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ORIGINAL ARTICLE

Percutaneous intervention in the correction of congenital heart deffects (DCC): experience in as UMAE

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Abstract

Introduction: *Congenital heart defects are common in infants and adults, affecting quality of life if not corrected. Unlike open surgery, percutaneous intervention allows correction with a high success rate and speedy recovery. In Mexico, there are not enough studies to describe their efficacy and safety.* **Methods:** *A cohort study was conducted in the Hospital "Manuel Avila Camacho", in Puebla, Mexico, including 149 patients with congenital heart defects repaired by percutaneous intervention, recording data from clinical records. The following were documented: post-guided fluoroscopy, hemodynamic changes, cardiac catheterization drilling anatomical changes, and complications six months later such as infection or bleeding at the puncture site, device migration, endocarditis, or death. SPSS was used, using descriptive and inferential statistics.* **Results:** *The patients' congenital heart defects treated were ductus arteriosus, atrial septal defect, and aortic coarctation, with ductus arteriosus being recorded as the most frequent congenital heart defect. Primary angioplasties were performed in 75% and stenting in the rest. Anatomical corrections of congenital defects were successful in 96.4% of patients ($p < 0.01$), with minimal adverse effects ($p < 0.01$).* **Conclusions:** *We conclude that our hospital has good efficacy and safety in percutaneous intervention, comparable to published reports.* (Gac Med Mex. 2016;152:598-603)

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Introduction

Congenital heart defects (CHDs) are heart structural anomalies produced by errors in cardiac embryogenesis that occur with more severity in the neonatal period or at pediatric age. These defects are estimated to be the most common congenital malformation, with published incidence being variable[1]. In Mexico, as in other countries, the exact size of this population is unknown. In a recent multicenter study carried out by Mendieta et al. in 23,926 children, the incidence of congenital heart diseases in a 5-year period was 7.4 x 1,000 live births, with patent ductus arteriosus (PDA) standing out at first place among preterm newborns and interatrial communication (IAC) among full-term newborns[2]. USA statistics range between 100,000 and 500,000 CHD cases[3]. According to Arizmendi et al., in 2012, registries in Spain estimated there were approximately 100,000 patients with some type of moderate or serious cardiac malformation[4].

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The fact of identifying and effectively treating CHD represents one of the greatest advances of modern age medicine and cardiovascular surgery. With the publication of the book "Congenital Malformations of the Heart", written by Dr. H. Taussig, the doors to the understanding of CHDs were opened; concomitantly, the first landmarks in their correction were established: John H. Gibbon performed the first open heart surgery in a patient with IAC; Robert Gross described the arterial ductus ligation for the first time; Clarence Crawford, the resection of an aortic coarctation (AC), and Dr. Taussig, together with Blalock, published her experience with palliative shunt for cyanogenic heart diseases[4]. In Mexico, the first interventional procedure was carried out in 1953 at the Ignacio Chávez National Institute of Cardiology, a percutaneous valvulotomy, and in 1966, atrioseptostomy, performed by Dr. Rahskind for first time, became the routinely used interventional procedure[5].

Most CHDs are diagnosed at pediatric age, and this is why almost all affected subjects reach adulthood with the defects surgically solved and, in some cases, with residual defects that require subsequent management. In this case, it is more accurate talking about surgical repair than surgical correction, since this intervention is not definitive, given that an estimate of 40%-55% of these patients will require life-long special follow-up, and 25% will require special care in reference units highly specialized in medical and surgical follow-up of CHD at adulthood[1]. In contrast, without therapeutic intervention, more than half affected subjects are deemed not likely to reach adulthood. Fortunately, thanks to cardiology, surgery and pediatrics good job, 85% of children born with a congenital heart disease are currently meeting this goal[1,2], thus changing the panorama over the past 30 years[6], since the development and incorporation of new surgical techniques have reduced mortality from 20% in the decade of 1970 down to 5% in the current era[7].

