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Results of Neonatal Screening in a Fourth-Level Institution in Bogotá, Colombia

Resultados del tamizaje neonatal en una institución de cuarto nivel en Bogotá (Colombia)

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ABSTRACT

Introduction: Law 1980, 2019, regulates the practice of neonatal screening and constitutes it as the right of every newborn. Hospital Universitario San Ignacio is the pioneer hospital in Colombia to implement these activities according to the law as part of the comprehensive newborn care program. **Objective:** To describe the first results of the implementation of basic neonatal screening as it was stated by law in a fourth-level institution in Bogota, Colombia. **Materials:** Observational, descriptive, cross-sectional study from October 1, 2020, to January 1, 2022. The sample included live births, excluding those who died in the first month of life. **Results:** 1255 newborns were assessed. The red reflex was abnormal in 0.2%, 4.5% were not performed, and the rest were normal. Basic metabolic screening (BMS) was authorized by the EPS in 63.2% of the patients, and the mean time for sampling was the first 5 days of life. Adherence of family members was 69.6%. The neonatal TSH screening was performed in 100% of the newborns,

and 98.2% were normal. In screening for congenital heart disease, 94% of patients were normal. The hearing screening result was normal in 99.6%. **Conclusions:** Neonatal screening as indicated in Colombian law is feasible for implementation, its results benefit patient care so strategies for its implementation must be developed. Continuity must be given to increase the opportunity in other hospitals.

Keywords
neonatal screening; heart diseases; congenital hypothyroidism; audiology; cataract.

RESUMEN

Introducción: La Ley 1980 de 2019 regula y amplía la práctica del tamizaje neonatal y lo constituye como derecho de todo recién nacido. El Hospital Universitario San Ignacio es pionero en Colombia en implementarla, como parte del programa de atención integral al recién nacido. **Objetivo:** Describir los primeros resultados de la implementación del tamizaje neonatal en una institución de cuarto nivel en Bogotá (Colombia). **Método:** Estudio observacional-descriptivo, de tipo transversal entre el 1.º de octubre de 2020 y el 1.º de enero de 2022. Muestra censal de los nacidos vivos con exclusión de los fallecidos en el primer mes de vida. **Resultados:** Se analizaron 1255 recién nacidos. El reflejo rojo fue anormal en 0,2% de los recién nacidos y en 4,5% no se realizó#. Del tamizaje neonatal básico (TNB), hubo autorización por la EPS en 63,2% de los pacientes, y en promedio el tiempo para la toma de la muestra fue de 5 días. La adherencia de los familiares para la toma de TNB de forma ambulatoria (después de las 72 horas desde del egreso) fue del 69,6%. El tamizaje de TSH neonatal se tomó# al 100% de los recién nacidos y en 98,2% fue normal. El tamizaje para cardiopatías congénitas fue reportado como normal en el 94% de los pacientes. El resultado de audiología fue normal en el 99,6%. **Conclusiones:** El tamizaje neonatal es factible de implementar. Sus resultados benefician la atención de los pacientes, por lo que se deben continuar desarrollando estrategias para su ejecución.

Palabras clave
tamizaje metabólico básico; cardiopatías; hipotiroidismo; audiología; reflejo rojo; neonatología.

Introduction

Primary health care is "essential health care accessible to all individuals and families in the community through means acceptable to them, with their full participation, and at a cost affordable to the community and the country." It is constituted as a strategy to provide health services, and its objectives include disease prevention, which has different levels of action related to the natural history of a disease (1).

Secondary prevention is carried out when the individual already has the disease, with the objectives of generating an early diagnosis and timely intervention and avoiding its progression. This reduces the prevalence of the disease by curing it or, if this is not achieved, by avoiding the occurrence of complications.

Among the secondary prevention activities is screening, a procedure applied to a population to estimate the risk of the presence of a disease that is still in its asymptomatic phase. Wilson and Jungner's principles establish what a disease must fulfill to be susceptible to screening: it must be an important health problem, there must be an accepted treatment for patients, there must be available resources for diagnosis and treatment, there must be a latent phase or preclinical stage, there must be an adequate test, and it must be accepted by the population, the natural history of the disease must be understood, there must be a policy regarding whom to treat as patients, screening must be an ongoing process, and the costs of finding a case concerning medical care must be economically balanced (2).

