Leukocyte-Poor Platelet Rich Plasma As An Adjuvant Of Arthroscopic Rotator Cuff Repairs Reduces Retears Rates But Does Not Improve Functional Outcomes A Double-Blind Randomized Controlled Trial

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Declarations

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Abstract

Objective: The main purpose of our study was to assess whether the use of leukocytepoor platelet rich plasma (LP-PRP) as an adjuvant to ARCRs decreases the rate of retears compared to a control group. The secondary objective of our study was to analyze whether LP-PRP improves the patient-reported outcomes (PROMs).

Methods: This was a a double-blind randomized controlled trial at a single center. A consecutive series of 96 patients with rotator cuff tears < 3 cm were enrolled and randomly allocated to a control group (double-row suture-bridge ARCR alone, n = 48) and a study group (double-row suture-bridge repair followed by one LP-PRP injections at the tendon repair site during surgery, n= 48). The visual analog scale (VAS) for pain, the American Shoulder and Elbow Surgeons (ASES) score, the Single Assessment Numeric Evaluation (SANE) and The Pittsburgh Sleep Quality Index were evaluated preoperatively and at 6 and 12 month follow up. An MRI examination was performed to evaluate tendon integrity at 6 months follow up according to the Sugaya classification. Both, patients and assessors were blinded to the intervention received during surgery.

Results: The mean age was 56.1 (\pm 2.98). Of the 96 patients, 90 had MRI performed at 6 months after surgery (94% radiological follow-up). The retear rate in PRP group was 15.2% (7/46) [CI 95% 6%-28%] which was lower than that in the control group (34.1%, (15/44) [CI 95% 20%-49%], P = .037. Therefore, the Risk Ratio of rupture in patients exposed to PRP was 0.44 (CI 95% 0.2 - 0.9; p = 0.037). Overall, the ASES, VAS, SANE and Pittsburgh scores showed statistical improvement after the operation (P < .01). There were no significant differences in functional scores between the groups at any of the

postoperative follow-up times. Most of the patients exceeded the MCID for the ASES, SANE and VAS scores without significant differences between the groups.

Conclusion: In patients with RCTs < 3 cm undergoing double-row suture-bridge repair, a 5-mL dose of LP- PRP placed at the tendon-bone interface at the time of surgery can significantly reduce the postoperative retear rate. However, the use of LR-PRP in terms of postoperative pain and patient reported outcomes failed to show clinically meaningful effects.

Level of evidence: I

Keywords: leukocyte-poor - platelet rich plasma - arthroscopic rotator cuff repairsretears – patient reported outcomes

What are the new findings

In patients with RCTs < 3 cm undergoing double-row suture-bridge repair a 5-mL dose of LP- PRP placed at the tendon-bone interface at the time of surgery:

- Significantly reduce postoperative retear rate.
- Does not improve patient reported outcomes PROMs.

Introduction

Regardless of recent advances in rotator cuff repair techniques, the rate of unhealed or recurrent rotator cuff tears remains high. Recent studies using modern techniques have reported retear rates between 20% and 60%, depending on the preoperative tear size, which has been shown to result in worse clinical outcomes [1-3] As a response, adjuvant platelet-rich plasma (PRP) therapies have become increasingly popular in an effort to augment tendon healing after arthroscopic rotator cuff repair (ARCR). [4-9]

PRP consists of an autologous concentrate extracted from a patient's own blood used to enhance the healing process by injecting it into or onto the injured soft tissue. The healing process is stimulated by the release of growth factors from platelet alpha-granules since it triggers tenocyte proliferation and also promotes extracellular matrix cell proliferation, cell differentiation, chemotaxis and angiogenesis. [10-11]_Even though platelet-rich therapies seem to have a positive effect on tendon repair according to basic science studies, whether this leads to improved tendon healing and better functional outcomes remains unclear in clinical evidence. While some studies have demonstrated that adjuvant ARCR with PRP can reduce retear rates [4-9] others have not reported any structural benefit. [12-14]

