[Sports Physical Therapy]

Rotator Cuff Repair Rehabilitation: A Level I and II Systematic Review

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Background: There is no consensus for the optimal postoperative rehabilitation protocol after rotator cuff repairs.

Objective: To determine if there is sufficient level I or II evidence available in the literature for establishment of a uniform, optimal rotator cuff rehabilitation protocol.

Data Sources: A systematic review of level I and II English-language, prospective, randomized controlled trials published between 1966 and 2008 was performed. MEDLINE, EMBASE, the Cochrane Database of Systematic Reviews, and secondary references were appraised for studies that met the inclusion criteria. Search terms included rotator cuff, supraspinatus, infraspinatus, subscapularis, teres minor, rehab, rehabilitation, physical therapy, and physiotherapy.

Study Selection: Inclusion criteria were English-language level I or level II studies, including randomized clinical trials involving the rehabilitation of rotator cuff repairs. Exclusion criteria were non-English language, level IV or V studies, or studies involving shoulder rehabilitation of diagnoses other than rotator cuff repairs. Three independent reviewers arrived at a consensus for including 4 studies in this review out of 12 studies identified by the literature search.

Data Extraction: Included studies underwent worksheet quality appraisal independently by each of the 3 authors identifying strengths, weaknesses, and biases. The quality appraisal was then discussed among the authors and consensus reached regarding the strengths, weaknesses, and value of the included studies.

Results: Two studies examined the use of continuous passive motion for rotator cuff rehabilitation, and 2 studies compared an unsupervised, standardized rehabilitation program to a supervised, individualized rehabilitation program. These studies did not support the use of continuous passive motion in rotator cuff rehabilitation, and no advantage was shown with a supervised, individualized rehabilitation protocol compared to an unsupervised, standardized home program. Each investigation had weaknesses in study design that decreased the validity of its findings.

Conclusion: There is not enough high-level evidence to develop an evidence-based medicine approach to rotator cuff rehabilitation. There is a need for well-designed level I and level II trials to elucidate the optimal rotator cuff repair rehabilitation protocol.

Keywords: systematic review; rotator cuff repair; rehabilitation

Rotator cuff repair is a commonly performed orthopaedic surgical procedure. The results of rotator cuff repair for pain relief and functional improvement have been favorable. Adherence to strict postoperative restrictions and detailed postoperative rehabilitation protocols are critical to the success of surgery. The frequency and location of therapy, duration of immobilization, initiation of active and assisted motion, continuous passive motion (CPM) devices, cryotherapy, and modalities

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No potential conflict of interest declared.

DOI: 10.1177/1941738108331200

are central issues in rotator cuff rehabilitation. There is currently no uniform postoperative protocol for the rehabilitation of rotator cuff repairs.

The goal of this systematic review is to assemble the available randomized controlled trials (RCTs) in rotator cuff repair rehabilitation to facilitate the development of the optimal evidence-based rehabilitation protocol. We hypothesize that there is insufficient level I and level II evidence available to support a recommendation on these issues in rotator cuff repair rehabilitation.

METHODS

An exhaustive literature search was performed to identify studies appropriate for this systematic review. PubMed (1966 through the end of 2008), EMBASE (1980 through the end of 2008), and the Cochrane Controlled Trials Register were searched for manuscripts appropriate for this study. Inclusion criteria included English-language level I or level II studies including randomized clinical trials involving the rehabilitation of rotator cuff repairs. Exclusion criteria included non-English language, level IV or V studies, studies published only as abstracts (grey literature), or studies involving shoulder rehabilitation of diagnoses other than rotator cuff repairs. Search terms included rotator cuff, supraspinatus, infraspinatus, subscapularis, teres minor, rehab, rehabilitation, physical therapy, and physiotherapy. Bibliographies of identified studies were searched for additional appropriate studies. A manual review of the last 6 months of appropriate journals was also performed in case they had not yet been added to the searched databases. The journals searched included the *Journal of Shoulder and Elbow Surgery*, *American Journal of Sports Medicine*, *Arthroscopy*, the *Journal of Bone and Joint Surgery* (American and British volumes), and *Clinical Orthopaedics and Related Research*.

