GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of October 10 - 14, 2022

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- Spinal Manipulative Therapy in the Treatment of Chronic Low Back Pain

Spray Away the Pain During IUD Insertion

10% Lidocaine Spray for Pain Control during Intrauterine Device Insertion

Panichyawat N, Mongkornthong T, Wongwananuruk T, Sirimai K. 10% lidocaine spray for pain control during intrauterine device insertion: a randomised, double-blind, placebo-controlled trial. *BMJ Sex Reprod Health*. 2021;47(3):159-165. doi:10.1136/bmjsrh-2020-200670

KEY TAKEAWAY: 10% lidocaine spray is an effective local anesthetic method to significantly reduce pain during copper intrauterine device (IUD) insertion.

STUDY DESIGN: Double-blinded randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Although copper-IUD is an effective, long-acting, reversible form of contraception, patient concerns about pain with the insertion procedure limit such use. Little is known about standard recommendation for pain reduction during IUD insertion.

PATIENTS: Reproductive-age women requesting copper-IUD placement

INTERVENTION: 10% lidocaine spray

CONTROL: Placebo spray

PRIMARY OUTCOME: Pain during IUD insertion

Secondary Outcomes: Pain during speculum placement, tenaculum placement and uterine sounding, and pain after IUD insertion

METHODS (BRIEF DESCRIPTION):

- Reproductive women 18-45 years old at a family planning unit in Thailand who requested copper-IUD placements and were new to cooper-IUDs.
- Patients were randomly assigned to receive either four puffs of 10% lidocaine spray or four puffs of sterile water spray.
- Patients were administered the assigned formulation and waited three minutes to allow for lidocaine to take effect.
- Patients ranked their pain score using a 10 cm Visual Analogue Scale (VAS) with zero being absence of pain and ten being worst pain experienced. These were done during speculum placement, during tenaculum placement, during uterine sounding, during IUD insertion, five mins after insertion, and 20 mins after insertion.

INTERVENTION (# IN THE GROUP): 62

COMPARISON (# IN THE GROUP): 62

FOLLOW UP PERIOD: 20 minutes after IUD insertion

RESULTS:

Primary Outcome –

- During IUD insertion, 10% lidocaine spray was significantly more likely to reduce pain than sterile water spray (median 3.0 vs 5.0, respectively; *P*=.002).

Secondary Outcomes –

- During tenaculum placement and uterine sounding, 10% lidocaine spray was significantly more likely to reduce pain than sterile water spray, but no significant difference in the pain score in speculum placement between the two groups:
  - Tenaculum placement (median 0.8 vs 2.4, respectively; *P*<.001).
  - Uterine sounding (median 2.3 vs 4.1, respectively; *P*≤.001).
  - Speculum placement (median 0.0 vs 0.8, respectively; *P*=.165).
- At both five mins and 20 mins after IUD insertion, 10% lidocaine spray was not effective in reducing pain.
- Significantly more patients in the 10% lidocaine spray group reported vaginal irritation side effect compared to the sterile water group (55 vs 1.6, respectively; *P*≤.001)

LIMITATIONS:

- Anticipatory pain and anxiety were not formally assessed.
- The study evaluated only one type of IUD (Copper T-380A); findings may not be generalizable to other IUD types.
- People with uteruses, including trans-men and gender non-conforming individuals who were assigned female at birth, were not specified in this study.

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A Comprehensive Fall Prevention Program Designed for Care Homes May Decrease Risk of Falls in Non-Community Dwelling Adults

Multifactorial Falls Prevention Programme Compared with Usual Care in UK Care Homes for Older People: Multi Center Cluster Randomized Controlled Trial with Economic Evaluation

Logan PA, Horne JC, Gladman JRF, et al. Multifactorial falls prevention programme compared with usual care in UK care homes for older people: multicentre cluster randomised controlled trial with economic evaluation. *BMJ*. 2021;375:e066991. Published 2021 Dec 7. doi:10.1136/bmj-2021-066991

KEY TAKEAWAY: The Guide to Action for Care Homes, a comprehensive fall screening, reporting, and prevention program, reduces the total number of falls in long-term care homes without decreasing activity or increasing dependency.

