



Preliminary Results of Teleconsultations Temporarily Allowed during the COVID-19 Pandemic

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Purpose: During the COVID-19 pandemic, Korea has temporarily expanded coverage of teleconsultation to ensure access to essential health services. As a preliminary study, we investigated service utilization patterns and the characteristics of doctors and patients involved in these temporary teleconsultation services.

Materials and Methods: Using national health insurance claims data from February 23, 2020 to June 30, 2020 from the Health Insurance Review and Assessment Service, 228269875 cases were identified. Among them, 567390 cases that received teleconsultation services were included in our study. We performed descriptive analyses according to the types of healthcare institutions.

Results: In total, 6193 healthcare institutions provided teleconsultation. Of these, 5466 (88.3%) were clinics. Physicians providing teleconsultations were most likely to be doctors of internal medicine (34.0%) or pediatricians (7.0%) and based in the Seoul Metropolitan area (30.4%). In terms of patients undergoing teleconsultation, the most common major disease categories treated were circulatory system diseases (I00–I99). In a detailed analysis, hypertensive diseases (I10–I15) were the most common diagnoses, with a total of 88726 cases (15.6%), followed by diabetes mellitus at 60298 cases (10.6%). The proportion of Medical Aid recipients receiving teleconsultations was higher (9.5%) than other socioeconomic groups. Among all participants, 356622 cases (84.6%) were from a return visit, and 108838 cases (19.2%) received teleconsultation services without being prescribed drugs.

Conclusion: Temporarily allowed teleconsultation services were provided mostly to the following patients: 1) those scheduled for revisitation, 2) those with chronic diseases, and 3) those living in pandemic hotspots.

Key Words: SARS-CoV-2, COVID-19, telemedicine, national health insurance, Korea

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INTRODUCTION

The COVID-19 pandemic crisis has exerted tremendous pressure on health systems around the world. As the pandemic continues to strain global societies, it remains indispensable to maintain or ensure social distancing and limited face-to-face contact in order to prevent super spreader events.¹⁻⁴ In particular, telemedicine has helped reduce the risk of potential exposure to the virus while maintaining essential health services. By definition, telemedicine refers to a practice of medicine that delivers healthcare services at a distance using information and communications technology. Prior to the COVID-19 pandemic, telemedicine services were provided only in limited circumstances to ensure healthcare access and to im-

prove patient experiences.^{5,6} Moreover, telemedicine services were not allowed in South Korea due to the following aspects: 1) lack of evidence on the efficacy and cost-effectiveness of telemedicine and 2) a lack of agreement on optimal telemedicine strategies through which to reach target populations and methods of services to be provided.

However, amid these unprecedented times, South Korea initiated steps to expand coverage of telemedicine, especially teleconsultations, on a temporary basis from February 24, 2020, ensuring access to essential health services for the greater population. In the initial stages, teleconsultation services were similar to the price of traditional in-person visits (\$11–16, approximately) at all types of institutions. However, from May 2020, clinics have been paid an additional amount (\$3–5) for teleconsultation as part of incentives set by the Korean government. At the onset of the COVID-19 pandemic, all healthcare providers were able to participate in providing teleconsultation services without any restrictions and to select target patients independently based on medical necessity.

In this study, we aimed to examine the preliminary results of the use of teleconsultation services temporarily allowed in South Korea during the COVID-19 pandemic. Additionally, we further investigated the characteristics of healthcare providers and patients involved in teleconsultation services according to region, levels of care, and underlying medical conditions.

