DATA REPORT

Prevalence and Management of Symptoms Associated With Statin Therapy in Community Practice

Insights From the PALM (Patient and Provider Assessment of Lipid Management) Registry

When compared against placebo in randomized trials, statins are extremely well tolerated, causing muscle-related side effects in 1% or fewer of treated patients.1 Yet in routine practice, patients often report having symptoms which are misattributed to their statin.2-4 Using data from the PALM Registry, we examined patient-reported rates of statin intolerance, characteristics of patients with perceived side effects, and response to perceived statin intolerance in contemporary practice.

METHODS AND RESULTS

The data, analytic methods, and study materials will not be made available to other researchers for purposes of reproducing the results. The PALM Registry enrolled 7938 patients from 140 primary care, cardiology, and endocrinology practices in the United States (May 27, 2015 to November 12, 2015) and has been described in detail.5 Trained study coordinators identified eligible patients (patients on a statin, at risk for cardiovascular disease [CVD], or with prevalent CVD, in the Data Supplement) at the time of their visit, who were then sequentially enrolled. Of 9788 eligible patients, n=7937 (81%) consented and enrolled in the study. Patients were then surveyed on statin use, perceived statin-related symptoms and response to symptoms, beliefs about statins and CVD, and sociodemographic characteristics (response rate 95.3%, in the Data Supplement).

Clinical characteristics and medications were abstracted from the medical record by study coordinators. All patients had core laboratory lipid levels (LabCorp, Burlington, NC). Categorical variables were compared with Mantel–Haenszel $\chi^2$ tests and continuous variables using Wilcoxon rank-sum tests. Multivariable logistic regression modeling was used to evaluate factors associated with symptoms using generalized estimating equations to account for clustering within site, with backward model selection at $P<0.05$ for variable retention. Candidate variables were chosen based on either associations with statin use (eg, demographics, atherosclerotic cardiovascular disease history, education, and insurance) or prior associations with statin intolerance (eg, thyroid disease and body mass index). Continuous variables were modeled using splines to account for nonlinearity. Statistical analyses were performed using SAS version 9.4 (Cary, NC). All participants provided signed informed consent. Each site obtained institutional review board approval for participation.

Frequency and Types of Statin-Associated Symptoms

Among 7563 patients, 5916 (78.2%) reported ever using a statin (5316 current, 600 former). Among former users, the time since the last statin use was <1 month for 13%, 1 month to <5 years for 33%, and >5 years for 17%. Overall, 2600 reported at least 1 symptom while on statin therapy, including 41.8% of current users and 63.2% of prior users. The most commonly reported symptoms were muscle aches/cramps (29% current, 51% former), fatigue (14% current, 20% former), and weakness (10% current, 20% former). Memory loss was reported by 10% of current and 9% of prior statin users, followed by constipation (9% current, 8% former), nausea (5% current, 8% former), hives/itching (3% current, 5% former), and other (1% current, 2% former).

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Factors Associated With Symptoms

Table shows the characteristics of patients with and without self-reported statin-associated symptoms. In multivariable modeling among current statin users, female sex (odds ratio [OR], 1.38; 95% confidence interval [CI], 1.24–1.55), coronary artery disease (OR, 1.29; 95% CI, 1.15–1.43), increasing body mass index (OR, 1.22 per 5 increase up to 30; 95% CI, 1.09–1.37), decreasing age (OR, 1.04 per 5-year decrease; 95% CI, 1.01–1.07), thyroid disease (OR, 1.22; 95% CI, 1.06–1.40), higher education (at least some college versus none; OR, 1.17; 95% CI, 1.03–1.33), and diabetes mellitus (OR, 1.13; 95% CI, 1.00–1.27) were associated with increased odds of reporting symptoms. Among former statin users, non-Hispanic ethnicity (OR, 2.23; 95% CI, 1.42–3.49), increasing body mass index (OR, 1.22 per 5 increase; 95% CI, 1.05–1.42), coronary artery disease (OR, 1.54; 95% CI, 1.07–2.21), and female sex (OR, 1.45; 95% CI, 1.05–2.00) were associated with increasing odds of reporting symptoms.

Those with symptoms reported lower beliefs in statin efficacy and safety and were less likely to report completely trusting their doctor (Table). Symptomatic patients reported increased worry about CVD compared with those without symptoms.

