

IV. 新型コロナウイルス感染症に関する論文等

IV. 1 Safe return to elective surgery following a coronavirus disease outbreak: An observational study

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Abstract

Background: Resumption of suspended surgical services following coronavirus disease (COVID-19) outbreaks is challenging in routine clinical practice. We investigated the results of pre-admission screening for patients awaiting surgery during the COVID-19 pandemic.

Methods: This retrospective study included 100 consecutive patients who underwent surgical procedures under general anesthesia at a single institution in May 2020. Patients were instructed to avoid nonessential outings and record symptoms and temperatures every day over 2 weeks before admission. All patients underwent real-time reverse transcriptase polymerase chain reaction (RT-PCR) tests and chest computed tomography (CT) the day before admission.

Results: In addition to clinical findings, pre-admission RT-PCR results were negative, and CT imaging did not suggest COVID-19 infection in any patient. All surgical procedures were performed as scheduled; the virus was not detected in any extubated tracheal tubes in the operating room. No patient developed postoperative COVID-19 infection, and no nosocomial infections occurred throughout the study period and over 1 month thereafter.

Conclusions: As confirmed by negative PCR test results of extubated tracheal tube swabs, we observed that 2-week avoidance of nonessential outings before admission for surgery, combined with RT-PCR testing and chest CT shortly before admission enabled successful resumption of elective surgeries at a hospital that experienced a COVID-19 outbreak.

Key words : outings, SARS-CoV-2, screening, surgery, tracheal tube

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INTRODUCTION

The coronavirus disease (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has negatively affected surgical and medical services to a significant extent. Our hospital in Kobe City, Hyogo Prefecture, Japan is a tertiary care center that provides treatment for specified infectious diseases. Patients with COVID-19 were admitted to our hospital since early March 2020, and we acknowledge that nosocomial transmission is likely to have occurred among healthcare workers and patients. We identified 35 patients with confirmed COVID-19 positive test results, and 242 (>10%) of all healthcare workers were isolated at home following close contact with patients with COVID-19 infection, which necessitated deferral of elective surgeries and emergency department closure. Nosocomial transmission was well controlled at the end of April 2020, despite continued admissions of patients with severe COVID-19. We resumed elective surgeries on May 11 2020 after 3-week suspension. However, owing to the lack of recommendations or guidelines regarding resumption of surgical procedures during a COVID-19 outbreak, we proposed a screening method to safely resume elective procedures. We aimed to minimize the risk of postoperative COVID-19 pneumonia, which invariably results in high mortality and also to prevent nosocomial infections, particularly those associated with the use of general anesthesia and aerosol generation during intubation and extubation maneuvers¹⁻³⁾. We report the outcomes of our screening strategy at a hospital that experienced a COVID-19 outbreak.

I . PATIENTS AND METHODS

We retrospectively investigated consecutive patients who underwent an elective surgical procedure under general anesthesia at Kobe City Medical Center General Hospital between May 11, 2020 and June 2, 2020. Figure 1 shows a flowchart of the screening procedure used before hospital admission.

Patients were instructed to avoid all nonessential outings such as traveling and dining out and record symptoms and temperatures daily over 2 weeks before admission. Patients were informed that if they developed symptoms such as fever ($\geq 37.5^{\circ}\text{C}$), cough,

throat pain, anosmia, or dysgeusia, they should contact a physician via phone to confirm whether they could be admitted as scheduled. Contact with an individual with confirmed or suspected COVID-19 was to be reported. Patients underwent real-time reverse transcriptase polymerase chain reaction (RT-PCR) testing for SARS-CoV-2 using nasopharyngeal swabs, as well as plain chest computed tomography (CT) the day before admission. Furthermore, patients were interviewed to obtain information regarding lifestyle and symptoms over 2 weeks prior to admission.

Nasopharyngeal swabs for RT-PCR testing were obtained by otolaryngologists at a booth prepared outside the hospital (Fig. 2). RT-PCR tests were performed in accordance with the protocol established by the National Institute of Infectious Diseases in Japan⁴⁾. Using thin-slice CT imaging, we screened for ground-glass opacities or consolidation, which is occasionally associated with COVID-19^{5,6)}. Images were reviewed by radiologists, as well as pulmonologists for comprehensive evaluation. CT was not performed in pediatric patients who needed sedation.

Moreover, we performed RT-PCR testing of swabs obtained from cuffs and tips of tracheal tubes shortly after extubation (Fig. 2) because these samples tend to show more specific results compared with those obtained following testing of nasopharyngeal swabs. Patients who were not extubated in the operating room were excluded from this study. Hypothetically, this double-check screening minimizes contamination during postoperative management and enables close observation of asymptomatic patients in whom the SARS-CoV-2 is detected. Postoperative pulmonary complications, including COVID-19 pneumonia and 30-day mortality were evaluated in addition to nosocomial infection that was monitored throughout the study period and for 1 month thereafter.