The priority of the Ten-Year Public Health Plan is to prevent disability, so mortality, morbidity, and avoidable disability are not tolerated. In the pediatric population, one of the most widely recognized and applied screening procedures worldwide is neonatal screening, which is defined as the set of actions involved in the early detection of metabolic, endocrine, visual, or auditory alterations for which treatment is available and which, if not detected promptly, increase morbidity, generate physical or cognitive disability and increase infant mortality (3,4).

Resolution 3280 of 2018 establishes "the technical and operational guidelines of the Comprehensive Care Route for the Promotion and Maintenance of Health and the Comprehensive Health Care Route for the Maternal Perinatal Population, and guidelines for its operation are established," thus establishing visual and hearing screening, screening for congenital heart diseases, and basic neonatal

screening (BNS) as necessary activities for the adequate care of the newborn.

On the other hand, Act 1980 of 2019 indicates the starting point for NBT, including testing for congenital hypothyroidism, phenylketonuria, galactosemia, cystic fibrosis, congenital adrenal hyperplasia, biotinidase deficiency, and hemoglobin defects. It should be taken into account that screening does not imply diagnostic tests and that a positive screening result should be confirmed with the study that is considered the gold standard for the pathology studied (5). It is a right of every living newborn (6,7), which is why the Ministry of Health and Social Protection is in charge of guaranteeing its operability and compliance with the law, given that it is considered part of the process to comply with the Sustainable Development Goals:

> #3: ensure healthy lives and promote well-being for all at all ages: by 2030, end preventable newborn and under-five deaths by ensuring that all countries aim to reduce newborn mortality to at least 12 per 1,000 live births and under-five mortality to at least 25 per 1,000 live births. (1,7)

Despite this, it is not an easy road, and there are still several administrative constraints that make sampling difficult.

Materials and methods

An observational, descriptive, cross-sectional, descriptive study was conducted in the period from October 1, 2020, to January 1, 2022, to describe the results of the implementation of neonatal screening activities in compliance with Resolution 3280 of 2018 and Law 1980 of 2019 in a fourth-level institution in Bogota (Colombia). It was approved by the Ethics Committee of the Hospital Universitario San Ignacio. The study population consisted of a census sample of live births during that period. All patients were included, except those who died in the first month of life.

To collect the data, the hospital's statistics office was asked for the registry of live births in the period described. Subsequently, the variables were verified in the medical records of the SAHI system, taking into account the characteristics of the mother, such as age and type of affiliation, and information on the newborn, such as APGAR, Ballard, birth weight, and sex. Data were then collected for the 5 screens to be investigated (neonatal umbilical cord TSH, critical congenital heart disease at 24 hours of life, pre-discharge red reflex, auditory, and basic metabolic). Data were collected using Research Electronic Data Capture (REDcap) software (Table 1).

Table 1
Characteristics of the neonatal screening tests

Technique	The cut-off point for normal	Procedure
Neonatal TSH		
Sample taken from the umbilical cord at birth	Less than 15 uUi/ml.	Cord blood sample. Four drops of blood are withdrawn from the fetal end and placed on the filter paper of the corresponding card. The technique used is *Delfia (Dissociation Enhaced Lanthanide Fluoroimmunoassay)*, a kit designed for the quantitative determination of TSH in dried whole blood samples on filter paper (14).
Screening for critical congenital heart diseases		
Pulse oximetry	Greater than 90% saturation with a gradient of less than 3% between preductal (right hand) and postductal (either foot) saturation.	Placement of the neonatal sensor on the back of the right hand and subsequently on either foot. Ensure that the light-emitting photodiode is at the opposite end of the receiving photodiode (15).
Hearing screening		
Otoacoustic emissions (OAE)	Good response/passes the test.	Placement of a small probe into the baby's ear canal to send a series of very brief acoustic stimuli that produce sound and record the cochlea's response (16).
Visual screening		
Red reflex	Normal: if the light reflections from both eyes have the same color, brightness, and clarity.	Ensure a dark place or opaque light to avoid pupillary miosis. Adjust the power of the ophthalmoscope lens disk to 0 diopters. Hold the ophthalmoscope directly at a distance of 30 to 50 cm from the neonate's eyes and direct the light of the instrument toward the neonate. Assess the presence of the red reflex in both eyes, which should be within the luminous cone. To comparatively evaluate the symmetry of the bilateral red reflex (17).
Basic neonatal screening (8)		
Biotinidase activity	Normal: higher than 74 U.	Semiquantitative fluorometric determination of biotinidase enzyme activity in dried blood from newborn heel prick samples.
Automated hemoglobin electrophoresis	Normal: FA pattern/phenotype	Qualitative measurement of the presence of hemoglobin variants S, C, F, D, A, and E in a heel end sample collected on filter paper by high-
		performance liquid chromatography (HPLC).
Quantitative phenylalanine	Apparent negative result of less than 2.1 mg/dl	Fluorometric method that quantifies phenylalanine values in dried blood collected on filter paper (Whatmann 903). VICTOR Kit, PerkinElmer.
Galactose	Negative: higher than 3.5 U/g HB	Semiquantitative determination of galactose 1 phosphate uridyl transferase (GALT).
17-alpha hydroxyprogesterone	Negative less than or equal to 29.9 nmol/L In premature infants (27-36 weeks) negative less than or equal to 60 nmol/L	Filter paper for the quantitative determination of 17-hydroxyprogesterone through the Delfia technique *(Dissociation Enhanced Lanthanide Fluorescent Immunoassay)*.
Trypsin	Normal: less than 70 ng/ml	Quantitative determination of immunoreactive trypsinogen (IRT) in the filter paper blood sample obtained from the heel.

