

Clinical Investigation

Prospective Randomized Comparison of the Effectiveness of Radiation Therapy and Local Steroid Injection for the Treatment of Plantar Fasciitis



Emine Canyilmaz, MD,* Fatih Canyilmaz, MD,[†] Ozlem Aynaci, MD,*
Fatma Colak, PhD,* Lasif Serdar, MD,* Gonca Hanedan Uslu, MD,[‡]
Osman Aynaci, MD,[§] and Adnan Yoney, MD*

*Department of Radiation Oncology, Faculty of Medicine, Karadeniz Technical University, Trabzon, Turkey; [†]Department of Orthopaedics and Traumatology, Yavuz Selim Bone Disease and Rehabilitation Hospital, Trabzon, Turkey; [‡]Department of Radiation Oncology, Kanuni Research and Education Hospital, Trabzon, Turkey; and [§]Department of Orthopaedics and Traumatology, Faculty of Medicine, Karadeniz Technical University, Trabzon, Turkey

Received Nov 9, 2014, and in revised form Feb 2, 2015. Accepted for publication Feb 3, 2015.

Summary

Based on retrospective and prospective data, radiation therapy is effective for the treatment of plantar fasciitis. Local injections of corticosteroids are used to control pain when other conservative treatments have failed. We performed a randomized, prospective trial to compare the effects of radiation therapy with those of local corticosteroid injections. We show the superiority of radiation therapy concerning pain relief and recommend radiation therapy for treating plantar fasciitis.

Purpose: The purpose of this study was to conduct a randomized trial of radiation therapy for plantar fasciitis and to compare radiation therapy with local steroid injections.

Methods and Materials: Between March 2013 and April 2014, 128 patients with plantar fasciitis were randomized to receive radiation therapy (total dose of 6.0 Gy applied in 6 fractions of 1.0 Gy three times a week) or local corticosteroid injections a 1 ml injection of 40 mg methylprednisolone and 0.5 ml 1% lidocaine under the guidance of palpation. The results were measured using a visual analog scale, a modified von Pannewitz scale, and a 5-level function score. The fundamental phase of the study was 3 months, with a follow-up period of up to 6 months.

Results: The median follow-up period for all patients was 12.5 months (range, 6.5-18.6 months). For the radiation therapy patients, the median follow-up period was 13 months (range, 6.5-18.5 months), whereas in the palpation-guided (PG) steroid injection arm, it was 12.1 months (range, 6.5-18.6 months). After 3 months, results in the radiation therapy arm were significantly superior to those in the PG steroid injection arm (visual analog scale, $P < .001$; modified von Pannewitz scale, $P < .001$; 5-level function score, $P < .001$). Requirements for a second treatment did not significantly differ between the 2 groups, but the time interval for the second treatment was significantly shorter in the PG steroid injection group ($P = .045$).

Reprint requests to: Emine Canyilmaz, MD, Department of Radiation Oncology, Faculty of Medicine, Karadeniz Technical University, Trabzon, Turkey. Tel: 904623775601; E-mail: dremocan@ktu.edu.tr

Conflict of interest: none.

Conclusion: This study confirms the superior analgesic effect of radiation therapy compared to mean PG steroid injection on plantar fasciitis for at least 6 months after treatment. © 2015 Elsevier Inc. All rights reserved.

Introduction

Plantar fasciitis is included in the heterogeneous group of degenerative benign diseases involved with osseous and tendinous structures of spurs. Approximately 15% of patients visiting a podiatrist's office complain of heel pain. In nearly 73% of cases, spur formation is radiologically detectable (1, 2). An abnormal pronation in the back foot due to increased body weight, varus deformity, or inappropriate shoes chronically stretch the plantar aponeurosis, causing microlesions that consequently result in chronic inflammation and formation of a bony heel spur (3). Bony heel spurs are more common in women than in men, most commonly between 40 and 49 years of age (4). Diagnosis is based on clinical examination, radiography, ultrasonography, scintigraphy, and magnetic resonance imaging (5).

Generally, plantar fasciitis can be effectively treated with a combination of conservative modalities such as nonsteroidal anti-inflammatory medications, steroid injections, phonophoresis, night splints, orthotic devices, shoe modifications, extracorporeal shock-wave therapy, and/or stretching exercises (6-9). These methods are used alone or in various combinations, and no single method clearly stands out as superior. However, 10% of patients do not respond to these treatments or combination of treatments and require surgery to relieve their symptoms (10).

