



Drotachek

Drotaverine Hydrochloride 40 mg & 80 mg Tablets

la Renon

BACKGROUND:

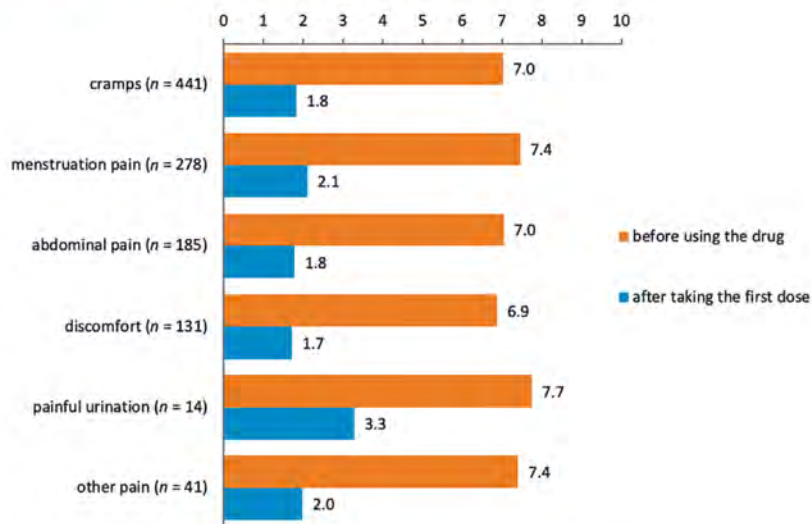
Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder, characterized by recurrent abdominal pain, cramping, bloating, constipation and diarrhea in the absence of detectable structural abnormalities.

The prevalence of IBS ranges from 3.7% to 22% in the asian population and 70% of IBS patients have abdominal pain or discomfort significantly affecting the patient's quality of life.^{1,2}

Drotaverine is used for the relief of spasmodic pain arising from smooth muscle diseases like IBS.

CLINICAL EVIDENCE:

1. Subjective severity of symptoms before and after taking the first dose of drotaverine by symptoms³



After the first dose, the mean severity scores had decreased by ~5 points for cramps, menstruation pain, abdominal pain unrelated to menstruation, and discomfort (in most cases caused by pain and/or cramps)- Drotaverine is effective for all symptoms

2. Pain severity score (vas) in drotaverine vs mebeverine on the basis of days⁴



At the end of the study, the pain severity decreased in drotaverine (group A) from 6.02 to 1.78, a 70.4% reduction. However, in mebeverine (group B), the severity of pain reduced from 6.72 to 3.62, a 46.1% reduction.

3. Efficacy and safety of drotaverine hydrochloride in irritable bowel syndrome: A randomized double-blind placebo-controlled study. ²

No. of Patients: 180 patients [Drotaverine (n=87) & Placebo (n=93)]

Duration: 4 weeks

Dose: Drotaverine HCl 80 mg three times daily or Placebo

Result:

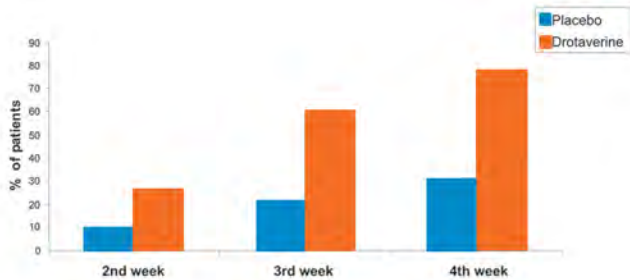


Fig: Relief In Pain Frequency And Severity

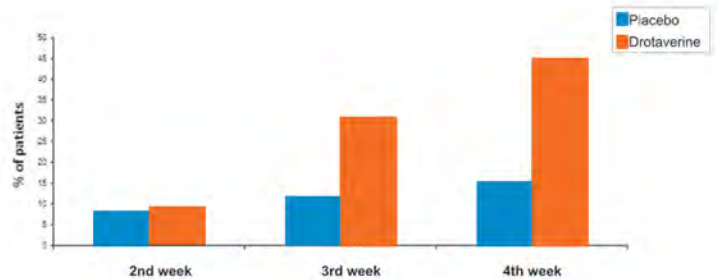


Fig: Improvement in Stool Frequency

Global relief in abdominal pain:

A. Drotaverine Group: 85.9% B. Placebo Group: 39.5%

Conclusion:

Treatment with drotaverine HCl given three times daily for 4 weeks is more effective than a placebo in reducing abdominal symptoms related to IBS.