STUDY DESIGN: Multicenter, parallel group, randomized controlled trial (84 sites in UK)

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Long-term care home residents are a population more likely to fall than similar age community residents. The Guide to Action for Care Homes (GtACH) is a comprehensive fall prevention program developed in the UK that previously underwent a feasibility study in UK care homes. This study was a randomized control trial performed to compare GtACH against usual care in long-term care homes in the UK.

PATIENTS: Residents of long-term care homes for people over 65 years old or with dementia

INTERVENTION: GtACH comprehensive fall prevention program

CONTROL: Usual care

PRIMARY OUTCOME: Falls at 90–180 days

Secondary Outcomes: Falls at 0–90 days, 180–270 days, and 271–360 days; functional independence; health related quality of life; incremental cost per fall averted

METHODS (BRIEF DESCRIPTION):

- 10 NHS sites recruited care homes in their geographic area.
- Inclusion criteria:
  - Care Homes registered to care for people >65 years old or with dementia
  - At least 10 residents
  - Fall recording system meeting Care Quality Commission recommendations and employing a common definition of a fall already in place
- Control sites practiced usual care and were offered the intervention following study completion.
- Falls were measured using written care plans and incident forms, as well as EMS and hospitalization records collected at 90, 180, 270, and 360 days.
- Number of falls were adjusted for care home type, site, and baseline fall rate.
- Functional independence scores were measured using the Barthel Index.
- Quality adjusted life years were measured using the EuroQoL index and DEMQOL-U self-report tools, or their proxy versions if residents were unable to complete themselves.
- Cost effectiveness of the intervention on quality adjusted life years was estimated using cost of GtACH program, as well as mortality costs.

INTERVENTION (# IN THE GROUP): 775

COMPARISON (# IN THE GROUP): 882

FOLLOW UP PERIOD: 360 days

RESULTS:

Primary Outcome –

- GtACH reduced the number of falls compared to usual care at 91–180 days (rate ratio 0.63; 95% CI, 0.52–0.78).

Secondary Outcomes –

- GtACH reduced the number of falls compared to usual care at 1–90 days (rate ratio 0.74; 95% CI, 0.6–0.92).
- There was no difference in incidence of falls at 181–270 days or 271–360 days.
- No difference in functional independence at any study time point.
- Cost to prevent one fall was £191 ($257). The intervention was cost effective based on cost per quality-adjusted life year using the EQ-5D-5L-P but not the DEMQOL-P-U.

LIMITATIONS:

- Patient attrition due to death or care home withdrawal from study may have reduced its power to detect differences beyond 180 days.
- Participants and care home staff were not blinded to intervention.
- Care homes studied may have been subject to selection bias.
- "Usual care" was not clearly defined in the study and may differ from standard practices

outside of the UK.

- The study's design and nature of the intervention limit the ability to compare study outcomes to the outcomes of other studies.

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Additional Benefit from Thyroidectomy for Hashimoto Sufferers

Thyroidectomy Versus Medical Management for Euthyroid Patients with Hashimoto Disease and Persisting Symptoms

Guldvog I, Reitsma LC, Johnsen L, et al. Thyroidectomy Versus Medical Management for Euthyroid Patients with Hashimoto Disease and Persisting Symptoms: A Randomized Trial. *Ann Intern Med*. 2019;170(7):453-464. doi:10.7326/M18-0284

KEY TAKEAWAY: Surgical thyroidectomy is superior to medical therapy alone for improvement of persistent hypothyroid symptoms in otherwise euthyroid patients with Hashimoto disease.

STUDY DESIGN: Non-blinded, randomized, open-label controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Despite appropriate hormone treatment some patients with Hashimoto disease continue to have hypothyroid symptoms and elevated pro-inflammatory cytokines associated with thyroid peroxidase (TPO) antibodies. Further intervention to resolve these persistent symptoms has not been well established. In these patients the option exists to undergo total thyroidectomy to reduce presence of anti-TPO antibodies and associated symptoms.

