GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of May 23 - 27, 2022

SPOTLIGHT: Home Not-So-Sweet Home: Exploring the Adverse Events When Long-Term Care Residents Transition Back to the Nursing Home

- Do PRP Injections Help Patients with Knee Pain?
- May the Force: Does MET Work to Treat Low Back Pain?
- Can a Novel Omega-3 Agent be Effective in Treating Severe Hypertriglyceridemia?

Home Not-So-Sweet Home: Exploring the Adverse Events When Long-Term Care Residents Transition Back to the Nursing Home

GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Adverse Events in Long-term Care Residents Transitioning from Hospital Back to Nursing Home

Kapoor A, Field T, Handler S, et al. Adverse Events in Long-term Care Residents Transitioning from Hospital Back to Nursing Home. *JAMA Intern Med*. 2019; 179(9):1254–1261. doi:10.1001/jamainternmed.2019.2005

KEY TAKEAWAY: Adverse events developed in nearly 4 out of 10 discharges from hospital back to long-term care centers. While many of them could be considered "less serious", most were preventable or ameliorable.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: Adverse events are very common when Long-term Care (LTC) residents transition from hospital stays back to LTC. Some examples include medication interactions, skin tears, falls, and pressure ulcers. It's important to understand why these events happen and how we can work to prevent them.

PATIENTS: Long-term care residents that are transitioning from inpatient back to LTC

INTERVENTION: Hospitalization

CONTROL: No hospitalization

OUTCOME: Adverse events

METHODS (BRIEF DESCRIPTION):

- Participants included 555 LTC residents randomly selected from 32 nursing homes in six New England states.
- LTC residents were followed for 45 days after being discharged from the hospital.
- Study of LTC residents discharged from hospital back to LTC from March 1, 2016 to December 31, 2017.
- The comparison group were LTC residents in the United States who experienced an adverse event that were not recently discharged from the hospital. This database is compiled by the Center for Medicare and Medicaid Services.
- Adverse events were identified using the definition outlined by the Harvard Medical Practice Study.
- Nurses completed chart abstractions to identify adverse events. Physicians made the final judgments about the validity of the adverse events.
- A K between 0.60 and 0.80 reflects substantial agreement, and a score between 0.41 and 0.60 represents moderate agreement.

INTERVENTION (# IN THE GROUP): 555 LTC residents, with a total of 762 discharges

COMPARISON (# IN THE GROUP): Not available

FOLLOW UP PERIOD: 45 days

RESULTS:

- Physician reviewers judged 379 of the 716 possible events (53%) to be adverse events (substantial agreement; K=0.61; 95% CI, 0.55–0.66).
- The most common adverse events were related to resident care with pressure ulcers, skin tears, and falls with injury (197).
- Health care-acquired infections (108) and events related to medication (64) were the next most common categories of adverse events.
- Of the 379 total adverse events, 267 (70%) adverse events were found to be preventable or ameliorable, with less serious events more often considered preventable or ameliorable compared with more severe events.
  - Severity: Moderate agreement (K=0.42; 95% CI, 0.35–0.49)
  - Preventability: Moderate agreement (K=0.35; 95% CI, 0.26–0.45)

LIMITATIONS:

- Nursing homes were only sampled in New England vs. the entire United States which limits generalizability.
- There is subjectivity when it comes to classifying adverse events because the nurses auditing the charts were responsible for deciding if the adverse events met the criteria identified by the Harvard Medical Practice Study.
- The retrospective review of charts using the trigger tool methodology will not capture all adverse events.
- Some events were not able to be deemed preventable vs unpreventable due to lack of access of the entire hospital record.
- The association between patient characteristics and patient care guidelines were not fully studied.

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Do PRP Injections Help Patients with Knee Pain?

Effect of Intra-articular Platelet-Rich Plasma vs Placebo Injection on Pain and Medial Tibial Cartilage Volume in Patients with Knee Osteoarthritis: The RESTORE Randomized Clinical Trial

Bennell KL, Paterson KL, Metcalf BR, et al. Effect of Intra-articular Platelet-Rich Plasma vs Placebo Injection on Pain and Medial Tibial Cartilage Volume in Patients With Knee Osteoarthritis: The RESTORE Randomized Clinical Trial. *JAMA*. 2021; 326(20):2021–2030. doi:10.1001/jama.2021.19415

KEY TAKEAWAY: Intraarticular platelet-rich plasma (PRP) injections are not more effective than placebo in the management of knee osteoarthritis.

