Perceptions of Statin Discontinuation among Patients with Life-Limiting Illness

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Abstract

Background: Optimal management of chronic medications for patients with life-limiting illness is uncertain. Medication deprescribing may improve outcomes in this population, but patient concerns regarding deprescribing are unclear.

Objective: The aim of this study was to quantify the perceived benefits and concerns of statin discontinuation among patients with life-limiting illness.

Design: Baseline data from a multicenter, pragmatic clinical trial of statin discontinuation were used.

Setting/Subjects: Cognitively intact participants with a life expectancy of 1–12 months receiving statin medications for primary or secondary prevention were enrolled.

Measurements: Responses to a 9-item questionnaire addressing patient concerns about discontinuing statins were collected. We used Pearson chi-square tests to compare responses by primary life-limiting diagnosis (cancer, cardiovascular disease, other).

Results: Of 297 eligible participants, 58% had cancer, 8% had cardiovascular disease, and 30% other primary diagnoses. Mean (standard deviation) age was 72 (11) years. Fewer than 5% of participants expressed concern that statin deprescribing indicated physician abandonment. About one in five participants reported being told to take statins for the rest of their life (18%) or feeling that discontinuation represented prior wasted effort (18%). Many participants reported benefits of stopping statins, including spending less money on medications (63%), potentially stopping other medications (34%), and having a better quality of life (25%). More participants with cardiovascular disease as a primary diagnosis perceived that quality-of-life benefits related to statin discontinuation (52%) than participants with cancer (27%) or noncardiovascular disease diagnoses (27%) [$p=0.034$].

Conclusion: Few participants expressed concerns about discontinuing statins; many perceived potential benefits. Cardiovascular disease patients perceived greater potential positive impact from statin discontinuation.

Keywords: deprescribing; medication discontinuation; statins

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Introduction

THERE IS INCREASING AWARENESS that deprescribing, the process of tapering or stopping drugs for the purpose of minimizing polypharmacy and improving patient outcomes, is important for patients with life-limiting illness.^{1–5} Conversations between prescribers and patients are a crucial part of the deprescribing process to align prescribing with patients' goals for care.^{1,4} However, clinicians' perceptions about patients' concerns regarding medication deprescribing can contribute to reluctance to start conversations about considering medication discontinuation.^{4,6,7}

The need to gain clarity on the issue of deprescribing is growing given regulatory pressure to optimize medication use⁸ and growing evidence that suggests that stopping some medications (e.g., statins) may be associated with improved quality of life for patients with life-limiting illness.⁹ To date, this area of research has primarily focused on older adults with multiple morbidities^{10–12} and adults with life-limiting illness.^{3,13} While concerns about medication discontinuation have been discussed in studies exploring medication decision making for adult^{6,14,15} and geriatric populations⁶ and for specific disease states, including depression,¹⁶ dementia,⁷ and diabetes,¹⁷ few studies have described perspectives of patients with life-limiting illness. Furthermore, some studies report that prescribers are concerned that discontinuing medications may be viewed by patients as a sign of having been given up on.¹⁸ The purpose of this analysis was to quantify the perceived benefits and concerns of statin discontinuation among patients with life-limiting illness.

We analyzed baseline data from a multicenter, parallel-group, unblinded, pragmatic clinical trial of discontinuing statin therapy in the setting of advanced life-limiting illness. Results from the parent study demonstrated evidence for the safety and benefit of statin discontinuation in this population.⁹ We sought to describe patients' perceived risks, benefits, and concerns with statin discontinuation. We also explored whether these perceived risks, benefits, and concerns differed according to whether the patient's primary life-limiting illness was a cardiovascular disease or another condition. Ultimately, improved communication and shared decision making between healthcare providers and patients are essential for the deprescribing process^{1,4,19}; therefore, our goal was to seek data to inform that process.

