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ROLE OF PLATELET RICH PLASMA IN TREATMENT OF ROTATOR CUFF TENDINOPATHY AND PARTIAL THICKNESS TEAR: FOLLOW UP BY ULTRASOUND

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ABSTRACT

The pathophysiology of RCT is characterized by progressive, degenerative changes within the tendon as a result of overuse, altered shoulder mechanics, and a limitation of the normal tendon repair system with a fibroblastic and a vascular response known as angiofibroblastic degeneration. Reduced pain and improved function are the goals of conventional therapy, which includes relative rest, pain medication, physical therapy, corticosteroid injections, and surgery. However, many patients are refractory to standard care, particularly in severe cases; and rehabilitation time can be lengthy and time consuming for many. The effectiveness of conservative compared to surgical intervention is unclear. No therapy has been shown to uniformly improve clinical, functional, and radiological outcomes across severity grades of RCT, and no therapy specifically targets the presumed degenerative pathology of RCT

Introduction

Shoulder pain is the third most common musculoskeletal reason for seeking medical care affecting between 7% and 26% of adults at any time. It results in substantial impact on quality of life and may lead to sick leave in the working population. Rotator cuff disease is the most common cause of shoulder pain seen by physicians. The prevalence of symptomatic RCD increases with age, occurring in about 2.8% of those older than 30 years and in 15% of those older than 70 years. In the United States, rotator cuff disorders lead to 4.5 million yearly physician visits (Hermans et al., 2013).

Rotator cuff disease (RCD) consists of tendinopathy of one or more of the four muscles that together form the rotator cuff, full- or partial-thickness tears of these rotator cuff tendons, or bursitis of the subacromial bursa. Subacromial bursitis, tendinopathy, or both can lead to a clinical entity known as subacromial impingement syndrome that is often characterized by shoulder pain during abduction of the arm between 60° and 120°. This characteristic, known as a painful arc, suggests a subacromial or rotator cuff disorder. The exact mechanism of injury causing these conditions is unknown (Hermans et al., 2013).

The pathophysiology of RCT is characterized by progressive, degenerative changes within the tendon as a result of overuse, altered shoulder mechanics, and a limitation of the normal tendon repair system with a fibroblastic and a vascular response known as angiofibroblastic degeneration. Reduced pain and improved function are the goals of conventional therapy, which includes relative rest, pain medication, physical therapy, corticosteroid injections, and surgery. However, many patients are refractory to standard care, particularly in severe cases; and rehabilitation time can be lengthy and time consuming for many. The effectiveness of conservative compared to surgical intervention is unclear. No therapy has been shown to uniformly improve clinical, functional, and radiological outcomes across severity grades of RCT, and no therapy specifically targets the presumed degenerative pathology of RCT (Shams et al., 2016).

It is known that tendons have limited regeneration ability. Hence, new treatment modalities targeting the biology such as platelet-rich plasma (PRP) could be an option for the treatment of this pathology. Its injection might provide the necessary cellular and humeral mediators to induce a healing cascade. There is some clinical evidence that application of autologous platelets may help to revascularize the area of injury, and promote tendon healing. This might improve pain and functional outcomes in rotator cuff pathologies (Shams et al., 2016).

In the evaluation of the painful shoulder, several noninvasive imaging modalities exist to help guide diagnosis and treatment. These include radiography, ultrasonography, magnetic resonance imaging, magnetic resonance arthrography, computed tomography, and computed tomographic arthrography (Photopoulos, 2016). Ultrasound (US) and magnetic resonance imaging (MRI) have comparable accuracies in detection and measurement of rotator cuff tears (Jacobson, 2011).

Ultrasound (US) provides the distinct advantages of being inexpensive and accessible, having no contraindications, using no ionizing radiation and its` capacity to perform dynamic maneuvers. US can effectively diagnose rotator cuff muscle atrophy and fatty infiltration of the supraspinatus, infraspinatus, and teres minor (Photopoulos, 2016).

Rehabilitation is effective in the management of subacromial impingiment syndrome with a small positive effect on strength of the rotator cuff in the short term and a small positive effect on long-term function (Hanratty et al., 2012).

Platelet-rich plasma (PRP) is a preparation of concentrated autologous platelets containing growth factors and bioactive substances essential to musculoskeletal healing. In vitro and animal model studies suggest that direct in vitro application of PRP to injured tissue may address the structural failure of the tendon in RCT and that PRP might thereby accelerate healing and repair of injured tissue. PRP has been suggested as a treatment option for refractory tendinopathies, including RCT. Early clinical evidence suggests that PRP improves pain and function outcomes in some tendinopathies

compared to control injection and baseline status (Scarpone et al., 2013).

Aim of the Work

We aimed to asses the effect of Platelet Rich Plasma (PRP) injections under musculoskeletal ultrasound guidance in patients with rotator cuff tendinopathy, and partial thickness tear in comparison with those who received a well established rehabilitation program only, at baseline assessment and after three months using clinical, functional and ultrasonographic evaluation.

Patients and Methods

Subjects:

Our study is a prospective study which was carried out at Minia University Hospital. All patients were recruited from Rheumatology and Rehabilitation outpatient clinic in the period from November 2016 to May 2017. The study included 60 patients with shoulder pain diagnosed as having Rotator Cuff Tendinopathy using Musculoskeletal Ultrasound (MSUS). They were further devided into two groups, (group1) 30 patients received a well established rehabilitation program and (group 2) 30 patients received single PRP injection. Follow up of both groups after 3 months was done.

Ethical considerations:

The nature of the present study was explained to all patients. The laboratory and radiological procedures represent standard care and pose no ethical conflicts. A verbal consent was obtained from all patients.

Inclusion Criteria:

(1) Patients included in our study were adults above 20 years.

(2) Shoulder pain for more than 3 months with no or poor response to medical treatment for at least three months.

(3) Pain on palpation at the insertion site of the cuff in the proximal humerus and/or decreased range of motion with shoulder flexion, abduction, and internal and external rotation.

(4) Painful arc and/or an impingement sign.

(5) Diagnosis of rotator cuff tendon disease, such as a tendinosis or a partial-thickness tear of less than 1.0 cm upon sonographic examination.

(6) For patients with bilateral presentation, the most painful shoulder was treated.

Exclusion Criteria:

(1) Patients below 20 years.

(2) Presence of other obvious pathology for the rotator cuff pain, such as a history of trauma, fracture or rheumatic joint diseases, (e.g; Rheumatoid Arthritis, Gout, Spondyloarthropathies…etc).

(3) Cervical radiculopathy.

(4) Prior surgery to either the shoulder or neck region.

(5) A history of local steroid injection within six weeks.

(6) Presence of an unstable medical condition, a known uncontrolled systemic disease or major organ failure (eg; uncontrolled diabetes mellitus, chronic renal disease, chronic liver disease).

(7) Coagulopathy; platelet level less than150.000 microliter, or patients on anticoagulants.
(8) Hemoglobin level of less than 11g/dl.

Methods:

Patients were divided into 2 groups according to the plan of treatment.

Group1: Included thirty patients with Rotator Cuff pathology received Physical treatment only.

Group2: Included thirty Patients with Rotator Cuff pathology received single PRP injection under US.

Patients in both groups were subjected to:
1- Complete History Taking
2- Musculoskeletal Examination
3- Functional Assessment Scores
4- Laboratory Investigations
5- Musculoskeletal Ultrasonography
6- Plane X-Ray (shoulder and cervical spine)
7- Treatment (Rehabilitation Program or PRP injection)
(Appendix 3)

1- Complete history taking including: name, age, sex, occupation, residence, marital status, special habits and handedness. In addition to main complaint assessment, taken in patient's own words (shoulder pain and, or limitation of movement of shoulder joint).

2-Musculoskeletal examination (Jain et al., 2013):

A) Inspection of the shoulder girdle, supraspinatus and infraspinatus fossae for atrophy and swelling.

B) Palpation for tenderness:

i- At the insertion site of the cuff in the proximal humerus.

ii- The long head of the biceps tendon in the bicipital groove between the greater and lesser tuberosities of the humeral head.
iii- The acromioclavicular joint was also palpated for tenderness by following the distal end of the clavicle to the acromioclavicular junction.

C) Range of Motion:

The patient is sitting on a chair or standing, a goniometer is used to assess the following:

1-Forward Flexion: Normal shoulder complex flexion ROM for adults is 180 degrees.

2-Isolated Abduction: Normal shoulder complex abduction ROM for adults is 180 degrees.

3-External /Internal Rotation at zero Degrees (in neutral): Normal value of Internal rotation is 70 degrees, external rotation 90 degrees. The previous measures were according to the American Academy Orthopedic Surgeons (AAOS) (Burrows, 1965).

D) Special Tests: Each of the rotator cuff tendons' selected tests were assessed in addition to those specific ones for impingement syndrome. The test is considered positive for weakness and corresponding pathology if the patient was unable to do the requested movement nor maintain upper limb movement in certain positions. In addition to the pain developed during performing the desired action (Hermans et al., 2013 and Jain et al., 2013).

1-Tests for Subscapularis:

A) Lift-off Test:

The examiner assists the patient to get in a position where he/ she touches their lower back with the arm fully extended and internally rotated. A test is judged positive if the patient is unable to lift the dorsum of his hand off his/her back reflecting weakness of the subscapularis (Fig. 58a) (Gerber & Krushell, 1991).

B) Belly Press Test:

The examiner instructs the patient to press the abdomen with the hand flat and attempts to keep the arm in maximum internal rotation. The test result is normal when the elbow does not drop backward, meaning that it remains in front of the trunk. A positive test, sign of subscapularis weakness, is when the elbow drops back behind the trunk (Fig. 58b) (Gerber et al., 1996).

C) Belly-Off Sign:

The examiner assesses the subscapularis in this test by passively

bringing the shoulder of the patient into flexion and maximum internal rotation with the elbow 90° flexed. The elbow of the patient is supported by one hand of the examiner while the other hand brings the arm into maximum internal rotation placing the palm of the hand on the abdomen (Scheibel et al., 2005). The patient is then asked to keep the wrist straight and actively maintain the position of internal rotation as the examiner releases the wrist. If the patient cannot maintain the above position, lag occurs and the hand lifts off the abdomen resulting in a positive belly-off sign. Otherwise, the test is negative (Fig. 58c) (Scheibel et al., 2005).

