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Title: Patient-Reported Changes in Weight, Appetite, and Lifestyle During Evolocumab Therapy

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Abstract:

Background

Evolocumab is a PCSK9 inhibitor that has demonstrated efficacy in lowering LDL-C levels and in reducing cardiovascular event risk. Even though initial clinical trials have not consistently reported weight change as an adverse effect, Anecdotal patient reports show potential changes in body weight associated with its use.

Objective

To assess patient-reported changes in body weight, appetite, and lifestyle behaviors after initiation of evolocumab using an anonymous online questionnaire.

Methods

It was a cross-sectional, online survey carried out among self-identified current or former users of evolocumab. Participants completed a survey questionnaire regarding weight changes and their timing, appetite, lifestyle modifications, and subjective effects of the drug. Their responses were summarized by using descriptive statistical methods; 95% confidence intervals (CIs) were measured for each proportion, and Fisher's exact test was later applied for comparing subgroups.

Results:

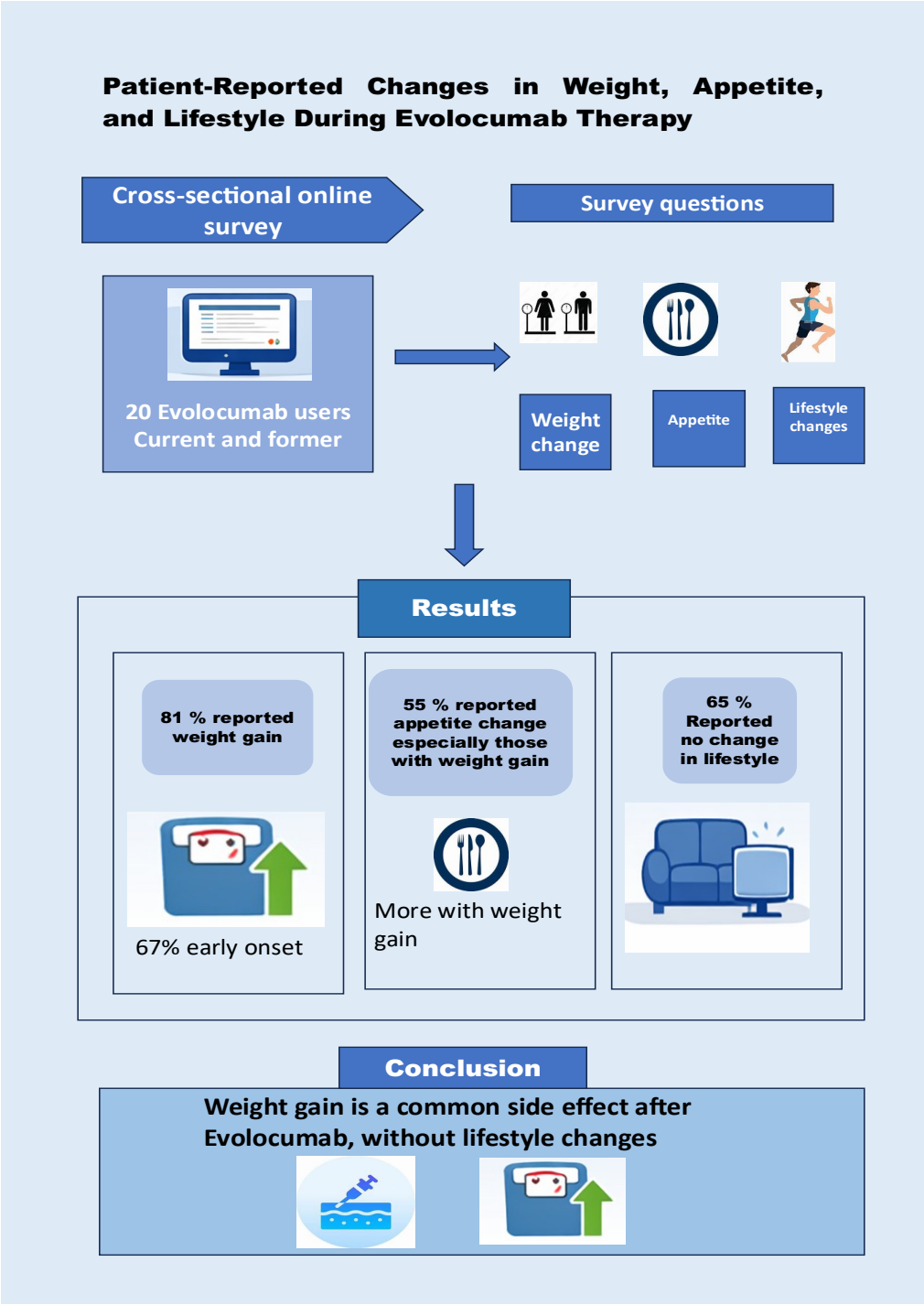
After initiating evolocumab, 19 (90%; 95% CI 68–99%) out of 20 respondents conveyed weight changes. Seventeen participants (81%; 95% CI 59–95%) reported

