



Creation of a Pilot Surgical Program for the Comprehensive Management of Patients with Congenital Urological Malformations

Creación de un programa quirúrgico piloto para el manejo integral de pacientes con malformaciones urológicas congénitas

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Abstract

Keywords

- ▶ congenital abnormalities
- ▶ urologic surgical procedures
- ▶ congenital, hereditary, and neonatal diseases and abnormalities
- ▶ urogenital abnormalities
- ▶ urologic diseases
- ▶ congenital anomalies of the kidney and urinary tract

Objectives Congenital malformations constitute the first cause of morbidity and mortality in childhood in Latin America. That is why, since 2001, a surveillance system for congenital malformations has been implemented in Bogota - Colombia. However, despite the increase in detection, an impact on treatment has not been achieved. The present study describes our experience with a novel social program focused on congenital urologic disorders.

Methods The present manuscript is a retrospective observational study. We reviewed two national databases containing patients with congenital malformations. Patients were actively contacted to verify the status of the malformations. Children in whom the malformation was confirmed were offered a free consultation with a multidisciplinary group. After screening for surgical indications, patients were scheduled for surgery.

Results Between November 2018 and December 2019, 60 patients were identified. In total 44, attended the consultation; the remaining did not attend due to financial or travel limitations. The most common condition assessed was hypospadias. In total, 29 patients underwent surgery. The total cost of care was of US\$ 5,800.

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Conclusions Active search improves attention times and reduces the burden of disease. The limitations to be resolved include optimizing the transportation of patients and their families, which is a frequent limitation to access health care.

Resumen

Palabras clave

- ▶ anomalías congénitas
- ▶ procedimientos quirúrgicos urológicos
- ▶ enfermedades y anomalías neonatales congénitas y hereditarias
- ▶ anomalías urogenitales
- ▶ enfermedades urológicas
- ▶ anomalías congénitas del riñón y del tracto urinario

Objetivos Las malformaciones congénitas corresponden a la principal causa de morbimortalidad en la infancia en América Latina, motivo por el cual desde el 2001 se viene implementando un sistema de vigilancia epidemiológica de malformaciones congénitas en Bogotá, Colombia. Sin embargo, a pesar del aumento en la cobertura del reporte obligatorio, no se ha logrado un impacto sobre su tratamiento. Este estudio busca mostrar nuestra experiencia con un programa integral de pacientes con malformaciones urológicas congénitas.

Métodos El presente es un estudio observacional retrospectivo. Los menores con malformaciones congénitas fueron identificados en dos bases de datos nacionales que incluyen pacientes con malformaciones congénitas. Los pacientes reportados fueron contactados telefónicamente para verificar el estado actual de la malformación. A aquellos niños en quienes se les confirmó la malformación, se les ofreció de manera gratuita una consulta con un grupo multidisciplinario. Una vez confirmadas las indicaciones quirúrgicas, fueron llevados a cirugía.

Resultados Se identificaron 60 pacientes entre noviembre del 2018 y diciembre de 2019. De los pacientes identificados, 44 acudieron a consulta. Los demás no asistieron por limitaciones económicas. La principal condición valorada fue hipospadias. En total, 29 pacientes fueron llevados a cirugía. El costo total de la atención de estos pacientes fue de 22 millones de pesos colombianos.

Conclusiones La búsqueda activa mejora los tiempos de atención y reduce la carga de la enfermedad. Una de las limitaciones aun por resolver es optimizar el transporte de los pacientes y sus familias, que resulta una limitación frecuente para el acceso a la salud.

