
The S^Tatin Adverse Treatment Experience (STATE) Survey: Experience of Patients Reporting Side Effects of Statin Therapy

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Disclosures

- **Mary Katherine Cheeley:** reports speakers bureau for and Investigator Initiated Study grant from Regeneron/Sanofi.
- **Terry A. Jacobson:** reports being a consultant for Amarin, Amgen, Astra-Zeneca, Esperion, and Regeneron/Sanofi; Steering Committee Member, REDUCE-IT Trial and Amarin.
- **Peter H. Jones:** reports consultant/advisory board for Amgen and Sanofi/Regeneron.
- **Ralph LaForge:** reports consulting for Nikon.
- **Kevin Maki:** reports advisor/consultant for and clinical research grants from Akcea; stocks/bonds for Amarin; advisor, advisor/consultant and stocks/bonds for Amgen; advisor/consultant for Corvidia Therapeutics; advisor/consultant for DSM; advisor/consultant for and clinical research grants from Matinas; advisor/consultant for and clinical research grants from Pharmavite; and advisor/consultant and speaker for Regeneron/Sanofi.
- **J. Antonio G. López and Pin Xiang:** employees of and stockholders in Amgen Inc.
- **Donald M. Bushnell and Mona L. Martin:** were employees of Health Research Associates, which received funds to conduct this research, and have no financial interests in Amgen Inc.
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“I am still struggling, yeah. And that’s the only reason I’m willing to try this last one.”

“It would be easier to take statins if they got rid of the side effects, okay.”

“I don’t know where to turn next. I know the consequences of getting off, no matter how much I focus on my diet, I may not be able to control it [my cholesterol].”



Background & Objective

Background

- The 2013 ACC/AHA guidelines recommended moderate- to high-intensity statins in most patients^{1,2}
- 2018 guidelines now also recommend high-intensity statins for many high-risk individuals³
- 10-29% of patients report statin-associated muscle symptoms, which are a major determinant of statin nonadherence, discontinuation, and switching⁴

Objective

- Describe the patients' experiences after reporting ≥ 1 recent statin-associated adverse event
- Identify opportunities to improve:
 - Patient adherence
 - Medication management
 - Clinical practice
 - Patient outcomes

ACC, American College of Cardiology; AHA, American Heart Association

1. Stone NJ, et al. *Circulation*. 2014;129(25 suppl 2):S1-S45. 2. Pencina MJ, et al. *N Engl J Med*. 2014;370(15):1422-1431. 3. Grundy SM, et al. *J Am Coll Cardiol* 2018; [published online ahead of print, Nov 10]. doi:10.1016/j.jacc.2018.11.005. 4. Jacobson TA, et al. *J Clin Lipidol*. 2018;12(1):78-88.

Stages of STATE Survey Development

Qualitative Development

- ✓ Opinion leader interviews
- ✓ Concept elicitation via qualitative patient interviews
- ✓ Generation of preliminary survey
- ✓ Cognitive patient interviews

Pilot Validation

- ✓ Evaluated initial STATE performance and design
- ✓ Clinic-based recruitment and survey administration
- ✓ Taken via computer by 98 patients (49 with statin-related symptoms and 49 without)
- ✓ Decisions made to edit select items

Quantitative Evaluation

- ✓ Commercial vendor collected survey data across the US
- ✓ 1,500 respondents with hyperlipidemia who had experienced difficulties from a statin within the past 6 months

Statin Adverse Treatment Experience (STATE) Survey Domains

Survey Goals

- Describe the patient's experience after reporting a recent side effect from a statin
- Inform clinical practice and encourage risk-benefit discussions
- Potentially help identify patients at risk for stopping their statin therapy



Statin Side-Effect History

- Patient journey
- Predictors of statin adherence



Clinical Characteristics

- Clinical and behavioral characteristics
- Potential predictors of risk for stopping statin treatment



Symptom Severity

- Patient's perspective of statin tolerability
- Patient burden
- Symptom Severity Score



