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Optimal Care Forum for Evidence-Based Medicine

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Learning objectives	• Discuss approaches to weight loss in obese patients that include lifestyle/behavioral, procedural and pharmaceutical interventions • Describe how using MRI-guided targeted biopsy for prostate cancer detection can result in fewer unnecessary biopsies and reduced diagnosis of insignificant cancers compared to a systematic prostate biopsy approach • Compare atrial fibrillation ablation outcomes in heart failure with reduced ejection fraction (HFrEF) versus heart failure with preserved EF (HFpEF) • Identify when spine surgery for degenerative disc disease is indicated as an appropriate intervention • Examine the incidence of periprosthetic joint infection in patients undergoing total joint arthroplasty (TJA) and its association with preoperative and postoperative colonoscopy

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Obesity treatments summarized and compared

Obesity, defined in the United States as excess fat storage and BMI 30 or higher, is present in over 40% of the U.S. adult population.[1] This condition is commonly accompanied by one or more adiposity-based chronic diseases (ABCD). ABCDs, such as type 2 diabetes mellitus, osteoarthritis, sleep apnea, cardiovascular diseases, some cancers, metabolic dysfunction-associated steatotic liver disease (MASLD, also known as NAFLD), and others limit quality of life and longevity, and are associated with enormous health care dollar expenditures and burden of disease.[2] Each ABCD has a host of different treatment options, yet all treatment regimens share a common goal of weight loss to reduce the disease burden, disease progression and complications from disease.

Approaches to weight loss include lifestyle and behavioral, procedural and pharmaceutical interventions. Several aspects have been addressed in previous issues of this newsletter, and updates are provided below.[3,4,5,6,7] Clinically meaningful sustained weight reduction has been ascribed to as little as a 5% reduction.

Lifestyle and behavioral interventions

Lifestyle and behavioral interventions are numerous and may include efforts to improve physical activity, diet, sleep and stress management in both the short and long term. These types of interventions are often necessary, but not sufficient to impact obesity sustainably and substantially. The effectiveness of interventions to address obesity that included increasing physical activity and improving nutrition, and that lasted 6 months or less, has been examined in a recent systematic review and meta-analysis.[8] In this review, 14 randomized controlled trials with a combined total of 2,407 participants were identified who met inclusion criteria. Specific interventions varied, as did level and intensity of engagement (e.g., in-person and frequent, to remote and intermittent). Average baseline weight across individuals in all included studies ranged from 82 kg to 139 kg. The pooled mean difference in weight change was -2.59 kg (95% CI, -3.47 to -1.72). This is less than the ≥ 5% reduction in body weight that is the usual goal of weight loss in obese patients.

Procedural interventions

As recently outlined in the last issue of this newsletter, common bariatric surgery procedure types include the roux-en-Y gastric bypass and endoscopic sleeve gastroplasty (ESG).[9] These procedural interventions have reported efficacy of sustained weight reduction of 13%–26% over a 20-year period. Serious complications are relatively low when performed by experienced surgeons at established bariatric centers.[10]

Sustained benefits have been well described. A randomized controlled trial that compared bariatric surgery plus intensive medical therapy versus intensive medical therapy alone demonstrated significantly better outcomes in quality of life, lipid profile and glucose control over a 5-year period for the surgery group.[11] An observational study of 20,235 patients with severe obesity and type 2 diabetes mellitus showed bariatric surgery was associated with a significantly lower risk of macrovascular diseases at 5 years (2.1% in the surgical group versus 4.3% in the nonsurgical group; hazard ratio, 0.60 [95% CI, 0.42-0.86]), as well as a lower incidence of coronary artery disease (1.6% in the surgical group versus 2.8% in the nonsurgical group; hazard ratio, 0.64 [95% CI, 0.42-0.99]).[12]

