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Review

Robotic-assisted percutaneous coronary intervention in the COVID-19 pandemic

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ABSTRACT

Coronavirus disease-2019 (COVID-19) has a profound impact on the health care system worldwide. In the COVID-19 pandemic, hospitals are required to halt elective surgeries and procedures for preventing nosocomial infections and saving medical resources. In these situations, emergency procedures are required for life-threatening cardiovascular diseases such as acute coronary syndrome and cardiogenic shock. To prevent the spread of COVID-19, a social distance is essentially required. In ordinary percutaneous coronary intervention (PCI), operators manipulate the devices standing at the patient's tableside during the whole procedure, which may involve a certain risk of exposure to patients with COVID-19. A robotic-assisted PCI (R-PCI) allows operators to manipulate devices remotely, sitting at a cockpit located several meters away from the patient, and in addition, the assistant can be at the foot of the bed, much further from the access site. R-PCI can help to minimize the radiation exposure and the amount of person-to-person contact, and consequently may reduce the risk for the exposure to the virus.

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Introduction

The coronavirus disease-2019 (COVID-19) is the infection caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which was identified as a novel causative microorganism of viral pneumonia at the end of 2019 [1]. Since December 2019, COVID-19 has rapidly spread across the world from Wuhan, China. The World Health Organization declared the COVID-19 outbreak a pandemic in March 2020. COVID-19 continues to have a profound impact on the health care system worldwide.

In Japan, more than 800,000 people have been infected and over 15,000 people have died from COVID-19 as of July 2021 [2]. A number of disease clusters and nosocomial infections have occurred to date. Therefore, the development of a system for infection prevention is very important in hospitals. Clinical care of patients with COVID-19 overwhelms the medical resources such as personal protective equipment (PPE) supplies, ventilators, or extracorporeal membrane oxygenation, leading to occupy medical staff, medical floors, and intensive care units. For preventing nosocomial infections and saving medical resources, elective surgeries and procedures have been halted. In these situations, emergency procedures are required for life-threatening cardiovascular diseases such as acute coronary syndrome (ACS) and cardiogenic shock.

In this review article, we summarize the efficacy of robotic-assisted percutaneous coronary intervention (R-PCI) which has a potential to minimize interpersonal contact in the COVID-19 pandemic.

COVID-19

Transmission

The transmission routes of SARS-CoV-2 are direct contact, respiratory droplets secreted from infected individuals, and aerosol transmissions [3-5]. In general, infected people spread virus particles by talking, breathing, coughing, and sneezing. The large droplets secreted from patient's mouth quickly fall to the ground, but smaller aerosols drift in the air for a while and can spread 1-2 meters from patients [6,7]. Although the median estimates of half-life are approximately 1.1–1.2 hours, SARS-CoV-2 can survive in aerosols longer than 3 hours, which indicates that the virus has stability characteristics in transmitting through the air [8,9]. Furthermore, the virus is stable to exist on the surfaces of some objects for a while, particularly on stainless steel and plastic surfaces, where it can remain active up to 72 hours [9]. Aerosols are created in common clinical settings. The US Centers for Disease Con-

trol and Prevention (CDC) defines "aerosol-generating procedures (AGPs)" as procedures that create uncontrolled respiratory secretions or procedures with the potential to generate infectious respiratory particles at higher concentrations than breathing, coughing, sneezing, or talking [10]. AGPs contain sputum induction, noninvasive positive pressure ventilation, intubation, and cardiopulmonary resuscitation (CPR). During these procedures, we need to prevent the infection much more strictly [11].

Infection prevention

Generally, it is essential for the prevention of COVID-19 to keep a social distance, to wear a facemask, to wash hands frequently, and to ventilate a room regularly [1,7,8]. Healthcare providers, particularly medical staff who perform AGPs, have higher risks of exposure from patients or infectious materials including body substances (e.g. blood, tissue, and specific body fluids), contaminated medical equipment, environmental surface, or air [12]. In clinical settings, appropriate PPE should be worn such as facemasks, gown, eye shield, and gloves. When caring for patients with COVID-19, we should wear N95 respirators or masks, equivalent or better [12]. N95 respirators cannot block completely the transmission of viral droplets and aerosols, even if completely sealed [13], but can halve the risk of respiratory infections compared to surgical masks [14].

