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Optimal Care Forum for Evidence-Based Medicine

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Activity description	Practicing evidence-based medicine (EBM) is important in today's health care environment. This model of care offers clinicians a way to enrich quality, provide patient satisfaction, reduce costs and improve outcomes. A common implementation of EBM involves the use of clinical practice algorithms during medical decision-making to encourage optimal care. This widely recognized practice is designed to address the persistent problem of clinical practice variation with the help of actionable information at the point of care. These e-newsletters enable health care professionals to put new EBM into practice.
Learning objectives	• Recognize the clinical utility of coronary artery calcium (CAC) scoring in the primary prevention of cardiovascular disease, including its role in refining ASCVD risk assessment, guiding statin therapy decisions, and identifying patients who may benefit from intensified preventive strategies. • Evaluate the role of amiloride as a noninferior and potentially more tolerable alternative to spironolactone in the management of resistant hypertension, and recognize colchicine as an effective, cost-efficient option for secondary cardiovascular prevention in patients with established ASCVD. • Assess the comparative effectiveness, safety and cost-efficiency of Roux-en-Y gastric bypass (RYGB) relative to other bariatric procedures, and apply this evidence to guide surgical referrals and shared decision-making in patients with severe obesity, including those with compensated cirrhosis. • Compare the long-term effectiveness of computed coronary CT angiography (CCTA) versus invasive coronary angiography (ICA) in patients with stable chest pain, and apply evidence-based strategies to reduce unnecessary invasive procedures while maintaining equivalent quality of life and cardiovascular outcomes.

Accreditation statement

In support of improving patient care, this activity has been planned and implemented by Optum Health Education and Optum. Optum Health Education is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC) to provide continuing education for the health care team.

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The role of the coronary artery calcium score in the primary prevention of cardiovascular disease

A recent *JAMA Cardiology* editorial on coronary artery calcium (CAC) screening began with "CAC testing is extremely appealing as a primary prevention strategy to personalize risk assessment and individualize the intensity of preventive therapy. This is because the test is widely available, fast, highly reproducible, low radiation, directly reflective of total coronary plaque burden, and highly predictive of future atherosclerotic cardiovascular disease (ASCVD) events."[1] Because of these attributes, CAC scoring is an important tool in assessing cardiovascular risk, especially in asymptomatic patients. Additionally, in patients presenting with stable chest pain who have a low pretest probability of coronary artery disease (CAD), it can serve as a single test to reliably exclude CAD. Because atherosclerosis is a generalized process, the CAC also provides indirect evidence on the risk of future stroke and peripheral arterial disease. This article discusses the benefits, indications and considerations of using CAC scoring in clinical practice.

The CAC screening is favored in a range of circumstances as it is simple, noninvasive and cost-effective (generally less than $150). It is a low-dose CT scan of the chest that uses minimal radiation exposure that's equivalent to the amount of radiation exposure of a transatlantic flight. Whereas traditional risk factors only provide estimates of likelihood for CAD, the CAC provides direct evidence of the disease by detecting calcium deposits in the arteries. Studies have indicated that by showing patients evidence of CAD on a CAC, they are more likely to modify risk factors, accept statin therapy and maintain statin compliance. One downside of CAC screening is the identification of abnormalities of the lung, particularly in smokers, which occasionally leads to additional testing.

Patients most likely to benefit from CAC scoring are those over age 40 who are at risk for cardiovascular events but who are asymptomatic, or uncertain about initiating preventive therapy. **These include 2 main groups:**

Group 1

Statin-naive patients with ASCVD risk greater than 7.5%. For these patients with an intermediate to high calculated risk of cardiovascular disease (ASCVD) but who are hesitant to start statin therapy, a CAC score can provide more clarity and reassurance on whether statin use is warranted.