Respondent Demographics

- Define and characterize the study population



Impact Severity

- Statin therapy effects on patient's daily lives
- Impact Severity Score



Health Information and Beliefs

- Potential predictors of patients who are at risk for discontinuing their statin therapy

Sample Selection

Inclusions

- ✓ ≥18 years old
- ✓ Resides in the US
- ✓ Do not have an excluded condition*
- ✓ Took a statin in the last 2 years[†]
- ✓ Experienced side effects
- ✓ With ≥1 statin-associated side-effect in past 6 months[‡]

20% of patients who had taken a statin in the last 2 years experienced a statin-related symptom

Total Invited:
43,053

42,899

39,422

34,287

21,319

4,367

1,500

Exclusions

- ✗ <18 years old
- ✗ Do not live in the US
- ✗ Have an excluded condition*
- ✗ Have not taken one or more statins in the last 2 years[†]
- ✗ Had not experienced side effects
- ✗ Most recent experience of side effects over 6 months ago[‡]

*Conditions include fibromyalgia, multiple sclerosis, muscular dystrophy, untreated thyroid disease, liver disease, kidney disease requiring dialysis, any condition requiring treatment with corticosteroids or cyclosporine. [†]10,785 (25.1%) were never prescribed a statin drug, 577 (1.3%) were prescribed a statin, but did not take the medication, and 1,606 (3.7%) took a statin previously but not in the past 2 years. [‡]6 months was selected to minimize recall bias given that these are patient self-reported experiences.

Study Population

	Currently Taking Statin n = 1,168 (77.9%)	Stopped Statin n = 332 (22.1%)
Age (years)		
Mean (SD), median	58.1 (13.0), 60.0	58.3 (13.4), 61.0
55+ (high 91)	65.8%	65.1%
Sex		
Women	58.9%	62.7%
Race		
White	89.1%	88.6%
Black or African American	6.5%	7.8%
Ethnicity		
Hispanic/Latino	12.2%	12.3%
Statin history		
Tried 1 statin	56.0%	59.6%
Tried ≥ 2 statins	44.0%	40.4%

