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INTERVENTIONAL CARDIOLOGY: CHARACTERIZATION OF THE HEMODYNAMIC SERVICE IN CONGENITAL CARDIOPATHIES OF A BRAZILIAN SCHOOL HOSPITAL

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ABSTRACT

Cardiac catheterization technology allows the diagnosis, follow-up and treatment of congenital or acquired diseases. An example of this is the improvement of methods performed especially for the pediatric aged group. **Aim:** To characterize the Congenital Cardiopathies Hemodynamic Service of a Brazilian School Hospital regarding the variables - gender, age group, types of health care system (public or private), cardiac anomaly diagnosis and surgical intervention or percutaneous catheterization treatment. **Material and Methods:** Retrospective, descriptive study by analysis of the Brazilian Hemodynamics Service database, from 1999 to 2017, and variables for characterization were recorded. **Results:** A total of 667 catheterization reports were analyzed in 573 patients, which 328 (57%) are males and 245 (43%) are females. By the public health care system, 605 (91%) exams were performed and, by the private health care system, 62 (9%) exams were performed. Analyzes between number of patients ($p=0.2639$) and number of exams performed ($p=1.0000$) and types of health care system were not statistically significant. The percutaneous interventional procedure was therapeutic in 6.5% (42/667) among all those carried out. Pulmonary valve stenosis (15.5%) and Tetralogy of Fallot (14.0%) were among the most prevalent diagnoses in male gender, while complex congenital heart disease (19%) and ventricular septal defect (14%), in the female gender. **Conclusion:** The profile of this Brazilian Hemodynamic Service indicates predominance of procedures in both nursing and childhood males and performed by the public health care system; the most frequent heart diseases were complex congenital heart disease, pulmonary valve stenosis, Tetralogy of Fallot and interventricular communication.

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INTRODUCTION

Cardiology in congenital heart disease has shown incalculable progress and, at the present time, there has been a real transformation both in the diagnostic spectrum and in the conduct in general. The evolution of the different exams performed in clinical and semiological exams, in the systematization of clinical knowledge, up to the endless help of echocardiography, reaching, interventional catheterization, the hemodynamic milestone in diagnostic/therapeutic procedure, in addition to assisting open surgical intervention,

when necessary, for the elaboration of the most adequate surgical plan in relation to the diagnosis of the anomaly (Mourato *et al.*, 2014). Specifically, in the field of interventional catheterization, this progress occurred with Rashkind's atrioseptostomy in 1966, in the transposition of the great arteries (Rashkind & Cuaso, 1979). Currently, the technique extends to other anomalies such as pulmonary atresia with intact ventricular septum, tricuspid atresia, left atrioventricular valve atresia, mitral stenosis, among others. Furthermore, the method, in addition to widening the panorama of anomalies, has increased effectiveness, both in

the correction of obstructive defects, such as aortic and pulmonary strictures, and in coarctation of the aorta, and in the closure of septal defects, such as interatrial and ventricular communication, canal and in so many other situations, hitherto unimaginable. The 1980s were consecrated as the era of balloons for the performance of atrioseptostomy and valvuloplasty, and the 1990s, in turn, the era of endoprostheses for closing defects with umbrellas and coils and also for dilating structures through the stent (Kim, 2017). The advances made in the diagnosis and treatment of heart diseases in recent years are unquestionable. Despite this, congenital heart disease remains an important cause of neonatal and pediatric morbidity and mortality, with an increasing prevalence in the population. In addition, acquired heart diseases also have a high impact on patients' health, such as rheumatic fever, as a major cause of heart valve disease in the population (Zühlke *et al.*, 2017), and Kawasaki disease, an important etiological factor in coronary aneurysms (Chen *et al.*, 2017). The Cardiac Catheterization or Hemodynamic Study in Congenital Heart Diseases is an invasive procedure, performed on patients with congenital heart disease, with the objective of obtaining anatomical and functional information of the heart and its arteries and valves. The examination allows the diagnosis of various cardiac diseases (congenital or acquired) and the evaluation of their repercussions, in addition to the possibility of correcting various defects during the procedure, without the need for cardiac surgery and also allowing the assessment of the result of cardiac surgery, if necessary (BIBS, 2016). In these broad applications and indications, interventional catheterization has achieved sufficient credibility and reliability, mainly due to the effectiveness of the procedure and at an acceptable cost to the point that, in many anomalies, it can be applied to the most needy population in real social favor, which allowed the consolidation of the procedure as an effective therapeutic option and with lower risks, thus becoming a method, in certain cases, even superior to the surgical one (Qureshi *et al.*, 2000). Given the above, the present study aims to characterize the Hemodynamics Service in Congenital Heart Diseases of a Teaching Hospital, in the interior of the State of São Paulo, Brazil, by reviewing the reports of catheterizations of cardiac chambers performed in 1999 to 2017, considering gender, age group, types of health care system - Public or Private, diagnosis of cardiac anomaly and treatment by surgical intervention or percutaneous catheterization.