Group 2

Adults with 10-year ASCVD risk of 5% to less than 7.5% and additional risk factors that are not considered in the ASCVD risk equation. Most important among these is a family history of early coronary disease. Others include elevated HS-CRP, metabolic syndrome, elevated lipoprotein(a), low HDL levels, and persistently elevated LDL >160 mg/dl.

In addition to these groups, CAC screenings can be helpful for patients who previously discontinued statin therapy due to side effects but now have additional LDL-lowering options. If they meet indications for treatment and would consider alternative therapies, CAC scoring can guide decision-making.

CAC interpretation falls into 4 score bands based on the calcium score:

- If the CAC score is zero, the risk of cardiovascular events is very low. In this case, statin therapy may not be necessary unless the patient has additional risk factors like diabetes, LDL-C >190 mg/dL, a family history of premature coronary heart disease (CHD), or a smoking history. A CAC of zero is a highly reliable "warranty" against CAD over the next 10 years with an event rate well under 1% (0.3%).[2]

- If the CAC is 1-99, this indicates some element of coronary artery disease. Statin therapy is generally favored for these patients to reduce the risk of future myocardial infarction as well as vascular events elsewhere.
- If the CAC ≥ 100, these patients have significant coronary plaque and should be treated with statins, low-dose aspirin and aggressive modification of other cardiovascular risk factors.
- If the CAC > 300, the patient is at a high risk of cardiovascular events. These patients should be treated as if they already have established ASCVD using maximal guideline-directed medical therapy (GDMT). When these patients are asymptomatic, ischemia testing is not indicated as multiple well-controlled trials have documented that medical therapy and coronary interventions have equivalent long-term outcomes, other than in those patients with left main and 3 vessel disease.[3] Depending on the comfort level of the primary care physician (PCP), referral to cardiology may be considered.

Rechecking the CAC is generally not indicated when the score is above zero. Early plaque tends to be predominantly composed of fibro-atheromatous material. As this plaque matures, particularly under the influence of statin therapy, it becomes increasingly calcified, and the CAC rises. This is not necessarily indicative of increased CAD risk. In fact, studies have shown that this "mature" plaque is associated with a lower risk of future myocardial infarction than lipid predominant plaque.[4] Given this, there is no value to repeat CAC testing in patients who have a positive CAC and are on GDMT. In other words, CACs do not decrease over time even with maximal GDMT, and an increase in the CAC does not add prognostic significance when patients are being treated. In patients with zero or very low CACs who elect not to use GDMT, repeating the CAC in 5 to 10 years is reasonable, but without clear literature to support this recommendation. Table 2 (below) from a recent *JAMA Cardiology* Special Communication has useful guidance.[5]

Table 2. When Coronary Calcium (CAC) testing may be too early, too late or too often in 2024*

Variable	Too early	Too late**	Too often***
Clinical scenarios	• Males aged < 40 years without risk factors • Females aged < 50 years without risk factors • Males with DM age < 35 years • Female with DM age < 45 years • Below 5% ASCVD risk unless a strong lifetime risk burden such as family history of premature coronary disease or current smokers	• Already on statin therapy • CAC does not measure statin efficacy against reducing plaque volume • Age > 65 years with many ASCVD risk factors in whom a treatment decision is not uncertain • Age ≥ 80 years	• Repeating CAC score if CAC ≥ 300 for progression of disease • Repeating CAC score if CAC ≥ 100 and on risk-reduction therapy • Repeating a CAC score in older patients > 75 years if CAC = 0

Abbreviations: atherosclerotic cardiovascular disease (ASCVD); diabetes mellitus (DM)

* These suggestions cannot take the place of an individualized clinical assessment of a patient and their risk status. They are intended to aid the clinician in their discussion of whether the CAC score test, if obtained, is likely to provide information that will change therapy.

** Too late to change clinical management.

*** There may be individual circumstances where a repeat CAC score is warranted, but this requires careful consideration and should not be performed routinely.

