The nature and consistency of exercise reporting in rehabilitation following rotator cuff repair

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Abstract

Purpose:

Rotator cuff repair is conventional surgery, and postoperative rehabilitation programs are routine. Optimization and implementation of evidence-based exercise are dependent on comprehensive reporting of intervention content and dosage. The purpose of this study is to examine the content and consistency of reporting of postoperative exercise programs following arthroscopic rotator cuff repairs.

Methods:

Keyword search of PUBMED, EMBASE, Scopus, SPORTDiscuss, AMED, CINAHL, and Cochrane were performed from January 1950 to March 2019. All the studies that discussed rehabilitation following rotator cuff repairs of human adults were included. A Proforma Consensus on Exercise Reporting Template (CERT) assessment form was used to extract data.

Results: Thirty-one studies were included in this report. Out of 19 items prescribed by the panel of exercise experts, only 1 study scored 63%. A mean score of 3.83 and a median of 3 with a range of 12 was registered. Out of these 31 studies, three studies scored 0 out of 19.

Conclusion:

Variation in content in rotator cuff post-operative regimens was evident, as was a lack of complete reporting of intervention specifics. Lack of exercise reporting is a clear barrier to implementation of best practice.

Keywords: postoperative, rotator cuff, rehabilitation, exercise reporting guideline.
Lay Summary

Exercise therapy is an important part of rehabilitation following any injury or surgery. There are multiple factors like the number of times the exercises was done in a day, how hard was the exercise, what type of equipment used, motivation level of the individual, how often the exercises were performed, will influence the outcome of the exercise program. The nature of this study is to find out if the exercise programs in the published studies are self-explanatory. Authors used a new guideline that is specific to exercise therapy called Consensus on Exercise Reporting (CERT) to see if the studies published following rotator cuff surgery reported all the key factors of exercise. Can these exercise programs be replicated without contacting the original authors for an explanation regarding how the exercises were performed by the patients following rotator cuff surgery? And why it is important to follow certain guidelines when reporting studies with exercise in a standard way.
Co-Authorship Statement

Dinesh Balachandran conducted the research for his master’s thesis under the supervision of Dr. Joy MacDermid, Dr. Tom Overend and Dr. Trevor Birmingham who are co-authors of the manuscript in this thesis.
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Chapter 1

Introduction

The glenohumeral joint or the shoulder joint is the most mobile joint of the human body, but this increased mobility makes the joint the most unstable joint in the human body.\textsuperscript{1} The stability of the shoulder joint is brought about by the muscles of the rotator cuff and by ligaments and joint capsule, and any injuries to any of these may cause functional limitation. Rotator cuff injuries are the most common of the shoulder injuries accounting for nearly 4.5 million hospital visits in the United States of America.\textsuperscript{2} In the year 2012, 250,000 patients underwent rotator cuff repair in the USA alone at an estimated cost of 3 billion dollars.\textsuperscript{3}

The chances of rotator cuff injury increase as age advances, people over 60 years being more susceptible to rotator cuff injury.\textsuperscript{4} With the world population aging at an unprecedented rate, this problem of rotator cuff injury puts much pressure on the individuals and health care. According to the American Academy of Orthopaedic Surgeons, rotator cuff tears are a common cause of shoulder pain among adults. About 85\% of all shoulder pain can be attributed to rotator cuff involvement.\textsuperscript{5}

The shoulder joint performs a wide range of motion and has to withstand heavy demands of daily activities over the years. The bony structure of the glenohumeral joint relies heavily on the muscular and ligamentous stabilizers throughout the movements.

1. Shoulder joint

1.1 Skeletal anatomy

The structural component of the joint consist of the scapula, which is a flat triangular-shaped bone with an anterior projection called the glenoid fossa which forms the concave surface of the shoulder joint. The head of the humerus, which is called the long bone of the arm, forms the convex surface of the joint. The clavicle or the collar bone acts as the strut that connects upper extremity bone (humerus) to the axial skeleton (acromion process of scapula) anteriorly and
articulates with the sternum medially. The shoulder complex primarily consists of the glenoid humeral (GH) joint and three other smaller joints, namely the acromioclavicular (AC) joint, sternoclavicular (SC) joint and scapulothoracic joint (ST) joint. A joint capsule envelopes the GH joint.

The GH joint is a synovial ball and socket joint. Both the articulating surfaces are covered by hyaline cartilage. The glenoid fossa is deepened and expanded by a fibrous structure called the glenoid labrum which is attached on the rim of the fossa and allows the attachment of glenohumeral ligaments to the glenoid fossa. The glenoid labrum deepens the glenoid fossa from 2.5 to approximately 5mm. Only about 25% to 30% of the head of the humerus is in contact with the glenoid fossa. Stability of the shoulder joint depends heavily on muscular control for securing the limb to the thorax to provide a stable base for the movements of the upper extremity. The joint stability is provided by rotator cuff muscles, glenoid labrum, joint capsule, the long head of biceps brachii, and related bony processes.

1.2 Joint Capsule and bursae

The joint capsule is a fibrous sheath that covers the joint structure. The joint capsule extends from the anatomical neck of the humerus to the border/rim of the glenoid fossa. The laxity of the capsule permits greater motion of the joint, especially abduction. The inner surface of the capsule is lined by a synovial membrane which produces synovial fluid to reduce friction between the articulating surfaces. The friction is further reduced by the presence of several sacs filled by a synovial fluid called bursae. Several bursae are found around the shoulder joint, but two
clinically significant bursae are the subacromial bursa and subscapular bursa.

The subacromial bursa is the largest bursa in the body and is necessary for the normal functioning of the shoulder joint. It lies deep to the deltoid muscle and coracoacromial arch and separates the supraspinatus tendon from the acromion and coracoid process.

The subscapular bursa lies between the subscapularis tendon and neck of the scapula. This bursa protects the tendon of subscapularis at the point where it passes under the coracoid process and over the neck of the scapula.