With all the information collected, a univariate analysis was carried out using frequency distribution and analysis of measures of central tendency and dispersion of the continuous variables. The results are presented in tables and histograms. A bivariate cross-tabulation analysis was also performed with the variables of interest (neonatal TSH result according to the mother's thyroid gland pathology history and the echocardiogram result according to the heart disease screening result). REDCap was used to analyze the reports generated, and the SPSS statistical package was used to analyze the exported reports.

Likewise, using the chi-square statistical test (χ^2) and bivariate analysis, we compared the proportions of abnormal TSH results in the newborn screening, among those with mothers having hyper- or hypothyroidism or without a history of these, and compared the frequency of the oximetry test result at 24 hours of life versus the echocardiogram result.

Results

According to the census of live births at the Hospital Universitario San Ignacio in the period from October 1, 2020, to January 1, 2022, data were obtained for 1293 patients. Thirty-eight patients were excluded from the database due to death.

The birth weight of the newborns was, on average, 2850.9 grams (SD: 591.0 grams), with a gestational age by Ballard of 37.6 weeks (SD: 2.4 weeks), an APGAR at one minute of 8 (SD: 1) and 9 (SD: 1) at five minutes, respectively. 50.5 % were female, and none were identified as undifferentiated sex. The mean maternal age was 28.2 years (SD: 6.6 years) (Table 2). Eighty-eight percent of the mothers were affiliated with the contributory social security system.

Table 2
Description of population

Variables	n	Minimum	Maximum	Mean	SD
Ballard	1293	23.0	42.0	37.6	2.4
APGAR at 1 minute	1293	0.0	10.0	7.7	1.3
APGAR at 5 minutes	1293	0.0	10.0	8.9	1.0
Birth weight	1293	309.0	4886.0	2850.9	591.0
Maternal age	1293	13.0	47.0	28.2	6.6
Age at the time of hearing screening	838	1.0	32.0	7.6	4.8
Age at the time of basic metabolic screening	558	2.0	59.0	4.8	4.9

SD: standard deviation.

As for the audiology consultation, 66.6% of the newborns attended. The hearing screening was performed on average at 7.6 days of life (SD: 4.8 days) (Table 2). The result was normal in 99.6% of the cases (Figure 1). It should be taken into account that of the 419 patients who did not undergo this screening, 71.5% were followed up in the Mother Kangaroo Program, where they are screened as part of the care package; however, we do not have this statistical data. The total number of non-attendees was therefore 119, corresponding to 9.5% of the entire sample.

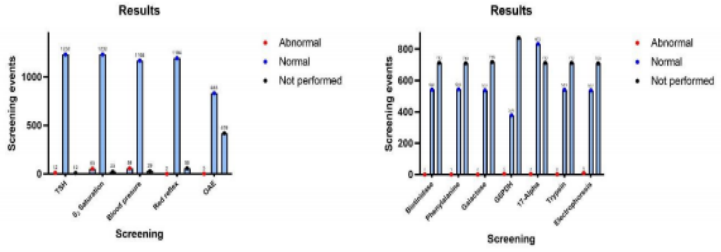

Figure 1
Screening results

As for the red reflex for visual screening, it was evaluated in 95.3% of the patients. Of these, it was abnormal in 0.2% of the cases (Figure 1).

