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Learning objectives	• Discuss migraine diagnosis and treatment in the age of gepants, ditans, and CGRP monoclonal antibodies. • Examine pharmacological evidence of pemafibrate for hypertriglyceridemia/diabetic dyslipidemia, viscosupplementation and stopping RAS inhibitors in advanced chronic kidney disease. • Apply medical management for PSA screening in men over 69, stopping cancer screening based on life expectancy, osteoarthritis of the ankle, and inguinal hernia repair.

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Migraine diagnosis and treatment in the era of gepants, ditans and CGRP monoclonal antibodies

Migraine impacts over 37 million people in the United States.[1] Women are three times more susceptible than men, with an estimated 30% of women affected by migraine over a lifetime. Migraine can lead to substantial disability, interfering with daily activities, school, work and social interactions. The 2019 Global Burden of Diseases, Injuries, and Risk Factors Study ranked headache disorders 14th among global causes of disability (based on disability-adjusted life-years).[2,3] When evaluating years lived with disability, headache disorders ranked third globally, just below low back pain and depressive disorders.[2]

The costs of migraine include the direct medical expenses related to diagnosis and treatment as well as the loss of productivity during migraine attacks. Over the past few years, the FDA has approved several newer migraine medications including CGRP monoclonal antibodies, gepants (CGRP receptor antagonists), and ditans (5-HT1f receptor antagonists). These medications are much more expensive than standard treatments, but are not generally more effective. This article will provide a brief overview of migraine diagnosis and treatment, with a particular focus on the costs, effectiveness, and clinical indications of these newer medications.

Diagnosis

As a primary headache disorder, migraine is a clinical diagnosis. The initial evaluation of the patient with headache should include diagnostic features, potential red flags and the degree of headache-related disability. The International Classification of Headache Disorders-3 diagnostic criteria[4] for migraine without and with aura are listed in Table 1.

Table 1. Summary of the ICHD-3 diagnostic criteria for migraine without and with aura

Migraine without aura	Migraine with aura
A. At least 5 headache attacks fulfilling criteria B–D B. Headaches lasting 4-72 hours C. Headache has ≥2 of the following: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by routine activity D. During headache ≥1 of the following • Nausea and/or vomiting • Photophobia and phonophobia E. Not better accounted for by other ICHD-3 diagnosis	A At least two migraine attacks fulfill criteria B and C B. One or more of the following fully reversible aura symptoms: • Visual • Sensory • Speech and/or language • Motor • Brainstem • Retinal C At least three of the following characteristics: • At least one aura symptom spreads gradually, ≥5 minutes • Two or more aura symptoms occur in succession • Each individual aura symptom lasts 5-60 minute • At least one aura symptom is unilateral • At least one aura symptom is positive • The aura is accompanied, or followed within 60 minutes, by headache

There are validated tools that can help determine migraine-related disability, including the MIDAS and HIT-6. Absent a validated questionnaire, basic elements of disability include migraine frequency, severity and the number of days where activities, school, work and/or social interactions are impaired. In the absence of any red flags, imaging and other laboratory testing are not indicated in the diagnostic evaluation.

Initial treatment

The goal of migraine treatment is to lower the frequency and severity of headaches, reducing related disability. The degree of disability should inform initial treatment. For example, the patient with occasional migraines that are brief in duration and rarely interfere with daily activities may benefit from lifestyle changes (described below) and a trial of over-the-counter analgesics taken at headache onset. In contrast, the patient with more severe migraines that halt activities and occur more frequently may need lifestyle changes, a migraine-specific abortive medicine to treat headaches acutely, as well as a daily medicine to help prevent headaches.

