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Nonoperative treatment of chronic, massive irreparable rotator cuff tears: a systematic review with synthesis of a standardized rehabilitation protocol

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Purpose: A massive, irreparable rotator cuff tear may cause significant pain and dysfunction. However, the efficacy of nonoperative treatment modalities in this subset of patients is not currently well known. Also, there is currently no gold standard nonoperative protocol to guide treatment. The goal of the present systematic review is to determine if there is any evidence to support the use of various nonoperative treatment modalities and synthesize a standardized nonoperative treatment protocol for the patient with a massive irreparable rotator cuff tear.

Methods: A comprehensive review of the literature utilizing PRISMA guidelines was performed. Studies involving clinical outcomes of nonoperative treatment of massive, irreparable rotator cuff tears were included. Articles were reviewed by 2 reviewers to determine inclusion or exclusion based on established criteria. Selected articles were reviewed for results of clinical and functional outcomes. The studies were also reviewed to determine their level of evidence and potential sources of bias. A standardized nonoperative treatment protocol was developed by taking described elements of the protocols used in studies that demonstrated clinical improvement beyond the MCID for the outcome scores used by the authors.

Results: A total of 10 studies met inclusion criteria for our studies. Of the included studies, 1 was Level III evidence and the remaining 9 were Level IV evidence. Multiple studies showed significant improvement exceeding the MCID for functional outcome scores following treatment. Also, several studies demonstrated significant improvements in strength and range of motion. The overall success of nonoperative treatment ranged from 32%-96%. The synthesized nonoperative treatment protocol is characterized by requiring some supervised physical therapy, often requiring 12 weeks or more, focusing on supine exercises with gradual progression to upright. Corticosteroid injections and nonsteroidal anti-inflammatory drugs may also be of benefit.

Conclusion: Despite low-quality evidence, nonoperative treatment has been shown to be efficacious for patients with chronic, massive, irreparable rotator cuff tears. Using these results, a synthesized rehabilitation program was developed to guide clinicians when treating patients with massive irreparable rotator cuff tears.

Level of evidence: Level IV; Systematic Review of Level III and Level IV Studies

Keywords: Massive rotator cuff tear; rehabilitation; nonoperative treatment; physical therapy; standard therapy protocol

No institutional review board approval was required for this systematic review.

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Rotator cuff tears are one of the most prevalent conditions affecting the adult shoulder, occurring in an estimated 9%-39% of the adult population.[13,23] In the United Sates, approximately 17 million individuals are affected with rotator cuff tears,[15] and the prevalence significantly increases with age.[31] In patients with a rotator cuff tear in one shoulder, 67% also have a tear in the contralateral shoulder.[28] However, many rotator cuff tears are asymptomatic. Minagwa suggests symptomatic rotator cuff tears account for only 34.7% of all tears compared with 65.3% that are asymptomatic.[31] It is unclear why some tears are symptomatic and others are not. Yamaguchi et al[51] showed a correlation with tear size progression and the development of pain in a previously asymptomatic rotator cuff tear. When symptomatic, a rotator cuff tear may be a source of significant pain and dysfunction, leading to a diminished quality of life.[30]

In the case of symptomatic tears, multiple operative and nonoperative treatment options are available. The choice of treatment is often dictated by patient demographics, rotator cuff tear characteristics (size, chronicity, number of tendons involved), and the presence or absence of glenohumeral osteoarthritis or other associated pathology.[40] To classify tear chronicity, Goutallier et al[19] introduced a classification system based on the amount of fatty infiltration in the rotator cuff muscles. Additionally, Patte et al[35] introduced a classification to distinguish the amount that the torn rotator cuff tendon(s) have retracted from their insertion on the greater tuberosity. Subsequent studies have shown that chronic rotator cuff tears involving 2 or more tendons, Goutallier grade 3 or 4 fatty infiltration, and significant retraction (Patte grade 3) are much less likely to be amenable to repair.[4,7,20,43,44] This subset of tears is commonly referred to in the literature as massive, irreparable rotator cuff tears.[34]

Chronic rotator cuff tears may benefit from both nonoperative and surgical treatments. In 2014, the Multicenter Orthopaedic Outcomes Network (MOON) shoulder group demonstrated that 75% of patients with chronic atraumatic rotator cuff tears improved with physical therapy and did not require surgery.[25] Of note, this study included both small, minimally retracted "repairable" tears and massive, retracted "irreparable" atraumatic rotator cuff tears as a single cohort. However, few studies have addressed the efficacy of nonoperative treatment modalities specifically in the subset of patients with chronic, massive, irreparable tears. Also, to our knowledge there is no current gold standard nonoperative treatment protocol for patients with massive, irreparable rotator cuff tears. Because many patients may prefer to avoid the risks associated with surgery or may be poor surgical candidates based on medical comorbidities, an effective standardized nonoperative protocol may aid clinicians treating this patient group.

The first goal of the present systematic review was to compile and review the available evidence to determine the efficacy of nonoperative treatment modalities for the cohort of patients with massive, irreparable tears. The second aim was to develop a synthesized nonoperative treatment protocol based on the best available evidence.

