The 2021 CCS dyslipidemia guidelines

George Thanassoulis MD MSc
Director, Preventive and Genomic Cardiology
Mike and Valeria Rosenbloom Center for Cardiovascular Prevention

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George Thanassoulis MD MSc FRCPC

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Objectives

1. Overview the new 2021 recommendations for the management of dyslipidemia

2. Discuss the role of non-statin therapies in the management of patients with dyslipidemia

3. Review how the new recommendations affect management through case-based learning
Overview of 2021 Guidelines
Overview of 2021 Guidelines
Overview of 2021 Guidelines

Treatment Intensification Approach for Patients with Atherosclerotic Cardiovascular Disease (ASCVD)

Patients with Atherosclerotic Cardiovascular Disease (ASCVD)
Receiving maximally tolerated statin dose.

If LDL-C is ≥1.8 mmol/L or if ApoB ≥0.70 g/L** or if non-HDL-C ≥2.4 mmol/L

LDL-C 1.8-2.2 mmol/L or ApoB 0.70-0.80 g/L or non-HDL-C 2.4-2.9 mmol/L

Consider ezetimibe ± PCSK9 inhibitor

LDL-C >2.2 mmol/L or ApoB >0.80 g/L or non-HDL-C >2.9 mmol/L or high PCSK9i benefit patient*

Consider PCSK9 inhibitor ± ezetimibe

If TG is ≥1.5 to 5.6 mmol/L

Consider Icosapent ethyl 2000 mg BID†

*May also be considered for patients without ASCVD but with DM requiring medication treatment in patient ≥50 years of age, and ≥1 additional CV risk factor (from REDUCE-IT™):
- men ≥55 y and women ≥65 y
- cigarette smoker or stopped smoking within 3 months
- hypertension (≥140 mmHg systolic OR ≥90 mmHg diastolic) or on BP medication
- HbA1C ≥6.04 mmol/l, for men ≥1.3 mmol/l, for women
- hsCRP >2.0 mg/L
- Renal dysfunction: egFR >30 and <60 mL/min
- Retinopathy
- Micro- or macroalbuminuria
- ABI <0.9 without symptoms of intermittent claudication

**At low levels of LDL-C or non-HDL-C, measurement of apoB is more accurate than other markers.

*Patients shown to derive largest benefit form intensification of statin therapy with PCSK9 inhibitor therapy are identified in Table 3.
PICO #1

Do pregnancy-related conditions (hypertensive disorders of pregnancy and other related complications) identify women at increased risk of premature cardiovascular disease warranting lipid screening?
1. Among **women who have had a pregnancy complication** such as hypertensive disorders of pregnancy, gestational diabetes, pre-term birth, stillbirth, low birthweight infant, or placental abruption, we recommend screening with a **complete lipid panel in the late postpartum period**, since these women have a higher risk of premature CVD and stroke with onset 10-15 years after index delivery. (Strong Recommendation; Moderate Quality Evidence).

2. We **recommend counselling women** who have any of these pregnancy-related complications of the increased lifetime risk of ASCVD, and reinforcing the importance of healthy behaviours.

3. To assist with decisions about lipid-lowering pharmacotherapy in this patient population, **we recommend favouring CV age, over 10-year risk calculators** (Strong Recommendation; Low Quality Evidence).
Pregnancy-related complications increase CV risk

Honigsberg M et al JACC 2020
PICO #2

Can consideration of lipoproteins, such as triglyceride-rich lipoproteins, apolipoprotein B and/or lipoprotein(a) improve risk assessment?
We recommend that for any patient with triglycerides > 1.5 mmol/L, non-HDL-C or ApoB be used instead of LDL-C as the preferred lipid parameter for screening (Strong Recommendation, High-Quality Evidence).
2021 CCS Dyslipidemia Guidelines

1. **We recommend measuring Lp(a) level once in a person’s lifetime** as a part of the initial lipid screening. (Strong Recommendation; High Quality Evidence).