All patients with migraine should consider lifestyle changes as part of their treatment regimen. The American Migraine Foundation describes five key lifestyle changes that may improve migraine outcomes:[5]

- **Sleep:** Recommend and discuss good sleep hygiene. Migraines can interfere with sleep, while poor sleep may serve as a migraine trigger.
- **Exercise:** At least 30-50 minutes of moderate-intensity aerobic activity, several days per week, is recommended to reduce migraine frequency and severity.
- **Eating:** The role of dietary triggers (such as chocolate) for migraine is not clear, but maintaining a balanced, nutritious diet and good daily hydration are important for migraine care. Minimizing daily caffeine intake may also help.
- **Diary:** Keeping a headache diary is an important tool for monitoring headache trends, although research suggests that diary compliance can be challenging.
- **Stress:** Stress can trigger migraine attacks, and managing stress may help improve headache outcome.

Abortive treatment

The abortive treatments for migraine comprise all medication(s) taken acutely at headache onset. These range from simple analgesics to the various migraine-specific prescription drugs such as triptans, ergots, antiemetics, and the newer 5-HT_{1f} inhibitors and CRGP receptor antagonists. When choosing the appropriate abortive medication, consider the following approach:

- Use evidence-based treatments.
- Recommend that medication be used immediately at headache onset (not at aura onset, for those with aura).
- If nausea is present early in the migraine course, choose a non-oral formulation and consider adding an antiemetic.
- When migraines are severe, use a migraine-specific medication. Simple analgesics can be tried for milder migraines.
- When appropriate, advance the medication dose before switching to a new medication.
- Use scheduled dosing strategies where appropriate, such as menstrual-related migraine. Frovatriptan, due to its 26-hour half-life, is preferred for this indication.
- Consider cost. Generic options tend to be as effective as non-generics and much less expensive for the patient.
- Avoid opioids and barbiturates.
- Guard against medication overuse.

Medication-overuse headache is an important cause of chronic headache, that is thought to result from the cumulative rebound effect of abortive medication overuse. The diagnostic criteria include (1) ≥15 headache days per month in a patient with a pre-existing headache disorder, (2) regular overuse of an abortive medication, and (3) the headaches are not better accounted for by another diagnosis.[4] Limiting prescriptions can help to prevent the overuse of medication. For example, a triptan can be prescribed to allow for the treatment of two headache days per week on average, but no more. Patient education and avoidance of opioids and barbiturates can also be helpful.

Triptans are regarded as the standard of care for acute migraine treatment.[6] The triptan class (5-$HT_{1B/1D}$ receptor agonists) includes several medication options, each with various half-lives and routes of administration. Many triptans have low-cost generic versions. Triptans can be combined with simple analgesics to optimize their effects for some patients. The contraindications for triptan use include significant coronary artery disease, a history of stroke, peripheral vascular disease and refractory hypertension.

Lasmiditan (Reyvow®) is the first "ditan" approved by the FDA for the abortive treatment of migraine. In a phase-3 clinical trial, lasmiditan improved headache outcomes significantly better than placebo.[7] The 200 mg lasmiditan dose led to 32.2% of patients reporting headache freedom at two hours compared to 15.3% with placebo. With the 100 mg dose, 28.2% of patients reported headache freedom.[7] In the absence of head-to-head treatment trials, odds ratios have been used to compare the effectiveness of various migraine treatments. In a meta-analysis, the odds ratios for pain freedom and for pain relief at two hours for lasmiditan versus placebo was lower than the odds ratios for most triptans.[8] Consequently, the current indication for lasmiditan remains as a second-line treatment for patients who do not benefit from several trials of triptans or who have absolute cardiovascular contraindications. According to GoodRx®, the retail price for lasmiditan is over $700 for a month's supply (8 tablets), while generic sumatriptan costs about $12 for a similar supply.