In closed space such as a catheterization laboratory, it is difficult to keep enough distance from a patient. During procedures, operators are required to stand by the patient table for several hours. Furthermore, if the patient's condition gets worse, AGPs such as suctioning, intubation, or CPR may be required. Catheterization laboratories are usually positive-pressure ventilated to prevent circulation of pathogens, which would not be an ideal strategy for preventing infection from COVID-19 [15,16]. Therefore, COVID-19 or suspected COVID-19 patients with poor respiratory status should be intubated prior to arrival at the catheterization laboratory, and also a patient with borderline respiratory status should be considered for intubation. In general, catheterization laboratories are designed as Level III clean areas and it requires approximately one hour of ventilation to remove airborne aerosols sufficiently [16].

COVID-19 and ACS

Management of ACS during COVID-19 pandemic

COVID-19 patients with cardiovascular disease have higher mortality and COVID-19 itself can also cause cardiovascular emergencies such as ACS, pulmonary embolism, and myocarditis [8,17]. Proper and prompt treatments are required for ACS; however, a small study from Hong Kong reported that time was extended from onset of ST elevation myocardial infarction (STEMI) to recanalization in the COVID-19 pandemic [18]. The Japanese Association of Cardiovascular Intervention and Therapeutics recommends that in cases of STEMI and hemodynamically unstable non-ST elevation ACS (NSTE-ACS), rapid screening for COVID-19 should be performed in parallel with the diagnosis of ACS [16]. If COVID-19 is less likely, emergency revascularization should be performed, and prolonged door to balloon time may be acceptable for testing and infection protection preparation [16]. In cases of definite or highly suspected COVID-19, urgent revascularization should be considered at a facility which can handle COVID-19. If such a patient comes to a facility, which cannot manage COVID-19, recanalization therapy by intravenous administration of tissue plasminogen activator needs to be considered and then the patients should be transferred [16]. Although fibrinolytic therapy is an alternative strategy to primary PCI during the COVID-19 pandemic [17,19], the superiority of PCI over fibrinolytic therapy has already been demonstrated in

terms of establishing Thrombolysis In Myocardial Infarction grade 3 flow and risk of bleeding complications [20-22]. An additional PCI can improve the prognosis in patients with regardless of unsuccessful and successful revascularization by fibrinolytic therapy [23,24]. In view of these facts, primary PCI would remain the standard of care for STEMI patients during the COVID-19 pandemic.

Robotic-assisted PCI

The R-PCI system, the CorPath® GRX system (Corindus, Waltham, MA, USA), has been developed to reduce the radiation exposure to the operator and the physical burden from the heavy radiation protective equipment. R-PCI allows operators to manipulate PCI devices remotely sitting at a cockpit located several meters away from the patient, and in addition, the assistant can be at the foot of the bed much further from the access site. The details of the CorPath GRX system were described elsewhere [25,26]. Briefly, the CorPath GRX system consists of an interventional cockpit and a bedside unit (Fig. 1). The interventional cockpit is a radiation-shielded mobile workstation that contains a console with joysticks and touchscreen controls to move the balloon/stent delivery system, guidewire, or guiding catheter. The bedside unit is composed of a single-use cassette, articulating arm, and robotic drive. During the PCI procedure, the single-use cassette is mounted on a robotic drive and loaded with interventional equipment, which translates commands from the cockpit to independently manipulate each device. The system accepts all commercial 0.014-inch guidewires and rapid-exchange balloon/stent catheters, and standard coronary guiding catheters of various sizes. Gaining a vascular access and engagement of the guiding catheter are manually performed. The fluoroscopy is controlled by the seated operator and contrast injection and exchange of devices in the cassette are performed by the tableside assistant.

R-PCI and COVID-19

In conventional PCI, operators manipulate the devices standing at the patients' tableside during the whole procedure. Therefore, conventional PCI style may involve a certain risk of exposure to patients with COVID-19. Regarding this matter, R-PCI may have a potential to reduce the risk [27,28]. In R-PCI with the present CorPath system, someone needs to be close to the table for preparation of the patient and exchange the PCI devices in the cassette. However, except those timings, all catheterization laboratory staff can stay away from the tableside. In a pandemic situation such as COVID-19, R-PCI may help to minimize the amount of person-to-person contact [29].