2. For all patients in the setting of primary prevention **with a Lp(a) ≥50 mg/dL (or ≥100 nmol/L)**, we recommend earlier and more intensive health behaviour modification counselling and management of other ASCVD risk factors (Strong recommendation; Expert consensus).
Need to consider ALL atherogenic lipoprotein particles not ONLY LDL-C

- Non-HDL-C (indirect measure)
- ApoB (direct measure)
- ApoB > non-HDL-C >> LDL-C
Apolipoprotein-B

- Each of the atherogenic lipid particles ($LDL$, $Lp(a)$, $IDL$, $VLDL$) contain 1 molecule of Apo-B
- Serum concentration of Apo-B reflects the total number of these particles in the circulation
- Measuring apo-B provides information about the number and total atherogenicity of the lipid profile
High apoB = danger

Cardiovascular Risk is determined by the NUMBER OF PARTICLES NOT the CHOLESTEROL CONTENT

Large Cholesterol-rich particles

LDL-C= 3.5 mmol/L

Small dense cholesterol-depleted particles

LDL-C= 3.5 mmol/L

Nombre accru de particules
Risque accru

Nombre accru de particules
Risque accru
Risk tracks ApoB - always

Framingham Offspring Study

Lipoprotein(a)

- LDL-like particle with a Apolipoprotein (a) covalently bound to Apolipoprotein-B
- Lp(a) levels are explained by genetics
  - Number of repeats in KIV-2 is inversely correlated to plasma levels
  - SNPs in Lp(a) are associated with plasma levels
Lipoprotein(a)

- Increased Lp(a) is associated with MI, ischemic stroke, aortic stenosis and mortality

- Risk increases starting at ≥30 mg/dL and becomes clinically significant ≥ 50 mg/dL

- Some individuals with extreme levels (> 180 mg/dL) may have a prognosis similar to htz FH

Erqou et al JAMA 2009
Lipoprotein (a) and Risk of Recurrent CVD

- Compared with individuals with Lp(a)<10 mg/dL (18 nmol/L), the multifactorially adjusted MACE incidence rate ratios were:
  - 1.28 (1.03–1.58) for 10 to 49 mg/dL
  - 1.44 (1.12–1.85) for 50 to 99 mg/dL
  - 2.14 (1.57–2.92) for ≥100 mg/dL

- High concentrations of Lp(a) are associated with high risk of recurrent CVD in individuals from the general population

Future Lp(a) therapy

Antisense therapy targeting apolipoprotein(a): a randomised, double-blind, placebo-controlled phase 1 study

Sotirios Tsimikos, Nicholas J Viney, Steven G Hughes, Walter Singleton, Mark J Graham, Brenda F Baker, Jennifer L Burke, Qingping Yang, Santico M Marouina, Richard S Geary, Rosanne M Cooke, Joseph L Witzum

Safety, Tolerability, and Efficacy of Single-dose AMG 890, a Novel siRNA Targeting Lp(a), in Healthy Subjects and Subjects With Elevated Lp(a)

Michael J Koren, Patrick Maurice Moriarty, Joel Neutel, Seth J Baum, Martha Hernandez-llias, Howard S Weintraub, Jennifer Helliwell, Tracy Varriou, Winnie Sohn, Huel Wang, Mary Elliott-Davey, Helina Kasahana, Gerald F Watts

1Jacksonville Center for Clinical Research, Jacksonville, FL; 2University of Kansas Medical Center, Kansas City, KS; 3Orange County Research Center, Tustin, CA; 4Excel Medical Clinical Trials, Boca Raton, FL; 5QPS MRA, Miami, FL; 6NYU Langone Medical Center, New York, NY; 7Amgen, South San Francisco, CA; 8Amgen, Cambridge, MA; 9Amgen, Thousand Oaks, CA; 10Amgen, Newbury Park, CA; 11Amgen Ltd, Cambridge; 12University of Western Australia, Perth, Australia

Baseline values are the mean of screening and day 1 pre-dose values. If only 1 value was available, that value was used as the baseline value.