In 2019, the FDA approved the first gepant, ubrogepant (Ubrelvy™), for the acute treatment of migraine in adults. An open-label study of 50 mg and 100 mg (up to two doses per headache attack) demonstrated good safety and tolerability,[9] and several clinical trials have shown efficacy. In a 1:1:1 (50 mg: 100 mg: placebo) randomized trial (n=16,720), 27.8% of participants reported freedom from the most bothersome migraine symptom at 2 hours in the placebo group, 38.6% in the 50-mg group, and 37.7% in the 100-mg group.[10] Comparing odds ratios, ubrogepant was not more effective than commonly used triptans.[8] The gepant drug class does not constrict blood vessels, so these medications can be used when triptans are contraindicated due to cardiovascular disease. The average retail price for Ubrelvy is $1,764 per month according to GoodRx.

A second gepant, rimegepant (Nurtec®) followed ubrogepant with FDA approval for the acute treatment of migraine in 2020. Similar to ubrogepant, rimegepant can be used in patients with cardiovascular disease. In a comparison of the odds ratios, rimegepant versus placebo was not more effective than the commonly used triptans.[8] The average retail price for Nurtec ODT (oral dissolvable tablet) is $1,057 per month according to GoodRx.

Among patients who require a migraine-specific abortive medication, triptans remain first-line. Lasmiditan, rimegepant and ubrogepant cost much more than triptans but are not clearly more effective. The American Headache Society discourages the use of ditans and gepants as abortives unless (1) the patient has a contraindication or cannot tolerate triptans or (2) has had an inadequate clinical response to at least two triptan trials.[6] If a patient has not had an adequate response to two triptans, referral to a headache specialist may be reasonable.

Preventative treatment

Preventative medications are prescribed for daily use and are intended to decrease migraine frequency and severity. The American Headache Society provides examples where a patient with migraine may benefit from preventative medication(s):[6]

- Migraines interfere with the daily routine despite abortive treatment(s).
- Attacks are frequent (≥6 per month) or disabling (but less frequent, ≥2 per month)
- Abortive treatments are not tolerated or are contraindicated.
- The patient prefers a preventative medication.

Although implied by the 2nd and 3rd bullets, but not explicitly stated, patients with medication-overuse headache may benefit from a preventative medication during withdrawal of the overused abortive medication(s).

Once the decision is made to start a preventative medication, the pros and cons of the various options can be weighed. A given drug may be more suitable based on a patient's comorbidities. For example, topiramate has an appetite suppression effect, so patients with migraine who are also overweight may benefit two-fold from a topiramate trial. Although certain antidepressant medications can be effective migraine preventative therapies, the preventative dose of amitriptyline, for example, is typically lower than the antidepressant dose. These lower doses may not be adequate to treat depression. The sedation effect of amitriptyline, however, may be helpful for patients with migraine and insomnia.

Regardless of which preventative medication is selected, a few basic principles should be followed:

1. Start at a low dose and advance slowly to help avoid intolerable side effects.
2. Aim to reach a therapeutic dose. The ideal dose of any medication is one that effectively treats headaches without causing intolerable side effects.
3. Give an adequate treatment trial, allowing for at least 8 weeks at the target therapeutic dose before switching medications.
4. Establish realistic expectations. Preventative medications rarely eliminate migraines. The goal is to decrease frequency and severity, improving migraine-related disability.
5. Continue abortive treatments during preventative medication trials.

There are several migraine preventative medications with established efficacy (≥2 Class I trials) or probable efficacy (One Class I or ≥2 Class II trials) as well as long-standing use. Table 3 lists examples of these drugs, potential side effects, and dosing strategiesprobable efficacy (One Class I or ≥2 Class II trials) as well as long-standing use. Table 3 lists examples of these drugs, potential side effects, and dosing strategies.