MATERIAL AND METHODS

This is a retrospective, descriptive study, whose data were obtained by reviewing the catheterization reports of both right and left cardiac cavities with cineangiocoronariography, atriography, ventriculography and angiographic study of the heart and/or the circulatory system performed in patients, in the Hemodynamics and Interventional Cardiology Service of a Teaching Hospital, in the interior of the State of São Paulo, Brazil, in the period of September 1999, when this Service was inaugurated, until March 2017. For the selection and inclusion of patient reports, the following criteria were considered: 1) reports of pediatric patients of both genders with or without previous diagnosis of heart diseases, valvular diseases and/or congenital or acquired arteriovenous malformations, 2) reports of adult patients of both genders with previous diagnosis of heart disease, valvular heart disease and/or congenital arteriovenous malformations, 3) reports of adult and pediatric patients who underwent the procedure at the Hemodynamics and Interventional Cardiology Service of a Brazilian School

Hospital. Exclusion criteria were considered: 1) reports of patients of both genders without congenital heart disease and/or over 65 years old, 2) reports of patients with visceral malformations other than cardiac and/or venoarterial. The following data were collected: gender, diagnosis of the lesion, treatment by thoracic surgical intervention and/or by catheterization, exams performed by the types of health care system (Public or Private). In order to get a better demographic characterization the age group was classified according to recommended growing phases: neonate (0 - 29 days), nursing (1 month - 1 year), childhood (2-10 years), adolescence (11-17 years), young adult (18-40 years), adult (41-65 years) (WHO, 2013). According to the Regulatory Norms for Research involving human beings, Resolution Number 466/12 of the Health Ministry the present study was approved by the Ethics Committee of the Medical School (Report #.064.965/2017), and for being a laboratory registry-scan study the informed consent was not applied.

Statistical Analysis

The results were submitted to statistical analysis, and when applicable, Chi-square (χ^2) or Fisher exact tests were used for comparison between variables. Significance level was established in 5%. The results were expressed in percentages (%). The statistical tests were performed using the GraphPad InStat program, 3.0 version, GraphPad Software Inc, San Diego - California, USA, www.graphpad.com.

RESULTS

From September 1999 to March 2017, 573 patients underwent cardiac catheterization procedures at the Brazilian Hemodynamics Service in Congenital Heart Diseases, 328 (57%) of whom were male and 245 (43%) were female. Of this total, 515 (90%) patients were from the public health care system, being 299 (52%) male and 216 (38%) female. In the private system there were a total of 58 (10%) patients, 29 (5%) for each gender equally. The difference between the number of patients of both genders and types of health care system was not significant (Fisher's exact test, $p=0.2639$). Regarding the age group, Tables 1 and 2 show, respectively, the distribution of the number (N) of male and female patients, from the public and private health care systems. The comparison between the age groups of male patients and types of health care systems revealed a higher prevalence of patients from the public system (91%), in all groups, in relation to patients from the private system. However, the age groups, nursing (46%) and childhood (30.5%), were the most prevalent in both types of health care systems. The comparison between the age groups of female patients and types of health care systems revealed a higher prevalence of patients from the public system (88%), in all groups, in relation to patients from the private system. However, the age groups, nursing (41.2%) and childhood (39%), were the most prevalent in both types of health care systems. Regarding the number of exams, 667 catheterizations were performed, 362 (54%) in males and 305 (46%) in females. Of this total, 605 (91%) exams were performed by the public health care system, 328 (49%) of which were male and 277 (42%) were female. And, by the private health care system, 62 (9%) exams were performed, 34 (5%) of which were male and 28 (4%) were female. The difference between the number of exams performed by patients of both genders and types of health care systems was not significant (Fisher's exact test, $p = 1.0000$).