As a data snapshot date: 2/14/2020
PICO #3

In primary prevention, what is the evidence for CAC to improve risk assessment? Specifically, should low CAC (or CAC=0) be used to avoid statin therapy in select individuals?
2021 CCS Dyslipidemia Guidelines

1. We suggest that CAC screening using computed tomography imaging may be considered for asymptomatic adults ≥ 40 years and at intermediate risk (FRS 10%-20%) for whom treatment decisions are uncertain (Strong Recommendation, Moderate-Quality Evidence).

2. We recommend that CAC screening using computed tomography imaging not be undertaken for: (1) high-risk individuals; (2) patients receiving statin treatment; or (3) most asymptomatic, low-risk adults (Strong Recommendation; Moderate-Quality Evidence).

3. We suggest that CAC screening may be considered for a subset of low-risk individuals > 40 years with a family history of premature ASCVD (men < 55 years; women ≤†65 years) in addition to identifying known genetic causes of CAD such as elevated Lp(a) or FH. (Weak Recommendation; Low-Quality Evidence).
Case Discussion
- Screening and Primary Prevention -
Case 1 Mrs. Tremblay

55F for CV risk assessment

2 prior pregnancies – 2 healthy daughters

Developed hypertension during both pregnancies.

BP 135/85 mm HG

BMI 29/m2, normal blood glucose/Hgba1C

TC 5.9 mmol/L

HDL-C 1.2

TG 3.0 mmol/L

LDL-C 3.3 mmol/L

FRS—5% risk of CV event in 10 years
Case 1 Mrs. Tremblay

Which of the following is the most appropriate statement:

1. She is at low-risk for CV events. No further management needed.
2. She is at high-risk for CV events. Start lipid-lowering therapy with high-dose statin.
3. Her risk is likely underestimated. Consider total atherogenic burden and other risk factors for better risk assessment.
4. Her risk is likely underestimated. Would recommend exercise stress testing and coronary artery calcium scan.
Case 1 Mrs. Tremblay

Which of the following is the most appropriate statement:

1. She is at low-risk for CV events. No further management needed.
2. She is at high-risk for CV events. Start lipid-lowering therapy with high-dose statin.
3. Her risk is likely underestimated. Consider total atherogenic burden and other risk factors for better risk assessment.
4. Her risk is likely underestimated. Would recommend exercise stress testing and coronary artery calcium scan.
Case 1 Mrs. Tremblay

55F for risk assessment
2 prior pregnancies – 2 healthy daughters

Developed hypertension during both pregnancies
BP 135/85 mm HG
BMI 29 kg/m2
TC 5.9 mmol/L
HDL-C 1.2 mmol/L
TG 3.0 mmol/L
LDL-C 3.3 mmol/L

FRS – 5% risk of CV event in 10 years
Case 1 Mrs. Tremblay

59F for risk assessment
2 prior pregnancies – 2 healthy daughters

Developed hypertension during both pregnancies
BP 135/85 mm HG
BMI 29 kg/m2
TC 5.9 mmol/L
HDL-C 1.2 mmol/L
TG 3.0 mmol/L
LDL-C 3.3 mmol/L
FRS – 5% risk of CV event in 10 years

Non-HDL-C 4.7 mmol/L!
apoB 1.25!
Lp(a) 120 nmol/L!
Overview of 2021 Guidelines
PICO #4
In adults already receiving or intolerant to statins, what is the role of other lipid-modulating drugs compared with placebo reduce CVD events?

PICO #5
In secondary prevention, what is the most appropriate lipid/lipoprotein threshold for intensification of therapy?
• Lower LDL is better
  • “close-enough” is not good enough
  • WHO should we treat intensively?

