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Research Article / Araştırma Makalesi

Evaluation of clinical and functional results of ultrasound-guided injections in patients with arthroscopic rotator cuff tear repair

Artroskopik rotator manşet yırtığı onarımı yapılan hastalarda ultrason kılavuzluğunda yapılan enjeksiyonların klinik ve fonksiyonel sonuçlarının değerlendirilmesi

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ABSTRACT

Objective: The aim of this study was to investigate the efficacy of ultrasound-guided injections in patients undergoing rotator cuff tear repair.

Method: The results of ultrasound-guided injections of 225 patients (142 women, 83 men) after arthroscopic rotator cuff repair were evaluated. 75 Platelet rich plasma (PRP), 75 Hyaluronic Acid (HA) and 75 combined PRP+HA injections were performed.

Visual Analogue Scale (VAS) scores recorded before injection, at the first and sixth months after injection. ASES (American Shoulder and Elbow Surgeons Score) and CMS (Constant-Murley Score) scores were used for functional evaluation.

Results: In all 3 groups VAS scores were significantly lower at the first and sixth months after injection (respectively $p < 0.001$, $p < 0.001$, $p < 0.001$). CMS and ASES scores were significantly higher at the first and sixth months after injection in all three groups (respectively $p < 0.001$, $p < 0.001$, $p < 0.001$).

VAS scores in the first month were significantly lower in PRP and PRP+HA groups than the HA group ($p=0.006$). ASES and CMS scores in the first month were significantly higher in PRP+HA group than HA and PRP groups (respectively $p < 0.001$, $p < 0.001$). VAS scores in the sixth month were significantly lower in PRP+HA group than HA and PRP groups ($p < 0.001$). ASES and CMS scores in the sixth month were significantly higher in PRP+HA group than HA and PRP groups (respectively $p < 0.001$, $p < 0.001$).

Conclusion: PRP and HA injections applied in order to accelerate recovery after surgery are effective in rotator cuff tears undergoing arthroscopic repair, and the combined application is associated with better pain and functional recovery.

Level of evidence: Retrospective study, IV.

Keywords: *Platelet-rich plasma, rotator cuff tear, hyaluronic acid, subacromial injection, arthroscopic tendon repair*

ÖZ

Amaç: Bu çalışmanın amacı rotator manşet yırtığı onarımı yapılan hastalarda ultrason eşliğinde yapılan enjeksiyonların etkinliğini araştırmaktır.

Yöntem: Bu çalışmada artroskopik rotator manşet tamiri sonrası 225 hastada (142 kadın, 83 erkek) ultrason eşliğinde yapılan enjeksiyonların sonuçları değerlendirildi. 75 Trombositten zengin plazma (PRP), 75 Hyaluronik Asit (HA) ve 75 kombine PRP+HA enjeksiyonunun sonuçları değerlendirildi. Enjeksiyon öncesi ve enjeksiyon sonrası birinci ve altıncı aylarda Vizuel Analog Skala (VAS) skorları kaydedildi. Fonksiyonel değerlendirme için American Shoulder and Elbow Surgeons Score (ASES) ve Constant-Murley Score (CMS) skorları kullanıldı.

Sonuçlar: Her 3 grupta da VAS skorları enjeksiyondan sonraki birinci ve altıncı aylarda anlamlı derecede düşüktü (sırasıyla $p < 0.001$, $p < 0.001$, $p < 0.001$). Her üç grupta da CMS ve ASES skorları enjeksiyondan sonraki birinci ve altıncı aylarda enjeksiyon öncesine göre anlamlı derecede yüksekti (sırasıyla $p < 0.001$, $p < 0.001$, $p < 0.001$).

Birinci aydaki VAS skorları PRP ve PRP+HA gruplarında HA grubuna göre anlamlı derecede düşüktü ($p=0.006$). Birinci aydaki ASES ve CMS skorları PRP+HA grubunda HA ve PRP gruplarına göre anlamlı derecede yüksekti (sırasıyla $p < 0.001$, $p < 0.001$). Altıncı aydaki VAS skorları PRP+HA grubunda HA ve PRP gruplarına göre anlamlı derecede düşüktü ($p < 0.001$). Altıncı aydaki ASES ve CMS skorları PRP+HA grubunda HA ve PRP gruplarına göre anlamlı derecede yüksekti (sırasıyla $p < 0.001$, $p < 0.001$).

