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Learning objectives	• Discuss primary osteoporosis and low bone mass pharmacologic treatment recommendations. • Examine pharmacological evidence for recurrent renal stones not impacted by HCTZ therapy, and the use of Glucagon in insulin dependent DM 2011 to 2021. • Apply medical management regarding prostate cancer of active surveillance vs. surgery or radiation with a 15-year follow up of the ProtecT Trial, address hearing impairment and cognitive decline and frailty in the elderly using physical activity.

Accreditation statement

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Commercial support
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Primary osteoporosis and low bone mass pharmacologic treatment recommendations update

Primary osteoporosis in adults, particularly in post-menopausal women, has a high prevalence, estimated at over 10 million in the U.S. alone. Low bone mass (osteopenia), associated with high risk of progression to osteoporosis, may be present in over 40% of older adults in the U.S.[1] These conditions greatly increase the risk of fracture with resultant associated morbidity and mortality. Several interventions have demonstrated effectiveness to reduce the risk of fracture in these groups and include both pharmacologic and nonpharmacologic treatment. The American College of Physicians recently published an update to its clinical practice guideline for pharmacologic treatment to prevent fracture in patients with these conditions, and are summarized in **Figures 1-3**.[2] The recommendations are based primarily on a network meta-analysis and systematic review published in the same issue of the Annals of Internal Medicine.[3]

Bisphosphonates remain the first-line therapy to prevent fracture for all patients with primary osteoporosis with average risk of fracture, with high-certainty of evidence in females. One of the primary reasons for discontinuation of bisphosphonates is gastrointestinal side effects caused by oral agents. This is avoided with the use of the intravenous preparation of yearly zoledronic acid. A less-strong recommendation, based on moderate-certainty evidence, is to use the RANK ligand inhibitor denosumab as second-line pharmacotherapy in females who cannot use bisphosphonates . In males, the certainty of evidence of benefit of denosumab as second line is even lower. For patients with low bone mass, the recommendation is to take an individualized approach whether to start pharmacologic treatment with bisphosphonates. Since the evidence of effectiveness is of low certainty for this situation, shared decision-making should be central to the conversation. Clinician treatment thresholds may not be the same as patient thresholds, so use of a tool like the Fracture Risk Assessment Tool (FRAX®[4]), plus conversations around the 10-year risk of a major osteoporotic fracture should be encouraged.[5] The guideline included reporting evidence of patient preferences. These preferences include consideration of the medication profile of benefits and harms, costs, administration frequencies and routes. Other agents and classes to treat primary osteoporosis or low bone mass to prevent fracture in those with average risk of fracture were evaluated, but did not have evidence of effectiveness, long term safety or both, to be recommended for routine use over bisphosphonates or denosumab.

The guideline also provides a recommendation for patients with primary osteoporosis and very high risk of fracture. These are patients who are older (>74 years), have had a fracture within the previous year, a history of multiple fractures or failure of other therapies. For this smaller subset of patients, a conditional recommendation based on moderate and low certainty of evidence is to use a sclerostin inhibitor or recombinant PTH, followed by a bisphosphonate.

Compared with placebo, bisphosphonate use is estimated to reduce risk of any clinical fracture by 24 fewer events per 1,000 patients after three or more years of treatment for a number needed to treat (NNT) of 42. This number drops to an NNT of 18 to prevent one radiographic vertebral fracture. In the high-certainty of evidence randomized controlled trials examined, there was no increase in serious adverse events or withdrawals due to adverse events from use of bisphosphonates. There were observational cohort studies that suggest there may be a higher risk of osteonecrosis of the jaw (ONJ) or atypical femoral fractures (AFF). Based on the included observational studies, the risk of ONJ was estimated at between 1 to 3 in 10,000 bisphosphonate users. Risk of AFF was estimated between 11 to 60 per 10,000 patient years. Since these estimates are based on observational data, the evidence is considered of low certainty. Another study demonstrated that treatment with bisphosphonates for three years prevented up to 149 hip fractures from osteoporosis and was associated with as few as 2 AFF.[6] This suggests that over 70 osteoporotic hip fractures are prevented for every AFF induced with bisphosphonate treatment. To reduce risk of ONJ or AFF further, discontinuing bisphosphonate therapy should be considered as early as feasible once risk of fracture has been reduced. After three years of use, risk of fracture remains lowered even after discontinuation of bisphosphonates.[7] Guidelines suggest a drug holiday after five years of bisphosphonate therapy. For example, the American Assoc. of Clinical Endocrinologist 2020 guideline states “For oral bisphosphonates, consider a bisphosphonate holiday after five years of treatment if fracture risk is no longer high (such as when the T score is greater than -2.5, or the patient has remained fracture free), but continue treatment up to an additional five years if fracture risk remains high (Grade B; BEL 2).[8] Denosumab had similar benefits to bisphosphonates, but with larger NNTs and much higher costs. Average spending per Medicare beneficiary for a bisphosphonate (generic zoledronic acid in this example) is about $50 for the drug plus the infusion cost, whereas the average spending for denosumab for one year can be ~$3,200 (goodrx.com).

