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The role of pharmaceutical care in the use of rifaximin for the treatment of diarrhea

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Abstract: the management of diarrhea represents a prevalent issue within the realm of healthcare. Rifaximin is recommended to treat traveler's diarrhea and irritable bowel syndrome. At the same time, it is important to rationally use an antimicrobial drug to prevent the development of antimicrobial resistance. Aim: to evaluate the role of pharmaceutical care in using rifaximin to treat diarrhea, based on a questionnaire. A questionnaire survey was done among 55 pharmacy professionals and 42 pharmacy visitors regarding the dispensing and use of rifaximin for diarrhea treatment. The survey of pharmacy visitors revealed that rifaximin was used for the treatment of small intestinal bacterial overgrowth syndrome (32 cases), traveler's diarrhea (7 cases), and irritable bowel syndrome with diarrhea (3 cases). Patients did not undergo stool culture before rifaximin prescription, which could have prevented antimicrobial resistance and ruled out other causes of diarrhea. It was found that 14% of respondents reported improvement the next day, while 83.3% reported improvement within three days. Pharmacists can educate visitors about the importance of completing the treatment course. Five percent of respondents reported nausea as an adverse reaction. Pharmacists dispensed rifaximin for the treatment of diarrhea in adults almost three times more often than in children. The tablet form of the drug was used in 94.5% of cases, while the oral suspension was used in 5.5% of cases. The majority of pharmacy visitors (89.0%) received rifaximin with a doctor's prescription, and 10.9% without a prescription, which emphasizes the importance of pharmaceutical care to prevent irrational use of the drug. The results of the study show that 92.7% of pharmacists provide recommendations on the safety of rifaximin use, and 78.2% recommend abstaining from alcohol during treatment. Only 21.8% of pharmacists warn about the possible staining of urine, which can cause concern for patients. The majority of pharmacists (89.1%) systematically ask women about possible pregnancy, which indicates their awareness of safe pharmacotherapy. Pharmacists also clarify the simultaneous use of rifaximin with other drugs: 32.7% ask about taking oral contraceptives, 7.3% – antiarrhythmic drugs, and 3.6% – warfarin. <mailto:https://meshb.nlm.nih.gov/record/ui?ui=D002648> Pharmacists can enhance the effectiveness of rifaximin treatment by preventing its uncontrolled use, emphasizing the importance of completing the treatment course and informing about possible adverse reactions. When providing pharmaceutical care to visitors taking rifaximin, pharmacists should educate them about potential changes in urine color. Additionally, pharmaceutical workers advise women taking oral contraceptives to use additional contraceptive methods while taking rifaximin.

Keywords: [Rifaximin](#); [Diarrhea](#); [Pharmaceutical Services](#); [Anti-Bacterial Agents](#); [Drug Resistance](#); [Bacterial](#).

Introduction

The pursuit of effective treatments for diarrhea constitutes a significant objective in the fields of medicine and pharmacy. Both experimental and clinical studies are evaluating the efficacy of rifaximin, a broad-spectrum antimicrobial agent, across various etiologies of diarrhea (Fan et al., 2022; Lacy et al., 2023). Rifaximin inhibits protein synthesis in bacteria by binding to the β -subunit of DNA-dependent RNA polymerase. It was shown that the drug also activates the pregnane X receptor, which contributes to the suppression of the transcriptional nuclear factor (NF)- κ B in inflammatory bowel diseases (Robertson and Nagalli, 2024). International and Ukrainian recommendations indicate that rifaximin is an effective treatment for traveler's diarrhea, irritable bowel syndrome, and hepatic encephalopathy (Tkach and Dorofiev, 2022; Patel et al., 2022). According to the results of a meta-analysis of seven studies involving nearly 1,000 patients, the drug has been shown to prevent the development of hepatic encephalopathy in individuals with a history of liver disease (Elmoursi et al., 2023). According to the results of another placebo-controlled, double-blind study, it was found that the use of rifaximin (500 mg per day, for 3 months) contributes to the reduction of endotoxemia and systemic inflammation (Patel et al., 2021). In a clinical study involving 78 patients, it was found that taking the drug for 14 days improves the quality of life for patients with irritable bowel syndrome with diarrhea. The authors of the study emphasize the importance of further study of the pharmacological properties of drugs (Zhuang et al., 2020). According to the results of a clinical study by B. E. Lacy et al., the use of rifaximin contributed to the reduction of abdominal pain, bloating, and diarrhea in patients with irritable bowel syndrome. (Lacy et al., 2023).

