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Bump-Friendly Workouts Bring Big Benefits

GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Physical Exercise in Pregnancy: Benefits, Risks and Prescription

Ribeiro MM, Andrade A, Nunes I. Physical exercise in pregnancy: benefits, risks and prescription. *J Perinat Med.* 2021 Sep 6;50(1):4-17. doi: 10.1515/jpm-2021-0315. PMID: 34478617.

KEY TAKEAWAY: Physical exercise in pregnancy has a multitude of benefits with limited risks on maternal and fetal morbidity in the peripartum period. A proper exercise prescription is based on maternal fitness level prior to pregnancy and should follow international guidelines, which recommend 150 minutes a week of moderate intensity exercise set by the American College of Obstetricians and Gynecologists (ACOG) and other international obstetrical organizations.

STUDY DESIGN: Systematic review of 32 meta-analyses (MA), nine systematic reviews (SR), and 16 randomized controlled trials (RCT)

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Maternal obesity and lack of physical exercise during pregnancy can lead to excessive weight gain and other peripartum comorbidities that can have immediate and lasting effects on both maternal and fetal health. Multiple international obstetrical organizations have established guidelines for pregnant women without providing a clear prescription of acceptable forms of exercise. This has led to limited or unenthusiastic recommendations from providers and fear amongst pregnant women about associated adverse effects.

PATIENTS: Pregnant women

INTERVENTION: Exercise

CONTROL: Non-exercise group

PRIMARY OUTCOME: Rates of excessive weight gain, gestational diabetes (GDM), fetal macrosomia, delivery type, gestational hypertension (GHTN), preeclampsia, urinary incontinence, and depression

METHODS (BRIEF DESCRIPTION):

- Following PRISMA guidelines, studies were identified using specific terms of pregnancy, physical exercise or physical activity.
- Studies published in English or Portuguese between January 1990 and December 2020, with full-text options available and studied maternal and fetal outcomes related to physical exercise during pregnancy were included in the review.
- The Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework was then used to assess the quality of evidence across studies with scores of high or low quality of evidence.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Peripartum period

RESULTS:

Primary Outcome –

- Exercise decreased the risk of excessive weight gain compared to non-exercise (4 MAs, 3 RCTs) which varied from 18% (odds ratio [OR] 0.82; 95% CI, 0.68–0.99) to 61% (OR 0.39; 95% CI, 0.17–0.89).
- Exercise decreased the risk of GDM compared to non-exercise (8 MAs, 2 SRs, 1 RCT) which varied from 28% (risk reduction [RR] 0.72; 95% CI, 0.58–0.91) to 59% (RR 0.41; 95% CI, 0.24–0.68).
- Exercise reduced the risk of fetal macrosomia compared to non-exercise (5 MAs, 1 SR) which varied from 4% (RR 0.96; 95% CI, 0.94–0.98) to 61% (RR 0.41; 95% CI, 0.25–0.68).
- Exercise reduced the risk of infants who were large for gestational age compared to non-exercise (5 MAs, 1 SR) which varied from 19% (RR 0.81; 95% CI, 0.69–0.96) to 49% (RR 0.51; 95% CI, 0.30–0.87).
- Exercise reduced the risk of cesarean sections compared to non-exercise (3 MAs, 1 RCT; OR 0.33; 95% CI, 0.11–0.97).
- Exercise reduced the risk of instrumental delivery compared to non-exercise (2 MAs, 1 RCT; OR 0.76; 95% CI, 0.63–0.92).
- Exercise reduced GHTN compared to non-exercise (1 SR, 3 MAs; RR 0.61; 95% CI, 0.43–0.85).
- Exercise reduced the risk of preeclampsia compared to non-exercise (1 SR, 3 MAs; RR 0.59; 95% CI, 0.37–0.90).

- Exercise reduced the risk of urinary incontinence during pregnancy compared to non-exercise (OR 0.48; 95% CI, 0.32–0.73).
- Exercise reduced the risk of urinary incontinence during the postpartum period compared to non-exercise (2 SR, 1 RCT; OR 0.61; 95% CI, 0.48–0.77).
- Exercise decreased the risk of prenatal depression compared to non-exercise (1 RCT; OR 0.33; 95% CI, 0.21–0.53).

LIMITATIONS:

- The review mainly used RCTs and meta-analyses, which may have skewed clinical significance due to some data being repeatedly used.
- Multiple studies used a non-specific or ill-defined exercise program preventing clear evaluation of a specific intervention.
- Clinical outcomes of certain studies may have been skewed because a greater number of patients were of healthy weight rather than overweight or obese.
- No measure of heterogeneity reported

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The views expressed herein are those of the author and do not necessarily reflect the official policy of the Department of the Army, Defense Health Agency, Department of Defense, or the U.S. Government.

