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Research Article

Assessment of Efficacy and Safety of Pharmacotherapies in Patients of Irritable Bowel Syndrome

Nadisha Oberoi[1], Razi Ahmad[2], Bilal Wani[3], Sana Rehman[4], Mohammad Habib[5], Priyanshu Bisht[6], Riputa Shourie[7]

[1]Pharmacology, Hamdard Institute of Medical Science and Research, Jamia Hamdard, New Delhi, IND
[2]Pharmacology and Therapeutics, Hamdard Institute of Medical Sciences and Research, Jamia Hamdard, New Delhi, IND.
[3]Gastroenterology and Hepatology, Hamdard institute of medical sciences and research, New Delhi, IND
[4]Pharmacology, Hamdard Institute of Medical Sciences and Research, New Delhi, New Delhi, IND
[5]Department of Medicine, Hamdard Institute of Medical Sciences & Research (HIMSR) Jamia Hamdard, New Delhi, IND
[6]Pharmacology, Hamdard Institute of Medical Science and Research, Jamia Hamdard, New Delhi, IND
[7]Pharmacology, Hamdard Institute of Medical Science and Research, Jamia Hamdard, New Delhi, IND

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Corresponding Author:

Nadisha Oberoi
Pharmacology, Hamdard Institute of Medical Science and Research, Jamia Hamdard, New Delhi, IND

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ABSTRACT

This prospective, open-label observational study evaluated the efficacy and safety of commonly used pharmacotherapies in patients with irritable bowel syndrome (IBS) over a 12-month period. A total of 214 adult patients diagnosed according to Rome IV criteria were included. Symptom severity, bowel habits, and quality of life were assessed using the Visual Analogue Scale (VAS), Complete Spontaneous Bowel Movements (CSBM), IBS Severity Scoring Scale (IBS-SSS), and IBS-Quality of Life (IBS-QOL) scores at baseline and follow-up visits (6, 9, and 12 months).

Results demonstrated a significant reduction in abdominal pain severity across most treatment groups, with notable improvement observed with 5-HT4 agonists, selective serotonin reuptake inhibitors (SSRIs), and tricyclic antidepressants (TCAs). Improvement in bowel habits was most pronounced with 5-HT4 agonists, while SSRIs and antispasmodics showed moderate benefit. IBS severity scores showed a shift from severe to mild/moderate categories over time, and quality of life improved significantly, particularly in patients receiving 5-HT4 agonists, SSRIs, and TCAs.

Adverse effects were consistent with known drug profiles, with dry mouth most common in TCA users and dizziness associated with μ-opioid receptor agonists. Overall, 5-HT4 agonists, SSRIs, and TCAs demonstrated superior efficacy, while μ-opioid agonists showed limited benefit.

In conclusion, pharmacological management of IBS leads to significant clinical improvement, with optimal outcomes achieved through individualized, mechanism-based therapy targeting both peripheral and central pathways.

Keywords: *efficacy and safety, pain on vas, quality of life (QOL), irritable bowel syndrome, treatment of IBS.*

INTRODUCTION

Irritable bowel syndrome (IBS) is a highly prevalent chronic disorder of gut-brain interaction. (Nathani RR,2026) It is routinely encountered by healthcare providers. Estimated to affect around 1 in 10 people globally, its prevalence rates appear to differ between countries, but the magnitude of the effect in terms of cost and quality of life, seems comparable around the world. (Black CJ,2020) It vastly reduces patient's quality of life and imposes a significant economic burden to the healthcare system.

