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Guidelines for pediatric catheterization laboratories in times of COVID-19: Ecuador.

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ABSTRACT

Objective: The general objective of this guideline is to propose a regulation for the performance of programmed or emergency catheterizations in pediatric patients with confirmed or suspected COVID-19.

Health question covered by the Guide: How should pediatric patients diagnosed or suspected of COVID-19 who require a scheduled or emergency cardiac catheterization be cared for?

Population: The target population is pediatric-age patients with cardiovascular diseases that require scheduled or emergency cardiac catheterization and in whom the diagnosis of COVID-19 is suspected.

Guidelines: biosecurity recommendations are made in the care of this specific group of patients.

Keywords:

MESH: Cardiac Catheterization; Child; Heart Defects, Congenital;, Containment of Biohazards; Coronavirus Infections, Personal Protective Equipment.

Free Text: SARS-COV-2

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INTRODUCTION

The pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus – that causes coronavirus disease 2019 (COVID-19) arrived in Ecuador in February 2020 and is currently community-transmitted, mainly impacting the two most populated cities in the country: Guayaquil and Quito. ^{1,2}

In mid-March of this year, a health emergency was declared in the country after the World Health Organization classified COVID-19 a pandemic disease. From then on, non-essential activities in hospitals were suspended, reducing the number of pediatric cardiovascular surgeries and catheterizations, and only emergency/urgent operations were performed both in hemodynamic rooms and catheterization laboratories (Cat-Lab) for adults and pediatrics, as has happened in other centers around the world. ³⁻⁷

In Ecuador, only two of the three pediatric hospitals have a Cat-Lab: one in Guayaquil belonging to the "Junta de Beneficencia" (private, with social action) and another in Quito belonging to the Ministry of Public Health. Public and private hospitals and those of the Ecuadorian Social Security Institute, although they are not pediatric specialty centers, have Cat-Lab where certain pediatric procedures are performed.⁸

There are difficulties and controversies associated with cardiovascular catheterizations in children within the context of the pandemic in Ecuador, such as PCR-COVID-19 screening tests (sensitivity between 66–88% in the first days of infection) in all patients admitted for invasive procedures of all kinds. In what phase of the disease in the locality? Which patient do we consider to be worthy of an elective or non-elective procedure? What is the distance between the Cat-Lab and the patient's home? How many procedures can be performed, and what is the existing demand? What impact would delaying percutaneous diagnostic and therapeutic procedures likely have on heart disease patients and on the health system.^{7,9-11}

The health emergency period was divided into phases called "red traffic light" (when only emergency/urgent care is carried out in health institutions), "yellow traffic light", and "green traffic light" when scheduled at 30-50 times will be performed % and 70% of its capacity, respectively. A few days ago (writing on DATE), some cities and cantons entered the yellow traffic light, and others are about to do so, but we do not have clear guidelines on how care will be given in the pediatric Cat-Lab of the country.²

For these reasons, we propose guidelines for the performance of catheterizations in pediatric patients with either confirmed or suspected COVID-19, either emergency or scheduled.

DOMAIN 1: SCOPE AND PURPOSE

OBJECTIVE

The general objective of this guideline is to propose a regulation for the performance of scheduled or emergency catheterizations in pediatric patients with confirmed or suspected COVID-19.

HEALTH QUESTION COVERED BY THE GUIDE

How should pediatric patients diagnosed or suspected of COVID-19 who require scheduled or emergency cardiac catheterization be cared for?

POPULATION

The target population is pediatric-age patients with cardiovascular diseases that require scheduled or emergency cardiac catheterization, and in whom the diagnosis of COVID-19 is suspected.

DOMAIN 2: PARTICIPANTS INVOLVED

GUIDE DEVELOPMENT GROUP

Cardiology | Pediatrics

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TARGET POPULATION, PREFERENCES, AND VIEWS

The population was chosen by the study group because it is the objective of work in the main Public Hospitals of Pediatric services in the specialty of Cardiology.

Opinions were collected as surveys to capture the opinions and preferences of patients. Participation in the guide development group was carried out through telemedicine, and a review of the literature was carried out on values and preferences on the biosafety of patients undergoing cardiac catheterization in the COVID-19 pandemic. The information collected was captured during the guideline development process in various telemedicine meetings.

TARGET USERS OF THE GUIDES

The possible users of this guide are doctors who perform cardiac catheterization in children and adults in Specialty hospitals in Ecuador.

DOMAIN 3: RIGOR OF DEVELOPMENT

SEARCH METHODS

The MEDLINE and PUBMED databases were used for the literature search. The search period was December 1, 2019 to March 30, 2020. The search terms were COVID-19 OR Coronavirus Infections AND "Catheterization Laboratory" OR Catheterization AND Personal Protective Equipment OR Biosecurity OR Containment of Biohazards.