Introduction

Congenital malformations are the most important cause of morbidity and mortality in childhood in Latin America.¹ It is estimated that around 6% of children worldwide are born with a congenital anomaly.² Although some of these malformations can be treated surgically and non-surgically, some of them will cause lifelong impact, especially in low- and middle-income countries (LMICs), where a disproportionate rate of congenital malformations is observed.² Low income may be an indirect determinant of congenital malformations, with nearly 94% of severe congenital anomalies occurring in LMICs.²

Due to the aforementioned information, since 2001, an epidemiological surveillance system for congenital malformations has been implemented in Bogotá, Colombia, as an agreement between the Colombian Ministry of Health, the Institute of Human Genetics at Pontificia Universidad Javeriana, and the Hospital Universitario San Ignacio. The surveillance program made it possible to achieve near-universal coverage with the mandatory reporting of all children who were found to have congenital malformation. Children are reported in the “Latin American Collaborative of Congenital Malformations Study” (“Estudio Colaborativo Latino Americano de Malformaciones Congénitas”, ECLAMC,

in Spanish), a program of clinical and epidemiological investigation of congenital anomalies in Latin American hospitals.³ However, despite these efforts, a direct impact on the timely treatment of these disorders has not yet been achieved.^{4,5}

For this reason, the “Program for the comprehensive surgical management of patients with a congenital malformation in Hospital Universitario San Ignacio” was created. Its main objective was to coordinate with the Bogotá District Health Department to identify children with congenital urological malformations and offer operative surgical treatments that enable the reduction of the burden of the disease.⁶

Before the present study, all congenital anomalies were identified and reported to the governmental entities, but no active follow-up was established. The usual pathway for patients with congenital urological anomalies in Colombia requires the primary care provider to identify the anomaly and refer to the specialist accordingly. Referrals would depend on insurance company approval and network availability. After being referred and assessed by the specialist, surgical intervention is ordered, requiring the insurance company's authorization. In Colombia, each insurance company has a contract with different service providers, and the authorization for a medical procedure will depend on the

supplier's availability. Nevertheless, there are high rates of surgery rejection from insurances, probably due to the outsourcing of health services and the overflow of patients in fourth-level hospitals.

Given the availability of multiple pediatric surgical specialties in our hospital, we aim to show how a comprehensive program in referral centers can benefit patients by improving prognosis, reducing costs, and ensuring complete care for them and their families.⁷

Methods

The present manuscript is a retrospective observational study that describes our experience with a novel social program focused on congenital urologic disorders. Two national databases were consulted and reviewed, namely the National System of Public Health Surveillance (Sistema Nacional de Vigilancia en Salud Pública, SIVIGILA, in Spanish) and the Surveillance Database of children with congenital defects based on the case-control methodology of the ECLAMC. Both databases require mandatory reporting of all congenital anomalies detected at birth in the national territory and were accessed through the Human Genetics Institute at Pontificia Universidad Javeriana. The Institutional Review Board (IRB) searched using the parameter "Event 215," representing all reported congenital disorders, selecting only the urological events.

All patients that belonged to the Bogota care network were included and contacted by telephone. Complete demographic and clinical assessments were conducted to look for the current medical status of the anomaly and barriers to access healthcare, which mainly involve surgery and pediatric urological consultation. One patient who was undergoing an adequate follow-up by his medical insurance was excluded. Once the diagnosis was confirmed by phone and the barriers were detected, patients were offered a free evaluation within a 30-day timeframe by a multidisciplinary team (Genetics, General Surgery, and Pediatric Urology). If the patients/caregivers accepted the invitation, the team would evaluate all children in person, selecting those who met the surgery criteria. All cases included in the present study were treated at no cost to the family. Cases were booked for surgery according to clinical standards. The interventions were performed by the same team, which included two pediatric anesthesiologists, who assessed the patients clinically. The postoperative follow-up was conducted in hospital facilities at a variable time, depending on the necessities of each case.

The program was financed by an endowment from an association between Fundación Arturo Calle, Hospital Universitario San Ignacio, and medical staff collaboration. This cooperative endeavor would cover all medications and medical supplies required for the intervention. The medical staff involved received no additional compensations, they donated extra not-billed work time, and the hospital charged no additional fees for these patients (operating room, inpatient care, and anesthesia time).