Because of its known anti-inflammatory effects, radiation therapy has been used for at least 60 years. However, its exact mechanism remains unknown. The probable mechanisms of action of radiation therapy in nonmalignant disease are the anti-inflammatory effects of low-dosage ionizing radiation: modulation of E-selectin adhesion on endothelial cells, decreased leukocyte adhesion, apoptosis in endothelial cells and leukocytes are enhanced, and reduced oxidative burst in activated macrophages (11-13). The antiproliferative and immunomodulatory effects which play a role in irradiation with fraction doses higher than 2 Gy are likely less important (14). The reported results of plantar fasciitis radiation therapy vary from 50% to 70% of patients reporting complete pain relief (15, 16). Fractional doses of 0.5 to 1.0 Gy and total doses of 3 to 6 Gy are commonly applied for plantar fasciitis (17, 18).

Conservative treatment for plantar fasciitis frequently involves corticosteroid injection into the heel. Local corticosteroid injection is used to control pain when other conservative treatments have failed. Local corticosteroid injections have been used with ultrasonography-guided (UG), palpation-guided (PG), or scintigraphy-guided techniques. PG injection is an effective and common treatment. Some studies favor the UG injection method, whereas other

studies favor the PG or scintigraphy-guided techniques (19, 20). Kane et al (20) reported no statistical differences in outcome between patients who underwent UG and those who had PG injection. Likewise Yucel et al (5) reported no statistical differences in outcome between UG- and PG-injected patients.

To our knowledge, no previous single study has compared radiation therapy with PG steroid injections for plantar fasciitis. The aim of the present study was to compare radiation therapy with PG steroid injections for the conservative treatment of plantar fasciitis.

Methods and Materials

Patients

Between March 2013 and April 2014, 128 patients were enrolled in our study and randomized to 2 groups. Matching patients with the criteria defined in the study protocol were randomized to 2 groups by the same orthopedist (F.C.) according to their order of admission. Patient assessment by scoring their pain was performed after randomization by the same radiation oncologist (E.C.). Of these, 58 patients received a total dose of 6.0 Gy given in 3-weekly fractions of 1 Gy (radiation therapy arm); 2 patients received a total dose of 6.0 Gy given in 2-weekly fractions of 1 Gy; and 64 patients received an injection of 40 mg (1 ml) of methylprednisolone and 0.5 ml of 1% lidocaine in the painful heel spur, using palpation (PG steroid injection arm). The trial design and Consolidated Standards of Reporting Trials (CONSORT) flow chart is summarized in Figure 1 (21).

In this prospective, randomized trial, patients were included if they met the following criteria: (1) symptoms and clinical diagnosis of a painful heel spur; (2) duration of symptoms longer than 6 months; (3) radiologically proven heel spur; (4) Karnofsky performance status ≥ 70 ; and (5) age ≥ 40 years. Patients who had previous radiation therapy, trauma to the foot, severe psychiatric disorders, rheumatic and/or vascular diseases, or were pregnant or breastfeeding were excluded from the study. The use of analgesics before enrollment was not restricted. Patients were referred to our institution by orthopedists, and all had recurrent symptoms after previous conservative treatments.

All procedures were in accordance with the ethical standards of the Responsible Committee on Human Experimentation (institutional and national) and with the Helsinki Declaration of 1975 (revised in 2008). The trial was approved by the local ethics committee. All patients were informed about the side effects of both treatment regimens as well as the possible carcinogenic risk of radi-

