GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

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SPOTLIGHT:
Can You Unlock Your Rotator Cuff with Blood Flow Restriction Training?

- Is Hyperoxygenation a Valid or Purposeless Intrauterine Resuscitation Technique?
- Isotretinoin and Mental Health: Maybe the Black Box Should Be Gray
- Do Spiritual Interventions Lower Blood Pressure?
- Are Exercise Protocols an Effective Treatment for Symptoms of Fibromyalgia?
- Blood Flow Restriction Training as a Treatment for Rotator Cuff Tendinopathy

Can You Unlock Your Rotator Cuff with Blood Flow Restriction Training?

Blood Flow Restriction Training for the Rotator Cuff: A Randomized Controlled Trial

Brumitt J, Hutchison MK, Kang D, et al. Blood Flow Restriction Training for the Rotator Cuff: A Randomized Controlled Trial. *Int J Sports Physiol Perform.* 2020;15(8):1175-1180. Published 2020 Aug 19. doi:10.1123/ijspp.2019-0815

KEY TAKEAWAY: Exercise with blood flow restriction (BFR) to the proximal upper extremity does not increase rotator cuff strength and supraspinatus tendon size compared to exercise alone.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Low-load exercise training with BFR has been shown to improve strength and muscle size possibly due to stimulation of metabolic pathways from metabolite accumulation and cellular swelling. Thus, BFR may be recommended as part of exercise counseling for patients seeking to improve muscle strength and size. This study aimed to evaluate the effects of BFR on the rotator cuff specifically.

PATIENTS: Graduate school students

INTERVENTION: Blood flow restriction to the proximal upper arm with exercise

CONTROL: Exercise only

PRIMARY OUTCOME: Strength of supraspinatus and external rotators

Secondary Outcome: Supraspinatus tendon size

METHODS (BRIEF DESCRIPTION):

- 46 graduate students, with a mean age of 25 years old were included in the study.
- Participants <18 years old, current upper extremity pathology, upper extremity surgery in the last six months, cervical or thoracic surgery during the last year, and any contraindication for BFR training were excluded from the study.
- Patients were randomized to either:
  - Exercise with BFR to the proximal upper arm with the limb occlusion pressure set to 50% during the entire session
  - Exercise alone
- The exercise program consisted of the following:
  - Sidelying external rotation
  - Twice weekly exercise sessions for eight weeks
  - Four sets of exercises with the number of repetitions in order of 30/15/15/15 and 30-second rest in between for eight minutes.
- Strength was measured using a handheld dynamometer by a co-investigator blinded to treatment.
- Supraspinatus tendon thickness was measured using diagnostic ultrasound by a co-investigator blinded to treatment.

INTERVENTION (# IN THE GROUP): 24

COMPARISON (# IN THE GROUP): 23

FOLLOW-UP PERIOD: Eight weeks

RESULTS:

Primary Outcome –

- There were no significant increases in supraspinatus strength between BFR with exercise compared to exercise alone (mean difference 7.4 lbs vs 7.7 lbs; *P*=.75).
- There were no significant increases in external rotator strength between BFR with exercise compared to exercise alone (mean difference 9.8 lbs vs 9.7 lbs; *P*=.71).

Secondary Outcome –

- There were no significant increases in supraspinatus tendon thickness between the groups.

LIMITATIONS:

- Subjects were allowed to continue with their regular exercise routine except for external rotation exercises, but compliance was not monitored.
- The study population only included graduate students so applications to older or younger populations are unknown.
- It is unclear if the baseline characteristics (e.g. gender, prior exercise experience) of the participants between the two groups were completely similar.
- The time of occlusion and exercise sessions may not be long enough to stimulate metabolic pathways to significantly improve strength and size.
- BFR was distal to the muscle of interest. Thus, any beneficial effects from occlusion to the muscle may not be fully elucidated.
- The sample size for each group was small.

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Is Hyperoxygenation a Valid or Purposeless Intrauterine Resuscitation Technique?