D) Bear Hug Test:

The examiner instructs the patient to place the palm of the involved side on the opposite shoulder, extend the fingers (so that the patient could not resist by grabbing the shoulder), and position the elbow anterior to the body. The examiner then asks the patient to hold that position (resisted internal rotation) as the examiner tries to pull the patient's hand from the shoulder with an external rotation force applied perpendicular to the forearm. The test is considered positive indicating subscapularis weakness if the patient cannot hold the hand against the shoulder (Fig. 58d) (Barth et al., 2006).

(Figure 58): a) Lift off test, b) Belly Press test, c) Belly Off sign and d) Bear Hug test.

2-Tests for Supraspinatus and Infraspinatus:

B) Jobe's Test (Empty Can Test):

This test is performed by first assessing the deltoid with the arm at 90° of abduction and neutral rotation. The shoulder is then internally rotated and angled forward 30°; the thumbs should be pointing toward the floor. Manual muscle testing against resistance is performed with the examiner pushing down at the distal forearm. This test is regarded as positive when there is weakness to resistance with arm in 90° of abduction as compared with when it is angled forward 30°, and is indicative of supraspinatus pathology (Fig. 59a) (Jobe FW & Jobe CM., 1983).

B) External Rotation Lag Sign at zero Degrees (neutral position):

The patient is seated with his or her back to the physician. The elbow is passively flexed to 90°, and the shoulder is held at 20° elevation (in the scapular plane) and near maximum external rotation (i.e., maximum external rotation minus 5° to avoid elastic recoil in the shoulder) by the physician. The patient is then asked to actively maintain the position of external rotation as the physician releases the wrist while maintaining support of the limb at the elbow. The sign is positive when a lag, or angular drop, occurs. The magnitude of the lag is recorded to the nearest 5°. A positive test indicates postero-superior cuff (supraspinatus and infraspinatus) deficiency (Fig. 59b) (Cameron et al., 2007).

C) Drop Arm Test:

This test assesses the supraspinatus and is performed by passively abducting the patient's shoulder to 180 degrees and then observing as the patient slowly lowers the arm to the waist. This test is positive when the arm drops to the side. The patient may be able to lower the arm slowly to 90 degrees (because this is a function mostly of the deltoid muscle as opposed to the supraspinatus) but will be unable to continue the maneuver as far as the waist. In this case, too, the test is positive (Fig. 59c) (Woodward & Best, 2000).

(Figure 59): a) Jobe test, b) External rotation lag sign at (zero degrees) and c) Drop arm test.

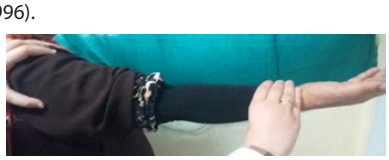
3-Test for Teres Minor (Hornblower's Sign):

The examiner supports the patient's arm at 90 degrees of abduction in the scapular plane with elbow flexed at 90 degrees. The patient then attempts external rotation of the forearm against resistance of the examiner's hand. If the patient cannot externally rotate, they assume a position characteristic of a positive hornblower's sign (Fig. 60) (Walch et al., 1998).

(Figure 60): Test for Teres Minor (Hornblower's Sign).

4-Test for Biceps Tendon (Speed's Test):

The patient is asked to flex his shoulder (elevate it anteriorly) against resistance (from the examiner) while the elbow is extended and the forearm supinated. The test is positive when pain is localized to the bicipital groove for biceps tendon pathology (Fig. 61) (Crenshaw &Kilgore., 1996).



(Figure 61): Test for Biceps Tendon (Speed's Test).

5-Impingement Signs/Tests:

A) Neer's Sign:

The impingement sign is elicited with the patient seated and the examiner standing. Scapular rotation is prevented with one hand while the other hand raises the arm in forced forward elevation, causing the greater tuberosity to impinge against the acromion. A positive test is if the maneuver produces pain (Fig. 62a) (Neer, 1983).

B) Hawkin's Sign:

The examiner forward flexes the humerus to 90° and forcibly internally rotates the shoulder. This maneuver drives the greater tuberosity farther under the coracoacromial ligament. Pain with this maneuver is considered positive for impingement (Fig. 62b) (Hawkins and Kennedy, 1980).

(Figure 62): a) Neer's sign, b) Hawkin's sign.

3- Functional Assessment Measures (Appendix I):

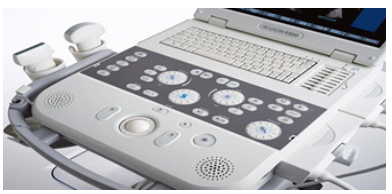
1- Visual Analog Scale (VAS) (Price et al., 1983 and Williamson and Hoggart 2005).

2- Western Ontario Rotator Cuff Index (WORC). The total score ranges from 0 to 2100, where 0 is the best possible score, with the patient fully asymptomatic, whereas 2100 is the worst possible score, with the patient greatly symptomatic (Kirkley et al., 2003 and Raman & Macdermid, 2012).

3- Shoulder Pain and Disability Index (SPADI). Originally, 0 = best and 100 = worst (Roach et al., 1991 and Maffulli & Furia., 2012).

4- Laboratory Investigations:
a) Complete Blood Count (CBC)
b) Random Blood Sugar and HbA1C.

5-Imaging (Musculoskeletal Ultrasound Examination):
It was done by 2 operators with more than 7 years of experience in musculoskeletal ultrasonography. Siemens ACUSON P300 ultrasound system Equipment (Siemens, Healthcare, Boulevard, Malvern and USA) portable machine with linear probe 10–18 MHz. was used for evaluating the rotator cuff lesions. Generous application of US coupling gel to the skin was indispensable (Fig. 63) (Bruyn et al., 2010 and Ottenheijm et al., 2010).



(Figure 63): Siemens Acuson P300 Equipment

Standard Protocols for Shoulder Examination:
US examination was done following EULAR guidelines (Appendix 4) in a systematic and standardized manner as following:

1- Firstly, bony landmarks (i.e. humeral head, glenoid, coracoid process, acromion and clavicular bone) were identified in the corresponding standard scans.

2- Transverse and longitudinal scans of the biceps tendon groove, rotator cuff and subacromial subdeltoid bursa were applied, beginning with the long head of biceps tendon followed by subscapularis tendon and finally the supra and infraspinatus tendons.

3- Also, transverse scan of the posterior glenohumeral recess and longitudinal scan of the acromioclavicular joint were performed. Any pathology was confirmed in two orthogonal planes, and dynamic maneuvers were extremely useful in evaluating pathology (Naredo et al., 2007 and Bruyn & Schmidt, 2011).

MSUS Assessment Parameters:
Consensus were made on definitions of relevant potential pathological structural changes related to tendinopathy, including: Fibrillar Disruption (FD), Neovascularity (NV), Calcifications (CA) and finally Tendon Thickness (TT). Hereafter, a standardised protocol for US capturing was developed, consisting of both static images in Grey Scale sequence (GS), dynamic movie sequences and a Doppler scan sequence (Ingwersen et al., 2016).

Description of US procedures for capturing image of FD, NV, CAs and TT:

(1) Fibrillar Disruption (FD):
FD was defined as a clear collagen fascicle discontinuity or irregularity of fibrils in an otherwise regular parallel structuring of fibres in the tendon. A GS picture in the longitudinal axis of the tendon was taken at the sight where FD was most apparent (Fig. 64a) (Ingwersen et al., 2016).

The FD static image was used for classifying the presence of FD. A GS posteroanterior (PA) dynamic movie sequence (PA movie) in the longitudinal plane of the supraspinatus tendon was captured by moving the transducer slowly in the PA direction. Further, a craniocaudal (CC) transversal GS dynamic movie sequence (CC movie) of the supraspinatus tendon was recorded by moving the transducer slowly in the CC direction. The static image and the movie sequence recordings were used as confirmation and assistance in assessing the grade of structural changes, and to secure identification of potential ambiguous GS features, such as anisotropy. FD was classified in relation to tendon thickness as: 0=normal, 1=mild, 2=moderate, 3=severe, 4=partial rupture (table 4.1) (Ingwersen et al., 2016).

(2) Neovascularity (NV):
It's defined as a visualised PD signal with minimal artefactual noise (Fig. 64b) (Ingwersen et al., 2016).

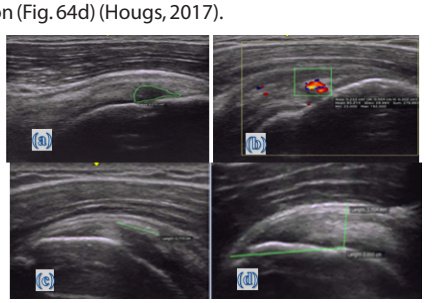
Table (4.1): Grading scales with definitions for FD and NV (Ingwersen et al., 2016):

Grade	FD	NV
0	Normal	Normal (no signal)
1	Mild (involving under 25% of the height of the tendon)	Mild (single small signal in the ROI)
2	Moderate (involving 25–50% of the height of the tendon)	Moderate (Doppler activity in <25% of the ROI)
3	Severe (involving more than 50% of the height of the tendon)	Severe (Doppler activity in 25–50% of the ROI)
4	Partial rupture (disruption of the fibres in the full thickness of the tendon)	Extreme (Doppler activity in more than 50% of the ROI)

FD, fibrillar disruption; NV, neovascularity; ROI, region of interest.

It's defined as distinct white borders, imbedded in the length of the tendon, often with 'shadows' underneath (Fig. 64c) (Ingwersen et al., 2016).

(4) Tendon Thickness (TT):
It's defined as the height, from the humeral head, at a point 20 mm from the supraspinatus tendon-snip (tendon insertion) in the longitudinal axis of the tendon, to the most superficial part of the tendon (Fig. 64d) (Hougs, 2017).



(Figure 64): MSUS Assessment Parameters, adopted from (Ingwersen et al., 2016)

6-Treatment:
A) Rehabilitation Program for group 1 included the following:
Rehabilitation Program for patients in group 1 included the following: (TENS) (sessions applied for about 15 minutes, three times per week for 12 weeks), (therapeutic ultrasound): (sessions applied for 8 minutes, three times per week for 12 weeks). The therapeutic exercise Programs (supervised and home-based) were applied, including: (range of motion exercises, stretching exercises, exercises for improving scapular stability, strengthening exercises of the rotator cuff and scapular muscles). The program was unified to all patients.