MATERIALS AND METHODS

Study design, setting, and population

This retrospective, observational study was conducted to determine who provided and who received teleconsultation services. We used claims data from the Health Insurance Review and Assessment Service (HIRA) in South Korea from February 23, 2020, to June 30, 2020. South Korea has implemented man-

datory universal health coverage for all residents since 1989. More than 97% of the population is enrolled in the National Health Insurance (NHI) scheme; the remaining 3% who are considered vulnerable populations are covered through a government-subsidized Medical Aid program.^{7,8} All healthcare providers in South Korea are to submit claims to the HIRA for reimbursement for the services they provided to National Health Insurance and Medical Aid beneficiaries. Accordingly, the HIRA is able to collect and manage comprehensive data on healthcare utilization, diagnoses, and care provided across the country. Of the 228269875 cases submitted to HIRA during the study period, 567390 cases covered teleconsultation services and included in our study.

Data collection

Our study results were based on the number of consultations, not on an individual basis for each patient. The billing data sent to HIRA from each healthcare institution includes the diagnosis, the history of treatment, including drug prescription and surgery, the number of visits, and the number of days of hospitalization. In addition, HIRA collects information about healthcare institutions, such as type, region, healthcare provider, and medical equipment. Each patient's data are linked through a unique identifier code. We used this code to merge separate datasets for history of treatment, diagnosis, and general information (Fig. 1). We identified the participating healthcare providers as those who submitted claims on teleconsultation at least once during the study period. Regions were defined as areas in which the healthcare institutions were located and categorized into three regions (Seoul metropolitan area, Daegu and Gyeongsangbuk province, and others). Notably, South Korea experienced regional differences in the surge of COVID-19 patients, during the first wave in specific, which formed three main categories that divided the country based on the status of regional hotspots: 1) severely affected Daegu and Gyeong-

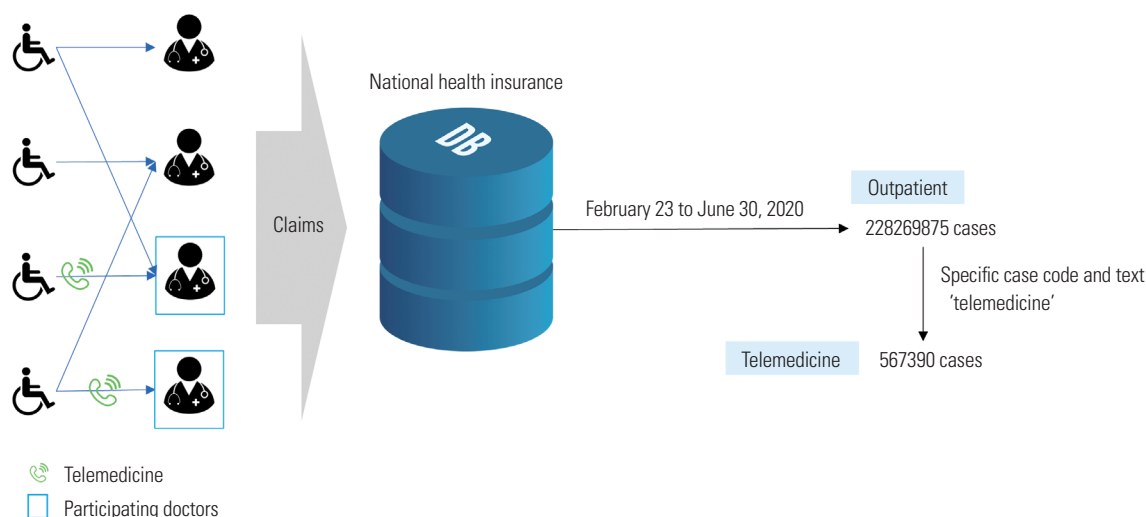


Fig. 1. Data collection and processing workflow.

sangbuk regions as the epicenter of the national outbreak between February and March 2020⁹; 2) a densely populated metropolitan area where more than half of the country's population lives;¹⁰ and 3) other remaining regions that do not fall under these criteria.