Table 1. Percentage distribution of the number of male patients from the Public and Private Health Care Systems, according to age group

Age Group/Health Care System	Male Public N=299 (91%)		Male Private N=29 (9%)		Total N=328	
	N	%	N	%	N	%
	Neonate	40	12	2	0.6	42
Nurseling	134	41	16	5	150	46
Childhood	92	28	8	2.5	100	30.5
Adolescence	28	8.5	2	0.6	30	9.1
Young adult	4	1.2	1	0.3	5	1.5
Adult	1	0.3	0	0.0	1	0.3

Table 2. Percentage distribution of the number of female patients from the Public and Private Health Care Systems, according to age group

Age Group/Health Care System	Female Public N=216 (88%)		Female Private N=29 (12%)		Total N=245	
	N	%	N	%	N	%
	Neonate	19	7.8	3	1.2	22
Nurseling	88	35.9	13	5.3	101	41.2
Childhood	87	35.5	8	3.5	95	39
Adolescence	17	6.6	1	0.4	18	7
Young adult	4	1.8	3	1.2	7	3
Adult	1	0.4	1	0.4	2	0.8

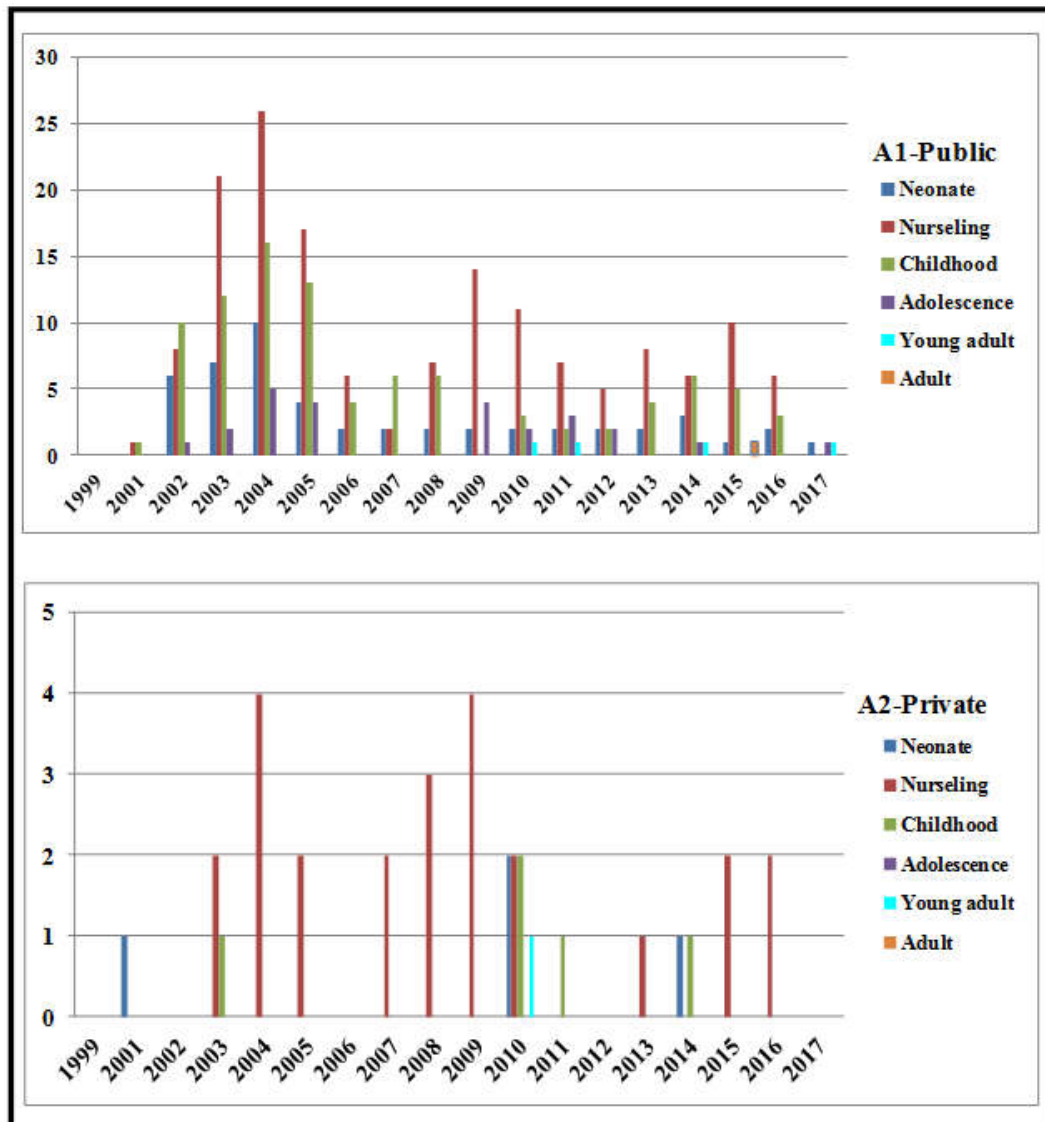


Figure 1. Distribution, according to age group, of the number of exams performed per year by male patients, from the Public Health Care System (A1-Public) and Private Health Care System (A2-Private)

Figures 1 and 2 show, respectively, the distribution of exams performed, per year, by male (A) and female (B) patients, according to the age group, from the public health care system (1) and the private health care system (2). The years from 2002 to 2005 were the ones that registered the