A database from the urological cases was created using Excel (Microsoft Corp., Redmond, WA, US) for Windows. The

evaluated variables included gender, age at first assessment and at the time of the first and second surgeries (if needed), and the genetic and urological diagnoses. If complications occurred, they were reported and sorted out by the medical team. The variables were tested for normality using the Shapiro-Wilk method. The asymmetrical distributions were described in terms of medians and interquartile ranges (IQRs).

Results

From November 2018 to December 2019, 60 patients were identified in the databases. Due to financial problems (the program did not cover travel expenses), 16 patients could not attend the initial appointment. Only 44 were able to attend the consultation; however, 8 did not have a urological diagnosis or did not need surgery, and 7 patients could not attend medical appointments or surgery because of economic limitations. These patients were not included in the program description. The clinical team saw patients who attended the consultation within the first thirty days after being identified in the database.

Overall, the sample was composed of 28 male patients and only 1 female patient. The variables regarding age showed an asymmetrical distribution. The median age at the first procedure was of 43.24 (standard deviation [SD]: 42.25) months. At the time of surgery, the youngest patient was 4 months old, and the oldest, 138 months old. Among them, nine required a second surgery. Most patients came from Bogotá. Only one came from rural areas (Funza). The demographic description of the patients is shown in **Table 1**.

Twelve urological diagnoses were found; **Table 1** summarizes the clinical findings. In general, the most prevalent diagnosis among the 29 patients taken to surgery was hypospadias, with procedures performed in 14 cases. The locations of the hypospadias were as follows: six penoscrotal, four distal, and four medial. The second most common diagnosis in terms of frequency was cryptorchidism; five cases were bilateral, and one was on the right side.

The genetic assessment determined that fifteen of our patients did not need further studies or evaluations. Three patients had a suspicion of Smith-Lemli-Opitz syndrome, and two, of Prune Belly syndrome. We also identified cases of isolated Prader Willi, Seckel 5 syndrome and primary microcephaly type 9, 46 XY sexual development disorder, omphalocele-exstrophy-imperforate anus-spinal defects (OIES complex), Goldenhar syndrome, and DiGeorge syndrome. Three of the patients were instructed to continue the follow-up with karyotypes, which were only done in patients with clinical findings suggestive of chromosomal alterations.

The most frequent procedure was hypospadias correction, in 14 cases. Those were followed in frequency by orchidopexy. The surgeries for hypospadias correction were performed using the Bracka, Thiersh-Duplay, and Tip techniques. Foreskin and oral mucosa grafts were used. Laparoscopic orchidopexies were performed after exploration for cryptorchidism. At the time of the first surgery, 14 of

Table 1 Demographic data of the study sample

Demographics	
Gender: n (%)	
Female	1 (3.4)
Male	28 (96.5)
Age in months: mean ± standard deviation	43.24 ± 42.25
Origin: n (%)	
Bogotá	28 (90.6)
Rural areas	1 (9.4)
Urologic diagnosis: n (%)	
Hypospadias	13 (44.8)
Cryptorchidism	5 (17.2)
Renal agenesis	1 (3.4)
Urinary retention in prune belly syndrome	1 (3.4)
Rectourethral fistula	1 (3.4)
Epispadias	1 (3.4)
Hydronephrosis	1 (3.4)
Disorder of sex development 46XX	1 (3.4)
Left ureterocele – double collecting system	1 (3.4)
Pyelocalyceal ectasia	1 (3.4)
Bladder exstrophy	1 (3.4)
Cryptorchidism + hypospadias	1 (3.4)
Primary obstruction of the bladder neck	1 (3.4)

the patients were treated as ambulatory patients. The 15 remaining had an average hospitalization of 1.68 days.

Nine of the patients needed a second intervention, and five of those were related to hypospadias correction. Three patients are waiting for their second intervention. However, due to the COVID-19 pandemic, the program has been put on hold.