The principal diagnosis of each teleconsultation service provided was identified from the primary diagnosis listed on claims under the Korean Standard Classification of Diseases and Causes of Death-7 (KCD-7), which is modified from the International Classification of Diseases and Related Health Problems, 10th edition (ICD-10). Comorbidities were summarized using the Charlson Comorbidity Index: this index includes 17 comorbidity categories, and each condition is assigned a score of 1, 2, 3, or 6, with the sum of the index scores indicating the disease burden and estimated risk of mortality.¹¹ Furthermore, we identified patients with severe and complex medical conditions, such as cancer, cardiovascular diseases, rare diseases, and severe incurable diseases by using certain claims codes that are assigned to those conditions for lower co-payment. A first-visit patient was defined as one who had not visited healthcare providers or did not seek care for the identified diagnosis within the last 6 months. We also examined whether consultation was provided only or whether drugs were also prescribed at the point of care.

Statistical analyses

We performed descriptive analysis in this study, presenting baseline characteristics as means with standard deviations or numbers with percentages. We divided all healthcare institutions according to their levels of care. Thereafter, the participation rate of healthcare institutions, number of consultations, and costs pertaining to teleconsultations were calculated. For each doctor, we assessed his/her regional location, levels of care, and type of specialty. Lastly, we examined each patient's diagnosis, disease severity, age, type of health insurance coverage, status of the first visit, and services provided in detail. Statistical analyses were performed with SAS software (version 9.4; SAS Institute, Cary, NC, USA)

Ethics statement

The Institutional Review Board (IRB No. 2020066) approved this study. The requirement for informed consent was waived, as this study analyzed an anonymous dataset only.

RESULTS

In total, 6193 healthcare institutions provided teleconsultation services at least once between February 23, 2020 and June 30, 2020. Regarding the type of institution, 5466 clinics participated, accounting for 88.3% of all institutions providing teleconsultation services. The participation rate of teleconsultation services among tertiary teaching hospitals accounted for 0.5%

Table 1. Healthcare Institution, Utilization, and Cost of Teleconsultation

	Total	Teleconsultation participated	p value
Healthcare facility, n (%)			<0.001
All	34481 (100)	6193 (100)	
Tertiary teaching hospital	42 (0.1)	30 (0.5)	
General hospital	317 (0.9)	192 (3.1)	
Hospital	1492 (4.3)	406 (6.6)	
Long-term care hospital	1463 (4.2)	99 (1.6)	
Clinic	31167 (90.4)	5466 (88.3)	
Healthcare utilization, n (%)			<0.001
All	228269875 (100)	567390 (100)	
Tertiary teaching hospital	11113863 (4.9)	87767 (15.5)	
General hospital	20516061 (9.0)	152040 (26.8)	
Hospital	18066920 (7.9)	49028 (8.6)	
Long-term care hospital	1034838 (0.5)	10631 (1.9)	
Clinic	177538193 (77.8)	267924 (47.2)	
Healthcare cost, US dollars (%)			<0.001
All	2984822805 (100)	8173475 (100)	
Tertiary teaching hospital	257990953 (8.6)	1548426 (18.9)	
General hospital	323005346 (10.8)	2144631 (26.2)	
Hospital	236224856 (7.9)	575864 (7.1)	
Long-term care hospital	11332985 (0.4)	111070 (1.4)	
Clinic	2156268665 (72.2)	3793484 (46.4)	

Percentages may not total 100 because of rounding.