When determining which pharmacological agents to use in treating patients with primary osteoporosis or low bone mass, an individualized approach is recommended, with use of shared decision-making when indicated.

Figure 1. Treatments to reduce fractures in postmenopausal females with primary osteoporosis.

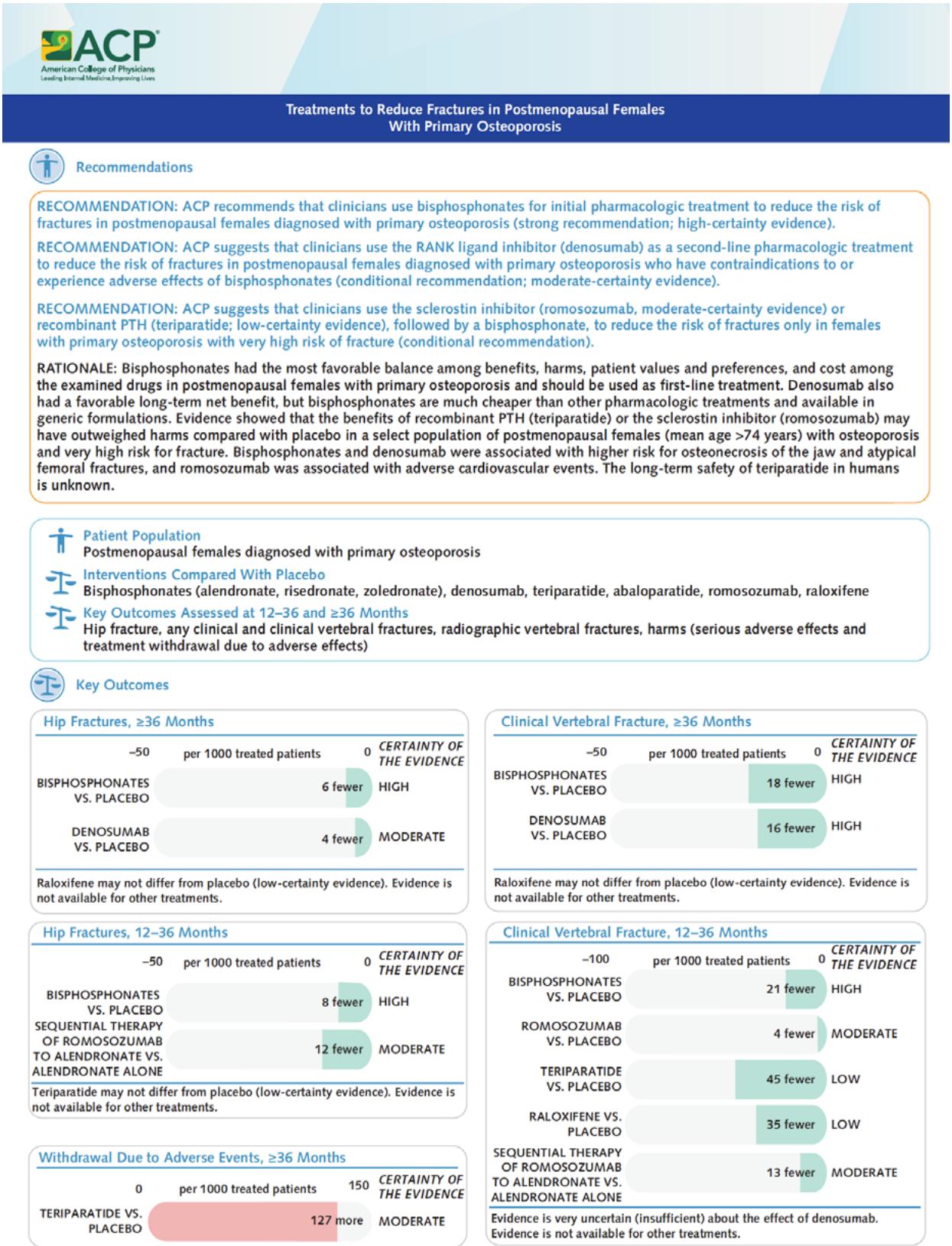

Figure 1. continued. Treatments to reduce fractures in postmenopausal females with primary osteoporosis.

Serious Adverse Events, ≥36 Months

	CERTAINTY OF THE EVIDENCE
Bisphosphonates and denosumab resulted in no differences in serious adverse events and withdrawals due to adverse events in RCTs.	HIGH
Bisphosphonates and denosumab were associated with higher risk for osteonecrosis of the jaw and atypical femoral or subtrochanteric fractures in observational studies, with higher risk after longer treatment duration.	LOW
Romosozumab followed by alendronate probably did not increase risk for serious harms or withdrawal due to adverse effects compared with bisphosphonate alone at 12- to 36-month outcome assessment in an RCT.	MODERATE
Romosozumab was associated with higher risk for adverse cardiovascular events and raloxifene was associated with thromboembolism in observational studies.	LOW
Long-term safety of teriparatide in humans is unknown.	INSUFFICIENT

Clinical Considerations

- Clinicians should prescribe generic medications if possible rather than more expensive brand-name medications.
- Clinicians treating postmenopausal females with osteoporosis should encourage adherence to recommended drug treatments and healthy lifestyle modifications, including exercise, and counseling for evaluation and prevention of falls.
