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“I Was a Little Surprised”: Qualitative Insights From Patients Enrolled in a 12-Month Trial Comparing Opioids With Nonopioid Medications for Chronic Musculoskeletal Pain

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Abstract

Chronic musculoskeletal pain is a major public health problem. Although opioid prescribing for chronic pain has increased dramatically since the 1990s, this practice has come under scrutiny because of increases in opioid-related harms and lack of evidence for long-term effectiveness. The Strategies for Prescribing Analgesics Comparative Effectiveness (SPACE) trial was a pragmatic 12-month randomized trial comparing the benefits and harms of opioid versus nonopioid medications for chronic musculoskeletal pain. The current qualitative study was designed to better understand trial results by exploring patients' experiences, including perceptions of medications, experiences with the intervention, and whether expectations were met. Thirty-four participants who were purposefully sampled based on treatment group and intervention response participated in semistructured interviews. The constant comparison method guided analysis. Results revealed that participants often held strong beliefs about opioid medications, which sometimes changed during the trial as they gained experience with medications; participants described a wide variety of experiences with treatment effectiveness, regardless of study group or their response to the intervention; and participants highly valued the personalized pain care model used in SPACE.

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Perspective: SPACE trial results indicated no advantage for opioid over nonopioid medications. Qualitative findings suggest that, for both treatment groups, preexisting expectations and anticipated improvement in pain shaped experiences with and responses to medications. The personalized pain care model was described as contributing to positive outcomes in both groups.

Keywords

Chronic pain; opioids; nonopioid analgesics; qualitative research; patient–provider communication

Chronic musculoskeletal pain is a major public health problem associated with disabling physical and emotional consequences for patients and with significant costs related to medical treatment and lost worker productivity.¹⁶ The use of opioid analgesics to treat chronic pain has increased dramatically in recent years,^{7,25} paralleled by increases in opioid-related harms, including addiction and death.^{1,23,34} Although the harms of opioids have become apparent, evidence for the long-term effectiveness of opioids for chronic pain is lacking; a recent systematic review found no randomized trials that examined effects of opioids on pain, function, or quality of life at 1 year.¹⁰

Despite the lack of evidence on the long-term effectiveness of opioids, these medications are frequently perceived to be strong, powerful pain relievers.^{2,3,8} Such perceptions may have an important influence on patients' responses to opioid medications; evidence suggests that patients' expectations can indeed shape outcomes.^{32,40} This phenomenon may be especially true for pain outcomes, which are subjective and self-reported. For example, in a pooled analysis of 4 acupuncture trials for migraine, tension headache, low back pain, and osteoarthritis, patients who had higher treatment expectations were more likely to have a clinical response to the intervention.²⁶ In a secondary analysis of behavioral physical therapy interventions for patients with low back pain, the investigators found a significant positive association between patient treatment expectations and improvements in pain intensity and disability.¹⁸ Studies such as these suggest that patients' responses to opioids might be similarly influenced by their expectations of the effectiveness or strength of these medications.

The Strategies for Prescribing Analgesics Comparative Effectiveness (SPACE) trial was a pragmatic trial comparing the benefits and harms of opioid versus nonopioid medication therapy over 12 months for patients with chronic back pain or hip or knee osteoarthritis pain.²¹ Main SPACE trial results indicated that opioid therapy did not differ from nonopioid therapy on the primary outcome of pain-related function over 12 months, although most patients in both treatment groups experienced improved function from baseline to the 12-month follow-up. Additionally, nonopioid medications were significantly better than opioids on pain intensity and tolerability outcomes.²⁰

Given the evidence suggesting that treatment expectations can influence treatment response, we sought to gain a more complete understanding of the potential role of expectations in the SPACE trial. This point was particularly important because participants were not masked to their assigned treatment group and the main outcomes were self-reported. To better understand expectations and subjective experiences with the SPACE trial, we conducted a qualitative, postintervention evaluation. Qualitative evaluations and mixed methods

approaches to clinical trials are increasingly being used to help to understand and interpret clinical trial results. Such approaches can help to elucidate possible reasons underlying quantitative results and can be especially useful for understanding the outcomes of complex interventions such as those used in pain management.¹¹ Qualitative data also have the potential to capture aspects of participants' experiences with an intervention that are not easily measured quantitatively, potentially revealing avenues for future lines of inquiry or important clinical implications.^{30,31}

For this postintervention evaluation, we conducted in-depth qualitative interviews with purposefully sampled SPACE participants in an effort to understand patients' experiences with the SPACE trial, including their views and anticipated benefits of opioids versus nonopioids, experiences with the intervention, and to what extent expectations were met after completing the study.

