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Clinical Performance of Mosapride and Esomeprazole in Patients Diagnosed with Gastroesophageal Reflux. Study of Real-Life Cohort in Primary Care

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ABSTRACT

Introduction: Gastroesophageal Reflux Disease (GERD) is the regurgitation or rise of gastric or duodenal contents beyond the gastroesophageal junction, and its prevalence ranges from 15% to 30%. It has been underdiagnosed due to lack of consultation with a health professional and due to self-medication. Interventions include pharmacological ones, such as prokinetics and Proton Pump Inhibitors (PPIs).

Objective: To compare the clinical performance in real life and the safety of mosapride and esomeprazole in treating patients diagnosed with GER from primary care clinics in 12 Colombian cities.

Methods: We conducted an analytical cohort study, including patients older than 18, diagnosed with GER, who started treatment with mosapride 5 mg, or 10 mg and esomeprazole 10 mg, 20 mg, or 40 mg. The clinical outcomes were symptoms such as heartburn, reflux, epigastric pain, hoarseness, nausea, and the number of episodes of any of the symptoms in the last month. Measures of association between mosapride and esomeprazole were estimated.

Results: A total of 298 patients were analyzed. The cohort exposed to mosapride contained 84 (28.2%), and the esomeprazole cohort 214 (71.8%). The most frequent symptoms were reflux 282 (94.6%), nausea 210 (70.4%), and dysphonia 203 (68.1%). A decrease in symptoms was evidenced in both medications, such as heartburn, reflux, epigastric pain, nausea, dysphonia and episodes of symptoms (for all cases $p<0.001$). Finding that mosapride only had a better performance in improving epigastric pain (RR: 0.4 95% CI 0.2-0.7). Adherence to medical control, 270 (90.6%). No serious or non-serious adverse events were recorded.

Conclusion: This study made it possible to determine the clinical effectiveness of mosapride and esomeprazole in real-life conditions, impacting the improvement of symptoms before and after their use. The use of these drugs did not show serious or non-serious adverse events, and their adherence to medical control was higher than 80%.

Keywords: Gastroesophageal reflux; Heartburn; Abdominal pain; Digestive signs and symptoms; Proton pump inhibitors

Introduction

Gastroesophageal Reflux Disease (GERD) is the regurgitation or rise of gastric or duodenal contents past the gastroesophageal junction [1]. It is divided according to the Montreal classification into esophageal and extraesophageal syndromes, and the symptoms are usually characterized by heartburn, chest pain, epigastric pain, cough, dysphonia, dental alterations, and sleep disorders, among others [2-4]. It is one of the five most frequent reasons for consultation in primary care. Its prevalence ranges from 15% to 30% in the United States and Europe, 40% exclusively for Mexico, and 15% to 20% in Latin America [5], where Colombia reports prevalences between 11% and 17%, which suggests that GERD is a frequent and progressive disease, that has been underdiagnosed due to the lack of consultation with a health professional and due to self-medication taking into account the over-the-counter sale medication for your treatment [2].

A study carried out in the United States was able to determine that the costs associated with GERD were estimated at approximately 9 billion $ a value that requires detailed monitoring from the first levels of care to reduce costs in the context of prevention and good management of the illness [6]. Risk factors such as Lower Esophageal Sphincter (LES) relaxation, hiatal hernia, delayed gastric emptying; abnormal esophageal peristalsis, poor eating habits, obesity, psychological disorders, smoking, and alcohol intake have been identified [4].

Diagnosis is an eminently clinical endeavor where the presence of typical symptoms (heartburn and regurgitation) two or more times a week suggests starting treatment to avoid complications such as erosive disease and dysplasia that precede neoplastic pathologies. Among the interventions are non-pharmacological ones, such as changes in lifestyles and diet, and pharmacological management, which describes the use of drugs such as antacids, histamine antagonists, prokinetics, and Proton Pump Inhibitors (PPI).