Likewise, although some authors showed significant improvements in functional scores in patients treated with PRP, [6] others argue that these improvements are not clinically relevant. [4,8] In a recent systematic review, Citanovich et al [15] conclude that the lack of consistency in the literature is partly due to the variability of the studies analyzed in terms of type of lesion, the different PRP preparation protocols and underlying composition, and the difference in the dose, location and timing of PRP administration. The main purpose of our study was to assess whether the use of leukocyte-poor platelet rich plasma (LP-PRP) as an adjuvant to ARCRs decreases the rate of retears compared to a control group. The secondary objective of our study was to analyze whether LP-PRP improves the patient-reported outcomes (PROMs). We hypothesized that in the short term, although the LP-PRP would reduce retear rates, it would not significantly improve patient-reported outcomes (PROMs) compared to a control group.

Materials and Methods

Participants

This study was designed as a single- blinded (clinical and radiological evaluators), 1:1 randomized prospective clinical trial and was performed at a university hospital in Buenos Aires, Argentina.

The Italian Hospital is a high-complexity third-level university hospital located at Buenos Aires, with 750 beds and 38 critical care beds for adult patients. This study was approved by the ethics committee of our institution (institutional review board: 2381, study protocol No. 2290) and it was registered ClinicalTrials.gov (NCT04703998 protocol:5702) All patients provided written informed consent to participate in this investigation.

All patients underwent diagnostic shoulder radiographs and magnetic resonance imaging (MRI) for differential diagnosis, in particular since some of the inclusion and exclusion criteria were based on these diagnostic tools. The study group underwent double-row suture-bridge ARCR followed by one LP-PRP injections at the tendon-bone interface during surgery. The control group underwent double-row suture- bridge ARCR alone without any injections. The inclusion criteria were (1) a full-thickness supraspinatus tear less than 3 cm diagnosed by magnetic resonance imaging (MRI); (2) failure of 3-month nonoperative treatment consisting of analgesic medications and physical therapy; (3)

subscapularis tear I-III according to Lafosse classification. [16] The exclusion criteria were (1) subscapularis tear (Lafosse IV-V) and or infraspinatus tears identified on preoperative MRI or at the time of arthroscopic surgery; (2) previous corticosteroid within 6 months prior to surgery (3) degenerative arthritis of the glenohumeral joint; (4) previous injury or surgery to the same shoulder; and (5) known rheumatoid arthritis, neuromuscular, or autoimmune diseases. Poner como se midió infiltración grasa y atrofia muscular con las citas. Fatty infiltration \geq 3 according to Goutallier [17] or severe muscle atrophy according to the tangent sign method. [18]

Patients were recruited consecutively from September 2020 to October 2021. A total of 350 patients with rotator cuff tears diagnosed by MRI were admitted to our hospital and assessed for elegibility of whom 103 patients were registered and available for this study based on the inclusion and exclusion criteria. The flowchart representing the participants included in the study is shown in **Fig 1**. After obtaining informed consent from enrolled patients, a centralized computer-generated randomization was performed for treatment arm allocation. Patients were randomly assigned to a control group (suturebridge ARCR alone) and a study group (suturebridge ARCR followed by one leukocyte-poor platelet rich plasma (LP-PRP) injections at the tendon -bone interface during surgery. whereas 4 patients (two from partial bursal RCTs, one from a RCT > 3 cm and one from a subscapularis tear Laffose grade 4 were excluded at the time of arthroscopic that were not diagnosed by preoperative imaging. Eventually, 103 patients were enrolled for further analysis **Fig 1**. All assessments were conducted at a single center. Both the evaluators of the clinical scores and the postoperative structural results were blinded to group allocation.

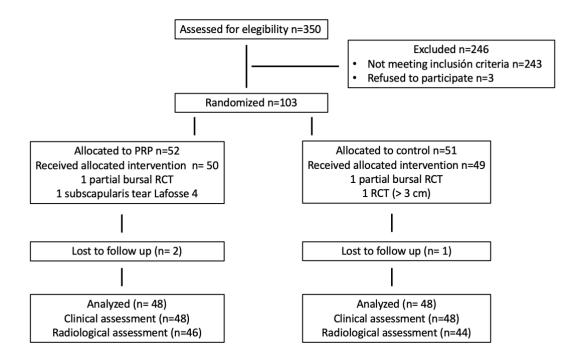


Figure 1: Flow chart diagram of the included patients.

