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ORIGINAL RESEARCH ARTICLE

Clinical Characteristics and Treatment of Irritable Bowel Syndrome in a Colombian Population: A Cross-Sectional Study

Daniel Andrés Hernández-Velásquez[1,2] · Esteban Rodríguez-Martínez[1,2] · Jhonathan David Montoya-Meneses[1,2] · Juan Sebastián González-Ceballos[1,2] · Katherin Mosquera-Pérez[1,2] · Laura Patiño-Mazuera[1,2] · Melissa González-Montoya[1,2] · Andrés Gaviria-Mendoza[1,2] · Jorge Enrique Machado-Alba[1]

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Abstract

Background Irritable bowel syndrome (IBS) is a functional disorder that leads to abdominal pain; its diagnosis is based on Rome IV criteria (recurrent abdominal pain at least 1 day per week in the last 3 months with more than two of the following: related to defecation, associated with a change in stool frequency and/or with a change in stool appearance).

Objective To characterize an outpatient population diagnosed with IBS in Colombia during 2017–2018.

Methods A cross-sectional study based on a review of clinical records of patients with a primary diagnosis of IBS. A representative sample of 380 individuals was recruited from a population of 38,182 people with a new diagnosis of IBS from a drug-claim database. Sociodemographic, clinical (symptoms, type of IBS, alarm features, etc.), treatment (pharmacological or not), and follow-up variables (for those with additional medical care at 3–12 months) were analyzed. The diagnosis and treatment used in the consultation were compared with clinical guidelines.

Results Most of the 380 patients were women ($n = 238$; 62.6%), and the mean age was 40.1 ± 15.0 years. None of the physicians recorded the Rome IV criteria in the medical records. Unclassified IBS was the most prevalent subtype ($n = 311$; 81.8%), and the main symptom was abdominal pain ($n = 327$; 86.1%). Only 73 patients (19.2%) had follow-up data. The most frequently used drugs were aluminum hydroxide ($n = 203$; 53.4%) and hyoscine *N*-butyl bromide ($n = 200$; 52.6%). Regarding drugs included in the clinical practice guidelines, 19 people received loperamide (5.0%), 3 received trimebutine (0.8%), and 1 received sertraline (0.3%).

Conclusions The patients were diagnosed without clearly established criteria, and they were treated symptomatically with little follow-up.

Key Points

Most patients diagnosed with IBS were unclassified and lacked clear diagnostic criteria.

The majority of drugs prescribed were to treat symptoms and are not supported by evidence.

A low proportion of patients had follow-up consultations during the next 3–12 months after initial IBS diagnosis.

✉ Jorge Enrique Machado-Alba
machado@utp.edu.co

[1] Grupo de Investigación en Farmacoepidemiología y Farmacovigilancia, Universidad Tecnológica de Pereira-Audifarma S.A, Calle 105 No. 14-140, 660003 Pereira, Risaralda, Colombia

[2] Grupo de Investigación Biomedicina, Facultad de Medicina, Fundación Universitaria Autónoma de las Américas, Pereira, Colombia

1 Introduction

Irritable bowel syndrome (IBS) is a functional bowel disorder in which abdominal pain is associated with changes in the frequency and consistency of defecation. It is assumed that there is no structural alteration that causes the symptoms [1]. IBS can be classified as IBS with predominant constipation, IBS with predominant diarrhea, IBS with mixed bowel habits, and unclassified IBS [2].

IBS is a disease with an estimated worldwide prevalence ranging from 10.0% to 20.0% [3, 4]. Literature on IBS in Colombia is scarce; however, a study conducted in Bogotá found a prevalence of 24.0% with a predominance of IBS with constipation (41.9%), followed by unclassified IBS (25.1%) [5].

Currently, the diagnosis of IBS is based on the Rome IV criteria, which have been revised over the years since 1999 [6]. According to the Rome IV criteria, recurrent abdominal pain (as a predominant symptom) must be present at least 1 day per week on average in the last 3 months, in addition to two or more of the following criteria: pain related to defecation, with a change in the frequency of feces and/or with a change in the appearance of feces [7]. In some patients with alarm features (warning signs or "red flag" symptoms that may indicate an underlying organic cause), initial complementary studies should be performed before making the diagnosis of IBS [6].