- Adequate calcium and vitamin D intake should be part of fracture prevention in all postmenopausal females with low bone mass or osteoporosis.
- Clinicians should assess baseline risk for fracture based on individualized assessment of bone density, history of fractures, response to prior treatments for osteoporosis, and multiple risk factors for fractures in postmenopausal females with primary osteoporosis.
- Current evidence suggests that increasing the duration of bisphosphonate therapy to longer than 5 years probably reduced risk for new vertebral fractures but not risk for other fractures at the expense of increased risk for long-term harms. Therefore, clinicians should consider stopping bisphosphonate treatment after 5 years unless the patient has a strong indication for treatment continuation.
- The decision of a temporary treatment discontinuation (holidays) should be individualized and based on baseline risk for fractures, type of medication and its half-life in bone, duration of discontinuation, benefits and harms of discontinuation, and higher risk for fracture due to drug discontinuation.
- Females initially treated with an anabolic agent should be offered an antiresorptive agent after discontinuation to preserve gains and because of serious risk for rebound and multiple vertebral fractures.
- Older postmenopausal females with primary osteoporosis who are at increased risk for falls and other adverse events due to polypharmacy or drug interactions need individualized treatment selection based on comorbidities and concomitant medications associated with higher risk for falls/fractures.tt

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Figure 2. Treatments to reduce fractures in males with primary osteoporosis.

