GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

Volume 4 - Issue 17

FPIN
Family Physicians Inquiries Network

What's in this week's issue?

Week of April 22 - 26, 2024

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Mindfulness Matters for Chronic Low Back Pain

GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Mindfulness-Based Interventions for Chronic Low Back Pain: A Systematic Review and Meta-Analysis

Paschali M, Lazaridou A, Sadora J, et al. Mindfulness-based Interventions for Chronic Low Back Pain: A Systematic Review and Meta-analysis. *Clin J Pain.* 2024;40(2):105-113. Published 2024 Feb 1. doi:10.1097/AJP.0000000000001173

KEY TAKEAWAY: Mindfulness-based interventions may decrease pain in adults with chronic low back pain (CLBP).

STUDY DESIGN: Systematic review and meta-analysis of 18 studies, including 15 randomized controlled trials (RCTs) and three non-controlled studies (N=873)

LEVEL OF EVIDENCE: STEP 3 (downgraded due to lack of comparison with the control group, significant heterogeneity of surveying methods, and risk for bias)

BRIEF BACKGROUND INFORMATION: CLBP is a leading cause of disability, affecting millions of people. Pharmacotherapy with NSAIDs or opioids have only small, short-term benefits and significant safety risks. Mindfulness-based interventions are safe and prior individual studies demonstrated reductions in pain intensity in patients with CLBP.

PATIENTS: Adults with CLBP

INTERVENTION: Mindfulness-based interventions (MBIs)

CONTROL: Standardized self-reported pain scores pre and post-MBI

PRIMARY OUTCOME: Reduction in pain score from baseline

METHODS (BRIEF DESCRIPTION):

- Patients included adults (mean 54 years old) with CLBP (1 study included adults <45 years old; 1 included adults >65 years old).
- MBIs were comprised of:
  - Mindfulness-based stress reduction (7 studies)
  - Mindful meditation (3 studies)
  - Mindfulness-oriented recovery enhancement (2 studies)
  - Mindfulness-based cognitive therapy, dialectical behavioral therapy, meditative cognitive behavioral therapy, mindfulness-based care for chronic pain, self-compassion, and loving-kindness meditation (1 study each)
- Patient self-assessment at baseline and after MBI with standardized pain scores included:
  - Brief Pain Inventory or Visual or Numerical Analog Scale (11 studies)
  - McGill Pain Questionnaire (3 studies)
  - Multidimensional Pain Inventory (PROMIS) (1 study)
  - Scored from 0–10 with zero for no pain and 10 for the worst pain.

INTERVENTION (# IN THE GROUP): 873

COMPARISON (# IN THE GROUP): 873 (the same cohort of patients scored at the end of the intervention for 18 studies with 19 study arms)

FOLLOW-UP PERIOD:

- Eight weeks (17 studies)
- Two weeks (1 study)

RESULTS:

Primary Outcome –

- MBIs reduced the mean pain compared to baseline (4.4 vs 4.6, respectively; standardized mean difference [SMD] –0.86; 95% CI, –0.95 to –0.77).

LIMITATIONS:

- The authors calculated SMDs between baseline and post-intervention, not between intervention and control groups.
- MBIs were comprised of nine interventions.
- Standardized pain scores comprised five scales.
- Three studies had a narrower age range.
- Three studies had a high risk of bias, although the other 15 had moderate to low risk.

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Pay No Mind to Platelet-Rich Plasma Injections for Acute Achilles Tendon Rupture

Platelet-Rich Plasma Injection for Acute Achilles Tendon Rupture: Two-Year Follow-Up of the PATH-2 Randomized, Placebo-Controlled, Superiority Trial

Keene DJ, Alsousou J, Harrison P, et al. Platelet-rich plasma injection for acute Achilles tendon rupture: two-year follow-up of the PATH-2 randomized, placebo-controlled, superiority trial. *Bone Joint J*. 2022;104-B(11):1256-1265. doi:10.1302/0301-620X.104B11.BJJ-2022-0653.R1

KEY TAKEAWAY: Platelet-rich plasma (PRP) injection does not improve function or quality of life for acute mid-tendon Achilles rupture.

STUDY DESIGN: Placebo-controlled, randomized, multicenter, two-arm single blinded trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: The Achilles tendon is the most ruptured tendon in the human body. Its rupture can result in immediate and prolonged disability. PRP is a popular intervention for musculoskeletal soft-tissue injuries and shows promise for regenerative therapy. Despite positive effects on tendon healing under laboratory conditions, PRP's clinical application is still under heavy investigation, particularly in the context of Achilles ruptures.

