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ORIGINAL RESEARCH

Shared Decisions: A Qualitative Study on Clinician and Patient Perspectives on Statin Therapy and Statin-Associated Side Effects

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BACKGROUND: Despite guideline recommendations and clinical trial data suggesting benefit, statin therapy use in patients with atherosclerotic cardiovascular disease remains suboptimal. The aim of this study was to understand clinician and patient views on statin therapy, statin-associated side effects (SASEs), SASE management, and communication around statin risks and benefits.

METHODS AND RESULTS: We conducted qualitative interviews of patients with atherosclerotic cardiovascular disease who had SASEs (n=17) and clinicians who regularly prescribe statins (n=20). We used directed content analysis, facilitated by Atlas.ti software, to develop and revise codebooks for clinician and patient interviews. The most relevant codes were "pile sorted" into 5 main topic domains: (1) SASEs vary in severity, duration, and time of onset; (2) communication practices by clinicians around statins and SASEs are variable and impacted by clinician time limitations and patient preconceived notions of SASEs; (3) although a "trial and error" approach to managing SASEs may be effective in allowing clinicians to keep patients with atherosclerotic cardiovascular disease on a statin, it can be frustrating for patients; (4) outside sources, such as the media, internet, social networks, and social circles, influence patients' perceptions and often impact the risk benefit discussion; and (5) a decision aid would be beneficial in facilitating clinician decision-making around SASEs and discussion of SASEs with the patients.

CONCLUSIONS: Statin use among patients with atherosclerotic cardiovascular disease remains suboptimal because of various patient- and clinician-related factors. The development of a decision aid to facilitate discussion of SASEs, clinician decision-making, and SASE management may improve statin use in this high-risk population.

Key Words: atherosclerotic cardiovascular disease ■ qualitative research ■ statin-associated side effects ■ statins

Statin therapy is associated with a lower risk of cardiovascular events and mortality in patients with established atherosclerotic cardiovascular disease (ASCVD).[1,2] Despite the class I recommendation by evidence-based guidelines to initiate high-intensity statins in patients with clinical ASCVD,[3,4] statin and high-intensity statin therapy use in this high-risk population remains suboptimal.[5] There are likely multiple reasons involving both patients and clinicians contributing to this underuse.

Studies have found patient concerns about perceived statin-associated side effects (SASEs) as a major reason for lower rates of statin use.[6-8] Even when clinicians attest to the safety and effectiveness of statins, many patients remain apprehensive. Although rates of reported SASEs are low in randomized controlled trials of statin therapy, the frequency of reported SASEs is higher in clinical practice.[8] Although these SASEs may not be causal,[8] lack of clinician-patient communication about the risks versus

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CLINICAL PERSPECTIVE

What Is New?

- Using qualitative interviews among patients with statin-associated side effects, we identified 5 domains that drive management and communication between clinicians and patients around statin therapy.

What Are the Clinical Implications?

- These 5 domains can be used to develop an aid to improve communication and management in patients with statin-associated side effects.

Nonstandard Abbreviation and Acronym

SASE	statin-associated side effect

benefits of statin therapy, lack of adequate time invested in discussing potential SASEs, and ineffective strategies to manage adverse effects all likely contribute to patients' concerns and suboptimal use of statins.[6,7] Furthermore, there is a lack of data on clinician versus patient perceptions of SASEs and a lack of objectivity in assessing the adverse effects. A better understanding of patient and clinician perceptions of statin therapy and SASEs, a more thorough assessment of adverse effects, and a method for improving clinician-patient communication about statin risks and benefits are needed.

Although SASEs remain a significant barrier to effective statin use, other clinician- and patient-related factors must not be overlooked. Therapeutic inertia, which encompasses clinical inertia among other factors, is the clinician's failure to initiate or intensify therapy when indicated; it also plays a role in statin underuse.[8,9]

As part of a larger study aimed at improving guideline-concordant statin use in patients with clinical ASCVD, we conducted in-depth qualitative interviews with clinicians and patients to assess their views on statin therapy and SASEs, including their perspectives on management of adverse effects and communication around statin risks and benefits. By presenting perspectives from both clinicians and patients with ASCVD who experienced SASEs, our primary aim was to highlight the areas where clinical care and outcomes related to statin therapy can be improved by improving communication between clinicians and their patients with ASCVD. These interviews could identify what drives clinical decision-making around the use of statin therapy in patients with SASEs, patient perception around risks and benefits of statin therapy in the context of SASEs, and what gaps may exist between clinicians and patients on communication of SASEs. By highlighting these themes, we also describe basic components of a clinical decision support tool and patient-centered communication aid that could assist in the management of patients with clinical ASCVD and SASEs and improve guideline-concordant statin therapy use in these patients.

METHODS

The Consolidated Criteria for Reporting Qualitative Research guided our reporting of methods and results.[10] Because of the nature of the data, study data will not be made available to other researchers.