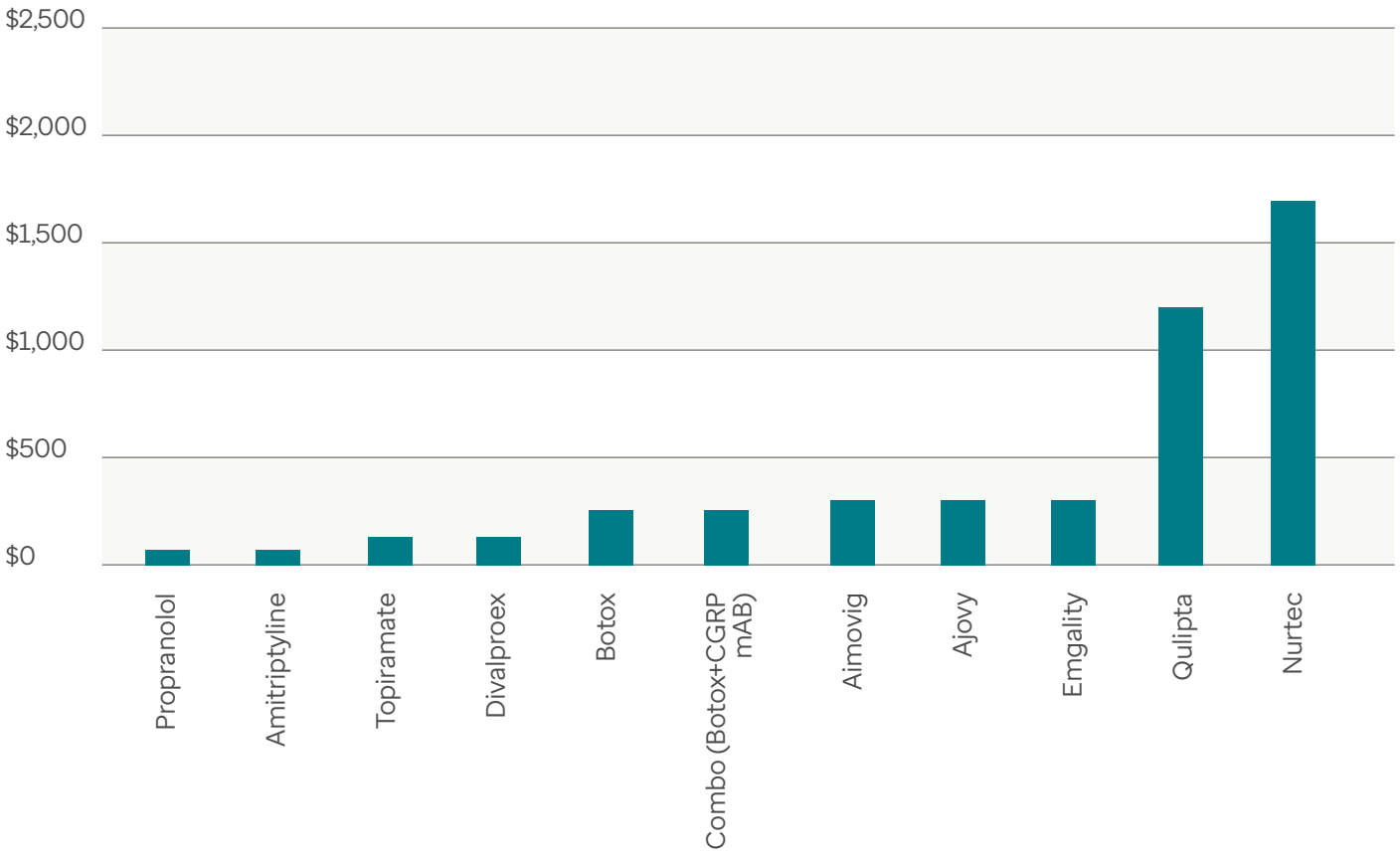
Table 3: Commonly used migraine preventive medications

