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"Regale una Vida" a successful social program for underprivileged children with congenital heart disease in a middle-income country

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Abstract: More than 135 million children are born every year worldwide, and about 4 million will die during first month of life. Around 40–70% of those with congenital heart disease will require surgical treatment during the first year of life but many will die without appropriate treatment, especially in low- and middle-income countries (LMIC). Covering the costs is and will always be a big challenge for governments in LMIC, and non-governmental organizations (NGOs) organizing surgical journeys can provide adequate but temporary solutions. The necessity to supply the governmental health coverage was the reason to create a social responsibility program "Regale una vida". The aim of this article is to present the experience of a successful social program in pediatric cardiac surgery in a middle-income country and compare the surgical results with those covered by the government. Review of the process needed to build and successfully maintain a social program since 1994. Retrospective analysis of the program comparing results with patients supported by the government, from January 2010 through December 2019. More than 50,000 patients have been evaluated, and 3,000 patients and more than 1,000 echos performed in the last 9 years pre-pandemic. About 7% of the evaluated children were found to have some cardiac abnormality, receiving treatment (195/year). Around 70 of those patients/year received cardiac surgery totally covered by the program. RACHS-1 category 2 patients were more frequent in social program group (40% *vs.* 30%), but Rachs-1 category 4 were less frequent (2.8% *vs.* 6.2%) (P<0.001). Global mortality rates are lower in the social program (1.4% *vs.* 3.4%) (P<0.003). 89.7% of the patients are between 1 and 18 years and only 0.1% are neonates. "Regale una vida" is a successful example of a safe, permanent (available 24/7 throughout the year), highly effective, reproducible, and self-sustainable social responsibility program. It includes active search of patients, transfer to a high-quality hospital and surgical, Interventional, or medical treatment, benefiting a big number of congenital heart disease (CHD) patients with low resources. Even during COVID-19 pandemic, with only a small reorganization, social responsibility programs can keep achieving their goal, maintaining excellent and cost-effective results.

Keywords: Pediatric cardiac surgery; low- and middle-income countries; social program

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Introduction

More than 135 million children are born every year worldwide, and about 4 million will die during first month of life. With an estimated prevalence of 4–9.6 cases/1,000 live births, congenital heart disease (CHD) accounts for 1.3 million cases, and unfortunately more than 261,000 deaths every year (1,2).

Around 40–70% of CHD patients will require surgical treatment during the first year of life, but due to socioeconomic conditions and lack of adequately trained medical teams in low- and middle-income countries (LMIC) many patients will die without receiving appropriate surgical procedures. Besides, those who do not get early care will experience the consequences with significant disabilities, even those with simple and fixable conditions as atrial or ventricular septal defects (3).

According to Unger (4), in 1995 the number of cardiac surgeries worldwide was 169/1 million inhabitants but very poorly distributed around the globe: 1,222 in USA, 786 in Australia, 569 in Europe, 147 in South America and 37, 25 and 18 in Russia, Asia and Africa respectively. The total number of procedures has increase in the last 2 decades, but primarily in developed countries and the relation with LMIC has been steadily. Nowadays around 2,500 surgeries/million/year are made in the USA and 1,200/million/year in some European countries like Germany (5). In pediatric cardiac surgery it is estimated that between 80 to 100/million inhabitants or 8–10/1,000 newborns/year surgical procedures are needed. In South America in 2007 were performed 44/million and it decreased to 42/million according to the last survey in 2016, due to a decrease of procedures especially in Venezuela (6). In the rest of the LMIC the rate of surgeries has remain stable, but due to increase in birth rate and the difficulty to open new state-of-the-art medical centers it is estimated that around 90% of patients with CHD around the world lack access to surgical care (7).

Health coverage in Colombia

With an estimated population of 48,258,494 and a decreasing birth rate of 15.3/100,000 inhabitants, Colombia is cataloged as a middle-income country; 649,115 kids were born in 2018 and 7,329 died during first year of life with CHD as the second cause of mortality with more than 13% of cases (8).

In 1993, a Health reform was implemented aiming to provide universal coverage in health, retirement and disability including primarily kids with CHD that were previously excluded due to high cost to the health system. The idea of the Colombian universal health coverage consists of dividing the population in economically active (contributive regime) and economically inactive (subsidized regime) making it a solidarity regime in which the contributive population subsidize at least in part the universal coverage. The Health and Social Protection ministry stated that "the number of affiliates to the General System of Social Security in Health (SGSSS in Spanish) has increased from 29.21% of the population in 1995 to 94.66% in 2018". According to governmental information the number of affiliates to the SGSSS reached 47,028,888 divided in 48% belonging to the subsidized group, 46% in the contributive regime and 4.2% to exceptional regime i.e., military forces (9).

