GOOD EVIDENCE MATTERS

GEMs of the Week

SPOTLIGHT

A Pain in the Gut: Is OMT Effective in Treating the Symptoms of IBS?

Postpartum Long-Acting Contraception:

The Earlier the Better?

MAFLD:

To Intermittently Fast or Not to Fast?

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A Pain in the Gut: Is OMT Effective in Treating the Symptoms of IBS?

Effectiveness of Osteopathic Manipulative Treatment in Adults with Irritable Bowel Syndrome: A Systematic Review and Meta-Analysis

Buffone F, Tarantino AG, Belloni F, et al. Effectiveness of Osteopathic Manipulative Treatment in Adults with Irritable Bowel Syndrome: A Systematic Review and Meta-Analysis. *Healthcare (Basel)*. 2023;11(17):2442. Published 2023 Aug 31. doi:10.3390/healthcare11172442

KEY TAKEAWAY: Osteopathic manipulative therapy (OMT) improves abdominal pain and constipation in patients with irritable bowel syndrome (IBS) compared to sham OMT, medical treatment, or no treatment. However, there is no difference between treatments for diarrhea or IBS symptom severity.

STUDY DESIGN: Systematic review and meta-analysis of five randomized controlled trials (RTCs) and one ongoing RCT (N=190)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to overall low methodological quality of included studies)

BRIEF BACKGROUND INFORMATION: IBS is a common, chronic condition affecting one in 10 adults and is frequently encountered by a family clinician. The pathophysiology of IBS is poorly understood, and therefore difficult to treat. This study evaluated the efficacy of OMT on IBS symptoms as no similar meta-analyses had previously been completed.

PATIENTS: Adults with IBS

INTERVENTION: OMT

CONTROL: Sham OMT, medical treatment, no treatment

PRIMARY OUTCOME: IBS severity, abdominal pain, frequency of constipation and diarrhea

Secondary Outcome: Major adverse events

METHODS (BRIEF DESCRIPTION):

- A systematic review identified six articles which studied effectiveness of OMT in IBS treatment.
- 190 adult patients ≥18 years old in Germany, Netherlands, and France with a diagnosis of IBS meeting the Rome Criteria IV were included in the study.
  - 72% female, 28% male, mean age of 46 years old
- Patients receiving any concurrent manual therapy other than OMT at the time of the study were excluded.
- The intervention consisted of OMT ranging from 45–60-minute sessions over periods ranging from 3–13 weeks.
- All studies compared treatment groups to control groups receiving sham OMT, no treatment, or medical treatment.
  - The included studies did not state which medications were used.
- Measurements of primary outcomes were not consistent in all the studies. The following scales were used:
  - IBS severity was measured with the Likert scale, IBS severity scale, or IBS Quality of Life Questionnaire (IBSQOL).
    - Higher scores on the Likert scale or IBS severity scale represents more severe symptoms.
    - Higher scores on the IBSQOL indicate a better quality of life.
  - Abdominal pain was assessed using the Visual Analog Scale (VAS), with higher scores indicating more severe pain.
  - Constipation and diarrhea were assessed based on frequency. The authors did not specify definitions of frequency of constipation or diarrhea.
- The secondary outcome measured major adverse events.

INTERVENTION (# IN THE GROUP): 109

COMPARISON (# IN THE GROUP): 81

FOLLOW-UP PERIOD: Varied (28 days to 1 year)

RESULTS:

Primary Outcome –

- OMT improved abdominal pain compared to the control group (effect size [ES] –1.1; 95% CI, –1.7 to –0.62).
- OMT improved constipation frequency compared to the control group (ES –0.66; 95% CI, –1.1 to –0.20).
- OMT did not improve diarrhea frequency compared to the control group measured using the IBS severity scale and Likert scale (ES –1.2; 95% CI, –2.8 to 0.43).
- OMT did not improve IBS symptom severity compared to the control group measured with IBS severity scale and Likert scale (ES –0.34; 95% CI, –0.83 to 0.16).

Secondary Outcome –

-

- There was no significant difference for OMT for major adverse events compared to the control in three of the five completed RCTs.

LIMITATIONS:

- The quality of evidence was rated “low” for abdominal pain and “very low” constipation for diarrhea.
- One study had a “low risk of bias” for randomization while three had some concerns.
- Inclusion criteria for both the intervention and control group were liberal.
- The types of intervention techniques, frequency and duration were not limited.

