Sports Medicine and Rehabilitation Journal

Research Article
Published: 04 Jul, 2020

Clinical Improvement and Signs of Healing in the Treatment of Partial Rupture of Supraspinatus Tendon Using Platelet Rich Plasma: A Prospective Study

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Abstract

The incidence of Partial Rupture of the Rotator Cuff (PRRC) in the general population is high, ranging from 15% to 32%. Therefore, this kind of rupture has a high impact on health systems. PRRC healing does not occur spontaneously, or through non-anatomical procedures, such as open or arthroscopic acromioplasty, which has shown to be ineffective for healing or preventing the progression of the lesion.

The study was carried out with patients from the Ambulatory of Regenerative Medicine of the Center for Studies on Tissue Regeneration (CERT), with partial lesions of the supraspinatus tendon and pain. The study consisted of 26 joints (shoulders) of 24 patients, aged between 28 and 79 years (average of 51 years). The treatment was based on a technique which consisted of an injection of 5 mL of subacromial Xylocaine (1% without constrictor vessel) followed by 10 perforations of the tendon injury area using a 22 G (0.70 mm × 25 mm) needle, and a peritendinous injection of 6 mL of platelet rich plasma guided by ultrasound. Comparative analysis of pre and post treatment images was performed.

Post-procedure evaluations were performed, when patients responded questionnaires to assess quality of life and reported the percentage of pain improvement.

All patients included in the study, presented partial lesions of the supraspinatus tendon, with an average size of 7.68 mm. The lesion healing was measured by ultrasonography, with significant difference between the pre-treatment and post-treatment measure.

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Received Date: *11 Jun 2020*

Accepted Date: *01 Jul 2020*

Published Date: *04 Jul 2020*

Citation:

de Castro RLB, Antonio BP, de Castro MFC, de Castro GC. Clinical Improvement and Signs of Healing in the Treatment of Partial Rupture of Supraspinatus Tendon Using Platelet Rich Plasma: A Prospective Study. Sports Med Rehabil J. 2020; 5(1): 1051.

Introduction

The incidence of Partial Rupture of the Rotator Cuff (PRRC) in the general population is high, ranging from 15% to 32%. In the dominant shoulder of professional overhead athletes, the incidence can reach 40%. Therefore, this kind of rupture has a high impact on health systems [1,2]. The progression of the rupture is correlated with the percentage of thickness of the involved tendon, and the plastic deformation when the forces capable of leading to total rupture become smaller [3]. Patients with less than 50% of tendon rupture have a 14% chance of lesion progression, whereas for patients with more than 50% of tendon rupture, the chance of progression is 55%. Therefore, early diagnosis is important, preferably in the early stages of Ellman's classification [4]. Imaging and histological studies have demonstrated that PRRC healing does not occur spontaneously, nor through non-anatomical procedures, such as open or arthroscopic acromioplasty, which has shown to be ineffective for healing or preventing the progression of the lesion [5,6].

The conventional treatments for PRRC are mainly conservative [7]. Subacromial injection of anesthetics or corticosteroids is often used to treat patients with persistent symptoms after rehabilitation therapy and use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) [8]. Although treatment with NSAIDs and corticosteroid injections are known to alleviate inflammation and shoulder pain, severe gastrointestinal side effects may occur following to prolonged administration of oral NSAIDs [9]. Despite the symptom's relief, corticosteroid injections do not demonstrate efficacy in healing either, causing joint changes and increasing tendon fragility, which may worsen the progression of the disease [10].

The pathogenesis of PRRC is still controversial and subject of research, as well as the attempt to improve the quality of the tendon to avoid the progression to a total rupture. Masten demonstrated

that curettage of PRRCs with a 000 curette in the tendon insertion as a treatment form in small lesions that still with good mechanical structure [11].

