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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	• Establish knowledge of shoulder pain related to rotator cuff disorders (primarily rotator cuff tendinopathy and non-traumatic rotator cuff tears) and explore the current management paradigm which primarily focuses on non-operative treatment with judicious use of surgical intervention for specific cases. • Examine evidence-based reports on the effects of GLP-1 receptor agonists (GLP-1 RAs) in preventing adverse kidney and/or cardiovascular outcomes for individuals with diabetes mellitus (DM) and for those with obesity but without DM and evaluate a cost effectiveness analysis that looks at the sum of the total benefits of all avoided events. • Determine if the addition of H pylori stool antigen (HPSA) screening to an established CRC screening program impacts mortality from gastric cancer. • Describe the current standard of care for individuals with concomitant severe aortic stenosis and obstructive coronary artery disease (CAD) using a surgical approach with combined aortic valve replacement and coronary bypass grafting (SAVR plus CABG) and compare with a percutaneous approach using transcatheter aortic valve replacement combined with percutaneous coronary intervention (TAVR + PCI) and the potential risks and benefits. • Discuss screening recommendations for prostate cancer using blood-based prostate-specific antigen (PSA) screening.

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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No commercial support was received for this activity.

Evidence-based management of non-traumatic rotator cuff disorders

Rotator cuff tendinopathy and the painful shoulder

Shoulder pain is commonly related to a range of disorders of the rotator cuff – a group of 4 muscle-tendon units controlling shoulder movement and stability. These disorders include tendinopathy, partial and full thickness defects, and cuff-related arthropathy. Such disorders are the most common reason for adults seeking upper limb specialty care, resulting in over 9 million physician visits per year in the United States.[1]

The underlying cause continues to be debated with concepts such as "intrinsic tendon disease or degeneration," "shoulder impingement" or a combination leading to cuff compromise. Older age, male sex, smoking, manual labor, comorbidities (hypertension, diabetes, obesity and hypercholesterolemia), family history and genetics have all been associated with rotator cuff disorders.[1] However, tendon senescence appears to be the common underlying factor based on current evidence showing increased prevalence of these conditions with age, regardless of occupation or arm dominance, alongside the fact that rotator cuff defects frequently occur without the presence of trauma.[2]