Methods

The SPACE Study

The SPACE trial was a pragmatic, randomized, comparative effectiveness trial conducted with patients in multiple Veteran's Administration (VA) primary care clinics from 2013 to 2015. The study's objective was to compare benefits and harms of opioid therapy versus nonopioid medication therapy over 12 months for patients with moderate to severe chronic back pain or hip or knee osteoarthritis pain who were not already receiving regular opioid therapy. Accordingly, eligible patients were randomized to either the opioid or nonopioid intervention group. Both groups received active, treat-to-target medication management delivered by a study pharmacist within a telecare collaborative management model.²² The 2 study groups differed only in the medications offered, and multiple medications were available within each group. Medications were tailored to individual patient preferences and adjusted as needed to reach therapeutic targets. After completion of the intervention, most participants in the opioid group worked with the study pharmacist to taper off opioids and transition to nonopioid pain medications. Participant medication management was subsequently returned to their primary care provider. Procedures were approved by the Minneapolis VA Institutional Review Board and Research and Development Committee. Informed consent was obtained from all participants. See Krebs et al²¹ for a detailed study protocol, recruitment outcomes, and participant characteristics. Of 240 patients who were randomized, 234 completed the study, and all but 1 patient received medication treatment in their assigned study group.

Eligibility and Recruitment

Participants who completed the 12-month trial and were willing and able to return to the medical center for a qualitative interview were eligible to participate in this qualitative study. Patients were purposefully sampled from trial completers to reflect 4 subgroups defined by 2 variables: treatment group assignment (opioid group or nonopioid group) and pain treatment response (responder or nonresponder). Pain treatment response was defined as improvement of at least 30% on the Brief Pain Inventory Interference Scale^{19,38} from baseline to the 12-month follow-up assessment. We sought to obtain at least 5 to 8 participants in each of the 4

subgroups; this size is consistent with published recommendations on the adequacy of subgroup sample size required for saturation (ie, sampling to the point of redundancy in the data, when no new theoretical insights emerge) and allows searching for disconfirming evidence.²⁴ In addition to sampling on the basis of these criteria, we selected a diverse sample in terms of age, sex, and race in an effort to obtain a wide range of experiences and viewpoints. To optimize recall of study experiences, patients were invited to participate in the interviews within 2 months of intervention completion. Once patients agreed to participate, arrangements were made for a face-to-face interview. Participants were compensated \$20 after completing the interview.

Interviews

All interviews were conducted face to face in a private room. Two experienced qualitative interviewers (M.D. and A.J.) conducted several interviews together to ensure consistency among interviews before conducting the remainder of the interviews individually. Interviews took 45 to 60 minutes, were semistructured, and followed an interview guide of open-ended questions. The interviews started with general questions about pain and pain management (eg, how pain first started, past pain treatments) and then shifted focus to experiences in the SPACE trial, including reasons for participation, goals for pain management, preferences for treatment group assignment, opinions about pain medications, and changes in pain since starting the study. All interviews were digitally audio-recorded, professionally transcribed, checked for accuracy, deidentified, and imported into NVivo 10 (QSR International, Melbourne, Australia) for analysis.

Data Analysis

All authors participated in data analysis, which was led by the first author and guided by an inductive approach with the constant comparison method.^{9,27} This iterative, consensus-based process consists of 2 broad phases, open coding and focused coding. During open coding, team members read all transcripts, noting common, recurrent, and salient themes within and between transcripts. This process led to the development and subsequent refinement of a code list. Once the codes were stable and consistent, analysts conducted focused coding, in which codes derived in the first analytic phase were applied to all transcripts. Analysts divided all transcripts evenly, coding every fourth transcript in common and meeting to compare coding. Discrepancies were resolved by consensus. Analysts were masked to the overall quantitative results of the SPACE trial until qualitative data analysis was completed. Because of the nature of the interviews, analysts were not blinded to assigned treatment group.