In conclusion, the coronary artery calcium (CAC) score is a powerful tool in assessing cardiovascular risk, especially in asymptomatic individuals. It provides direct evidence of coronary disease, helps refine risk classification, and can guide decisions about statin therapy and other preventive measures. However, it is important to use CAC scoring appropriately and understand when the test is most useful or when it may not provide additional clinical value. By carefully considering these factors, primary care providers can better tailor prevention strategies and optimize patient care.

To help educate our patients on the role of CAC, *JAMA* published an informative patient infographic: What Is a Cardiac CT Calcium Score? | Patient Information | JAMA | JAMA Network.

Amiloride as a viable alternative to spironolactone in resistant hypertension

For patients with resistant hypertension as defined by requiring more than 3 drugs to achieve control, spironolactone has been the typical fourth drug of choice.[6] A recent randomized controlled trial profiled in *JAMA* compared amiloride, a potassium-sparing diuretic, with spironolactone in these patients.[7] The study was conducted in South Korea from 2020 to 2024 with 60 patients randomized to receive spironolactone and 58 to receive amiloride. All patients had an at-home-measured systolic blood pressure (SBP) greater than 130 mm Hg and were already on a fixed-dose triple medication combination (angiotensin receptor blocker, calcium channel blocker and thiazide).

The primary endpoint was the between-group difference in home SBP change at week 12, with a noninferiority margin of −4.4 mm Hg. The secondary endpoint was the achievement rate of home- and office-measured SBP of less than 130 mm Hg. At week 12, mean home SBP decreased by 13.6 mm Hg in the amiloride group and 14.7 mm Hg in the spironolactone group, demonstrating noninferiority of amiloride (between-group difference in change, −0.68 mm Hg; 90% CI, −3.50 to 2.14 mm Hg). Home-measured SBP of less than 130 mm Hg was achieved by 66.1% in the amiloride group and 55.2% in the spironolactone group. Office-measured SBP of less than 130 mm Hg was achieved by 57.1% and 60.3%, respectively. One case of hyperkalemia-related discontinuation occurred in the amiloride group, with no cases of gynecomastia in either group.

Both drugs, amiloride and spironolactone, are considered cost-effective for treating resistant hypertension. But amiloride, with its lower incidence of hyperkalemia and lack of antiandrogenic adverse effects, may improve patient adherence due to its more favorable side-effect profile. This study suggests that amiloride is a noninferior and potentially more tolerable alternative to spironolactone for patients with resistant hypertension, aligning well with value-based care principles by optimizing treatment efficacy, safety and cost-effectiveness.

Colchicine for secondary cardiovascular prevention: A value-based perspective

Two recent meta-analyses on the effectiveness of colchicine for use in secondary cardiovascular prevention showed significant benefit. The study by Michelle Samuel and others synthesized data from 6 randomized controlled trials (RCTs) involving over 21,000 patients with established atherosclerotic vascular disease (ASCVD) (for example, post-myocardial infarction, stable CAD, stroke).[8] The trials evaluated the long-term use of low-dose colchicine (0.5 mg daily) versus placebo or no treatment, with follow-up periods ranging from 12 to 33.6 months. The analysis from the other meta-analysis by d'Entremont is based on 9 trials including over 30,000 patients with known ASCVD receiving colchicine versus placebo.[9]