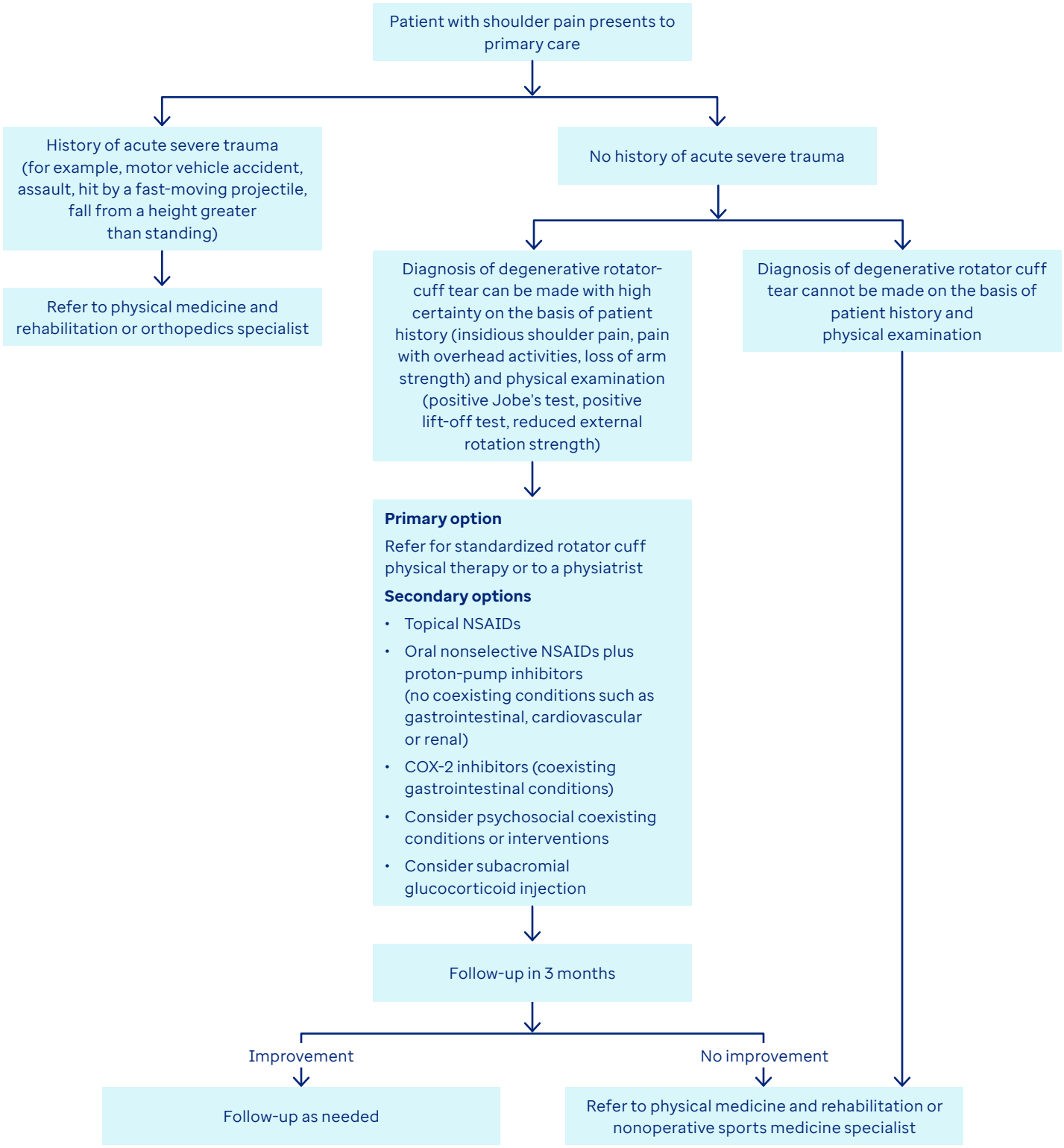
Studies examining the natural history of rotator cuff defects at 5 years follow-up demonstrate that these defects can enlarge over time.[3,4] Data also suggests a level of accommodation is present given the high prevalence of rotator cuff disorders in the general population.[5] **The overall significance of such disease progression with rotator cuff disorders remains unclear considering the lack of correlation between pathophysiological severity (initial cuff defect size and thickness, and muscle quality on imaging) and levels of symptom intensity or capability**.[1]

Standardizing the clinical evaluation

Structural changes to the rotator cuff can often be asymptomatic while also presenting with lateral shoulder pain of gradual onset, worsened at night, with overhead activities (especially above shoulder level), or reaching behind the back. Examination can reveal muscle atrophy, shoulder asymmetry and reduced active range of motion (while passive range may be normal), with pain limiting performance of specific maneuvers which have variable sensitivity and specificity. Imaging can include plain radiographs (to examine concurrent osteoarthritis, joint dislocation, proximal migration of the humeral head, glenoid wear and loss of the acromiohumeral interval), ultrasonography (US), and magnetic resonance imaging (MRI) (showing rotator cuff defect size and location, tendon traction, muscle atrophy and fatty infiltration – present in up to 45% with persistent defects – a feature associated with worse outcomes).[1]

While MRI provides better image quality, US is relatively inexpensive and portable, with a similar sensitivity and specificity for diagnosing full thickness defects. However, US is operator dependent, and both US and MRI lack diagnostic accuracy for accurately delineating partial thickness defects.[1] Routine imaging using US or MRI should be reserved for the specialist in cases of diagnostic uncertainty, and where specific information on defect characteristics are required for treatment planning (see figure 1).