The analytic team used procedures established in the literature on qualitative methods to ensure rigor and validity. Procedures included engaging in reflexivity (eg, questioning interpretations, becoming aware of one's own expectations in the data), depth of description (ie, seeking out rich, particular details of participants' words and experiences), and actively looking for alternative interpretations of the data that might challenge study findings and conclusions.^{4,9,12,13}

Results

Thirty-four patients were interviewed, at which point saturation was reached. Participants were 6 women and 28 men, ranging in age from 31 to 78 years (mean 58.9; standard deviation 12.5). Demographics for the full SPACE trial are reported in Krebs et al.²⁰ Two participants self-identified race as black or African American, 31 as white, and 1 participant identified with multiple categories. Eighteen participants were in the opioid group, including 10 nonresponders and 8 responders, and 16 were in the nonopioid group, including 7 nonresponders and 9 responders. In the interviews, participants discussed their expectations of the intervention, including beliefs about opioids and nonopioids, whether they had a preference to receive opioids or nonopioids, and why. Participants discussed the degree of pain relief and other changes they experienced during and after the intervention, and how these results aligned with their original expectations. The participant quotes that follow are labeled according to the subgroups used for purposeful sampling (ie, opioid group or nonopioid group; responder or nonresponder).

Expectations of Opioid and Nonopioid Medications

Interviewers asked patients to recall their preferences for treatment group (ie, opioids or nonopioids) at the beginning of the study. Several patients indicated a preference for the opioid group because of the perception that opioids are stronger.

I definitely wanted the opiate [group] ... I guess I was just thinking that it would be stronger medicine. (13440, opioid group; responder)

I was kind of hoping that it would be the narcotics because ... usually narcotics are stronger than nonnarcotics, and I was hoping that I could get something that would be stronger. (11083, nonopioid group; responder)

There's a reason it's controlled—usually because it's better. So in my mind, when you're in serious pain, you need serious medication—which, serious medication is opioids. (12009, nonopioid group; responder)

Others voiced concerns about being randomized to the opioid group. Many feared addiction.

I had hesitations about the opioid group.... I was concerned about long-term use, addiction issues, because, you know, if you feel that good, are you really going to want to stop, ever? And I can answer that honestly, no, you don't want to stop. You feel good. (13606, opioid group; nonresponder)

I had an opinion that I didn't want to end up on anything that could become addictive. Hydrocodone works. I'm not going to say it doesn't. But if every time I took one I was afraid, oh my God, would this be the one that makes me addicted? (10882, nonopioid group; responder)

Impairment while on opioids was another worry. One patient indicated that, although he believed opioids might be more effective, he was concerned about how they might affect his job working on school buses:

Narcotics can lead to a lot of trouble. You're driving, you're taking [an opioid medication], and you get behind the wheel because you have to drive somewhere.

Now you are driving on an illegal drug.... You have to take it because you hurt really bad in the morning, for whatever reason you have to drive ... you've put yourself open for a liability of massive proportions. For a non-narcotic, if it only works half as well, it still allows you to retain control and not be as drowsy. It's safer to not be on a controlled substance. Especially when you have a drive like I do. I mean, I work on school buses. I wouldn't even dream about taking [an opioid] at work. (11161, nonopioid group; responder)

Some negative perceptions of opioids were influenced by past personal experiences or those of friends or family.

I had more of like a hallucinogenic type of reaction [to codeine]. It really freaked the hell out of me. And I did not do well. (11790, nonopioid group; nonresponder)

I've just seen my friends and family who have those problems, they can't just quit...I've got an Army buddy of mine who still does opioids just because he thinks it makes him a nicer person. That's him. There's always concern about getting addicted to pills. (13103, opioid group; responder)

Some patients reported no concerns about opioids. One patient, when asked if he had any concerns about being randomized to the opioid group, replied:

I wasn't worried about if I ended up in the opiate group. I wasn't worried about the addiction situation because I don't like drugs to begin with. And I don't drink, I don't smoke ... so I figured, I looked at it as, you know, it's just a pill you've got to put in your mouth ... I mean, I didn't think it was going to kill me or anything. (10976, opioid group; nonresponder).

