

CLINICAL EFFICACY OF ITOPRIDE: A PROKINETIC AGENT WITH DUAL MODE OF ACTION AND POSITIVE SAFETY PROFILE FOR THE MANAGEMENT OF UPPER GASTROINTESTINAL DYSMOTILITY DISORDERS

Author	Study design	Sample size	Treatment arms	Result
Itopride in Functional Dyspepsia				
Chojnacki C <i>et al.</i> ³⁵	Open-label	52	Itopride	Itopride improved post-prandial distress syndrome and epigastric pain syndrome in 70.3% and 56.0% patients respectively.
Ganaton Post Marketing Surveillance study group ⁴⁴	Post marketing surveillance	2,108	Itopride	Global efficacy of itopride reported as excellent 49.64% patients, good in 39.24%, fair in 9.49% and poor in 1.63% patients
Holtmann G <i>et al.</i> ⁴⁶	RCT	554	Itopride vs. placebo	In patients with functional dyspepsia 50mg, 100mg, 200mg itopride and placebo yielded 57%, 59%, 64% and 41% patients' symptom free respectively. Itopride was reported to be significantly superior to placebo, with the greatest symptom-score improvement (p=0.05). Itopride yielded a greater response rate than placebo (73% vs. 63%, p=0.04)
Huang X <i>et al.</i> ⁴⁷	Meta analysis study	2,620	Itopride vs. domperidone	Itopride improved Postprandial fullness- RR:1.21 (95%CI:1.03-1.44, P=0.02) Early satiation- RR:1.24 (95%CI: 1.01-1.53, P=0.04) LDQ scores- WMD:-1.38 (95%CI: -1.75 to -1.01, P<0.01) Itopride had similar effect for epigastric discomfort-RR: 1.00 (95%CI: 0.88-1.14, P=0.98)
Sawant P <i>et al.</i> ⁴⁸	RCT	56	Itopride vs. domperidone	Complete symptomatic relief was observed in 81% patients in itopride group compared to 70% patients in domperidone group.
Otsubo T <i>et al.</i> ⁵⁰	-	11	Itopride	Itopride improved subjective symptoms by 72.7%.
Sun J <i>et al.</i> ⁵¹	Prospective observational study	587	Itopride	75.15% treatment response rate was observed after 4 weeks with Itopride. Difference in the total symptom score before and after treatment was -5.62±3.27 corresponding to a 69.23±26.53% reduction from baseline (p<0.001).
Saji S <i>et al.</i> ⁵²	Randomized double-blind placebo-controlled study	67	Itopride vs. placebo	Symptom score significantly decreased in itopride group compared to placebo (9.3 vs. 14.4, P=0.0004) Itopride showed significant improvement in global assessment relief compared to placebo (11 patients vs. 1 patient)
Kamath S <i>et al.</i> ⁵³	Single-blind randomized comparative study	60	Itopride vs. Metoclopramide	Itopride showed moderate to complete relief of symptoms in 100% patients treated with itopride and 53% patients treated with metoclopramide
Shenoy KT <i>et al.</i> ⁵⁴	Open-label non comparative study	30	Itopride	Itopride showed moderate to complete symptom relief in 73% patients at the end of 2 weeks.
Kumar RA <i>et al.</i> ⁵⁵	Open-label non comparative study	36	Itopride	Itopride showed moderate to complete symptom relief in 85% patients at the end of 2 weeks.
Amrapurkar DN <i>et al.</i> ⁵⁶	Double-blind randomized comparative study	60	Itopride vs. Mosapride	Itopride reported global efficacy rate in significantly more number of patients than mosapride group (93.3% vs. 63.33%, P<0.05)
Chiba T <i>et al.</i> ⁵⁷	HRQoL	-	Itopride	Itopride significantly improved the SF-36 mental health scale, GSRS indigestion syndrome score and constipation syndrome score (p < 0.05).
Itopride in diabetic gastroparesis				
Stevens JE <i>et al.</i> ⁵⁸	Double-blind randomized	25	Itopride vs. placebo	Itopride accelerated both solid (p=0.09) and liquid (p=0.09) gastric emptying. Emptying with placebo was slower (solids: r=0.39, p=0.057; liquids: r=0.44, p<0.03).
Venkatesh V <i>et al.</i> ⁵⁹	Open label clinical trial	743	Itopride with pantoprazole	Itopride in combination with pantoprazole indicated a significant improvement in the severity and frequency of all the symptom parameters of the disease (p<0.001)
Budennaya I Yu <i>et al.</i> ⁶³	Randomized prospective open-label comparative study	34	Itopride vs. control	Significant decrease in the amount of time needed for delayed gastric emptying: 89.0 min to 53.0 min Decrease in the symptoms of intestinal dyspepsia (p=0.005)
Shah MA <i>et al.</i> ⁶⁴	Comparative study	100	Itopride vs. placebo	Itopride showed a significant decrease in post prandial glucose level compared to placebo (222.40 mg/dl vs. 331.8 mg/dl)
Ganaton Post Marketing surveillance study group. ⁶⁵	Post marketing surveillance study	573	Itopride	Global efficacy of itopride as excellent (44.5%), good (40.14%), fair (13.61%), and poor (1.75%)