Steps of Rehabilitation Program:
1- Heat and massage:
Heat and massage were done to prepare the tissues for range of motion exercises. Local heat was applied for about five minutes with a moist heating pad. Light therapeutic deep tissue massage was done also for five minutes to the surrounding tissues to prepare the area for range of motion and strengthening exercises.

2-Transcutaneous Electrical Nerve Stimulation (TENS):
(TENS) was delivered via electrodes placed over the intact skin

surface near the source of pain. The device used in our study was Endomed 582 (Fig. 65) and settings were (conventional mode, 100 Hz, 15 mA, 150 msn). Sessions applied for 15 minutes, three times per week for 12 weeks.

Figure 65): Endomed 582 Equipment

3-Therapeutic Ultrasound:

Ultrasound machine (Enraf Nonius - Sonoplus590 US device) (Fig. 66) was used to deliver low-intensity pulsed ultrasound therapy (LIPUS). The apparatus provided the following options: I MHz frequency with transducer having an affective radiating area of 5.0 cm2, intensity up to 1.5 W/cm2 in pulsed mode, gel was used as a coupling media. Sessions were applied for 8 minutes three times per week for 12 weeks.

(Figure 66): Enraf Nonius -Sonoplus590 US device

4- Therapeutic Exercises:

Patients underwent a supervised exercise program, three sessions weekly for 12 week, and they were advised to make the same exercises at home in the other days. In each exercise, three sets of 10-15 repetitions were done and adjusted according to pain threshold of patient.

Types of Therapeutic Exercises:

I- Range of motion exercises:

They were done to improve shoulder girdle and GHJ range of motion. Pendulum exercises were used to improve GHJ motion, they were initiated passively and progressed as tolerated toward active-assisted exercises, they were performed with a bar or wand and the assistance of the uninvolved arm (Edwards et al., 2016). Exercises should not cause more than a mild level of pain. If the patient experienced pain, the intensity of the stretch or the number of repetitions was decreased; anyone who felt sharp or tearing pain stopped exercising immediately and consulted us. Rest after stretching for two or three minutes, then perform repetitions. When patient can perform a set of 10 repetitions through a complete range of motion without pain, exercises were increased to two sets (Simons & Roberts, 2016).

II- Stretching Exercises:

Many patients with Subacromial Impingiment Syndrome and Rotator Cuff Tendinopathy have inadequate flexibility in the muscles of their anterior shoulder and chest, and tightness in the posterior capsule of their glenohumeral joint, so a stretching program included the following exercises: Posterior capsule stretch and Anterior Capsule Pectoralis minor stretch. Each stretch was held for 30 seconds and repeated three times. A rest interval of about 60 seconds between sets was generally adequate. Early, patient stretched once a day to the extent that they can without causing pain (Parsons, 2015).

Once pain subsided, patients became able to stretch twice daily. When patients reached the final phase of shoulder rehabilitation, and were preparing to resume their usual activities, we told patients to stretch two to three times daily, and had them continue this regimen until they achieved full, pain-free shoulder movement (Parsons, 2015).

III- Improve scapular stability:

These exercises help to better stabilize and synchronize scapular movements, and so can increase the capacity of the rotator cuff muscles to stabilize the glenohumeral joint (De Mey et al., 2009 and Edwards et al., 2016). Specific exercises for scapular control in the early to middle phases of shoulder rehabilitation were identified, including the 'low row' exercises, which activate the key scapular-stabilizing muscles, including the rhomboid, without putting high demands on the GHJ joint (Kibler et al., 2008 and Edwards et al., 2016). Other exercises included side lying external rotation, side lying forward flexion, prone horizontal abduction with prone extension (Sciascia et al., 2012 and Edwards et al., 2016).

IV- Strengthen the rotator cuff:

Each one of the four rotator cuff tendons were strengthened in the following steps: Isometric holds in the mid-range of each muscle main action, followed by performing main action of each muscle actively without resistance and finally patients performed main action actively against resistance (free weights), the rehabilitation volume consisted of two to three sets of 10 to 20 repetitions. As soon as the patient could perform a workout without difficulty, the amount of weight being used were increased (Parsons, 2015).

V- Scapular strengthening:

For these exercises, patient lied face down on an elevated surface, like a bed. The head was held in line with the body, hanging over the edge of the bed or bench. The patient arms rested below the body with his/her arms extending next to the head to form a "Y"; and thumbs were facing up. The position kept for a second or two, then arms return again to the floor. It was repeated for 10 to 15 times. Movements should be steady, smooth, and pain-free. Using the same body position, patient squeezed his/her shoulder blades down and backwards towards the spine while moving the arms to form a "T." To increase the difficulty of these exercises, the number of repetitions was increased to 20 to 30 times. Using 1 pound weights was used to increase the difficulty (Simons & Roberts, 2016).

B) PRP injection for group 2:

PRP injection was prepared in clinical pathology department, minia university hospital, under complete sterile condition using sterile needles {sealed with plaster before injection} and a sterile probe cover, real time ultrasound guidance was provided during the procedure.

Preparation:

PRP is an autologous concentration of platelets obtained by whole blood centrifugation with specific protocol. Several semi-automatic machines have been developed for centrifugal separation of PRP for therapeutic use, but in our study we used the manual method which is the commonest, most simple, and flexible one (Mei-Dan and Carmont, 2012). Under aseptic conditions, 10 times the volume of required PRP venous blood was withdrawn using 21-gauge or larger needle slowly, as the speed with which blood is drawn may influence platelet quality and premature activation of platelets may occur if a small needle is used to draw blood. The withdrawn blood was then mixed with heparin in a ratio of 1:10 (heparin: blood). The blood was centrifuged at 1000 rpm for 10 minutes to separate a platelet rich plasma from the red blood cells as well as the white blood cells. The plasma was then transferred to a new glass tube and centrifuged at 3000 rpm for 15 minutes. Platelets will form a pellet at the bottom of the tube.

At the end of the centrifugation process a pure platelet rich plasma (P-PRP) was obtained with a concentration 4 times greater than baseline. Platelets are resuspended in the required volume that was 3ml and delivered to the patient in a sterile glass tube with the Ca

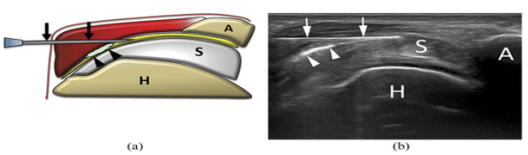
gluconate, in a separate container, in a ratio of 0.3 ml ca gluconate/ ml PRP. Ca gluconate was mixed with PRP immediately before the injection. Once the PRP is separated from the whole blood, it is stable for up to 8 hours, or for even longer periods (Mei-Dan and Carmont, 2012).

Ultrasound Guided Injection:

The patient was seated on a table or in the supine position. The ultrasound screen is placed near the head of the bed. After accurate disinfection of both the skin and the probe, a longitudinal ultrasound scan along the supraspinatus, keeping the lateral acromion in view is obtained to visualize the SASD bursa (Messina et al., 2015). A 21 G or larger size (Luer-type syringe) needle is inserted with the bevel turned downwards in a lateral approach with respect to the probe (Mei-Dan and Carmont, 2012).

Once correct positioning of the needle tip has been achieved, the 3ml PRP was injected slowely into the bursa. When successfully completed, this injection will result in the symmetric expansion of the SASD bursa. After the procedure, the needle is removed and a plaster is applied at the puncture site (Fig. 67) (Messina et al., 2015). We avoided the use of local anesthetics prior to PRP injection as they had the greatest ability to interfere with coagulation and decrease platelet aggregation.

There is also a pH-based variation in platelet function which is also important to recognize when considering the use of local anesthetics (Lansdown & Fortier, 2017).



(Figure 67): (a) Scheme and (b) ultrasound image of subacromial–subdeltoid (SASD) bursa injection. The needle (arrows) is inserted within the SASD bursa, filled with hyperechoic material (arrowheads) representing PRP injectate. A, acromion; H, humerus; S, supraspinatus tendon, adopted from (Messina et al., 2015).

Post injection: patients followed general recommendations (rest, using cold packs) and were allowed to do light range of motion exercises 2–5 days post injection. Regarding Non Steroidal Antiinflamatory drugs (NSAIDs), they were avoided, at least 2 days before PRP application and throughout the treatment timeframe, usually up to 2 weeks post-injection except acetaminophen which was allowed for untolerable post injection pain (Mei-Dan and Carmont, 2012).

Follow up Examination:

After three months both groups underwent clinical examination, functional assessment and standarized musculoskeletal ultrasound examination of the shoulder.

Statistical analysis:

Statistical analysis was performed with SPSS statistical software, version 16 (SPSS Inc., Chicago, Illinois, USA). Difference between the treatment groups according to variables was tested with chi-square ($\chi 2$) test, student t test. The level of statistical significance was set P value level < 0.05. Correlation between the study variables was determined with Pearson's correlation coefficients (r) for parametric variables. The level of statistical significance was set at P value level (0.05 and 0.01).

RESULTS

This study included 60 patients (44 females, 16 males) diagnosed as rotator cuff tendon disease both clinically and sonographycically; all of the patients were attending the Rheumatology and Rehabilitation outpatient clinic, Minia University Hospital during the period from November 2016 to May 2017. Patients in both groups were age and sex matched. All patients were assessed at baseline and after three months of treatment. Patients were divided according to the treatment strategy into two groups:

Group I: Included 30 patients diagnosed as rotator cuff tendon disease and received a supervised rehabilitation program. Those patients were then categorized into Group Ia and Group Ib as follow:

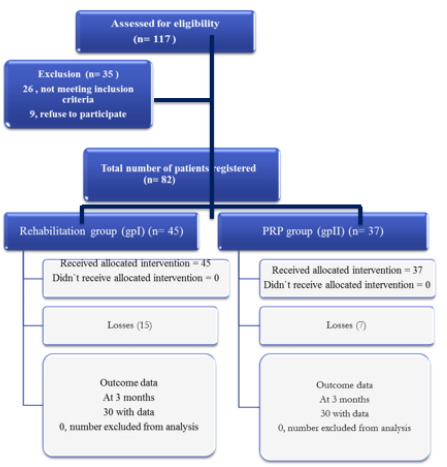
Group Ia: Patients at baseline assessment before receiving a supervised rehabilitation program.