weight gain, while 4 (19%; 95% CI 5–41%) experienced weight loss. Weight changes were observed within the first few weeks by 14 individuals (67%; 95% CI 43–85%). Regarding lifestyle behavior most participants (13/20; 65%) did not perceive any change. Sixteen respondents (84%) noticed a significant impact of evolocumab on their weight, with perceived impact more frequent among those reporting weight gain (88% vs 25%, p = 0.02). 11 respondents (55%) conveyed appetite changes, especially those who disclosed weight gain (59% vs 25%, p = 0.3).

Conclusions:

An exploratory online survey indicated weight gain after initiating evolocumab, usually early during therapy and was independent of lifestyle changes. These results highlight the relevance of patient-perceived drug effects on quality of life. This survey supports to conduct the prospective studies to evaluate weight-related effects of PCSK9 inhibitors.

Graphical Abstract



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Introduction

Dyslipidemia is described as abnormal levels of blood lipids, indicated by elevated total cholesterol, triglycerides (TGs), and low-density lipoprotein cholesterol (LDL-C), and/or reduced high-density lipoprotein cholesterol (HDL-C). Current epidemiological data suggest that hypercholesterolemia affects about one-third of adults worldwide. It is a major and potentially modifiable risk factor for cardiovascular disease. Elevated levels of low-density lipoprotein cholesterol (LDL-C), increased triglycerides (TG), and reduced high-density lipoprotein cholesterol (HDL-C) are each independently and collectively associated with a higher risk of cardiovascular events in the general population. Resultantly, numerous clinical trials have focused on improving lipid profiles in patients with dyslipidemia for both primary and secondary prevention of cardiovascular events. As low-density lipoprotein cholesterol (LDL-C) is a strong independent, well-recognized and established risk factor for the development of cardiovascular disease. So, based on the currently available evidence, most recent clinical guidelines emphasize more lowering LDL-C as the primary therapeutic target in the management of dyslipidemia. [1–4]

Statins act by inhibiting HMG-CoA reductase that is the rate-limiting enzyme in the mevalonate pathway of cholesterol synthesis. They greatly modify the natural history of atherosclerosis and its related complications by significantly reducing

cardiovascular mortality. This benefit is mediated primarily through a dose-dependent reduction in low-density lipoprotein cholesterol (LDL-C) of approximately 20–55%, typically observed within 30 days of initiating therapy.[5,6]

As more potent statins have been developed and approved. The most effective agents have achieved mean reductions in low-density lipoprotein cholesterol (LDL-C) of up to 55% at the highest approved doses. Corresponding coronary heart disease (CHD) outcome trials have demonstrated that greater LDL-C lowering is associated with a proportional reduction in CHD events. A decade ago, individuals who failed to achieve optimal low-density lipoprotein cholesterol (LDL-C) levels or were unable to tolerate effective statin doses had few effective alternative therapeutic options. Available alternative agents included the cholesterol absorption inhibitor ezetimibe, extended-release (ER) niacin, bile acid sequestrants, and fibrates. However, these therapies generally reduce LDL-C by only 12% to 18%, may be associated with significant adverse effects. Furthermore, in recent cardiovascular outcome trials, they have not demonstrated additional reductions in coronary heart disease (CHD) events when added to statin therapy.[7]

Over the past few years, monoclonal antibodies targeting proprotein convertase subtilisin–kexin type 9 (PCSK9) have emerged as a novel class of lipid-lowering agents. Exhibiting marked efficacy in reducing low-density lipoprotein cholesterol (LDL-C) levels.[8]

