

Implementation of diagnostic screening for congenital heart disease in Hidalgo, Mexico

Implementación del tamizaje diagnóstico de cardiopatías congénitas en Hidalgo, México

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Abstract

Objective: Implementing screening through pulse oximetry (PO) and a knowledge management model (KMM) for early detection of life-threatening congenital heart disease (CHD) in the neonatal period. **Material and methods:** Pilot study of PO implementation supported by clinical criteria performed in newborns at two public hospitals of Hidalgo State. Those who tested positive were referred for echocardiography and those diagnosed with critical CHD (CCHD) were referred to specialized hospitals for treatment. **Results:** 1748 newborns were screened: 29 positive, 62% with CHD and 13.8% with CCHD, one death, three referrals to palliative treatment. **Conclusion:** PO as a method of screening helps in early diagnosis of CHD added to clinical and echocardiography studies. KMM fosters innovation and resource management.

Key words: Oximetry. Knowledge management. Screening. Congenital heart disease.

Resumen

Objetivo: Implementar el tamizaje mediante la oximetría de pulso (OP) y un modelo de gestión del conocimiento (MGC) para la detección oportuna de cardiopatías congénitas (CC) que amenazan la vida en el período neonatal. **Material y métodos:** Estudio piloto de implementación de OP apoyado en criterios clínicos, realizado en recién nacidos (RN) de dos hospitales públicos de Hidalgo. Los pacientes que resultaron positivos fueron objeto de ecocardiografía (EC) y los diagnosticados con cardiopatías congénitas críticas (CCC) se refirieron a tratamiento. **Resultados:** Se tamizó a 1,748 RN (29 positivos), CC en 62% y CCC en 13.8 %, 1 muerte y 3 programados para operación paliativa. **Conclusiones:** La OP ayuda en el diagnóstico de CC en combinación con criterios clínicos y EC. Un MGC favorece la innovación y la gestión de recursos.

Palabras clave: Oximetría. Gestión del conocimiento. Tamiz. Cardiopatía congénita.

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Introduction

The most common serious congenital anomalies that occur at birth are cardiac type (8 to 11 per 1,000 live births [LB])^{1,2}, with a mortality of 18 to 25% within the first year of life; some cannot be diagnosed before or at the time of death^{3,4}. About one quarter of these children will have a critical congenital heart disease (CCHD),⁵ potentially lethal⁶. Newborns (NBs) who are discharged without a diagnosis are at risk of suffering cardiovascular collapse and death, therefore, early detection is crucial for improving prognosis⁷. In Mexico, there were 17,596 deaths resulting from congenital heart disease (CHD) recorded in children younger than one year in a five-year period (2010 to 2014), 346 of which occurred in the State of Hidalgo⁸.

Measuring oxygen saturation (SO_2) by pulse oximetry (PO) in NBs to identify hypoxemia increases CCHD early detection⁹. PO is a non-invasive test with high specificity and moderate sensitivity to recognize CCHD.^{10,11} Since 2011 it has been recommended as part of the detection procedures in NBs¹². This article discusses PO implementation in order to propose a neonatal cardiac screening (NCS) program in Hidalgo, Mexico.

Material and methods

An observational, descriptive pilot study was carried out over a period of six months to analyze the usefulness of PO as NCS. Previously, reference agreements for treatment in Mexico City's specialized hospitals were established. This study received approval from DIF-Hidalgo Children's Hospital (HND-H – *Hospital del Niño DIF-Hidalgo*) ethics and research committee.

Study population

All NBs of the *Hospital Obstétrico* (HO) and *Hospital General de Pachuca* (HG) of the *Servicios de Salud de Hidalgo* (SSH) were included. The tests were performed in the NBs in joint accommodation within the first 24 to 72 hours of life.

Procedures

Using the knowledge management model (KMM), strengthening needs were identified, and competences were developed in practice communities to generate, store, distribute and use knowledge among operational staff, middle management and senior management staff, as well as for the administration of human, financial and equipment resources.

