Evaluating severe hypercholesterolemia in an uninsured, vulnerable population receiving care at a community clinic

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Abstract

Background

Individuals with LDL-C ≥ 190 mg/dL (severe hypercholesterolemia) require treatment with high-intensity statins and should be evaluated for underlying causes including Familial Hypercholesterolemia (FH). The characteristics of patients with LDL-C ≥ 190 mg/dL has been reported in routine healthcare settings, but limited data exist about uninsured populations.

Objectives

To examine the scope of LDL-C ≥ 190 mg/dL in a clinic serving uninsured populations.

Methods

Patients with LDL-C ≥ 190 mg/dL at North Dallas Shared Ministries, a charity, community clinic in Dallas, TX, were identified via query of the electronic health record, and data was extracted from medical charts. Patients were interviewed to obtain family history and assess knowledge of cholesterol levels.

Results

Among 662 patients with lipid measurements, 27 had LDL-C ≥ 190 mg/dL (67% female, 78% Hispanic, mean age 52 years). Median pretreatment LDL-C was 210.5 mg/dL. Almost all (93%) were prescribed a statin, but only 33% were prescribed high-intensity statin. Treated LDL-C was 141 mg/dL. No patients had an ICD-10 diagnosis of FH, and only 31% had laboratory tests for secondary causes of hypercholesterolemia. Only 15% had any documentation of family history of hypercholesterolemia and/or ASCVD. After interviewing, we discovered previously undocumented family history of hypercholesterolemia in 54% and ASCVD in 31%.

Conclusions

Among the uninsured with LDL-C ≥ 190 mg/dL in a community clinic, the use of high-intensity statins was suboptimal, and most were not evaluated for causes of severe hypercholesterolemia. Future efforts to address gaps and education are warranted to improve care for severe hypercholesterolemia patients in this vulnerable population.

Condensed Abstract

Few studies evaluate severe hypercholesterolemia in uninsured populations. We queried the electronic health record at a charity community clinic to characterize individuals with severe hypercholesterolemia. Our results suggest more education is needed for patients and providers regarding severe hypercholesterolemia and FH to better care for this vulnerable population.

Introduction

Patients with severe hypercholesterolemia (defined as LDL-C levels ≥ 190 mg/dL) have a high risk of developing premature atherosclerotic cardiovascular disease (ASCVD) and recurrent coronary events¹⁻⁴. Clinical trial data have demonstrated that high intensity statins provide the greatest ASCVD risk reduction when compared to moderate-intensity statins or placebo for individuals with severe hypercholesterolemia and/or ASCVD^{1,2,5,6}. For this reason, guidelines recommend maximally tolerated statin therapy for patients with severe hypercholesterolemia with a goal of reducing low-density lipoprotein cholesterol (LDL-C) to below 100 mg/dL, and such individuals should be evaluated for underlying causes of severe hypercholesterolemia including hypothyroidism, nephrotic syndrome, and cholestasis^{1,5}.

Additionally, a significant portion of patients with LDL-C ≥ 190 mg/dl will have Familial Hypercholesterolemia (FH)⁷. FH is an autosomal dominant condition characterized by a substantial elevation of LDL-C⁸. Identifying and treating FH patients remains a top public health priority for effective ASCVD prevention^{8,9}. In fact, the United States Centers for Disease Control and Prevention (CDC) designated FH as one of three Tier 1 genomic conditions requiring early detection and early intervention^{9,10}.

While the characteristics of patients with LDL-C ≥ 190 mg/dl has been reported in routine healthcare systems, limited data exist about such individuals in vulnerable populations such as the medically underserved at charity, community clinics^{8,11}. These clinics serve uninsured individuals who are unable to access care even from safety-net healthcare systems¹². Furthermore, no data exists regarding the burden of FH and associated treatment gaps for this population. Here, we sought to begin addressing these gaps by describing the burden of severe hypercholesterolemia at a primary care, charity, community clinic.