Malformations currently amenable to correction by intervention can be divided into two main groups: the first one is comprised by native malformations, which are simple anomalies such as IAC, PDA, interventricular communication (IVC) and aortic stenosis (AS), among others, and the second group is comprised by complex conditions that are secondary to surgical corrections during childhood, such as pulmonary branch stenosis (PBS), prosthetic duct obstruction, dehiscence of previous closure and venous or arterial neoformations, among others. The first group is easier to diagnose and treat, since in the second group it is important to know the initial diagnosis, date and variety of surgical intervention, type of implanted prosthetic material, etc., which is information not always is feasible to be obtained from the patient or his/her family[8].

The indications used as diagnostic method include pulmonary vascular resistances, left and right ventricle function and pressure gradients evaluation, and shunt quantification when non-invasive assessment is uncertain; performing coronary angiographs and assessment of extracardiac vessels, such as aortopulmonary collateral arteries, is also useful[9].

Currently, percutaneous closure is the treatment of choice for most cases of patent ductus arteriosus. The devices most widely used to this purpose are stainless steel, spiral-shaped coils with adhered polyester fibers to reduce the thrombogenicity of the device. Ductus complete closure (without residual shunt) is obtained in 60%-80% of cases immediately after implantation, a figure that reaches to be > 90% in the months that follow the procedure[10].

There are many published studies describing the use of percutaneous catheterization as a method to correct CHD; its rate of success is higher than 80% and has adverse events of variable grade since, as any other technique, it is not free of complications which, although these occur in lower proportions, they can do it according the defect to be corrected[11]. There are other works with higher incidence of complications, such as the one published by Holzer et al., a randomized, multicenter trial with 1,135 patients who underwent balloon pulmonary angioplasty. There were adverse effects in 22% of cases, and these events were classified on levels 3-5 of the classification by Bergersen et al.; mostly level 3, they included vascular rupture, embolization of the device, significant hemodynamic alterations, presence of serious arrhythmias and death at a minimal proportion (0.015%)[12,13].

As we can observe, multiple studies have internationally been carried out on the efficacy and safety of the different percutaneous intervention procedures applied to CHD, but reports are limited in Mexico. In our high specialty medical unit (UMAE – *Unidad Médica de Alta Especialidad),* where these procedures began to be practiced almost four years ago, with an emphasis on the closure of defects such as IAC and PDA, with aortoplasties for AC and aortic valve dilatation for AS, we don't have publications describing the efficacy and safety of these procedures and, therefore, our purpose has been to describe them.

Materials and methods

Methodology

A descriptive, analytical, cross-sectional, single group, cause-effect, ambidirectional cohort study was conducted, with a population of 149 patients of the Cardiology Department, with indistinct age and from both genders, with congenital defects repaired with percutaneous intervention at the Hemodynamics Ward of the Manuel Ávila Camacho UMAE of

Puebla, over the period encompassed from February 1, 2011, through January 31, 2014. The cohort was comprised by all patients who met the selection criteria during the study period.

Procedures

After authorization was obtained from the UMAE Research and Teaching Committee, patient medical records and files, obtained from the medical record department, were reviewed for the study period. Files from patients with new cases of CHD repaired by percutaneous intervention, regardless of age and from both genders, were selected. CHDs were initially detected by the clinical cardiologist of the outpatient clinic by integrating physical examination and diagnostic tests, with echocardiogram standing out. The purposes of the study were established, with the efficacy variable being regarded as the presence of any anatomical modification after fluoroscopy-guided catheterization recorded on the hemodynamics procedure forms and, as safety variables, the changes in mean blood pressure (MBP), heart rate (HR) and oxygen saturation (SaO_2) prior, during and after the procedure, arrhythmias, stroke and cardiac perforation documented on the trans-anesthetic record sheet. All patients were assessed 24 h after the procedure with electrocardiogram, chest X-ray and transthoracic bi-dimensional and Doppler echocardiogram; subsequently, they were assessed at 15 days and 6 months with clinical examination, electrocardiogram, chest X-ray and/or echocardiography, and late complications, such as infection or bleeding at the puncture site, device migration, endocarditis or death report were recorded. The data were recorded in a form with predesigned questions and previously categorized answers.

