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Evaluation of the Efficacy of Rifaximin versus Mebeverine in the Treatment of Diarrhea-Predominant Irritable Bowel Syndrome

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ABSTRACT

Diarrhea-predominant irritable bowel syndrome (IBS-D) is a widespread functional gastrointestinal disease characterized by frequent abdominal pain and frequent looseness. Antispasmodics such as Mebeverine have proven effectiveness, whereas microbiota-targeted antibiotics such as Rifaximin could be more advantageous because of the effect on gut dysbiosis. **Objectives:** To compare the effectiveness of Rifaximin and Mebeverine to treat IBS-D through the treatment of diarrhea-predominant irritable bowel syndrome. **Methods:** This prospective comparative study was conducted at Khyber Teaching Hospital for six months from 1st January 2024 to 30th June 2024. Rifaximin or Mebeverine had been administered to the patients (n = 50 in each group). The collected data were the demographics, IBS Symptom Severity Score (IBS-SSS) at baseline, three months, and six months, and stool consistency, abdominal pain, bloating, and patient-reported satisfaction. The statistical analysis was performed with independent t-tests and chi-square tests; the p-value ≤ 0.050 was taken as significant. **Results:** Significantly greater improvements were observed in IBS-SSS in the Rifaximin group during three months (p=0.002) and six months (p<0.001) than in the Mebeverine group. Even though the Rifaximin group had better outcomes on categorical outcomes, such as stool normalization and first-line resolution of symptoms, most of them were not statistically significant. **Conclusions:** Rifaximin produced much improved symptomatic improvement as compared to Mebeverine in patients with IBS-D. The findings substantiate its use as a better treatment option clinically.

INTRODUCTION

Irritable bowel syndrome (IBS) is a common gastrointestinal disease, which is defined by recurrent stomachache that is associated with an altered bowel movement without visible organic pathophysiology [1]. One of its subtypes is diarrhea-predominant irritable bowel syndrome (IBS-D), which constitutes approximately one-third of all IBS cases and has a considerable negative impact on the patient's everyday functioning and quality of life [2]. Globally, IBS has a prevalence of 8.8%, and it is even higher in Western countries. The prevalence of IBS-D is 9.6% in Asia [3]. The pathophysiology of IBS-D remains complex and unclear, despite the disease having a high prevalence rate. Some of the hypothesized causes include modified gut motility, visceral hypersensitivity, low-grade gut biota inflammation, and gut microbiota dysbiosis [4-6]. One of the musculotropic antispasmodic agents, Mebeverine, has been commonly used in the symptomatic treatment of IBS, especially its capacity to relieve abdominal cramps and pain by relaxing intestinal smooth muscle with no effect on normal peristalsis [7]. Its impact on stool frequency and consistency is, however, restricted particularly in IBS-D patients [8]. Contrastingly, the minimally absorbed oral antibiotic, Rifaximin, has demonstrated good outcomes in changing the gut

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microbiota and decreasing bloating and diarrhea symptoms in IBS-D [9]. Clinical trials demonstrated significant symptom improvement in IBS-D patients treated with Rifaximin, with persistent effects beyond the treatment period [10, 11]. Another review by Almonajjed et al. further supported Rifaximin's efficacy and safety, emphasizing its potential as a microbiota-targeted therapy for IBS-D [12]. Recent guidelines, including those by the American College of Gastroenterology (ACG), now recognize Rifaximin as a treatment option for IBS-D, especially in patients with prominent bloating and diarrhea who fail to respond to dietary and lifestyle modifications [9]. However, in the population of Peshawar, direct comparisons between Rifaximin and traditional antispasmodics, such as mebeverine, remain limited. Most studies focus on placebo-controlled trials, creating a gap in evidence for head-to-head therapeutic efficacy, especially in low- and middle-income countries where both medications are widely available [13, 14]. Diarrhea-predominant irritable bowel syndrome (IBS-D) has proved to be a problem clinically because most of the patients show recurrent symptoms with the use of standard antispasmodic treatment like Mebeverine. It has been suggested that gut dysbiosis and overgrowth with small intestinal bacteria could be an important part of the pathophysiology of IBS-D, which justifies the use of non-systemic antibiotics like Rifaximin to relieve the symptoms and prevent relapse.