Figure 1. Management algorithm for suspected rotator cuff defect



COX-2, Cyclooxygenase-2; NSAIDs, non-steroidal anti-inflammatory drugs

Rotator cuff disorder management

Expert consensus supports early surgical repair of traumatic rotator cuff defects, usually after high-energy injuries, in suitable patients. However, most patients with symptomatic rotator cuff disorders, including tendinopathy and non-traumatic partial or full thickness defects, can and should be managed non-surgically.[1,6]

Physical therapy: The cornerstone of care

Evidence suggests physical therapy for rotator cuff disorders (standardized protocols focused on enhancing muscle strength, endurance, scapular posture) to be extremely effective in reducing pain and improving function in substantial proportions of patients (over 80%) up to 10 years following initial care.[1,5,7]

A large, randomized control trial (RCT) demonstrated non-surgical and surgical treatments for rotator cuff disorders in patients who remained symptomatic after 3 months of initial rehabilitation, provided equivalent improvements in comfort and capability at 2 years.[6] Studies have shown the equivalence of non-operative management with surgical closure of defects on symptom alleviation for at least 5 years after initial presentation [8,9,10] along with recurrent defects not being associated with greater levels of pain or incapability.[10] When a clinical diagnosis is made in primary care, physical therapy can be commenced. However, if there is significant diagnostic uncertainty, a specialist referral (physiatry, orthopedics, sports medicine) is recommended alongside a patient-specific management plan.[1] Even brief, tailored guidance on best practices can be effective. A multicenter RCT involving patients with rotator cuff disorders showed progressive exercise program was not superior to a single best practice advice session with a physical therapist in improving shoulder pain and function.[11]

The value of mental and social health support

Evidence also shows the dominant association between mental health (feelings of worry, despair, unhelpful thoughts including catastrophization and kinesiophobia) and social health (loss of roles and identities, social stressors) with pain and function over pathophysiology severity of rotator cuff disorders.[12,13,14] The misinterpretation of symptoms as injury can limit the ability of individuals to accommodate these disorders while risking overutilization. Therapeutic strategies should evaluate and respond to psychosocial factors. This can be achieved using screening tools, such as mental health surveys assessing symptoms of depression and anxiety, communication that bolsters patient agency around self-management, and behavioral therapies, as needed. The evidence for behavioral interventions for rotator cuff disorders is sparse, but substantial data exists on the positive impact of such therapies for musculoskeletal pain-related psychological distress in general.[1,2] Data supporting the use of manual therapy, acupuncture, therapeutic US, transcutaneous electrical nerve stimulation, shock-wave therapy and pulsed electromagnetic field therapy is currently insufficient.

Pharmacological options and adjunctive therapy

Pain relief for rotator cuff disorders may include non-steroidal anti-inflammatory drugs plus proton-pump inhibitors (with no coexisting gastrointestinal, cardiovascular or renal conditions) or COX-2 inhibitors as an alternative. However, there is a lack of high-quality evidence supporting use of NSAIDs. Opioids are not recommended due to their risk profile and lack of evidence around their superiority with nonopioid therapy. While glucocorticoid injections (combined with local anesthetic) are commonly utilized, evidence is inconsistent with a relatively small set of trials supporting a single injection for short-term symptomatic relief and functional improvement.[1] Notably, subacromial corticosteroid injections are shown to provide no long-term benefit in patients with rotator cuff disorders[11] and preoperative steroid injections are shown to have a higher risk of subsequent revision following rotator cuff defect repair.[15] No high-quality trials currently support the use of orthobiologics (platelet rich plasma, stem cells) in the management of these conditions.

Surgical management: The clinical face-off

Surgical treatments for rotator cuff disorders commonly include arthroscopic (most commonly) or open rotator cuff closure and subacromial decompression. While adverse events following surgery (post-operative stiffness, infection, DVT) are comparatively low, they can be serious, debilitating and potentially life-threatening. Surgical management of rotator cuff disorders, including cuff defects, should be reserved for patients where symptoms do not improve following a minimum of 3 months of non-operative treatment. However, the specific indications and timing of surgery continue to be a source of contention. While the trial showed equivalence of non-operative and operative strategies over the longer-term for persistent rotator cuff disorders, surgery was still shown to yield slightly greater symptomatic and functional improvement following repair of full thickness rotator cuff defects.[6] Other high-quality trials show universal improvement in pain and function at one and 2 years, and no significant differences between rotator cuff surgery and physical therapy combined, versus physical therapy alone.[16,17]