Medications	Common side effects	Starting dose	Reasonable target dose*
Topirimate	Weight loss, tingling sensations, diarrhea, and dizziness are often self-resolving; lower doses used for migraine rarely cause cognitive complaints	25 mg once daily	100 mg in divided doses
Divalproex sodium/ valpoate sodium	Avoid with pregnancy and use with caution in women of child-bearing age; can cause weight gain, hair loss, sleepiness; understand common and rare side effects before prescribing.	Immediate release (IR): 250 mg orally twice daily Extended release (ER): 500 mg orally once daily	IR/ER: 1,000 mg/day
Beta-blocker	Weight gain, sexual dysfunction, fatigue, upset stomach, coldness/ tingling of hands and feet	Metoprolol tartrate: 25 mg BID Propranolol: 20 mg BID Timolol: 20 mg daily Atenolol: 50 mg daily Nadolol: 40 mg daily	50 to 100 mg 120-240 mg in 2-3 divided doses 20-30 mg 1-2 times daily 100 mg daily 80-240 mg daily
Tricyclic antidepressant	Sedation, nausea/vomiting, dry mouth, constipation, weight gain	Amitriptyline: 10 mg at bedtime Nortriptyline: 10 mg at bedtime	30-75 mg/day
Serotonin-norepinephrine reuptake inhibitor	Difficulty sleeping, dizziness, constipation or diarrhea, nausea/ vomiting, dry mouth, sweating, nervousness. Prolonged withdrawal syndrome	Venlafaxine: 37.5 mg in the morning Duloxetine: 30 mg per day	75-150 mg 1-2 times daily 30-60 mg daily
Magnesium	Diarrhea, nausea, abdominal bloating; can interact with other medications	400 mg daily	400-600 mg daily
Riboflavin	Can cause discoloration of urine; other side effects are rare.	400 mg daily	400 mg daily

* Advance medications slowly. The true target dose is that which effectively treats headaches without intolerable side effects. An example for medication advance: topiramate should be started at 25 mg once daily x 1 week and increased by 25 mg weekly (BID dosing) until target dose achieved.

Newer medications have been FDA-approved for the prevention of migraine, including a group of monoclonal antibody medications and gepants. However, similar to the abortive medications described above, the newer preventatives are much more expensive than the drugs listed in Table 3, but do not appear to be more effective. Using published clinical trial data, the figure below highlights the cost versus efficacy of a group of drugs by plotting the costs to avoid one migraine day per month.

Cost to avoid 1 migraine day monthly



Notably, medications such as propranolol, amitriptyline and topiramate have very favorable cost data based on efficacy, while the newer drugs (right-hand side of the x-axis) are much more expensive, yet not more effective. For these reasons, the newer gepant and monoclonal antibody treatments are considered 3rd-line options for migraine preventatives. Onabotulinumtoxin A (Botox®) is considered 2nd-line as it is well-tolerated and effective, but more expensive than the oral 1st-line drugs.

Summary

The newer migraine medications will help some patients with migraine who cannot take 1st-line treatments because of a lack of effect, intolerable side effects or absolute contraindications. Absent these factors, 1st-line treatments should always be trialed first. The newer agents are much more expensive, without providing added efficacy. Since many factors can affect a patient's response to migraine treatment, when at least two 1st-line medication trials fail, some patients will have greater benefit from referral to a headache specialist than from a trial with a gepant, ditan or monoclonal CGRP antibody.

Pemafibrate for hypertriglyceridemia/diabetic dyslipidemia

This was a in a long-term CV outcomes study managed by Paul Ridker of the Harvard Vascular Biology Lab. [11] It was a study of a new fibrate, pemafibrate. Elevated triglycerides (TG) and low HDL are associated with adverse cardiovascular (CV) outcomes in patients with Type 2 diabetes and others with the metabolic syndrome. However therapeutic options for this condition have not shown improved CV outcomes. These include multiple studies of niacin and other fibrates including gemfibrozil and fenofibrate, the latter of which continues in widespread use. [12,13,14] A recent study of EPA fish oil showed a 4.8% reduction in CV risk over 5 years, but it was later shown that the control product, mineral oil, increased LDL and LDL oxidation and therefore casts these results in doubt. [15]