The governmental expenditure in health in Colombia accounts for 10% of the national budget but only 5% of the national GDP (10), while in USA account for 14.38% of GDP and 22.5% of the national budget (11). Unfortunately, with this amount of expenditure the government is unable to fulfill all the needs causing a health coverage deficit especially in the most vulnerable segment like low-income families, rural areas inhabitants with inadequate access to big cities that are located mainly in the center and northwestern part of the country, where the biggest hospitals are. Besides, the economic burden of a kid with CHD makes the transfer to medical centers even harder, given the fact that CHD is more common in low-income families with multiple kids. This non-adequately-covered by the government segment of the population is the main target for the social program "Regale una vida".

Pediatric cardiac surgery in Colombia

Based on the worldwide prevalence of CHD, more than 5,000 kids are born with CHD/annually in Colombia (6). About 50% require surgical management during the first year of life. That gives us a minimum of 2,500 new surgeries/year, added to the surgeries needed for those patients surviving over first year. The most benign expectations talk of at least 5,000 surgeries needed for CHD every year in Colombia.

According to Sandoval *et al.*'s (12) survey in 2016, 2,372 were performed in the biggest 13 centers across the country, with Fundación Cardioinfantil (FCI) performing 482, accounting for 20% of the total surgeries within Colombia.

In this study, 4 institutions were audited by international organisms certifying that the information is adequate and correct.

Another study by Sabatino *et al.* (13) showed a different information regarding the volume of surgeries in 2016. This study showed that only 1,281 (54% of the procedures reported by Sandoval *et al.*) surgeries were reported to the Colombian Health System. These data were extracted from the National Database (RIPS) managed by the Health and Social Security Ministry that is used not only to keep a registry of procedures but also to transfer the economic resources from the government to the Health institutions.

FCI

As a result of the inequity in health access the FCI was created in 1973, by the hard work of two brothers, a cardiologist and a cardiac surgeon (Reinaldo and Camilo Cabrera respectively), initially as an non-governmental organization (NGO) in order to provide surgical management to low-income pediatric patients with CHD. The idea grew and thanks in part to the donations of ordinary people the actual location of FCI started to be built in 1993, that actually has more than 80,000 mts^2, with state-of-the-art technology, with the highest quality standards and all surgical specialties, all integrated and focused on cardiovascular medicine in adults and in pediatric patients. Nowadays is the only institution in Colombia with a specialized Institute for Congenital Cardiopathies including a department for Adults with Congenital Cardiopathies and an exclusive ICU for CHD patients, with 17 beds where more than 430 postoperative patients recover as well as some of the 340 patients taken to the cath lab every year.

From 1997 to 2020 more than 10,700 children have been operated on, and in the last 16 years (2005 to 2020) more than 11,000 have received cardiac treatment (6,853 surgeries and 4,500 interventional treatment including electrophysiology management), of which 30% have been treated free of charge by the social program (around 200 treatments/year) according to the internal database confirmed by IQIC and WDPCHS. FCI has been consistently ranked as the 3rd best hospital in Latinamerica and the best hospital in Colombia, according to America Economia (14).

Social program "Regale una vida"

Once the FCI was fully established, the social program "Regale un vida" or "Give a Life", was officially created, with the main objective of fulfilling the mission of the institution that is to give complete cardiac treatment for free to every kid with CHD and no economic resources. The International Hospital Federation (IHF) Awards, which celebrates and recognizes hospitals and healthcare organizations with demonstrable excellence, innovations, and outstanding achievements in the healthcare industry, gave to Fundación Cardioinfantil Instituto de Cardiología from Colombia the Gold Award IHF /Bionexo Excellence Award for Corporate Social Responsibility for their project "Give a Life" in 2018.

Donors

The social program is 100% financed by national and international donors. The biggest percentage of the funds is obtained through national retail donations. The rest of the funds come through special fundraising events (Golf tournament, concerts, Gala dinner, etc.) organized by the US-based 501 (c-3) company called "American Friends of the FCI".