most exams, making a total of 162 (49%), among the 328 performed by the public health care system, in the male gender. Their distribution by age group: neonate - 50 exams (15.1%), nursing - 155 (47.3%), childhood - 93 (28.5%), adolescence - 25 (7.6%), young adult - 4 (1.2%) and adult - 1 exam (0.3%), revealed a significant difference ($\chi^2 = 104.67$; $p = 0.0355$). Nursing and childhood were the phases with the highest prevalence of exams, making a total of 75.8%, followed by the neonate phase (Figure 1-A1).

According to the public health care system, in the female gender, the years from 2002 to 2005 were the ones that registered the most exams, making a total of 119 exams (43%), among the 277 performed. Their distribution by age group: neonate - 24 exams (8.6%), nursing - 116 (41.8%), childhood - 106 (38.2%), adolescence - 25 (9%), young adult - 5 (2%) and adult - 1 exam (0.4%), revealed a significant difference ($\chi^2 = 120.73$; $p = 0.0022$). Nursing and childhood were the phases with the highest prevalence of exams, making a total of 80%, followed by the adolescence phase, but with a difference of only 0.4% for newborns (Figure 2-B1). Higher prevalence of exams - 14 (50%) occurred in the years 2013 to 2015, of the total of 28 performed by the private health care system, in the female gender, with 7 (25%) exams only in the year 2015.

