GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

Volume 1 - Issue 44

FPIN
Family Physicians Inquiries Network

What's in this week's issue?

Week of November 1 - 5, 2021

SPOTLIGHT: Preventing Falls with Exercise? It Works!

Preventing Falls with Exercise? It Works!

GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Effect of a Home-Based Exercise Program on Subsequent Falls among Community-dwelling High-risk older adults after a Fall, A Randomized Clinical Trial

Lui-Ambrose T, Davis J, Best J et al. Effect of a Home-Based Exercise Program on Subsequent Falls among Community-Dwelling High-Risk Older Adults After a Fall, A Randomized Clinical Trial. *JAMA*. 2019; 32(21):2092-2100.

KEY TAKEAWAY: Among adults 70 years old and older who suffered a fall, a home strength/balance training program significantly reduces subsequent falls.

STUDY DESIGN: Single-blinded randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: In older adults, falls are a leading cause of chronic disability. The most effective method to prevent additional falls in this population has not been established. This study was designed to determine if a home-based exercise program prevents falls in community-dwelling older adults who sought medical care after a prior fall.

PATIENTS: Adults more than 70 years old

INTERVENTION: Home strength and balance retraining

CONTROL: Usual care with fall prevention care

OUTCOME: Self-reported number of falls

METHODS (BRIEF DESCRIPTION):

- Included patients had a mean age of 82 years old with a fall in the past 12 months.
- An exercise program was delivered by physical therapy for 12 months.
- A fall was defined as "unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in a stroke or an epileptic seizure".
- Patients were recruited from a fall prevention clinic and were divided into two groups to receive either home based Otago Exercise Program (5 strengthening exercises and 11 balance retraining exercises with goal to progress to a greater level of difficulty over time) plus usual care vs usual care alone.

INTERVENTION (# IN THE GROUP): 173 (1 excluded)

COMPARISON (# IN THE GROUP): 172

FOLLOW UP PERIOD: 12 months

RESULTS:

- The home exercise group experienced less falls than the usual care group at 12 months follow up (236 vs 366 falls; 1.4 vs 2.1 falls per person year).
  - Absolute difference in falls per person year: 0.74 (95% CI, 0.04–1.8)
  - Incident ratio in falls per person year: 0.64 (95% CI, 0.46–0.90)

LIMITATIONS:

- Not generalizable to entire elderly community due to:
  - Excluded conditions (neurodegenerative disease, dementia, stroke history, inability to walk 3 m).
  - Recruitment limited to one center that specialized in fall prevention.
  - Data were collected by an unblinded assistant.

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Has BPPV Got You Wobbly on Your Feet? You Might Consider a Combo of Vitamin D & Calcium Supplementation

Prevention of Benign Paroxysmal Positional Vertigo with Vitamin D Supplementation: A Randomized Trial

Jeong SH, Kim JS, Kim HJ, et al. Prevention of benign paroxysmal positional vertigo with vitamin D supplementation: A randomized trial. *Neurology*. 2020; 95(9): e1117-e1125. doi:10.1212/WNL.0000000000010343

KEY TAKEAWAY: Supplementation of vitamin D and calcium should be considered in patients with frequent attacks of benign paroxysmal positional vertigo (BPPV), especially when serum vitamin D is subnormal, to prevent recurrence of BPPV.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Several studies have found higher prevalence of vitamin D deficiency and insufficiency and decreased bone mineral density in patients diagnosed with BPPV than in patients without. There were no prior RCTs to assess the effect of vitamin D and calcium supplementation in prevention of BPPV.