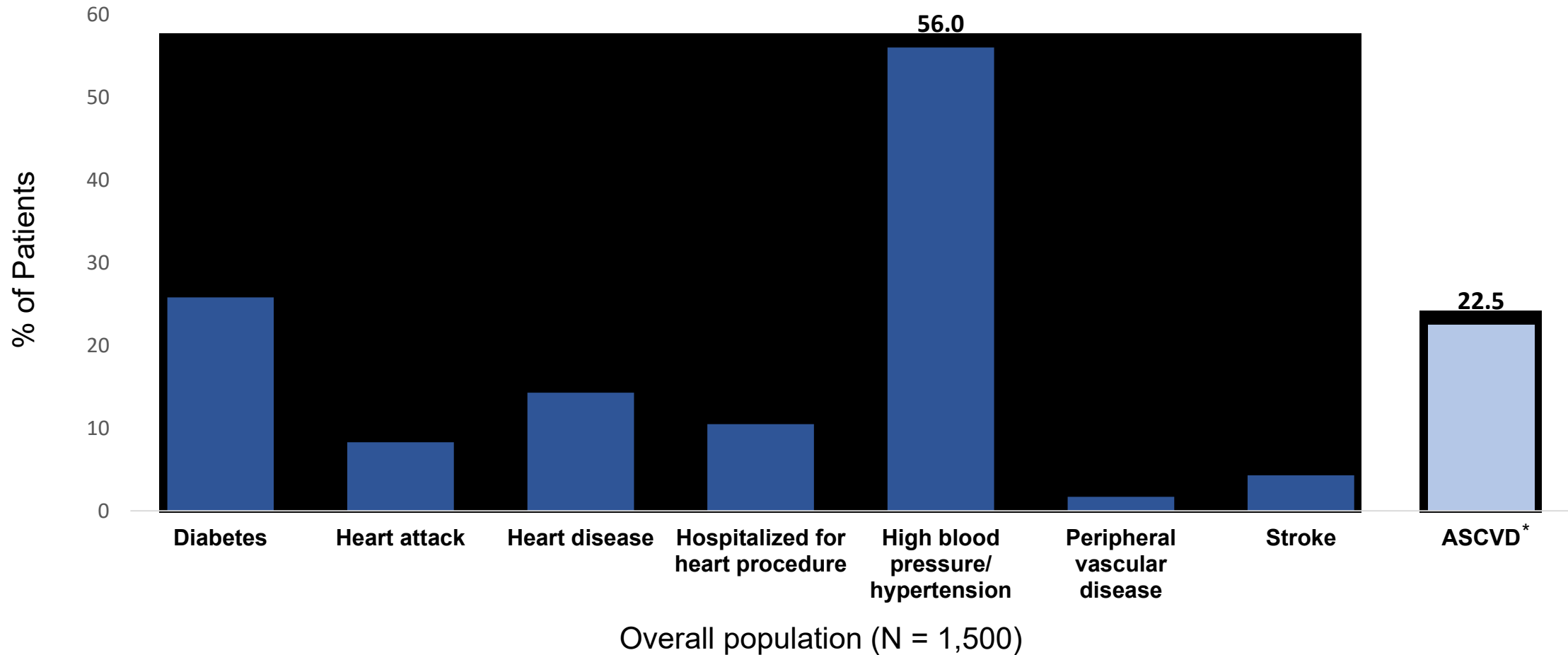


	LightSpeed Panel*	US Census
55+ (high 91)	18%	33%
Women	70%	51%

*Drawing from a younger and female population with over 40,000 patients.

Patients were relatively older with no difference in patient characteristics between current statin users and those who have discontinued their statins

Clinical Characteristics



*ASCVD is the combination of heart attack, heart disease, hospitalized for heart procedure, peripheral vascular disease, and stroke.

Many patients had high-risk clinical comorbidities

Key Reasons for Continuing and Stopping Statins

Reasons to continue statin therapy, by order of importance (n = 1,168):

Mean Score

I want to avoid a heart attack or stroke 8.5

I want to lower my cholesterol 8.3

My doctor recommended it 8.3

I am at a high risk for heart disease 6.9

I have a family history of heart disease 6.4

I have a personal history of heart disease 4.0

10 = Extremely important

0 = Not important at all

Reasons to stop statin therapy, by order of importance (n = 332):