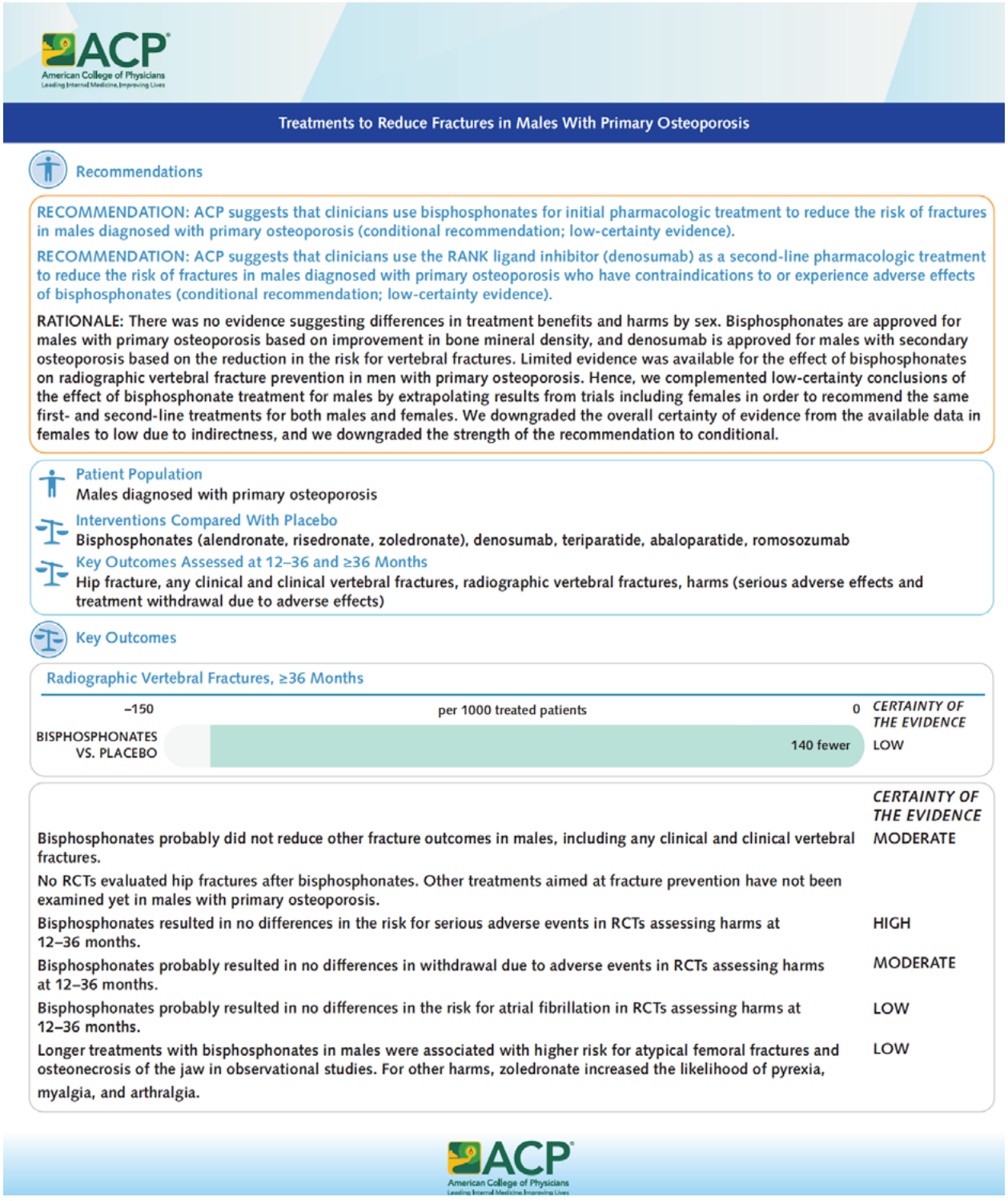
