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ORIGINAL ARTICLE

Efficacy of Rifaximin and Probiotics in the Treatment of Small Intestinal Bacterial Overgrowth When Used Concomitantly or Sequentially

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Abstract

Background: With the prevalence of small intestinal bacterial overgrowth (SIBO) on the rise, treatment has become of paramount importance for patients suffering from this disease. Antibiotics used to treat SIBO include rifaximin, ciprofloxacin, metronidazole, and neomycin. Probiotics reinforce the small intestine's internal microbiota and help cure many diseases.

Aim: In this study, we aimed to evaluate the efficacy of rifaximin together with a multi-strain probiotic in patients with SIBO. In a multi-center open-labeled prospective study, recruited patients were randomized into two groups treated with rifaximin as a base and probiotics that varied in the timing of initiation (concomitantly; group A or sequentially; group B) for treating the clinical manifestations of the disease. The primary endpoint evaluated the clinical response to treatment, and the secondary endpoint evaluated the eradication rates.

Results: Eradication rates revealed that 69.8% of the patients in group A and 74.8% of the patients in group B were successfully treated and returned with negative lactulose hydrogen breath test results. Clinical response rates were divided into partial and complete responders; partial responders were reported in 23.3% and 26.6% of patients in groups A and B, respectively, and complete responders were reported in 62.7% and 59.5% of patients in groups A and B, respectively. Overall, partial or complete responders' combined rate comprised 86% and 86.2% in groups A and B, respectively. There were no reported side effects by patients treated with rifaximin and the multi-strain probiotic for both protocols.

Conclusion: The addition of probiotics, both concomitantly or sequentially, to the treatment regimen acts synergistically with rifaximin to improve outcomes. According to our study, there were no statistical differences between the two regimens. In conclusion, the extension of probiotics in the sequential regimen provided a more prolonged clinical response rate.

Keywords: SIBO, Small intestinal bacterial overgrowth, lactulose hydrogen breath test, LHBT, rifaximin, probiotics.

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INTRODUCTION

Small intestinal bacterial overgrowth (SIBO) is a common sequel of maldigestion and malabsorption. The prevalence of the disease is not fully established but is estimated to range from 0 to 20% among healthy individuals [1]. The most common risk factors include disturbances in the small bowel anatomy and motility, as happens in diabetic enteropathy, underlying connective tissue disease, chronic opiate use, diverticula, small bowel adhesions, and blind loops. It occurs when there is an abnormal migration of bacteria from one site of the small intestine to another, leading to an increase in the overall innate microbiota population in this part where they commonly should not be found. Therefore, the resulting change in the gut microbiome is the main trigger for the disease's development. The human gut is inhabited by 10^{14} microorganisms, including bacterial cells, which is roughly 10 times higher than the number of cells in the human body [2], and recently a new estimate indicated a ratio of 1:1 [3].

Although recent studies show a one-to-one ratio between resident microbes and human cells [3], The human gut microbiota is diverse and composed of many organisms, including bacteria, fungi, and viruses. Bacteria, however, compromise the most significant portion of this microbiome. The small intestinal microbiota is comprised mainly of Gram-positive and aerobic bacteria. In contrast, the large intestinal microbiota contains predominantly Gram-negative and anaerobic bacteria, including Bacteroidetes and Firmicutes. At the same time, *Actinobacteria, Fusobacteria, Verucomicrobia, and Cyanobacteria* are also present, albeit in a smaller proportion [4].

SIBO is associated with a wide variety of gastrointestinal manifestations with diverse clinical presentations and substantial overlap with other heterogeneous diagnoses, like irritable bowel syndrome (IBS). The gold standard for diagnosing SIBO would be a quantitative culture of aspirated small bowel fluid. This method is limited, however, by the high cost of this invasive procedure, the varying nature of bacterial concentrations throughout the small bowel in different individuals, the inability to culture a high percentage of the bacteria colonizing the gut, and the fact that possible contamination by oropharyngeal flora during the collection of the sample could alter the result. [5-6]. Breath tests are simple, non-invasive methods for diagnosing bacterial overgrowth. The diagnostic yield of hydrogen breath tests in SIBO largely depends on the type of substrate used. A rise in the hydrogen level of $\geq$ 20 ppm (parts per million) after 90 min during glucose or lactulose breath testing is usually considered a positive result. Compared to small bowel fluid culture, glucose hydrogen breath testing (GHBT) has been shown to be more specific but less sensitive, yielding a higher rate of false negatives and a lower rate of false positives.