Methods

Setting and Participants

The study was conducted at North Dallas Shared Ministries (NDSM) and was approved by the Institutional Review Board at UT Southwestern Medical Center. NDSM is a cooperative effort of 47 congregations that combine resources to deliver assistance to the poorest families and individuals in Dallas, TX. Among its many programs, NDSM includes a charity, community clinic that provides care to uninsured populations. The clinic first opened in 2000 and grew rapidly to become a full-time primary care clinic, now open 7 AM – 7 PM weekdays. As of 2019, over 7000 medically underserved individuals receive routine health care at NDSM annually¹³. These patients are uninsured and are unable to receive routine healthcare from safety-net healthcare systems. The electronic health records (EHR) used at NDSM is Athena Electronic Health Records (Watertown, MA) since 2016¹⁴.

Data Collection

We queried the EHR at NDSM for patients who met our eligibility criteria since 2016 (when HER was implemented at NDSM). Inclusion criteria included any recorded LDL-C ≥ 190 mg/dL. We did not exclude any individuals among those with LDL-C ≥ 190 mg/dL. The charts were manually reviewed to collect information on demographics, past medical and family medical history, untreated and treated LDL-C levels, comorbidities, and use of lipid lowering drugs. Physical exam findings were reviewed for documentation of arcus senilis and xanthomas (for FH). We searched charts (both clinic notes and laboratory results) for evidence of secondary causes of severe hypercholesterolemia, including hypothyroidism (Thyroid Stimulating Hormone (TSH) level), cholestasis (bilirubin), and nephrotic syndrome (urine protein). For those without evidence of secondary causes, we sought to establish whether they fulfill FH diagnostic criteria for Simon Broome and/or Dutch Lipid Clinic Network (DLCN) ^{15,16}(Appendix A and B). Additionally, Make Early Diagnosis to Prevent Early Deaths (MEDPED) criteria was used to determine the FH status of patients using age and lipid levels ^{17,18}(Appendix C).

All charts that met inclusion criteria were reviewed by JP and BW, with supervision by a University of Texas Southwestern (UTSW) FH clinic physician, ZA. Study data was stored within the Research Electronic Data Capture (REDCap) database and the study was approved by the UTSW Institutional Review Board.

Patient Interviews

Patients who met qualification criteria were called via telephone for two purposes: we gathered further past medical and family history (not previously recorded EHR) needed to assess whether they fulfill Simon Broome and/or DLCN FH diagnostic criteria; and patients were asked a series of questions about their knowledge of cholesterol and hypercholesterolemia (Appendix D). The interviews were conducted in the patient's native language by fluent interviewers. All patients were free to answer or not answer any question that was posed to them.

Statistics

Continuous variables were summarized as means with standard deviation and/or medians with associated interquartile ranges (IQR's). Categorical variables were summarized with percentages. The interviews with patients were conversational and from the information gathered, summary statistics were created.

Results

Study Population

Between 2016 and 2020, LDL-C values were measured for 662 unique patients at NDSM clinic. Twenty-seven of these patients met inclusion criteria, having at least one measured LDL-C ≥ 190 mg/dL (Table 1). Population mean age was 52 years with a range of 38-79 years as well as a female predominance (67%). Most patients self-identified as Hispanic (74%) and white (63%), which reflects the proportion at

the NDSM clinic overall. Sixty-three percent of patients also had hypertension and 30% had also been diagnosed with type 2 diabetes mellitus. Three patients (11%) had hypothyroidism, a possible secondary cause of hypercholesterolemia, but over half (59%) did not have all the laboratory tests needed to exclude secondary causes of severe hypercholesterolemia (TSH, urine protein, and/or bilirubin).

Lipid levels

Of the 27 patients who met inclusion criteria, 26 were untreated LDL-C levels, 21 patients also had treated LDL-C levels available (Figure 1), and six had multiple measurements of LDL-C $\geq$ 190 mg/dL. The mean time period between pre- and post-treatment lipid measurements was 0.98 years.

Mean pre-treatment total cholesterol levels (standard deviation) were 300.9 mg/dL (21.7) and 219.6 mg/dL (45.4) after treatment. LDL-C levels were 213.6 mg/dL (18.2) before treatment and 137.4 mg/dL (35) post-treatment. HDL-C pre-treatment was 48.5 mg/dL (13.2) and 49 mg/dL (11.8) post-treatment. Median triglyceride levels (range) were 207 mg/dL (88 - 375) pre-treatment and 163 mg/dL (64 - 460) post-treatment (Table 1).

Statin prescriptions

Almost all patients (93%) were prescribed a statin medication (Figure 2). After treatment, 14% of patients achieved LDL-C levels below 100 mg/dL and 10% had LDL-C levels that remained above 190 mg/dL.

