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Original Article

Congenital Malformations: Incidence and Prevalence in the Department of Caldas, Colombia 2016-2017

Malformaciones congénitas: incidencia y prevalencia en el departamento de Caldas, Colombia 2016-2017

Malformações congênitas: incidência e prevalência no departamento de Caldas, Colômbia 2016-2017

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ABSTRACT

Introduction. Congenital malformations are routinely monitored; however further analysis of risk factors is required. The objective was to determine the incidence and prevalence of congenital malformations for the 2016-2017 period in Caldas and to explore the maternal risk factors. **Methodology.** A retrospective and descriptive study with a secondary source of information based on the cases notified by Caldas to the National Public Health Surveillance System of Colombia in the 2016-2017 period. **Results.** Between 2016-2017, 18,979 births occurred in Caldas, of which 282 had congenital malformations, with a prevalence of 14.8 per 1,000 live births. The highest frequency of malformations was found in the osteomuscular system with 101 cases (35.8%), followed by the central nervous system with 43 cases (15.2%). The mothers' mean age was 26.2 SD=7.2 years. A statistically significant association was found between the type of congenital malformation and maternal age (P <0.05), when the ages of between 21 to 33 years were excluded from the analysis. **Discussion.** The coverage of population reports has increased from local hospital levels to the national level. The need to go beyond monitoring to an in-depth analysis of risk factors is evident. **Conclusions.** The incidence and prevalence of congenital malformations in Caldas follows the national and regional trend. Maternal age is a sensitive risk factor for the primary prevention of congenital

malformations.

Keywords:
Congenital Abnormalities; Diseases Registries; Prevalence; Epidemiological Monitoring; Risk Factors.

RESUMEN

Introducción. Las malformaciones congénitas se vigilan de manera rutinaria, sin embargo se requiere profundizar en el análisis de factores de riesgo. El objetivo fue determinar la incidencia y prevalencia de malformaciones congénitas para el periodo 2016-2017 en el departamento de Caldas y explorar los factores de riesgo maternos. **Metodología.** Estudio retrospectivo y descriptivo con fuente de información secundaria a partir de los casos notificados por Caldas al Sistema Nacional de Vigilancia en Salud Pública de Colombia en el periodo 2016-2017. **Resultados.** Entre 2016 y 2017 ocurrieron 18,979 nacimientos en Caldas, de los cuales 282 presentaron malformaciones congénitas, con una prevalencia de 14.8 por cada 1,000 nacidos vivos. La mayor frecuencia de malformaciones se encontró en el sistema osteomuscular con 101 casos (35.8%), seguido del sistema nervioso central con 43 casos (15.2%). La media de edad de las madres fue de 26.2 DE=7.2 años. Se encontró asociación estadísticamente significativa entre el tipo de malformación congénita y la edad materna (P <0.05), al excluir para el análisis las edades entre 21 y 33 años. **Discusión.** Se ha pasado de un registro del nivel local hospitalario al nivel nacional a través de registros poblacionales con cobertura nacional. Se evidencia la necesidad de trascender del monitoreo al análisis a profundidad de factores de riesgo. **Conclusiones.** La incidencia y prevalencia de malformaciones congénitas de Caldas sigue la tendencia nacional y regional. La edad materna es un factor de riesgo sensible para la prevención primaria de malformaciones congénitas.

Palabras Clave:
Anomalías Congénitas; Registros de Enfermedades; Prevalencia; Monitoreo Epidemiológico; Factores de Riesgo.

RESUMO

Introdução. As malformações congênitas são monitoradas rotineiramente, porém é necessária uma análise mais aprofundada dos fatores de risco. O objetivo foi determinar a incidência e prevalência de malformações congênitas para o período 2016-2017 no departamento de Caldas e explorar os fatores de risco maternos. **Metodologia.** Estudo retrospectivo e descritivo com fonte de informação secundária baseada nos casos notificados por Caldas ao Sistema Nacional de Vigilância Sanitária da Colômbia no período 2016-2017. **Resultados.** Entre 2016 e 2017, ocorreram 18,979 nascimentos em Caldas, sendo 282 com malformações congênitas, com prevalência de 14.8 por 1.000 nascidos vivos. A maior frequência de malformações foi encontrada no sistema musculoesquelético com 101 casos (35.8%), seguido do sistema nervoso central com 43 casos (15.2%). A média de idade das mães foi de 26.2 DP=7.2 anos. Foi encontrada associação estatisticamente significativa entre o tipo de malformação congênita e a idade materna (P<0.05), ao excluir da análise as idades de 21-33 anos. **Discussão.** Passou-se de um registro em nível hospitalar local para nível nacional através de registros populacionais com abrangência nacional. A necessidade de ir além do monitoramento para uma análise aprofundada dos fatores de risco é evidente. **Conclusões.** A incidência e prevalência de malformações congênitas em Caldas segue a tendência nacional e regional. A idade materna é um fator de risco sensível para a prevenção primária de malformações congênitas.