Another patient believed that her past addictions better equipped her to resist addiction to opioids:

The only concern I had was that I do have a very addictive nature, but I also am a survivor.... And so as far as addiction.... I've come through that kind of stuff before, and I know that I'll be able to make it through. (11082, opioid group; nonresponder).

Experiences With Opioid Treatment

Participants in the opioid group described a variety of outcomes of their pain medication treatment. Notably, the subjective experience of benefit or lack of benefit that patients reported did not always match their responder status based on change in numeric scores. Some patients described good results from opioids.

Patient: So, my [pain] control has been great.

Interviewer: Do you have any long-term concerns about being on opioids?

Patient: No. (13413, opioid group; responder)

I don't think I would've had as quick of feel-good results [in the nonopioid group]. ... When I was on the first med, it really got me energized. It improved my outlook ... it got me wanting to do more and be more. (13606, opioid group; nonresponder)

I just want[ed] to be able to walk around the block. Then I wanted to [walk] a half mile. And then, you know, I constantly increased that and now I'm up to 4 miles a day, 6 days a week.... And it was all because of the medication. (10976, opioid group; nonresponder)

This participant went on to say later in the interview, "The relief was way better than what I ever thought it would be" (10976, opioid group; nonresponder).

Some nonresponders in the opioid group described opioids as working in the short term, but losing effect over time.

Participant: When I first started, it would take the pain away and it would be great, but now when I take the medications, it still helps with the pain, but there's still pain. It's more tolerable ... They're worn off. They are wearing down basically.

Interviewer: Did the medications work the way you thought that they would?

Participant: They did at first ... but then they wore down to where it's not as much as I would've hoped for, but enough to keep me going. (11082, opioid group; nonresponder)

I had immunity ... it's less effective. But in the beginning, it was much better. (11305, opioid group; nonresponder)

I thought the morphine was really working well up until I fell. And ... then it didn't cut through the back pain. (11431, opioid group; nonresponder)

Other patients, including some classified as responders, reported disappointment with the relief they got from opioids.

I guess I didn't even know what to expect. It helped, but it didn't fix it. (10987, opioid group; responder)

I thought I'd get more relief from [the opioid].... [Now] I'm taking 2 tablets [of acetaminophen] 3 times a day, and that seems to be working just as well as [the opioid] did. (11422, opioid group; responder)

Some responders in the opioid group did not want to continue taking opioids because of concerns about addiction or undesirable side effects: "I have a niece that got hooked on opioids, so it scared me" (10987, opioid group; responder).

One patient described how he reduced his opioid dose himself, during the study, because of addiction concerns.

"These drugs are addictive, okay? They take control of your life. These opioids are screwing up your mind. You become addicted. Thank God I weaned off of it myself, because I felt that monkey on my back" (13168, opioid group; responder).

Another patient explained that the opioids provided pain relief but interfered with her quality of life and ability to reach personal goals.

I'm glad I'm not on opiates anymore. They were effective, but it felt like I was living my life in a sleepy stupor. I did not like being tired and, you know, I could

lay down on the floor and fall asleep. My quality of life, I thought, diminished because of the opiates. I think, how, why would you want to take these in your right mind? How can you even function? I wanted to be a more active participant in my life. I wanted to reestablish friendships and I wanted to get projects done around the house. And I felt none of that was going to happen as long as I was on those opiates. All I wanted to do was sleep. (13427, opioid group; responder)

Another opioid responder described undesirable side effects that outweighed benefits of opioids.

They all worked, everything [the pharmacist] gave me worked.... But some of the medicines at the beginning, I just didn't like the feeling I had. And I think the first one, which was the morphine, more scared me than anything.... All I got was like a woozy feeling. So, I wasn't really on that one too long. A month or 2, I think. And I was scared to take—it worked. It worked real good. But it was the constipation. (13981, opioid group; responder)

Other patients, including responders, reported that opioids did not provide much pain relief.

It's almost like it would deaden my mind and make me like I was drunk or loopy. It wouldn't actually affect the pain, because you'd still be all googly, but you still knew you had the pain. (11239, opioid group; nonresponder)

I really don't know if it's doing any good. Well, like I say, just like the morphine, they don't eliminate the pain. You know, I'd still be on the morphine if it eliminated the pain. It don't. (13168, opioid group; responder)

Experiences With Nonopioid Treatment

Some patients described surprise that nonopioid medications were more effective than expected.