Key findings

- **Efficacy:** In the Samuel study, colchicine reduced the relative risk of major adverse cardiovascular events (MACE) — a composite of cardiovascular death, myocardial infarction, ischemic stroke and urgent coronary revascularization — by 25%. It significantly lowered the incidence of myocardial infarction (29% reduction), ischemic stroke (37% reduction) and revascularization (33% reduction). No significant effect was observed on cardiovascular mortality. In the d'Entremont study, the absolute risk reduction (ARR) of colchicine for MACE was 0.9%, with a number needed to treat of approximately 111. The ARR for need for coronary revascularization was 0.9% and for myocardial infarction was 0.4% (NNT=250).
- **Safety:** No increase in all-cause or non-cardiovascular mortality was found. Serious adverse events, including infections, pneumonia and cancer, were not significantly different between colchicine and control groups. A non-significant trend toward more gastrointestinal hospitalizations was noted in the Samuel study analysis.
- **Subgroup consistency:** Benefits were consistent across age, sex and diabetes status, although underrepresentation of women limits conclusions for that group.
- **Trial variability:** The CLEAR-SYNERGY trial, conducted during the COVID-19 pandemic, showed attenuated benefits, likely due to underreporting of nonfatal events and inadequate inflammation control (hsCRP >2 mg/L). Excluding this trial in sensitivity analyses in the Samuel study paper strengthened colchicine's observed benefits.

Implications for primary care

Colchicine is a low-cost, well-tolerated anti-inflammatory agent with a favorable safety profile and substantial efficacy in reducing recurrent cardiovascular events. Its mechanism — targeting neutrophil activity and cytokine release — complements statin therapy and addresses residual inflammatory risk. Despite guideline endorsements (European Society of Cardiology Class IIa; FDA approval), uptake remains low.

Value-based care considerations

- **Cost-effectiveness:** Colchicine offers high clinical value at low cost, aligning with value-based care goals.
- **Population health:** Broad applicability across diverse cardiovascular risk profiles supports its use in routine secondary prevention.
- **Implementation opportunity:** Primary care providers can play a pivotal role in initiating and monitoring colchicine therapy, particularly in patients with recent myocardial infarction or stable coronary artery disease already on statins.

In summary, colchicine represents a compelling, underutilized strategy for reducing cardiovascular risk in high-risk patients, with strong evidence supporting its integration into standard secondary prevention protocols.

Roux-en-Y gastric bypass as preferred bariatric surgery procedure

Previous issues of this newsletter have highlighted the potential benefits of bariatric surgery.[10,11,12] The By-Band-Sleeve trial is a large, pragmatic, United Kingdom–based randomized controlled trial comparing the clinical and cost-effectiveness of 3 bariatric procedures in adults with severe obesity[13] — Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG) and adjustable gastric banding (AGB). Conducted across 12 National Health Service (NHS) hospitals, the study followed 1,346 participants for 3 years post-randomization.

Key findings

- **Weight loss outcomes:** RYGB led to the greatest weight loss (mean total weight loss: 26.8%), followed by SG (19.4%) and AGB (14.0%). RYGB and SG were both significantly superior to AGB in achieving ≥50% excess weight loss. SG was inferior to RYGB in this regard.
- **Quality of life (QOL):** Measured by EQ-5D-5L, both RYGB and SG improved QOL more than AGB. RYGB showed a clinically meaningful advantage over SG in some domains, including physical function and self-esteem.
- **Metabolic improvements:** RYGB had the highest rates of diabetes remission (76% in those with baseline diabetes), followed by SG (62%) and AGB (50%). RYGB also showed superior improvements in lipid profiles and blood pressure control.
- **Safety profile:** All procedures had low perioperative mortality. SG had the lowest rate of adverse events from 30 days to 3 years post-op. RYGB had more internal hernia repairs and AGB had the highest rate of reoperation.
- **Cost-effectiveness:** From a UK NHS perspective, RYGB was the most cost-effective option, yielding the highest quality-adjusted life years (QALYs) despite higher upfront costs. SG and AGB were less cost-effective, with AGB being the least favorable.

Implications for value-based care

For patients with severe obesity, RYGB offers the best balance of long-term weight loss, metabolic improvement, QOL gains and cost-effectiveness. SG may be appropriate for patients prioritizing a lower risk of adverse events, though with slightly less benefit. AGB is no longer supported as a first-line surgical option due to inferior outcomes and higher reoperation rates.

Primary care providers play a critical role in identifying candidates for bariatric surgery, supporting shared decision-making and coordinating long-term follow-up. This trial reinforces the importance of aligning surgical referrals with evidence-based, value-driven care pathways.