It has been proven that the drug is minimally absorbed when taken orally (<1%) and is not metabolized as it passes through the gastrointestinal tract (Picci et al., 2023). At the same time, it has been shown that rifaximin, in certain cases, induces CYP3A4, an enzyme responsible for the metabolism of 60% of drugs. In patients with liver cirrhosis, the absorption of rifaximin increases, which is accompanied by a higher risk of drug interactions

(Kawaratani et al., 2022). It is reported that drug can reduce the effectiveness of estrogen-containing oral contraceptives. Therefore, it is recommended to use additional methods of contraception during treatment with rifaximin. Rifaximin should not be taken concurrently with sorbents, as they may reduce its absorption (DrugBank Online). It has been shown that taking rifaximin may lead to urine discoloration (Robertson and Nagalli, 2024). The results of the clinical trial have demonstrated that the administration of the drug (550 mg twice daily for 6 months) was not associated with serious adverse reactions in patients. However, the drug adversely affected blood clotting test results (Aby et al., 2023). It has been demonstrated that the use of rifaximin may lead to the development of resistance in *Escherichia coli*, a bacterium that plays a crucial role in the pathogenesis of inflammatory bowel diseases. The mechanism of resistance is associated with changes in the genes of bacteria and the activity of efflux pumps [14]. Therefore, to prevent the emergence of bacterial resistance to rifaximin, it is important to use it rationally (Farrell 2013).

Aim

To evaluate the role of pharmaceutical care in using rifaximin to treat diarrhea, based on a questionnaire.

Materials and methods

In the investigation, a cohort of 55 individuals from the pharmaceutical domain were engaged: comprising managers (n=5), pharmacists (n=21), and pharmacy assistants (n=29). Such a sample is sufficient, as it includes representatives of various levels of professional activity in the pharmacy. As a result, the study covers a wide range of practical knowledge and experience, allowing for a comprehensive view of rifaximin dispensing and use practices. Moreover, such a sample reflects the real conditions of pharmaceutical care in different types of pharmacies, which increases the general validity and relevance of the obtained results. A questionnaire comprising 15 inquiries was formulated for pharmacy professionals, focusing on areas including recommending rifaximin for diarrhea and the dispensation criteria. A survey of 42 pharmacy visitors was also performed. The questionnaire consisted of 5 questions about the experience of using rifaximin. Participation in the survey was voluntary. Participants were guaranteed anonymity. The

data analysis of the study was performed using Microsoft Excel software.

Results

A survey of pharmacy visitors showed that they took rifaximin for the treatment of intestinal overgrowth syndrome (32 cases), traveler's diarrhea (7 cases), and irritable bowel syndrome with diarrhea (3 cases), which is shown in Figure 1.

