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PRESCRIBING PATTERNS AND THE USE OF ANTHELMINTIC DRUGS IN COLOMBIAN PATIENTS: A CROSS-SECTIONAL STUDY

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KEY WORDS

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Anthelmintics
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ABSTRACT

Intestinal parasites continue to be a public health problem in low- and middle-income countries. Broad use of anthelmintics during deworming programs is still necessary in many regions. However, description of the usage of these medications in general medical practice has been limited. The objective of this study was to determine the use of anthelmintic drugs and their indications in a group of Colombian patients. This was a descriptive study from a drug-dispensing database, identifying patients with prescriptions for anthelmintic drugs. A total of 381 cases were randomly selected, and their medical records were reviewed, analyzing sociodemographic, clinical, and pharmacological variables (indication of use). The lack of diagnosis registration or clinical manifestations of parasites was determined as a prescription without indication. In total, 50.9% (n = 194) of patients were female, and 67.4% of all patients were under 18 yr of age. The diagnosis of helminthiases was clearly stated in 114 (29.9%) patients, and only 4.2% (n = 16) of these had microbiological confirmation. The most commonly used anthelmintic drug was albendazole (70.4% of all prescriptions). The use of anthelmintics was not indicated in 266 cases (69.8%). Nutritional supplements or vitamin prescriptions were associated with using anthelmintics without indication (odds ratio: 2.25; 95% confidence interval: 1.26–4.03). A high proportion of patients lacked symptoms or diagnoses in their clinical records that supported the use of anthelmintic drugs.

Many parasites can affect humans; in general, the main groups are protozoa, arthropods, and helminths, with the last group having been reported to be the most common and prevalent cause of human infections worldwide (Werner, 2014; MinSalud, 2022; WHO, 2023).

Intestinal parasites continue to be a public health issue in developing countries (Sandoval, 2012; WHO, 2023). It is estimated that 1.5 billion people may be infected with soil-transmitted helminths worldwide (WHO, 2023). It has been found that the populations with the most exposure to intestinal parasites are those in low- and middle-income countries due to housing conditions, lifestyle habits, and the sanitary state of food and water (Sanchez, 2006; Vázquez and Campos, 2009).

Children are the group most commonly affected by parasite infection, especially in malnourished populations, due to an immature immune system and their lifestyle and behavior habits (Carmona-Fonseca, 2004; Rodríguez, 2015). Intestinal parasite infection can cause or exacerbate gastric symptoms, anemia, vitamin A deficiencies, growth retardation, cognitive disorders, memory loss, and a decreased ability to learn, in addition to the possibility of parasite migration, which may become the cause of different medical complications, including death (Sanchez, 2006; Ochoa, 2019).

In Colombia the Ministry of Health and Social Protection carried out a study in which 7,860 children residing in different geographical areas of the country participated; they found that 30% of the volunteers were infected with some intestinal soil-transmitted helminths (MinSalud, 2015). These soil-transmitted helminth infections included common parasites such as *Ascaris lumbricoides*, *Ancylostoma duodenale*, and *Trichuris trichiura* (Carvajal-Restrepo et al., 2018; Idris et al., 2019; MinSalud, 2022).

Considering the high prevalence of intestinal worms, the application of deworming campaigns with the use of mass drug administration is recommended in many areas of the country and around the world (once a year in areas with a prevalence ≥20%; WHO, 2006; MinSalud, 2013). A variety of anthelmintic drugs are used to treat parasite infection, which have all shown good effectiveness and safety profiles to date (Idris et al., 2019).

However, anthelmintic drugs can also cause several adverse drug reactions such as headaches, sleep disorders, and seizures, among others. The use of these drugs, like all drugs, should be responsible, clearly justified, and cost-effective (Idris et al., 2019). Furthermore, these are drugs with a microbiological spectrum coverage, which means they have very precise indications, and

their indiscriminate use can have negative consequences. For example, in veterinary medicine, they might develop selective pressure and parasitological resistance (James et al., 2009; Tinkler, 2020). However, there are no conclusive reports of parasite resistance to anthelmintics (Vercruysse et al., 2011; Tinkler, 2020).

