GOOD EVIDENCE MATTERS

GEMs of the Week

SPOTLIGHT

Squats or Scalpel?

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Is Benzyl Benzoate Superior to Permethrin in Treating Scabies?

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Squats or Scalpel? Strength Training vs Total Hip Replacement for Severe Osteoarthritis

Total Hip Replacement or Resistance Training for Severe Hip Osteoporosis

Frydendal T, Christensen R, Mechlenburg I, et al. Total Hip Replacement or Resistance Training for Severe Hip Osteoarthritis. *N Engl J Med*. 2024;391(17):1610-1620. doi:10.1056/NEJMoa2400141

KEY TAKEAWAY: Hip replacement significantly improves hip pain and function and is superior to resistance training alone in adults with severe hip osteoarthritis (OA).

STUDY DESIGN: Multisite, non-blinded, randomized control trial

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

BRIEF BACKGROUND INFORMATION: Total hip replacement surgery is the mainstay treatment for severe hip OA but has a high financial cost. Resistance training, a low-cost non-surgical alternative, has shown some benefit in improving hip pain and function, however, few studies have directly compared its effectiveness to total hip replacement in patients with severe OA.

PATIENTS: Adults ≥50 years old

INTERVENTION: Resistance training

CONTROL: Total hip replacement

PRIMARY OUTCOME: Hip pain and function

Secondary Outcome: Quality of life, physical activity, serious adverse events

METHODS (BRIEF DESCRIPTION):

- The study was a statistician-blinded, randomized control trail conducted at four orthopedic clinics in three regions in Demark.
- Patients were included if they were ≥50 years with severe hip OA and an indication for total hip replacement as assessed by an orthopedic surgeon.
- Patients were excluded if they had severe walking deficits, body mass index (BMI) >35, leg or foot fracture in the last 12 months, planned surgery in the affected leg or foot in the next six months, cancer or cancer treatment, or neurologic disease.
- Average patient age was 68 years old with 50% of participants being women, <10% of patients smoked, approximately 30% had previous supervised exercise regimen, and baseline Oxford Hip Score score was 25.
- Patients were randomized using a computer-generated randomization software.
- Both patients and clinicians were aware of their group assignments.
- The hip-replacement group received standard preoperative and postoperative education, pain management, and a home-based exercise program.
- Orthopedic surgeons conducted hip replacement using the posterior surgical approach.
- The resistance-training group received individual one-hour supervised sessions twice weekly for three months, adherence was defined as completion of 18 or more supervised sessions.
- Exercises included stationary bike warm up followed by four resistance exercises (leg press, hip extension, hip flexion, and hip abduction) completed on both legs using weight machines with progression over the three months.
- After three months, patients continued the exercises on their own at a gym of their choice.
- The primary outcome of hip pain and function was assessed using a patient-reported Oxford Hip Score. Scores range from 0–48, with higher scores indicating less pain and better function
  - Minimal clinically important difference (MCID) = 5 points.
- The secondary outcomes were measured using the following:
  - Quality of life was measured using the Hip Disability and Osteoarthritis Outcome Score. Scores range from 0–100, with higher scores indicating better quality of life.
  - Physical activity was measured using the University of California, Los Angeles (UCLA) physical activity score. Scores range from 1–10, with higher scores indicating more regular physical activity with higher intensity.
  - Serious adverse events included infection, hip dislocation, or development of lower extremity neurologic symptoms.

INTERVENTION (# IN THE GROUP): 53

COMPARISON (# IN THE GROUP): 56

FOLLOW-UP PERIOD: Six months

RESULTS:

Primary Outcome –

- Resistance training did not improve hip pain and function at six months compared to the hip-replacement group (change from baseline 4.5 vs 16 points, respectively; adjusted mean difference [aMD] 11; 95% CI, 8.9–14).

Secondary Outcome –

- Resistance training group improved quality of life in all subcategories compared to the hip replacement group.
  - Pain (15 vs 39, respectively; aMD 24; 95% CI, 18–30)
  - Symptoms (14 vs 39, respectively; aMD 26; 95% CI, 20–32)
  - Activities of daily living function (12 vs 33, respectively; aMD 21; 95% CI, 15–26)
  - Hip-related quality of life (11 vs 44, respectively; aMD 33; 95% CI, 25–40)
  - Sports and recreation function (9.2 vs 41, respectively; aMD 32; 95% CI, 25–39)
- The resistance training group had slightly lower physical activity compared to the hip replacement group (0.5 vs 1.2, respectively; aMD 0.7; 95% CI, 0.1–1.3).
- The number of serious adverse events was similar between the two groups.

LIMITATIONS:

- The study was unblinded, which may overestimate the benefits of surgery when compared to resistance training.
- Both groups received exercise education and pain management, which may have affected the results.
- The study's small sample size limits its generalizability.
- By six months, 9% of patients in the hip-replacement group did not undergo hip surgery while 21% of the resistance-training group underwent hip surgery.

