Situation analysis of percutaneous interventions in congenital heart defects during COVID-19 pandemic in Brazil. Current recommendations by Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista and future planning

Anáise situacional das intervenções percutâneas em cardiopatias congênitas durante a pandemia de COVID-19 no Brasil. Recomendações atuais da Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista e planejamento futuro

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ABSTRACT – The disease caused by COVID-2019 has caused an impact on worldwide realities, including care of patients at clinics and hospitals. The medical societies have recommended patients in stable clinical conditions to stay at home, in order to reduce exposure of healthcare teams and patients. Elective cardiac catheterization procedures should be postponed; however, if performed, some measures must be taken, such as minimizing the number of staff in the room, testing patients for COVID-19 and using appropriate personal protection equipment. The same measures should be adopted for congenital heart defect catheterization, considering some issues. Hence, by means of a recent survey of electronic forms, we characterize how the pandemic has affected cath labs procedures for congenital heart defect in Brazil, and provide a national overview of the current situation and a practical recommendation guide.

Keywords: Cardiac catheterization; Heart defects, congenital; COVID-19; Coronavirus infections; Brazil

RESUMO – A pandemia da COVID-19 impacta na realidade de todos, e com os atendimentos a pacientes em clínicas e hospitais não tem sido diferente. Sociedades médicas têm inclusive manifestado-se para que pacientes em condição clínica estável permaneçam em casa, visando à diminuição da exposição das equipes de saúde e do próprio paciente. Procedimentos eletivos de cateterismo cardíaco devem ser adiados e, em casos de sua realização, medidas como minimizar o número de pessoas em sala, testar os pacientes para COVID-19 e usar Equipamentos de Proteção Individual adequados devem ser tomadas. As mesmas medidas podem ser adotadas para o cateterismo de cardiopatias congênitas, mas alguns pontos ainda devem ser considerados. Assim, por meio de recente pesquisa em formulário eletrônico, caracterizamos como a pandemia afetou os procedimentos de hemodinâmica em cardiopatias congênitas no Brasil, oferecendo um panorama nacional da situação atual e um guia de recomendações práticas.

Descritores: Cateterismo cardíaco; Cardiopatias congênitas; COVID-19; Infecções por coronavírus; Brasil

INTRODUCTION

The respiratory disease caused by the new severe acute respiratory syndrome coronavirus (SARS-CoV-2), originated in China, in December 2019, has rapidly spread...
throughout all regions of the world, and was declared a pandemic by the World Health Organization, on March 11, 2020. So far, more than 5 million cases and over 340 thousand deaths have been documented worldwide. In Brazil, the first confirmed case of the disease caused by the new coronavirus (COVID-19) was reported on February 26, 2020. Data from the Ministry of Health of May 24, 2020, described 347,398 cases of and 22,013 deaths from the disease in the country.

Each individual infected can spread the virus to an average of three people. This is explained both by the high viral load in the upper respiratory tract and by the possibility of transmission by asymptomatic subjects. The high rate of transmission translates into high prevalence and mortality, even though lethality is not very high (approximately 4% in the world). It is also important to consider the excess burden of both material and human resources at hospitals. The infection rate of healthcare professionals is high (up to 41% in some reports, in China), and the scarcity of personal protective equipment (PPE) contributes to this. Therefore, the focus of pandemic control is to prevent infection spreading, by means of social distancing and personal hygiene measures.

There are cardiovascular manifestations resulting from COVID-19, such as myocarditis and severe arrhythmias, which may be due to exacerbated immune response, viral injury directly on cardiomyocytes, and/or severe hypoxemia resulting from lung injury. Although in the pediatric population COVID-19 infection has a good prognosis, and only 0.2% of those infected and aged under 19 years progress to more severe cases, patients with congenital heart disease deserve special attention. There are no data concerning the role of comorbidities in COVID-19 infection in children; however, it is reasonable to consider patients with heart failure, chronic hypoxemia or pulmonary hypertension are at risk of developing more severe infection.

To minimize the exposure of healthcare teams and reinforce social distancing, the medical societies have had uniform opinions: clinically stable patients must stay at home. Regarding cardiac catheterization, in general, the recommendations are to postpone elective procedures, minimize the number of people in the room, test patients for COVID-19 with clear indication, and provide appropriate PPE for each case. The same measures may be adopted for catheterization of congenital heart diseases, but a few details should be considered.