I was hoping to get into [the opioid] group ... But there's always that thought, it's like, well, hopefully, I won't get addicted to the stuff. That's why I was like, I can't believe that ibuprofen, 800 milligrams, solved the problem. (10949, nonopioid group; responder)

Another patient had hoped for the opioid group because, "I knew [opioids] worked." He said after completing the study in the nonopioid group that, "We had a little trouble at first, but finally we got them dialed in and it was great. I was really managing my pain well. I was very happy after we had it all dialed in and everything" (13239, nonopioid group; nonresponder).

One patient who was treated in the opioid group during the study and transitioned to nonopioid medications after study completion described his experience with both approaches, including his surprise that the nonopioid medications seemed to be as effective as the opioid he had been taking.

Patient: Well, the hydrocodone was probably most effective because it was more powerful of any that I've taken. And, you know, it does more than just relieve the pain on my knee, it relieves anxiety and, you know, a few other things.

Interviewer: And, now, when you switched over from the hydrocodone to the acetaminophen and lidocaine, were the results any different than what you expected?

Patient: No, the results were about what I expected. The extra heat on my knee that provided some relief and the acetaminophen ... between the two of them, it did the same about as the hydrocodone. I was a little surprised. (13281, opioid group; nonresponder)

A patient in the nonopioid group indicated that he initially believed opioids were stronger, but had a good response to an anti-inflammatory medication.

I thought, I'll give [the nonopioids] a try.... You have to take hydrocodone multiple times a day, and after 4 to 6 hours the pain's back, then you have to take the meds again. Where with the meloxicam I can take it in the morning and if I forget to take my morning dose the next day, I'm still fine. I can go easily 24 hours on one dose ... without noticing any pain" (12009, nonopioid group; responder).

Other patients described positive effects of nonopioid medications on their activities. For example, the following patient described how his activity improved after he joined the SPACE study:

I wanted to be active again. It was killing me—just as soon as I came home from work, I was completely exhausted from not sleeping, you know, getting 2, 1 to 2 hours of sleep from just holding my knee, trying to figure out any way to stop the pain. And going through the pain study that took a year, but finally it's like thank goodness. (10949, nonopioid group; responder)

He went on to explain that ibuprofen turned out to be most effective medication for him.

"Smooth sailing. Yep.... And I've gone from not being able to exercise to walking 5 miles a day now, every morning" (10949, nonopioid group; responder)

Other patients similarly noted they were able to be more active and had improved fitness since being treated in the nonopioid group.

I have no problem with the lawn work now. I've increased my walking, and that's pretty good. (11417, nonopioid group; responder)

I can pick my kid up, throw him around, spin him around, whatever, and I feel great.... I even feel like getting teary because I'm just so happy. I am. I'm able to do a lot of things that I couldn't. A lot more things than I thought I would be able to even [do].... I'm also a lot more muscular than I was a year and a half ago, too. (12009, nonopioid group; responder)

He went on to describe how his results surprised him.

I was expecting it not to be 180-degree turn because I went from being just miserable every day to being just, for the most part, happy. I can basically just bounce right out of bed." In addition, this patient described a change in his beliefs about opioid and nonopioid medications after participating in the SPACE study. I assumed ... opioids were powerful. So they were necessary for extreme pain when

that's not the case. So I do have a lot more respect, I guess, for nonopioids. (12009, nonopioid group; responder)

One patient described surprise at the effectiveness of a topical cream:

I didn't really expect the topical cream to work, to be honest. I thought something had to be ingested, [but] ... it was a site-specific pain. And I didn't really think about that at the beginning of the study. You start numbing it up, you get the pain receptors used to this burning and eventually once they're used to the burning, they don't—your receptors aren't as active, it doesn't hurt as much. (11161, nonopioid group; responder)

Some patients described insufficient relief from nonopioid medication treatment.