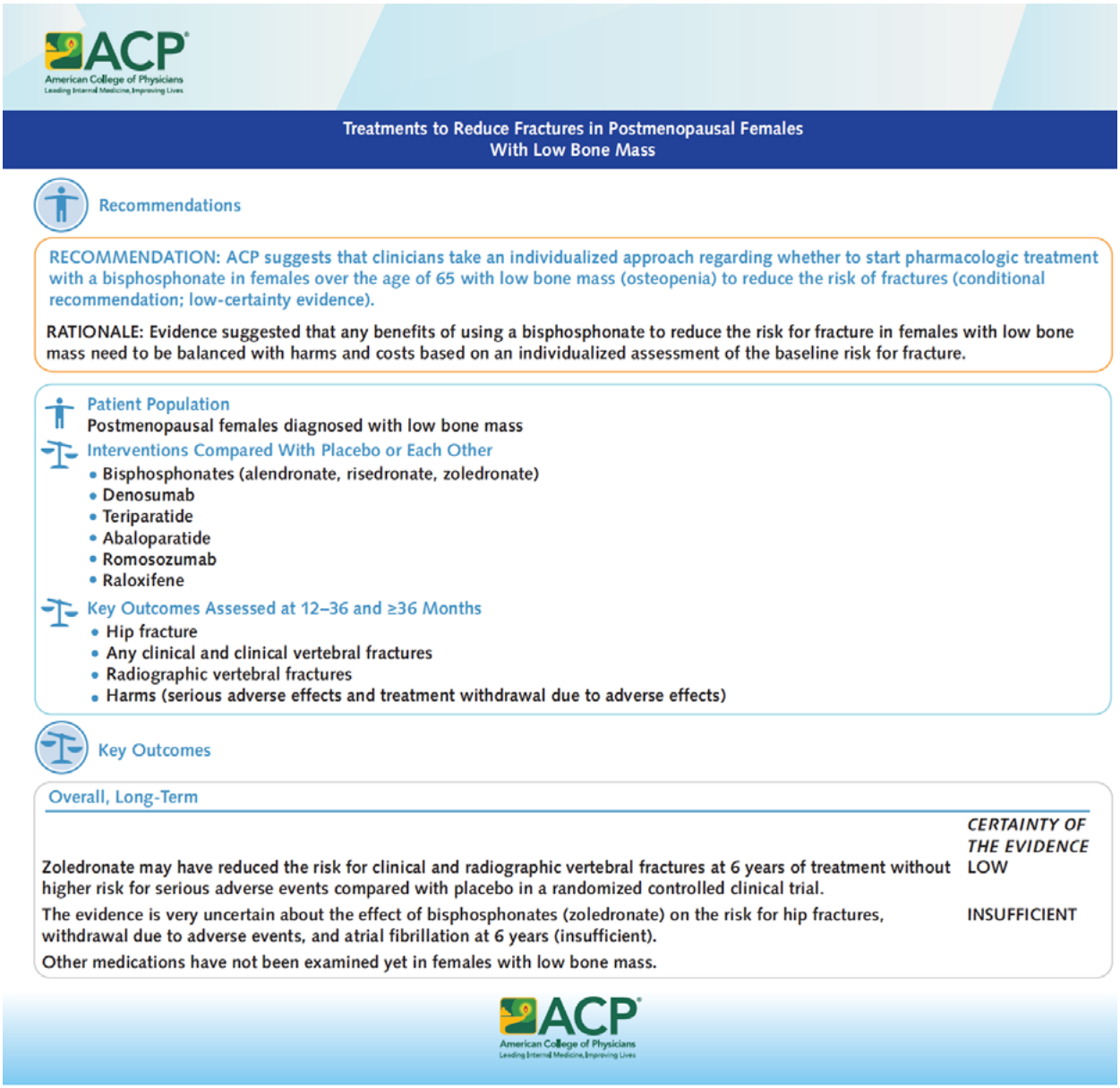