Table 2. Characteristics of Teleconsultation Participating Doctors

	Total (n=143848)	Teleconsultation participated (n=17185)	p value
Region, n (%)			<0.001
Seoul metropolitan area	35413 (24.6)	5218 (30.4)	
Daegu and Gyeongsangbuk province	14319 (10.0)	2906 (16.9)	
Other area	94116 (65.4)	9061 (52.7)	
Type of healthcare facility, n (%)			<0.001
Tertiary teaching hospital	18428 (12.7)	4360 (25.4)	
General hospital	27055 (18.6)	3871 (22.5)	
Hospital	44151 (30.3)	1996 (11.6)	
Long-term care hospital	6728 (4.6)	288 (1.7)	
Clinic	49283 (33.8)	6687 (38.9)	
Specialty, n (%)			<0.001
Internal medicine	65140 (24.5)	5892 (34.0)	
Family medicine	10195 (3.8)	645 (3.7)	
General surgery	30558 (11.5)	914 (5.3)	
Pediatrics	9575 (3.6)	1204 (7.0)	
Obstetrics and gynecology	15455 (5.8)	719 (4.2)	
Otolaryngology	16404 (6.2)	642 (3.7)	
Orthopedics	36097 (13.6)	1199 (6.9)	
Psychiatry	15140 (5.7)	736 (4.3)	
Others	67040 (25.2)	5381 (31.1)	

Percentages may not total 100 because of rounding.

Table 3. Characteristics of Patients who Participated in Teleconsultations

Diagnosis	Type of healthcare facility				p value	
	All	Tertiary teaching hospital	General hospital	Hospital		Long-term care hospital
1st (most common)	Diseases of the circulatory system (I00–I99)	Diseases of the circulatory system (I00–I99)	Diseases of the circulatory system (I00–I99)	Mental and behavioral disorders (F00–F99)	Mental and behavioral disorders (F00–F99)	Diseases of the circulatory system (I00–I99)
2nd	Endocrine, nutritional and metabolic diseases (E00–E90)	Neoplasms (C00–D48)	Endocrine, nutritional and metabolic diseases (E00–E90)	Endocrine, nutritional and metabolic diseases (E00–E90)	Diseases of the circulatory system (I00–I99)	Endocrine, nutritional and metabolic diseases (E00–E90)
3rd	Diseases of the respiratory system (J00–J99)	Endocrine, nutritional and metabolic diseases (E00–E90)	Mental and behavioral disorders (F00–F99)	Diseases of the circulatory system (I00–I99)	Endocrine, nutritional and metabolic diseases (E00–E90)	Diseases of the respiratory system (J00–J99)
4th	Mental and behavioral disorders (F00–F99)	Diseases of the nervous system (G00–G99)	Diseases of the musculoskeletal system and connective tissue (M00–M99)	Diseases of the respiratory system (J00–J99)	Diseases of the nervous system (G00–G99)	Diseases of the digestive system (K00–K93)
5th	Diseases of the musculoskeletal system and connective tissue (M00–M99)	Diseases of the musculoskeletal system and connective tissue (M00–M99)	Diseases of the genitourinary system (N00–N99)	Diseases of the musculoskeletal system and connective tissue (M00–M99)	Diseases of the respiratory system (J00–J99)	Diseases of the musculoskeletal system and connective tissue (M00–M99)
Charlson comorbidity index, n (%)						<0.001
0	239472 (42.2)	28213 (32.2)	48469 (31.9)	20819 (42.5)	3397 (32.0)	138574 (51.7)
≥1	327918 (57.8)	59554 (67.9)	103571 (68.1)	28209 (57.5)	7234 (68.1)	129350 (48.3)
Severe and complex conditions, n (%)						<0.001
Yes	38849 (6.9)	21073 (24.0)	11880 (7.8)	2123 (4.3)	714 (6.7)	3059 (1.1)
No	528541 (93.2)	66694 (76.0)	140160 (92.2)	46905 (95.7)	9917 (93.3)	264865 (98.9)
Age, n (%)						<0.001
0–18	37751 (6.3)	5551 (3.0)	4566 (12.7)	6235 (0.9)	95 (8.0)	21304 (6.7)
19–44	77249 (14.7)	12924 (9.7)	14795 (12.9)	6308 (6.5)	688 (15.9)	42534 (13.6)
45–64	212839 (35.6)	31267 (33.9)	51596 (36.7)	17998 (31.7)	3370 (40.5)	108608 (37.5)
65–79	160284 (32.1)	28128 (34.6)	52652 (24.4)	11953 (30.3)	3220 (24.0)	64331 (28.3)
≥80	79267 (11.3)	9897 (18.7)	28431 (13.3)	6534 (30.7)	3258 (11.6)	31147 (14.0)
Type of insurance, n (%)						<0.001
National Health Insurance Service Beneficiaries	513578 (90.5)	83407 (95.0)	135759 (89.3)	35862 (73.2)	7710 (72.5)	250840 (93.6)