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In the case of prokinetics, their impact on increasing the basal pressure of the LES has been described, generating a restriction of the passage of gastric contents into the esophagus, optimizing esophageal peristalsis, and hastening the clearance of esophageal acid. PPIs are characterized by inhibiting acid production without producing tolerance and have shown better effectiveness than anti-H2. Currently, PPIs differ by bioavailability, half-life, and percentage of protein binding. In these last two cases, monotherapy or combined management has shown improvement in esophageal contractility, including in patients with dyspepsia. However, the patient's characteristics must be considered [7]. These drugs are used more frequently due to their effectiveness in clinical practice and availability in the first levels of care [3]. In accordance with the above, the objective of this study was to compare the clinical effect and safety of esomeprazole with mosapride in the treatment of patients diagnosed with GERD, in the context of an observational study, under conditions of real-life clinical practice and who attended the consultation of a group of primary care physicians in 12 cities in Colombia.

Materials and Methods

Design and population

An analytical cohort study was carried out. The inclusion criteria were: Patients older than 18 years, with a diagnosis of gastroesophageal reflux, and who were candidates (without a pharmacological contraindication) to start treatment with mosapride and esomeprazole. Concomitantly with medical treatment, all patients received non-pharmacological indications such as changing eating habits, smoking, and alcoholic beverages. The included patients consulted their primary care physician in 12 Colombian cities. Patients who did not voluntarily accept the use of their personal data and clinical records were not considered.

Definition of cohorts

Two cohorts were structured according to the group of medications started (independent variables). The "exposed" cohort comprised patients who started treatment with 5 mg or 10 mg mosapride, and the "non-exposed" cohort comprised patients who started treatment with 10 mg, 20 mg, or 40 mg esomeprazole. The clinical outcomes or dependent variables were the presence of symptoms such as heartburn, reflux, epigastralgia, dysphonia, nausea, the number of episodes of any of the symptoms in the last month, and endoscopic findings in patients who underwent upper gastrointestinal endoscopy.

Information collection

Patients' information was collected through an electronic format available on the platform (web page) of the group responsible for data collection, which had remote access from any device within the framework of the Biomedical Registry of Clinical Outcomes (RBDC), prior authorization of the patient. This project was approved by an independent human research ethics committee (018-2015).

Statistical analysis

A descriptive analysis of the information was carried out. Absolute and relative frequencies were used for the qualitative variables, whereas measures of central tendency and dispersion according to the data distribution were used for the quantitative variables. For the contrast of hypotheses of the categorical variables, we used different statistical tests: Chi^2 (comparison of outcomes between drugs) and McNemar for related groups (comparison of outcomes before and after), and we used Wilcoxon for quantitative variables (Related Groups). For both cases, the cut-off point to consider statistical significance was a p-value less than 0.05.

The proportions of symptoms according to the medication were compared, and enrollment was defined as the record of a patient who had been evaluated by the primary care physician for the first time, meeting selection criteria; In the same way, it was defined as control, when the patient attended the second appointment to evaluate the symptoms presented in the follow-up. Adherence to medical follow-up was determined as attendance at the follow-up for the same reason as the first consultation, evaluating the consumption of the prescription referred by the patient, and with the same doctor who initially evaluated and started the pharmacological treatment according to the physical examination and clinical judgment of the treating physician.

The relative risk with their respective 95% confidence intervals was estimated, comparing the incidence of patients who reported improvement in both cohorts, defined as the number of patients who did not report symptoms in the follow-up appointment compared to the enrollment.

Results

We analyzed 298 patients with a median age of 47 years with an interquartile range (IQR) between 33-58 years. The mosapride cohort comprised 84 (28.2%) patients, and the esomeprazole cohort of 214 (71.8%). The follow-up of the patients who attended the control ranged from 22 to 63 days after the baseline assessment or start of follow-up. Of the 298 patients, 270 attended their follow-up with the same doctor for a 90.6% adherence. The rest of the baseline characteristics of the population are described in Table 1.

Sex n (%)	Mosapride (n=84)	Esomeprazole (n=214)	Total (n=298)
Female	47 (55.9)	122 (57)	169 (56.7)
Male	37 (44.1)	92 (43.0)	129 (43.3)
Age-years			
Under 30	7 (8.3)	48 (22.4)	55 (18.4)
Between 31 and 50	28 (33.3)	90 (43)	118 (39.6)
Between 51 and 70	38 (45.2)	58 (27.1)	96 (32.2)
Over 71	11 (13.1)	18 (8.4)	29 (9.7)
Med-IQR*	54 (43-64)	44 (32-56)	47 (33-58)
Symptomatology ‡			
Heartburn	54 (64.3)	104 (48.6)	158 (53)
Reflux	82 (97.6)	200 (93.4)	282 (94.6)
Epigastralgia	15 (17.9)	54 (25.2)	69 (23.1)
Nausea	52 (61.9)	158 (73.8)	210 (70.4)
Dysphonia	54 (64.3)	149 (69.6)	203 (68.1)
Symptom concomitance			
One	5 (6)	14 (6.5)	19 (6.4)
Two	22 (26.2)	63 (29.4)	85 (28.5)
Three	28 (33.3)	51 (23.8)	79 (26.5)
Four	23 (27.4)	59 (27.6)	82 (27.5)
Five	6 (7.1)	27 (12.6)	33 (11.1)