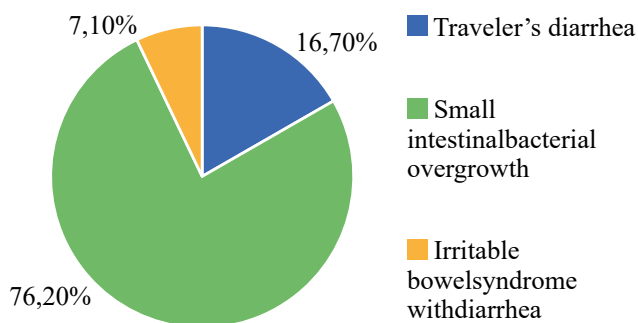


Figure 1. Conditions under which visitors to pharmacies used rifaximin

It was found that before rifaximin was prescribed to patients, stool culture was not performed to determine sensitivity to antibiotics. At the same time, culture helps to determine whether the antibiotic will be effective against the pathogen, helps to prevent antimicrobial resistance, and excludes other causes of diarrhea. The obtained results emphasize the importance of pharmaceutical care in prescribing rifaximin by doctors for treating diarrhea.

To the question «When did you feel the effect of rifaximin?» almost 14% of respondents replied that they noticed an improvement the next day, and 1 respondent found it difficult to answer. In comparison, the majority (83.3%) noticed improvement after 3 days of using the drug. The pharmacist can provide the visitor with information about the importance of adherence to the course of rifaximin treatment, which will help optimize the effectiveness of antimicrobial therapy.

During the study, 5.0% of respondents who visited pharmacies reported the occurrence of adverse reactions after using rifaximin. Most often, visitors noted the onset of nausea, which is a predicted dose-dependent reaction and is consistent with literature data (Robertson and Nagalli, 2024). The pharmacist can play an important role in monitoring and preventing adverse reactions to rifaximin by providing information and advice to patients

about drinking enough water, avoiding alcohol and caffeine. The study showed that pharmacists dispensed rifaximin for the treatment of diarrhea in adults almost 3 times more often than in children (Fig. 2.).

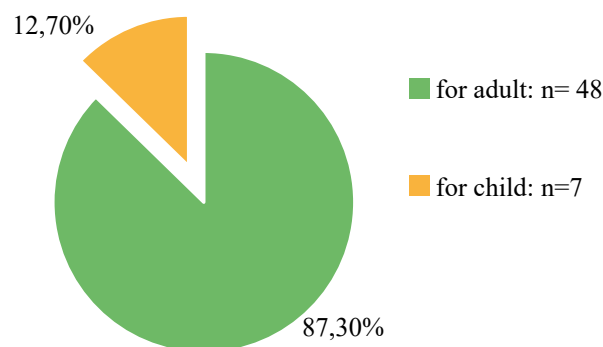


Figure 2. Results of analysis of rifaximin dispensing by pharmacists for different age groups of patients

The results of a survey of pharmaceutical specialists about the dosage form of rifaximin release showed the following: oral suspension is used in 5.5% of cases (n=3), while tablets are released in 94.5% of cases (n=52). Thus, the analysis shows a significant advantage of the tablet form of rifaximin among consumers, considering the age characteristics of the patients (Fig. 2).

The analysis of the results of the study showed that the majority of visitors (89.1%) asked to dispense rifaximin with a doctor's prescription. However, 10.9% of pharmacists had requests to release rifaximin without a prescription. The obtained results confirm the importance of pharmaceutical care in preventing the irrational use of rifaximin for the treatment of diarrhea.

It was found that a significant majority of pharmacists (92.7%, n=51) provide recommendations on the safety of rifaximin use, while a minority (7.3%, n=4) do not. According to the instructions of the Ministry of Health of Ukraine, rifaximin, like any drug, has certain features of use. Pharmacists, dispensing drugs, must inform the visitor about the rules of use. Further analysis was focused on examining of the recommendations given by pharmacy workers when dispensing rifaximin.

It was established that the majority of surveyed pharmaceutical specialists (78.2%, n=43) recommend refraining from drinking alcoholic beverages when using rifaximin, while 21.8% (n=12) do not consider it necessary. Previous research results

indicate that concurrent alcohol consumption may enhance central nervous system depression when using antibiotics, particularly rifaximin (Mergenhagen et al., 2020). Therefore, pharmacists, when dispensing rifaximin, are obliged to inform visitors about the possible consequences of alcohol consumption during treatment.