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Postpartum Long-Acting Contraception: The Earlier the Better?

Immediate vs Delayed Postpartum Insertion of Long-acting Reversible Contraception Methods: Meta-Analysis of Randomized Controlled Trials

Provinciatto H, Meirelles Dias YJ, Abonizio Magdalena SL, et al. Immediate vs Delayed Postpartum Insertion of Long-acting Reversible Contraception Methods: Meta-analysis of Randomized Controlled Trials. *Am J Obstet Gynecol*. 2025;232(2):139-149.e16. doi:10.1016/j.ajog.2024.09.019

KEY TAKEAWAY: Initiating long-acting reversible contraceptives (LARC) before hospital discharge among postpartum women increases its likelihood of utilization at six months and reduces the risk of pregnancy, without significant effects on breastfeeding or adverse events.

STUDY DESIGN: Meta-analysis of randomized controlled trials (RCTs) (N=2,507)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to substantial trial heterogeneity and disease-oriented outcomes)

BRIEF BACKGROUND INFORMATION: Postpartum women are at risk of short interval repeat pregnancies. Short-interval pregnancy is associated with an increased risk of adverse neonatal and maternal outcomes. Initiation, utilization, and adverse outcomes of long-acting reversible contraceptives in the immediate postpartum period have been studied in the past. They have shown conflicting results with regards to efficacy, safety, and utilization, likely due to differences in study populations, timing, and follow-up.

PATIENTS: Postpartum women

INTERVENTION: Immediate initiation of LARC

CONTROL: Delayed initiation of LARC

PRIMARY OUTCOME: Short interval pregnancies within six months, expulsion, breastfeeding rates, and serious adverse events

METHODS (BRIEF DESCRIPTION):

- A systematic search of RCTs comparing immediate vs delayed insertion of LARC among postpartum women was conducted using PubMed, Embase, Cochrane Library, and ClinicalTrials.gov from inception through December 19, 2023, in all languages.
- Authors included randomized trials of postpartum women which reported data on at least one end point/outcome.
- A total of 24 randomized trials comprising 2,507 participants from USA, Sweden, Egypt, Brazil, Uganda, and Sri Lanka were eligible for inclusion.
- LARC method included contraceptive implants (n=8 trials) and intrauterine devices (n=16 trials).
- Studies included vaginal deliveries (n=7 trials), Cesarean sections (n=6 trials) and both types of deliveries (n=11 trials).
- "Immediate initiation" was defined as initiation of LARC before hospital discharge, while "delayed initiation" was defined as initiation of LARC between 4–12 weeks after birth.
- Primary outcome was utilization of LARC at six months.
- Utilization of intrauterine devices (IUDs) was measured by physical exam and/or ultrasound assessments.
- Utilization of implants was measured by in-person or telephone surveys.
- Short interval pregnancies within six months included both confirmed and suspected pregnancies.
- "Any breastfeeding" was defined as breastfeeding regardless of the addition of other liquids or solid.
- Serious adverse events comprised uterine perforation and pelvic inflammatory disease.
- IUD expulsions were identified by clinical examination and confirmed with pelvic ultrasonography when indicated.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Six months

RESULTS:

Primary Outcome –

- Immediate insertion of LARC increased the likelihood of LARC utilization at six months compared to delayed insertion (13 studies, n=778; relative risk [RR] 1.2; 95% CI, 1.1–1.4; I^2=63%).

Secondary Outcome –

- Immediate insertion of LARC markedly reduced the risk of pregnancy within six months compared to

delayed insertion (4 studies, n=624; RR 0.16; 95% CI, 0.04–0.71; I^2=0%).

- There was a higher rate of expulsion for immediate insertion compared to delayed insertion (11 studies, n=930; RR 3.1; 95% CI, 1.4–7.0; I^2=42%).
- The rate of intrauterine device expulsion was higher for immediate insertion compared to delayed insertion after vaginal delivery (6 studies, n=349; RR 5.1; 95% CI, 2.0–13; I^2=15%), but there was no difference between the two groups in women who had a Cesarean delivery.
- Immediate insertion of LARC resulted in no difference in the rates of exclusive breastfeeding, any breastfeeding, or serious adverse events of uterine perforation and pelvic inflammatory disease compared to delayed insertion.

