The role of physical activity as conservative treatment for massive rotator cuff tears in elderly patients: a systematic review

Lorenzo Alirio Diaz Balzani, Rocco Papalia, Anna Maria Alifano, Erika Albo, Giuseppe Francesco Papalia, Mauro Ciuffreda, Chiara De Andreis, Chiara Fossati, Vincenzo Denaro

Department of Orthopaedic and Trauma Surgery, Campus Bio-Medico University of Rome, Rome, Italy

The aim of this systematic review is to determine the effectiveness on functional and pain outcomes of different exercise protocols as a conservative treatment for massive, irreparable rotator cuff tears in elderly patients. A literature search was carried out consulting Pubmed -Medline, Cochrane central and Scopus to select randomized clinical trials, prospective and retrospective cohort studies or case series, that evaluated functional and pain outcomes after physical therapy in patients aged 65 or over, affected by massive rotator cuff tears. The present systematic review followed the Cochrane methodology for systematic reviews and the reporting was implemented using through the PRISMA guidelines. The Cochrane risk of bias tool and MINOR score were used for methodologic assessment. Nine articles were included. Data concerning physical activity, functional outcomes and pain assessment were obtained from the included studies. The exercise protocols assessed within the included studies were extremely wide with equally different methods of evaluation of the outcomes. However, most of the studies demonstrated a trend of improvement after the treatment, in terms of functional scores, pain, ROM and quality of life. An intermediate methodological quality of the included papers was assessed through the risk of bias evaluation. Our results showed a positive trend in patients who underwent physical exercise therapy. Our conclusion is that further studies of a high level of evidence are needed to achieve consistent evidence to improve clinical practice in the future.

INTRODUCTION

Rotator cuff tear is a condition that frequently affects the elderly population impairing quality of life and involving the function of the entire upper limb *(1)*. It is estimated that 30% of patients older than 60 years have a diagnosis of rotator cuff tear *(2)*. The glenohumeral joint is the most unstable

■ Lorenzo Alirio Diaz Balzani[1],
■ Rocco Papalia[1],
■ Anna Maria Alifano[1],
■ Erika Albo[1],
■ Giuseppe Francesco Papalia[1],
■ Mauro Ciuffreda[1],
■ Chiara De Andreis[1],
■ Chiara Fossati[2],
■ Vincenzo Denaro[1].
 [1]*Department of Orthopaedic and Trauma Surgery, Campus Bio-Medico University of Rome, 00128 Rome, Italy.*
 [2]*Department of Movement, Human and Health Sciences, University of Rome "Foro Italico", 00100 Rome, Italy.*
Correspondence : Erika Albo, MD, Department of Orthopaedic and Trauma Surgery, Campus Bio-Medico University of Rome, Italy, Via Alvaro del Portillo, 21, 00128 Roma. Phone 06.225418825.
Email : e.albo@unicampus.it

joint of the locomotor system, due to the small surface contact area between the humeral head and the glenoid. The rotator cuff is the most important dynamic stabilizer *(3)*. The progressive degeneration of the rotator cuff results in an abnormal distribution of loads with consequent changes in the articular cartilage surface and subchondral bone. These alterations lead to eccentric cartilage consumption and bone remodeling with severe limitation of joint movements *(4)*. In the elderly, there is an increased prevalence of massive rotator cuff tears, as with the advance of aging the tendon tissue faces adipose and fibrotic degeneration, with a disarray of fibers and loss in tensile strength *(5)*. The definition of massive rotator cuff tear is not univocal *(6)*, because it can be defined as tears with >5 cm in size in either anterior-posterior or medial-lateral *(7)* or involving two or more tendons *(8)*. The massive tear is defined as "irreparable" when there is fatty infiltration >50%, classified according to Goutallier, on computed tomography associated with an acromiohumeral interval less than 6mm evaluated with true anteroposterior X-ray. The clinical presentation is characterized by gradually increasing inflammatory pain (more severe at night) and chronic evolution associated with crepitus, rigidity and functional limitation *(9)*. The progressive articular disuse can result in capsular fibrosis and capsulitis, muscular hypotrophy and pseudoparalysis *(10,11)*. The pathologic entity of massive rotator cuff tears, with glenohumeral arthritis, is commonly referred to as "rotator cuff arthropathy" *(12)*. Rotator cuff repair, for degenerative massive tears, has been largely discouraged as a treatment in older adults, because poor tendon tissue quality, prevent a stable repair, with a significantly increased risk of retear *(13)*. The treatment standard for massive and irreparable rotator cuff tears includes the reverse shoulder arthroplasty, in which a deficient rotator cuff is excluded from the shoulder biomechanical system and its function is supplied by the deltoid muscle. However, in the focus of personalized medicine and patient-based decisional process, assessing the general status and functional request of the patient is crucial in determining the need for replacement surgery. Therefore, it has been advocated that physical exercise for strengthening and improve-