PATIENTS: Adults with acute Achilles tendon rupture

INTERVENTION: PRP injection

CONTROL: Placebo injection

PRIMARY OUTCOME: Limitations related to injury
Secondary Outcome: Difficulty to perform tasks, mental and physical wellbeing

METHODS (BRIEF DESCRIPTION):

- Included patients >18 years old with a clinical diagnosis of complete acute mid-tendon Achilles rupture that was managed non-operatively within 12 days of injury and with a history of ability to walk independently before injury.
- Excluded patients were those who had a rupture that was at the level of the tendinous insertion site or musculo-tendon junction, had a history of significant unrelated leg injury or disease (including peripheral vascular disease), diabetes mellitus, hematologic disease, concomitant use of systemic corticosteroids or anticoagulation, pregnancy, breastfeeding, active or recent chemotherapy, or hepatic or renal failure.
- Participants were randomized to intervention via an online allocation system.
    - One group received PRP injections, while the other received placebo injections. The injections were administered by either an attending surgeon (75–76% of injections), surgical resident, fellow, or specialized physical therapists.
        - Placebo injections were an empty syringe administered into the center of the tendon gap.
    - Both groups underwent ankle immobilization for three weeks post-injection, followed by advancement of activity under physical therapist supervision.
    - Both groups completed questionnaires for patient-reported outcomes via face-to-face meetings or over the phone at four, seven, 13, and 24 weeks after randomization, and then again at two years post-intervention.
- Primary outcomes were measured using the Achilles Tendon Rupture Score (ATRS).
    - The ATRS asks patients to grade their perceived level of limitation related to their injured Achilles tendon on a scale of 0 (major limitations) to 10 (no limitations) across 10 categories (limitations due to decreased strength, limitations during activities of daily living, running, and others).
- Secondary outcomes were measured using the Patient Specific Functional Scale (PSFS), and the 12-item Short-Form Health Survey questionnaire (SF-12).
    - The PSFS asks patients to grade three activities important to them that they have difficulty with because of their injury from 0 (unable to perform) to 10 (no difficulty).
    - The SF-12 asks patients to grade general physical and mental well-being across eight domains including physical functioning, bodily pain, general health perceptions, social functioning, and others.

INTERVENTION (# IN THE GROUP): 114
COMPARISON (# IN THE GROUP): 116

FOLLOW-UP PERIOD: Two years

RESULTS:

Primary Outcome –

- There were no significant differences in limitations related to injury at two years between PRP injections and placebo (adjusted mean difference [AMD] –0.75; 95% CI, –5.5 to 4.0).

Secondary Outcome –

- There were no significant differences at the end of two years between PRP injections and placebo in difficulty in performing tasks or mental and physical well-being at two years.
    - Difficulty performing tasks (AMD –0.023; 95% CI, –0.61 to 0.57).
    - Physical well-being (AMD 0.41; 95% CI, –1.8 to 2.6)
    - Mental well-being (AMD –0.15; 95% CI, –2.8 to 2.5)

LIMITATIONS:

- Volumes of collected blood were different between groups (55 mL for PRP, 5 mL for placebo) which may have compromised the blinding process.
- The PSFS and SF-12 may be influenced by recall bias depending on the structure of the questioning (i.e. if patients are asked to recall and make comparisons to pre-injury functional status).

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Personalized Colorectal Cancer Screening in Older Adults

Personalized Multilevel Intervention for Improving Appropriate Use of Colorectal Cancer Screening in Older Adults: A Cluster Randomized Clinical Trial

Saini SD, Lewis CL, Kerr EA, et al. Personalized Multilevel Intervention for Improving Appropriate Use of Colorectal Cancer Screening in Older Adults: A Cluster Randomized Clinical Trial. *JAMA Intern Med*. 2023;183(12):1334-1342. doi:10.1001/jamainternmed.2023.5656

KEY TAKEAWAY: The number of orders a doctor places for colorectal cancer screening does not change when the screening is more individualized.

STUDY DESIGN: Unmasked, clustered randomized clinical trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Current colorectal cancer (CRC) screening guidelines recommend screening all average-risk patients 45–75 years old, however as patients increase in age, the risks vs benefits of screening are not often individualized. Pre-screening tools, such as the Microsimulation Screening Analysis-Colon (MISCAN-Colon), may be used to better assess an individual's risk and help both patients and clinicians make a more informed decision about CRC screening.

PATIENTS: Adults 70—75 years old

INTERVENTION: Personalized information booklet

CONTROL: General information booklet

PRIMARY OUTCOME: Rate of ordering CRC screening

Secondary Outcome: Rate of screening completion, association of screening order placement with initial personal risk

METHODS (BRIEF DESCRIPTION):

- The study was conducted at two sites in the Veterans Affairs (VA) healthcare system in Ann Arbor, Michigan.
- Patients were included if they were at an average risk for CRC and currently due for CRC screening based on the 2008 US Preventive Services Task Force (USPSTF) guidelines.
- Patients were excluded if they were at increased CRC risk (based on personal or family history), had limited life expectancy, were previously documented to have declined screening, scheduled for an urgent appointment or hospital follow-up, or had a medical decision maker.
- The intervention group received a personalized CRC screening decision aid booklet using the MISCAN-Colon tool that included risks and benefits of screening based on age, sex, prior screening, and comorbidities.
- The control group received a general CRC screening informational booklet.
- Both groups received primary care provider (PCP) counseling and education and were offered one of three CRC screening options (FIT test, colonoscopy, or flexible sigmoidoscopy).
- Participating PCPs received standardized CRC screening education and training. In addition, the provider CRC screening performance metric was modified during the study to promote more individualized screening decisions.
- Two weeks after the intervention, patients' charts were reviewed to evaluate the total number of CRC screening tests ordered in each group.
- Six months after the intervention, patients' charts were reviewed for CRC screening completion.