More recently, a non-randomized controlled trial followed 2,867 women with obesity for a median follow-up of 23.9 years and found those who underwent bariatric surgery had a significantly lower risk of breast cancer (hazard ratio [HR], 0.68; 95% CI, 0.49–0.94; P = 0.019; adjusted HR, 0.72; 95% CI, 0.52-1.01; P = 0.06).[13] As this protective effect was most pronounced in women with the highest baseline insulin levels, the mechanism of benefit is thought to be related to the decrease in insulin resulting from decreased weight from the surgery. Adverse events of bariatric surgery typically include sequelae related to gastrointestinal malabsorption, refractory esophageal reflux in the ESG group, and reoperation for internal hernias in the roux-en-Y gastric bypass group. Despite the high efficacy and relatively low risks of these types of bariatric surgeries, by some estimates, less than 1% of eligible patients undergo these procedures.[14]

Pharmaceutical interventions

Glucagon-like peptide-1 receptor agonists (GLP-1RAs) have garnered much attention in the lay press for use in weight loss and have recently been FDA-approved for not only weight reduction, but also for reducing cardiovascular disease risk.[15] A systematic review and network meta-analysis recently published in the *Lancet* reviews the effectiveness of multiple drug classes for weight loss in obesity.[16] This review examined 132 trials enrolling 48,209 participants and compared effectiveness of drugs to lifestyle modification alone. Phentermine-topiramate was identified as the most effective for achieving ≥ 5% weight reduction (odds ratio [OR] 8·02, 95% CI 5·24 to 12·27; mean difference [MD] of percentage bodyweight change −7·98, 95% CI −9·27 to −6·69) followed by GLP-1RAs (OR 6·33, 95% CI 5·00 to 8·00; MD −5·79, 95% CI −6·34 to −5·25). Findings also revealed semaglutide (a GLP-1RA) had the largest effect (above the 5% threshold), and that phentermine-topiramate had among the highest risk of adverse events leading to medication discontinuation (typically paresthesias, constipation, and/or cognitive complaints). Phentermine-topiramate may be prescribed as its generic components.

The medication classes work in various ways and all result in decreased caloric intake or absorption. Importantly, as weight is reduced, so is energy expenditure.[17] When these medications are discontinued, the balance between weight regulatory hormones such as ghrelin and leptin result in caloric intake returning to "normal" (pre-medication levels) for that individual and, with a decreased energy need, the weight returns. In other words, weight regain is common and expected when any pharmaceutical intervention for obesity is discontinued. This means patients typically need to remain on these medications for life to maintain the weight-reduction benefits unless they significantly increase energy expenditure.[18]

Intervention comparisons

All forms of obesity treatment should include lifestyle or behavioral interventions as costs are reasonable and adverse events rare. Addition of bariatric surgery or pharmaceutical interventions should be done using shared decision-making. A recent cost-effectiveness analysis examined endoscopic sleeve gastroplasty (ESG) versus a GLP-1RA (semaglutide) and found that ESG was far more cost-effective than GLP1-RA therapy, concluding that "ESG is cost saving compared with semaglutide for class II obesity." This finding is due to the increased effectiveness and lower costs of ESG and the increased dropout rates over time with semaglutide. The annual price of semaglutide must decrease by more than threefold to achieve non-dominance with ESG."[19] Pricing analysis was based on information from the Institute for Clinical and Economic Review.[20]

Summary of evidence

Lifestyle and behavioral interventions combined with endoscopic sleeve gastroplasty performed by experienced surgeons at designated bariatric surgery centers appears to be the most cost-effective approach to sustained and clinically meaningful weight loss in obese patients. While GLP-1RAs appear to be effective for weight reduction and are well-tolerated compared with other effective drugs, they are cost-prohibitive when compared with alternative interventions and have a high rate of discontinuation with subsequent weight regain.