A representative case

A 50-year-old woman with medical history of type 1 diabetes mellitus and end-stage renal disease on hemodialysis, was transferred to our hospital with a state of acute respiratory failure and vital shock. The patient was intubated for mechanical ventilation and administered catecholamines to increase the blood pressure. She had a fever and a high level of inflammatory reaction in the blood test, white blood cells: 20,500 /μL and C-reactive protein: 13.0 mg/dL. A chest X-ray and a computed tomography scan revealed bilateral pneumoniae and bilateral pleural effusions (Fig. 2). An antigen test and a polymerase chain reaction test for COVID-19 were performed. A 12-lead electrocardiogram showed ST elevation in V3-6 leads and abnormal Q wave in I, II, III, aVF, and V3-6 leads (Fig. 3). The blood test revealed the elevated levels of creatine kinase MB (CK-MB) and cardiac troponin T (TnT), CK-MB: 69 U/L and TnT: 29.4 ng/ml. The patient was diagnosed as having STEMI, cardiogenic shock, and suspected concurrent COVID-19 infection. In
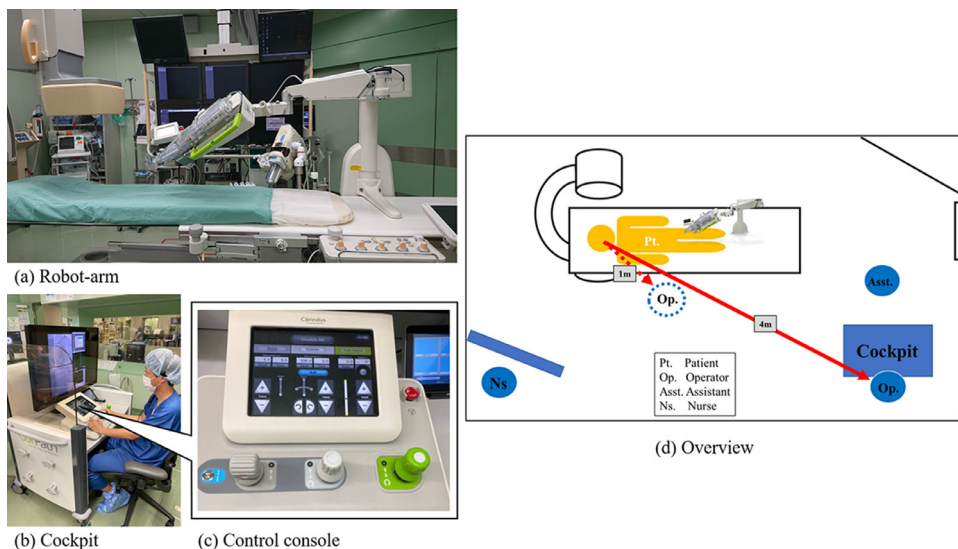
(a) Robot-arm

(b) Cockpit

(c) Control console

(d) Overview

Fig. 1. The CorPath GRX system. (a) The bedside unit consists of a single-use cassette, articulating arm, and robotic drive. (b) An operator remotely controls the movement of percutaneous coronary intervention devices, sitting down at a radiation shielded cockpit. (c) The cockpit contains a console with joysticks and touchscreen controls to control movement of the balloon/stent delivery system, guidewire, or guiding catheter. (d) Overview of the CorPath GRX system in the catheterization laboratory. The cockpit is 4 meters away from the patient.
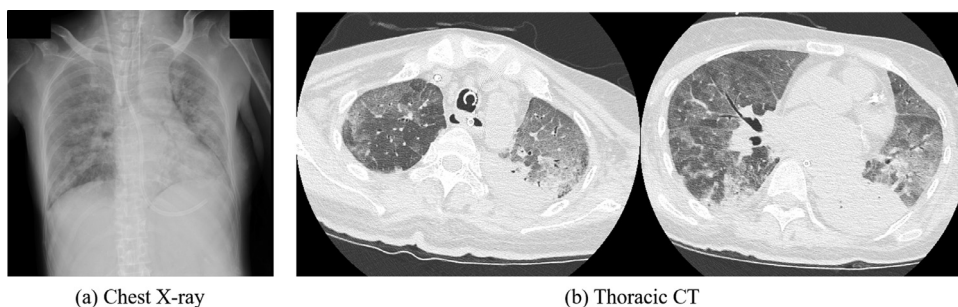