New approaches are necessary for a better prognosis of PRRC. Rha [12] demonstrated that the dry needling technique guided by ultrasonography when associated with Platelet Rich Plasma (PRP), decreased or healed the PRRC. However, the goal of the article was to evaluate the improvement in tendinopathy, without focusing on the healing of tendon injuries.

The clinical and imaging improvement of the supraspinal tendon tendinopathies with PRP injections already has current scientific evidences [13,14], however, the healing rates and the influence of the PRP injection on PRRC are still unknown.

The aim of this study is to evaluate the influence and healing rates of PRP injections guided by ultrasonography in PRRCs.

Methods and Materials

This study was approved by the Committee of Ethics in Research of the Ifor Hospital. The information regarding each patient was used after the written consent of the patient or his/her responsible person, through a dated and signed "Informed Consent Term".

This study consists of a series of cases, with pre and post-treatment evaluation with prospective and retrospective data. The study was carried out with patients from the Ambulatory of Regenerative Medicine of the Center for Studies on Tissue Regeneration (CERT), with partial lesions of the Supraspinatus Tendon and pain, without clinical improvement with other clinical treatments. The study consisted of 26 joints (shoulders) of 24 patients, aged between 28 and 79 years (average of 51 years), and follow-up from June 2017 until February 2019.

We have included patients who had a partial lesion of the supraspinatus tendon examined and measured by ultrasound, with shoulder pain to perform the arc movement and/or impingement test, and failure with conservative treatment. Patients younger than 25 years of age, pregnant women, patients with neoplasia, liver disease or severe nephropathies, autoimmune diseases, acute or chronic inflammatory or infectious diseases, presence of another shoulder disease (fracture or arthritis of rheumatic origin), use of infiltration with corticosteroid in the affected shoulder in the last 6 months, hypersensitivity to lidocaine, presence of severe systemic pathology and any conditions that could put the patient at risk during the study, were excluded. Patients under anti-inflammatory or corticoid use 6 weeks before PRP application were also excluded.

The treatment was based on a technique which consisted of an injection of 5 mL of subacromial Xylocaine (1% without constrictor vessel) followed by 10 perforations of the tendon injury area using a 22 G (0.70 mm × 25 mm) needle, and a peritendinous injection of 6 mL of Platelet Rich Plasma guided by ultrasound.

Peripheral blood was collected using 3 vacuum tubes (BD Vacutainer 8.5 mL) containing citric acid, sodium citrate and dextrose as anticoagulants. The collected material was centrifuged at 580 G for 10 min. After centrifugation, 2 mL of the upper portion and the Buffy coat were discarded. The remaining plasma, referred to as PRP, was collected and transferred to a 10 mL syringe for further use in the treatment [15].

The ultrasound equipment used by the surgeon was a General Electronic Logic 9 (Healthcare, Milwaukee, USA), with a linear 13 MHz transducer, and the ultrasound equipment used by the sonographer was a General Electric Logic 5 (Healthcare, Milwaukee, USA), with a linear transducer of 4 to 12 MHz.

Table 1: Report of pain improvement percentage by each joint that received PRP. Percentage obtained through the WORC questionnaire.

Joints	Improvement of pain (%)	Joints	Improvement of pain (%)
1	100%	15	100%
2	70%	16	80%
3	100%	17	60%
4	100%	18	90%
5	80%	19	70%
6	80%	20	50%
7	90%	21	100%
8	90%	22	85%
9	100%	23	70%
10	100%	24	80%
11	50%	25	85%
12	80%	26	95%
13	75%		
14	100%		

Comparative analysis of pre and post treatment images was performed by the same orthopedic surgeon and a sonographer, with an average of 145 days between each exam (46 to 455 days), where 11 patients were evaluated by the surgeon and 13 by the sonographer. Post procedure evaluations were performed between 6 and 25 weeks, when patients responded to the Western Ontario Rotator Cuff (WORC), SF-36 questionnaire to assess quality of life and reported the percentage of pain improvement through a score ranging from 0% to 100%. All evaluations were performed before and after treatment. Statistical analyzes were performed using the GraphPad Prism program, using Wilcoxon matched pairs signed rank test.

