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ORIGINAL ARTICLE

Opioid use disorders national registries and opioids sales registries: A 10-year prevalence study from a middle-income country

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ABSTRACT

Objectives: (1) To estimate the prevalence, geographic distribution, and demographic characteristics of patients diagnosed with mental and behavioral disorders due to the use of opioids in Colombia, between 2009 and 2018. (2) To describe the opioid sales trends in Colombia over the last few years.

Methods: We conducted an observational study analyzing information from Individual National Registry of Health Services and the Colombian official database for pharmaceuticals prices and quantities sold. The included ICD-10 codes were mental and behavioral disorders due to the use of opioids (F11) codes subdivisions.

Results: 12,557 cases of mental and behavioral disorders due to opioid use were reported, with a rate of 3.0 per 100,000 inhabitants for the studied period. Men represented 74.2 percent, with a male:female ratio of 2.9:1. The highest prevalence was found between 20 and 24 years, in the northwest Colombian area. A progressive increase in the total number of opioid units sold during the study period was found, and the most frequently sold opioids were tramadol (55 percent) and codeine (20 percent).

Conclusions: Recognition of opioid use disorders has increased in the last 10 years; it affects more males than females, mostly young adults, and is higher in certain affluent regions of Colombia. We found a progressive annual increase in the sales of opioids in the country, which could be related to the increase in the rate of registries. Studies that have analyzed opioid abuse in Latin America are limited, and further studies are needed to evaluate this situation in middle-income countries from the region.

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INTRODUCTION

Millions of people around the world experience conditions that lead to chronic pain and many of them receive prescription opioids.¹ However, in addition to analgesia, some effects associated with opioids such as feelings of well-being, relaxation, and satisfaction can lead to disorders due to dependence on these drugs.^{2,3} Opioid use disorders (OUDs) are a group of chronic recurrent disorders

that cause significant clinical and functional impairment. Alarmingly, rates of OUDs and deaths from opioid overdoses have reached unprecedented levels in the last two decades, a problem that has been widely recognized in the United States, but should be considered as a global public health concern. In 2016, around 26.8 million people were living with OUDs globally, with more than 100,000 deaths annually attributable to opioid overdoses, including more than 47,000 deaths in the United States in

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2017. Since that year, the United States has experienced an opioid epidemic, characterized not only by high mortality but also by high rates of disability and hospitalizations due to overdoses.^{3,7,8} Information regarding access and availability of opioids is still limited in Latin America. 9 Available studies have mainly focused on individual countries and specific conditions or diseases that cause chronic pain. 10-16 The countries with the lowest reported opioid consumption in the region include Guatemala, Ecuador, and Bolivia.¹⁷ While countries such as Chile, Argentina, Colombia, Brazil, and Uruguay have reported an increase in the consumption of daily doses of opioids during recent years.¹⁷ In Colombia, some data on the prevalence of exposure to opioids without a prescription estimate that around 1 percent of the population has used some opioid without a prescription at least once in their life.¹⁸ Nevertheless, the current opioid use, incidence, and demographic characteristics of patients with OUD are unknown. Therefore, the present work seeks to establish the prevalence of OUD in Colombia, to describe the demographic characteristics of patients with these disorders based on annual data from the official administrative clinical records of the Ministry of Health between 2009 and 2018, and to describe the opioid sales trends in Colombia.

METHODS

In Colombia, the Individual Health Services Delivery Registry (RIPS) groups demographic and clinical data were recorded by medical personnel during any medical contact. This database is subject to continuous quality assessment performed by the Colombian Ministry of Health and groups information from the private and public health services that are provided in the country. To calculate the prevalence, we used information from the National Individual Registry of Health Services (RIPS), which included all mental and behavioral disorders due to use of opioids (F11) codes subdivisions from the International Classification of Diseases, 10th edition (ICD-10). We analyzed data belonging to a decade (from 2009 to 2018). Data corresponding to department, sex, and age groups were analyzed. For prevalence calculations as well as for demographic information, we consulted the projections made by the National Administrative Department of Statistics (DANE). Prevalence per 100,000 individuals was calculated using a numerator of any person

diagnosed with OUD. The denominator was the number of inhabitants reported by DANE in each year, age group, sex, or geographical area.

We used the database from the Drug Price Information System (SISMED) to obtain the information about the numbers of units sold of each opioid drug (buprenorphine, codeine, dihydrocodeine, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodone, tapentadol, and tramadol), including any route of administration and combinations of opioids with other drugs. For each drug, we estimated the total number of units sold in any of the commercial channels: commercial channels sales (laboratory and wholesaler), institutional channel sales (laboratory and wholesaler), purchases, EPS-IPS-DTS-CCF sales, and recovery. We used data from 2012 to 2018 because there is no information recorded in the SISMED's database before this period.

