GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of April 15 - 19, 2024

SPOTLIGHT: Evidence-Based Strategies to Improve Abnormal Cancer Screening Follow-Up

- Does Ambulatory Palliative Care Improve the Health of Patients with Chronic Illness?
- Low-Carb, High-Fat vs High-Carb, Low-Fat Diets for T2DM Management
- Dry Needling After Running? Something to Consider.

Evidence-Based Strategies to Improve Abnormal Cancer Screening Follow-Up

A Multilevel Primary Care Intervention to Improve Follow-Up of Overdue Abnormal Cancer Screening Test Results: A Cluster Randomized Clinical Trial

Atlas SJ, Tosteson ANA, Wright A, et al. A Multilevel Primary Care Intervention to Improve Follow-Up of Overdue Abnormal Cancer Screening Test Results: A Cluster Randomized Clinical Trial. *JAMA*. 2023;330(14):1348-1358. doi:10.1001/jama.2023.18755

KEY TAKEAWAY: Electronic health record (EHR) reminders with outreach and EHR reminders with outreach and navigation significantly increase the proportion of patients who complete the recommended follow-up after an abnormal cancer screening test compared to EHR reminders alone or usual care.

STUDY DESIGN: Unblinded, cluster randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Abnormal cancer screening tests must be followed up with appropriate diagnostic tests and procedures. Many of these screening tests originate in the primary care office but often require coordination with specialists and other departments for follow-up. As primary care volumes increase, this becomes more challenging and remains an area of opportunity to improve in primary care offices.

PATIENTS: Adults with an abnormal cancer screening test

INTERVENTION: EHR reminders, outreach, and/or navigation

CONTROL: Usual care

PRIMARY OUTCOME: Completion of recommended follow-up within 120 days of study enrollment

METHODS (BRIEF DESCRIPTION):

- This randomized controlled trial consisted of 44 primary care offices within three larger health systems in Boston.
- Included participants:
  - Women 40–80 years old with an abnormal mammogram
  - Women 21–65 years old with an abnormal Papanicolaou test with or without a human papillomavirus test
  - Adults 40–80 years old with a positive fecal immunochemical test or an abnormal short-interval colonoscopy (1–5 years)
  - Adults 55–80 years old with current or former smoking and an abnormal low-dose CT chest
- The study consisted of three intervention groups:
  - Group 1: EHR reminders
  - Group 2: EHR reminders and outreach
  - Group 3: EHR reminders, outreach, and navigation
- In all three intervention groups, EHR reminders for follow-up testing were visible to both patients and PCP offices.
- If follow-up tests were not completed at two weeks, patients in groups two and three received either a physical or electronic reminder letter.
- If follow-up tests were not completed at four weeks, patients in these two groups received a phone call reminder.
- If follow-up tests were not completed at eight weeks, patients in group three received a call from a patient navigator who assessed several social determinants of health and connected patients to social services.

INTERVENTION (# IN THE GROUP):

- Group 1: 2,344
- Group 2: 1,848
- Group 3: 2,087

COMPARISON (# IN THE GROUP): 1,878

FOLLOW-UP PERIOD: 120 days

RESULTS:

Primary Outcome –

- Completion of recommended follow-up was better in the following groups when compared to usual care.
  - EHR reminders, outreach, and navigation (adjusted absolute difference 8.5%; 95% CI, 4.8–12)
  - EHR reminders and outreach (adjusted absolute difference 8.1%; 95% CI, 4.5–12)
- There was no difference between EHR reminders and usual care.

- Completion rates were relatively low in all groups, with 31% completion in the group receiving all three interventions and 23% in usual care.

LIMITATIONS:

- The methods required an EHR that was able to interpret abnormal cancer screening results and determine a follow-up plan in an automated fashion. While EHR technology continues to advance, not all primary care offices have access to an EHR with this capability.
- This study took place during the COVID-19 pandemic which may have limited communication and patient participation in follow-up testing.
- The study was not blinded and did not evaluate cost-effectiveness.

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Does Ambulatory Palliative Care Improve the Health of Patients with Chronic Illness?