First, the Brazilian reality is extremely heterogeneous. Up to May 24, 2020, 37.8% of cases had been documented in the Southeast region, 34.5% in the Northeast, 20% in the North, 4.6% in the South, and 3.1% in the Midwest. Analyzing the mortality rate per 100,000 inhabitants, we noticed more discrepancy among states: ranging from 0.6 in Mato Grosso do Sul to 42.1 in Amazonas. Access to health and financial resources is uneven, which makes it almost impossible, in some regions, to adopt some measures, such as testing all patients taken to the cath lab. Cities with less people infected tend to adopt less strict measures, as implemented in the United States and could also be applied to Brazil.

In addition, selecting elective patients is not simple in the case of congenital heart diseases. For instance, is a cyanotic patient awaiting surgery at greater risk when exposed to COVID-19, or by having the procedure indefinitely postponed? Even clearly elective procedures, such as closing an atrial septal defect, which will not be carried out in the most critical period of the pandemic, must be rescheduled at some point, when a defined action protocol is needed. Discussing each case with the entire team responsible for patient care is key in deciding whether or not to perform a procedure.

### Scenario of the Brazilian Intervention Centers for Congenital Heart Diseases During the Pandemic

By means of a recent electronic survey, we characterized how the pandemic has affected cath lab procedures in congenital heart diseases in Brazil. Based on the collected data, we aim to make recommendations for this population. In sum, an online questionnaire (docs.google.com/forms) was sent to interventional cardiologists working with congenital heart diseases, in the period April 16 to 20, 2020. The analysis comprised demographic data, financing characteristics of the organization (whether public or private), service volume, date of change in routines to face the pandemic, and characteristics of the changes according to profile of patients candidate for intervention, protective measures, and perceived restriction of PPE, workers redistributed to care for cases not related to the cath lab, existence of a special committee to select cases for cardiac catheterization, and whether or not there was a follow-up plan. Survey responses were individually revised, based on demographic data, to ensure that duplicate responses were not included.

The centers were divided into groups based on financing aspects - public, private or both; for the purpose of analysis, the latter were allocated to the private group, since there was a source of income other than the Unified Health System (SUS, acronym in Portuguese). The survey questionnaire was returned by 26 centers in 11 states and the Federal District, with representatives from all Brazilian regions (Figure 1). Out of 26 centers, 24 (92.3%) were located in states that had already had over 1,000 confirmed cases of COVID-19 at the time of the survey, 17 of them (65.4%) in states with more than 3,000 cases confirmed, including eight centers in São Paulo, the epicenter of the epidemic in Brazil so far (30.7%). The mean of cardiac catheterization procedures carried out by the respondents
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Source: adapted from https://covid.saude.gov.br.

Figure 1. Distribution of the centers performing interventions in congenital heart diseases participating in the survey, according to the distribution of cases of COVID-19.

Figure 2. Procedures that should be performed during the pandemic, according to the opinion of the survey responders.

in 2019 was 210.3 (SD=141.9) procedures/year, with great variability among the centers, ranging from 30 to 527 procedures/year.

Of the participating centers, 46.2% treated only SUS patients, 30.8% were private hospitals and 23% treated patients both from the public and private systems. Until the survey deadline, on April 20, 2020, only one center (private and exclusively pediatric) had maintained its scheduling routine. In 53.8% (14 centers) all elective procedures had been canceled, keeping exams available for inpatients and urgencies. Another nine centers (34.6%) adopted the same attitude, providing, however, care for some elective cases, considering severity of the disease or change in physiology, and two (7.7%) facilities had completely interrupted care according to organizational decision.

It was also asked which procedures would continue to be performed during the pandemic (Figure 2). Procedures in hemodynamically unstable children and aortic or pulmonary valvuloplasty in neonates were continued in 92.3% and 84.6% of centers, respectively. On the other hand, the least mentioned procedures were atrial septal defect closure (3.8%), closure of patent ductus arteriosus in older children (7.7%), and percutaneous pulmonary valve replacement (7.7%).

Regarding the availability of PPE, most centers did not report problems, 61.5% worked with restrictions, however in conditions suitable for the exams, and 30.8% had not yet suffered any restrictions. When performing the procedures, 56% of respondents considered patients as suspected of presenting COVID-19 and reinforced respiratory protective measures were taken for the anesthesiologist and, at least, the first operator, while 36% continued with the usual care for exams. Only in one private center, COVID-19 testing was routinely done on patients before the exams. Only three (11.5%) centers reported having done tests on patients known to be positive for COVID-19. It was also asked if a multidisciplinary committee had been formed to review the cases and make decisions about possible procedures, in the context of the pandemic, and a large portion (69.2%) of the centers had not established such group, and the decision was possibly made at the discretion of the operator. Four centers reported the existence of the committee and another four (30.8%) evaluated the possibility of establishing one. In three centers (11.5%), at least one interventional cardiologist was reassigned due to the pandemic.