Patient Interviews

We included patients with a documented history of ASCVD (ischemic heart disease, ischemic cerebrovascular disease, or peripheral arterial disease), aged ≥18 years, receiving care at the Michael E. DeBakey Veterans Affairs Medical Center. Patients with ASCVD were initially identified using the *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) diagnosis and the *Current Procedural Terminology* codes. The positive predictive value for the identification of patients with ASCVD was 95% for this algorithm compared with manual chart review of 200 random patients from this cohort.[11] After manual chart review to confirm presence of ASCVD, further inclusion criteria were used to identify patients for qualitative interviews. These criteria included receipt of primary care at the Michael E. DeBakey Veterans Affairs Medical Center, at least one SASE documented in the electronic health record, and an inability to tolerate moderate- or high-intensity statin therapy, as defined in the 2013 cholesterol management guideline.[4] SASEs were identified using the Department of Veteran Affairs' adverse drug reaction system[11] and confirmed by manual chart review. Last, patients were excluded if they had a history of metastatic cancer or if they were receiving hospice care. Using these criteria and patient consent, 21 patients with a history of ASCVD and a history of SASEs were screened by the study's research coordinator. We further excluded 4 of these 21 patients for the following reasons: a female patient with history of hypertension but no ASCVD on chart review, a female patient with SASE to nonstatin therapy only, a female patient who could not clearly recall SASE to statin therapy, and a male patient with nonalcoholic steatohepatitis in whom statin therapy was not used but otherwise there was no documented SASE that the patient could recall. Therefore, our final sample size for

patient interviews included 17 patients who were interviewed about their experiences with SASEs and clinician-patient communication around risks and benefits of statin therapy.[12] Patients were invited to participate in a brief telephone interview via an opt-out letter.

Clinician Interviews

Twenty clinicians who regularly prescribe and/or manage statin therapy at a large Veterans Affairs Medical Center in the southeastern United States were interviewed. We included cardiologists, primary care physicians, primary care nurse practitioners, and clinical pharmacists that regularly prescribe and/or manage SASEs to obtain diverse perspectives consistent with a maximum variation sampling strategy. Clinicians were contacted via an opt-out e-mail inviting them to participate in a brief telephone interview about their perceptions of SASEs and their statin management and communication strategies with patients with SASEs.

Our sample size for both patients and clinicians was guided by a maximum variation sampling approach, a purposive sampling approach[12,13] that ensured diverse perspectives in patients with SASEs from various race/ethnicity backgrounds. This sampling approach also allowed us to capture diverse perspectives from a varied sample based on provider type (ie, physicians, advanced practice providers [nurse practitioners or physician assistants], and pharmacists), number of years of practice in the veterans affairs system, and practice specialty (internal medicine or cardiology). The core themes and shared patterns crosscutting this variation facilitated identification of components of a future communication aid with a potential to be widely adopted among a diverse group of clinicians.

After receiving approvals by the Institutional Review Board and Veterans Health Administration Research and Development Committee, a qualitative methodologist conducted all clinician and patient interviews between July 2018 and May 2019, to ensure consistency in data collection. Patients and clinicians gave verbal consent, and all interviews were audio recorded and professionally transcribed. Interviews were semistructured, and the full interview guides can be found in Tables S1 and S2. Given sample heterogeneity, especially for the clinicians, thematic saturation was not the goal of our interviews. Rather, our goal was to identify themes that crosscut this heterogeneity within and across both groups, which is consistent with a maximum variation sampling approach.[12]

Statistical Analysis

Directed content analysis approach guided our analysis and was facilitated by the Atlas.ti qualitative software (v.8; Atlas.ti Scientific Development GmbH, Berlin, Germany).[14] A directed content analysis approach was used given the availability of prior research on this topic. By using a directed content analysis approach, our aim was to extend the prior findings, which were mostly inferred using either large structured data sets or survey questions. These concepts included the variability in communication around SASEs and the impact of social networks on patients' perception of SASEs. Improving the efficiency of the analytic approach by anchoring it on prior research also allowed us to explore the interplay of perception on statins and SASEs between various stakeholders involved in the interview process (clinicians and patients). Furthermore, this approach not only facilitated detailed capture of clinician and patient perspectives on SASEs, it also allowed our team to further understand how these concepts can inform the design, content, and development of a communication aid for a future large-scale implementation study.

The study's qualitative methodologist and research coordinator developed and revised individual codebooks for clinician and patient interviews. The qualitative methodologist and the research coordinator each coded 2 transcripts and compared their findings through a process of negotiated consensus where coding discrepancies were discussed and resolved. On consensus, remaining transcripts were analyzed independently, with the qualitative methodologist and the research coordinator spot-checking each other's work for accuracy. Codebooks were largely composed of a priori (ie, deductive) codes gleaned from the interview guide; a few a posteriori (ie, inductive) codes were also developed. All transcripts were individually coded, and analysts regularly met in consensus meetings to compare findings, discuss coding discrepancies, and modify the codebook to improve clarity of the codes. If needed, previously coded transcripts were revisited to revise coding.[15] Interim results were presented to the full study team for discussion. Team discussion focused on the scope of the analyses and facilitated the identification of the most relevant codes to include in the final analysis; codes were then "pile sorted" into 5 main topic domains by the study's qualitative methodologist.[16,17] Within each topic domain, closely related and/or overlapping codes were combined to streamline the data. Points of congruence and divergence in clinician and patient perspectives were identified in each domain, which facilitated and informed the identification of the major themes.

RESULTS

Our final sample size included 17 patients. Our patient sample was largely men (94.1%) with an average age of 66 years (SD, 8.07 years). Approximately 65% were

Black patients and 35% were White patients (Table 1). Fifteen patients (62.5%) had history of ischemic heart disease, 6 patients (25%) had history of ischemic cerebrovascular disease, and 3 patients (12.5%) had history of peripheral arterial disease. The mean number of years since the last adverse effect from statins was 4.70 years (SD, 2.91 years). Patient interviews lasted between 11 and 50 minutes.