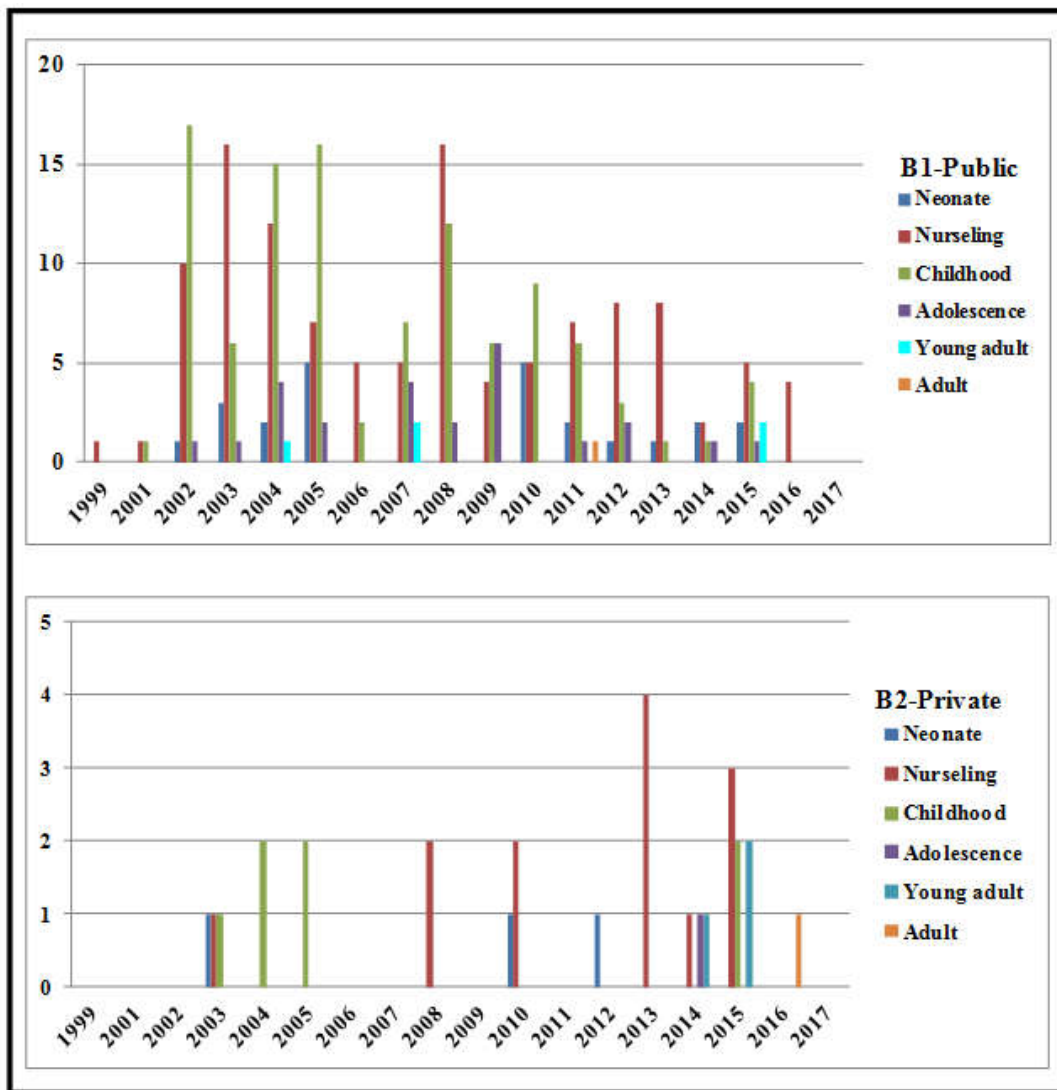


Figure 2. Distribution, according to age group, of the number of exams performed per year by female patients, from the Public Health Care System (B1-Public) and Private Health Care System (B2-Private)

By the private health care system, in 2010 there was a higher prevalence of exams - 7 (21%), of the total of 34 performed, in males. Their distribution by age group: neonate - 4 exams (12%), nursing - 24 (70%), childhood - 5 (15%) and young adult - 1 exam (3%), did not reveal statistical difference ($\chi^2 = 35.848$; $p = 0.4758$). There were no exams performed in the adolescence and adult phases. Like the exams carried out by the public health care system, the nursing and childhood phases were the most prevalent, making a total of 85%, followed by the neonate phase (Figure 1-A2).

Their distribution by age group: neonate - 3 exams (11%), nursing - 13 (46%), childhood - 7 (25%), adolescence - 1 (3.5%), young adult - 3 (11%) and adult - 1 exam (3.5%), revealed a significant difference ($\chi^2 = 79.952$; $p = 0.0052$). Like the exams performed by the public health care system, the nursing and childhood phases were the most prevalent, making up a total of 71%, followed equally by the neonate and young adult phases (Figure 2-B2). Among the 362 exams performed in males, 19 (5.5%) were exclusively therapeutic procedures, eight (2%) for hemodynamic assessment of pulmonary reactivity and the remaining 335 exams (92.5%)

