

# CLINICAL PEARLS

## Acotiamide in Functional Dyspepsia



Reviewed by:

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**Acotiamide**, a first-in-class prokinetic agent, has proven efficacy in functional dyspepsia, and is surely recommended for this functional, non-organic condition



## CLINICAL PEARLS

Acotiamide in Functional Dyspepsia

### A YOUNG WOMAN WITH FUNCTIONAL DYSPEPSIA SUCCESSFULLY TREATED WITH ACOTIAMIDE

#### CASE PRESENTATION

- A 36-year-old female executive, working in an MNC, presented with complaints of bothersome post prandial fullness/bloating and epigastric pain for about 3 months with multiple episodes/week.
- As narrated by her, onset of symptoms occurred about 6 months back after she switched to a new role at her organization, which resulted in a more stressful and rigorous workload.

#### PAST HISTORY

- She had no significant past medical or surgical history.

#### EXAMINATION & INVESTIGATIONS

- The physical examination findings were unremarkable.
- Laboratory investigations showed a normal full blood count, renal function test, liver function test, fasting blood glucose and thyroid enzymes.
- Upper gastrointestinal endoscopy was within normal limits (no evidence of structural disease).

#### DIAGNOSIS

- Functional dyspepsia (according to Rome IV criteria).

#### TREATMENT & FOLLOW-UP

- She was started on acotiamide 300 mg daily and advised to follow a regular meal pattern with smaller meals, and avoid high-fat meals.
- She presented for follow-up at 3 weeks, and reported significant improvement in symptoms.

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Acotiamide in Functional Dyspepsia

### ACOTIAMIDE IN FUNCTIONAL DYSPEPSIA

- Acotiamide, a **novel and first-in-class prokinetic agent**, has proven efficacy for functional dyspepsia.<sup>1,2</sup>
- It acts by modulating the upper gastrointestinal motility to alleviate the abdominal symptoms resulting from hypomotility.
- Acotiamide has been shown to have profound effects on restoring delayed gastric emptying and impaired accommodation in patients with functional dyspepsia.<sup>3</sup>

### EVIDENCES ON EFFICACY OF ACOTIAMIDE

- Several clinical trials have shown the efficacy of acotiamide for improving symptoms in patients with functional dyspepsia.<sup>2</sup>
- For instance, in a randomized, double-blind, placebo-controlled, parallel-group comparative Phase III trial conducted in Japan, **acotiamide 300 mg/day for 4 weeks was found to be more effective than placebo for improving symptoms, and quality of life.**<sup>2</sup>
  - » The drug was well-tolerated with no significant adverse events.
- Furthermore, as an added advantage, acotiamide may also improve the anxiety score of patients with functional dyspepsia.<sup>4</sup>

### REAL-WORLD INDIAN DATA ON THE EFFICACY OF ACOTIAMIDE IN FUNCTIONAL DYSPEPSIA

#### Aim

To evaluate the effectiveness of acotiamide in management of functional dyspepsia over a 4-week period in a real-world setting.<sup>5</sup>

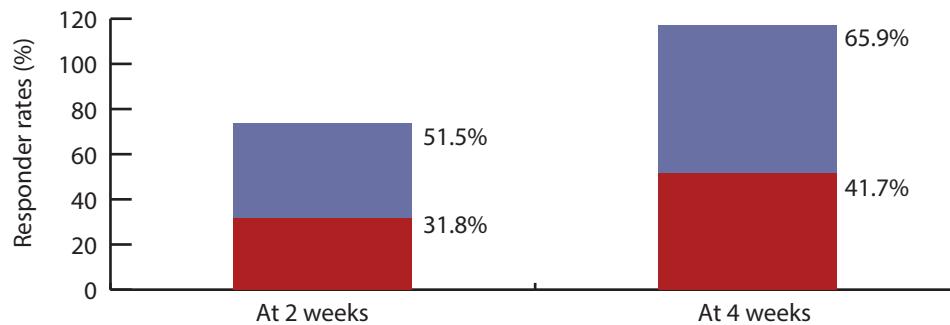
#### Methods

- A prospective, observational, real-world study
- Subjects: 132 patients (85 male, 47 female) > 18 years of age diagnosed with functional dyspepsia and treated with acotiamide 300 mg/day for 4 weeks at a gastroenterology unit of a medical school in India.