SELECTING THE EVIDENCE

The level of evidence selected was 1A for metaanalysis, systematic reviews and 1B for randomized clinical studies, without language restriction. Due to the pandemic and the reporting of studies lacking control, evidence 2A and 2B from observational studies were considered.

STRENGTHS AND LIMITATIONS OF THE EVIDENCE

Due to the nature of the evidence, the "recommendation" is used when the evidence is 1A or 1B. Hint is used when the evidence is 2-A and 2-B.

RECOMMENDATIONS

1. Guidelines for cardiovascular catheterization in children with positive or suspected COVID-19 and in cases of emergency/urgency.

1.1. It is suggested that the hospitalized patient be accompanied by their parent or legal guardian, both wearing a surgical mask throughout the hospitalization. Chest teleradiography or chest tomography will be performed according to medical indication, with temperature recordings of both the patient and the family member.

1.2. The confirmed COVID-19 patient is recommended to stay in an isolated room together with a family member or in a COVID-19 patient cohort room. The suspected COVID-19 patient must be in an isolated room with their family member. Emergency/urgency catheterization with no RT-PCR-SARS-COV-2 test or no result will be considered suspicious.

1.3. It is recommended to perform hematic biometry, clotting times, urea, creatinine, blood glucose, C-reactive protein (CRP), or other necessary blood determination, ECG, or other required complementary examination. Ideally, perform the RT-PCR-SARS-COV-2 test and have the result before the procedure in all patients.

1.4. In the reception room of the Cat-Lab, it is suggested to record the temperature of the patient and their family member. Personnel must be dressed in PPE: surgical cap, disposable surgical boots, transparent goggles with face seal, N95 mask or equivalent, breathable protective suit, full-body overalls, disposable anti-fluid gown, and handling gloves.

1.5. It is suggested that the area nursing staff will transfer the patient to the procedure room. The family member will wait in the patient's room and will be called when the procedure is complete.

1.6. In the procedure room (optimally with negative pressure ventilation), it is recommended that personnel should be dressed in Personal Protective Equipment (PPE), in addition to the lead suit over the breathable protective suit. The interventional cardiologist and his assistant should wear leaded lenses, a sterile disposable gown over the leaded suit, sterile double surgical gloves and, if necessary, lead surgical gloves.

1.7. It is suggested to have video-assisted intubation and an anti-aerosolization camera if the patient requires a tracheal tube. It is also suggested to have high-efficiency particulate collecting air filters (HEPA) for the breathing bags (ambu or similar).

1.8. Once the procedure is finished, it is recommended that the garments and material be discarded inside the procedure room according to the institution's biosafety protocol. Once extubated and awakened, the patient will go to the Cat-Lab recovery room.

1.9. It is recommended that the recovery room staff be dressed in the PPE described in point 6. If necessary, the relative will be asked to accompany them, who must wear a cap, mask, surgical boots, and a disposable gown.

1.10. After recovery, it is recommended that the patient and family be transferred to their hospital room.

1.11. It is recommended that 1 h after the end of the procedure, the cleaning and disinfection of the Cat-Lab be carried out with personnel dressed in PPE, as described in point 6 (cleaning protocol).

2. Guidelines for Pediatric Cat-Lab Scheduled Reopening

2.1. During the initial reopening phase of the Cat-Lab, it is suggested to allocate two business days for catheterization procedures, with one patient per day. The increase in days of procedures and the number of patients will be gradual depending on the epidemiological behavior of the pandemic.

2.2. It is suggested that a week before a telephone contact will be made with a family member of the patient to indicate the date of the procedure and will be asked questions to rule out febrile and/or respiratory symptoms during the last 14 days, either of the patient or of a family member who shares the house. The patient will only be cited if the data from this telephone survey are negative.

2.3. It is suggested that the patient should go to the hospital 1 day before the procedure accompanied by their parent or legal guardian. In the patient preparation room of the outpatient clinic, the temperature of both the patient and the family member will be taken and recorded (a temperature of more than 37.5°C taken with an infrared thermometer on the forehead will be considered fever). Chest radiography will also be performed to rule out the presence of radiological images compatible with pneumonia. Ideally, the RT-PCR-SARS-COV-2 test should be performed in the institution by nasopharyngeal swab to the patient and family and have the result on the same day. If neither the patient nor the family member has a fever, if the aforementioned radiological alterations do not exist, and if the RT-PCR-SARS-COV-2 test is negative, the hospitalization will continue. If this test is not available, it is advisable to follow the guidelines in section 1.

2.4. It is suggested that the patient be transferred to the room together with his family member by the hospital staff. The use of a surgical mask must be guaranteed during the entire hospitalization time, and the patient and his family member will be fed so that the latter is not exposed to the contagion of COVID-19 and the danger that the virus enters the hospital due to the need to search for food.

