CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a 45 year old male with paraplegia from a traumatic spinal cord injury, is an exercise intervention to address shoulder strength more effective than wheelchair ergonomics/propulsion stroke education in reducing pain and/or improving function in shoulder overuse injuries?

AUTHOR

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CLINICAL SCENARIO

Forty-five year old patient recently sustained a complete thoracic level SCI and is presenting to inpatient rehabilitation. Patient is learning how to perform transfers and wheelchair mobility to improve independence during his inpatient stay. This patient is already experiencing shoulder pain due to the sudden increase in functional demands. Shoulder overuse injury is common in this patient population due to the demands placed on the UE for transfers, ADLs and mobility.[1-10] Shoulder pain has been reported in 30-75% of manual wheelchair users.[6] Shoulder pain and overuse injuries can negatively impact a paraplegic's function and independence, causing significant debility. Knowing the most appropriate, best supported intervention that can offer tangible reduction in shoulder pain and improvement in function can drastically impact a patient's quality of life and independence.

SUMMARY OF SEARCH

- Three electronic databases were searched, with ten studies found that met the specified inclusion and exclusion criteria, including 1 systematic review, 3 RCTs, and 6 quasi-experimental repeated measure designs. Three studies were reviewed in detail in this appraisal.
- Evidence from the three highest quality studies shows that in SCI subjects with shoulder pain who use manual wheelchairs:
    - A shoulder strengthening and stretching home-based program can decrease Wheelchair Users Shoulder Pain Index (WUSPI) scores and shoulder pain.
    - A shoulder exercise program paired with movement/technique optimization for UE weight-bearing tasks and wheelchair propulsion is more effective than an attention control/education intervention.
    - A shoulder exercise program paired with EMG biofeedback to ensure proper muscle activation or relaxation of overactive muscles can also improve WUSPI total scores and pain ratings.
    - Each program had different areas of focus (scapular strengthening vs rotator cuff strengthening) with different exercise parameters (when specified) and ranged from 8-12 week duration.

CLINICAL BOTTOM LINE

Current evidence does not provide a direct comparison of shoulder exercise programs and wheelchair ergonomics/propulsion stroke interventions in SCI patients who are suffering from shoulder pain and who use manual wheelchairs. Patients who performed a home-based exercise program demonstrated a decrease in shoulder pain and increase in function when compared to no intervention[9] and an attention control education group.[1] Patients who received a home-based shoulder exercise program and EMG biofeedback improved to a greater capacity compared to no intervention,[9] and appeared to improve to a greater capacity when compared to shoulder exercise intervention alone (no between group data provided).[2] Patients who also received movement optimization technique feedback along with a shoulder exercise program also improved in pain rating and function, however, the degree of influence of each intervention is unclear as both were provided to the same group.[1] Skilled physical therapy intervention through providing an appropriately tailored home-based shoulder stretching and strengthening program with EMG biofeedback and possible movement optimization should be used in paraplegic patients with shoulder pain to address pain and improve function.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Paraplegia Paraplegic SCI Spinal Cord Injury	Exercise program Exercises Shoulder strengthening Shoulder strength	Manual wheelchair ergonomics Manual wheelchair propulsion Propulsion Propulsion strokes Education	Shoulder injuries Shoulder overuse injuries Overuse injuries

Final search strategy:

Pubmed:

1. Spinal Cord Injury [MeSH Terms]
2. Paraplegia OR paraplegic OR SCI OR spinal cord injury
3. (exercise OR exercises OR strengthening OR strength) AND shoulder
4. manual wheelchair ergonomics OR manual wheelchair propulsion OR propulsion OR propulsion stroke OR "spinal cord education"
5. ("overuse injuries" OR injuries) AND "shoulder pain"
6. #1 AND #3 AND #4 AND #5
7. #2 AND #3 AND #4 AND #5
8. (#1 OR #2) AND #3 AND #5
9. (#1 OR #2) AND #4 AND #5
10. #8 OR #9

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
Pubmed	27	((#1 OR #2) AND #4 AND #5)
CiNAHL	55	S1 AND S2 AND S3 AND S4
Web of Science	42	#1 AND #3 AND #4 AND #5

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Outcome measures addressed shoulder pain and function • Adults with spinal cord injuries (paraplegia) who have the ability to propel self in manual wheelchair • Randomized controlled trials, systematic reviews, or quasi-experimental designs (repeated measures) • Protocol included physical therapy strengthening exercise program for the shoulders • Subjects can have complete or incomplete spinal cord injuries
Exclusion Criteria
• Articles/studies not published in English • Case reports, case studies, case series, letters to the editor, abstracts, dissertations, powerpoint slides/conference presentations

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Study quality score	Level of Evidence	Study design
Mulroy et al, 2011[1]	Pedro: 9/11	1b	RCT
Middaugh et al, 2013[2]	Pedro: 7/11	1b	RCT
Curtis et al, 1999[3]	Pedro: 4/11 Modified Downs & Black: 17/29	2b	RCT
Nash et al, 2007[4]	Modified Downs & Black: 14/29	2b	Quasi Experimental Design: Repeated measures: single group
Finley et al, 2007[5]	Modified Downs & Black: 19/29	2b	Quasi Experimental Design: Repeated measures: single group
Van Straaten et al, 2014[6]	Modified Downs & Black: 18/29	2b	Quasi Experimental Design: Repeated measures: single group (BL, post intervention (12wks), follow-up (>24wks)
Norrbrink et al, 2012[7]	Modified Downs & Black:15/29	2b	Quasi Experimental Design: Repeated measures: single group
Serra-Ano et al, 2012[8]	Modified Downs & Black: 14/29	2b	Quasi Experimental Design: Repeated measures: single group:T1 – T2 = no program; T2-T3 = 8 weeks training program; no comparison group
Nawoczenski et al, 2006[9]	Modified Downs & Black: 20/29	2b	Quasi Experimental Design: Repeated measures with asymptomatic control group
Cratsenberg et al, 2015[10]	Amstar: 7/11	1a	Systematic Review