Only 33% were prescribed a high intensity statin, defined as atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily. Most patients that were prescribed atorvastatin were only taking 10-20 mg daily. Other statins prescribed included simvastatin (15%) and lovastatin (26%). Two patients had not been prescribed a statin medication, relying solely on lifestyle modification per EHR provider notes.

Family history

Documentation about family history was sparse, with 19% having any documentation of hypercholesterolemia in their family and 15% having any documentation of ASCVD in their family.

FH diagnosis

No patients had an ICD-10 diagnosis of FH, and no patients had any mention of FH or FH family screening anywhere within the medical record.

Because of missing family history documentation, determining FH status from the Simone Broome or DLCN criteria, which includes family history, was incomplete. No patients fulfilled criteria for "Definite FH" for either Simon Broome or DLCN. One patient met criteria for "possible FH" for the Simone Broome Criteria. All 27 patients met DLCN criteria for "possible FH." Using MEDPED, no patients met criteria for FH diagnosis.

Patient interviews

Of the 27 patients (8 English speakers, 19 Spanish speakers) that met inclusion criteria, we were able to interview 13 (4 English speakers, 9 Spanish speakers) (Table 2). Over half (54%) of the patients had family history of high cholesterol and 31% had a family history of cardiovascular disease, neither of which were previously documented in the EHR. With this new information, nine (69%) now met criteria for “Possible FH” based on the Simone Broome criteria.

Approximately half (54%) of the patients claimed to have never heard of the terms LDL-C (low density lipoprotein-cholesterol) and HDL-C (high density lipoprotein-cholesterol). The patients that had heard of these terms commonly understood them as “one is bad, and one is good” however being unsure which was which. Almost all (92%) patients could recall being told they had high cholesterol by a health care provider either at NDSM or another clinic. Additionally, 15% of patients recalled hearing the term “Familial Hypercholesterolemia” but no patients could give a detailed description of the disease.

All patients reported knowing the importance of lowering cholesterol levels, citing reasons such as “eliminating heart attack and stroke” and “to live... [not wanting] to die.” In addition, 92% cited ways that they knew to lower cholesterol including “exercise, eating properly, less stress” and “staying away from certain [fried] foods”, but only one patient stated taking medication as an action that could be taken.

Of the 13 patients contacted, only 4 reported currently adhering to statin therapy. The reasons given by patients for not being on statin therapy ranged from intolerance (headaches, cramps), difficulty in obtaining prescription refills, and patients stopping medication after their cholesterol levels “normalized” (Table 3).

Table 1. Demographics and characteristics of patients with LDL-C $\geq$ 190 mg/dL obtained from EHR at NDSM clinic.

Characteristic	Value (n = 27)
Age (years), mean (range)	52 (38-79)
Female, n (%)	18 (67)
Ethnicity, n (%)	
Hispanic	20 (74)
Non-Hispanic	5 (19)
Unknown	2 (7)
Race, n (%)	
Black/ African American	5 (19)
Caucasian	17 (62)
Unknown	5 (19)
Past Medical History, n (%)	
Diabetes	8 (30)
Hypertension	17 (63)
Hypothyroidism	3 (11%)
Current/Former Smoker, n (%)	8 (30)
Family History: Hypercholesterolemia, n (%)	
Yes	1 (4)
No	4 (15)
Not Documented	22 (81)
Family History: ASCVD, n (%)	
Yes	0 (0)
No	4 (15)
Not Documented	23 (85)
Total Cholesterol, median (range) mg/dL	
Pre-Treatment*	301 (254-354)
Post-Treatment†	207 (160-324)
LDL-Cholesterol, median (range) mg/dL	
Pre-Treatment*	210.5 (188-246)

Post-Treatment†	141 (92-211)
HDL-Cholesterol, median (range) mg/dL	
Pre-Treatment*	48 (28-85)
Post-Treatment†	45 (34-72)
Triglycerides, median (range) mg/dL	
Pre-Treatment*	207 (88-375)
Post-Treatment†	163 (64-460)

*Pre-Treatment n=26

†Post-Treatment n=21

Table 2. Responses of patients with LDL cholesterol $\geq$ 190 mg/dL in a charity, community clinic