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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.

Swiss Ball for Reduced Duration of Labor

Active Pelvic Movements on a Swiss Ball Reduced Labor Duration, Pain, Fatigue and Anxiety in Parturient Women: A Randomized Trial

Delgado A, Amorim MM, Oliveira ADAP, et al. Active Pelvic Movements on a Swiss Ball Reduced Labor Duration, Pain, Fatigue and Anxiety in Parturient Women: A Randomized trial. *J Physiother*. 2024;70(1):25-32. doi:10.1016/j.jphys.2023.11.001

KEY TAKEAWAY: Targeted Swiss ball pelvic movements reduce the duration of the first stage of labor compared to routine labor care.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Primary care physicians providing care to parturient women seek non-pharmacologic methods to improve maternal and neonatal outcomes during labor and delivery. Though systematic reviews have indicated Swiss ball benefit for reducing pain, they have been inconsistent on its effect on the duration of labor. This study aimed to investigate the impact of structured Swiss ball pelvic movements on maternal and neonatal outcomes.

PATIENTS: Parturient women

INTERVENTION: Protocol-driven Swiss ball exercises

CONTROL: Routine labor care

PRIMARY OUTCOME: Duration of the first stage of labor

Secondary Outcome: Maternal and neonatal outcomes

METHODS (BRIEF DESCRIPTION):

- Patients were recruited from four obstetric units in Brazil.
- Pregnant patients in active labor with a low-risk, term pregnancy of a single, cephalic fetus were included in the study.
- Patients with fetal demise, cesarean section indication on admission, difficulty remaining upright, psychiatric drug use, epidural analgesia, or oxytocin administration prior to recruitment were excluded from the study.
- Patients in the intervention group had a mean age of 25 years old whereas those in the control group had a mean age of 26 years old.
- Patients were randomized 1:1 to either Swiss ball exercises or routine care.
- The Swiss ball exercises were based on pelvic biomechanics, labor stage, and early pushing urge under guidance of a trained physiotherapist, with patients self-determining positions and frequency of exercises, and mean duration of exercises being 152 minutes.
- The control group received routine obstetric care.
- Blinded investigators collected maternal and neonatal endpoints before and after interventions.
- The primary outcome measured the duration of the first stage of labor, beginning with admission with the patient at least five cm dilated until reaching 10 cm cervical dilation.
- Many secondary outcomes were measured, with the authors stratifying these into maternal and neonatal outcomes.
    - Maternal outcomes measured the durations of the second stage of labor, pain intensity (at 30-minute intervals), anxiety, fatigue, cesarean section, vulvar swelling, need for instrumental delivery, episiotomy, use of epidural, cervical swelling, vaginal tears, number of sutures, synthetic oxytocin use, and maternal satisfaction.
    - Neonatal outcomes measured were a need for neonatal resuscitation, need for neonatal intensive care unit (NICU) admission, and five-minute Apgar score of <7.
- Investigators used intention-to-treat method for analysis and estimated absolute risk reductions for dichotomous outcomes.

INTERVENTION (# IN THE GROUP): 100

COMPARISON (# IN THE GROUP): 100

FOLLOW-UP PERIOD: 24 hours postpartum

RESULTS:

Primary Outcome –

- Swiss ball exercises significantly shortened the first stage of labor compared to control (–179 minutes; 95% CI, –213 to –146).

Secondary Outcome –

- Swiss ball exercises shortened the second stage of labor compared to control (–19 minutes; 95% CI, –25 to –13).

- Swiss ball exercises decreased pain intensity at 90 minutes compared to control (–2 points; 95% CI, –2.3 to –1.6).
- Swiss ball exercises reduced maternal anxiety compared to control (–9 points; 95% CI, –11 to –8).
- Swiss ball exercises reduced maternal fatigue compared to control (–18 points; 95% CI, –21 to –16).
- Swiss ball exercises decreased risk of cesarean section compared to control (absolute risk reduction [ARR] 0.14; 95% CI, 0.03–0.25).
- Swiss ball exercises decreased the risk of vulvar swelling compared to control (ARR 0.11; 95% CI, 0.03–0.19).
- Swiss ball exercises did not affect outcomes for instrumental delivery, episiotomy, use of epidural, cervical swelling, vaginal tears, sutures, synthetic oxytocin use, or maternal satisfaction compared to control.
- Swiss ball exercises did not affect neonatal outcomes of resuscitation, NICU admission, or five-minute Apgar scores compared to control.