ment of residual ROM could be beneficial for patients affected by massive tears of the rotator cuff *(5)*. The choice of conservative treatment for the elderly is often advised, given the frailty of older patients and the surgical risk annexed to multiple comorbidities. Therefore, the reverse arthroplasty should be reserved for those active subjects, with a high functional request and a good to an excellent general medical condition. Several conservative strategies have been advocated indeed, including pharmacologic pain management (corticosteroid, Hyaluronate injections), physical therapy and strengthening exercise for extrinsic shoulder muscles *(14)*. The main purpose of this study is to systematically review the available literature, investigating the evidence on the role of therapeutic physical exercise treatments for massive and/or irreparable rotator cuff tears in elderly patients. The intervention effectiveness was evaluated by assessing the improvement of functional and pain outcomes. The secondary endpoint was to investigate the quality of life of the patients after physical exercise intervention.

MATERIALS AND METHODS

The present systematic review followed the Cochrane methodology for systematic reviews and reporting was implemented through the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. No protocol for systematic review has been registered. The research question was formulated following the PICO framework:
– Population: older patients with massive and/or irreparable rotator cuff tear
– Intervention: rehabilitation; physical activity program
– Comparison: surgical treatment and other conservative treatment different from exercise-based strategies
– Outcome of interest: functional status, pain, quality of life

Study inclusion criteria were:
• Peer-reviewed studies of each level of evidence according to Oxford Classification;

more specifically: Randomized clinical trials (RCT), Non-Randomized Controlled Trials (NRCT), Prospective and Retrospective Cohort Studies (PCS and RCS, respectively), Case-Control Studies (CCS) and Case Series (CS);
• Studies including patients with an average age superior to 65 years, according to the definition of "elderly" (15) with shoulder pain due to massive and/or irreparable rotator cuff tear;
• Studies reporting at least one pain assessment or one disability assessment for the evaluation of clinical outcomes (disability and pain) of patients treated with any physical activity (cardiovascular or anaerobic) or exercise programs that included loaded (against gravity or resistance) as a component;
• Studies written in English and Italian languages.

Study exclusion criteria:
• Case reports, technical notes, letters to editors, instructional course, systematic reviews and meta-analyses;
• Studies including patients with cervical spine involvement, shoulder instability or frozen shoulder;
• Studies including patients with partial - thickness rotator cuff tears;
• Studies in which physical activity was part of a post-operative rehabilitation program or a multidisciplinary program.

A literature search was carried out between April and September 2020, consulting Pubmed-Medline, Cochrane central and SCOPUS. The search string used was the following: ("rotator cuff"[MeSH Terms] OR ("rotator"[All Fields] AND "cuff"[All Fields]) OR "rotator cuff"[All Fields]) AND (("rehabilitation"[Subheading] OR "rehabilitation"[All Fields] OR "rehabilitation"[MeSH Terms]) OR ("exercise"[MeSH Terms] OR "exercise"[All Fields] OR ("physical"[All Fields] AND "activity"[All Fields]) OR "physical activity"[All Fields])). The literature search was conducted by two reviewers (L.D.B. and A.M.A) that identified the eligible studies by electronic search. Firstly, the retrieved papers were screened by title, then by reading the whole abstract. In case of disagreement, a third reviewer (E.A.) was consulted. After the exclusion of non-relevant articles, the eligibility of the remaining papers was established through the evaluation of full-text. After the electronic search was completed, further potentially missed studies were manually searched among the reference lists of the included papers and the relevant systematic reviews already published. The search process is summarized in the PRISMA flowchart. Data were extracted by two reviewers (A.M.A. and E.A.) and divergences were discussed, if necessary.

Improvement in pain and disability, both assessed at the end of the treatment, were considered as the primary outcome of the analysis. The secondary endpoint was to investigate the quality of life of the patients after physical exercise intervention.

