GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of May 16 - 20, 2022

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Breathe Don't Barf: A Combination Approach to Rumination Syndrome Treatment

GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Outcomes of Treating Rumination Syndrome with a Tricyclic Antidepressant and Diaphragmatic Breathing

Robles A, Romero YA, Tatro E, Quezada H, McCallum RW. Outcomes of Treating Rumination Syndrome with a Tricyclic Antidepressant and Diaphragmatic Breathing. *Am J Med Sci*. 2020; 360(1):42–49. doi:10.1016/j.amjms.2020.04.003

KEY TAKEAWAY: Combining a tricyclic antidepressant (TCA) with diaphragmatic breathing/relaxation techniques is an effective treatment approach for the management of rumination syndrome (RS).

STUDY DESIGN: Single, non-blinded trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small sample size and lack of statistical analysis)

BRIEF BACKGROUND INFORMATION: Rumination syndrome (RS) is a functional gastrointestinal disorder characterized by effortless postprandial regurgitation and accompanied by gastric visceral hypersensitivity and is often misdiagnosed. The onset of symptoms is commonly preceded by a psychologically stressful event, often with anxiety as an accompanying complaint. In this background of gastric visceral hypersensitivity, anxiety, and psychological stress, the combination of TCA with diaphragmatic breathing/relaxation techniques for the treatment of RS was evaluated.

PATIENTS: Adults with RS

INTERVENTION: Diaphragmatic breathing and TCA medication

CONTROL: Baseline

OUTCOME: Baseline improvement

Secondary Outcome: Social wellbeing, weight, pain medication use, GI symptoms

METHODS (BRIEF DESCRIPTION):

- 44 patients were referred to an academic motility center that met the Rome IV criteria for RS.
- Each patient received hands on instructions and/or diaphragmatic breathing technique, along with relaxing auditory media, and were started on a TCA for a minimum of three months.
- TCA dosing was nortriptyline 42.5 mg, amitriptyline 74.6 mg, or doxepin 20 mg or 50 mg.
- After a minimum of three months of therapy, participants were seen in person or interviewed over the phone and asked to complete a symptom questionnaire.
- Outcomes were measured by descriptive data and displayed as number of patients, percentage, or mean.

INTERVENTION (# IN THE GROUP): 44

COMPARISON (# IN THE GROUP): Not applicable

FOLLOW UP PERIOD: Three months

RESULTS:

Primary Outcome –

- Combining a TCA with diaphragmatic breathing/relaxation techniques resulted in 91% of patients reporting improvement, with a mean subjective improvement from baseline of 69%.

Secondary Outcome –

- The average time to notice improvement of symptoms was 6.3 weeks.
- Weight increased or stabilized in 81% of patients who reported previous weight loss.
- 90% of patients reported improvement in abdominal wall pain.
- 82% stopped taking opioid pain medication at time of follow-up.
- 100% of patients with J-tubes at start of study had J-tubes removed due to weight gain
- Patients that started with TPN were transitioned to J-tubes.
- 55% of patients reported that their symptoms "never" affected their ability to engage in and/or function in school, work, personal relationships and/or desired hobbies.

LIMITATIONS:

- Unblinded, non-randomized, single-center study.
- Small number of participants.
- Study is limited to the outcomes of one drug class (TCA).
- Lack of validated symptom questionnaire.
- No statistical analysis conducted.

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How to Save Money in the ED? Social Workers May Be the Answer

Association of a Geriatric Emergency Department Innovation Program With Cost Outcomes Among Medicare Beneficiaries

Hwang U, Dresden SM, Vargas-Torres C, et al. Association of a Geriatric Emergency Department Innovation Program With Cost Outcomes Among Medicare Beneficiaries [published correction appears in JAMA Netw Open. 2021 Mar 1;4(3):e217149] [published correction appears in JAMA Netw Open. 2021 Jun 1;4(6):e2117178]. *JAMA Netw Open*. 2021; 4(3):e2037334. Published 2021 Mar 1. doi:10.1001/jamanetworkopen.2020.37334

KEY TAKEAWAY: Providing geriatric evaluation and treatment in the ED setting through transitional care nurses or social workers is associated with decreased Medicare costs.