After standardizing the screening technique, information was recorded using case report forms and a capture mask in the Microsoft Access software.

PO was performed at two sites: pre-ductal (prd) using the right hand and post-ductal (pod) using either foot, placing the sensor between the index and middle fingers of the hand and between the second and third toe of the foot, in translucent areas and with good blood flow.

The American Academy of Pediatrics' CCHD screening algorithm was used, with three possible outcomes¹¹:

- 1. Negative (neg):** SO_2 of 95% or more in both readings (prd and pod) or when the difference between them was $\leq 3\%$.
- 2. Immediate positive (IP):** $\text{SO}_2 < 90\%$ prd or pod in the first registration.
- 3. Positive (P):** Result of three positive tests. SO_2 between 90 and 95% (prd and pod) or an absolute difference in oxygen saturation $> 3\%$ between both sites in the first registration; another test was made one hour after the first one and the test was concluded if it was negative; when it was positive, it was repeated one hour after the second one.

Follow-up of abnormal results

Clinical assessment was made by the head of the Pediatrics Department and, when appropriate, referred to *Hospital del Niño DIF Hidalgo* (HNDH) for diagnostic confirmation by clinical evaluation and echocardiography (EC); the CCHD cases were referred to *Hospital Infantil de México Federico Gómez* (HIM-FG) for surgical treatment, while those with simple heart disease (SHD) received follow-up at HNDH.

Statistical analysis

For demographic data, a descriptive analysis was carried out using tables and graphs and central tendency measures for SO_2 , oximetry quality analysis was carried out: sensitivity, specificity and positive and negative predictive values; in addition, the relationship between the screening and the EC results was determined. The SPSS statistical package for Windows 2013 was used.

Equipment

Radical-7®-Masimo oximeters for PO under movement and low-perfusion conditions (Masimo-SET®), specialized software for NCS (Eve™) and Newborn disposable sensors (Masimo-Rainbow®SET) were used¹³.

Table 1. Characteristics of the study population

		n = 1748	WOG [†] $\bar{x} \pm SD$	RD [‡]		Weight in kg $\bar{x} \pm SD$	SH [§] $\bar{x} \pm SD$	SO2 [§] $\pm \bar{x} \pm SD$
				V	A			
PGH*	M F	n = 517 (51.1%) n = 494 (48.9%)	39 (± 1) 38.91 (± 1.48)	218 (42.2%) 210 (42.5%)	299 (57.8%) 284 (57.5%)	3.02 (± 0.45) 2.94 (± 0.46)	29 (± 11) 30 (± 11)	
OH**	M F	n = 350 (47.5%) n = 387 (52.5%)	39.04 (± 0.96) 39.15 (± 0.97)	230 (65.7%) 252 (65.1%)	120 (34.3%) 135 (34.9%)	3.11 (± 0.43) 3.07 (± 0.39)	27 (± 10) 27 (± 10)	prd 96.18 % (± 2.45)
TOTAL	M F	n = 867 (49.59%) n = 881 (50.41%)	39 (± 1)	910 (52%)	838 (48%)	3.03 (± 0.44)	28 (± 11)	pod 96.59 % (± 2.29)

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**Obstetrics Hospital.

†Weeks of gestation.

‡Route of delivery (V: vaginal; A: abdominal).

§Extrauterine life hour at which the screening was performed.

§Oxygen saturation (prd: pre-ductal; pod: post-ductal).

Source: *Neonatal Cardiac Screening (NCS)* pulse oximetry registry of the Dirección General de Proyectos Estratégicos – Secretaría de Salud de Hidalgo.

Philips HD 11 XE echocardiography system was used for EC testing, as well as Qlab software, tissue Doppler imaging and an interval of transducer frequencies from 1 to 15 MHz for neonatal applications¹⁴.