Table 3. Characteristics of Patients who Participated in Teleconsultations (Continued)

	Type of healthcare facility					p value
	All	Tertiary teaching hospital	General hospital	Hospital	Long-term care hospital	
Medical Aid recipients	53812 (9.5)	4360 (5.0)	16281 (10.7)	13166 (26.9)	2921 (27.5)	17084 (6.4)
New patient in 6months, n (%)						
Yes	64939 (15.4)	9331 (13.1)	9282 (8.4)	4848 (16.0)	566 (9.9)	40912 (20.1)
No	356622 (84.6)	62131 (86.9)	101622 (91.6)	25535 (84.0)	5149 (90.1)	162185 (79.9)
Services related to teleconsultation, n (%)						
Medical consultation only	108838 (19.2)	18500 (21.1)	18236 (12.0)	17101 (34.9)	3337 (31.4)	51664 (19.3)
Medical consultation and drug prescription	458552 (80.8)	69267 (78.9)	133804 (88.0)	31927 (65.1)	7294 (68.6)	216260 (80.7)
Healthcare cost per person, US dollars, mean (SD)	20 (89)	28 (149)	22 (124)	27 (40)	28 (37)	16 (12)

Percentages may not total 100 because of rounding.

of all participating institutions. The total number of teleconsultations claims was 567390 cases, while clinics had the highest participation rate (47.2%). Although the number itself is not high, long-term care hospitals provided 10631 teleconsultation cases. The total amount of teleconsultations during the study period accounted for \$8173475, and 46.4% of the total amount of teleconsultation bills was claimed by clinics (Table 1).

When analyzing teleconsultation services by region, in the Seoul Metropolitan area, 5218 doctors provided teleconsultation services in total, with this being the greatest number of doctors by region (30.4%). The hardest-hit Daegu-Gyeongsangbuk province accounted for a lower number of doctors who participated in teleconsultation (n=2906, 16.9%), although the proportion of teleconsultation participating doctors was higher than the proportion of doctors in this region (10.0%). For each type of healthcare institution, the number of participating doctors was highest in clinics at 6687 (38.9%), followed by doctors at tertiary teaching hospitals (n=4360, 25.4%). By specialty, doctors of internal medicine (n=5892, 34.0%) and pediatricians (n=1204, 7.0%) participated the most (Table 2).

The most common major disease category among individuals who received teleconsultations were circulatory system diseases (I00–I99), followed by endocrine, nutritional, and metabolic diseases (E00–E90), and respiratory diseases (J00–J99). Neoplasms (C00–D48) were recorded as the second most prevalent at tertiary teaching hospitals, and mental and behavioral diseases were ranked first at long-term care hospitals. Of the total number of patients who received teleconsultation services, 327918 (57.8%) patients had a Charlson Comorbidity Index score of 1 or higher, and Charlson Comorbidity Index scores were higher at tertiary teaching hospitals, general hospitals, and long-term care hospitals. The number of patients with severe and complex conditions, who are subject to a low co-payment policy, was greatest at tertiary teaching hospitals, with a frequency of 21073 (24.0%) patients. This indicates that patients with severe conditions are more likely to be admitted to higher levels of care. In terms of age, most cases were from patients between 45–64 (35.6%) and 65–79 (32.1%) years. Although Medical Aid recipients are responsible for 3% of the total population in South Korea, they accounted for 9.5% of the teleconsultation services. The proportions of Medical Aid recipients were disproportionally high at hospitals and long-term care hospitals at 26.9%, and 27.5%, respectively. Among all patients included in this study, 356622 (84.6%) cases were for a return visit to healthcare institutions, and the rate of first-visit patients was slightly higher at clinics (20.1%). There were 108838 cases (19.2%) that only received teleconsultation services without any drugs prescribed, and the corresponding rate was highest in hospitals and long-term care hospitals, 34.9%, and 31.4%, respectively. The cost per patient was lowest at the clinic level at \$16 (SD=12) (Table 3).