PATIENTS: Adult patients with BPPV

INTERVENTION: Vitamin D 400 IU daily and 500 mg calcium carbonate twice daily

CONTROL: No supplementation

OUTCOME: Total number of BPPV recurrences per patient (annual recurrence rate of BPPV per 1 person-year), serum 25-hydroxy vitamin D level, annual fall rate, annual fracture rate, quality of life

METHODS (BRIEF DESCRIPTION):

- Patients diagnosed with BPPV diagnosed at eight hospitals in South Korea between December 2013 and May 2017 were included.
  - Diagnosis based on:
    - History of recurrent brief attacks of vertigo or positional dizziness induced by head motion;
    - Atypical positional nystagmus characteristic of BPPV; and
    - Not attributable to another disorder.
- Patients were randomly assigned to receive vitamin D 400 IU daily and calcium carbonate 500 mg twice daily for one year or follow ups without vitamin D evaluation or supplementation.
- Patients were instructed to call into the study center when suspected BPPV recurred and then were evaluated in nearest clinic to confirm recurrence.
- Patients in both groups also had monthly telephone interviews regarding occurrences of vertigo, falling, or fracture during the preceding month.
- Quality of life was assessed with UCLA-DQ questionnaire at baseline, 6 months, and 12 months.
  - UCLA-DQ measures dizziness frequency and severity and its fear and impact on quality of life. Score ranges from 5–25 with higher scores indicating higher severity.

INTERVENTION (# IN THE GROUP): 518

COMPARISON (# IN THE GROUP): 532

FOLLOW UP PERIOD: 12 months

RESULTS:

- Vitamin D and calcium supplementation resulted in a lower BPPV recurrence rate than no supplementation (Incidence Rate Ratio [IRR] 0.76; 95% CI, 0.66–0.87; ARR –0.27; 95% CI, –0.40 to –0.14; NNT=3.7).
- Serum 25-hydroxy vitamin D levels increased at each from baseline to two months follow up in the intervention group (13 vs 24, respectively; *P*<.001).
  - This improvement persisted at one year follow up (13 vs 24, respectively; *P*<.001).
- Both groups' quality of life improved, however statistical analysis was not presented in the study.
- Fall and fracture frequency did not differ between groups.

LIMITATIONS:

- No placebo control.
- There could have been some misclassification of vertigo by the questionnaire used in the study to determine if patient was having BPPV.
- Study performed only in South Korea, and therefore not necessarily applicable study to the general population in other countries based on ethnicity.

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The Significant Impact of Long-Standing Diabetes on Mortality in Older Adults

Mortality Implications in Prediabetes and Diabetes in Older Adults

Tang O, Matsushita K, Coresh J, et al. Mortality Implications of Prediabetes and Diabetes in Older Adults. *Diabetes Care*. 2019; 43(2):382–388. doi:10.2337/dc19-1221

KEY TAKEAWAY: Long-standing diabetes in older adults has a significant impact on short term mortality. Prediabetes does not significantly affect short-term, all-cause, or cardiovascular mortality.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: The risk of cardiovascular events and mortality increases in adults with diabetes. While much has been studied in middle aged adults, less is known about length of time with hyperglycemia/diabetes and short-term, all-cause, and cardiovascular mortality in older adults.

PATIENTS: Elderly adults

INTERVENTION: Prediabetes, recently diagnosed diabetes, short-term diabetes, or long-term diabetes

CONTROL: No hyperglycemia or diabetes

OUTCOME: All-cause and cardiovascular mortality

METHODS (BRIEF DESCRIPTION):

- All patients participated in the previous Atherosclerosis Risk in Communities study, who were 66–90 years old.
- Participants were grouped as follows:
  - No diabetes
  - Prediabetes: Defined as HbA1C 5.7–6.4%
  - Recently diagnosed diabetes: Defined as HbA1C ≥6.5% and diagnosed within the last year or on pharmacological treatment
  - Short-term diabetes: Defined as 1–10 years
  - Long-term diabetes: Defined as ≥10 years
- Outcomes were measured by semi-annual phone calls to the patients, state records, and the national death index.
- Cardiovascular death was defined by fatal CHD, HF, hemorrhagic/ischemic stroke, or ICD 10 codes indicating cardiovascular causes.
- ANOVA statistical analysis compared all-cause mortality and cardiovascular mortality (per 1000 person years of follow up) overall and by diabetes status.
  - Results were compared using ratios and differences.
  - Variables were accounted for including age, race, smoking status, cardiovascular risk factors, and BMI.

