Managing Dyslipidemia: Evolving Roles of Nonstatins and Newer Drugs

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CPE Information and Disclosures

Kathleen A. Lusk declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

The American Pharmacist Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

CPE Information

• Target Audience: Pharmacists & Technicians
• ACPE#:  0202-0000-16-166-L01-P/T
• Activity Type: Application-based

Learning Objectives

1. Discuss the 2016 ACC Expert Consensus Statement’s recommendations for use of non-statin therapies.
2. Identify appropriate patients in whom non-statin therapies may be warranted.
3. Assess the efficacy and safety of PCSK9 inhibitors in adults with hypercholesterolemia.
4. Use the JCPP Pharmacists Patient Care Process to optimize patient health and medication outcomes.

Self-Assessment Question 1

1. Which of the following non-statin therapy is most commonly recommended as second line therapy to statins based on the 2016 ACC Expert Consensus Statement?
   a. Niacin
   b. PCSK9 inhibitor
   c. Ezetimibe
   d. Bile acid sequestrant

Learning Objectives

Technicians
1. Identify medications used for the treatment of dyslipidemia.
2. List common side effects of dyslipidemia medications.
3. List the routes of administration for dyslipidemia medications.
Self-Assessment Question 2

2. Which of the following patients is the best candidate for a non-statin therapy?
   a. 39 yo Caucasian man with DLP taking simvastatin 20 mg PO QHS, ASCVD 10 year risk = 3%, LDL 102 (38% reduction)
   b. 44 yo Asian woman with HTN, DLP, CAD s/p NSTEMI (6 months ago), taking atorvastatin 80 mg PO daily, LDL=180 (42% reduction)
   c. 70 yo African American man with HTN, DLP, ischemic stroke, taking rosuvastatin 20 mg PO daily, LDL 78 (55% reduction)
   d. 52 yo Hispanic woman with HTN, diabetes, and DLP, taking atorvastatin 40 mg PO daily, ASCVD 10 year risk = 25%, LDL 98 (58% reduction)

Self-Assessment Question 3

3. What percent LDL reduction can be expected when evolocumab is added to statin therapy?
   a. 10%
   b. 25%
   c. 50%
   d. 90%

Self-Assessment Question 4

4. Which of the following is an important counseling point for the alirocumab?
   a. Store the medication in the refrigerator
   b. Inject the appropriate dose weekly
   c. This medication may cause muscle pain
   d. This medication should not be used with a statin

Epidemiology and Importance

• 42.8% American adults >20 years old have elevated cholesterol
• >50% of patients with borderline high risk are unaware
• <50% of highest risk patients receiving treatment

Why does it matter?

↑ TC and LDL and ↓ HDL is linked to CHD

Classification

Primary
- Dyslipidemia
- Familial hypercholesterolemia
  - Homozygotes
  - Heterozygotes
- Familial hypertriglyceridemia
- Familial combined hyperlipidemia

Secondary
- End-stage renal disease
- Nephrotic syndrome
- Hypothyroidism
- Medications
- Cigarette use
- Diabetes mellitus
- Excessive alcohol consumption
- Obstructive liver disease
- Pregnancy
- Caloric excess
- Sedentary lifestyle

Classification

Diagnosis: Dyslipidemia (DLP)

• Total cholesterol (TC) >180 mg/dL
• LDL cholesterol >130 mg/dL
• Triglycerides (TG) >200 mg/dL
• HDL cholesterol <40 mg/dL
• Any combination of these abnormalities

Hyperlipidemia (HLP)
Elevations of lipids in the blood
Address Risk Factors and Comorbidities

<table>
<thead>
<tr>
<th>Comorbidity or Risk Factor</th>
<th>Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>Treat appropriately</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Treat appropriately</td>
</tr>
<tr>
<td>Physical inactivity</td>
<td>Encourage regular aerobic activity</td>
</tr>
<tr>
<td>Tobacco use/Cigarette smoking</td>
<td>Encourage smoking cessation</td>
</tr>
<tr>
<td>Medications that adversely affect FLP</td>
<td>Facilitate therapeutic substitution</td>
</tr>
<tr>
<td>Excessive alcohol intake</td>
<td>1 daily drink in women 2 daily drinks in men</td>
</tr>
<tr>
<td>Poor nutrition</td>
<td>TLC diet, Mediterranean diet</td>
</tr>
<tr>
<td>Obesity/overweight</td>
<td>Encourage safe/healthy weight loss</td>
</tr>
<tr>
<td>Stress</td>
<td>Encourage stress relieving activities</td>
</tr>
</tbody>
</table>