Medical diagnostic brigades

"Regale una Vida" started non-permanent brigades in 1997 but since 2003 are organized at least 1 every month. 12–14 brigades are organized annually, covering population from 24 out of 32 provinces and more than 350 municipalities, mostly rural (*Figure 1*). Each brigade evaluates an average of 300 patients, 150 echocardiograms are made and approximately 20 children/brigade are selected to be transferred to FCI for surgical/interventional treatment (15).

The medical brigades consist of a 3-day trip of FCI interdisciplinary team including two pediatric cardiologists, three general pediatricians, two nurses, one social worker, one "Regale una vida" administrative representative and 1 or 2 engineers in charge of logistics in case very poor communication capacity between brigade and our internal electronic chart is found. Echocardiography and EKG equipment is taken as well, and all the information collected during the brigades travels to the FCI internal database in case the patients need in-hospital treatment.

An important amount of information in forms of brochures is distributed locally not only about CHD, but also about healthy nutritional habits, early recognition of diseases, endocarditis, etc.

In order to be possible to travel to the brigades, FCI has

Figure 1 Places of diagnostic medical brigades per year in all Colombian territory and the strategic allies.

numerous and very important allies, consisting of NGO that are in charge of the complete organization. Initially they socialize and advertise for the brigade into the population mainly through radio stations, the main communication media in the rural areas. Allies are also in charge of the in-place logistics, organization and entertaining the patients and families during the brigades. An average of 20 people work for the success of every brigade and the average cost for every brigade in 2019 was around $6,300 US dollars.

Methods

Review of the process needed to build and successfully maintain a social program through a retrospective cohort of pediatric patients receiving cardiac treatment from the social program data, since 1994.

We also analyze patients receiving cardiac surgery comparing results with those supported entirely by the government using a retrospective analysis of the local and international audited database from January 2010 to December.

Preoperative variables including Rachs-1 category classification and post-operative results were analyzed using chi-square test and exact Fisher test and Student *t*-test and Mann-Whitney U test using STATA 15 program.

Results

For the last 25 uninterrupted years, more than 50,000 patients have been evaluated during the brigades,

with more than 3,000 patients/year and more than 1,000 echos/year performed during the last 9 years pre-pandemic. More than 190 patients/year receive any type of treatment and about 70 of those patients/year receive cardiac surgery (*Figure 2A-2C*).

The demographic characteristics of the patients receiving surgical treatment can be seen in *Table 1*, including distribution across RACHS-1 category. Statistical differences were found in RACHS 2 category (40% in social program versus 30% in non-social patients) and in RACHS 4 category (2.8% *vs.* 6.2%, P=0.001). Mortality rates are lower in the social program patients (1.4% *vs.* 3.4%, P=0.003). 89.7% of the patients treated by the social program are between 1 and 18 years and only 0.1% are treated during the neonatal period.

During COVID-19 pandemic 665 echos were performed in 1,122 patients evaluated in 6 brigades, 112 of whom were transferred to FCI for hospitalization and cardiac treatment (60%, 28%, 12% for surgery, interventionist treatment and EEF management respectively).

Discussion

Many initiatives have been proposed and implemented, especially during the time of virtuality due to COVID-19 pandemic, in order to improve and facilitate the medical and nursing knowledge of the heart team with free continuous medical education, or standardization and help of pediatric cardiac surgery programs such as: International Quality Improvement Collaborative (IQIC), World University for Pediatric and Congenital Heart Surgery, Congenital Heart Academy webinars, STS/EACTS Latin American forum in cardiac surgery, Global Council on Education for Congenital Heart Surgery of the World Society for Pediatric and Congenital Heart Surgery (16), and many others around the world from private institutions.

On the one hand, in order to minimize the impact of lack of cardiac care in LMICs groups of volunteers have created NGOs, primarily from USA and Europe, bringing surgical care in form of "Short term medical Missions" to fulfill this necessity, and to teach the local cardiac surgical centers to manage their own cases, but without adequate government support these efforts are only temporal and not permanent or sustainable. More than 80 NGO organizations have been described recently as a "Short term medical missions" (17,18).

On the other hand, private institutions in LMIC have developed long-term sustainable programs with autonomous budget in order to provide top-quality cardiac care, focused on low-income patients with no adequate governmental covering. The program we are referring today has been functioning uninterrupted for the last 25 years with good results, sustainability and with a way of working that can be easily reproducible in other LMICs.