Four patients had complications related to the procedure. The complications and the Clavien-Dindo Classification are shown in ►Table 2. No complications were life-threatening, and they were sorted out by the program's surgeons. No mortality was observed. All patients attended the postoperative control. The time until the first postoperative control varied from 1 to 57 days, with a median of 9 (IQR: 11) days. No short-term sequelae or non-procedure-related complications were detected. The total duration of the follow-up was from 8 to 3,830 days, with a median of 39 (IQR: 497) days.

Cost of Surgery

Because all the surgeons lived in Bogotá, the surgical team did not pay for transportation, accommodation, or meals. The total cost of care for all the operated patients was of US\$ 5,800, with an average of US\$ 193,33 per patient. It is

Table 2 Complications of the procedure and Clavien-Dindo classification

Complications	N (%)	Clavien-Dindo classification
No	25 (86.2)	Not applicable
Yes	4 (13.8)	
<i>Urocutaneous fistula</i>	1 (3.45)	IIIa
<i>Granuloma</i>	1 (3.45)	I
<i>Peristomal infection</i>	1 (3.45)	I
<i>Graft retraction</i>	1 (3.45)	I

noteworthy that the hospital care was free, and the surgeons did not receive monetary compensation for their work.

Discussion

Disability-adjusted life years (DALYs) have become a standard measure to estimate disease burden. However, there is scarce literature^{6,8,9} on delayed access to surgical procedures in congenital anomalies, which contributes to long-term disability and significantly impacts individuals, families, healthcare systems, and societies. Childhood disability is a significant cause of DALYs, especially in LMICs, where around 150 million children suffer from some type of disability, and there is poor access to medical care.⁹ Multiple studies⁹ have shown that children with disabilities have a lower quality of life when compared with children with no disabilities. Therefore, surgical correction of congenital anomalies has been demonstrated to cause a significant reduction in the healthcare system's burden. Consequently, identifying children with congenital malformations and performing timely surgical treatments is critical in resource-limited environments. The identification of active cases and prompt surgical treatment programs are essential for patients with unmet needs for surgical procedures.^{6,9}

The frequency of urogenital malformations has been studied in many countries in Latin America. The prevalence is of 11.3/10,000 cases for hypospadias, with a tendency to grow in Chile, Brazil, and Uruguay. This data suggests that the impact of these malformations will be more significant in the future. For this reason, programs for their early management would be a viable solution to prevent complications and disability.¹⁰

As shown in our results and in those of previous studies¹¹ performed in Colombia, the model of active surveillance with telephone follow-up can significantly reduce unmet goals for surgical intervention. The patients of the present study were examined by a multidisciplinary team and treated within the first 30 days after the team had established the diagnosis, a suitable waiting time when compared with developed countries like Italy, where an elective surgery can take up to 35 days, or Poland, where it can take up to 250 days.¹² Additionally, compared with other studies previously conducted by our group¹³, such as the "Transdisciplinary"

management of patients with sexual development disorders in Colombia, a reduction in the age at surgical intervention was observed. All of the patients in the current program underwent surgery at a median age of 29 months, while previous to the implementation of the program, the mean age was of 60 months.¹¹ Additionally, all of our patients were examined by a multidisciplinary group, a missing aspect in previous studies.¹¹

Within emerging countries, surgical services are concentrated primarily in cities and, in some cases, reserved for those who can afford the procedures.^{14,15} It is known that the wealthiest third of the world's population benefits from 74% of surgical interventions, whereas the poorest third receives only 3.5%.¹⁶ Social inequalities and decreased access to health care facilities in LMICs cause minor surgical pathologies to transform over time into fatal diseases or lifelong disabilities.^{17,18} A study conducted by Wu et al.⁹ in the Dadaab Refugee Camp, in Kenya, reported that only 13.5% of all children with congenital anomalies and secondary disabilities who needed surgical treatment had received adequate management.⁹ Another study performed by Ozgediz and Riviello¹⁹ showed that most patients with conditions requiring surgical intervention in Africa never reached a health service. To our knowledge, global surgical access has not yet been studied in Colombia. However, as in many LMICs, there is a gap in the access to surgical opportunities in certain areas. Herein, we have demonstrated how, despite active surveillance and free access to surgical programs, consultation and surgery opportunities are still limited if transportation fees are not included in a charity program. Sixteen patients could not attend the medical appointment due to this issue, and another seven patients were lost to medical follow-up.