The frequency of informing visitors by pharmacy staff about the potential red-orange discoloration of urine during rifaximin intake, as indicated in the Ministry of Health instructions, was analyzed. Of the pharmacists surveyed, 21.8% (n=13) confirmed that they warn visitors about possible urine discoloration, while the majority, 78.2% (n=42), do not provide such information (Fig. 3). In cases where pharmacists informed visitors about this adverse reaction, they provided the following recommendations when it occurred:

- 53.8% (n=7) recommended to consult with doctor;
- 7.7% (n=1) advised to immediately stop using the drug and consult with doctor;
- 38.5% (n=5) recommended to continue use of the drug.

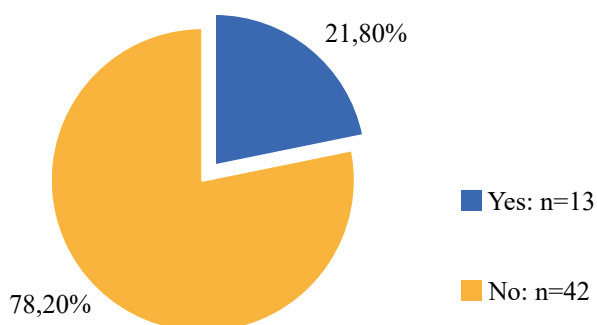


Figure 3. Survey results of pharmacists regarding informing about urine discoloration when using rifaximin

Rifaximin can penetrate through the damaged intestinal mucosa into the circulatory system, especially with pathologies of the gastrointestinal tract, which causes the color of urine (Cheng et al., 2012). The discoloration is safe and does not require a change in treatment regimen, but awareness of the possible occurrence of this symptom is critical to avoid patient anxiety.

It was found that the majority of pharmacists (89.1%, n=49) routinely inquire about the potential pregnancy status of women prescribed rifaximin.

However, 10.9% of respondents indicated that they do not conduct such inquiries. The results obtained indicate a high awareness among pharmacists regarding the use of rifaximin during pregnancy, which is critically important for safe pharmacotherapy.

The recommendations of pharmaceutical specialists regarding the administration of rifaximin to meals were analyzed. It was found that 52.7% (n=29) of respondents recommended taking the drug regardless of food intake. Additionally, 20.0% (n=11) recommended taking it before meals, an equal proportion (20.0%, n=11) advised taking it after meals, and 7.3% (n=4) suggested taking it during meals. The obtained results indicate a variety of approaches to the recommendations for taking rifaximin, which may indicate the ambiguity of the manufacturer's instructions or the individual approaches of pharmacists to each patient.

The informational work of pharmacists during the simultaneous use of rifaximin with other drugs was studied. It was found that 32.7% (n=18) of female visitors clarified the simultaneous use of oral contraceptives. While 7.3% (n=4) ask whether the visitor is taking antiarrhythmic drugs and 3.6% (n=2) ask about taking warfarin. However, the greater half (56.4%) of pharmacists do not specify the use of other drugs when taking rifaximin.

Thus, rifaximin is characterized by low systemic absorption in the digestive tract, in particular in the intestines. Its effect on the cytochrome P450 system is minimal. However, when used simultaneously with oral contraceptives, rifaximin can reduce the concentration of estrogens in the blood, which potentially leads to a decrease in the effectiveness of contraception and the risk of unplanned pregnancy. Based on this, pharmaceutical specialists must inform women about the need to use additional contraceptives during treatment with rifaximin.