INTERVENTION (# IN THE GROUP): 3,691

COMPARISON (# IN THE GROUP): 2,100

FOLLOW UP PERIOD: Median of 5.6 years

RESULTS:

- After adjusting for cardiovascular risk factors, long-standing diabetes was associated with:
  - Increased all-cause mortality (Hazard Ratio [HR] 1.7; 95% CI, 1.4–2.1)
  - Increased cardiovascular mortality (HR 1.7; 95% CI, 1.2–2.5)
- Pre-diabetes and recently diagnosed diabetes were not associated with an increased all-cause or cardiovascular mortality.
- All-cause mortality (per 1,000 person years) by subgroup:
  - No diabetes: 21 (95% CI, 19–24)
  - Prediabetes: 24 (95% CI, 21–27)
  - Recently diagnosed diabetes: 34 (95% CI, 25–35)
  - Short-term diabetes: 30 (95% CI, 25–35)
  - Long-term diabetes: 49 (95% CI, 42–56)
- Cardiovascular mortality (per 1,000 person years) by subgroup:
  - No diabetes: 5.8 (95% CI, 4.6–7.4)
  - Prediabetes: 6.6 (95% CI, 5.2–8.5)
  - Recently diagnosed diabetes: 12 (95% CI, 7–19)
  - Short-term diabetes: 8.2 (95% CI, 5.9–11)
  - Long-term diabetes: 17 (95% CI, 14–22)

LIMITATIONS:

- Median follow up time and number of deaths limited the evaluation of cardiovascular mortality.
- Possibility of more confounders, like kidney function, in this multimorbid patient population.
- Not a representative population of patients demographically.

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Left Atrial Appendage Occlusion for Atrial Fibrillation is Effective

Left Atrial Appendage during Cardiac Surgery to Prevent Stroke

Whitlock RP, Belley-Cote EP, Paparella D, et al. Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke. *N Engl J Med*. 2021; 384(22):2081–2091. doi:10.1056/NEJMoa2101897

KEY TAKEAWAY: Patients with atrial fibrillation who underwent left atrial appendage occlusion during an already scheduled cardiac surgery had lower incidence of ischemic stroke compared to those with usual care alone, including anticoagulation.

STUDY DESIGN: Multicenter, randomized trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Current guidelines recommend anticoagulation for patients with atrial fibrillation and at high risk for a stroke. Anticoagulation is known to decrease stroke and embolic events in this population by two thirds. However, it is thought that most of these events originate in the left atrial appendage as it serves as a pocket for thrombus to form and potentially embolize to cause a stroke. Surgical occlusion of this area has only been studied as an alternative to anticoagulation and has not been well studied as an adjuvant treatment option to further decrease risk of stroke and embolic events.

PATIENTS: Adults with atrial fibrillation and at risk for a stroke

INTERVENTION: Surgical occlusion of left atrial appendage

CONTROL: Usual atrial fibrillation care

OUTCOME: Ischemic stroke or systemic embolism

Secondary Outcomes: Any stroke or noncerebral systemic embolism, mortality, chest-tube drainage, re-exploration for bleeding, hospitalization for heart failure, myocardial infarction, major bleeding

METHODS (BRIEF DESCRIPTION):

- Patients 18 years or older (mean 71 years old; 68% male) with a history of atrial fibrillation, at risk of stroke, and were scheduled to undergo cardiac surgery with cardiopulmonary bypass were enrolled in the trial.
  - Stroke risk defined as a CHA_2DS_2-VASc score of at least 2, with an average participant score of 4.2.
- The randomized treatment group underwent left atrial appendage occlusion in addition to the planned cardiac surgery.
- 50% of all patients in both groups were on an anticoagulant prior to the procedure.
  - At hospital discharge, just over 80% were on an anticoagulant.
- All participants had follow-up every six months for almost four years, which included a stroke questionnaire to assess for any symptoms of a stroke and ensuring compliance with anti-coagulation.
- Neurologists reviewed stroke and TIA reports to confirm "true" cases.

INTERVENTION (# IN THE GROUP): 2,400

COMPARISON (# IN THE GROUP): 2,411

FOLLOW UP PERIOD: 3.8 years

RESULTS:

Primary Outcome:

- The occlusion group had less of a risk for ischemic stroke compared to the non-occlusion group (4.8% vs 7%, respectively; HR 0.67; 95% CI, 0.53–0.85).