Effect of Maternal Hyperoxygenation on Neonatal Outcomes Among Women in Labor with Pathological Cardiotocography: An Open-Label Randomized Controlled Trial

Sulaiman SP, Jha N, Bethou A, Nandeeha H, Jha AK. Effect of maternal hyperoxygenation on neonatal outcomes among women in labor with pathological cardiotocography: an open-label randomized controlled trial. *Am J Obstet Gynecol.* 2024;230(4):454.e1-454.e11. doi:10.1016/j.ajog.2023.09.093

KEY TAKEAWAY: Hyperoxygenation in women in labor with pathologic fetal heart rate tracing compared to usual care did not improve the five-minute Apgar score.

STUDY DESIGN: Randomized, open-label, two-arm parallel, blinded outcome assessor clinical trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Maternal low-flow oxygen has been hypothesized as a potential treatment for suspected fetal hypoxia/acidemia in the setting of pathologic fetal heart rate (FHR) tracing. However, most trials have shown no significant improvement in clinical parameters with the use of low-flow oxygen. Conversely, maternal hyperoxygenation has not been extensively studied. This study examined if high-flow oxygen may have increased benefits to neonatal clinical outcomes compared to low-flow oxygen.

PATIENTS: Singleton parturients with pathologic FHR tracing

INTERVENTION: High-flow oxygen

CONTROL: Low-flow oxygen

PRIMARY OUTCOME: Apgar score at five minutes

Secondary Outcome: Admission to neonatal intensive care, cord blood gas parameters, cesarean delivery

METHODS (BRIEF DESCRIPTION):

- Singleton parturients, ≥18 years old, at term gestation and in active labor, with pathologic FHR tracing, were included in the study.
- Excluded were patients with placental abruption, cord prolapse, multifetal pregnancy, fetal growth restriction (FGR), fetal congenital malformation, chorioamnionitis, or a history of previous cesarean delivery. Those with heart disease and mechanically ventilated were also excluded.
- Patients were randomized to one of two arms:
  - The hyperoxygenation group received 10 L/min of oxygen via a nonrebreathing mask.
  - The usual care group received 6 L/min of oxygen via a simple face mask.
- Outcome assessors, but not patients, were blinded to the intervention.
- FHR tracings were monitored throughout the labor course using a cardiotocograph.
- The emergency cesarean delivery team was activated following 25 minutes of pathologic FHR tracing, with delivery of neonates within 15 minutes.
- Operative delivery was performed if beyond the second stage of labor.
- Neonatal cord blood was collected, and neonatal resuscitation was performed following the neonatal resuscitation protocol (NRP) guidelines.
- Apgar scores were collected at one and five minutes after birth.

INTERVENTION (# IN THE GROUP): 74

COMPARISON (# IN THE GROUP): 74

FOLLOW-UP PERIOD: Not applicable

RESULTS:

Primary Outcome –

- The five-minute Apgar score was not statistically different in the hyperoxygenation vs usual care group (median score 9; *P*=.12).

Secondary Outcome –

- There was no significant difference between the two groups in NICU admission rates or blood gas parameters.
- The hyperoxygenation group, as compared to the usual care group, had a higher base deficit in the umbilical vein (7.4 vs 7.0 mmol/L; *P*=.04) and higher lactate level in the umbilical artery (7.1 vs 6.4 mmol/L; *P*=.03).
- The level of methyl malondialdehyde in the cord blood was significantly lower in the hyperoxygenation group vs the usual care group (8.3 vs 13.4 µmol/L; *P*=.00).
- The incidence of cesarean delivery was significantly lower in the hyperoxygenation group vs the usual care group (4.1% vs 26%; *P*=.00).

LIMITATIONS:

- The patient population was sourced from a single center in India with no breakdown of socioeconomic factors.
- Physicians and patients were not blinded.
- No breakdown for hypertensive disorders, thyroid disorders, or diabetes mellitus which have varying fetal morbidity/mortality rates depending on severity/control.
- The effect of varying time intervals of oxygen therapy based on each participant's natural progression was not discussed.
- Results may not correlate to Cat III FHR described by ACOG as FIGO practice guidelines were utilized.