We interviewed 20 clinicians. These included cardiologists (n=4), primary care physicians (n=5), primary care nurse practitioners (n=6), and clinical pharmacists (n=5). Clinicians were 60% White individuals, 50% women, 20% Black individuals, 20% Asian, and 10% Hispanic. Interviewed clinicians were on average 11 years in clinical practice (Table 2). Among the clinicians who were physicians, 5 were board certified in internal medicine, 1 in family medicine, and 4 in cardiovascular medicine. Clinician interviews lasted between 17 minutes and 1 hour 24 minutes, with an average length of 20 to 40 minutes.

Patient and clinician data were integrated within our discussion of the 5 themes described below (Figure).

Table 1. Baseline Characteristics of Patients With ASCVD

Patient Characteristics (n=17)	Value
Age, mean (SD), y	65.82 (8.07)
Men, n (%)	16 (94.12)
Race, n (%)	
White	6 (35.29)
Black	11 (64.71)
Duration since last adverse effect from statin therapy, mean (SD), y	4.70 (2.91)
Ischemic heart disease, n (%)*	15 (62.50)
Ischemic cerebrovascular disease, n (%)*	6 (25.00)
Peripheral arterial disease, n (%)*	3 (12.50)

ASDVD indicates atherosclerotic cardiovascular disease.
*Numbers add up to >17 because some patients had >1 form of ASCVD.

Table 2. Baseline Characteristics of Primary Care and Cardiology Clinicians

Clinician Characteristics (n=20)	Value
Men, n (%)	10 (50)
Race/Ethnicity, n (%)*	
White	12 (60)
Black	4 (20)
Asian	4 (20)
Hispanic	2 (10)
Clinician type, n (%)	
Physician	9 (45)
Nurse practitioner	6 (30)
Pharmacist	5 (25)
Time in practice, mean (SD), y	11.05 (7.25)
Board certification, n	
Internal medicine	5
Family medicine	1
Cardiovascular medicine	4

*Percentages add up to >100% because some clinicians belonged to >1 racial group.

SASEs Are a Highly Individualized Experience

Our clinician and patient interview data suggested that the experience of SASEs varied from one patient to another in terms of severity and timing after initiating statin therapy.

According to our clinicians, SASEs did not always neatly fit into the commonly used categories of "mild" (eg, myalgias that are tolerable), "moderate" (eg, myalgias that impact activities of daily living), and "severe" (eg, rhabdomyolysis). So, what may be a mild adverse effect for one patient may be perceived as severe for another patient. For example, a cardiology clinician explained how myalgias may be considered severe by a 60-year-old patient with limited functional capacity, thereby leading to statin discontinuation. However, an older 70-year-old highly functional patient may not be too bothered by myalgias and would remain adherent with statin therapy.

Compared with clinicians, patients attributed a higher number of symptoms or health conditions to the effects of statin therapy. Table 3 provides a breakdown of SASEs that clinicians reported, which stands in contrast to patient-reported SASEs. Although clinicians and patients report myalgias as an SASE, patients also attributed the onset of type 2 diabetes mellitus, memory loss, and dermatologic issues, for example, to statins. Patients also reported individual differences in the onset of SASEs. SASE onset could occur within a few weeks of statin use or occur after several years, as one patient described:

> *Well, as you know, early on I was younger and everything, and wasn't bothered too much by medications. You know, I had to take medications but didn't suffer too much the side effects, but as I got older, side effects became much more obvious.*

The individualized nature of SASEs was also demonstrated by how soon patients became aware that statins caused their symptoms. One patient immediately attributed his/her itching and hives to the statin therapy, whereas another patient said that it took time for him/her before he/she attributed statin as the cause of his/her symptoms. The patient explained:

Table 3. Comparison of Clinician- and Patient-Reported SASEs

Clinician-Reported SASEs	Patient-Reported SASEs
Musculoskeletal • Myalgias: muscle/joint pain that is bilateral, body wide, or limited to lower extremities/muscle groups • Muscle fatigue/weakness Rhabdomyolysis (less common) Gastrointestinal (less common) • Acid reflux/GERD • Diarrhea Other • Sexual dysfunction • Statin taste (from cutting tablet in half)	Musculoskeletal • Muscle/joint pain/stiffness/cramps • Muscle weakness/atrophy Gastrointestinal • Upset stomach/nausea • Diarrhea • Stomach cramps Neurological • Vertigo • Dizziness • Headaches • Memory loss Dermatological • Skin lesions • Hives • Red streaks that ran up and down leg Cardiovascular • Shortness of breath • Chest pains (possibly related to statin) • Irregular heartbeat Other reported adverse effects • Tiredness • Cataracts • Type 2 diabetes mellitus • Sexual dysfunction (possibly related to statin)

GERD indicates gastroesophageal reflux disease; and SASE, statin-associated side effect.