• Evidence-based
  • Thresholds based on RCTs

• Actionable
  • ?less clinical inertia
Treatment Approach for Patients with a Statin Indicated Condition

**STATIN INDICATED CONDITIONS**

**LDL ≥5.0 mmol/L**
- (or ApoB ≥1.45 g/L or non-HDL-C ≥5.8 mmol/L)
- (familial hypercholesterolemia or genetic dyslipidemia)

**Most patients with diabetes:**
- Age ≥40y
- Age ≥50y & DM ≥15y duration
- Microvascular disease

**Chronic Kidney Disease**
- Age ≥50y and eGFR < 60 mL/min/1.73 m² or ACR ≥3 mg/mmol

**Atherosclerotic Cardiovascular Disease (ASCVD):**
- Myocardial infarction (MI), acute coronary syndromes (ACS)
- Stable angina, documented coronary artery disease by angiography
- Stroke, TIA, documented carotid disease
- Peripheral arterial disease, claudication and/or ABI < 0.9
- Abdominal aortic aneurysm (AAA) — abdominal aorta > 3.0 cm or previous aneurysm surgery

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**INITIATE STATIN TREATMENT**

**If LDL-C ≥ 2.5 mmol/L**
- (or <50% reduction) or ApoB ≥ 0.85 g/L or non-HDL-C ≥ 2.2 mmol/L

**Discuss add-on therapy with patient:**
- Evaluate reduction in CVD risk vs. cost/access and side-effects

**ADD-ON**
- Ezetimibe or PCSK9 inhibitor

**Monitor**
- Response to statin Rx
- Response to add-on lipid-lowering Rx
- Healthy behavior modifications

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**If LDL-C ≥ 2.0 mmol/L or ApoB ≥ 0.80 g/L or non-HDL-C ≥ 2.6 mmol/L on maximally tolerated statin dose**

**IF LDL-C ≥ 1.8 mmol/L or ApoB ≥ 0.70 g/L or non-HDL-C ≥ 2.4 mmol/L on maximally tolerated statin dose**

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**NO**

**YES**

**ADD-ON**
- Ezetimibe 1st line (BA5 as alternative — add-on to other drugs)

**INTENSIFICATION**

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**Review/Discuss health behavioral modifications (refer to Figure 1)**

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**Intensification threshold**
2021 CCS Dyslipidemia Guidelines

1. We recommend use of high-intensity statin therapy in addition to appropriate health behaviour modifications for all secondary prevention CVD patients. For patients who do not tolerate a high-intensity statin, we recommend the maximally tolerated statin dose (Strong Recommendation; High-Quality Evidence).
2021 CCS Dyslipidemia Guidelines

2. We recommend intensification of lipid-lowering therapy with ezetimibe and/or PCSK9 inhibitor therapy for all secondary prevention CVD patients in whom LDL-C remains ≥ 1.8 mmol/L (or non-HDL-C ≥ 2.4 mmol/L or ApoB ≥ 0.7 g/L) on maximally tolerated statin dose. (Strong recommendation; High Quality Evidence). If ezetimibe is used initially and LDL-C remains ≥ 1.8 mmol/L (or non-HDL-C ≥ 2.4 mmol/L or ApoB ≥ 0.7 g/L) PCSK9 inhibitor therapy is recommended.

3. We recommend intensification of lipid-lowering therapy with a PCSK9 inhibitor (evolocumab or alirocumab) – with or without the addition of ezetimibe – for secondary CV prevention patients shown to derive the largest benefit from PSCK9 inhibitor therapy in whom LDL-C remains ≥ 1.8 mmol/L (or non-HDL-C ≥ 2.4 mmol/L or ApoB ≥ 0.7 g/L) on maximally tolerated statin dose. Refer to Figure 3. (Strong Recommendation; Moderate-Quality Evidence).
Treatment Intensification Approach for Patients with Atherosclerotic Cardiovascular Disease (ASCVD)

Patients with Atherosclerotic Cardiovascular Disease (ASCVD) Receiving maximally tolerated statin dose.