Statistical management

Statistical management was carried out with the SPSS program (version 21), and descriptive statistics was used, with CHD frequencies and proportions being obtained and data being tabulated. Inferential statistics was used by applying contingency tables in order to determine the relationship of qualitative variables, and Student's t-test was used on quantitative variables for the comparison of means in MBP, HR and SaO_2 related samples; significance was established at a p-value ≤ 0.01.

Results

During the 3 years of study, 149 CHD new confirmed cases were assessed at the Clinical Cardiology Department. Average age (μ) was 6.59 ± 5.58 years, with lower and upper class limits of 1 and 21 years, respectively. With regard to gender, there were 66.4% of female patients and 33.6 of male patients, with a female:male ratio of 1.9:1, which is comparable with findings reported by Galván et al. in the La Raza National Medical Center (CMN – *Centro Medico Nacional)* in 2009[3].

The heart diseases found in the study were the following: PDA, IAC, AC, pulmonary stenosis (PS), AS, IVC and PBS; the most common was PDA, followed by IAC, and the least frequent was PS (Table 1).

Preformed procedures

Cardiac interventional procedures performed during the study period were mostly percutaneous closures (84%) to close intracardiac defects such as IAC and IVC or extracardiac vascular communications such as PDA; the remaining 16% underwent balloon percutaneous angioplasty to treat PS, AS and AC (Table 2). Of the angioplasties performed, 75% were primary and the rest required vascular endoprosthesis placement. The devices used were the following: Amplatzer Ductus Occluder, stents and coils for intracardiac defects correction, with the use of Amplatzer standing out in a vast majority of the defects. For the correction of extracardiac defects, balloon angioplasty was used with and without applying any device, as shown in table 3.

Efficacy and safety of percutaneous intervention in patients with CHD

Percutaneous catheterization for the correction of CHD was successful in 96.6% of cases ($p < 0.01$); of note, percutaneous closure of intracardiac anatomical defects was successful in 99% of patients with PDA (n = 100; $p < 0.01$). In contrast, there were 3.4% of failed procedures, since correction of the congenital defect was not observed and surgical route was required for its management.

With regard to documented complications during the procedure, 1.3% of patients experienced hypotension, but its clinical and statistical relevance was negligible ($p > 0.01$). The behavior of MBP in the remaining patients was not significant, as were HR and SaO_2 ($p > 0.01$). During the follow-up, infection at the site of puncture was determined in 0.7% of patients. No complications such as endocarditis, stroke, device migration or deaths, among others, were identified.

Discussion

In the present study, an analysis was carried out on percutaneous interventions in patients with CHD, based on a sample of 149 patients of 1 to 21 years of age over a 3-year period.

Table 1. CHD incidence of distributed by ages

Ages (years)	PDA		IAC		IVC		PS		AS		PBS		AC		Total n
	F	%	F	%	F	%	F	%	F	%	F	%	F	%	
1	20	20	1	4.5	–	–	1	16.6	–	–	–	–	–	–	22
2	24	24	–	–	–	–	–	–	1	16.6	1	100	–	–	26
3	9	9.0	–	–	1	33.3	2	33.3	1	16.6	–	–	2	18.1	15
4	7	7.0	–	–	–	–	1	16.6	–	–	–	–	1	9.0	9
5	8	8.0	–	–	–	–	1	16.6	1	16.6	–	–	1	9.0	11
6	4	4.0	–	–	–	–	–	–	1	16.6	–	–	2	18.1	7
7	7	7.0	–	–	–	–	–	–	–	–	–	–	–	–	7
8	2	2.0	–	–	–	–	–	–	–	–	–	–	–	–	2
9	1	1.0	1	4.5	–	–	–	–	–	–	–	–	–	–	2
10	3	3.0	–	–	1	33.3	–	–	–	–	–	–	–	–	4
11	4	4.0	5	22.7	–	–	–	–	–	–	–	–	–	–	9
12	1	1.0	2	9.0	–	–	–	–	–	–	–	–	1	9.0	4
13	1	1.0	3	13.5	–	–	–	–	–	–	–	–	–	–	4
14	1	1.0	2	9.0	–	–	–	–	–	–	–	–	3	27.2	6
15	2	2.0	2	9.0	1	33.3	–	–	–	–	–	–	–	–	5
16	1	1.0	1	4.5	–	–	1	16.6	1	16.6	–	–	–	–	4
17	1	1.0	2	9.0	–	–	–	–	1	16.6	–	–	–	–	4
18	3	3.0	3	9,0	–	–	–	–	–	–	–	–	1	9.0	7
21	1	1.0	–	–	–	–	–	–	–	–	–	–	–	–	1
Total	100	100	22	100	3	100	6	100	6	100	1	100	11	100	149

