La Renon

EIREF

Pantoprazole 40 mg & Itopride Hydrochloride 150 mg SR Capsules

CLINICAL EVIDENCE

A Placebo-Controlled Trial of Itopride in Functional Dyspepsia

N Engl J Med:354: 832-40; 2006

- BACKGROUND

The **efficacy of Itopride**, a dopamine D2 antagonist with acetyl cholinesterase effects was assessed in **patients with functional dyspepsia.**

- METHODS

Study has been done on randomly assigned 554 patients.
Patients with functional dyspepsia were randomly assigned to receive either Itopride (50 mg,100 mg, or 200 mg three times daily) or placebo.
After eight weeks of treatment, primary efficacy end points were analyzed.

- RESULTS

Following eight weeks, **41 % of the patients** receiving placebo were symptom-free or had marked improvement, as compared with **57 %, 59 %, & 64 %** receiving Itopride at a dose of 50 mg, 100 mg, or 200 mg three times daily, respectively.

Although the **symptom score improved significantly** in all four groups. An overall analysis revealed **that Itopride was significantly superior to placebo,** with the greatest symptom-score improvement in the 100 mg and 200 mg groups.

- CONCLUSIONS

Itopride significantly **improves symptoms in patients** with functional dyspepsia.

PPI IN DIABETES

PATIENT GROUP	PARAMETERS	
	FPG (mg/dl)	HBA1c (mmol/mol)
Control Group	147	7.4
PPI Treated Group	127	7.1

Acta Diabetol: 873-880: (52); 2015

- CONCLUSION

PPIs treatment is associated with greater glycemic control in patients with type 2 diabetes, particularly in those on insulin.

EIREF (PANTOPRAZOLE AND ITOPRIDE)

- As per study conducted on 743 patients of diabetic gastroparesis for a period of 3 weeks with the combination therapy of Pantoprazole and Itopride, it was found to be significant in improving the severity as well as the frequency of the diabetic gastroparesis disease.[1]

- Also, the major symptoms of gastroparesis such as nausea, vomiting, early satiety, bloating, postprandial fullness, epigastric pain and regurgitation were also reduced after the end of therapy.[1]

PANTOPRAZOLE IN EIREF

- The serum concentration of pantoprazole is not dose-dependent.[2]

- Patients taking pantoprazole 40 mg/day had a greater percentage of symptom-free days at 12 months compared to patients taking ranitidine 150 mg twice daily.[2]

- PEM (Prescription-event monitoring) study has defined the reported safety profile of pantoprazole as used in general practice.[2]

ITOPRIDE IN EIREF

- Approximately 50 percent greater improvement in symptom score than placebo.[3]

- Itopride significantly improved symptoms in patients with functional dyspepsia.[3]

- It works by dual action by antagonizing dopamine receptors and inhibiting the activity of acetyl cholinesterase.[4]

- Good efficacy in terms of global patients assessment, postprandial fullness, early satiety in the treatment of patients with FD.[4]

References :

1. Journal of the Indian Medical Association :106(12):814;2008
2. Clinical and Experimental Gastroenterology;(3):2010
3. N Engl J Med:354:832(40); 2006
4. World J Gastroenterol;2012

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INDICATION

- GERD
- NAB (Nocturnal acid breakthrough)
- Diabetic Gastroparesis
- Functional Dyspepsia
- Gastritis

PHARMACOLOGY

- **Pantoprazole** is a membrane permeable substituted benzimidazole derivative that decreases gastric acid secretion by irreversibly inhibiting the H+/K+-ATPase located within gastric parietal cells. It has high tissue selectivity for the canalicular lumen of the parietal cell, which has a pH of 1.

- Like other PPIs, it is a weakly basic prodrug that accumulates within this highly acidic environment and becomes rapidly activated into a cationic sulfonamide.

- The protonated form then covalently binds to specific cysteine residues on the H+/K+ ATPase enzyme, thus irreversibly inactivating the pump.

- **Itopride,** a novel Prokinetic agent, works by antagonizing dopamine D2-receptors and inhibiting acetylcholinesterase.

- It not only stimulates release of acetylcholine, but also inhibits its degradation, thus promoting gastrointestinal motility.

STORAGE

- Store at a temperature not exceeding 30° C. keep at cool and dry place.

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