Considering the concept of “shoulder impingement," when cuff tendons are "pinched" or compressed between the bones of the shoulder causing pain when lifting the arm due to inflammation or irritation from repetitive movements or overuse. Subacromial decompression remains one of the most performed procedures for treating symptoms attributed to the rotator cuff. However, multiple randomized trials show the lack of superiority of subacromial decompression versus sham surgery for patients with rotator cuff disorders,[18,19,20] with authors suggesting this procedure is not needed in those responding to specific exercise treatments for up to 10 years.[21] Despite these findings, the proponents for surgery assert the lack of comparative information for rotator cuff disorders, along with the opportunity to change the natural history of the defect through anatomical restoration (that is, disease modification that would otherwise be impossible without surgery).[2] However, the disease modification rationale remains contentious considering the data supporting non-operative strategies and positive self-reported function despite ongoing structural defects that persist post-operatively.[1,22] Notably, the disease modification rationale for rotator cuff defect closure to slow progression of rotator cuff arthropathy is also not backed by evidence.[2]

In summary, approximately 50% of people develop some form of rotator cuff disorder during their lifetime, and a fraction of this population will seek care following symptoms becoming a concern. While a large proportion of the population accommodate these conditions (like a bulging spinal disc or degenerative meniscus in the knee), others will need to be guided toward recognizing these are normal, age-appropriate disorders that can be effectively managed with a high degree of symptomatic control and functional improvement with robust non-operative strategies delivered from the outset.

What do patients with rotator cuff disorders want?

Qualitative studies show people with rotator cuff disorders wish for restful sleep, maintaining meaningful activities and life roles, handling work and life transitions, improved pain management capabilities, support for despair and frustration to move toward hope and progress, and engagement in social roles (avoidance of loneliness).[23] Feeling they are being heard, getting effective and directed care, and not being dismissed is critical. These elements should be incorporated during the clinician-patient engagement. Further, the use of surgical management should be limited. Patients resistant to robust physical therapy and non-operative treatment strategies may benefit from surgical intervention following a shared decision-making interaction and counseling incorporating the evidence-based guidance in this forum article.

GLP-1 receptor agonists protect against kidney and cardiovascular disease but at high cost

High-value care is defined as care that delivers the best patient outcomes at the most affordable price. “Affordable price” varies by which perspective is taken — patient copay (or uninsured cost), cost to the insurer, cost to society (for example, cost to Medicare, which is ultimately paid by taxes). By convention, an intervention is generally considered cost-effective from a societal perspective if it results in the desired outcome for less than $100,000 U.S. dollars. This is typically reported in cost per quality-adjusted life years (QALYs).

The perspective of patient versus healthcare system is not always explicitly stated in evidence-based reports but is nonetheless important to examine. A recent robust meta-analysis of randomized controlled trials examining the effects of GLP-1 receptor agonists (GLP-1 RAs) demonstrated high-quality evidence of patient-level benefit of this class of drugs in preventing adverse kidney and/or cardiovascular outcomes.[24] The analysis ultimately synthesized data from 11 different trials, including 85,373 patients, with a mean follow-up of 25.2 months. Primary outcomes were major adverse cardiovascular events (MACE) and a composite kidney outcome that included worsening kidney function, kidney failure and death from kidney failure. Analyses examined all patients and sub-analyses looked at those with diabetes mellitus (DM) and those with obesity but without DM. There was no significant difference in serious adverse events between those who took the GLP1-RA and those who took placebo. Representative results are summarized in the table below.

As clinicians, it is important as we evaluate research studies that we focus not only on the relative risk reduction, which is typically the headline, but also the absolute risk reduction as it is this latter number that allows us to calculate the number needed to treat (NNT) and cost to avoid an event. While results show significant risk reduction for meaningful patient-level outcomes, inclusion of a cost analysis reveals the associated high price. This study looked at GLP-1 RAs compared with placebo, and did not examine this drug class compared to other drug classes.