Results

Twenty-four patients were included in this study, aged between 28 and 79 years old, with an average of 51 years (11 male and 13 female), presenting partial lesions of the supraspinatus tendon verified by the ultrasound method from 1.5 mm to 17.1 mm (average of 7.68 mm). The study was carried out from June 2017 to February 2019 with an

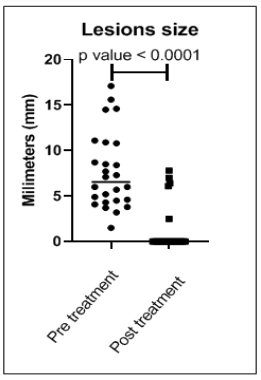

Figure 1: Comparative analysis of the sizes (in millimeters) of the supraspinatus tendon lesions, pre and post treatment. Images obtained by ultrasonography. N=26 joints. *p value <0.0001 analyze by Wilcoxon Test.

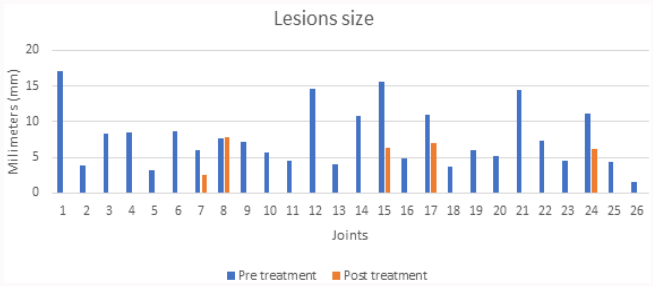

Figure 2: Analysis of the sizes (in millimeters), comparing pre and post treatment of each supraspinatus tendon lesion. Images obtained by ultrasonography. N=26 joints.

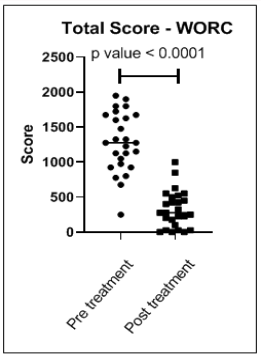

Figure 3: Comparative analysis of the WORC questionnaire score, pre and post treatment. N=26 joints. *p value <0.0001 analyze by Wilcoxon Test.

average of 22 months.

Those patients reported other comorbidities: 1 knee osteoarthritis, 1 spine osteoarthritis, 2 wrist osteoarthritis, 2 dyslipidemias, 2 diabetes, 2 lumbosacral radiculopathy, 1 ankle osteoarthritis, 1 chronic rupture of the posterior cruciate ligament, 2 Systemic Arterial Hypertension (SAH), 1 bowel cancer (diagnosis after treatment), 1 Ménièré syndrome, 2 cardiac arrhythmias, 2 hypothyroidism, 1 total knee prosthesis, 2 insomnia, 1 diverticulitis, 1 total hip prosthesis.

No adverse effects were reported with treatment. The pain improvement reported by the subjects was 84% on average, and only one patient did not report improvement of clinical symptoms, as shown in Table 1.

The healing of the lesion was measured by ultrasonography for all 26 lesions, from which 21 healed completely, 4 decreased in size and 1 maintained the same size with significant difference between the pre-treatment and post-treatment measures (data presented in Figure 1 and 2).

Tables 2 and 3 show individual variations in the supraspinatus tendon lesion size reduction according to the evaluator. When evaluated by the sonographer, the median reduction of the lesion was 6 mm, whereas the median reduction was 4.55 mm when evaluated by the orthopedic surgeon.

Figure 3 shows the statistical difference in the reduction of the WORC questionnaire score before and after the PRP treatment, demonstrating its efficacy.