#### Results

- Responder rates at 2 weeks: 31.8% to 51.5%
- Responder rates at 4 weeks: 41.7% to 65.9%

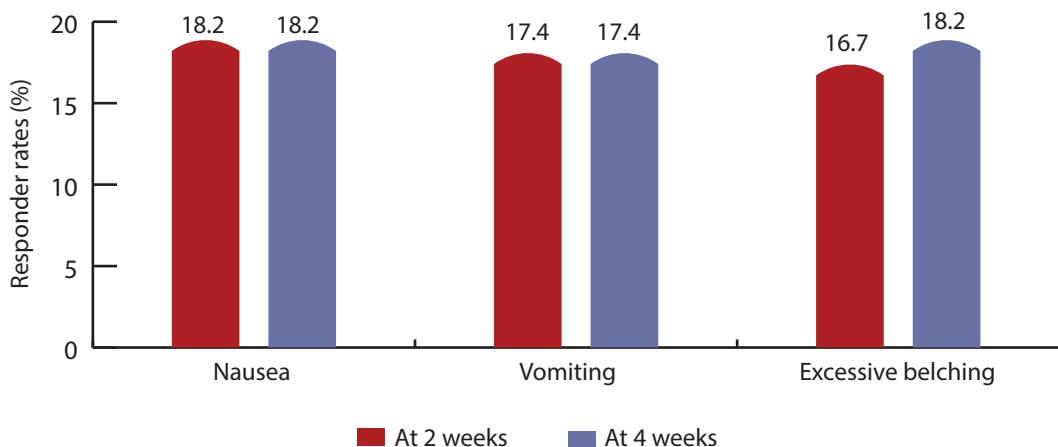
#### Responder rates with acotiamide for functional dyspepsia



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### Acotiamide in Functional Dyspepsia

#### Responder rates with acotiamide for associated symptoms



- Significant improvement in the Short-Form Nepean Dyspepsia Index (SFNDI) questionnaire total scores was noted at 4 weeks.
- Only 5.30% patients reported mild adverse events like dizziness, headache and nausea.

## CONCLUSION

Acotiamide improves symptoms, quality-of-life, and is well-tolerated in Indian patients with functional dyspepsia.<sup>5</sup>

## DIAGNOSTIC CRITERIA FOR FUNCTIONAL DYSPEPSIA

### ROME IV CRITERIA<sup>6,7</sup>

#### Functional dyspepsia\*

Diagnostic criteria\*\*

- One or more of the following:
  - » Bothersome postprandial fullness
  - » Bothersome early satiation
  - » Bothersome epigastric pain
  - » Bothersome epigastric burning

AND

- No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms

\*Must fulfill criteria for Postprandial Distress Syndrome (PDS) and/or Epigastric Pain Syndrome (EPS).

\*\*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis



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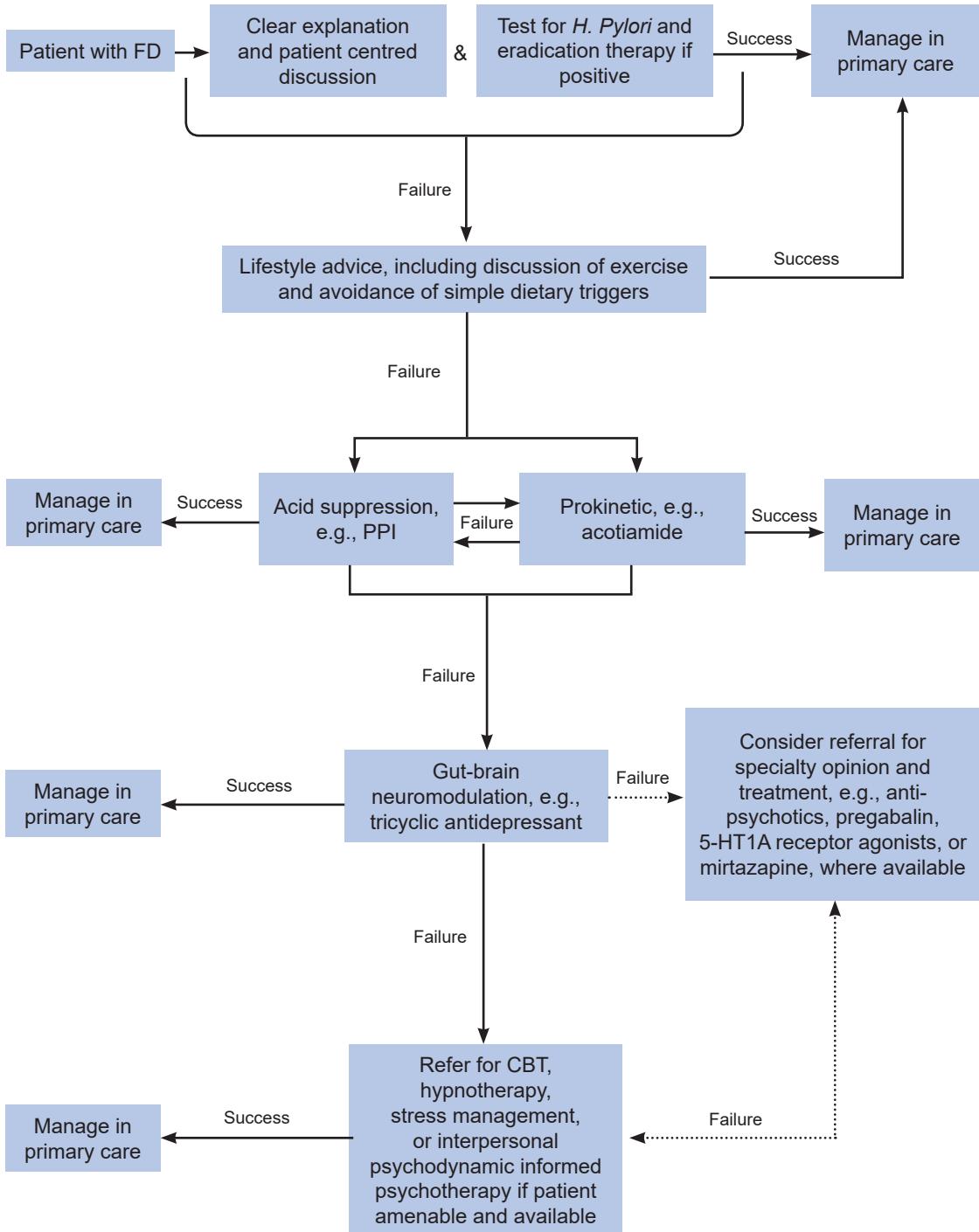
### Treatment Algorithm For Functional Dyspepsia (British Society of Gastroenterology Guidelines, 2022)<sup>8</sup>

