GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

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SPOTLIGHT: Two is Better than One! Adjunct Dexamethasone Improves Pain and Nausea in Acute Renal Colic

Two is Better than One! Adjunct Dexamethasone Improves Pain and Nausea in Acute Renal Colic

Dexamethasone and Ketorolac Compare with Ketorolac Alone in Acute Renal Colic: A Randomized Clinical Trial

Razi A, Farrokhi E, Lotfabadi P, et al. Dexamethasone and ketorolac compare with ketorolac alone in acute renal colic: A randomized clinical trial. *Am J Emerg Med*. 2022;58:245-250. doi:10.1016/j.ajem.2022.05.054

KEY TAKEAWAY: Adding dexamethasone to ketorolac is superior to ketorolac monotherapy for pain relief in acute renal colic and results in less use of narcotics and antiemetics.

STUDY DESIGN: Randomized, double-blind, placebo-controlled clinical trial (N=120)

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: In acute renal colic, NSAIDs are regarded as first-line pain therapy. Though typically effective in these cases, narcotics are limited by their side effect profile. A critical approach to decrease narcotic use is multidrug pain control. The corticosteroid Dexamethasone is a well-establish adjunct administered for enhanced analgesia and antiemetic benefits in anesthesia and surgery, but its utility in acute renal colic has not been studied.

PATIENTS: Patients presenting to the Emergency Department with flank pain due to renal colic

INTERVENTION: 30 mg IV ketorolac with 8 mg IV dexamethasone

CONTROL: 30 mg IV ketorolac with placebo

PRIMARY OUTCOME: Pain severity based on visual analog scale (VAS)

Secondary Outcome: Grade of vomiting and the need for narcotics or antiemetic drugs after the study

METHODS (BRIEF DESCRIPTION):

- At a single Emergency Department in Iran, adults with confirmed acute renal colic were randomly divided into intervention (ketorolac and Dexamethasone) and control (ketorolac and placebo) groups.
- The pain was quantified using a standard 10-point visual analog scale (VAS) immediately before injection and at 30- and 60-minutes post-treatment.
  - VAS scale: 1–3 = mild pain, 4–6 = moderate pain, 7–10 = severe pain.
- Participants were also graded on the severity of nausea and vomiting.
- At 60 minutes, the study concluded, and narcotics or antiemetics were administered for symptom relief if necessary.

INTERVENTION (# IN THE GROUP): 60

COMPARISON (# IN THE GROUP): 60

FOLLOW-UP PERIOD: 1 hour

RESULTS:

Primary Outcome –

- At 30 minutes, the group receiving Dexamethasone had greater reductions in pain scores than those receiving placebo.
  - (–5 vs –3, *P*<.005)
- At 60 minutes, or the study's conclusion, the differences between intervention and placebo were no longer statistically significant.
  - (–7 vs –5, *P*<.068)

Secondary Outcome –

- Those receiving Dexamethasone were less likely to require narcotic pain relief after the study than those who received ketorolac alone.
  - (NNT = 5; 95% CI; 3–19, *P*<.001)
- Those receiving Dexamethasone were less likely to require antiemetic medications after the study than those who received ketorolac alone.
  - (NNT=6; 95% CI; 4–44, *P*<.022)

LIMITATIONS:

- The study was only 60 minutes in duration, without additional follow-up.
- The study was small (120 participants total) and conducted in only one location/population.

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What is the Benefit of Diabetes Education for Diabetes Patients?

The Effect of Education Given to Type 2 Diabetic Individuals on Diabetes Self-Management and Self-Efficacy: Randomized Controlled Trial

Eroglu N, Sabuncu N. The effect of education given to type 2 diabetic individuals on diabetes self-management and self-efficacy: Randomized controlled trial. *Prim Care Diabetes*. 2021;15(3):451-458. doi:10.1016/j.pcd.2021.02.011

KEY TAKEAWAY: Face-to-face diabetes education sessions with an educational booklet was shown to help improve patient self-management, self-efficacy, and metabolic goals in patients with type 2 diabetes.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Many studies have demonstrated a positive correlation between diabetes education and improved metabolic goals. However, few studies have investigated the effect of diabetes education on patient self-efficacy and self-management.

PATIENTS: Adults with type 2 diabetes

INTERVENTION: Diabetes education plus standard of care

CONTROL: Standard of care

PRIMARY OUTCOME: Diabetes self-management, self-efficacy, and metabolic lab values, including HbA1c, lipid panel, fasting blood sugar, and BMI at initial, three, and six months.