were catheterizations for pre and/or diagnostic evaluation or postoperative in patients who required thoracic surgery. The therapeutic procedures performed in males, in order of prevalence, were: 1) Percutaneous pulmonary venous valvuloplasty - 8 exams (43%); 2) Aortic angioplasty with stent - 4 exams (21%); 3) Percutaneous Occlusion of Arterial Canal Persistence - 4 exams (21%); 4) Atriosseptostomy by balloon catheter - 1 exam (5%); 5) Aortic valvuloplasty by balloon dilation - 1 exam (5%) and 6) Percutaneous venous valvotomy - 1 exam (5%). Likewise, among the 305 exams performed in females, 23 (7.6%) were exclusively therapeutic procedures, one (0.4%) for hemodynamic assessment of pulmonary reactivity and the remaining 281 exams (92%) were catheterizations for assessment pre and/or postoperative diagnosis in patients who required thoracic surgery.

Table 3. Distribution of diagnoses among male patients (N = 328)

Diagnoses	N	%
Pulmonary valve stenosis	51	15.5
Tetralogy of Fallot	47	14
Interventricular communication	39	12
Interatrial communication	33	10
Complex congenital heart disease	29	9
Aortic coarctation	22	7
Double-inlet left ventricle	13	4
Pulmonary arterial hypertension	13	4
Complete atrioventricular septal defect	10	3
Transposition of the great arteries	10	3
Double-outlet right ventricle	9	3
Patente ductus arteriosus	7	2
Total anomalous pulmonary vein drainage	6	2
Mitral stenosis	6	2
Partial anomalous drainage of pulmonary veins	5	1.5
Aortic stenosis	5	1.5
Left atrial isomerism	5	1.5
Ebstein's anomaly	3	1
Tricuspid atresia	3	1
Coronary artery aneurysm	2	0.5
Double-outlet left ventricle	2	0.5
Pulmonary artery stenosis	2	0.5
Aortic and mitral regurgitation	2	0.5
Eisenmenger's syndrome	2	0.5
Shone's syndrome	2	0.5

Table 4. Distribution of diagnoses among female patients (N=245)

Diagnósticos	N	%
Complex congenital heart disease	46	19
Interventricular communication	34	14
Tetralogy of Fallot	32	13
Pulmonary valve stenosis	23	9,5
Interatrial communication	17	7
Aortic coarctation	12	5
Double-inlet left ventricle	11	4,5
Transposition of the great arteries	10	4
Total anomalous pulmonary vein drainage	9	3,5
Tricuspid atresia	6	2,5
Complete atrioventricular septal defect	6	2,5
Double-outlet right ventricle	5	2
Pulmonary arterial hypertension	5	2
Ebstein's anomaly	4	1,5
Aortic regurgitation	4	1,5
Coronary-cavitary fistula	4	1,5
Left atrial isomerism	4	1,5
Patente ductus arteriosus	4	1,5
Eisenmenger's syndrome	4	1,5
Pulmonary artery aneurysm	1	0,5
Double-outlet left ventricle	1	0,5
Aortic valve stenosis	1	0,5
Pulmonary arteriovenous fistula	1	0,5
Tricuspid regurgitation	1	0,5

The therapeutic procedures performed in the female gender, in order of prevalence, were: 1) Percutaneous pulmonary venous

valvuloplasty - 10 exams (44%); 2) Aortic angioplasty with stent - 6 exams (26%); 3) Percutaneous Occlusion of Arterial Canal Persistence - 5 exams (22%); 4) Brachiocephalic trunk angioplasty - 1 exam (4%) and 5) Percutaneous venous valvotomy - 1 exam (4%). Regarding the diagnoses found in the patients, of both types of health care system - Public and Private, in the male gender there were 25 different diagnoses and in the female, 24 diagnoses (Tables 3 and 4, respectively). Pulmonary valve stenosis and Tetralogy of Fallot are among the most prevalent in males, making up a total of ~30% of cases, while complex congenital heart disease and interventricular communication are the most prevalent in females, with a total of 33%.