LIMITATIONS:

- The number of RCTs selected for certain analyses were limited due to variation in definitions of immediate and delayed insertion, eligibility criteria, and follow-up protocols resulting in substantial heterogeneity in analyzed endpoints including the primary outcome (I^2=63%).
- Both funnel plot and the Egger regression test suggested the possibility of publication bias.
- Breastfeeding was an indirect measurement in most trials which may introduce bias.

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MAFLD: To Intermittently Fast or Not to Fast?

The Effect of Intermittent Fasting Diet in Comparison with Low-Calorie Diet on Inflammation, Lipid Profile, Glycemic Index, Liver Fibrosis in Patients with Metabolic-Associated Fatty Liver Disease (MAFLD)

Karimi M, Akhgarjand C, Houjaghani H, et al. The Effect of Intermittent Fasting Diet in Comparison with Low-Calorie Diet on Inflammation, Lipid Profile, Glycemic Index, Liver Fibrosis in Patients with Metabolic-Associated Fatty Liver Disease (MAFLD): A Randomized Controlled Trial. *Clin Ther*. 2025;47(4):e9-e16. doi:10.1016/j.clinthera.2025.01.007

KEY TAKEAWAY: A low-calorie diet may be more beneficial in liver fat reduction compared to intermittent fasting for patients with metabolic dysfunction-associated fatty liver disease (MAFLD).

STUDY DESIGN: Single-blind randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small sample size and short duration)

BRIEF BACKGROUND INFORMATION: MAFLD is a disease of liver steatosis due to patients having at least one metabolic risk factor such as diabetes mellitus (DM), obesity, dyslipidemia, and hypertension. Understanding the best method to reduce their obesity and type of diet to reduce the amount of fat on their liver is important for the patient to know, specifically which diet will provide the best prevention of cirrhosis. Intermittent fasting (IF) and low-carbohydrate diets (LCDs) have shown positive results, but a study has not been conducted to compare their efficacy.

PATIENTS: Adult patients with MAFLD

INTERVENTION: IF

CONTROL: LCD

PRIMARY OUTCOME: Degree of liver steatosis and fibrosis

Secondary Outcome: Changes in liver enzyme levels, lipid parameters, inflammatory or oxidative levels

METHODS (BRIEF DESCRIPTION):

- The study was conducted at a clinic in Tehran, Iran.
- 52 adults with MAFLD with known MAFLD were included in study with diagnoses including participants 20–50 years old, male and female, no recent use of medications or supplements, and diagnosed with steatohepatitis and liver fibrosis with Matavir-score ≥F2.
- Patients were randomized 1:1 to intervention group (IF) or control group (LCD).
  - Stratified block randomization with age and body mass index (BMI) used.
  - Only lab personnel were blinded.
- The primary outcome instrument used was the Fibro Scan (Cap and transient elastography) to assess for liver steatosis and fibrosis with higher numbers meaning worsening fibrosis or steatosis
- Secondary outcomes were measured using the following:
  - After 12 hours fast, blood samples were taken
  - Lipid profile, ALT, AST, GGT
  - Oxidative stress markers: TAC and TOS
  - Inflammatory markers: hs-CRP
- Statistical tests used to analyze data included independent t-test, chi-square, repeated-measures ANOVA, and ANCOVA.

INTERVENTION (# IN THE GROUP): 26

COMPARISON (# IN THE GROUP): 26

FOLLOW-UP PERIOD: Three months

RESULTS:

Primary Outcome –

- IF showed a lower reduction in liver fibrosis and liver steatosis compared to LCD:
  - Liver fibrosis (–0.004 vs –0.74 Kpa; $P<.01$)
  - Liver steatosis (–45 vs –2.4 dB/m; $P<.001$)

Secondary Outcome –

- GGT notably improved in LCD group (–9.2; $P<.05$).
- ALT, AST, LDL, and triglycerides improved in both groups without significant difference between groups.
- There were no significant change in TAC, oxidative stress index, and inflammatory markers between the groups.

LIMITATIONS:

- The study had a small sample size of 52 participants.
- The interventions had a short duration of 12 weeks.
- Single blind nature of the study where only laboratory personnel were blinded could introduce bias.

- The study population was limited to individuals 20–50 years old with a BMI of 25–35.
- Actual physical activity was self-reported only.
- Diet and exercise were the similar for the most part, but IF group did have a higher fiber intake.

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