Methods

Manuscript identification and selection

This study was conducted in accordance with the 2009 Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.[33] A systematic review of the literature regarding the existing evidence for nonoperative treatment of massive, irreparable rotator cuff tears was performed using the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, PubMed, and MEDLINE. The queries were performed in May 2020.

The literature search strategy included the following search: "rotator cuff"[All Fields] AND (tear*[All Fields] OR "injury"[All Fields] OR "injuries"[All Fields]) AND ("Massive"[All Fields] OR "irreparable"[All Fields]) AND ("rehabilitation"[All Fields] OR "physical therapy"[All Fields] OR "physiotherapy"[All Fields] OR "therapy"[All Fields] OR "conservative"[All Fields] OR "nonoperative"[All Fields] OR "non-operative"[All Fields] OR "non operative"[All Fields]). Inclusion criteria were as follows: clinical outcomes of nonoperative treatment of massive, irreparable rotator cuff tears, English language, and human studies. Multiple definitions of "irreparable" were accepted if the definition was clearly stated in the article. Studies including surgical interventions were included only if there was an independent analysis of a cohort of patients treated nonoperatively. Studies were excluded if they involved cadaveric studies, animal studies, basic science articles, case reports, editorial articles, and surveys. All references within included studies were cross-referenced for inclusion if missed by the initial search. If a duplicate study population was encountered, the manuscript with the longer mean follow-up was included to avoid overlap.

Two investigators (K.S. and D.L.) independently reviewed the abstracts from all identified articles. Full-text articles were obtained for review (if necessary) to allow for further assessment of inclusion and exclusion criteria. Additionally, all references from the included studies were reviewed and reconciled to verify that no relevant articles were missing from the systematic review.

Bias

Studies that are lower-level evidence (Level III or V) are affected by both selection and performance. Selected studies were reviewed to ensure that authors minimized bias while recognizing the limitations present within the selected studies.

Data collection

The level of evidence of the studies was assigned according to the classification as specified by Wright et al.[50] The information was

collected from the included studies. Patient demographics, follow-up, nonoperative treatment modalities, and objective and subjective outcomes were extracted and recorded. For continuous variables (eg, age, timing, follow-up, outcome scores), the mean and range were collected if reported. The specific details of the nonoperative interventions (type of program, frequency/duration, range of motion and strengthening exercises, and other modalities) were recorded.

For each study, the change in functional outcome score from baseline to final follow-up was recorded. These data were then analyzed to determine whether the change in score observed met the minimal clinically important difference (MCID) for that particular score. The MCIDs for various shoulder outcome measures was summarized in a systematic review by Dabija and Jain.[12] Multiple MCIDs or a range of MCIDs have been reported for several outcome scores. When a range of MCIDs for a given outcome score was presented, we chose to use the lowest end of that range as the MCID threshold. If we were unable to locate an MCID for a given outcome score specifically for rotator cuff disease, we used the MCID validated for other shoulder pathologies for that outcome assessment.

Several outcome scores have validated an MCID specifically for rotator cuff tears or rotator cuff disease including the Constant score (MCID = 8, 10),[12,26,45] the visual analog scale (VAS) (MCID = 1.37),[12,42] and the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) (MCID 6.2-13.9, 17.9, 21.9, 26.9).[12,17,41,48] The Shoulder Rating Questionnaire (MCID 12, 13),[12,32,49] the Shoulder Disability Questionnaire (MCID 4-8),[12,36] the Disabilities of the Arm, Shoulder and Hand score (MCID 3.9-15),[5,12,38] and the Oxford Shoulder Score (MCID 2-7)[22] were validated for unspecified shoulder disorders. The University of California Los Angeles shoulder score (MCID 2.0, 2.4, 3.6, 8.7)[12,22,39,47] was validated for proximal humerus fractures, shoulder arthroplasty, and rotator cuff repair surgery. The Subjective Shoulder Value (MCID 12.1, 26.6)[47] was validated for proximal humerus fractures. We were unable to locate an MCID for the EuroQol 5D score (EQ-5D-5L) or the Activities of Daily Living score.

Statistical analysis

Given the inherent heterogeneity and limitations of Level III and Level IV evidence studies, a quantitative synthesis was not possible. Data from selected studies were presented within a range and presented individually within Tables I-III.

Development of a synthesized nonoperative rehabilitation protocol

After all data were collected, we determined which of the included studies reported significant improvement (statistically significant improvement with the change exceeding the MCID) in patient outcomes. Studies that demonstrated a significant improvement were reviewed to extract the specific details of the nonoperative intervention and protocol used. Using this information, we synthesized a nonoperative protocol for treating massive, irreparable rotator cuff tears.

Results

Literature search

Our search of the literature initially returned 308 articles (Fig. 1). We removed 11 duplicate articles, and 262 others after reviewing the titles of the articles. Thirty-five articles were then reviewed, and an additional 22 were excluded based on the abstracts. Thirteen articles were reviewed for eligibility and 10 articles met inclusion criteria for our review of the nonoperative treatment of massive irreparable rotator cuff tears.[2,3,10,11,21,27,46,52-54]

Demographic data

Demographic data are summarized in Table I. The 10 studies included in our review consisted of a total of 507 patients. The average age was 69.2 years and 54% were female. The dominant arm was involved in 75% of cases. The average duration of symptoms prior to the study intervention was 21 months. The average follow-up was 23 months.