Mean Score

Bothered by side effects 7.1

Cannot tolerate the side effects 6.7

Side effects interfere too much with life 6.5

Side effects are not worth the level of risk 6.2

I'd prefer natural approaches to health 4.4

I don't like to take medication in general 3.6

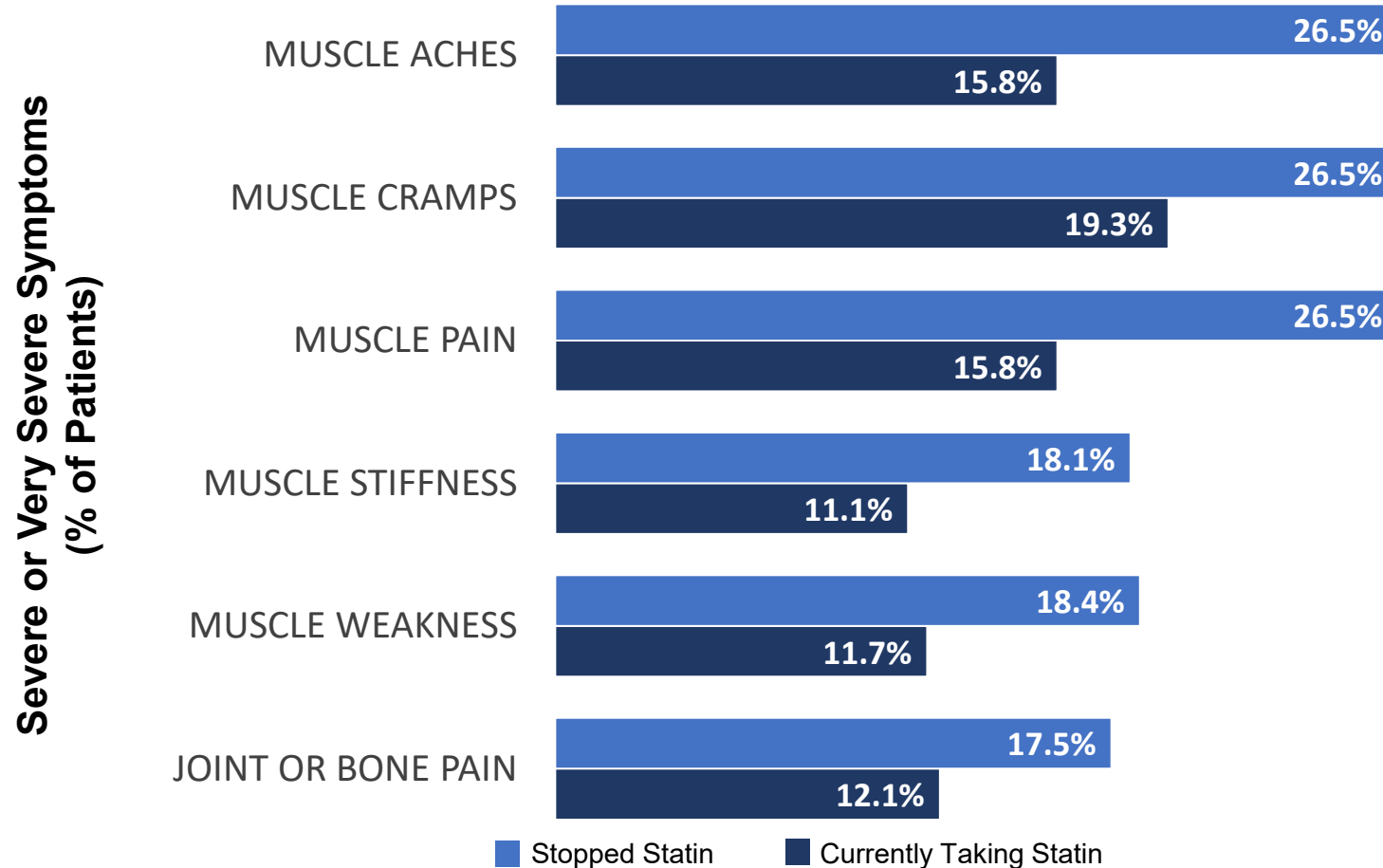
Cost outweighs the potential benefit 2.7

Inconvenient to take medication everyday 2.1

Increasing Importance

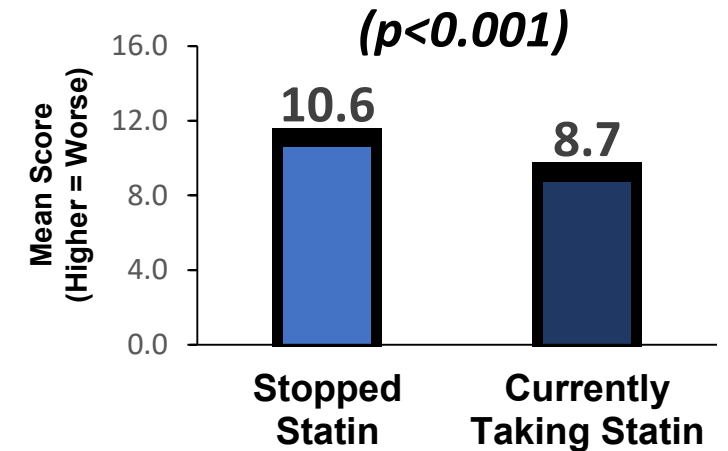
- Prevention of heart attack/stroke was the main reason to take statins despite symptoms
- Many patients are bothered by their side effects and stop medication

Symptom Scores by Current Statin Use



Differences for the symptoms were statistically significant ($p < 0.05$).