The specificity and sensitivity of the GHBT range anywhere between 78%-97% and 15.7%-62%, respectively. In contrast, lactulose testing is more sensitive but less specific, with a reported sensitivity of 31%–68% and specificity of 65%–97.9% [7]. It is worth noting that GHBT is often falsely negative among those with distal SIBO, as glucose is completely reabsorbed in the proximal small bowel and often does not reach the site of bacterial overgrowth. Similarly, in patients with fast gut transit, hydrogen breath tests often yield false-positives due to early substrate delivery to the colon, increasing the chance of a false-positive result. Combining other microbiome approaches, including

cultivation methods, with a metagenomics study allows for more accurate and convincing findings. Recent studies have successfully used this combination to identify new bacterial strains [8].

The usual antibiotics for treating SIBO are tetracyclines, fluoroquinolones, metronidazole, and co-trimoxazole. Rifaximin has emerged lately as the preferred agent among clinicians for SIBO management. Rifaximin is a synthetic rifamycin derivative with an additional pyrimidazole ring, which renders it nonabsorbable, achieving low gastrointestinal absorption (<0.4%) while retaining good antibacterial activity across a wide spectrum, acting against Gram-positive and Gram-negative aerobic and anaerobic bacteria. It inhibits bacterial RNA synthesis by binding to the beta subunit of bacterial DNA-dependent RNA polymerase. The preferred use of rifaximin stems from its reduced toxicity profile and its utility in irritable bowel syndrome, a condition with significant clinical overlap with SIBO [9-11]. Furthermore, rifaximin has the potential to induce a positive modulation of the gut microbiota [12-15]. It preserves intestinal microbiota diversity and stimulates the growth of beneficial bacterial species, including *Lactobacilli* and *Bifidobacteria,* while keeping the overall composition of the gut microbial community stable. It also has cytoprotective properties and reduces ammonia-producing colonic bacteria. This makes rifaximin a non-conventional "Eubiotic" agent.

The eradication rate of SIBO also seems to be dose-related. A previous study reported a dose-dependent eradication rate where higher doses of rifaximin were associated with a higher eradication rate [16]. Additionally, the effectiveness of rifaximin was tested against antibiotics with a noticeable difference. In a recent meta-analysis aimed at investigating the effectiveness of rifaximin in bacterial overgrowth, the efficacy of rifaximin in eradicating SIBO was 64% compared to 41% with other systemic antibiotics, including tetracyclines and metronidazole [17]. Another meta-analysis looking at eight studies showed that the effectiveness of rifaximin in the normalization rate of breath testing was 49.5% [18].

Probiotics may also have a role in the treatment of SIBO by reducing the bacterial load and alleviating symptoms as concluded from a recent meta-analysis [19]. Rifaximin and the probiotic (*Lactobacillus casei)* when used together led to a pronounced improvement in patient symptoms as compared to antibiotics when used alone as shown from a recent study [20]. The selection of the proper probiotic is important though because not all available probiotics have the same effect on SIBO. The beneficial Lactobacilli and Bifidobacterium classified as beneficial bacteria seem to be reasonably effective in this regard. A study that evaluated the effects of adding probiotics to the treatment regimen on the hydrogen breath test however, had revealed methane positive breath tests which casted some doubt on the use of probiotics in SIBO [21]. In the study, patients who used probiotics had more frequent positive lactulose hydrogen breath tests than non-users. This suggests that probiotics may stimulate the overgrowth of methane producing bacteria. These controversial results indicate a need for large scale studies that would negate or verify this concept. Hence, this study was designed to further investigate how probiotics affect SIBO management.

MATERIALS AND METHODS

Aim of the study: a randomized open-label study to evaluate the efficacy of rifaximin

together with a multi-strain probiotic in eradicating small intestinal bacterial overgrowth (SIBO) when used concomitantly or sequentially and in treating the clinical manifestations of the disease.

Primary endpoint: The clinical response and the safety profile to the treatment regimen as evaluated at 2, 4, and 8 weeks from initiating therapy.

Secondary endpoint: The eradication rate of SIBO as concluded from the lactulose hydrogen breath test (LHBT) done at four and eight weeks from starting treatment.