Methods

Study design, data source, and participants

The study design and eligibility requirements of the parent study have been previously described.⁹ Briefly, the parent trial was a multicenter, parallel-group, unblinded, pragmatic clinical trial of statin discontinuation among adults with limited life expectancy.⁹ From June 3, 2011, to May 2, 2013, patients were enrolled, after relevant institutional review board approval, from 15 Palliative Care Research Cooperative Group (PCRC) member sites (10 academic medical centers; five community-based hospice/palliative care organizations) that were geographically dispersed across the United States.²⁰ Eligible participants for the parent study included English-speaking adults (aged ≥18 years) receiving a statin for 3 months or longer for primary or secondary prevention of cardiovascular disease, a documented diagnosis of advanced life-

limiting illness determined by at least one physician who indicated that he or she would not be surprised if the patient died in the next year, life expectancy of more than 1 month, and recent deterioration of functional status, with a reduction in the Australia-Modified Karnofsky Performance Status scale score²¹ to less than 80% in the previous 3 months. Participants remained in the study until death, 1 year after enrollment, or study closure, whichever occurred first. For this analysis, participants were included if they were cognitively intact (defined as a Short Portable Mental Status Questionnaire²² score ≥6) so that data were available regarding self-reported patient concerns about medication discontinuation.

Data collection

Baseline assessment. Baseline assessments included demographics, primary life-limiting diagnosis, individual and aggregate comorbid conditions, statin medication history, and performance status. Aggregate comorbidity was measured using the Charlson Comorbidity Index score.²³ Quality of life was measured using the McGill Quality-of-Life Questionnaire (MQOLQ),²⁴ reflected by a single-item overall quality-of-life score and selected subscales (physical symptom, psychological symptom, existential well-being, and support). A total score was computed as the mean of the four subscales. If at least half of the items in a subscale were answered, missing values were imputed using the mean of the completed items. Scores ranged from 0 to 10, with higher scores indicating better quality of life. Primary life-limited diagnoses were categorized into cancer, cardiovascular disease, and other. A primary diagnosis of cardiovascular disease included atherosclerotic heart disease or stroke.

Symptoms were measured using the Edmonton Symptom Assessment System (ESAS) score.²⁵ The nine standard items on the scale (i.e., pain, fatigue, nausea, depression, anxiousness, drowsiness, appetite, well-being, and breathing) were supplemented with four additional items specific to statin use (muscle-related pain, weakness, headache, and fever). Scores were summed from the nine standard items for the ESAS total score, the four supplemental items for the ESAS statin score, and for all 13 items for the ESAS 13-Q. The same imputation rule used for determination of quality of life was applied to missing responses. Performance status was measured using the Australia-Modified Karnofsky Performance Status scale, with scores ranging from 0 (death) to 100 (no symptoms, no evidence of disease).

Medication use. The number of nonstatin medications was documented, including regularly scheduled medications, medications administered as needed on at least 50% of the days in the prior week, and administered as needed on fewer than 50% of the days in the prior week. All three measures were combined into a variable quantifying the total number of nonstatin medications.

Outcome measures. Participants were asked nine questions regarding their perceptions about discontinuing statins before randomization. Given a lack of published validated questionnaires at the time of study initiation, questions were developed *de novo* and pilot tested by an interdisciplinary team of investigators from nursing, internal medicine, geriatric medicine, cardiology, oncology, and palliative care to

ascertain patients' concerns based on the investigators' clinical experience and existing literature. Questions addressed three domains of patient concerns: potential benefits, potential risks, and other reservations. Potential benefits about discontinuation were indicated by any positive response to questions addressing concerns about costs ("If I stop this medication, I will spend less money on medications"), quality of life ("If I stop this medication, I will have a better quality of life"), symptoms ("If I stop this medication, I will have fewer symptoms"), and stopping other medications ("If I stop this medication, I may be able to stop other medications that I take."). Potential risks related to discontinuation were indicated by a positive response to the question about poor outcomes ("If I stop this medication, I will experience another problem in addition to those I already have."). Other concerns about discontinuation were indicated by any positive response to questions addressing conflicts with the advice of the original prescribing physician ("I have been previously told that I should never discontinue this medication."), wasted effort ("Stopping would mean that all that effort was wasted."), abandonment ("Stopping this medication means that my doctor has given up on treating me"), and fear that discontinuation is a sign of imminent death ("Stopping this medication means that my doctor thinks I am about to die."). Answer choices included agree, disagree, or unknown (disagree and unknown responses were grouped together).