(a) Chest X-ray

(b) Thoracic CT

Fig. 2. Chest X-ray and thoracic computed tomography (CT) of the case. (a) A chest X-ray and (b) a thoracic CT showed bilateral ground-glass shadow and pleural effusion. A central venous catheter is placed in the superior vena cava, and an intubation tube is placed in the trachea.
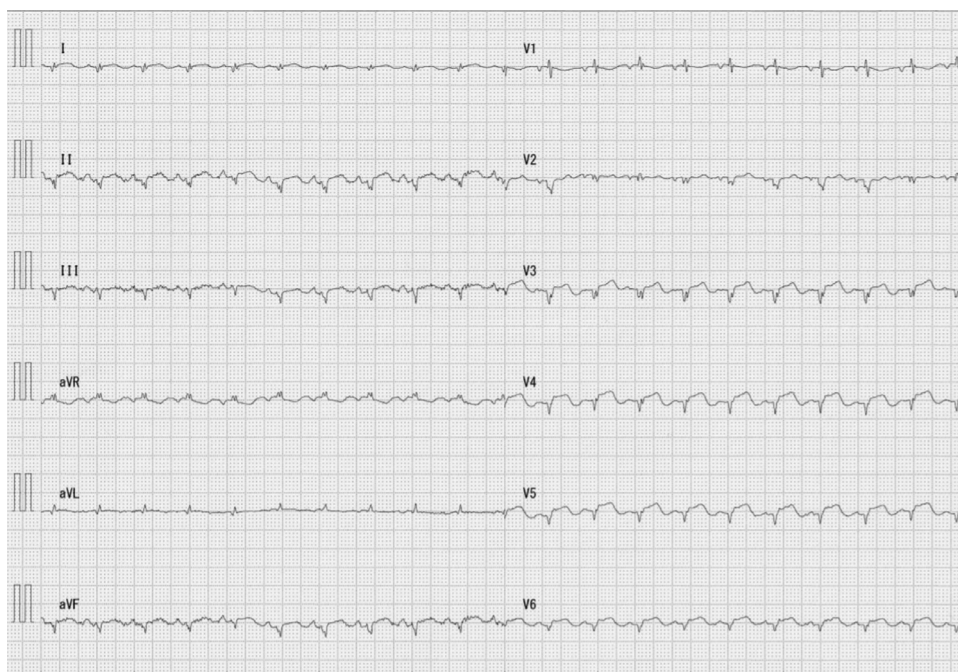

Fig. 3. Electrocardiogram of the case. An electrocardiogram showed ST elevation in V3-6 leads and abnormal Q wave in I, II, III, aVF, and V3-6 leads.

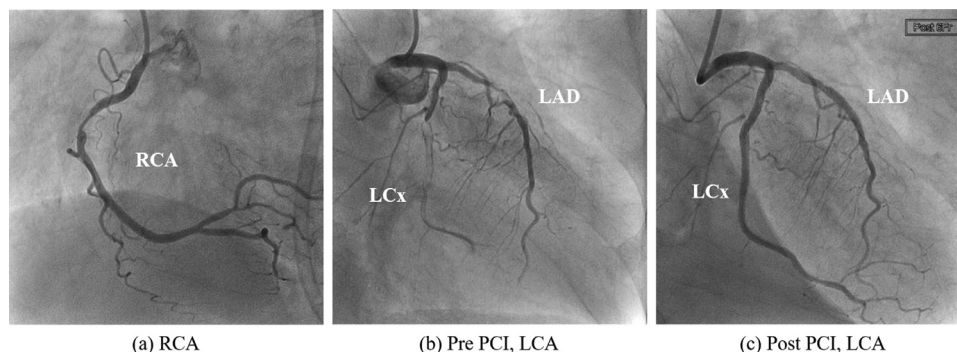| (a) RCA | (b) Pre PCI, LCA | (c) Post PCI, LCA |