Patient selection

Inclusion criteria

Consenting patients 18-80 years of age who complained primarily of abdominal bloating, distention, flatulence, and postprandial distress or pain with or without alteration of bowel motion for the past 12 weeks either continuously, most of the time, or for at least 3 days per week for the same period. The patient would be considered for evaluation whenever the patient had abdominal bloating and flatulence, which all patients should experience, and the other symptoms may or may not be present simultaneously. The symptoms should not be attributed to a known gastrointestinal disease, physical illness, mental stress, or food intolerance. The diagnosis of SIBO was established by the lactulose hydrogen breath test done over three hours after proper preparation, at time of enrollment to the study and at four and eight weeks post enrollment. Patients eligible for enrollment presented a surge of hydrogen production in the early phases of the examination.

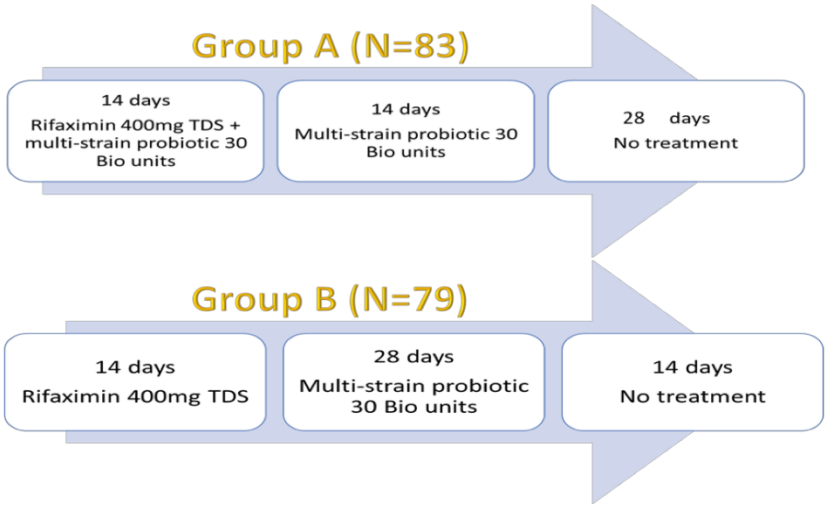
Exclusion criteria

- All patients who suffered from any known gastrointestinal disease except for irritable bowel syndrome with predominant diarrhea.
- Patients with chronic diseases (neurogenic, kidney, liver, or cardiocirculatory) who were not compensated and were not stable on treatment.
- Patients who were known to be allergic to rifamycin group drugs.
- Patients who had any type of cancer.
- Patients who were on anti-flatulence agents or who were using medications that could lead to abdominal distention and flatulence.

Patient disposal

Patients were randomly assigned to one of two pathways: (Figure 1). Group A (concomitant regimen): rifaximin alpha 400 mg three times daily, and a multi-strain probiotic (Proflora intense 30 billion CFUs) was taken once daily concomitantly for 14 days, thereafter rifaximin alpha was stopped, but the probiotic was continued independently for another 14 days. Clinical evaluation was made by the patients themselves using a visual analog scale (VAS) constructed to cover the main features of the disease, namely: bloating; abdominal distention; abdominal pain; and change of bowel habit from the state of diarrhea or constipation to normal. The eradication rate of SIBO was made through the evaluation of a three-hour lactulose hydrogen breath test for included patients. In group A, this test was performed at weeks 4 and 8- and 4-weeks post-study. On the other hand, this test was conducted on group B at weeks 4, 8 and two weeks following the completion of treatment.

Figure 1. Patient plan of management for the concomitant (group A) and the sequential (group B) therapeutic regimens



Group B (sequential regimen): Rifaximin alpha 400 mg three times daily alone for 14 days, then the multi-strain probiotic (Proflora intense 30 billion CFUs) was started sequentially and was taken once daily for 28 days. Clinical evaluation was made by the patients themselves using the same visual analog scale (VAS) used for group A. The eradication rate of SIBO was concluded from the evaluation of a three-hour lactulose hydrogen breath test. In group A, this test was performed at weeks 4, 8, and 4 following the end of treatment.. On the other hand, this test was conducted on group B at weeks 4, 8, and two following the completion of the duration of treatment.