Statistical analysis

We used descriptive statistics to characterize participants. Differences between groups were tested using Pearson chi-square tests for categorical data outcomes and *t*-test analysis of variance for continuous outcomes. We used Pearson chi-square to compare concerns regarding discontinuation between participants into three diagnosis groups (cancer, cardiovascular disease, and other) defined using patients' primary life-limiting diagnosis.

Results

Among the 381 participants enrolled in the parent trial, 297 (78%) were cognitively intact and included in this analysis. Excluded participants were significantly older ($p < 0.001$); however, there were no significant differences between included and excluded participants by other measured demographic variables, baseline symptom burden, or quality of life (data not shown).

Most ($n = 184$, 62%) participants had a primary diagnosis of cancer, 8% ($n = 23$) had a primary diagnosis of cardiovascular disease, and 30% ($n = 90$) comprised the other diagnosis category. The most prevalent life-limiting diagnoses in the other category were chronic obstructive pulmonary disease ($n = 42$, 47%) and renal disease ($n = 12$, 13%). Participant characteristics at the time of study enrollment are displayed in Table 1. Participants with a primary diagnosis of cancer were significantly younger than participants with cardiovascular disease and other primary diagnoses (mean age (SD) = 69 (10) years versus 78 (14) versus 75 (11), respectively; $p < 0.001$) and reported taking significantly fewer medications on study enrollment (mean (SD) = 11 (5) years versus 13 (4) versus 13 (5), respectively; $p < 0.001$). In contrast, there were no significant differences in the distribution of sex, mean baseline symptom burden (i.e., ESAS total score, ESAS statin score, or ESAS 13-Q score), or mean baseline quality of life (i.e., MQOLQ total score) between primary diagnosis groups.

Frequencies of responses to questions regarding patient concerns about stopping statins are displayed in Table 2. Approximately 18% of participants agreed that they were told to never discontinue their statin medications. In addition, 18% agreed that discontinuing their statins would mean that all the previous efforts in taking their statins were wasted, and 14% agreed that they would experience problems if they discontinued their statins. On the other hand, 92% and 93% of participants disagreed with the statements that stopping their statin medications would mean that their doctor was giving up on them or that their doctor thought they were about to die.

Regarding the potential benefits of stopping statin medications, a notable proportion of participants agreed that discontinuation of statins would result in fewer symptoms (19%), better quality of life (25%), or would mean they may discontinue other medications (34%). In addition, 63% agreed that discontinuing their statins would result in spending less money on medications.

Significant differences in patient concerns between diagnosis groups were observed regarding the possibility of stopping other medications and perceived quality of life. Patients with cardiovascular disease as their primary diagnosis were significantly more likely to respond that they may be able to stop other medications if they stop their statins (61% compared with 29% among patients with a primary diagnosis of cancer and 37% among patients with other primary diagnoses, $p = 0.004$). In addition, patients with a primary diagnosis of cardiovascular disease were significantly more likely than the

TABLE 1. PATIENT CHARACTERISTICS BY PRIMARY LIFE-LIMITING DIAGNOSIS

Variable	Total (n=297) (Mean (SD))	Primary life-limiting diagnosis			p
		Cancer (n=184) Mean (SD)	Cardiovascular disease (n=23) Mean (SD)	Other (n=90) Mean (SD)	
Female sex, n (%)	130 (43.8)	81 (44.0)	8 (34.8)	41 (45.6)	0.65
Age at enrollment, (years)	71.8 (11.0)	69.4 (9.8)	77.7 (13.9)	75.1 (11.1)	< 0.001
Number of medications (n=293)	11.5 (5.0)	10.6 (4.7)	12.7 (4.1)	13.1 (5.4)	< 0.001
MQOLQ total score (n=236)	7.0 (1.3)	6.9 (1.3)	7.1 (1.1)	7.1 (1.5)	0.60
ESAS score [0–90] (n=278)	27.1 (16.0)	27.8 (15.9)	27.1 (15.8)	25.7 (16.4)	0.62
ESAS statin score [0–40] (n=276)	7.0 (6.2)	7.2 (6.1)	6.7 (6.9)	6.6 (6.3)	0.77
ESAS 13-Q score [0–130] (n=278)	34.2 (20.6)	34.9 (20.1)	33.8 (20.5)	32.6 (21.7)	0.71

Abbreviations: ESAS, Edmonton symptom assessment system; MQOLQ, McGill quality-of-life questionnaire; SD, standard deviation.