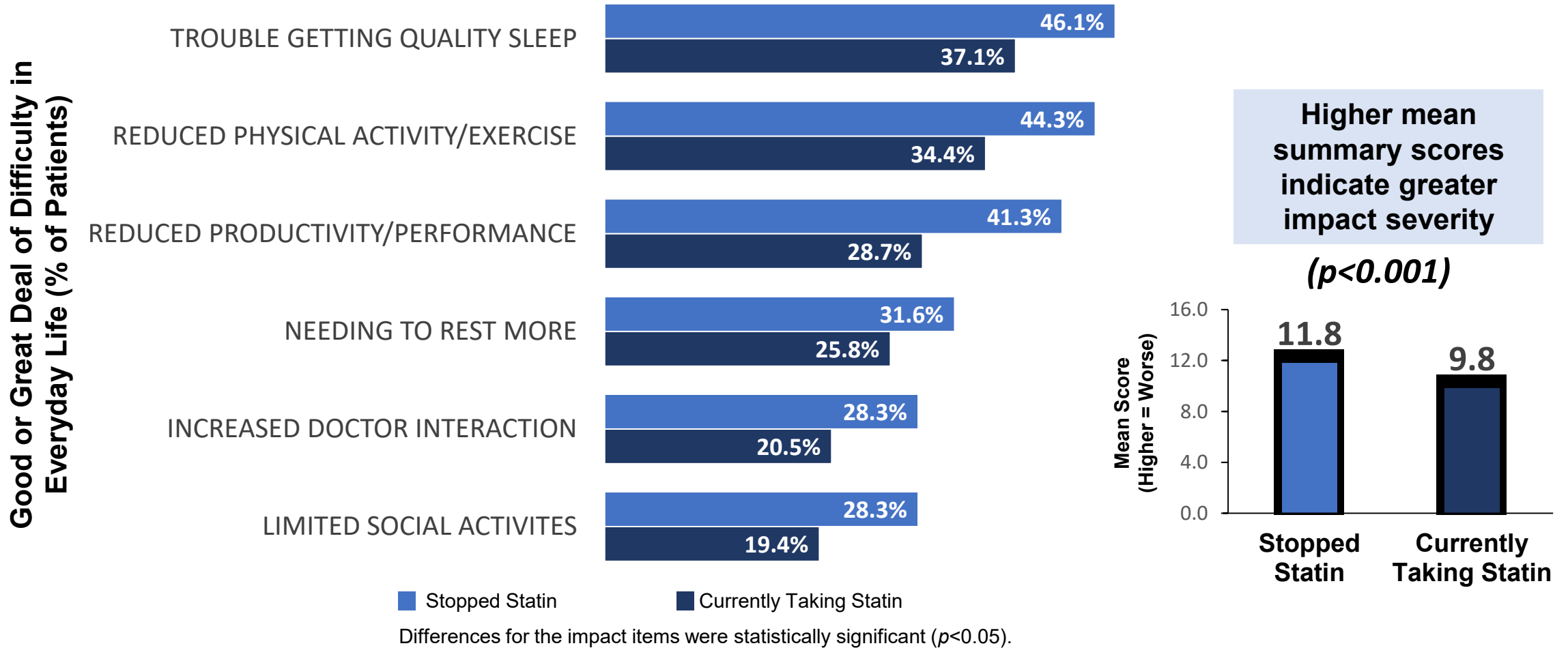
Higher mean summary scores indicate greater symptom severity



Symptom score includes the categories presented on the left along with Memory Problems and Tiring Easily.