The duration of recruitment for the study: 12 months

Statistical analysis

To analyze the data, the Statistical Package for Social Sciences (SPSS) software version 26 was used. Data normality was checked using Shapiro-Wilk test. Descriptive analysis was done for categorical data using percentages, while for the continuous data the mean and the standard deviation (SD) were used when appropriate. Chi-Square/Fisher exact test was used to assess the differences between the control and intervention groups for categorical variables, and an independent sample t-test was used for continuous data. A paired t-test was conducted to find out if there was a difference between the two groups. A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

Demographic details:

One hundred sixty-two patients were enrolled in the study over twelve months. They were randomly assigned to each arm of the study as 83 patients in group "A" and 79 patients in group "B". The mean age was 39 years and 37 years for groups A and B, respectively, and the mean weight was 82 and 77 kg for patients in the groups with no differences noted. Females prevailed in both groups at a ratio of 1.6:1 for group A, and 1.9:1 for group B. Most enrolled patients were local citizens from the UAE (Table 1).

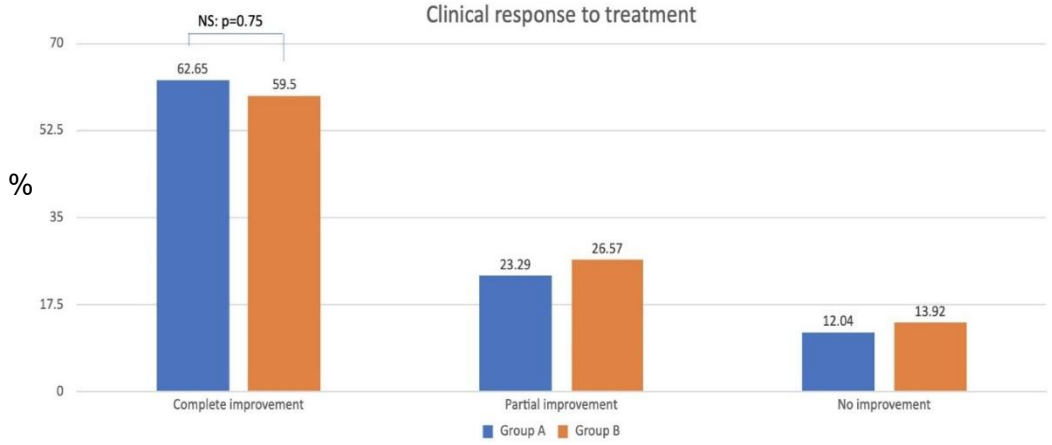
Table 1. Demographic details of participants

	A (N=83)	B (N=79)
N	83	79
Age	39 (24-58)	37 (21-55)
Females : Males	51:32 (1.6:1)	52:28 (1.9:1)
Weight	82 (52-96)	77 (56-88)
UAE citizen: Expats	56:27 (2.1:1)	52:27 (1.9:1)

Clinical response:

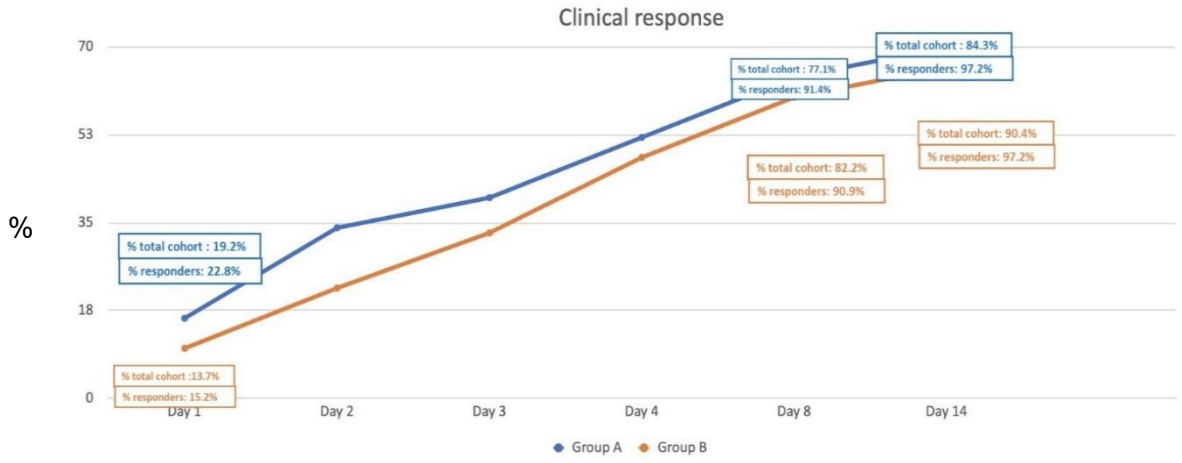
The primary endpoint for the patients in both groups was a complete resolution of all symptoms at week 8, and that occurred in 62.7% and 59.5% of treated patients in groups A and B, respectively. Partial responders were defined as patients who had improvement of one, two, or three symptoms, but the main complaint of bloating and flatulence persisted. This was reported by another 23.3% and 26.56% in groups A and B, while 12.0% in group A and 13.9% in group B did not respond to treatment (Figure 2).