TABLE 2. PARTICIPANT AGREEMENT TO STATEMENTS REGARDING STATIN DISCONTINUATION BY PRIMARY LIFE-LIMITING DIAGNOSIS

Statement	Response	Total (n = 297) n (%)	Primary life-limiting diagnosis			p
			Cancer (n = 184) n (%)	Cardiovascular disease (n = 23) n (%)	Other (n = 90) n (%)	
I have been previously told that I should never discontinue this medication.						0.34
	Agree	52 (17.5)	37 (20.1)	3 (13.0)	12 (13.3)	
	Disagree	234 (78.8)	141 (76.6)	20 (87.0)	73 (81.1)	
	Unknown	11 (3.7)	6 (3.3)	0 (0.0)	5 (5.6)	
Stopping statins would mean that all my previous efforts were wasted.						0.88
	Agree	52 (17.5)	34 (18.5)	4 (17.4)	14 (15.6)	
	Disagree	228 (76.8)	141 (76.6)	18 (78.3)	69 (76.7)	
	Unknown	17 (5.7)	9 (4.9)	1 (4.3)	7 (7.8)	
If I stop my statins, I will experience another problem in addition to those I already have.						0.54
	Agree	40 (13.5)	22 (12.0)	3 (13.0)	15 (16.7)	
	Disagree	228 (76.8)	145 (78.8)	17 (73.9)	66 (73.3)	
	Unknown	29 (9.8)	17 (9.2)	3 (13.0)	9 (10.0)	
If I stop my statin, I will have fewer symptoms.						0.51
	Agree	56 (18.9)	32 (17.4)	6 (26.1)	18 (20.0)	
	Disagree	189 (63.6)	118 (64.1)	12 (52.2)	59 (65.6)	
	Unknown	52 (17.5)	34 (18.5)	5 (21.7)	13 (14.4)	
If I stop my statins, I will have better quality of life.						0.29
	Agree	73 (24.6)	43 (23.4)	9 (39.1)	21 (23.3)	
	Disagree	173 (58.2)	108 (58.7)	11 (47.8)	54 (60.0)	
	Unknown	51 (17.2)	33 (17.9)	3 (13.0)	15 (16.7)	
If I stop my statins, I will spend less money on medications.						0.36
	Agree	186 (62.6)	115 (62.5)	18 (78.3)	53 (58.9)	
	Disagree	98 (33.0)	61 (33.2)	5 (21.7)	32 (35.6)	
	Unknown	13 (4.4)	8 (4.3)	0 (0.0)	5 (5.6)	
If I stop my statin, I may be able to stop other medications that I take.						0.004
	Agree	101 (34.0)	54 (29.3)	14 (60.9)	33 (36.7)	
	Disagree	164 (55.2)	112 (60.9)	6 (26.1)	46 (51.1)	
	Unknown	32 (10.8)	18 (9.8)	3 (13.0)	11 (12.2)	
Stopping my statins means that my doctor has given up on treating me.						0.089
	Agree	10 (3.4)	3 (1.6)	1 (4.3)	6 (6.7)	
	Disagree	272 (91.6)	172 (93.5)	21 (91.3)	79 (87.8)	
	Unknown	15 (5.1)	9 (4.9)	1 (4.3)	5 (5.6)	
Stopping my statins means that my doctor thinks I am about to die.						0.19
	Agree	9 (3.0)	3 (1.6)	1 (4.3)	5 (5.6)	
	Disagree	275 (92.6)	173 (94.0)	22 (95.7)	80 (88.9)	
	Unknown	13 (4.4)	8 (4.3)	0 (0.0)	5 (5.6)	

other two diagnosis groups to agree that stopping statin medications may result in fewer symptoms or better quality of life (52% compared with 27% among patients with a primary diagnosis of cancer and 27% of patients with other primary diagnoses, $p = 0.034$) (data not shown).