Palavras-chave:
Anormalidades Congênitas; Registros de Doenças; Prevalência; Monitoramento Epidemiológico; Fatores de Risco.

Introduction

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The terms birth defect, congenital anomaly and congenital disorder are used interchangeably to refer to a wide range of pathologies that arise from alterations during embryo or fetus development, including any type of developmental failure, either physical, psychological, functional, sensory or motor. It also includes molecular disorders and congenital metabolic disorders, defined as those arising from an alteration in the structure or function of a gene or protein(1). Physical defects that affect the body structure are called congenital malformations, in reference to morphogenesis alterations. They have different types of manifestations, such as the absence of organs or organ parts (for example: anopthalmia, anotia, anencephaly), seriously over or under-sized organs (for example: macrodactilia, microtia), changes in shape or misplacement in the body (for example: clinodactyly, radial hypoplasia) (1,2).

Depending on the degree of affectation or the magnitude of the anatomical or functional repercussions, they are classified as major or minor. Major birth defects are those that significantly compromise function and social acceptance. If not corrected, they produce substantial biological, psychological and social limitations for the individual and reduce their quality of life, with potential medical, surgical and psychological effects that interfere with the individual's social acceptance (for example: hip dysplasia, cleft lip and palate). Minor birth defects are mainly cosmetic disorders that do not compromise body functions (for example, polythelia and preauricular fistula) (2,3).

Congenital malformations are causes of infant mortality and chronic disability that have major impacts on those affected, their families, health systems and society. The World Health Organization (WHO) estimates that 303,000 newborns die worldwide each year during their first four weeks of life for this reason (4).

In view of this problem, international organizations have been established through collaborative projects that have developed and implemented epidemiological surveillance programs and systems to detect and care for these disorders (4). In 1974, in Helsinki, Finland, the International Clearinghouse for Birth Defects Surveillance and Research (ICBDSR) was established as a voluntary non-governmental organization officially related to the WHO, which brings together surveillance and research programs on congenital anomalies from all over the world, with 43 member programs in 2015 (5,6).

A reference in the region is the Latin American Collaborative Study on Congenital Malformations (ECLAMC, for the Spanish original), of which Colombia is a member, initially with the participation of a surveillance study in Bogotá. Afterwards, starting in 2021, the "Birth Defects" event was included in the Public Health National Surveillance System (SIVIGILA, for the Spanish original). Even though the ECLAMC data were the only available source of epidemiological information for several decades, its coverage is low and its operational design is complex (7,8).

In Colombia, Bogotá and Cali participate in the ICBDSR. Bogotá began participating in 2006 through a project developed by the Secretary of Health and Pontificia Universidad Javeriana, and it has reported data to SIVIGILA since 2012, covering 94% of births. Cali began to report data in 2010 through the Cali campus of Pontificia Universidad Javeriana, using ECLAMC criteria, and it has been reporting data to SIVIGILA since 2016, covering 98% of births (9).

Surveillance in Colombia has advanced substantially thanks to the mandatory reporting of events. Events are reported by means of Notification Form Code 215 of the Colombian National Health Institute (INS, for the Spanish original) to SIVIGILA, in which each case is reported individually by the primary unit that produces the information (the health provider institution that provides the health care). The form includes sociodemographic, clinical and risk factor data on the mother and child, as well as laboratory data (10). According to the 2012-2021 Public Health Ten-Year Plan (11), the surveillance of birth defects in Colombia is a cross-cutting component driven by the comprehensive development of children and adolescents. This commitment was also made internationally at the Sixty-seventh World Health Assembly in 2014, through the Action Plan for Newborn Health (12), which in turn contributes to the goal of reducing child mortality (Sustainable Development Goals) in the region of the Americas (13).