The therapeutic approach is based on the IBS subtype and predominant symptoms [6], and can be nonpharmacological or pharmacological [8]. Nonpharmacological treatment is focused on lifestyle and dietary changes [for example, a low fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP) diet], while pharmacological treatment is aimed at managing different symptoms, such as abdominal pain, constipation, diarrhea, and abdominal distension [6, 8].

Considering the limited knowledge about the pathology of IBS and the therapeutic approach for patients with IBS at the local level, this study sought to determine the clinical characteristics and treatment of IBS among a random sample of Colombian patients in the primary care setting during the years 2017 and 2018.

2 Materials and Methods

A descriptive cross-sectional study was conducted. The patients were identified from a population in a drug-claim database, belonging to Audifarma SA, the largest drug dispensing company in the country, which has information on more than 8.5 million Colombians. In this database, 38,182 patients, aged 18 years and older, from one health insurer (which provides access to individual medical records) who presented a diagnosis of IBS for the first time were identified. The diagnoses were recognized by codes of the International Classification of Diseases, tenth edition (ICD-10: K580, K589), during the period from September 2017 to October 2018. Pregnant patients were excluded.

To review the details of the clinical records of each study patient, a simple random sample was calculated and selected using Epidat v4.2, with a confidence interval of 95% and an error of 5%, which resulted in 380 individuals. The information was directly reviewed in the medical records (clinical data were not available in a structured database).

The following data were collected and measured from the included patients at the time of first diagnosis of IBS.

(a) Sociodemographic: age, sex, education and origin.

(b) Clinical symptoms (e.g., abdominal pain, bloating, diarrhea, constipation, nausea, flatus, etc.), alarm features (age over 50 years, gastrointestinal bleeding, unintentional weight loss, family history of inflammatory bowel disease or colorectal cancer, palpable abdominal mass or lymphadenopathy, severe nonfluctuating symptoms, anemia, and refractory diarrhea) [6], type of diagnosis (IBS with constipation, IBS with diarrhea, or mixed IBS and unclassified IBS). Additional diagnostic procedures (e.g., fecal occult blood test, stool tests, hemograms, colonoscopies, endoscopies, etc.) were also recorded. The IBS assessment should be made routinely using only the clinical diagnostic criteria; however, some patients may be eligible to undergo additional diagnostic procedures, especially those with alarm features to evaluate organic causes.

Regarding the type of IBS, we included those recorded by the treating physician (diagnosis codes) but also reclassified them using the symptoms described in the clinical records.

(c) Comorbidities (e.g., arterial hypertension, type 2 diabetes mellitus, dyspepsia, hypothyroidism, dyslipidemia, etc., as well as the sum of comorbidities).

(d) Treatment (nonpharmacological, such as low FODMAP diet or general recommendation of dietary changes [9]; pharmacological). The pharmacological treatment of IBS was reviewed, which is usually divided by clinical practice guidelines according to symptomatology or type of IBS: pain (peppermint oil, otilonium bromide, pinaverium bromide, trimebutine, mebeverine, tricyclic antidepressants, selective serotonin reuptake inhibitors), abdominal distension (rifaximin, pinaverium bromide), IBS with diarrhea (rifaximin, ondansetron, alosetron, cilansetron, ramosetron, tricyclic antidepressants, loperamide), and IBS with constipation (polyethylene glycol, bisacodyl, lubipristone, psyllium, linaclotide, sodium picosulfate) [6]. Medications prescribed by the doctor for the treatment of IBS that were not specifically described in the Colombian clinical practice

guidelines (which are in line with international recommendations) were also identified [6], as well as the associated comedications. The duration of pharmacotherapy was not assessed.

The follow-up consultations of those patients who had additional medical care within 3 to 12 months after the initial diagnosis of IBS were also reviewed to analyze their symptoms, type of IBS, and number of attentions.

Clinical history software was used to review the previously mentioned characteristics of the study population. The data were validated, and any inconsistency was adjusted by at least two researchers to guarantee their reliability. Access to the clinical records application was provided by the health insurer. SPSS v26.0 was used for statistical analysis.