Figure 3. Treatments to reduce fractures in postmenopausal females with low bone mass.



Recurrent renal stones not impacted by HCTZ therapy

For decades, the cornerstone of treatment for recurrent calcium oxalate/phosphate stones has been treatment with HCTZ. This is related to the fact that hypercalciuria is commonly associated with recurrent renal stones and there are good data demonstrating a reduction in urinary calcium excretion with HCTZ use. There are prior studies showing efficacy in reducing recurrent stones, but there have been methodological flaws with many of these studies, and the HCTZ doses were often in the 50-100 mg/day range and therefore often associated with side effects of treatment.

To that end, a group of investigators studied 416 patients with recurrent calcium oxalate stones and randomized them to placebo or three doses of HCTZ 12.5 mg/day, 25 mg/day, or 50 mg/day.[9] Patients were followed for a mean of 2.9 years, and follow up included both symptomatic recurrence and CT discovered new or enlarging stones. A recurrent stone or significant growth of an existing stone occurred in 60 of 102 patients (59%) in the placebo group, in 62 of 105 patients (59%) in the 12.5-mg hydrochlorothiazide group (rate ratio vs. placebo, 1.33; 95% confidence interval [CI], 0.92 to 1.93), in 61 of 108 patients (56%) in the 25-mg group (rate ratio, 1.24; 95% CI, 0.86 to 1.79), and in 49 of 101 patients (49%) in the 50-mg group (rate ratio, 0.92; 95% CI, 0.63 to 1.36). There was no relation between the hydrochlorothiazide dose and the occurrence of a primary end-point event (P=0.66). There was a trend toward lower symptomatic recurrence in the 50 mg HCTZ/day group that did not reach statistical significance. Although generally well tolerated, in the 25 mg HCTZ/day and 50 mg HCTZ/day groups, there were increased rates of hypokalemia, gout, and new onset DM2, seen in the range of 3-5% of patients.

So how can we integrate these data into our treatment algorithms? Interestingly, the patients receiving hydrochlorothiazide had the expected decrease in urinary calcium excretion. However, urine relative supersaturation ratios for calcium oxalate and calcium phosphate, an excellent proxy for stone formation, were not lower among patients receiving hydrochlorothiazide. Additionally, urinary citrate levels were reduced on treatment which might also counteract the effect of the reduced urinary calcium. Given that the treatment non-adherence rate was about 25%, this could have affected results. If patients are successfully treated with HCTZ therapy for recurrent stones and have no side effects on therapy, treatment might be continued. These data would weigh against new initiation of treatment for recurrent calcium stones.

Glucagon use in insulin dependent DM 2011 to 2021

Severe hypoglycemia in patients with insulin dependent DM is common and dangerous.[10] Consequences include an increased rate of hospital admission, readmission and mortality. Guidelines therefore recommend that these patients have a prescription available for glucagon use in the event of severe hypoglycemia.

To assess the use of glucagon in this patient population, researchers used the Optum Labs Data Warehouse to examine the prescription rate for glucagon.[11] The study population included over 2.8 million Medicare Advantage and commercial patients with DM. Of the ~308,000 patients using short acting insulin, only 8,7% of patients were prescribed glucagon, and of the ~236,000 on only long-acting insulin, only 2.3% of patients were prescribed glucagon. Moreover, during the ten years of the study, prescription rates dropped by 22%. Even in the subpopulation of patients who required ED evaluation or hospital admission, only 25% were prescribed glucagon.

Interestingly, despite the availability of nasal glucagon that can easily be administered by family members and caretakers, most of the prescriptions were of the cumbersome vial and syringe kits, despite price parity between the various products. The cost of a glucagon kit is in the range of ~$275, however several commercial and MA plans, including UHC, offer this at zero copay. Patients with diabetes using multi-dose insulin regimens and those using long-acting insulin only who have had severe hypoglycemia should be prescribed glucagon with instructions for appropriate use.

Prostate cancer – active surveillance vs. surgery or radiation – 15–year follow up of the ProtecT Trial

Based upon the results of prior studies, active surveillance (AS) for low-risk prostate cancer has been shown to have equal survival compared to treatment with radical prostatectomy or radiation therapy.[12] Due to the ubiquitous serious side effects of treatment, AS is the preferred management in both the NCCN and AUA guidelines. However, rates of AS remain at only 60% across the U.S., despite other countries in the world, and the urologist MUSIC collaborative in Michigan, reaching AS rates above 90%.

Adding to this body of literature is the ProtecT Trial, a UK trial now reports the 15-year follow up of 1,643 men who were diagnosed with localized prostate cancer and randomized to AS, radical prostatectomy or radiation therapy.[13] 77.2% of the men were in Gleason grade group 1 (Gleason score, 3+3=6) and would qualify for AS today. However, 24% had intermediate disease, some of whom might qualify for AS, and 9.6% had high-risk disease. The primary outcome was death from prostate cancer, and the secondary outcomes were death from any cause, metastases, disease progression, and initiation of long-term androgen-deprivation therapy.