Evolocumab (REPATHA®, Amgen, Inc.) is one of them which is a fully human monoclonal IgG2 antibody that selectively binds proprotein convertase subtilisin/kexin type 9 (PCSK9). Individuals with genetic deficiency of proprotein convertase subtilisin–kexin type 9 (PCSK9) exhibit low levels of low-density lipoprotein cholesterol (LDL-C), and pharmacologic inhibition of PCSK9 with monoclonal antibodies prevents LDL receptor degradation, increasing hepatic LDL uptake and lowering circulating LDL cholesterol. As assessed at the average of weeks 10 and 12 in patients with primary hyperlipidemia or mixed dyslipidemia receiving evolocumab as monotherapy, treatment with evolocumab at doses of 140 mg twice weekly or 420 mg once a month for 12 weeks produced roughly 55–75% reductions in LDL-C compared with placebo in numerous randomized, placebo-controlled clinical trials.[9,10]

Currently it has been approved for homozygous familial hypercholesterolemia and severe heterozygous hypercholesterolemia but in US In the United States, it is indicated for the treatment of primary hyperlipidemia and mixed dyslipidemia to further reduce LDL-C, as an adjunct to diet, either alone or in combination with a maximally tolerated statin or other lipid-lowering therapies.[11,12]

Evolocumab has proved a favorable safety profile in large randomized controlled trials and long-term extension studies. Commonly reported adverse effects limited primarily to injection-site reactions, upper respiratory symptoms, and

musculoskeletal complaints. Notably, initial trials and post-marketing safety reviews have not reported weight change or appetite alteration as significant or pre-determined adverse outcomes.

The absence of reporting of these metabolic or behavioral effects shows under-recognition rather than true absence. Our report highlights a potential association between evolocumab use and changes in body weight and appetite, thereby focusing on an important gap in the existing literature. By documenting these findings, this study can contribute a novel clinical perspective by emphasizing the need for more clinical awareness and further studies to better characterize less commonly reported adverse effects of PCSK9 inhibitors.

Methods:

Study Design

This study was a cross-sectional, questionnaire-based survey conducted thoroughly online. The primary objective was to explore patient-described weight changes associated with evolocumab. The study was observational and hypothesis-generating with no intervention or follow-up. No personally identifiable information was gathered, and all participation was anonymous and voluntary. Participants were self-identified evolocumab users recruited through online platforms and patient forums. Eligibility required current or prior use of

evolocumab and completion of an online questionnaire. No demographic, clinical, or treatment-duration data were collected.

Survey Instrument and data collection

The questionnaire comprised of multiple-choice and yes/no questions designed to assess key outcomes as described by the patients, including the presence, timing, and direction of weight change after initiating evolocumab. As well as self-reported lifestyle modifications, perceived drug-related effects on weight, and changes in appetite or hunger. All questions were described in neutral, non-leading language to reduce response bias. The survey was performed through a web-based secure form. Responses were automatically anonymized and stored in a protected database. Only de-identified and aggregate data were used for analysis.

Outcome Measures

The primary outcome was weight change as patient reported following initiation of evolocumab. Secondary outcomes included timing and direction of weight change, self-reported lifestyle modifications, perceived drug-related effects on weight, and changes in appetite.

Statistical Analysis

Given the small sample size and observational design, analyses were descriptive and exploratory. Categorical variables were summarized using counts and

percentages, with 95% confidence intervals calculated via the Clopper–Pearson method. Fisher's exact test was used for subgroup comparisons. No multiple-comparison adjustments were applied. Analyses were performed in R (v4.3), with a p-value < 0.05 considered suggestive of an association.