In a detailed analysis of the diagnoses of patients who participated in teleconsultations, hypertensive diseases (I10–I15)

were found to be the most common diagnoses, with a total of 88726 cases (15.6%), followed by diabetes mellitus (E10–E14) at 60298 cases (10.6%) and diseases of the esophagus, stomach, and duodenum (K20–K31) at 20009 cases (3.5%). The top 10 diagnoses accounted for 50.7% of all teleconsultation cases at the clinic level. In tertiary teaching hospitals, ischemic heart diseases (I20–I25) were the most common diagnosis at 5880 (6.7%) cases, followed by cerebrovascular diseases (I60–I69) at 5175 cases (5.9%), and the top 10 diagnoses accounted for 41.6% of all teleconsultations. This indicated that teleconsultations were provided for a large variety of diagnoses. Among long-term care hospitals, organic, including symptomatic, mental disorders (F00–F09) and schizophrenia, schizotypal, and delusional disorders (F20–F29) ranked first (n=2746, 25.8%) and second (n=2193, 20.6%), respectively, accounting for 46.5% of all teleconsultations, indicating that psychiatric diseases were most common in these institutions (Supplementary Table 1, only online).

Meanwhile, in long-term care hospitals, the top 10 diseases were responsible for 82.5% of diagnoses, and teleconsultation services were concentrated on major diagnoses. In clinics, 69837 cases (26.1%) of hypertension and 35628 cases (13.3%) of diabetes were recorded. As for the volume of teleconsultations during specific periods of time, February and March reported the highest number of COVID-19 cases and had the most teleconsultations across all levels of care (tertiary teaching hospitals, general hospitals, hospitals, and clinics), and this number was particularly high in general hospitals and clinics. Notably, there was a different trend observed in May after incentives

were applied to clinics when providing teleconsultations. In result, we saw an increase in teleconsultation services at clinics, while all other types of healthcare institutions experienced decreases in such services (Fig. 2), suggesting that incentive policies within clinics may attribute to an increase in the number of teleconsultations during the COVID-19 pandemic.

DISCUSSION

In South Korea, teleconsultation services were temporarily allowed in response to the COVID-19 pandemic from February 24, 2020, although the volume or details of services provided has yet to be studied. When we examined the volume of teleconsultations at the national level during the study period, clinics participated the most in terms of the number of participating institutions. Physicians providing teleconsultations were most likely to be doctors of internal medicine or pediatricians, based in the Seoul Metropolitan area, and practicing at clinics. Also, patients with circulatory and endocrine diseases, especially hypertension and diabetes mellitus, used teleconsultation services the most, which is consistent with cases in the United States.¹² Considering the levels of care, tertiary teaching hospitals provided more teleconsultation services to severe patients. Medical Aid recipients received more teleconsultation services than patients covered under the national health insurance scheme. Among beneficiaries who received teleconsultations, before having access to these services, 15.4% of patients had not been treated for the presenting diagnosis within the

