GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of May 22 - 26, 2023

SPOTLIGHT: Does Screening for Sub-Clinical Cardiovascular Disease Lead to Improved Mortality?

- Just Move! A Different Approach to Non-Operative Management of Acute Achilles Tendon Rupture
- Are Opioid Treatment Programs Really the Best Option for Methadone Maintenance Therapy for Opioid Use Disorder?
- At Home Blood Pressure Monitor: The New Norm?

Does Screening for Sub-Clinical Cardiovascular Disease Lead to Improved Mortality?

Five-Year Outcomes of the Danish Cardiovascular Screening (DANCAVAS) Trial

Lindholt JS, Søgaard R, Rasmussen LM, et al. Five-Year Outcomes of the Danish Cardiovascular Screening (DANCAVAS) Trial. *N Engl J Med*. 2022;387(15):1385-1394. doi:10.1056/NEJMoa2208681

KEY TAKEAWAY: Population-based invitations for comprehensive cardiovascular disease screening in Danish men 65–74 years old did not lower the risk of death when compared to the control group after five years of follow-up.

STUDY DESIGN: Randomized, controlled, partially blinded trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Cardiovascular disease is the number one cause of death world-wide. Currently, there is limited data to suggest a benefit to population-based screening for cardiovascular disease to decrease the risk of death.

PATIENTS: Danish men 65–74 years old

INTERVENTION: Comprehensive cardiovascular screening

CONTROL: Standard care

PRIMARY OUTCOME: Death from any cause

Secondary Outcome: Stroke, myocardial infarction, amputation due to cardiovascular disease, aortic dissection, aortic rupture

METHODS (BRIEF DESCRIPTION):

- 46,611 men 65–74 years old from the National Registry of 15 municipalities of Denmark were randomized in a 1:2 allocation to be invited to undergo comprehensive cardiovascular screening or to be in a control group.
  - Of the 16,736 invited participants, 10,471 (62.5%) completed screening.
- Screening included:
  - Non-contrast electrocardiography-gated computed tomography to determine coronary-artery calcium score, presence of atrial fibrillation, and presence of aortic/iliac aneurysms.
  - Ankle-brachial blood pressure measurements and blood work to determine the presence of type 2 diabetes mellitus, hypertension, peripheral artery disease, and hypercholesterolemia.
- Analyses of outcomes were performed according to the intention-to-screen principle. All participants invited to screen were included in data analysis in the prespecified 5-year time frame.
- Participants in the control group were unaware of the study and were unaware of the assignments.
- The complete analysis is planned at a 10-year interval.

INTERVENTION (# IN THE GROUP): 16,736

COMPARISON (# IN THE GROUP): 29,790

FOLLOW-UP PERIOD: Median 5.6 years

RESULTS:

Primary Outcome –

- There was no significant difference in death from any cause between invited and control groups (12.6% vs 13.1%; HR 0.95; 95% CI, 0.9–1.0).

Secondary Outcome –

- Screening improved the following compared to standard care:
  - Stroke (HR 0.93; 95% CI, 0.86–0.99)
  - Composite death/stroke/MI (HR 0.93; 95% CI, 0.89–0.97)
- There were no significant differences between the screening group compared to the control group in myocardial infarction, aortic dissection, aortic rupture, or amputation.

LIMITATIONS:

- Results cannot be generalized to females, non-whites, men less than 65 or older than 74 years old, and men living in other countries with different healthcare systems.
- Intention-to-treat design assessed the effects of all invited participants who agreed to undergo screening, which may underestimate the results of actual screened individuals.
- This study is statistically powered based on a planned 10-year follow-up.

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Just Move! A Different Approach to Non-Operative Management of Acute Achilles Tendon Rupture

Accelerated Rehabilitation in Non-operative Management of Acute Achilles Tendon Ruptures: A Systematic Review and Meta-Analysis

Coopmans L, Amaya Aliaga J, Metsemakers WJ, et al. Accelerated Rehabilitation in Non-operative Management of Acute Achilles Tendon Ruptures: A Systematic Review and Meta-analysis. *J Foot Ankle Surg*. 2022;61(1):157-162. doi:10.1053/j.jfas.2021.07.007

KEY TAKEAWAY: Accelerated rehabilitation for acute Achilles tendon rupture (AATR) is shown to have similar clinical outcomes to prolonged immobilization when assessing patient-reported functional activity, symptoms, and re-rupture rate.

STUDY DESIGN: Meta-analysis comparing six randomized control trials

LEVEL OF EVIDENCE: STEP 2 (downgraded due to small sample size

BRIEF BACKGROUND INFORMATION: Given the risks associated with surgical interventions, non-operative management is becoming more common in the treatment of AATR. Previous studies have shown increased tendon healing with early weight-bearing and mobilization. However, the optimal non-operative protocol for the management of AATR remains uncertain, as evidenced by a lack of robust and current literature. This study may provide additional support for accelerated rehabilitation for AATR.