1.3 Ligaments of the shoulder joint

The joint capsule is reinforced with ligaments, which significantly contribute to joint stability. Mostly these ligaments are lax through the mid-range of motion and progressively gets taut as they near joint end-range of motion. The common ligaments are glenohumeral ligaments (GHL) and coracohumeral ligament. Each of the GH ligaments provides stability in combinations at different degree of GH joint motion. The superior GHL is an inferior stabilizer when the arm is adducted and in neutral rotation. The middle GHL is an anterior stabilizer when the arm is adducted and at 30° - 45° abduction. The inferior GHL is the most important anterior stabilizer when the arm is in the abduction and external rotation. The coracohumeral ligament is the inferior and posterior stabilizer with the arm in adduction.
2. Rotator cuff muscles

The rotator cuff (RC) is comprised of four muscles and several tendons that form a horseshoe-shaped structure which inserts into the head of the humerus. The four muscles are subscapularis, infraspinatus, supraspinatus, and teres minor that arise from the scapula and their tendons blend in with the capsule as they attach to the tuberosities of the humerus. These muscles and their distal tendons form a cuff-like structure around the shoulder joint and provide the much-needed stability to the otherwise unstable shoulder joint. Specific rotator cuff muscles have independent actions that, when combined, contribute to the stability of the glenohumeral joint.

The subscapularis is the largest of the rotator cuff muscles, and an essential active shoulder stabilizer. It originates from the spine of the scapula and inserts into the inferior facet of the greater tuberosity. It is primarily an internal rotator and serves as a shoulder abductor stabilizer of the humeral head.

The supraspinatus is the most commonly affected rotator cuff muscle and initiates shoulder abduction to 90°. The supraspinatus originates from the supraspinous fossa and inserts into the superior aspect of the greater tuberosity. It is also a stabilizer and aids in forward flexion (the first 30°) and external rotation of the humerus.

The infraspinatus primarily guides external rotation and generates about 60% of the external rotation. It originates from the infraspinous fossa of the scapula and inserted into the middle facet of the greater tuberosity. The infraspinatus muscle provides dynamic stability and resists posterior and superior translation of the head of the humerus.

The teres minor attaches medially to the dorsal surface of the scapula just below infraspinatus and inserts laterally to the greater tubercle of the humerus. Along with infraspinatus, teres minor produces external rotation and glenohumeral stabilizer.
2.1 Rotator Cuff Disease

Rotator muscles and their tendons help in various movements of the shoulder joint and thus are vital for the functional day to day activities. Rotator cuff disease could be:

- Rotator cuff impingement;
- Rotator cuff tendonitis or tendinopathy;
- Shoulder bursitis;
- Calcific tendonitis;
- Rotator cuff tear.

Rotator cuff impingement – is a clinical syndrome in which soft tissues of the subacromial bursa get trapped and compressed between the humeral head and subacromial arch causing pain on elevation of the affected arm and/or when lying on the affected side\(^\text{10}\).

Rotator cuff tendinopathy – it is an overuse condition which clinically manifests as pain and impaired performance due to injury to RC tendons\(^\text{11}\).

Shoulder bursitis – the inflammation of the bursa can cause pain and restriction of movement. Subacromial bursitis is the most frequently inflamed among the shoulder bursas.
Calcific tendonitis – It is a condition where a small calcium deposits within the tendons of the rotator cuff muscles\textsuperscript{12}.

Rotator cuff tears – A tear in the rotator cuff muscles can be either due to microtrauma or macro-trauma. Micro traumatic tears occur over the years with repeated using of the shoulder joint. These micro tears are also called as “wear and tear” and is common in old age whereas macro-traumatic tears are sudden and are because of trauma. Rotator cuff tears are classified as partial-thickness tears or full-thickness tears. Partial-thickness rotator cuff tears are a common pathology and may be asymptomatic\textsuperscript{13}. The Ellman classification\textsuperscript{13} defines the tear based on location and the degree of tear. Based on location, the tears can be articular, bursal, or intratendinous. Based on the degree of tear:

- Grade I - < 3mm (<25%)
- Grade II - 3-6mm (25- 50%)
- Grade III - > 6mm (>50%).

Partial-thickness tears can develop into a full-thickness tear in 28\% of the population\textsuperscript{13}. Full-thickness tears do not heal spontaneously and progress in size gradually. Full-thickness tears may involve only part of one tendon (usually the supraspinatus) and may extend to become massive involving multiple tendons. DeOrio and Cofield\textsuperscript{14} developed the most commonly used full-thickness tear classification based on the tear size.\textsuperscript{15} The tear is small if it is less than 1 cm, medium if the tear is between 1 and 3 cm, large is 3-5 cm and massive if the tear is more than 5 cm.

3. Rotator cuff tear management/treatment

Management of rotator cuff tear can be either conservative or surgical. Conservative management includes the use of Nonsteroidal anti-inflammatory drugs (NSAIDs), exercise therapy, use of physical modalities, and corticosteroid or hyaluronic acid injections into the glenohumeral joint or subacromial bursa depending on the tear. The success rate of conservative management ranges from 33\% to 82\% in the literature\textsuperscript{16}. The goal of these conservative treatments is to reduce pain and restore function. Manual physical therapy techniques, along with exercises, are proven to be an effective method in treating partial tears. Typically, rotator cuff
injury patients respond to treatment within 6 to 12 weeks of conservative management. If the symptoms persist even after six months, then surgical treatment should be considered.

3.1 Indications for the rotator cuff repair

Ever since the first rotator cuff surgery in 1911, there is a lack of consistent and evidence-based indications for a rotator cuff surgery\(^1\). The least controversial indication is the full thickness tear after a failed conservative treatments\(^2\). Other relative indications are if the patient is young and active, if the tear is acute and/or traumatic and if there is significant weakness\(^3\).