4. Comparative evaluation of efficacy and safety of drotaverine versus mebeverine in irritable bowel syndrome: A randomized double-blind controlled study. ³

No. of Patients: Group A (n = 100) & Group B (n = 100)

Duration: 4 weeks

Dose: Group A (n = 100) received 80 mg Drotaverine and Group B (n = 100) received 135 mg Mebeverine three times a day

Result:

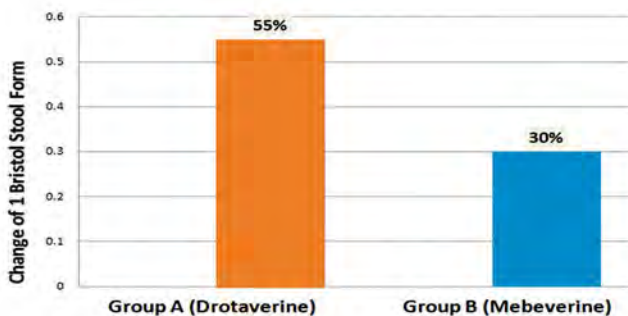


Fig: Change of 1 Bristol Stool Chart score in Group A and B on Day 28

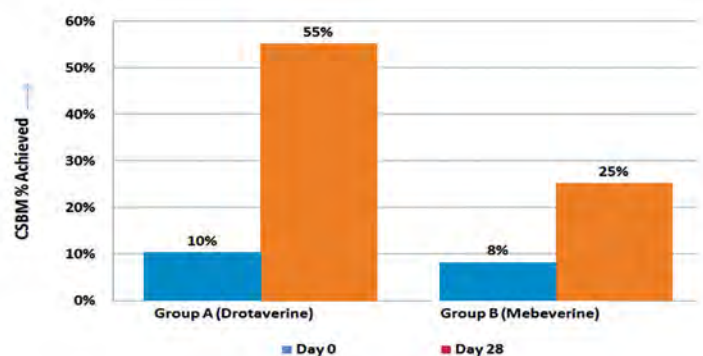


Fig: Complete smooth bowel movement (CSBM) in Group A and B on Day 0 and Day 28

Conclusion:

Drotaverine is significantly superior in efficacy as compared to Mebeverine in alleviating pain severity (starting from day 3), frequency, and stool-related symptoms of IBS.

Drotachek

Drotaverine Hydrochloride 40 mg & 80 mg Tablets



DESCRIPTION:

Drotachek-40/80 contains drotaverine hydrochloride in the strength of 40 mg and 80 mg and is available as a film-coated tablet. Drotaverine hydrochloride is an isoquinoline derivative and is a potent spasmolytic drug used for the relief of spasmodic pain arising from smooth muscle diseases like IBS.

INDICATION:

Irritable Bowel Syndrome (IBS)

MECHANISM OF ACTION:

- Drotaverine hydrochloride is an anti-spasmodic drug that relieves contractions (spasms) associated with smooth muscles in the abdomen.
- It is a selective inhibitor of phosphodiesterase 4 (PDE4), an enzyme responsible for cyclic adenosine monophosphate (cAMP) degradation. Inhibition of PDE4 leads to elevated levels of cAMP leading to smooth muscle relaxation.

KEY BENEFITS OF DROTACHEK IN IBS⁴:

- **Site-Specific Action:** acts directly on abdominal smooth muscles
- Exerts two-fold antispasmodic action on the smooth muscles of the gut.
- Significantly superior in efficacy as compared to Mebeverine in alleviating pain severity, frequency and stool-related symptoms of IBS.
- It is selectively inhibiting PDE isoenzyme IV (Phosphodiesterase 4) in the gut resulting in a powerful spasmolytic action.
- Binds to the surface of the smooth muscle and alters its membrane potential and permeability.

DOSES:

The recommended dosage of Drotaverine Hydrochloride is 40 mg-80 mg of TID or as prescribed by a registered medicinal professional.

PRESENTATION:

Drotachek-40/80 is available as a strip of 15 tablets.

References:

1. Xue et al. Medicine (2017) 96:51
2. The Saudi Journal of Gastroenterology, Volume 20
3. J. Clin. Med. 2022, 11, 3156
4. Saudi Journal of Gastroenterology | Volume 27 | Issue 3 | May-June 2021

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