IBS is of multifactorial origin. Genetic and epigenetic factors, stress-related nervous and endocrine systems, immune dysregulation and the brain-gut axis seem to be contributing factors that predispose individuals to IBS. (Chong PP,2019)

The Rome IV criteria defines IBS as a disorder of gut-brain interaction (DGBI). (Drossman DA,2016) DGBIs involve gastrointestinal symptoms leading to motility disturbances, visceral hypersensitivity, altered gut microbiota, altered mucosal and immune function and altered central nervous system processing. (Ettienne EB,2025)

Increased epithelial barrier permeability and an abnormal gut flora might lead to increased activation of the intestinal immune system. The link between immune alterations and severity of gastrointestinal symptoms and the positive effect of anti-inflammatory treatments in IBS further highlight the relevance of neuroimmune interactions in this condition. (Ohman L,2010)

Some of the currently used drug classes of IBS agents include: Antispasmodics, Tricyclic antidepressants, Selective serotonin reuptake inhibitors (SSRIs), Opioid receptor agonists, serotonin receptor antagonists, chloride channel activators, and guanylate cyclase C (GC-C) agonists and antibiotics. (Camilleri M,2009)

IBS is classified into four distinct subtypes based on bowel habits: (Gomez,2025)

IBS-D (diarrhoea-predominant), IBS-C (constipation-predominant), IBS-M (mixed type with alternating diarrhoea and constipation) and IBS-U (unsubtyped).

Many observational studies and randomized controlled trials (RCTs) have assessed the efficacy of licensed pharmacological therapies in adults with IBS. [Black CJ, 2020) However, the RCTs have been unable to generate convincing data on relative efficacy and safety.

With this background, the current study is aimed to determine efficacy and safety of pharmacotherapies in an Indian patient population and to estimate the overall clinical impact of personalized and combined treatment modalities for IBS.

METHODOLOGY

Study Design

This was a prospective, open-label observational study conducted on patients attending the outpatient clinics of the Department of Medicine at HAHC Hospital attached to Hamdard Institute of Medical Sciences & Research, New Delhi carried out for a total of 12 months. The study was conducted following the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice after approval from the Institutional Ethics Committee (IEC). All patients were fully informed about the details of the study and provided their written informed consent prior to inclusion into the study. The details of the treatment regimen of the patients were recorded after thorough patient interview and checking of the patient OPD records and investigations. The symptomatic control achieved by the pharmacotherapy was assessed by Visual Analogue Scale (VAS) and IBS - Quality of Life Score measured at the baseline (time of enrolment in the study) and at each follow-up visits. (6,9&12months)

Information regarding the signs and symptoms of gastro-intestinal disturbances and any other adverse events was sought and recorded on each follow up visit. After completion of study period, the data was compiled and assessed for statistical analysis.

Study Participants

All adult patients with IBS (according to the Rome IV criteria) were screened for the eligibility criteria.

Sample size

The sample size was calculated using the standard formula:

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Where:

- N = required sample size
- Z = Z value at 95% confidence interval (1.96)
- p = estimated prevalence of IBS (14) (Ghoshal UC,2017), (Abraham P,2008)
- q = 1 − p
- d = allowable error (precision)

Based on this calculation, the minimum required sample size was 214 participants.

Inclusion criteria:

- Age 18 years and above, of any gender.

- IBS Patients fulfilling Rome IV criteria• Patients consenting to participate in the study.

Exclusion criteria:

- Patients with structural GI alterations that could affect GI motility.
- Patients having active peptic ulcer disease, or history of any chronic condition associated with abdominal pain.
- Patients not able to or not giving consent for the study participation.
- Patients with red flag signs of IBS - Rectal Bleeding, Unintentional weight loss or persistent fever and malaise.

Efficacy end points

Abdominal pain severity.

The 10-point Abdominal Pain Numeric Rating Scale (APS- NRS) was used to assess participant abdominal pain, with 10 representing the most severe pain and 0 representing no pain. (Spiegel,2009) Pain severity was categorized as mild (VAS 1-3), moderate (VAS 4-6), and severe (VAS 7-10).

Complete Spontaneous Bowel Movements (CSBM).

The changes in complete spontaneous bowel movements (CSBM), per week as compared with two weeks prior to the start of treatment regimens were noted as "Yes" (improvement in CSBM) and "No" (no improvement) (Lacy BE,2012)

IBS - Severity Scoring Scale.