	<i># of patients</i>	<i>% of patients</i>
Total patients interviewed	13	
Yes, family history of high cholesterol	7	54%
Yes, family history of heart disease	4	31%
Yes, current or remote tobacco use	5	38%
Unfamiliar with the terms “LDL” and “HDL”	7	54%
Remember being told that they have high cholesterol	12	92%
Currently taking a statin drug	4	31%
Familiar with the term “Familial Hypercholesterolemia”	2	15%
Claim they know how to lower their cholesterol	12	92%
Believe lowering cholesterol is important for their health	13	100%

Table 3: Selected patient quotes related to barriers to care, taken from phone interviews of patients with LDL cholesterol $\geq$ 190 mg/dL in a charity, community clinic

Barrier to care	Patient quote/anecdote
Statin intolerance	"I have taken different [statins] before. I stopped taking some because it gave me cramps in my legs."
	"...they put me on statins of 10 mg. The 20 mg make me feel funny. I don't know what it is, all my joints were sore, so I had to get off it. [...] I took the pills, but I think I need to go back to the 10 mg. The 20 and 40 were too much for me."
Care gaps	"I also can't get the prescriptions enough. Being a trucker, it's hard to eat right and do what you need to do."
	"My mama died of a massive heart attack at 39. My brother also just had a triple bypass."
Patient education	"[I can treat my cholesterol by] tak[ing] cholesterol medicine and eat[ing] less fat, sugar, carbohydrates and flour."
	"There is one, [HDL or LDL] that is good and one that is bad, but I don't remember which one is which."
	Lowering cholesterol is important "because it can clog arteries."
	"[elevated cholesterol] can give me a heart attack, it can raise my blood pressure, and it can cause thrombosis."
	"I have heard of HDL and LDL, but they were not explained in the clinic."

Discussion

In an uninsured population receiving care at a charity community clinic, we identified several gaps: only 10% of all patients had had lipid levels measured; few patients with severe hypercholesterolemia were on high intensity statin drugs; and family history was missing in nearly all patients as was laboratory work-up for secondary causes of severe hypercholesterolemia. FH was not mentioned in any of their medical records. Subsequently, after calling the severe hypercholesterolemia patients to gather more information, many had previously unknown family histories of premature ASCVD and hypercholesterolemia.

While many studies have looked at FH and severe hypercholesterolemia within large health systems, prior studies have not looked at the burden of disease at a charity, community clinic serving underserved, uninsured populations who are unable to access care even from safety-net healthcare systems^{12,19,20}. An estimated 26 million uninsured patients rely on one of 1,400 charity, community clinics across the United States²¹. Such patients suffer from disparities in care, often getting fewer treatments or treatments not adherent to guidelines, and the uninsured have higher morbidity and mortality relative to the general population²¹.

Our findings at NDSM are consistent – albeit more pronounced – with patient cohorts in various, large health care systems. Within our study, the population mean age of 52 and female predominance (67%) are similar to the demographics of previous studies of patients with severe hypercholesterolemia and

possible FH ^{20,22,23}. At NDSM, only 33% were prescribed a high-intensity statin compared to 42% across patients in the CASCADE-FH registry which was conducted across 11 different US lipid clinics ²⁰. In addition, the treated LDL-C levels with statin therapy were higher in our study than comparative studies both in the US and abroad.^{20,23-25}

In our study population, 30% of patients were previously diagnosed with Type II Diabetes Mellitus (T2DM). This is a higher rate than the national age adjusted prevalence of 13.0% and much higher than other cohorts of patients with severe hypercholesterolemia and FH ^{20,26}. Further, studies published by Pijlman et al. in the Netherlands and Climent et al. using the Dyslipidemia Registry of the Spanish Arteriosclerosis Society have both found that cohorts of patients with mutation positive FH have a decreased prevalence of T2DM than the general population and those with severe hypercholesterolemia ^{24,27}. Based on our findings, there are a few possibilities for this discrepancy. First, our cohort of patients has not been genetically tested for FH mutations and this is in line with findings from the Spanish Arteriosclerosis Society that patients with suspected FH have a prevalence of T2DM more similar to the general population ²⁷. Additionally, decreased access to care in this patient population could result in the increased prevalence of T2DM when compared to patients with severe hypercholesterolemia described in other studies. One of the contributing factors to the decreased prevalence of T2DM in the FH population is the assumption that patients who have been screened and diagnosed early with FH are more likely to have routine, aggressive care at an earlier age, leading to a generally healthier lifestyle ²⁷. This does not fit the context of our patient population at NDSM as these patients have not been diagnosed with FH and have not been treated as aggressively as severe hypercholesterolemia patients in other medical systems. This along with the increased rate of type 2 diabetes in the uninsured population compared to insured may explain this difference ²⁸.