Results

Over a period of six months, 1,748 NBs were screened at HG (n = 1,011, 57.8%) and HO (n = 737, 42.2%), 49.59% males and 50.41% females, with 39 \pm 1 gestational weeks (GW); 52% were vaginal and 48% were abdominal deliveries; 3.03 \pm 0.44 kg; screening time was at 28 \pm 11 hours of extrauterine life; mean prd SO₂ was 96.18%, and pod, 96.59% (Table 1).

At first screening, 95.5% were negative, 0.7% immediate positive and the rest positive (3.8%); one hour later, only 43% of positives remained in that state and, two hours later, 72.41% of them were recorded to be positive (Fig. 1). Twenty-nine ECs were carried out, among which 14 cases of simple heart disease and 3 of CCHD were confirmed (Fig. 2); a relationship was identified ($\chi^2 = 979$, $p > 0.05$) between the results of the screening and the EC confirmation (Fig. 1). In addition, one CCHD was clinically identified and did not require screening.

Operational procedures were designed for the reference of cases with P or IP screening, as well as direct telephone communication processes of the HO and HG Pediatrics Department heads and the cardiologist in order to arrange date and time for clinical evaluation and EC at HND-H. Another procedure served to manage PgE₁ acquisition and distribution through the State Social Health Protection System (REPSS – *Régimen*

Estatal de Protección Social en Salud) to support NBs with ductal-dependent cardiac anomalies.

In NBs with ductal-dependent anomalies, the cardiologist started pharmacological treatment in the HG Neonatal Intensive Care Unit with PgE₁ at an initial dose of 0.05 to 0.1 pg/kg/min, with effectiveness being assessed with SO₂ and known adverse reactions being taken care of. In addition, stimuli were reduced to a minimum to avoid stress, normothermia was maintained, and parenteral solutions were administered with 10% dextrose and sodium bicarbonate.

The local cardiologist referred all CCHD cases to the HIM-FG Cardiology Department, and NBs of more than 37 WOG, weight higher than 2,850 g, without respiratory distress and with no data consistent with infection were considered eligible for operation.

At HIM-FG, two therapeutic options were established according to the conditions of the neonate:

1. If the case could be attended on an outpatient basis, the patient received an appointment and was registered at waiting list for palliative surgery.
2. Serious cases were admitted to the Intensive Care Unit for medical-surgical treatment.

Once palliative surgical treatment was established, counter-referral was made to the hospital of origin with indicated treatment according to the type of heart disease and follow-up at HIM-FG until 18 years of age. Of the four CCHD cases, three required palliative intervention and two deaths occurred (Table 2).

In this study, the necessary competences were developed for the neonatal cardiac screening, diagnostic procedures and an epidemiological surveillance system to be implemented in two SSH public hospitals,