This research was classified according to resolution 8430/93 of the Ministry of Health of Colombia as a risk-free study and was endorsed by the Bioethics Committee of the Universidad Tecnológica de Pereira and the research ethics committee of the insurer. The data of the patients were handled confidentially, and it was not necessary to apply individual informed consent.

3 Results

A total of 238 of the 380 patients were female (62.6%). The average age was 40.1 ± 15.0 years. The age group of 31–49 years (162 patients; 42.6%) was the most frequent. Regarding the regions, more than half of the sample came from the Andean region. Most of the patients presented with a secondary educational level. Table 1 presents the other sociodemographic variables.

The predominant type of IBS reported by the physician was unclassified IBS (81.8%), followed by IBS with diarrhea. Unclassified IBS was slightly more common in women. IBS with diarrhea was more frequent in men. The most common symptoms were abdominal pain, bloating, and diarrhea (see Table 2). None of the physicians explicitly recorded or mentioned the Rome IV criteria in the medical records.

The most common comorbidity was arterial hypertension (14.2%), followed by dyslipidemia and dyspepsia. Similarly, the most common comedications were angiotensin II receptor antagonists, antidiabetics, and lipid-lowering drugs.

The diagnostic procedures performed were fecal occult blood test ($n = 21$, 5.5% of patients) and stool test ($n = 21$, 5.5%), and for 83 cases (21.9%), various other procedures were performed. Only one patient had a record of a colonoscopy (0.3%). A total of 123 patients (32.4%) presented alarm features; the most common were age over 50 years, rectal bleeding, and anemia. Table 2 presents the clinical variables of the people included in the sample.

The treatment received by the patients was based mainly on aluminum hydroxide, hyoscine *N*-butyl bromide, and

Table 1 Sociodemographic variables of a group of patients from Colombia diagnosed with irritable bowel syndrome (IBS)

Variable	Frequency ($n = 380$)	%
Sex		
Female	238	62.6
Male	142	37.4
Age at time of consultation		
18–30 years	124	32.6
31–49 years	162	42.6
≥ 50 years	94	24.7
Region		
Andean	215	56.6
Caribbean	156	41.1
Orinoquía	9	2.4
Education level		
High school	157	41.3
Technical	70	18.4
Primary	49	12.9
University	35	9.2
Not specified	69	18.2
Comorbidities		
Arterial hypertension	54	14.2
Dyslipidemia	41	10.8
Dyspepsia	40	10.5
Migraine	32	8.4
Smoking	28	7.4
Diabetes mellitus type 2	24	6.3
Asthma	18	4.7
Hypothyroidism	15	3.9
Overweight, obesity	12	3.2
Hemorrhoids	10	2.6
Liver diseases	10	2.6
Other comorbidities	71	18.8
Sum of comorbidities		
One	108	28.4
Two	43	11.3
Three or more	44	11.6
Comedications		
Antihypertensives	53	13.9
Oral antidiabetics	24	6.3
Lipid-lowering drugs	23	6.1
Contraceptives	17	4.5
Proton pump inhibitors	16	4.2
Levothyroxine	15	3.9
Psychopharmaceuticals	14	3.7
Analgesics	8	2.1
Respiratory therapy (inhaled drugs)	8	2.1
Nutritional Supplements	7	1.8
Simethicone	3	0.8
Others	7	1.8

Table 2 Clinical characteristics of a group of patients from Colombia with a diagnosis of irritable bowel syndrome, according to sex