Surgical management is recommended when conservative treatment fails. Three types of surgeries are performed to repair the injured rotator cuff: open, arthroscopic, and mini-open repairs.

3.2 Open rotator cuff repair

The first open rotator cuff repair was done in 1911 by Dr. Codman\(^4\) and has been modified by Neer in 1972\(^5\). Studies on the outcome of open repair have shown positive results in functional improvements and pain relief\(^6,7\). The open repair method is still preferred by many surgeons in case of massive tears. Open repair is typically performed in large tears and if there is a need for tendon transfer. An incision of 3 – 6 cm is made over the anterior superior aspect of the shoulder, and the deltoid muscle is taken off the anterior acromion for a better view and to gain access to the underlying structures. Once access is gained, debridement of the adhesions is performed for better mobility of the tendon, and the torn tendon is attached to the greater tuberosity of the head of the humerus. This procedure is reported to have high satisfaction rates\(^8,9,10\), but it also has several disadvantages of injuries to deltoid muscle leading to deltoid dysfunction and post-operative pain\(^11\).

3.3 Arthroscopic rotator cuff repair

Burman performed the first reported arthroscopic surgery in 1931 on cadavers\(^12\) and since then
this procedure is hailed as one the most significant advancements in orthopedic surgeries of the last century. Arthroscopic rotator cuff repair is one of the most preferred surgical routines\textsuperscript{26} as it is minimally invasive and is reported to have fewer complications. Arthroscopic repair requires a small incision to insert several 7 to 8 mm thick cannulas. Even though it is the most preferred procedure, it is a technically challenging procedure and has a high failure rate.\textsuperscript{25,26}

3.4 Mini-open rotator cuff repair

To prevent taking down of the deltoid muscle during open repair, this method of arthroscopic assisted repair was described by Levy et al. in 1994\textsuperscript{21}. In this procedure, the arthroscopic portal is extended 1 to 2 cms, and instead of taking down the deltoid muscle, the fibers are split in the middle to gain access to the underlying structures. This procedure is shown to have similar results as the open rotator cuff repair with minimal risk of the deltoid muscle injury.

Despite the advancements made in the rotator cuff surgery, stiffness is the most common complication and has been reported in 4.9\%\textsuperscript{29} to 32.7\%\textsuperscript{30,31} of the patients who have undergone RC repair followed by nonhealing and re-tear. A successful rehabilitation program is a critical component in not only preventing these complications but also in the complete recovery of the patient.

3.5 Rehabilitation following repair

Following the surgical repair of the injured rotator cuff muscles, rehabilitation of the shoulder joint is crucial for the complete recovery. Though various rehabilitation protocols exist following a rotator cuff repair\textsuperscript{32}, the goals of these protocols can comply in 4 phases. Each progression from one phase to next depends on various factors like the age of the patient, gender, size of the tear, type of surgery performed, and other comorbidities.
Phase I (0 – 6 weeks)
The main objective of this phase is to maintain the integrity of the repair, educate the patient to goals of rehabilitation and modifications of activities of daily living and precautions to be taken during this period. The focus during this phase of the rehabilitation is to maintain the integrity of the repaired tendon.

Following the rotator cuff repair, patients are required to wear a shoulder immobilizer with abduction pillow. Studies have shown that immobilizer with an abduction pillow reduces the tension on the repaired supraspinatus tendons\(^{33}\). Patients are expected to wear the immobilizer all the time during this phase unless otherwise instructed by the surgeons.

During this phase, the reduction of pain and joint stiffness is vital for a good outcome following the repair. Pain can is managed by medications, cryotherapy, and TENS (Transcutaneous Electrical Nerve Stimulations). Passive range of motion is performed as studies have proven the beneficial effects on the tendon to bone healing. Passive ROM can be performed by using Continuous Passive Motion (CPM) by the therapist while at the hospital and by a trained assistant like a friend or relative after discharge\(^{34}\). Active range of motion of the elbow, wrist, and hand is prescribed to prevent joint stiffness. Pendular exercises also can be performed during this phase of rehabilitation.

It is essential during this phase to teach the patient’s attender/assistant these exercises and to educate the patients about the things that should be avoided during this phase like lifting, driving, pushing or pulling to prevent re-tear of the tendons.

Phase II (6 weeks to 10-12 weeks)
This phase is the collagen remodeling phase of the healing process. Some studies report that low-level muscle forces in this phase enhance the tensile strength of the tendon.\(^{35}\)

The focus of this stage is to achieve minimal pain and inflammation, maintain the range of motion by introducing active-assisted ROM exercises and improving coordination and strength. Active assisted ROM exercises are performed using pulleys, cane/wand/towel/ and or self-assisted. Coordination and strength can be achieved by upper limb proprioceptive exercises in supine lying. Sub-maximal isometric external and internal rotation without pain can be initiated during this phase of rehabilitation\(^{36}\).
Phase III (10-12 weeks – 16 weeks)
Remodeling phase of the collagen is complete, and healing is stable to allow strengthening exercises. The focus in this phase is to restore full range of motion without pain, neuromuscular control, and muscle endurance. During this phase, exercises using elastic resistance bands aids in muscle control and endurance. By this time, patients should have achieved 80 - 90% of ROM and be able to perform exercises without any pain. If the patient can perform activities of daily living and able to perform all the strengthening exercises without pain, then the next phase is initiated.

Phase IV (16 weeks – 24-26 weeks)
The objective of phase IV is to normalize muscular strength to the non-operated upper limb. Progressive strength training begins, and exercises to target scapula stabilizers are necessary. Exercises like standing row and bilateral external rotation using elastic resistance bands, wall push-ups, and progressing to push-ups, and modified plank help in strengthening the scapular stabilizers. All the exercises are progressed according to the patient’s tolerance. During this phase, the patient returns to perform all activities except overhead activities and return to competitive sports/recreational activities is restricted, but sports specific exercises can be started during this phase of rehabilitation.