In our limited interviews, we were able to elicit issues affecting hypercholesterolemia treatment and medication adherence from the perspective of patients. These gaps in care and intolerance to medications are similar to barriers to FH care identified by Jones et al. in their interviews with patients diagnosed with Familial Hypercholesterolemia in a large healthcare system ²⁹. However, Jones et al. did not identify inability to get prescriptions as a barrier to FH patient care ²⁹. We believe this may be due to the higher number of uninsured patient's that are treated at NDSM relative to the 97% insured patient population that was interviewed by Jones et al. Although the reasons for provider under prescribing and patient nonadherence are complex, these anecdotes perhaps give insight into specific opportunities at charity, community clinics and may be an area of improvement.

Our findings suggest that there is not enough knowledge about FH and severe hypercholesterolemia in the patient population as well as from providers. Future efforts should address these issues, with patient education on hypercholesterolemia within charity, community clinics as well as provider education about lipid screening and assessing patients with severe hypercholesterolemia.

Limitations

There are several limitations to the study. First, we were only able to obtain LDL-C values from patients at NDSM who had been given a lipid screening. While the 2018 AHA/ACC Cholesterol Guidelines recommends that all patients between the ages of 40-75 should be screened for lipid abnormalities annually, it is likely there are patients at the clinic with elevated LDL-C who have simply not been screened^{1,9,30}. Because all patient data was taken from the NDSM Athena EHR, our study is limited to patients who had an untreated lipid screening after NDSM switched to Athena's EHR in 06/2016. Therefore, patients with LDL-C ≥ 190 mg/dL prior to this time who had been given a statin would likely not be represented in this study. Further, our study has all the limitations that come with limited sample size. A greater understanding of the populations knowledge of cholesterol could be gleamed if we were able to have a larger sample size and speak to a greater proportion of patients.

Conclusions

Among a medically underserved community with LDL-C ≥ 190 mg/dL in a charity community clinic, we found use of high intensity statins was suboptimal and most patients were not evaluated for underlying causes of severe hypercholesterolemia. Future efforts to improve care and education are warranted for both providers and uninsured patients.

Abbreviations

FH
Familial Hypercholesterolemia.
ASCVD
Atherosclerotic cardiovascular disease
LDL-C
Low density lipoprotein-cholesterol
HDL-C
Low density lipoprotein-cholesterol
NDSM
North Dallas Shared Ministries
DLCN
Dutch Lipid Clinic Network

Declarations

Acknowledgements: None

- Funding: none
- Ethics approval: study was approved by UT Southwestern IRB. All experimental protocols were approved by the UT Southwestern Institutional Review Board.

- Consent to participate: since the study involved retrospective review of de-identified data, no individual consent forms were signed by patients.
- Consent for publication: n/a
- All methods were carried out in accordance with relevant guidelines and regulations
- Availability of data and material: “The data that support the findings of this study are available from the corresponding author upon request.”
- Code availability: n/a
- Authors contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Josh Peedikayil, Clark Measom, Brianna Wilson, Whitney Stuard, Angel Valencia, and Ashlyn Lafferty. Writing – review and editing: Reena Jasani, Cat Davis Ahmed, Marcus Hunrt, Amit Khera, Nora Gimpel, and Zahid Ahmad. All authors read and approved the final manuscript.

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Figures

Figure 1

Mean LDL-cholesterol levels before and after statin therapy.

The bars represent the mean values of LDL-cholesterol among the study population prior to and after treatment with a statin medication. The mean treatment period between untreated and treated values was approximately one year.

Figure 2

Statins prescribed to target patient population at NDSM clinic (LDL-C $\geq$ 190 mg/dL)

The bars represent the number of patients who were prescribed each form of therapy. Black bars represent therapy that is considered high intensity and grey bars indicate low or moderate intensity therapy. Total patients n = 27.

Supplementary Files

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