At the global level, the reported frequency of birth defects detected at birth is between 2 and 3% (1). According to the WHO, an estimated 270,358 deaths in the world were attributable to congenital anomalies during the first 28 days of life in 2010, of which neural tube disorders were among the most serious and common (5).

In the Americas, between 2010 and 2015, birth defects and chromosomal abnormalities were the main cause of death of minors between the ages of 1 and 4 (14). In Cuba in 2012, these diseases were the second main cause of infant death, with a rate of 1.2 per 1,000 live births (15).

In Colombia, 267,120 perinatal deaths were reported from 1999-2008, of which 22,361 were due to congenital anomalies, with an average rate of 26.18 per 100,000 live births. The main disorders reported were circulatory system disorders (32.3%), followed by central nervous system disorders (16%). The perinatal mortality rates per 10,000 live births were 28.1 for the group of malformations of the circulatory system and of 13.7 for central nervous system anomalies (16). The national prevalence of birth defects in 2016 was 108 cases per 10,000 live births. The highest frequencies were in male children under 1 year of age with mothers between the ages of 10 to 14 and over 40 years old. The highest proportion of reported cases were osteomuscular

system malformations, followed by congenital malformations of the central nervous system (17).

The national prevalence rate of birth defects in 2017 was 113.6 cases per 10,000 live births. The highest proportion were osteomuscular system malformations, followed by malformations of the circulatory and central nervous systems. By demographic and social characteristics, the highest prevalence was found in the male sex, with 116 cases per 10,000 live births. In terms of mother's age, the highest prevalence was found for women over 40 years of age (18).

In 2017, Colombia's population was 49,291,609, and a total of 162,760 births, 44,488 fetal deaths and 227,624 non-fetal deaths were reported that year (19). A study of perinatal mortality due to congenital anomalies from 1999-2008 found that departments, such as Antioquia, Caldas, Risaralda and Huila and others, were above the 90th percentile of the country's perinatal mortality rate on average (average national rate of perinatal mortality= 26.18 perinatal deaths per 100,000 live births) during the 10 years of the study. Caldas was in second place with 38.9 perinatal deaths per 10,000 live births (16).

In 2014, 130 cases of birth defects were reported in Caldas. The mothers' ages were between 14 and 44 years of age, with a mean age of 25.4. Regarding the variables of exposure to risk factors, such as teratogenic agents (physical, chemical, biological, medications), tobacco, psychoactive substance or alcohol consumption, the territorial body reported that some data was incomplete and some notice forms were incorrectly completed by health care personnel, which does not allow obtaining a full epidemiological profile of newborn birth defects nor of the probable risk factors to which the mothers were exposed (20).

According to statistics reported by the national statistics agency (DANE, for the Spanish original), the population of Caldas in 2016 was 989,941. This agency's forecast for the 2015-2020 period is a female fertility rate of 2.36, average fertility age of 26.44 years, and an estimated 77,287 births and 36,790 deaths (fetal and non-fetal) (21).

The risk factors that may have a positive influence on congenital malformations are: high maternal age, adolescent mothers, unwanted pregnancy, deficient prenatal control, self-medicating, alcohol and/or tobacco consumption during pregnancy, deficient diet, occupational factors, and infectious and chronic maternal diseases (19). Maternal age stands out as a highly sensitive risk factor for preventive action, and must be taken into consideration in any Primary Health Care program (PHC), since it is known that a high maternal age (over 40 years old) increases the risk of having children with malformations. The age group under 20 years of age also represents a risk factor for congenital malformations, particularly in the case of pregnancies caused by disruption, as well as in cases of low weight at birth and prematurity (19).

In analyzing and monitoring congenital malformations, the data related to maternal age and other associated risk factors, such as tobacco and/or alcohol consumption during pregnancy and a deficit in folic acid consumption during pregnancy, requires closer analysis at all political-administrative levels, starting by the departmental level. The reported cases should also be complemented with an analysis of the demographic and social context.

In line with the above, the objective of this study was to determine the incidence and prevalence of congenital malformations at birth in Caldas, Colombia in the 2016-2017 period, and to explore the maternal risk factors.

What is known about the topic?