PRP preparation

Extraction of 40 ml of peripheral blood was performed using a 20 gauge needle for vacutainer holder system. It was placed in 8 tubes with 6 ml EDTA serum (ethylenediaminetetraacetic acid). Two of them were used to perform serology, haematology control, and immunohematological donor/patient, and the remaining 6 tubes for a total 30ml of blood (5ml blood per tube) with 6 ml EDTA (1 ml per tube) were devoted to obtain PRP. We utilized a 2 spin protocol. First, the blood was centrifuged for 3 min at 1400 rpm. The product obtained was separated using a laminar flow cabinet, where the buffy coat was obtained with the plasma and referred to a dry 10-ml tube, which was again centrifuged for 4 min at 3000 rpm to achieve greater product concentration to yield 5ml of PRP. A process quality control was performed to the baseline blood and to the final PRP product through a haematology analyser ROCHE XT prior to the application of PRP. This assessment included: platelet count per mm³, total leukocytes per mm³, and specific leukocyte formula.

All the patients were treated with leukocyte-poor PRP (white blood cells below baseline levels). According to the PAW classification,[19] all the patients were P3/4-A α (P3: > 1 750 000 platelets/µl - A: white blood cells below baseline - α : neutrophils below or equal to baseline)

Surgical Procedure

All arthroscopic RCRs were performed with the patient under general anesthesia using a standard suturebridge technique by the same expert surgeon. After acromioplasty, double-row suture-bridge technique with separate medial- and lateral-row bioabsorbable anchors was used. Biceps tenotomy or tenodesis was performed in patients with tears, subluxation, and complete dislocation according to the surgeon's preference and patient's age. Subsequently, under the guidance of arthroscopy, a needle was percutaneously introduced between the rotator cuff and footprint, and a volume of 5 mL of Lp-PRP was injected in liquid form through the needle, whereas standard ARCRs without any augmentation were performed in the control group.

Postoperative Rehabilitation

The rehabilitation protocol was carried out according to the recommendations of the consensus statement on rehabilitation following ARCR of the American Society of Shoulder and Elbow Therapists. ,[20] All patients underwent the same regimen for rehabilitation. Postoperatively, all patients were maintained in a sling for 4 weeks, during which pendulum exercises and passive range of motion were started. Active range of motion was started at 6 to 8 weeks, and a progressive muscle-strengthening exercise was encouraged at 8 to 12 weeks. Only light daily activities were allowed to practice in the initial 3 months after surgery, whereas heavy manual work and sport activity were

allowed only after 4 months' postoperatively depending of the type of sport and the level of competition.

Outcome Evaluations

Outcome measures were collected preoperatively and at 6 and 12 months after surgery. The primary end point was at 6 months after surgery. Functional questionnaires were used for the assessment preoperatively and at 6 and 12 months after surgery.

Primary Outcome Measures

The primary outcome was based on MRI results. All MRI (a Siemens 1.5-T Avanto scanner, Berlin, Germany) were assessed by 2 blinded experienced musculoskeletal orthopaedic surgeons before surgery and at 6 months after surgery. If the results were inconsistent, a third investigator would assess and make the final result. The shoulder imaging protocols included coronal, sagittal fast spin echo fat-suppressed T2-weighted images (repetition time, 4500 milliseconds; echo time, 60 milliseconds), and axial fast spinecho proton density T2-weighted images (repetition time, 2500 milliseconds; echo time, 12 milliseconds). Rotator cuff tears measured as anteroposterior size were determined on MRI evidence before surgery. Retear was defined as absence of visible tendon fiber extending across the entire repaired tendon as type IV and V according to the Sugaya classification.[21] All MRI evaluations were blinded to the investigators.