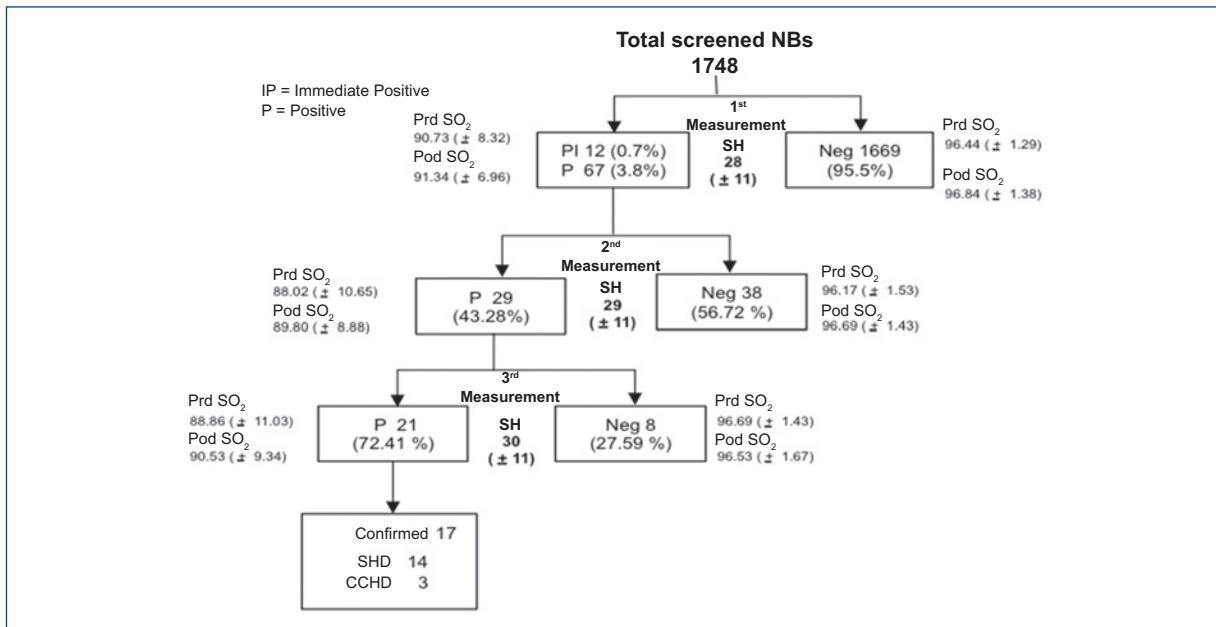


Figure 1. Neonatal cardiac screening implementation results. Pulse oximetry neonatal cardiac screening pilot test implementation results are shown. P and IP screening cases were confirmed with echocardiography. SO₂: oxygen saturation; Prd: pre-ductal; Pod: post-ductal; P: positive; IP: immediate positive.

Source: Neonatal Cardiac Screening (NCS) by pulse oximetry and Echocardiogram Records and Follow-up of Newborns with Suspected Heart Disease. Dirección General de Proyectos Estratégicos – Secretaría de Salud de Hidalgo.

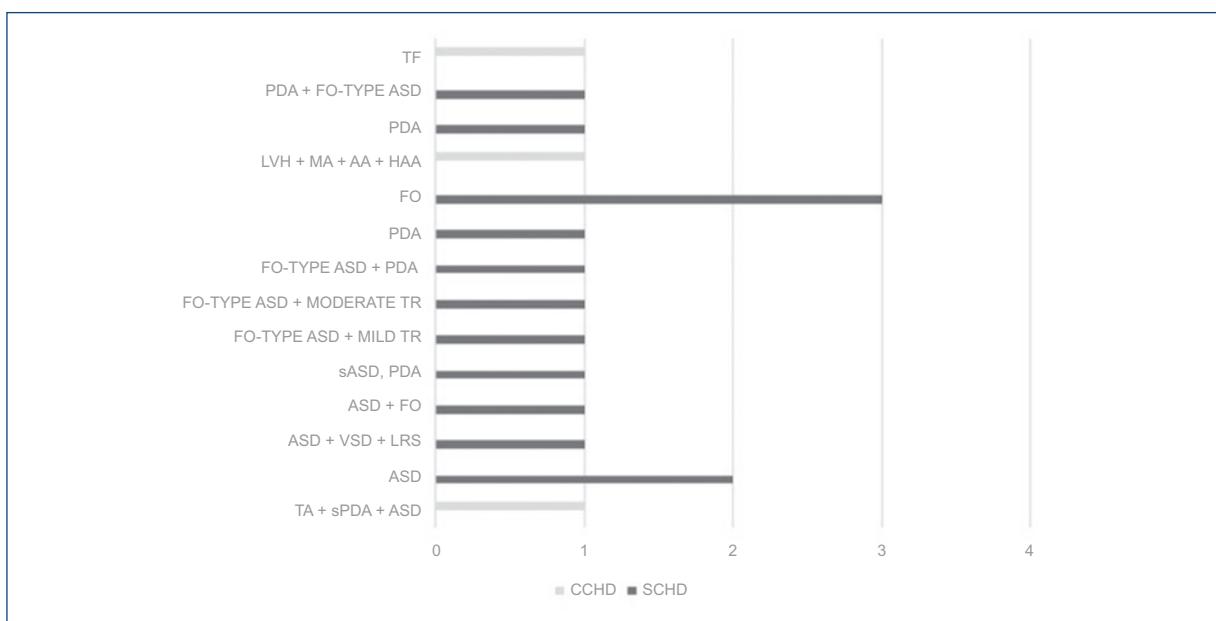


Figure 2. Number and types of heart disease identified by echocardiogram after screening. The diagnosed heart diseases are shown.