Pharmacologic Therapies

- HMG CoA Reductase inhibitors (statins)
- Ezetimibe
- Bile acid sequestrants
- Nicotinic acid
- Fibrates
- Fish oil
- Proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors
- Apolipoprotein B Antisense Oligonucleotide
- Microsomal Triglyceride Transfer (MTP) Inhibitor

2013 ACC/AHA Cholesterol Guidelines

Goals of Therapy
- Decrease ASCVD morbidity and mortality
- Percent LDL reduction
  - No longer specific TC, HDL, TG, or LDL targets

Groups Benefitting from Statins

<table>
<thead>
<tr>
<th>Group</th>
<th>Statin Intensity Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Prevention</td>
<td></td>
</tr>
<tr>
<td>LDL ≥ 190</td>
<td>High</td>
</tr>
<tr>
<td>LDL 70-180 + Diabetes</td>
<td>Acute coronary syndrome</td>
</tr>
<tr>
<td>LDL 70-180 + 40-75 yo + diabetes</td>
<td>5%: Moderate</td>
</tr>
<tr>
<td></td>
<td>Coronary/other arterial</td>
</tr>
<tr>
<td></td>
<td>revascularization</td>
</tr>
<tr>
<td></td>
<td>5%: high</td>
</tr>
<tr>
<td></td>
<td>Stroke/TIA</td>
</tr>
<tr>
<td></td>
<td>Peripheral artery disease</td>
</tr>
<tr>
<td>Secondary Prevention</td>
<td></td>
</tr>
<tr>
<td>Clinical ASCVD</td>
<td>Age ≤ 75: High</td>
</tr>
<tr>
<td>Age &gt; 75: moderate</td>
<td></td>
</tr>
</tbody>
</table>

Statin Monitoring

- Efficacy: FLP
  - Baseline, 4-12 weeks after initiation/titration, then q3-12 months
- Safety: adverse reactions

<table>
<thead>
<tr>
<th>Muscle Pain</th>
<th>Hepatic Function</th>
<th>Creatine Kinase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Daily (by patient)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Hepatotoxicity signs/symptoms</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Increased risk of myopathy</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Myopathy, sx of rhabdomyolysis</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Statin Intensity

<table>
<thead>
<tr>
<th>Low-Intensity</th>
<th>Moderate-Intensity</th>
<th>High-Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL &lt; 30%</td>
<td>LDL 30-49%</td>
<td>LDL ≥ 50%</td>
</tr>
<tr>
<td>Simvastatin 10-20mg</td>
<td>Rosuvastatin [5]-10mg</td>
<td>Atorvastatin (40)-80mg</td>
</tr>
<tr>
<td>Pravastatin 10-20mg</td>
<td>Simvastatin 20-40mg</td>
<td>Rosuvastatin 20-40mg</td>
</tr>
<tr>
<td>Lovastatin 20mg</td>
<td>Fluvastatin 40mg</td>
<td>Pitavastatin 2-4mg</td>
</tr>
<tr>
<td>Fluvastatin [20-40]mg</td>
<td>Lovastatin [40]mg</td>
<td>Atorvastatin [10-20]mg</td>
</tr>
</tbody>
</table>

( ) – down titration if 80 mg not tolerable
[ ] – not studied in US

Circulation 2014;129:S1-S45
### Goals of Therapy

**LDL Reduction**

<table>
<thead>
<tr>
<th>Primary Prevention</th>
<th>LDL Goal (mg/dL)</th>
<th>LDL Goal (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL ≥ 190</td>
<td>≥ 50% &lt; 100</td>
<td></td>
</tr>
<tr>
<td>Diabetes + ASCVD risk &lt; 7.5%</td>
<td>30-49% &lt; 100</td>
<td></td>
</tr>
<tr>
<td>Age 40-75 + ASCVD risk ≥ 7.5%</td>
<td>30-49% &lt; 100</td>
<td></td>
</tr>
</tbody>
</table>

**Secondary Prevention**

<table>
<thead>
<tr>
<th>Stable clinical ASCVD without comorbidities</th>
<th>LDL Goal (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 50% &lt; 100</td>
<td></td>
</tr>
<tr>
<td>Clinical ASCVD with comorbidities</td>
<td>≥ 50% &lt; 70</td>
</tr>
<tr>
<td>Clinical ASCVD + LDL ≥ 190</td>
<td>≥ 50% &lt; 70</td>
</tr>
</tbody>
</table>

*Comorbidities: diabetes, recent ASCVD, ASCVD while on statin, poor-controlled major ASCVD risk factors, elevated lipoprotein(a), CRD (not on dialysis)*

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### What if LDL goal not met?