Beyond the Bypass: Comparing DS and RYGB Outcomes in Long-Term Primary Care

Ten-Year Outcomes Following Roux-en-Y Gastric Bypass vs Duodenal Switch for High Body Mass Index: A Randomized Clinical Trial

Salte OBK, Olbers T, Risstad H, et al. Ten-Year Outcomes Following Roux-en-Y Gastric Bypass vs Duodenal Switch for High Body Mass Index: A Randomized Clinical Trial. *JAMA Netw Open*. 2024;7(6):e2414340. Published 2024 Jun 3. doi:10.1001/jamanetworkopen.2024.14340

KEY TAKEAWAY: A duodenal switch (DS) gastric bypass surgery reduces body mass index (BMI) compared to a Roux-en-Y gastric bypass (RYGB) in patients with a BMI of 50–60 after 10 years.

STUDY DESIGN: Open label randomized controlled study

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small size)

BRIEF BACKGROUND INFORMATION: Bariatric surgery is designed for patients with severe obesity to achieve significant long-term weight loss. It works by either physically limiting the amount of food the stomach can hold or altering the digestion and absorption process. RYGB is a widely performed bariatric surgery for weight loss. However, long-term results after biliopancreatic diversion with DS have been limited. This study aimed to compare the effectiveness of DS with RYGB in promoting weight loss.

PATIENTS: Patients with a BMI 50–60

INTERVENTION: DS

CONTROL: RYGB

PRIMARY OUTCOME: Change in BMI

Secondary Outcome: Anthropometric measures, lipid and glycemic profiles, bone mass density, adverse events, gastrointestinal (GI) tract symptoms, and health-related quality of life

METHODS (BRIEF DESCRIPTION):

- The study was conducted at Oslo University Hospital, in Oslo, Norway and Sahlgrenska University Hospital in Gothenburg, Sweden
- Patients 20–50 years old with a BMI of 50–60 who underwent bariatric surgery between March 1, 2006, to August 31, 2007 were included in the study.
- Patients were randomly allocated 1:1 into either DS or RYGB.
    - The intervention group received DS.
    - The control group received the RYGB.
    - Randomization of patients was done using LabVIEW software, version seven.
- After surgery, patients were monitored for the next 10 years on average to assess change in BMI as part of primary outcome.
- Secondary outcomes were defined as difference in anthropometric measures, lipid and glycemic measures, bone mass, adverse events, GI symptoms, and health-related quality of life
    - Dual-energy absorptiometry scans were measured at five and 10 years for both groups including lumbar back (L1–L4), femoral neck, total femur, and total accumulated bone mineral density (aBMD).
    - CTX-1 and P1NP levels were serum bone markers measured to also monitor bone mass.
    - GI symptoms were evaluated with GI symptom rating scale and bowel-function questionnaire.
    - Health-related quality of life was evaluated via the generic 36-Item Short Form Health Survey (SF-36) and obesity related problems scale.
    - Labs included a lipid panel, vitamins A and E, and HgA1c.
    - Adverse events were tracked throughout the study.

INTERVENTION (# IN THE GROUP): 30

COMPARISON (# IN THE GROUP): 31

FOLLOW-UP PERIOD: 10 years

RESULTS:

Primary Outcome –

- DS decreased BMI compared to RYGB (between-group difference 9.3; 95% CI, 5.4–13).
- Fewer patients had a BMI >40 after DS compared to RYGB (32% vs 70%, respectively; *P*=.009).

Secondary Outcome –

- DS resulted in less aBMD loss compared to RYGB (between group differences 0.17%; 95% CI, 0.07–0.26).
- DS resulted in similar GI symptoms compared to RYGB except for greater reflux symptoms (between group differences –1.2; 95% CI, –2.0 to –0.3).

- DS lowered HgA1c compared to RYGB (between group difference 0.9; 95% CI, 0.3–1.5).
- DS lowered vitamin A levels compared to RYGB (between group differences 14; 95% CI, 6–20).
- DS lowered vitamin E levels compared to RYGB (between group difference 0.6; 95% CI, 0.3–0.9).
- DS increased the total number of adverse events compared to RYGB (between group difference 38 events; 95% CI, 97–135).
- There was no significant difference in health-related quality of life, CTX-1, and P1NP levels for patients who underwent a DS compared to RYGB.