- Congenital anomalies include alterations at different levels of embryonic and/or fetal development. However, when talking about congenital malformations, we refer to those that produce physical defects and alterations in morphogenesis.
- The relevance of congenital malformations lies in the fact that they are a cause of infant mortality and chronic disability, not only affecting the correct development of the child, but also having repercussions on the parents and the health system.
- In the context of congenital malformations, there is evidence of an association with modifiable risk factors mainly due to exposure to teratogenic agents and maternal age.

Methodology

The study was of a quantitative, retrospective and descriptive nature. The cases of congenital malformations reported by Caldas by means of the epidemiological form to SIVIGILA during the 2016-2017 period were reviewed. The study's inclusion and exclusion criteria were established based on the case definitions of the Public Health Surveillance Protocol of the National Health Institute (INS). Inclusion criteria: Confirmed case: Any probable case (all newborns with any congenital abnormality visible at plain sight and by medical examination). All cases underweight for their gestational age. All cases with abnormal examination results for functional and metabolic anomalies defined as congenital anomalies according to clinical or paraclinical criteria; all outcomes of pregnancy, dead and alive, until 12 months of age, with probable diagnosis of congenital malformations during the 2016-2017 period; major malformations, and minor malformations when 3 or more minor malformations are reported in a newborn, or when they are accompanied

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by one or more major malformations. Syndromes: Down Syndrome and dysmorphic fetal alcohol syndrome. Exclusion criteria: minor malformations, when they are isolated, and conditions related to newborn prematureness of less than 37 weeks of pregnancy, and metabolic defects (10). 282 cases that fulfilled the inclusion criteria were included.

Incidence was calculated for each year (2016 and 2017) and prevalence was calculated for the entire period (the 2 years). Incidence was calculated based on *total new cases of congenital malformations in Caldas per year/ total live births during the studied period x 1,000;* and prevalence was calculated with the *cumulative number of cases of congenital malformations in Caldas in 2016 and 2017/total live births during the same period x 1,000.* The following univariate descriptive analysis was performed: the central tendency and dispersion measures are presented for quantitative variables, and frequency distributions are presented for the qualitative variables. In addition to a bivariate analysis to explore associations between the variables of interest (maternal age, risk factors), the respective contingency tables were made and Chi Square (χ^2) and Fisher's Exact Test were applied in the cases with expected values of less than 5. Statistical significance level $P<0.05$. The SPSS version 25 statistical package was used.

The project complied with Resolution 8430/1993 and was classified as Minimum Risk Research (22). The regional health authority provided authorization to access the data, in accordance with institutional confidentiality agreements. The study was approved by the Bioethics Committee of the Health Sciences Faculty of Universidad de Caldas, as documented in Minutes 34 of 2017.

Results

The analysis covered a total of 282 cases of congenital malformations that met the inclusion criteria: 133 cases reported in 2016 and 149 cases reported in 2017. The diagnosis was postnatal in 196 cases (69.5%) and prenatal in 86 cases (30.5%). In terms of condition at birth, 264 (93.6%) were born alive and 17 (6%) were born dead.

In Caldas, over the studied period, the study found an incidence of 14 congenital malformations per 1,000 live births/year in 2016; 16 congenital malformations per 1,000 live births/year in 2017 and a prevalence of 14.8 congenital malformations per 1,000 live births.

Between 2016 and 2017 in Caldas, Colombia, 18,979 births and a total of 194 infant deaths under 1 year of age were reported in both years, of which 39 were caused by congenital malformation.

The most frequent congenital malformations found, grouped by affected system or organ, were of the osteomuscular system with 101 cases (35.8%), followed by the central nervous system with 43 cases (15.2%), and the circulatory system with 39 cases (13.8%) (Table 1).

Table 1. Frequency and percentage distribution of cases by type of congenital malformation by affected system or organ. Caldas, Colombia 2016-2017 (n=282)

ICD-10 Code	Type of congenital malformation	Frequency	%
(Q65-Q79)	Osteomuscular system	101	35.8
(Q00-Q09)	Central nervous system	43	15.2
(Q20-Q28)	Circulatory system	39	13.8
(Q35-Q38)	Cleft palate and cleft lip	29	10.3
(Q90)	Down Syndrome	21	7.4
(Q10-Q18)	Eyes, ears, face and neck	14	5
(Q50-Q56)	Genital organs	12	4.3
(Q60-Q64)	Urinary system	11	3.9
(Q39-Q45)	Digestive system	10	3.5
(Q80-Q89)	Other malformations	1	0.4
(Q86)	Other syndromes: dysmorphic fetal syndrome	1	04
	Total	**282**	**100**

Source: Prepared by authors based on SIVIGILA data. Caldas, 2016-2017.