- Address statin adherence
- Intensify lifestyle changes
- Increase statin intensity (if possible)
- Control other risk factors
  - Hypertension
  - Diabetes
  - Tobacco use

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### PCSK9 Inhibitors

**Agent**

- **Alirocumab (Praluent)**
  - 75 mg q2 weeks (may up to 150 mg)
- **Evolocumab (Repatha)**
  - HoFH: 420 mg q30 days
  - 1st HLP/HeFH: 140 mg q2 weeks or 420 mg q30 days

**Indications/Dosing (subQ)**

- HoFH: homozygous familial hyperlipidemia
- HeFH: heterozygous familial hyperlipidemia

*Monitor LDL 4-8 weeks after initiation or titration*

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### What if LDL reduction/goal not met?

- Address statin adherence
- Intensify lifestyle changes
- Increase statin intensity (if possible)
- Control other risk factors
  - Hypertension
  - Diabetes
  - Tobacco use

---

### Treatment Algorithm

1. **Clinical ASCVD**
   - Yes: Age ≤ 75 → High
     - LDL-C ≥ 190 mg/dL
     - Diabetes + 40-75 yo + 10 year ASCVD risk ≥ 7.5% → Yes
     - Yes: Age ≤ 75 → High
     - Yes: Moderate to High
   - No: Age > 75 → Moderate
2. **LDL-C ≥ 190 mg/dL**
   - Yes: Age ≤ 75 → High
     - LDL-C ≥ 190 mg/dL
     - Diabetes + 40-75 yo + 10 year ASCVD risk ≥ 7.5% → Yes
     - Yes: Age ≤ 75 → High
     - Yes: Moderate to High
   - No: Age > 75 → Moderate
3. **Diabetes + 40-75 yo**
   - Yes: Age ≤ 75 → High
     - LDL-C ≥ 190 mg/dL
     - Diabetes + 40-75 yo + 10 year ASCVD risk ≥ 7.5% → Yes
     - Yes: Age ≤ 75 → High
     - Yes: Moderate to High
   - No: Age > 75 → Moderate
4. **10 year ASCVD risk ≥ 7.5%**
   - Yes: Age ≤ 75 → High
     - LDL-C ≥ 190 mg/dL
     - Diabetes + 40-75 yo + 10 year ASCVD risk ≥ 7.5% → Yes
     - Yes: Age ≤ 75 → High
     - Yes: Moderate to High
   - No: Age > 75 → Moderate
5. **No Statin or Moderate**
   - Yes: Moderate to High

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### 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies

Circulation 2014;129:S1-S45

Circulation 2016; pii: S0735-1097(16)32398-1
### PCSK9 Inhibitors

<table>
<thead>
<tr>
<th>Agent</th>
<th>Efficacy and Safety</th>
<th>Potential ↓ CV events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alirocumab</strong></td>
<td>↓ LDL &gt; than statin by 61%</td>
<td>• LDL &gt; than statin ± ezetimibe by 48-62%</td>
</tr>
<tr>
<td></td>
<td>↓ LDL &gt; than statin + ezetimibe by 30%</td>
<td>• LDL &gt; than statin ± ezetimibe by 52-60%</td>
</tr>
<tr>
<td></td>
<td>ADR: injection site reaction (7%), influenza (6%), nasopharyngitis (11%)</td>
<td>HoFH: ↓ LDL &gt; statin ± ezetimibe by 32.1%</td>
</tr>
<tr>
<td><strong>Evolocumab</strong></td>
<td>↓ LDL &gt; than diet, statin ± ezetimibe by 48-62%</td>
<td>ADR: injection site reaction (6%), influenza (8-9%), upper RTI (9%)</td>
</tr>
<tr>
<td></td>
<td>↓ LDL &gt; than statin + ezetimibe by 52-60%</td>
<td></td>
</tr>
</tbody>
</table>