Group Ib: Patients after receiving the rehabilitation program for three months.

Group II: Included 30 patients diagnosed as rotator cuff tendon disease and received single PRP Injection. Those patients were then categorized into Group IIa and Group IIb as follow:

Group IIa: Patients at baseline assessment before PRP Injection.

Group IIb: Patients after three months of PRP Injection.



(Figure 68): Flowchart of the study.

Demographic data of patients in gpI and gpII:

(Table 5.1) descripes the demographic characteristic of patients in group I and group II. The patients' age ranged from 23-77years with mean±SD (56.77±11.7) for group I and from 35- 67 with mean±SD (50.4±7.6) for group II. Males represent 30% (9 patients) for group I and 23.3% (7 patients) for group II, while the females represents 70% (21 patients) for group I and 76.7% (23 patients) for group II. The mean±SD of disease duration was (4.40 ± 2.27) for group I and (5.10±2.94) for group II. There was no significant difference between the studied groups regarding smoking and presence of diabetes mellitus (p= 0.166 and 1.000) respectively.

Table (5.1): Demographic data of patients in gpI and gpII:

		Rehabilitation (gpI) (n=30)	PRP (gpII) (n=30)	$\chi 2$ / t	p-value
Age (in years)	range	23- 77	35-67	2.487	0.074
	mean± SD	56.77±11.7	50.4±7.6		
Sex (%)	Males	9(30%)	7(23.3%)	0.341	0.559
	Females	21 (70%)	23(76.7%)		
Occupation (%)	Housewife	20 (66.7%)	23(76.7%)	1.743	0.627
	Farmer	6(20%)	3(10%)		
	Heavy worker	2(6.7%)	3(10%)		
	High professional	2(6.7%)	1(3.3%)		
Marital status (%)	Married	25 (83.3%)	28 (93.3%)	1.456	0.228
	Single	5 (16.7%)	2 (6.7%)		
Smokers (%)		7(23.3%)	3(10%)	1.920	0.166
Presence of Diabetes mellitus (%)		6(20%)	6(20%)	0	1.000
Duration (in months)	range	3- 12	3- 12	-1.032	0.306
	mean± SD	4.40±2.27	5.10±2.94		

Chi-square ($\chi 2$) test, Student t test, significant P value < 0.05, PRP= platlet rich plasma.

Clinical data of patients in Group I:

In (Table 5.2) there was statistically significant difference of clinical manifestations in patients at baseline in comparison to follow up regarding (abduction, external rotation of shoulder joint, impingement tests and speed's test) (p= 0.017, p=0.014, p=0.007, p=0.010) respectively.

(Table 5.2) Clinical data of patients in Group I:

		Rehabilitation group (gpI)		$\chi 2$ / t	p-value
		Baseline (gpIa) (n=30)	Follow up (gpIb) (n=30)		
Abduction of the shoulder joint	range	55- 135	80- 135	-2.464	**0.017***
	mean ±SD	96.67±15.56	105.33±11.37		
Flexion of the shoulder joint	range	69- 135	90- 135	-0.845	0.401
	mean ±SD	113.47±13.64	116±9.14		
Internal rotation of the shoulder joint	range	40- 70	50- 70	-1.608	0.113
	mean ±SD	55.83±8.10	58.67±5.24		
External rotation of the shoulder joint	range	30- 60	40- 55	-2.538	**0.014***
	mean ±SD	42.50±7.04	46.33±4.34		
Impingiment tests	Positive	27(90%)	25 (83.4%)	9.833	**0.007***
Speed's test	Positive	28(93.3%)	20 (66.7%)	6.667	**0.010***
Lift Off test	Positive	27 (90%)	22 (73.3%)	2.783	0.095
Empty can test	Positive	30 (100%)	30 (100%)	0	1.000
Hornblower's sign	Positive	5 (16.7%)	4(13.3%)	0.131	0.718

Chi-square ($\chi 2$) test, Student t test, significant P value < 0.05.
Functional assessment of patients in Group I:

In (Table 5.3) there was statistically significant difference of functional assessment scores in patients at baseline in comparison to follow up regarding SPADI (PS and total) and WORC scores (p=0.028, p=0.032, p=0.023) respectively.

(Table 5.3) Functional assessment of patients in Group I:

		Rehabilitation group (gpI)		$\chi 2$ / t	p-value
		Baseline (gpIa) (n=30)	Follow up (gpIb) (n=30)		
Abduction of the shoulder joint	range	55- 135	80- 135	-2.464	**0.017***
	mean ±SD	96.67±15.56	105.33±11.37		
Flexion of the shoulder joint	range	69- 135	90- 135	-0.845	0.401
	mean ±SD	113.47±13.64	116±9.14		
Internal rotation of the shoulder joint	range	40- 70	50- 70	-1.608	0.113
	mean ±SD	55.83±8.10	58.67±5.24		
External rotation of the shoulder joint	range	30- 60	40- 55	-2.538	**0.014***
	mean ±SD	42.50±7.04	46.33±4.34		
Impingiment tests	Positive	27(90%)	25 (83.4%)	9.833	**0.007***
Speed's test	Positive	28(93.3%)	20 (66.7%)	6.667	**0.010***
Lift Off test	Positive	27 (90%)	22 (73.3%)	2.783	0.095
Empty can test	Positive	30 (100%)	30 (100%)	0	1.000
Hornblower's sign	Positive	5 (16.7%)	4(13.3%)	0.131	0.718

Student t test, significant P value < 0.05, SPADI= Shoulder Pain and Disability Index, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index.

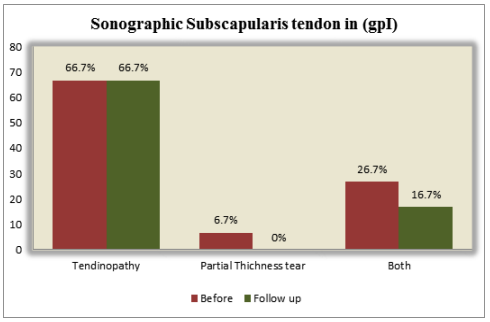
Muscloskeletal Ultrasound findings of patients in Group I:

In (Table 5.4) there was statistically significant difference of sonographic data in patients at baseline in comparison to follow up regarding supraspinatus tendinopathy, and partial thickness tear (p=0.003). Other parameters showed improvement in follow up group but it wasn't statistically significant.

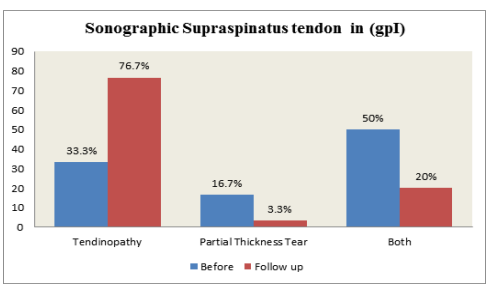
(Table 5.4) Muscloskeletal Ultrasound findings of patients in Group I:

		Rehabilitation group (gpI)		$\chi 2$ / t	p-value
		Baseline (gpIa) (n=30)	Follow up (gpIb) (n=30)		
Biceps tendon	**Tendinopathy**	22(73.3%)	16(53.3%)	2.584	0.108
Subscapularis tendon	**Tendinopathy**	20(66.7%)	20(66.7%)	7.692	0.053
	PTT	2(6.7%)	0(0%)		
	Both	8(26.7%)	5(16.7%)		
Supraspinatus tendon	**Tendinopathy**	10(33.3%)	23(76.7%)	11.645	**0.003***
	PTT	5 (16.7%)	1(3.3%)		
	Both	15(50%)	6(20%)		
Supraspinatus Fibrillar tendon disruption	**25%**	4(13.3%)	4(13.3%)	9.125	0.058
	50%	10(33.3%)	2(6.7%)		
	75%	4(13.3%)	2(6.7%)		
Subacromial subdeltoid bursitis	**Bursitis**	29(96.7%)	25(83.3%)	2.963	0.085
Supraspinatus Tendon thickness	**range (mm)**	5.4- 9.8	5.1- 9.8	1.475	0.146
	mean ±SD	7.86±1.27	7.41±1.10		

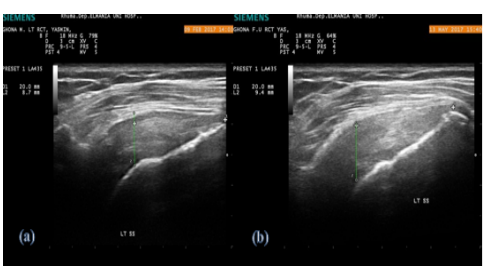
Chi-square ($\chi 2$) test, t test, PTT= Partial Thickness Tear, significant P value < 0.05.



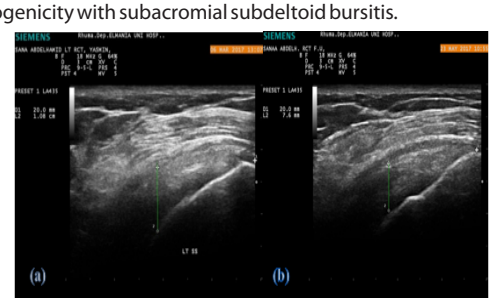
(Figure 69): Sonographic subscapularis tendon findings in (gp I).



(Figure 70): Sonographic supraspinatus tendon findings in (gp I).(a)



(Figure 71): Supraspinatus tendon: longitudinal view. (a)before receiving Physical therapy Program ; showing tendinopathy , partial thickness tear and subacromial subdeltoid bursitis, (b) follow up after receiving therapy; showing mild improvement in tendon echogenicity with subacromial subdeltoid bursitis.



(Figure 72): Supraspinatus in another patient: longitudinal view. (a)before receiving Physical therapy Program; showing tendinopathy , partial thickness tear and subacromial subdeltoid bursitis, (b) follow up after receiving therapy; showing mild improvement in tendon echogenicity and thickness with subacromial subdeltoid bursitis.

Clinical data of patients in Group II:

In (Table 5.5) there was statistically significant difference of clinical manifestations in patients at baseline in comparison to follow up regarding range of motion and special tests of the shoulder joint. Apart from Hornblower's sign (p= 0.023), all clinically examined parameters showed significant improvement (p< 0.0001).