TF: tetralogy of Fallot; PDA: patent ductus arteriosus; ASD: atrial septal defect; FO: foramen ovale; LVH: left ventricular hypoplasia; MA: mitral atresia; AA: aortic atresia; HAA: hypoplastic aortic arch; PDA: patent ductus arteriosus; TR: tricuspid regurgitation; sASD: small atrial septal defect; VSD: ventricular septal defect; LRS: left-to-right shunt; TA: tricuspid atresia; sPDA: small patent ductus arteriosus; CCHD: complex congenital heart disease; SCHD: simple congenital heart disease.

Source: Neonatal Cardiac Screening (NCS) by pulse oximetry and Echocardiogram Records and Follow-up of Newborns with Suspected Heart Disease. Dirección General de Proyectos Estratégicos – Secretaría de Salud de Hidalgo.

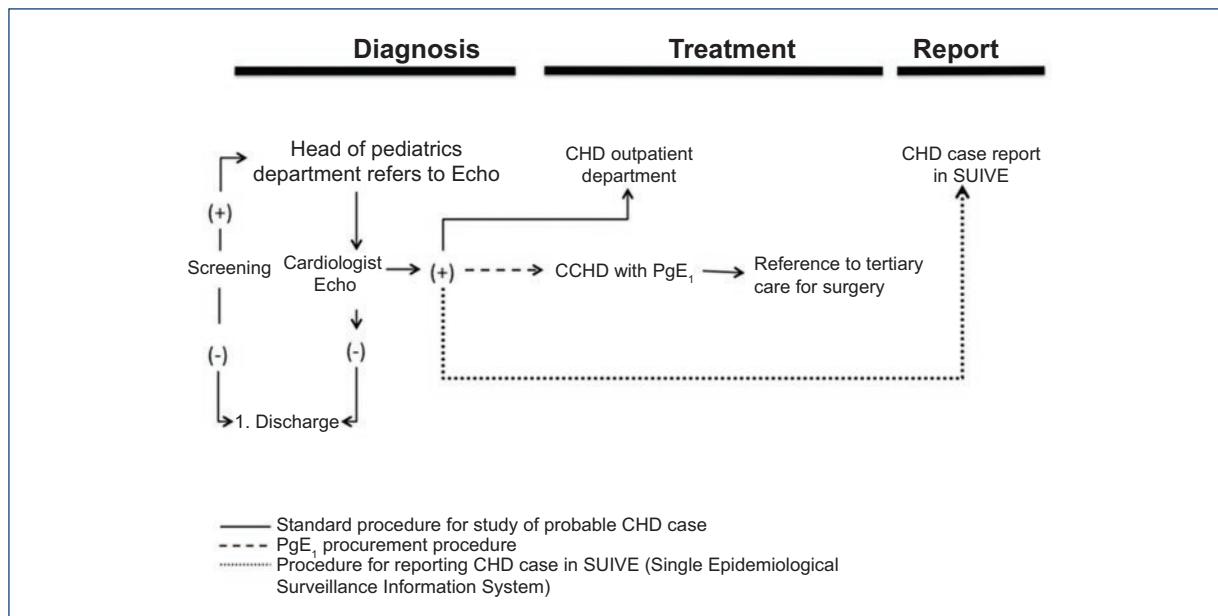


Figure 3. Diagnosis, treatment and report of congenital heart disease cases. The operating procedures for diagnosis, care, referral and report of congenital heart disease cases are shown.

Source: Dirección General de Proyectos Estratégicos – Secretaría de Salud de Hidalgo.

