ABSTRACT

There are several significant barriers to managing patients with fibromyalgia syndrome (FMS) and providing optimal care. While some of these barriers are encountered by healthcare providers, others are common both to patients and providers. The pharmacist, particularly the community pharmacist, is in a unique position to overcome these barriers and improve the quality of care. This article reviews the barriers encountered by providers (eg, lack of education about FMS and lack of consistent response to any one treatment over time) and by patients and providers alike (eg, intense patient history and the complexity of treating FMS). It also presents several strategies that community pharmacists can implement to overcome these barriers and improve the quality of care. These strategies include patient and provider education, communication, empathy, medication counseling, patient advocacy, and the use of assessment tools.


THE PHARMACIST PLAYS A CRUCIAL ROLE

The pharmacist plays a crucial role in overcoming barriers to the appropriate management of fibromyalgia syndrome (FMS) and improving the quality of care in affected patients.

As a trusted and knowledgeable healthcare professional, the pharmacist—particularly the community pharmacist—is in a unique position to overcome barriers to care by providing both physicians and patients with accurate information, clinical reinforcement, and strategies to implement FMS interventions and promote patient compliance.

There are numerous barriers to optimal care of FMS, including lack of education about the syndrome and the poor success rate of available treatments. These and other barriers are discussed in greater detail in this article, in addition to strategies the pharmacist can implement to overcome them.

HEALTHCARE PROVIDER BARRIERS

Barriers that healthcare professionals encounter when managing patients with FMS include lack of education about this “new” syndrome, a considerable amount of misinformation about FMS that needs to be dispelled, and persistent questions about whether FMS is “real” and whether it is physiological or psychological. Other major barriers are the lack of measurable laboratory tests and imaging studies to confirm a physiologic etiology, the lack of consistent response to any one treatment over time, and the lack of reimbursement for treatment of a complex syndrome.

Fibromyalgia syndrome, which is considered by many to be an invisible disability, is a diagnosis of exclusion that must rely on the patient’s assessment of pain, the physician’s observations during the physical examination, and the patient’s medical history and reports of symptoms that are associated with other ail-
ments. Given that the typical primary care visit in this country lasts only 8 or 9 minutes, the physician does not have enough time to observe the patient adequately and record his or her observations in detail.

Approximately 50% to 60% of visits to primary care physicians fail to identify a cause of the patient’s pain, despite exhaustive testing. Results of X rays, blood tests, specialized scans, and muscle biopsies are normal, as is the erythrocyte sedimentation rate, an objective marker of inflammation. Thus, FMS is often diagnosed by default—that is, after other diffuse pain conditions such as rheumatoid arthritis, systemic lupus erythematosus, hypothyroidism, and polymyalgia rheumatica have been ruled out.

In addition, the diagnosis of FMS is often delayed. The average time to a definitive diagnosis is 5 years, in part because patients with FMS symptoms may take up to 2 years to make an appointment to see a physician. On average, patients see 4 physicians before an accurate diagnosis is made.

A patient whose history mirrors several of the healthcare provider barriers noted above is presented in Table 1. That she came to the pharmacist for advice after prescribed medications made her feel worse emphasizes why it is so important for pharmacists to be educated about FMS, and underscores the crucial role pharmacists can play in this regard.

**PATIENT/PROVIDER BARRIERS**

The major barriers for patients and healthcare providers are an intense patient history, numerous visits to multiple providers and trials of multiple treatments that have failed to produce adequate pain relief, the complexity of treating FMS, poor and/or inconsistent success rates of available treatments, the time-intensive and burdensome nature of managing FMS, comorbid mood and cognitive disorders, and the lack of cost-effective care.

An intense patient history, as demonstrated by detailed answers and copious notes on the chronic pain evaluation form, as well as the identification of numerous pain sites in nearly all areas of the body, is overwhelming to most primary care providers. Similarly, the patient who has failed to respond adequately to multiple treatments prescribed by multiple providers is stigmatized by the FMS diagnosis and branded as difficult to manage, challenging, time-consuming, or demanding. The repeated inability to treat such a patient effectively is a source of frustration for most providers, who often conclude that it is easiest to refer the patient to another provider.