The evaluation of the risk of bias of the selected studies was undertaken using the Cochrane risk of bias assessment tool, for randomized studies, and the Methodological Index for Non-Randomized Studies (MINORS) score, for the non-randomized ones. The Cochrane tool for assessing the risk of bias is based on the evaluation of five bias domains (sequence generation, allocation concealment, blinding, incomplete data addressing, and selective reporting) for which it is assigned a final judgment of "high," "low" or "unclear" risk. For the assessment of non-randomized clinical trials, according to MINORS Score (16), the global ideal score is 16 for non-comparative studies and 24 for comparative studies. Two reviewers (A.M.A and L.D.B.) rated independently all the included papers. Final data were discussed and confirmed with a third reviewer (E.A.).

The population size, effect size and the risk of bias were considered for a thorough qualitative synthesis of the included papers. For those studies in which the effect size was not reported, Cohen's d was calculated by the means and standard deviations at baseline and follow-up. An effect size minor or equal to 0.4 was considered low, between 0.4 and 0.8 was considered medium and an effect size greater than 0.8 was considered high. Studies were categorized as high quality, H (if they had low risk of bias, large population and high effect size);

intermediate quality, I (if they had medium to high risk of bias or one low value between population size and effect size); low quality, L (if the risk of bias was high and both population and effect sizes were low).

RESULTS

The electronic search yielded a total of 3207 records. After duplicates removal, 1687 records were evaluated by title and abstract. 1589 papers were excluded by title because not relevant to the research topic. Ninety-eight full-text papers were assessed for eligibility, of which 89 were excluded because they did not satisfy the inclusion criteria for the following reasons: for age (n =63), for study design (n= 15), for diagnosis (n= 11). At the end of the selection process, 9 papers were included. (Figure 1).

Of the included studies, 1 was RCT of the level of evidence (LOE) I [17], 5 were CS of LOE IV [18-22] and 1 was a P-CS [23] and 2 were R-CS of LOE II and III respectively [24,25]. In the included papers, a total of 417 patients were conservatively treated for massive and/or irreparable rotator cuff tears. Within the studies, the number of participants varied from 10 [18] to 108 [25]. The mean age of patients at the time of treatment was 71 years and ranged between 65 [24,25] and 80 years [19]. The mean time of the follow-up was 19 months, ranging from 3 to 48 months. The final follow-up was at 1 year or more in 5 papers [17,20,23-25]. The outcome measures used in these studies were: Range of Motion (ROM) in 7 studies [17,19-21,23-25]; Visual analog pain scale (VAS) in 3 studies [21,22,25] ; American Shoulder and Elbow Surgeons (ASES) score in 2 studies [20,25], Constant score in 2 studies [19,23], Short Form-36 (SF-36) in 2 studies [17,18], Oxford Shoulder Disability Questionnaire (OSDQ) in 1 study [18], Oxford Shoulder Score (OSS) in 2 studies [17,21], Measure Yourself Medical Outcome Profile (MYMOP) in 1 study [17], Subjective Shoulder
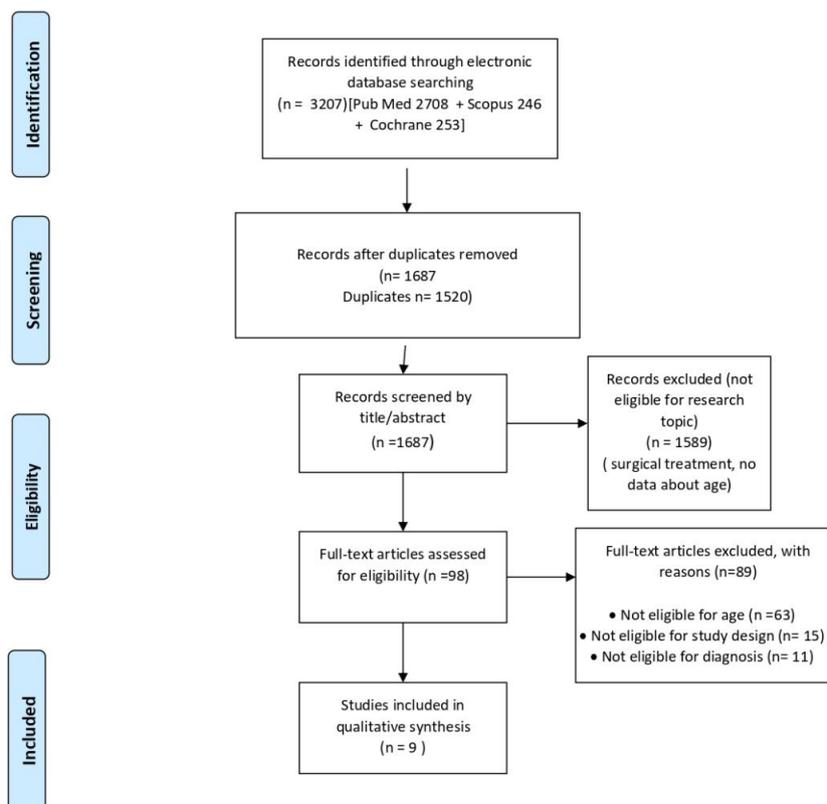

Figure 1. — PRISMA Flow Diagram.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n.a.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6-7
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5-6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7-8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5-6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7-9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n.a.
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n.a.
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	13
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n.a.
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	13
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n.a.
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15-17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

Figure 2. — PRISMA Check.