PATIENTS: Adult patients with AATR

INTERVENTION: Accelerated rehabilitation program

CONTROL: Prolonged immobilization

PRIMARY OUTCOME: Patient-reported limitations/difficulties

Secondary Outcome: Achilles tendon re-rupture rate

METHODS (BRIEF DESCRIPTION):

- Inclusion criteria: at least 18 years old, time of injury <14 days, first rupture of Achilles tendon, unilateral rupture of Achilles tendon
- Using these inclusion criteria, a literature search was performed utilizing PubMed, EMBASE, and Web of Science. The researchers narrowed 3,346 to six randomized control studies that adequately addressed their clinical question.
- These studies randomized patients into two groups:
  - Prolonged immobilization
  - Accelerated rehabilitation (i.e., early weight bearing, early controlled motion of the ankle joint, or both)
- The data was compiled between the studies using two metrics:
  - Achilles tendon rupture score (ATRS): standardized 10-question survey assessing symptoms and physical activity level after AATR. A high score correlated with a decrease in limitations/difficulties related to Achilles tendon injury. This metric was compared through a mean difference of the averages for each group.
  - Re-rupture risk was assessed by the number of re-ruptures in at least a six-month period and was assessed using odds ratios.

INTERVENTION (# IN THE GROUP): 204

COMPARISON (# IN THE GROUP): 202

FOLLOW-UP PERIOD: Length of time

RESULTS:

Primary Outcome –

- Accelerated rehabilitation did not influence patient-reported levels of limitations or difficulties compared to prolonged immobilization (mean difference –0.93; 95% CI, –6.0 to 4.1).

Secondary Outcome –

- There was no difference in Achilles re-rupture risk between prolonged immobilization and accelerated rehabilitation in the observed follow-up periods (odds ratio 0.97; 95% CI, 0.46–2.0).

LIMITATIONS:

- The study was small and included only 406 participants.
- The definition of accelerated rehabilitation varied between studies. Some studies focused on early weight bearing vs early mobilization vs focusing on both. There was also a difference in the timing of early weight bearing. This makes the reproducibility of the study and the determination of a recommended treatment protocol challenging.
- There was a low number of female participants and no pediatric participants.

- The study did not address potential randomization for comorbid conditions that could affect tendon healing.
- It was difficult for studies to monitor patient adherence to the treatment protocols outside of the clinical setting (i.e., patients not strictly adhering to non-weight bearing protocol).

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The views expressed in this GEM are the authors' and do not reflect the official policy or position of the U.S. Army, the Tripler Army Medical Center, or the U.S. government.

Are Opioid Treatment Programs Really the Best Option for Methadone Maintenance Therapy for Opioid Use Disorder?

Office-Based Methadone Treatment for Opioid Use Disorder and Pharmacy Dispensing: A Scoping Review

McCarty D, Bougatsos C, Chan B, et al. Office-Based Methadone Treatment for Opioid Use Disorder and Pharmacy Dispensing: A Scoping Review. *Am J Psychiatry*. 2021;178(9):804-817. doi:10.1176/appi.ajp.2021.20101548

KEY TAKEAWAY: Patients stable on methadone have similar outcomes in treatment retention, treatment satisfaction, employment, and engagement in family/social activities whether the treatment was office-based or at opioid treatment programs.

STUDY DESIGN: Systemic review of 21 studies (6 randomized control trials, 8 observational studies, 4 descriptive studies)

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: Currently, methadone is virtually only prescribed in federally certified opioid treatment programs (OTPs) in the United States. This restricts access to life-saving treatment, particularly in rural areas, as most OTPs are urban-based. In many other countries, however, office-based methadone treatment, with prescriptions by primary care physicians (PCPs), and dispensing at pharmacies is the standard of care. This paper aims to assess whether office-based methadone treatment can enhance access without affecting outcomes and potentially modify federal regulations.