Studies identified by the search were then reviewed for appropriateness for inclusion in this systematic review. Appropriate studies then underwent worksheet quality appraisal independently by each of the study's authors, identifying strengths, weaknesses, and biases. The quality appraisal was then discussed among the authors, all fellowship-trained shoulder surgeons, and consensus reached regarding the strengths, weaknesses, and value of the included studies. The worksheet utilized was adapted from the CONSORT (Consolidated Standards of Reporting Trials) checklist of items to include when reporting a randomized trial.[1]

RESULTS

Twelve articles were identified by the initial database search. The initial review excluded 6 studies because they met the exclusion criteria. Two of the remaining 6 were noted to assess the role of cryotherapy in the postoperative shoulder. Although these 2 studies included rotator cuff repairs, the actual outcomes of the rotator cuff repair patients could not be identified and evaluated. Thus, these 2 studies were also excluded. This left 4 articles included in our systematic review. Two of the manuscripts examined the use of CPM after rotator cuff repair, and 2 manuscripts examined the use of standardized, unsupervised physical therapy compared to individualized, supervised therapy after rotator cuff repair.

Continuous Passive Motion

Raab et al[8] presented a level II evidence RCT to determine the effect of CPM on rotator cuff repair rehabilitation. Patients undergoing a primary rotator cuff repair between 1992 and 1994 were included. Exclusion criteria were not reported. Twenty-two patients refused entry into this study. Seven were subjectively excluded intraoperatively by the physician because the rotator cuff repair was too tight, and 2 patients were excluded by the physician due to a low "pain threshold."

Randomization was performed by drawing in the operating room after the completion of the surgical procedure. A total of 32 patients were randomized to 1 of 2 groups. The control group consisted of patients enrolled in a standardized physical therapy program. The study group consisted of patients in the standardized physical therapy program plus CPM for the first 3 weeks for 8 hours a day. After randomization, 1 patient in the CPM group was excluded because the CPM was discontinued due to increased pain. One patient was excluded because of a recurrent rotator cuff tear at 6 weeks. Three patients were lost to follow-up and excluded, and 1 patient was missing the preoperative evaluation form and was excluded. The authors did not report to which groups these patients were randomized. Therefore, 26 patients completed the study. Patients enrolled had a mean age of 56 years (range not provided). Eighteen were male and 8 were female; 12 patients were in the control group and 14 patients in the study group. There were no demographic differences between the groups. However, the CPM group had a higher percentage of large or massive tears (57%) compared to the control group (25%). A statistical analysis of this discrepancy was not performed.

The outcome measures used were an adaptation of the Hospital for Special Surgery System for Assessing Shoulder Function[7] and the Mayo Clinic preoperative and postoperative analysis of the shoulder. Outcomes were determined at 3-month follow-up. The mean and range of the actual patient follow-up was not reported in this article.

The aggregate shoulder scores for both the control group and the CPM group were improved at 3 months without statistically significant differences. Subscore analysis did show a statistically significant improvement in the CPM group for (1) range of motion when examining all patients (male and female combined) (P = .01), (2) pain relief in females (P = .02), (3) range of motion in males (P = .01), and (4) pain relief in patients older than 60 years of age (P = .04). A power analysis, confidence interval assessment, and an intention-to-treat analysis were not performed. However, a blinded, independent assessor was used to determine outcome scores.

The authors concluded that CPM had (1) no effect on shoulder scores, (2) improved range of motion, and (3) improved pain relief in women and patients over 60 years of age at 3 months following rotator cuff repair.