Table I. — Summary of the main characteristics of the included studies

Study	Type of study	LOE	Follow-up (months)	Number of patients	Mean age (years)
Yamada et al. 2000	RCS	III	48	40	65
Ainsworh et al. 2006	CS	IV	3	10	76
Levy et al. 2008	CS	IV	9	17	80
Ainsworth et al. 2009	RCT	I	12	54	78
Collin et al. 2015	PCS	II	24	45	67
Christensen et al. 2016	CS	IV	5	30	70
Yian et al. 2017	CS	IV	24	21	74
Gutiérrez-Espinoza et al. 2018	CS	IV	3	92	68
Yoon et al. 2019	RCS	III	42	108	65

LOE= level of evidence; RCS=retrospective cohort study; CS= case series; RCT= randomized clinical trial; PCS= prospective cohort study.

Value (SSV) in 1 study *(20)*; Japanese Orthopaedic Association (JOA) Score in 1 study *(24)*; Constant-Murley in 1 study *(22)*, DASH (Disabilities of the Arm, Shoulder and Hand) in 1 study *(22)*, University of California at Los Angeles score (UCLA) in 1 study *(25)*; Euro Qol- 5 Dimension score (EQ-5D score) in 1 study *(21)*. A summary of the main characteristics of the included studies is reported in Table I.

The training protocols applied in the studies were mainly focused on stretching exercises and muscle strengthening. Specifically, the programs included: rotator cuff strengthening exercises *(18,24,25)*, passive range of motion exercises *(24,25)*, deltoid rehabilitation program *(17,19-21,23,25)*, posture correction associated to the re-education of muscle recruitment and proprioceptive education *(17,18,23)* and posterior glenohumeral and scapular mobilization *(22)*. Two studies did not report the mean duration of symptoms before starting the treatment *(19,23)*. In all trials the time from symptoms onset to beginning of the exercise program was superior to 6 months *(17,18,21,22,24,25)*. The exercise program was performed in combination with local steroid injections in 5 papers, but few of these provided adequate information about dose and number of administrations *(17,19,20,24)*. A description of the interventions is detailed in Table II.

In elderly patients with massive rotator cuff tears, exercise programs demonstrated an improvement

in shoulder pain and function. In the study by Ainsworth et al. *(18)* at the end of a tailored protocol based on anterior deltoid strengthening and functional rehabilitation, all patients experienced an improvement in the section of SF-36 dedicated to physical health (mean 22 points). Moreover, functional status evaluated through OSDQ improved from 34.2 to 23.6 points at 3-months follow up. The same authors, in 2009, carried out an RCT *(17)* comparing an intervention group that received an individually tailored exercise program and ultrasound with a control group treated with therapeutic ultrasound. The physical functioning domain of SF-36 showed a significant improvement for the intervention group at 3- and 12-months follow-up. However, the OSS showed better results in the intervention group with a significant difference at 3 and 6 months (respectively, p = 0,002and p = 0,008) that became not significant at 12 months (p =0,16). Similarly, MYMOP was statistically improved in the intervention group at 3 months (p = 0.052) and 6 months (p = 0.047) but not at 12 months (p = 0.847). The authors also showed an increase of shoulder range of motion in active elevation and internal/external rotations in both groups, with a significant value in favour of the control group only during active elevation at 3- and 6 months follow up (respectively, p = 0.015 and p = 0.051) and external rotation at 6 months (p = 0.024). For a cohort of 30 patients, Christensen et al. *(21)* adopted