Note: ‡ Patients may have one or more symptoms at the time of evaluation, * Median-Interquartile range

Table 1: Baseline population characteristics

Adherence to follow-up for the control of symptoms, according to the drug, showed that for the mosapride group, 76/84 (90.4%) patients attended their follow-up appointment, while for the esomeprazole group, it was 193/214 (90.1%).

Clinical performance

The symptomatology of both groups of drugs (enrolment vs. follow-up) was compared to determine the association between them. In the

same way, the frequencies of the episodes of all the symptoms found were calculated. The detail of the proportions of improvement by medication is presented in Table 2.

	Mosapride (n=76)			Esomeprazole (n=193)		
Symptoms	**Enrollment**	**Follow-up**	**p Value †**	**Enrollment**	**Follow-up**	**p Value †**
Heartburn	50 (58.1)	12 (14)	<0,001	83 (43)	27 (14)	<0,001
Reflux	73 (84.9)	35 (40.7)	<0,001	176 (91.2)	93 (48.2)	<0,001
Epigastralgia	18 (20.9)	7 (8.1)	0.02	37 (192)	3 (1.6)	<0,001
Nausea	51 (59.3)	19 (22.1)	<0,001	138 (71.5)	68 (35.2)	<0,001
Dysphonia	49 (57)	10 (11.6)	<0,001	131 (67.9)	66 (34.2)	<0,001
Note: Statistical test: † McNemar.						

Table 2: Improvement of symptoms between enrollment and control, according to the medication started

Likewise, the incidence of improvement was determined according to the number of symptoms for each cohort, presented in Table 3.

	Mosapride (n=77)	Esomeprazole (n=194)	Relative risk	CI 95%	p-value †
Symptoms					
Heartburn	40/54	77/104	1.0	0.8-1.2	0.9
Reflux	37/82	107/200	0.8	0.6-1.1	0.2
Epigastralgia	6/15	51/54	0.4	0.2-0.7	<0,000 *
Nausea	28/52	90/158	0.9	0.7-1.2	0.6
Dysphonia	40/54	83/149	1.3	1.1-1.6	0.01
Note: † Chi^2 test, *Fisher test					

Table 3: Estimation of relative risks of severity according to drug cohorts

EVDA findings

Of the total number of patients included, due to medical criteria, according to the symptoms, clinical findings, or history, 98 (32.2%) underwent upper digestive tract endoscopy (EVDA) before starting medical treatment to determine concomitant diagnoses, finding positive findings in all cases such as gastroesophageal reflux, acute gastritis, chronic gastritis, esophagitis, presence of H.pylori and hiatal hernia. Likewise, it was possible to show that 31 (32.3%) patients had one finding, 52 (54.1%) 2 findings, and 13 (13.5%) 3 findings.

Serious adverse events

Serious and non-serious adverse events were not reported in any of the cohorts, and treatment discontinuation due to an adverse event was not documented in any case.

Discussion

GERD is considered a physiological process; however, it becomes a pathology when the physiological anti-GER mechanisms are decompensated. These mechanisms are classified as anti-reflux barriers (LES tone, competence of the phreno-esophageal ligament and diaphragmatic sphincter), esophageal clearance (adequate esophageal peristalsis and salivary excretion), and esophageal mucosal resistance (presence of bicarbonate ions in the esophageal mucosa, intercellular junction, and mucous flow) [8]. Additionally, there are aggressor processes that increase the probability of GERD, among which are increased pepsin secretion, duodenal reflux, and poor eating habits, such as the intake of alcoholic beverages, excessive consumption of acidic foods and behaviors post-feeding. This pathophysiology supports the use of drugs such as proton pump inhibitors and prokinetics since they strengthen the physiological anti-reflux mechanisms both in esophageal clearance and in the production of hydrochloric acid [9,10].