I was hoping that I could get back some of the things that I lost like, because of my pain I had to quit my volunteer job at the food shelf. I was hoping I could get back to that, but so far that's not been the case. I was hoping I would be able to go out for walks again, but it's been so painful that I've not been able to do that. (11083, nonopioid group; responder)

Another patient described some improvement in pain, but not enough:

"I made progress, but I'm still frustrated with the pain" (11677, nonopioid group; nonresponder).

Experiences With Pain Care Management

Participants in both study treatment groups described the value of the pain care management approach used in the SPACE trial. A number of patients from both study arms commented on the individualized treatment they received from the clinical pharmacist who managed their medication regimen.

Interviewer: What was the most important thing that you got from participating in SPACE?

Patient: Individual treatment. I mean, [the pharmacist] was great.... And she listened to me. I mean, she wouldn't do anything I didn't want to do. She wouldn't coax me into any which way. I had to want to do it. It had to be my choice. (11788, nonopioid group; responder)

[The study pharmacist] was wonderful.... It was nice to see her and ... it calmed me down a little bit about worrying about taking [opioids] and being on them for year. (10987, opioid group; responder)

Of particular note, 1 participant attributed his improvement during the trial more to the support of the pharmacist than to the opioid medications he was prescribed. When asked if he thought his results would have been different if he had been in the nonopioid group, he responded, "I think if the physical or the verbal support with [the pharmacist] was the same, I don't think there would've been a difference taking a bunch of Tylenol as opposed to the opioids" (13103, opioid group; responder).

Discussion

The goal of this qualitative follow-up study was to further understanding of SPACE trial results by elucidating participants' expectations of and subjectiv experiences with the trial interventions. The primary result of the SPACE trial was that opioid therapy did not differ from nonopioid therapy for pain-related function. Notably, most patients in both treatment groups had improvement in function from baseline to 12-month follow-up. In addition, pain intensity and medication-related adverse symptom outcomes were significantly worse for opioids compared with nonopioids, but differences between groups were small.²⁰ Results of in-depth interviews with patients have several key implications for interpretation of the main SPACE trial results.

Beliefs About Opioid and Nonopioid Medications

First, we found that many patients expressed strongly held beliefs about the relative effectiveness and risks of opioid and nonopioid medications and that some patients noted changes in these beliefs over time, based on experiences during the trial. Participants frequently described beliefs that opioids were “stronger,” with 1 participant compellingly describing them as “serious medication” for “serious pain.” Some participants expressed fears of addiction or impairment. Others had concerns based on their past experiences with opioids or those of friends or family. Interestingly, patients often expressed these concerns while indicating their belief in opioids as effective, powerful medications. These findings corroborate widespread perceptions of opioids as powerful “painkillers,” which is how they are commonly described by public health officials, consumer advocates, and journalists.^{2,3,8} These qualitative findings are also consistent with quantitative prerandomization perceptions of the 2 treatment arms in SPACE; overall, participants reported perceiving opioids as substantially more effective and somewhat less safe than nonopioid medications.²¹

Interviews also depicted how patients' perspectives sometimes changed over time as they gained experience with medications. Some patients in the opioid group expressed disappointment in the results of opioids, describing expectations for greater relief than they experienced or diminishing effectiveness as time went on. Likewise, some patients in the nonopioid group described surprise that nonopioids could work as well as they did. Current opioid prescribing guidelines recommend discussing patient expectations and establishing realistic goals for pain and function before initiating therapy.¹⁴ Our findings support this approach.

Because patients and health care providers were not masked to SPACE treatment assignment, expectations about opioid and nonopioid medication interventions may have influenced the primary patient-reported outcomes in the trial. If present, bias owing to positive expectations about opioid effectiveness would likely favor the opioid treatment group.²⁶ Our qualitative results illuminate how preconceptions may have been at least partially countered by experience over the course of the trial; this phenomenon has been previously described and could hypothetically ameliorate a biasing effect of expectations on reported outcomes over long-term follow-up.³⁶