Study designs

Our review included 9 case series (Level IV)[2,3,10,11,21,27,46,52,54] (3 retrospective, 6 prospective) and 1 case-control study (Level III).[53] There were no Level I or II studies identified. Eight of the 10 studies analyzed patients as one single cohort.[2,3,10,21,27,46,52,54] One study divided patients into 5 groups based on rotator cuff tear location.[11] One study compared patients with an intact subscapularis or teres minor hypertrophy to those lacking one or both features.[53]

The studies included multiple definitions of a massive, irreparable rotator cuff tear. The most common definition criteria included a rotator cuff tear involving at least 2 tendons: Goutallier grade 3 or 4 fatty infiltration and Patte grade 3 retraction (see Table I). Magnetic resonance imaging (MRI) was most frequently used for diagnosis, although some studies included ultrasonography or arthroscopy for diagnosis.

Nonoperative treatment success

Most studies defined failure of nonoperative treatment as persistent pain and/or functional loss following intervention. The overall success rates of nonoperative treatment ranged from 32%-100% (Table III). Most patients who failed nonoperative treatment went to have surgery (either partial rotator cuff repair, arthroscopic débridement, or reverse total shoulder arthroplasty).

Vad et al[46] found that poor outcomes were associated with abduction and external rotation strength <3/5,

Table I Patient demographics and study characteristics

Study	Type of study	Patients	Age, y, % female	Diagnostic criteria for MIRCT	Average follow-up
Vad et al,[46] 2002	Retrospective case series	40 patients with MIRCT treated nonoperatively (also included 32 patients with MIRCT treated with arthroscopic debridement, 36 patients with RCT treated with arthroscopic repair)	Mean 61.3 (range 46-85), 54% female	RCT >5 cm in largest dimension, not feasible for repair based on RCT size and tissue quality, diagnosed with MRI	3.2 y (range 2-7 y)
Ainsworth et al,[3] 2006	Prospective case series	10 patients with MIRCT nonoperatively	Mean 76 (range 70-83), 40% female	Full-thickness RCT, retracted past glenoid rim, diagnosed with US	3 mo
Zingg et al,[54] 2007	Retrospective case series	40 patients with massive RCT treated nonoperatively, 19 of 40 available for final follow-up, 11 of 19 had MIRCT, 8 of 19 had a repairable RCT at the time of initial diagnosis	Mean 64 (range 54-79), 37% female	Full-thickness RCT, ≥2 tendon involvement, ≥Goutallier grade 3 infiltration, AHI <7 mm, diagnosed with radiography and MRI	4 y (range 30-65 mo)
Levy et al,[27] 2008	Prospective case series	17 patients with MIRCT treated nonoperatively	Mean 80 (70-96), 65% female	Full-thickness RCT, 3 tendon involvement, Patte grade 3 retraction, ≥Goutallier grade 3 infiltration, diagnosed by MRI or US	9 mo
Collin et al,[11] 2015	Prospective case series	45 patients with MIRCT treated nonoperatively; patients divided into 5 groups based on rotator cuff tear location	67 (range 56-76), 62% female	Full-thickness RCT, ≥2 tendon involvement, ≥Goutallier grade 3 infiltration in at least 1 tendon, diagnosed with MRI; patients also had to have pseudoparalysis (<90° active anterior elevation with full passive ROM)	2 y
Christensen et al,[10] 2016	Prospective case series	30 patients with MIRCT treated nonoperatively; 6 of 30 patients failed to complete the nonoperative program, so the final results were based on 24 patients	70.4 (49-89), 33% female	RCT with no tendon tissue visible on US; if in doubt, MRI or arthroscopy was performed to confirm	5 mo
Yian et al,[52] 2017	Prospective case series	30 patients with MIRCT treated nonoperatively; 18/30 patients completed nonoperative treatment and presented for final follow-up	74 (range 55-890) 63% female	Full-thickness RCT, ≥2 tendon involvement, Patte grade 3 retraction, Goutallier grade 4 infiltration, diagnosed with MRI	2 y
Agout et al,[2] 2018	Prospective case series	71 patients with MIRCT treated nonoperatively; 68/71 patients completed nonoperative treatment and presented for final follow-up	70.9 (range 54-87), 56% female	Full-thickness RCT, ≥2 tendon involvement, ≥Goutallier grade 2 infiltration in at least 1 tendon, diagnosed with MRI	12 mo
Gutiérrez-Espinoza et al,[21] 2018	Prospective case series	92 patients with MIRCT treated nonoperatively	67.9 ± 4.5, 60% female	Full-thickness RCT involving ≥2 tendons and ≥Goutallier grade 3 infiltration in at least 1 tendon, diagnosed with US and MRI	3 mo
Yoon et al,[53] 2019	Retrospective case-control	162 patients with MIRCT divided into 2 cohorts: group A (n=67), intact subscapularis or teres minor hypertrophy; and group B (n=41), subscapularis not intact or no teres minor hypertrophy or lacking either feature	Group A: 64.5 (range 52-78), 64% female, Group B: 65.7 (range 55-79), 63% female	Full-thickness RCT, ≥2 tendons involved, Goutallier grade 4 infiltration, Patte grade 3 retraction, diagnosed with MRI	Group A: 42.2 mo, group B: 40.7 mo

RCT, rotator cuff tear; *MIRCT*, massive, irreparable rotator cuff tear; *MRI*, magnetic resonance imaging; *AHI*, acromial-humeral index; *US*, ultrasonography; *ROM*, range of motion.