The description of the usage of anthelmintic medications in general medical practice (outside deworming campaigns) has been limited. In this sense this research is aimed to determine the use of anthelmintic drugs and their indications in a sample of outpatients affiliated with the Colombian Health System.

MATERIALS AND METHODS

Study design

This study was a descriptive cross-sectional study. The medical records were initially reviewed of patients of all ages and genders, with at least 1 anthelmintic medication prescribed over 7 mo (between 1 April and 31 October 2017), in an outpatient medical consultation from a healthcare insurer of the Colombian Health System, which has 2.5 million affiliates across 16 major cities in the country.

Setting and participants

In Colombia access to medicines in the Health System is granted through a benefit plan that covers all its affiliates and is carried out after a medical prescription. The information was taken from the drug-claim database of the company Audifarma S.A, which dispensed drugs, at the time of the study, to more than 6.5 million people in the Colombian Health System (including those from the healthcare insurer of study). We included data from outpatient medical consultations, focusing on general medical practice. The data do not cover specific deworming campaigns or medications directly purchased by the patients.

We excluded patients with formulation of anthelmintic drugs for extraintestinal parasitosis, such as the cerebral, cutaneous, pulmonary, hepatic, and migrant/complicated forms (upon clinical record review).

Sample size

A total of 74,384 users were found to have at least 1 anthelmintic formulation at the observation period. Using the Epi Info™ software, a random sample of 381 patients was calculated for inclusion to review their clinical records, considering an expected frequency of 50%, an alpha error of 5%, and a confidence interval of 95%.

Data sources and variables

The anthelmintics included were albendazole, ivermectin, mebendazole, pyrantel pamoate (and their combined presentations with oxantel), piperazine, praziquantel, and nitazoxanide. In addition, prescriptions combined with other antiparasitics, including metronidazole, tinidazole, and teclozan, were described.

The recorded variables were sociodemographic (age, sex, city of residence), anthropometric (weight, height, body mass index [kg/m^2]), clinical variables (reasons for consultation, indication for use of the anthelmintic drugs, diagnoses of helminthiasis, prescription made by a physician or other healthcare professional, other diagnoses), paraclinical (stool and hemoglobin to identify the presence or absence of anemia), and pharmacological profile (prescribed drugs and comedications).

To explain the rationale for using anthelmintics, 2 scenarios were considered. First, prescription without indication for using anthelmintics: when the patient lacked the diagnosis of intestinal parasitosis in their clinical record or stool analysis. The attending physician did not have a diagnostic impression of intestinal parasitosis from the signs and symptoms described. However, manifestations that might suggest parasitosis such as the presence of anal itching and the visualization of helminths in stools or vomit, by the patient, their representative, or the physician, even if the patient lacked a diagnosis, accounted for a prescription with indication. Second, prophylactic deworming: according to the guidelines of the Ministry of Health and Social Protection of Colombia (MinSalud, 2013, 2022) and according to the recommendations of the World Health Organization (WHO) (WHO, 2006), children between 1 and 14 yr of age, pregnant women in the second and third trimesters of pregnancy, women of childbearing age (15–49 yr), and lactating women should be considered for prophylactic deworming because of the high prevalence of parasites in the soil and reservoirs. Other adults would be considered eligible only if their declared profession is farmer or miner, as well as inmates.

Data analysis

The statistical package SPSS Statistics version 24.0 for Windows (IBM Corp., Armonk, New York) was used for data analysis. Descriptive statistics were used to analyze the results, including central tendency measures for quantitative variables and frequencies or proportions for categorical data. Bivariate analyses were performed to find variables related to the use of anthelmintics in prescriptions without indication (yes/no) using chi-squared tests. Subsequently, a multivariate binary logistic regression model was run to identify factors related to prescriptions without indication. Age, sex, and those variables significantly related to the outcome in the bivariate analyzes were included as covariates. A value of $P < 0.05$ was considered significant.

Ethical approval

The research was approved by the Bioethics Committee of the Universidad Tecnológica de Pereira, in the category of "research without risk" (approval code: CBE-SYR-162016). Principles established by the Declaration of Helsinki were followed.