> *…I only figured it out by accident. I would never think that a drug [could cause side effects], no, I couldn't put that two and two together.*

Clinician-Patient Communication Around Statins/SASEs Is Variable

Our interviews revealed that the amount of information related to SASEs conveyed by the clinicians to patients varied, some patients recalled learning little about SASEs, and there was variability in the discussions around risk-benefit of statin therapy for secondary ASCVD prevention. One patient stated:

> *I think, you know, I vaguely remember my provider saying that there are some side effects, but it's nothing to really worry about. The way that she said it was if it's a symptom that turns out to be serious, then get in contact with her, and I guess we would discuss it. It was kind of vague in terms of that, but I don't remember her explicitly telling me what each individual side effect would be or what to look out for.*

Another patient stated:

> *She told me about the side effect of the soreness. That's the main complaint, and that's exactly what I started getting as far as for me. …She said the medication works. She said if you have to, spread it out like 1 day on, 1 day off, she said, but whatever you do, keep taking it because it works.*

Clinicians varied in how much information they conveyed to patients about SASEs, which was confirmed in our patient interviews. One primary care clinician explained how *"generally you pick out the most important"* adverse effects to discuss given time limitations. One patient understood that clinicians are pressed for time during the clinical encounter, but stated:

> *…I mean I understand some of that stuff, but on the other hand, you know, you're not dealing with a '57 Chevy, it's a person, it's a human life, you know, and it's very important, you know, to take the time to tell you about stuff.*

In addition to time limitations, clinicians avoided providing patients with the entire list of potential SASEs as it could make patients more aware or "*tuned in*" and develop SASEs that may not be statin related. A clinician explained:

> *I think that an important part of prescribing statins is to understand what aches and pains the patient has before you begin, because once you mention that these drugs can or might cause symptoms, then people are going to be tuned in to whether they have changes.*

Patients recalled learning little about SASEs or having more in-depth discussions about SASEs with their clinicians. Muscle pain and gastrointestinal issues were the adverse effects patients recalled being told about by their clinicians most frequently. "It was mostly about muscle pain," recalled one patient, "*they (ie, the clinician) didn't mention the memory [loss] at all*." Print information on statins (eg, pamphlets) was not frequently provided to patients; a few patients also suggested that clinicians rely on the prescription insert as the sole information source on risks and benefits of any medication.

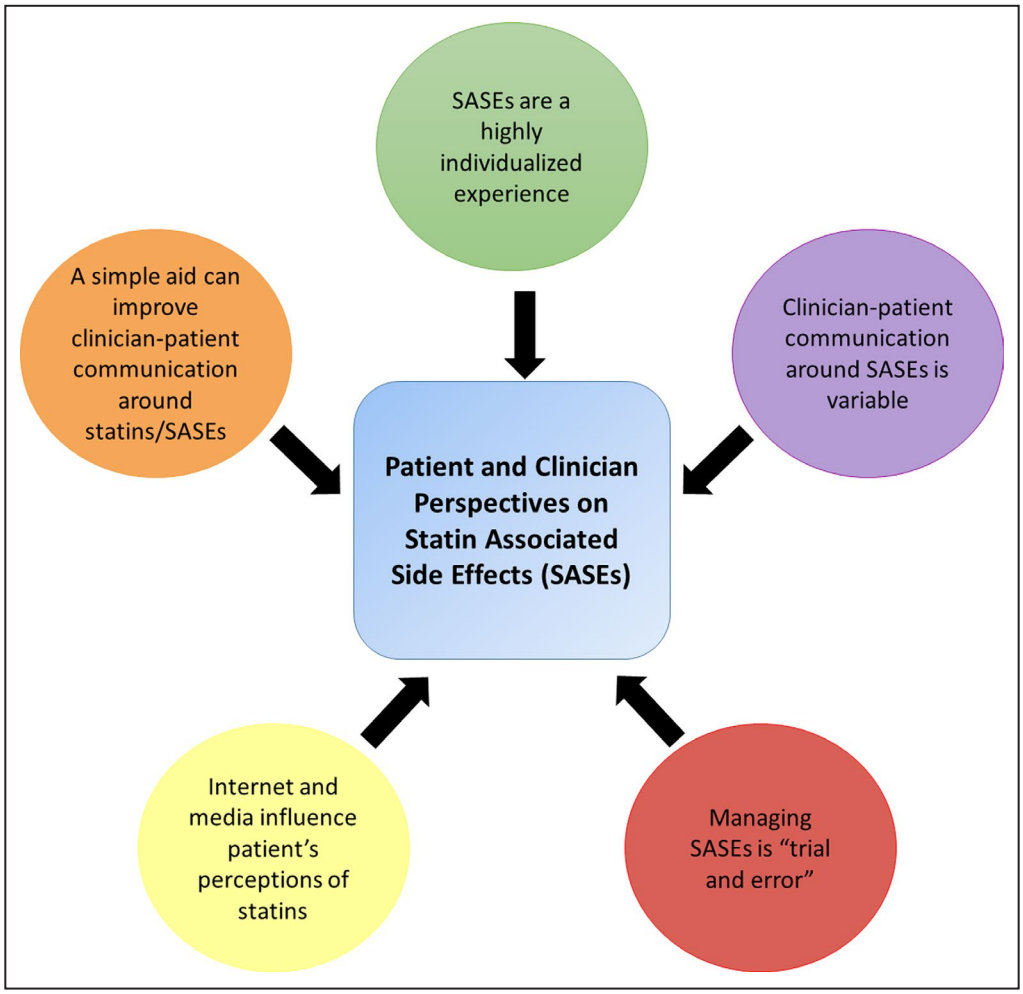

Figure 1. Five major themes impacting patient and clinician perspectives on statin-associated side effects (SASEs).