Statin Intensity and LDL-C Levels in Current Statin Users

Among current statin users, there was no difference in the rate of high-intensity statin use by symptom reporting (30.3% with symptoms versus 28.2% without; P=0.11), but those with symptoms were slightly more likely to be taking non-statin lipid-lowering therapy (27.4% versus 25.0%; P=0.049). LDL-C (low-density lipoprotein cholesterol) levels were higher among those with symptoms compared with those without (median, 89.0 versus 86.0 mg/dL; P<0.001).

Response to Symptoms

Most patients (50.8% overall) tried at least 1 intervention to stay on statin therapy. Among current statin users, 57.0% of symptomatic patients reported not taking any action to treat the symptom, 24.0% switched statins, 11.3% stopped then rechallenged with the same statin, 12.2% reduced the dose, 8.1% added an additional medication, 5.5% reduced statin frequency, and 2.8% reduced exercise. Among symptomatic former statin users, 25.9% reported no intervention, 33.4% switched statins, 39.1% stopped then rechallenged, 19.1% reduced the dose, 11.1% added an additional medication, 10.9% reduced statin frequency, and 2.6% reduced exercise.

Impact on Medication Persistence

Adverse effects were the leading reason for discontinuing therapy (51.2% of former users discontinued because of side effects). Willingness to retry a statin among those who discontinued because of symptoms was high; 26.8% reported they would not at all be willing to retry a statin, 17.8% were unlikely, 23.1% possibly, 18.2% were very likely, and 11.5% reported they would almost certainly retry a statin.

COMMENT

Despite data from randomized trials supporting the safety of statin therapy and very low rates of excess muscle-related complaints when statins are compared with placebo, very high numbers of adults who take statins continue to report statin-associated symptoms. In our study of adults currently or formerly on statin therapy in routine clinical practice, 41.8% of current and 63.2% of former statin users report at least 1 symptom on statin therapy. This is consistent with prior observational studies, with rates of muscle-related complaints ranging from 10% to 69% in different analyses.3,6

Groups most likely to report symptoms included women and those with diabetes mellitus or thyroid disease, consistent with other studies.6 Patients with coronary artery disease and those with higher levels of education were also more likely to report symptoms. Symptomatic patients felt less sure that statins were efficacious and were less likely to report completely trusting their doctor.

Our study does not establish causation between statin use and symptoms. In clinical trials, statins have not been shown to cause any of the symptoms that participants were asked about except for muscle-related symptoms. Further, the rates of muscle-related symptoms seen in PALM exceed that shown in trials.4 This suggests that patients are likely misattributing symptoms with a high background incidence to their statin. Furthermore, patients with negative expectations about statin adverse effects may be more likely to experience them (the nocebo effect).7 Adults who reported symptoms on statins were more likely to worry about CVD, potentially reflecting a higher level of health-related anxiety. Whether real or not, perceived statin-related symptoms often led patients to discontinue therapy. Our data offer hope for improving statin utilization. Many adults with symptoms successfully continued statin therapy, and nearly half of former users were willing to retry a statin. This is consistent with previous studies showing that many who discontinue statin therapy can tolerate rechallenge.8,9 Although current guidelines recommend that patients presenting with symptoms be rechallenged to establish causation before switching to an alternate statin,10 patients who continued on therapy were more likely to report switching to another statin or changing the dose. In contrast, rechallenge was more common among those who ultimately stopped therapy. Optimal strategies to identify true versus perceived statin intolerance while balancing patient preferences remain unclear.

Limitations

First, patients were queried about symptoms rather than side effects while on a statin. The patient survey

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### Table. Characteristics of Adults With and Without Symptoms While on a Statin