RESULTS

A total of 381 records of people who received anthelmintic dispensations during the study period were reviewed. In total, 50.9% (n = 194) were women and 67.4% (n = 257) were under 18 yr of age, with a median age of 10 yr (interquartile range [IQR)]: 4–26 yr), distributed in 16 cities of Colombia. Table I shows the sociodemographic and anthropometric variables of the patients. Neither pregnant nor lactating women were found in the sample.

General practitioners were the most frequent prescribers, representing 76.4% (n = 291) of all prescriptions (Table I). The reasons for seeking clinical attention were consistent with symptoms of intestinal parasites in 17.3% (n = 66) of patients. Only 29.7% (n = 113) of all patients had a diagnosis of intestinal parasitosis reported in the clinical records; none of these reported the etiological agents. Only 16 stool analyses were reported, of which 5 found protozoa (*Endolimax nana*, *Giardia lamblia*, *Entamoeba histolytica*), and only 1 reported some helminth (*Ascaris lumbricoides* eggs). Likewise, 71 blood tests were recorded, confirming

Table I. Sociodemographic and anthropometric characteristics of a sample of patients treated with anthelmintics.

Variables	Total (n = 381)	Age <18 yr* (n = 257)	Adults* (n = 124)
Sociodemographic			
Female n (%)	194 (50.9)	125 (48.6)	69 (55.6)
Median age (IQR)	10 (4–26)	6 (3–10)	35 (26–50)
City of residence n (%)			
Barranquilla	84 (22.0)	54 (21.0)	30 (24.2)
Cartagena	80 (21.0)	54 (21.0)	26 (21.0)
Ibague	37 (9.7)	21 (8.2)	16 (12.9)
Santa Marta	30 (7.9)	23 (8.9)	7 (5.6)
Valledupar	27 (7.1)	18 (7.1)	9 (7.2)
Bucaramanga	25 (6.6)	14 (5.4)	11 (9.0)
Monteria	25 (6.6)	21 (8.2)	4 (3.2)
Other cities	73 (19.1)	52 (20.2)	21 (16.9)
Anthropometric			
Height (cm) median (IQR)	138 (103–160)	116 (95–139)	164 (156–173)
Weight (kg) median (IQR)	33 (16–60)	20 (15–34)	67 (58–74)
BMI (mean ± SD)	19.6 ± 4.9	16.9 ± 2.6	24.9 ± 3.9
Prescriber type			
General medicine	291 (76.4)	168 (65.4)	123 (99.2)
Pediatrics	60 (15.7)	60 (23.3)	0 (0.0)
Nursing	23 (6.0)	23 (8.9)	0 (0.0)
Family medicine	6 (1.6)	6 (2.3)	0 (0.0)
Internal medicine	1 (0.3)	0 (0.0)	1 (0.8)

Abbreviations: IQR: interquartile range; BMI: body mass index in kg/m^2; SD: standard deviation.
* The percentages were calculated according to the total of each column, not on the total number of participants.

anemia in 14 cases; only 1 of them had symptoms related to intestinal parasites. Other diagnoses included routine medical control (n = 87, 22.8%), dermatological disorders (n = 39, 10.2%), gastrointestinal-related disorders (n = 37, 9.7%), and others (n = 105, 27.6%), with the last consisting of respiratory conditions, musculoskeletal problems, headaches, and a lack of normal physiological development.

Of all patients, 280 were prescribed other drugs besides anthelmintics (73.5%), such as nutritional supplements and vitamins (n = 130, 34.1%), corticosteroids (n = 49, 12.9%), antifungals (n = 44, 11.5%), antihistamines (n = 44, 11.5%), antiulcer drugs (n = 38, 10.0%), and analgesics (n = 38, 10%), as well as others such as antibiotics, antispasmodics, muscle relaxants, and antihypertensives.

Use of anthelmintic medications

The most widely used anthelmintic was albendazole, followed by pyrantel pamoate and mebendazole. Table II shows the anthelmintic drugs identified in the study. Ivermectin, praziquantel, and nitazoxanide were not reported in the sample. A total of 28 patients (7.3%) received anthelmintic combinations. Of these, 25 patients had a combination of albendazole with pyrantel pamoate and 3 of mebendazole with pyrantel pamoate.