Figure 2. Clinical response to treatment at week 8



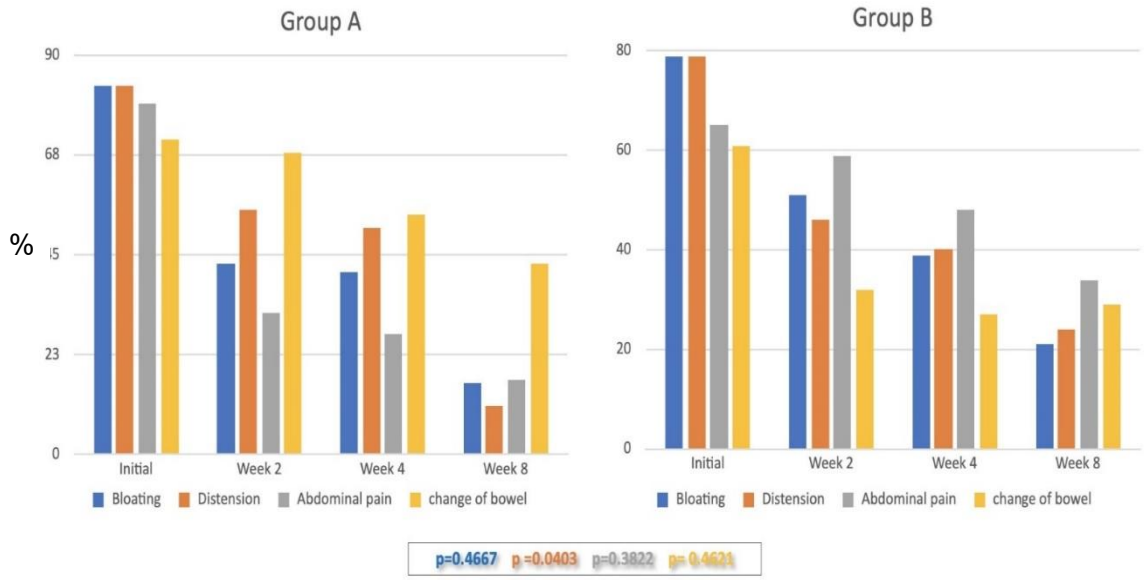
At the end of rifaximin treatment (400 mg of rifaximin alpha TDS for 14 days), it appeared that the clinical responders' percentages in both groups, complete and partial, were 95.9% in group A and 97.1% in group B, representing 84.3% of the whole cohort for group A and 83.5% for group B. Response, however, for both groups started as early as the first day of treatment with few patients experiencing a change in their clinical condition from baseline (19.2% vs. 13.7% for groups A and B, respectively). Most of the patients who experienced a good response appeared to have achieved that after the first week of treatment (77.1% for group A and 82.2% for group B, respectively) (Figure 3).

Figure 3. Clinical response over the first two weeks of the study.



For patient-reported outcomes, flatulence was considered the main symptom in SIBO, diagnosed by this cohort's lactulose hydrogen breath test. Other symptoms reported included distention, abdominal pain, and alteration of bowel habits. Patients were instructed to report their response as per VAS (visual analog score) at weeks 2, 4, and 8. Flatulence, abdominal distention, and abdominal pain significantly improved over the treatment period for both groups. Alteration of bowel habits, however, revealed a remarkable improvement in group B that was less noted in group A (Figure 4).

Figure 4. Evaluation of symptoms by patients as established by VAS covering the four main symptoms of SIBO.



Eradication rate:

All patients in both groups had to undergo a repeat lactulose hydrogen breath test to evaluate the success of eradication at week 4 and week 8. The eradication rate for groups A and B was 72.5% and 70.1% at week 4, respectively. At week 8, however, the eradication rate was 69.8% for group A and 74.8% for group B (Figure 5).

Figure 5. Eradication rate after treatment as determined by lactulose hydrogen breathing test.