<table>
<thead>
<tr>
<th>Current Statin Users</th>
<th>Former Statin Users</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>At Least 1 Symptom, n=2221</strong></td>
</tr>
<tr>
<td>Age</td>
<td>67.0 (60.0–74.0)</td>
</tr>
<tr>
<td>Female</td>
<td>47.4%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>84.9%</td>
</tr>
<tr>
<td>Black/African American</td>
<td>12.7%</td>
</tr>
<tr>
<td>Asian</td>
<td>2.1%</td>
</tr>
<tr>
<td>Other</td>
<td>0.3%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>9.1%</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>58.5%</td>
</tr>
<tr>
<td>Government</td>
<td>39.8%</td>
</tr>
<tr>
<td>Other (non-US)/none</td>
<td>1.8%</td>
</tr>
<tr>
<td>Highest level of education</td>
<td></td>
</tr>
<tr>
<td>At least some college</td>
<td>66.2%</td>
</tr>
<tr>
<td>Obese (BMI ≥30)</td>
<td>52.1%</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>128.0 (118.0–140.0)</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>76.0 (70.0–80.0)</td>
</tr>
<tr>
<td>High-intensity statin</td>
<td>30.3%</td>
</tr>
<tr>
<td>Current nonstatin LLT</td>
<td>27.4%</td>
</tr>
<tr>
<td>CAD</td>
<td>42.1%</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>8.0%</td>
</tr>
<tr>
<td>Prior stroke or TIA</td>
<td>8.2%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>44.6%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>80.8%</td>
</tr>
<tr>
<td>Current smoker</td>
<td>10.3%</td>
</tr>
<tr>
<td>History of elevated liver function tests</td>
<td>3.2%</td>
</tr>
<tr>
<td>History of myopathy</td>
<td>4.2%</td>
</tr>
<tr>
<td>Thyroid disease</td>
<td>18.0%</td>
</tr>
<tr>
<td>Dialysis or CKD</td>
<td>10.2%</td>
</tr>
<tr>
<td>LDL-C</td>
<td>89.0 (72.0–111.0)</td>
</tr>
<tr>
<td>Statins are effective, % agree to strongly agree</td>
<td>72.4%</td>
</tr>
<tr>
<td>Statins are safe, % agree to strongly agree</td>
<td>48.3%</td>
</tr>
<tr>
<td>Statins cause liver damage, % agree to strongly agree</td>
<td>38.7%</td>
</tr>
<tr>
<td>Statins cause muscle aches, % agree to strongly agree</td>
<td>62.2%</td>
</tr>
<tr>
<td>Statins cause memory loss, % agree to strongly agree</td>
<td>21.2%</td>
</tr>
<tr>
<td>How often do you worry about heart attack or stroke?</td>
<td></td>
</tr>
<tr>
<td>% often or occasionally</td>
<td>44.7%</td>
</tr>
<tr>
<td>How much do you trust your doctor with decisions about your medical care?</td>
<td></td>
</tr>
<tr>
<td>% completely</td>
<td>61.8%</td>
</tr>
</tbody>
</table>

High-intensity statin defined as atorvastatin ≥40 mg, rosuvastatin ≥20 mg. Statin intensity not assessed in former statin users. Categorical variables presented as median (25th–75th percentile). BMI indicates body mass index; BP, blood pressure; CAD, coronary artery disease; CKD, chronic kidney disease; LDL-C, low-density lipoprotein cholesterol; LLT, lipid-lowering therapy; and TIA, transient ischemic attack.
Conclusions

In community practice, more than half of adults formerly or currently on statins reported symptoms while on statin therapy, which was the leading cause of discontinuation. Given the preponderance of evidence about statin safety from randomized trials, much of this is likely because of misattribution of background symptoms to statins. Even among those on statins, those with symptoms had higher LDL-C levels, potentially reflecting lower adherence. Those reporting symptoms also had less belief in statin efficacy and safety and less trust in their doctors. Although many patients did not attempt rechallenge, the majority of adults who discontinued statins because of side effects were willing to be rechallenged. These data underscore the magnitude of perceived statin-associated symptoms in community practice and support the need for more robust intervention strategies to address both real and perceived symptoms of statin therapy.

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FOOTNOTES


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Supplemental Material

PALM Inclusion Criteria

- Prior clinical atherosclerotic cardiovascular disease, including prior coronary artery disease, cerebrovascular disease, or peripheral arterial disease
- LDL-C ≥130 mg/dL on last clinic check
- Age ≥40 with diabetes or chronic kidney disease
- Age ≥65 years
- Age ≥40 with two of the following: male sex, hypertension, or smoking
- Adults ≥40 with 10-year predicted risk by pooled cohort equations of ≥5%
PALM SURVEY QUESTIONS

The PALM survey was delivered on an iPad which adapted the survey based on participant responses. While formal reliability/validity tested was not performed, the survey was pilot tested in a group of 11 patients (ages 20-72) to ensure patient understanding of questions. In response to participant feedback, questions were modified to decrease the perception by participants that statins caused particular side effects. The following questions were asked of PALM participants used in this analysis

[TO ASSESS STATIN UTILIZATION]

Please indicate if you are currently taking, or have previously taken, any of the following statin cholesterol-lowering medications. (Statins listed included atorvastatin, simvastatin, pravastatin, rosuvastatin, fluvastatin, lovastatin, pitavastatin, and an option for “a statin but do not know the name”)

[ASKED OF CURRENT STATIN USERS]

Have you experienced any of the following symptoms while taking a statin? Please select all that apply. Click here for examples of statin medications

- Muscle aches / cramps
- Memory loss, forgetfulness, or confusion
- Weakness
- Nausea/vomiting/stomach upset
- Constipation
- Fatigue
- Hives and/or itching
- Other: ______

(If any symptoms reported) Did you try any of these methods to reduce or avoid these symptoms? Please select all that apply.