**ADR:** injection site reaction (7%), influenza (6%), nasopharyngitis (11%)

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### Administration

#### Alirocumab

- **Pen**
- Prefilled syringe

#### Evolocumab

- **Pen**
- Prefilled syringe
- On-Body Infusor/Prefilled Cartridge

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### Alirocumab Pen

- Refrigerate
- Warm to room temperature before administration (30-40 minutes)
- Inspect for particles/discoloration
- Wash hands/clean area of injection
- Remove cap
- Subcutaneous injection
  - Abdomen, thigh, upper arm
  - 90° angle, push button (“click”), release
  - Hold in place until window is yellow (20 seconds)
- Dispose of pen in sharps container

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### Alirocumab Prefilled Syringe

- Refrigerate
- Warm to room temperature before administration (30-40 minutes)
- Inspect for particles/discoloration
- Wash hands/clean area of injection
- Remove cap
- Subcutaneous injection
  - Abdomen, thigh, upper arm
  - 45° or 90° angle
  - Depress plunger slowly
- Dispose of pen in sharps container

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### Evolocumab Pen (SureClick Autoinjector)

- Refrigerate (or use in 30 days)
- Warm to room temperature before administration (30 minutes)
- Inspect for particles/discoloration
- Wash hands/clean area of injection
- Remove cap
- Subcutaneous injection
  - Abdomen or upper arm (pinch), thigh (stretch)
  - 90° angle, push button (“click”), release
  - Hold in place until window is yellow (15 seconds)
- Dispose of pen in sharps container

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### Evolocumab Prefilled Syringe

- Refrigerate
- Warm to room temperature before administration (30 minutes)
- Inspect for particles/discoloration
- Wash hands/clean area of injection
- Remove cap
- Subcutaneous injection
  - Abdomen, thigh, upper arm
  - 45° or 90° angle
  - Depress plunger slowly
- Dispose of syringe in sharps container

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**Eur Heart J 2015;36(19):1186-94**


**Lancet 2015;385:341–50**

**N Engl J Med 2014;370:1809-19**

**JAMA 2014;311(18):1870-82**

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[https://www.praluent.com/administration](https://www.praluent.com/administration)

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[http://www.pdr.net/full-prescribing-information?druglabelid=3781](http://www.pdr.net/full-prescribing-information?druglabelid=3781)
### JCPP Pharmacists Patient Care Process

- Meet demand of evolving healthcare system
- Collaboration of many organizations
  - Develop standardized pharmacist patient care process
- Applies to wide variety of patient care services

<table>
<thead>
<tr>
<th>Consistency</th>
<th>Predictability</th>
<th>Measurability</th>
</tr>
</thead>
</table>

### Collect

Collection of subjective and objective information to understand relevant medical history and clinical status

- Current medication list and medication use history
  - Prescription and nonprescription medications, herbal products, and dietary supplements
- Health data (medical history, health/wellness information, biometric test results, and physical assessment findings)
- Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors

### Assess

Assess information collected and analyze clinical effects of therapy in context of overall health goals to identify and prioritize problems and achieve optimal care

- Each medication for appropriateness, effectiveness, safety, and adherence
- Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care
- Immunization status and need for preventive care and other health care services

### Plan

Develop individualized patient-centered care plan in collaboration with other health care professionals and patient/caregiver that is evidence-based and cost-effective

- Addresses medication-related problems and optimizes medication therapy
- Sets goals of therapy to achieve clinical outcomes
- Engages patient through education, empowerment, and self-management
- Supports care continuity, including follow-up and transitions of care as appropriate

### Implement

Implements care plan in collaboration with other health care professionals and patient/caregiver

- Addresses medication/health-related problems, and engages in preventive care strategies
- Initiates, modifies, discontinues, or administers medication therapy as authorized
- Provides education and self-management training to patient/caregiver
- Contributes to coordination of care, including the referral or transition of the patient to another health care professional
- Schedules follow-up care to achieve goals of therapy

### Follow up: Monitor and Evaluate

Monitors and evaluates the effectiveness of care plan and modifies plan in collaboration with other health care professionals and patient/caregiver

- Medication appropriateness, effectiveness, and safety
- Patient adherence
- Clinical endpoints that contribute to the patient’s overall health
- Outcomes of care (achievement of goals of therapy)
Approach to Patient Care