If LDL-C is ≥1.8 mmol/L or if ApoB ≥0.70 g/L or if non-HDL-C ≥2.4 mmol/L

If TG is ≥1.5 to 5.6 mmol/L

LDL-C 1.8-2.2 mmol/L or ApoB 0.70-0.80 g/L or non-HDL-C 2.4-2.9 mmol/L

LDL-C >2.2 mmol/L or ApoB >0.80 g/L or non-HDL-C >2.9 mmol/L or high PCSK9i benefit patient* Consider icosapent ethyl 2000 mg BID†

Consider ezetimibe ± PCSK9 inhibitor

Consider PCSK9 inhibitor ± ezetimibe

Table 3: Secondary prevention patients shown to derive the largest benefit from intensification of statin therapy with the addition of a PCSK9 inhibitor

Recent acute coronary event (ACS)
- hospitalized index ACS to 52 weeks post index ACS

Clinically evident ASCVD and any of the following:
- diabetes mellitus or metabolic syndrome
- polyvascular disease (vascular disease in ≥2 arterial beds)
- symptomatic PAD
- recurrent MI
- MI in the past 2 years
- previous CABG surgery
- LDL-C ≥ 2.6 mmol/L or heterozygous FH
- lipoprotein (a) ≥ 60 mg/dL (120 mmol/L)

ASCVD = atherosclerotic cardiovascular disease; PAD = peripheral arterial disease; MI = myocardial infarction; CABG = coronary artery bypass graft; LDL-C = low density lipoprotein cholesterol; FH = familial hypercholesterolemia
2021 CCS Dyslipidemia Guidelines

1. We recommend the use of icosapent ethyl to lower the risk of CV events in patients with ASCVD, or with diabetes and ≥1 CVD risk factors, who have an elevated fasting triglyceride level of 1.5-5.6 mmol/L despite treatment with maximally tolerated statin therapy (Strong Recommendation; High-Quality Evidence).
2021 CCS Dyslipidemia Guidelines

1. We recommend the use of a PCSK9 inhibitor (alirocumab or evolocumab) to lower LDL-C in patients with heterozygous FH without clinical ASCVD whose LDL-C remains above the threshold (i.e., LDL-C ≥2.5 mmol/L or < 50% reduction from baseline; or Apo-B ≥ 0.85 mg/dL or non-HDL-C ≥ 3.2 mmol/L)) despite maximally tolerated statin therapy with or without ezetimibe therapy (Strong Recommendation; High-Quality Evidence).

2. We recommend the use of a PCSK9 inhibitor (alirocumab or evolocumab) for patients with heterozygous FH and ASCVD whose LDL-C remains above the threshold ≥ 1.8 mmol/L (or ApoB ≥ 0.7 mg/dL or non-HDL-C ≥ 2.4 mmol/L) despite maximally tolerated statin therapy, with or without ezetimibe. (Strong Recommendation; High-Quality Evidence).
18,144 patients within 10 days post ACS (N=18144); LDL>1.3 mmol/L; not on LLT < 3.2 mmol/L; on LLT < 2.6 mmol/L
Primary endpoint: CV death, MI, UAP requiring rehospitalization, coronary revascularization (≥30 days), or stroke

Mean LDL-C at 1 year: 1.4 mmol/L for simvastatin/ezetimibe vs 1.8 mmol/L for simvastatin alone

FOURIER

27,564 patients with history of CVD event (chronic stable ASCVD) plus additional RFs;
Fasting LDL-C ≥ 1.8 mmol/L or non-HDL-C C ≥ 2.6 mmol/L
Primary Endpoint: CV death, MI, stroke, hosp. for UA, or coronary revasc

Median LDL-C Levels Over Time: All Patients

Primary Endpoint: Composite of CV Death, MI, Stroke, Hospitalization for UA, or Coronary Revascularization

ARR=1.5%
HR=0.85 (0.79-0.92)
P<0.001

ODYSSEY OUTCOMES

18,924 post ACS patients (1-12 months); LDL-C ≥ 1.8 mmol/L or non-HDL ≥ 2.6 mmol/L or apo B ≥ 80 mg/dL

Primary Outcome: CHD death, non-fatal MI, fatal or non-fatal stroke, UAP requiring hospitalization

ARR* 1.6%
HR 0.85
(95% CI 0.78, 0.93)
P=0.0003

Schwarz GG. N Engl J Med 2018
Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia