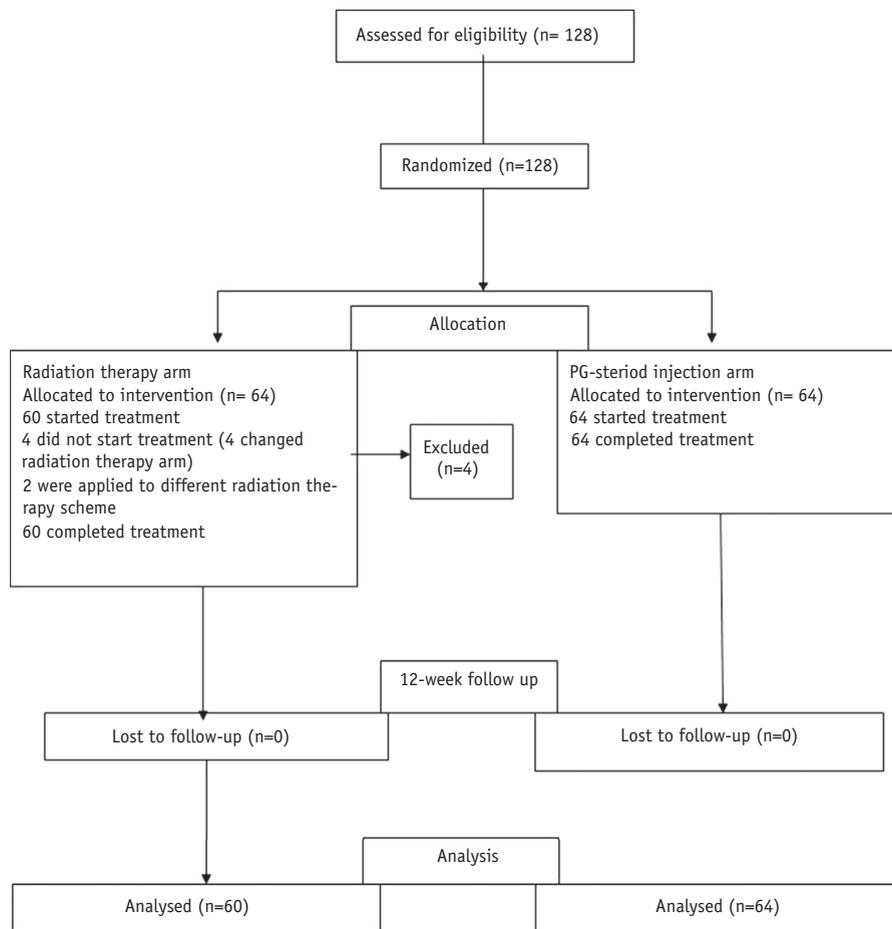


Fig. 1. Trial design and CONSORT flow chart. CONSORT = Consolidated Standards of Reporting Trials.

ation therapy. All patients provided written informed consent before entering the trial.

Treatment

Radiation therapy was performed using a 6-MV photon beam of a linear accelerator, applying lateral parallel opposing portals. All patients receiving radiation therapy underwent planning using a simulator, and each patient was put in a supine position with the affected leg immobilized. The same target volume definition was used for all patients in the radiation therapy arm. We used standardized treatment portals localized at the simulator. Standard treatment volume included the whole calcaneus, plantar fascia insertion, and the Achilles tendon insertion with appropriate fall off. The target volume consisted of the calcaneus and the region of the plantar aponeurosis (Fig. 2). The size varied from 7.0 × 8.0 cm to 9.0 × 10.0 cm. Radiation therapy fractions generally were administered 2 to 3 times per week, adding up to a whole-treatment time of 2 to 3 weeks. We chose to complete the scheme applied 3 times per week for 2 weeks in this study. This scheme was preferred because it is more suited to our clinic schedule.

Radiation therapy sessions were performed on Monday, Wednesday, and Friday (Fig. 2).

All PG steroid injection applications were conducted by a single orthopedist to avoid the effects of person-related differences on the results. PG steroid injections were applied to 79 heels in 68 plantar heel spur patients. Patients were put into a prone position with the ankle in a neutral position and knee flexed 90°. A 22-gauge 1.5-inch needle was connected to a 3-cm³ syringe filled with 40 mg of methylprednisolone (1 ml) mixed with 0.5 ml of 1% lidocaine. The painful area and medial tubercle of calcaneus were determined by palpation. The skin was sterilized with alcohol and iodine. The needle was inserted 2 to 3 cm anteromedially to the tenderest point in the inferior heel, near the calcaneal tuberosity, and moved toward the tenderest area.

All patients were followed in our clinic. Follow-up examinations were performed every 6 weeks by examining the patient in the clinic, mailing questionnaires to the patients, or interviewing the patient on the telephone.