The IBS-SSS is an internationally validated assessment tool used to evaluate the intensity of IBS symptoms. It is a composite score of abdominal pain, bloating/distension, and satisfaction with bowel habits. Each measure is rated from 0 to 100, with total scores ranging from 0 to 500. Scores between 75-175 are considered mild, 175-300 moderate or >300 severe IBS(Francis,1997)

IBS- Quality of life score

The IBS-QOL is a 34-item self-report quality-of-life questionnaire assessing the impact of IBS and its treatment. It contains eight disease-relevant domains: dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, and sexual and relationship issues with each item rated on a 5-point scale Standard IBS-QOL is 0-100 transformed score. (Bakr,2025)

Safety and points.

Adverse drug Events associated with drugs were recorded throughout the study at the timepoints.

Statistical Analysis

The collected data were compiled and analysed using descriptive statistics (mean ± SD, percentages). For comparison between groups, paired t-test and Chi-square test were applied where appropriate. A p-value <
0.05 was considered statistically significant and p-values less than 0.01 considered highly significant.

RESULTS

Participants

Baseline characteristics of the 214 participants are presented in Table 1. The majority of patients were aged 41-50 years (38.32%), followed by 51-60 years (25.70%). A higher prevalence of IBS was observed in males (63.08%) compared to females (36.92%). Most participants (71.03%) had no history of smoking or alcohol consumption. Hypertension was the most common comorbidity, present in 25.70% of patients. IBS with constipation (IBS-C) was the predominant subtype (75.70%), followed by IBS with diarrhoea (IBS-D) (16.36%) and mixed IBS (IBS-M) (5.14%).

Antispasmodics were the most frequently prescribed medications (20.56%), followed by 5-HT4 agonists (17.29%) and selective serotonin reuptake inhibitors (SSRIs) (15.42%).

TABLE 1: Baseline characteristics of study participants

Parameters	Categories	Antispasmodic (n=44)	µAgonist (n=36)	A/B (n=34)	$5HT_4$ agonist (n=37)	SSRA (n=33)	TCA (n=30)
Gender	Male	27	20	19	26	21	22
	Female	17	16	15	11	12	8
Age	19-30 years	6	5	4	3	2	5
	31-40 years	11	9	6	5	3	1
	41-50 years	16	10	18	3	20	15
	51-60 years	7	9	3	22	6	8
	>60 years	4	3	3	4	2	1
Personal history	Smoking	8	6	5	7	4	5

	Alcohol	6	4	5	1	7	4
	No	30	26	24	29	22	21

Symptomatic control was assessed using the Visual Analogue Scale (VAS) and IBS-Quality of Life scores at baseline and at follow-up visits (6, 9, and 12 months). Data on gastrointestinal symptoms and adverse events were recorded at each follow-up.

Efficacy Outcomes

Abdominal Pain Severity.

At baseline, severe pain was highest with antispasmodics (23), A/B (22), and μ-agonists (21), with minimal mild pain (0-2). By Visit I, severe pain significantly decreased with antispasmodics (23→9; $p < 0.01$) and 5HT4 agonists (17→8; $p < 0.05$), while TCAs showed modest improvement (11→8). At Visit II, severe pain continued to decline across groups; however, moderate pain increased in μ-agonists (15→21), A/B (12→21), and SSRIs (12→29), while TCAs improved (17→10; $p < 0.05$). By Visit III, severe pain further reduced with antispasmodics (23→3), μ-agonists (21→3), 5-HT4 agonists (17→4), and SSRIs (12→3) ($p < 0.01$), while A/B showed moderate improvement (22→14; $p < 0.05$). In contrast, moderate pain increased in antispasmodics (20→33), μ-agonists (15→32), and SSRIs (12→32), but remained low with TCAs (17→9). Mild pain increased in TCAs (2→14), 5-HT4 agonists (0→11), and antispasmodics (0→8) ($p < 0.05$). (Table *2*)

TABLE 2: Pain Severity Score (VAS)

VAS Score	Antispasmodic	μAgonist	A/B	5HT4 agonist	SSRI	TCA
Baseline						
Mild pain	1	0	0	1	0	2
Moderate Pain	20	15	12	19	12	17
Severe Pain	23	21	22	17	21	11
Visit I						
Mild pain	4	0	0	4	0	7
Moderate Pain	31	12*	10*	25	8*	15*
Severe Pain	9**	24	24	8**	25	8*
Visit II						
Mild pain	6	2	1	6	1	18
Moderate Pain	28	21	21	21	29	10
Severe Pain	10**	13**	12*	10**	3**	2**
Visit III						
Mild pain	8	1	1#	11	1	14
Moderate Pain	33	32	19	15	32	9
Severe Pain	3**	3**	14*	4**	3**	7*

** = Highly significant ($p < 0.01$)

* = Significant ($p < 0.05$)

= Possible trend or borderline significance ($0.05 \leq p < 0.1$)

p values denoted for each visit are in comparison with the baseline scores.