Variables	Total Frequency ($n = 380$) (%)	Female Frequency ($n = 238$) (%)	Male Frequency ($n = 142$) (%)
Type of IBS described by the doctor			
Predominant diarrhea	64 (16.8)	37 (15.5)	27 (19.0)
Predominant constipation	4 (1.1)	3 (1.2)	1 (0.7)
Mixed bowel habits	1 (0.3)	0 (0.0)	1 (0.7)
Unclassified	311 (81.8)	198 (83.2)	113 (79.6)
Type of IBS according to clinical data			
Predominant diarrhea	102 (26.8)	55 (23.1)	47 (33.1)
Predominant constipation	61 (16.1)	46 (19.3)	15 (10.6)
Mixed bowel habits	26 (6.8)	17 (7.1)	9 (6.3)
Unclassified	191 (50.3)	120 (50.4)	71 (50.0)
Symptoms			
Abdominal pain	327 (86.1)	206 (86.6)	121 (85.2)
Distension	189 (49.7)	118 (49.6)	71 (50.0)
Diarrhea	129 (33.9)	72 (30.3)	57 (40.1)
Flatus	101 (26.6)	56 (23.5)	45 (31.7)
Constipation	88 (23.2)	63 (26.5)	25 (17.6)
Nausea	61 (16.1)	37 (15.5)	24 (16.9)
Dyspepsia	30 (7.9)	17 (7.1)	13 (9.2)
Vomit	28 (7.4)	16 (6.7)	12 (8.5)
Belching	15 (3.9)	10 (4.2)	5 (3.5)
Other symptoms	15 (3.9)	7 (2.9)	8 (5.6)
Headache	14 (3.7)	8 (3.4)	6 (4.2)
Reflux	10 (2.6)	8 (3.4)	2 (1.4)
Tenesmus	8 (2.1)	4 (1.7)	4 (2.8)
Alarm features			
Age >50 years	95 (25.0)	65 (27.3)	30 (21.1)
Rectal bleeding	25 (6.6)	15 (6.3)	10 (7.0)
Anemia	10 (2.6)	10 (4.2)	0 (0.0)
Colon cancer family history	6 (1.6)	6 (2.5)	0 (0.0)
Weight loss	5 (1.3)	4 (1.7)	1 (0.7)
Abdominal mass	2 (0.5)	2 (0.8)	0 (0.0)
IBD Family history*	2 (0.5)	0 (0.0)	2 (1.4)
Nocturnal symptoms	1 (0.3)	0 (0.0)	1 (0.7)
Refractory diarrhea	1 (0.3)	0 (0.0)	1 (0.7)
Sum of alarm features			
0	257 (67.6)	153 (64.3)	104 (73.2)
1	102 (26.8)	71 (29.8)	31 (21.8)
2	18 (4.7)	11 (4.6)	7 (4.9)
3	3 (0.8)	3 (1.3)	0 (0.0)
*Number of follow-ups***			
0	303 (79.7)	191 (80.3)	112 (78.9)
1	56 (14.7)	34 (14.3)	25 (17.6)
2	13 (3.4)	12 (5.0)	2 (1.4)
≥ 3	4 (1.1)	1 (0.4)	3 (2.1)

* IBD: Inflammatory bowel disease. ** Number of IBS follow-up consultations from 3 to 12 months after the initial consultation at the time of the study

recommendations for dietary changes. Of the medications indicated by the clinical practice guidelines, they only received loperamide, bisacodyl, trimebutine, and sertraline. The calculated mean dose of hyoscine *N*-butyl bromide was 30 mg/day, while omeprazole was the most used in the proton pump inhibitors group at an average dose of 20 mg/day. Of note, 52 patients (13.7%) received mesalazine and 25.0% were prescribed an antiparasitic agent (especially those with IBS with predominant diarrhea). Table 3 presents the different therapies found, as well as their distribution of use according to the type of IBS.

Only 73 patients (19.2%) had follow-up consultations for their disease within the following 3 to 12 months after diagnosis, including 44 women (60.3%) and 29 men (39.7%), mainly between 31 and 49 years of age. During follow-up, the most frequently described symptoms were abdominal pain (55 patients; 75.3%), abdominal distension (29 patients; 39.7%), flatus (20 patients; 27.4%) and diarrhea (19 patients; 26.0%).

The follow-up consultations showed that the most common subtype of IBS was unclassified IBS ($n = 57$, 78.1% of those with follow-up), followed by IBS with diarrhea ($n = 14$, 19.2%).