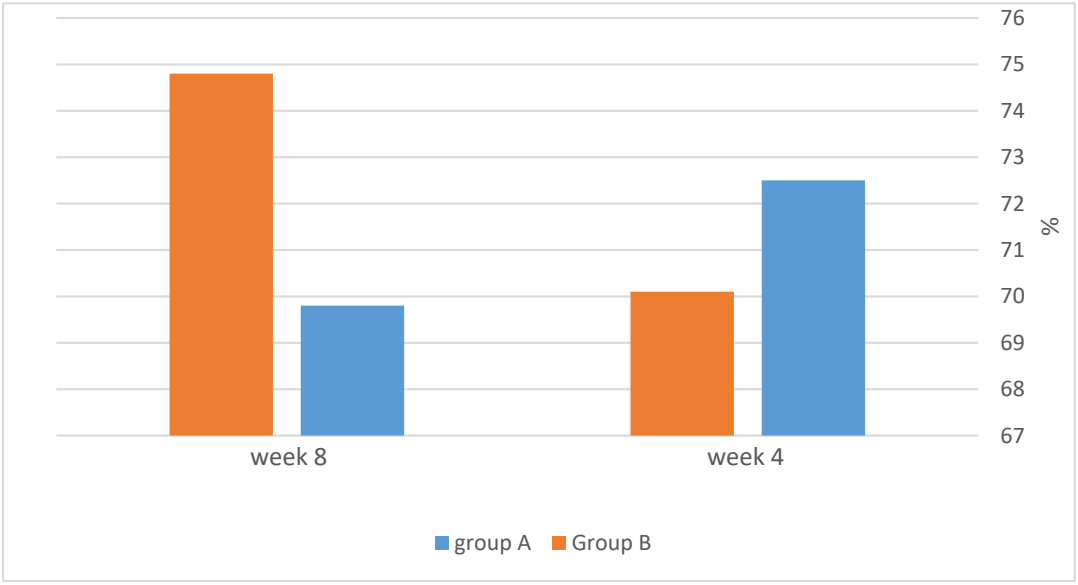


Figure 6. Correlation between eradication and clinical response for both groups.

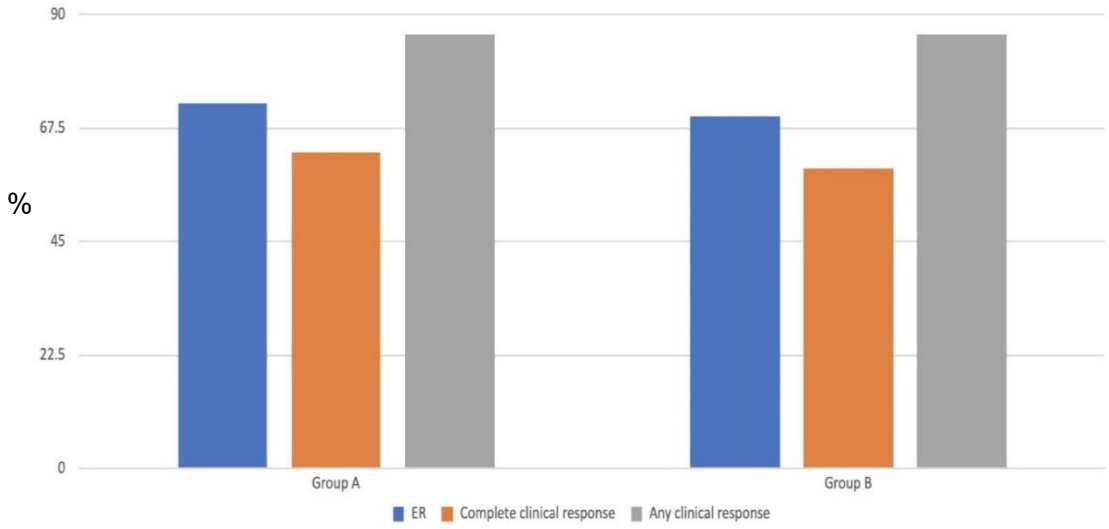
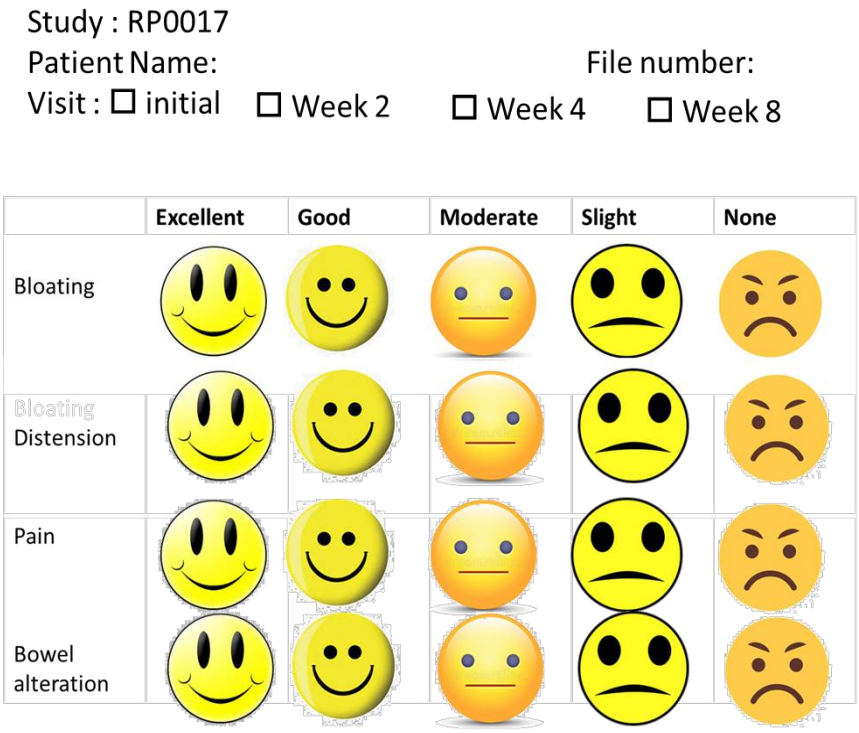