- Reduced the dose
- Reduced how often I take it
- Temporarily stopped taking it
- Switched to another statin
- Added another medication to help relieve side effects of statin (e.g., Coenzyme Q10)
- Reduced exercise
- Other ______
- I didn’t do anything
[ASKED OF FORMER STATIN USERS]

You indicated that you were previously taking a statin medication to lower your cholesterol. What was the longest amount of time you were on a statin before stopping?

- [ ] Less than 1 month
- [ ] More than 1 month but less than 1 year
- [ ] More than 1 year but less than 5 years
- [ ] More than 5 years.
- [ ] I don’t know / can’t remember

When was the last time you took a statin?

- [ ] in the past month
- [ ] in the past year
- [ ] in the past 5 years
- [ ] more than 5 years ago
- [ ] I don’t know / can’t remember

What was the reason for stopping your last statin? Please select all that apply.

- [ ] My doctor felt it was no longer needed
- [ ] I didn’t like taking a medication every day
- [ ] Too expensive / cost
- [ ] I lost/changed my insurance
- [ ] I did not notice any improvement in how I felt while on this medication
- [ ] I prefer natural remedies or supplements instead of prescription medicines
- [ ] I had side effects
- [ ] A friend or relative recommended I stop
- [ ] Information I read (online, magazine) or heard suggested that I stop
- [ ] Other ______
- [ ] I don’t know / can’t remember

Did you ever experience any of the following symptoms while taking a statin? Please select all that apply.

- [ ] muscle aches / cramps
- [ ] memory loss, forgetfulness, or confusion
- [ ] weakness
- [ ] nausea/vomiting/stomach upset
- [ ] constipation
- [ ] fatigue
- [ ] hives/itching
- [ ] other ______________

- [ ] I did not experience any symptoms
- [ ] I don’t know / can’t remember

(If any symptoms reported) Did you try any of these methods to reduce or avoid these symptoms? Select all that apply.
[] Reduced the statin dose
[] Reduced how often I took it
[] Temporarily stopped taking it
[] Switched to another statin
[] Added another medication to help relieve side effects of statin (e.g., Coenzyme Q10)

[] Reduced exercise
[] Other _____
[] I didn’t do anything

[ASKED OF NEVER STATIN USERS]
Has a doctor recommended you take a statin medication to lower your cholesterol any time in the last 10 years? Examples of statins include atorvastatin (Lipitor, Caduet), simvastatin (Zocor, Vytorin, Simcor), pravastatin (Pravachol), rosuvastatin (Crestor), fluvastatin (Lescol), lovastatin (Mevacor, Advicor), and pitavastatin (Livalo).

[] yes
[] no
[] don’t remember

[IF YES TO QUESTION 14] Why are you not currently on a statin? Please select all that apply.

[] I am concerned about side effects
[] Too expensive / cost
[] Lack of insurance
[] I don’t like to take prescription medications
[] I would rather focus on diet and exercise
[] I prefer natural remedies or supplements instead of prescription medicines
[] I don’t think I need a cholesterol lowering medication
[] Other: _____
[] I don’t know / can’t remember

If your doctor recommended it, how likely would you be to try another statin to lower your cholesterol or reduce your risk of heart attack or stroke?
How often do you think or worry that you may have a heart attack or stroke?

- [ ] I often think or worry about it
- [ ] I occasionally think or worry about it
- [ ] I rarely think or worry about it
- [ ] I never think or worry about it

Please indicate how much you agree or disagree with the following statements.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>Don’t Know/Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>People with high cholesterol are more likely to have a heart attack or stroke than people with low cholesterol.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>People don’t need to worry about their cholesterol if they have never had a heart attack or other heart problem.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Statin medications are effective in reducing the risk of heart disease and stroke</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Statins are safe medications</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I think statins can cause diabetes</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I think statins can cause muscle aches or pain</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I think statins can cause liver damage</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I think statins can cause memory loss</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

How much would you say you trust your doctors’ decisions about your medical care?

|                  |                  |                  |                  |                  |                  |
|------------------|------------------|------------------|------------------|------------------|
| Completely distrust | Generally distrust | Neither trust nor distrust | Generally trust | Completely trust |

What is the highest level of education you have completed?
[] Middle school / Junior High
[] High school
[] Some college or vocational school
[] Graduated from college or vocational school
[] Post-graduate degree