Sonuç: Ameliyat sonrası iyileşmeyi hızlandırmak için uygulanan PRP ve HA enjeksiyonları artroskopik onarım geçiren rotator manşet yırtıklarında etkilidir ve kombine uygulama daha iyi ağrı ve fonksiyonel iyileşme ile ilişkilidir.

Kanıt düzeyi: Retrospektif çalışma, IV.

Anahtar Sözcükler: *Trombositten zengin plazma, rotator manşet yırtığı, hyaluronik asit, subakromiyal enjeksiyon, artroskopik tendon onarımı*

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INTRODUCTION

Rotator cuff tear is the most common shoulder problem treated by orthopedic surgeons. The incidence of rotator cuff tear has been increased, especially in older ages. Rotator cuff injuries have been reported in more than 30% of patients over 60 years of age (1). The choice of treatment for rotator cuff tears is mainly surgical and the most commonly used surgical procedure is arthroscopic repair (2). Even though the arthroscopic rotator cuff repair can heal the function and pain, the rate of postoperative re-tear varies between 5% and 51% (3). The mechanical properties of the repaired tendon are never the same as the intact tendon (4). The repair capacity of the tendon is low and the effectiveness of interventions such as injections is limited. Re-tear after surgery, post-op scarring and adhesions limit clinical recovery (5).These limitations have led to increased interest in materials such as platelet-rich plasma (PRP), rich in growth factors, that accelerate healing in the repaired tendon, and hyaluronic acid (HA), which reduces scar-adhesion development (6,7). Although there are studies reporting the efficacy of PRP or HA to accelerate recovery in rotator cuff tears after arthroscopic repair (8-10), there are not enough studies on combined (PRP and HA) application after arthroscopic rotator cuff tears repair.

In this study, we evaluated the pain relief and functional improvement results following PRP, HA and combined PRP+HA injectates under ultrasound guidance after arthroscopic rotator cuff repair.

MATERIAL and METHODS

This is a clinical observation study with a retrospective design. The study complies with the principles of the Declaration of Helsinki. Informed written consent was obtained from the patients for participation in the study. Canakkale Onsekiz Mart University Faculty of Medicine Clinical Research Ethics Committee approval was obtained (2022/156).

Patient selection

In this study, the pain and functional improvement results of 225 patients who have been applied subacromial ultrasound- guided (PRP, HA, PRP and HA combined) injection on the 15th day after arthroscopic rotator cuff repair were evaluated. Patients who underwent arthroscopic surgery due to rotator cuff tear between March 2021-March 2022 (all arthroscopic repairs with the single row technique for tears smaller than 3 cm by the same surgeon in a single centre) (Figure 1) and injections on the 15th day after surgery were included in the study. Patients with local infection at the injection site, coagulopathy, who used subacromial/intra-articular steroid within the last 6 weeks and non-steroidal anti-inflammatory drugs for the last 1 week were excluded from the study.

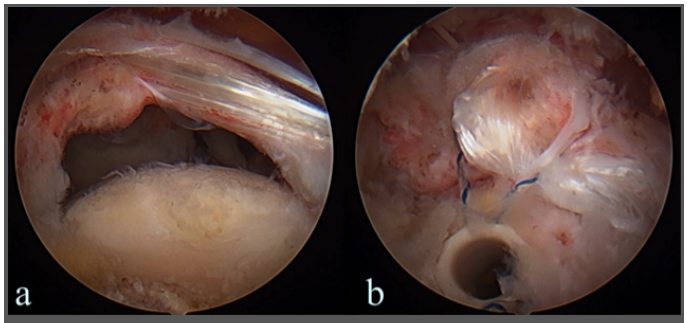

Figure 1. Arthroscopic view of a full-thickness rotator cuff tear before (a) and after (b) arthroscopic repair

PRP/HA preparation

20 cc venous blood was taken from the patients. Sterile PRP kit containing sodium citrate was used to prevent clotting (Vacusera-Disera Medical Product Logistics Industry and Trade Inc.,Turkey). 5 mL of PRP was obtained by centrifugation with venous blood taken from the patient at 3200 rpm for 15 minutes.

Truvisc 48 mg 2.4 ml 2% viscoelastic sodium hyaluronate solution (Biodem Health Services Limited Company, Turkey) was injected as hyaluronic acid.