The mission of the social program "Regale una vida" is to give high quality treatment to every patient identified during the brigades, exactly the same treatment that non-social patients would receive in FCI including ECMO therapy if needed, as demonstrated in previous studies, with an overall survival of 98.4%, with median ICU stay of 2 days and total in-hospital stay of 4 days (19) (*Table 1*).

We present the economic costs of the patients supported by the social program compared to the cost of temporal international "short-term" missions. For 2019 the average cost for every patient in the social program was 8,651 US dollars, including 3 patients requiring ECMO therapy, increasing the average cost. This includes patient and family transfer to and from FCI, lodging, nourishment, diagnostic workup including cath or MRI/CT if needed, surgical and medical treatment and postoperative control. "Non-permanent NGO brigades" abroad have reported average costs of $6,831 US/patient (20), but not including transfer to and from, and maintenance of patients and families, making "regale una vida" a cost-effective and self-sustainable program reproducible in other LMIC around the world.

The social program is a highly successful program not only because of the clinical quality but financially as well, and the fidelity of donors is maintained by an intense communication effort and an annual magazine report where all clinical results are shown.

More than 3 million dollars are collected every year from more than 100,000 donors and 100% are reinvested for the medical diagnostic brigades, patients transfer to FCI (always with another family member), diagnostic workup, surgical/interventionist costs, ICU recovery, keeping patients in-town until clinic follow-up and transfer back to city of origin; 26% of donations go to specific destinations like physical and technological infrastructure like a state-of-the-art new CICU.

Social program during COVID-19

First patients with COVID-19 were diagnosed in March 2020 in Colombia, reaching over 112,000 deaths up to July 2021. This pandemic obliged us to change institutional