Lastayo et al[4] conducted a level I RCT comparing the functional outcomes of CPM with manual passive range of motion for patients with a rotator cuff repair. Patients undergoing rotator cuff repair between 1991 and 1994 were eligible for inclusion in the study. Exclusion criteria consisted of previous shoulder surgery, massive rotator cuff tears, instability, inflammatory disease, reflex sympathetic dystrophy, fracture, osteoarthritis, and adhesive capsulitis.

Randomization was performed using a table of random numbers. The mean age of patients enrolled was 63 years (range, 30-80). There were 14 men and 17 women. Fifteen shoulders were randomized to the manual passive range of motion group (performed by a trained relative or nurse) and 17 shoulders were randomized to CPM use for 4 hours a day for 4 weeks. After the 4-week period, the 2 groups continued their rehabilitation using an identical rehabilitation protocol.

Outcomes assessment was performed with a visual analog scale to measure pain, a goniometer to measure range of motion, a dynamometer to measure isometric strength, and the Shoulder Pain and Disability Index (SPADI),[9] a validated outcomes questionnaire. Intraobserver (range, 0.72-0.97) and interobserver reliability (range, 0.11-0.56) of the range of motion and strength measurements were performed. The mean follow-up at final outcome assessment was 22 months (range, 6-45). The authors did not comment if any patients were lost to follow-up.

No statistically significant difference was found between groups for pain and disability as measured by the SPADI, range of motion, or strength. Although there was no difference in pain scores determined by the visual analog scale at 4 weeks, there was less pain in the CPM group at 1 week (P = .046). Subgroup analysis of age and tear size did not show any differences between the groups. Women had significantly less pain in the CPM group compared to men (P = .03).

A retrospective power analysis was performed, but confidence intervals were not reported. An independent assessment of outcomes was performed by a physical therapist but the assessor was not blinded to treatment group.

The authors concluded that CPM is a safe technique with good to excellent outcomes when used after rotator cuff repair. However, CPM does not provide a better outcome than a program of manual passive range of motion exercises, which is more cost effective.

Supervised Physical Therapy Versus Unsupervised Physical Therapy

Hayes et al[3] conducted a level II RCT comparing range of motion, muscle force, and functional outcomes of individualized, supervised physical therapy versus a standardized, unsupervised home program. Patients undergoing rotator cuff repair from 1999 to 2001 were eligible for inclusion. Exclusion criteria consisted of an irreparable rotator cuff tear, an incomplete rotator cuff repair, previous shoulder surgery, additional procedure performed during the index rotator cuff repair, diabetes, and rheumatoid arthritis.

Randomization was determined by a random numerical sequence of computer-generated digits. Although the patient was blinded to his or her randomized allocation, the surgeon was not. The mean age of patients enrolled was 60 years (range, 41-83). Forty men and 18 women were enrolled. Thirty-two patients were enrolled into the standardized, unsupervised home therapy and 26 patients were enrolled into the individualized, supervised therapy. During the first week, both groups underwent an identical, standardized home program. Patients in both groups were encouraged to discontinue use of a sling after the first postoperative day. The individualized, supervised therapy was commenced during the second postoperative week. The subjects in the supervised therapy group received 16 ± 11 treatments over

17 ± 9 weeks. Baseline forward elevation strength was significantly greater in the supervised therapy group compared to the unsupervised therapy group.

A mean follow-up was not reported. At the final 24-week follow-up, 6 patients in the supervised physical therapy group (23%) and 10 patients in the unsupervised therapy group (31%) were lost to follow-up. Data were missing for up to 31% of data points in the supervised therapy group and up to 44% in the unsupervised therapy group. Nine patients from the unsupervised therapy group crossed over to the supervised therapy group. One patient in the supervised therapy group sought additional treatment via acupuncture. An intention-to-treat analysis was performed.

Outcomes measures utilized in this study included visual estimation of passive range of motion (reliability measurements performed historically), manual muscle testing for strength (reliability measurements performed historically), and the Shoulder Service Questionnaire, a modified version of the Shoulder Rating Questionnaire.[6] Data points were collected at 6 weeks, 12 weeks, and 24 weeks.

