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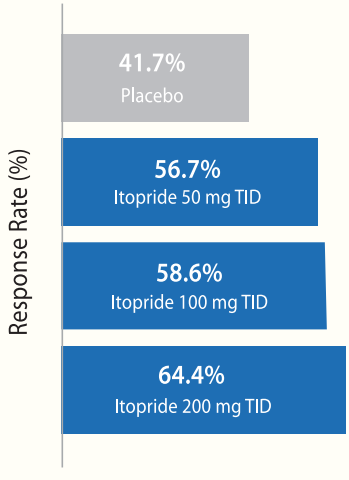
A Placebo-Controlled Trial of Itopride in Functional Dyspepsia

13

- Functional dyspepsia is a common gastrointestinal disorder characterized by chronic upper abdominal discomfort without identifiable structural disease. Current pharmacologic therapies provide only modest benefit and many patients remain symptomatic.
- Disturbances in gastric motility and sensory function play a central role in symptom generation. However, effective therapies targeting these mechanisms remain limited.
- Itopride, a dopamine D_2 receptor antagonist with acetylcholinesterase inhibitory activity, enhances gastric motility. This randomized trial evaluated its efficacy and safety in patients with functional dyspepsia.

Study Design	Population	Center	Duration	Intervention	Key Outcomes
Multicenter randomized double-blind placebo-controlled trial	**554** patients with functional dyspepsia	Germany	**8 weeks**	Itopride 50, 100, or 200 mg TID vs placebo for 8 weeks	Global symptom improvement significantly higher with itopride (57–64%) vs placebo (41%)

Global Symptom Response Rate in Functional Dyspepsia



Conclusion

- Itopride significantly improved global symptom relief in functional dyspepsia compared with placebo. Response rates increased progressively with higher doses.
- By enhancing gastric motility through dopamine antagonism and acetylcholinesterase inhibition, itopride addresses underlying dysmotility. This mechanistic approach contributes to meaningful symptom improvement.
- The incidence of adverse events was comparable between itopride and placebo groups. No clinically significant cardiac safety issues were observed.

Ref: Holtmann G, Talley NJ, Liebregts T, Adam B, Parow C. A placebo-controlled trial of itopride in functional dyspepsia. N Engl J Med. 2006;354(8):832–840.

Itopride hydrochloride
next generation, dual acting gastrointestinal prokinetic for fast & satisfactory relief from symptoms of gastric motility disorders

Itonorm®
Itopride hydrochloride 50 mg tablet

Dual Action. Fast Relief.

Drug Review

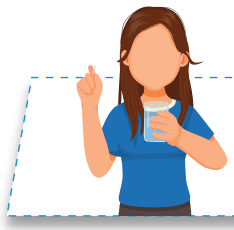
Gastric motility disorder[1,2,3,4]

- Gastrointestinal (GI) motility disorders encompass a wide array of signs and symptoms and functional dyspepsia (FD) and gastroparesis are the main associated syndromes.
- FD diagnosed based on the Rome IV criteria- The presence of one or more of the following symptoms: epigastric pain or burning, early satiety, and postprandial fullness in the absence of structural disease.
- Prokinetic agents are the mainstay therapy for FD and gastroparesis, to improve gastric emptying and relieve symptoms.
- Conventional prokinetics (e.g. domperidone, metoclopramide) only block dopamine D2 receptors (DD2R) but have no effect on acetylcholinesterase. Thereby, complete relief of functional dyspepsia symptoms can not be achieved.

Proven Safety and results[6,7,8,9,10]

- Itopride does no cross the BBB hence exerts no CNS effects (e.g. headache, nausea, dyskinesia). It does not cause hyperprolactinemia and has no impact on QT interval, as a result doesn't affect heart rate.
- The drug is metabolized by flavin-containing monooxygenase 3 (FMO3) pathway hence no drug-drug interactions with CYP450 inhibitors.
- Itopride is a relatively safer molecule compared with other prokinetics, with no extrapyramidal symptoms or cardiotoxicity concerns, can be used for long-term in GI motility disorders either alone or in combination with other drugs.
- Itopride has good efficacy in terms of global patients' assessment, postprandial fullness, and early satiety in the treatment of patients with FD and shows a low rate of adverse reactions.
- Significant improvement in glycemic indices was also evident posttreatment with itopride.Itopride showed effectiveness in addressing symptoms of reduced GI motility in patients with diabetes, with improved quality of life.
- Itopride 100 mg t.i.d is effective in decreasing pathologic reflux in patients with GERD and therefore it has the potential to be effective in the treatment of this disease.

Dosage, administration and recommendations of Itopride



Dosage & Administration

Itonorm® 50 mg tablet orally three times a day 30 mins before meals

Recommended by- BSG BRITISH SOCIETY OF GASTROENTEROLOGY | AMERICAN ACADEMY OF FAMILY PHYSICIANS STRONG MEDICINE FOR AMERICA | 一般財団法人 日本消化器病学会 The Japanese Society of Gastroenterology

Ref.: 1. Brian E. Lacy, Kirsten Weiser; Gastrointestinal Motility Disorders: An Update. Dig Dis 1 July 2006; 24 (3-4): 228–242..; 2. the treatment of dysmotility. EMJ Gastroenterol. 2014;3:42-7.; 3. Oshima T. Functional Dyspepsia: Current Understanding and Future Perspective. Digestion. 2024;105(1):26-33. .; 4. Camilleri M, Atieh J. New Developments in Prokinetic Therapy for Gastric Motility Disorders. Front Pharmacol. 2021 Aug 24;12:711500. ; 5-Dite, Petr & Rydlo, Martin & Dockal, Milan & Martinek, Arnost. (2014).; 6-7. Huang X, Lv B, Zhang S, Fan YH, Meng LN. Itopride therapy for functional dyspepsia: a meta-analysis. World J Gastroenterol. 2012 Dec 28;18(48):7371-7. .; 8-a new prokinetic, in patients with mild GERD: a pilot study. World J Gastroenterol. 2005 Jul 21;11(27):4210-4. ; 9. Rai RR, Choubal CC, Agarwal M, Khaliq AM, Farishta FJ, Harwani YP, Kumar SY. A Prospective Multicentric Postmarketing Observational Study to Characterize the Patient Population with Reduced Gastrointestinal Motility among Indian Diabetic Patients Receiving Itopride: The Progress Study. Int J Appl Basic Med Res. 2019 Jul-Sep;9(3):148-153. .; 10. Chaudhuri, S. (2023). Role and safety of prokinetic drugs in the treatment of upper gastrointestinal motility disorders: an Indian perspective. International Journal of Research in Medical Sciences, 11(10), 3937–3944.

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