Of the basic metabolic screening, the procedure was authorized by the health promotion company (EPS) in 793 patients (63.2%), and of these, a sample was taken in 552 (69.6 %). At the time of the metabolic screening, 344 (62.3%) patients were hospitalized, and it was performed in 37.7% on an outpatient basis. The average duration of the performance was 4.8 days (SD: 4.9 days) (Table 2). Adherence to the outpatient (after 72 hours from discharge) BNS performance was 69.6%.

A sample for biotinidase activity was taken from 542 (43.2 %) patients and was normal in all cases. Quantitative phenylalanine was obtained in 43.4% of newborns and was abnormal in 0.2% of patients. Galactosemia screening was performed in 537 (42.8%), with no abnormal results. The 17 α-hydroxyprogesterone was looked for in 43.3% of patients, and of these, 2.4% were abnormal. The immunoreactive trypsinogen test (IRT) was run in 43.3% of the infants and was abnormal in 0.4% of the individuals studied. Finally, hemoglobin electrophoresis (a high-performance liquid chromatography technique) was performed in 43.5% of the newborns, with abnormal results in 1.6% of the cases (Figure 1).

Neonatal TSH screening was performed on 100% of the newborns. It was normal in 98.2% of them, and abnormal in 1%. Most of the mothers (88%) had no history of thyroid gland pathology; 0.7% had a history of hyperthyroidism, and 11.3% had a history of hypothyroidism. A bivariate analysis was carried out with cross-tabulation of the variables of interest (pathological history of the mother's thyroid gland and abnormal TSH), and a correlation was found in 0.2% of the cases (Table 3).

Table 3
Neonatal TSH results according to the pathological history of the mother's thyroid gland.

Maternal history	TSH		Total
	Abnormal	Normal	
No	9	1115	1124
Yes	3	148	151
Total	12	1263	1275

Regarding screening for critical congenital heart disease at 24 hours of life, 98.2% of the newborns had pre- and post-ductal saturations taken at 24 hours of life. In 95.7% of the patients, it was normal and in 4.3% it was abnormal. Arterial blood pressure was obtained in 97.8% of the newborns in the 4 extremities at 24 hours of life: in 95.3% of the patients it was normal and in 4.7% it was abnormal. Echocardiogram was performed on 29.2% of the patients in the study, and of these, 22.7% were found to have some type of abnormality. A bivariate analysis was performed with cross tabulation with the variables of interest (abnormal echocardiogram and abnormal pre- and post-ductal saturations at 24 hours of life), and a correlation was documented in 5.7% of the cases (Table 4).

Table 4
Echocardiogram results according to the screening result for heart disease.

Pre- and post-ductal saturations at 24 hours of life	Echocardiogram result		Total
	Abnormal	Normal	
Abnormal	21	29	50
Normal	62	254	316
Total	83	283	366

Discussion

In Colombia, according to Law 1980 of 2019, newborns are entitled to a mandatory and free basic hearing, visual, and neonatal screening, including tests for congenital hypothyroidism, phenylketonuria, galactosemia, cystic fibrosis, congenital adrenal hyperplasia, biotinidase deficiency, and hemoglobin defects (7).

The Hospital Universitario San Ignacio is a pioneer in Colombia in the screening of newborns, and since October 1, 2020, it has implemented the conduct of basic neonatal screening requests for all patients born in the institution. This is carried out in the clinical laboratory between the third and fifth day of life, and in the case of discharge, the order is explained and delivered to the parents, who perform it on an outpatient basis, stressing the importance of adhering to this (8).

According to the census of live births during the study period, 63.2% of live births had the opportunity to access BNS with EPS approval. However, coverage was lower than expected in 43.9% of the cases evaluated during the study period. The adherence of the family members when they were given the order for the outpatient BNS test was lower than expected, probably due to the parents' lack of knowledge or awareness of the importance of detecting these pathologies early, since, although they are rare, they require treatment and timely follow-up to influence the prognosis of cognitive and motor disability, multisystemic alterations, and early death (7-9). Emphasis should be placed on the importance of the parents taking this screening at the time of the order and taking into account that attendance at the outpatient screening may have been affected by the COVID-19 pandemic, depending on the period analyzed, among other factors such as distant housing or scarce resources for travel.