INTERVENTION (# IN THE GROUP): 258

COMPARISON (# IN THE GROUP): 173

FOLLOW-UP PERIOD: Two weeks and six months

RESULTS:

Primary Outcome –

- There was no significant difference in the overall number of CRC screening orders placed in the intervention group compared to control (63% vs 66%, respectively; –4.0 percentage points; 95% CI, –15 to 7.4).

Secondary Outcome –

- CRC screening completion was higher in the control group compared to the the intervention group (56% vs 41%, respectively; –13 percentage points; 95% CI, –25 to –1.6).
- Low-risk patients in the intervention group were less likely to receive screening orders when compared to the control (59% vs 71%, respectively).
- High-risk patients receiving the intervention were more likely to receive screening orders when

compared to the control (68% vs 52%, respectively; correlation coefficient 0.05; *P*=.049).

LIMITATIONS:

- 98% of the participants were male and 87% were White, which limited generalizability.
- The study was performed at two VA facilities in one area of the country, which also limited generalizability.
- The predominant CRC screening ordered was FIT, which is less likely to cause harm and could have been a more attractive screening option when compared to colonoscopy.

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The opinions and assertions contained herein are those of the authors and are not to be construed as official or as reflecting the views of the US Navy Medical Department, the Navy at large, or the Department of Defense.

Let's Play: Time in Season or in Game and Injury Prevalence

Time of Season and Game Segment is Not Related to Likelihood of Lower-Limb Injuries: A Meta-Analysis

Doyle TLA, Schilaty ND, Webster KE, Hewett TE. Time of Season and Game Segment Is Not Related to Likelihood of Lower-Limb Injuries: A Meta-Analysis. *Clin J Sport Med*. 2021;31(3):304-312.
doi:10.1097/JSM.0000000000000752

KEY TAKEAWAY: The risk of anterior cruciate ligament (ACL), groin, or hamstring injury is not associated with the time in game segment or the time of season the athlete is in.

STUDY DESIGN: Meta-analysis of 21 total sets of data from 15 epidemiological studies (12,678 total injuries)

LEVEL OF EVIDENCE: STEP 1

BRIEF BACKGROUND INFORMATION: The prevailing hypothesis is that fatigued muscles absorb less energy, which leads to overstretching, structure failure, and ultimately injury. Although there are studies that have investigated the change that can occur in lower-limb mechanics with laboratory-induced acute fatigue, there is limited research on the effect of game segment or the time of season on injury occurrence. The aim of this meta-analysis is to determine what effects, if any, the time of season or game segment has on injury incidence.

PATIENTS: Injured athletes

INTERVENTION: Effect of time of season and game segment

CONTROL: Not applicable

PRIMARY OUTCOME: ACL, hamstring, and groin injury

METHODS (BRIEF DESCRIPTION):

- Patient inclusion criteria: "Level 1" athletes of both sexes and all ages who sustained ACL, groin, or hamstring injuries where the timing of injury occurrence with respect to season or game segment could be determined.
- Players of all National Collegiate Athletics Association (NCAA) sports were included to include rugby, football, soccer, and basketball.
- Data was used to determine the incidence of ACL, groin, or hamstring injuries, outlined by when in the season and the game segment the injury occurred.
- The timing of the injuries were compared between the 1st and 2nd halves of the season, and the 1st and 2nd halves of the game.
- The primary outcome was measured as injury to the ACL, hamstring, and groin in the athletes.
- Odds ratio >1 denoted injury tended to occur earlier in season, or earlier in game segment.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Not available

RESULTS:

Primary Outcome –

- There was no evidence that timing in the sports season influences injuries between the 1st vs 2nd halves of the season.
  - ACL (odd ratio [OR] 1.3; 95% CI, 0.43–3.8)
  - Groin (OR 1.8; 95% CI, 0.63–5.1)
  - Hamstring (OR 1.2; 95% CI, 0.88–1.5)
- There was no difference in incidence of ACL or hamstring injuries between 1st and 2nd halves of games.
  - ACL (OR 0.43; 95% CI, 0.07–2.6)
  - Hamstring (OR 0.85; 95% CI, 0.58–1.2)

LIMITATIONS:

- The meta-analysis only looks at the timing of the injury within the game or season, it does not show if the injuries are fatigue related.
- A scarce number of articles provided sufficient detail as to the timing of the injuries within the season/game, or detail on the type of injury sustained. This limited the power of the study.
- Meta-analysis only looked at absolute numbers of injuries, with no consideration for how many minutes a player played.
- The study did not explore injury patterns between different sexes and different sports.

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