Table II Functional outcomes, range of motion, and strength

Study	Functional outcome scores				Overall treatment success	Range of motion	Strength
	Outcome score	Change from baseline	MCID met?	*P* value			
Vad et al,[46] 2002 (note: group 1a: PT only, group 1b: PT + CSI)	SRQ	**+26.1**	**Yes**	<.05	Group 1a: 60.7%. Group 1b: 75.0% ($P < .05$)	Group 1b took less time (5.3 mo vs. 9.3 mo, $P < .05$) to gain maximal ROM compared to group 1a	9/40 (23%) had abduction /external rotation <3/5
Ainsworth et al,[3] 2006	SDQ	**+10.0**	**Yes**	No statistical analysis performed	100%	Not reported	Not reported
	SF-36, Physical Health	+10.0	N/A				
	SF-36, Emotional Health	−23.0	N/A				
	SF-36, General Health	−9.0	N/A				
Zingg et al,[54] 2007	Relative Constant score	83%*	N/A	N/A	83% (33/40 patients)	Mean forward flexion improved 24° ($P = .04$), abduction improved 21° ($P = .070$), internal rotation decreased 9° ($P = .054$), external rotation decreased 1° ($P = .864$), 5/6 patients with pseudoparalysis (<90° forward flexion) at baseline regained range of motion at final follow-up	Mean abduction strength was 3.1 kg (range 0-10 kg)
	SSV	**68%***	**Yes**	N/A			
	VAS	**11.5**†	**Yes**	N/A			
	ADL	9.2†	N/A	N/A			
Levy et al,[27] 2008	Constant score	**+37.0**	**Yes**	No statistical analysis performed	82% (14 of 17 patients).	Mean forward flexion improved 120° (no *P* value)	2 patients improved to pull-strength of 2 lb but the overall mean of the group did not change.

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Table II Functional outcomes, range of motion, and strength (*continued*)

Study	Functional outcome scores				Overall treatment success	Range of motion	Strength
	Outcome score	Change from baseline	MCID met?	*P* value			
Collin et al,[11] 2015	Constant score	**+13.0**	**Yes**	<.05	53% (24/45 patients)	24/45 patients (53%) had >160° anterior elevation; external rotation was preserved in patients with anterosuprior RCTs but was not restored in patients with anteroposterior and posterosuprior RCTs	Not reported
Christensen et al,[10] 2016	OSS	**+11.7**	**Yes**	<.05	80% (24 of 30 patients)	Mean abduction improved 34.4° ($P = .005$), flexion and external rotation had no statistical difference. Pain reported on VAS abduction, flexion, and external rotation all improved ($P = .001$, $P < .001$, $P = .015$)	Strength improved for abduction and flexion at 45° and 90°
	EQ-5D Index	+0.084	N/A	<.001			
	EQ-5D VAS	+20.0	N/A	<.001			
Yian et al,[52] 2017	ASES (9 mo / 2 yr)	**+26.0 / +23.0**	**Yes/ yes**	<.001 / .001	40% (12 of 30 patients)	Mean forward flexion improved 28° ($P = .01$)	Strength increased 0.8 kg ($P = .03$)
	Pain (9 mo / 2 yr)	+3.4 / +3.0	N/A	<.001 / <.001			
	SSV (9 mo / 2 yr)	**+20% / +15%**	**Yes/ yes**	<.001 / .01			
Agout et al,[2] 2018	Constant score	+16.4	**Yes**	<.001	96% (68/71 patients).	Mean forward flexion improved 25.2°	Not reported
	Weighted Constant score	+21.9%	N/A	<.001			
	SSV	**+26.2%**	**Yes**	<.001			
Gutiérrez-Espinoza et al,[21] 2018	Constant score	**+24.9**	**Yes**	<.001	100% (12/12 patients)	Not reported	Not reported
	DASH	**+28.7**	**Yes**	<.001			
	VAS	**+3.6**	**Yes**	<.001			

Yoon et al,[53] 2019 (note: Group A: intact subscapularis + teres minor hypertrophy, group B: lacking one or both features	VAS	Group A: +0.7 Group B: +0.6	No	No	>.05 (group A vs. B)	Group A: 57% Group B: 32% (P = .012)	Internal rotation was 3 patients (measure by highest spinal segment reached) greater for group B at baseline and final follow-up (P < .001)	Not reported
	ASES	Group A: +2.9 Group B: +3.7	No	No	>.05 (group A vs. B)			
	UCLA	Group A: **+2.5** Group B: **+2.0**	**Yes**	**Yes**	>.05 (group A vs. B)			