LIMITATIONS:

- 13 patients did not follow up at the end of the 10-year trial which can skew results as well as introduce attrition bias.
- The small sample size of the study may undermine the efficacy and power of the secondary outcomes.
- The lack of blinding may increase the risk of underreporting of adverse events in DS group.
- The study does not extensively address patient adherence to prescribed supplementation and lifestyle changes, which could impact BMI changes.
- The study includes only adults with class IV obesity therefore the finding may not be applicable to the boarder population.

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Progestogens Preventing Post-Procedural Recurrence of Endometriosis Symptoms

Long-Acting Progestogens vs Combined Oral Contraceptive Pill for Preventing Recurrence of Endometriosis Related Pain: The PRE-EMPT Pragmatic, Parallel Group, Open Label, Randomized Controlled Trial

Cooper KG, Bhattacharya S, Daniels JP, et al. Long acting progestogens versus combined oral contraceptive pill for preventing recurrence of endometriosis related pain: the PRE-EMPT pragmatic, parallel group, open label, randomized controlled trial. *BMJ*. 2024;385:e079006. Published 2024 May 15. doi:10.1136/bmj-2023-079006

KEY TAKEAWAY: For patients with endometriosis who have undergone conservative surgery for endometriosis, there is no significant difference between combined oral contraceptive pills (COCPs) and long-acting progestogens (LAPs) for reducing recurrence of pain for up to three years post-surgery.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to limited generalizability and lack of blinding)

BRIEF BACKGROUND INFORMATION: Endometriosis often requires surgical intervention to remove lesions. Hormonal therapy is generally recommended following surgery to decrease symptom recurrence. LAPs may improve compliance given decreased frequency of administration.

PATIENTS: Women 16–45 years old who underwent surgery for endometriosis

INTERVENTION: Depot medroxyprogesterone acetate (DMPA) 150 mg every three months or levonorgestrel intrauterine device (IUD)

CONTROL: Ethinyl-estradiol/levonorgestrel 30 mcg/150 mcg daily

PRIMARY OUTCOME: Pain at three years

Secondary Outcome: Endometriosis health profile-30 (EHP-30) core and modular domains, follow-up treatment, further treatment, second line medical treatment, pelvic pain, fatigue, quality of life

METHODS (BRIEF DESCRIPTION):

- Women 16–45 years old diagnosed with or with symptoms of endometriosis, scheduled for surgery for lesion removal were included in the study.
- Individuals with infertility, attempting to conceive, surgery for other than simple peritoneal lesions, and concern for malignancy were excluded from the study.
- Participants underwent a washout period of four weeks if previously on gonadotropin releasing hormone (GnRH) analogues.
- Participants were randomized to COCPs vs LAP with computer-based randomization and minimization of disease stage, extent of required excision, age, surgery center, and LAP chosen.
  - Participants choose which LAP (DMPA vs IUD) if assigned to LAP group
- Pain at three years post-surgery was measured via the visual analog scale (VAS) during periods, during intercourse, and at any other time.
- The following were measured as the secondary outcomes:
  - The EHP-30 core domains included control and powerlessness, social support, emotional wellbeing, and self-image which assessed the quality of life in patients with endometriosis.
  - The EHP-30 modular domains included work life, relationships with children, sexual relationships, feelings about medical profession, feelings about treatment, and feelings about infertility.
  - Fatigue was measured using the Fatigue Severity Score. Scores range from 7–63, with a score <37 suggestive of a potential lack of measurable fatigue.
  - Quality of life was measured using the EQ-5D-5L index which assessed mobility, self-care, usual activities, pain, and anxiety/depression.
  - Pain during periods, intercourse, and at any other time was measured using the VAS. Scores range from 0–100, with higher scores indicating worse pain.

INTERVENTION (# IN THE GROUP):

- LAP: 205
- IUD: 91
- DMPA: 114

COMPARISON (# IN THE GROUP): 200

FOLLOW-UP PERIOD: Three years

RESULTS:

Primary Outcome –

- There was no significant difference in pain at three years post-surgery for LAP compared to COCP (adjusted mean difference [aMD] –0.8; 95% CI, –5.7 to 4.2).

Secondary Outcome –

- There was no significant difference in any of the secondary outcomes for LAP compared to COCP.

LIMITATIONS:

- 91% of patients described ethnicity as "White," and they were recruited exclusively within the United Kingdom limiting the external validity of this study.
- The duration of endometriosis is often longer than the follow-up period of three years in this study, which may lead to undetected differences in treatment options.
- Poor adherence to initial treatment arm allocation limited the ability to determine statistically significant difference between COCPs and LAPs.
- The lack of blinding of participants and clinicians may introduce expectation and performance biases.