Prostate cancer detection using MRI-guided targeted biopsy results in fewer unnecessary biopsies and reduced diagnosis of insignificant cancers compared to a systematic prostate biopsy approach

Prostate-specific antigen (PSA) is a sensitive but not specific serum marker for clinically important prostate cancer. In the U.S., following detection of elevated PSA, a transrectal ultrasound guided systematic (TRUS) prostate biopsy of usually 12 areas in the prostate is the typical approach for suspected prostate cancer.[21] Avoiding unnecessary biopsies for low-risk prostate cancer is important not only to reduce the rate of diagnosis and subsequent ineffective treatment, but also because patients in active surveillance programs for low-risk prostate cancer may opt for more invasive treatment, partially to avoid repeated biopsies.[22]

A recent systematic review and meta-analysis of the use of prebiopsy MRI to help determine the need for, and location of, prostate biopsy highlights the benefits of this approach over the conventional systematic ('blind') TRUS biopsy approach.[23]

- The analysis included more than 80,000 patients from 12 different studies.
- Clinically significant prostate cancer detection rates were not significantly different between PSA screening plus MRI versus PSA screening without MRI (for PI-RADS 3-5, OR 1.02 (95%CI; 0.75-1.37), for PI-RADS 4-5, OR 0.85 (95% CI; 0.49-1.45)).
- Positive predictive value (PPV) for significant cancers, biopsy indication and biopsy adherence were all more favorable for the PSA plus MRI group compared to the PSA without MRI group, with higher PPV, lower biopsy rate and higher biopsy adherence.
- For the MRI group, the odds ratio (OR) for biopsy was 0.28 (95% CI, 0.22-0.36; p≤0.001) and OR for detecting insignificant cancers was 0.34 (95% CI, 0.23-0.49; p=0.002).

In short, prebiopsy MRI following elevated PSA helped identify clinically significant prostate cancer and screened out those clinically insignificant cancers that don't require a biopsy. This approach can result in fewer unnecessary biopsies compared with the traditional approach of PSA plus systematic prostate biopsies. It can also detect many fewer low-risk prostate cancers for which treatment is not recommended, yet are carried out in 40% of men. These recommendations should be incorporated into practice and are consistent with several urological guidelines.[24,25]

Prostate-specific antigen screening and 15-year prostate cancer mortality

The option of screening for prostate cancer using a shared decision-making approach has become the standard of care following the publication of the 15-year outcomes of the European Study of Screening for Prostate Cancer (ERSPC) trial.[26] At 16 years, the benefit of screening was small. The number of men needed for screening to prevent one prostate cancer death was 570. Eighteen men needed to receive definitive treatment to prevent one prostate cancer death. Added to this literature characterizing the magnitude of the screening benefit is the 15-year follow up of the U.K. CAP trial that evaluated the effect of a one-time prostate-specific antigen (PSA) screening invitation in 415,337 men, randomized 1:1 to screening versus no screening.[27] Approximately 34% of the invited men had a satisfactory PSA screen.

At 15 years, the cumulative risk of prostate cancer in the intervention group was 0.47 per 1,000 person years compared to 0.50 per 1,000 person years in the control group, equating to a HR of 0.92. Importantly, clinically insignificant Gleason score 6 cancers were diagnosed at a 37% higher rate at 2.2% of the screened group compared to 1.6% of the control group. The detection rate of intermediate and high-grade cancers was not different in the screened versus control groups. All cause mortality was also not different in the 2 groups (23.2% in the intervention group versus 23.3% in the control group respectively).

In this trial, the overall reduction in prostate cancer death rate was 9 per 1,000 person years, with no reduction in overall mortality. This magnitude of reduction in prostate cancer mortality was smaller than the a priori defined effect size considered important for clinical and public health benefit. This study adds to our understanding not only of the small benefit of PSA screening for reducing prostate cancer mortality, but also the very long-time horizon post treatment needed to see this small benefit. This last point is particularly relevant as the harms from PSA screening in men over the age of 69 will likely exceed the benefit of screening, and we continue to screen this population at a high rate.