STUDY DESIGN: Prospective cross-sectional study

LEVEL OF EVIDENCE: STEP 4

BRIEF BACKGROUND INFORMATION: The aging of the US population reflects increased utilization of medical resources in all healthcare environments. The Geriatric Emergency Department (GED) was conceptualized in 2007 and accredited in 2018 by ACEP. GEDs have been shown to decrease length of inpatient treatment, reduce admissions, and reduce 30-day readmissions. The purpose of this study was to evaluate the effect on total Medicare payer costs by comparing patients seen by a transitional care nurse (TCN) and/or a social worker (SW) administering GED initiatives.

PATIENTS: Medicare fee-for-service (FFS) beneficiaries ≥ 65 years old

INTERVENTION: GEDI WISE program consultation

CONTROL: No intervention

OUTCOME: Cost

Secondary Outcome: Bundled value effects

METHODS (BRIEF DESCRIPTION):

- ED patients were screened for participation qualification.
  - Inclusion criteria: 65-118 years old, Medicare fee-for-service (FFS) beneficiaries enrolled for a minimum of 12 months, Emergency Severity Index (ESI) >1
  - Exclusion criteria: patients who left ED against medical advice, critically ill patients
- Intervention was defined as evaluation and resources provided by GEDI WISE protocol trained SW or TCN.
- Medicare charges were tracked following initial ED visit over 60 days.
- Medicare expenditures were calculated summing all payments from Medicare claims in dollars, inclusive of hospital admissions or discharges from the ED of all services rendered to the beneficiary as recorded in their outpatient, inpatient, carrier, DME, home health services, hospice, and skilled nursing facility claim files.

INTERVENTION (# IN THE GROUP): 24,839

COMPARISON (# IN THE GROUP): 20,798

FOLLOW UP PERIOD: 60 days

RESULTS:

- Treatment was associated with statistically significant mean savings per beneficiary.
- 30 days after ED index encounter
  - Mount Sinai Medical Center (MSMC) ED $2,436 (95% CI, $1,760–$3,111)
  - Northwestern Memorial Hospital (NMH) ED $2,905 (95% CI, $2,378–$3,431)
- 60 days after ED index encounter
  - MSMC ED $1,200 (95% CI, $231–$2,169)
  - NMH ED $3,202 (95% CI, $2,452–$3,951)

LIMITATIONS:

- The degree to which the TCN or SW provided and facilitated geriatric focused care per patient was not measured.
- The exclusion criteria may limit generalizability.
- Variation in implementation at the two sites were not measured.

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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 Air Force Medical Department, the Air Force at large, or the Department of Defense.

Catching Zzzs and Cutting Lbs: Does Increased Sleep Duration Result in Decreased Energy Intake and Weight in Overweight Adults?

Effect of sleep extension on objectively assessed energy intake among adults with overweight in real-life settings: A randomized clinical trial.

Tasali E, Wroblewski K, Kahn E, Kilkus J, Schoeller DA. Effect of Sleep Extension on Objectively Assessed Energy Intake Among Adults With Overweight in Real-life Settings: A Randomized Clinical Trial. *JAMA Intern Med*. 2022; 182(4):365–374. doi:10.1001/jamainternmed.2021.8098

KEY TAKEAWAY: Sleep counseling may reduce energy intake and be an effective, short-term weight loss strategy for overweight adults.

STUDY DESIGN: Single-center, blinded, parallel-group, randomized clinical trial (RCT)

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Obesity and lack of sleep are health epidemics with adverse health consequences. Despite a growing body of evidence that lack of sleep may contribute to obesity, there has been little studied about increased sleep duration as an approach to decrease energy intake and to enact weight loss.

PATIENTS: Overweight adult men and women with habitual sleep of <6.5 hours of sleep per night

INTERVENTION: Individualized counseling with a goal of 8.5 hours of sleep per night

CONTROL: No treatment

OUTCOME: Change in energy intake, energy expenditure, and body weight from baseline

Secondary Outcome: Significance in changes for sex or presence of menses covariables

METHODS (BRIEF DESCRIPTION):

- 80 adult patients 21-40 years old who were overweight (BMI 25-29.9) and with a mean sleep duration of less than 6.5 hours of sleep per night over the previous six months were enrolled and randomized after a 2-week habitual sleep period at baseline.
- All patients had their sleep continuously monitored by wrist actigraphy within their home environments. Patients had their weights tracked on a blinded scale twice each morning fasting.
- All participants were initially blinded. At the 2-week follow-up, the intervention group was unblinded while the control group remained blinded for the remainder of the study.
- Energy intake, energy expenditure, body weight and composition were calculated at the end of each 2-week period with change in energy intake from baseline as the primary outcome.
- Secondary analyses were conducted to see if significance for sex or presence of menses covariables.