Secondary Outcome Measures

Secondary outcome measures were questionnaires related to pain, function and sleep disorders. All functional outcomes were performed by the same research fellow, who was blinded to patients allocation. Data including a visual analog scale (VAS) for pain, the American Shoulder and Elbow Surgeons (ASES) score, the Single Assessment Numeric Evaluation (SANE) and the Pittsburgh Sleep Quality Index (PSQI) were collected before surgery 6 and 12 months after surgery.

The percentage of patients who exceeded the minimal clinically important difference (MCID) for the VAS, ASES and SANE score were evaluated in each group. The MCID for the VAS, ASES and ASES score were 1.4, 11.1 and 17.5 respectively.[15,22] Adverse events were also assessed. All data entry was independently validated and blinded to group allocation and investigators.

Sample Size Calculation

To calculate the sample size, the expected values of the variable "retears" was used, which was the primary outcome. Previous studies showed that for complete rotator cuff tears, the rate of retear was 45-56% in patients undergoing ARCRs alone and 15-20% in those undergoing repair with supplementation of PRP. [23] Given this information, in the present study we estimated to detect a difference of approximately 30-35%. According to these results, a sample size of 80 (n= 40 per group) participants was required to achieve statistical significance in the retear rate at a 0.05 level with 90% power. Considering the possibility of a loss to follow-up of 15% of the patients per group, 45 patients per group will be included.

Data Analysis

Quantitative variables are presented as mean and standard deviation or median and interquartile interval according to the observed distribution. Categorical variables are presented as proportions. The 95% confidence intervals will be calculated for each of the estimators. The comparison of continuous data between two groups was analyzed with the t test if the distribution of the variables was normal or with the Mann-Withney-Wilcoxon test if it was not. The analysis of categorical data was carried out with the chi-

square test. For the comparative variables preoperatively and postoperatively, tests for paired samples were used. A p value less than 0.05 was considered statistically significant. Data analyses were performed using STATA/SE, version 14.1, software (College Station, TX).

Results.

Initially, 103 patients were registered and available for this study based on the inclusion and exclusion criteria. However, 2 patients with a partial bursal rotator cuff tear, one patient with a subscapularis tear Lafosse 4, and one patient with a supraspinatus tear > 3 cm were excluded at the time of arthroscopic surgical repair because they did not match the preoperative imaging studies and did not meet the inclusion criteria. Moreover, 3 patients were lost to follow-up. Thus, the final analysis included 96 patients (48 patients in each group). The main demographic characteristics of the patient, injuries and surgery are described in Table 1. We did not find significant differences between the groups in any of the baseline characteristics analyzed. (Table 1).

| | All (N=96) | Control (N=48) | PRP (N=48) | P value |
|-----------------------------|-------------|----------------|-------------|---------|
| Age mean SD | 56.1 (2.98) | 56.1 (3.43) | 56.2 (2.49) | .36 |
| Sex n,% | 54 (56.2%) | 26 (54.2%) | 28 (58.3%) | .26 |
| Side n,% | 57 (59.4%) | 29 (60.4%) | 28 (58.3%) | .39 |
| Dominance n,% | 60 (62.5%) | 29 (60.4%) | 31 (64.6%) | .58 |
| BMI mean, SD | 26.7 (1.38) | 26.7 (1.40) | 26.8 (1.37) | .21 |
| TBQ n,% | 19 (19.8%) | 9 (18.8%) | 10 (20.8%) | .48 |
| DBT n, % | 8 (8.33%) | 4 (8.33%) | 4 (8.33%) | .17 |
| Tear size coronal mm, n, SD | 22.4 (6.38) | 22.5 (6.61) | 22.4 (6.21) | .52 |

Table 1. Preoperative Characteristics of the Included Patients

| Tear size Sagital mm, n, SD | 19.9 (4.71) | 19.8 (4.45) | 20.1 (5.01) | .56 |
|--------------------------------|-------------|-------------|-------------|-----|
| Goutallier Pre n (range) | 1.2 (1;2) | 1.2 (1;2) | 1.4 [1;2] | .26 |
| N suture anchors mean, (range) | 3.7 (2;4) | 3.7 (2;4) | 3.6 (2;4) | .56 |
| Subscapularis n, (%) | 16 (16.7%) | 10 (20.8%) | 6 (12.5%) | .17 |
| Biceps n,(%) | 39 (40.6%) | 19 (39.6%) | 20 (41.7%) | .39 |
| ASES pre mean, SD | 44.5 (7.44) | 44.1 (7.63) | 45.0 (7.29) | .52 |