METHODS (BRIEF DESCRIPTION):

- Patient inclusion criteria:
  - Patients older than 18 with an A1c value greater than 6.5% who are literate, had not received diabetes education before, and were diagnosed at least six months before the study
- Study intervention:
  - Patients were randomized via a random number generator and split into two groups:
  - The intervention group received face-to-face diabetes education from the primary investigator tailored to the patient's needs and knowledge gaps about their disease.
    - The patients were also given an education booklet to take home.
    - Education sessions averaged 45 minutes and occurred once at the start of a six-month observation period.
  - The control group received standard of care but did not receive diabetes education from the primary investigator or the booklet until after the six-month observation period.
- Outcomes measured:
  - Patient self-management was evaluated using the Diabetes Self-Management Questionnaire (DSMQ), which has 16 questions.
    - This survey evaluates glucose management, dietary control, physical activity, and healthcare use.
    - It scored 0–10, with 10 indicating a patient with a high level of self-management.
    - This was given to patients before and after the six-month period.
  - Patient self-efficacy, defined as "the judgment of an individual regarding the capacity to achieve a certain level of performance," was evaluated with the self-efficacy scale for patients with type 2 diabetes (DSS), which measures diet and food control, medical treatment, and physical exercise.
    - Scores range from 20–100, with higher scores correlating to increased self-efficacy.
    - This was given to patients twice before and after the six-month period.
  - Metabolic measures included in the study were HbA1c, lipid panel, fasting blood sugar, and BMI.
    - These were measured at the start of the six-month period and then every three months.

INTERVENTION (# IN THE GROUP): 40

COMPARISON (# IN THE GROUP): 38

FOLLOW-UP PERIOD: 6 months

RESULTS:

Primary Outcome –

- The intervention group demonstrated a statistically significant increase in self-management scores on the DSMQ after six months over the control group.
  - (Average increase in 5.4 points with *P*=.001)

- The intervention group demonstrated a statistically significant increase in self-efficacy scores on the DSS after six months.
  - (Mean increase of 33 points, *P*=.001).
- The control group also demonstrated a statistically significant increase in DSS scores.
  - (Mean difference 7.7, *P*=.001).
- The difference between the experimental and control groups after six months was also statistically significant (*P*<.01).
- There was a statistically significant drop in HbA1c values, total cholesterol, LDL, fasting blood glucose, and BMI for the intervention group, which was not the case for the control group.
  - Mean HbA1c dropped from 8.8 to 6.5.
  - Mean total cholesterol dropped from 211 to 171.
  - Mean LDL dropped from 135 to 115.
  - Mean fasting blood glucose dropped from 194 to 119.
  - The mean BMI dropped from 31 to 29.

LIMITATIONS:

- The greatest limitation is the small sample size (N=38).
- Most patients in the experimental and control groups were taking various diabetes medications.
  - The data concerning HbA1c values, total cholesterol, LDL, fasting blood glucose, and BMI would have been stronger if they had used patients who were either not on medication yet or were all on the same medication at the same dose.
- 12 patients in the experimental group and eight in the control group study were already experiencing complications of diabetes, indicating greater severity of the disease than the rest of the patients.
  - The data would have been stronger without these patients included in the study.
- There was no reasonable way to "blind" study personnel or patients.

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Is Electroacupuncture In or Out with Depression-Related Insomnia?

Effect of Electroacupuncture on Insomnia in Patients With Depression: A Randomized Clinical Trial

Citation Yin X, Li W, Liang T, et al. Effect of Electroacupuncture on Insomnia in Patients With Depression: A Randomized Clinical Trial. *JAMA Netw Open*. 2022;5(7):e2220563. Published 2022 Jul 1. doi:10.1001/jamanetworkopen.2022.20563

KEY TAKEAWAY: Electroacupuncture (EA) may diminish insomnia and improve well-being in patients suffering from depression.

STUDY DESIGN: Multicenter, patient and assessor-blinded, randomized controlled clinical trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Depression is one of the top leading causes of disability worldwide. The incidence of depression and insomnia co-occurring is expected to continue to rise if modalities are not put in place to mitigate this. Although traditional acupuncture has been an evidence-based practice and successful for years, this modern approach to acupuncture with electrical stimulation is on the rise to becoming the modality of choice for many practitioners.