PT, physical therapy; *CSI*, corticosteroid injection; *SRQ*, Shoulder Rating Questionnaire; *SDQ*, Shoulder Disability Questionnaire; *SF-36*, 36-item Short Form Survey; *SSV*, Subjective Shoulder Value; *VAS*, visual analog scale; *ADL*, Activities of Daily Living; *OSS*, Oxford Shoulder Score; *EQ-5D*, EuroQol-5D; *ASES*, American Shoulder and Elbow Surgeons Shoulder Assessment Form; *DASH*, Disabilities of the Arm, Shoulder, and Hand score; *UCLA*, University of California Los Angeles shoulder score; *MCID*, minimal clinically important difference; *ROM*, range of motion; *RCTs*, rotator cuff tears.
Patient-reported outcomes varied; however, most of the studies demonstrated improvements in the outcomes measured. Those that exceed the MCID are highlighted in bold.
* Compared to age/gender-matched normal shoulder, no change reported.
† Absolute value, no change reported.

muscular atrophy, superior migration of the humeral head, decreased passive range of motion, and glenohumeral osteoarthritis. Yian et al[52] found that active forward flexion <50° at baseline was associated with nonoperative treatment failure. Collin et al[11] found that treatment failure was common in patients with anterior rotator cuff tears. However, this finding was disputed by Agout et al,[2] where no correlation between rotator cuff tear location and treatment success was found. Yoon et al[43] found that patients with an intact subscapularis or teres minor hypertrophy had a 57% rate of nonoperative treatment success, compared with 32% in patients lacking an intact subscapularis or teres minor hypertrophy or lacking both features.

Functional outcome scores

Functional outcome scores are detailed in Table III. The most commonly reported scores included the Oxford Shoulder Score, Subjective Shoulder Value, Constant score, ASES score, and the VAS. Following nonoperative treatment, 4 studies found a significant improvement in the mean Constant score, which met the MCID.[2,11,21,27] One study reported a relative Constant score of 83% compared with an age- and gender-matched normal shoulder following nonoperative treatment.[54] Two studies showed no significant change in the Constant score power subcategory.[2,27] One study[10] showed a significant improvement in Oxford Shoulder Score and one showed improvement in Shoulder Disability Questionnaire,[3] both of which met the MCID. Three studies showed significant improvement in the Subjective Shoulder Value score, which met the MCID.[2,52,54] VAS pain score also improved in 2 studies (which both met MCID) [21,54] and did not have a significant change in 1 study.[53] The ASES score had a significant improvement meeting MCID in one study[52] and did not have a significant change in an another study.[53] Ainsworth et al[3] showed an improvement in SF-36 subcategories of pain and role limitation due to physical health but a decline in role limitation due to emotional health and perceived general health. Yoon et al[53] compared patients with an intact subscapularis or teres minor hypertrophy to a group lacking one or both features and found no difference in VAS, ASES, or University of California Los Angeles shoulder scores between the groups.

Range of motion and strength

Several studies also reported changes in range of motion and strength after the nonoperative intervention (see Table II). Reported gains in active forward flexion improved by a mean of 49° (range 24-120°) at final follow-up.[2,27,52,54] Several studies also reported improvements in active abduction and external rotation.[10,54] A subanalysis based on rotator cuff tear location by Agout et al[2] did not find any significant differences in strength or range of motion

Table III Physical therapy protocols and other modalities

Study	Program description	Frequency/duration	Range of motion	Strengthening	Special exercises	Other modalities
Vad et al,[46] 2002	Physical therapy program (details not specified)	Frequency not specified; total duration: group 1a: 8.2 weeks (range 1-22 weeks), group 1b: 10.3 weeks (range 2-24 weeks)	Not specified	Not specified	Not specified	Oral medication (group 1a) or oral medication + CSI (average 1.6 injections; range 1-4) (group 1b)
Ainsworth et al,[3] 2006	Torbay hospital rehabilitation program for massive RCTs; involves both formal therapist-supervised sessions and a home exercise program	30-min sessions once a week for the first 4 weeks and then once every 2-3 weeks; a home exercise program was also performed 2-3 times per day; total duration: 5 mo	Gentle stretching within the limits of pain. Progression includes (1) supine shoulder flexion to 90°, (2) supine ER with yellow theraband, (3) supine 20° sways with arm straight, (4) supine flexion with progressive weights, (5) repeat activities 1-4 with 45° inclination, (6) standing wall slides, (7) sitting elevation through flexed elbow, (8) sitting raising and lowering hand in elevation, (9) sitting ER with yellow theraband, and (10) sitting/standing proprioception	Anterior deltoid and teres minor eccentric strengthening; muscle recruitment training; use therabands and empty 1-L tonic water bottles (gradually increasing weight); progression combined with ROM protocol (see left)	(1) Posture correction to optimize glenoid position and subacromial space; (2) Weightbearing exercises to improve proprioception; (3) Functional activities that improve function without pain (eg, turning a light switch on/off)	None
Zingg et al,[54] 2007	Standardized rehabilitation program to restore free passive shoulder ROM and strength	Frequency not specified; total duration: average 48 mo (range 30-65 mo)	Not specified	Not specified	Not specified	Subacromial CSI
Levy et al,[27] 2008	Reading Shoulder Unit anterior deltoid rehabilitation program. Home exercise program with baseline therapist instruction and 2 follow-up supervised sessions at 6 and 12 weeks	3-5 times/day 7 days/week; total duration: 12 weeks	Pendulum exercises, supine assisted forward flexion progressing to inclined position	Supine forward flexion with small hand weights, progressing to inclined position; deltoid concentric contracture exercises	None	Subacromial CSI, NSAID medication, or analgesic medication