Discussion

The implementation of Antimicrobial stewardship programs has led to an increased role of pharmacists in ensuring their rational use and preventing antibiotic resistance. Pharmacists involved in stewardship play a crucial role in improving treatment outcomes of infectious diseases, reducing the risk and spread of antibiotic resistance, and contributing to healthcare cost savings. Howe-

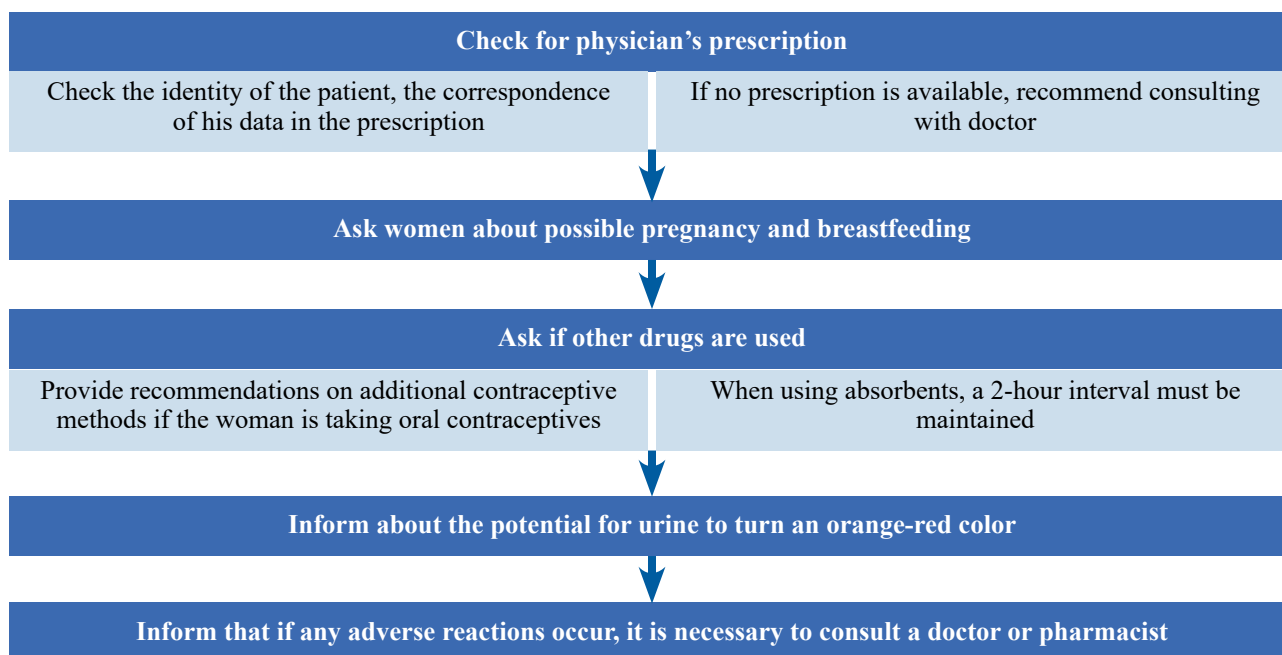


Figure 4. Pharmaceutical care when dispensing rifaximin

ver, outpatient antimicrobial prescribing often remains overlooked. Studies have shown that over 12% of all outpatient visits in the USA result in antimicrobial prescribing, with 23–30% of these prescriptions being «inappropriate» based on the established diagnosis (Chua et al., 2019). Strategies such as prospective pharmaceutical consultation and pre-authorization of prescriptions are employed to optimize antimicrobial use. However, these strategies are primarily implemented in hospital settings and are significantly more challenging to implement in outpatient practice (Mohareb et al., 2021). Monitoring prescriptions and the use of antimicrobial agents by pharmacists in pharmacies is an important task. Special attention should be paid to monitoring the use of rifaximin. In Fig. 4. presents the algorithm for pharmaceutical care during the dispensing of rifaximin.

Conclusions

1. Rifaximin is used for the treatment of various types of diarrhea, but it is important to perform a stool culture before prescribing it to determine antibiotic sensitivity. Most patients experience improvement within 3 days, but some may have adverse effects, such as nausea. Pharmacists can enhance the effectiveness of rifaximin treatment by providing information on the importance of stool culture, adherence to the treatment course, and possible adverse reactions.