These conditions generate the presence of signs and symptoms, both gastric and extra-gastric. In this study, the presence of reflux sensation was found in 97.5%, representing the most frequent clinical condition and characteristics of GERD, which was similar in other studies, where the percentage of presentation varied between 85 and 95% [7]. Heartburn was reported in 53%, similar to that described by Herregods et al., with 49.2%. [11]. When comparing the clinical effectiveness in the two groups (esomeprazole versus mosapride) regarding the improvement of symptoms such as the sensation of reflux, heartburn, and nausea, no statistically significant differences were observed (reflux p=0.2; heartburn p=0.9; nausea p=0.6). It was evidenced that there was a 60% reduction in epigastric pain in patients treated with mosapride (RR: 0.4 95% CI 0.2-0.7), which could suggest that regardless of the treatment, pharmacological management is an alternative to improve GERD symptoms, obviously associated with changing eating habits and reducing risk factors. These results, when contrasted with the previously reported results where the use of esomeprazole+mosapride was compared versus only esomeprazole, showed similar results as there were no differences at the time of reporting response to treatment (p=0.67) between the two groups [7,12].

The presence of these symptoms permanently impacts the patient's quality of life considerably, not only because of their presence, but also because of the modification of their diet to which they are forced to improve the symptoms by not receiving medication or not consulting a doctor, since it has been described that the foods that are consumed independently to improve symptoms do not have the necessary nutritional requirements, achieving in extreme cases the progressive loss of weight and the presence of pathologies related to malnutrition. Thus, the medical approach with the start of pharmacological treatment must be linked to a diet modification that involves complete foods from the nutritional point of view and adjusting risk factors such as alcohol intake and smoking, among others [13,14].

When contrasting the presence of dysphonia as part of the extra-gastric symptoms, this study reported 68%, which is not far from that reported by other works (55%). However, a Peruvian study reported a prevalence of 10%, which is noteworthy and could be understood as a possible under diagnosis since the relationship between ENT pathologies versus GER is clear (p=0.01); This shows that combined management is an adequate therapeutic alternative to avoid complications such as dysphonia and respiratory pathologies such as pneumonia or bronchial pathology [15].

Cho showed improvement in overall symptoms by 74%; however, in his study, he compared the combination of mosapride and esomeprazole versus esomeprazole alone. When contrasted with this study, these results are far from clinical effectiveness since, in both groups, the average improvement was 51%. Even though the clinical effectiveness was good in both studies, it is important to consider Cho's results, where the sample size was smaller. Clearly, the percentage of symptom improvement was higher when combining the inhibitors, which is probably the best alternative since mosapride is suggested to be used in the company of a proton pump inhibitor [7,16].

Medications such as mosapride and proton pump inhibitors to control GER symptoms improve the patient's quality of life and reduce the risks of complications, such as extra-gastrointestinal impacts, and the probability of progressing to neoplastic disease. The modification of lifestyles in the management of GER makes it possible to optimize medical interventions, which would increase the effectiveness of the treatment; however, a patient who reduces the risk factors for GER also reduces the risks of suffering from other diseases that They are related to both bad eating habits and exposure to toxic substances such as tobacco and alcohol [17].

Real-life follow-up studies where the clinical performance of medical interventions is evaluated under the usual conditions of a health professional are relevant to know the adherence and use that are prescribed in primary care daily and that at the same time are available in pharmacies without a doctor's order [18].

Conclusion

In conclusion, this study made it possible to determine the clinical effectiveness of mosapride and esomeprazole in real-life conditions, impacting the improvement of symptoms before and after their use. The use of these drugs did not show serious and non-serious adverse events, and their adherence to treatment was higher than 80%, suggesting adequate tolerability of these drugs and their impact on quality of life.

Limitations

It is important to mention that this is an observational study, meaning it does not intend to control the variables since it is considered a real-life study. We believe that there may be confounding variables that may affect the outcomes in the groups, which were not considered in the registry questionnaire.

Conflict of Interest

This study was sponsored by Abbott, which was not involved in the construction of this manuscript.

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Authors' Contribution

Carlos Alberto Castro, Conception, data collection information analysis, article writing, final revision. Guillermo Sánchez-Vanegas, Conception, article writing, final revision. Diana Buitrago-García, Conception, article writing, final revision.

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