PATIENTS: Adults with depression and insomnia

INTERVENTION: Electroacupuncture (EA) treatment with standard care, sham Acupuncture (SA) with standard care

CONTROL: Standard care alone

PRIMARY OUTCOME: Sleep quality

Secondary Outcome: Mental health state, sleep efficiency, times of sleep awakenings, total sleep time

METHODS (BRIEF DESCRIPTION):

- 415 adults with co-morbid insomnia and depression were screened from 2016 to 2018 in three hospitals, and 270 eligible adults were recruited.
  - 194 women and 76 men with a mean age of 50.3 years
  - Randomized in a 1:1:1 ratio to receive EA, SA with standard care, or standard care alone
- Before intervention, patients underwent a baseline evaluation of sleep and mental condition using Pittsburgh Sleep Quality Index (PSQI) to assess sleep quality for the past month to measure primary outcome, and higher scores indicated worse sleep quality and more sleep disorders.
- The Insomnia Severity Index, Actigraphy data which objectively assesses patient's sleep status, Depression status using the 17-item Hamilton Depression Rating Scale Score [HDRS-17], anxiety level with Self-rating Anxiety Scale, and the dose of antidepressants (if taken) was used to measure secondary outcome.
  - Higher scores indicated worse quality of sleep and higher depression and anxiety levels, respectively.
- Intervention group: Patients in the EA group received a 30-minute treatment three times a week for eight uninterrupted weeks.
  - The regular acupuncture method was applied at acupuncture points, with 0.25 × 25-mm and 0.30 × 40-mm real needles with rotating or lifting-thrusting manipulation after needle insertion.
  - The two electrodes of the electro-stimulator were then connected to the needles delivering a continuous wave based on the patient's tolerance.
  - Objective measurements were attained through wrist-worn actigraphy.
- Patients in the SA group with standard care felt a pricking sensation when the blunt needle tip touched the skin without needle insertion. All indicators of the nearby electro-stimulator were set to zero, with the light switched on.
- Control group: Patients receiving standard care alone were recommended and guided by psychiatrists to exercise regularly, mindful eating, and manage their stress levels by complying with their prescribed medications.

INTERVENTION (# IN THE GROUP): Electroacupuncture (EA): 90, Sham acupuncture (SA): 90

COMPARISON (# IN THE GROUP): Standard care: 90

FOLLOW-UP PERIOD: Length of time

RESULTS:

Primary Outcome –

- At eight weeks, the EA group had a significant reduction in sleep and mental health symptoms compared to both the SA group and the control group.

- EA vs SA group PSQI score −3.6-point difference (95% CI, −4.4 to −2.8).
- EA vs Control group PSQI score –5.1-point difference (95% CI, −6.0 to −4.2)

Secondary Outcome –

- At eight weeks, the EA group showed significant improvement in sleep efficiency, sleep time, and number of sleep awakenings compared to the SA and control groups.
  - EA vs SA group HDRS-17 score −5.5 (95% CI, −6.8 to −4.3) and −5.8 (95% CI, −6.8 to −4.7), respectively
  - EA vs Control group HDRS-17 score −8.8 (95% CI, −10 to −7.4) and −5.8 (95% CI, −7.1 to −4.5), respectively
- The EA had significantly lower scores on their Insomnia Severity Index, Self-rating Anxiety Scale and had longer total sleep time recorded in the actigraphy than the SA and control group.
  - EA vs SA group sleep efficiency 1.8 (95% CI, –0.2 to 3.7) and 4.2 (95% CI, 2.6–5.8), respectively
  - EA vs control group sleep efficiency 2.4 (95% CI, 0.50–4.4) and 5.4 (95% CI, 3.9–6.9), respectively
  - EA vs SA group Insomnia Severity Index –2.6 (95% CI, −3.4 to −1.8) and –4.3 (95% CI, –5.4 to –3.3), respectively
  - EA vs Control group Insomnia Severity Index –3.7 (95% CI, –4.6 to –2.8) and –6.0 (95% CI, –7.1 to –4.8), respectively
  - EA vs SA group Self-rating Anxiety Scale −1.7 (95% CI, −2.6 to −0.7) and –1.6 (95% CI, –3.0 to –0.10), respectively
  - EA vs Control group Self-rating Anxiety Scale –2.4 (95% CI, –3.5 to –1.3) and –3.2 (95% CI, –4.6 to –1.7), respectively
  - EA vs SA group Total sleep time recorded 13.9 (95% CI, 5.5–22) and 27 (95% CI, 16–39), respectively
  - EA vs Control group Total sleep time recorded 17.3 (95% CI, 9.9–25) and 26.6 (95% CI, 16–37), respectively

LIMITATIONS:

- Acupuncturists were not blinded due to the treatment procedure.
- The blinding exercise was only done once after the completion of the intervention.
- Objective measurements were attained through wrist-worn actigraphy, and due to the scarce number of devices, one or two nights of actigraphy assessment were conducted.
- A longer treatment period could provide explicit objective outcome assessment.
- The Standard care group was not blinded to their allocation.