Table 2. Procedures performed with percutaneous intervention

Diagnosis	Procedure					
	Percutaneous closure		Percutaneous balloon angioplasty		Total (n = 149)	
	F	%	F	%	F	%
PDA	100	81	–	–	100	67
IAC	22	17	–	–	22	15
IVC	3	3	–	–	3	2
PS	–		6	25	6	4
AS	–		6	25	6	4
PBS	–		1	4	1	1
AC	–		11	46	11	7
Total (n)	125	100	24	100	149	100

Table 3. Devices applied in CHD repair

Diagnosis	Procedure								Total (n = 149)	
	Amplatzer		Stent		Coil		None			
	F	%	F	%	F	%	F	%	F	%
PDA	97	80	–	–	3	100	–	–	100	67
IAC	22	18	–	–	–	–	–	–	22	15
IVC	3	2	–	–	–	–	–	–	3	2
PS	–	–	–	–	–	–	6	33	6	4
AS	–	–	–	–	–	–	6	33	6	4
PBS	–	–	1	1	–	–	–	–	1	1
AC	–	–	5	5	–	–	6	33	11	7
Total (n)	122	100	6	5	3	100	18	99	149	100

Congenital heart diseases treated at the hospital over the study period were more commonly observed in children younger than 5 years (48.3%), which drives to an abnormal distribution curve. This phenomenon is justified by the incidence of CHD described in previous studies and its lower occurrence at adulthood. Just as Arzamendi et al. Akagi et al. and other authors describe, most congenital heart diseases are identified at pediatric age[9,14].

If congenital heart diseases are classified according to their incidence, the main was PDA, which is consistent with observations reported by Mendieta et al.[2] in a multicenter study recently carried out in Mexico with 23,926 children[2]. This phenomenon has been directly associated with a history of prematurity. Patent ductus arteriosus is an infrequent cardiovascular risk condition at adulthood, and its presence can trigger endocarditis, pulmonary hypertension, congestive heart failure and sudden death[11]. In our study group, most patients with this malformation (99%) had been diagnosed at pediatric age. With regard to the use of devices for patent ductus arteriosus percutaneous closure in the study population, the Amplatzer Ductus Occluder was used 97% of cases, with this device offering practically immediate occlusion. It should be noted that our hospital has wide experience on its use since several years ago. These results are consistent with those described by other authors, such as Howaida et al. in 2013, who, in a multicenter randomized controlled trial, compared the adverse effects of the use of Amplayzer and coils for the closure of ductus arteriosus. The device was successful in 97%-99%[10], with the advantage that it is replaceable and can close ductus arteiosi even larger than 10 mm in diameter. Thus is mentioned by Spies et al. in a review of congenital defects transcatheter closure[11], where the device was used in ducti even larger than 12 mm, with a high percentage of success and minimal complications by subsequent embolization. In contrast with these findings, works have been carried out on the use of coils in the closure of PDA, just as Howaida et al. also describe[10], but the results obtained are not very convincing, since immediate closure is produced in a lower percentage than with occlusion devices, leaving a residual short-circuit and with the possibility of coil embolization[10]. In our study, coils were used in 3% of patients, owing to the ductus arteriosus tubular anatomy, with 100% efficacy and no embolizations recorded in the follow-up.