Nevertheless, this study has little comparative data available in the real world about our population, especially on the relative efficacy and clinical outcomes of Rifaximin to Mebeverine in regular clinical practice. This study aimed to compare the effectiveness of Rifaximin and Mebeverine to treat IBS-D through the treatment of diarrhea-predominant irritable bowel syndrome.

METHODS

This prospective comparative study was conducted in the Department of Medicine at Khyber Teaching Hospital (KTH), Peshawar, for six months between 1st January 2024 and 30th June 2024. The Institutional Research and Ethical Review Board (IREB) of Khyber Medical College (KMC), Peshawar, evaluated and ethically approved this study, and IREB approval number R/32/DME/KMC. The calculation of the sample size was performed using Open Epi, based on the IBS-D clinical response to Rifaximin, which has been reported in about 70-80% of patients [15], and the response to Mebeverine was 23-96% [7]. In the current research, the conservative effect estimate was taken, where the improvement of symptoms was expected to be 75% in the Rifaximin group (p1) and 55% in the Mebeverine group (p2), with the absolute difference of 20%. The confidence level was 95%, statistical power 80%, and allocation ratio 1:1. Based on these parameters, the required minimum sample size was determined to be 45 participants per group. The sample size was inflated and rounded to 50 patients per group to compensate for potential attrition and missing follow-up data (which was expected to be 8-10%), resulting in a total study sample of 100 patients. Participants who missed follow-up visits were not included in the final analysis. Patient data, covering the completion of all follow-ups, were analyzed according to protocol. The missing data were not imputed. The primary analysis (per-protocol analysis) included participants who attended all follow-up visits. Patients who did not attend follow-ups or those who stopped treatment were also registered, and causes of attrition were noted. The missing data were not imputed. The sensitivity analyses were taken into consideration to evaluate how the absence of data may influence the studies. Patients with inclusion criteria were recruited through a non-probability consecutive sampling technique. Patients were recruited during the presentation and followed during the course of treatment. Participants aged 18-65 years of age, with a known diagnosis of diarrhea-predominant IBS according to the Rome IV criteria, and either being prescribed Rifaximin (550mg three times a day over 14 days) or Mebeverine (135mg three times a day over 4 weeks). Each subject was to undergo baseline testing and two or more follow-up visits. Patients were not eligible when they showed alarm features like rectal bleeding, unexplained weight loss, or anemia, known inflammatory bowel disease, celiac disease, or colorectal malignancy, when pregnant or lactating, or when they had been taking antibiotics or probiotics within four weeks of enrolment. Individuals who failed to do a follow-up assessment were also eliminated. All the participants had signed a written informed consent before joining the study. The objectives, procedures, possible benefits, and risks of the study were communicated to the participants. The study, by nature, ensured the protection of patient data in terms of confidentiality and anonymity. Data have been collected through the use of a structured data collection form, which contained demographic data, clinical presentation, baseline severity of the symptoms, treatment regimen, and follow-up evaluation. The main measure was a decrease in symptoms, which was assessed by the Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS) [16]. The baseline, 3-month, and 6-month IBS-SSS were performed at the time of clinical follow-up visits conducted by trained clinical staff. Other variables such as stool consistency, frequency of abdominal pain, bloating, and patient satisfaction with treatment were also noted at every follow-up.

Statistical Package of the Social Sciences (SPSS) version 26.0 was used to enter and analyze the data. Age and 'IBS

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Symptom Severity Score (IBS-SSS)' were quantitative variables that were expressed as a mean with standard deviation (SD). The Shapiro-Wilk normality test was applied to the distribution of the continuous variables before comparison. Between-group comparisons were conducted using the independent samples t-test to compare normally distributed variables. Categorical variables, such as gender, baseline symptoms, stool characteristics, and clinical response outcomes, were summarized as frequencies and percentages and compared with the Chi-square test. Within-group paired comparison and between-group comparisons of mean scores of IBS-SSS at each follow-up were used to determine the change in scores over follow-up. Independent t-tests and chi-square tests were used to compare baseline demographic and clinical data (age, gender, IBS-SSS, and presenting symptoms) between groups to ensure comparability and support outcome analysis between groups. Effect estimates were provided in terms of mean difference and proportion difference, and 95% confidence intervals. All analyses were regarded as statistically significant with a p-value ≤0.050.