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Mulroy et al[1]:** A well-designed and executed RCT comparing home-based stretching/strengthening with recommendations on how to optimize movement technique for transfers, raises, & wheelchair propulsion to an attention control group that received a 1 hour educational video. Symptomatic subjects were randomly assigned, allocation was concealed, and outcome measures were assessed by a blinded assessor. The author's also performed an intention-to-treat analysis, decreasing bias by including those participants that dropped out in the analysis.
- **Middaugh et al[2]:** A RCT comparing a home-based exercise program to a home-based exercise program that also received EMG biofeedback training. Shoulder pain as well as cervical pain was assessed. Subjects were randomly assigned, with assessors blinded to subject intervention. This study did note not having enough power to analyse between group differences and does not have a "true" control group without intervention.

- **Nawoczenski et al[9]:** This article was chosen over the poor quality RCT by Curtis et al.[3] because when scoring with the Modified Downs and Black on both, this study was found to have a higher score. The study is relevant, does include a control group, though it is an asymptomatic group, and compared it to the exercise intervention group. Though this study lacked randomization, it did assess possible confounding effect by doing independent t-tests of demographic data and Pearson correlations between demographic variables and dependent variables. The study also performed intention-to-treat analysis, where it was unclear if Curtis et al. did. Also in Curtis et al, not all subjects in either group were experiencing pain, which made the reader question their findings.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Clinical Trial of Exercise for Shoulder Pain in Chronic Spinal Injury by: Nawoczenski DA, Ritter-Soronen JM, Wilson CM, Howe BA, Ludewig PM. (2006).[9]

Aim/Objective of the Study/Systematic Review:

The objective of the study was to determine the effects of an 8 week home-based scapular and shoulder exercise intervention on shoulder pain and functional disability in SCI patients with symptoms of shoulder impingement.

Study Design

Quasi Experimental Design: Repeated measures with asymptomatic control group

- All subjects performed baseline outcome measures
- Subjects separated into intervention group and asymptomatic control group based on results of physical examination → Asymptomatic control group presented with no history of shoulder pain in previous 3 months and negative findings on impingement tests/clinical examination
- There was no blinding of subjects or assessors
- Outcome measures for all subjects measured at: baseline, after 8 weeks of intervention/control
- Significance level set at $p<0.05$
- 2 way mixed model ANOVA to determine main effects for group (between subject factor) and time (within subject comparison)
- Post hoc analysis via Tukey-Kramer Adjustments when significance was detected. Testing for difference within group over time and between groups for pre-test and post-test scores.
- T-tests and Pearson correlations used to assess confounding effects for demographic variables
- Intention-to-treat analysis performed

Setting

- Movement Analysis Laboratory in Department of Physical Therapy at Ithaca College-Rochester Campus
- Orthopaedic Biomechanics Laboratory at the University of Minnesota

Participants

- This study utilized a sample of convenience
- All subjects were diagnosed with SCI, except 1 individual had Spina Bifida; Author's do not state which group the patient with spina bifida was in.
- Intervention group: N = 21, Mean age: 47 y.o, 15 males, 6 females, Mean BMI = 24.7, Mean years since injury:17.0, Mean # transfers/day: 20.7, Mean hours in WC/day: 12.4, Level of injury: cervical incomplete = 3, Thoracic: High (T2-T7) =7, Low (T8-T12) = 7, Lumbar = 4; Extent of Injury: Incomplete = 13, Complete = 8
- Asymptomatic Control group: N = 20, Mean age: 38 y.o, 13 males, 7 females, Mean BMI = 27.0, Mean years since injury:9.2, Mean # transfers/day: 16.5, Mean hours in WC/day: 14.3, Level of injury: cervical incomplete = 0, Thoracic: High (T2-T7) =7, Low (T8-T12) = 12, Lumbar = 1; Extent of Injury: Incomplete = 6, Complete = 14
- Baseline characteristics between groups: significance found for age, and years since injury
- Baseline characteristics between groups: no significance found for BMI, # transfers/day or hours in WC/day
- N= 2 subjects in intervention group lost at follow-up, but intention-to-treat analysis was performed
- Of intervention group subjects, n = 14 were highly adherent (completed >75% program), n = 3 were moderately adherent (25% - 75%), n= 2 were non-adherent (<25%) via self-report exercise adherence log

Intervention Investigated

Control

- Baseline: Asymptomatic control group completed pre-test outcome measures
- No intervention performed
- 8 weeks: returned to lab to complete outcome measures

Experimental

- Baseline: Completed pre-test outcome measures; EMG biofeedback used to ensure proper muscle activation and/or aid in muscle relaxation (serratus anterior, pec major, upper/mid trap). Subjects also shown anatomy pictures of targeted muscles with each exercise
- Given HEP with stretching (upper trap, pec major, long head biceps, posterior capsule) and resistance band strengthening (mid and lower trap, serratus anterior, shoulder ER); exercise given in customized pamphlet with subject's pictures of performing exercises. All exercises performed at 90* or less of shoulder flexion.
    - Exercise not given if targeted muscle couldn't be activated without significant EMG activity of upper trap/pec major, or if it caused shoulder pain
    - Exercise frequency and dosage not specified
- Subjects were asked to complete adherence exercise log
- Subjects were called each week by the investigator to answer subjects questions about exercises/technique
- 4 weeks (or sooner if necessary): subjects return to lab for progression of exercises (increasing resistance and/or repetitions); EMG biofeedback used if needed (author's don't define what constituted "needed" means for this time point)
- 8 weeks: returned to lab to complete outcome measures