Complete spontaneous bowel movement (CSBM).

At baseline, CSBM improvement was minimal, with only antispasmodics (1), TCAs (1), SSRIs (2), and 5-HT4 agonists (3) showing response, while μ-agonists and A/B showed none. By Visit I, slight increases were observed with 5-HT4 agonists (3→5) and SSRIs (2→4), while other groups remained unchanged. At Visit II, further improvement was noted with 5-HT4 agonists (5→9), SSRIs (4→6), antispasmodics (1→3), TCAs (1→2), and A/B (0→2), whereas μ-agonists showed no response throughout. By Visit III, the greatest improvement was seen with 5-HT4 agonists (3→10), followed

by SSRIs (2→8), antispasmodics (1→6), and TCAs (1→4), while A/B remained unchanged (2) and μ-agonists continued to show no effect. (Table *3*)

TABLE 3: Complete spontaneous bowel movement (CSBM)

CSBM Improvement	Antispasmodic	μ Agonist	A/B	5HT4 agonist	SSRI	TCA
Baseline						
Yes	1	0	0	3	2	1
No	43	36	34	34	31	29
Visit I						
Yes	1	0	0	5	4	1
No	43	36	34	32	29	29
Visit II						
Yes	3	0	2	9	6	2
No	41	36	32	28	27	28
Visit III						
Yes	6*	0	2	10**	8*	4#
No	38	36	32	27	25	26

** = Highly significant ($p < 0.01$)
* = Statistically Significant ($p < 0.05$)
# = Possible trend or borderline significance ($0.05 \leq p < 0.1$) p values denoted for each visit are in comparison with the baseline scores.

IBS - Severity Scoring Scale.

At baseline, most patients were classified as having severe IBS, particularly in the antispasmodic (33), μagonist (28), and A/B (28) groups, with few mild cases across all groups. By Visit I, early improvement was observed in the 5-HT4 agonist and SSRI groups, with a reduction in severe cases and emergence of mild cases, while antispasmodics and TCAs showed minimal change; μ-agonists and A/B remained largely unchanged. At Visit II, significant shifts toward reduced severity were noted, particularly with 5-HT4 agonists, SSRIs, and antispasmodics, with increased mild and moderate cases. TCAs also demonstrated clearer improvement, whereas μ-agonists showed limited response and A/B showed modest change. By Visit III, marked reduction in severe cases was observed with 5-HT4 agonists, SSRIs, and TCAs, accompanied by increased mild cases. Antispasmodics showed sustained improvement, while A/B demonstrated moderate benefit. μ-agonists remained least effective, with a persistently higher proportion of severe cases. (Table *4*)

TABLE 4: IBS - Severity Scoring Scale.

IBS - Severity Scoring Scale	Antispasmodic	μAgonist	A/B	5HT4 agonist	SSRI	TCA
Baseline						
Mild	1	0	1	1	1	1
Moderate	19	8	5	18	13	11
Severe	33	28	28	18	19	18
Visit I						
Mild	2	1	1	3	3	2
Moderate	12	11	11	19	15	12
Severe	30	24	22	15	15	16
Visit II						
Mild	4	2	2	7	6	4
Moderate	17	13	16	24#	20	17
Severe	23	21	16	6**	7*	9
Visit III						
Mild	5#	4	3	11*	8*	6
Moderate	31*	13	23	23	19	22

Severe	8**	19	8*	3**	4*	2**

* = Significant ($p < 0.05$)
** = Highly significant ($p < 0.01$)
# = Possible trend or borderline significance ($0.05 \leq p < 0.1$) p values denoted for each visit are in comparison with the baseline scores.