Death from prostate cancer occurred in 2.7%: 3.1% in the AS group, 2.2% in the prostatectomy group, 2.9% in the radiotherapy group (P=0.53 for the overall comparison). Death from any cause occurred in 356 men (21.7%), with similar numbers in all three groups. Metastases developed in 9.4% in the active-surveillance group, 4.7% in the prostatectomy group, and in 5.0% in the radiotherapy group. Long-term androgen-deprivation therapy was initiated 12.7%, 7.2%, 7.7%, respectively; clinical progression occurred in 25.9%, 10.5%, and 11.0%, respectively. In the active-surveillance group, 24.4% were alive without any prostate cancer treatment at the end of follow-up. Interestingly, no differential effects on cancer-specific mortality were noted in relation to the baseline PSA level, tumor stage or grade, or risk-stratification score.

So how does this help us in our AS discussions with our patients? The primary endpoint of prostate cancer death was no different with AS compared to treatment. With respect to disease progression needing treatment, because 23% of the patients in this trial would not have met current guidelines for AS, it is expected that the rates of treatment over time would be higher than in trials that focused only on low-risk prostate cancers. The largest such trial showed that at ten years from diagnosis, in a population of 993 men with low to intermediate risk cancers, 63% of patients remained on AS with a survival of 98.5%. We now have strong data from multiple sources that AS versus treatment does not impact prostate cancer survival, and patients can thus be reassured that enrolling in an AS program is safe and will avoid the toxicities of prostatectomy and radiation therapy. A minority of these patients will evolve over time and thus require treatment, but this is safely monitored in AS programs. If these patients do go on to need treatment, they still would have avoided the toxicity of treatment during the years that they spent on AS.

To improve our current rates of AS, this spring we will launch the "Prostate Cancer – Improving Active Surveillance" (ProCIAS) program. This will entail two key elements. The first is a sophisticated, web based, interactive shared decision-making program to teach patients about their options for low-risk prostate cancer. The second element will be a reporting program that will measure the AS rates for the urologists in your market such that you can refer to urologists who appropriately utilize AS in lieu of prostatectomy and radiation therapy in your patients with low-risk prostate cancer.

Addressing hearing impairment to address cognitive decline

Recent drug development suggests therapies for certain types of dementia may be in the pipeline (e.g.; donanemab, lecanemab). However, some pharmaceutical treatments are often associated with high direct (cost of drug) and indirect (cost of MRI surveillance, adverse drug events, etc.) costs with uncertain clinical benefit, resulting in poor cost-effectiveness and value.[14] Given the high incidence and burden of dementia, treatment options are imperative. There are effective lower-cost interventions available. Prevention of hearing loss can result in a substantial risk reduction for dementia.[15] Hearing loss is highly prevalent in the aging population. A recent systematic review and meta-analysis suggests that addressing hearing impairment after it has already occurred may also decrease risk of cognitive decline in the long term and may even improve cognitive test scores in the short term.[16] Eight of the studies included, representing almost 127,000 patients, examined the association between hearing aid use and long-term cognitive decline, with the pooled analysis showed almost a 20% lower hazard ratio compared to those with uncorrected hearing loss. The risk of bias among the studies was deemed moderate to low. The costs and complications associated with hearing aids are much lower than current and proposed medication interventions and should be considered as a part of initial prevention and therapy for those at risk and who have hearing impairment.

Addressing frailty in the elderly using physical activity

A recent systematic review and network meta-analysis reveals that resistance training may be the most effective non-pharmacologic intervention to reduce frailty. [17] Although 69 randomized-controlled trials were included, the certainty of the evidence from the findings was determined to be moderate at best. That said, the findings can provide some guidance on effective and feasible interventions for frailty. Frailty is common in the elderly and is often considered a 'pre-disability state' characterized by decreased physiologic reserve and increase susceptibility to the detriments of stress. Frailty is often a precursor to cognitive decline, lower quality of life, mood disorders, and other poor health-related outcomes. Effective prevention and treatment, therefore, are important clinical interventions within a value-based framework of care, and contribute directly toward the quadruple aim.

The recent article found evidence of effectiveness for physical activity and for nutrition intervention in reducing frailty, versus usual care. Physical activity was found more effective, with the most effective being resistance training followed by mind-body exercise, mixed physical training, and finally aerobic training. Treatment of comorbid conditions that often accompany frailty, such as diabetes mellitus, chronic kidney disease, or heart disease, will often involve medication as part of medical management. The current study highlights the importance and effectiveness of non-pharmacologic treatment of frailty itself.

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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.

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