Primary Outcome

Of the 96 patients, 90 had MRI performed at 6 months after surgery (94% radiological follow-up). The retear rate in PRP group was 15.2% (7/46) [CI 95% 6%-28%] which was lower than that in the control group (34.1%, (15/44) [CI 95% 20%-49%], P = .037. Therefore, the Risk Ratio of rupture in patients exposed to PRP was 0.44 (CI 95% 0.2 - 0.9; p = 0.037). One patient in the control group and one patient in the study group were reoperated because of persistent pain and unsatisfactory functional outcomes 1 year after surgery. The rest of the patients who suffered retears did not receive any treatment, as they were satisfied with good clinical outcomes due to pain relief and functional improvement.

Secondary Outcomes

There was significant improvement in the ASES score from 44.1 (\pm 7.63) to 89.2 (\pm 7.32) after 12 month follow up in control group (P < .001) and from 45.0 (7.29) to 87.9 (\pm 8.24) in the PRP group (P < .001). There was significant improvement in the SANE score from 46.0 (\pm 3.25) to 84.7 (\pm 7.03) after 12 months follow up in the control group (p < .001) and from 46.2 (\pm 4.08) to 88.2 (\pm 6.48) in PRP group (p < .001). Also, the Pittsburgh score significantly improved from 14.4 (\pm 2.94) to 3.08 (\pm 0.61) after 12 months in the control group (p < .001). There

was significant improvement in the VAS from 7.17 (± 0.86) to 1.52 (± 0.62) after 12 months in the control group (p < .001) and from 7.10 (± 0.83) to 1.46 (± 0.54) in the PRP group (p < .001). However, no significant differences were found between both groups neither at the basal, 6 and 12 months comparison in the ASES, SANE, Pittsburg or VAS scores (Table 2 and Figures 1,2,3 and 4). Finally, most of the patients exceeded the MCID for the ASES, SANE and VAS scores without significant differences between the groups. (Table 2)

Table 2. Comparison of the ASES, SANE, Pittsburg or VAS scores in the preoperative,and after 6 and 12 months postoperative.

| | All | Control | PRP | |
|----------------|-------------|-------------|-------------|---------|
| | (N=96) | (N=48) | (N=48) | P value |
| VAS pre | 7.14 (0.84) | 7.17 (0.86) | 7.10 (0.83) | 0.718 |
| VAS 6m | 3.68 (0.77) | 3.69 (0.80) | 3.67 (0.75) | 0.896 |
| VAS 12m | 1.49 (0.58) | 1.52 (0.62) | 1.46 (0.54) | 0.6 |
| ASES pre | 44.5 (7.44) | 44.1 (7.63) | 45.0 (7.29) | 0.54 |
| ASES 6m | 72.6 (7.11) | 72.5 (7.15) | 72.6 (7.15) | 0.943 |
| ASES 12m | 88.5 (7.78) | 89.2 (7.32) | 87.9 (8.24) | 0.434 |
| SANE pre | 46.1 (3.67) | 46.0 (3.25) | 46.2 (4.08) | 0.72 |
| SANE 6m | 74.6 (6.93) | 73.0 (5.23) | 76.2 (8.02) | 0.022 |
| SANE12m | 86.5 (6.96) | 84.7 (7.03) | 88.2 (6.48) | 0.012 |
| Pittsburgh Pre | 14.1 (3.03) | 14.4 (2.94) | 13.8 (3.12) | 0.331 |
| Pittsburgh 6m | 3.86 (1.24) | 4.02 (1.42) | 3.71 (1.01) | 0.218 |

Finally, most of the patients exceeded the MCID for the ASES, SANE and VAS scores without significant differences between the groups. (Table 3)