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Isotretinoin and Mental Health: Maybe the Black Box Should Be Gray

Risk of Suicide and Psychiatric Disorders Among Isotretinoin Users: A Meta-Analysis

Tan NKW, Tang A, MacAlevey NCYL, Tan BKJ, Oon HH. Risk of Suicide and Psychiatric Disorders Among Isotretinoin Users: A Meta-Analysis [published correction appears *in* JAMA Dermatol. 2024 Jan 1;160(1):118. doi: 10.1001/jamadermatol.2023.5582]. *JAMA Dermatol.* 2024;160(1):54-62. doi:10.1001/jamadermatol.2023.4579

KEY TAKEAWAY: Isotretinoin did not increase the risk of suicide or psychiatric diagnoses.

STUDY DESIGN: Systematic review and meta-analysis of 25 studies (10 prospective cohorts, 13 retrospective cohorts, 1 case-control, 1 case-crossover) (N=1,625,891)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to lack of randomized trials and only one case-control study in the meta-analysis)

BRIEF BACKGROUND INFORMATION: Isotretinoin can be a highly effective treatment for severe acne vulgaris, but it carries a black box warning by the US Food and Drug Administration since 2005 due to the potential increased risk of depression or suicidal thoughts. However, the actual degree of increased risk is unclear. This study aims to investigate the effect of isotretinoin on suicidality or underlying psychiatric disorders.

PATIENTS: Patients with acne vulgaris

INTERVENTION: Isotretinoin use

CONTROL: No isotretinoin use

PRIMARY OUTCOME: Risk of suicide or diagnosed psychiatric disorder

METHODS (BRIEF DESCRIPTION):

- Studies were conducted in Asia, Australasia, Europe, and North America, or with multinational cohorts.
- Included studies had to report both the absolute risk (AR) and risk factors for psychiatric disorders, and the relative risk (RR) of the disorders compared with controls.
- Excluded studies were of the wrong study design or did not report relevant outcomes.
- The International Classification of Diseases (ICD) codes were used to define psychiatric diagnoses or events.
- Average demographics of patients: Male and female with mean age 16–38 years old.
- The intervention group took oral isotretinoin; specific doses and duration of treatment were not reported in aggregate.
- The control group included patients not on oral isotretinoin, but there was no report on the use of topical or non-isotretinoin oral medications.
- Sufficient data was available for meta-analysis to calculate AR and RR for suicide and psychiatric disorders in patients using isotretinoin.
    - Regarding suicide, the analysis included the outcomes of self-harm, suicidal ideation, suicide attempts, and completed suicide.
        - These were measured on timeframes ranging from during treatment to as long as ten years post-treatment, using pertinent ICD-10 diagnosis codes in the medical record and/or a variety of standardized scales.
    - The specific psychiatric disorders assessed varied between studies but included depression, mood disorders, sleep disorders, suicidal ideation, anxiety, psychotic disorders, and bipolar disorder.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Up to 10 years

RESULTS:

Primary Outcome –

- Isotretinoin use was not associated with suicide attempts compared to no isotretinoin use:
    - During treatment (3 trials, n=456,765; RR 0.84; 95% CI, 0.45–1.6; I^2=62)
    - Six months (3 trials, n=456,765; RR 1.1; 95% CI, 0.57–2.3; I^2=80)
    - One year (2 trials, n=449,570; RR 1.2; 95% CI, 0.62–2.1; I^2=88)
    - Five years (2 trials, n=449,570; RR 0.85; 95% CI, 0.68–1.1; I^2=49)
    - Ten years (2 trials, n=35,699; RR 1.0; 95% CI, 0.85–1.3; I^2=0)

- After adjustment for age, isotretinoin use was not associated with suicide attempts compared to no isotretinoin use:
  - At two years (2 trials, n=449,570; RR 0.92; 95% CI, 0.84–1.0; I^2=0)
  - At three years (2 trials, n=449,570; RR 0.86; 95% CI, 0.77–0.95; I^2=0)
  - At four years (2 trials, n=449,570; RR 0.85; 95% CI, 0.72–1.0; I^2=23)
- Over one year, isotretinoin was not associated with an increased risk of self-harm, suicidal ideation, suicide attempts, or completed suicide compared to no isotretinoin use:
  - Self-harm (AR 0.35%; 95% CI, 0.29–0.42)
  - Suicidal ideation (AR 0.47%; 95% CI, 0.07-3.1)
  - Suicide attempt (AR 0.14%; 95% CI, 0.04–0.49)
  - Completed suicide (AR 0.07%; 95% CI, 0.02-0.31)
    - Comparisons were not provided for all categories, but two longitudinal studies are cited that reported AR of suicide attempts in adolescents of 0.84% and 1.3%.
- At one year from treatment, while 4.6% of isotretinoin users had developed a psychiatric disorder, isotretinoin use was not associated with an increased risk of developing a psychiatric disorder (RR 1.1; 95% CI, 0.99–1.2).