LIMITATIONS:

- Professional physiotherapists did not accompany the control group participants throughout their labor.
- The small sample size of 200 in only four obstetrical units may limit the generalizability of the findings.
- Active pelvic movement interventions performed by physiotherapists were not defined.
- Professional physiotherapists do not commonly provide laboring patients in person instructions and support in the United States, thereby limiting applicability of the findings.
- Interpretation of pain, anxiety, and fatigue is subject to variations in inter-rater reliability.
- The study had a short follow-up interval of only 24 hours.

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Is Benzyl Benzoate Superior to Permethrin in Treating Scabies?

Comparison of Topical Permethrin 5% vs Benzyl Benzoate 25% Treatment in Scabies: A Double-Blinded Randomized Controlled Trial

Meyersburg D, Hoellwerth M, Brandlmaier M, et al. Comparison of Topical Permethrin 5% vs. Benzyl Benzoate 25% Treatment in Scabies: A Double-blinded Randomized Controlled Trial. *Br J Dermatol*. 2024;190(4):486-491. doi:10.1093/bjd/ljad501

KEY TAKEAWAY: Benzyl benzonatate improved treatment of non-crusted scabies compared to permethrin in patients >12 years old.

STUDY DESIGN: Single center, double blind randomized prospective study

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Permethrin is still considered the first-line treatment for scabies, but emerging reports support reduced efficacy of permethrin in treating scabies infestations. Recent research has detected a mutation at the permethrin scabies binding site, which may confer resistance to permethrin and explain its decrease in effectiveness. This study aimed to compare the efficacy of benzyl benzoate and permethrin in treating scabies infestations.

PATIENTS: Patients >12 years old

INTERVENTION: Benzyl benzoate 25%

CONTROL: Permethrin 5%

PRIMARY OUTCOME: Cure rate

Secondary Outcome: Treatment-emergent adverse events (TEAEs)

METHODS (BRIEF DESCRIPTION):

- The study included patients >12 years old with a confirmed diagnosis of scabies by symptom review and confirmed by dermoscopic examination.
  - Household relatives of people diagnosed were also included if they met inclusion criteria and agreed to participate.
- The patients were recruited at a health facility in Salzburg, Austria from September 2022 to June 2023, with those assigned to permethrin having mean age of 26 years old and that of benzyl benzoate being 31 years old.
- The following patients were excluded:
  - Those treated for scabies in the past three weeks with benzyl benzoate, permethrin or ivermectin
  - Patients with crusted scabies infestation
  - Patients with hypersensitivity or allergy to any ingredients of the two medications.
  - Patients who were pregnant or breastfeeding
- Patients were randomized 1:1 to either benzyl benzoate or permethrin.
  - Patients in the intervention group received 60 g of benzyl benzoate 25% emulsion.
  - Patients in the comparator group received 60 g of permethrin 5% cream.
- Both treatments were applied daily for three consecutive days.
- Standardized instructions were given to patients in both arms.
- Patients were evaluated for treatment at follow up by dermoscopic examination for mites and signs of infection.
- On the telephone, follow-up patients were asked about pruritus or lesions.
- Cure rate was the primary outcome, which was measured by presence of mites under dermascopy.
- The secondary outcome was the number of treatment emergent adverse events which were measured by self-report of participants.
- In the statistical analysis the authors used a correlation analysis. The strength correlations were assigned as follows:
  - Very weak (r=0–0.19)
  - Weak (r=0.2–0.39)
  - Moderate (r=0.40–0.59)
  - Strong (r=0.6–0.79)

INTERVENTION (# IN THE GROUP): 55

COMPARISON (# IN THE GROUP): 55

FOLLOW-UP PERIOD: Three week in-person follow-up; 4–8 week telephone follow up

RESULTS:

Primary Outcome –

- Benzyl benzoate 25% resulted in a higher cure rate compared to permethrin 5% (87% vs 27%, respectively; *P*<.001).

Secondary Outcome –

- Permethrin treatment showed increased likelihood of pruritic post-treatment which was moderately negatively correlated with successful treatment (r –0.41; *P*<.001).
- Of all patients treated those who received benzyl benzoate, 23 participants (43%) reported moderate burning and tingling after application which resolved in 2–60 minutes, while three participants (6%) treated with permethrin complained of itching.
- At follow-up, the presence of pruritus and mite density in the permethrin group showed a moderate correlation with treatment failure (r 0.54; *P*<.001).
- There was no significant difference between age, sex, and mite density at baseline and intervention.

LIMITATIONS:

- Researchers failed to transparently account for variations in the study medications' smell, color, texture, consistency, and TEAEs.
- Researchers' inability to control treatment dosage, adequacy and timing of applications, post-application instructions may have implications for the results.
- The applicability of study outcomes to clinicians and patients in the United States is limited given low availability of benzyl benzoate 25% in the country.
- Performance of the study in a single center impacts generalizability to diverse populations.
- Using telephone follow-up visit, without the ability to examine skin, and only using symptoms as an indicator for reoccurrence may limit the accuracy of the outcome measures.

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