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RESULTS

Between 2009 and 2018, a total of 12,557 patients (4,119 women and 8,438 men) who were treated in Colombia with any of the diagnoses including mental and behavioral disorders due to the use of opioids (F11 codes) were included in this study, resulting a mean rate of 3.9 per 100,000 inhabitants in this period (Figure 1). The highest prevalence was estimated for the 2018 year. The age group with the highest prevalence was 20-24 years (Figure 2). In the analysis by departments, the regions with the highest rates per 100,000 inhabitants were as follows: Quindío (50.4), Risaralda (19.6), and Antioquia (6.6). When evaluating the distribution of disorders according to sex, 74.2 percent of the cases occurred in men, with a male:female ratio of 2.9 men for each woman.

Regarding opioids sales, between 2012 and 2018, a total of 660,203,089 units were sold in Colombia (Table 1); tramadol was the most frequently sold opioid (55 percent of the total), followed by codeine (20 percent), dihydrocodeine (8 percent), and methadone (6 percent). We found an increasing trend in the opioids sales for the period of study (Figure 3). We reported a peak in the units of tramadol sold in 2017, increasing 4.3 times as compared to 2016 report; this alarming trend did not continue in 2018.

DISCUSSION

This work on the prevalence of OUD in Colombia from official national statistics suggests a consistent

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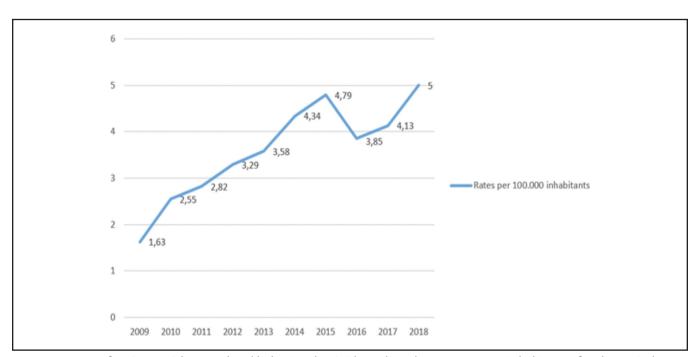


Figure 1. Rates of patients with mental and behavioral opioid use disorders per 100,000 inhabitants, for the period 2009-2018.

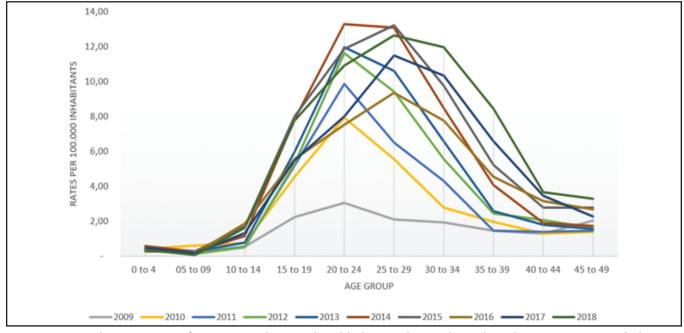


Figure 2. Rates by age group of patients with mental and behavioral opioid use disorders per 100,000 inhabitants, between 2009 and 2018.

increase in the prevalence of patients with OUD consulting healthcare services in the last 10 years in Colombia. This study adds evidence on a public health concern that had not been characterized in Colombia, adding significant evidence to the scarce literature on the OUD in Latin America. Despite a

rising concern of health authorities about drug abuse and recent evidence warning about the risk of an opioid epidemic in the coming years in regions such as Latin America, robust evidence in the region is still lacking. ^{19,20} This research also adds new evidence on the opioids sales, which is considered as

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| Table 1. Opioid units sales, 2012-2018 | | | | | | | | |
|--|------------|------------|------------|------------|------------|-------------|-------------|-------------|
| | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2012-2018 |
| Buprenorphine | 68,255 | 104,670 | 209,964 | 405,030 | 509,566 | 605,903 | 743,080 | 2,646,468 |
| Codeine | 5,221,647 | 11,067,785 | 16,126,672 | 30,856,704 | 21,317,196 | 20,439,571 | 27,692,076 | 132,721,650 |
| Dihydrocodeine | 8,851,432 | 8,135,448 | 3,925,339 | 9,464,602 | 8,119,157 | 6,040,445 | 6,148,122 | 50,684,544 |
| Hydrocodone | - | - | - | - | - | - | - | - |
| Hydromorphone | 98,479 | 347,940 | 1,070,309 | 3,614,550 | 4,821,135 | 4,766,630 | 5,859,453 | 20,578,496 |
| Meperidine | 61,441 | 203,912 | 696,993 | 643,399 | 959,671 | 1,493,204 | 2,231,610 | 6,290,230 |
| Methadone | 225,665 | 997,118 | 3,573,344 | 5,765,393 | 6,157,809 | 8,972,763 | 10,807,800 | 36,499,891 |
| Morphine | 241,080 | 821,770 | 2,057,990 | 168,170 | 4,388,148 | 5,675,067 | 7,008,163 | 20,360,386 |
| Oxycodone | 638,479 | 842,302 | 1,939,310 | 2,272,371 | 4,131,181 | 3,855,962 | 5,927,755 | 19,607,359 |
| Tapentadol | - | - | 147,632 | 584,332 | 1,637,925 | 2,383,766 | 3,070,277 | 7,823,931 |
| Tramadol | 32,024,744 | 35,727,873 | 25,071,942 | 35,618,061 | 36,447,133 | 157,016,186 | 41,084,194 | 362,990,133 |
| Total | 47,431,222 | 58,248,816 | 54,819,495 | 89,392,611 | 88,488,920 | 211,249,498 | 110,572,528 | 660,203,089 |