DISCUSSION

A retrospective documentary survey was carried out, with quantitative analysis of hemodynamic procedures reports, from 1999 to 2017, with the aim of characterizing the profile of the Hemodynamics Service in Congenital Heart Diseases of a Brazilian Teaching Hospital, considering gender, age group, types health care system - Public and Private, treatment by thoracic surgery or percutaneous catheterization and diagnosis of cardiac anomaly. Six hundred sixty seven catheterization reports were analyzed, which were performed on 573 patients of both genders, in the referred period. There was no significant difference between the number of patients and exams performed in relation to gender. Although there was no statistical difference, the highest prevalence was in male patients (57%) and from the public health care system (91%), and also in the nursing and childhood age groups, for both types of health care system (public and private), these results being corroborated by the literature (Mourato *et al.*, 2014; Hoang *et al.*, 2018). The prevalence of the male gender in certain conditions and the susceptibility to infectious/inflammatory processes is not yet well established, but it is known that the heterozygous loci related to protection from infection are located on the X chromosome. than the female gender due to the presence of a single X chromosome being, therefore, more susceptible to some diseases and the consequences inherent to them and to infectious/inflammatory processes (Morris *et al.*, 2009; Ho *et al.*, 2018). From the 17th century onwards, congenital heart disease started to be diagnosed by correlating symptoms with necropsy data. They are the most common of all congenital anomalies, occurring in about 1% of births, and responsible for 3-5% of neonatal deaths and, among these, the most prevalent diagnoses described are ventricular and atrial septal defect, patente ductus arteriosus, pulmonary valve stenosis, Tetralogy of Fallot, aortic coarctation, transposition of great arteries and aortic stenosis (Van der Linde *et al.*, 2011). In Brazil, the most frequent recorded subtypes are interventricular communication, atrial septal defect, pulmonary stenosis, Tetralogy of Fallot, aortic coarctation, transposition of great arteries and aortic stenosis (Pinto Júnior *et al.*, 2015). In the present study, in accordance with the literature, the most diagnosed heart diseases were omplex congenital heart disease, pulmonary valve stenosis, Tetralogy of Fallot and interventricular communication. At the same time, the inestimable progress of cardiology in congenital heart disease, there has been, in this specialty, an intense revolution both in diagnosis and in conduct in general. The field of interventional cardiology in congenital heart disease has been growing at an exponential rate, being an alternative to the surgical procedure itself. On the other hand, percutaneous interventions in the

pediatric age group may be limited by the size of the patient or by the very anatomy of the cardiac anomaly (Van der Linde *et al.*, 2011; Leirgul *et al.*, 2014; Belo *et al.*, 2016).

As a result of technological advances, a greater number of congenital heart diseases are amenable to treatment by catheterization. The images obtained, increasingly improved, allow for better selection of patients, in many cases avoiding surgery, while those with more complex congenital heart disease may require less invasive surgical procedures, due to better planning, indicated for the correction of flaws. physiological, resulting in faster recovery, shorter hospital stay, longer survival and better quality of life for patients (Albert *et al.*, 2011; Richardson, 2015; Kim, 2017). Another favorable aspect that should be highlighted is that, indirectly, interventional catheterization contributed to the improvement of operative techniques. Due to the progress achieved, there is currently the interconnection of interventional catheterization with surgery, as a complement of procedures favorable to the reduction of risks, the improvement of preoperative conditions and the facilitation of surgical correction, using it in a first interventionist evaluation. Pulmonary atresia with hypoplastic right ventricle, total anomalous pulmonary vein drainage, Ebstein's anomaly with pulmonary stenosis are some examples of this interconnection (Albert *et al.*, 2011; Richardson, 2015; Kim, 2017), as performed in the present Brazilian Hemodynamics Service in Congenital Heart Diseases. Therapeutic catheterization began in 1966, when the balloon catheter septostomy technique was introduced, thus directing the creation of new methodologies and procedures. Later, with the performance of pulmonary valvuloplasty and aortoplasty in aortic coarctation, a new phase in the history of interventional catheterization was initiated, reaching about 30% of congenital heart diseases treated or palliated through this procedure (Rashkind & Cuaso, 1979; Albert *et al.*, 2011; Richardson, 2015; Kim, 2017). In the present Brazilian Hemodynamics Service in Congenital Heart Diseases, the prevalence of therapeutic procedures was about 6.5% (42/667), a rate lower than that of the literature, probably due to the short time of operation of the Service, compared to other centers, and also due to the large number of congenital heart diseases that required surgical treatment (92%), due to the characteristics of greater severity and complexity.