Results:

A total of 20 participants completed the questionnaire. The analysis was done to assess self-reported experiences following using evolocumab. No demographic or clinical characteristics were collected. Overall, 19 respondents (90%) reported a change in weight after initiating evolocumab. Of these, weight gain was more frequently observed, with 17 respondents (81%) indicating gain and 4 respondents (19%) indicating weight loss. The 95% confidence interval (CI) for any reported weight change was 68%–99%, and for weight gain was 59%–95%, suggesting that perceived weight change, particularly gain, was common among participants. (Table. 1)

Question	n / N	%	95% CI
Experienced weight change	19/20	90%	68% to 99%
Weight change within weeks	14/21	67%	43% to 85%
No lifestyle changes reported	13/20	65%	40% to 85%
Perceived significant impact	16/20	84%	60% to 97%
Appetite changes	11/20	55%	32% to 76%
Weight gain	17/21	81%	59% to 95%
Weight loss	4/21	19%	5% to 41%

Table. 1: *Detailed summary of questionnaire responses with 95% CIs*

Among respondents highlighting weight change, 14 (67%) noticed the change within the first weeks of therapy (95% CI: 43%–85%), that indicated an early onset. Formal comparative testing could not be applied due to the absence of a control group, but the timing was notable.

Lifestyle modifications were not commonly found. Thirteen respondents (65%) reported no changes in diet or exercise. This pattern was similar in all subgroups, with 11 of 17 participants (65%) reporting weight gain and 2 of 4 participants (50%) reporting weight loss, all denying lifestyle changes. Fisher's exact testing also

showed no statistically significant difference in lifestyle changes between the weight gain and weight loss groups (p = 1.0), as it was expected given the small sample size. (Table. 2)

Weight change group	Lifestyle change	No lifestyle change	Total
Weight gain	6	11	17
Weight loss	2	2	4
Total	8	13	21

Table. 2: Lifestyle modifications by weight-change direction

Most respondents perceived evolocumab as having a great impact on their weight, with 16 participants (84%) complained of a significant effect. This perception was more common among those reporting weight gain (15 of 17, 88%) compared with those reporting weight loss (1 of 4, 25%), with Fisher's exact testing suggesting an association (p = 0.02). It was interpreted cautiously due to the exploratory nature of the analysis. Changes in appetite or hunger were described by 11 respondents (55%), including 10 of 17 (59%) with weight gain and 1 of 4 (25%) with weight loss; this difference was not statistically significant (p = 0.3). (Table. 3)

Outcome	Weight gain n/N (%)	Weight loss n/N (%)	Fisher exact p-value
Perceived significant impact	15/17 (88%)	1/4 (25%)	0.02
Appetite changes	10/17 (59%)	1/4 (25%)	0.3
No lifestyle changes	11/17 (65%)	2/4 (50%)	1.0

Table. 3 *Perceived impact, appetite changes, and lifestyle change by weight-change direction*

Overall, weight gain was seen as the most commonly reported outcome. It was documented early in onset and independent of lifestyle changes. A more strong, perceived drug-related impact was present among participants with weight gain, and appetite changes were noted by over half of this group, suggesting a possible but unproven link. All results are summarized in the following tables. Some denominators differ across questions (e.g., N=20 vs N=21) due to question-specific response counts, as reported in the source results.

Discussion:

This study offers preliminary data on the adverse-effect profile of evolocumab, which a new therapeutic option for patients with hard-to-treat dyslipidemia. It is based on patient-reported outcomes.

With recent researches dyslipidemias remain a rapidly evolving field of investigation, contributing on the understanding of molecular mechanisms and genetic determinants, clarifying their contribution to atherosclerosis, expanding available options and thus demonstrating how pharmacologic therapies can reduce ASCVD risk in affected populations.[13]

Statin therapy is advocated as the first-line pharmacologic treatment across multiple lipid-lowering clinical guidelines.[14] In the JUPITER trial, randomization to rosuvastatin 20 mg succeeded in achieving a median reduction of approximately 50% in LDL-C levels overall. However, the individual response was different substantially, with percent reductions ranged from small increases to decreases exceeding 80%.[15] But it also has been consistently shown that desired optimal low-density lipoprotein cholesterol (LDL-C) targets are not achieved in every patient. Several factors contribute to this lack, including the inability of a sign proportion of individuals to tolerate adequate statin doses or any statin therapy at all, a condition known as statin intolerance (SI). In most cases, SI presents clinically as muscle pain. Registry data also estimate the prevalence of SAMS to range between

7% and 29%.[16] Unfortunately, it has also been found that among patients on statin treatment and high adherence, only a small proportion of patients achieved LDL-cholesterol targets owing to other factors.[17]