Both patient and clinician interviews described communication around reasons for statin initiation and how the benefits of statins outweigh the risks. For example, one patient was told that statins could cause adverse effects, but she/he was encouraged to try the statin for its health benefits:

> *She (clinician) knew how I feared about certain medicine, that's why she would always sit down and talk with me about things. And she told me that all medicine has side effects but…she said some patients never had a side effect. Then she told me try [the statin], and it was to help lower my cholesterol. And I would benefit from them.*

Statin benefits were especially emphasized for patients for secondary prevention of ASCVD, as one pharmacist noted:

> *It's almost like you (ie, secondary prevention patients) really don't have a choice, and then the primary [prevention group] is like you may have a choice, but your better choice would be to take it.*

However, clinicians noted that statin initiation is more difficult for primary prevention patients in whom there are no current symptoms. Yet, the decision to engage in statin therapy should align with patients' wishes. A cardiology clinician who frequently managed statin intolerance stated,

> *I can't guide them (ie, the patients), and they have to guide me in terms of taking statins to extend life (ie, quantity of life) but weighing that against the impact of side effects on the patient's quality of life.*

Both clinician and patient interviews indicated how patients frequently voiced their concerns about SASEs to their clinicians. Patient response was mixed when it came to clinicians inquiring about the onset of SASEs. Some patients felt their clinicians communicated with them about adverse effects when they came for routine tests, but a few patients struggled talking with their clinicians when SASEs developed. For example, one clinician was not convinced that a patient's perceived adverse effects were caused by statin therapy:

> *I told him (ie, the clinician) …I'm having some type of reaction from the medication. And he told me no, that wasn't reaction from that medication. But I already had Googled it online and it had said, you know, having red spots or red streaks down your leg was a reaction to the medication. And I showed it to him….*

Another patient believed his/her clinician had the right intentions initiating statins, even switching statin medications and reducing the dose. However, the patient still struggled communicating with the clinician about balancing the benefits of statins with what the patient felt was intolerable statin-induced myalgia:

> *And I knew he (ie, clinician) was right, so what do you tell him? I mean…it's not that I don't want to take them (ie, statins), it's that I should just, I can't take them, they won't work.*

Managing SASEs Is Essentially "Trial and Error"

Our analyses revealed that although clinicians' goal was to find a tolerable dose of statin therapy in patients with clinical ASCVD mostly using a "trial and error approach," some patients found this approach frustrating given their disabling symptoms.

Clinicians stated that their overall goal for patients with SASEs was to find a tolerable statin medication and dose that no longer caused significant, life-disrupting adverse effects. However, management of SASEs was often considered "trial and error." Eliciting patients' experiences with SASEs facilitated the management process. This included asking the patient questions about the adverse effects he/she was experiencing (eg, When did the adverse effects begin? What type of adverse effects? Correlation with statin initiation?). This also included assessing if the patient was adherent to the medication, determining his/her willingness to continue with statins after experiencing SASEs, and regularly communicating with patients about their experiences with adverse effects. Clinicians described management approaches, such as running laboratory tests to assess creatine kinase and/or liver function and evaluation to rule out secondary causes, such as low vitamin D, hypothyroidism, or arthritis. Some clinicians asked patients to take a statin "holiday" to suspend the medication to see if symptoms resolve. Changing statin medications and/or the dose titration were additional SASE management options. Nonstatin alternatives, such as CoQ10 (taken concurrently with the statin), ezetimibe, and proprotein convertase subtilisin/kexin type 9 inhibitors, were other alternatives suggested by clinicians. A few clinicians also referred patients to a cardiologist or pharmacist.

Some patients were frustrated by this "trial and error" approach to SASE management. One patient said:

> *So I tried it (ie, the statin) with this new doctor, went through that whole process starting with the first statin, then going to the second statin. Did that whole process all over again, and I didn't like it.*

Another patient explained how his/her clinician changed his/her statin dose, then changed the statin drug, until after the third medication change it was decided that the patient "wasn't able to take those type of medications." Patients also discussed self-titration efforts to help with adverse effects, with several stopping the medication on their own when adverse effects became intolerable. Patients also discussed use of nonstatin alternatives, like ezetimibe, fenofibrate, and proprotein convertase subtilisin/kexin type 9 inhibitors, niacin, vitamin supplements (eg, vitamins K and D), CoQ10, aspirin, fish, and flax seed oils. Physical activity and dietary changes were stated as additional alternatives to lowering cholesterol in place of the statin.

The Internet, Social Networks, and Other Media Sources Influence Patients' Perceptions of Statins

Our analyses in this domain revealed that although patients used a vast array of resources (internet, social media, and television) and social networks (friends, family members, and other patients) to inform their views and perception about statin therapy, clinicians worried about the authenticity of such sources. Patient reluctance and/or negative perceptions of statins were fueled, in part, by information they accessed outside of

the clinical encounter. Patients reported using WebMD, Facebook, Epocrates, and search engines like Google and Yahoo to learn about statins and SASEs. Clinician interviews confirmed this patient behavior. A pharmacist said:

> *So most of my patients are scared of statins, I will say, especially I think it's more about being more well informed. A lot of them will go do online Google searches on WebMD and whatnot, so most of our patients have that preconception of statins are going to cause muscle pain or muscle cramps.*

A primary care clinician characterized patients as "Googleologists" and believed that although an informed patient helps clinicians "stay on your toes," she/he questioned the accuracy of statin information gleaned from Google searches. Similarly, a cardiologist described his/her struggles explaining to patients.