Interventional cardiology is a constantly evolving specialty. Detailed echocardiographic guidance is critical to the success of many percutaneous cardiac interventions. Most centers have this routine of echocardiographic evaluation ((Mourato *et al.*, 2014; Pinto Júnior *et al.*, 2015; Belo *et al.*, 2016; BIBS, 2016), including the present Service, in which all patients underwent it. Echocardiography is a complementary, non-invasive exam of choice in confirming clinical suspicion, replacing or allying with hemodynamic study, which in turn, increasingly and appropriately, can replace or better schedule cardiac surgery in correction of many hemodynamic disorders (Karsenty *et al.*, 2017). In this wide application, interventional catheterization has achieved sufficient credibility, mainly due to the effectiveness of the procedure and at an affordable cost to the point that, in many anomalies, it can be applied to the most needy population for real social benefit, consolidating the method as an effective diagnostic-therapeutic option. This fact was confirmed in the present study, in which 91% of the exams were performed by the public health care system and 9% by the private health care system, as it is a teaching hospital with a predominance of public treatment. In addition

to echocardiography, with the advent of advanced non-invasive imaging modalities (cardiac magnetic resonance, multislice computed tomography), the value of cardiac catheterization in the diagnosis, anatomical and hemodynamic evaluation of cardiac disease has decreased.

However, due to its precision and more straightforward concept, catheterization still offers valuable data both on the structure and pathophysiology of the underlying cardiac lesion and on complex lesions; when other complementary, non-invasive exams do not provide sufficient and specific information; in the decision on pharmacological or surgical treatment in patients with pulmonary hypertension; in the surveillance of graft vasculopathy in post-transplant patients and in electrophysiological studies (Gorenflo *et al.*, 2010; Johns *et al.*, 2018). Thus, this procedure, of great importance for clinical and surgical cardiology, remains the gold standard for diagnosis and/or therapy for countless patients with congenital heart disease (Moustafa *et al.*, 2018; Mawad & Mertens., 2018). In fact, in relation to the procedure for assessing the hemodynamics of pulmonary reactivity, it was necessary in about 2%, among the procedures performed with diagnostic support for non-invasive methods. Pulmonary arterial hypertension is not mentioned among the most common diagnoses in the specialized literature, as is the case with total complete atrioventricular septal defect. In the present study, these two diagnoses also had a prevalence of 36% each, among the twenty-five found. This prevalence is higher than that reported in the literature, which was 24.7% for pulmonary arterial hypertension and 10.4% for complete atrioventricular septal defect (Belo *et al.*, 2016). The exams in female patients in the public health care system had a more homogeneous distribution in relation to male patients, since the implementation of the Service. The public health care exams, for both genders, had a lower prevalence and were more sporadic during the analyzed period. There is no data in the literature comparing types of public/private health care systems, as performed in the present study. The performance of interventional cardiac catheterization in congenital heart diseases requires skill, competence and excellent training not only by the entire interventionist medical team, but also by the support group such as radiologists, nurses, technicians, who must also be qualified and trained, in conformity. In addition, the Service of a training institution must be fully equipped, have surgical support and availability of intensive care in the pre and, especially, in the postoperative period (Butera *et al.*, 2015; Sheikh, 2015). These recommendations are available and implemented in the Hemodynamics and Interventional Cardiology Service of the Brazilian Institution of the present study, thus providing advances in scientific knowledge for further research on this topic, providing elements that support health professionals and managers in the planning and implementation of actions for excellent care for small patients.

Conclusion: The characterization of the Hemodynamics Service of a Brazilian Teaching Hospital indicates a greater number of procedures in the male gender, in the phases of nursing and childhood, performed by the Public Health Care System and the most frequent heart diseases diagnosed were complex congenital heart disease, pulmonary valve stenosis, Tetralogy of Fallot and interventricular communication.

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