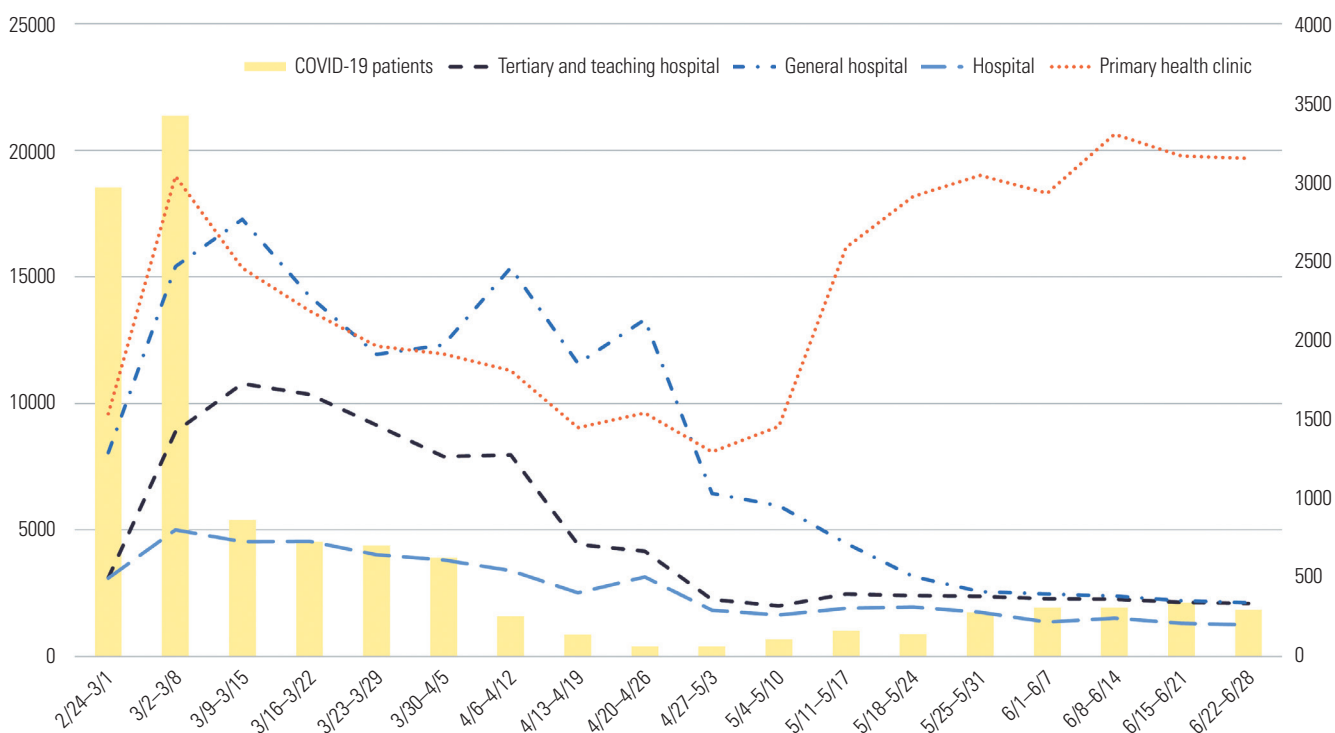


Fig. 2. Teleconsultations by period and incentive offered.

past 6 months, and 80.8% received drug prescriptions through teleconsultations. Lastly, we noted that the participation of clinics significantly increased after the introduction of incentives.

A similar trend of increasing teleconsultation services has been observed across the world since the beginning of the COVID-19 pandemic in 2020. In the United States, the number of telehealth visits increased by 35%, while in-person visits decreased by up to 59%. In the UK, a dramatic rise in telehealth services was reported right after the COVID-19 pandemic began: the volume of virtual visits increased from 25% to 75% of the total, and more than 97% of healthcare institutions delivered non-face-to-face services. Healthcare issues related to prisons where telehealth services were not adopted or provided during the pandemic were also noted.¹³⁻¹⁵ As teleconsultation services are intended to reduce potential infectious exposure, we also found that the teleconsultation services were more likely to be provided at the epicenter of outbreaks and to increase at the time of a spike in new cases. In our study, only 567390 cases (0.25%) out of 228269875 cases of medical use used teleconsultation. Although the trend is similar, the proportion is very low, compared to teleconsultation rates in other countries. The reason for these results is that both medical providers and patients have low awareness of teleconsultation: in a previous study, the barriers to teleconsultation included difficulties in connecting to the phone, difficult to understand patient status, or insufficient communication.¹⁶