IBS- Quality of Life (IBS-QOL).
At baseline, IBS-QOL scores varied across groups, with the μ-opioid agonist group having the highest score (70.25), while 5-HT4 agonists (55.75), SSRIs (~56), and TCAs (~56) had lower baseline values, indicating poorer quality of life. By Visit I, improvements were observed with 5-HT4 agonists (55.75→63.25), SSRIs (~56→64), and TCAs (~56→64). In contrast, μ-opioid agonists and antispasmodics remained relatively stable, while the A/B group showed minimal change. At Visit II, further improvement was seen across groups, with the A/B group increasing to 72.50. The 5-HT4 agonist, SSRI, and TCA groups also improved to approximately 67-74, while μ-opioid agonists and antispasmodics showed modest gains. By Visit III, the highest scores were observed with 5-HT4 agonists (→76.50), followed by SSRIs and TCAs (~74-75), indicating sustained improvement in quality of life. The A/B group maintained its gains, while μ-opioid agonists and antispasmodics showed comparatively smaller improvements. (Table *5*)

TABLE 5: IBS– Quality of Life (IBS-QOL) scores

IBS-QOL	**Antispasmodic (n=44)**	**μ Agonist (n=36)**	**A/B (n=34)**	**$5HT_4$ agonist (n=37)**	**SSRI (n=33)**	**TCA (n=30)**
Baseline	65.75 ± 7.05	70.25 ± 7.65	64.10 ± 8.40	55.75 ± 7.40	56.00 ± 7.30	55.50 ± 7.65
Visit I	65.90 ± 7.00	70.25 ± 7.65	64.80 ± 7.35	63.25 ± 7.20**	64.95 ± 7.25**	64.60 ± 7.60
Visit II	68.90 ± 7.10*	70.80 ± 7.55	72.50 ± 8.40	69.75 ± 7.50**	67.80 ± 7.40**	74.20 ± 7.55**
Visit III	68.90 ± 7.10#	70.25 ± 7.65	72.50 ± 8.40*	76.50 ± 7.25**	75.20 ± 7.15**	74.20 ± 7.55**

* = Significant ($p < 0.05$)
** = Highly significant ($p < 0.01$)
# = Possible trend or borderline significance ($0.05 \leq p < 0.1$) p values denoted for each visit are in comparison with the baseline scores