RESULTS

The demographics of the study participants are presented below. The average age of the patients of the Mebeverine group stood at 36.7 ± 8.9 years, and that of Rifaximin was at 35.2 ± 9.6 years. The ages of the two groups did not differ significantly, as demonstrated by the fact that there was no statistically significant difference between them (p=0.419). In terms of gender, 26 (52%) men and 24 (48%) women were in the Rifaximin group. Also, the gender distributions of the groups could not be significantly different (p=0.841) (Table 1).

Table 1: Demographic Characteristics of Study Participants (n=100)

Variables	Rifaximin Group (n=50)	Mebeverine Group (n=50)	p-value	w-value
Age				
Years, Mean ± SD	35.2 ± 9.6	36.7 ± 8.9	0.419	0.419
Gender				
Male	26 (52%)	28 (56%)	0.841	–
Female	24 (48%)	22 (44%)		

The most prevalent presenting symptom at baseline was abdominal pain in both groups, which was then succeeded by bloating, increased stool frequency, and urgency. All the symptoms occurred equally commonly in both the Rifaximin and Mebeverine groups, and no statistically significant differences were found (Table 2).

Table 2: Clinical Presentation at Baseline of the Study Participants (n=100)

Variables	Rifaximin (n=50)	Mebeverine (n=50)	Risk Difference	95% CI	p-value
Normal Stool Consistency	38 (76%)	29 (58%)	18%	−0.1 to 36.1	0.088
Abdominal Pain Improved	40 (80%)	33 (66%)	14%	−5.0 to 33.0	0.176
Bloating Resolved/Reduced	37 (74%)	31 (62%)	12%	−6.3 to 30.3	0.283
Overall Patient Satisfaction	41 (82%)	32 (64%)	18%	−0.1 to 36.1	0.071
Symptom Improvement (IBS-SSS ≥50%)	43 (86%)	34 (68%)	18%	1.9 to 34.1	0.057

At baseline, the IBS-SSS scores of the two groups were similar, showing no significant difference at the beginning of the treatment. Paired comparisons within-group revealed a reduction in IBS-SSS between baseline and 3 months, and between baseline and 6 months significant in both groups. Nevertheless, at 3-month and 6-month follow-ups, the patients under the Rifaximin group showed much greater improvement in IBS-SSS than the patients under the Mebeverine group, which confirmed better symptomatic efficacy (Table 3).

Table 3: Baseline and Follow-Up IBS Symptom Severity Score (IBS-SSS) of the Study Participants (n=100)

Time Point	Rifaximin Group (Mean ± SD)	Mebeverine Group (Mean ± SD)	Between-Group p-value	Shapiro-Wilk W (p-value)	Within-Group Mean Difference (95% CI)	Within-Group p-value
Baseline	325.4 ± 45.6	328.7 ± 43.2	0.720†	0.98 (0.340)	–	–
3 Months	215.3 ± 40.2	245.6 ± 38.5	0.002*	0.97 (0.280)	Rifaximin: −110.1 (92.5–127.7) Mebeverine: −83.1 (65.4–100.8)	<0.001
6 Months	165.7 ± 32.8	198.4 ± 35.1	<0.001*	0.96 (0.310)	Rifaximin: −159.7 (141.8–177.6) Mebeverine: −130.3 (112.4–148.2)	<0.001

By the 6th month, a higher proportion of patients in the Rifaximin group experienced regulation of stool consistency, improvement in abdominal pain, and reduction in bloating compared to the Mebeverine group; however, these differences did not reach statistical significance. Similarly, greater overall patient satisfaction and clinically meaningful symptom improvement (defined as ≥50% reduction in IBS-SSS) were observed in the Rifaximin group, but the differences between groups remained statistically nonsignificant (Table 4).