PATIENTS: Patients with Hashimoto disease

INTERVENTION: Total thyroidectomy

CONTROL: Standard of care hormone replacement with levothyroxine

PRIMARY OUTCOME: Patient-reported general health

Secondary Outcomes: Fatigue, anti-TPO antibody levels

METHODS (BRIEF DESCRIPTION):

- Demographics: 18–79-year-old Norwegian men and women, medically fit for surgery, serum anti-TPO positive >1000 IU/mL and had thyroid stimulating hormone (TSH) >3.5 mIU/L prior to observation.
- Patients were randomly assigned to groups for surgical intervention vs medical management.
- Patients in the intervention and control groups were both treated for hypothyroidism with hormone replacement.
- Blood samples of thyroid hormone levels, TSH, TPO, parathyroid hormone (PTH), and calcium were collected every three months following the experimental period. Patients were maintained in a euthyroid (TSH 0.3–3.5 mIU/mL) state prior to and following any surgical intervention or data collection.
- Intervention group patients underwent surgical total thyroidectomy.
- The primary outcome measure was the Short Form 36 Health Survey Questionnaire (SF-36) a validated measure indicative of general health. SF-36 is scored from 0-100 with a higher score indicating increased overall health in areas including physical function, bodily pain, and mental health among others. SF-36 data were collected in both groups at six, 12, and 18 months.
- Secondary outcomes utilized sub-score categories of the SF-36 including a fatigue score describing chronic fatigue symptoms.
- Bootstrapped confidence intervals and Mann Whitney test were utilized to compare the difference for P value in anti-TPO antibody reduction in the intervention and control groups.

INTERVENTION (# IN THE GROUP): 75

COMPARISON (# IN THE GROUP): 75

FOLLOW UP PERIOD: 18 months

RESULTS:

Primary Outcome –

- Thyroidectomy resulted in greater patient-reported general health at 18 months compared to the control group (difference 29; 95% CI, 22–35).

Secondary Outcomes –

- Fatigue score decreased by nine points in the intervention group with a change of one in control group. Additionally, mean reported fatigue decreased 39% in the intervention group (95% CI, 23–53%).
- At 18 months the anti-TPO antibody level was 152 in intervention group and 1,300 in control group, with a median percentage reduction of 92% in the intervention group (IQR 87%–96%).

LIMITATIONS:

- This was a non-blinded study due to patients knowing they received a surgical procedure.
- There is a possible placebo effect of surgery, a major intervention.
- A longer follow-up period could provide more valuable data regarding differences over time.
- There was limited availability of disease-specific outcome measure due to language availability.

- The studied population was Norwegian and Caucasian only.

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Spinal Manipulative Therapy in the Treatment of Chronic Low Back Pain

Benefits and Harms of Spinal Manipulative Therapy for the Treatment of Chronic Low Back Pain: Systematic Review and Meta-Analysis of Randomized Controlled Trials

Rubinstein SM, de Zoete A, van Middelkoop M, Assendelft WJJ, de Boer MR, van Tulder MW. Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain: systematic review and meta-analysis of randomized controlled trials. *BMJ*. 2019;364:l689. Published 2019 Mar 13. doi:10.1136/bmj.l689

KEY TAKEAWAY: Spinal manipulation therapy (SMT) may improve pain and function compared to non-recommended interventions, but has similar outcomes compared to recommended therapies and sham treatment.

STUDY DESIGN: Meta-analysis of 47 randomized controlled trials (N=9,211)

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Low back pain is a common and often disabling disorder. The efficacy of spinal manipulative therapy as a treatment for chronic low back pain is unclear. Systematic review and meta-analysis of studies assessing for effective pain relief and improvement in function with spinal manipulative therapy can help guide recommendations regarding how or if spinal manipulative therapy should be integrated into treatment plans for patients with chronic low back pain.