The complexity of treatment as a barrier to care is neatly summarized by findings from a health insurance database of patients with FMS and a comparison group of randomly selected patients who did not seek treatment for FMS. The findings indicate that those with FMS were twice as likely to receive pain medication and 5 times as likely to receive multiple pain medications. Those with FMS also accounted for 4 times as many physician visits and 4 times as many emergency department visits, and their mean healthcare costs were 3 times higher.

The poor success rates of available treatments underscore the fact that there is no single treatment for FMS that is consistently effective. At best, pharmacologic treatments provide modest-to-moderate resolution of some symptoms over a variable time span, and chronic pain itself is a barrier to compliance with recommended interventions such as physical therapy and exercise. Moreover, the best treatments involve lifestyle changes that can be very difficult for patients with FMS to achieve.

The time-intensive nature of managing the multiple symptoms experienced by many patients with FMS can be overwhelming, as can ruling out other conditions with similar symptoms and then scheduling a prolonged visit or a series of visits for follow-up once the diagnosis of FMS is confirmed. Compounding the difficult task of managing multiple

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**Table 1. Case Presentation**

- 56-year-old woman
- Insidious onset of whole-body pain over several months, beginning at age 18
- Currently has aching, constant, unremitting pain
- Physical examination is unremarkable except for tenderness
- Blood tests and imaging studies are negative
- Physician diagnosed fibromyalgia, but patient is unclear what it is
- Poor sleep
- Significant depressive symptoms
- Tells pharmacist that she stopped taking medications prescribed by her doctor because “they make me worse”
- Asks pharmacist about alternative sleep products
symptoms against the backdrop of poor success rates of available treatments are the comorbid mood and cognitive disorders that often accompany FMS. Patient frustration with poor results can increase anger, anxiety, and other mood disorders, while depression can interfere with the patient’s ability to seek care and attempt beneficial lifestyle changes. In addition, the mental fogginess reported by many patients with FMS (ie, fibro-fog) can make it difficult to cope with the multiple issues associated with a diagnosis of FMS.

Another important barrier is the lack of cost-effective care. A diagnosis of FMS is not always a covered condition, a circumstance that can lead to polypharmacy and the use of drugs that are not approved for FMS, but are on formulary and less expensive than nonformulary drugs that are approved for FMS. Complementary and alternative medicine treatments are usually not covered either. Although home-based exercise and strength-training regimens cost little or nothing, they require patient buy-in and education.

Strategies to Overcome Barriers

Effective strategies to overcome barriers to care that can be implemented by the community pharmacist include patient education, communication, empathy, medication counseling, patient advocacy, and the use of assessment tools.

Patient Education

Patient education begins with a detailed explanation of FMS, its symptoms, and its comorbidities. The pharmacist should emphasize that successful therapy of FMS is multifaceted and includes ongoing education, drug therapy to ease pain and improve sleep, cognitive-behavioral therapy, muscle conditioning and stretching after pain and sleep problems have been treated, stress reduction, proper sleep hygiene (Table 2), the use of heat and other nondrug therapies, and dietary changes. Patients should also be told the good news about FMS medications (ie, randomized double-blind studies for a wide range of drugs are under way or have recently been completed) as well as the bad news (ie, no single class of drugs is likely to help more than a subgroup of patients for any length of time).

Successful patient education requires effective communication between healthcare providers and patients, as well as strong listening skills and empathy, which should not be confused with sympathy. Empathy involves “taking a step back” to gain some objective understanding of the patient’s clinical picture before offering help. Sympathy, on the other hand, connotes that the provider has become emotionally involved in the patient’s clinical experience, a situation that helps nobody.

All providers should recognize and appreciate the pain and suffering the patient with FMS is experiencing, and should show empathy and concern when evaluating and counseling a patient. Providers should also hear patients without judgment, avoid responding negatively to depressed, frustrated, or angry emotions expressed by patients, and accurately reflect back to the patients themselves an understanding of their concerns and symptom descriptions to validate their experience.