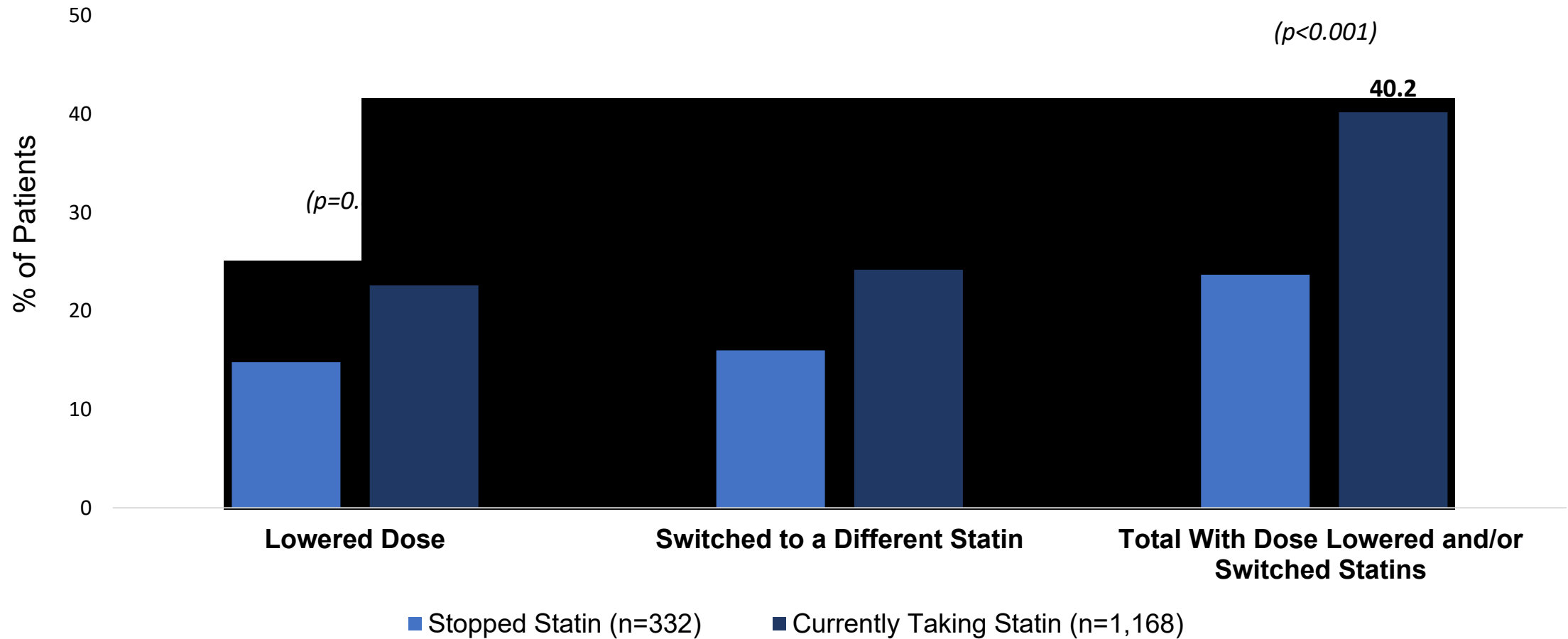
Those who stopped statins reported greater symptoms from medication