Collin et al,[11] 2015	Formal therapist-supervised PT focusing on strength, ROM, and proprioception	5 total sessions, frequency not specified; total duration: 2 y	Scapular mobility	Scapular mobility and positioning (targeted pectoralis minor, upper trapezium, elevator scapulae); strengthening of lower trapezius, upper serratus anterior, rotator cuff (especially teres minor), and deltoid	Gentle manual recentering, proprioception exercises	None
Christensen et al,[10] 2016	Neuromuscular exercise program; combination formal therapist-supervised PT program and home exercise program	3 times/week (2 home sessions, 1 therapist-supervised session for the first 3 mo, 3 home sessions with 1 therapist-supervised session every other week for the last 2 mo); total duration: 5 mo	Forward flexion and external rotation ROM exercises (incorporated with strengthening exercises)	Deltoid and teres minor strengthening; deltoid strengthening progressing from supine assisted forward flexion, supine unassisted forward flexion, inclined forward flexion, and upright forward flexion with weights; teres minor strengthening progressing from gravity-resisted external rotation to theraband resisted	None	Pain medication
Yian et al,[52] 2017	Reading Shoulder Unit anterior deltoid rehabilitation program; home exercise program with baseline therapist instruction and 2 follow-up supervised sessions at 6 and 12 weeks	3-5 times/day 7 days/week; total duration: 12 weeks	Same as Levy et al (above)	Same as Levy et al (above)	None	NSAID or pain medications, subacromial steroid injection (10 patients)
Agout et al,[2] 2018	Details of the rehabilitation program were unspecified	Frequency not specified; total duration: 12 mo	Not specified	Not specified	Not specified	Analgesic medication, NSAID medication, subacromial CSI at the discretion of the treating surgeon
Gutiérrez-Espinoza et al,[21] 2018	Formal therapist-supervised PT	2 times/week; total duration: 12 weeks	Posterior glenohumeral mobilization and scapular mobilization	Scapular and glenohumeral control exercises; begins with low-load/low-activation exercises with arms below the level of the	Proprioception exercises	None

(*continued on next page*)

Table III Physical therapy protocols and other modalities (*continued*)

Study	Program description	Frequency/duration	Range of motion	Strengthening	Special exercises	Other modalities
Yoon et al,[53] 2019	Home exercises program with supervised follow-up every 3-6 mo	Frequency not specified; total duration: group A: 42.2 ± 9.0 mo (range 24-62), group B: 40.7 ± 9.3 mo (range 24-60)	Self-assisted passive ROM exercises to maintain/obtain a supple shoulder joint	shoulders with gradual progression of load Rotator cuff and deltoid strengthening	None	NSAID medication, narcotic skin patches, subacromial CSI

RCTs, rotator cuff tears; *ROM*, range of motion; *PT*, physical therapy; *ER*, external rotation; *CSI*, corticosteroid injection, *NSAID*, nonsteroidal anti-inflammatory drug.
In developing a standard protocol, we extracted data from studies where improvement exceeded the MCID (in italics).

between the 5 groups. Using electromyography data, Christensen et al[10] reported decreased anterior deltoid activity during isometric flexion at 90°. Three studies reported improvements in mean strength following nonoperative treatment.[10,52,54]

Imaging

Two studies reported radiographic and MRI changes at final follow-up compared baseline. Yoon et al reported a mean acromial-humeral index decrease of 0.8 mm in the subscapularis intact or teres minor hypertrophy group compared with a 0.9-mm decrease in the group lacking either an intact subscapularis or teres minor hypertrophy ($P > .05$).[43] Zingg et al also found an average acromial-humeral index decrease of 2.6 mm ($P = .005$).[54] This study also found progression of glenohumeral osteoarthritis stage ($P = .014$), fatty infiltration ($P = .001$), and rotator cuff tear size ($P = .003$).

Specific components of the nonoperative treatment

The nonoperative treatment modalities are detailed in Table III. A variety of methods were used including supervised physical therapy, home exercise programs, subacromial corticosteroid injections, and pain medications (analgesics and nonsteroidal anti-inflammatory drugs). Forward flexion and external rotation exercises were the most employed range of motion exercises. Several studies used a program to gain forward elevation, which graduated from supine to upright exercises. Deltoid and teres minor strengthening were the most common strength-building exercises. Three studies used a specific anterior deltoid rehabilitation program.[3,27,52] Of the 5 studies including a subacromial corticosteroid injection,[2,27,43,46,52] only 1 study independently analyzed the treatment effect of the injection.[46] No studies independently analyzed the effect of pain medications on treatment outcome. The duration of treatment was highly variable. Some studies report a supervised physical therapy program for 8-12 weeks,[21,27,46,52] whereas others had patients performing home exercises for up to 48 months.[2,3,10,11,53,54]