Outcome Measures (Primary and Secondary)

- WUSPI (Wheelchair User's Shoulder Pain Index)
    - Total Score Range: 0-150 (Lower Score indicates decreased pain and improved function)
    - If question not applicable and/or subject didn't complete, a PC-WUSPI (performance corrected) score was applied and used in statistical analyses
- SRQ (Shoulder Rating Questionnaire)
    - Total Score Range: 17-150 (higher score shows greater shoulder function/fewer impingement symptoms)
    - Score is weighted: Global assessment rating x 1.5, pain score x 4, daily activity score x 2, recreational/activity score x 1.5, work score x 1
- Satisfaction Score
    - Independent of above calculation: Range 2-10 (higher number indicates greater satisfaction) when asked "how would you rate your overall degree of satisfaction with your shoulder?"
- Not specified by whom measures administered or where; assume in lab

Main Findings

Subjects in exercise intervention group improved in WUSPI, SRQ scores, and Satisfaction score between time points (pre and post)

Subjects in asymptomatic control group did not significantly improve in WUSPI, SRQ, Satisfaction scores between time points

Pre and Post means and SEM for each outcome measure provided in figures, therefore hard to determine exact points.

Time Change Scores (pre to post-test) (mean (SE)):

- WUSPI*: = Intervention group: -22.85 points (7.59); Control: 2.01 points (1.31); 95% CI between groups (-37.17- -12.55)
- SRQ** = Intervention: 15.62 (3.20); Control: -1.75 (1.37); 95% CI between groups (13.78 - 20.96)
- Satisfaction Score*** = Intervention: 2.38 (0.47); Control: -0.10 (0.31); 95% CI between groups (2.17 - 2.79)

* Negative score indicated reduction of pain/improvement in function

**Positive score indicates reduction in shoulder symptoms/improved function

*** Higher score indicates greater satisfaction

Note: CI for between group differences were calculated by CAT author (A. Friedline Weber)

There were significant Group X Time Interactions for all 3 outcome measures due to significant pre-post improvements in the interaction while there were no improvements across time points in the control group.

Authors also broke down individual items of the WUSPI for each group at both time points, providing mean (SEM), but is in graph form, so determining actual data points to calculate p-values is difficult

Original Authors' Conclusions

An 8 week home-exercise program focusing on stretching and strengthening scapular muscles/external rotators reduces pain, improves function, and improves patient satisfaction in SCI population (and 1 spina bifida diagnosis) when compared to an asymptomatic control group. Generalizability should be to SCI patients with full innervation of scapular musculature. Furthermore, the author stated "Interventions targeted to the scapula may effectively minimize the progression of shoulder impingement symptoms and ultimately the secondary disability associated with shoulder pain." (pg. 1613)

Critical Appraisal

Validity

On the Modified Downs and Black, this study scored a 20/29. Overall strengths are it took into account confounders of demographic data by running appropriate statistical tests, provided baseline demographic data for the reader, clearly described outcome measures, and performed intention-to-treat analyses when subjects were lost to follow-up.

This study however, does have some limitations. Overall, it has questionable validity. First of all, it is a sample of convenience with no mention of power analysis for the reader to know if number of subjects in each group were sufficient to reach appropriate power. Also, while there is a control group, the subjects were asymptomatic, so this isn't allowing a comparison of one intervention to the gold standard of treatment (ie. Exercise program vs wheelchair propulsion stroke). Having the control group doesn't offer further information about a specific intervention because the control group subjects were pain free and received no intervention. It simply says that those pain free individuals remained pain free during study duration without intervention. Also, there is no randomization or blinding of subjects or assessors due to the control being asymptomatic subjects, posing room for biases. Furthermore, exercise frequency and dosage are not specified, making it difficult for the reader or someone trying to utilize this program for a specific patient to recreate the methodology of this study.

Interpretation of Results

An 8 week strengthening/stretching shoulder program, paired with EMG biofeedback when learning the exercises, resulted in a statistically significant improvement in WUSPI, SRQ and Satisfaction score. Since the control group didn't have shoulder pain/symptoms, comparing the intervention to this group isn't helpful or appropriate. Because of this, results were interpreted as a single group repeated measure design, where the pre and post intervention scores on the WUSPI, SRQ, and satisfaction scale improved (statistically significant) due to the exercise interventions. The author's provided change scores for each outcome measure, allowing the reader to use clinical judgement in determining clinical significance of this study (effect size). Knowing from previous research the MDC for the WUSPI has been reported as 5.10 points,[11] a change score of ~23 points appears clinically significant. The MCID or MDC for the SRQ or Satisfaction score are not published/known, but a change score of ~15 points on a 17-150 point scale (SRQ) seems fair, and 2 points on a 2-10 point scale (satisfaction score), could be meaningful change.

For between group data, CI for time-change scores between groups were calculated by CAT author (A. Friedline Weber). The CI's don't contain 0, which means the results are significant, however, the CI range is large, meaning the precision of the results in poor.

The above stated reasons paired with lack of quality of study design (blinding, randomization, a control group that isn't appropriate/useful), and uncertainty if the sample sizes were even appropriate to determine significance, cause the CAT author to rate the overall clinical significance of this study as fair.

(2) Description and appraisal of (Strengthening and Optimal Movements for Painful Shoulders (STOMPS) in Chronic Spinal Cord Injury: A Randomized Controlled Trial) by (Mulroy et al, 2011)[1]

Aim/Objective of the Study/Systematic Review:

The primary purpose was to determine the effect of a 12 week home-based shoulder exercise program paired with UE task/movement instruction compared to an educational control group on shoulder pain in people with SCI. The secondary purpose, though not the focus of this appraisal, was to investigate the impact of the intervention on physical activity/participation and to determine if improvements in pain or function were maintained 4 weeks post completion of exercise intervention.