Atrial fibrillation ablation outcomes in heart failure with reduced ejection fraction (HFrEF) versus heart failure with preserved EF (HFpEF)

Evidence from randomized clinical trials (RCTs) suggests that catheter ablation may be superior to conventional rate or rhythm control for improving clinical outcomes in patients with coexisting atrial fibrillation (AF) and heart failure (HF). However, these studies primarily included patients with HFrEF. It is unclear whether patients with HFrEF derive the same benefit from catheter ablation as patients with HFrEF. Understanding this is important as information collected during the second 25-year period of the Framingham Heart Study reveals that the lifetime risk of HFpEF is estimated at around 19.3%. This is almost twice the approximate 11.4% lifetime risk associated with HFrEF.[28] A recent systematic review and meta-analysis examined the literature to determine the outcomes of AF ablation in the subsets of patients with HFrEF and HFpEF.[29]

The 12 randomized controlled trials included 2,465 patients and the comparators were conventional rhythm and/or rate control.

- There were 1,552 participants with HFrEF and 913 participants with HFpEF.
- The primary outcome was HF events, defined as HF hospitalization, clinically significant worsening of HF, or unscheduled visits to a clinician for treatment intensification.
- Secondary outcomes included cardiovascular and all-cause mortality.

Catheter ablation compared with conventional therapies was associated with reduced risk of cardiovascular death in patients with HFrEF (37 of 526 patients [7.0%] versus 78 of 516 patients [15.1%]; RR, 0.49) but not in patients with HFpEF (15 of 468 patients [3.2%] versus 17 of 481 patients [3.5%]; RR, 0.91). Catheter ablation compared with conventional therapies was also associated with reduced risk of all-cause mortality in patients with HFrEF (84 of 687 patients [12.2%] versus 137 of 676 patients [20.3%]; RR, 0.63) but not in patients with HFpEF (34 of 468 patients [7.3%] versus 43 of 481 patients [8.9%]; RR, 0.95). Lastly, with respect to HF hospitalizations and symptoms, the same pattern was observed. Catheter ablation was associated with a decrease in risk of HF events compared with conventional therapies in patients with HFrEF (107 of 560 patients [19.1%] versus 178 of 548 patients [32.5%]; RR, 0.59), while no benefit was observed in patients with HFpEF (51 of 468 patients [10.9%] versus 55 of 481 patients [11.4%]; RR, 0.93).

The authors conclude that “the currently available randomized evidence suggests that catheter ablation for AF was associated with reduced risk of HF events in patients with HFrEF but with no or limited efficacy in patients with HFpEF.” This includes no improvements in cardiovascular and all-cause mortality in patients with HFpEF, although the numbers of patients with these outcomes were small in these trials. There are 2 trials currently enrolling patients with HFpEF and until these results are available, catheter ablation should not be considered a standard of care for patients with HFpEF, particularly since the procedure carries risks, has a 2-year failure rate requiring a second ablation in the range of 40–50%,[30] and carries a cost of approximately $25,000.

Evidence to avoid spinal fusion, this time in the cervical region

In patients with degenerative disc disease, conservative measures, including cognitive behavioral interventions for chronic pain, are first-line therapy and often sufficient. For those in whom it is indicated, such as those with persistent neurological involvement with dysfunction, surgery may also be appropriate. Approaches to spine surgery for degenerative disc disease vary depending on the spine segment. Fusing 2 or more spinal segments together is frequently used in both the cervical and lumbar regions. In the lumbar region, spinal decompression with fusion in most patients is no better than decompression alone for most patient-centered outcomes and has been summarized in previous issues of this newsletter.[31, 32] A recent systematic review of outcomes from anterior cervical discectomy and fusion (ACDF) compared with cervical disc arthroplasty (CDA) alone also favored the non-fusion group.[33]

The meta-analysis looked at 10-year outcomes after surgery and included studies reporting on 428 patients in the ACDF group and 498 in the CDA group. At 10 years after the index surgery, the CDA group did better on the Neck Disability Index where lower is better (mean difference= -2.0; CI: -3.842 to -0.161; P= 0.033) and the Visual Analog Scale where lower is better (mean difference= -0.25, CI: -0.359 to -0.134, P<0.001). However, this group did worse on the Japanese Orthopaedic Association back and neck questionnaire where lower is worse (mean difference = -0.38; 95% CI: -0.712 to -0.047; P =0.025). None of these differences reached the minimal clinically important difference (MCID). Most importantly, the CDA group had significantly fewer secondary surgeries (OR =0.395; 95% CI: 0.252–0.620; P< 0.001) and fewer adverse events (OR =0.560; 95% CI: 0.323–0.972; P =0.039).