The current trial was a double blind randomized controlled trial (DBRCT) looking at 10,497 patients with Type 2 diabetes, triglyceride levels between 200 and 499 mg/dL, and HDL cholesterol levels of 40 mg/dL or less. The primary endpoint was a composite of nonfatal myocardial infarction, ischemic stroke, coronary revascularization or death from cardiovascular causes (major adverse cardiovascular events (MACE)). The median baseline fasting triglyceride level was 271 mg/dL, HDL cholesterol level 33 mg/dL, and LDL cholesterol level 78 mg/dL. At four months into the trial, there were approximate 25% reductions in TG and VLDL levels, an 8% increase in HDL levels, but also a 14% increase in LDL levels. At the trial completion, a primary endpoint event occurred in 572 patients in the pemafibrate group and in 560 of those in the placebo group (hazard ratio, 1.03; 95% confidence interval, 0.91 to 1.15), with no apparent improvement in any prespecified subgroup. There was an observed decrease in GFR in the pemafibrate group, as is also seen with fenofibrate. 12% more patients in the pemafibrate group compared to the control group had a decrease in GFR, which returned to baseline after drug discontinuation.

We now have one more large, well conducted DBRCT showing that fibrate therapy, while significantly reducing TG levels and to a lesser extent increasing HDL levels, was not associated with any improvement in long term CV outcomes. Looking at a representative sample of 30% of the Optum Health pharmacy claims, we have estimated that over 45,000 patients are taking fenofibrate, at a cost of $4.3 million. It is likely that a small portion of these patients have baseline TG levels over 500 and are using fenofibrate for the prevention of pancreatitis. The use of fenofibrate for the purpose of improving CV outcomes should be questioned.

Viscosupplementation meta-analysis

In the September 2022 issue of the Forum, we reviewed a paper showing that the use of hyaluronic acid viscosupplementation (Visco) has not decreased despite the American Academy of Orthopedic Surgeons recommending against its use. [16] With this background, a recent meta-analysis of Visco use was published in the British Medical Journal. [17] The analysis focused on large, placebo based randomized controlled trials with at least 100 participants. 169 trials provided data on over 21,000 patients. Overall, there was an insignificant reduction in pain scores of approximately 2% (0.2 on a ten-point VAS score). The accepted minimally important difference on a VAS score is 1.3, or greater than six times the observed magnitude of effect in this meta-analysis. Similar non-clinically meaningful benefits were seen for functional outcomes. In the studies published since 2009, the authors stated, “strong evidence has shown that the pain reduction associated with viscosupplementation is clinically equivalent to the pain reduction associated with placebo when the equivalence margin is 0.2 SMD units (or a margin of 5 mm on a 100 mm visual analogue scale)”. The risk of serious adverse events (SAE) was 49% higher in the Visco group with an overall incidence of 3.7%.

Importantly, the analysis included studies where the placebo group had no intervention (as opposed to placebo injection). Prior studies of DJD trials showed a very large placebo effect size when the intervention group received injection therapy and the placebo group received no intervention. [18] Also, the authors discovered at least 15 industry-funded trials enrolling over 5,000 patients that were never published. They raised the ethical issue of continuing to enroll Visco trials when the serious adverse event rate is appreciable and overwhelming evidence points to a lack of clinical benefit. The major limitation of the study is that the findings represent summary estimates and do not exclude the possibility that selected osteoarthritis patient populations could benefit from Visco.

The authors conclude that “Strong conclusive evidence indicates that, among patients with knee osteoarthritis, viscosupplementation is associated with a clinically irrelevant reduction in pain intensity and with an increased risk of serious adverse events compared with placebo. Our findings do not support the broad use of viscosupplementation for the treatment of knee osteoarthritis.”

