INTERNATIONAL JOURNAL OF
PHARMACEUTICAL AND HEALTHCARE INNOVATION
journal homepage: www.ijphi.com

Review Article

OPEN ACCESS

Revisiting Functional Dyspepsia Therapy: The Role of Itopride Hydrochloride

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Article Info

Article history:

Manuscript ID:

IJPHI1102170207032026
Received: 11-FEB-2026
Revised : 17-FEB-2026
Accepted: 07- MAR -2026
Available online:
MAR -2026
DOI: 10.62752/ijphi.v3i2.238

Keywords:
Itopride hydrochloride, functional dyspepsia, gastric motility, prokinetic medication, and gastric emptying.

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0009-0003-0171-5809

Abstract

Functional dyspepsia and gastroesophageal reflux disease (GERD) are common and often distressing gastrointestinal disorders that significantly affect patients' quality of life and daily productivity. Among the available therapeutic options, itopride hydrochloride has emerged as a promising prokinetic agent because of its unique dual mechanism of action: dopamine D_2 receptor antagonism and acetylcholinesterase inhibition, which enhances gastrointestinal motility and accelerates gastric emptying. This review revisits the pharmacological profile, pharmacokinetics, clinical efficacy, safety, and cost-effectiveness of itopride in the management of functional dyspepsia, GERD, and related motility disorders. Evidence from clinical trials, including comparative studies with proton pump inhibitors and other prokinetics, highlights its effectiveness in improving symptoms such as bloating, early satiety, nausea, epigastric pain, and postprandial distress, with a favorable tolerability profile and minimal cardiac or central nervous system adverse effects. Additionally, pharmacoeconomic analyses suggest that itopride is a cost-effective treatment option in certain healthcare settings. Overall, itopride hydrochloride offers a balanced combination of efficacy, safety, and economic value, making it a valuable therapeutic choice in the management of upper gastrointestinal motility disorders. In addition to other benzamides, itopride increases colonic peristalsis and propels luminal contents, which may assist in the management of functional bowel problems.

1. Introduction:

Functional dyspepsia is a common digestive illness characterized by persistent discomfort and pain in the upper abdomen[1,2]. It is classified as a functional gastrointestinal illness, which implies that there is no obvious structural or metabolic defect to explain the symptoms; common symptoms include early satiety (feeling full after a small meal), nausea, and upper abdominal discomfort. It is unclear what causes functional dyspepsia, however it could be a combination of variables such as irregular gastric motility, increased stomach sensitivity, or stress[3,4,5]. It is frequently identified after other illnesses have been ruled out, and therapy is usually centered on symptom management by dietary changes, drugs (such as antacids or prokinetics), and lifestyle adjustments[6,7,8]. Gastroesophageal reflux disease (GERD) is a chronic digestive ailment in which stomach bile irritates the esophageal lining this happens when the lower esophageal sphincter (LES), a muscle that ordinarily keeps acid from leaking backward into the esophagus, weakens or relaxes abnormally as a result, acid reflux develops, causing symptoms like heartburn, regurgitation, chest pain, difficulty swallowing, and a sour taste in the mouth[9, 10,11]. Obesity, pregnancy, smoking, alcohol consumption, and certain medications are among the leading causes of GERD. Large meals, reclining down after eating, ingesting acidic, spicy foods can all induce and worsen it as well untreated GERD can eventually lead to consequences such as esophagitis, esophageal strictures, and an increased risk of esophageal cancer[12,13,14].

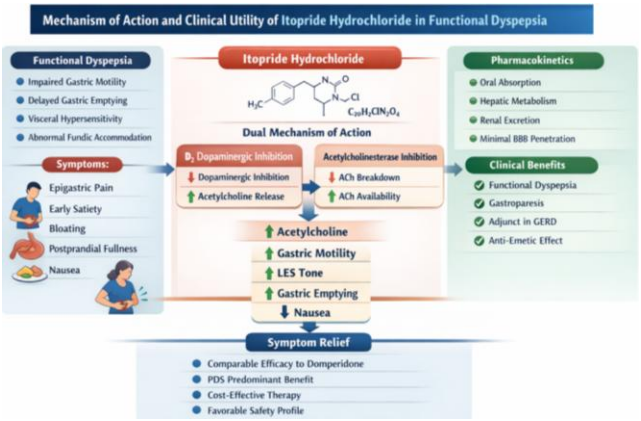

Fig 1. Mechanism of Action & Clinical Utility of Itopride Hcl in Functional dyspepsia