Table 3. Comparison between the percentage of patients who exceeded the MCID for the

 different scores between the groups between the basal measurement and the 12 months

 measurement

| | All (n=96) | Control (n=45) | PRP (n=45) | P value |
|--------------|------------|----------------|------------|---------|
| VAS - n (%) | 83 (86%) | 40 (88.8%) | 43 (95.5%) | 0.12 |
| ASES – n (%) | 93 (96.9%) | 47 (97.9%) | 46 (95.8%) | 0.99 |
| SANE – n (%) | 90 (93.8%) | 43 (89.6%) | 47 (97.9%) | 0.20 |

No major complications occurred intra- or perioperatively. Also, no adverse events were related to Lp-PRP, including local inflammatory reaction, shoulder bursitis, and fibrosis.

Discussion

There were three relevant findings in this study. The main finding was that LP-PRP used as an adjuvant to the ARCRs significantly reduced the rate of retears in the MRI evaluation at 6 months postoperatively. Secondly, although the majority of the patients who underwent ARCR showed significant clinical improvement, there were no significant differences between those in whom LP-PRP was used as an adjuvant and those in which it was not. Finally, the use of intraoperative PRP is a safe procedure that was not associated with any complications.

Numerous RCTs published in the last decade have consistently demonstrated the ability of PRP to reduce retears when used as an adjuvant to ARCR. [4-8,15] In a recent systematic review, Hurley et al included 18 RCTs with 1147 patients evaluating the efficacy of PRP and platelet-rich fibrin (PRF) in ARCRs. The authors found that the use of PRP resulted in significantly decreased rates of incomplete tendon healing for all tears combined (17.2% vs 30.5%). In contrast, platelet-rich fibrin PRF resulted in a significantly longer operation time and showed no benefit in improving tendon healing rates. .[6]

Two important issues to take into account when using PRP are the surgical technique and the site of application of the PRP. In a recent meta-analysis of 9 RCTs, Villarreal-Villarreal.[7] performed a subgroup analysis evaluating nonlinked versus linked double-row RCR techniques, and applying the PRT within the bone-tendon interface versus applying PRT on any other zone. The authors found that the greatest benefit was obtained with linked double-row techniques, with a risk reduction of 51% with the linked techniques compared to 38% with the nonlinked techniques. Regarding the site of application of the PRP, the authors reported that placing PRP in the bone-tendon interface reduced risk for retear by 55%, while not placing the PRT on the bone-tendon interface

did not provide a significant risk reduction for retear.[7] In our study, out of the 96 patients, 90 had an MRI performed at 6 months after surgery (94% radiological follow-up). In all patients, we performed a linked double-row and we placed the PRP in the bone-tendon interface. Consistent with the results of previous studies, we found that the rate of retears was significantly lower in the group treated with PRP (15%) than in the control group (34%), with a risk reduction of 66% for retears.

Regarding the tear size, it is important to highlight that, in order to achieve a homogeneous sample of patients in our study, we included tears < 3 cm. However, two recent meta-analyses have shown that the benefits of PRP in reducing retears appear to be independent of lesion size. [7,8] Zhao et al reported a reduction risk of retears of 36% using PRP as an adjuvant of ARCR for tears < 3cm and of 49% for tears > 3cm. [8] Similarly, Villaroel et al evaluated the retear rate dividing by tear sizes and found a retear risk reduction of 47% in tears < 3 cm and 51% in tears > 3 cm. [7]