Table 2. Report on the treatment of newborns with complex congenital heart disease

Diagnosis	SO ₂ (%) prd / pod	Therapeutic follow-up
– LVH, MA, AA, HAA, STR	78 / 86	Death
– TA, ASD	31.8 / 47.1	Palliative operation
– PA, PDA, STR	ND / ND	Palliative operation / Death
– TF	78 / 82	Palliative operation

LVH: left ventricular hypoplasia; MA: mitral atresia; AA: aortic atresia; HAA: hypoplastic aortic arch; STR: severe tricuspid regurgitation; TA: tricuspid atresia; ASD: atrial septal defect; PA: pulmonary atresia; PDA: patent ductus arteriosus; STR: severe tricuspid regurgitation; ND: no data; TF: tetralogy of Fallot. Screening was not performed because the NB had clinical data consistent with severe hypoxia within the first hours of life and was immediately referred for evaluation by the pediatric cardiologist, who confirmed the diagnosis with EC. Source: Neonatal Cardiac Screening (NCS) by pulse oximetry and Echocardiogram Records and Follow-up of Newborns with Suspected Heart Disease. Dirección General de Proyectos Estratégicos – Secretaría de Salud de Hidalgo.

establishing the link and the reference for palliative treatment at tertiary care hospitals and initial pharmacological control of these anomalies as well (Fig. 3).

The development of management competences also stood out, and the acquisition of prostaglandin E1 (PgE₁), necessary for initial treatment of ductal-dependent heart disease, was achieved. An algorithm that establishes the route, timely acquisition and supply was designed for that purpose (Fig. 3).

The health system in Hidalgo, as well as in Mexico, does not consider congenital heart diseases in the formal morbidity record; there are only isolated data on these anomalies, and since the ICD-10 Q24.9 classification (congenital malformation of heart, unspecified) is generally used, the detailed incidence of these birth defects is therefore unavailable.

To start the registry of congenital heart diseases, the epidemiological study of cardiovascular defects was designed, validated by the *Subdirección de Epidemiología de los SSH*. Based on the confirmation of these cases by EC, the study started being filled out, and registered in the Single Information System for Epidemiological Surveillance (SUIVE – *Sistema Único de Información para la Vigilancia Epidemiológica*) in the “other diseases of local or regional interest” section, and therefore it is possible having the morbidity record of these malformations at birth (Fig. 3). The HND-H Cardiology Department maintains the SHD cases on follow-up.

Discussion

The NOM 034 SSA2 2013 standard¹⁵ establishes that birth defects should be deliberately searched during NBs assessment by clinical examination and, in case of suspicion, they should be stabilized and referred for

diagnosis, treatment and follow-up. It also establishes that fetal heart disease should be diagnosed by ultrasound since the 18th week of gestation; these are the malformations that are most difficult to diagnose before birth, and thus there is a significant number of affected NBs with no diagnosis^{16,17}, which is a situation that is aggravated by early discharge¹⁸. For the SSH hospitals, it is difficult to treat this kind of conditions because they don't have the specific infrastructure and resources and it is complicated transferring these patients to the high specialty centers in Mexico City, as reflected by 177 deaths resulting from unspecified CHD and 17 CCHD-associated deaths between 2009 and 2013¹⁹.

Until the start of this protocol, clinical and radiological assessment by SSH experienced physicians were the only common methods to identify heart disease prior to NBs discharge, and only occasionally was there confirmatory EC available. Medical publications refer that in the presence of a murmur, the possibility of establishing a diagnosis is particularly exacerbated^{20,21}; however, the presence of heart murmurs in newborns within the first week of life varies, since they may be absent or inaccurate due to the underlying anatomy, to a prolonged decrease of pulmonary vascular resistance or reduced ventricular function by circulatory changes occurring after birth^{22,23}.