> *…that Googling is good, but we have more evidence-based research and clinical trials.*

Both patient and clinician interviews revealed how social networks were another source of information on statins. According to clinicians, patient's friends and/or family members may share their negative experiences with statins, which influences how the patient perceives the drug. One primary care clinician stated:

> *…some of them (ie, patients) will say yes, my sister-in-law is on it or yes my friends are on it and we don't like this medication or something like that.*

Similarly, patients heard about SASEs from friends, relatives, other patients, and neighbors:

> *"I had heard a lot of different things, a lot of different stories about statins from my neighbors, and my wife's friend, and this, that, and other, who were taking them, and had been taking them, and had side effects from them," noted one patient. She/he wanted to discontinue statin therapy after hearing others' experiences, but his/her clinician recommended statin medication for secondary prevention.*

Television advertisements, billboards, print advertisements, and the prescription insert were additional sources of information that influenced patient's perceptions of statins. For television advertisements, a cardiology clinician felt that patients "*quote the TV for everything*" and the television advertisements lead the patient to ask questions about statin adverse effects during the clinical encounter, such as "*is this something that's going to damage my liver?*" "*Is this something that's going to make me diabetic?*" "*Is this going to cause Parkinson's or Alzheimer's down the road*?" Similarly, one patient described not knowing the cause of his/her pain until he/she saw an advertisement on television:

> *But see, my pain went on for quite a while before I knew what was causing it, what medication was causing it. And that's where I had seen the ad, on TV, and I started talking about it with my friends and neighbors and kinfolks, and that's what it was [ie, the statin].*

A Simple Aid Can Improve Clinician-Patient Communication Around Statins/SASEs

Clinicians and patients agreed that a decision support tool that summarized recent guidelines, was simple and algorithmic, and included resources and visuals to improve communication is needed. A patient stated:

> *Because if you do see a picture like that, I know me, a lot of times a picture is worth a thousand words.*

Another patient mentioned the utility of videos explaining risks and benefits of statin therapy.

> *…you know, with all the technology now and everything, in fact, your team could probably come up with something…post a video you can click on, you know, make it required if you're taking, or prescribed statins that it's a requirement that you watch this…that's very inexpensive and that's very easy, everybody's got a smart phone now, they can click on it and watch it for 5 minutes. Five minutes should be plenty, I mean if it's kind of laid out.*

Clinicians expressed how a decision aid could facilitate their statin decision-making and adverse effect management. The clinical decision support tool should be simple and in the form of an algorithm or a decision tree that is colorful with few branches, circles, arrows, or boxes to minimize confusion. This decision aid should summarize recent guidelines on statin use, and include statin starting dosages, options for various statins, safety profiles, strategies to manage SASEs (eg, nonstatin alternatives, ruling out secondary causes of SASEs, and statin titration), and strategies to rechallenge statin intolerant patients. Clinicians felt the decision aid would be most useful during the clinical encounter and should be available in a variety of formats to meet clinician preferences (eg, mobile application, pocket card, and desktop computer link). Clinicians stated:

> *It needs to be brief. I personally like things that are more colorful than not because I think in color. I need something that is, if it's going to be a flowchart, it needs to be more of a true flowchart and not a spider web. Those are too hard to follow. It needs to be something I can easily access and I know has been, that is updated and reliable.*

> *… I would say that's something that I would think other providers would look at. They don't want to read through pages and pages of recommendations but just a simple algorithm.*

Clinicians also desired a patient-centered communication aid that included disease management education (eg, managing high cholesterol and managing cardiovascular disease), information they can share with patients about the differences between statins and nonstatin therapies, the myths and truths about statins, SASEs, and natural therapies, and information conveying self-care strategies to alleviate myalgias, that adverse effects are reversible, and that not all patients will experience SASEs. The communication aid should be available in a variety of delivery formats (eg, in paper versions, such as posters and pamphlets, as well as electronically accessible, such as videos, websites, and PDFs) to reinforce information, and be engaging and interactive, geared toward patients with low literacy levels, and highly visual.

Clinicians and patients suggested a few elements to make the communication aid more visually appealing. These included depicting a patient having a heart attack (eg, clutching chest) or stroke (eg, drooping face) to reinforce how the benefits of statins (ie, prevention of an initial or subsequent event) outweigh the risks. They also suggested visuals depicting the frequency of true statin myalgias in comparison to the overall number of patients taking statin medications, illustrating the severity of statin adverse effects on a scale from mild to severe, developing a short video depicting an older patient talking about statin adverse effects, visuals that educate patients about why statins are prescribed, and a visual depiction of extreme muscle tiredness or weakness.

DISCUSSION

We interviewed 20 clinicians who regularly prescribe and manage patients receiving statin therapy and 17 patients with ASCVD to understand their perspectives on statin intolerance. Our findings indicate several areas where care could be improved to increase guideline-concordant statin therapy use and communication between clinicians and patients about statin therapy. One area involves taking a more patient-centered approach to conceptualizing the severity of SASEs. Categories of mild/moderate/severe should take into account the degree that perceived symptoms impact patient quality of life. What may be "mild" to one patient may be "severe" to another; patients also varied in adverse effect onset, number of symptoms, and *how* symptoms impacted their quality of life and activities of daily living. More effective and open communication about the impact of SASEs on patient quality of life and activities of daily living is needed. For example, encouraging clinicians to inquire more deeply about the impact of adverse effects may help build trust and rapport between patients and clinicians so the patient feels heard, which may positively impact patients' willingness to use statin therapy. Our findings also highlight the importance of why clinicians need to inquire and understand how social networks and media sources drive patients' perception about statin therapy and SASEs, at times even more than what is communicated by clinicians in a healthcare setting. Our findings are in line with a previous study, which reported how patients' perceptions of SASEs influence statin therapy use and adherence.[18] On the other hand, our results identified several emergent themes for SASEs are highly variable from one patient to another and the "trial and error approach" to managing SASEs can be frustrating for patients. Our results also identified what components do patients and clinicians desire when developing an aid to improve communication and management of SASEs.