When comparing facilities that provide exclusive care to SUS patients and those that have another form of financing (private or public-private), we noted some differences in the responses of the form, mainly with regard to the restriction...
on the use of PPE, with 90% of the SUS services presenting some restriction, including two facilities reporting having interrupted the procedures, or conducting them without adequate PPE, while 43.7% of private facilities operated without restrictions. Likewise, only 10% of public facilities continued with elective exams in addition to urgencies versus 50% of private centers. Another divergent aspect was regarding the prospect of returning to elective activities, and 60% of the SUS facilities had no date versus 18.7% in private centers.

**DATA ANALYSIS AND GUIDANCE**

The questionnaire showed some important features. First, the great variety of centers that carry out interventions in congenital heart diseases, and their irregular distribution across the country, give rise to difficulties in adopting homogeneous management regarding procedures in times of pandemic. Most centers have cancelled the elective procedures, however this decision may not have been adopted by a crisis committee, since almost 70% of facilities had no multidisciplinary committee for this purpose. Interrupting elective procedures, which, at first, is extremely correct, must be reassessed everyday by the crisis committee, according to the reality of each region and organization, taking into account material resources (number of cath labs, inventory of PPE, availability of intensive care unit beds etc.) as well as human resources available. Another point to be discussed is the inclusion of a “Heart COVID Team”, exclusively dedicated to the discussion of such patients, taking into account all the variables that are unprecedented for the teams involved. The rationale for such a team is the new challenges that COVID-19 has brought for everyone, and the discussion of cases by a multidisciplinary team, which would bring multiple points of view and minimize the risks for patients, families and teams.

Second, over 85% of centers seem to reach a consensus about carrying out catheterizations for urgencies and inpatients. Although the definition of urgency is obvious, in this time of pandemic it is necessary to clearly define what should be considered urgency/emergency for cath lab procedures, in order to unify the concepts and, therefore, optimize resources and reduce the exposure of patients and healthcare professionals to the disease.

Third, we also found that, in most facilities, there was no determination of appropriate “flows” before, during or after cardiac catheterization.

By the end of the survey, only 11% of professionals had been reallocated to other areas in need, and this figure may change throughout the pandemic, considering our important clinical profile and delivery of services in other areas wherever necessary, such as intensive care units, neonatal units, and assistance with venous and/or arterial line access in critically-ill patients.

**RECOMMENDATIONS**

Performing interventional procedures in patients with ischemic and structural heart diseases during the new coronavirus pandemic, has been debated nationally and all over the world. On the other hand, in patients with congenital heart diseases, there are few opinions, and not focused on the Brazilian reality. We therefore understand the Department of Congenital Heart Diseases of the Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista (SBHCI) must have a statement to assist and guide physicians and hospitals regarding the indication and performance of these procedures.

The definition of all cases and actually performing the procedures are based on a tripod, including indication, the procedure itself and post-procedure care (Figure 3). All phases are interconnected and need to be considered together.

![Figure 3. Critical moments when performing procedures in congenital heart diseases during the COVID-19 pandemic.](image)

**Indication**

The indication of procedures to be performed and in whom has been based on some stratifications. They are usually classified as urgency/emergency, semi-elective and elective, taking into account the pathophysiology and the possibility of postponing the procedures. Urgencies and emergencies (interventions that need to be carried out as soon as possible) are easier to define, as well as catheterizations considered elective (with the possibility of waiting for more than 90 days), as shown in figure 2. The great difficulty is the semi-elective procedures, which we herein classified as heart diseases requiring intervention in less than 90 days, to avoid worsening of the patient’s clinical picture. Table 1 classifies and presents examples of procedures conducted in congenital heart disease, according to recently established criteria published by the Society for Cardiovascular Angiography and Interventions (SCAI), and adapted to the Brazilian reality after discussions with the authors of these recommendations. Since this is a guide, we understand the need to individualize patient care and procedures, since each hospital has its own characteristics and practices.
Table 1. Classification and examples of procedures carried out in congenital heart diseases based on the severity of the previous clinical condition

