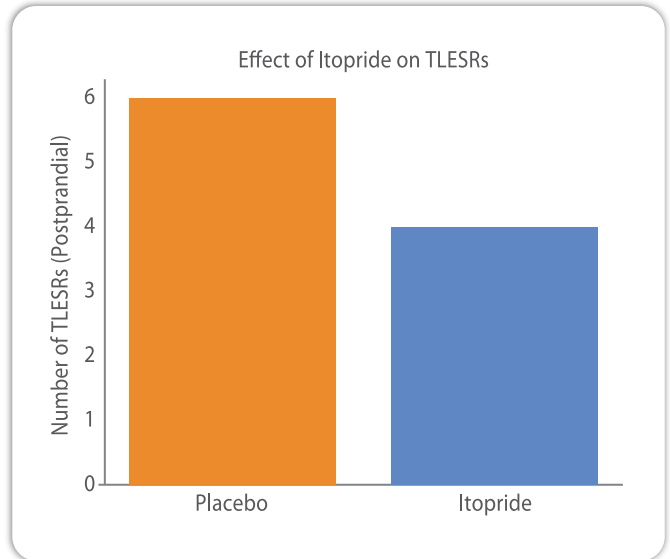


Effect of Itopride on esophageal motility and lower esophageal sphincter function in man

- Gastroesophageal reflux is largely driven by transient lower esophageal sphincter relaxations (TLESRs), a key mechanism compromising the anti-reflux barrier.
- Conventional therapies mainly reduce acid but do not adequately address underlying motility dysfunction, particularly TLESRs.
- This study evaluates whether itopride can modulate esophageal motility and reduce TLESRs, targeting a fundamental pathophysiological mechanism of reflux.



Study design: Randomized, crossover, placebo-controlled manometry study



Population

12 healthy volunteers



Center

Belgium



Intervention

Itopride 50 mg, 100 mg TID vs placebo (3-day pretreatment)



Key Outcome

Significant ($p = 0.04$) inhibition of meal-induced TLESRs without affecting LES pressure or peristalsis

Conclusion

- Itopride significantly inhibits transient LES relaxations, a key driver of reflux.
- It maintains normal esophageal motility and LES pressure, ensuring physiological safety.
- These findings support itopride as a mechanism-based therapeutic option in GERD management.

Ref: Scarpellini E, Vos R, Blondeau K, Boecxstaens V, Farré R, Gasbarrini A, Tack J. Effect of itopride on esophageal motility and lower esophageal sphincter function in man. *Aliment Pharmacol Ther.* 2010;33(1):99–107.

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Itopride hydrochloride

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

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Dual Action. Fast Relief.


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 not 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



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, Farišta 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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