<table>
<thead>
<tr>
<th>Patient Care Steps</th>
<th>JCPP Pharmacist Patient Care Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Evaluate fasting lipid panel (FLP)</td>
<td>Collect/Assess</td>
</tr>
<tr>
<td>2. Assess presence of ASCVD</td>
<td>Collect/Assess</td>
</tr>
<tr>
<td>• If no ASCVD, perform ASCVD Risk Calculation</td>
<td></td>
</tr>
<tr>
<td>3. Determine statin intensity of choice (if applicable) and goals of therapy</td>
<td>Plan/Implement</td>
</tr>
<tr>
<td>4. Recommend lifestyle changes/non-pharmacologic therapies and management of comorbidities</td>
<td>Plan/Implement</td>
</tr>
<tr>
<td>5. Education patient on therapy(ies)</td>
<td>Plan/Implement</td>
</tr>
<tr>
<td>6. Schedule monitoring/follow-up</td>
<td>Follow up</td>
</tr>
<tr>
<td>7. Reassess FLP, adherence, and lifestyle changes</td>
<td>Collect/Assess</td>
</tr>
<tr>
<td>8. Optimize statin and non-pharmacologic therapies (if needed)</td>
<td>Plan/Implement</td>
</tr>
<tr>
<td>9. Determine need for non-statin therapies</td>
<td>Assess</td>
</tr>
</tbody>
</table>

Case 1: Assessment/Plan

1. Evaluate FLP (Collect/Assess)
   TC > 180, LDL > 130, HDL < 40

2. Assess presence of ASCVD (If no ASCVD, perform 10 Year ASCVD Risk Calculation) (Collect/Assess)
   Yes, patient has history of CAD s/p MI (no 10 Year ASCVD Risk Calculation needed)

3. Determine statin intensity of choice (if applicable) and goals of therapy (Collect/Assess)
   High intensity statin b/c ASCVD and ≤ 75 yo (atorvastatin 40-80 mg daily OR rosuvastatin 20-40 mg daily)
   Goals of therapy: reduce ASCVD events, LDL reduction of > 50% (possibly LDL < 70)

4. Recommend lifestyle changes/non-pharmacologic therapies and management of comorbidities (Plan/Implement)
   TLC or Mediterranean diet, smoking cessation, decrease alcohol use, weight loss, stress relief, and increase physical activity
   HTN management

5. Education patient on therapy(ies) (Plan/Implement)
   Importance of treating dyslipidemia
   Non-pharmacologic counseling
   • Drug, dose, route, frequency, duration
   • Potential adverse effects

6. Schedule monitoring/follow-up (Follow-up)
   Efficacy: Monitor FLP at 4-12 weeks, then every 3-12 months.
   Safety: Monitor muscle pain daily by patient, liver function panel if patient has s/o of liver dysfunction, and CK if patient develops muscle pain

Patient Case 1

HPI
JF is a 57 yo African American man presenting to your ambulatory care clinic

PMH
HTN, GERD, CAD s/p MI (1 year ago)

FH
Father – died of MI at 44 yo, Mother – alive and healthy

SH
(+ ) tobacco: 1 ppd, (+ ) alcohol: 5-6 beer/day, (- ) illicit drugs
Very busy with stressful job, eats “whatever the cafeteria at my office has that day”

SH
(+ ) tobacco: 0.5 ppd, (+ ) alcohol: 3-4 beer/day, (- ) illicit drugs
Still busy at work, trying to eat better, but “cheats” sometimes

Meds
Amlodipine 10mg daily, omeprazole 20mg daily, ramipril 5mg daily, ASA 81mg daily, carvedilol 12.5mg BID

Vitals
BP 115/72 mmHg, HR 70, RR 16, Temp 98.4°F, Ht 5’9”, Wt 188 lbs

Labs

<table>
<thead>
<tr>
<th>Today</th>
<th>1 month ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC 138</td>
<td>220</td>
</tr>
<tr>
<td>HDL 35</td>
<td>26</td>
</tr>
<tr>
<td>TG 140</td>
<td>175</td>
</tr>
<tr>
<td>LDL 68</td>
<td>157</td>
</tr>
</tbody>
</table>

Case 1: Follow-up Visit (1 month later)

HPI
JF is a 57 yo African American man returning to the clinic

PMH
HTN, GERD, CAD s/p MI (1 year ago)

FH
Father – died of MI at 44 yo, Mother – alive and healthy

SH
(+ ) tobacco: 0.5 ppd, (+ ) alcohol: 3-4 beer/day, (- ) illicit drugs
Still busy at work, trying to eat better, but “cheats” sometimes

Meds
Amlodipine 10mg daily, omeprazole 20mg daily, ramipril 10mg daily, ASA 81mg daily, carvedilol 12.5mg PO BID, atorvastatin 40 mg daily

Vitals
BP 132/78 mmHg, HR 70, RR 16, Temp 98.7°F, Ht 5’9”, Wt 183 lbs

Labs

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Patient Case 1: Follow-up Visit (1 month later)

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JF is a 57 yo African American man returning to the clinic.