Clinicians cited the "power of suggestion" as another reason to avoid extensive discussion of SASEs to prevent patients from incorrectly associating their symptoms with the statin medication. This thinking is in line with the "nocebo effect," which is a phenomenon that

refers to adverse events that result from expectations of harm from a therapeutic intervention.[19,20] Patients relied on internet tools, such as Google, WebMD, or Facebook, social networks, and media as sources of (mis)information that influenced their statin perceptions and decision-making capacity. This is supported by a study in which >40% of patients reported that their healthcare decisions are affected by social media.[21] Therefore, clinicians should take a more active role to discuss potential statin misinformation at the time statins are initiated, or when patients are rechallenged after the onset of adverse effects.[22] This conversation should cover known adverse effects of statins in addition to focus on their potential benefits. As patients are becoming more active consumers of health information than in the past, clinicians should help guide them to trusted sources of information, either on the internet or through educational handouts for patients.[23-25] Clinicians should balance the discussion of statin risks *and* benefits to ensure that the decision to initiate or rechallenge statin therapy, even for high-risk secondary prevention patients, is a shared decision between the patient and the clinician.[26] As one clinician noted, only the patient can "guide" the clinician in terms of a quantity versus quality of life decision about statin therapy.

Clinicians reported that a decision-making and communication aid would equip them to navigate through decision checkpoints and optimize communication with their patients to efficiently bridge the current gaps in care.[7] A simple and highly visual decision tool to facilitate clinician decisions about statin initiation, changing/titrating statins after development of adverse effects, and possible alternate treatments could be useful.[27] Clinicians could use this communication aid during a patient's clinic visit to visually depict the development of atheroma and its effects, make them aware of their level of risk, show the frequency of true SASEs versus perceived SASEs among all statin users, and depict the severity of statin adverse effects on a graded scale with checkpoints and alternative treatment options. This could potentially make patients more involved in the decision-making process and increase their willingness to try strategies recommended by their clinicians in light of SASEs. Clinicians recommended multiple formats for the communication aid, including mobile applications, desktop shortcuts, and pocket cards. This would make the materials easily accessible to the clinicians in the relatively short clinic visit rather than the clinicians having to navigate the websites and lose time that could otherwise be used for improved communication and trust building between the clinicians and the patients. Although several decision aids, such as the statin choice decision aid and diabetes mellitus medication choice aid, have been available and may facilitate shared decision-making,[28] studies have also shown that their use even when embedded within the electronic health record is low.[29] This is not unexpected as clinicians are notably overburdened with information, and studies have shown clinical reminder fatigue and burnout that results in ignoring the decision support.[30,31] Therefore, the design and implementation of such decision aid must be done with careful review of existing workflows, garnering participation and buy-in by the clinical users and using human factor best practices.

From introducing a different statin to lowering the strength or adding nonstatin alternatives, most clinicians strove to keep patients on statins at a tolerable level to ensure good quality of life. However, this "trial and error" statin management approach, as recommended by treatment guidelines,[3] was frustrating for some patients. Therefore, it is important for clinicians to set expectations at the time of statin initiation about SASEs as part of the benefit versus risk discussion. Clinicians should also clearly lay out their treatment plan to the patients, emphasizing that almost two thirds of the patients with SASEs are able to tolerate some form of statin therapy with this "trial and error approach"[32,33] and that they are there to work with the patient if he/she has further SASEs. Clinicians should also reassure patients that if they do not tolerate this "trial and error" approach to statin therapy, there are other medication options, especially in patients with established cardiovascular disease. To improve communication with patients and to facilitate shared decision-making in treatment options, most of the interviewed clinicians agreed that an adverse effect management algorithm with treatment pathways and options would benefit both patients and clinicians. It would allow the clinicians to follow a more evidence-based treatment approach when dealing with patients with SASEs, and it would assist them in communicating with the patients the importance of taking statins and the overall goal to keep the patients on statins while allowing them to have a good quality of life. The patients would benefit in that the treatment pathways would be clearer and process less frustrating.

Our findings are limited given that we conducted one-time interviews. Patient interviews may also have been limited by recall bias and length of time since first statin initiation. However, many patients had clear recollections of SASEs and the impact of those SASEs on their lives. Given that this study was performed within the Department of Veterans Affairs, we were limited in terms of the number of women patients with ASCVD who were included in the qualitative interviews. Although this study focused on the veteran patient population receiving care in a single medical center, our results are consistent with prior observations in the literature.[7,8] This provides reassurance about the generalizability of our findings and

increases the transferability of our findings to nonveteran patient populations.

CONCLUSIONS

Statin use among patients with clinical ASCVD remains suboptimal. This may be attributable to clinician- and patient-related factors, including poor clinician-patient communication, the individualized nature of SASEs, suboptimal management of SASEs, and greater influence on patients' statin-associated perceptions by nonclinician resources. A targeted communication aid used to improve clinician-patient communication with a decision aid to guide clinicians on different treatment options for patients with SASEs could improve statin use in this patient population. Finally, patients who use the internet or social media for some of their medical information may appreciate receiving a list of trustworthy medical sites and sources of scientifically sound medical information.

ARTICLE INFORMATION

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Supplementary Material

Tables S1–S2

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SUPPLEMENTAL MATERIAL

Table S1. Patient Interview Guide.

[verbal consent]

[start recorder]

1. Health care providers prescribe medications called statins to lower cholesterol levels that are too high. When did your health care provider first prescribe you statin medication?

    a. How did your health care provider talk to you about taking a statin medication to lower your cholesterol level? (probe: educational information in print, secure messaging, phone and from whom [doctor, nurse, pharmacist])

    b. How long was the discussion? Was your statin prescribed by a VA or non-VA provider?