Phase V (24-26 weeks - 32 weeks)
By this phase, patients should be able to perform all the activities with no pain. The main focus of this phase is the gradual return to strenuous work and gradual return to competitive sports or recreational activities.
4. Purpose of this study

Numerous rehabilitation protocols exist for rehabilitation following RC repair and primarily based on the clinical experience on the surgeons and physiotherapist. However, there is no consensus on an exercise program that is ideal for rehabilitation following RC repair, leading to many trials and publications to develop a standard exercise protocol. With the increase in publications, it is essential to find if these exercise protocols can be replicated with the information that is provided by the authors in their studies. There was no standardized method for reporting exercise programs until a Consensus on Exercise Reporting Template (CERT) (a 16-item checklist was developed to improve exercise reporting in all evaluative study designs by a panel of exercise experts) was published in 2016. Although there is lots of researches demonstrating the evidence of rehabilitation following rotator cuff repair, due to missing information in these trials they could not be replicated and thus limits the use of these evidence in clinical practice. This study aims to:

1) examine the completeness of exercise reporting in studies following rotator cuff repair;

2) find if the level of exercise reporting varies across study design, year of publication and the profession of the first author.
1. Introduction:

Rotator cuff (RC) tears are a common shoulder injury and may need surgical repair. In the USA alone, the repair of rotator cuff accounts for about 75,000 operations in a year\(^1\). About 10% of partial-thickness tears heal spontaneously. However, 53% of partial-thickness tears progress and 28% become full-thickness tears\(^{37}\), but most of the full-thickness tears can be asymptomatic. Full-thickness tears do not heal spontaneously and progress gradually in size\(^{38,39}\). Sometimes these asymptomatic tears may cause pain and reduced shoulder range of motion. Conventional methods like medical injections can treat RC tears, and by physiotherapy when these methods fail, then surgical repair of the rotator cuff is necessary to reduce pain and restore shoulder range of motion. Surgical repair is a variable procedure as some of the partial-thickness tears may heal by no surgical intervention; the natural history of rotator cuff indicates that the small tears will enlarge without surgical repair\(^{40}\). In recent years, there is a significant increase in the amount of surgery performed to repair the rotator cuff. According to Colvin et al., there is a 141% increase in rotator cuff surgery between the years 1996 and 2006,\(^{41}\) this may be because of the longer life span as a result of medical advancements and change in the treatment preferences by the patient and physicians.

Though surgical repair prevents small tears from developing into massive tears, rehabilitation following surgery is essential to minimize stiffness, muscle atrophy\(^{42}\) and to improve the function of the joint and to prevent further tears. Surgical techniques to repair the rotator cuff have changed over time, and with advancements in arthroscopic rotator cuff repairs, it is now less invasive, and
less recovery time spent by the patient. Despite this, rehabilitation is crucial in helping the patients with the recovery and getting them back to their life as quickly as possible and in the prevention of re-tear. Physiotherapy interventions consist of exercise, modalities, hands-on techniques that can be applied individually or in combination. Because of this multimodal intervention that needs to report depending on the complexity of the clinical research, the trial reports sometime fail to capture all the components of the intervention. Exercise therapy by physiotherapists is a crucial element in a rehabilitation program following a repair of the rotator cuff. Exercise intervention consists of several components, all of which will affect the overall outcome of the rehabilitation program. Clear documentation of the implementation parameters of rehabilitation programs is fundamental to fidelity and scaling up of effective interventions. Evidence-based practices have transformed healthcare in the past few decades. The National Academy of Medicine, formerly known as Institute of Medicine, set a goal that by 2020, 90% of clinical decisions will be supported by updated clinical information and will reflect best available evidence to achieve best patient outcomes. Evidence-based practice is the key to improving the quality of health care worldwide. Yamato et al. concluded that the completeness of intervention reporting in physiotherapy was weak. In this study, the authors reviewed random sample reports of RCTs from PEDRO database, and completeness of intervention was evaluated using Template for Intervention Description and Replication (TIDieR) checklist. This study showed that in intervention groups, 23% of trials did not describe at least half of items in TIDieR and in the controlled group, 75% of the trials described half of the items. The conclusion from this study is that clinicians and researchers would not be able to replicate these interventions with the information reported in these studies. Although there were various checklists for trial interventions like Consolidated Standards of Reporting Trials (CONSORT) 2010 statement and TIDieR
checklist and guide, until recent years, the researchers lacked guidance for reporting exercise interventions. The Consolidated Standards of Reporting Trials (CONSORT) 2010 statement suggests that authors should report “The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.” Both TIDieR and CONSORT authors have made general guidelines for reporting of interventions in clinical trials. According to Page et al., while standard reporting guidelines focus on making sure that specific components of specific study designs are included, these guidelines often provide minimal reporting requirements for intervention component. Exercise has many dimensions like frequency, duration, type, intensity, and rest intervals. There needs to be a clear guideline specifically for an exercise intervention in clinical research. The Consensus on Exercise Reporting Template (CERT) was developed as an extension of both the CONSORT statement and TIDieR to improve the quality of exercise reporting in all study design. Therefore, the objective of this study is to collect and summarise components of the exercise programs that have been reported in randomized controlled trials addressing rehabilitation following rotator cuff repair.

2. Methods:

The Consensus on Exercise Reporting Template (CERT) assessment form was used to extract data. The CERT has a 16-item checklist and was modeled on TIDieR. An international panel of exercise experts came up with these 16 items, which are the minimal data that were needed to be reported in any exercise intervention so that other researchers can replicate it. The 16 items on CERT can be classified into the following seven categories – What: materials, Who: provider, How: delivery, Where: location, when, How much: dosage, Tailoring: what, how, How well: planned, actual. Each item has a description of what should be reported in an exercise intervention. If one of the items on the checklist is reported, a score of 1 is given and if the item is not reported
or adequately reported a score of 0 is given. Items 7, 14 and 16 has two subdivisions namely a and b. A total score of 19 is given if all the items are reported.