Reportedly, the use of teleconsultation improves access to healthcare services¹⁷ and maintains high patient satisfaction,^{18,19} even in times of a pandemic. In order to prepare and respond to the recurrent outbreaks of infectious diseases in the future, it is necessary to discuss the direction teleconsultation is taking. Currently, there are key challenges to be addressed regarding current teleconsultation services. First, low-income and older populations may face difficulties in dealing with digital technology; therefore, the introduction of teleconsultation requires close attention to ensure that existing health inequalities are not exacerbated.¹⁷ Second, training and standard guidelines for teleconsultation services should be provided to health care practitioners who are not familiar with new technology.²⁰ Third, adequate compensation for teleconsultation services is necessary, as it is directly associated with participation, as demonstrated in our study results.²¹ An increase in teleconsultation services was observed after the incentives were applied, which possibly verifies the effectiveness of appropriate remuneration. It is also necessary to generate evidence on the efficacy and cost-effectiveness of teleconsultation. In our study, we only analyzed data from early in the COVID-19 pandemic, although we expect to be able to provide evidence through long-term data collection and analysis in the future.

We analyzed claims data to assess the current state of teleconsultation use at the national level in Korea. We examined both healthcare providers and patients to identify characteristics of temporarily allowed teleconsultation services. There

are still some limitations that mainly arise from claims data. Due to the availability of claims data, our study period was restricted to before and after the first wave of COVID-19; thus, changes in teleconsultation use throughout the prolonged pandemic could not be identified. Another limitation is that it was not possible to examine satisfaction among healthcare providers and patients or the quality of care provided. Future research is required to measure and understand the quality of teleconsultation services.

In conclusion, we noted that teleconsultations temporarily allowed during the COVID-19 pandemic were provided most often to the following patients: 1) those scheduled for revisitation; 2) those with chronic diseases, such as hypertension and diabetes mellitus; and 3) those residing in pandemic hotspots. These trends in patient utilization of teleconsultation services in South Korea paralleled global trends. Findings from the study provide implications on suitable populations for teleconsultation and support the need for adequate reimbursement that incentivizes healthcare providers to offer teleconsultation services. Further research on the quality of care through teleconsultation is necessary to prepare and respond to recurring outbreaks of infectious disease henceforth.

AUTHOR CONTRIBUTIONS

Conceptualization: Jin Yong Lee, Jee-Ae Kim, Hansang Kim, and Hyejin Lee. **Data curation:** Hansang Kim, Soomin Kim, and Sang-A Cho. **Formal analysis:** Hansang Kim, Soomin Kim, and Sang-A Cho. **Funding acquisition:** Choon-Seon Park. **Investigation:** Jee-Ae Kim and Choon-Seon Park. **Methodology:** Jin Yong Lee, Jee-Ae Kim, Hyejin Lee, and Seung Mi Yoo. **Project administration:** Jee-Ae Kim and Choon-Seon Park. **Resources:** Jee-Ae Kim and Soomin Kim. **Software:** Hansang Kim, Soomin Kim, and Sang-A Cho. **Supervision:** Jin Yong Lee and Jee-Ae Kim. **Validation:** Hansang Kim and Soomin Kim. **Visualization:** Hansang Kim and Hyejin Lee. **Writing—original draft:** Hyejin Lee, Hansang Kim, and Seung Mi Yoo. **Writing—review & editing:** Jin Yong Lee, Jee-Ae Kim, Hyejin Lee, Seung Mi Yoo, Choon-Seon Park, Soomin Kim, and Sang-A Cho. Approval of final manuscript: all authors.

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