Bariatric surgery is cost-effective in patients with obesity

A recent retrospective cohort study, conducted within the Veterans Health Administration (VHA), evaluated the survival and cost-effectiveness of bariatric surgery — specifically sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) — among patients with obesity, including a subgroup with compensated cirrhosis.[14] The study compared outcomes with those of patients enrolled in MOVE! — the weight management and healthy lifestyle program for Veterans supported by VA's National Center for Health Promotion and Disease Prevention (NCP) . The number of patients enrolled were as follows: 4,301 SG patients, 1,906 RYGB patients, and 31,055 MOVE! participants.

Key findings:

- **Survival benefit:** Bariatric surgery was associated with improved survival. Among all patients, surgery extended life expectancy by 0.2 years. For those with cirrhosis, the gain was 0.9 years, though not statistically significant due to a small sample size.
- **Cost-effectiveness:** Despite higher upfront costs, bariatric surgery was cost-effective over a 10-year period. For patients with cirrhosis, SG had an incremental cost-effectiveness ratio (ICER) of $18,679 per quality-adjusted life-year (QALY), and RYGB had an ICER of $44,704 — both well below the $100,000 willingness-to-pay threshold. In fact, surgery was cost-saving in some models.

- **Weight loss and comorbidity impact:** Surgery led to sustained reductions in BMI and improved glycemic control. RYGB showed greater weight loss than SG. These benefits translated into lower disutility scores and improved QALYs.
- **Cirrhosis subgroup:** Patients were well-compensated (Child-Turcotte-Pugh class A), and surgery was not associated with increased hepatic decompensation or hepatocellular carcinoma. The findings support the safety and efficacy of bariatric surgery in this population.

Implications for value-based care

- Bariatric surgery offers a high-value intervention for patients with obesity and compensated cirrhosis, improving both longevity and quality of life.
- While initial costs are higher, long-term savings and health gains justify the investment, especially when considering reduced burden from obesity-related comorbidities. Given the requirement for long-term GLP1-RA therapy for maintenance of weight loss, bariatric surgery is a more cost-effective approach to managing obesity.
- Primary care providers play a critical role in identifying eligible patients, addressing misconceptions about surgical risk, and advocating for access amid payer-related barriers.

Clinical takeaway:

Bariatric surgery should be considered a viable, cost-effective option for patients with obesity with or without compensated cirrhosis who have not achieved durable weight loss through lifestyle interventions. PCPs should be proactive in discussing surgical options and coordinating multidisciplinary care to optimize outcomes under value-based care models.

Noninvasive approach just as effective over long-term quality of life measurement in select patients with stable chest pain

The randomized clinical trial "Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease (DISCHARGE)" compared computed tomography (CCTA) with invasive coronary angiography (ICA) as first-test strategies in patients with stable chest pain initially referred to ICA, stratified by sex, with a median follow-up of 3.5 years.[15] Findings of this original study demonstrated a CCTA-first approach results in a striking 78% reduction in unnecessary ICAs and a 28% reduction in unnecessary stents, with equivalent cardiovascular outcomes.[16]

A secondary analysis of the DISCHARGE randomized clinical trial was recently published that compared health-related quality of life (QOL) outcomes in patients with stable chest pain who underwent either computed tomography (CCTA) or invasive coronary angiography (ICA) as their initial diagnostic test.[17] The study included 3,561 patients across 26 European centers, with a median follow-up of 3.5 years. Both CCTA and ICA groups experienced significant improvements in QOL over time, including physical functioning, mental health and perceived health status. There were no statistically significant differences in QOL outcomes between the CCTA and ICA groups at 1 or 3.5 years.

By demonstrating equivalence between CCTA and ICA in long-term patient-centered outcomes, these data further support the existing literature on the use of CCTA as the primary modality for the evaluation of suspected CAD in stable outpatients.

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