2.1 Study Selection:

Inclusion Criteria:
The sample of trials was identified through a systematic search for publications that reported exercise intervention as a part of postoperative rehabilitation following rotator cuff repair. Studies were included if they were any research designs that compared exercise-based rehabilitation following a rotator cuff surgery from January 1950 to March 2019. Trials were selected if they are based on human adults (over 18 years old) and involved any type of exercise program like home-based, delayed vs. accelerated, and with or without any outcome measures. No study was excluded based on the language.

Exclusion Criteria:

Studies were excluded if they were 1) not focused on rehabilitation following rotator cuff repair 2) ongoing trials.

2.2 Search Strategy:

A systematic search of multiple electronic databases (PubMed, AMED, EMBASE, Scopus, SPORTDiscuss, CINAHL, and Cochrane Library) was performed and included publications up to March 2019. The search strategy included a combination of relevant free-text and MeSH terms for the population and intervention. The search was performed using a variety of exercise based post-
surgical rehabilitation of rotator cuff terms for the search (see Allied and Complementary Medicine, AMED search strategy in Appendix 1)

2.3 Assessment of Intervention Description

Intervention description of the eligible studies was assessed using the Consensus on Exercise Reporting Template (CERT)\(^9\), which contains 16 items listed under 7 sections (Appendix 2). Items 1 and 2 capture the materials (types of equipment) and the provider of the intervention along with the experience and training. Item 3 to 7 cover the core elements of exercise intervention for replication of the trials like how the exercise was delivered including whether exercises were performed in a group or individually, type of supervision, motivation strategies, measurement and reporting of adherence, rules for progression of exercise program. Items 8 to 11 focused on the description of each exercise for replication (with illustrations, protocol sheet or photographs), the content of any home program component, nonexercised components and how adverse events that occur during exercises are documented and managed. Item 12 focused on where the exercise was performed (setting). Item 13 covered the when and how much (dosage of the exercise) aspect of exercise. Items 14 and 15 focused on the what and how like whether exercises were generic or tailored and decision rule that determines the starting level of exercise. Item 16 required how well the exercise program was delivered and performed as planned.

The interventions of each included trial were appraised for completeness of reporting of each item on the checklist. Items adequately reported in the intervention description was given 1 point, and those missing or failed to report the intervention checklist adequately was given zero. If all the items on the checklist were reported in the intervention trial, a total of 19 was given. Authors used
the CERT: Explanation and Elaboration statement which contains minimum recommended items for describing exercise intervention whenever clarification was needed regarding what needs to be reported in an exercise intervention. A single reviewer coded the CERT items in all the 31 studies included in the review.

2.4 Data Extraction:

The primary researcher extracted and analyzed data such as, the setting in which the study and exercises were taught and performed, who prescribed and taught the exercises, what type of exercise equipment were used (if any), how the exercise program was progressed and how exercise program was conducted as per plan,

3. Results:

The initial search produced 1936 articles; of those, 454 were duplicates. This resulted in 1482 articles. Out of the selected 1482 articles, 1345 were rejected based on title and irrelevant to exercise rehabilitation. The remaining 137 were examined, and 106 articles were rejected based on the abstract and full-text. Following this, 31 articles were included in the final review (see Figure 1).
3.1 Results of the description of the included studies

The title, participant characteristics, the country in which the study was conducted, the year in which the study was performed, the study design, the type of surgery that was performed, the qualifications of the authors of the study and CERT scores are presented in Table 1. Out of 31 selected studies, 21 are RCT’s, six are case series/study, three were prospective studies, and one was a retrospective study design. All the studies in the review are based on various rehabilitation protocol like delayed, accelerated, long periods of immobilization, supervised and unsupervised, delayed and early rehabilitation, and effects of different exercises like aquatic therapy following a rotator cuff repair. Of the 31 studies, arthroscopic surgery was performed in 25 studies, three mini-open, one open technique, and in two studies, surgery methods were not reported. Ten of the studies was conducted in the United States of America, four in South Korea, two in Australia, two in Turkey, two in Canada, two in Italy, two in Taiwan, and one each in Sweden, Hong Kong, France, Austria, Belgium, Finland, and Poland.

3.2 Results of exercise intervention reporting

The reporting standards of exercise interventions is expressed as CERT scores in Table 1. The scores of the included studies ranged from 0 to 12 for reporting exercises following a rotator cuff repair. As CERT is designed to evaluate exercise reporting across all study designs, we compared the scores across different study designs of the included studies. Until 2016, there were no specific reporting guidelines for reporting exercises\(^8\) for any study design; this review compared the CERT scores across various timelines based on the year of publications to check if the availability of CERT has improved exercise reporting in the recent past.
The RCT’s (n=21) on average scored 2.95, the Prospective studies (n=3) scored 4.33, Retrospective studies (n=1) scored 9, and case studies/series (n=6) recorded a score of 5.83 (Figure 2). Based on the year in the studies were published, the studies published between the year 1998 and 2003 (n=3) got 5.66 average while studies between 2004-2009 (n=4) scored 8. While the studies published between the years 2010-2014 (n=13) which is the highest number of publications scored only 2, and studies published around 2015-2019 (n=11) got 4 points on average (Figure 3). Based on the profession/qualifications of the first author, the MD’s and Surgeons (n=16) averaged 1.69 in reporting the exercise interventions, whereas PT’s (n=14) scored 3.5 and Registered Nurses (n=1) got 4 points on average (Figure 4).