Sixty-nine patients (18.1%) had combined therapy with another antiparasitic drug, where the most frequent association was with tinidazole (n = 39, 56.5% of the combinations), followed by metronidazole (n = 26, 37.7%) and teclozan (n = 6, 8.7%). From the group of patients with these drug combinations, 20.3% (n = 14) had symptoms reported in their clinical record that justified the use of antiparasitic medication, while only 16.6% (n = 52) of the cases who received anthelmintic drugs alone had symptoms.

Six types of different prescription regimens were found for albendazole; these were mainly a single dose (n = 147, 51.0% of albendazole prescriptions), with other regimens being every 24 hr for 2 days (n = 103, 35.8%), every 15 days (n = 19, 6.7%), and other (n = 19, 6.7%). The latter included every 12 hr for several days, every 8 days for several weeks, and every 6 mo.

Something similar was reported for pyrantel pamoate, with findings of the following regimens: formulations every 24 hr for 2 days (n = 57, 58.8% of pyrantel prescriptions), ranges from a single

Table II. Frequency of use of anthelmintic drugs and dose according to age group.

	Total (n = 381)		Age <18 yr (n = 257)		Adults (n = 124)	
Drug	n (%)	mg/day*	n (%)	mg/day*	n (%)	mg/day*
Albendazole	288 (75.6)	370	194 (75.5)	354	94 (75.8)	400
Pyrantel pamoate	97 (25.5)	428	67 (26.1)	374	30 (24.2)	550
Mebendazole	19 (5.0)	174	12 (4.7)	158	7 (5.6)	200
Piperazine	5 (1.3)	23.4	5 (1.9)	23.4	—	—

* Values presented as means.

Table III. Variables associated with unjustified anthelmintic prescriptions in a binary logistic regression model.

Variables*	Sig.	OR	95% CI	
			Lower	Upper
Use of additional antiparasitic drug	<0.01	0.42	0.23	0.80
Anthelmintic in combination therapy	0.03	0.32	0.12	0.86
Prescription of nutritional supplements/vitamins	<0.01	2.25	1.26	4.03

Abbreviations: Sig: significance; OR: odds ratio; 95% CI: 95% confidence interval.
* Model adjusted for age group <18 yr, female sex, place of residence, reason for consultation, use of pyrantel pamoate, prescriber, and comedications (antibiotics, antifungals, antispasmodics).

dose to 1 to 3 doses per day (n = 34, 35.0%), doses every 15 days (n = 3, 3.1%), and other regimens (n = 3, 3.1%). Piperazine was used in a single dose (n = 3) or every 24 hr for 2 days, while mebendazole was prescribed only every 24 hr for 2 days.

Rational prescription analysis

The prescriptions without indication were present in 69.8% (n = 266) of cases since they had no record or diagnostic impression of intestinal parasitosis. However, when including the prophylactic deworming criteria, only 11.3% (n = 43) of the patients would have prescriptions without indication.

The multivariate analysis adjusted for age, sex, and those variables with statistical significance in the bivariate tests showed that the prescription of nutritional supplements and vitamins (odds ratio [OR]: 2.25; 95% confidence interval [CI]: 1.26–4.03) was associated with a greater probability that the patient received a prescription of an anthelmintic without indication, while the use of additional antiparasitic drugs (OR: 0.42; 95% CI: 0.23–0.80) or an extra anthelmintic drug in combined therapy (OR: 0.32; 95% CI: 0.12–0.86) reduced this risk (Table III).

DISCUSSION

This investigation made it possible to determine the profile of indications for the prescription of anthelmintic drugs in a group of Colombian patients. It was shown that only a third of all prescriptions have a related diagnosis of intestinal parasitosis found in the clinical records, with less than 20% having a symptomatic relationship based on clinical suspicion of intestinal parasitosis. At the same time, regardless of the clinical condition of the patient, more than half of them received an anthelminthic under a justified prophylactic prescription. However, at least 1 out of 10 patients received treatment without any indication.