Medication Counseling

Medication counseling provides the pharmacist with an unparalleled opportunity to educate and advise patients about the proper use of prescription and over-the-counter (OTC) drugs. According to a recent survey of medication counseling for OTC products, community pharmacists provide over 1.5 million recommendations per month for pain relievers; nearly 600,000 recommendations per month for topical analgesics; over 1.3 million recommendations per month for headache medications; nearly 800,000 recommendations per month for laxatives; and nearly 700,000

Table 2. Sleep Hygiene Pointers

<table>
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<th>Pointers</th>
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<tr>
<td>To sleep better at night without having to take a sleeping aid:</td>
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<td>• Try to keep a consistent sleep schedule. Wake up and go to bed around</td>
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<td>the same time every day.</td>
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<tr>
<td>• Avoid napping during the day and go to bed only at bedtime.</td>
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<tr>
<td>• Exercise regularly, but at least 4–6 hours before bedtime.</td>
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<tr>
<td>• Try to avoid alcohol, caffeine, and nicotine.</td>
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<tr>
<td>• Do not drink large amounts of fluid right before going to sleep.</td>
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<tr>
<td>• Remove bright clocks and other sources of light from your bedroom.</td>
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<tr>
<td>• Draw the shades and curtains to block outdoor sources of light.</td>
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<tr>
<td>• Remove loudly ticking clocks and other sources of noise from your</td>
</tr>
<tr>
<td>bedroom and nearby rooms. Close the windows and/or draw the drapes</td>
</tr>
<tr>
<td>to muffle outdoor noises.</td>
</tr>
<tr>
<td>• Keep the room temperature comfortable.</td>
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recommendations per month for antidiarrheal agents.\textsuperscript{6}

When counseling patients who ask about OTC products for pain, sleep problems, fatigue, migraine, anxiety, or depression, pharmacists should be alert to the possibility of FMS and consider referring the patient to a physician in the community who is experienced in treating FMS.

When counseling patients with diagnosed FMS who are starting therapy with a prescription agent or agents, the pharmacist should follow the suggestions outlined in Table 3. Patients with diagnosed FMS who have recently started drug therapy and are stopping by the pharmacy counter to pick up a refill or complain about side effects or possible drug interactions should be asked about symptomatic improvement or worsening, dosage amounts and dose scheduling, and the nature of the side effects they are experiencing.

For example, the patient who is taking a medication with sedative side effects once a day in the morning and complains of sleep problems at night and feeling tired all day should be advised to take the medication at night and follow the sleep hygiene pointers in Table 2. Similarly, the patient who stops taking her medication because of side effects that developed shortly after starting therapy should be encouraged to retry the medication at a lower dose (and/or to reduce the number of doses per day) and give the medication an adequate therapeutic trial before stopping it.

\textbf{Advocacy and Use of Assessment Tools}

Community pharmacists should be encouraged to be advocates for their patients with FMS. Patient advocacy is essentially an extension of patient education that focuses on gathering relevant educational materials from a variety of sources (such as the American Pain Foundation), disseminating them at health fairs, and making them available at healthcare venues. Advocacy also includes referring patients to support groups and helpful Web sites (Sidebar) and getting involved at the local, regional, and state levels in promoting increased awareness of FMS and better care for affected patients. It is worth noting that May 12 was recently designated as National Fibromyalgia Awareness Day.

The Fibromyalgia Impact Questionnaire (FIQ) is an assessment tool that is used in studies to evaluate pain, sleep disturbances, fatigue, mood, and cognitive disturbances in patients with FMS.\textsuperscript{7} Although not intended for distribution to patients visiting the pharmacy counter, community pharmacists stand to benefit from reading it to learn about the symptoms of FMS, the signs of improvement or worsening, and the impact of the syndrome on a patient's life. The FIQ is reproduced on the inside back cover of this publication for pharmacists to photocopy, share with colleagues, and use as a reference guide in the pharmacy.