LIMITATIONS:

- Three studies had a high risk of bias, and 16 had a moderate risk.
- There was a high degree of heterogeneity across studies.
- Relative risks for some outcomes had wide confidence intervals in some studies, which could indicate the study was underpowered.
- Not all studies evaluated isotretinoin users for comorbid psychiatric conditions.
- Potential confounding effects include detection bias, as persons taking isotretinoin are generally monitored closely for adverse effects including psychiatric conditions. Similarly, given the existing black box warning, individuals whom clinicians assess to be at higher risk for suicidality or other adverse psychiatric outcomes may not be offered treatment.

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Do Spiritual Interventions Lower Blood Pressure?

Spiritually Based Interventions for High Blood Pressure: A Systematic Review and Meta-Analysis

Khabiri R, Jahangiry L, Abbasian M, et al. Spiritually Based Interventions for High Blood Pressure: A Systematic Review and Meta-analysis. *J Relig Health.* Published online April 2, 2024. doi:10.1007/s10943-024-02034-3

KEY TAKEAWAY: Spiritual interventions including meditation, transcendental meditation, mindfulness meditation, and yoga significantly decrease systolic and diastolic blood pressures.

STUDY DESIGN: Meta-analysis and systematic review of 23 randomized control trials (N=1,865)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to significant heterogeneity)

BRIEF BACKGROUND INFORMATION: The World Health Organization (WHO) identified spirituality as the 4th dimension of health in 1998. However, there is a lack of consensus on the role of spiritual health on overall physical health with the majority of the evidence based on observational studies. This study evaluates the effects of spiritually-based interventions on systolic and diastolic blood pressures.

PATIENTS: Adults

INTERVENTION: Spiritual therapies

CONTROL: Various comparators including no intervention

PRIMARY OUTCOME: Systolic blood pressure (SBP) and diastolic blood pressure (DBP)

METHODS (BRIEF DESCRIPTION):

- Studies were conducted in the USA, Canada, India, Spain, and England and included only studies written in English or Persian.
- Adults ≥18 years old were included in the study.
- The spiritual intervention included meditation, transcendental meditation, mindfulness meditation, and yoga.
- The studies compared these individuals to those with various other therapies which included health promotional programs, health education as well as no intervention.
- Blood pressure changes were clinically measured at baseline and at the end of the intervention.

INTERVENTION (# IN THE GROUP): 1,018

COMPARISON (# IN THE GROUP): 847

FOLLOW-UP PERIOD: Variable (1–192 weeks)

RESULTS:

Primary Outcome –

- Spiritually based interventions significantly decreased SBP compared to control (15 studies, n=1,105; weighted mean difference [WMD] −7.6; 95% CI, −9.6 to −5.7; I^2=95).
- Spiritually based interventions significantly decreased DBP compared to control (13 studies, n=999; WMD −4.8; 95% CI, −6.5 to −3.1; I^2 = 98).

LIMITATIONS:

- Significant heterogeneity was observed.
- A significant publication bias was observed in the meta-analysis.
- There were discrepancies between the numbers stated by the authors and the numbers totaled in the included table for both the intervention and control groups.

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Are Exercise Protocols an Effective Treatment for Symptoms of Fibromyalgia?

Effects of Different Protocols of Physical Exercise on Fibromyalgia Syndrome Treatment: Systematic Review and Meta-Analysis of Randomized Controlled Trials

Albuquerque MLL, Monteiro D, Marinho DA, Vilarino GT, Andrade A, Neiva HP. Effects of different protocols of physical exercise on fibromyalgia syndrome treatment: systematic review and meta-analysis of randomized controlled trials. *Rheumatol Int.* 2022;42(11):1893-1908. doi:10.1007/s00296-022-05140-1

KEY TAKEAWAY: Programs combining strength and aerobic exercise, at 2–3 sessions per week at moderate intensity for 13–24 weeks, reduce fibromyalgia disease burden and pain with large effect sizes.