The second place of occurrence was IAC in 14.7% of studied patients, which is a figure that is comparable to that described by Mendieta[2], and closure was satisfactorily achieved with Amplatzer in 100% of cases. It is important mentioning that there are studies that are not in favor of the benefits of congenital defects percutaneous closure, such as the one conducted by Kotowycz et al., a randomized multicenter study in a cohort of 718 patients; these authors concluded that the percutaneous catheterization technique for the correction of congenital cardiac septal defects had more possibilities of reoperation within the first year and on the long-term than surgical correction[15].

The most notorious congenital heart diseases at third place were PS and AS (both in 4% of cases), which were managed by means of percutaneous balloon angioplasty, a method that was satisfactory in 85.7% of patients with PS, but failed in all patients with AS. With regard to the former, pulmonary balloon valvuloplasty is the technique of choice in neonates, infants and children, when it is the indicated method. As other authors describe, when the pulmonary valve anatomy allows for it, this method can be efficacious in over 90% of cases[8,16], just as it was observed in our study. Unlike the favorable results obtained in other hospital centers for the management of congenital heart diseases, no improvement was observed in our hospital with the use of balloon angioplasty for the correction of AS, even at pediatric age. Nevertheless, symptom improvement was reported in 100% of patients with AS who were treated, which might be due to a relative improvement on the valvular surface that would modify left ventricle end-diastolic volumes and pressures, thus decreasing left atrium pressure and, consecutively, pulmonary vasculature gradients. However, this is only the hypothetical foundation and confirmatory studies are required.

More than half the cases with native AC were treated with primary angioplasty as a therapeutic alternative, which is a widely accepted method in cardiology hospital centers, as referred by Arzamendi et al.[4]. However, stent implantation is widely extending as a new therapeutic method in the treatment of this type of congenital lesion, and probably it has been surpassing primary angioplasty alone as an indication over the past few years. Stents' rigid frame can reduce the incidence of re-stenosis and minimize the formation of aneurisms, which are complications that have been described with some frequency in coarctation simple angioplasty in adolescents and adults[9]. In this study, although stents were used in little less than half the patients with AC, efficacy was 100% with both management methods.

In general, the percutaneous intervention procedures used in our study for the correction of congenital defects achieved the expected anatomical corrections in 96% of patients ($p < 0.01$), which is a similar figure than those reported by other authors[7,8,10], and adverse effects were considerably lower than those that have been documented.

In our work, the low incidence of complications deriving from the percutaneous catheterization procedure ($p > 0.01$) was notorious, with these complications being classified as non-catastrophic and not requiring inotropic support during or after the procedure. These results are comparable to those obtained in national and international studies. Yang et al., in a randomized, controlled, comparative, multicenter trial, performed in a 1-year cohort that included 229 children with perimembranous ventricular septal defects, compared the advantages of surgical and trasncatheter closure and observed results favoring the use of endovascular therapy, since the occurring adverse events were less, without any change in the approach technique being required due to complications during the procedure or blood transfusion due to bleeding, as it happened in the surgical closure group[16]. Our results are also consistent with those by Kotowycz et al.[15] and Tzifa et al.[17], but are quite different of those obtained by Holzer et al. In a multicenter randomized trial that included 1,315 patients with pulmonary angioplasty, 22% of patients experienced 3-5 level adverse events according to the classification by Bergensen et al. (2011)[13], mainly vascular rupture, device embolization, important hemodynamic disturbances, cardiac blockages and even asystole or death (level 5) in 0.015% of cases[12]. It should be mentioned that, as observed by Ammar[18], although the defects' repair is carried out immediately in more than 90% of patients, defect recurrence can be observed at long-term follow-up. However, evidence in favor is greater, and constitutes the fundamental basis that supports the use of percutaneous catheterization in the management of congenital heart diseases since, as previously described, open-heart repair increases mortality and reduces life expectancy in comparison with percutaneous catheterization[19,20].

These arguments allow concluding that the percutaneous intervention procedures that are practiced at the Manuel Ávila Camacho CMN High Specialty Hospital of Puebla, in Zaragoza, are efficacious and safe.

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