Intervention

Patients were placed in a lateral position with the shoulder to be injected on top and in internal rotation. Sterile conditions were provided. The 4-16 MHz frequency linear probe was placed along the long axis of the supraspinatus tendon. (Sonoscape E1 exp, 20537 Hamburg, Germany). The subacromial bursa was found to be a hypo-anechoic structure extending laterally to the place of attachment of the supraspinatus tendon. With a 25 gauge needle, the subacromial region between the deltoid and supraspinatus tendon was moved from lateral to medial with an in-plane approach. After the needle tip was seen in the subacromial bursa, 5 ml PRP, 2.4 ml HA, 2.5 ml PRP + 2.4 ml HA injectates were injected simultaneously under ultrasound guidance (Figure 2). All injections were performed by the same clinician. All injections were administered in the post-operative 15th day.

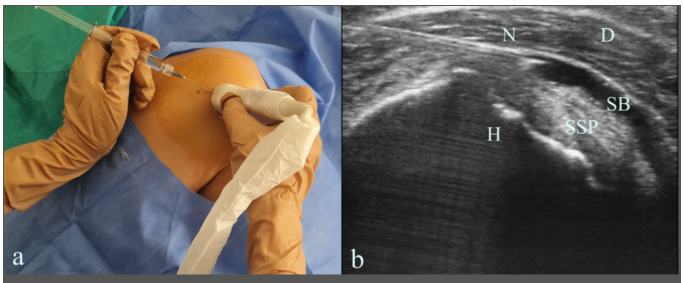

Figure 2. The position of the patient and the probe (a), who underwent subacromial injection with ultrasound guidance, sonographic view of the needle in the subacromial bursa (b)

N: needle, H: Humerus, D: Deltoid, SB: Subacromial Bursa, SSP: Supraspinatus

Patients were advised to rest and avoid difficult shoulder movements such as throwing, heavy lifting and rotating. Non-steroidal anti-inflammatory drugs were prohibited for 2 weeks. All patients were taken into rehabilitation program after injection. Phase 1 exercises were started on post-operative day 2. Phase 2 exercises were started after post-operative week 6. A simple arm sling was used for 1 month post-operatively.

Assessment of the intervention

Pain and functional status were evaluated using the VAS, ASES (American Shoulder Elbow Scores) and CMS (Constant-Murley Score) with follow-up visits before and at the first and sixth months after injection.

VAS (11) is a scale used to monitor pain severity. A bar or line is given as a scale on which the patient marks the severity of pain as a distance. The patient rates pain on a scale of 0 (none) to 10 (the strongest possible pain)

ASES (12) consists of 2 parts: the patient's self-assessment and the doctor's assessment. There are scored items in the patient's self-assessment part. These items are divided into 2: pain (1 item) and function (10 items). The pain question is scored on a scale (visual analogue scale) between 0 (no pain) and 10 (the worst pain ever). Questions related to function are related with 10-daily life activities. In addition, they are inquired about the occupational and sports activities. The scores from the pain and function subsections are converted into percentages, where each represents 50% of the final score. The scores in ASES range from 0 (no function) to 100 (normal function). The final score (possible maximum score 100) is calculated by multiplying the pain section's score (possible maximum score 10) by five (possible maximum score 50) and multiplying the cumulative activity score (possible maximum score 30) by 5/3 (possible maximum score 50).

CMS is a 100-point scale consisting of a number of individual parameters (13).

The test is divided into 4 sub-scales: pain (15 points), daily life activities (20 points), strength (25 points) and shoulder joint range of motion related to flexion, external rotation, abduction and internal rotation (40 points).

A higher score corresponds to a higher quality of function. The subjective findings of the participants (pain severity, daily life activity) constitute 35 points and the objective measurements constitute the remaining 65 points.

Statistical Analysis

The research data were evaluated using SPSS 21.0 statistical program. The suitability of continuous variables to normal distribution was investigated using visual (histograms and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). For the descriptive statistics of the study, mean and standard deviation were used for the data suitable for the normal distribution, and median, minimum and maximum were used for the data not suitable for the normal distribution. Mann Whitney U Test or Kruskal Wallis Variance Analysis was used to compare the continuous variables that did not have parametric properties in independent groups, Wilcoxon Test or Friedman Test was used to compare the continuous variables that did not have parametric properties in dependent groups. For statistical significance, the condition that the p value is determined to be less than 0.05 was sought.

RESULTS

Demographic features of the patients are shown in the table (Table 1). The results of PRP, HA and combined injections applied for 225 patients (142 female, 83 male) who underwent arthroscopic repairs due to rotator cuff tear were evaluated.