Discussion

The most important finding of our systematic review is that nonoperative treatment appears to be a moderately efficacious treatment for massive, irreparable rotator cuff tears, with follow-up limited to 4 years or less. Although there was some variability in the definition of a massive, irreparable rotator cuff tear, most studies defined massive tears as a full-thickness tear with severe muscular atrophy and tendon retraction. In our review, despite significant

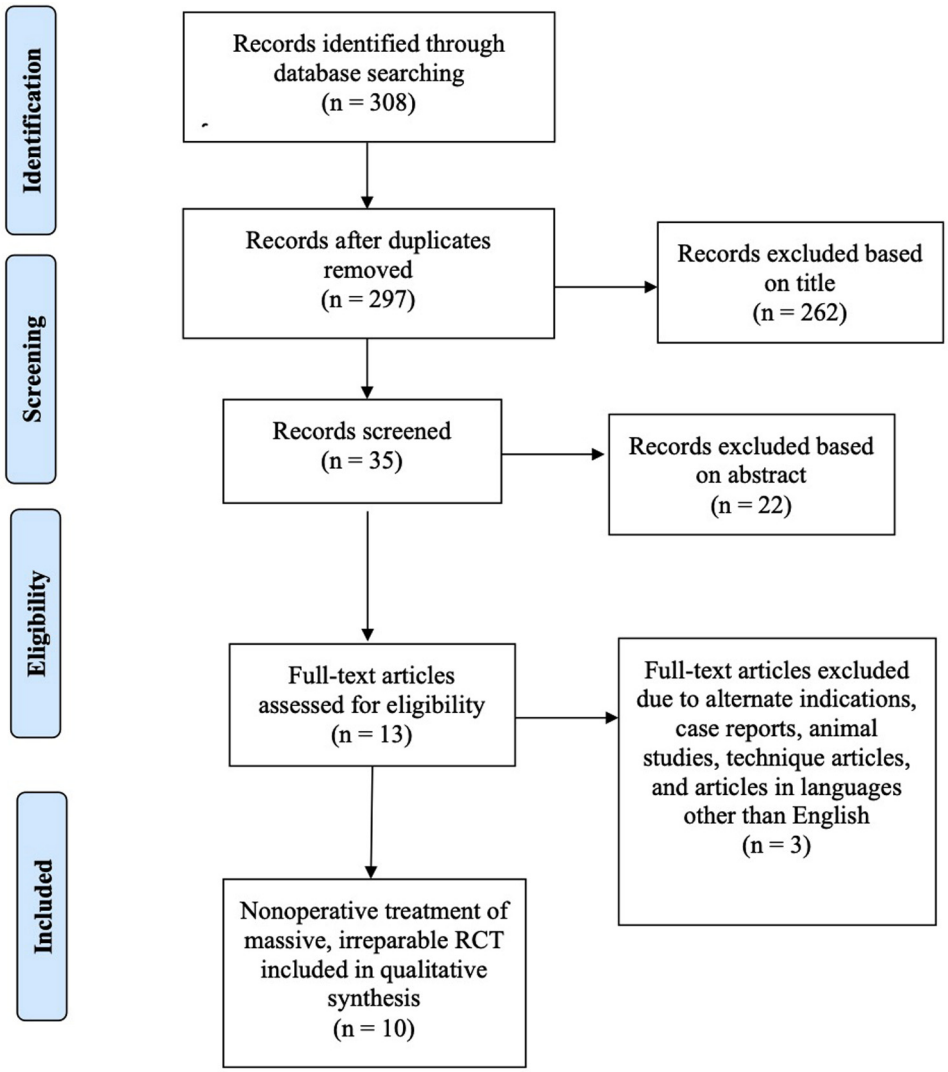

Figure 1 Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) article search flow diagram.

variation in treatment, most of the included studies demonstrated clinically significant improvement in 1 or multiple functional outcome scores. Several studies also demonstrated improved shoulder range of motion and some improvements in strength following nonoperative interventions. In one study, patients showed satisfactory outcomes despite radiographic evidence of worsening osteoarthritis and rotator cuff tearing.[54]

Likely related to the variation in treatment, the overall success rate of nonoperative treatment appeared variable between studies (32%-100%). This finding is consistent with several prior studies that have investigated the results of nonoperative treatment of full-thickness rotator cuff tears[8,18,25] and emphasizes the need for an accepted effective protocol.

Several authors tried to determine predictors of success of nonoperative treatment. Vad et al[46] and Yian et al[52] showed a correlation between decreased baseline range of motion and poor outcomes. Collin et al[11] and Yian et al[52] found conflicting results of the impact of rotator cuff tear location.[4] Dunn et al[14] found that in a large series of patients with chronic rotator cuff tears, the most important predictor of nonoperative treatment success was patient expectations about the effectiveness of rehabilitation. However, this variable was not studied in any of the studies included in our review.

The most common nonoperative treatment for massive, irreparable rotator cuff tears in this review was physical therapy. Of the included studies, there was tremendous variation in the reported therapy strategies. Both formal therapist-supervised rehabilitation programs and non-supervised home exercise programs were used. Although these 2 models were not directly compared in any of the studies, both interventions did improve patient outcome scores. These improvements are consistent with a systematic review by Littlewood et al[29] that found no difference in

formal physical therapy compared with home exercise programs for rotator cuff tendinopathy.