PMH
HTN, GERD, CAD s/p MI (1 year ago)

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Father – died of MI at 44 yo, Mother – alive and healthy

SH
(+): tobacco: 0.5 ppd, (+): alcohol: 3-4 beer/day, (-): illicit drugs
Still busy at work, trying to eat better, but “cheats” sometimes

Meds
Amlodipine 10mg daily, omeprazole 20mg daily, ramipril 10mg daily, ASA 81mg daily, carvedilol 12.5mg PO BID, atorvastatin 40 mg daily

Vitals
BP 132/78 mmHg, HR 70, RR 16, Temp 98.7°F, Ht 5’9”, Wt 183 lbs

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<td>140</td>
</tr>
<tr>
<td>LDL</td>
<td>88</td>
</tr>
</tbody>
</table>

Case 1: Follow-up Visit
Assessment/Plan

7. Reassess FLP, adherence, and lifestyle changes (Collect/Assess)
   LDL=68 (decreased by 57%)
   LDL percent reduction goal: > 50% → MET
   Potential LDL goal: < 70 → MET

8. Optimize statin and non-pharmacologic therapies (if needed) (Plan/Implement)
   Reinforce adherence and lifestyle changes/non-pharmacologic.
   Ensure comorbidities managed appropriately.

9. Determine need for non-statin therapies (Assess)
   Since both goals met, no statin dose change or non-statin therapy necessary.

Case 2: Assessment/Plan

HPI
JC is a 41 yo Caucasian woman presenting to your clinic.

PMH
Diabetes, dyslipidemia/HeFH, HTN

FH
Father: dyslipidemia, Mother: CAD diagnosed at 54 yo

SH
(-): tobacco, (+): alcohol: 1 glass of wine/day, (-): illicit drugs
Vegetarian, eats mostly veggies and tofu, runs 1-2 miles daily

Meds
Metformin 1000 mg BID, simvastatin 40 mg QHS (started 3 months ago), APAP 500mg q6 hours pm HA, amlodipine 10 mg daily

Vitals
BP 128/68 mmHg, HR 67, RR 16, Temp 97.9°F, Ht 5’3”, Wt 165 lbs

Labs
<table>
<thead>
<tr>
<th>Today</th>
<th>3 months ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST</td>
<td>143</td>
</tr>
<tr>
<td>ALT</td>
<td>100</td>
</tr>
<tr>
<td>TC</td>
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<tr>
<td>HDL</td>
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<td>LDL</td>
<td>37.2</td>
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<td>TG</td>
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<tr>
<td>A1C</td>
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</tbody>
</table>

Case 2: Assessment/Plan

1. Evaluate FLP (Collect/Assess)
   TC > 180, LDL > 130

2. Assess presence of ASCVD (If no ASCVD, perform 10 Year ASCVD Risk Calculation) (Collect/Assess)
   No, but the patient has LDL ≥ 190 (no 10 Year ASCVD Risk Calculation needed)

3. Determine statin intensity of choice (if applicable) and goals of therapy (Plan/Implement)
   High intensity statin b/c LDL ≥ 190 (also patient has HeFH)
   D/C simvastatin and initiate high intensity statin (atorvastatin 40-80 mg daily OR rosuvastatin 20-40 mg daily)
   Goals of therapy: reduce ASCVD events, LDL reduction of > 50% (possibly LDL < 100)

4. Recommend lifestyle changes/non-pharmacologic therapies and management of comorbidities (Plan/Implement)
   Continue diet and exercise, EtOH consumption reasonable
   HTN and diabetes management

5. Education patient on therapy(ies) (Plan/Implement)
   Importance of treating dyslipidemia
   Non-pharmacologic counseling
   Pharmacologic counseling
   – Drug, dose, route, frequency, duration
   – Potential adverse effects

6. Schedule monitoring/follow-up (Follow-up)
   Efficacy: Monitor FLP at 4-12 weeks, then every 3-12 months
   Safety: Monitor muscle pain daily by patient, liver function panel if patient has s/sx of liver dysfunction, and CK if patient develops muscle pain
HPI: JC is a 41 yo Caucasian woman presenting to your clinic.