The study was approved by the Ethics Committee of our hospital (No. 20022). Written informed consent was waived in accordance with the Council for International Organizations of Medical Sciences guidelines.

II . RESULTS

Of the 132 patients who underwent surgery under general anesthesia during the study period, 100 were investigated in this study. We excluded 23 patients

who were considered emergency or urgent cases, 6 patients who did not undergo extubation in the operating room, and 3 patients for reasons described in Figure 3. Table 1 shows patient characteristics and types of surgeries performed. With regard to comorbidities associated with an increased risk of COVID-19-induced mortality ⁷⁾, hypertension was reported in 39%, diabetes in 17%, chronic renal failure necessitating dialysis in 5%, cerebrovascular disease in 5%, and cardiovascular disease in 4% of patients; 22% of patients showed two or more of these aforementioned comorbidities.

All patients agreed to preoperative screenings and instructions and the written consents were obtained when a surgery was planned. Actually, they all avoided nonessential outings over 2 weeks prior to admission, as instructed. One patient developed fever >38°C for 3 days within a week of admission, which was attributed to urinary tract infection and was successfully treated using oral antibiotics, with normal chest CT images. Two patients reported nonspecific symptoms (Table 2).

CT was not performed in any of the four pediatric patients included in the study. Approximately 50% (44 of 96) of the patients included in this study showed completely normal CT findings. Most reported findings, such as linear opacities, small calcified nodules, endoluminal secretions, emphysema, fibrosis, and bronchiectasis were nonspecific for COVID-19 infection. Ground-glass opacities and infiltration were observed in four patients; these findings were further reviewed by pulmonologists and were attributed to aspiration pneumonia, bacterial pneumonia, or atypical adenomatous hyperplasia (Table 2). RT-PCR assays did not detect SARS-CoV-2 positivity in any of the 100 nasopharyngeal swabs evaluated in this study.

All surgeries were performed as scheduled after screening. SARS-CoV-2 was not detected in any sample obtained from the extubated tracheal tubes in 100 patients. Ninety-six patients were discharged uneventfully, and four patients were hospitalized for 30 days. Two patients developed aspiration (not COVID-19) pneumonia and received antibiotics. No 30-day mortality was observed, and no patient developed nosocomial infection throughout the study peri-

od or over 1 month thereafter.

Figure 4 shows daily numbers of individuals with confirmed COVID-19 in Kobe City from the date when we decided to resume surgical services and to the end of the study period. Eight individuals were confirmed during 23 days of the study period, including 2 in the thirties, 2 in the forties, and 4 in the seventies. (Data available at Kobe City Official Site. https://www.city.kobe.lg.jp/a73576/kenko/health/infection/protection/covid_19.html)

III . DISCUSSION

A month after the World Health Organization declared the COVID-19 outbreak a pandemic on March 11, 2020, the Prime Minister of Japan declared a state of emergency on April 7, 2020. Our hospital was the only institution designated for management of patients with COVID-19 in Kobe, and we admitted all patients with severe COVID-19. The number of admissions rapidly increased by early April 2020, and presumed subsequent nosocomial infection led to SARS-CoV-2 infection in seven patients and 28 healthcare workers. We suspended elective surgeries on April 20, 2020, closed the emergency department, assigned specific hospital zones, organized COVID-specific teams, arranged screening stations at all hospital entrances, and minimized staff-staff contact. Some of these practices were previously introduced by a Taiwanese hospital and could successfully control spread of COVID-19 ⁸⁾. These measures also appeared to be effective at our hospital, as confirmed by a reduced rate of transmission across healthcare workers by mid April 2020.

Resumption of routine medical practice is challenging in a hospital that experiences an outbreak. As a tertiary care center, we resumed elective surgeries on May 11, 2020 after 3-week suspension. Presymptomatic COVID-19 patients may develop postoperative COVID-19 pneumonia, which is associated with high mortality rates. An international, multicenter cohort study reported a mortality rate of approximately 20% (53 deaths among 280 cases) in elective cases with perioperative SARS-CoV-2 infection ⁹⁾, which is consistent with the findings of an early report from Wuhan, China ¹⁰⁾.