Table 3 Treatment and diagnostic procedures used in relation to the type of irritable bowel syndrome of a group of patients from Colombia

Variables	Total ($n = 380$)	Type of IBS according to clinical data			
		With predominant diarrhea ($n = 102$)	With predominant constipation ($n = 61$)	With mixed bowel habits ($n = 26$)	Unclassified ($n = 191$)
Pharmacological treatment—n (%)					
Aluminum hydroxide	203 (53.4)	57 (55.9)	32 (52.5)	10 (38.5)	104 (54.5)
Hyoscine *N*-butyl bromide	200 (52.6)	58 (56.9)	23 (37.7)	10 (38.5)	109 (57.1)
Proton pump inhibitors	112 (29.5)	29 (28.4)	21 (34.4)	8 (30.8)	54 (28.3)
Antiparasitic agents	95 (25.0)	33 (32.4)	13 (21.3)	6 (23.1)	43 (22.5)
Mesalazine	52 (13.7)	13 (12.7)	8 (13.1)	4 (15.4)	27 (14.1)
Ranitidine	42 (11.1)	17 (16.7)	3 (4.9)	1 (3.8)	21 (11.0)
Acetaminophen	41 (10.8)	21 (20.6)	5 (8.2)	2 (7.7)	13 (6.8)
Bisacodyl*	31 (8.2)	0 (0.0)	26 (42.6)	1 (3.8)	4 (2.1)
Metoclopramide	29 (7.6)	10 (9.8)	4 (6.6)	3 (11.5)	12 (6.3)
Loperamide*	19 (5.0)	18 (17.6)	0 (0.0)	0 (0.0)	1 (0.5)
Sucralfate	17 (4.5)	3 (2.9)	4 (6.6)	1 (3.8)	9 (4.7)
Naproxen	8 (2.1)	4 (3.9)	1 (1.6)	0 (0.0)	3 (1.6)
Trimebutine*	3 (0.8)	1 (1.0)	0 (0.0)	2 (7.7)	0 (0.0)
Diclofenac	3 (0.8)	1 (1.0)	1 (1.6)	0 (0.0)	1 (0.5)
Sertraline*	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)
Ibuprofen	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)
Other medications**	128 (33.7)	26 (25.5)	11 (18.0)	5 (19.2)	35 (18.3)
Non-pharmacological treatment—n (%)					
Recommendation of dietary changes	190 (50.0)	47 (46.1)	35 (57.4)	14 (53.8)	94 (49.2)
Low FODMAP diet	7 (1.8)	0 (0.0)	0 (0.0)	2 (7.7)	5 (2.6)
Diagnostic procedures—n (%)					
Fecal occult blood test	21 (5.5)	7 (6.9)	5 (8.2)	2 (7.7)	7 (3.7)
Stool test	21 (5.5)	12 (11.8)	3 (4.9)	2 (7.7)	4 (2.1)
Complete blood count	13 (3.4)	5 (4.9)	2 (3.3)	0 (0.0)	6 (3.1)
Abdominal ultrasound	10 (2.6)	2 (2.0)	1 (1.6)	3 (11.5)	4 (2.1)
Barium enema	4 (1.1)	2 (2.0)	1 (1.6)	1 (3.8)	0 (0.0)
Colonoscopy	1 (0.3)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Endoscopy	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)
Other procedures	54 (14.2)	21 (20.6)	11 (18.0)	5 (19.2)	17 (8.9)

Low FODMAP diet. *Drugs recommended in clinical practice guidelines. **Other medications: rehydration salts, sulfasalazine, thiamin, tramadol, fluoxetine, dexamethasone

4 Discussion

The present study describes the clinical and treatment characteristics of IBS in a group of Colombian patients. It was found that IBS occurs more frequently in women, consistent with findings from previous studies [10–13]. The average age of the people included in this study is also close to that reported in other studies [10–12].

The research found that the most common subtype was unclassified IBS. In contrast, other studies report that the most common subtypes were IBS with predominant constipation, mixed bowel habits IBS, or IBS with predominant diarrhea [5, 10, 12]. In addition, one previous study recorded differences by sex and found a greater prevalence of mixed IBS among women and a greater prevalence of IBS with diarrhea among men [12]. The higher prevalence of unclassified IBS found herein may be due to the lack of application of the Rome criteria in these patients, thus it may generate erroneous diagnoses, in which symptoms are nonspecific and can be easily attributed to another disease.

The results of this research differ from the literature regarding alarm features, since it was found that the main feature was age over 50 years, while in another report, the most common was nocturnal symptoms [14]. It is worth mentioning that, for this variable, the published information is scarce, and there are no recent studies that focus directly on this topic, so the distribution of the frequency of alarm features could change over the years and should be examined in future studies.