Fig. 4. Coronary angiography of the case. Coronary angiography showed a tight stenosis in right coronary artery (a) and thrombotic lesions in left anterior descending artery and left circumflex artery (b). An excellent result was obtained by robotic assisted-PCI (c).
LCA, left coronary artery; LAD, left anterior descending artery; LCx, left circumflex artery; PCI, percutaneous coronary intervention; RCA, right coronary artery.
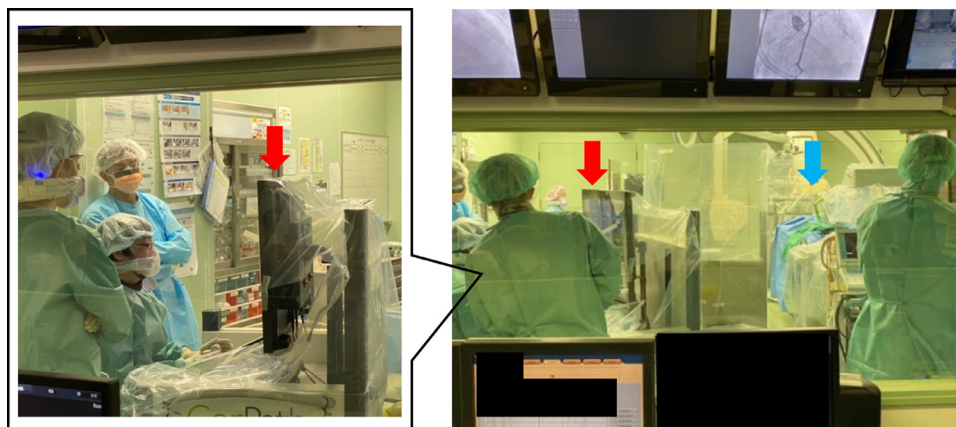

Fig. 5. An overview image during the procedure in a patient suspected COVID-19. The operator stayed at the cockpit (red arrow) 4 meters away from the table (blue arrow), and the assistants also maintained a sufficient distance from the patient.

consideration with the patient's condition, an urgent revascularization therapy with full PPE was performed. In addition, in order to keep the distance between the patient and the catheterization laboratory staff, R-PCI was chosen.

All staff inside the operating room wore full PPE; N95 masks or powered air purifying respirator systems (CleanSpace® HALO, CleanSpace Technology Pty Ltd., Artarmon, Australia), face shields, gowns, double gloves, and socks. The patient was on a ventilator with high-efficiency particulate air filter. Arterial access was secured manually to the left femoral artery. After administration of appropriate anticoagulation and antiplatelet agents, coronary angiography (CAG) was performed manually. CAG revealed severe stenosis with thrombus in the left anterior descending artery (LAD), thrombotic obstruction in the left circumflex artery (LCx), and severe stenosis in the right coronary artery (Fig. 4). Both the lesions at the LAD and the LCx were judged as culprit lesions and we started R-PCI under support of intra-aortic balloon pumping (IABP). The operator was stationed in a cockpit 4 meters away from the patient, and the assistants at the tableside kept their distance from the patient as much as possible (Fig. 5). After manual engagement of a 6 Fr. guiding catheter in the left coronary artery, a 0.014-inch SION Blue guidewire (Asahi Intecc., Aichi, Japan) was robotically advanced into the distal LCx. Then, a 2.5 mm semi-compliant Traveler balloon catheter (Abbott Vascular, Santa Clara, CA, USA) was inserted into the lesion robotically. Following dilatation with the balloon, optical coherence tomography (OCT) was performed manually by the assistants. OCT revealed diffuse atherosclerotic stenosis in the LCx. Three XIENCE stents (Abbott Vascular) were placed robotically and deployed to fully cover the lesion. Regard-

ing the LAD lesion, the insertion of the guidewire and the delivery of the balloon and the stent catheter were performed by the R-PCI system. A XIENCE stent was implanted at the LAD lesion. Final CAG showed excellent results at both the LAD and the LCx without any complications (Fig. 4).

The patient was found negative for the COVID-19 PCR test on the following day. On day 3, IABP was withdrawn and staged PCI for the RCA stenotic lesion was performed manually and succeeded. Mechanical respiratory support was withdrawn on day 32.

Clinical significance of R-PCI in the COVID-19 pandemic

R-PCI in STEMI patents is challenging. There has been limited information on clinical performance of R-PCI in STEMI patients, because previous R-PCI studies excluded those patients [30]. It has been demonstrated that procedural time was about 10 minutes longer in R-PCI than that in manual PCI in stable patients [31,32], which could be caused by more time in robotic drive setup and loading the robotic drive with PCI devices. Therefore, there is a concern that R-PCI in STEMI patients would prolong door-to-balloon time. Regarding this issue, more training and experience may ameliorate this problem. R-PCI with the CorPath system allows all staff to be away from the patient bedside for most of the time during the procedure, thus minimizing the proximity to the patient. In special situations, such as the COVID-19 pandemic, lowering the infection risk of medical staff might be prioritized over slight prolongation of procedure time. As reports of R-PCI in patients with COVID-19 or STEMI are still scarce, further studies are warranted to evaluate the utility, particularly in pandemic environments.