3.3 Results of specific exercise interventions

The 31 studies included in this review reported wide diversity of exercise program: five studies with home-based exercise programs,10,27,30,33,34 seven studies with slow and accelerated exercise protocols,11–13,21,22,24,31 two studies with early and delayed exercise protocols,18,23 two studies with exercise based on aqua therapy,37,38 one study with continuous passive motion,26 one study with pulleys,14 three studies based on immobilization,16,17,32 four studies with passive motions and immobilization protocols,15,19,25,35 one study based on supervised exercises,28 five studies with land-based exercises.20,29,36,39,40 These exercise programs are provided and performed in hospitals, clinics, community centers, and at home. Six of the studies reported that adherence measured but only 3 reported how the adherence to exercise was measured. Home exercise programs were inadequately reported in 13 of the studies. Only 6 studies adequately reported the exercise equipment that was used in the exercise program.
4. Discussion:

Randomized controlled trials have been growing exponentially\textsuperscript{51}, but studies have shown that most of the findings are not clinically applied. This study shows that RCT’s, the gold standard of clinical trials, have poor reporting in exercise interventions following a rotator cuff repair. An effective intervention reported in the RCT has the potential to change clinical practices, but for that protocols reported must be reproduced safely by other clinicians.\textsuperscript{52} Abell et al.\textsuperscript{53} reported that 43\% of authors did more in the intervention than what they reported. The unclear reporting of exercise interventions in the RCT’s may be due to the constraints in the length of publications. As a solution, CERT authors recommend that the exercise program protocols be reported as an online appendix.\textsuperscript{50} Only two\textsuperscript{54,55} of the 21 RCT’s included provided an online appendix of the exercise protocol, whereas three of the six case studies provided online appendixes of the exercise protocols. When Hoffmann et al.\textsuperscript{56} in their study contacted the corresponding authors for more information regarding their interventions, it is reported that there are several reasons for lack of information like legal copyrights restrictions and difficulty to publicize the tailored interventions as it is complex. Hoffman et al. also suggested that there is a lack of awareness about the importance of making intervention materials available.

According to Mimouni et al.\textsuperscript{57}, the number of publications has increased linearly between 1998 and 2013 in the field of rehabilitation. In the early years of publications, the emphasis was on electrophysical agents, but over the years, exercise therapy has become the most supported intervention.\textsuperscript{58} Between the years 2010 to 2016; many guidelines for reporting interventions like CONSORT(2010)\textsuperscript{47}, SPIRIT(2013)\textsuperscript{59}, TIDieR (2014)\textsuperscript{48}, and CERT (2016)\textsuperscript{50} was published. With journals like International Journal Of Sports Physical Therapy requires authors to use a TIDieR checklist or Modified CERT checklist\textsuperscript{49}, we hope that all the journals make this a requirement.
from the authors so that the published research can benefit all the other researchers, clinicians, and patients.

The average CERT scores based on the qualifications of the first author is in Figure 4. We wanted to see if the reporting of exercise is affected by the qualifications of the author who writes the research. Out of 31 studies, the first authors of 16 studies were either Surgeons or MD’s, and they scored an average of 1.69 whereas Physiotherapists were first authors in 14 studies and recorded an average score of 3.5 and one study with Registered Nurse as the first author scored 4. This low scores from studies authored by MD’s and Surgeons may be because they are not the ones prescribing and delivering the exercise intervention, but the low score of 3.5 from physiotherapy authored studies is a concern and needs more detailed studies to understand the reasons for the lack of reporting. Incomplete reporting of interventions is not only a problem in the Physiotherapy field, but Hoffmann et al.\textsuperscript{56} in their studies reported that 60\% of non-pharmacological interventions are inadequately reported. Yamato et al.\textsuperscript{46} in their study, suggest that for complex interventions to not only use online appendixes but using video or websites demonstrating the interventions as a way to report the interventions adequately.

Six of the papers reported exercise adherence, but only three studies reported how the adherence, or the fidelity was assessed for the program. Adherence can be defined as the commitment of a person to a plan or goal. Non-adherence by a patient can lead to ineffective intervention or result in failed rehabilitation protocol. Exercise adherence can be measured by diary writing or follow up calls or texts. Adherence can be measured using simple tools like Sports Injury Rehabilitation Adherence Scale (SIRAS)\textsuperscript{60}, which is a 3-item scale that can be filled by the therapist. Fidelity is the extent to which the intervention occurred as planned by the investigators. Fidelity can be measured by training all the involved personnel’s teaching exercise or by direct observation by the
researcher when the protocol is delivered and during follow-ups. Since both adherence and fidelity are critical to therapeutic benefit, their absence in clinical studies evaluating the benefit of postoperative protocols is a significant deficit.

According to Susan et al.\(^{61}\), exercise trials should include specific descriptions of the exercises that should enable a researcher, clinician, or a care seeker to know how to replicate or administer the exercises in the study. Exercise dosage must include repetitions/sets/sessions, session duration, rest intervals, how much resistance or load, type of muscle contraction, exercise mode, or intensity. Few studies that reported the frequency, number of sets, and duration of the exercise fail to report rest intervals as part of exercise prescription. Rest intervals between sets and exercises are usually decided by the physiotherapist according to their own clinical experience as there is no peer-reviewed literature that supports the effect of rest period on exercises following rotator cuff surgery but Salles et al.\(^{62}\) found that the rest between sets can influence the efficiency, safety, and ultimate effectiveness of a strength training program. Just because some aspects of exercise intervention are not adequately reported, it does not mean poor quality of the study. However, principles of good scientific reporting would suggest that dosages are the essential information in any clinical trial, so the lack of formal reporting guidelines does not negate the responsibility of authors to provide enough information that an intervention could be replicated.

The most striking findings of this review were the absence of reporting on the extent to which the intervention was delivered in all the studies except one. Not everything that is planned in a study goes accordingly. There are various factors that can cause the interventions to go not according to the plan, factors like patient’s motivation, pain, or other co-morbid conditions that may hinder the exercise interventions. Environmental factors like extreme weather or lack of transport to the rehabilitation center can affect the exercise plans. Even though this item is not required for
replication of the intervention, but it throws light into the practical difficulties in the execution of the intervention and this information can help other clinicians from not repeating the same mistakes.