PMH: Diabetes, dyslipidemia/HeFH, HTN

SH: Father: dyslipidemia, Mother: CAD diagnosed at 54 yo

FH: (-) tobacco, (+) alcohol: 1 glass of wine/day, (-) illicit drugs

Vegetarian, eats mostly veggies and tofu, runs 1-2 miles daily

All: NKDA

Meds: Metformin 1000 mg BID, rosuvastatin 40 mg daily (started 2 months ago), APAP 500mg q6 hours prn headache, amlodipine 10 mg daily

Vitals: BP 126/62 mmHg, HR 67, Temp 98.6°F, Ht 5’3”, Wt 152 lbs

PE: Normal

Labs:

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<th>Today</th>
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<th>5 months ago</th>
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<tbody>
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<td>130</td>
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<tr>
<td>LDL</td>
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</tbody>
</table>

Case 2: Follow-up Visit (2 months later)

**HPI:**
JC is a 41 yo Caucasian woman presenting to your clinic.

**PMH:**
Diabetes, dyslipidemia/HeFH, HTN

**SH:**
Father: dyslipidemia, Mother: CAD diagnosed at 54 yo

**FH:**
(-) tobacco, (+) alcohol: 1 glass of wine/day, (-) illicit drugs

Vegetarian, eats mostly veggies and tofu, runs 1-2 miles daily

**All:**
NKDA

**Meds:**
Metformin 1000 mg BID, rosuvastatin 40 mg daily (started 2 months ago), APAP 500mg q6 hours prn headache, amlodipine 10 mg daily

**Vitals:**
BP 126/62 mmHg, HR 67, Temp 98.6°F, Ht 5’3”, Wt 152 lbs

**PE:**
Normal

**Labs:**

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<td>192</td>
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**Assessment/Plan**

7. Reassess FLP, adherence, and lifestyle changes (Collect/Assess)

LDL=152 (decreased by 47%)

Potential LDL goal: < 100 → NOT MET

8. Optimize statin and non-pharmacologic therapies (if needed) (Plan/Implement)

Lifestyle appropriate
HTN and diabetes appropriately managed

9. Determine need for non-statin therapies (Assess)

Since both goals not met and statin therapy in optimized, consider addition of non-statin agent.

- Ezetimibe or PCSK9 inhibitor

**Key Points**

- Optimize statin therapy
- Focus on lifestyle modifications
- Ezetimibe and PCSK9 inhibitors may play role
- Use of JCPP Pharmacists Patient Care Process to optimize patient health and medication outcomes

**Self-Assessment Questions 1**

1. Which of the following non-statin therapy is most commonly recommended as second line therapy to statins based on the 2016 ACC Expert Consensus Statement?
   - a. Niacin
   - b. PCSK9 inhibitor
   - c. Ezetimibe
   - d. Bile acid sequestrant
Self-Assessment Question 2

2. Which of the following patients is the best candidate for a non-statin therapy?
   a. 39 yo Caucasian man with DLP taking simvastatin 20 mg PO QHS, ASCVD 10 year risk = 3%, LDL 102 (38% reduction)
   b. 44 yo Asian woman with HTN, DLP, CAD s/p NSTEMI (6 months ago), taking atorvastatin 80 mg PO daily, LDL=180 (42% reduction)
   c. 70 yo African American man with HTN, DLP, ischemic stroke, taking rosuvastatin 20 mg PO daily, LDL 78 (55% reduction)
   d. 52 yo Hispanic woman with HTN, diabetes, and DLP, taking atorvastatin 40 mg PO daily, ASCVD 10 year risk = 25%, LDL 98 (58% reduction)

Self-Assessment Question 3

3. What percent LDL reduction can be expected when evolocumab is added to statin therapy?
   a. 10%
   b. 25%
   c. 50%
   d. 90%

Self-Assessment Question 4

4. Which of the following is an important counseling point for the alirocumab?
   a. Store the medication in the refrigerator
   b. Inject the appropriate dose weekly
   c. This medication may cause muscle pain
   d. This medication should not be used with a statin

Managing Dyslipidemia: Evolving Roles of Nonstatins and Newer Drugs

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