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International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine

10th Biennial ISAKOS Congress • June 7-11, 2015 • Lyon, France

Paper #77

Treatment of Epicondylitis by Ultrasound-Guided Local Injections of Autologous Conditioned Plasma (ACP®): A Double-Blind Placebo-Controlled Randomized Clinical Trial With 1-Year Follow-Up

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Summary:
In this prospective randomized study, two ultrasound-guided ACP injections were significantly no different compared to saline solution injections in the treatment of recent epicondylitis

Abstract:
INTRODUCTION
Local injections of corticosteroid are the standard treatment of epicondylitis despite their potential risk to impair the tendon healing process. Local injections of platelet-rich plasma (PRP) have been proposed to enhance tendon repair. Ultrasound guidance of intra-tendinous injections seems to optimize the technical procedure. The main objective of this study was to assess the efficacy of two local injections of PRP in the treatment of recent epicondylitis.

METHODS
A prospective double-blind randomized placebo-controlled trial was conducted during 2011-2012. Inclusion criteria were recent epicondylitis (pain=3 months), confirmed by MRI and/or ultrasound and informed consent. Exclusion criterion was previous corticosteroid infiltration. Two ultrasound-guided injections were performed at 4 weeks interval of either Autologous Conditioned Plasma (ACP, Arthrex) or saline solution. The evaluator was blinded to the treatment. The primary evaluation criterion was the relative improvement from baseline to 6 months in pain score. Secondary criteria were the assessment of pain (yes/no) on isometric contraction of the second radial and of the extensor digitorum communis, the Roles-Maudsley score (1 to 4), the proportion of asymptomatic patients (PS =1) at 6 and 12 months follow-up and the proportion of patients with persistent pain (PS>2) at 12 months follow-up. Based on a sample size calculation, 21 patients in each group were needed.

RESULTS
Fifty patients were included, 25 in each group, 34 men/16 women, mean age 47±9.2 years in the ACP group and 46.4 ±8.6 years in the control group. Six patients dropped out of the study between baseline and 6 months, 3 in each arm. At 6-month follow-up, no statistically significant difference was found between groups for mean relative improvement in pain (ACP:-63.2±22.4%, control:-69.7±25.1%, p=0.24). No statistically significant difference was found for the secondary criteria. In the two groups, the pain score decreased significantly between two consecutive visits from 6.8±0.8 (PRP) and 7±1 (control) at baseline to 2.5±1.6 (PRP) and 2.1±1.6 (control) at 6 months and 1.65 ±1.5 (PRP) and 1.8±2.1 (control) at 12 months. At 6-month, 34% of all patients were asymptomatic and 66% at 1-year. The proportion of patients with persistent pain at 12 months was 23.8% in both groups. No adverse-effect was observed.

CONCLUSION

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The therapeutic effect of two ultrasound-guided ACP injections for epicondylitis of recent evolution (= 3 months) was not significantly superior to injections of saline, in a prospective randomized double-blind study with 12-months follow-up. The similarly favorable outcome registered in both study groups, may be linked to a stimulating role of ultrasound-guided intra-tendinous injections ("prolotherapy") on the process of tendon repair.