2. The study showed that pharmacists dispensed rifaximin more frequently for treating adult patients than children (87.0% for adults and 12.7% for children). Additionally, nearly 33.0% of pharmacy staff dispensed rifaximin to women using oral contraceptives. Over 78.0% of pharmacists do not inform patients about the potential red-orange urine discoloration when dispensing rifaximin.

3. The study's results emphasize the importance of pharmaceutical care to prevent the irrational use of rifaximin and improve the effectiveness of diarrhea treatment, which is a significant contribution to the healthcare field.

Financing

This research did not receive external funding.

Conflict of interests

There are no conflicts of interest.

Consent to publish

All authors read and approved the final version of the article. All authors agreed to publish this article.

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article

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Роль фармацевтичної опіки при застосуванні рифаксиміну для лікування діареї

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Анотація: лікування діареї є однією з найпоширеніших проблем у сфері охорони здоров'я. Для терапії діареї мандрівника та синдрому подразненого кишечника рекомендовано використовувати рифаксимін. Водночас важливим є раціональне використання антимікробного препарату для запобігання розвитку антимікробної резистентності. Мета: оцінити роль фармацевтичної опіки, при застосуванні рифаксиміну для лікування діареї на основі анкетування. Проведено опитування серед 55 фармацевтичних працівників та 42 відвідувачів аптек щодо особливостей відпуску та застосування рифаксиміну для лікування діареї. Опитування відвідувачів аптек показало, що рифаксимін застосовували для лікування синдрому надмірного росту мікроорганізмів у кишечнику (32 випадки), діареї мандрівників (7 випадків) та синдрому подразненого кишечника з діареєю (3 випадки). Пацієнтам не проводили посів калу перед призначенням рифаксиміну, що могло б запобігти антимікробній резистентності та виключити інші причини діареї. Виявлено, що 14% респондентів зазначили покращення наступного дня, 83,3% – через три дні. Фармацевти можуть інформувати відвідувачів про необхідність дотримання курсу лікування. П'ять відсотків респондентів повідомили про нудоту як небажану реакцію. Фармацевти відпускали рифаксимін для лікування діареї у дорослих майже втричі частіше, ніж у дітей. Таблетована форма препарату використовувалась у 94,5% випадків, тоді як оральна суспензія – у 5,5% випадків. Більшість відвідувачів аптек (89%) отримували рифаксимін за рецептом лікаря, а 10,9% – без рецепта, що підкреслює важливість фармацевтичної опіки для попередження нераціонального використання препарату. Результати дослідження свідчать, що 92,7% фармацевтів надають рекомендації з безпеки використання рифаксиміну, а 78,2% рекомендують утримуватися від вживання алкоголю під час лікування. Лише 21,8% фармацевтів попереджають про можливе фарбування сечі, що може викликати занепокоєння пацієнтів. Більшість фармацевтів (89,1%) систематично запитують жінок про можливу вагітність, що свідчить про їхню обізнаність щодо безпечної фармакотерапії. Фармацевти також уточнюють про одночасне застосування рифаксиміну з іншими лікарськими засобами: 32,7% запитують про прийом пероральних контрацептивів, 7,3% – антиаритмічних препаратів, і 3,6% – варфарину. Фармацевти можуть підвищити ефективність лікування рифаксиміном, запобігаючи неконтрольованому застосуванню лікарського засобу, інформуючи про важливість дотримання курсу лікування та повідомляючи про можливі небажані реакції. При забезпеченні фармацевтичної опіки відвідувачам, які приймають рифаксимін, фармацевти повинні інформувати їх про можливі зміни кольору сечі. Крім того, фармацевтичні працівники рекомендують жінкам, які приймають оральні контрацептиви, використовувати додаткові методи контрацепції під час прийому рифаксиміну.

Ключові слова: рифаксимін, діарея, фармацевтична опіка, антимікробні препарати, антибіотикорезистентність



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