(Table 5.5) Clinical data of patients in Group II:

		PRP (gpII)		χ2 / t	p-value
		Baseline (gpIIa) (n=30)	Follow up (gpIIb) (n=30)		
Abduction of the shoulder joint	range	80- 120	100- 180	-12.301	<0.0001*
	mean ±SD	100.33±10.90	161.33±24.88		
Flexion of the shoulder joint	range	90- 135	110- 180	-11.721	<0.0001*
	mean ±SD	113.33±12.27	168.17±22.50		
Internal rotation of the shoulder joint	range	50- 70	65- 90	-13.573	<0.0001*
	mean ±SD	58.17±5.00	83.67±8.99		
External rotation of the shoulder joint	range	35- 60	45- 70	-13.277	<0.0001*
	mean ±SD	43.50±5.89	65.83±7.08		
Impingiment tests	Positive	30(100%)	5(16.7%)	46.458	<0.0001*
Speed's test	Positive	23(76.7%)	4(13.3%)	24.310	<0.0001*
Lift Off test	Positive	30 (100%)	6(20%)	40.000	<0.0001*
Empty can test	Positive	30 (100%)	5 (16.7%)	42.857	<0.0001*
Hornblower's sign	Positive	7(23.3%)	1(3.3%)	5.192	0.023*

Chi-square (χ2) test, Student t test, significant P value < 0.05, PRP= platlet rich plasma.

Functional assessment of patients in Group II:

In (Table 5.6) there was statistically significant difference of functional assessment scores in patients at baseline in comparison to follow up regarding (SPADI (PS, DS and total), VAS and WORC scores (p< 0.0001).

(Table 5.6) Functional assessment of patients in Group II:

			PRP (gpII)		t	p-value
			Baseline (gpIIa) (n=30)	Follow up (gpIIb) (n=30)		
SPADI score	Pain score (PS)	range	44- 100	0- 99	12.934	<0.0001*
		mean ±SD	81.20±14.14	15.53±23.95		
	Disability score (DS)	range	25- 98.8	0- 77.5	12.561	<0.0001*
		mean ±SD	73.53±15.88	13.87±20.61		
	Total	range	6.69- 95.38	0- 82.3	11.349	<0.0001*
		mean ±SD	74.58±19.08	14.36±21.93		
VAS		range	60- 100	0- 90	14.382	<0.0001*
		mean ±SD	85.67±10.73	20.00±22.59		
WORC		range	90.8- 95.6	92- 100	-13.464	<0.0001*
		mean ±SD	92.56±1.29	98.77±2.17		

Student t test, significant P value < 0.05, SPADI= Shoulder Pain And Disability Index, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index, PRP= platlet rich plasma.

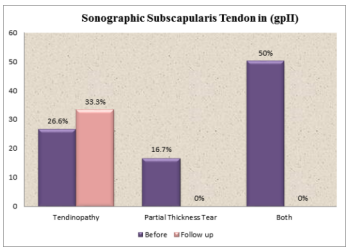
Muscloskeletal Ultrasound findings of patients in Group II:

In (Table 5.7) there was statistically significant difference of sonographic data in patients at baseline in comparison to follow up regarding (biceps tendinopathy, subscapularis tendinopathy, supraspinatus tendinopathy, supraspinatus tendon thickness, supraspinatus fibrillar tendon disruption) (p <0.0001), and subacromial subdeltoid bursitis (p= 0.001) respectively.

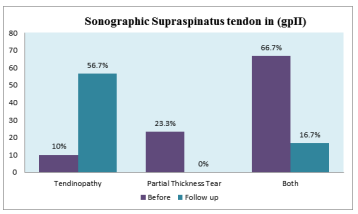
(Table 5.7) Muscloskeletal Ultrasound findings of patients in Group II:

		PRP		χ2 / t	p-value
		Baseline (gpIIa) (n=30)	Follow up (gpIIb) (n=30)		
Biceps tendon	Tendinopathy	25(83.3%)	5 (16.7%)	26.667	<0.0001*
Subscapularis tendon	Tendinopathy	8(26.7%)	10(33.3%)	34.949	<0.0001*
	PTT	5 (16.7%)	0 (0%)		
	Both	15(50%)	0(0%)		
Supraspinatus tendon	Tendinopathy	3(10%)	17(56.7%)	33.800	<0.0001*
	PTT	7(23.3%)	0 (0%)		
	Both	20(66.7%)	5(16.7%)		
Supraspinatus Fibrillar tendon Disruption	25%	7(23.3%)	5 (16.7%)	26.117	<0.0001*
	50%	9 (30%)	2(6.7%)		
	75%	8(26.7%)	0(0%)		
Subacromial subdeltoid bursitis	Bursitis	29(96.7%)	18(60%)	11.882	0.001*
Supraspinatus Tendon thickness	range (mm)	5.1- 9.8	5.2- 8.5	4.079	<0.0001*
	mean ±SD	7.80±1.40	6.55±0.93		

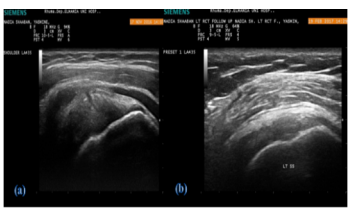
Chi-square (χ2) test, t test, significant P value < 0.05, PRP= platlet rich plasma, PTT= Partial Thickness Tear.



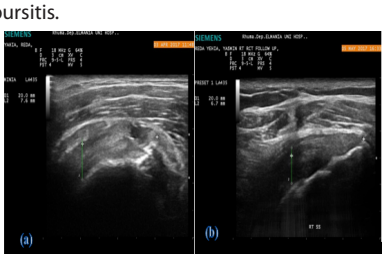
(Figure 73): Sonographic subscapularis tendon findings in (gp II).



(Figure 74): Sonographic supraspinatus tendon findings in (gp II).



(Figure 75): Supraspinatus tendon: (a)longitudinal view before receiving PRP injection; showing tendinopathy, partial thickness tear (bursal surface) and subacromial subdeltoid bursitis, (b) longitudinal view follow up after receiving PRP; showing improvement in tear size, tendon echogenicity and subacromial subdeltoid bursitis.



(Figure 76): Supraspinatus tendon in another patient: (a) longitudinal view before receiving PRP injection; showing tendinopathy, partial thickness tear and subacromial subdeltoid bursitis, (b) longitudinal view follow up after receiving PRP; showing improvement in tear size, tendon echogenicity and subacromial subdeltoid bursitis.

Comparison of Clinical parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

In (Table 5.8) there was no statistically significant difference of clinical manifestations in patients of both groups when comparing both groups at baseline assessment.

(Table 5.8) Comparison of Clinical parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

		(gpIa) at baseline (n=30)	(gpIIa) at baseline (n=30)	χ2 / t	p-value
Abduction of the shoulder joint	range	55- 135	80- 120	-1.057	0.295
	mean ±SD	96.67±15.56	100.33±10.90		
Flexion of the shoulder joint	range	69- 135	90- 135	0.040	0.968
	mean ±SD	113.47±13.64	113.33±12.27		
Internal rotation of the shoulder joint	range	40- 70	50- 70	-1.342	0.185
	mean ±SD	55.83±8.10	58.17±5.00		
External rotation of the shoulder joint	range	30- 60	35- 60	-0.597	0.553
	mean ±SD	42.50±7.04	43.50±5.89		
Impingiment tests	Positive	27(90%)	30(100%)	3.630	0.163
Speed's test	Positive	28(93.3%)	23(76.7%)	3.268	0.071 0.145
Lift Off test	Positive	27 (90%)	30 (100%)	3.158	0.076
Empty can test	Positive	30 (100%)	30 (100%)	0	1.000
Hornblower's sign	Positive	5 (16.7%)	7(23.3%)	0.417	0.519

Chi-square ($\chi 2$) test, Student t test, significant P value < 0.05.

Comparison of Clinical parameters between patients in both Groups (gpIb and gpIIb) at follow up:

In (Table 5.9) there was statistically significant difference of clinical manifestations in patients of both groups when comparing both groups at follow up assessment regarding (range of motion of shoulder joint and special tests with exception of hornblower's sign) (p< 0.0001, p= 0.353) respectively, in favor of PRP group.

(Table 5.9) Comparison of Clinical parameters between patients in both Groups (gpIb and gpIIb) at follow up:

		Rehabilitation Follow up (gpIb) (n=30)	PRP Follow up (gpIIb) (n=30)	$\chi 2$ / t	p-value
Abduction of the shoulder joint	range	80- 135	100- 180	-11.215	<0.0001*
	mean ±SD	105.33±11.37	161.33±24.88		
Flexion of the shoulder joint	range	90- 130	110- 180	-11.769	<0.0001*
	mean ±SD	116±9			
Internal rotation of the shoulder joint	range	50- 70	65- 90	-13.152	<0.0001*
	mean ±SD	58.67±5.24	83.67±8.99		
External rotation of the shoulder joint	range	40- 55	45- 70	-12.858	<0.0001*
	mean ±SD	46.33±4.34	65.83±7.08		
Impingiment tests	Positive	25 (83.4%)	5(16.7%)	26.682	<0.0001*
Speed's test	Positive	20 (66.7%)	4(13.3%)	17.778	<0.0001*
Lift Off test	Positive	22 (73.3%)	6(20%)	17.143	<0.0001*
Empty can test	Positive	30 (100%)	5 (16.7%)	42.857	<0.0001*
Hornblower's sign	Positive	4(13.3%)	1(3.3%)	1.964	0.353

Chi-square ($\chi 2$) test, Student t test, significant P value < 0.05.

Comparison of functional assessment parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

In (Table 5.10) there was no statistically significant difference of functional assessment scores in patients of both groups when comparing both groups at baseline assessment regarding SPADI (PS, DS and total), VAS and WORC scores).