Table 1. Demographic and clinical characteristics of the patients

		n	%
Gender	**Female**	142	63,1
	Male	83	36,9
Age (*mean±SD*)		225	61,3±10
Side	**Left**	76	33,8
	Right	149	66,2
VAS score *median(min-maks)(post-operative 2 weeks)*		225	6 (3-9)
ASES score *median(min-maks) (post-operative 2 weeks)*		225	28,3 (6,6-60)
CMS score *median(min-maks) (post-operative 2 weeks)*		225	41 (30-63)

The results of 75 patients who underwent PRP after arthroscopic repair, 75 patients who underwent HA, 75 patients who underwent combined PRP+HA were evaluated with VAS, ASES and CMS scores before injection, in the first month after injection and in the sixth month after injection.

In all 3 groups (PRP, HA ve PRP+HA), VAS scores were significantly lower at the first and sixth months after injection than before injection (respectively $p<0.001$, $p<0.001$, $p<0.001$), and CMS and ASES scores were significantly hig–

her at the first and sixth months after injection than before injection (respectively p<0.001, p<0.001, p<0.001).

VAS scores in the first month were significantly lower in PRP and PRP+HA groups than the HA group (p=0.006). ASES and CMS scores in the first month were significantly higher in PRP+HA group than HA and PRP groups (respectively p<0.001, p<0.001) (Table 2).

Table 2. Comparison of VAS, ASES, CMS scores of the groups at the 1st month after the procedure

	PRP group		PRP+HA combined group		HA group		p
	Mean±SD	Medium (min-max)	Mean±SD	Medium (min-max)	Mean±SD	Medium (min-max)	
ASES [1, 3]	60,9±11,1	60 (38,3-86,6)	69 ±11	70 (40-95)	58,6±9,2	60 (38,3-76,6)	**<0,001***
VAS [2, 3]	2,8±1,1	3 (0-6)	2,7±1,6	3 (0-7)	3,3±1,2	3 (1-7)	**0,006***
CMS [1, 3]	70,3±8,8	70 (50-89)	78,6±9,2	80 (58-92)	70±7,4	70 (56 -88)	**<0,001***

*Kruskal-Wallis H test

[1] *A statistically significant difference was found between PRP and PRP+HA groups*

[2] *A statistically significant difference was found between PRP and HA groups*

[3] *A statistically significant difference was found between HA and PRP+HA groups*

VAS scores in the sixth month were significantly lower in PRP+HA group than the HA and PRP groups (p<0.001). ASES and CMS scores in the sixth month were significantly higher in PRP+HA group than the HA and PRP groups (respectively p<0.001, p<0.001) (Table 3).

Table 3. Comparison of VAS, ASES, CMS scores of the groups at the 6th months after the procedure

	PRP group		PRP+HA combined group		HA group		p
	Mean±SD	Medium (min-max)	Mean±SD	Medium (min-max)	Mean±SD	Medium (min-max)	
ASES [1, 2]	71,6±10,7	71,6 (51,6-90)	84,5±9,3	86,6 (56,6-100)	71,6±10,1	71,6 (40-91,6)	**<0,001***
VAS [1, 2]	2,6±,9	3 (1-5)	1,9±1,4	2 (0-5)	2,6±1,3	2 (0-5)	**<0,001***
CMS [1, 2]	80,9±7,2	81 (58-93)	90,1±3,8	91 (79-95)	81,4±6,9	83 (63-93)	**<0,001***

*Kruskal-Wallis H test

[1] *A statistically significant difference was found between PRP and PRP+HA groups*

[2] *A statistically significant difference was found between HA and PRP+HA groups*

DISCUSSION

We found that ultrasound-guided combined PRP and HA injection after arthroscopic rotator cuff repair had more favourable effects on pain and function than single PRP or HA applications. A successful rotator cuff tear repair is possible with the healing of the repaired head from tendon to bone. Tendon-to-bone healing is a repair process consisting of three phases consisting of inflammation, proliferation and remodelling. Growth factors and bioactive molecules in PRP are effective in all stages that potentially increase the tendon healing process locally at the site of intervention, including proliferation, migration, cell differentiation and angiogenesis (14). HA acts as a target for the inflammatory and proliferative phases in the three-phase tendon-to-bone healing process. The anti-inflammatory effects of HA accelerate tendon-to-bone healing in rotator cuff repair (15). HA also increased biomechanical strength in an animal model by increasing chondroid formation and tendon maturation at the tendon-bone interface (16). We believe that combined PRP and HA injection will support all phases of tendon healing and affect postoperative healing, recovery of function and pain process.