Figure 7. Patient Visual Analog Scale



For patients in group A, the eradication rate appeared to be higher than the overall clinical response for complete responders (69.8% eradication vs. 62.5% clinical response). The clinical evaluation was higher when partial responders were considered and added (86% clinical response vs. 69.8% eradication).

In group B the overall clinical response for complete responders was (74.5% eradication vs. 59.5% clinical) when partial responders were added, the overall assessment was (85.9% clinical vs. 74.5% eradication).

There were no reported side effects by any patient treated with rifaximin and the multi-strain probiotic for both protocols.

DISUSSION

At 4 weeks, our study showed comparable eradication rates in both groups of patients taking rifaximin and probiotics; 72.5% vs. 70.1% in groups A and B, respectively, which did not show a statistical preference for either ($p=0.4662$). Compared to previously reported data of rifaximin given alone at 70.8% [17]. However, our study showed additional improvement in the eradication rate after 8 weeks in group B; but not in group A. This suggests an advantage for extending the use of probiotics beyond rifaximin.

In clinical response rates, our study showed that patients in group A and group B had comparable but remarkable improvement in their VAS score from 80% to less than 20% in most symptoms. This effect becomes more evident with time, most apparent after one week. Similar to eradication rates, clinical data also suggest that the sequential start of probiotics with rifaximin might provide additional efficacy; this efficacy seems to sustain and last with time. Nonetheless, this outcome depended on subjective reported

data. These data were consistent with repeated assessments in the following weeks. Furthermore, given the relatively benign course of the disease, controlling the symptoms and improving the patients' experiences of the disease remains a priority treatment goal.

The effectiveness of rifaximin may be attributed to its ability to re-modulate the internal microbiota of the intestine by promoting the growth of beneficial bacterial species such as *Lactobacilli* and *Bifidobacteria,* while maintaining the overall composition of the gut microbial community stable. Rifaximin has also been found to lower the viability and virulence of the bacteria by reducing its adhesion to intestinal walls and the ammonia toxins produced by the bacteria [22]. Moreover, rifaximin has an excellent safety profile and a lack of drug interactions [23]. These benefits promote intestinal diversity and maintain a stable microbiota, allowing patients to progress clinically.

Clinical improvement of symptoms was noted significantly in all patients with SIBO except for changes in bowel habits. This may indicate a difference in the mechanism of these different symptoms or could be related to different types of microbiota contributing to each symptom.