PATIENTS: Patients with opioid use disorder receiving methadone treatment

INTERVENTION: Office-based methadone treatment

CONTROL: OTP-based methadone treatment

PRIMARY OUTCOME: Treatment retention, positive urine drug screens, satisfaction with care, quality of life

METHODS (BRIEF DESCRIPTION):

- The Cochrane database and Ovid Medline were searched, in addition to reference lists of relevant articles. The studies focused on methadone dispensing in office-based settings or through the pharmacy.
- Randomized control trials and controlled observational studies were prioritized. Descriptive and observational studies were included when priority evidence was unavailable.
- Studies were eligible if treatment was conducted in the United States or other highly developed countries These included France, Australia, United Kingdom, and Ireland.
- The authors used a descriptive approach to summarize the literature and did not synthesize or grade the quality of evidence when assessing outcomes of treating patients with opioid use disorder with methadone in office-based settings.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Six months to 15 years

RESULTS:

- In the United States randomized controlled trials (RCTs) comparing office-based prescribing vs care at OTPs found no differences in illicit drug use, satisfaction was similar or rated higher with office-based care, retention rates were similar or higher with office-based care, and patients initiated new employment and family and social services at a similar or higher rate with office-based care.
- In non-United States RCTs, retention rates were similar between treatment locations, and methadone induction in the primary care setting was feasible and acceptable to physicians and patients.
- In United States observational studies, there were low rates of illicit drug use and diversion, high rates of retention, and patients reported increased satisfaction and improvement in quality of life in office-based programs.
- In non-United States observational studies, there were lower rates of illicit drug use, psychological health problems, and crime rates in office-based programs.
- In pharmacy studies, there were higher retention rates and employment rates, lower rates of illicit drug use, and drive times, and a decrease in methadone-related deaths in office-based programs.

LIMITATIONS:

- The United States RCTs were unblinded and had small sample sizes, making them underpowered and difficult to detect differences in outcomes.
- Study samples were too small to detect infrequent adverse events.
- Follow-up periods varied tremendously.
- Observational studies were primarily descriptive, not controlling for confounders, and didn't include comparison groups.
- Generalizability is difficult because there have been no US studies in the last 20 years.
- Use of historical data from the retrospective analysis may have limited applicability to US settings.

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At Home Blood Pressure Monitor: The New Norm?

Impact of Home Blood Pressure Data Visualization on Hypertension Medical Decision Making in Primary Care

Cohen DJ, Wyte-Lake T, Canfield SM, et al. Impact of Home Blood Pressure Data Visualization on Hypertension Medical Decision Making in Primary Care. *Ann Fam Med*. 2022;20(4):305-311. doi:10.1370/afm.2820

KEY TAKEAWAY: Viewing blood pressure readings either on paper or on an electronic health record (EHR) based visualization tool results in a similar length of discussion with patients.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: High blood pressure (BP) affects more than 100 million Americans and contributes to many health risks including cardiovascular mortality. Only 24–54% of Americans diagnosed with hypertension have controlled BP. Better visualization and understanding of BP readings could potentially contribute to overall improved health outcomes.

PATIENTS: Patients with hypertension

INTERVENTION: BP readings with EHR visualization tool

CONTROL: BP readings on paper

PRIMARY OUTCOME: Length of BP discussion

Secondary Outcome: Length of visit

METHODS (BRIEF DESCRIPTION):

- Patients from 15 primary care providers (PCPs) based in three academic, community-based primary care practices in the Midwestern United States, with home and office BP measurements.
- Patients could use publicly available BP monitors such as those at pharmacies if they did not have their own.
- PCPs reviewed home BP readings and medications with patients, either using paper charts or through an EHR visualization tool.
- Inclusion criteria included practices with the same EHR and patients with HTN.
- Exclusion criteria excluded patients with cognitive impairment, acute illness, and mental illness.
- Most patients in both groups were female, over 60 years old, and identified as White.
- Physicians had an average age of 44.6 years and 79.9% had practiced for six years or more.
- Videos were analyzed qualitatively by a team to assess discussions and similarities between encounters.
- For measures of appointment length and BP discussion efficiency, the time of the total visit, and time of BP discussion were calculated from video recordings.

INTERVENTION (# IN THE GROUP): 47

COMPARISON (# IN THE GROUP): 26

FOLLOW-UP PERIOD: Not available

RESULTS:

Primary Outcome –

- When medication changes were discussed, and BP was not at goal the length of BP discussion in the paper group was on average 6.2 minutes (range 4–9) versus the EHR visualization tool group average of 6.8 minutes (range 2–16).
- When the patient's medications changes were not discussed, and BP controlled the length of BP discussion in the paper group was on average 3.9 minutes (range 1–8) versus the EHR visualization tool group average was 3.2 minutes (range 2–5).

Secondary Outcome –

- When medication changes were discussed, and BP was not at goal the length of visit in the paper group was on average 26.2 minutes (range 15–29) versus the EHR visualization tool group average was 18.8 (range 4–29).
- When medication changes were not discussed, and BP was at goal the length of visit in the paper group was on average 17.5 minutes (range 6–29) versus the EHR visualization tool group average of 17.3 (range 6–28).
- Statistical analysis for significance not conducted for outcomes.

LIMITATIONS:

- The study included a relatively small number of clinics and patients.
- Patient literacy was not considered.
- A potential confounding bias included access and use of home monitors as compared to other BP monitors.

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