Itopride hydrochloride is a gastrointestinal prokinetic and motility activator that preferentially improves acetylcholine absorption while blocking dopamine D2 receptor antagonists and inhibiting acetylcholinesterase, making it useful in the treatment of gastrointestinal disorders[15]. Increased acetylcholine levels enhance gastro-duodenal harmony by increasing gastrointestinal peristalsis, expanding the minor esophageal sphincter pressure, stimulating gastric motility, and hastening gastric drainage[16]. Itopride hydrochloride (Ito.HCl) is a hydrochloride of N-p-[2(dimethylamino)ethoxy] benzylveratramide, a replaced benzamide with antiemetic and prokinetic properties[17], its empirical formula is $C_{20}H_{27}ClN_2O_4$ with molecular weight 394.9 and the structure is shown in Fig. 2.

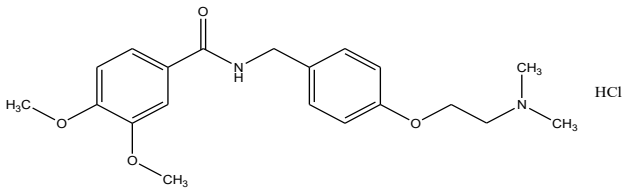

Fig 2. *N*-(4-(2-(dimethylamino)ethoxy)benzyl)-3,4-dimthoxybenzamide hydrochloride

Itopride, a recently developed prokinetic medication, is used to treat the symptoms of gastrointestinal disorders, such as persistent indigestion, gastroesophageal reflux disease, and non-ulcer dyspepsia. Itopride hydrochloride has a special dual-type mode of action, which reduces the activity of acetylcholinesterase (AchE) and blocks the dopamine-2 (D2) receptor by inhibiting the release of acetylcholine and gastrointestinal stimulant with a distinct mode of action than other medications, offering a novel option for treating the abnormalities of gastrointestinal motility[18,19].

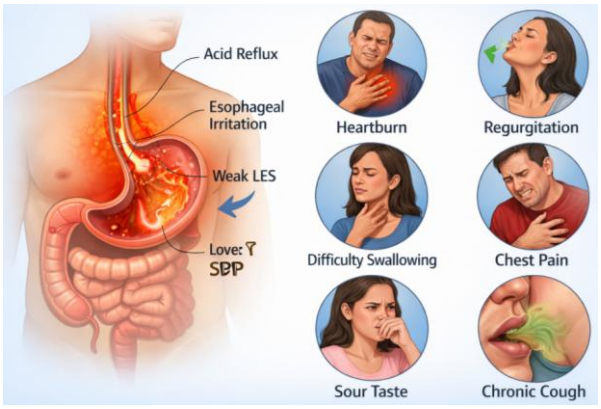

Fig 3. Symptoms of GERD

Various research methods, such as spectrophotometry, TLC, liquid chromatography with ultraviolet detection, fluorescence detection, electrochemical methods, tandem-mass spectrometry, chemiluminescence detection, and ion-selective electrodes, have been documented for itopride in therapeutic fluids, such as human plasma, to improve stomach motility, accelerate gastric emptying, and decrease gastric reflux; prokinetic

medications help alleviate symptoms. Various medications are available, such as domperidone, cisapride, and metoclopramide, which are common effective GERD therapies; but they show resistance; therefore, there is a need for new medications for effectiveness[20,21].

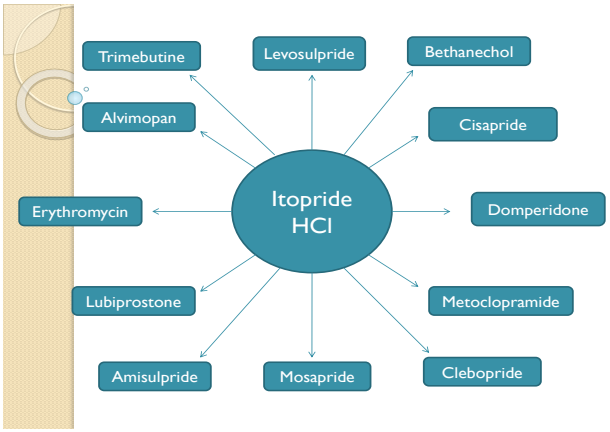

Fig 4. Drugs homogeneous to Itopride hydrochloride

2. Pharmacological activity of itopride hydrochloride

a. Prokinetic Action: Prokinetic action refers to the ability of certain medications to enhance the motility of the gastrointestinal (GI) tract, thereby improving the movement of food and waste through the digestive system, prokinetic agents work by stimulating the muscles of the GI tract, enhancing the coordinated contractions[22,23]. Itopride increases the motility of the gastrointestinal system this leads to faster gastric emptying, improved peristalsis, and alleviation of symptoms such as bloating, nausea, and discomfort commonly associated with gastrointestinal disorders[24,21].

