Leukocyte-Poor Platelet Rich Plasma as an Adjuvant of Arthroscopic Rotator Cuff Repairs Reduces Retear Rates But Does Not Improve Functional Outcomes: A Double-Blind Randomized Controlled Trial

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INTRODUCTION:
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).
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.
RESULTS: The mean age was 56.1 (±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.
DISCUSSION AND 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.

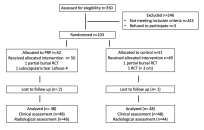

Figure 1: Flow chart diagram of the included patients.

Table 1. Preoperative Characteristics of the Included Patients

	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	28.7 (1.38)	28.7 (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
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

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

	All (N=96)	Control (N=48)	PRP (N=48)	*P value*
VAS pre	7.34 (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
Pittsburgh 12m	3.00 (0.79)	3.08 (0.61)	2.92 (0.94)	0.307

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.