The predominant symptom was abdominal pain, followed by distension and diarrhea, similar to the findings of Hungin et al. in the USA [15]. It is common for patients to present to healthcare institutions mainly due to the discomfort generated by the pain and the discomfort that accompanies abdominal distension, while other symptoms such as constipation require less consultation with the physician.

It was found that the most commonly prescribed treatment was aluminum hydroxide, followed by the antispasmodic hyoscine *N*-butyl bromide and dietary changes. In a study that reviewed the treatments used and their satisfaction in the USA, antispasmodics were the most commonly used drugs to treat IBS with diarrhea, a result comparable to this study, while polyethylene glycol, lubiprostone, and linaclotide were used to treat IBS with constipation. The most recommended nonpharmacological management was the use of probiotics, followed by dietary changes [16]. Regarding aluminum hydroxide, no information was found to support its formulation as a first-line therapy for IBS. Regarding the use of hyoscine *N*-butyl bromide in IBS, the evidence is limited, and although its usefulness has been shown in some studies [17, 18], it is still low compared with other antispasmodic medications [19]. Other treatments proposed, such as rifaximin or probiotics, were not identified in the patients included in this study [20]. A high proportion of patients also received antiparasitic agents or mesalazine, which is indicated only for inflammatory bowel disease, raising further concerns about the appropriateness of the treatments and diagnoses made in these group of patients that consult with gastrointestinal symptomatology.

Contrary to what the literature dictates, it was observed that diagnostic procedures are formulated for patients who consult for IBS, a practice that, apart from generating a monetary cost to the user, does not support the diagnosis of the disease, since it has been demonstrated in several studies that the diagnosis of IBS is mainly clinical and that any other action aimed at confirming its presence, including colonoscopy, stool studies, and hematological studies, among others, has low efficacy [14, 21–23]. However, it must be considered that the treating physician may request these diagnostic aids to rule out other pathologies that are generating the clinical manifestations.

Among the limitations of this analysis is its observational nature and the extraction of information from clinical records and not directly from patients, so it is possible that some variables of interest for follow-up were not evaluated, for example, if patients were referred or not to consultation by a specialist in gastroenterology or if they had a change in the diagnosis of irritable bowel over time. We had to use a random sample of patients because we did not have access to the clinical information of the entire population. Furthermore, the patients selected were from only one healthcare insurer, limiting the generalizability of the results to the entire population. The information regarding drugs different from those prescribed by the physician was not available (e.g., use of over-the-counter medications, such as probiotics).

On the other hand, it presented relevant strengths. The data was reviewed directly in clinical records and allowed to analyze symptoms and diagnostic approach. It includes drug patterns as well as other useful information, i.e., alarm features, use of diagnostic procedures or number of follow-ups after the initial diagnosis, making this manuscript an important descriptive evidence regarding IBS symptoms and treatment in Colombia.

5 Conclusions

These findings suggest that the majority of patients with IBS are women, individuals with few comorbidities, who present to medical consult mainly for pain, abdominal distension, and diarrhea, but who were diagnosed without clearly established criteria. Their symptoms are often treated with

antacids and antispasmodics. Finally, they had little follow-up of the disease, which opens the possibility for new studies that investigate the possible long-term clinical outcomes of these patients.

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Author Contributions A.G.M.: drafting of the manuscript, data collection, data analysis, description of results, and discussion; D.A.H.V.: drafting of the manuscript, statistical analysis; E.R.M.: description of results and discussion of the article; J.D.M.M.: description of results and discussion of the article; J.S.G.C.: description of results and discussion of the article; K.M.P.; description of results and discussion of the article; L.P.M.: description of results and discussion of the article; M.G.M.: description of results and discussion of the article; J.E.M.A.: drafting of the manuscript, critical revision of the manuscript for important intellectual content, and study supervision. All authors read and approved the final version.

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Availability of data and material (name of repository) Protocolos.io.

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Declarations

Conflict of interest The authors declare no conflicts of interest.

Ethics Approval The protocol was approved by the Bioethics Committee of the Universidad Tecnologica de Pereira in the risk-free research category. The ethical principles established by the Declaration of Helsinki were respected. Patient personal data were not considered.

Consent to Participate No applicable, is a retrospective observational study.

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