Another critical aspect that was poorly reported in 13 of the studies was regarding the home program components like other exercises, stretching and functional tasks. While these may not be needed for replication of the exercise interventions, these components may influence the intervention outcome directly. Also, non-exercise components such as manual therapy, massage, physical modalities provided were not reported or if reported, were not adequately described. It is important to report non exercise components as they also influence the outcome of the intervention.

All the studies used terms like resistive strengthening program, strength training, elastic rubber bands, dumbbells used, or CPM was used. However, only six studies were able to report the type of equipment adequately and their levels of intensity like the level of the band or the weight of the dumbbells used without which the exercise interventions cannot be replicated. Another category that was reported the most is the setting in which the exercises are performed. Out of the 31 studies, 14 studies (45% of the studies) adequately reported the setting in which the exercise was performed. This is consistent with a study by Tew et al., in which the location where exercises were performed was reported in 37% of the included studies.

Mirapeix et al. found that participants perceived the quality of rehabilitation service based on their experiences with environmental factors, including three physical factors (facility design, ambient conditions, and social factors). However, the study does not establish a link between the patient's perception and their adherence to the exercise program; it is crucial to report where the exercise was performed like a rehabilitation center or exercise room in the physiotherapy department.
Some studies\textsuperscript{65–67} have found evidence of patients motivation level to the outcome of the rehabilitation program, and yet none the studies reported if any motivational strategies were used in their studies. McGrane et al.\textsuperscript{68} reviewed four psychological strategies like self-determination theory, social cognitive theory, cognitive behavioral therapy and motivational interviewing which has a positive influence on exercise behavior and reviewed how a physiotherapist can apply these in their practice.

Another category that was missing from all the studies, except five, was whether the exercises were performed individually or in a group. Also, apart from six studies, all the other studies failed to explain the reasons for exercise progression as the implementation of exercise intervention is determined by how the progression is managed except in one study. Hoffmann et al.\textsuperscript{56} in their study of the poor description of nonpharmacological interventions concluded that 61\% of the interventions in their study was inadequately described and could not be replicated without contacting the original authors for further information.

At the beginning of this study, it was decided to extract data as it is reported in the studies and not to have any assumptions of what the authors of the selected studies have reported and if the authors did not report clearly where the studies where conducted, it was given a score of zero for that item.

Authors decided to use CERT instead of TIDieR as TIDieR is a reporting guideline for any intervention whereas CERT was explicitly designed for exercise intervention and because CERT was modeled on the TIDieR headings and consist of the same seven categories.

It is possible that the poor reporting of the exercise intervention was due to the lack of reporting guidelines. With the development of CERT as a guideline for exercise intervention reporting, journals must require authors to follow these guidelines.
Authors also recognize that the CERT checklist is generalized for all exercise interventions, but when authors plan an exercise intervention, they can use the checklist as a guide to report their study. There may be some checklists which may not apply to a study, e.g., home program components, but as long the critical elements of the exercises are reported, it will benefit everyone.

5. Conclusion:

Reporting of postoperative rehabilitation following arthroscopic rotator cuff repair provides minimal detail on the specifics of the programs, how they are progressed, or success criteria of their interventions. Clinicians are unlikely to be able to replicate the findings of currently published studies. A specific exercise guideline for intervention reporting can be used to provide necessary detail in physical therapy research, which will benefit researchers, clinicians, and patients. The burden of adequately reporting an intervention must not be the responsibility of the authors alone but shared with journal editors, reviewers, funding agencies, and all others that are involved in the trial. According to suggestions of Yamato et al.⁴⁶, the impact of the research should not be just based on the number of publications and citations but expanded to include the completeness of reporting using specific guidelines based on the intervention and trials. We recognize the importance of an adequately reported intervention and recommend the same.
Recommendations:

Exercise/rehabilitation intervention reporting guidelines should be considered by journals, funding bodies, and authors as a way of improving the reporting of interventions. Researchers should consider sharing details of their rehabilitation programs and other supporting tools in an open-access format to improve uptake and fidelity.
Chapter 3 Discussion

This structured review examined the nature of exercise reporting in studies following rotator cuff repair and whether reporting changes with study designs, the year in which the study was published and on the profession of the first author. This report will keep the researchers mindful of the key things that needed to be reported when they publish any research based on exercise interventions. The completeness of exercise descriptions has not been widely studied and only very few studies have been published in this regard. With the availability of CERT, which can be used to report exercise interventions in all the study designs, the journals and editors of various healthcare journals and medical associations should encourage and endorse the use of CERT as a tool to report exercises in their journals and research. A study by Hoffman et al. highlighted the poor reporting in non-pharmacological interventions that are published.

This study examined and extracted data was from 31 studies that were published between 1950 and 2019. Data were extracted using the CERT assessment form created by Slade et al. and using CERT: Explanation and Elaboration statement by the same authors as a source of reference. This study revealed that exercise interventions used in the 31 studies were reported insufficiently to allow full replication of the studies.

The most striking finding of this review was that all the studies used terms like resistive strengthening program, strength training, elastic rubber bands, dumbbells used, or CPM. However, only six studies were able to report the type of equipment adequately and their levels of intensity like the level of the band or the weight of the dumbbells used without which the exercise interventions cannot be replicated.

The absence of reporting on the extent to which the intervention was delivered was noted. Not everything that is planned in a study will go as planned by the researchers. There are various factors that can cause the treatment program to go not according to the plan, factors like patient’s motivation, pain, or other co-morbid conditions that may hinder the exercise interventions. Environmental factors like extreme weather or lack of transport to the rehabilitation center can affect the exercise plans. Even though this item is not required for replication of the intervention, but it throws light into the practical difficulties in the execution of the intervention and this information can help other clinicians from not repeating the same mistakes.
All the findings of this study reflect the studies that were done with other reporting guidelines like TIDieR, CONSORT, and SPIRIT.