No statistically significant differences between groups were found for passive range of motion, muscle force, or functional outcomes measures. Both groups demonstrated outcomes that were consistent with near full passive shoulder range of motion and muscle force capacity, and a markedly improved overall shoulder status.

A blinded, independent assessor was used to determine outcomes. A power analysis was performed during enrollment, which determined 57 patients were necessary to have an 80% ability to detect a 20° difference in passive abduction. Confidence intervals were not reported. Compliance with the rehabilitation protocols was not assessed.

The authors concluded that an unsupervised, standardized physical therapy program is comparable in outcomes with a supervised, individualized physical therapy program for rehabilitation after rotator cuff repair.

Roddey et al[10] conducted a level II study in which they hypothesized that there was no difference between outcomes after arthroscopic rotator cuff repair with a videotape-based home exercise program compared to personal instruction by a physical therapist. Patients with a full-thickness rotator cuff tear determined by MRI who were willing to undergo surgical repair were eligible for inclusion in this study. Patients who had previous ipsilateral shoulder surgery or rheumatoid arthritis were excluded. Patients with concomitant injuries (labral tears, biceps tears) and concomitant surgical interventions (labral repair, manipulation) were not excluded.

Randomization was determined by a coin toss. The mean age of patients enrolled was 58 years (range, 34-78). Sixty-nine men and 39 women were enrolled. Fifty-four patients were randomized to a videotape-based home program and 54 patients underwent a program with direct physical therapy supervision. Both groups were given the therapist's telephone number and instructed to call if they had any questions throughout the course of study. Baseline data were similar between the groups, except a trend toward better mean SPADI scores (P = .06) was found in the home exercise group.

A mean follow-up was not reported. Twenty patients (37%) did not return from the home exercise group and 17 patients (31%) did not return from the physical therapy group at final follow-up. Three patients in the home exercise group did not have baseline data recorded. All data points were recorded in 57% of the home exercise group and 69% of the physical therapy group.

Validated outcomes measures used in this study were the SPADI and University of Pennsylvania Shoulder Scale.[5] Data points were collected at 12, 24, and 52 weeks.

No statistically significant differences in outcomes were found between the groups as determined by the SPADI and University of Pennsylvania Shoulder Scale. There was no difference in therapy protocol compliance and no difference in additional phone contacts with the physical therapist between groups.

The assessor of outcome was not blinded to each participant's type of rehabilitation. A power analysis was performed but confidence intervals were not reported.

The authors concluded that there was no difference in self-reported outcomes of function during the first year between patients who received videotaped exercise instruction and those who received personal therapist–directed exercise instructions.

DISCUSSION

The level I and II evidence for rotator cuff repair rehabilitation is exceedingly small. Our systematic review found 4 articles with a high level of evidence that examined either CPM use after rotator cuff repair or the use of standardized, unsupervised physical therapy compared to individualized, supervised therapy after rotator cuff repair. Each study had weaknesses that decreased the validity of its conclusions.

The study by Raab et al[8] concluded that CPM did not affect overall shoulder scores but did have a

beneficial effect on range of motion for all patients and pain relief in female patients and those over 60 years of age. However, these conclusions may be questioned due to the imperfect study design and the biases inherent to this study. There is significant selection bias due to the flaws in randomization process. A large number of patients refused to participate in this study. Nine patients were excluded from the randomization process due to the subjective decision of the treating surgeon. Dropouts and losses to follow-up after the randomization process were excluded from data analysis. In addition, data were not analyzed on an intention-to-treat basis. Differences in baseline data, such as rotator cuff tear size and outcomes subscores, suggest either a problem with randomization or an insufficient number of patients enrolled. The latter issue would be better addressed if a prestudy power analysis was performed. There was a significant exclusion bias within this study due to the large number of patients refusing to enter the study, dropouts, and patients lost to follow-up. Detection bias was also present due to the nonvalidated outcomes instruments used to assess patient response to the intervention. The durability of the results of this study can be questioned due to the short follow-up period. Concomitant pathology found during rotator cuff repair (osteoarthritis, labral tears, biceps tears, etc) was not discussed and can potentially confound the results. The internal validity of the study is weakened by multiple surgeons enrolling patients in this study (at least 12). Lastly, compliance with both the physical therapy protocol and the CPM protocol was never assessed. Therefore, due to the multiple biases and weakness of the study design, the applicability of the conclusions of this study to clinical practice must be questioned.