STUDY DESIGN: Multisite, double-blind RCT

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: There are many treatments available for knee osteoarthritis (OA) with varying degrees of effectiveness. Due to the relative safety and proposed mechanism of efficacy, PRP is being used more frequently in the management of knee OA, but there is little direct evidence to support its use.

PATIENTS: Patients at least 50 years old with tibiofemoral OA

INTERVENTION: Autologous PRP injected weekly for three weeks

CONTROL: Saline placebo injected weekly for three weeks

OUTCOME: Pain and medial tibial cartilage volume

METHODS (BRIEF DESCRIPTION):

- Patients with radiographic evidence of mild to moderate tibiofemoral OA, knee pain most days of the week, and average pain score greater than or equal to four (0-10; higher scores=worse pain) were randomly assigned to treatment or placebo using computer generated numbers.
- Each patient in the treatment group received three weekly injections of platelet-rich plasma.
- Outcomes were measured at 12 months and included an evaluation of pain score and radiograph comparison.
- Overall knee pain score was evaluated by the same 11-point pain scale administered at baseline.
- Radiographic findings were measured via tibial cartilage volume, which was assessed at baseline and 12 months with knee MRI evaluated by the same assessor.

INTERVENTION (# IN THE GROUP): 144

COMPARISON (# IN THE GROUP): 144

FOLLOW UP PERIOD: 12 months

RESULTS:

- PRP injections did not reduce pain compared to placebo (Difference between groups -0.4; 95% CI, -0.9 to 0.2).
- PRP injections did not change medial tibial cartilage volume compared to placebo (Difference between groups -0.2%, 95% CI, -1.9 to 1.5%).

LIMITATIONS:

- Large number of comparison (>30) without correction for false discovery rate.
- PRP injection composition is not standard and has many variations.
- Patients in the study included only those with mild to moderate OA, thus results may not apply to those with severe disease.
- Third, the participants from this study were from specific communities and these results may not apply generally to those in the worldwide medical setting.

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May the Force: Does MET Work to Treat Low Back Pain?

The effect of muscles energy technique in the management of chronic mechanical low back pain: A scoping review

Ahmed UA, Nadasan T, Van Oosterwijck J, Maharaj SS. The effect of muscles energy technique in the management of chronic mechanical low back pain: A scoping review. *J Back Musculoskelet Rehabil.* 2021; 34(2):179–193. doi:10.3233/BMR-200011

KEY TAKEAWAY: Muscle Energy Technique (MET) may be effective in improving the self-management of mechanical low-back pain (MLBP); thus preventing long-term disability and improving function and activity limitations in patients with chronic MLBP.

STUDY DESIGN: Systematic review of 11 articles (10 RCTs and 1 case study; N= 376)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to lack of statistical analysis)

BRIEF BACKGROUND INFORMATION: Low back pain (LBP) is one of the most prevalent musculoskeletal conditions leading to activity limitations. MET can provide a non-invasive, safe, and inexpensive treatment option preventing long-term disability, improving function, and decreasing activity limitations.

PATIENTS: Patients with mechanical low back pain (MLBP)

INTERVENTION: MET

CONTROL: Conventional therapy (TENS, therapeutic U/s, mobility exercises)

OUTCOME: Safety and efficacy

Secondary Outcomes: Pain and disability

METHODS (BRIEF DESCRIPTION):

- Among the selected studies, two studies were carried out in North Africa, three were conducted in India, two in North America, one in South America, and two in Europe. All studies included both males and females with chronic MLBP 20 to 60 years old.
- Interventions ranged from five to 24 sessions, conducted within a span of one to eight weeks.
  - Sham group: Detuned ultrasound, controlled corrective positioning of the participants, and specific adjuvant exercises aimed at treating specific musculoskeletal dysfunction including stretching, strengthening and self-correction exercises
  - Non-specific exercise program: Aerobics and lower limb stretching exercises
  - MET treatment group
- Pain and disability-related outcomes were measured using self-reported clinical outcome measures that included visual analogue scales, numeric pain rating scales, or validated questionnaires like the Oswestry Disability Index (ODI) or Quebec Back Pain Disability Scale (QBPDS).
- Trunk ROM measured by electrogoniometres, inclinometers, measuring tape, and performance of the modified-modified Schober test.
- No statistical analysis was completed

INTERVENTION (# IN THE GROUP): 188

COMPARISON (# IN THE GROUP): 188

FOLLOW UP PERIOD: 2 weeks to 6 months

RESULTS:

Primary Outcome –

- Analysis of the retrieved articles showed that MET is a favorable intervention that is safe and can be effective as a standalone treatment or in combination with other treatment strategies for patients with chronic MLBP with physical and psychosocial benefits.