Experiences With Treatment Effectiveness

A second important implication for the SPACE main trial results is that participants described a wide variety of experiences with treatment effectiveness, regardless of their treatment group assignment (ie, opioid or nonopioid) and whether they met the threshold for responder status (ie, 30% improvement on the Brief Pain Inventory Interference scale). Some patients who were considered nonresponders described improvement in pain and physical function, whereas some of those considered to be responders described inadequate improvement. Because pain, functional impairment, and well-being are inherently subjective concepts, we do not find it surprising that objective and subjective measures of treatment outcomes were incompletely aligned. Furthermore, patients who met the 30% improvement threshold may have been disappointed if this was less improvement than they had anticipated. The mean prerandomization self-reported rating of likely personal improvement during the study was 7.5 on a scale of 0 (no improvement) to 10 (a great deal of improvement). Although we did not ask patients in this study to quantify acceptable or desirable levels of improvement, prior research has demonstrated that patients' expectations for the magnitude of improvement are sometimes greater than the expected benefits of existing therapies.^{33,35} Interviews also suggested that pain relief alone was not sufficient for some patients to consider medications effective. Several patients indicated they had less pain while taking opioids but still chose to discontinue them because of concerns about addiction, undesirable side effects, or interference with function and quality of life. These findings highlight the clinical importance of assessing more than just pain intensity when evaluating effectiveness of prescribed pain treatments. Although pain intensity scores provide an important metric by which to gauge a patient's improvement, it is also important to engage patients in a discussion of what such scores mean in the context of their own lives and experiences.

The SPACE Pharmacist Care Model

Finally, we found a strong theme of satisfaction with the pain care model—personalized medication management delivered by a clinical pharmacist—used in both arms of the SPACE trial. Many patients described this personalized contact as just as important as the medications they were taking. The views of these SPACE participants are consistent with research indicating that effective patient–provider communication is inextricably linked to important, measurable outcomes, including patient satisfaction, adherence to treatment, and relief of symptoms.^{5,6,15,17,37}

The importance of a caring clinician providing tailored advice and support has been corroborated in other studies of patients with chronic pain. Participants in a randomized trial consisting of medication management, brief cognitive-behavioral therapy, and pain self-management education delivered by a nurse care manager identified the nurse as key to successful pain management, fulfilling 3 specific roles: helping patients to find what works for their pain, holding patients accountable for their pain management, and motivating and providing emotional support.²⁹ In another study involving pain self-management and medication management for patients with chronic pain and depression, the nurse care manager was similarly identified as critical to successful pain management.³⁰ Patients in both of these studies emphasized that the self-management, medication management, or

other clinical care provided were not the only “active ingredient” in the minds of participants, but that the clinicians delivering the interventions played an integral role as well. In the same way, the personalized care and measurement-based medication management from the pharmacist care manager is likely to be at least partially responsible for the clinical response rates in the SPACE study. Exposing both arms to this care management approach, with similar contact rates and pharmacist time in both arms, effectively controlled for communication and therapeutic alliance factors that could bias findings if 1 group received more intensive contact than the other.

This study is limited in that all participants were VA patients in 1 metropolitan area who agreed to enroll in a randomized, controlled trial. As a result, qualitative results might not be applicable to other patients with chronic pain taking medications in a nonresearch environment.^{28,39} In addition, because patients were interviewed at the same medical center where they received the SPACE intervention, it is possible that they felt more comfortable reporting only positive experiences. However, because some were critical of the intervention, and because participants provided rich, detailed descriptions of their experiences with the intervention, rather than speaking in generalities, we believe that such a social desirability bias is unlikely.

Conclusions

The SPACE trial, the first randomized controlled trial to compare long-term outcomes of opioid versus nonopioid medications for chronic pain, found no advantage of opioids over 12 months. Moreover, opioids caused significantly more medication-related adverse symptoms than nonopioid medications.²⁰ The current qualitative study provides important insights that help to enhance our understanding of the SPACE trial results. First, the role of expectations played a prominent role in patients’ experiences with SPACE. These included expectations that opioids are strong, powerful medications and expectations of pain improvement that may or may not have matched the study definition of a clinically important response (ie, a 30% decrease on the Brief Pain Inventory Interference scale). Together, these expectations seemed to shape patients’ experiences with and responses to the intervention, leading to results that surprised some patients, whereas others perceived little change. In addition to the role of expectation, patients expressed a high degree of satisfaction with the personalized pharmacist care model that patients in both study arms experienced. The presence of a caring, responsive clinician seeking to improve patients’ pain may in part help to explain why, although opioids showed no advantage over nonopioids, patients in both study arms improved.

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