.

Since 2017, all confirmed hepatitis C patients (HCV RNA positive) in Korea are expected to be reported and managed by a monitoring system managed by the KDCA. The number of patients reported to the KDCA were 6,396, 10,811, and 9,810 in 2017, 2018, and 2019, respectively. Among 9,810 patients reported to the KDCA as having an HCV infection in 2019, 1,000 patients were duplicates reported from different centers; we finally analyzed 8,810 patients. In the United States in 2019, a total of 4,136 new cases of acute hepatitis C were reported to the Centers for Disease Control and Prevention from 44 states, and based on this number, the Centers for Disease Control and Prevention estimated 57,500 new acute cases of HCV in 2019.[12] From 2010 to 2019, the number of estimated annual acute HCV infections increased by 387% in this study. The number of new cases was highest in the patient age range of 20 to 39 years. This may be a result of the ongoing opioid epidemic and associated injection drug use. In contrast, in Korea, the problem of drug abuse occurring mainly in young people is small, and the HCV incidence is significantly higher in older adults because the data includes newly reported chronic hepatitis C cases rather than reflecting only acute HCV infection. In the future, long-term follow-ups of 10 years or more should be analyzed to determine the change in number of HCV cases reported by the KDCA, and efforts to differentiate acute infection from newly reported chronic hepatitis C should also be made.

The mean age of patients diagnosed with HCV in 2019 was 69.2 years, and the majority (80%) had comorbidities. The comorbidities of cirrhosis (31.3%) and HCC (20.2%) in HCV patients in our study were higher than those from the multicenter cohort study by Nam (cirrhosis, 17.1%; HCC, 13.7%).[13] This value is high, even after considering overestimation, because this analysis is based on a big data investigation using operational definitions. Although this study showed a high rate of care cascade inpatients with HCV in Korea, the high rates of comorbid cirrhosis and HCC in newly diagnosed patients with HCV indicate a delayed diagnosis of HCV. Therefore, the diagnosis of HCV in its early stages through active screening tests and complete virus eradication is important for reducing disease burden.

The linkage to care rate was 78.2% in our study. In another Korean study, the linkage to care rate was defined as the rate of patients tested for HCV RNA over those with anti-HCV-positivity and was found to be 60%.[14] In a global modeling study of the HCV care cascade between 2015 and 2020, 33% of total HCV viremic patients received diagnosis, and 45% of diagnosed patients were treated.[15] As a high income area, in South Korea, 45% of diagnosed patients were treated with an annual treatment rate of 6.1%, showing a higher rate of linkage to care than other regions. Our definition of linkage to care was more comprehensive because the rate was defined as two or more visits to medical institutions anywhere in the country with HCV as the main disease code; thus, the actual rate may have been higher. There was no difference in the rate between men and women, but it was significantly lower in patients aged 70 years or older. Considering that the number of patients aged 70 years or older accounted for over 30%, measures to increase the linkage to care and treatment in older patients are important.

The treatment rate in our study was defined as those who were treated within 1.5 years of diagnosis. However, since the end of follow-up in our data was December 2020, patients with a follow-up period of less than 1 year were included. Thus, the treatment rate would be increased with a longer follow-up period. Previous studies have reported treatment rates of 13.5%[16] and 53.8%.[13] However, those studies did not include patients treated in a hospital which differed from the hospital in which the patient was diagnosed. Specifically, the treatment rate in 2019 provides an overview of the treatment circumstances 5 years after DAA was widely distributed in Korea. With the introduction and spread of DAA in 2015, patients who had not been treated in the past would have been recommended treatment from 2015 to 2018. Therefore, to gradually increase the treatment rate to 80% by 2030, it is necessary to identify the characteristics of patients who are not yet receiving treatment and to motivate them to receive treatment alongside diagnosis of new patients. Since the number of untreated patients after diagnosis was significantly higher in men and those over 80 years of age than in women and younger patients, follow-up in these groups is required.

This study had several limitations. First, the current concept of newly identified HCV infection includes both newly reported chronic HCV infection and newly developed acute HCV infection. Thus, separate reporting system for these two diseases should be prepared in the future. Second, since this study only included patients registered as positive for HCV RNA with the KDCA in 2019, the number of patients may have been underestimated. Third, the 1.5-year for defining the linkage to care rate and treatment rate was an arbitrary standard. Fourth, as the KNHIS does not allow DAAs for patients with HCC, treatment rate of 58.1% may have been underestimated. Fifth, it is difficult to determine detailed clinical data, such as HCV RNA of individual patients, and whether HCV elimination was achieved. Finally, this study only contained data from 2019. However, as all HCV patients have been mandatorily registered in the KDCA since 2017, the 2019 data should serve as a cornerstone for serially examining the status of HCV epidemiology in Korea. To achieve the 2030 HCV elimination goal of a treatment rate of 80%, active efforts will be needed to increase the linkage between care and treatment rates.

The new HCV infection rate was 17.2 per 100,000 person-years (n=8,810) in Korea in 2019. Among newly infected HCV patients, the linkage to care rate was 78.2% and the treatment rate was 58.1%. To reach the goal of HCV elimination by 2030, it is necessary to collect annual statistics on the incidence and care cascade of HCV and establish proper strategies to improve diagnosis and linkage to care.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

Study concept and design: D.W.J., M.J.K., A.J., Y.E.C. Data acquisition: D.W.J., M.J.K., A.J., E.L.Y., H.G.S., Y.E.C. Data analysis and interpretation: D.W.J., M.J.K., A.J., Y.E.C. Drafting of the manuscript: D.W.J., M.J.K., A.J., Y.E.C. Critical revision of the manuscript for important intellectual content: D.W.J., M.J.K., A.J., Y.E.C. Statistical analysis: D.W.J., M.J.K., A.J., E.L.Y., Y.E.C., J.L. Administrative, technical, or material support; study supervision: D.W.J., M.J.K., A.J., Y.E.C. Approval of final manuscript: all authors.

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SUPPLEMENTARY MATERIALS

Supplementary materials can be accessed at https://doi.org/10.5009/gnl220322.

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