The importance of CCHD early detection lies in the fact that the first manifestation of acute heart failure may be circulatory collapse, which can lead to death if not taken care of quickly. Diagnostic delay is related to significant morbidity for all CHDs. In Mexico there is no systematic echocardiography and this leads to a ductal-dependent CCHDs low detection rate and to lower opportunities for their care, which has led to high mortality due to undiagnosed heart diseases in recent years^{24,25}.

In this study, an average of 3 CHD cases per month were identified in a six-month period, with timely diagnosis and follow-up in 100% of cases and without deaths in 50% of CCHD cases within the first year of life. A total of 1,748 NBs at the HHS were screened from March to September 2015, 27 with positive screening, and out of these, 17 had some heart disease detected by EC, out of which three were CCHD. The prevalence of all CHDs (10 per 1,000 LB) was similar to that of other populations in studies of the same characteristics as this^{23,26,27}, while the prevalence of CCHD (1.5 per 1,000 LB) is lower with regard to other populations^{26,28}, which is similar to that reported by a previous study conducted in a Mexican population (1.9 per 1,000 LB)²³.

With a sensitivity of 88.2%, specificity of 99.3% and a false-positive rate of 0.7% for all CHDs, the most common

condition was foramen ovale, followed by atrial septal defect (Fig. 2); sensitivity for CCHD was 100%, with specificity of 99.3% and a false-positive rate of 0.7%. These results confirm the high specificity and low false-positive rate of pulse oximetry recorded in studies similar to this and others conducted on a large scale^{11,13,28-30}.

In Hidalgo, there is no statistical record of CHDs prior to this pilot test, and thus it is not possible for a retrospective comparison to be carried out, which makes it necessary for cardiac screening to be established within the neonatal screening series of tests.

The implementation of cardiac screening as a SSH pilot program introduced important changes in the systematic procedures of physicians and nurses in the pediatrics departments. Flowcharts were developed that facilitate prompt attention in all cases and pharmacological treatment of ductal-dependent heart diseases until these cases are accepted in Mexico City's tertiary care hospitals for palliative surgical treatment. These results can be compared with those reported in medical papers regarding survival of NBs with ductal-dependent CHDs.

The main points of this study are the first-time application of the neonatal cardiac screening through a KMM in the country, and therefore in Hidalgo, as well as the design of algorithms for a prospective follow-up that favors the treatment of NBs diagnosed with these problems.

Early detection by PO and a thorough physical examination has provided an opportunity for the proper care of these patients. With this pilot test, hospital stay of the mother-son binomial was adjusted beyond 12 hours after resolution, as established by the NOM-007-SSA2-2016 standard, and this facilitated the performance of PO.

During the implementation of the program, a reduction in hospital stay of NBs with detected CCHD was observed thanks to the fact that specific diagnoses were established, which facilitates their transfer to tertiary care units in Mexico City.

To extend the cardiac screening test to all SSH primary care hospitals and units, it is necessary to sensitize and raise awareness in the personnel through communities of practice, in addition to creating an area of opportunity to achieve collaborative work and establish it systematically as part of neonatal screening.

Cardiac screening testing takes no more than 10 minutes and can be carried out by any trained health personnel. This test is feasible and convenient, since it speeds up the transfer of the NB to tertiary care hospitals, which reduces hospital stay and attention costs. If we want to improve early detection of CCHD, it is advisable to perform PO after the first 24 hours of life and before 72 hours, or within the first 24 hours of life prior to discharge.

PO is a non-invasive technique that quantifies oxygen saturation (SO_2) as a reflection of hypoxemia. A pulse oximeter that tolerates movement and low oxygen perfusion should be used², which makes it possible to detect CCHDs involving hypoxemia, including hypoplastic left ventricular syndrome, pulmonary valve atresia, truncus arteriosus, total anomalous pulmonary venous connection, complete transposition of the great arteries, tetralogy of Fallot and tricuspid valve atresia, such as those that were recorded during this study.

All components in cardiac screening must be planned, starting with the training of the health personnel that performs the test, sensitization of parents and availability of an efficient system for prompt reference to specialized hospital centers to establish appropriate treatment.

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Conflict of interests

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of people and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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