Brought to you by

Itonorm[®]
Itopride hydrochloride 50 mg tablet

For full Article



Author	Study design	Sample size	Treatment arms	Result
Adverse events reported under treatment with Itopride in functional dyspepsia				
Talley NJ <i>et al.</i> ⁷	RCT	1170	Itopride vs. placebo	The safety and tolerability profile were comparable with placebo, with the exception of prolactin elevations, which occurred more frequently on itopride (18/579) than placebo (1/591).
Chojnacki C <i>et al.</i> ³⁵	Open-label	52	Itopride	Itopride showed few adverse events such as diarrhea, dizziness, increased salivation and facial flushing No changes in ECG were recorded
Holtmann G <i>et al.</i> ⁴⁶	RCT	554	Itopride vs. placebo	Abdominal pain, diarrhea, nausea, and constipation were the most frequently reported events Serious adverse events during the treatment period were seen in 2.8 percent of the patients in the placebo group and 1.2 percent of patients in the overall active-treatment group. Prolactin levels significantly increased during treatment with 100 mg and 200 mg of itopride given three times daily. Treatment with itopride was not associated with any electrocardiographic changes; in particular, there was no prolongation of the corrected QT interval.
Ganaton Post Marketing Surveillance study group ⁴⁴	Post marketing surveillance	2,108	Itopride	Global tolerability reported as excellent in 65.09% patients, good in 33.90% patients, and poor in 1.01% patients Adverse events reported were diarrhea, dizziness, constipation and itching.
Huang X <i>et al.</i> ⁴⁷	Meta analysis study	2,620	Itopride vs. domperidone, mosapride, placebo	Itopride treatment was well tolerated, few adverse events reported in patients in Itopride group were abdominal pain, diarrhea, nausea and constipation.
Sawant P <i>et al.</i> ⁴⁸	RCT	56	Itopride vs. domperidone	Itopride did not cause prolongation of QT interval nor any abnormality in any serum biochemistry values.
Sun J <i>et al.</i> ⁵¹	Prospective observational study	587	Itopride	Nine patients (1.54%) had adverse events: four were probably related to the study drug (diarrhea [two cases], abdominal pain, drug eruption), three were possibly related (diarrhea [two cases], dizziness) and two were not related No adverse reactions were serious enough to warrant discontinuation of therapy.
Saji S <i>et al.</i> ⁵²	Randomized double-blind placebo-controlled study	67	Itopride vs. placebo	Itopride showed no prolongation of QT interval.
Kamath S <i>et al.</i> ⁵³	Single-blind randomized comparative study	60	Itopride vs. Metoclopramide	No adverse events reported in itopride treated group while one patient in metoclopramide reported moderate abdominal pain No abnormalities in serum chemistry or ECG observed
Shenoy KT <i>et al.</i> ⁵⁴	Open-label non comparative study	30	Itopride	Itopride exhibited excellent tolerability in 93% patients and good in 7% patients. No prolongation of QT on ECG observed No abnormality in haemogram or serum chemistry observed
Kumar RA <i>et al.</i> ⁵⁵	Open-label non comparative study	36	Itopride	Five patients reported adverse events such as headache, loose stool, giddiness, abdominal pain, and burning micturition. No prolongation of QT on ECG observed No abnormality in haemogram or serum chemistry observed
Amarapurkar DN <i>et al.</i> ⁵⁶	Double-blind randomized comparative study	60	Itopride vs. Mosapride	Tolerability of itopride versus mosapride reported as excellent 76.7% vs 26.7% (P<0.05) and poor in 0% vs. 20% None of the patients in itopride group reported any adverse events while five patients in mosapride group reported diarrhea, dry mouth fatigue, constipation, dizziness, and headache as adverse events.
Adverse events reported under Itopride treatment in diabetic gastroparesis				
Stevens JE <i>et al.</i> ⁵⁸	Double-blind randomized	25	Itopride vs. Placebo	No serious adverse events were reported.
Ganaton Post Marketing Surveillance study group ⁶⁵	Post marketing surveillance study	573	Itopride	Mild to moderate adverse events such as diarrhea, dizziness, abdominal pain, fatigue and insomnia and no severe adverse events reported. Global tolerability rated as excellent (62.65%), good (36.65%), and poor (0.7%).