Discussion

Regarding the literature in this topic, Tashjian et al. [16] analyzed

Table 2: Pre and post-treatment lesion size (in millimeters) of each joint evaluated by the sonographer. The difference between pre and post-treatment lesion size is represented by Δ Joint, where (-) means that the lesion has decreased in size and (+) means that the lesion has increased in size.

Joints	Lesion Pre	Lesion Post	Δ Joint
1	17,1	0	(-) 17,1 mm
2	3,8	0	(-) 3,8 mm
6	8,7	0	(-) 8,7 mm
8	7,7	7,8	(+) 0,1 mm
9	7,1	0	(-) 7,1 mm
10	5,7	0	(-) 5,7 mm
14	10,8	0	(-) 10,8 mm
15	15,6	6,4	(-) 9,2 mm
16	4,9	0	(-) 4,9 mm
17	10,9	7	(-) 3,9 mm
19	6	0	(-) 6 mm
22	7,3	0	(-) 7,3 mm
24	11,1	6,1	(-) 5 mm

Table 3: Pre and post- treatment lesion size (in millimeters) of each joint evaluated by the orthopedic surgeon. The difference between pre and post-treatment lesion size is represented by Δ Joint, where (-) means that the lesion has decreased in size.

Joints	Lesion Pre	Lesion Post	Δ Joint
3	8,4	0	(-) 8,4 mm
4	8,5	0	(-) 8,5 mm
5	3,2	0	(-) 3,2 mm
7	6	2,5	(-) 3,5 mm
11	4,6	0	(-) 4,6 mm
12	14,6	0	(-) 14,6 mm
13	4,1	0	(-) 4,1 mm
18	3,7	0	(-) 3,7 mm
20	5,2	0	(-) 5,2 mm
21	14,5	0	(-) 14,5 mm
23	4,5	0	(-) 4,5 mm
25	4,3	0	(-) 4,3 mm
26	1,5	0	(-) 1,5 mm

the epidemiology and progression of partial lesions (asymptomatic and symptomatic) of the rotator cuff treated non-surgically. Mall et al. [4] evaluated 30 asymptomatic ruptures of the rotator cuff with partial thickness. In a follow-up after 2 years (average), 20 of the asymptomatic lesions remained so, whereas 10 of the lesions became symptomatic. Ultrasound was performed in the follow-up to evaluate the progression of the lesion. Looking at the lesions that remain asymptomatic, none of these progressed to a full thickness lesion. In the 10 lesions that became symptomatic, 40% progressed to a total thickness rupture. Pain was highly correlated with progression of the partial thickness lesion, therefore, it can be used as a sign of increased lesion and warrants further evaluation, such as an imaging study. Maman et al. [17] evaluated 30 patients with symptomatic partial rotator cuff lesion in an average of 24 months with MRI. These researchers found that only 10% of the symptomatic partial thickness lesions progressed in size (>5 mm), which was significantly lower than the 50% progression reported in the same study for

total thickness lesions, but also alerted for progression of the size of symptomatic rotator cuff lesion. The location of the lesion (bursal face or articular face) did not affect the progression. These data suggested that the progression of partial thickness symptomatic lesion is at a significantly reduced rate compared to symptomatic lesions of full thickness. Therefore, the initial non-operative treatment is reasonable due to the decreased risk of progression.