Future perspective

Improvements in the R-PCI system and AI technology may enable us to handle more difficult cases, reduce human errors, and remote R-PCI. Current R-PCI have automated wiring aid technique called Rotate on Retract (RoR) and additional automated features will be provided to assist with complex tasks such as crossing lesions, navigating tortuosity, and precisely measuring the anatomy for appropriate device size selection in the future [33]. Remote R-PCI has already been actualized [34]. Madder et al. reported robotic-telestenting in a preclinical model from over 3,000 miles away [35]. If a remote R-PCI network system is established, more patient's lives would be saved, especially in some special situations, such as pandemic or disaster, with difficulty of prompt patient transport.

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Declaration of Competing Interest

There is no conflict of interest to disclose.

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References

[1] World Health Organization. Coronavirus disease (COVID-19) pandemic. Available at https://www.who.int/emergencies/diseases/novel-coronavirus-2019 (Accessed July 13, 2021).

[2] Ministry of Health, Labour and Welfare. Novel coronavirus (COVID-19). Available at https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00079.html (Accessed July 13, 2021).

[3] Yuan H, Cao X, Ji X, Du F, He J, Zhou X, et al. An updated understanding of the current emerging respiratory infection: COVID-19. Biomed Res Int 2020;2020:6870512.

[4] Falahi S, Kenarkoohi A. Transmission routes for SARS-CoV-2 infection: review of evidence. New Microbes New Infect 2020;38:100778.

[5] Atri D, Siddiqi HK, Lang JP, Nauffal V, Morrow DA, Bohula EA. COVID-19 for the cardiologist: basic virology, epidemiology, cardiac manifestations, and potential therapeutic strategies. JACC Basic Transl Sci 2020;5:518–36.

[6] Centers for Disease Control and Prevention. How COVID-19 Spreads. Available at https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html (Accessed Aug 14, 2021).

[7] Liu L, Wei J, Li Y, Ooi A. Evaporation and dispersion of respiratory droplets from coughing. Indoor Air 2017;1:179–90.

[8] Jayaweera M, Perera H, Gunawardana B, Manatunge J. Transmission of COVID-19 virus by droplets and aerosols: A critical review on the unresolved dichotomy. Environ Res 2020;188:109819.

[9] van Doremalen N, Bushmaker T, Morris DH, Holbrook MG, Gamble A, Williamson BN, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. N Engl J Med 2020;382:1564–7.

[10] Centers for disease control and prevention. Clinical questions about COVID-19: questions and answers. Available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html (Accessed July 13, 2021).

[11] Tran K, Cimon K, Severn M, Pessoa-Silva CL, Conly J. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. PLoS One 2012;7:e35797.

[12] Centers for Disease Control and Prevention. Interim infection prevention and control recommendations for healthcare personnel during the coronavirus disease 2019 (COVID-19) pandemic. Available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html (Accessed July 13, 2021).

[13] Ueki H, Furusawa Y, Iwatsuki-Horimoto K, Imai M, Kabata H, Nishimura H, et al. Effectiveness of face masks in preventing airborne transmission of SARS–CoV-2. mSphere 2020;5 e00637-20.

[14] Iannone P, Castellini G, Coclite D, Napoletano A, Fauci AJ, Iacorossi L, et al. The need of health policy perspective to protect healthcare workers during COVID-19 pandemic. A GRADE rapid review on the N95 respirators effectiveness. PLoS One 2020;15:e0234025.

[15] Welt FGP, Shah PB, Aronow HD, Bortnick AE, Henry TD, Sherwood MW, et al. Catheterization laboratory considerations during the coronavirus (COVID-19) pandemic: From the ACC's Interventional Council and SCAI. J Am Coll Cardiol 2020;75:2372–5.

[16] Ikari Y, Yamada S, Ehara N, Kozuma K, Shinke T, Sugano T, et al. The Japanese association of cardiovascular intervention and therapeutics position statement on coronary invasive procedures during the COVID-19 pandemic in Japan. Cardiovasc Interv Ther 2021;36:139–44.

[17] Mahmud E, Dauerman HL, Welt FGP, Messenger JC, Rao SV, Grines C, et al. Management of acute myocardial infarction during the COVID-19 pandemic: a position statement from the Society for cardiovascular angiography and interventions (SCAI), the American College of Cardiology (ACC), and the American College of Emergency Physicians (ACEP). J Am Coll Cardiol 2020;76:1375–84.