Deepak L. Bhatt, M.D., M.P.H., P. Gabriel Steg, M.D., Michael Miller, M.D., Eliot A. Brinton, M.D., Terry A. Jacobson, M.D., Steven B. Ketchum, Ph.D., Ralph T. Doyle, Jr., B.A., Rebecca A. Juliano, Ph.D., Lixia Jiao, Ph.D., Craig Granowitz, M.D., Ph.D., Jean-Claude Tardif, M.D., and Christie M. Ballantyne, M.D., for the REDUCE-IT Investigators*
Primary End Point:
CV Death, MI, Stroke, Coronary Revasc, Unstable Angina

Hazard Ratio, 0.75
(95% CI, 0.68–0.83)
RRR = 24.8%
ARR = 4.8%
NNT = 21 (95% CI, 15–33)
P=0.00000001
PICO #6

In primary and secondary prevention, what is the evidence for CV benefit of omega-3 from:
(i) dietary sources, or
(ii) OTC formulations/supplements?
1. We do not recommend the use of over-the-counter omega-3 polyunsaturated fatty acids supplements (marketed as natural health products in Canada) to reduce CVD risk (Strong Recommendation; High-Quality Evidence).
Low Dose Omega-3 Mixtures Show No Significant Cardiovascular Benefit

<table>
<thead>
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<th>Source</th>
<th>No. of Events (%)</th>
<th>Rate Ratios (CI)</th>
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<tr>
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<td>Treatment</td>
<td>Control</td>
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<tr>
<td>Coronary heart disease</td>
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<tr>
<td>Nonfatal myocardial infarction</td>
<td>1121 (2.9)</td>
<td>1155 (3.0)</td>
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<td>Coronary heart disease</td>
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<tr>
<td>Stroke</td>
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<td>Ischemic</td>
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<tr>
<td>Revascularization</td>
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<td>Noncoronary</td>
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<tr>
<td>Any major vascular event</td>
<td>5930 (15.2)</td>
<td>6071 (15.6)</td>
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Case
- Treatment intensification and Secondary Prevention -
Case: Mr. Young

• 54 yrs old, non-smoker, 6 months post-ACS, stented pLAD + pCIRC

• BMI = 27 kg/m²
• BP 130/80
• No diabetes
• TC = 3.8 mmol/L
• HDL-C = 1.2 mmol/L
• TG = 1.6 mmol/L
• LDL-C = 1.8 mmol/L (on atorvastatin 80 mg + ezetimibe daily)
Case: Mr. Young

- 54 yrs old, non-smoker, 1 month post-ACS, stented pLAD + pCIRC

- BMI = 27 kg/m²
- BP 130/80
- No diabetes
- TC = 3.8 mmol/L
- HDL-C = 1.2 mmol/L
- TG = 1.6 mmol/L
- LDL-C = 1.8 mmol/L (on atorvastatin 80 mg + ezetimibe daily)
  - apoB = 0.85 g/L
  - Lp(a) = 100 mg/dL
Case 1 Mrs. Tremblay

Which of the following is **the most appropriate statement**: 

1. This patient is young and therefore not at high-risk. No additional therapy is needed.

2. This patient is young and at high-risk but is near LDL-C target. No additional therapy is needed.

3. This patient is young and at high-risk. He would have been eligible for PCSK9i trial and likely shown high-benefit from therapy. Recommend PCSK9i.

4. This patient is young and at high-risk. He would have been eligible for IPE trial which showed a large benefit. Recommend IPE.

5. This patient is young and at high-risk. Recommend PCSK9i+IPE.
Case 1 Mrs. Tremblay

Which of the following is the most appropriate statement:

1. This patient is young and therefore not at high-risk. No additional therapy is needed.
2. This patient is young and at high-risk but is near LDL-C threshold. No additional therapy is needed.
3. This patient is young and at high-risk. He would have been eligible for PCSK9i trial and likely shown high-benefit from therapy. Recommend PCSK9i.
4. This patient is young and at high-risk. He would have been eligible for IPE trial which showed a large benefit. Recommend IPE.
5. This patient is young and at high-risk. Recommend PCSK9i+IPE.
Questions?