It is possible, that when a patient level cost effectiveness analysis is completed, that this drug class may ultimately be found cost-effective. But that analysis must look at the sum of the total benefits of all avoided events (those below as well as reductions in MASH/cirrhosis, total joint arthroplasty and spine surgery, OSA, progression to DM2 in obese patients, etc.). Today, at their current costs, these drugs are not cost-effective when used solely for downstream disease prevention. Where they are likely to be cost-effective is when they are used in patients with DM2 to replace other expensive branded drugs or allow the conversion of a multi-dose insulin regimen to a basal insulin only regimen (see accompanying article in this Forum edition). As a society, we must address the potential patient benefits and weigh them against the available financial resources when selecting the most appropriate therapy.

Table 1. Outcomes in patients taking GLP-1 RAs vs. placebo

Outcome avoided	Relative risk reduction	Absolute risk reduction	Number needed to treat (NNT)	Cost to avoid one outcome (in USD)*
Worsening of composite kidney outcome in those with DM	18%	0.6%	164	$3,644,840
Worsening of composite kidney outcome in those without DM	19%	0.5%	210	$4,667,174
Risk of MACE	13%	1%	74	$1,644,623
Risk of death from all causes	12%	1%	101	$2,244,688

* Representative cost for drugs in the GLP-1-RA class as listed at goodrx.com/classes/gip-receptor-glp-1-receptor-agonists as of Dec. 2, 2024.

Using GLP-1RA therapy to convert a multi dose insulin regimen to basal insulin only regimen in DM2

This highly interesting randomized, open label study was conducted at the Cleveland Clinic.[25] It looked at 60 adults with DM2 who were well-controlled (HbA1c < 7.5%) on basal plus prandial insulin (MDI regimen). Patients were on < 120 units of insulin daily. In 40 patients, the prandial insulin was replaced with semaglutide titrated to 1 mg weekly along with their insulin degludec and the other 20 patients continued their MDI regimen. The prandial insulin was discontinued on Day 1 of the semaglutide and patients were instructed to only use a sliding scale dose of the short-acting insulin based on their home glucose monitoring. After 6 months of treatment, the results comparing the semaglutide/degludec regimen to the basal/prandial regimen were as follows:

- HbA1c < 7.5%: 90% controlled compared to 75% controlled.
- Weight change: -20 pounds compared to +2.6 pounds. 45% of semaglutide patients lost more than 10% TBW.
- Change in insulin dose: -56% versus +7%. 10% of patients discontinued all insulin. All patients were able to discontinue prandial insulin.
- There was no difference in hypoglycemic rates or severity between the 2 groups.

The design of this study, along with the results of the study, could easily be transferred to the real-world setting. Semaglutide 1 mg weekly is priced at about $12,000 yearly. Although expensive, the cost would be offset by the elimination of the prandial insulin cost and, in many patients, reduction in HGM costs as daily HGM could replace 4 times daily HGM once prandial insulin is discontinued. It is possible that these patients could also discontinue SGLT2i therapy, if in use, as the CV and renal benefits of the SGLT2i regimen would be replaced by those of the semaglutide, assuming the patients did not have HFrEF.

Adding h pylori testing to routine colorectal cancer screening may not work to prevent death from gastric cancer

There were an estimated 26,890 new cases of gastric cancer in 2024, and about 10,880 deaths in the United States.[26] Helicobacter pylori is a chronic infection known to be a cause of gastric cancer. Curative treatment is both available and can potentially decrease risk of gastric cancer.

A recent study in Taiwan examined if combining H pylori stool antigen (HPSA) screening with the routine biennial colorectal cancer (CRC) screening with fecal immunochemical test (FIT) in the general population of eligible adults (age 50–69 without symptoms suggestive of CRC) would result in better gastric cancer detection than FIT alone.[27] The rationale for this design included the feasibility of adding this test to an already established cancer screening program. The study enrolled patients from 2014–2018 and final follow-ups occurred in 2020. Approximately 240,000 patients were enrolled randomized. Of these, 63,508 patients were invited for HPSA + FIT while 88,995 were invited for FIT alone. Looking at this cohort, there was no significant difference in gastric cancer mortality. Rates were 15 per thousand in the HPSA + FIT group and 13 per thousand in the FIT alone group (mean difference, 2 per thousand (0.002%) [95% CI, −0.004% to 0.007%]; P = 0.57). A sub-analysis that examined those who were contactable and followed through with the screening, and also took into account length of follow-up and other patient characteristics, detected lower rates of gastric cancer in the HPSA + FIT group at 28 per thousand compared to 40 per thousand (0.79 [95% CI, 0.63-0.98], but there was still no difference in mortality (1.02 [95% CI, 0.73-1.40]).