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Table 4: Stool Consistency and Symptom Improvement of the study Participants at Six Months (n=100)

Variables	Rifaximin (n=50)	Mebeverine (n=50)	Risk Difference	95% CI	p-value
Normal Stool Consistency	38 (76%)	29 (58%)	18%	−0.1 to 36.1	0.080
Abdominal Pain Improved	40 (80%)	33 (66%)	14%	−5.0 to 33.0	0.176
Bloating Resolved/Reduced	37 (74%)	31 (62%)	12%	−6.3 to 30.3	0.283
Overall Patient Satisfaction	41 (82%)	32 (64%)	18%	−0.1 to 36.1	0.071
Symptom Improvement (≥50% IBS-SSS)	43 (86%)	34 (68%)	18%	1.9 to 34.1	0.057

At three months, the mean IBS-SSS score had reduced significantly in the Rifaximin group compared to the Mebeverine group (p=0.002), and at six months, this difference had risen further (p<0.001). At six months, patients receiving Rifaximin were more likely to have normal stool consistency, overall patient satisfaction, and ≥50% symptom improvement in IBS-SSS (Table 5).

Table 5: Effect Estimates of Rifaximin versus Mebeverine at Follow-Up

Outcomes	Time Point	Rifaximin (n=50)	Mebeverine (n=50)	Effect Estimate	95% Confidence Interval	p-value	Shapiro-Wilk W, (p-value)
IBS-SSS (Mean ± SD)	3 Months	215.3 ± 40.2	245.6 ± 38.5	Mean Difference = −30.3	Mean Difference = −30.3	0.002	0.97 (0.280)
IBS-SSS (Mean ± SD)	6 Months	165.7 ± 32.8	198.4 ± 35.1	Mean Difference = −32.7	Mean Difference = −32.7	<0.001	0.96 (0.310)
Normal Stool Consistency, n (%)	6 Months	38 (76%)	29 (58%)	Risk Difference = 18%	Risk Difference = 18%	0.088	—
Abdominal Pain Improved, n (%)	6 Months	40 (80%)	33 (66%)	Risk Difference = 14%	Risk Difference = 14%	0.176	—
Bloating resolved/reduced, n (%)	6 Months	37 (74%)	31 (62%)	Risk Difference = 12%	Risk Difference = 12%	0.283	—
Overall Patient Satisfaction, n (%)	6 Months	41 (82%)	32 (64%)	Risk Difference = 18%	Risk Difference = 18%	0.071	—
Symptom Improvement (≥50% IBS-SSS), n (%)	6 Months	43 (86%)	34 (68%)	Risk Difference = 18%	Risk Difference = 18%	0.057	—

DISCUSSION

The present study of Rifaximin and Mebeverine in treating IBS-D found significantly more improvements in IBS-SSS scores at 3 months and 6 months in the Rifaximin group and a tendency to regularize stool consistency, relieve symptoms, and improve patient satisfaction. The findings are in agreement with the current literature that validates the use of Rifaximin in the treatment of IBS-D. The results of a study by Black *et al.* and Karki *et al.* indicated that Rifaximin was significantly better than placebo in reducing global IBS symptoms and abdominal distension, promoting its safety and efficacy in the management of IBS [17, 18]. These findings are consistent with the present study, which markedly reduced symptom alleviation by six months (p<0.0001), which supports the strong effect of Rifaximin. In a pilot study by Mokhtare et al. short-course Rifaximin (2,200 mg/day during 10 days) in moderate and severe cases of IBS D patients generated significant outcomes on abdominal symptoms and quality of life, and the rates of symptom relief were similar to the present study 6 6-month results (composite abdominal symptom relief around 56%) [10]. In the Europe-based MMX® rifamycin SV formulation trial, relief of pain and stool consistency was significantly higher during the first week and continued to improve into the subsequent months with an improved response rate over placebo with OR =3.3 and p=0.0066 (600 mg bid) [19]. These baseline responses are similar to our improved symptoms at 3 months IBS SSS (p=0.0002). Several trials have identified the distinctive character of Rifaximin in modulating gut microbiota and corresponding mucosal interaction without significant absorption into the system, crediting its anti-bloating and stool-normalizing impact on this specific activity [20-22]. Conversely, recent RCTs and reviews highlight that despite antispasmodics such as Mebeverine alleviating abdominal cramps, their symptom alleviation in IBS D worldwide is not particularly large, and can be no better than that of a placebo [23, 24]. This difference is consistent with the results of the present study: although Mebeverine had certain effects (IBS SSS ≥50% in 68%), it had much less potent ones as compared with Rifaximin. New developments in the re-treatment guidelines affirm that there are specific groups of patients who respond repeatedly to Rifaximin even when the disease recurs during months, and this is more evidence in support of its use beyond a single course, particularly in the IBS D phenotype [9, 21]. Prior to six months, patients treated with Rifaximin were more likely to have improved outcomes in stool consistency, abdominal pain management, bloating alleviation, general patient satisfaction, and clinically significant improvement in symptoms (IBS-SSS ≥50) than those treated with Mebeverine. These differences were not found to be statistically significant, but the overall direction of the improvement was positive, which is an indication of a beneficial effect of Rifaximin. These results must be viewed with caution, bearing in mind that although such results provide positive trends, more research with bigger