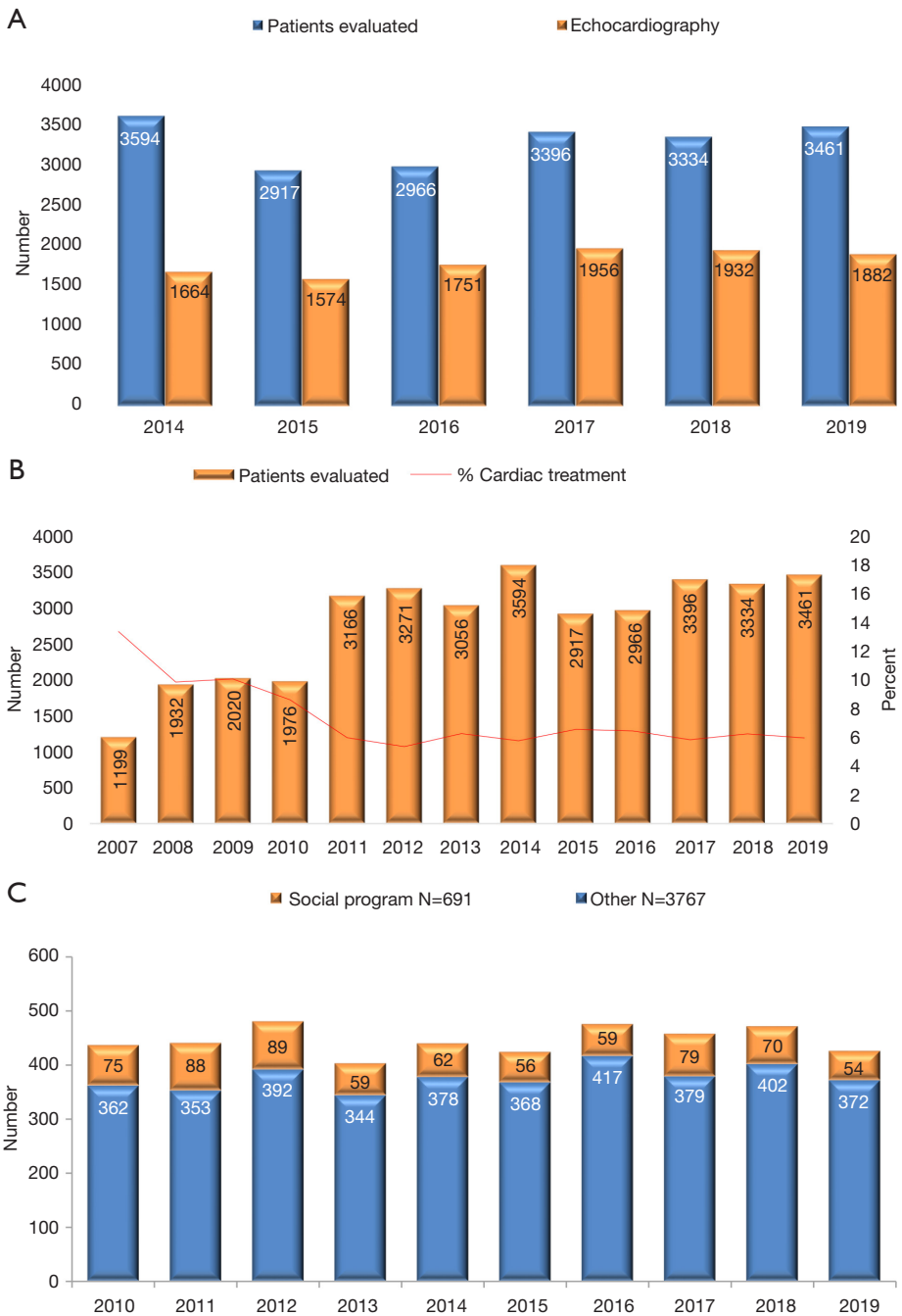

Figure 2 Number of patients evaluated in the program and number of treatment provided. (A) Social program "Regale un vida" patients evaluated and echocardiography number per year; (B) social program "Regale un vida" patients evaluated per year *vs.* in-hospital cardiac treatment percentage; (C) number of total patients operated per year throughout the government regime and social program.

strategies at FCI creating "safe routes" to decrease the likelihood of COVID infection, including polymerase chain reaction (PCR)-test to every patient before surgery and the implementation of virtuality for cardiac surgery clinic and continuing medical education.

For 2021, a new type of brigade was implemented consisting of a local pediatrician in charge of the initial screening of patients during the months previous to the

Table 1 Demographic characteristics of the patients receiving surgical treatment

Variable	Social program N=691	Governmental N=3,767	P value
Age in years	5.9 (2.3–11.2)	1.2 (0.4–5.3)	<0.001
Categorical age			
1 to 30 days	1 (0.1)	474 (12.6)	<0.001
1 to 12 months	65 (9.4)	1219 (32.4)	<0.001
1 to 18 years	620 (89.7)	1925 (51.1)	<0.001
>18 years	5 (0.7)	150 (4.0)	<0.001
Male	345 (49.9)	1,918 (50.9)	0.633
ICU days	2 (2–4)	3 (2–7)	<0.001
In hospital stay	7 (6–12)	10 (6–20)	<0.001
RACHS-1 score			
1	173 (25.0)	947 (25.1)	0.954
2	273 (39.5)	1,125 (29.6)	<0.001
3	179 (25.9)	957 (25.2)	0.782
4	19 (2.8)	234 (6.2)	<0.001
Not classifiable	47 (6.8)	504 (13.4)	<0.001
ECMO	6 (0.9)	43 (1.1)	0.691
Any type of neurological event	4 (0.6)	31 (0.8)	0.504
Global mortality	10 (1.4)	138 (3.7)	0.003

Data are presented as median with the 25th to 75th percentile interval, or n (%). ICU, intensive care unit; ECMO, extracorporeal membrane oxygenation.

brigade, now consisting only of 1 pediatric cardiologist, 1 pediatrician, 1 RN and 1 representative of the social program. Every patient selected for surgery receives a complete evaluation by our social worker that is made virtually reducing to more than 50% the number of workers traveling and making the brigade even more cost-effective. Allies are still in charge of logistic support and the implementation of a remote connection to FCI in case more in-depth consult is needed.

Weaknesses of the program

(I) Neonates born in rural areas or after the brigade with critical CHD can be lost due to long periodicity between brigades in the same region;
(II) Strict follow-up is difficult and can be done only in the following brigade (usually in 12 months) although telemedicine is being implemented;
(III) Depending on donors for the sustainability of the program can jeopardize it in case of a financial crisis of the country.

Conclusions

Covering the costs of surgical treatment for patients with CHD is and will always be a big challenge for governments in LMIC, and NGOs organizing surgical journeys can provide only temporal solutions.

"Regale una vida" is a successful example of a safe, highly effective and reproducible social program, showing a permanent solution, benefiting a big number of CHD patients, especially those with low resources, located in rural areas far from big hospitals.

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