Study Design

Prospective Randomized Controlled Trial

- All subjects administered outcome measures at baseline, post 12 week intervention, and 4 weeks post completion of study by blinded assessor
- Subjects were randomly assigned to interventions group via computer
- Subjects were compensated for participation in study (2 payments of $50)
- Subjects offered to receive other intervention at end of study participation
- Power analysis performed with ANOVA design and a p value of 0.05, power = 0.80, determined 30 participants for each intervention group were needed for a between groups medium effect size of 0.65 on the WUSPI; to compensate for attrition 40 subjects were enrolled per group
- Statistical analyses conducted at 0.05 significance level
- Sharpiro-Wilks Test used to screen data for normality
- ANOVAs for means and chi-square or Fisher tests for proportions to compare demographic/medical history characteristics between groups (exercise intervention and attention control)
- Repeated ANOVAs compared main outcome measures at baseline and after 12 week intervention
- Post hoc testing performed when significant interaction was found between group and time
- "Similar analyses" used to investigate difference in shoulder pain/outcomes due to exercise/movement optimization between individuals who demonstrated specific pain-inducing activities and those who did not; also to evaluate the persistence of the treatment effects at 4 weeks for all outcomes in both intervention groups
- Intention-to-treat analysis for all participants during 3 times points using mixed model analyses: intervention group and time were included; intercept of dependent variables at baseline across participants was the random effect

Setting

Setting not specified; assume it was conducted in an academic institution research laboratory. Exercise intervention was performed in subject's home since it was a home-based program.

Participants

A sample of convenience was utilized with subjects recruited from outpatient clinic March 2004 – December 2005.

N = 80 (N = 40 for intervention and attention control group)

- Exercise/Movement Optimization Group Demographic Data:
    - N = 31 male; Age = mean (SD): 47 y.o (9); Latino or Hispanic: 21; Race = Black/AA: 8, White: 18, Unspecified: 14; ASIA A: 25, ASIA B: 9, ASIA C: 3, ASIA D: 1, Unknown: 2; Level Injury = High (T2-T7) = 27, Low (T8 and below) =13; Duration of SCI (mean (SD)) = 17.9 years (9.2); Duration Shoulder Pain = L: 71 months; R: 66 months

- Attention Control Group Demographic Data:
    - N = 26 male; Age = mean (SD): 47 y.o (12); Latino or Hispanic: 23; Race = Black/AA: 2, White: 19, Unspecified: 19; ASIA A: 25, ASIA B: 5, ASIA C: 5, ASIA D: 1, Unknown: 4; Level Injury = High (T2-T7) = 16, Low (T8 and below) =24; Duration of SCI (mean (SD)) = 22.3 years (11.8); Duration Shoulder Pain = L: 61 months; R: 65 months

- Race (p = 0.03) and high versus low paraplegic (p = 0.01) were only two baseline differences between groups

Drop Outs:

- N = 9 drop outs prior to receiving intervention (n =5 in exercise/movement optimization group; n = 4 in attention control group)
    - N = 35 received exercise/movement optimization intervention; N = 36 received attention control
- N = 13 withdrew before finishing 12-week intervention period (n = 9 in exercise/movement optimization group; n = 4 from attention control)
- N = 6 in attention control group lost to follow-up prior to 4 weeks follow-up assessment
- Number available for post-intervention analysis: n = 26 in exercise/movement optimization group; n = 32 in attention control group
- Authors reported "No significant differences in demographics or baseline outcome measures existed between participants who withdrew and those who completed the immediate post intervention evaluation" (Pg. 311)

Adverse Events:

- 27 cumulative AEs in 23 participants (n= 12 in exercise/optimization group; n = 11 in attention control); n = 2 due to study, with one being neck pain and another being an elbow abrasion.

Intervention Investigated

Control

- Administered baseline outcome measures
- Subjects viewed a 1 hour education video discussing general shoulder pain management/concepts, shoulder anatomy, and MOI
- Subjects received handout and brochure detailing information from video; information was intentionally vague and did not mention/recommend specific behaviour changes
- Administered outcome measures after 12 week intervention period
- Administered outcome measures 4 weeks after 12 week intervention conclusion (follow-up period)
- Outcome measures administered by same blinded assessor at all time points; physical therapist had to score >90% on standardization score sheet for outcome measures, demonstrated understanding and training on the measure

Experimental

- Administered baseline outcome measures
- Received instruction by physical therapist for 12 week HEP and optimization strategies for transfers, depression raises, and WC propulsion technique
- Subjects received binder with pictures and written instructions of stretches, strengthening exercises, and equipment needed to perform
- Movement Optimization: subjects received list of 10 recommendations from the APTA PT Journal to promote improved performance and efficiency of transfers and WC propulsion
- "Physical Activity Calendar" to chart adherence and any adverse events was completed by subjects
- Dosage: 3x/week for 12 weeks: Included stretching phase (ant/post capsule and musculature), warm-up phase (4 active movements), and resistive shoulder exercise phase (same 4 activities in warm-up phase, but with resistance); instructions provided by PT if goal was hypertrophy or endurance.
    - Level resistance selected so patient could perform 8 reps if was for hypertrophy or 15 reps for endurance; adjusted by increasing resistance of theraband/hand weights
    - Hypertrophy (shoulder adduction, ER): Dosage was 3 x 8 reps, with 1-2 min rest between sets
    - Endurance (shoulder elevation in scapular plane, scapular retraction): Dosage was 3 x 15 reps, with 1-2 min rest between sets
- 4 weeks into intervention: strength testing and technique assessed (resistance adjusted if needed and adherence examined based upon familiarity to perform exercises)
- End of 12 week intervention: administered outcome measures
- Administered outcome measures 4 weeks after 12 week intervention conclusion (follow-up period)
- Outcome measures administered by same blinded assessor at all time points; physical therapist had to score >90% on standardization score sheet for outcome measures, demonstrated understanding and training on the measure

Outcome Measures (Primary and Secondary)

Author's investigated numerous outcome measures across WHO ICF model framework. Only the WUSPI, VAS pain rating scale, and selected wheelchair propulsion speed are reported in this appraisal to investigate influence of intervention on shoulder pain and function.