<table>
<thead>
<tr>
<th>Urgency/emergency (hospitalized)</th>
<th>Semi-elective (&lt;90 days)</th>
<th>Elective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardiocentesis</td>
<td>Stenosis of pulmonary arteries with hypertension or severe right ventricle dysfunction</td>
<td>OS ASD closure</td>
</tr>
<tr>
<td>Atroioseptostomy</td>
<td>Coarctation of aorta with uncontrolled HTN</td>
<td>PDA closure or VSD with no CHF</td>
</tr>
<tr>
<td>Vascular occlusion in case of hemothysis/CHF</td>
<td>Closure of PDA with CHF</td>
<td>Pulmonary valve stenosis with progressing gradients reaching values of indication</td>
</tr>
<tr>
<td>PDA stenting in patient with no other source of pulmonary or systemic flow</td>
<td>Aortic valve stenosis with progressing gradients reaching values of indication</td>
<td>Preoperative diagnostic catheterization in stable patient</td>
</tr>
<tr>
<td>Critical neonatal aortic stenosis</td>
<td>Venous stenosis or occlusion to alleviate symptoms</td>
<td>Percutaneous pulmonary valve replacement</td>
</tr>
<tr>
<td>Critical pulmonary atresia/stenosis</td>
<td>Severe hypoxemia (SO₂ &lt; 70%) in univentricular physiology</td>
<td>Routine biopsy after heart transplantation</td>
</tr>
<tr>
<td>Postoperative period of recent surgery (&lt;72 hours) with hemodynamic instability</td>
<td>Hemodynamic assessment in patients with pulmonary hypertension to define management</td>
<td></td>
</tr>
<tr>
<td>Biopsy after heart transplant in inpatient suspected of rejection</td>
<td>Pre-Glenn diagnostic catheterization</td>
<td></td>
</tr>
<tr>
<td>Temporary pacemaker implantation in complete heart block</td>
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</tbody>
</table>

Source: adapted from Morray et al.

OS ASD: ostium secundum atrial septal defect; HTN: hypertension; PDA: patent ductus arteriosum; VSD: ventricular septal defect; CHF: congestive heart failure; SO₂: oxygen saturation.

Procedures

Carrying out the procedures after correct indication has two main points: triage or testing for COVID-19 and the procedure itself. The availability of COVID-19 tests in Brazil is known to be reduced, and the kits have been reserved for symptomatic patients, preventing generalized previous triage, which would be ideal. To this date, procedures in COVID infected patients in the participant centers have been scarce. We believe these figures may increase in the coming months, and an adequate preparation and training of teams is necessary, especially on the correct use of PPE and the management of suspected or confirmed patients in the cath lab.

Since it is a respiratory virus, with human-to-human transmission, care must be focused on aerosol production with respiratory secretion, and in the contact with surfaces that may have viruses. Team care and handling in the cath lab have been published and, in the pediatric population, we can follow the same flow, with the following changes:

- N95 mask for all professionals involved, considering that most pediatric examinations require anesthesia with orotracheal intubation.
- Waterproof aprons.
- Two pairs of gloves (one for donning, one for after doffing).
- Face shield or goggles for everyone with contact with respiratory secretions (anesthesiologist and operators).
- Team training for donning, use, and doffing of PPE. Several illustrative videos can be found on the internet.
- Meetings with the Infection Control Committee, for local adjustments that may be necessary, as per different regional realities.

- For inpatients coming from the ward and, mainly, from the ICU, something that deserves discussion is to evaluate the possibility of intubation at the site of origin, avoiding this process in the cath lab, since most labs do not have positive pressure, increasing even more aerosol production of secretions and the consequent spreading to the team.

Post-procedure

Since this is an atypical situation, the post-procedural flow of these patients needs to be adapted, to minimize the risk of contamination and reduce, as much as possible, the use of hospital beds. Again, local adaptation is necessary, but ideally, these patients should be referred for post-anesthetic recovery/procedure in an intensive care unit environment and extubation should be carried out outside the cath lab, primarily in patients with suspected infection, and in those with a positive test for COVID-19.

Hospital discharge and further follow-up

Every patient undergoing a procedure must be contacted after hospital discharge, to be screened for COVID-19 symptoms. Phone contact is ideal, with direct questions, within 10 to 14 days after hospital discharge – considered as SARS-CoV-2 incubation period.

Family members, guardians and patients should receive written orientations on COVID-19 symptoms, as well as some form of contact shall symptoms develop.

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DECLARATION OF CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: JRN, SRA and LCS; data collection: JRN; data interpretation: JRN, SRA and RNC; writing of the text: RMS, RNC, ALAB, JRN and SRA; approval of the final version to be published: JRN, ALAB, CBP, FB, MJH, LCS, SRA, RNC and RMS.

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