It is interesting that previously, surgery was widely seen as a high-cost treatment option. Nonetheless, surgical and anesthetic services are nowadays recognized as public-health interventions that prevent death and disability, in spite of being cost-effective for health care systems.¹⁹ Although surgical care can be more challenging to deliver than medical treatments, social initiatives may improve access to surgical procedures through donation programs and non-profit ventures, reducing the gap in the access to surgery.¹⁸ As shown in the present study, we have supported the development of an affordable program in an LMIC through donations and nonprofit ventures. If the physical infrastructure is available and trained human resources are set up at no cost, the gap in the access to surgical procedures among the underprivileged population might decrease. However, it is worth mentioning that social programs do not supply medical insurance coverage, and a considerable effort is required on behalf of health systems to achieve more accessible services.

Our program works on a small scale. Nevertheless, programs like the Global Initiatives for Emergency and Essential Surgical Care from the World Health Organization can reduce the aforementioned gap.¹⁹ This initiative was established in 2005 to share knowledge, advise on policy formation, and

develop educational resources to reduce the burden of diseases treated through surgery in LMICs.²⁰ Likewise, our program consisted of reducing morbidity and mortality in underprivileged children with congenital malformations by reducing the waiting times for surgery and providing a multidisciplinary approach to the disease. This reduction in time also reduces the burden of the disease, as shown in a Chilean study published in 2019 by Martinez et al.²¹

Another project, "The Disease Control Priorities in Developing Countries,"¹⁵ an ongoing campaign that aims to determine priorities for disease control across the world, estimated that only 11% of premature death or disability could be averted with surgical services concentrating on trauma, cancer, and congenital deformities.¹⁷ In total, 0.9% of deaths could be sidetracked by surgical care delivered to treat non-emergency conditions such as congenital anomalies.²² Future studies by our group will investigate our program's mid- and long-term effects at a local and national level to reduce premature disability.

We know that our cohort does not represent the entire population because patients with access problems or who required long periods of hospitalization were not included. Additionally, we acknowledge that the present study does not analyze long-term surgical results because of difficulties in follow-up due to the pandemic. However, our main objective was to offer free surgical treatment and access to a vulnerable population who otherwise would not have prompt access to surgical care. Currently, we continue collecting data.

Conclusion

Improving surgical capacity in LMICs is essential to reduce the burden of disease and disabilities. Since it is more challenging to deliver surgery treatment than medical management, it is necessary to create social programs to mitigate gaps in success to surgical procedures. Our program aims not to make a parallel system but to help the Colombian health system with its shortcomings, as surgical procedures are also a public health concern.

Additionally, multidisciplinary medical teams and numerous efforts from different entities are required in order to achieve this kind of project in LMICs. In our case, free access to infrastructure and the foundation grant were necessary. Nevertheless, more studies under different circumstances and designs are required in Colombia to evaluate the cost-effectiveness of this type of program.

Ethical Approval and Consent to Participate

Approval was obtained from the Ethics Committee of Hospital Universitario San Ignacio (reference number: FM-cue-8399-15). The procedures used in the present study adhere to the Declaration of Helsinki. The parents/legal guardians of all subjects signed written consents to allow us to use the patients' information for academic and scientific purposes, including medical publications.

Consent for Publication

Not applicable

Author Contributions

All authors contributed to the study's conception and design. The scheduling of surgeries and planning of the doctors' appointments were performed by NF, IZ, JES, JFP, and JCC. Data collection and analysis were performed by NF, JVC, DV, and JGP. NF, JVC, and DV wrote the first draft of the manuscript. All authors read and approved the final manuscript.

Availability of Data and Material

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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Conflict of Interests

The authors have no conflict of interests to declare.

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