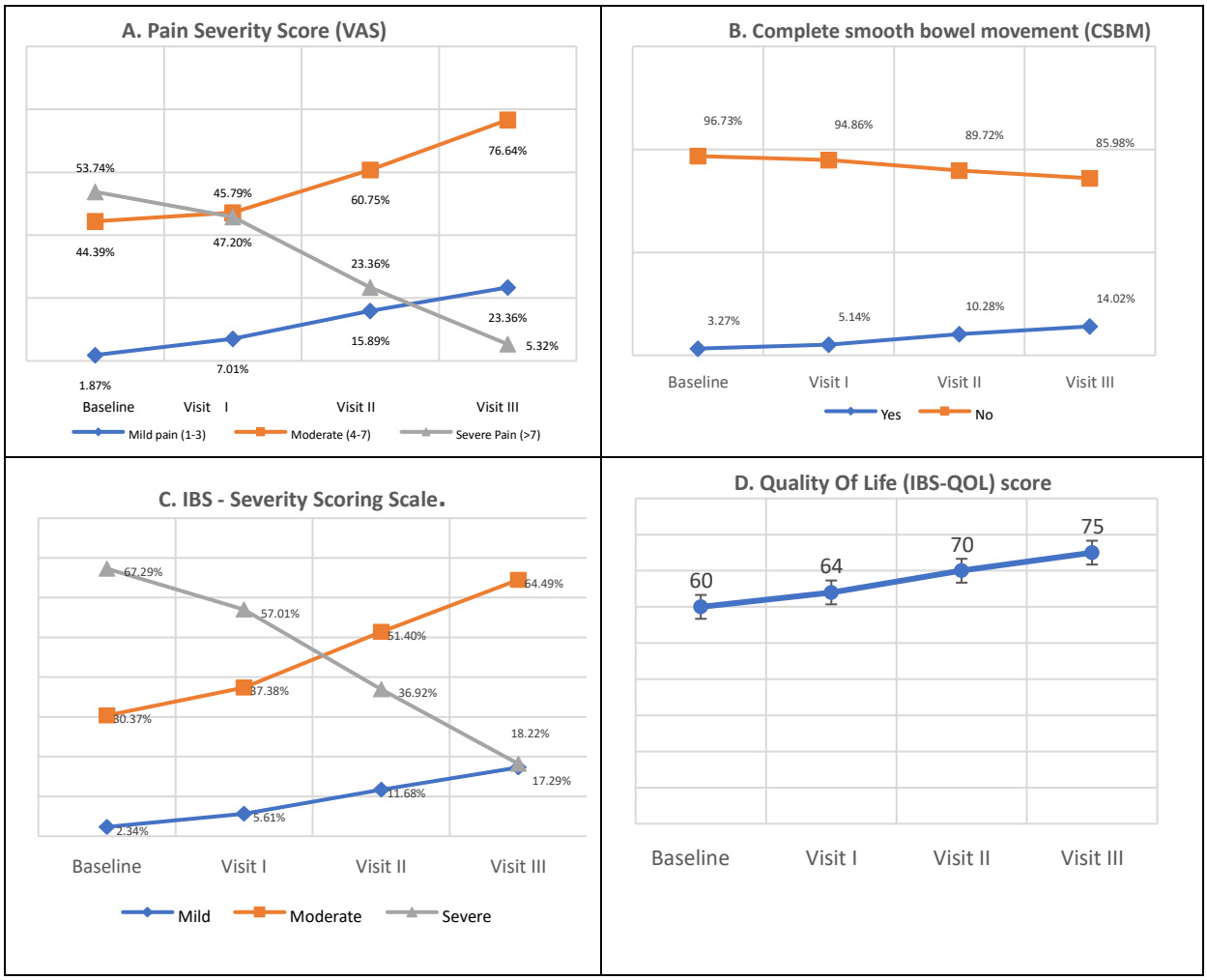

FIGURE 1: Across Visits Pain severity assessed using the Visual Analog Scale (VAS), categorized as mild (1–3), moderate (4–7), and severe (>7) The percentage of patients with CSBM ("Yes") increases over time, indicating improvement in bowel function (Panels A and B). IBS severity scoring scale distribution (mild, moderate, severe). A shift from severe to moderate and mild categories is noted over successive visits, reflecting clinical improvement. (Panel C). Quality of Life (IBS-QOL) Mean scores show a consistent increase from baseline to Visit III, indicating improved patient-reported outcomes. (Panel D) Data are presented as percentages for categorical variables and mean ± (error bars, if SD/SEM specify) for continuous variables across baseline,
Visit I, Visit II, and Visit III.

Safety Outcomes

Dry mouth was the most common adverse effect, particularly in the TCA group (29/30, 96.7%), followed by antispasmodics (16) and SSRIs (5). Dizziness was predominantly reported with μ-agonists (29/36). Nausea was most frequent with antispasmodics (15) and SSRIs (10), with fewer cases in A/B (5) and TCAs (5).

Vomiting was highest with antispasmodics (11) and occurred in μ-agonists (5), A/B (4), 5-HT4 agonists (7), SSRIs (1), and TCAs (1). (Table *6*) Sexual dysfunction was observed with SSRIs (4) and TCAs (5). Headache and fatigue were rare, reported in ≤2 patients across groups. Overall, adverse effects were drug class-specific, with TCAs with dry mouth, and SSRIs with gastrointestinal and sexual side effects.