(Table 5.10) Comparison of functional assessment parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

(Table 5.10) Comparison of functional assessment parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

			(gIa) at baseline (n=30)	(gIIa) at baseline (n=30)	t	p-value
SPADI score	Pain score (PS)	range	48- 100	44- 100	0.038	0.970
		mean ±SD	81.33±13.32	81.20±14.14		
	Disability score (DS)	range	32.5- 100	25- 98.8	0.129	0.897
		mean ±SD	74.04±14.50	73.53±15.88		
	Total	range	40- 97.7	6.69- 95.38	0.550	0.584
		mean ±SD	76.91±13.22	74.58±19.08		
VAS		range	50- 100	60- 100	-0.604	0.548
		mean ±SD	83.30±18.58	85.67±10.73		
WORC		range	90.48-95.52	90.8- 95.6	-0.277	0.783
		mean ±SD	92.47±1.22	92.56±1.29		

Student t test, significant P value < 0.05, SPADI= Shoulder Pain And Disability Index, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index

Comparison of functional assessment parameters between patients in both Groups (gpIb and gpIIb) at follow up:

In (Table 5.11) there was statistically significant difference of functional assessment scores in patients of both groups when comparing both groups at follow up assessment regarding SPADI (PS, DS and total), VAS and WORC scores (p< 0.0001) in favor of PRP group.

(Table 5.11) Comparison of functional assessment parameters between patients in both Groups (gpIb and gpIIb) at follow up:

			Rehabilitation Follow up (gIb) (n=30)	PRP Follow up (gIIb) (n=30)	t	p-value
SPADI score	Pain score (PS)	range	52- 98	0- 99	12.227	<0.0001*
		mean ±SD	74.27±10.90	15.53±23.95		
	Disability score (DS)	range	32.5- 81.25	0- 77.5	12.647	<0.0001*
		mean ±SD	67.62±10.72	13.87±20.61		
	Total	range	40- 86.92	0- 82.3	12.632	<0.0001*
		mean ±SD	70.18±10.25	14.36±21.93		
VAS		range	50- 100	0- 90	12.907	<0.0001*
		mean ±SD	80.00±11.74	20.00±22.59		
WORC		range	90.95- 95.52	92- 100	-12.747	<0.0001*
		mean ±SD	93.15±1.05	98.77±2.17		

Student t test, significant P value < 0.05, SPADI= Shoulder Pain And Disability Index, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index, PRP= platlet rich plasma.

Comparison of sonographic assessment parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

In (Table 5.12) there was no statistically significant difference of sonographic data in patients of both groups when comparing both groups at baseline assessment except in sonographic finding of subscapularis tendon disease with (p= 0.014).

(Table 5.12) Comparison of sonographic assessment parameters between patients in both Groups (gpIa and gpIIa) at baseline assessment:

		(gIa) at baseline (n=30)	(gIIa) at baseline (n=30)	$\chi 2$ / t	p-value
Biceps tendon	Tendinopathy	22(73.3%)	25 (83.3%)	0.884	0.347
Subscapularis tendon	Tendinopathy	20(66.7%)	8(26.7%)	10.559	0.014*
	PTT	2(6.7%)	5 (16.7%)		
	Both	8(26.7%)	15(50%)		
Supraspinatus tendon	Tendinopathy	10(33.3%)	3(10%)	4.817	0.090
	PTT	5 (16.7%)	7(23.3%)		
	Both	15(50%)	20(66.7%)		
Supraspinatus Fibrillar tendon Disruption	25%	4(13.3%)	7(23.3%)	5.036	0.412
	50%	10(33.3%)	9 (30%)		
	75%	4(13.3%)	8(26.7%)		
Subacromial subdeltoid bursitis	Bursitis	29(96.7%)	29(96.7%)	0	1.000
Supraspinatus Tendon thickness	range	5.4- 9.8	5.1- 9.8	0.174	0.863
	mean ±SD	7.86±1.27	7.80±1.40		

Chi-square ($\chi 2$) test, t test, PTT= Partial Thickness Tear, significant P value < 0.05.

Comparison of sonographic assessment parameters between patients in both Groups (gpIb and gpIIb) at follow up:

In (Table 5.13) there was statistically significant difference of sonographic data in patients of both groups when comparing both groups at follow up assessment regarding (biceps tendinopathy, subscapularis tendinopathy, supraspinatus tendinopathy, supraspinatus tendon thickness and subacromial subdeltoid bursitis (p=0.003, p <0.0001, p=0.019, p= 0.002, p=0.045) respectively.

(Table 5.13) Comparison of sonographic assessment parameters between patients in both Groups (gpIb and gpIIb) at follow up:

		(gIb) Follow up (n=30)	(gIIb) Follow up (n=30)	$\chi 2$ / t	p-value
Biceps tendon	Tendinopathy	16(53.3%)	5 (16.7%)	8.864	0.003*
Subscapularis tendon	Tendinopathy	20(66.7%)	10(33.3%)	17.333	< 0.0001*
	PTT	0(0%)	0 (0%)		
	Both	5(16.7%)	0(0%)		
Supraspinatus tendon	Tendinopathy	23(76.7%)	17(56.7%)	9.991	0.019*
	PTT	1(3.3%)	0 (0%)		
	Both	6(20%)	5(16.7%)		
Supraspinatus Fibrillar tendon Disruption	25	4(13.3%)	5 (16.7%)	3.202	0.525
	50	2(6.7%)	2(6.7%)		
	75	2(6.7%)	0(0%)		
Subacromial subdeltoid bursitis	Bursitis	25 (83.3%)	18(60%)	4.022	0.045*
Supraspinatus Tendon thickness	range	5.1- 9.8	5.2- 8.5	3.260	0.002*
	mean ±SD	7.41±1.10	6.55±0.93		

Chi-square ($\chi 2$) test, t test, significant P value < 0.05.

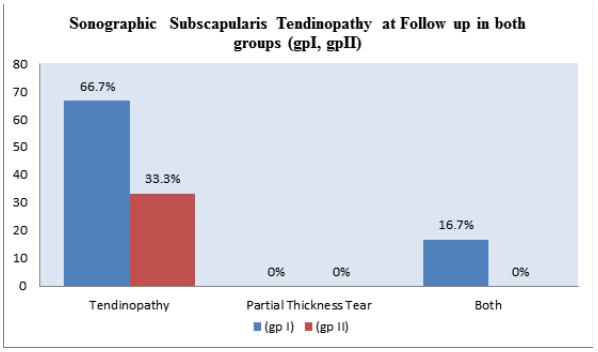
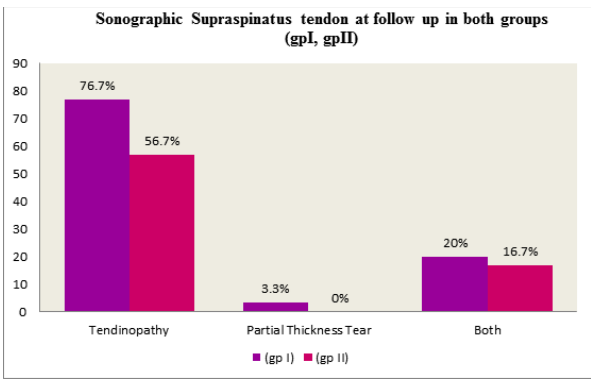


Figure 77): Sonographic subscapularis tendon assessment in both groups at follow up.



(Figure 78): Sonographic supraspinatus tendon assessment in both groups at follow up.

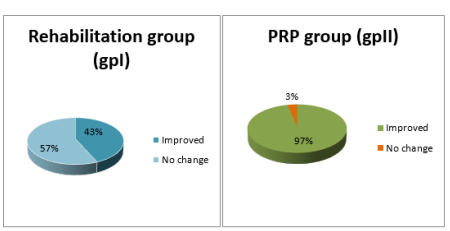
Comparison of Sonographic Improvement in subscapularis and supraspinatus tendon between patients in both Groups (gpIb and gpIIb) at follow up:

(Table 5.14): describes the percentage of patients in both groups at follow up assessment showing either improvement, no change or worsening of their sonographic subscapularis and supraspinatus tendon findings relative to baseline assessment. As regarding subscapularis tendon, in (gpIIb) (96.7% of patients showed improvement, 3.3% didn't change and 0%worsened), while in (gpIb) (43.3% showed improvement, 56.7% didn't show any changes and 0%worsened). Regarding sonographic supraspinatus tendon findings, in (gpIIb) (83.3% of patients showed improvement, 13.3% didn't change and 3.3%worsened). In (gpIb) (46.7% showed improvement, 50% didn't show any changes and 3.3 %worsened).

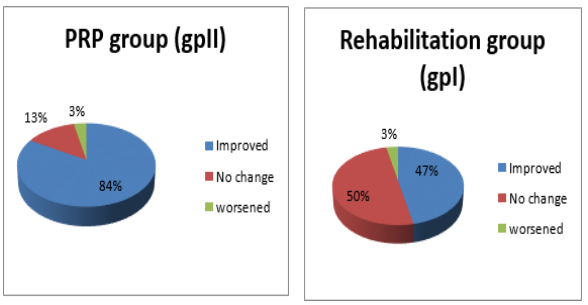
(Table 5.14): Comparison of Sonographic Improvement in subscapularis and supraspinatus tendon between patients in both Groups (gpIb and gpIIb) at follow up:

		gpIb	gpIIb	$\chi 2$	p- value
Subscapularis tendon	Improvement	(13) 43.3%	(29) 96.7%	15.718	**0.0001**
	No change	(17) 56.7%	(1) 3.3%	1.023	0.311
	Worsening	(0) 0%	(0) 0%		
	Total			19.979	< **0.0001***
Supraspinatus tendon	Improvement	14 (46.7%)	25 (83.3%)	5.595	**0.018**
	No change	15 (50%)	4 (13.3%)	1.651	0.198
	Worsening	1 (3.3%)	1 (3.3%)	0	1.000
	Total			9.741	**0.008**

Chi-square ($\chi 2$) test, significant P value < 0.05.



(Figure 79): Percentage of patients in both groups at follow up assessment showing either improvement or no change of their sonographic subscapularis tendon findings.



(Figure 80): Percentage of patients in both groups at follow up assessment showing improvement, no change or worsening of their sonographic supraspinatus tendon findings.

Correlation between functional assessment scores (SPADI, VAS and WORC), clinical and sonographic findings in Group Ia at baseline assessment:

In (Table 5.15), there was significant positive correlation between WORC score and forward flexion of shoulder joint (p=0.023), and significant negative correlation between WORC score and supraspinatous tendinopathy (p=0.024).