STUDY DESIGN: Systematic review and meta-analysis of 16 randomized controlled trials (N=796)

LEVEL OF EVIDENCE: STEP 3 (downgraded due to significant heterogeneity)

BRIEF BACKGROUND INFORMATION: Fibromyalgia is a chronic pain condition that can have a detrimental effect on a patient's quality of life. Pharmacologic interventions for symptoms of fibromyalgia, while existing, have limited efficacy and can be associated with adverse effects. If effective, lifestyle interventions including exercise programs may help physicians and patients optimize the non-pharmacologic treatment of fibromyalgia.

PATIENTS: Adults with fibromyalgia

INTERVENTION: Exercise protocol

CONTROL: No exercise intervention

PRIMARY OUTCOME: Disease burden

Secondary Outcome: Patient quantification of pain

METHODS (BRIEF DESCRIPTION):

- Individuals >18 years old with a diagnosis of Fibromyalgia per the American College of Rheumatology criteria were included in the study.
  - The majority of studies evaluated populations in Europe and South America.
- Participants underwent a variety of exercise protocols consisting of subgroups of aerobic, strength, flexibility, or combined training methods.
- All exercise protocols consisted of 2–3 days per week lasting for 13–24 weeks.
- Session duration ranged from <30 minutes to >60 minutes.
- Intervention periods ranged from a minimum of eight weeks to eight months.
- All studies compared each treatment group to a control group that received no intervention.
- Effect on disease severity was measured by a standardized Fibromyalgia Impact Questionnaire (FIQ) and participant surveys quantifying pain.

INTERVENTION (# IN THE GROUP): 422

COMPARISON (# IN THE GROUP): 330

FOLLOW-UP PERIOD: Variable (8 weeks to 8 months)

RESULTS:

Primary Outcome –

- Exercise interventions had a beneficial effect on reducing disease burden compared to the control groups with a large effect size (16 trials, n=796; standardized mean difference [SMD] –1.3; 95% CI, –1.5 to –0.48).
  - Aerobic training groups had a high effect size (4 trials; SMD –0.82; 95% CI, –1.2 to –0.48; I^2=26%)
  - Strength training groups had moderate effect size (2 trials; SMD –0.66; 95% CI, –1.1 to –0.25; I^2=0%)
  - Combined intervention groups had a high total effect size with high heterogeneity (5 trials; SMD –1.3; 95% CI, –2.6 to –0.06; I^2=94%)

Secondary Outcome –

- The effect of exercise intervention on patient-reported pain outcomes was further stratified across the intervention period and session time.
- Protocols with an intervention period between 13 and 24 weeks improved pain with a high effect size but had a high heterogeneity index (SMD –1.0; 95% CI, –1.5 to –0.50; I^2=87%).
- Protocols with session duration between 30 and 60 minutes reduced patient pain, but also had high heterogeneity (SMD –1.1; 95% CI, –1.6 to –0.53; I^2=87%).

LIMITATIONS:

- Significant heterogeneity of exercise protocols across studies

- The majority of studies evaluated populations in Europe and South America raising concern for relevance.

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Blood Flow Restriction Training as a Treatment for Rotator Cuff Tendinopathy

Blood Flow Restriction Training in Patients with Rotator Cuff Tendinopathy: A Randomized, Assessor-Blinded, Controlled Trial

Kara D, Ozcakar L, Demirci S, Huri G, Duzgun I. Blood Flow Restriction Training in Patients With Rotator Cuff Tendinopathy: A Randomized, Assessor-Blinded, Controlled Trial. *Clin J Sport Med*. 2024;34(1):10-16. doi:10.1097/JSM.0000000000001191

KEY TAKEAWAY: Low-load blood flow restricted (BFR) training of the upper extremity in patients with rotator cuff injury increases biceps brachii muscle hypertrophy and shoulder internal rotation (IR) strength compared to non-blood flow resistance (non-BFR) training.