2. Do you know if you are taking a statin to help lower your risk of having a heart attack or stroke (primary prevention) or are you taking a statin to lower your risk of having <u>another</u> heart attack or stroke (secondary prevention)?

3. Have you ever <u>not</u> taken your statin medication? **(if yes)** What are some reasons you may not take the statin medication that your health care provider prescribed for you? (Follow-up questions: hard to remember to take it every day, may not remember to renew prescription, access to the VA to get prescription, costs of statin drugs, non-VA prescriptions).

4. Health care providers sometimes talk about the 'risks versus benefits' of taking a new medication when they prescribe them. That is, how a medication may help you versus the potential for side effects.

Did your health care provider ever talked to you about the risks versus benefits of taking statin medication to lower your cholesterol?

    a. **(If yes)** Can you tell me about that conversation? How long was it?

    b. Did your health care provider ask you how you felt about taking statin medication? How did they ask you about your concerns? (probe: sources-if any-of information provided to patient-print, electronic, etc.)

    c. Did you still have concerns about taking statin medication after you talked to your health care provider? What remaining/additional concerns did you have?

    d. **(If no)** Did you find out about the risks versus benefits in any other way? (probe sources of information: print, electronic)

5. Can you describe for me how you felt when you started taking statin medications to lower your cholesterol level? Can you describe any side effects that you experienced? (probe severity of side effects)

6. Did you know X, Y, Z **(fill in with patient's side effects)** could happen when you started taking statins?

a. **(If yes)** How did you know that X, Y, Z **(fill in with patient's side effects)** could be potential side effects? (probe sources of information: RX insert, friends, provider, online sources, other sources of information)

b. **(If no)** How did you find out that X, Y, Z **(fill in with patient's side effects)** were side effects of statin medications? (probe sources of information)

7. What did you do when you started experiencing side effects? (Follow up: discuss with health care provider-in-person, by phone, by secure messaging; stop taking medications on own?)

8. **(If followed up with health care provider)** How did you tell them about your side effects? What did your health care provider want to do? (probe: change in dose/type of medication, non-statin medication).

a. What did <u>you</u> want to do? What was decided? How have you felt since your visit? (probe: recurrence of symptoms).

b. How often does your provider ask you about your concerns about statin side effects? (probe: every visit, only when you report a side effect)

9. Sometimes health care providers use pictures to explain treatment options to patients. What sorts of pictures or images can you think of that would help you see some of the risks and benefits of statin treatment for high cholesterol?

Table S2. Clinician Interview Guide

[verbal consent]

[start recorder]

1. What does the term 'statin associated musculoskeletal side effects' mean to you?

2. What percentage of your patients do you prescribe statin therapy for primary prevention? For secondary prevention?

3. What do you think is a guideline concordant statin dose for patients with CVD?

    a. What percent of your CVD patients are prescribed a guideline concordant statin dose?

4. [pharmacists only] How comfortable are you initiating/titrating statins that have the potential to be associated with musculoskeletal side effects?

5. How often do you see statin associated side effects in your practice?

6. How do you classify the severity of these side effects when you do see them?

    a. In your opinion, what do mild side effects look like? What about moderate side effects? What about severe?

7. What is your management strategy for patients prescribed statin medications?

    a. Does your management strategy change for these patients if they are taking statins for primary versus secondary prevention? (If yes) How so?

8. For patients that have been recently hospitalized, how often do you notice that statin medications drop off from their medication history? What do you do in those cases when that happens?

9. Can you describe for me how you manage patients with statin associated side effects? Follow-up: statin types and doses; non-statin lipid lowering therapies

    a. Does your management strategy change depending on the severity of these side effects? (If yes) How do you manage patients with mild side effects? Moderate? Severe?

10. Do you use an algorithm to help you manage patients taking statin medications?

    a. (If yes) What algorithm do you use? What has it been like using this algorithm in your clinical practice? What are the benefits of this algorithm? What are its drawbacks?

b. (If no) Are you aware of any existing algorithms to help with management of statin intolerance? Do you think you would be open to using an algorithm to manage these patients? What would be some potential benefits for you in using an algorithm? What would be some potential drawbacks?

11. How do you talk to patients about statin associated side effects? (probe for specific examples about risks/benefits).

    a. What language or terms do you use with patients? How does this language compare with the language you use in the patient's medical record to document statin associated side effects?

12. How might your discussion about these side effects be different for patients that need statins for primary versus secondary prevention?

13. How do you elicit patients concerns about the potential side effects of statin therapy? What have your experiences been like?

    a. How do your patients talk with you about statin associated side effects? What language or terms to they use when describing these side effects?)

14. If you were provided a communication aid to help you make decisions around prescribing statins to high-risk CVD patients not on a statin, including those with musculoskeletal side effects, what components would you like to see included?

    a. What kinds of pictographs would be helpful when explaining statin associated side effects to patients? Would having decision support along with this clinical reminder be helpful?

15. When would it be most helpful to receive this communication aid? Before the clinical visit or while you are with the patient?

16. How would you like to see the communication aid delivered? Would you prefer a direct note you have to sign or a clinical reminder?

17. Do you find clinical reminders more of a help or a hindrance to your work? (probe for specific examples)

    a. How do you respond to these reminders? (probe for specific examples) Do you respond to some clinical reminders more than others? (probe user fatigue) What are some characteristics of the ones you do respond to?