The highest proportion of patients corresponded to the pediatric population, a situation consistent with international and local reports of soil-transmitted helminth infections, which have a higher prevalence in children and adolescents (Jourdan et al., 2018; Gonzalez Quiroz et al., 2020). The prevalence of intestinal parasites and the geographic distribution found in this study show a higher proportion of anthelminthic use in coastal cities, especially on the Atlantic coast; this finding is similar to other epidemiological reports of infection by soil-transmitted helminths, which have reported an overall prevalence greater than 20% for this type of infection (MinSalud, 2015; Gonzalez Quiroz et al., 2020). The Colombian Amazon region has records of the prevalence of soil-transmitted helminths being above 50%; however, this region was not represented in a significant way in the present study.

Of the few stool tests reported in the medical records, only 1 was positive for helminth infection. This could indicate that anthelmintic drugs are being used empirically for the treatment of other types of parasitic diseases, such as protozoa, for which there is no indication or approval according to the scientific literature. On the other hand, for patients living in areas with a high prevalence of parasitosis, the use of anthelmintics can be considered mandatory, especially in children with or without clinical symptoms and, therefore, without the need for prior confirmatory paraclinical tests (Ochoa, 2019).

The prescriptions made by professional nurses were not appropriate according to the signs, symptoms, and clinical diagnosis. However, this practice might be accepted in prophylactic deworming programs (Ochoa, 2019). The prescription made by health personnel other than doctors is a previously discussed issue in the country, given the population's healthcare needs (Céspedes et al., 2010); however, they are not permitted in the national prescription standard (MinSalud, 2016).

The use of albendazole as the main anthelmintic therapy seems to be adequate considering its pharmacological properties, which allows it to be used in most types of helminth infection for a brief period (even in single doses), with an acceptable safety profile (Moser et al., 2017; Ochoa, 2019). However, we found different inappropriate prescription patterns for albendazole and pyrantel pamoate. The different prescribing patterns found for anthelmintic drugs may suggest heterogeneity in the basic pharmacology knowledge of healthcare professionals since there are no scientific or evidence-based recommendations for periodic treatment with anthelmintic drugs unless therapeutic failure has been proven (Jourdan et al., 2018). In this regard the WHO recommends the implementation of medical guidelines as key interventions to promote the rational use of medications, as well as the inclusion of problem-based pharmacotherapy training in undergraduate curricula, continuing in-service medical education as a licensure requirement, along with supervision, audit, and feedback from physicians (WHO, 2022).

Surprisingly, more than two-thirds of all patients received an anthelmintic drug despite not having an intestinal parasitosis diagnosis, although many of these patients are eligible for prophylactic deworming according to WHO guidelines (MinSalud, 2013; WHO, 2006). It should also be considered that not all gastrointestinal symptoms need to be treated with antiparasitic drugs. The indiscriminate and repetitive use of these drugs, which happens when a patient manifests the very first and slight symptom of diarrhea or appetite alteration, may also be considered inappropriate (Ochoa, 2019).

In the multivariate model, it was found that the use of an additional antiparasitic medication was unjustifiably associated

with less use of anthelmintics. This may be related to the higher proportion of symptoms in the subgroup of patients who received these drug combinations. On the other hand, the prescription of nutritional supplements was a related risk factor when used without indication. The inadequate consumption of nutritional supplements has been previously described (Machado-Duque et al., 2020).

The present work has certain limitations. First, the sample was calculated from the total dispensations of drugs at the national level by a single company in charge of dispensing them, but no stratification was carried out by geographical region, which may vary in their local prevalence of parasitosis. Because of its retrospective observational design, some variables of clinical interest and follow-up were not available. It is also possible that the healthcare professionals found signs or symptoms suggestive of parasitosis but failed to report them in clinical records, despite prescribing anthelmintic drugs. New studies that allow measurement and monitoring of the prevalence of various parasites according to geographical, age, and socioeconomic distribution and the adequacy of deworming schemes are required to promote the rational use of anthelmintic drugs, avoiding unjustified exposure, the possible risks of adverse reactions, cost overruns, and helminth resistance that could eventually arise.

CONCLUSIONS

Anthelmintic drugs have been used in a considerable proportion of people without clear indication and even in patients without symptoms. Their use may be explained as prophylactic deworming, but clear medical indications or diagnoses are not recorded in the clinical records. Additionally, multiple doses and combinations of anthelmintic drugs were found, which have not been recommended in the medical literature. All of this may indicate a problem of indiscriminate prescription of this group of drugs.

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