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Original article

Short-term effects of high-intensity laser therapy on frozen shoulder: A prospective randomized control study

Sae Hoon Kim*, Yeon Ho Kim [1], Hwa-Ryeong Lee [2], Young Eun Choi [2]

Department of Orthopaedic Surgery, Seoul National University College of Medicine, Seoul National University Hospital, Seoul, Republic of Korea

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ABSTRACT

Background: Frozen shoulder, which is characterized by shoulder pain and limitation of the range of motion (ROM), is a common disorder. High-intensity laser therapy (HILT) was recently introduced in the musculoskeletal therapeutic field.
Objective: The objective of this study is to evaluate the clinical efficacy of HILT in patients with frozen shoulder.
Design: A prospective randomized controlled study.
Method: Patients with frozen shoulder were randomly divided into 2 groups: a HILT group ($n = 33$) and a placebo group ($n = 33$). The treatment was administered 3 times per week on alternate days for 3 weeks. For all patients, the visual analog scale (VAS) for pain, VAS for satisfaction, and passive ROM were measured at baseline and 3, 8, and 12 weeks after the treatment.
Results: The HILT group had a lower pain VAS score at 3 weeks (3.2 ± 1.7 vs. 4.3 ± 2.2, $p = 0.033$) and 8 weeks (2.2 ± 2.0 vs. 3.4 ± 2.7, $p = 0.042$), however, no statistically significant difference in the pain VAS was observed between the two groups at the final follow-up (12 weeks). No statistical difference in the ROM and the satisfaction VAS was observed between the 2 groups at serial follow-ups.
Conclusions: In management of frozen shoulder, HILT provided significant pain relief at 3 and 8 weeks, but not at the final follow-up time point. HILT is a noninvasive adjuvant treatment that can reduce pain in frozen shoulders. Further study is needed in order to optimize the dose and duration of HILT.

1. Introduction

Frozen shoulder is one of the most common causes of shoulder pain and disability, with a prevalence of 2–5% among the general population (Bunker, 1997; Hannafin and Chiaia, 2000; Lewis, 2015). It is characterized by shoulder pain and limitation in range of motion (ROM) (Neviaser and Hannafin, 2010). Many studies have attempted to determine the pathophysiology of frozen shoulder and the best treatment modality (Bunker et al., 2000; Uhthoff and Boileau, 2007; Tamai et al., 2014). Fibrosis and contracture of the joint capsule, preceded by synovitis are known symptoms of frozen shoulder. However, the initiator of synovitis remains unclear (Lewis, 2015).

Several approaches have been used successfully for management of frozen shoulder. These include medical treatment (Buchbinder et al., 2004), physical therapy and exercise (Griggs et al., 2000; Levine et al., 2007), intra-articular steroid injections (Ryans et al., 2005), hydraulic distension (Buchbinder and Green, 2004), blockade of the suprascapular nerve (Dahan et al., 2000), manipulation under anesthesia (Farrell et al., 2005), arthroscopic release (Le Lievre and Murrell, 2012), and skillful neglect (Diercks and Stevens, 2004). The main goal in all types of treatment of frozen shoulder is regaining the ROM and pain management. Traditionally, gentle passive stretching exercise with pain management is one of the basic treatment options (Griggs et al., 2000; Kivimaki et al., 2007; Levine et al., 2007; Marinko et al., 2011; Donatelli et al., 2014).

There are numerous adjuvant treatments to exercise therapy in order to help the patient regain ROM and restore function to the affected shoulder (Cheing et al., 2008; Chen et al., 2014; Desmeules et al., in press; Green et al., 2003; Guyver et al., 2014; Page et al., 2014a; Sun et al., 2001; Van der Heijden et al., 1999). Among adjuvant treatments, low-intensity lasers were employed in the early days of laser therapy and, recently, high-intensity laser therapy

* Corresponding author. Tel.: +82 (0)2 2072 3930, +82 (0)10 5230 0128 (mobile); fax: +82 (0)2 764 2718.
E-mail addresses: drjacobkim@gmail.com (S.H. Kim), nextverup@gmail.com (Y.H. Kim), irin0627@naver.com (H.-R. Lee), dmdms13@naver.com (Y.E. Choi).
[1] Tel.: +82 2 2072 2368; fax: +82 2 764 2718.
[2] Tel.: +82 2 2072 3930; fax: +82 2 764 2718.

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(HILT) has been introduced and used in musculoskeletal disorders (Santamato et al., 2009; Fiore et al., 2011; Štiglić-Rogoznica et al., 2011; Zati et al., 2012; Alayat et al., 2014; Dundar et al., in press; Kheshie et al., 2014). Currently, there is no universally accepted theory that explains the mechanism of the postulated laser effects (Knappe et al., 2004; Quinto-Su and Venugopalan, 2007; Oliveira et al., 2012). However, it is postulated that there are three types of laser tissue interaction that can be distinguished: photochemical effects, photothermal effects, and photomechanical/photoionizing effects (Knappe et al., 2004). In HILT, an Nd:YAG laser is employed. The laser has a wavelength of 1064 nm which causes minor and slow light absorption by chromophores and delivers radiation non-invasively to deep tissue to ensure treatment efficacy (Basford, 1995). In addition to having a higher power than low-intensity lasers, lasers used in HILT have a shorter laser emission time and a longer laser emission interval (low duty cycle). Therefore, a large amount of laser irradiation can be delivered to deep tissues (Zati and Valent, 2006; Santamato et al., 2009).

The primary purpose of this study was to compare the respective pain levels at different intervals between HILT and placebo control in patients with frozen shoulder using a prospective randomized comparison model. In addition, range of motion and satisfaction were also compared. The null hypothesis of the study was that pain levels would not differ between the two groups during follow-up at each time point.