In this large prospective randomized cohort study, the addition of HPSA screening to an established CRC screening program did not result in decreased mortality from gastric cancer. That said, there was evidence that those who went through with screening with HPSA + FIT had a lower incidence of gastric cancer compared to those who went through with the FIT alone screening.

TAVR plus PCI compared to combined surgical aortic valve replacement and coronary artery bypass grafting

The current standard of care for patients with concomitant severe aortic stenosis and obstructive coronary artery disease (CAD) is a surgical approach using combined aortic valve replacement and coronary bypass grafting (SAVR plus CABG). A recent study looked at a combined percutaneous approach using TAVR- and FFR-informed PCI, compared to the standard surgical approach in a large international, prospective, open label, randomized controlled trial.[28]

The study was conducted at 18 tertiary medical centers across Europe. Patients age 70 and older with severe aortic stenosis and complex CAD who could be treated via either approach were enrolled. The primary endpoint was a composite of all-cause mortality, myocardial infarction and disabling stroke, along with several other procedure-specific outcomes. 172 patients were enrolled, with 91 assigned to the FFR-guided PCI plus TAVR group and 81 assigned to the SAVR plus CABG group. FFR-guided PCI plus TAVR appeared superior to surgery. The primary endpoint was met in 4% of patients in the percutaneous group versus 23% of patients in the surgical group (risk difference −18·5 [90% CI −27·8 to −9·7]), which was below the 15% prespecified non-inferiority margin. Importantly, all-cause mortality was 0% in the FFR-guided PCI plus TAVR group compared to 10% in the SAVR plus CABG group, and life-threatening or disabling bleeding was 2% compared to 12%. The hospitalization duration was also shorter in the FFR-guided PCI plus TAVR group at 7 versus 10 days. The SAVR plus CABG group, on the other hand, had a higher rate of atrial fibrillation at 14% compared to 4% in the FFR-guided PCI plus TAVR group.

Given the consistent benefits of the percutaneous approach in patients with concomitant severe aortic stenosis and obstructive CAD, this may represent a new standard of care if these results can be reproduced in community settings.

Shared decision-making remains vital in prostate cancer screening and treatment decisions

Understanding of prostate cancer has advanced in recent years and we now know it is a multi-factorial and heterogeneous disease with predominantly 2 courses: low-risk indolent cancer and progressive cancer with metastatic potential. Screening recommendations for prostate cancer in average-risk individuals using blood-based prostate-specific antigen (PSA) screening varies among different groups, though all recommend robust shared decision-making. There is also strong evidence to recommend against screening this group of patients over age 69 or with a life expectancy less than 10 years.[29]

One of the reasons for highlighting the importance of shared decision-making is the lack of robust evidence that screening saves lives or even improves quality of life. In those who are ultimately diagnosed with low-risk prostate cancer (the most common type of prostate cancer), treatment with active surveillance (AS) is less harmful and more efficacious than other forms of treatment.[30] Active surveillance should be strongly considered even for those with favorable intermediate-risk disease (most Gleason Group 2).[31] Johns Hopkins researchers followed 1,800 men with very low-risk and low-risk prostate cancer with AS for 15 years and the cumulative rate of death/metastasis from prostate cancer was 0.1%.[32] However, from 2010 to 2020, a recent study showed that across the U.S., active surveillance use for GG2 cancers only increased from 4% to 12%.[31] Many times, patients will eventually die of other disease processes unrelated to prostate cancer. Two recent articles further highlight the risks of prostate cancer treatment with radiation therapy or prostatectomy instead of active surveillance.

Published findings from a cohort study with data from 3,946 patients with prostate cancer included 1,711 (43%) patients who underwent prostatectomy or radiation therapy.[33] This group had much higher rates of complications relating to their treatment over the subsequent 12 years, compared with those who did not have these invasive procedures. The incidence per 1,000 person-years of any one of the 10 treatment-related complications that were measured was 124.26 for prostatectomy, 62.15 for radiotherapy and 23.61 for untreated participants. Complications were typically life altering and included radiation proctitis, radiation cystitis, bladder cancer, sexual and urinary complications.