Clinical Implications of poor reporting of exercises

Abell et al.\textsuperscript{53} in their study on exercise reporting following cardiac rehabilitation reported that 91\% of the authors had to be contacted for additional information regarding their published studies and 61\% responded and provided additional information regarding the missing items. They also concluded that with missing information on such (cardiac) complex intervention will have a huge impact on the benefits in clinical practices. With the world’s population aging and with the life expectancy increasing it is important to be able to get patients back to their daily life as soon as possible following an injury and to prevent re-injuries. The inadequacy of reporting in exercise interventions following rotator cuff repair will have consequences in the translation of these researches into clinical practice which in turn can affect the productivity of the individual. A re-tear or improper rehabilitation following a surgical repair can put immense stress on the already strained healthcare system.

A study by Charlton et al.\textsuperscript{69} on the exercise interventions for the prevention and treatment of groin pain injury in athletes states that despite the effectiveness of the resistance training in the management of groin injuries, none the studies that utilized external loads described the intensity of the exercises adequately for replication of the rehabilitation program. This not only affects the patient directly, but it also reduces the quality of the RCT’s which are considered to be the highly reliable form of scientific evidence which influences the healthcare policies and practices.

With the amount of information missing from the exercise interventions trials regarding exercises, direct and immediate action is required to improve this problem of poor reporting. This may have been impossible in the past but with CERT providing guidelines to report key elements of exercises in any study design, the researchers must consider using these available tools while they plan out their interventions.
Limitations of the study

One of the major limitations of this study was that only one reviewer screened, identified and extracted data. Another limitation of this study was that no attempt was made to contact the original authors for the missing information. Also, authors of this study recognize that sometimes a researcher may feel that the qualifications and experience of the researcher who implements the intervention may not be needed or just a mention of Thera-band would be adequate and may feel that this study is an overly harsh assessment of their research. This review was done to find the gaps in our researches and to improve better reporting of exercise interventions.

Recommendations

Based on the results of this review, we recommend that a minimum reporting standard needs to be established when planning and publishing exercise interventions. Firstly, journal directors and editors must recognize that vital pieces of information are missing from the researches and should reconsider recommending the use of guidelines as strictly as they enforce word limits. CERT guidelines are readily available and are designed especially for exercise intervention can be used. The onus is on the journal editors to guide authors to use CERT guidelines to improve the quality of the researches on exercise interventions.
Competing Interests

The authors have no competing interests.

Author’s Contributions

Dinesh Balachandran drafted the thesis. Dr. Joy MacDermid, Dr. Tom Overend and Dr. Trevor Birmingham carefully read, modified and approved the final version.
References


Fig 1. Flow diagram depicting the study selection process

Total search yields
N = 1936

Records excluded based on duplicates
N = 454

Records after removing duplicates
N = 1482

Records excluded based on title
N = 1345

Records after excluding based on title
N = 137

Records after excluding based on abstracts
N = 31
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<th>Study design</th>
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<td>Arthroscopic</td>
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<td><strong>Roo et al. 2015</strong> Passive mobilization after arthroscopic rotator cuff repair is not detrimental in early postoperative period.</td>
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<td><strong>Piitulainen et al. 2015</strong> Does adding a 12-month exercise programme to usual care after a rotator cuff repair effect disability and quality of life at 12 months? A randomized controlled trial</td>
<td>N = 67 patients Age (M) 54 years</td>
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<td><strong>Lisinski et al. 2012 Supervised versus uncontrolled rehabilitation of patients after rotator cuff repair-clinical and neurophysiological comparative study</strong></td>
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<td><strong>Wang et al. 2011 Using a T-Bar device in a rehabilitation program improved the range of motion for rotator cuff repair patients</strong></td>
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<td><strong>Roddey et al. 2002 A randomized controlled trial comparing 2 instructional approaches to home exercise instruction following arthroscopic full-</strong></td>
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following surgical rotator cuff repair: a feasibility study
Figure 2 CERT score based on the study design

![CERT Score for the Group based on Study Design](image)

Figure 3 CERT score based on the year of the study

![CERT Score for the group based on year of the study](image)
Figure 4 CERT Score for the group based on profession
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Appendix 2 Proforma CERT assessment form

Author and Year

Title

Journal

Study Location

Reviewer and date

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**TOTAL SCORE**
## Appendix 3 CERT score for articles

<p>|                  | Item 1 | Item 2 | Item 3 | Item 4 | Item 5 | Item 6 | Item 7a | Item 7b | Item 8 | Item 9 | Item 10 | Item 11 | Item 12 | Item 13 | Item 14a | Item 14b | Item 15 | Item 16a | Item 16b |
|------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Lastayo et.al 1998 | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      |
| Roddey et.al 2002 |        |        |        |        |        | ✓      | ✓      |        |        |        |        |        |        |        |        |        |        |        |
| Kim et.al 2003    | ✓      |        |        |        |        |        | ✓      | ✓      |        |        |        |        |        |        |        |        |        |        |
| Hayes et.al 2004  |        |        |        |        |        |        |        |        | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      |        |        |        |        |
| Carlson et.al 2007| ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      |
| Brady et.al 2008  | ✓      | ✓      | ✓      | ✓      | ✓      |        |        |        | ✓      | ✓      | ✓      | ✓      |        |        |        |        |        |        |        |
| Klintberg et.al 2009 | ✓   | ✓      | ✓      | ✓      | ✓      |        |        |        | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      | ✓      |
| Parsons et.al 2010 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Wang et.al 2011   | ✓      | ✓      |        |        |        | ✓      |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Koo et.al 2011    |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | ✓      |
| Duzgun et.al 2011 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | ✓      | ✓      |
| Arndt et.al 2012  |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Kim et.al 2012    |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | ✓      | ✓      |</p>
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**Curriculum Vitae**

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