The study of Lastayo et al[4] concluded that CPM is safe after rotator cuff repair and provided good to excellent outcomes. Nevertheless, it was no more efficacious than a program of manual passive range of motion that was more cost effective. Although patients had less pain in the CPM group at 1 week, postoperative pain regimens were not standardized or examined. The design of the study was strong in limiting a number of biases. However, due to the lack of assessor blinding, performance bias was not eliminated by this study design.

Hayes et al[3] concluded that an unsupervised, standardized physical therapy program was as efficacious as an individualized, supervised physical therapy program. The results and conclusions of this study may be affected by substantial exclusion bias due to the loss of follow-up and missing data points. The lack of parity of baseline measurements suggests that there was a problem with randomization or an insufficient number of patients were enrolled in the trial. Although the initial number of patients enrolled was sufficient according to the power analysis, the significant loss of follow-up hinders the ability to detect a statistically significant difference in outcomes based on the potential of attrition bias. The use of a nonvalidated outcomes instrument introduces detection bias in the study design. Selection bias was also present, as the investigators were aware of which group each patient was randomized to prior to patient consent. It is unknown if a statistically significant difference in outcomes would be detected if the biases were minimized and a greater number of patients were enrolled and completed this trial.

Roddey et al[10] concluded that there was no difference in self-reported outcomes when comparing a videotape-based home exercise program with a supervised physical therapy program. Similar to the study of Hayes et al,[3] the results and conclusions of this study may be affected by substantial exclusion bias due to the loss of follow-up and missing data points. Selection bias was present in this study due to the suboptimal randomization process by flipping a coin.[2] Performance bias was inherent to this study due to the lack of assessor blinding. The patients available at final follow-up were significantly less than that determined by the initial power analysis, thus decreasing the ability of this study to detect a statistically significant difference between the groups. The authors did provide a post hoc power analysis that suggested that only 7 patients per group were necessary to find a clinically meaningful difference.

CONCLUSION

After examining the level I and level II evidence available in the literature, the evidence does not demonstrate significant improvements in outcome scores with the use of CPM in rotator cuff rehabilitation. However, subgroup analysis in 1 study suggested that CPM did improve range of motion and improved pain relief in women and patients greater than 60 years of age. In addition, there is no proof of an advantage of a supervised, individualized rehabilitation protocol compared to an unsupervised, standardized home program. Each investigation had weaknesses in study design that decreased the validity of its findings. There is a need for well-designed level I and level II trials to elucidate the optimal rotator cuff repair rehabilitation protocol.

ACKNOWLEDGMENT

This systematic review was performed under the auspices of the Multi-centered Orthopaedic Outcomes Network (MOON) Shoulder Consortium. The physician members include: Vanderbilt University: John E. Kuhn and Warren R. Dunn; Washington University: Rick W. Wright; University of Colorado: Eric C. McCarty and Armando F. Vidal; University of Iowa: Brian Wolf; Hospital for Special Surgery: Robert G. Marx; Ohio State University: Grant Jones, Julie Bishop, and David Flanigan; University of California San Francisco: C. Benjamin Ma; Orthopedic Institute: Keith M. Baumgarten; and Knoxville Orthopedic Clinic: Edwin Spencer and Brian Holloway.

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