INTERVENTION (# IN THE GROUP): 40

COMPARISON (# IN THE GROUP): 40

FOLLOW UP PERIOD: 28 days

RESULTS:

Primary Outcome –

- Sleep counseling resulted in decreased energy intake (-270 kcal/d; 95% CI, -393 to -147 kcal/day).
- There were no differences in energy expenditure between the groups (-54 kcal/d; 95% CI, -135 to 27 kcal/day).
- Sleep counseling resulted in weight reduction (-0.87 kg; 95% CI, -1.4 to -0.35).

Secondary Outcome –

- Outcomes for energy intake, energy expenditure, and weight reduction were similar across sexes and in the presence of menses.

LIMITATIONS:

- Study was conducted over a short period of time, unclear if results can be generalized for longer periods of time or with greater magnitude.
- Limited generalizability to a typical primary care population.
  - Very strict exclusion criteria including, but not limited to: absence of acute or chronic medical conditions, prior or current psychiatric conditions, diabetes, OSA, irregular menses, or napping.
- Single-blinded study design where only the control group remained blinded throughout the duration of the study.
- Unclear if wrist actigraphy is an accurate depiction of sleep patterns and duration.

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The New Frontier in Type I Diabetes Management: The Artificial Pancreas

Randomized Trial of Closed-Loop Control in Very Young Children with Type 1 Diabetes

Ware J, Allen JM, Boughton CK, et al. Randomized Trial of Closed-Loop Control in Very Young Children with Type 1 Diabetes. *N Engl J Med.* 2022; 386(3):209–219. doi:10.1056/NEJMoa2111673

KEY TAKEAWAY: Hybrid closed-loop therapy safely improves glycemic control in very young children with type I diabetes as compared with sensor-augmented pump therapy.

STUDY DESIGN: Open-label, multicenter, randomized, crossover trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Management of type I diabetes in very young children can be difficult for various physiological and practical reasons. Sensor-augmented pump therapy is becoming more popular but has not been shown to improve glycemic control in this age group. Hybrid closed-loop systems (i.e., artificial pancreas) may be a better alternative, but has not been studied well enough in these patients.

PATIENTS: Children one to seven years old with Type I Diabetes

INTERVENTION: Hybrid closed-loop therapy

CONTROL: Sensor-augmented pump therapy

OUTCOME: Time spent in the target glucose range, glycated hemoglobin, time spent in hypo- or hyper glycemic state

Secondary Outcome: Adverse events

METHODS (BRIEF DESCRIPTION):

- 74 pediatric patients on insulin-pump therapy were randomized to first receive:
  - Closed-loop therapy: artificial pancreas consisting of continuous glucose monitor controlling an insulin pump via an algorithm
  - Sensor-augmented pump therapy: user must manually adjust basal dosages
- Participants received their assigned initial therapy for 16 weeks, then underwent a one-to-four-week washout period, and finally received 16 weeks of the other therapy.
- Participants' device use and blood glucose levels were assessed at the end of both trial periods. They were also contacted throughout the study period to monitor for adverse effects.

INTERVENTION (# IN THE GROUP):

- Closed-loop period first group: 39
- Sensor-augmented pump period first group: 35

COMPARISON (# IN THE GROUP): Not available

FOLLOW UP PERIOD: Through end of second treatment

RESULTS:

Primary Outcome –

- Closed-loop therapy resulted in 8.7% more time spent in target glucose range compared to sensor-augmented pump therapy (95% CI, 7.4–9.9).
- Closed-loop therapy resulted in a 0.4% lower glycated hemoglobin compared to sensor-augmented pump therapy (95% CI, −0.5 to −0.3).
- Closed-loop resulted in 8.5% less time in a hyperglycemic state compared to sensor-augmented pump therapy (95% CI, −9.9 to −7.1).
- There was no difference in time spent in a hypoglycemic state or the coefficient of variation of the glucose.