As for healing, the rotator cuff has a limited capacity for intrinsic healing without repair. Several investigators have evaluated spontaneous healing of the rotator cuff in animal models [18,19]. The absence of evidence of rotator cuff healing was found in 3 weeks in a 12 mm lesion in a model with rabbits with supraspinatus tendon injury [18]. Similarly, an active but inadequate response was found in a model of supraspinatus lesions in rats, where 78% of tendons had persistent defects 12 weeks after the creation of a 2 mm^2 lesion, the material and structural properties of the reparative tissue were significantly lower than the normal tendon [19]. In another model of supraspinatus lesions in rats, only scar tissue was found around the tendon stump after 12 weeks from the moment the tendon peels off the humerus. This evidence suggests a limited potential for spontaneous healing of the rotator cuff. In a clinical series that evaluated patients with partial and total rotator cuff lesions, surgically treated cuff lesions, limited healing occurred in case the repair was not performed. In one series, none of the patients treated with arthroscopic debridement and acromioplasty for rotator cuff injuries with partial thickness (who were followed up by a second arthroscopy) showed evidence of healing [20]. In another study, there was no evidence of tendon healing, as measured by ultrasonography at an average of 101 months after the initial study in 26 patients treated with arthroscopic acromioplasty for partial rotator cuff lesions, at the time of the follow-up evaluation, 35% of the lesions progressed from partial thickness to full thickness [6]. Another series of cases evaluated the results of arthroscopic subacromial decompression and debridement of small and medium chronic rotator cuff lesions in 114 patients, and a second surgery was necessary in 25 patients in a follow-up of 13.7 months [21,22]. These studies demonstrate that arthroscopy for debridement of the rotator cuff lesion and acromioplasty will not result in cure or spontaneous tendon healing. The occurrence of a new rupture after rotator cuff injury surgery was reported in some series between 13% and 94%, despite excellent clinical outcomes [23]. Failure in tendon healing does not prevent an excellent outcome, although better results have been correlated with intact repairs. In the case series of the current study, the partial ruptures of the rotator cuff had an average of 8.57 mm and were symptomatic. For an average follow-up of 22 months, 21 from a total of 26 lesions healed completely, 3 decreased in size and 1 maintained its size. The results demonstrated that 80.7% of the lesions healed completely. The results of the evaluation of the function and improvement of pain also showed an average evaluation of 83.8% of pain decrease.

The WORC score is a research tool based on specific self-reported condition questionnaire to assess physical symptoms, sport, recreation, work, social function and emotions. Consists of 21 visual analog scale items. The score is moderately correlated to the SF-36 in our measurements. In our study, the comparison of the results of the scale when measured before the procedure and in the post-procedure evaluation, showed a statistically significant difference with $p<0.0001$.

Some cases need to be analyzed separately because of the discrepancy between the results of wound healing and the improvement of pain. The size of the lesion of joint 7 of our study group remained the same, without improvement of the image. However, her evaluation of pain improvement was 90% and had a significant improvement in the WORC score. Patient did not present any other noteworthy data to explain the discrepancy, other than the ability to improve pain by reducing the inflammatory process.

In the study we also did not identify any adverse reactions or complications from the treatment, which attest the biosafety of the method.

Conclusion

Based on the data from our study, we conclude that the dry needling technique and ultrasound-guided platelet rich plasma injection for the treatment of shoulder supraspinal tendon partial lesions can increase the healing rate of the lesion and improve pain and shoulder function significantly. We also concluded that the technique is safe, with no complications.

Limitations

The study consisted of a series of cases, with prospective and retrospective data. No control group or placebo group were used, since the idea was to find out whether the improvement of the lesions was due to the injection of platelet rich plasma or the dry needling.

Regarding the evaluation of the lesion size before and after treatment, from a total of 26 lesions, 13 were evaluated by a single sonographer, and 11 by the surgeon himself. Ideally, all cases should have been analyzed by the sonographer. However, when analyzing and comparing both groups statistically with Mann-Whitney test, pain improvement tables ($p=0.6356$), lesion size tables ($p=0.2869$) and WORC scores ($p=0.2694$), it is possible to affirm that there were no significant differences between the two groups (sonographer and orthopedic surgeon).

Clinical Messages

Dry needling technique and ultrasound-guided platelet rich plasma injection treatment can increase the healing rate of the shoulder supraspinal tendon partial lesions, improve pain and shoulder function significantly and shows no adverse reactions or complications, which attest the biosafety of the method.

Acknowledgement

All sources of support were provided by CERT. We would like to thank CERT staff for technical support.

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