TABLE 6: Adverse effects

Adverse effect	Antispasmodic (n=44)	μ Agonist (n=36)	A/B (n=34)	$5HT_4$ agonist (n=37)	SSRI (n=33)	TCA (n=30)
Nausea	15	0	5	0	10	5
Vomiting	11	5	4	7	1	1
Chronic fatigue	0	0	0	1	1	0
Headache	1	0	2	0	0	1

Dizziness	3	29	0	0	0	0
Dry Mouth	16	0	0	0	5	29
Sexual Dysfunction	0	0	0	0	4	5

DISCUSSION

This prospective observational study assessed the efficacy and safety of commonly prescribed pharmacotherapies in patients with irritable bowel syndrome (IBS) over a 12-month period. The findings demonstrate clinically meaningful improvements across key domains, including abdominal pain severity, bowel habits, disease severity, and quality of life, alongside distinct drug-specific safety profiles.

At baseline, most patients had moderate to severe abdominal pain. Over time, a consistent shift toward milder pain categories was observed with antispasmodics and 5HT4 agonists by Visit I ($p < 0.01$ and $p < 0.05$, respectively), and further across groups by Visit III ($p < 0.01$). SSRIs and TCAs showed gradual improvement, with TCAs demonstrating significant benefit by later visits.

Significant reductions in severe pain across multiple groups indicate effective modulation of visceral hypersensitivity, a central mechanism in IBS pathophysiology. In contrast, μ-opioid receptor agonists and A/B therapy showed comparatively limited improvement, suggesting a narrower therapeutic role.

Improvement in complete spontaneous bowel movements were most pronounced with 5HT4 agonists ($p < 0.01$ at Visit III) consistent with their prokinetic action, followed by SSRIs and antispasmodics ($p < 0.05$) likely mediated via brain-gut axis modulation, while μ-agonists showed no significant change, potentially due to their constipating effects, underscoring the importance of tailored therapy.

The IBS Severity Scoring Scale (IBS-SSS) outcomes further corroborate these findings, with a substantial reduction in the proportion of patients categorized as "severe" across most treatment arms. With 5HT4 agonists ($p < 0.01$), SSRIs ($p < 0.05$), and TCAs ($p < 0.01$) by Visit III suggesting that both peripheral and central mechanisms play a critical role in symptom amelioration. Whereas antispasmodics demonstrated moderate improvement and μ-agonists and A/B therapy remained less effective.

Quality of life improved significantly in the 5HT4 agonist, SSRI, and TCA groups ($p < 0.01$) likely reflecting their neuromodulatory effects on central pain processing and psychological comorbidities while changes with μ-agonists were minimal limiting their overall clinical utility.

The observed adverse effect profile aligns with known pharmacological mechanisms. The high incidence of dry mouth with TCAs reflects their strong anticholinergic activity, while its occurrence with antispasmodics may be attributed to similar antimuscarinic effects. Dizziness associated with μ-opioid agonists is consistent with CNS depression. Sexual dysfunction observed with SSRIs and TCAs is well documented and related to serotonergic modulation.

Overall, these findings support the current understanding that IBS management requires an individualized approach that targets both gastrointestinal motility and central neuromodulation to provide the most comprehensive benefit.

Rationale for this study was to evaluate the efficacy and safety for pharmacotherapies in IBS. Although most IBS patients in our clinical setting receive combination therapy tailored to individual symptoms, this study focused on evaluating the outcomes of monotherapy in patients where a single agent was initiated.

Supportive treatments (laxatives, multivitamins, probiotics & antacids) were not included in analysis. Hence, the study is limited by its generalizability to all IBS cases, it enables a focused assessment of monotherapy outcomes.

CONCLUSIONS

Pharmacological treatment of IBS results in significant improvement in symptom severity, bowel function, and quality of life over time.

Among the evaluated therapies, 5-HT4 agonists, SSRIs, and TCAs demonstrated superior overall efficacy, emphasizing the importance of targeting both peripheral and central mechanisms. Antispasmodics provided moderate benefit, while μ-opioid receptor agonists showed limited efficacy and less favourable tolerability.

These findings reinforce the need for individualized, subtype-specific treatment strategies in IBS. A tailored combination of therapies appears to offer optimal long-term outcomes. Further randomized controlled studies with subtype-based stratification are warranted to strengthen the evidence base and guide clinical decision-making.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Disclosures

Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue.

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following:

Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work.

Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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