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Oral Azithromycin and Neonatal Sepsis in West Africa

Effect of Intrapartum Azithromycin vs Placebo on Neonatal Sepsis and Death: A Randomized Clinical Trial

Roca A, Camara B, Bognini JD, et al. Effect of Intrapartum Azithromycin vs Placebo on Neonatal Sepsis and Death: A Randomized Clinical Trial. *JAMA*. 2023;329(9):716-724. doi:10.1001/jama.2022.24388

KEY TAKEAWAY: Oral intrapartum azithromycin does not reduce the risk of neonatal sepsis or mortality.

STUDY DESIGN: Multisite, double-blind, placebo-controlled, randomized clinical trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Sepsis is one of the leading causes of neonatal death worldwide. Data from mass drug administration campaigns in sub-Saharan Africa where azithromycin was given to control trachoma, a chronic keratoconjunctivitis infection caused by recurrent Chlamydia, showed not only a decrease in Chlamydia infection but also a decrease in vertical transmission of other gram-positive and gram-negative bacteria. This suggests that azithromycin may reduce neonatal mortality. This investigation aimed to determine whether intrapartum azithromycin could be beneficial in decreasing neonatal mortality and neonatal sepsis in areas with the highest incidence.

PATIENTS: Pregnant women in active labor

INTERVENTION: Oral azithromycin

CONTROL: Placebo

PRIMARY OUTCOME: Neonatal sepsis or death in the first 28 days of life

Secondary Outcome: Short phrase skin infections, conjunctivitis, umbilical infections, malaria, other antibiotic use, hospitalizations (for newborns), and sepsis, malaria, fever, other antibiotic use, any hospitalization, death (for postpartum parents)

METHODS (BRIEF DESCRIPTION):

- The study was conducted in The Gambia and Burkina Faso.
- Participants were included if they were in active labor and at least 16 years old.
- Participants with known HIV, planned cesarian delivery, acute or chronic conditions, congenital disorders, macrolide allergies, or use of medications known to prolong QT interval were excluded.
- Participants were directed to take 2 g of oral azithromycin or a placebo under direct nurse supervision while in active labor.
- At 28 days post-delivery, participants either had a home visit, telephone visit, or visited the study health facility.
- Neonatal death due to stillbirth, APGAR score less than four, very low birth weight (<1.5 kg), and severe congenital malformations were excluded from the primary outcome data.
- Logistic regression was used to analyze data from the primary outcome. Data from the secondary outcome was analyzed using logistic regression, Fisher exact test, or the Kaplan-Meier method.

INTERVENTION (# IN THE GROUP): 5,991

COMPARISON (# IN THE GROUP): 5,992

FOLLOW-UP PERIOD: 28 days

RESULTS:

Primary Outcome –

- There was no significant difference in neonatal sepsis or mortality between the intervention and control groups.
  - (2.0% vs 1.9%; OR 1.1; 95% CI, 0.8–1.4)

Secondary Outcome –

- Newborns
  - The incidence of skin infections was lower for the intervention group than for the control group.
    - (0.80% vs 1.7%, OR 0.48; 95% CI, 0.34–0.67).
  - There was no significant difference in the incidence of conjunctivitis, umbilical infections, malaria, use of other prescribed antibiotics, or hospitalizations.
- Postpartum parents
  - The intervention group had a decreased incidence of mastitis compared to the control group.
    - (0.30% vs 0.50%; OR 0.53; 95% CI, 0.29–0.98).
  - The intervention group had a decreased incidence of fever compared to the control.
    - (0.10% vs 0.30%; OR 0.39; 95% CI, 0.14-0.98)

- There was no significant difference between the groups with regard to sepsis, malaria, antibiotic use, or hospitalizations.

LIMITATIONS:

- The incidence of infections may have been underreported as the follow-up was limited to a single visit 28 days post-intervention.
- Results may only apply to West African populations.

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