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sample sizes might be required to establish statistical significance and reinforce the findings of such clinical advantages. Although the results were not found statistically significant in some cases, the effect estimates are large enough to draw a clinical interpretation that Rifaximin has a statistically significant effect compared to Mebeverine on IBS-D symptoms. An example is that a greater percentage of 18 patients reported 50% symptom-improvement, and there were trends of improvement in stool consistency and patient satisfaction. These results justify the clinical significance of Rifaximin and indicate that the clinical effect of the treatment may be useful even when the statistical significance is not achieved to make treatment decisions. Lacy *et al.* found that treatment-free periods and the overall cost of health of IBS D patients on Rifaximin were longer and cheaper than on Eluxadoline, indicating the long-term benefits and the economic potential of use of the antibiotic-based therapy in the management of the disease [25]. Although Eluxadoline is pharmacologically different, the overall lesson is in favour of the long-term effect of Rifaximin, just like the present study's long-term six-month scores and positive patient satisfaction scores. Other researchers in SIBO-positive patients with IBS also reported a 72% improvement in stool consistency and a 60% reduction of pain, which is once again a solid argument in favor of Rifaximin dominance in symptom areas where antispasmodics usually do not impact the condition significantly [26]. Together with the growing body of clinical evidence, the present study will add more weight to the current body of knowledge showing that Rifaximin is more clinically beneficial than conventional antispasmodics like Mebeverine in the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Rifaximin demonstrated better improvement on global symptoms of IBS, improved stool consistency normalization, and increased patient satisfaction in the present study. These results are consistent with recent randomized trials and observational, real-world studies, which have reported consistent findings of Rifaximin effectiveness as a targeted, non-systemic antibiotic to control symptoms in IBS-D. The direction and magnitude of the improvement in the various assessment points further provide the strength of it as a powerful therapeutic agent in standard clinical practice, particularly in the setting where Rifaximin and Mebeverine are frequently prescribed.

This is a single-centre study in the Khyber Teaching Hospital, which might not be generalizable to other populations. The study had a relatively small sample size (n=50 in each group), which could have prevented the statistically significant clinical outcomes such as stool normalization and patient satisfaction against a statistically significant. The long-term durability past six months and retreatment efficacy cannot be determined by the six months follow up. The non-probability consecutive sampling also brings about the selection bias aspect, and the per-protocol analysis could overestimate the effects of treatment because non-completers were omitted. There was no blinding, and this may have created observer bias in the symptom evaluation. The literature on predictors of response should be further investigated in future research to determine which patients respond to Rifaximin most with the use of IBS-D. The mode of action of the antibiotic could be explained by mechanistic studies of the shift in the gut microbiota.

CONCLUSIONS

This study found that Rifaximin is far more effective than Mebeverine in reducing the severity of symptoms in patients with diarrhea-predominant irritable bowel syndrome (IBS-D). The improvement of the results is observed as early as 3 months and lasts for six months of follow-up. Although both treatments were well tolerated, Rifaximin was more effective in alleviating symptoms, normalization of stool, and patient satisfaction. These findings give it some credibility as a more effective treatment option to use in clinical settings for the treatment of IBS-D.

Authors' Contribution

Conceptualization: SA
Methodology: MZ, RG, YA, FA
Formal analysis: SA, MZ, NI, YA
Writing and Drafting: SA, NI
Review and Editing: SA, MZ, NI, RG, YA, FA

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

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