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From Ashes to Action: The Phoenix Criteria Transform Pediatric Sepsis Criteria

Development and Validation of the Phoenix Criteria for Pediatric Sepsis and Septic Shock

Sanchez-Pinto LN, Bennett TD, DeWitt PE, et al. Development and Validation of the Phoenix Criteria for Pediatric Sepsis and Septic Shock. *JAMA*. 2024;331(8):675-686. doi:10.1001/jama.2024.0196

KEY TAKEAWAY: The Phoenix Sepsis Score (PSS) improves pediatric sepsis identification compared to the 2005 International Pediatric Sepsis Consensus Conference (IPSCC) criteria, demonstrating better performance across high and low-resource settings.

STUDY DESIGN: Retrospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: An estimated 3.3 million deaths are attributable to pediatric sepsis annually. The current IPSCC criteria for diagnosing pediatric sepsis was developed 20 years ago and does not account for clinical settings with differing levels of resources. There is a need for new criteria that reflects current advances in medicine to help clinicians accurately identify sepsis and septic shock in pediatric populations.

PATIENTS: Pediatric patients evaluated in the emergency department (ED) or inpatient setting who had suspected infection in the first 24 hours

INTERVENTION: Four-organ system PSS

CONTROL: IPSCC criteria

PRIMARY OUTCOME: Performance of a criteria or score for predicting in-hospital mortality

METHODS (BRIEF DESCRIPTION):

- Pediatric patients <18 years old seen in the ED or the inpatient setting from 2010–2019 among 10 health systems across the United States, Colombia, Bangladesh, China, and Kenya were included in the study.
- Participants were excluded if they were newborns or born preterm (<37 weeks gestation).
- The intervention used the PSS, based on a four-system organ model (respiratory, cardiovascular, mean arterial pressure, coagulation, and neurologic) that aims to accurately identify children with sepsis.
    - Scores range from 0–13, with a score of ≥2 indicating an increased likelihood of sepsis.
- The comparator used the IPSCC based on vitals (heart rate, respiratory rate, and systolic blood pressure), and laboratory values (leukocytosis) in six age groups: Newborn, neonate, infant, toddler and preschool, school-aged child, adolescent, and young adult.
    - Included organ dysfunction criteria for the following categories: Cardiovascular, respiratory, neurologic, hematologic, renal, and hepatic
    - No actual score range or cutoff for diagnosis of SIRS or sepsis were given.
- The primary outcome assessed the prediction of in-hospital mortality in both high and low-resource settings.
    - Included organ dysfunction criteria for the following categories: Cardiovascular, respiratory, neurologic, hematologic, renal, and hepatic.
    - No actual score range or cutoff for diagnosis of SIRS or sepsis was given.
- Score performance measures based on models included the area under the precision recall curve (AUPRC) for predicting in-hospital mortality.

INTERVENTION (# IN THE GROUP): 45,855

COMPARISON (# IN THE GROUP): 581,317

FOLLOW-UP PERIOD: 2010–2019

RESULTS:

Primary Outcome –

- The PSS improved sepsis identification compared to the IPSCC severe sepsis criteria.
    - High-resource settings:
        - PSS (AUPRC 0.045; 95% CI, 0.041–0.049)
        - IPSCC (AUPRC 0.03; 95% CI, 0.027–0.035)
    - Low-resource settings:
        - PSS (AUPRC 0.12; 95% CI, 0.11–0.13)
        - IPSCC (AUPRC 0.098; 95% CI, 0.088–0.11)
- The PSS criteria demonstrated positive predictive value (PPV) and higher sensitivity than the IPSCC criteria in all resource settings.
    - High-resource settings:
        - PSS (PPV 5.3–7.1%; sensitivity 69–84%)
        - IPSCC (PPV 3.6–4.8%; sensitivity 59–71%)

- Low-resource settings:
  - PSS (PPV 22%; sensitivity 81%)
  - IPSCC (PPV 13%; sensitivity 49%)

LIMITATIONS:

- Retrospective data obtained from electronic health records (EHRs) for creating the score may have missing data and data entry errors.
- Specifications for pediatric patients with chronic organ dysfunction were not considered.
- There was a lack of data availability from low-resource settings (i.e. respiratory support use).
- The information obtained from high-resource settings was limited to US tertiary care centers.
- Data was obtained over 10 years, during which time there have been advances in medicine.

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