**Good communication, *H. Pylori* testing, and lifestyle advice**

**First-line treatments**

**Second-line treatment**

**Psychological therapies**



FD, functional dyspepsia; PPI, proton pump inhibitor; CBT, Cognitive-behavioural therapy

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### Acotiamide in Functional Dyspepsia

## REFERENCES

1. Vandenberghe A, Schol J, Van den Houte K, et al. Current and emerging therapeutic options for the management of functional dyspepsia. *Expert Opin Pharmacother.* 2020;21(3):365-376.
2. Ueda M, Iwasaki E, Suzuki H. Profile of acotiamide in the treatment of functional dyspepsia. *Clin Exp Gastroenterol.* 2016;9:83-8.
3. Zai H, Matsueda K, Kusano M, et al. Effect of acotiamide on gastric emptying in healthy adult humans. *Eur J Clin Invest.* 2014;44(12):1215-21.
4. Nakamura K, Tomita T, Oshima T, et al. A double-blind placebo controlled study of acotiamide hydrochloride for efficacy on gastrointestinal motility of patients with functional dyspepsia. *J Gastroenterol.* 2017;52(5):602-610.
5. Porika SK, Veligandla KC, Muni SK, et al. Real-World, Non-Interventional, Observational Study to Evaluate Effectiveness and Tolerability of Acotiamide Hydrochloride Hydrate in Treatment of Functional Dyspepsia. *Adv Ther.* 2018 Nov;35(11):1884-1893.
6. Ford AC, Mahadeva S, Carbone MF. Functional dyspepsia. *Lancet.* 2020;396(10263):1689-1702.
7. Drossman DA, Chang L (ed.). ROME IV. Functional Gastrointestinal Disorders. Disorders of Gut-Brain Interaction.
8. Black CJ, Paine PA, Agrawal A, et al. British Society of Gastroenterology guidelines on the management of functional dyspepsia. *Gut* 2022;0:1-27.

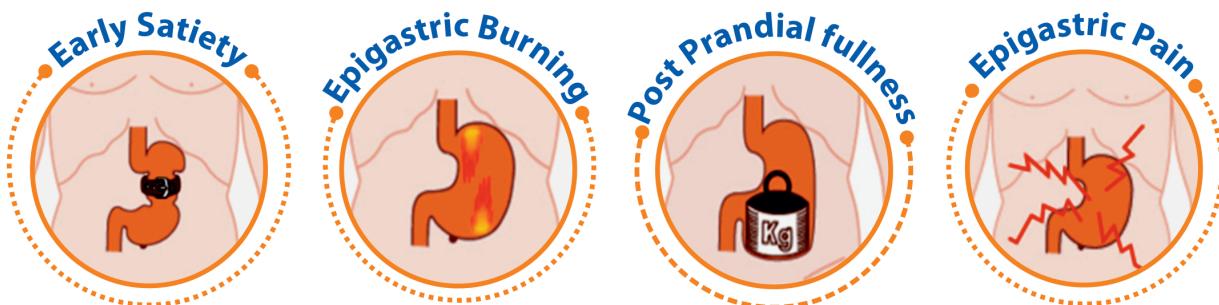


In Functional Dyspepsia



Rely on the **S.A.F.E.R prokinetic**

**Control over FD\* requires control over all 4 symptoms**



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