a neuromuscular exercise program with anterior deltoid and teres minor strengthening exercises. As primary outcome, Oxford Shoulder Score showed a significant improvement of shoulder function at 3- and 5- month and also between 3- month and final follow-up. Moreover, health status assessed through EQ-5D increased significantly from baseline to final follow-up. At 5 months follow-up, shoulder abduction significantly improved (p < 0.005), but the increase of ROM in flexion and external rotation was not significant. At the final follow-up, pain perceived during all these movements significantly decreased. Furthermore, the authors measured strength with a hand-held dynamometer registering a significant increase for abduction and flexion at 45° and 90°, even if 90° flexion was evaluated only for 13 patients able to reach 90° without pain. The strength increase was confirmed for internal and external rotation without statistical significance. In this paper, for the first time, EMG was used to confirm an increased activity of the anterior deltoid at the end of the exercise protocol. Nevertheless, EMG data did not support this hypothesis. Yoon et al. *(25)*, in their retrospective cohort study, demonstrated that an intact subscapularis tendon and a compensatory teres minor hypertrophy were associated with a significantly lower failure rate of conservative treatment and conversion to surgery rate during non-operative treatment. In the study group the rate of failure of non-operative treatment and conversion to surgery were respectively 43% and 39%, in contrast to 68% (p = 0.012) and 66% (p = 0.006) of the control group. At the final follow-up, ASES score, UCLA shoulder score and VAS pain score did not significantly differ between the two study groups. Moreover, there were no significant differences in ROM except for internal rotation (p < 0.001). A retrospective cohort study by Yamada et al. *(24)* revealed a significant improvement in range of motion, pain relief and muscle strength both in patients who underwent rotator cuff arthroscopic repair and patients treated by strengthening and passive range of motion exercises. The authors assessed the outcomes using the JOA score, made up of five sections analyzing pain, function, ROM, radiographic valuation and joint stability. The improvement in pain and function was significant in

both groups at the final follow-up. On the contrary, in conservatively treated patients the better results in ROM were not significant. Furthermore, 85% of these patients continued experimenting pain during activities of daily living (ADL) while a similar percentage of the operatively treated group had no symptoms. Yian et al. *(20)* adopted a 3-month anterior deltoid re-education (ADR) program for 21 participants with an overall success rate of 52% at the 2-year follow-up. The ROM improvement was greater in forward flexion. Moreover, the authors demonstrated that forward flexion of less than 50° at the beginning of the ADR program was significantly associated with an unsuccessful outcome at 2 years. ASES score improved from 39 points to 65 points at 9 months (p <0.001) and to 62 points at 2-years follow-up (p= 0.001); also, pain score and muscle strength increased but none of these values is statistically significant. The same rehabilitation program, in the study of Levy et al. *(19)*, obtained a positive effect in 82% of patients. The authors stated that the ADR program, in addition to anti-inflammatory drugs, improves overall shoulder function and pain in the aged population. Mean forward flexion improved from 40° to 160° at the last follow-up and all shoulder movements were improved. Moreover, the mean Constant score at 9-month follow-up was 63 while the mean preoperative score was 26. In a series of 45 patients with massive rotator cuff tear classified in 5 groups based on the tendon involved, the Constant score improved significantly (from 41 to 66, P <0.05) in the group with posterior-superior tear (supraspinatus and infraspinatus) compared to the group with anterior tear while the overall improvement was from 43 to 56 after 2 years (P < 0.05) *(23)*. Differently, in this study, the rehabilitation program was assisted by physiotherapists and included active and proprioceptive exercises finalized to strengthen all muscles involved in scapular stabilization and the entire deltoid muscle. In the paper of Gutierrez-Espinoza et al. *(22)*, 92 patients received posterior glenohumeral and scapular mobilization, with proprioceptive and control exercises for the scapula and the glenohumeral joint. The shoulder and upper extremity function, respectively evaluated with Constant-Murley and DASH score, showed