Secondary Outcome –

- There was one serious adverse event of severe hypoglycemia during the closed-loop period and one serious event during the sensor-augmented pump period, but this was determined to be unrelated to treatment.

LIMITATIONS:

- Participants were generally more highly motivated than the general population and did not include those with glycated hemoglobin levels over 11%.
- The trial population did not have adequate representation of ethnic minorities.
- Investigators were free to adjust therapy according to their clinical judgement which may have also affected trial results.

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Conservative vs Surgical Management of Closed, Displaced, Proximal, Humeral Fractures: Who Has Better Functional Outcomes?

Effect of Surgery vs Functional Bracing on Functional Outcome Among Patients with Closed Displaced Humeral Shaft Fractures. The FISH Randomized Clinical Trial. Rämö L, Sumrein BO, Lepola V, et al. Effect of Surgery vs Functional Bracing on Functional Outcome Among Patients With Closed Displaced Humeral Shaft Fractures: The FISH Randomized Clinical Trial. *JAMA.* 2020; 323(18):1792–1801. doi:10.1001/jama.2020.3182

KEY TAKEAWAY: In patients with closed, displaced, proximal humeral fractures, surgical fixation may improve disability, pain, and function more than operative bracing at six weeks. However, surgical fixation did not improve any outcomes more than functional bracing at 12 months.
STUDY DESIGN: Multi-center, randomized clinical trial
LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Humeral shaft fractures account for 1-3% of all fractures, with an estimated 60,000 emergency department visits each year. In the past, these fractures have predominantly been managed non-operatively. Surgical fixation, however, is becoming more common despite the lack of evidence supporting it as a more viable treatment option.

PATIENTS: Adults with unilateral, closed, displaced humeral shaft fracture
INTERVENTION: Open reduction and internal fixation (ORIF)
CONTROL: Functional bracing
OUTCOME: Disability at 12 months
Secondary Outcome: Pain, function, range of motion, satisfaction, quality of life, disability before 12 months

METHODS (BRIEF DESCRIPTION):

- Patients were randomly assigned to surgical fixation or functional bracing groups.
  - Surgical fixation: Standard ORIF with plate and screws done by experienced orthopedic surgeon with immediate ROM.
  - Functional Bracing: Plaster technician applied brace covering arm from shoulder to elbow with immediate assisted ROM and progressive rehabilitative program.
- Disability was measured by DASH (0-100; higher scores=more disability; minimal clinical importance= 10 points).
- Questionnaires were completed during follow-up visits and patients were assessed for fracture-related complications.
- Secondary outcomes scales:
  - Pain-at-rest and pain-on-activities were measured on a 10-point scale (0-10; higher scores=more pain; minimal clinical importance= 1.5 points).
  - Shoulder function was measured via Constant-Murley score (0-100; higher scores=better functionality).

INTERVENTION (# IN THE GROUP): 38
COMPARISON (# IN THE GROUP): 44

FOLLOW UP PERIOD: 12 months

RESULTS:
Primary Outcome –

- There was no difference in disability between the surgical and bracing groups at 12 months (between group difference 3.1 points; 95% CI, -9.6 to 3.3).

Secondary Outcome –

- Surgery improved disability more than bracing at:
  - 6 weeks: -9.9 points (95% CI, -16 to -3.5)
  - 3 months: −10.1 points (95% CI, −17 to −3.6)
- Surgery improved pain during activities more than bracing at 6 weeks (between group difference -1.2 points; 95% CI, -2.3 to -0.1).
  - This difference did not meet the threshold for clinical importance.
- Surgery improved function over bracing at 6 weeks (between group difference 31 points; 95% CI, 23 to 39).
- There were no significant between group differences in pain, function, elbow range of motion, quality of life, or patient satisfaction scores at 12 months.

LIMITATIONS:

- Results of the trial are not applicable to all displaced humeral fractures. Many patients were excluded from the study due to fractures that were either too proximal or too distal. Additionally, patients with complex fractures or comorbid conditions were excluded.
- Small sample size.

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