Secondary Outcome –

- MET plus specific exercises of the trunk muscles was effective in reducing pain, but there was no significant change in functional disability. However, the authors argued that it is possible that reducing solely the LBP complaints does not address psychosocial or other factors that may contribute to disability.

LIMITATIONS:

- Small sample size.
- Lack of a control group.
- The intervention periods and number of sessions might have been too limited to be able to reverse some outcomes in this chronic population.
- Single blinding of the assessors resulted in high risks of bias.
- Lack of statistical analyses.

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Can a Novel Omega-3 Agent be Effective in Treating Severe Hypertriglyceridemia?

Effectiveness of a Novel ω-3 Krill Oil Agent in Patients with Severe Hypertriglyceridemia: A Randomized Clinical Trial

Mozaffarian D, Maki KC, Bays HE, et al. Effectiveness of a Novel ω-3 Krill Oil Agent in Patients With Severe Hypertriglyceridemia: A Randomized Clinical Trial. *JAMA Netw Open*. 2022; 5(1):e2141898. Published 2022 Jan 4. doi:10.1001/jamanetworkopen.2021.41898

KEY TAKEAWAY: Omega-3-phospholipid/free fatty acid (ω-3-PL/FFA) may safely reduce triglyceride levels in adults with severe hypertriglyceridemia. Patient-oriented outcomes were not assessed.

STUDY DESIGN: Two-pooled, multi-site, double-blind, randomized placebo-controlled trials

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Hypertriglyceridemia can increase the risk of cardiovascular disease and is associated with an increased risk of renal disease, hypothyroidism, and fatty liver disease. There is great interest in finding a treatment that reduces triglyceride levels without causing adverse effects.

PATIENTS: Adults with severe hypertriglyceridemia

INTERVENTION: 4 g of ω-3-PL/FFA every day

CONTROL: Cornstarch

OUTCOME: Fasting triglycerides (TG) level at 12 weeks

Secondary Outcomes: Fasting TG level at 26 weeks, adverse events, cholesterol, HDL, LDL

METHODS (BRIEF DESCRIPTION):

- Adults with fasting TG levels of 500 to 1,500 mg/dL at two qualification visits, were randomly assigned to receive either ω-3-PL/FFA or cornstarch placebo after a 4-6 week diet, lifestyle, and medication stabilization period.
- Participants already on other lipid lowering agents were included.
- Patients were randomized 2.5:1 (ω-3-PL/FFA: placebo).
- Patients were seen at 4, 11, 12, 18 and 26 weeks for urinalysis, dietary counseling, physical examination, and fasting blood draw.
- The percentage change in fasting TG levels was calculated at 12 and 26 weeks.
- Percent changes in total cholesterol, HDL, and LDL were also measured.

INTERVENTION (# IN THE GROUP): 372

COMPARISON (# IN THE GROUP): 148

FOLLOW UP PERIOD: 26 weeks

RESULTS:

Primary Outcome –

- ω-3-PL/FFA reduced TG levels in more participants than the placebo group at 12 weeks (26% vs 15%; difference -11%; 95% CI, -20% to -1.5%).

Secondary Outcomes –

- ω-3-PL/FFA reduced TG levels in more participants than the placebo group at 26 weeks (34% vs 21%; difference -13%; 95% CI, -23% to -2.4%).
- There was no statistically significant difference in adverse events or percent change in total cholesterol, HDL, or LDL levels.

LIMITATIONS:

- The statistical power was low due to the similarity in differences between the placebo and treatment groups requiring the pooling of two trials.
- Although to a lesser degree, the placebo group also demonstrated a significant reduction in TG levels.
- Principal investigator of this trial served as a consultant for the sponsor of this study, Acasti Pharma Inc.

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