Taken together, these results indicate patients who undergo CDA for degenerative disc disease have fewer secondary surgeries and adverse events compared to those who undergo ACDF. Other outcomes appear to be clinically equivalent.

Surgery, needle fasciotomy or collagenase injection for dupuytren contracture

Dupuytren contracture (DC) is present in up to 30% of some populations, increasing with advancing age. There are multiple treatment options and a recent trial compared treatment by surgery, needle fasciotomy or collagenase injection.[34] Although collagenase injection and needle fasciotomy are office-based procedures, collagenase injection is expensive and the data on comparative efficacy are sparse. This study randomized about 100 patients each into the 3 treatment arms at 6 hospitals in Finland. Although participants were not blinded to their treatment allocation, the outcome assessors were. The primary outcome was > 50% tendon release along with patients reaching an acceptable symptom state.

Success rates were similar between the groups at 3 months ranging from 71% to 73%. But at 2 years, the success rates were maintained with surgery (78%), whereas they declined with both needle fasciotomy (50%) and collagenase injection (65%). Compared with surgery, both percutaneous groups had a higher rate of retreatment. Although collagenase injection was slightly more effective than needle fasciotomy, the number of treatments needed to have one patient reach the primary outcome with collagenase injection compared to needle fasciotomy was 6. With a cost of $6,400 per injection, this would equate to a cost of $38,400 to achieve a more effective outcome in one patient using collagenase injection over needle fasciotomy.

Since these patients most often present to primary care for advice on management, these results should inform the discussion that we have with our patients on the relative efficacy of the 3 procedures.

Does colonoscopy increase the risk of joint infection in those with a prior total joint arthroplasty?

There are not good data to inform whether there is a risk of periprosthetic joint infection (PJI) when having a colonoscopy within one year following a total joint arthroplasty (TJA). Periprosthetic joint infection (PJI) after TJA procedures is a rare but devastating complication that is associated with increased morbidity and mortality. The American Academy of Orthopedic Surgeons does not have a clear consensus statement for timing of colonoscopy because there is an unclear risk of PJI from transient bacteremia in accordance with the American Society for Gastrointestinal Endoscopy 2015 practice guidelines.

With this as background, a retrospective cohort study was published using the Military Data Repository (MDR).[35] The primary outcome was the incidence of PJI within one year after TJA in a cohort of patients who had a colonoscopy within 6 months prior to a TJA (preoperative colonoscopy cohort) and the incidence of PJI within one year of colonoscopy in those who had a colonoscopy following a TJA (postoperative colonoscopy cohort). In each cohort, patients were propensity matched to a control group that did not have colonoscopy. There were 11,482 patients over age 45 who had a colonoscopy within the 6 months prior to their TJA, and 7,497 patients over age 45 had a colonoscopy following a prior TJA. The risk of PJI within one year postoperatively in those in the preoperative colonoscopy cohort was 2.8% (n = 325) in patients who did have a colonoscopy versus 2.4% (n = 5504) in patients who did not have a colonoscopy within 6 months before surgery (OR 1.1, not significant). In the postoperative colonoscopy cohort, the risk of PJI within one year of the post-TJA colonoscopy date was 1.8% in the colonoscopy versus 2.1% in the control cohort, also not significant.

In the large military beneficiary cohort, no independent association was found between colonoscopy and PJI risk through the one year follow-up in patients who underwent preoperative or postoperative colonoscopy. These data can inform our recommendations to our patients and orthopedic colleagues when patients are due for colonoscopy around the time of a total joint arthroplasty.

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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.

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