(Table 5.15) Correlation between functional assessment scores (SPADI, VAS and WORC), clinical and sonographic findings in Group Ia at baseline assessment:

		SPADI	VAS	WORC
Flexion of the shoulder joint	(r)	-0.245	-0.157	0.414
	P	0.192	0.408	**0.023***
Supraspinatus Tendinopathy	(r)	0.360	0.251	-0.412
	P	0.051	0.181	**0.024***

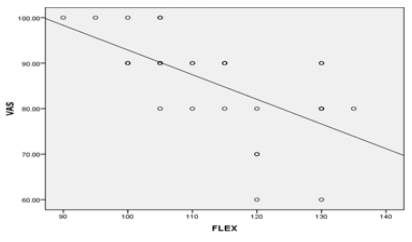
Pearson correlation coefficients (r). * Correlation is significant at the 0.05 level (2-tailed), SPADI= Soulder Pain And Disability Score, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index.

Correlation between functional assessment scores (SPADI, VAS and WORC), clinical and sonographic findings in Group Ib at follow up:
In (Table 5.16), a significant negative correlation between SPADI score and abduction of shoulder joint was found (p=0.012). There was significant negative correlation between VAS score, abduction and forward flexion of the shoulder joint (p=0.001; p=0.005) respectively and significant positive correlation between VAS score and supraspinatus tendinopathy (p=0.017). Also, significant positive correlation was found between WORC score, abduction and forward flexion of the shoulder joint (p=0.020; p=0.015) and a significant negative correlation between WORC score and supraspinatus tendinopathy (p=0.027) respectively.

(Table 5.16) Correlation between functional assessment scores (SPADI, VAS and WORC), clinical and sonographic findings in Group Ib at follow up:

		SPADI	VAS	WORC
Abduction of the shoulder joint	(r)	-0.452	-0.568	0.424
	P	**0.012***	**0.001****	**0.020***
Flexion of the shoulder joint	(r)	-0.335	-0.498	0.441
	P	0.070	**0.005****	**0.015***
Supraspinatus tendinopathy	(r)	0.304	0.431	-0.403
	P	0.103	**0.017***	**0.027***

Pearson correlation coefficients (r). *Correlation is significant at the 0.05 level (2-tailed) .**Correlation is significant at the 0.01 level (2-tailed). SPADI= Shoulder Pain And Disability Index, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index.



(Figure 82): Correlation between VAS score and flexion of the shoulder joint in group IIa at baseline assessment.

Correlation between functional assessment scores (SPADI, VAS and WORC), clinical and sonographic findings in Group IIb at follow up:
In (Table 5.18), there was significant negative correlation between the total SPADI score, abduction, flexion, internal rotation, external rotation, speed's test, lift off test and empty can test of shoulder joint (p <0.0001; p <0.0001; p <0.0001; p <0.0001; p= 0.001; p <0.0001; p <0.0001) respectively, and a positive correlation between the total SPADI score and sonographic supraspinatus tendon thickness (p= 0.012).

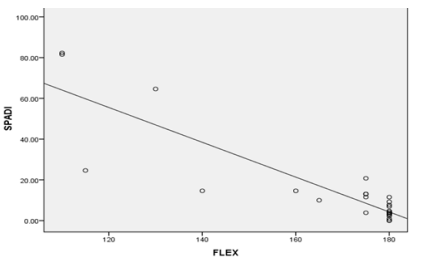
There was significant negative correlation between VAS score, abduction, forward flexion, internal rotation, external rotation and empty can test of the shoulder joint (p <0.0001; p <0.0001; p <0.0001; p <0.0001; p <0.0001; p= 0.001; p <0.0001) respectively, and significant positive correlation between VAS score and sonographic supraspinatus tendinopathy (p= 0.015).

Also a significant positive correlation was found between WORC score, abduction, forward flexion, internal rotation, external rotation, speed's test, lift off test and empty can test of the shoulder joint (p <0.0001; p <0.0001; p <0.0001; p <0.0001; p 0.001; p <0.0001; p <0.0001) respectively, and there was significant negative correlation between WORC score and sonographic supraspinatus tendinopathy (p= 0.007).

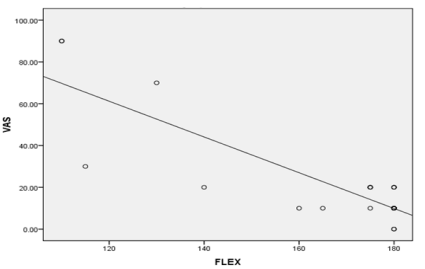
(Table 5.18) Correlation between functional assessment scores (SPADI, VAS and WORC), clinical and sonographic findings in Group IIb at follow up:

	SPADI	VAS	WORC	
Abduction of the shoulder joint	(r)	-0.857	-0.825	0.839
	P	<0.0001**	<0.0001**	<0.0001**
Flexion of the shoulder joint	(r)	-0.877	-0.852	0.868
	P	<0.0001**	<0.0001**	<0.0001**
Internal rotation of the shoulder joint	®	-0.797	-0.772	0.789
	P	<0.0001**	<0.0001**	<0.0001**
External rotation of the shoulder joint	(r)	-.853**	-0.819	0.848
	P	<0.0001**	<0.0001**	<0.0001**
Speed's test	(r)	-0.890	-0.883	0.895
	P	0.001**	<0.0001**	0.001**
Lift Off test	(r)	-0.740	-0.713	0.750
	P	<0.0001**	0.001**	<0.0001**
Empty Can Test	(r)	-0.813	-0.805	0.819
	P	<0.0001**	<0.0001**	<0.0001**
Supraspinatus tendon thickness	(r)	0.455	0.440	-0.484
	P	0.012*	0.015*	0.007**

Pearson correlation coefficients (r). * Correlation is significant at the 0.05 level. ** Correlation is significant at the 0.01 level, SPADI= Shoulder Pain And Disability Index, VAS= Visual Analogue Scale, WORC= Western Ontario Rotator Cuff Index.



(Figure 83): Correlation between SPADI score and flexion of the shoulder joint in group IIb.



(Figure 84): Correlation between VAS score and flexion of the shoulder joint in group IIb.

Discussion

Shoulder pain is one of the most commonly encountered musculoskeletal complain. Rotator Cuff Tendinopathy (RCT) is the most common cause of shoulder pain in adults. Initially pain usually settles down with rest or anti-inflammatory treatment and recurs with more demanding activities. As disease progresses pain and stiffness increase in intensity (Chaudbary et al., 2016).

In longstanding cases coarse crepitation and palpable snapping on passive rotation of shoulder indicates fibrosis or partial/ complete rupture of rotator cuff, secondary osteoarthritis of the shoulder may supervene and movements become severely restricted. RCT is diagnosed by clinical tests for Supraspinatus, Infraspinatus or Subscapularis and radiologically by means of X-rays, MRI and Ultrasonography (Chaudbary et al., 2016).

Rotator Cuff Tendinopathy (RCT) is treated conservatively by means of rest, physiotherapy, non steroidal anti-inflammatory drugs, steroid injection and surgerically, but still no satisfactory treatment available can improve degenerative pathology of RCT either clinically, functionally, histologically.

Autologous Platelet Rich Plasma (PRP) injection contains high concentration of platelets with various growth factors and bioactive substances (like VEGF,TGF-b, IGF1… etc) which stimulates natural healing cascade and halts or even revert degenerative process of RCT (Chaudbary et al., 2016).

Our study included 60 patients with rotator cuff tendinopathy (RCT) diagnosed both clinically and by Musculoskeletal Ultrasound (MSUS). We randomly gave 30 patients a supervised rehabilitation program, and the other 30 patients were injected with PRP.

Patients in both groups were assessed clinically (ROM and special tests), functionally [Visual Analog Scale (VAS), Western Ontario Rotator Cuff Index (WORC), Shoulder Pain and Disability Index (SPADI)] and sonographically. Patients were assessed at baseline and after 3 months of physical therapy treatment or injection of PRP. Physical therapy Program included the following: [hot packs, (TENS), and (therapeutic ultrasound)]. The therapeutic Exercise Programs (supervised and home-based) were applied, including: (range of motion exercises, stretching excercises, excercises improving scapular stability and strengthening excercises of the rotator cuff and scapular muscles). PRP injection was carried out

under complete sterile condition using sterile needles under ultrasound guidance, 3ml PRP was injected into the bursa without usage of local anesthetics prior to injection.

As regard Rehabilitation group, there was statistical significant difference in patients at baseline and follow up regarding clinical assessment (abduction, flexion of shoulder joint, impingement tests and speed's test) (p= 0.017, p=0.014, p=0.007, p=0.010) and sonographic assessment in supraspinatus tendinopathy (p= 0.003). This was in agreement with Calis et al., 2011 who treated 52 patients with different physical modalities plus exercise and found stastistically significant improvement in all their groups as regard clinical and functional parameters.

Also this was in agreement with Seven et al., 2017 , who selected 60 patients with chronic rotator cuff that were treated with supervised exercise program (three sessions weekly for 12 weeks), in addition to a home exercise program. A standard and proper physiotherapy program was found to be effective in providing flexibility, strength and mobility of RC, and reduced the risk of re-injury. Shoulder VAS, WORC, SPADI scores, and shoulder range of motion were significantly enhanced with a physiotherapy program.

In PRP group (gpII), there was statistical significant difference in patients at baseline and follow up regarding clinical assessment (p <0.0001), functional assessment (SPADI (PS, DS and total) and WORC scores (p <0.0001) and sonographic assessment in (biceps tendinopathy, subscapularis tendinopathy, supraspinatus tendinopathy, supraspinatus fibrillar tendon disruption and supraspinatus tendon thickness) (p <0.0001) and sonographic subacrmial subdeltoid bursitis (p= 0.001).

This was in agreement with Scarpone et al., 2013, who treated 19 shoulders single ultrasound-guided PRP injection, and found significant improvement clinical, functional and radiological outcomes which was studied with MRI severity scores.

Also, in agreement with our study, the study done by Shams et al., 2016 who evaluated the results of subacromial injection of (PRP) in 20 patients with symptomatic partial rotator cuff tears. In comparison with the baseline before injection, patients were significantly better at 12 weeks post injection clinically and functionally [Simple Shoulder Test (SST) (p= 0.013), American Shoulder and Elbow Surgeons Standarized Shoulder Assessment (ASES) (p= 0.001), Constant Murly Score (CMS) (p= 0.001) and Visual Analogue Scale (VAS) (p= 0.01)]. However, MRI showed a slight nonsignificant improvement in grades of tendinopathy/tear. This could be attributed to lack of sensitivity and specificity of MRI in detection of minimal changes in RCT as intrasubstance tears.