Stopping RAS inhibitors in advanced chronic kidney disease does not help eGFR

One goal of management of chronic kidney disease (CKD) is to halt or slow progression to later stages and to avoid end-stage renal disease (ESRD). The use of renin-angiotensin system inhibitors (RAS-I), which includes angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), has been shown to slow the progression of mild or moderate CKD. Despite the beneficial effect of these drugs in early CKD, some studies suggested that discontinuing these medications in more advanced CKD may be indicated, and may slow decline in eGFR. [19] With a recent study published in the New England Journal of Medicine, we now have high-level evidence that this is not the case. [20] In this multi-center study in the United Kingdom, 411 patients with advanced CKD (at least stage 4, not on dialysis) were randomized to continue or discontinue RAS-I drugs and followed prospectively. Outcomes included eGRF, progression to ESRD, initiation of dialysis, hospitalization, blood pressure, exercise capacity, quality of life, cardiovascular events and death. At three years, there were no differences in measured outcomes between the groups or any subgroups. RAS inhibition is a mainstay of prevention and treatment of early CKD. Continuation of this category of medications in later stages of the disease should be decided using a shared decision-making approach, as there is now evidence that discontinuation does not increase the likelihood of the negative outcomes studied.

Cost of low value PSA screening in men over age 69

The American Urological Society, the American College of Physicians, and the USPSTF all recommend the discontinuation of PSA screening at age 69. No published studies have shown benefit in PSA screening of men over age 69. PSA screening for men aged 70 years and older could lead to greater harms from false-positive results for cancers, invasive diagnostic biopsy, and treatment related to overdiagnosis and overtreatment of indolent tumors, including costly procedures, such as biopsy, imaging, prostatectomy and radiation therapy. A recent study in JAMA used the Optum Labs Data Warehouse to look at men over age 69 in a national sample of Medicare Advantage plans who received PSA screening from 2016-2018.[21] These data included, but were not limited to, Optum Health practices.

Strikingly, 39% of the men over age 69 received a PSA and the percentage increased from 2016 to 2018, reaching 42% in 2018. In 2018, fully 68% of men who had a PSA had a subsequent diagnostic cascade. Overall, the most common follow-up service was additional PSA testing (50%), followed by prostate biopsy (5.5%), imaging (4.5%), prostatectomy (2.4%), and prostate radiation (0.2%). The cost of the diagnostic cascade was over tenfold higher than the costs of the initial screening, and 7% of the patients incurred high-cost invasive procedures with potential harm. The conservative estimate on total spend in this population related to non-recommended PSA screening was $275 million.

The authors closed the paper by stating "Because guideline recommendations alone might not lead to long-term sustained effects of reducing low-value PSA cancer screening, innovative and perhaps harsher efforts to reduce both initial unneeded care and avoidable cascading effects—such as the implementation of Section 4105 of the Patient Protection and Affordable Care Act, which provides the Secretary of Health and Human Services the authority to provide no payment for USPSTF grade D services—may be warranted to decrease harm, enhance equity, and improve efficiency of medical spending"

We took this occasion to look at our internal data since PSA screening over age 69 is an Optimal Care low value care measure that is tracked monthly. In 2018 we screened 36% of our population over age 69, compared to 42% in this study. Since 2018, we have reduced this rate to 30%, however it has not further declined in the past two years.

Physician attitudes and reasons for hesitancy on stopping cancer screening based on life expectancy

An important area of cognitive dissonance among physicians and APC's is a significant overestimation of the benefit of medical interventions and an underestimation of the harms. This is particularly true when it comes to cancer screening. A recent survey of almost 1,900 U.S. primary care physicians (791 eligible respondents) showed various reasons why physicians may not be following national guidelines to stop routine cancer screenings when life expectancy is less than ten years.[22] The survey revealed even among physicians who agree that life expectancy should be used to guide stopping cancer screening, almost half worry that stopping cancer screening may be perceived as bias against those of low socioeconomic status against minority groups. About a third of respondents expressed doubt over the accuracy of life-expectancy prediction tools. The majority (64.4%) of respondents agreed patient care is better when over-screening is reduced.[23] A clinical decision-support algorithm based on these guidelines is available to help decrease low-value care, over-diagnosis and potentially harmful cascades of care.[24]