Table II. — A description of interventions of included studies

Study	Diagnosis	Type of study Number of patients	Protocol of intervention/injection	Outcomes summary	Main conclusions
Yamada et al. 2000	Massive rotator cuff tear	RCS 40 patients: Group 1: 14 Group 2: 26	Group 1: CS injection plus passive range of movement and rotator cuff strengthening exercises Group 2: rotator cuff repair	Group 1: JOA score increased from 53.2 to 71.1 (p=.0021). Group 2: JOA score increased from 58.8 to 85.9 (p <.0001).	Outcomes results were more favorably in the surgical group than in the conservative one
Ainsworth et al. 2006	Massive, irreparable rotator cuff tear	CS 10 patients	Posture correction and improving proprioception of shoulder. Strengthening, stretching and re-education of muscle recruitment. of anterior portion of the deltoid and teres minor No injection was used	OSDQ: improved from 34.2 to 23.6 (mean) SF36: limitation due to physical health from 25 to 35(mean)	All 10 patients showed an improvement of shoulder function at 3 months of follow up
Levy et al. 2008	Massive, irreparable rotator cuff tear	CS 17 patients	Anterior deltoid rehabilitation divided in two stages: in the first part exercises, with arm up-right within a comfortable arc of motion, and the second part with a small weight increasing the ROM Subacromial injection was performed at first Exercises were continued at least for 12 weeks.	Constant score: from 26 to 63 (mean) at final follow-up (all improved except for strenght) ROM: forward elevation improved from 40° to 160° (mean)	In 82% of patients the rehabilitation of anterior deltoid was sufficient to improve function and pain adequately and only 1 patient underwent RSA.
Ainsworth et al. 2009	Massive rotator cuff tear	RCT 54 patients Group A: 24 Group B: 30	Intervention group (Group A): tailored exercise program with stretching, resistance band exercises into internal and external rotation and therapeutic ultrasound Control group (Group B): therapeutic ultrasound, without the exercise program. Steroid injection if needed for pain	SF-36: statistically significant for Group A in the physical functioning domain at 3 months (p = 0.005), and 12 months (p=0.049) MYMOP: significant improvement for Group A at 3 months (p = 0.052) and 6 months (p = 0.047) but not at 12 months (p = 0.847). ROM: Group A showed improvement in external rotation at all time points statistically significant at 6months (p=0.024)	The rehabilitation program significantly improved shoulder pain and function in the short term.
Collin et al. 2015	Massive, irreparable rotator cuff tear	PCS 45	Five specific rehabilitation sessions based on strengthening exercises to stabilize and move the shoulder and to allow the function of deltoid muscle. No injection was used	Constant score: improvement from 43 to 56 (p < 0.05); Patients with postero-superior tear: from 41 to 66 (p < 0.05)	Outcomes of rehabilitation vary according to the site and number of the tears. The patients with isolated massive posterior tears had better outcomes from rehabilitation.

Study	Diagnosis	Type of study Number of patients	Protocol of intervention/injection	Outcomes summary	Main conclusions
Christensen et al. 2016	Irreparable rotator cuff tear	CS 30	The program consisted of one exercise for m. deltoideus anterior and one for m. teres minor including 2–3 min of warm-up before starting the exercise program Exercises were continued three times a week in a total of five months No injection was used	OSS: significant improvement from baseline to 5 months follow-up with a mean increase of 11.7 (95 % CI: 8.7–16.6) EQ-5D index values: significantly improvement from a median of 0.671 at baseline to 0.755 (p=0.009) ROM increased significantly for abduction from 93.7° to 128.1° (p = 0.005) VAS during abduction, flexion and external rotation all decreased significantly from baseline to 5 months follow-up; respectively (p = 0.001; p = <0.001; p = 0.015)	Exercise therapy focusing on m. deltoideus anterior and m. teres minor resulted in improved patient-reported function and quality of life even after long symptom duration.
Yian et al. 2017	Massive irreparable rotator cuff tear	CS 21	Anterior deltoid rehabilitation divided in two stages: in the first part exercises, with arm up-right within a comfortable arc of motion, and the second part with a small weight increasing the ROM Exercises were continued at least for 12 weeks Subacromial injection was performed at first	ASES score: improvement from 39 to 65 at 9 months (p < .001) and to 62 points at 2 years (p = .001) Pain score: improved from 6.7 points to 3.3 points at 9 months (P < .001) and to 3.7 points at 2 years (P < .001). Strength: increased from 1.1 kg to 2.1 kg at 9 months (P<.001) and to 1.9 kg at 2 years follow-up (P = .03) SSV: increased from 45% to 65% at 9 months (P<.001) and to 60% at 2 years (P = .01). ROM: forward flexion increased from 101° to 141° at 9 months (P < .001) and to 129° at 2 years (P = 0.01).	ADR program had a success rate of 57% (12 patients) at the 2-year follow-up. 14 % (3 patients) needed surgical treatment 28 % (6 patients) did not improve in ASES score significantly
Gutiérrez-Espinoza et al. 2018	Massive irreparable rotator cuff tear	CS 92	Manual therapy consisted in: posterior glenohumeral mobilization and scapular mobilization and a specific exercises program with proprioceptive and control exercises for the scapula and the glenohumeral joint. (maximum of 4 exercises per session) Two weekly sessions over 12 weeks were carried out. No injection was used	Constant-Murley improved from 38.4± 16.1 to 63.3 ±16.6 (p= 0.00) DASH improved from 63.9±16.4 to 35.3±17.4 (p=0.00) VAS during activity decreased from 5.6± 0.97 to 1.9±1.5 (p= 0.00)	A physical program based on manual therapy and specific exercises improves the function and reduces the pain during activity in these patients.