Our study had limitations: Firstly, the open-label design prevented concealment of treatment allocation. We believe this probably had a minor effect on the results of this study, as both treatment groups received the same treatments but with different regimens. Moreover, our outcomes were assessed by either objective testing via LHBT or patient-reported symptoms by VAS, which reduced the chances of assessment bias. Secondly, our study did not have a placebo group, making it difficult to quantify the treatment effect of probiotics.

In summary, our study showed that when combined with rifaximin, probiotics might exert additional therapeutic benefits. Response rates seem better with early initiation of probiotics, pointing to a possible synergistic effect. These findings are interesting but require confirmation of the clinical effectiveness trial. The regimen of choice and type of probiotics will need to be determined by comparing a variety of regimens.

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فاعلية ريفاكسيمين والبروبيوتيك في علاج فرط نمو البكتيريا في الأمعاء الدقيقة عند استخدامها بشكل متزامن أو متتابع

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الملخص

الخلفية والأهداف: مع زيادة انتشار فرط نمو البكتيريا المعوية الدقيقة (SIBO) أصبح العلاج ذا أهمية قصوى للمرضى الذين يعانون من هذا المرض. تشمل المضادات الحيوية المستخدمة لعلاج فرط نمو البكتيريا في الأمعاء الدقيقة ريفاكسيمين وسيبروفلوكساسين وميترونيدازول ونيومايسين. تعمل البروبيوتيك على تقوية الجراثيم الداخلية للأمعاء الدقيقة وتساعد في علاج العديد من الأمراض.

وتهدف هذه الدراسة متعددة المراكز لتقييم فعالية ريفاكسيمين مع بروبيوتيك متعدد السلالات في مرضى فرط نمو البكتيريا في الأمعاء الدقيقة. ، تم اختيار المرضى المعينين عشوائيًا إلى مجموعتين تم علاجهم باستخدام ريفاكسيمين كقاعدة وبروبيوتيك التي اختلفت في توقيت البدء (بشكل متزامن ؛ المجموعة أ أو بالتتابع؛ المجموعة ب) لعلاج المظاهر السريرية لـ المرض. قيمت نقطة النهاية الأولية الاستجابة السريرية للعلاج، وقيمت نقطة النهاية الثانوية معدلات الاستئصال

منهجية الدراسة: تم تحليل كافة الحوادث العرضية المتعلقة بالأدوية المبلغ عنها ذاتيا للفترة الزمنية المذكورة أعلاه والبالغة 58 حاً من وصف الدواء، وصرفه حتى إعطائه للمريض. تم إجراء تحليل لمحتوى تلك وتتعلق تلك الحوادث بأخطاء في عملية إدارة الدواء بدء ا الحوادث بطريقه تفصيله للحصول على جميع المعلومات المتعلقة بالدراسة حيث تم ترميز البيانات وتحليلها باستخدام (SPSS النسخة 20.0).

النتائج: أظهرت معدلات الاستئصال أن 69.8٪ من المرضى في المجموعة (أ) و 74.8٪ من المرضى في المجموعة (ب) قد عولجوا بنجاح وعادوا بنتائج اختبار تنفس هيدروجين اللاكتولوز السلبية . تم تقسيم معدلات الاستجابة السريرية إلى مستجيبين جزئيين وكاملين. تم الإبلاغ عن المستجيبين الجزئيين في 23.3٪ و 26.6٪ من المرضى في المجموعتين A و B على التوالي، وتم الإبلاغ عن مستجيبين كاملين في 62.7٪ و 59.5٪ من المرضى في المجموعتين A و B على التوالي. بشكل عام ، بلغ المعدل المشترك للمستجيبين الجزئي أو الكامل 86٪ و 86.2٪ في المجموعتين A و B على التوالي. لم يتم الإبلاغ عن أي آثار جانبية من قبل المرضى الذين عولجوا باستخدام ريفاكسيمين وبروبيوتيك متعدد السلالات لكلا البروتوكولين.

الاستنتاجات: تعمل إضافة البروبيوتيك، بشكل متزامن أو متتابع، إلى نظام العلاج بشكل تآزري مع ريفاكسيمين لتحسين النتائج. وفقًا لدراستنا، لم تكن هناك فروق ذات دلالة إحصائية بين النظامين. في الختام، قدم تمديد البروبيوتيك في النظام المتسلسل معدل استجابة سريرية أطول.

الكلمات الدالة: فرط نمو البكتيريا في الأمعاء الدقيقة، اختبار التنفس بالهيدروجين اللاكتولوز، ريفاكسيمين، البروبيوتيك.