Broken down by specific diagnosis, the most frequent malformations of the osteomuscular system were clubfoot with 39 cases (13.8%), followed by Polydactyly with 31 cases (11%). The most frequent diagnoses of central nervous system malformations were malformations of the aqueduct of Sylvius with 10 cases (3.5%), and 8 cases of anencephaly (2.8%). Among the congenital malformations of the circulatory system, the most predominant was common truncus arteriosus with 11 cases (3.9%), followed by ventricular septal defect with 7 cases (2.5%) (Table 2).

Table 2. Frequency and percentage distribution by type of congenital malformation specified by affected organ and system. Caldas, Colombia (2016-2017) (n=282)

ICD Code 10	Type of congenital malformation	Frequency	%
(Q65-Q79)	**Congenital malformations and deformities of the osteomuscular system**	**101**	**35.80**
	Clubfoot	39	13.80
	Polydactyly	31	11
	Gastroschisis	11	3.90
	Syndactyly	5	1.80
	Omphalocele	3	1.10
	Arthrogryposis multiplex congenita	2	0.70
	Craniosynostosis	2	0.70
	Upper limb reduction defect	2	0.70
	Congenital diaphragmatic hernia	2	0.70
	Radial agenesis	1	0.40
	Lower limb reduction defect	1	0.40
	Thanatophoric skeletal dysplasia	1	0.40
	Agenesis of the cranial bones	1	0.40
(Q00-Q09)	**Congenital malformations of the central nervous system**	**43**	**15.20**
	Malformations of the aqueduct of Sylvius	10	3.50
	Anencephaly	8	2.80
	Microcephaly	7	2.50
	Congenital hydrocephalus, unspecified	5	1.80
	Holoprosencephaly	4	1.40
	Arnold Chiari syndrome	2	0.70
	Congenital hydrocephalus	1	0.40
	Other specific brain malformations (mega cisterna magna)	1	0.40
	Macrocephaly	1	0.40
	Myelomeningocele	1	0.40
	Encephalocele, unspecified	1	0.40
	Occipital encephalocele	1	0.40
	Corpus callosum malformation	1	0.40

(Q20-Q28)	**Congenital malformations of the circulatory system**	**39**	**13.80**
	Common truncus arteriosus	11	3.90
	Ventricular septal defect	7	2.50
	Congenital stenosis of the pulmonary valve	4	1.40
	Atrial septal defect	3	1.10
	Atrioventricular septal defect	3	1.10
	Pulmonary valve atresia	2	0.70
	Patent ductus arteriosus	2	0.70
	Congenital stenosis of the tricuspid valve	2	0.70
	Hypoplastic right heart syndrome	2	0.70
	Discordant atrioventricular connection	1	0.40
	Tetralogy of Fallot	1	0.40
	Double inlet ventricle	1	0.40
(Q35-Q38)	**Cleft palate and cleft lip**	**29**	**10.30**
	Hard cleft palate with bilateral cleft lip	17	6
	Cleft lip	7	2.50
	Cleft palate	5	1.80
(Q35-Q38)	**Chromosomal abnormalities not elsewhere classified**	**21**	**7.40**
	Down Syndrome	21	7.40
(Q10-Q18)	**Malformations of eyes, ears, face and neck**	**14**	**5**
	Congenital absence of the pinna	6	2.10
	Microtia	5	1.80
	Microphthalmia	1	0.40
	Congenital cataract	1	0.40
(Q50-Q56)	**Congenital malformations of genital organs**	**12**	**4.30**
	Hypospadias	9	3.20
	Undetermined sex, hermaphroditism	2	0.70
	Rectovaginal fistulas	1	0.40
(Q60-Q64)	**Congenital malformations of the urinary system**	**11**	**3.90**
	Bilateral renal agenesis	6	2.10
	Congenital hydronephrosis	4	1.40
	Potter syndrome	1	0.40

(Q39-Q45)	**Congenital malformations of the digestive system**	**10**	**3.50**
	Congenital absence, atresia, stenosis of the small intestine	5	1.80
	Congenital absence, atresia and stenosis of anus without fistula	3	1.10
	Esophageal atresia without tracheoesophageal fistula	1	0.40
	Pierre Robin syndrome	1	0.40
(Q80-Q89)	**Other congenital malformati**	**1**	**0.40**
(Q86)	**Other syndromes**	**1**	**0.40**
	Dysmorphic fetal alcohol syndrome	1	0.40

Source: Prepared by authors based on SIVIGILA data. Caldas, 2016-2017.