The effects of PRP on rotator cuff repair have been extensively studied. Although good clinical results of PRP applied after arthroscopic repair have been reported (17-19), a number of systematic reviews and meta-analyses have shown that PRP applied during rotator cuff repair did not significantly improve clinical results (20-23). The discrepancy between clinical results may be due to differences in tear size (massive, full, partial), tear type (interstitial, bursal, on the articular face), symptom duration (subacute, chronic), PRP application time (intraoperative-postoperative), PRP application interval, PRP application technique (blind injection, ultrasound guidance). In our study, all injections were administered in the post-operative 15th day under ultrasound-guidance. Early administration might have affected the ultrasonographic image due to the inflammation and oedema associated with surgery and played a role in the effectiveness of the procedure. Late application would have caused delay for repair process of tendon healing in proliferation phase. We believe that the proper timing after surgery can increase the effectiveness of the procedure. A single session application provided better control in terms of follow-up of the patients. Repeated injection sessions could have dis–

rupted the compliance of the patients and might have necessitated exclusion from follow-up. By using high volume PRP (5 cc) and a high viscosity HA preparation (48 mg 2%), we aimed to provide maximum efficacy with a single injection in a single session.

There are a limited number of studies investigating the role of various biological agents such as HA in rotator cuff tendon healing. In studies that have shown positive effects, it has been shown that there is functional well-being in the early postoperative period (24). Oh et al. stated that antiadhesional efficacy of subacromial HA injection after arthroscopic rotator cuff repair was found to be short, although not statistically significant compared to the control group (25).

Previous studies have shown that various biological agents play an important role in rotator cuff tendon healing. In this study, the potential combined effect of these biological agents has been investigated. To date, a limited number of clinical trials have been conducted evaluating the effects of co-administration of a combined biological agent in a repaired rotator cuff tendon. Cai et al. stated that PRP and HA have shown better clinical results with combined administration in partial rotator cuff tears (26). Lee et al. suggested that the combined application of PRP and HA in knee osteoarthritis in a placebo-controlled canine model was superior and provided significantly better long-term cartilage protection (27). In an experimental study in rabbits, combined PRP and HA application was found to be more effective after arthroscopic rotator cuff tear repair (28).

The increased clinical and structural benefits of the HA and PRP combination may be related to both the specific properties of the conjugate and the duration of action in the joint. A randomized controlled clinical trial in which the significant effect of subacromial combined atelocollagen and HA application with cannula immediately after arthroscopic full-fold tear repair has been demonstrated in tendon repair (29). The combined application of HA and Type I atelocollagen has an effect on tendon healing by accelerating the progression to the remodelling phase.

The idea of applying biological materials that affect all 3 phases of the healing process after tendon repair is a very important approach to accelerate healing. The safe application of combined injectates is a new idea, and there is quite limited research on this method. In our study, we found that the combined PRP+ HA application was more effective in both pain relief and functional recovery in early and mid-term follow-ups. We did not observe any complications with the combined application. We wanted to emphasize that the combined treatment is effective by accelerating all stages of healing by affecting the inflammation and proliferation stages of tendon healing with the anti-inflammatory and anti-adhesive activity of HA. In this respect, we think that our study will make a significant contribution to the literature and will guide our routine practice during the postoperative recovery process.

The limitations of this study are the retrospective design that evaluates the early-to-mid-term follow-up results and not covering recurrent tears. Prospective controlled studies with a long follow-up period including recurrent tears will provide reliable data on this subject.

CONCLUSION

The combined application of injectates applied to accelerate postoperative recovery in rotator cuff tears undergoing arthroscopic repair is associated with better pain relief and functional recovery than single application (PRP or HA).

Ethics Committee Approval / Etik Komite Onayı

The approval for this study was obtained from Canakkale Onsekiz Mart University Faculty of Medicine Clinical Research Ethics Committee, Canakkale, Türkiye (Decision no:2022/156, Date: 14/12/2022).

Conflict of Interest / Çıkar Çatışması

The authors declared no conflicts of interest with respect to authorship and/or publication of the article.

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Author Contributions / Yazar Katkıları

Concept – DE,EE; Design - EE,DE; Supervision –EE; Materials–EE,DE Data Collection and/or Processing – DE,EE; Analysis and İnterpretation – EE,DE; Literature Review – EE; Writing manuscript – EE, DE ; Critical Reviews – EE,DE. All authors contributed to the final version of the manuscript and discussed the results and contributed to the final manuscript.

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