Also, Von Wehren et al., 2016 concluded that single subacromial injection of autologous conditioned plasma (ACP) in symptomatic partial rotator cuff tears has a better outcome clinically, functionally and radiologically 3 months after injection. In the MRI data, statistical pre- and post-comparisons did not reveal any statistically significant differences between location of partial rupture and the grade of tendinopathy. This could be attributed to previous cause mentioned before.

Rha et al., 2013, injected 20 patients who were diagnosed as supraspinatus tendoninopathy and / or partial thickness tear. Patients received two injections at a four-week interval between injections with, a post injection rehabilitation program was prescribed. Outcome measures were The Shoulder Pain and Disability Index, passive range of motion of the shoulder and sonographic assessment. Outcome measurements were made at baseline (time 0), two weeks after the first injection (time 1), immediately before the second injection (time 2), two weeks after the second injection (time 3) and at three- and six-month follow-up visits (times 4 and 5, respectively). There was a significant reduction in the Shoulder Pain and Disability Index and improvement of range of motion at times 1–5 compared to time 0 (p< 0.05).

Upon six-month follow-up sonographic examination in PRP group, two patients with partial-thickness tears (1 articular tear and 1 bursal surface tear) of the supraspinatus improved to tendinosis and two patients with tendinosis improved to normal status. So, platelet-rich plasma injections provide significant symptomatic relief and functional and sonographic improvement at six-month follow-up. This reflects the ability of the PRP to make structural changes in diseased tendons.

Another study confirming data obtained from our study is that one done by Chaudbary et al., 2016 on 20 patients who received single injection of 4 ml of autologous injection PRP intralesionally and in surrounding tendons. Patients were followed up for 3 months post injection. No analgesic was prescribed during follow up except paracetamol (650 mg) tab. Assessment of results done by VAS score and Functional shoulder tests assessing rotator cuff strength & endurance at pretreatment and 3 months later. Following PRP injection, patients show significant overall improvement in quality of life, there was significant improvement in function, endurance of patient and significant improvement in empty cane test, drop arm test and theta band external rotation at 90°. Mean VAS score significantly improved from severe category 7.8±0.6 points pretreatment to none 0.6±0.4 points at three months post PRP injection.

In agreement with our study, a study done by Tahririan et al., 2016. PRP significantly improved the activity, range of motion, functional outcomes and reduced pain in 17 patients with partial tearing of the tendon. The mean of Constant Shoulder Score (CSS) before and three months after intervention was (37.05 ± 11.03) and (61.76 ± 14.75) respectively, and a statistically significant difference was found (p< 0.001) with an improvement in all score parameters. There was no significant difference in CSS improvement between genders (p= 0.23).

Also, Randelli et al., 2011, showed that autologous platelet rich plasma (PRP) improved tendon healing and reduced pain in the first postoperative months in 26 patients underwent arthroscopic rotator cuff repair. A magnetic resonance image (MRI) was performed in all cases after more than 1 year post-op. All patients had the same accelerated rehabilitation protocol.

The pain score in the treatment group was improved at 3, 7, 14, and 30 days after surgery (p< 0.05). The Simple Shoulder Test (SST), Constant scores and strength in external rotation (SER), were significantly high in the treatment group at 3 months after surgery (p< 0.05). The follow-up MRI showed no significant difference in the healing rate of the rotator cuff tear. In the subgroup of grade 1 and 2 tears, with less retraction, SER in the PRP group was also significantly higher at 3, 6, 12, and 24 months postoperative (p< 0.05). The long-term results of subgroups of grade 1 and 2 tears suggest that PRP positively affected cuff rotator healing.

Another study done by Sahu et al., 2016 agreed with our study. Sixty patients, having tendinopathies at different areas (50% of them presented with supraspinatus tendinopathy, 21.7% with lateral epicondylitis, 6.7% with medial epicondylitis, 15% with De Quervain's tenosynovitis, and 6.7% with trigger finger were included in their study. Patients were assessed according to the visual analog scale (VAS) and Disabilities of the Arm, Shoulder, and Hand (DASH) score pre- and post-injection of PRP in the involved tendons.

Comparison of (DASH) score pre- and post-injection shows 7.23% decrease in the 1st week, 12.43% decrease in the 4th week, 28.92% in the 12th week, 57.63% in the 24th week. Comparison of the baseline VAS with each follow-up showed 22.55% decrease in the 1st week, 58.58% relief in 4th week, 54.90% relief in 12th week, and 66.76% relief in 24th week.

Also, in agreement with our study, a study done by Kesikburun et al., 2013 on 20 patients who received a single PRP injection. Two days after injection, a 3-week exercise program supervised by a physical therapist was started. The exercise program initially involved passive range of motion. When the pain subsided and movement was tolerated, stretching of the posterior capsule and pectoral muscles and light resistive exercises of the rotator cuff and scapular muscles were added to the program.

The patients moved onto a home-based program focusing on isotonic strengthening and stretching exercises for a further 3 weeks. The exercise program lasted a total of 6 weeks. Outcome measures were assessed at baseline and at 3 weeks, 6 weeks, 12 weeks, 24 weeks, and 1 year after the injection. There was significant improvement clinically (ROM), functionally, WORC score (p=0.001), the SPADI and VAS scores (pain with the Neer sign) (p= 0.001) at all assessment points compared with baseline.

In our study as regard comparison between Rehabilitation and PRP groups; there was statistical significant difference in patients at baseline and follow up regarding clinical assessment (p <0.0001) in favor of PRP group, functional assessment (SPADI (PS, DS and Total), VAS and WORC) (p <0.0001) in in favor of PRP group and sonographic assessment regarding (biceps tendinopathy, subscapularis tendinopathy, supraspinatus tendinopathy, supraspinatus tendon thickness and subacromial subdeltoid bursitis (p=0.003, p <0.0001, p=0.019, p= 0.002, p=0.045) respectively in favor of PRP group. While, at baseline no statistical significant difference was found between both groups except in sonographic finding of subscapularis tendon disease with (p= 0.014) (in favor of PRP group at baseline).

Comparable to our study, study done by Ilhanli et al., 2015, who selected 62 patients with chronic partial supraspinatus tears, patients were divided into two groups (PRP group (include 30 patient) and Physical Therapy (PT) group (include 32 patient). At 12th month after the end of the treatment, clinically significant improvement (in range of motion (ROM), neer's, hawkins' and drop arm tests (p< 0.05) was detected in both groups, pain was reduced significantly in both groups (p< 0.05). Functionally, an improvement of the DASH score and Beck Depression Inventory score was also observed in both groups (p< 0.05).

However, in PT group, increases in ROM degrees were significantly higher than the PRP group (p< 0.05) (except the internal rotation degrees of shoulder). Also, improvement in VAS in activity and in rest, after the treatment was higher in the PT group than the PRP group (p < 0.05).

In the PRP group, significantly higher improvement in VAS in sleep and DASH score at the end of the treatment (p < 0.05). They concluded that when comparing PRP with PT, PRP seemed to be a well-tolerated application showing promising results in patients with chronic partial supraspinatus tears.

In their study a standard Physical Therapy Program formed of [hot pack for 15 minutes, ultrasound in continuous mode (1.5 watt/cm2 for five minutes), trans-cutaneous electrical nerve stimulation in brief-intense mode for 15 minutes, range of motion (ROM), pandicular response, stretching and strengthening exercises with 10 repeatitions, and 500 mg acetaminophen as the rescue medication] was applied to the Physical Therapy (PT) group for 15 sessions (five sessions per week for three weeks). After the physical therapy, the exercise program was continued as homework during the follow-up period. While, in PRP group three intra-articular injections with an interval of one week were applied and a strengthening program was started after the end of the injections given only as homework during the treatment as well as during the follow-up.

The differences from our result may be due to differences in ethinicity, follow up duration and different (preparation technique for PRP, targeting site of injectate, and instructions before and after injection). Also, different rehabilitation protocol was prescribed to our patients.

In contrary to our results, study done by Nejati et al., 2017 who made a study on sixty-two patients, that were randomly divided into 2 groups and received either PRP or exercise therapy with 1-, 3-, and 6-month follow-up. Patients in the PRP group were injected twice: once at the beginning of the study and again 1 month after the first visit. While in Exercise group, patients received supervised exercise therapy in the hospital once a week for 3 months and performed the therapy exercises at home on the other days of the week. They concluded that both PRP injection and exercise therapy were effective in reducing pain and disability in patients with Subacromial Impingiment Syndrome (SAIS), with exercise therapy proving more effective results (significantly higher WORC scores and abduction ROM).

Radiological Improvement using MRI (was seen in each group in the appearance of supraspinatus tendinopathy (PRP (p= 0.06) and exercise therapy (p= 0.1)). However, no significant difference was found between the 2 methods (p=0.34).

In this study the positive short-term (6-12 weeks) role of exercise therapy resulted in strengthening the muscles of the rotator cuff, stabilizing the scapula, and increasing shoulder ROM and pain reduction. Each exercise session began with warm-up aerobic activities. The exercises were performed in 4 phases; phase 1 (passive and active-assistive ROM exercises), phase 2 (active ROM exercises). Postural exercises (scapular retraction) and glenohumeral ROM exercises were also performed 15 to 20 times per day. Strength training was performed on the external and internal rotator cuff muscles while the arms were placed at the sides of the body. This exercise was in the form of 3 sets per day, each with 10 repetitions. The stretching exercises performed in phase 1 were also performed in phase 2, but their duration was increased to 15 to 20 seconds. The aim of phase 3 was to strengthen the muscles of the rotator cuff and scapula. The reverse-fly, shoulder extension, and bent-over row exercises were performed using an elastic band or a 1- to 1.5-kg weight in 3 sets of 10 repetitions each. In phase 4, the exercises intended to train the scapular muscles were performed using a medicine ball.

The differences from our result may be due to differences in ethinicity, number of patients and we used special clinical tests for assessment, in addition to different functional outcomes and radiological follow up. Also follow up duration was different and we made single PRP injection and different (preparation technique for PRP, targeting site of injectate, preparations and instructions before and after injection). Also, different rehabilitation protocol was prescribed to our patients.

In Conclusion, the present study demonstrated that there is a conclusive benefit for clinical, functional and sonographic improvement in RCT from single PRP injection, in contrary to traditional physical therapy program.

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