Osteoarthritis of the ankle – Ankle fusion versus arthroplasty

Total ankle arthroplasty (TAA) is increasingly being offered without literature supporting a clear advantage over the standard of care, ankle fusion (AF). TAA is over three times the cost of fusion and randomized trials (RCTs) comparing the two are lacking. The first ever large RCT comparing TAA with ankle fusion was recently published in the Ann of Internal Medicine.[25] This was a pragmatic, randomized, open label trial in 303 patients with end stage DJD of the ankle, conducted in the UK. Patients were randomized 1:1 and followed for one year post surgery. The primary outcome was performance on the Manchester– Oxford Foot Questionnaire walking/standing survey. There were multiple secondary outcomes focused on pain and function. 21 patients withdrew prior to surgery and only four patients crossed over from fusion to TAA.

The TAA group improved on average by 49.9 points compared with 44.4 points in the AF group, with a mean MOXFQ-W/S domain score at 52 weeks of 31.4 (SD, 30.4) in the TAR group and 36.8 (SD, 30.6) in the AF group. This difference was not clinically or statistically significant. Importantly for a surgical trial, findings were similar on the per protocol and intention to treat analyses. Secondary outcomes largely mirrored the primary outcome with the expected exception that joint range of motion increased in the TAA group and decreased in the fusion group. Overall, adverse events were of similar frequency in the two groups, however 12 more patients had wound healing issues including infection in the TAA group and 10 patients had symptomatic nonunion in the fusion group. Thromboembolic complications were slightly more frequent in the fusion group.

Prior non-randomized trials have shown results similar to the above trial.[26,27] There has been a gradual change in practice of TAA from mobile-bearing implants to fixed-bearing implants and approximately half of the TAA patients in this study had each of the implant types. Further study will be needed on long term outcomes of the newer fixed-bearing implants, as in this study, the outcomes were slightly better with the newer implant type. In summary, both procedures broadly offered similar one-year outcomes and complication rates, however TAA is about 2.5 times more expensive than ankle fusion, therefore ankle fusion may be more cost effective.

Inguinal hernia repair operating time reduced with open approach under local anesthesia

Inguinal hernia repair is one of the most common general surgery procedures in the U.S. and can be achieved with robotic assistance, laparoscopically, or the traditional open approach. The open approach can be done under local anesthesia, whereas the others are done under general anesthesia. Previous studies described in this Forum suggest recommending laparoscopic inguinal hernia repair over the robotic-assisted approach as the laparoscopic approach takes less time, but with no increase in complication rates.[28,29] Laparoscopic repair is also done in the ASC whereas, due to the complexity of the robotic equipment, robotic repair is only done in the hospital outpatient setting and has markedly higher costs due to the robotic charge and the higher facility fees. A recent study adds to our understanding of the impact on operating time and on complications within 30 days of the various approaches. This retrospective cohort study examined over 100,000 patients, almost all men, with an average age of 63 and compared outcomes among patients undergoing initial unilateral inguinal hernia repair using an open approach under general or local anesthesia versus a laparoscopic approach.[30] Results showed the duration of surgery using the open approach with local anesthesia was significantly shorter (by over 10 minutes) than the laparoscopic approach. There was no significant time difference between the open approach with general anesthesia and the laparoscopic approach. There were no significant differences in complications among the three procedure types. The accompanying invited commentary suggests these findings support use of the open approach with local anesthesia in select patients, with less exposure to anesthesia and its concomitant potential complications.[31] Individual patient and surgeon factors should further guide the decision of the type of approach used, although at this time there are no data favoring a robotic approach.

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