Studies have reported high prevalence of nosocomial

infections following hospital admission in presymptomatic or asymptomatic patients with COVID-19¹¹⁻¹³). A preliminary study that investigated seroprevalence reported that the SARS-CoV-2 immunoglobulin G was detected in 3.3% of the preserved sera obtained from randomly selected outpatients who visited our hospital for evaluation of nonCOVID-19 conditions between March 31, 2020 and April 17, 2020, which indicates that Kobe had a significantly high SARS-CoV-2 transmission rate despite the limited number of cases confirmed by RT-PCR testing¹⁴. Although the reliability of the kit used in the study remains undetermined, this finding justifies the strict screening of patients awaiting surgery at that time. Therefore, we introduced the following strict screening system before hospital admission for elective surgeries:

(a) We implemented RT-PCR testing, which is widely recommended to confirm COVID-19 positivity^{15, 16}, despite highest sensitivity of only 70%¹⁷. The low sensitivity could be attributed to the timing of testing¹⁸ or inadequate sampling methods. The timing of sampling was determined as the day before admission because the most recent test results were considered the most reliable. Nasopharyngeal swab samples were obtained by otolaryngologists to ensure sample quality. We also performed chest CT to improve the effectiveness of screening¹⁹. Imaging studies are not routinely indicated as a screening tool in asymptomatic individuals²⁰; however pneumonic changes were commonly detected on CT in asymptomatic patients quarantined on the “Diamond Princess” cruise ship²¹.

Some asymptomatic or presymptomatic patients may be admitted despite negative results on RT-PCR and CT testing as false negatives, which remains a concern in clinical practice. The aforementioned interview included information regarding a history of travel to or residence in areas of COVID-19 prevalence or contact with individuals with confirmed or suspected COVID-19, although the routes of infection remained unknown in approximately 50% of patients with COVID-19 in Kobe at that time. Symptoms observed over 2 weeks prior to admission, including fever, cough,

throat pain, anosmia, and dysgeusia were recorded. However, we observed that the estimated percentage of asymptomatic individuals in the cohort from the “Diamond Princess” cruise ship and Japanese citizens evacuated from Wuhan was 17.9% and 33.3%, respectively^{22, 23}. In view of the usual incubation period of 4–7 days^{24, 25} and the fact that some patients never experience any symptoms^{13, 22, 23}, absence of symptoms shortly before admission may not always exclude SARS-CoV-2 infection. Cheng et al. reported that all the second cases experienced their first exposure within 5 days of symptom onset in the index case²⁶. (b) We instructed patients to strictly avoid nonessential outings for 2 weeks prior to admission. We performed RT-PCR testing, CT, and patient interviews regarding lifestyle and symptoms to identify ineligible patients to ensure a greater likelihood of safely “passing” the screening protocol. A “2-week stay” at home was considered a sufficient period for asymptomatic patients to develop symptoms or remain asymptomatic or be completely cured without the risk of transmission¹³.

Therefore, based on the aforementioned RT-PCR testing, CT, and patient interviews before admission, we did not need to postpone any surgeries secondary to suspected COVID-19, and we observed no COVID-19-induced respiratory complications postoperatively or associated nosocomial transmission. Furthermore, we confirmed absence of the virus in samples obtained from tracheal tubes shortly after extubation in all patients. A sample obtained from a tracheal tube reflects events within the upper and lower airways because the tube comes into contact with the pharynx during removal. Therefore, reliability of tracheal samples is theoretically similar to or greater than that of nasopharyngeal samples¹⁷; moreover, these samples can be obtained in a noninvasive manner. Patients in whom the virus was detected were isolated and closely observed on the day of surgery or on the following day to minimize the risk of postoperative nosocomial infection or mortality.

In mid May, Kobe showed no new patient with COVID-19, and the state of emergency was lifted

on May 21, 2020 in Hyogo Prefecture. Based on the results of this study, we conclude that our screening protocol can be simplified by omitting RT-PCR testing and CT before hospital admission, depending on the institution and COVID-19 prevalence. COVID-19 vaccines have yielded promising results^{27, 28)}. Global herd immunity can obviate the need for preoperative screening. However, in the eventuality of another COVID-19 wave or following the emergence of a novel virus variant that is resistant to existing vaccines or in the absence of long-term vaccine efficacy, avoidance of nonessential outings for 2 weeks prior to admission will be an important and effective approach, which we recommend as the most powerful factor in our screening protocol, although this approach could have a detrimental influence on patients in social, economic, and mental aspects. In addition, we have to keep in mind that only 8 cases with COVID-19 were reported during 23 days of the study period in a population of approximately 1,500,000 in Kobe City. It remains undetermined whether our approach is effective during COVID-19 pandemic.

Following are the limitations of this study: (a) The retrospective design is a drawback of this study. (b) Patient interviews regarding nonessential outings, contact with others, and symptoms were based on self-assessment and yielded subjective results. (c) Testing of tracheal tube swab samples is not routinely reported, and we have not tested swab samples in patients with active COVID-19 infection. (d) Successful resumption of elective surgeries at our hospital may primarily be attributed to the successful control of COVID-19 transmission across Kobe, where only less than 30 COVID-19 cases were reported in a population of approximately 1,500,000 in May, 2020.