Discussion

We assessed perceptions of statin discontinuation among persons with life-limiting illness. Study participants ex-

pressed relatively few concerns and also acknowledged potential benefits of statin discontinuation. Less than 10% of participants expressed worry that statin discontinuation meant that their doctor was giving up on them and less than one in five expressed worry regarding other potential risks associated with discontinuation. Furthermore, our data suggest that participants with cardiovascular disease as their primary diagnosis may best understand potential benefits of stopping statins. This is significant because these patients are representative of the patient group in

whom statin discontinuation may be viewed as clinically most complex.

Less than 10% of study participants expressed worry that discontinuation meant that their doctor was giving up on them or that their doctor thought they were going to die. This suggests that addressing statin, or perhaps other medication, discontinuation may not necessarily invoke the sense of abandonment in patients as many clinicians have reported.¹⁹ This is important because patients often will not bring up their concerns about medication discontinuation unless first provided with an opportunity to do so by their prescriber.^{7,16,17} Furthermore, some reports suggest that up to 90% of people are willing to try discontinuation of their medications if their doctor thought it appropriate.²⁶ Our finding suggests that worry about negative patient perceptions about medication discontinuation should not stand in the way of clinicians initiating conversations about possible deprescribing among patients with life-limiting illness.

The proportion of patients who expressed worry about potential risks associated with discontinuation in our study (14%) was considerably lower than in previous reports in other conditions such as depression¹⁶ and dementia.⁷ One possible reason for this difference is that prior discontinuation studies focused on symptom-related drugs (e.g., depression), while this study focused on statins, a preventive/nonsymptom-related medication. This is supported by reported differences in willingness to discontinue by drug type, where patients prescribed benzodiazepines or opiates reported much lower willingness (<20%)²⁷ to discontinue their use compared with those who were prescribed chronic disease drugs (>80%).²⁸

A sizable proportion of patients endorsed potential benefits of discontinuation, including fewer symptoms (18.9%), better quality of life (24.6%), or even stopping other medications (34.0%). Other studies suggest that patients who perceived having a large medication burden or use of unnecessary medications are more likely to want to discontinue medications.²⁶ The majority of these studies also indicated a monetary benefit to stopping.

The primary limitation of this study is the potential lack of generalizability because the study population included only participants who had agreed to participate in a trial involving potential randomization to statin discontinuation. Thus, participants in this study were likely to be at least somewhat open to the idea of discontinuation. Although only 13.5% of our study population expressed concerns regarding bad outcomes from potential statin discontinuation, more than 25% of patients eligible for the parent trial did not participate due to their own refusal or physician refusal.⁹ Some of this refusal was likely due to concerns regarding bad outcomes from statin discontinuation. However, it is important to note that our rate of refusal is actually lower than a previously reported feasibility study of deprescribing in older nonhospice patients, which experienced nearly 30% refusal.²⁹ Another limitation was that we did not use a validated tool to quantify patient perceptions regarding benefits and concerns of discontinuing statins. Although validated tools assessing attitudes toward deprescribing have been developed, these tools were not available at the time of data collection for this study nor have they specifically been validated in patients with life-limiting illness.^{22,30–32} Of note, the Patients' Attitudes Toward Describing (PATD) tool has been used to assess perceptions of statin deprescribing among hospitalized older adults in

Australia and yielded similar results to our study.³² Last, our study included a relatively small number of patients with a primary diagnosis of cardiovascular disease, which constrains the inferences we can make about this population.

Conclusions

As diseases progress and goals of care shift, discussions about the ongoing rationale for the use of specific medications should be revisited regularly.¹ As per previously published guidance on having deprescribing conversations,¹⁰ shared decision making, in which risks, benefits, and patient values are considered, should occur. Our findings suggest that consideration of discontinuing chronic medications in the setting of life-limiting illness should not be dissuaded by concerns about taking away patient hope or inducing a fear of abandonment.

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