Implementation and Effectiveness of Integrating Palliative Care Into Ambulatory Care of Noncancer Serious Chronic Illness: Mixed Methods Review and Meta-Analysis

Chyr LC, DeGroot L, Waldfogel JM, et al. Implementation and Effectiveness of Integrating Palliative Care Into Ambulatory Care of Noncancer Serious Chronic Illness: Mixed Methods Review and Meta-Analysis. *Ann Fam Med.* 2022;20(1):77-83. doi:10.1370/afm.2754

KEY TAKEAWAY: Models for integrative palliative care do not improve quality of life, offer little to no effect on overall symptom burden, and are not more effective for depressive symptoms when compared to the usual care.

STUDY DESIGN: Systemic review and meta-analysis of nine randomized controlled trials (RCTs) and five controlled or prospective cohort studies (N=2,934)

LEVEL OF EVIDENCE: Step 2 (downgraded due to the limited number of studies and variations in outcome)

BRIEF BACKGROUND INFORMATION: Patients with non-cancer serious chronic illnesses have complex care needs. Management of these patients requires a multi-disciplinary approach that might include palliative care services. However, more research needs to be done on the appropriate way to integrate palliative care in the overall management of such patients.

PATIENTS: Adults with chronic illness

INTERVENTION: Palliative care models

CONTROL: Usual care

PRIMARY OUTCOME: Patient satisfaction, quality of life, depressive symptoms

Secondary Outcome: Advanced directive (AD) documentation

METHODS (BRIEF DESCRIPTION):

- Inclusion criteria:
  - Adults ≥18 years old
  - US-based study
  - Published in English
- Patients who do not have a serious life-threatening chronic illness or condition and are not seen in ambulatory settings were excluded from the study.
  - Studies with <10 participants and a population of only cancer patients were also excluded.
- Models used for integrating palliative care in ambulatory settings included four shared care models, four care coordinators or social workers in care delivery, and four consultative care models.
- Palliative care models were used for the intervention group that focused on patients' quality of life, overall symptom burden, psychological support, and advanced care planning.
- The primary outcome measured patient satisfaction, quality of life, and depressive symptoms.
  - All primary outcomes were calculated using standardized mean difference (SMD).
- The secondary outcome was assessed using the percent completion of AD documentation at six months.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Two weeks to two years

RESULTS:

Primary Outcome –

- Models for integrating palliative care were not more effective compared to usual care in the following areas:
  - Quality of life (SMD of 4 studies 0.19; 95% CI, –0.03 to 0.41)
  - Depressive symptoms (SMD of 3 studies, –0.09; 95% CI, –0.35 to 0.16)
  - Patient satisfaction:
    - One RCT identified improved patient satisfaction with palliative care compared to usual care (4.1 vs 4.0, respectively; *P*=.03).
    - One controlled trial identified no improvement in patient satisfaction with palliative care compared to usual care (70 vs 72, respectively; *P*=.26).

Secondary Outcome –

- Palliative care models increased advanced directives documentation compared to usual care (relative risk [RR] 1.6; 95% CI, 1.4–1.9).

LIMITATIONS:

- A limited number of studies were available to conduct a meta-analysis.

- Most of the accepted standards for clinically meaningful differences used were not from palliative care populations.

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Low-Carb, High-Fat vs High-Carb, Low-Fat Diets for T2DM Management

Effect of Calorie-Unrestricted Low-Carbohydrate, High-Fat Diet Versus High-Carbohydrate, Low-Fat Diet on Type 2 Diabetes and Nonalcoholic Fatty Liver Disease: A Randomized Controlled Trial

Hansen CD, Gram-Kampmann EM, Hansen JK, et al. Effect of Calorie-Unrestricted Low-Carbohydrate, High-Fat Diet Versus High-Carbohydrate, Low-Fat Diet on Type 2 Diabetes and Nonalcoholic Fatty Liver Disease: A Randomized Controlled Trial. *Ann Intern Med.* 2023;176(1):10-21. doi:10.7326/M22-1787

KEY TAKEAWAY: Adults with type 2 diabetes (T2DM) who follow a low-carb, high-fat (LCHF) diet over six months experience a significant reduction in antidiabetic medication requirement and a reduction in hemoglobin A1C than those who follow a high-carb, low-fat (HCLF) diet. However, reductions are not sustained after three months of participants returning to their previous diets.