CONCLUSIONS

Our protocol, which included strict 2-week avoidance of nonessential outings before hospital admission, RT-PCR testing, and chest CT shortly before admission, facilitated successful resumption of elective surgeries during the COVID-19 outbreak, as confirmed by the absence of SARS-CoV-2-positivity on

RT-PCR testing of extubated tracheal tube swabs at a hospital affected by a COVID-19 outbreak, and this is the first report on successful resumption of surgeries in a hospital with COVID-19 outbreak in Japan in the first wave where no effective vaccine or drug was available.

Abbreviations

COVID-19: coronavirus disease, CT: computed tomography, RT-PCR: real-time reverse transcriptase polymerase chain reaction, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

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Availability of data and materials

The data of this survey are available from the corresponding author upon request.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethical Board (No. 20022). Written informed consent was waived in accordance with the Council for International Organizations of Medical Sciences guidelines.

Disclosure

This study was not supported by any funding agency. The authors have no conflicts of interest to declare.

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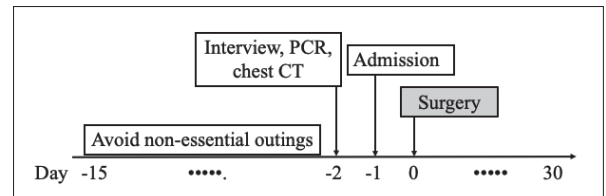


Figure 1. A schema of the screening protocol adopted for patients awaiting elective surgery.



Figure 2. Collection of two types of patient samples for polymerase chain reaction (PCR) testing. (Left) Otolaryngologists in personal protective equipment obtain nasopharyngeal samples. (Right) Extubated tubes are swabbed for reverse transcriptase PCR samples to confirm infection status of the patients.

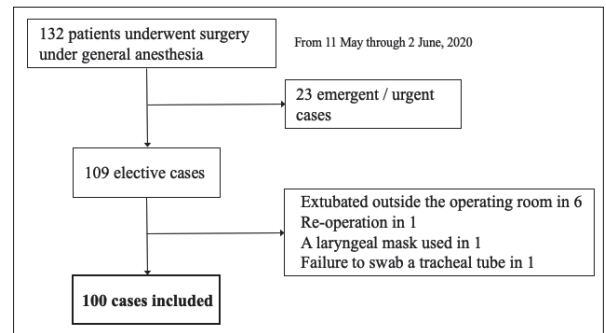


Figure 3. Flowchart of patient selection.

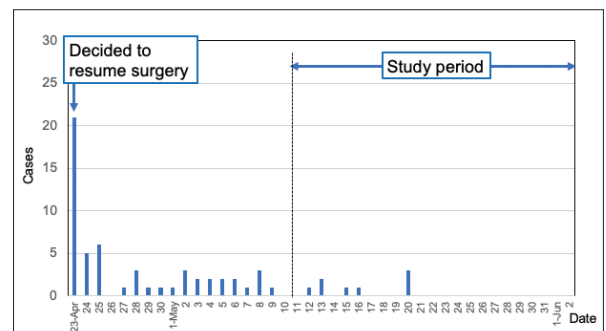


Figure 4. Numbers of individuals with confirmed COVID-19 in Kobe City from April 23rd to June 2nd, 2020.

Table 1. Patient characteristics and surgical specialties associated with surgical interventions

Age (median)	63		(1–90)
Male/female	52/48		
Current smoker	8		
Number of comorbidities associated with increased risk of mortality in COVID-19 cases ^a			
	None		57
	One		21
	Two or more		22
Specialty			
Gastrointestinal and hepatobiliary	20	Neurosurgery	6
Urology	19	Orthopedics	4
Obstetrics and gynecology	13	Breast	4
Head and neck	12	Cardiac	1
Thoracic	10	Dermatologic	1
Oral and dental	9	Plastic	1

a, Hypertension, diabetes, cardiovascular disease, cerebrovascular disease, chronic renal disease requiring dialysis.

Table 2. Summary of patient interviews on lifestyle and symptoms and computed tomography findings before admission

Interview			
Nothing to report			97
Transient symptoms			3
- Sore throat for 1 day			
- 37.7 °C for 1 day			
- Over 38 °C for 3 days		(Treated as UTI and resolved)	
Chest computed tomography			
Not performed		4 pediatric patients	
Nothing to report		44 (among 96)	
Findings (overlapping)			
Emphysema	9	Suspected tumor	2
Fibrosis	6	Ground glass opacity	4
Benign nodule or mucus	27	Infiltration	1
Linear opacity or scar	18		