- Primary Outcome Measure:
    - WUSPI (Wheelchair User's Shoulder Pain Index)
        - Total Score Range: 0-150 (Lower Score indicates decreased pain and improved function)

- Secondary Outcome Measure:
    - VAS
        - 0 – 10 cm single item rating for shoulder pain
    - Self-selected wheelchair propulsion speed over 25 m distance (in m/s)

Main Findings

Pre to Post Intervention Data:

WUSPI:

- Exercise/Movement Optimization Group:

    - Change Score: -36.3 points; significant within group difference at p<0.05; 95% CI: -48.5 to 23.7
- Attention Control Group:
    - Change Score: 0.2 points; 95% CI: -11.2 to 11.2
- Group & Time Interaction: p = <0.001, effect size: -1.2
- Negative score indicated reduction of pain/improvement in function

Single Item VAS:

- Exercise/Movement Optimization Group:
    - Change Score: -3.7 cm; significant within group difference at p<0.05; 95% CI: -2.3 to 5.0
- Attention Control Group:
    - Change Score: -0.5 cm; 95% CI: -1.3 to 1.9
- Group & Time Interaction: p = <0.001, effect size: -1.2
- Negative value indicated reduction of pain

Wheelchair Propulsion Speed (m/s):

- Exercise/Movement Optimization Group:
    - Change Score: 0.0 m/s; 95% CI: -0.1 to 0.1
- Attention Control Group:
    - Change: 0.0 m/s; 95% CI: -0.1 to 0.1
- Group & Time Interaction: p = 0.45, effect size: 0.14

Post Intervention to 4-week Follow-up Data:

- WUSPI: Exercise Group: Change Score (SD) =-0.9 (34.7) points; Attention Control: Change score (SD) =-6.1 (28.3); Group x Time Interaction: p = 0.34

Interaction Between Group x Time (all three time points: pre, post, 4 week follow-up) Based on Intention-to-treat Analysis

- WUSPI: p <0.001; Single Item VAS: p <0.001; Wheelchair Propulsion Speed: p = 0.70

Original Authors' Conclusions

Utilization of a home shoulder strengthening (primarily focusing on rotator cuff muscles) and stretching program with modification of technique with UE tasks and functional activities resulted in significant reduction of chronic shoulder pain in SCI (paraplegia) subjects. Though there was a decrease in shoulder pain, self-selected wheelchair propulsion and other physical activity/community activity measures did not improve pre to post intervention in the intervention or control group, but improvements in muscle strength and QOL were found. At 4-week follow-up, "positive results were maintained." (pg. 323)

Critical Appraisal

Validity

Using the PEDro scale, this study scored a 9/11, with overall strengths including random assignment of subjects, concealment of allocation of group assignment, blinding of outcome assessors, performing intention-to-treat analysis, and including between group statistics. Points were lost due to lack of blinding of subjects and therapists administering therapy.

The overall validity of this study is good. Though a sample of convenience is utilized, a power analysis was performed to determine sample size for medium effect size on the WUSPI. Unfortunately due to large attrition rate, less subjects were available for post intervention and at 4 week follow-up than power analysis had determined for the intervention group, increasing concern of a Type II error occurring. An intention-to-treat analysis was performed to try and account for the large attrition rate. Having the attention control group with symptomatic shoulder pain provides evidence that the exercise and movement optimization intervention improves shoulder pain and function scores on the WUSPI in this population, however because the same group received both interventions, there is confounding evidence of which intervention had more influence on outcomes. The authors do present exercise frequency and dosage used, allowing the reader the ability to utilize this program for a specific patient.

Interpretation of Results

While statistical significance was found and reported by the authors with p-values, looking at the 95% CI for WUSPI and VAS pain rating, 0 is included, which would indicate to the reader a lack of statistical significance for WUSPI and VAS pain rating within group, also affecting between group and time values. Furthermore, the

CI range is quite large, indicating less precision and more variability of the results. This indicates that statistical significance may in fact not have been found for the above stated items. Instead, it appears that clinical significance was detected. The effect sizes for WUSPI and VAS pain rating are reported as -1.2, indicating a relatively large treatment effect. Furthermore, knowing a previously reported MDC of 5.10 points[11] for the WUSPI, a change score of ~36 points found in this study pre-post exercise intervention should be considered clinically significant. For the VAS, a change score of 3.6 cm was found, which is almost twice the MCID on the VAS pain rating for shoulder pain reported in another study.[1]

With regards to the intention-to-treat analysis, between group differences were reported for the respective measures, however 95% CI's were not provided for the reader to determine precision. From the means provided, the reader could calculate change score for each measure from pre to 4 week follow-up. The intervention group demonstrated a change score of 40 points on the WUSPI and 3.9 cm on the VAS pain, further demonstrating clinical significance.

It is possible, that due to lack of power (for a moderate effect of 0.65 on the WUSPI) for the intervention group at post-intervention and 4 week follow-up, a type II error occurred, meaning results were not statistically significant (though reported to be by the authors), but clinical significance is still feasible, as appears to be the case.

The above stated reasons paired with overall good quality study design and performance of intention-to-treat analysis when high level of attrition occurred, the overall clinical significance of this study is good, though statistical significance is now in question. The reader is still unsure, however, if the exercise intervention or movement optimization (or both) contributing to the findings since both interventions were performed to the same group.