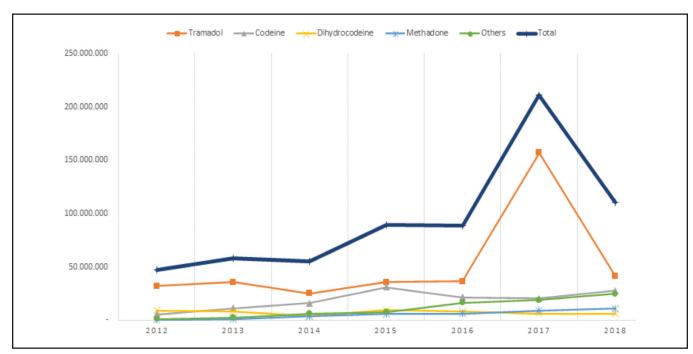


Figure 3. Trends of opioids unit sales, 2012-2018.

one of the most important risk factors for OUD and for overdose deaths. 1

Intriguing, the highest prevalent departments correspond to the Colombian coffee triangle, which has relatively high reports of illegal psychoactive substances consumption¹⁸ and also share environmental similarities that might explain this situation.

In high-income countries where the OUD and opioid prescription have been extensively described such as the United States, it is estimated that about

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21-29 percent of patients with prescribed opioids for chronic pain misuse them, and 4-6 percent of them will transition to heroin at some point. ²¹⁻²³ In Canada, the prevalence of prescription opioid use within the previous 12 months was estimated to be 16 percent in 2015, and by 2017, approximately one-third of those who had used an opioid did not always have a prescription. ²⁴ Nevertheless, in Colombian registries, we do not have information regarding the diagnosis of patients who bought opioid medications neither whether these medications were prescribed by a physician or sold over the counter.

The main limitations of this study are the underreporting and possible errors when entering the ICD-10 code. Furthermore, it is not possible to ensure that all patients with OUD would consult medical services, which might account for underreporting. Despite these limitations, this study shows an increase in OUD in the last 10 years in Colombia, particularly in certain regions of the country and population groups whose characteristics have been described as risk factors for OUD.¹ Some of these risk factors include, but are not limited to, young age, male sex, and geographical location in regions with high illegal psychoactive substances consumption.¹

Regarding opioids sales, we reported a progressive annual increase, which could be related to the increase in the rate of patients diagnosed with OUD. This aspect needs special vigilance as well as health policies targeting access to opioids, prevention, and long-term approaches to opioids misuse. In Colombia, a recent cohort study conducted in 24 cities reported a high rate of opioids use for pain management, in many cases for more than 12 months. Authors in this study highlight the importance of continuous monitoring for improving safety and minimizing the risk of dependency on these drugs.²⁵ Finally, it must be acknowledged that opioid availability may vary in different regions of the country, especially in populations other than large urban centers where per capita consumption of opioid drugs is low.²⁶

CONCLUSION

This study describes demographic and epidemiological data on mental and behavioral disorders due to the inadequate use of opiates in Colombia, taking into account national official databases. This study

reports a low prevalence of OUD, similar to other countries in the Latin America Region. Nevertheless, in recent years, there has been an alarming increase in the number of diagnoses related to these disorders, mostly affecting males in the age group of 20-30 years. These results provide data for a better understanding of OUD in Latin America and open new research opportunities to broaden the knowledge of OUD in middle-income countries, such as Colombia. Finally, this study highlights the importance of having local, updated, and reliable epidemiological information regarding opioids sales in our countries, which allows to address efforts on the safe and effective use of opioids, all within a regulatory framework that recognizes both medical indications and health policies in the region.

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Ethical responsibilities: Protection of people and animals: The authors declare that the procedures followed were in accordance with the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki.

Confidentiality of the data: The authors declare that they have followed the protocols of their work center regarding the publication of patient data.

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