[18] Tam CF, Cheung KS, Lam S, Wong A, Yung A, Sze M, et al. Impact of coronavirus disease 2019 (COVID-19) outbreak on ST-segment-elevation myocardial infarction care in Hong Kong. China. Circ Cardiovasc Qual Outcomes 2020;13:e006631.

[19] Zeng J, Huang J, Pan L. How to balance acute myocardial infarction and COVID-19: the protocols from Sichuan Provincial People's Hospital. Intensive Care Med 2020;46:1111–13.

[20] Andersen HR, Nielsen TT, Rasmussen K, Thuesen L, Kelbaek H, Thayssen P, et al. A comparison of coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. N Engl J Med 2003;349:733–42.

[21] Keeley EC, Boura JA, Grines CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. Lancet 2003;361:13–20.

[22] O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, et al. ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–140.

[23] O'Gara PT, Kushner FG, Ascheim DD, Jr Casey DE, Chung MK, de Lemos JA, et al. ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv 2013;82:E1–27.

[24] Fernandez-Avilés F, Alonso JJ, Castro-Beiras A, Vázquez N, Blanco J, Alonso-Briales J, et al. Routine invasive strategy within 24 hours of thrombolysis versus ischaemia-guided conservative approach for acute myocardial infarction with ST-segment elevation (GRACIA-1): a randomised controlled trial. Lancet 2004;364:1045–53.

[25] Kagiyama K, Ueno T, Mitsutake Y, Yamaji K, Ishimatsu T, Sasaki K, et al. First experience of robotic-assisted percutaneous coronary intervention in Japan. Intern Med 2019;58:3415–19.

[26] Kagiyama K, Mitsutake Y, Ueno T, Sakai S, Nakamura T, Yamaji K, et al. Successful introduction of robotic-assisted percutaneous coronary intervention system into Japanese clinical practice: a first-year survey at single center. Heart Vessels 2021;36:955–64.

[27] Vlachakis PK, Tentolouris A, Kanakakis I. Concerns for management of STEMI patients in the COVID-19 era: a paradox phenomenon. J Thromb Thrombolysis 2020;50:809–13.

[28] Virk HUH, Lakhter V, Tabaza L, George JC. Do we need robotics for coronary intervention more than ever in the COVID-19 era? Catheter Cardiovasc Interv 2020;96:E563–4.

[29] Tabaza L, Virk HUH, Janzer S, George JC. Robotic-assisted percutaneous coronary intervention in a COVID-19 patient. Catheter Cardiovasc Interv 2021;97:E343–5.

[30] Mahmud E, Naghi J, Ang L, Harrison J, Behnamfar O, Pourdjabbar A, et al. Demonstration of the safety and feasibility of robotically assisted percutaneous coronary intervention in complex coronary lesions: results of the CORA-PCI Study (Complex Robotically Assisted Percutaneous Coronary Intervention). JACC Cardiovasc Interv 2017;10:1320–7.

[31] Weisz G, Metzger DC, Caputo RP, Delgado JA, Marshall JJ, Vetrovec GW, et al. Safety and feasibility of robotic percutaneous coronary intervention: PRECISE (Percutaneous Robotically-Enhanced Coronary Intervention) Study. J Am Coll Cardiol 2013;61:1596–600.

[32] Patel TM, Shah SC, Soni YY, Radadiya RC, Patel GA, Tiwari PO, et al. Comparison of robotic percutaneous coronary intervention with traditional percutaneous coronary intervention: a propensity score-matched analysis of a large cohort. Circ Cardiovasc Interv 2020;13:e008888.

[33] Corindus. Corindus announces global launch of technIQ™1 smart procedural automation series for CorPath® GRX System. Available at https://www.corindus.com/ (Accessed July 13, 2021).

[34] Patel TM, Shah SC, Pancholy SB. Long distance tele-robotic-assisted percutaneous coronary intervention: A report of first-in-human experience. EClinicalMedicine 2019;14:53–8.

[35] Madder RD, VanOosterhout S, Parker J, Sconzert K, Li Y, Kottenstette N, et al. Robotic telestenting performance in transcontinental and regional pre–clinical models. Catheter Cardiovasc Interv 2021;97:E327–32.