A subject of controversy is whether leukocyte-poor (LP) or leukocyte-rich (LR) varieties of PRP are preferable as an adjuvant of ARCRs to improved tendon healing rates. According to basic science studies, high leukocyte counts in LR-PRP contain a large number of neutrophils, which release interleukin (IL)-6, IL-1b and tumor necrosis factor- α , producing an inflammatory process. [24,25] In addition, a disruption of the extracellular matrix (ECM) of tendons [24,25] and an inhibition of the anabolic effects of platelets may be caused by leukocyte-stimulated fibroblasts releasing catabolic cytokines. On the other hand, LP-PRP, which has a lower number of leukocytes and lower levels of catabolic cytokines, could enhance tendon healing by remodeling the ECM and stimulating the proliferation of tenocytes with larger collagen fibrils. [26] In a recent network meta-analysis of RCTs, Hurley et al evaluated whether there was evidence to support the use of LP- or LR-PRP as an adjunct to ARCR. It included 13 studies (868 patients), with 9 studies comparing LP-PRP with a control and 4 studies comparing LR-PRP with a control. LP-PRP was found to significantly reduce the rate of retear and/or incomplete tendon healing. However, the same effect could not be demonstrated for the LR-PRP. The authors highlight that it was not possible to determine whether the results differed between LP-PRP and LR-PRP; as no comparative studies were identified. Future RCTs comparing LR-PRP vs. LP-PRP would be very useful to finally define which of these two variants is more beneficial for tendon healing. However, it is important to note that based on current evidence, the subtype that has consistently been shown to improve tendon healing is LP-PRP. [5,7]

There is controversy about the cost-effectiveness of PRP as an adjuvant to ARCR. Samuelson et al [27] demonstrated that adjuvant PRP in ARCR would not be costeffective unless retear rates were reduced by at least 9.1%. In our study, we obtained a 66% risk reduction with a single intraoperative application of 5 ml of LP-PRP at the tendon-bone interface. Other authors have also obtained a decrease in retears using two [28] or even 3 doses of PRP. [29] However, the use of two or more doses could increase costs compromising the cost effectiveness of the treatment. It is important for future research works to compare the results between the application of different doses of PRP as an adjuvant of ARCRs to define whether the additional doses really provide any benefit or whether one dose is enough.

The ability of PRP to improve functional outcomes and pain in patients undergoing ARCRs has not been clearly demonstrated in the literature. In a recent meta-analysis published in 2020, Chen et al [4] evaluated the use of PRP for the improvement of pain and function in rotator cuff tears in 17 Level I RCTs. The authors reported a significant improvement in the Constant, UCLA, and VAS scores in the patients treated with PRP compared to the control group and found no significant differences between the groups

regarding the ASES score. However, the differences found did not reach the MCID for any PROMs. Subsequent studies have confirmed these findings. [6,7,8] In our study, we found similar results. Although most patients significantly improved pain, functional scores and sleep disorders, no significant differences were found between both groups neither at the 6- and 12-month comparison in the ASES, SANE, Pittsburgh or VAS scores. One question that arises from the analysis of the literature on the use of PRP as an adjuvant to ACRCs is why if PRP significantly reduces retears rate this does not translate into a similar improvement in functional scores. One possible explanation for this is that the published clinical trials are not designed to compare outcomes between patients with and without tendon healing, but rather to globally compare outcomes between patients who used PRP and those who did not. Therefore, the functional scores of the patients who had a favorable outcome could attenuate the impact of the less favorable scores of those with retears. However, Yang et al [3] conducted a recent meta-analysis comparing clinical outcomes between intact and retorn rotator cuffs after ARCR and found significantly worse outcomes in patients with incomplete tendon healing than in those with successful repairs. Similarly, Jeon et al [30] found that patients with healed repairs had improved shoulder functional scores and greater strength.

Our study has some limitations. First, all patients were treated with a single 5 mL dose of LP-PRP placed at the bone-tendon interface. Therefore, the favorable results found regarding tendon healing cannot be generalized to another type of PRP or to another dose or site of application. Secondly, in order to create a homogeneous group of patients, we included all tears < 3 cm with a Goutallier stage ≤ 2 . Therefore, the results of our study cannot be extrapolated to larger tears or tendons with greater structural deterioration. Lastly, although the follow-up time of one year was sufficient to evaluate the 2 main objectives of the study, which were retears at 6 months follow up and functional results

one year after surgery, we did not investigate the potential benefits of LP- PRP in a longer interval after ARCRs.

Conclusion

In patients with RCTs < 3 cm undergoing double-row suture-bridge repair, a 5-mL dose of LP- PRP placed at the tendon-bone interface at the time of surgery can significantly reduce the postoperative retear rate. However, the use of LR-PRP in terms of postoperative pain and patient reported outcomes failed to show clinically meaningful effects.

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