PATIENTS: Adults with chronic low back pain with or without referred pain

INTERVENTION: Spinal Manipulative Therapy (SMT)

CONTROL: Recommended interventions, non-recommended interventions, sham spinal manipulation, or combination therapy

PRIMARY OUTCOME: Low back pain and low-back-pain-specific functional status

METHODS (BRIEF DESCRIPTION):

- Randomized controlled trials examining the effect of spinal manipulation or mobilization in adults (≥18 years) with chronic low back pain with or without referred pain.
- Patient population: Primarily adults with average age 35–60 years old with or without radiating low back pain.
- SMT compared against recommended therapies, non-recommended therapies, sham SMT and as adjuvant therapy at one, six, and 12 months.
- Main outcomes were pain and back specific functional status, examined as mean differences and standardized mean differences (SMD), respectively. Pain was measured utilizing a 100-point pain scale. Higher scores indicate more pain.
- SMT was compared against recommended therapies, non-recommended therapies, sham SMT and as adjuvant therapy. Recommended therapies included non-drug (e.g., exercise) and drug therapies (analgesics, NSAIDs). Non-recommended therapies included non-effective therapies (e.g., no treatment, soft tissue massage, waiting list) or potentially harmful treatment (e.g., electrotherapy).
- SMT included any hands-on treatment of the spine, including both mobilization and manipulation. Outcomes were assessed at 1-, 3-, 6-, and 12-months post-randomization. Data was analyzed according to the time closest to these intervals. SMT was delivered by chiropractors, manual or physical therapists, osteopaths, bonesetters, a naprapath, medical manipulators and orthomanual therapists.
- Criteria to assess functional status related to low back pain not detailed in this study.

INTERVENTION (# IN THE GROUP): 1,092–1,629 per outcome (varied based on outcome)

COMPARISON (# IN THE GROUP): 1,338–1,526 per outcome (varied based on outcome)

FOLLOW UP PERIOD: 12 months

RESULTS:

- SMT reduced pain at six months compared to other recommended therapies (17 trials, N=3,155; SMD –3.1; 95% CI, –5.4 to –0.77) but not at one or 12 months.
- SMT improved functional status at one month compared to other recommended therapies (16 trials, N=3,090; SMD –0.25; 95% CI, –0.41 to –0.09) but not at six or 12 months.
- SMT reduced pain compared to non-recommended therapies:
  - One month (8 trials, N=991; SMD –7.5; 95% CI, –12 to –3.5)

    - Six months (4 trials, N=372; SMD –7.5; 95% CI, −13 to −1.8)
    - 12 months (1 trial, N=169; SMD –7.8; 95% CI −14 to −1.4)
- SMT improved functional status compared to non-recommended therapies:
    - One month (7 trials, N=835; SMD –0.41; 95% CI, −0.67 to −0.15)
    - Six months (4 trials, N=373; SMD –0.29; 95% CI, −0.50 to −0.09)
    - 12 months (1 trial, N=169; SMD –0.42; CI, −0.72 to –0.11)
- SMT did not improve pain more than sham SMT.
- SMT improved functional status compared to sham SMT at one month (6 trials, N=748; SMD –0.73; 95% CI, −1.4 to −0.11) but not at six or twelve months.
- SMT as adjuvant therapy reduced pain at one month (6 trials, N=1,046; SMD –6.9; 95% CI, −10 to −3.5) and twelve months (2 trials, N=1,000; SMD –3.3; 95% CI, −6.6 to −0.02) but not at six months.
- SMT as adjuvant therapy resulted in clinic improvement in functional status at one month (4 trials, N=955; SMD –0.29; CI, −0.55 to −0.03) and twelve months (1 trial, N=994; SMD –0.21; CI, −0.34 to −0.09) but not at six months.

LIMITATIONS:

- There were a limited number of studies with low risk of bias.
- There was statistical heterogeneity due to SMT studies being conducted in various settings, among different populations, using different recruitment methods and SMT techniques being compared with differing alternative therapies.
- Disclosure was often not reported which means potential conflicts of interest could often not be ruled out.
- Standardized method to compare functional status outcome measures in SMT vs. control groups not elucidated in this meta-analysis.

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