(3) Description and appraisal of (EMG Biofeedback and Exercise for Treatment of Cervical and Shoulder Pain in Individuals with a Spinal Cord Injury: A Pilot Study) by (Middaugh S, Thomas J, Smith A, McFall T, Klingmueller J, 2013)[2]

Aim/Objective of the Study/Systematic Review:

To examine the effects of a home-based shoulder exercise program in conjunction of EMG biofeedback training compared to exercise intervention alone on reducing shoulder pain in SCI patients who use manual wheelchairs.

Study Design

This study was a prospective, randomized controlled trial

- Outcomes were administered at beginning and end of a 2 week baseline period, 2 weeks after finishing 8 week exercise intervention, and contacted by phone 16 weeks after post-test for follow-up
- Outcome measures collected by blinded assessor
- After baseline assessment, patients randomly assigned to group A (home-exercise) or group B (home-exercise + EMG biofeedback)
- Power analysis performed for p = 0.05 and power =0.80 for an expected effect size of 1.2 on WUSPI determined 6 subjects were needed per group to determine within group differences; 12 subjects were needed per group to determine between group differences
- Within group differences calculated via 2-tailed t tests for correlated means
- Stability of pain report between two baseline points was determined from WUSPI scores
- Data of WUSPI score compared baseline 2 time point and 2 weeks following 8 week intervention
- Follow-up data also compared with baseline 2 time point to determine overall change over 6 month time frame

Setting

Outcome measures and interventions performed at the Medical University of South Carolina (MUSC) with subjects completing home-based exercise interventions at their home.

Participants

N = 7 in Home-based exercise group

- Demographics:
    - Injury Level: cervical = 1; Thoracic = 6; Lumbar = 0; Duration of SCI: 17 years (2-41 range); Age: 34.9 years (23-42 range); Gender: male = 5, female = 2; Education: 15.3 years; Manual WC, hours/week: 90; WC transfers/day: 14.6; Athletic Participation: 43%; Pain duration: 6.5

years (2-15 range); CES-D: mean score=8.2; median score = 10; satisfaction with life scale = 22.6

N = 8 in Home-based + EMG biofeedback group

- Demographics:
    - Injury Level: cervical = 1; Thoracic = 6; Lumbar = 1; Duration of SCI: 15 years (7-29 range); Age: 41 years (23-56 range); Gender: male = 7, female = 1; Education: 14 years; Manual WC, hours/week: 77; WC transfers/day: 16.6; Athletic Participation: 50%; Pain duration: 6.6 years (2.3-17 range); CES-D: mean score=14.8; median score = 10; satisfaction with life scale = 22.6

Authors did not perform statistical tests to determine between group differences at baseline. Authors reported the elevated Center for Epidemiologic Studies Depression Scale (CES-D) mean for home-based + EMG group due to one outlier. Also lower number hours/week using manual WC in home-based + EMG group due to one individual who uses manual and power WC.

No subjects were lost to follow-up. 14/15 reported to study site for 10 week assessment while 1 patient had follow-up via phone and completed the WUSPI via mail.

At 16 week after post-test follow-up, 1 subject from exercise + EMG biofeedback only completed interview and not WUSPI due to an acute shoulder injury. Group mean was used in place of the missing value for statistical analysis.

Intervention Investigated

Control

- Administered outcome measures before and after 2 week baseline period; used to determine stability of pain level/report
- Randomized into control (home-based exercise) group
- Completed 8 week home-based exercise intervention
    - Attend 2-90 minute sessions, scheduled 2 weeks apart to receive one-on-one instruction lead by a research assistant who was supervised by a physical therapist on home-based exercise program, using manual weights or therabands
    - Subjects educated on shoulder anatomy, rationale for exercises, and kinesiology on 1st education session
    - Exercises included: stretching of upper trapezius, biceps, pectoral muscles; Strengthening of posterior scapular muscles, shoulder ER, adductors, and extensors
    - Initial dosage: 1 x 5 reps with moderate resistance to minimize initial soreness; progressed by increasing resistance or number of sets
    - Exercises to be performed 1x/day, minimum 5x/week, and recorded in daily exercise/adherence log
    - Subjects contacted via phone weekly to discuss questions, concerns and encourage compliance
- Administered outcome measures 2 weeks post completion of 8 week program
- Phone call/mail follow-up 16 weeks after post-test data collection

Experimental

- Administered outcome measures before and after 2 week baseline period; used to determine stability of pain level/report
- Randomized into experimental group
- Completed 8 week home-based exercise + EMG biofeedback intervention
    - Attend 2-90 minute sessions, scheduled 2 weeks apart to receive one-on-one instruction lead by a research assistant who was supervised by a physical therapist on home-based exercise program, using manual weights or therabands
    - Attend 3-4 EMG biofeedback training sessions (targeting upper/lower trap, anterior deltoid, and infraspinatus bilaterally), performed by physical therapist. Emphasis placed on relaxing target muscles quickly with stationary tasks, progressed to performing while doing functional tasks (propulsion stroke), followed by performing WC propulsion by alternating 3-6 pushes with 2-3 second cruise phase (focusing on upper and lower trap relaxation). The latter sequence was also repeated with anterior deltoid and infraspinatus muscles.
    - EMG also used for posture training during wheelchair propulsion, with the goal being to reduce upper trap EMG activity by bringing attention to the subjects posture and providing verbal cues
    - Subjects educated on shoulder anatomy, rationale for exercises, and kinesiology on 1st education session
    - Exercises included: stretching of upper trapezius, biceps, pectoral muscles; Strengthening of posterior scapular muscles, shoulder ER, adductors, and extensors
    - Initial dosage: 1 x 5 reps with moderate resistance to minimize initial soreness; progressed by increasing resistance or number of sets
    - Exercises to be performed 1x/day, minimum 5x/week, and recorded in daily exercise/adherence log
    - Subjects contacted via phone weekly to discuss questions, concerns and encourage compliance