RCS=retrospective cohort study; CS= case series; RCT= randomized clinical trial; PCS= prospective cohort study; CS= corticosteroid; JOA =Japanese Orthopaedic Association; ROM= Range Of Motion; ADL = activities of daily living; SF-36 = Short Form36; SST = simple shoulder test; OSDQ = Oxford Shoulder Disability Questionnaire; RSA = reverse shoulder arthroplasty; OSS= Oxford Shoulder Score; MYMOP = measure yourself medical outcome profile; ADR= Anterior deltoid rehabilitation; ASES score= American Shoulder and Elbow Surgeons score; SSV= Subjective Shoulder Value; VAS= visual analog pain scale; CI = confident interval; EQ-5D = Euro Qol- 5 Dimension; DASH= Disabilities of the Arm, Shoulder and Hand; UCLA score = University of California at Los Angeles score.

Table III. — Cochrane risk of bias assessment tool

Study	Sequence generation	Allocation Concealment	Blinding	Incomplete data addressed	Selective reporting	Other bias
Ainsworth et al. 2009	LOW	LOW	HIGH	LOW	UNCLEAR	UNCLEAR

Table IV. — Qualitative synthesis of included studies

Study	Number of patients	Effect Size	Main score	MINOR	Qualitative synthesis
Yamada et al. 2000	40	n.a.	JOA score	21	I
Ainsworh et al. 2006	10	4	OSDQ	11	I
Levy et al. 2008	17	12.8	Constant score	13	I
Ainsworth et al. 2009	54	1	OSS	n.a.*	H
Collin et al. 2015	45	n.a.	Constant score	8	I
Christensen et al. 2016	30	2.8	OSS	15	H
Yian et al. 2017	21	n.a.	ASES	12	L
Gutiérrez-Espinoza et al. 2018	92	6.2	Constant-Murley	13	H
Yoon et al. 2019	108	1.4	VAS score	18	H

n.a.: data for calculation not available, * Quality assessment through Cochrane Risk of Bias Assessment Tool, H : high quality, I: intermediate quality, L: low quality; OSS: Oxford Shoulder Score; VAS: visual analog pain scale; ASES score: American Shoulder and Elbow Surgeons score; OSDQ: Oxford Shoulder Disability Questionnaire; JOA : Japanese Orthopaedic Association.

a statistically significant difference from baseline to final follow-up evaluation. Furthermore, at the 3month follow-up, VAS decrease during activity was statistically significant.

Only one of the included studies was I level RCT (17), and his risk of bias was assessed through the Cochrane Risk of Bias Assessment Tool. The MINORS score for comparative studies included were 21/24 (24) and 18/24 (25), while the non-comparative studies ranged from 8 (23) to 15 (21), with a mean of 12. Qualitative synthesis through population size, effect size and risk of bias showed that 4 studies were of high quality (H), the other 4 were of intermediate quality (I) and for only one, the quality was low (L). Details are reported in Tables III and IV.

DISCUSSION

This paper summarizes and critically appraises the results of 9 papers that reported the effects of different rehabilitation protocols as part or a unique conservative treatment strategy for massive rotator cuff tears in the elderly population. The purpose was to point out the evidence on the role of therapeutic physical exercise treatment for massive rotator cuff tears in elderly patients in terms of clinical outcome, pain reduction and, secondly, quality of life. The exercise protocols assessed within the included studies were extremely wide and heterogeneous in type, timing and modalities of exercise, with equally different methods of evaluation of the outcomes. However, most of the studies demonstrated a trend of improvement after the treatment, in terms of functional scores, pain, ROM and quality of life. Strengthening and stretching exercises were the most frequent treatment adopted in the included papers. Two case series (19,20) adopted a specific Anterior Deltoid re-education (ADR) showing a trend of improvement at the end of the treatment. The authors reported success in 57% (20) and 82% (19) of patients treated in terms of clinical outcomes, assessed with ASES and Constant score, pain, strength and ROM. Similarly, the papers in which the exercise protocol included deltoid rehabilitation (17,18,21,23), reported a trend of improvement