Even in areas where appropriate use of active surveillance for low-risk disease is increasing, inappropriate aggressive treatment is also on the rise. One study examined a cohort of 243,928 men in the Veterans Affairs health system and determined that aggressive treatment of prostate cancer in those with limited life expectancy has been increasing from 2000 to 2019.[34] About 20% of the cohort (50,045) had a life expectancy of less than 10 years, and about 5% (11,366) had life expectancy of less than 5 years. People with lower life expectancy have poorer outcomes and often don't live the 8 to 10 years to accrue any of the potential benefits from radiation therapy or prostatectomy for prostate cancer. In the study population, aggressive treatment for intermediate-risk disease increased in those with life expectancy less than 10 years from 37.6% to 59.8% (22.1%; 95% CI, 14.8%-29.4%) from 2000 to 2019. For those with life expectancy of less than 5 years, aggressive treatment for high-risk disease increased from 17.3% to 46.5% (29.3%; 95% CI, 21.9%-36.6%).

Given the high treatment-related complication rates and uncertain benefits of treatments other than active surveillance for low-risk and favorable intermediate risk (GG2) disease, life expectancy should be central to any discussion and shared decision-making around prostate cancer screening, and not just at the time of treatment decisions.[35] For those with intermediate and high-risk disease, the complications and uncertain long-term benefits of treatment should be robustly discussed.

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Kenneth Roy Cohen, MD, FACP

Dr. Kenneth Cohen is an experienced physician leader, practicing internist and researcher who has attained national recognition for health care quality improvement. He was one of the founding physicians of New West Physicians, which is the largest primary care group practice in Colorado and now part of Optum Care. He served as chief medical officer from 1995–2020. He now serves as the executive director of Translational Research for Optum Care and co-leads the Optum Center for Research and Innovation. Dr. Cohen has received awards of recognition and distinction for teaching, including the Lutheran Medical Center Physician of the Year award in 2011. Under his stewardship, New West Physicians was awarded the AMGA Acclaim award in 2015 and the CDC Million Hearts Hypertension Champion Award in 2017. He is a Clinical Associate Professor of Medicine and Pharmacy at the University of Colorado School of Medicine and School of Pharmacy. He is a Fellow of the American College of Physicians and a member of the Phi Beta Kappa and Alpha Omega Alpha honor societies.

Joshua Jacobs, MD, FAAFP

With over 20 years of clinical, academic and leadership experience regionally, nationally and internationally, Dr. Jacobs currently serves as primary care engagement lead national medical director for Optimal Care within Clinical Performance at Optum Care. He is a clinical professor of Family Medicine at the Washington State University College of Medicine. He graduated from Pomona College with honors and from the John A. Burns School of Medicine as a member of the Alpha Omega Alpha honor society.

Prakash Jayakumar, MD, PhD

Dr. Prakash Jayakumar is a surgeon leader dedicated to the value-based transformation of health care at the individual, organizational, and systems level. He serves as Senior Medical Director in Specialist Engagement and Precision Health at Optum, and Assistant Professor of Surgery at Dell Medical School, The University of Texas at Austin. Dr Jayakumar has worked extensively in developing integrated team-based models of specialty care that leverage digital health solutions at the point of care including those that leverage patient generated health data, wearable sensors, real time activity tracking, decision aids, and clinical decision support tools. He holds multiple visiting professorships at institutions in the US and the UK where he completed his medical degree with distinction (Kings College London), Scales Medal in orthopaedic sciences (University College London), orthopedic residency (London Deanery), PhD in Musculoskeletal Sciences (Balliol College, Oxford University), and Masters in Healthcare Design (Royal College of Art). He holds executive certifications in A.I in Health (M.I.T), Value-based Care (Harvard Business School), Health Care Innovation (INSEAD Business School), and a Harkness Fellowship in Health Care Policy and Practice Innovation (Commonwealth Fund).

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