Impact Scores by Current Statin Use



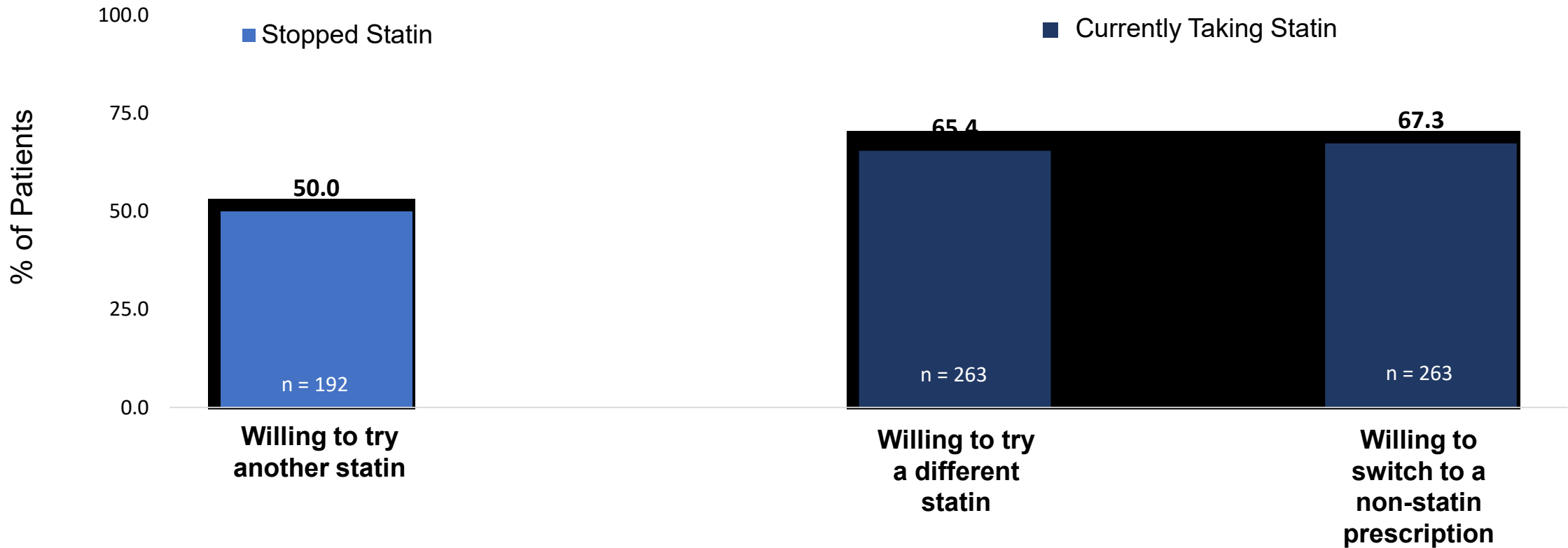
Those who stopped statins reported higher impact from medication

Changes to Statin Therapy Due to Side-Effects or Laboratory Results



More patients may stay on treatment when their therapy is adjusted

Willingness to Try Other Options



Most patients who are not at treatment goal are willing to try other options

Strengths and Limitations

Strengths

- First statin survey reporting comprehensive patient experiences and behavioral markers
- The STATE survey was developed using and highlighting the patient voice and journey
- Provides evidence for predictors of statin tolerability and adherence

Limitations

- Possible selection bias using panel-based market research vendor
- Generalizability to the broader population of statin users in the US and racial and ethnic minorities may be limited

Conclusions



First study to:

- Describe patients' adverse experiences with statins, in the patient voice
- Highlight how symptom and impact scores affect patients' decisions to continue or discontinue statin therapy



Providers need a greater awareness of statin tolerability from the patient's perspective

~1 in 5 patients who stopped statin have not communicated with their providers



Risk-benefit discussions should be encouraged, with the ultimate goal of keeping patients on effective lipid-lowering therapies



Patients are more likely to be successful with greater provider engagement and shared decision-making

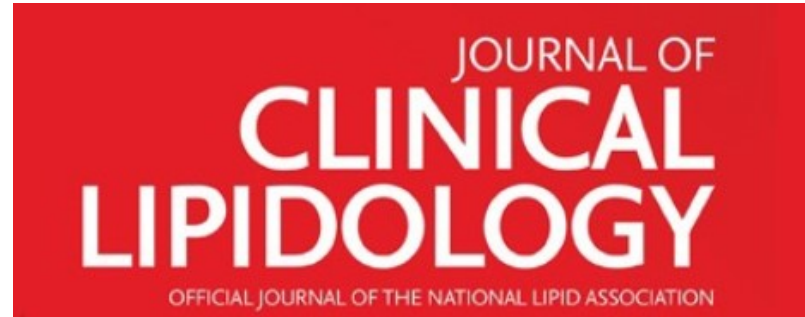
Success is possible...

“My numbers were ‘at goal’... my LDL was less than 100, so that small dose was ok”

“Once I started taking the injections... it was amazing how low the cholesterol went down, and with minimal side effects”

Want to learn more?

Manuscript Publication



Infographic