Of the 282 reported cases in the department of Caldas, Colombia, during the studied period, 160 cases (56.7%) were male, 116 (41.1%) female and 6 (2.1%) of undefined sex. The mothers' age was between 13 and 46 years, with an average age of 26.2 (SD= 7.2 years).

In the maternal age group analysis, the highest frequency in terms of cases of congenital malformations was the 20-24 age group with 85 cases (30.1%), followed by the 30-34 age group with 54 cases (19.1%), which is the usual behavior (Table 3).

Table 3. Frequency and percentage distribution of cases of congenital malformations by maternal age group. Caldas, Colombia (2016-2017) (n=282)

Age groups (years)	Cases	%
10-14	3	1
15-19	49	17.3
20-24	85	30.1
25-29	51	18
30-34	54	19.1
35-39	27	9.5
40-44	10	3.5
45-49	3	1
Total	**282**	**100**

Source: Prepared by authors based on SIVIGILA data. Caldas, 2016-2017.

Regarding the mothers' exposure to risk factors for congenital malformation included in the notification forms, it was found that 20 mothers did not consume folic acid during pregnancy and 10 mothers consumed alcohol during pregnancy. The frequencies and percentages of these variables are presented in Table 4.

Table 4. Frequency and percentage distribution of cases of risk factors according to notification. Caldas, Colombia (2016-2017) (n=282)

Variable	Categories	Frequency	%
Folic acid consumption during pregnancy	Yes	262	92
	No	20	8
Exposure to teratogenic agents	Yes	4	1.4
	No	278	98.6
Alcohol consumption during pregnancy	Yes	10	3.5
	No	272	96.5
Tobacco consumption during pregnancy	Yes	5	1.8
	No	277	96.2
Psychoactive substance consumption during pregnancy	Yes	3	1.1
	No	279	98.9

Source: Prepared by authors based on SIVIGILA data. Caldas (2016-2017).

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The cut-off point for the exploratory association analysis was a maternal age of 34, in line with the study by Nazer and Cifuentes (23). No statistically significant relationship was found between the type of congenital malformation and maternal age of less than 34 and maternal age of over 34 (P=0.183), using the χ^2 test. The exploration continued by excluding the ages between 21 and 33 from the analysis, taking into consideration the behavior of fertility in Caldas. In this case, a statistically significant association (P <0.05) was found between the type of congenital malformation and maternal age, with value of P= 0.049.

The association of risk factors was explored with the available cases (Table 4), and even though no statistically significant differences were found between the type of congenital malformation and consumption of alcohol during pregnancy (P= 0.16) and failure to consume folic acid during pregnancy (P=0.18) using the Fisher Exact test, the results were not conclusive.

What's new?

- The incidence of congenital malformations in the department of Caldas was 14 per 1,000 live births during 2016 and 16 per 1,000 live births in 2017, with a prevalence of 14.8 per 1,000 live births.
- The congenital malformations found in this study coincide with the national epidemiological behavior, with the musculoskeletal system being most frequently affected (35.8%), followed by the nervous (15.2%) and circulatory (13.8%) systems.
- When excluding the age of 21-33 years (taking into account the regional fertility behavior), a statistically significant association was found between the type of congenital malformation and maternal age.

Discussion

Congenital malformations are a significant cause of infant and child morbidity and mortality, which implies that actions are required to improve the information and epidemiological surveillance systems for these events. The coverage of population reports in Colombia, Mexico and Argentina has increased from the local hospital level to a recently implemented national level (8,24,25).