STUDY DESIGN: Randomized, assessor-blinded, controlled trial

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

BRIEF BACKGROUND INFORMATION: Low-load resistance training with BFR has gained popularity for strength training without resulting in high levels of joint stress or increased pain in injury. There is limited data on the effectiveness of this technique in the upper extremity. The study was conducted to assess the effects of low-load BFR training on shoulder muscle thickness, rotator cuff strength, function, and pain in patients with a rotator cuff injury.

PATIENTS: Adults with a diagnosis of rotator cuff tendinopathy

INTERVENTION: BFR physical therapy

CONTROL: Non-BFR physical therapy

PRIMARY OUTCOME: Shoulder muscle thickness and rotator cuff strength

Secondary Outcome: Shoulder pain and function

METHODS (BRIEF DESCRIPTION):

- 37 patients were assessed for inclusion.
- Patients included were 18–45 years old and had a diagnosis of rotator cuff tendinopathy with unilateral shoulder pain lasting at least three months, no contralateral pain, and at least three of the following criteria:
  - Neer sign, positive Hawkins sign, positive Jobe sign, painful arc, and positive resistance test against shoulder external rotation (ER).
- Patients were excluded if they had full-thickness rotator cuff tears, corticosteroid injection within six months prior, frozen shoulder, or declined participation in the study.
- Patients were blinded and randomized to one of the following treatments:
  - Low-load BFR training for rotator cuff tendinopathy using a BFR cuff pressure set to 50% of limb occlusion pressure (LOP) during exercise. 30 seconds of rest was given between sets and two minutes between exercises. The cuff was deflated during the two-minute rest periods. The BFR was increased each session until the desired max pressure was reached in session four.
  - Non-BFR training for rotator cuff tendinopathy
- Both groups participated in rehabilitation twice a week for eight weeks (16 sessions).
- The rehabilitation protocol was administered by physical therapists at the University Sports Medicine Clinic.
- Ultrasound measurement of muscle thickness in centimeters was performed by a physiatrist blinded to the study group.
- Muscle strength was assessed at 60 and 180 degrees using isokinetic testing for shoulder IR and ER.
- Resistance was measured using the one repetition maximum test (1-RM) for the test with free weights and OMNI Resistance (OMNI-RES EB) was used for the elastic bands with elastic resistance.
- Shoulder pain was assessed using the visual analog scale. Scores range from 0–10 with higher scores indicating worse pain. Scores were assessed at rest, at night, and after activity.
- Shoulder pain and function were evaluated by Shoulder Pain and Disability Index (SPADI). Scores range from 0–100 with higher scores indicating more should dysfunction.
- All measurements were performed one week before the start of the rehabilitation program, at the end of the intervention period, and at least 72 hours after the last training session.

INTERVENTION (# IN THE GROUP): 14

COMPARISON (# IN THE GROUP): 14

FOLLOW-UP PERIOD: Eight weeks

RESULTS:

Primary Outcome –

- BFR training increases biceps brachii muscle thickness more than non-BFR (mean difference [MD] 0.23 cm vs –0.10 cm; *p*=.002).
- BFR training increases muscle strength in shoulder IR at 60% more than non-BFR (MD 0.06 Nm/kg vs 0.01 Nm/kg; *p*=.04).
- BFR training does not improve ER or muscle thickness in the scapula retractor or deltoid muscle in the BFR compared to non-BRF groups.
    - ER (MD 0.05 Nm/Kg vs 0.03 Nm/kg)
    - Scapular retractor (MD 0.12 Nm/kg vs 0.25 Nm/kg)
    - Deltoid (MD 0.09 vs –0.06 Nm/kg)
    - P-values were not reported.

Secondary Outcome –

- Both groups showed improvement in pain and function with physical therapy but there was not a statistically significant difference in outcomes for BFR vs non-BFR groups.

LIMITATIONS:

- The small number of participants in the study may limit the overall results.
- Baseline strength assessment was limited in both groups by pain.
- The increase in strength in both groups may be related to decreased pain compared to an actual increase in strength.
- The anabolic response of blood flow resistance training was not shown and may be related to the number of repetitions or deflating cuff between exercises.

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