The discovery that PCSK9 plays a central role in regulating LDL homeostasis has opened new pathways for therapeutic intervention. PCSK9 functions as a chaperone that targets the LDL receptor for lysosomal degradation. Its inhibition enhances recycling of LDL receptors back to the cell surface, resultantly increasing LDL clearance. Human monoclonal antibodies such as evolocumab remove PCSK9 from the circulation, resulting in LDL-C reductions of approximately 60%, even effective in individuals already receiving statin therapy with suboptimal response.[18]

The Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk (FOURIER) trial was a large cardiovascular outcomes study in patients with established atherosclerotic cardiovascular disease, designed to evaluate the efficacy and safety of evolocumab as an adjunct to moderate- or high-intensity statin therapy. This study demonstrated that adding evolocumab to ongoing statin therapy markedly lowered LDL cholesterol to a median level of 30 mg/dL (0.78 mmol/L) and was associated with a significant reduction in cardiovascular event risk.[19]

Another trial found that after one year of using evolocumab, the incidence of cardiovascular events was significantly reduced, decreasing from 2.18% in the standard-therapy group to 0.95%.[20]

Patient adherence to therapy is mandatory to achieve the full clinical benefits of evolocumab despite its high efficacy in reducing LDL-C levels and cardiovascular events. From a patient-centered perspective, particularly for a relatively new therapeutic agent adequate understanding of treatment schedules and potential adverse effects is essential to optimize real-world effectiveness. Therefore, this study was formulated to evaluate the effects of evolocumab on patients' weight, appetite, lifestyle, and behavioral changes, assessing these areas from the patients' own viewpoints.

Regarding to its dosage and frequency, it is administered subcutaneously in the thigh, abdomen, or upper arm. Adults with ASCVD or primary hypercholesterolemia should be given either 140 mg every 2 weeks or 420 mg once in a month. Patients with age more than 10 years with Homozygous Familial Hypercholesterolemia should receive 420 mg monthly, which can be increased to every 2 weeks if further LDL-C reduction is required. In heterozygous familial hypercholesterolemia, similar dose can be initiated. Those with Homozygous

Familial Hypercholesterolemia who are undergoing LDL apheresis may should be administered 420 mg every 2 weeks, administered after apheresis.[21]

Common adverse effects that have been reported include nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection-site reactions in patients with primary hyperlipidemia, while patients with ASCVD most commonly experience adverse effects were diabetes, nasopharyngitis, and upper respiratory tract infection.[21]

Furthermore, with the use of PCSK9 inhibitors significant safety signals for muscle-related adverse events have been identified. These adverse effects predominantly include myalgia, muscle spasms, arthralgia, pain in the extremities, back ache, muscular weakness, and elevated blood creatine phosphokinase levels. Among these myalgia is the most frequently reported muscle-related adverse event.[22]

While existing literature primarily documents muscle-related adverse effects associated with PCSK9 inhibitors, weight gain has not been described. In this study, however, a novel association between evolocumab exposure and weight gain was seen that suggests a potential adverse effect that warrants further investigations. Another thing worthy of highlighting is that the reported weight gain and change in appetite in these patients were not associated with any change in lifestyle.

These findings from our study provide direction for future research on evolocumab, highlighting the need to further analyze the observed association with weight gain. In addition to pathophysiological analyses of the metabolic impacts of PCSK9 inhibition, future research should evaluate dose-response and time dependent relationships, account for metabolic and lifestyle factors, and validate this signal using prospective cohorts or randomized trials.

This study has limitations related to its exploratory design and modest sample size. Due to this causal interpretation cannot be made. Data were self-reported, and objective weight measurements were not provided. Nevertheless, the consistency and early timing of reported weight changes support the relevance of the observed association and justify further prospective investigations.

Conclusion:

In this exploratory survey, after starting treatment with evolocumab, a majority of participants perceived weight gain often occurring early and in the absence of lifestyle changes. They highlight the value of patient-reported outcomes in identifying potential side effects not evaluated in previous studies. Although these findings cannot validate a causal relationship, they provide direction for systematic

and prospective evaluation to find whether PCSK9 inhibitors influence weight and appetite in certain patient populations.

Ethical Considerations

Formal ERB approval was not required as the survey was anonymous, voluntary, and non-interventional. All ethical principles were upheld through informed consent and data confidentiality, with implying consent with submission of questionnaire.

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Conflicts of Interest

The authors report no conflicts of interest.

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