When comparing our coverage with neonatal screening programs in Latin America from 2008, adapted to 2014 according to the global overview of neonatal screening published by Rodriguez et al. (10), we found coverage similar to Panama, with a percentage of 48 % for congenital adrenal hyperplasia, phenylketonuria, galactosemia, hemoglobinopathies, and 6PDH glucose deficiency; however, regarding congenital hypothyroidism, the coverage reported in our study is higher, even higher than the 80% reported for the same year for Colombia, which is currently similar to other Latin American countries such as Chile, Costa Rica, Cuba, and Uruguay. In our study, we found 100% coverage of screening for congenital hypothyroidism in newborns.

66.6% of the newborns had hearing screening with otoacoustic emissions (OAE). The average age at which it was performed was 8 days of life, and although this figure is not within the goals, it does represent an advance in hearing screening in Bogotá when compared with the results of the study by Rojas-Godoy et al. (11), published in 2014, which evaluated compliance with the assessment of hearing ability for the early detection of neonatal hearing loss in force at that time in the Colombian regulations, in two fourth level of complexity health institutions in the capital.

In this study, it was found that only one of the two institutions recommended OAE as a screening test for 48% of newborns with known risk factors, with no evidence in the clinical history of the performance and results of the test. The other institution did not refer any patient for screening (11).

On the other hand, of the 1255 newborns analyzed in our study, 1194 patients (95.5 %) had their red reflex evaluated before discharge by pediatricians and neonatologists previously trained in this screening. Of these, two patients (0.2%) were found to have an abnormality

in the initial screening, and we do not yet have the results of the final ophthalmologic diagnosis of these patients. Toli et al. (12), in a multicenter study carried out over 3 years in Italy in specialized birth centers, indicated that the red reflex was performed on the third day of life in 97.3% of neonates by personnel with previous training similar to ours. From this, we obtained a higher frequency of positive or ambiguous results (4.83%), when compared to ours, of which only 0.01% were diagnosed with a major ocular disease such as retinoblastoma or unilateral or bilateral congenital cataract, with a false positive rate of 2% and no false negatives (12).

In 98.2% of the newborns, pre- and postductal saturations were taken at 24 hours of life to detect critical congenital heart disease. In 94% of them, the result was normal, and in 2% there were failures in recording the result in the clinical history. At the Hospital Universitario San Ignacio, when abnormal results are obtained, there are two additional measurements, with a difference of 30-60 minutes between each one, and depending on the new value, the need for additional procedures is defined, such as an echocardiogram (the gold standard for the confirmation of critical congenital heart disease). We observed that of the 50 patients who had an altered pulse oximetry test at 24 hours of life, an abnormal echocardiogram was described in 21 of them (25.3%), compared to the study by Flórez-Muñoz et al. (13), also performed in a region of Colombia, in which the percentage of patients with negative screening was higher than ours (99.1%) and less frequently required additional studies. Here, 0.91% had a positive screening, and 50% of them were false positives. Meanwhile, our false positive frequency was 58%.

Conclusions

The coverage of neonatal screening in newborns at the Hospital Universitario San Ignacio was 100% for neonatal TSH, 98.2% for congenital heart disease screening with pre- and post-ductal saturations at 24 hours of life, and 95.5% for red reflex evaluation. The audiology screening attendance was 66.6%.

It is necessary to continue emphasizing the importance of taking these for the care of newborns and thus comply with current regulations for important activities related to public health. It is also necessary to maintain alliances with the EPS for the approval of the entire screening package. The Ministry of Health and Social Protection must continue monitoring the rights of newborns to comply with the aforementioned Millennium Development Goals.

Likewise, multicenter studies are needed in Colombia after Law 1980 of 2019 to establish the current national coverage of basic neonatal metabolic screening, critical congenital heart defects, blindness, and congenital deafness. Also, continue with the parameterization and coordination of the technical aspects of neonatal screening samples and tests. Ideally, this information should be part of a repository in Colombia, where information can be managed and decisions can be made promptly.

Finally, screening is not just a test; both the health system and professionals must be trained on what happens after the results and how to counsel families involved in possible complex diagnoses, such as this type of disease.

Conflict of interests

None.

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