STUDY DESIGN: Prospective parallel-group, randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: The American Diabetes Association (ADA) recommends a moderate increase in monounsaturated fats and reduced carb intake for better management of glycemic control and lipoprotein levels in type 2 diabetics. This study compared the effects of a calorie-unrestricted low-carbohydrate, high-fat diet with a high-carbohydrate, low-fat diet on T2DM, lipids, and metabolic markers offering better evidence to the validity of the ADAs recommendation.

PATIENTS: Adults with T2DM

INTERVENTION: Calorie-unrestricted LCHF diet

CONTROL: Calorie-unrestricted HCLF

PRIMARY OUTCOME: Glycemic control

Secondary Outcome: Serum lipid levels, weight

METHODS (BRIEF DESCRIPTION):

- The trial took place over six months with a three-month post-trial assessment period.
- Participants: Adults with T2DM with stable A1C >6.5 between six months and 10 years (maximum 5 years if receiving insulin), total cholesterol <174 mg/dL, and LDL <97 mg/dL.
    - 50 participants had modified inclusion criteria to allow for A1C >6.5 for >10 years.
- Participants were randomized in a 2:1 ratio into the LCHF diet and HCLF diet.
    - Randomization occurred via a computer-generated sequence where sex and the number of antidiabetic medications were used to balance groups by disease severity and avoid gender differences.
- Study criteria included consuming calories equal to energy expenditure.
    - LCHF: 20% carbohydrate, 50–60% fat, 25–30% protein
    - HCLF: 50–60% carbohydrate, 20–30% fat, 20–25% protein
- In the LCHF group, any insulin dose was initially decreased by 20% to avoid hypoglycemia. Any other antidiabetic meds were continued.
- Study criteria included maintenance of daily activity level, without increase or reduction. A seven-day activity baseline was established at the start of the study using a three-axis logging accelerometer.

INTERVENTION (# IN THE GROUP): 124

COMPARISON (# IN THE GROUP): 61

FOLLOW-UP PERIOD: Nine months

RESULTS:

Primary Outcome –

- LCHF significantly reduced HbA1c at six months compared to the HCLF diet (mean difference [MD] –0.8%; 95% CI, –1.2 to –0.4).
- There was a return to near pre-trial HbA1c and fasting glucose levels three months after trial completion.

Secondary Outcome –

- LCHF significantly reduced the following compared to HCLF at nine months:
    - LDL (MD –10 mg/dL; 95% CI, –15 to –5)
    - Liver fat content (MD –4.7%; 95% CI, –6.3 to –3.1)
    - Body weight (MD –3.2 kg; 95% CI, –4.5 to –1.9)
    - Triglycerides (MD –25 mg/dL; 95% CI, –35 to –15)

LIMITATIONS:

- There was no control group.
- The study had a small sample size.

- Patients self-reported diet adherence.
- There was non-adherence among some participants in the LCHF group when it came to maintaining daily caloric consumption; thus, there was decreased daily caloric consumption.
- There was no masking to interventions and thus participants knew which diet they were receiving.

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Dry Needling After Running? Something to Consider.

Postrace Dry Needling Does Not Reduce Subsequent Soreness and Cramping- A Randomized Controlled Trial

Cushman DM, Cummings K, Skinner L, et al. Postrace Dry Needling Does Not Reduce Subsequent Soreness and Cramping- A Randomized Controlled Trial. *Clin J Sport Med.* 2021;31(3):225-231.
doi:10.1097/JSM.0000000000000794

KEY TAKEAWAY: A single session of postrace dry needling on soleus and quadriceps muscles does not decrease subjective delayed-onset muscle soreness (DOMS) and the occurrence of delayed-onset muscle cramping (DOMC) in full-marathon and half-marathon runners.

STUDY DESIGN: Single-blind, prospective, randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small sample size)

BRIEF BACKGROUND INFORMATION: Athletes of any sport can experience muscle soreness that occurs 24 hours after exercise, commonly referred to as DOMS. Dry needling has been used to treat muscle pain by targeting myofascial trigger points (MTrPs). Previous research focused on dry needling for chronic pain involving the upper extremity. There hasn't been research done on lower extremity pain immediately following post-exercise or on the prevalence and management of DOMC in distance runners.