- Administered outcome measures 2 weeks post completion of 8 week program
- Phone call/mail follow-up 16 weeks after post-test data collection

Outcome Measures (Primary and Secondary)

- Primary: WUSPI (Wheelchair User's Shoulder Pain Index)
  - Total Score Range: 0-150 (Lower Score indicates decreased pain and improved function)
  - Administered by blinded assessor at baseline, and 2 weeks after 8 week exercise intervention, as well as 16 weeks after post-test (via mail)
- Secondary: Compliance
  - Rated by physical therapist or research assistant using 10 cm VAS
  - Rated for exercise compliance and biofeedback skills (if appropriate for the group) using exercise log, exercise progression, and demonstrated biofeedback skills

Main Findings

- Baseline Time Points: No significant difference between 2 time points for either group, demonstrating stable pain report using the WUSPI
  - Exercise Group: $r = 0.92$, $p \leq 0.01$
  - Exercise + EMG Group: $r = 0.81$, $p \leq 0.01$

- Baseline 2 – 10 week post-test:
  - WUSPI
    - Exercise Group:
      - Non-significant reduction in pain; t= .87, df = 6, p = .42, effect size = 0.38; 27.3% change
      - Total score change score (mean(SEM)) with 2nd baseline point: -11.9 points (-5.17)
      - Total Score within group 95% CI (-22.71 – 45.79)
    - Exercise + EMG Group:
      - Significant reduction in pain; t = 3.15, df = 7, p = .02, effect size = 1.3; 64% change
      - Total score change score (mean(SEM)) with 2nd baseline point: -36.96 points (-6.22)
      - Total score within group 95% CI (7.27 – 66.65)
  - Compliance
    - Exercise Component:
      - Exercise Group: mean = 7.9 cm, range = 4.5-10
      - Exercise Group + EMG: mean = 8.9 cm, range = 1-10
    - EMG biofeedback Component:
      - Exercise Group + EMG: mean = 8.2 cm, range = 2.4-10

- Baseline 2– 6 months (including 16 week follow-up):
  - WUSPI
    - Exercise Group:
      - Significant reduction in pain (t= 2.86, df = 6, p = 0.03, effect size = 1.03); 27.3 % change between baseline and 10 week post-test; 35.7% change occurred after post-test to follow-up, though it was not a significant change (t = 1.66, df=6, p= .15, effect size = .79)
      - Total score change score (mean(SEM)) with 2nd baseline point: -27.45 points (-8.96)
      - Total score within group 95% CI (-3.82 – 58.00)
    - Exercise + EMG Group:
      - Significant reduction in pain; t = 4.18, df = 7, p = .004, effect size = 1.9; 64% change occurred between baseline and 10 week post-test; 18.3% occurred after post-test to follow-up, though it was not found to be significant (t = 2.17, df – 7, p= 0.07, effect size = .62)
      - Total score change score (mean(SEM)) with 2nd baseline point: -46.85 points (-9.27)
      - Total score within group 95% CI (19.46 – 74.24)

**Note: 95% CI for within group differences were calculated by CAT author (A. Friedline Weber)

  - Compliance
    - Exercise Group: 5 out of 7 individuals reported continuing stretching exercises (mean=2.8 days/week, range 1.5-7); 5 out of 7 reported doing strengthening exercises (mean = 2.8 days/week, range = 3-7)
    - Exercise Group + EMG: 8 out of 8 individuals reported continuing stretching exercises (mean = 4 days/week, range = 1.5-7); 5 out of 7 reported doing strengthening exercises (mean = 2.3 days/week, range = 1-7)

- Benefit from Participation – Rated by subjects
  - Exercise Group: 7.7 out of 10 (range 4.5-10)
  - Exercise + EMG Group: 8.8 out of 10 (range 7-10)

Original Authors' Conclusions

Study findings suggests that an 8-week shoulder, home-based exercise intervention paired with EMG biofeedback is more effective in reducing WUSPI total scores than a home-exercise intervention by itself in individuals with SCI using manual wheelchairs. Both groups had similar compliance ratings at 10 week post-test, therefore further indicating/supporting differences in WUSPI scores being due to the EMG biofeedback. Furthermore, reduction in WUSPI scores were maintained at 6 month follow-up in the exercise + EMG biofeedback group. Statistical significance was found for reduction in WUSPI pain scores for the exercise group at 6 month follow-up, though not found initially post-intervention.

Critical Appraisal

Validity

Using the PEDro scale, this study scored a 7/11, with overall strengths including random assignment of subjects, blinding of outcome assessors, and performing intention-to-treat analysis. Points were lost due to lack of blinding of subjects and therapists, group allocation not being concealed, and between group statistical comparisons not being included due to the study not having enough power to investigate between group differences.

The use of a control group that also received the home exercise intervention allows the reader to see the impact and effect of EMG biofeedback on the outcome measures. The study, however, does have some limitations and concerns over validity. First of all, a sample of convenience was utilized and while a power analysis was performed, subject sample size only allowed for within-group differences to be determined, not between. This only allows for parallel comparison of outcomes on the WUSPI from each group, not a direct comparison of between group interactions to see if one intervention is truly superior to the other. Also, it appears statistical analysis was not performed on demographic data, therefore, questioning the similarity of both the exercise and exercise + EMG groups at baseline and potential influence on study findings. The mean baseline WUSPI total score was also ~10 points greater in the Exercise + EMG group when compared to the exercise group.