\textbf{Table 3. Medication Counseling for Patients with FMS}

<table>
<thead>
<tr>
<th>Patients with severe, complex FMS tend to be unusually sensitive to medication side effects. When starting therapy for FMS, instruct patients to:</th>
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<tr>
<td>• Start the new medication(s) at half or less of the usual minimal starting dose.</td>
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<tr>
<td>• Titrate the drug(s) slowly over days or weeks.</td>
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<tr>
<td>• Be aware of potential side effects (but remind patients that these effects usually decrease over several weeks).</td>
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<tr>
<td>• Be alert for drug interactions with multiple agent use.</td>
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<tr>
<td>• Report any side effects of drug interactions so that the dosage(s) or dose schedule can be adjusted and a drug or drugs can be discontinued if necessary.</td>
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<tr>
<td>• Give each drug an adequate therapeutic trial before discontinuing it.</td>
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\textsuperscript{FMS} = fibromyalgia syndrome.
CONCLUSIONS
Pharmacists are uniquely positioned to provide patients and physicians with healthcare reinforcement, maintenance, and strategies to implement FMS interventions and promote compliance with therapy, thus reducing barriers to optimal care. By increasing their own knowledge of FMS and its treatments, pharmacists will be better able to counsel their patients about appropriate medication use and develop a trusting relationship with the patients they serve.

DISCUSSION

PROVIDER EDUCATION

Dr Natelson: I think there are many physicians who have never heard the word fibromyalgia.

Dr Hahn: On the other hand, there are many who have heard the word, but do not believe in it. That is the problem I have in the community.

Dr Lipman: That is why it is so important to emphasize that there is a solid body of evidence telling us there is a real syndrome called fibromyalgia. It is a diagnosis of exclusion, but it is real.

Dr Strassels: The whole issue of whether FMS is real or not real raises many of the same concerns that we have with other kinds of pain. To some degree, it boils down to: “If it’s not physiological, and I can’t wrap a cuff around your arm and squeeze it, then it’s not real.”

Dr Hahn: That is where we have to strengthen the level of education.

Dr Natelson: It reminds me of the situation with torsion dystonias, which are most commonly seen in Ashkenazic Jewish boys and which we now know are inherited genetic conditions. In the 1950s, many of these boys were told there was nothing wrong and were referred for psychoanalysis. There are also many illnesses with features of epilepsy where we cannot correlate the seizure with electrical activity. Historically, many conditions thought to be “in the head” have been shown to have an organic basis.

Dr Kirsh: We are hoping for more data on genetics in the future, but we cannot disregard the fact that there is a lot of psychiatric overlay in FMS.

Dr Natelson: When I see a patient who tells me that she has had pain and fatigue since childhood or adolescence, I think her chances of having a concurrent Axis I major depression are sky-high. She is also likely to have other medically unexplained illnesses. That certainly could be a somatization disorder. However, what I see much more often is the woman in her 40s who is well and suddenly notices the onset of pain and achiness that gradually progresses over the next 2 or 3 years. That is not somatization.

DOSING ISSUES

Dr Lipman: The recommendation to dose medications with sedative effects at night rather than the morning to avoid feeling tired all day was excellent. However, if the patient was taking pregabalin, she should have been put on twice-a-day dosing within 3 to 5 days of starting therapy.

Dr Natelson: The alternative might be to go from 50 mg to 100 mg at night before moving to twice-a-day dosing. In my experience, patients make decisions about drugs in the first 2 or 3 days. They say, “This drug has done X to me. I can’t take it.” So they take it once or twice and give up. Perhaps we can adjust the dose enough to achieve efficacy and get patients over the initial hump.

Dr Strassels: This issue comes up frequently. The evidence says X, Y, and Z, but the patient says A, B, and C.

Dr Lipman: It is very important to tell patients ahead of time what to expect when starting a drug and that the side effects will usually lessen within 4 or 5 days. If they know what to expect, they often stay on the drug longer.

COVERAGE ISSUES

Dr Penna: Are the health plans that are denying coverage for pregabalin providing a rationale for the denial? Is it a prior authorization or step therapy issue?

Dr Natelson: Yes, I have received a rationale for drugs that are not US Food and Drug Administration approved. But I have not received a rationale for denial of pregabalin coverage, even though it is an approved drug.

Dr Lipman: There is a clear direction under the comparative effectiveness initiatives out of Washington, modeled after the Canadian system, where patients have to fail 1 or 2 older, less expensive drugs before payers will pay for a new agent.

Dr Swims: Those are exactly the criteria in place in the Veterans Affairs system, which is sort of a huge health maintenance organization.

Dr Penna: That is a relatively common approach. It may be useful to have some systematic reviews or meta-analyses done summarizing the evidence for use of these various agents for these conditions.
REFERENCES