2.5. It is recommended that on the day of hospitalization, hematic biometry, clotting times, urea, creatinine, blood glucose, and C-reactive protein (CRP) be performed on the patient or other blood

determination that merits the case. The ECG will also be carried out if the patient has not had one in the last 6 months, as well as any other complementary exam that the medical staff requires.

2.6. It is suggested that if there are no medical contraindications (laboratory or other complementary tests), the next day, the patient will be transferred together with his family member to the Cat-Lab by the hospital staff. Upon arrival at the Cat-Lab reception room, the temperature of both the patient and the family member will be recorded again. If there is no fever, the scheduled procedure will proceed.

2.7. It is recommended that the Cat-Lab staff in the reception room should be dressed in PPE: surgical cap, surgical mask, disposable gown, gloves.

2.8. The regulations set out in numbers 1.7 to 1.11 will be followed.

RATIONALIZATION

Congenital heart diseases are within the group of catastrophic diseases, and it is considered that pediatric patients (vulnerable population) with these malformations have a higher risk of infection and complications from COVID-19, the impact that the delay in performing cardiac catheterization in them, especially when these interventions are of a therapeutic nature.¹²

One of the important pieces of information to decide which type of procedures can be performed in a certain center is to know the availability of beds in intensive care due to the eventuality of complications in catheterization. Therefore, it is necessary to know the incidence of patients with COVID-19 and the prevalence of severe cases in the institution. To reach this determination, it would be necessary to perform the RT-PCR test for SARS-CoV-2 in all patients who are hospitalized, since pediatric patients might be asymptomatic up to 14 days after infection. The drawback in our environment is that these tests are not carried out in the institutions where the Cat-Lab are; there is not enough of them, and there is a delay in the result since there is still a significant amount of unprocessed samples ^{10, 13}. Rapid blood tests have not been recommended for screening patients with suspected COVID-19 due to their low sensitivity in the initial stage of the disease (less than 30%). ^{9, 14}.

On the other hand, the molecular test for detection of SARS-CoV-2 could help prevent interventions in asymptomatic infected patients who, in addition to transmitting the virus within hospitals, could have serious complications during the procedure and hospitalization, demanding more days of hospitalization, bed occupancy in intensive care or rooms in isolation, and a greater amount of personal protective equipment (PPE) and, ultimately, the greater expenditure of medical and economic resources.¹¹

In all Cat-Labs, the necessary precautions are taken to provide quality care, which translates into safety for patients and their family environment. Security must also be provided to the scarce specialized personnel in these areas that exist in the country, since due to the type of procedure and the characteristics of the Cat-Lab, this personnel is exposed to maneuvers that produce aerosols (tracheal intubation, cardiopulmonary resuscitation), and cannot comply with social distancing, increasing the risk of occupational disease.^{10,15}

These guidelines are recommended until new, more effective therapies, or the availability of a vaccine for this disease becomes a reality. The intention is to unify criteria with respect to the procedures that the existing pediatric Cat-Lab in the country could perform or that, for emergency or urgency reasons given their geographic situation, could perform adult Cat-Lab, such as percutaneous atrioseptostomy with a balloon, while living with COVID-19, since this pandemic is an unprecedented situation worldwide, when new knowledge becomes available, these guidelines will surely have to be reviewed and improved so that they can provide better quality and safety of care to patients, their families and the health personnel who care for them.

CONSIDERATION OF BENEFITS AND DAMAGES

The benefits of treating COVID-19 positive pediatric patients with heart disease are the same as those for patients who do not have this infection. The group of patients with congenital heart disease is considered a vulnerable group to COVID-19 infection, a group in which mortality can double due to respiratory compromise, especially in the group of patients in whom they are accompanied by pulmonary hypertension, malnutrition, and use of percutaneous devices. The cardiac catheterization procedure has not been documented to increase the severity of COVID-19.

EXTERNAL REVIEW OF THIS GUIDE

This guide was observed by two external reviewers who made formatting suggestions based on the Appraisal of Guidelines Research and Evaluation (AGREE 2016) guidelines and in-depth reviews based on expert opinion.

UPDATE PROCEDURE

This guide will be updated every year, starting from the date of publication.

ADMINISTRATIVE INFORMATION OF THE ARTICLE

Abbreviations

PPE: Personal protective equipment. **Cat-Lab**: Catheterization laboratory.

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Not Applicable.

Authors' contributions

RERM, VCVR, SBDS, MEAM worked equally in the conformation of the guide, argumentation, bibliographic review, and documentation. RERM carried out the writing of the article and the editorial corrections. All authors read and approved the final version of the manuscript.

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Competing interests

The authors declare that they have no competing interests.

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Originality of the article

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