Secondary Outcomes:

- The two groups did not differ in 30-day mortality, all-cause mortality, hospitalizations for heart failure, incidence of perioperative bleeding, MI, or re-exploration after surgery.

LIMITATIONS:

- No comparison of occlusion with versus without anticoagulation.
- Stand-alone left atrial appendage occlusion was not addressed to determine if benefits outweigh risks.

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Gender-Specific Risk Factor Profiles for Patellofemoral Pain

Gender-Specific Risk Factor Profiles for Patellofemoral Pain

Boling MC, Nguyen AD, Padua DA, Cameron KL, Beutler A, Marshall SW. Gender-Specific Risk Factor Profiles for Patellofemoral Pain. *Clin J Sport Med*. 2021; 31(1):49–56.

KEY TAKEAWAY: Males and females have different kinematic risk factor profiles for developing patellofemoral pain. In females, risk factors include landing with less hip abduction and standing with increased knee internal rotation. In males, protective factors include landing with increased knee flexion and standing with decreased hip external rotation.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: Patellofemoral pain (PFP) is a common cause of chronic knee pain in physically active individuals. To date, biomechanical risk factors have been poorly studied with either small studies or conflicting evidence. The aim of this study was to look at a large cohort to make more conclusive statements regarding risk factors for developing patellofemoral pain.

PATIENTS: Male and female cadets of three United States service academies

INTERVENTION: Cadets who did develop PFP

CONTROL: Cadets who did not develop PFP

OUTCOME: Variables associated with the development of patellofemoral pain

METHODS (BRIEF DESCRIPTION):

- Population: First year students at the U.S. Military Academy, U.S. Naval Academy, or the U.S. Air Force Academy. Those with prior PFP and injury limiting participation in baseline measurements were excluded.
- Biomechanics Evaluation included a jump-landing task, lower-extremity isometric muscle strength testing, Q-angle measurement, and navicular drop measurement.
    - Measurements: Hip and knee kinematics, isometric muscle strength, quadriceps-angle, navicular drop
- Trial process: Cadets were monitored for PFP during their enrollment at a service academy via ICD-9 diagnostic codes.
- The following criteria had to be met from a documentation standpoint to qualify a cadet for inclusion into the PFP group:
    - Retropatellar knee pain with activities.
    - No findings suggestive of meniscus, bursa, or tendon pathology.
    - Pain with palpation of either patellar facet or pain with palpation of either femoral condyle anteriorly.

INTERVENTION (# IN THE GROUP): 188 (94 males and 94 females)

COMPARISON (# IN THE GROUP): 3,705 (2,355 males and 1,350 females)

FOLLOW UP PERIOD: From first summer of enrollment through enrollment completion or diagnosis of PFP

RESULTS:

- In females, the following increased the risk of developing PFP:
    - <10 degrees of hip abduction at initial contact (OR 1.9; 95% CI, 1.1–3.3).
    - >10 degrees of knee internal rotation at 50% the stance phase following landing (OR 1.7; 95% CI, 1.1–2.7).
- In males, the following decreased the risk of developing PFP:
    - >20 degrees of knee flexion at initial contact (OR 0.47; 95% CI, 0.29–0.77).
    - Between 0 and 5 degrees of hip external rotation at 50% stance phase following landing (OR 0.52; 95% CI, 0.27–0.77).
- Lower-extremity isometric muscle strength, Q-angle, and navicular drop measurements were not associated with risk of developing patellofemoral pain.

LIMITATIONS:

- The study population was limited to military cadets, which does not represent the general population.
- Motion analysis equipment is not readily available in the clinical setting.
- Those with previous PFP were excluded, so selection bias is present (missing those at higher risk for PFP).
- The study design did not control for cadet involvement in different types of physical activity or muscle development.

- There is information bias since the participants had to self-report symptoms for them to be evaluated by either an athletic trainer or physician.
- Some of the measures were only collected on the dominant leg. A complete assessment should have included both legs.

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