b. Anti-emetic Effect: The anti-emetic effect refers to the ability of certain substances to alleviate nausea and vomiting this effect is particularly beneficial in medical scenarios such as chemotherapy, where nausea is a common side effect, or in the treatment of motion sickness. Anti-emetic drugs work by blocking specific receptors in the brain, such as serotonin or dopamine receptors, which are involved in the vomiting reflex[25,26]. Itopride may also have an anti-emetic (anti-nausea) effect, due to its action on the central nervous system (CNS) via D2 receptor antagonism these effects makes it useful in the treatment of nausea and vomiting related to gastrointestinal dysmotility[27,28].

c. Improved Gastric Emptying: Improved gastric emptying refers to the enhanced rate at which the stomach contents are passed into the small intestine this is a physiological process crucial for efficient digestion and absorption of nutrients there are many factors contributing to improved gastric emptying include dietary modifications, physical activity, and the management of underlying conditions like diabetes or gastroparesis[29,30]. Itopride can enhance gastric emptying, because it is prokinetics which useful for patients who experience delayed gastric emptying (gastroparesis), a common feature in conditions like functional dyspepsia and other digestive issues[31].

3. Pharmacokinetic properties of Itopride:

a. This process can occur through various mechanisms, including passive diffusion, assisted diffusion, active transport, and endocytosis. This process can occur through many methods, including as passive diffusion, assisted diffusion, active transport, and endocytosis. Depending on the chemical qualities of the drug and the physiology of the absorption site, factors such as the drug's solubility, pH, and the presence of food in the gastrointestinal tract can all have a substantial impact on absorption rates. Oral drugs must pass via the stomach and intestines, where they may undergo first-pass metabolism in the liver before entering the bloodstream[32].

b. Distribution: Itopride is transported from the bloodstream to numerous tissues and organs, and its distribution is affected by a number of factors, including blood flow to tissues, capillary membrane permeability, the drug's lipophilicity, and binding affinity to plasma proteins. Drugs are often delivered faster to organs with high blood flow, such as the liver and kidneys, than to tissues with low perfusion rates, such as muscles and fat. Itopride is broadly distributed in bodily tissues, but it does not pass through the blood-brain barrier[18].

c. Metabolism: Itopride metabolism in the body takes place predominantly in the liver, where cytochrome P450 play an important role in turning medicines into metabolites. This process is divided into two stages: Phase I and Phase II reactions[33].

d. Excretion: The excretion of Itopride metabolites is eliminated from the body, primarily through the kidneys via urine the renal excretion involves filtration, re-absorption, and secretion within the nephrons, other pathways include biliary excretion through feces, and minor routes such as sweat and saliva[34].

4. Clinical uses of itopride hydrochloride

a. Functional Dyspepsia: Functional dyspepsia (FD) is a common gastrointestinal disorder characterized by persistent or recurring upper abdominal discomfort and pain such as an ulcer.

b. Gastroesophageal Reflux Disease (GERD): Itopride can help improve gastric motility and prevent reflux in some patients.

c. Gastroparesis: A condition where the stomach takes too long to empty its contents[35,36].

5. Side effects and safety profile of itopride HCl:
a. Gastrointestinal issues such as diarrhea, abdominal cramps, bloating, or constipation.
b. Headache or dizziness, likely due to its central nervous system effects.

c. Fatigue or drowsiness, especially if the medication is administered at higher doses.

d. Extrapyramidal Symptoms (EPS): Though rare, there is a risk of movement disorders, such as tremors, rigidity, or tardive dyskinesia, because of its dopamine receptor antagonism. However, these side effects are less common than with other dopamine antagonists[37].

e. Caution should be exercised when combining itopride with other drugs, such as warfarin or certain anticonvulsants, as they may alter the pharmacokinetics of itopride38, 39. Caution should be taken when combining Itopride with other drugs, such as warfarin or certain anticonvulsants, as they may alter the pharmacokinetics of Itopride[38,39].