Interpretation of Results

A 8 week shoulder exercise program with EMG biofeedback lead to a statistically significant reduction in WUSPI pain and total scores at 10 week post-test and after a 16 week-follow-up period. An 8 week shoulder exercise program alone did not result in a statistically significant reduction in WUSPI pain or total scores at post-test, but statistical significance was found at 16 week-follow-up period. Statistical significance reported by the authors with p-values was confirmed by the CAT author calculating within group 95% CI (CI's for the exercise + EMG biofeedback group did not contain 0). The CI were very large however, indicating lack of precision and greater variability in the sample.

Effect sizes for the intervention group were reported to be large, 1.3 at post-test and 1.9 at 16 week follow-up, demonstrating a large treatment effect. Furthermore, large change scores on the WUSPI were found for both groups at both time points (post intervention and after follow-up), all of which were greater than the MDC of the WUSPI (previously reported as 5.10 points),[11] indicating clinical significance. Greater change scores were observed in the exercise + EMG group, however, no between group statistics were performed to determine statistical/clinical significance. The exercise group did end up showing clinical significance with an effect size of 1.03 between baseline 2 and follow-up time points so it is therefore believed that exercise alone can improve pain and function, though it took longer to achieve these results when compared to the exercise + EMG group, and results never reached the same magnitude of improvement.

While statistical and clinical significance has been found for within-group changes, due to lack of power and inability to determine between-group differences/interactions, the clinical applicability of this study is still in question as only a parallel comparison can be made. This paired with small sample size and lack of baseline demographic statistics, the reader rates overall clinical significance of this study as fair to good.

EVIDENCE SYNTHESIS AND IMPLICATIONS

Evidence analysed in this clinical appraisal suggest that utilizing home-based shoulder strengthening and stretching interventions in paraplegics with shoulder pain is both safe and effective. Only 2 adverse events were reported that were related to study intervention and were minor in nature (elbow abrasion and neck pain).[1] There were no studies that directly compared shoulder exercise interventions to wheelchair ergonomics or propulsion stroke. One RCT found a 12-week shoulder stretching and strengthening program paired with movement technique optimization to be more effective in decreasing shoulder pain and WUSPI

scores than providing attention and education to the subjects, though no improvements in wheelchair propulsion speed were found.[1] Another RCT reported an 8 week shoulder strengthening and stretching program paired with EMG biofeedback appeared to be more effective than exercise alone in decreasing pain and improving function, though exercise alone did result in a significant reduction in pain at 16 week-follow-up.[2] EMG biofeedback with exercise resulted in a quicker and larger improvement in pain and function than exercise alone.[2] A third study, though not a RCT, found an 8 week scapular focused exercise program with EMG biofeedback was effective at reducing pain and improving function.[9] While this study did have a control group, it was asymptomatic and did not offer helpful comparison to determine effectiveness of the intervention. Improvements in shoulder pain and function were found to be maintained at 4 week[1] and 16 week[2] follow-up periods in their respective studies. General study limitations include all three studies having small sample sizes and utilizing samples of convenience. Specific study limitations include an asymptomatic control group in the study by Nawoczenski et al,[9] lack of power to determine between group interactions in Middaugh et al.[2], and the intervention group receiving both exercise and movement optimization interventions with only a comparison to an attention control in Mulroy et al.[1] This doesn't allow for the reader to dissect which intervention offered the most benefit (if any).

The 3 studies demonstrated individual study design flaws, concerns over validity and statistical/clinical significance, however, they provided insight and evidence into an intervention that may be appropriate for paraplegic individuals. All three studies are generalizable to the paraplegic SCI population who have innervation of scapular and shoulder musculature, as is presented in the clinical scenario. All studies assessed shoulder pain in individuals with chronic SCI and shoulder pain, however, paired with clinical judgement, these findings can be utilized in an inpatient setting. Integrating shoulder exercise programs, especially paired with EMG biofeedback or movement optimization, should hopefully decrease shoulder pain and improve function no matter the stage of SCI injury. The ultimate goal, regardless of injury stage, is to promote continued independence, function, and quality of life in paraplegics. This may be addressing current shoulder pain or trying to prevent it from occurring. The clinical significance and evidence supports that skilled physical therapy services are more effective than attention control or no intervention at all. Physical therapists should utilize a home-based shoulder exercise intervention, focusing on rotator cuff and scapulostabilizer strengthening, anterior shoulder and upper trapezius stretching, and use of EMG biofeedback in male paraplegic patients to decrease shoulder pain and improve function. Observation of and addressing UE technique with weight-bearing and wheelchair propulsion stroke has the potential to further decrease pain and improve function due to the repetitive nature paraplegics use their UE's throughout the day.

In the future, more high quality research with larger sample sizes should be conducted to assess shoulder exercise intervention compared to wheelchair ergonomics/propulsion stroke education in paraplegias with shoulder pain. Another high quality research study should be performed investigating the effects of a shoulder exercise intervention compared to activity/technique modification (ie. bringing items in cabinets to lower level, change technique for doing a press over or pressure relief) on pain and function. Both of these designs would help clinicians compare interventions to exercise, which the current evidence is supporting as the "gold standard" for treatment. Use of non-self-report measures such as range of motion and strength testing should also be included. While patient report and perceived reduction in pain has an influence on quality of life, function, and independence, having more objective measures will offer further detailed insight for the clinician about the effectiveness of the intervention. Finally, in the appraised evidence, the longest follow-up administration of outcome measures was 16 weeks. Extending this follow-up further to look at the ability to maintain reduced shoulder pain and improved function 6+ months after time of intervention is recommended. Since the patient will live with their SCI the rest of their lives, it would be valuable for the patients and clinicians to understand the long-term impact of the interventions on shoulder pain and function in this patient population.

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