In the case of Colombia, national-level reporting (SIVIGILA) began in 2010. The various departments have progressively begun to file reports, and reports have been in place in the entire national territory since 2012, though with uneven distribution. Caldas reported 47.64 cases per 10,000 live births in the 2010-2013 period (24). The analysis performed in this study found that 18,979 births were reported in Caldas in the 2016-2017 period, of which 282 had congenital malformations, for a prevalence of 1.4% (14.8 per 1,000 live births). This finding differs from the study of García et al. (24), according to which the prevalence of congenital malformations in Colombia was 0.35% between 2010 and 2013, and less than 1% in every year (26). However, another study points out that a prevalence, such as prevalence found of 1.4%, would be within the expected range if only major congenital malformations are considered, as in Argentina, for example, where the overall prevalence of major congenital anomalies at birth was 1.76% in the 2009-2012 period (8).

In this study, the highest frequency of cases of congenital malformations was found in the osteomuscular system, with 101 cases (35.8%); followed by central nervous system malformations, with 43 cases (15.2%), and circulatory system malformations in third place with 39 cases (13.8%), which is consistent with what has been reported on a national level for 2016 and 2017 (17,18) and at the departmental level in 2014 (20). In general, it can be said that Caldas follows the national and regional trend, where the classification by organs and systems indicates that muscular-skeletal system, central nervous system and circulatory system defects are the most frequent (24,27,28).

It was also found that males had the highest frequency of congenital malformations during the studied period, which is consistent with what was reported for Caldas in 2014 (20), on a national level in 2016 and 2017 (17,18), and in other countries, such as Mexico (29), Cuba (15) and Argentina (8).

The scientific literature has demonstrated the influence of different risk factors on congenital malformations, including maternal infections, such as syphilis or rubella, iodine and folate deficiency, maternal exposure to certain pesticides and other chemical products, as well as certain medications, alcohol, tobacco, psychoactive substances and radiation (4,28) The embryotoxic or teratogenic effects of alcohol on the fetus may produce death, dysmorphic changes, craniofacial disorder, cardiac or genitourinary malformations, cutaneous hemangiomas and/or changes in behavior (30).

In Colombia, the epidemiological form includes information on risk factor variables (10). This study found that central nervous system malformations were the second most frequent group, as was the case in Risaralda (27). According to the scientific literature, most congenital

effects are related to folic acid deficiency (7), which is also related to the mother's nutritional and socioeconomic conditions (4,28). The exploratory association analysis did not find statistically significant differences between the type of malformation and alcohol consumption during pregnancy and failure no consume folic acid during pregnancy, which is a non-conclusive result, but may motivate further analysis of these variables in other studies with a broader scope and depth.

It should be noted that in this study, analyzing the variable of maternal age by age group showed that the group with the highest frequency of cases of birth defects was the age group of between 20 and 24 years, with 30.1% of the cases, which is attributable to the fact that female reproduction is more frequent at this age. The national statistics agency (DANE) reports an average fertility age in Caldas of 26, which is similar to that of other countries, such as Mexico, where there is also an increase in fertility among women under 20 years old and between the ages of 20 and 24 (25). Despite the sociodemographic changes in fertility, it was found that when the age groups between 21 and 33 years old were excluded from the association analysis, statistically significant differences were found with type of malformation ($P<0.05$). Maternal age is a key aspect for targeting PHC prevention actions (19).

Since congenital anomalies are individually infrequent events, epidemiological studies require a large number of individuals. For this reason, the epidemiological surveillance systems, with large databases, adequate diagnosis quality and continuity over time, are useful for studying the causal factors, such as environmental pollutants, nutritional factors and maternal diseases (8). In Colombia, a fundamental change was the inclusion of the "Birth Defects" event in SIVIGILA, a system whose strength is that it is a mandatory reporting tool with national coverage that uses the International Classification of Diseases (ICD-10) coding system (24).

Conclusions

It was found that Caldas maintains the national and regional trend in terms of the frequency of cases and types of malformations during the studied years (2016 and 2017), compared to 2014 and 2015. Despite the sociodemographic changes, the analysis of the maternal age variable showed that when the age group of between 21 and 33 years was excluded from the association analysis, due to their fertility behavior, statistically significant differences were found with type of malformation ($P<0.05$). This helps conclude that maternal age is a determinant variable of analysis that would be worth pursuing in future studies with broader scope and depth.

With the congenital malformation epidemiological surveillance systems, it is necessary to move beyond monitoring to a more in-depth analysis of the risk factors and prevention strategies, taking maternal age into account.

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Conflict of Interest

The authors declare there is no conflict of interest.

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