PATIENTS: Marathon runners

INTERVENTION: Dry needling or sham needling

CONTROL: No needling

PRIMARY OUTCOME: Post-race pain

Secondary Outcome: Subjective post-race soreness and cramping

METHODS (BRIEF DESCRIPTION):

- Inclusion Criteria: Runners ≥18 years old who completed a half or full marathon and were available within one hour after the race.
- Exclusion Criteria: Runners with nonintact skin in the dry needling area, unable to complete follow-up surveys, or those who previously completed dry needling before the race.
- The runners were randomly assigned using a block-randomized list and blinded.
- A physician with five years of dry needling experience and a physical therapist with two years of dry needling experience performed the intervention.
- For the intervention group, dry needling or sham needling was performed on both the soleus and the quadriceps muscles.
- For the control group, the hamstring muscle was selected and did not receive either dry needling or sham needling in both intervention groups.
- Sham needling involved using a needle with the tip removed and dulled. The sham needle was positioned on the respective muscle similarly to dry needling but without any movement of the sham needle.
- Random-effect models were used to assess runners' perception of DOMS over time.
  - The grouping variable consisted of the runners receiving dry needling or sham needling to the soleus and the quadriceps muscles.
  - The time variable consisted of baseline and days one, two, three, and seven.
  - To objectively assess that DOMS was improving, the runners answered a numeric pain score with zero being the lowest and five being the highest.
  - The subjective response to DOMS was calculated based on the runner's selection from the following three choices: "Worse than expected" "As expected," or "Better than expected."
  - For each of the specific muscles, separate random-effects models were created for both the right and left sides.
- Binary logistic regression analysis was used to assess the runners' perception of DOMC.
  - Initially, the number of post-race cramps in 24 hours was collected as a numeric value. The numeric value was later changed to a dichotomous form.
  - If there was at least one cramp, this response was given a one. If there was no cramp, this response was given a zero.
  - Separate binary logistic regression analyses were created excluding the baseline control hamstring muscle for each of the specific muscles on both

the right and left sides on days one, two, three, and seven.

- Ordered regression analysis was used to compare the runners' subjective reports of DOMS and DOMC.
  - The ordinal outcome variables were collected as: "Worse than expected," "As expected," or "Better than expected."
  - To consider correlated observation across days one, two, three, and seven, a robust variance estimator was also used.

INTERVENTION (# IN THE GROUP): 28

COMPARISON (# IN THE GROUP): 34

FOLLOW-UP PERIOD: Seven days

RESULTS:

Primary Outcome –

- On days one and two, pain scores in the soleus muscles were higher in the dry needling group compared to the sham needling group:
  - Day one (odds ratio [OR] 2.2; 95% CI, 1.1–4.6)
  - Day two (OR 2.3; 95% CI, 1.1–4.8).
- At baseline, day three, and day seven, there were no significant differences in pain scores in the soleus muscles between the dry needling group and the sham needling group:
  - Left soleus muscle:
    - Day three (OR 2.5; 95% CI, 0.6–12)
    - Day seven (OR 1.2; 95% CI, 0.3–4.7)
  - Right soleus muscle:
    - Day three (OR 2.0; 95% CI, 0.4–9.4)
    - Day seven (OR 2.2; 95% CI, 0.5–10)
- There was no significant difference in pain scores of the quadriceps on either side in the dry needling group compared to the sham needling group (OR 1.9; 95% CI, 0.90–4.1).

Secondary Outcome –

- There was no significant predictor for DOMC after dry needling type and time in any muscle across days one, two, three, and seven.
- There was no statistically significant difference in DOMC between half-marathon or full-marathon runners post-race.
- The runners subjectively reported "Better than expected" with DOMS on days one, two, three, and seven compared to pre-race.
  - Day one (OR 2.2; 95% CI, 1.1–4.6)
  - Day two (OR 2.3; 95% CI, 1.1–4.8)
  - Day three (OR 2.4; 95% CI, 1.2–5.0)
  - Day seven (OR 4.0; 95% CI, 2.1–7.9)
- The runners subjectively reported "Better than expected" responses with DOMC on days one, two, three, and seven compared to pre-race.
  - Day one (OR 10; 95% CI, 3.5–31)
  - Day two (OR 7.4; 95% CI, 2.5–22)
  - Day three (OR 6.0; 95% CI, 2.1–17)
  - Day seven (OR 7.5; 95% CI, 2.7–21)

LIMITATIONS:

- The sample size was small.
- There were runners with prior dry needling experience which may compromise blinding effectiveness when receiving an intervention.
- There was an absence of objectively measuring muscle soreness.

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