A variety of physical therapy protocols were used. Three studies focused specifically on an anterior deltoid-strengthening program.[3,27,52] Multiple studies have demonstrated that in a shoulder with large rotator cuff tears, the humeral head migrates superiorly. Burkhart et al noted the superior migration of the humeral head results in ''unstable fulcrum kinematics'' and significantly increasing deltoid force during abduction.[9] The basis of the deltoid-strengthening rehabilitation program is to allow the deltoid to be able to overcome this biomechanical disadvantage so that the patient can still raise his or her arm.[27] Two of the studies using this protocol reported high proportions of patient success (82%-100%),[3,27] whereas a third study had less success (40%).[52]

In 5 of the included studies, corticosteroid injections were used in addition to physical therapy for nonoperative treatment.[2,27,43,46,52] Vad et al[46] found that patients receiving a corticosteroid injection in addition to physical therapy for irreparable rotator cuff tears had 75% overall excellent or good outcomes compared with 60.7% in the group receiving only physical therapy. Several prior studies have investigated the use of subacromial corticosteroid injections for rotator cuff disease. These studies have shown improvements in pain and range of motion following injection.[1,6,37] However, in a systematic review, Koester et al[24] concluded that there was little evidence to support the use of subacromial steroid injections in the treatment of rotator cuff disease. Further research is needed to understand the benefit of subacromial corticosteroid injections in the subset of patients with massive, irreparable rotator cuff tears. It is also important to note that there may be an increased postoperative infection risk for patients receiving a corticosteroid injection less than 1 month before having shoulder surgery.[16] Patients should be counseled of this when deciding on treatment options and the timing of these interventions.

A synthesized nonoperative protocol

Of the studies extracted from the literature for this systematic review, it is interesting to note that 3 articles did not describe their treatment protocols.[2,46,54] The nonoperative protocols used by 3 other studies failed to show clinically significant improvement in patient outcomes.[11,52,53]

Our recommended rehabilitation protocol (Supplementary Appendix S1) is therefore based on the remaining 4 studies: Ainsworth et al,[3] Christensen et al,[10] Gutiérrez -Espinoza et al,[21] and Levy et al.[27] These studies all provided a detailed description of their rehabilitation protocol while demonstrating a significant improvement in functional outcome scores (exceeding the MCID for the outcome measured), improvements in strength and range of motion, and a high overall treatment success (80%-100%).

When extracting the elements of the physical therapy protocol from these 4 studies, certain trends emerge[3,10,21,27]:

1. Supervised physical therapy is preferred. Programs may include both formal therapy and a home exercise program. However, there should be regular visits with a physical therapist to ensure the exercises are being performed correctly at the frequency and duration as prescribed.
2. The program should be prescribed for at least 2-3 sessions per week for a minimum of 12 weeks.
3. The first focus should be improving passive forward flexion and external rotation within the limits of pain. Patients should begin these exercises in a supine position, gradually progressing to an inclined and then upright position.
4. After range of motion is improved, the program should incorporate deltoid and teres minor strengthening exercises. These can also begin supine and progress to standing, with gradually increasing amount of resistance. Small hand weights and elastic bands can be used.
5. Scapular stabilization and proprioception exercises should also be incorporated in the protocol.
6. It is reasonable to consider a subacromial corticosteroid injection before beginning the rehabilitation program if pain is inhibiting range of motion or exercise performance.
7. Nonsteroidal anti-inflammatory drug medications may also be of benefit during the rehabilitation program. We recommend against the routine use of opioid pain medications in this setting.

Limitations

The major limitation of the present systematic review is the quality of evidence of the included studies. No Level I or Level II studies were available for inclusion. Nine of the 10 included studies were Level IV evidence and 1 was Level III. Therefore, the risk of selection bias was high in all studies included, and a meta-analysis could not be conducted with heterogenous patient populations. Furthermore, although limited evidence suggests that physical therapy for irreparable rotator cuff tears will help many patients, we expect, but without comparative trials cannot confirm, that surgical treatments may provide better outcomes. Also, this review included studies with <80% final follow-up, which may introduce the risk of exclusion bias. In several studies, patients could use corticosteroid injections or pain medications in addition to a rehabilitation program. However, these additional treatments were not given to all patients, and their effect was not measured as an independent variable. This increases the risk for performance bias. These

weaknesses highlight the need for future high-quality studies regarding the nonoperative treatment of massive, irreparable rotator cuff tears. Despite these limitations, physical therapy was shown to be effective for many patients improving patient-reported outcomes and function.

We recognize that the synthesized protocol offered may not be the best option for the nonoperative treatment, and that it is based on low-level evidence; however, this protocol could serve as a standard for future comparative studies to identify the best nonoperative treatment for irreparable rotator cuff tears.

Conclusion

Our systematic review has demonstrated that several different nonoperative treatment modalities may be effective for patients with massive, irreparable rotator cuff tears. Using these results, a synthesized standard rehabilitation protocol was developed. However, the available data are limited, with included studies of lower level of evidence. Future high-quality studies are needed to identify the optimal methods for nonoperative treatment.

Disclaimer

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Supplementary Data

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