2. Materials and methods

2.1. Inclusion and exclusion criteria

A prospective randomized controlled study was conducted after obtaining approval from the Institutional Review Board of the authors' institution (1303-020-471). Written informed consent was obtained from all patients participating in the study.

Sample size analysis was performed prior to the study based on the visual analogue scale (VAS) for pain, which was the primary outcome of the study. In our previous patients' data pool, the pain VAS of patients with frozen shoulder showed a normal distribution, with a standard deviation of 2. After setting the mean difference at a 1.5 scale (0.75, moderate to large effect size according to Cohen's d) in the experimental and control group, 29 subjects in each group were required to be able to reject the null hypothesis (power = 0.8, type I error = 0.05). Considering a dropout rate of 10%, a total of 66 patients were required.

The set criteria for inclusion was shoulder pain for at least 1 month prior to presentation at the clinic and limitation of passive movement of the shoulder joint compared to the contralateral asymptomatic shoulder (difference in forward flexion [FF]: 40°, external rotation at side [ER]: 20°, and internal rotation at back [IR]: 5 spine level). All patients underwent radiography (shoulder true anteroposterior view, 30° caudal tilt, and axial view) to rule out any bony abnormality, calcific tendinitis, and osteoarthritis. Patients with bilateral shoulder involvement, photoallergy, arthritic shoulder, calcific tendinitis, substantial trauma history, previous shoulder surgery, infection, rheumatoid arthritis, radiculopathy, and/or reflex sympathetic dystrophy were excluded from this study.

The patients were randomly (permuted-block randomization) allocated to either the HILT group or the placebo group (Fig. 1). Statistical analysis showed no difference in demographics between the groups (Table 1).

2.2. Treatment procedure

After allocation, the HILT group had 9 treatment sessions over 3 consecutive weeks (3 times per week on alternating days). The procedure was performed by a physical therapist with experience using a HILT machine (Hilthera®, Jeisys, Seoul, Korea). The device emits a wavelength of 1064 nm (Nd:YAG laser) and high-peak power (8000 W) laser for a short on time (120–150 μs), and provides enough thermal relaxation time to reduce the danger of burns.

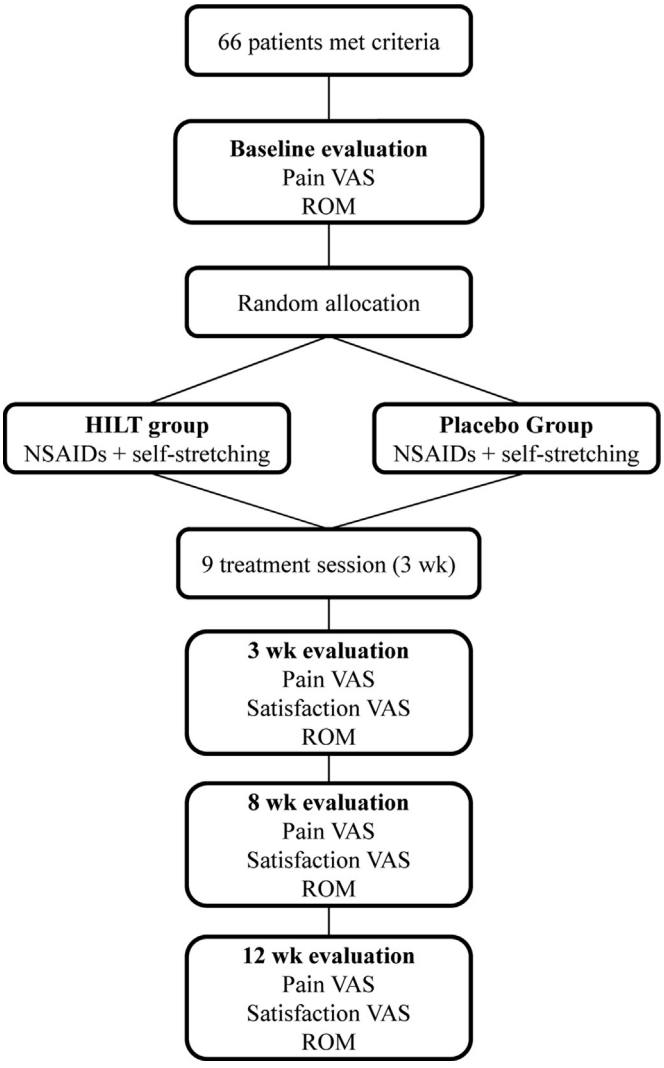

Fig. 1. Study design. VAS: visual analogue scale; ROM: range of motion; HILT: high-intensity laser therapy; NSAID: nonsteroidal anti-inflammatory drug.

The treatment consisted of 3 phases in each session (Fig. 2). The initial phase involved rapid manual scanning (100 cm^2/30 s) of the anterior joint line and posterior joint line of the shoulder with one shot of 850 mJ at a frequency of 30 Hz. The scanning was performed

Table 1
Demographics of both groups.

Demographics	HILT (n = 33)	Placebo (n = 33)	P value
Age (yr)	57.5 ± 8.7 (range, 41–71)	55.6 ± 7.9 (range, 34–72)	0.344
Gender (M:F)	28: 5	26: 7	0.523
Dominant side involvement	14	17	0.459
Duration of symptom (mo)	6.0 ± 4.9	4.6 ± 2.7	0.138
Diabetes mellitus	3	4	0.689

Data represent the mean ± SD or absolute number.
HILT = high-intensity laser therapy.