6. Caution to be taken:
a. Severe Liver or Kidney Impairment: Since Itopride is metabolized in the liver and excreted via the kidneys, patients with severe hepatic or renal impairment should use this drug with caution, as there may be an increased risk of toxicity.
b. Caution should be exercised when prescribing Itopride during breastfeeding, as it is unknown whether the drug is excreted in breast milk40, 41. Caution should be taken when prescribing Itopride during breastfeeding, as it is not known whether the drug is excreted in breast feeding[40,41].

7. Result and discussion:
A sub-analysis of the Nagoya multicenter randomized comparative trial assessed the therapeutic effects of the proton pump inhibitor rabeprazole versus the prokinetic agent itopride in patients with functional dyspepsia. In this study, 134 patients diagnosed according to the Rome III criteria were treated for 4 weeks with either rabeprazole (10 mg/day) or itopride (150 mg/day), and their dyspeptic symptoms were evaluated using standardized symptom scores. The results showed that rabeprazole led to a rapid and consistently greater reduction in overall dyspepsia scores compared with itopride at all assessment points (1, 2, and 4 weeks). Rabeprazole produced significant improvements in both major symptom subtypes, epigastric pain syndrome (EPS), and postprandial distress syndrome, whereas itopride benefits were primarily seen in patients with predominant PDS.34
In a study in which 40 patients with predominant bloating were assigned to receive either Itopride (50 mg three times daily) and Domperidone (10 mg three times daily), the symptoms were recorded using a 4-point Global Symptom Score, and patients were reassessed after 2 and 4 weeks, including a 5-point subjective relief scale. Both drugs provided significant symptomatic improvement; although domperidone showed slightly greater improvement in symptom scores at 4 weeks, there was no significant difference in overall subjective relief between the two groups. Although Itopride is safe, well tolerated, and demonstrated efficacy comparable to domperidone in the management of non-ulcer dyspepsia, 42 it supports its use as an effective alternative therapy.

Functional dyspepsia significantly impairs quality of life and productivity due to persistent abdominal pain and nausea. Itopride hydrochloride, a prokinetic agent that enhances gastric motility, has demonstrated effective symptom relief with good tolerability. A 10-year Markov model–based cost effectiveness analysis conducted from a Vietnamese societal perspective showed that itopride provided an additional 0.28 QALYs at an incremental cost of VND 11.2 million, resulting in an ICER of VND 39.7 million/QALY. This value is well below Vietnam's 1× GDP per capita threshold (VND 64.1 million), indicating that itopride is a highly cost-effective treatment option for functional dyspepsia in Vietnam, with robust results remaining in the sensitivity analyses[43].

8. Conclusion:
In conclusion, this review highlights that itopride hydrochloride remains a valuable and clinically relevant option in the management of functional dyspepsia and other gastrointestinal motility disorders. By combining dopamine D_2 receptor antagonism with acetylcholinesterase inhibition, itopride offers a dual mechanism that enhances gastric motility, accelerates gastric emptying, and relieves distressing symptoms, such as bloating, nausea, and upper abdominal discomfort. Evidence from comparative clinical studies, including the Nagoya Multicenter Randomized Comparative Trial, suggests that while proton pump inhibitors may provide faster relief in certain subtypes, itopride demonstrates meaningful benefits, particularly in postprandial distress syndrome, with good tolerability and a favorable safety profile. Additionally,

pharmacoeconomic findings indicate that itopride can be a cost-effective therapeutic option in appropriate healthcare. Overall, when prescribed judiciously and with consideration of patient-specific factors, itopride represents a balanced, effective, and well-tolerated strategy for improving symptom control and quality of life in patients with functional dyspepsia and related conditions.

Submission Declaration:
The authors confirm that the work is original and have read and approved the final manuscript for submission. The authors confirm that the work is original and have read and approved the final manuscript for submission.

Credit authorship contribution statement:
Dipali Tripathi: Conceptualization, Methodology, Investigation, Data curation, Writing- Original draft, Supervision; Arpita singh: Writing-reviewing and editing.

Conflict of Interest
The authors assert no competing interest interest.

Acknowledgements
I would like to express my deepest appreciation to Prof. Rahul Prem Kumar Mishra and Prof. Shobha Singh (Seth Vishambhar Nath Institute of Pharmacy Barabanki, Uttar Pradesh) to carry out my studies.

Funding
The authors declare that no financial support was received for this study.

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