of quality of life and clinical outcomes. More specifically, in the study conducted by Ainsworth et al. *(18)* the physical functioning domain of the SF-36 showed a significant improvement after the tailored "Torbay rehabilitation program". The same authors, in the RCT *(17)* carried out in 2009, found a significant difference comparing patients of the intervention group, who underwent a tailored protocol of physical exercises associated with therapeutic ultrasound, with patients of the control group, treated with ultrasound only. The trial *(17)* showed a significant improvement of the OSS in the interventional group, compared to the control group at 3 and 6 months. However, this difference was not more observed at 12 months. These findings reflect the central role of the deltoid muscle, especially in elderly people in whom rotator cuff tendons are insufficient, to counteract the deficiency of the rotator cuff *(19)*. The importance of anatomical localization of the rotator cuff tear was investigated only by one study *(23)*, confirming that site and number of lesions influence the outcome. Conversely, Yamada et al. *(24)* was the only paper reporting that most of the patients treated with physical activity only suffered persistent pain in ADL, although reported significant improvement in pain and JOA score. However, this paper was conducted comparing patients treated surgically or non-surgically and did not report specific information regarding the rehabilitation protocols. The main strength of the present investigation is the systematic framework, adhering to PRISMA and PICO standards. More-over, the added value in comparison to previous works, is that our study focuses on elderly patients, a constantly growing population in which con-servative strategies represent always a better choice.

In this systematic review, we included 1 RCT *(17)*, 5 case series *(18-22)*, 2 retrospective cohort studies *(24,25)* and 1 prospective cohort study *(23)*. The methodology of the included RCT was evaluated through the Cochrane Risk of Bias Assessment Tool. This highlighted several biases: the trial included had a high risk of bias with regards to the blinding of the participants and unclear risk of bias in "selective reporting" and "other bias". However, it is relevant to understand that because of the type of treatment considered, namely physical exercise,

blinding is actually impossible. Apart from this incongruity, the trial conducted by Ainsworth et al. *(17)* was properly designed, reporting a satisfying sample size calculation, power analysis, leading to an appropriate estimation of the results. The non-randomized studies were evaluated using the MINOR score. The study by Yamada et al. *(24)* and the study by Yoon *(25)* were the comparative studies included and obtained a score of 21 out of 24 *(24)* and 18 out of 24 *(25)*, showing a good methodology. Qualitative synthesis through population size, effect size and risk of bias showed that 4 studies were of high quality (H) *(17,21,22,25)*, the other 4 were of intermediate quality (I) *(18,19,23,24)* and for only one, the quality was low (L) *(20)*. For this last study, considered of low quality, the risk of bias was average-low (MINORS=12), but the population was rather small and the reported data did not allow the calculation of the effect size. An overall assessment of study quality judged methodology of the included papers to be intermediate-high. With regards to MINORS subitems, the worst item in non-randomized studies was the blinding of participants, as well as for randomized trials. However, given the type of therapeutic intervention considered, blinding was impossible. Apart from methodology considerations, the included papers had some relevant biases with regard to the purpose of the present study. In 2 of the included studies *(19,23)*, the duration of symptoms before starting the treatment is unclear. Thus, it is difficult to assess the real effectiveness or failure of the advocated treatment. Another important bias was that many studies associated a different therapy to physical exercise. In particular in the trial by Ainsworth et al. *(17)* ultrasound therapy was administered as part of the tailored protocol. However, ultrasound therapy was administered in both groups, given that the two groups achieved significantly different results, it could be assumed that physical exercise plays a major role. Nevertheless, the effect of the single treatment is not assessable, thus preventing the authors to definitely conclude on this intervention. In 50% of studies *(17,19,20,24,25)* a steroid injection therapy was performed before or in concomitance with the treatment, but is it not clear the dosage and the number of administrations. This makes it

difficult to distinguish clearly if the benefit obtained by patients was due to physical therapy or injections.

CONCLUSIONS

The present systematic review of the literature collected results from a few studies with a high level of evidence, and many with a low level of evidence. Therefore, due to the low statistical strength and the overall moderate-low level of evidence of the included studies, it is not possible to draw a final conclusion on the topic. However, the analysis of the available literature allowed us to address our primary endpoint. Results showed a trend of improvement in patients who underwent physical exercise therapy. It is presumed that exercise could play an important role in the treatment of massive rotator cuff tear, with benefits on functionality and pain in elderly patients. Concerning the quality of life, our secondary endpoint, there is limited evidence demonstrating that an improvement occurs, but sometimes exclusively for certain life quality domains (e.g. comfort scale of the SF-36). Given the highlighted trends, we suggest to carry out further studies of a high level of evidence, in particular by comparing different protocols of physical exercises, in order to achieve consistent evidence to support common clinical practice in the future.

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