Endpoint and statistics

The endpoint of this clinical trial was pain reduction. Pain levels were measured using a standardized questionnaire



Fig. 2. Simulator radiograph of radiation therapy for plantar fasciitis.

immediately before and after both treatment schemes, as well as during a follow-up visit 6 weeks after completion of treatment. All patients were followed for 6 months. In the case of an unfavorable response to radiation therapy or PG-steroid injection after 12 weeks, the patient was offered a second treatment series applying radiation therapy, steroid injection, or other treatment (eg, extracorporeal shock-wave therapy or ultrasound applications). The patient chose the treatment option. Regardless of the outcome of this second series, these patients remained in their treatment arms, with their results classified as unsatisfactory. The 6-month follow-up duration was chosen based on the retrospective experience that most beneficial effects are observed within 6 months.

Pain levels were determined using a graphic visual analog scale (VAS) with levels ranging from 0 (no pain) to 10 (maximum conceivable pain); a modified von Pannewitz pain score (where complete response [CR] = pain free; partial response [PR] = substantial pain improvement; minor response [MR] = pain improvement; and no change = pain unchanged or increased or worsening); and a 5-level function score (where excellent = 90-100 points; good = 70-85 points; fair = 40-69 points; and poor = 0-39 points) (3). Events were defined as the requirement for second treatment.

The compatibility of variables to normal distribution was investigated using visual (histogram and probability graphs) and analytical methods (One-Sample Kolmogorov-Smirnov). After examining the distribution of variables, Student *t* tests, Mann-Whitney U tests, χ^2 tests, and Fisher exact tests were used to compare data. Event-free probabilities were estimated and graphically represented as

time-to-event curves using the Kaplan-Meier method. The influence of cofactors was assessed using log-rank tests for censored survival data. Variables that were significant in the univariate analyses were entered into multivariate analyses.

In univariate analysis, disease and treatment associated with the dependent and independent variables were determined according to relevant published reports. In multivariate analysis, the significance in the univariate analysis or *P* value < .25 variables or likely to impact on the results reported in previous studies have shown that the variables were included in the analysis. *P* values of < .05 were considered statistically significant. SPSS version 13 software was used for all statistical analyses.

Results

A total of 128 patients were included in this trial. Four patients in the radiation therapy arm changed their mind after consenting, and they were included to PG steroid arm. We chose to complete the scheme applied 3 times per week for 2 weeks in this study. The treatment was 2 times per week for 3 weeks for 2 patients, and these patients were included. A total of 4 patients had to be excluded after randomization. Of these 124 patients, 60 were assigned to the radiation therapy arm, and 64 were assigned to the PG steroid injection arm. The trial design and CONSORT flow chart are summarized in Figure 1 (21).

Follow-up examinations were completed in October 2014; the median follow-up duration was 12.5 months (range, 6.5-18.5 months). The median follow-up duration for the radiation therapy arm was 13 months (range, 6.5-18.5 months), whereas for the PG steroid arm, it was 12.1 months (range, 6.5-18.6 months). Therefore, the durations of the follow-up period were not statistically different between the groups (*P* = .282).

The mean age of patients at enrollment was 52.6 years (range, 40-74 years of age) for the radiation therapy arm compared with 54.7 years (range, 40-74 years of age) for the PG steroid injection arm. Before therapy, we determined that patients in the 2 groups were comparable with respect to age, sex, body mass index (BMI), history of pain, limitations in their daily work and physical activity before treatment, treatment modalities used before radiation therapy or PG steroid injection, and performance of simple tests such as walking on their heels or toes. However, the mean duration of pain was significantly prolonged in the radiation therapy arm compared to the PG steroid arm (0.018). The patients' characteristics are summarized in Table 1.

Pretreatment VAS scores were higher in the radiation therapy arm. The pretreatment VAS score was 7.6 in the radiation therapy arm and 6.9 in the PG steroid arm. The pretreatment 5-level function score was 41.6 in the radiation therapy arm and 48.4 in the PG steroid arm. These differences were significantly different (*P* = .009 and

Table 1 Patient characteristics

Characteristic	Radiation therapy group	PG steroid group	P
No. of patients (%)	60 (48.4%)	64 (51.6%)	
Age (y)			.814
Mean	52.6 (40-74)	54.7 (40-74)	
Sex			.850
Female	46 (76.7%)	51 (79.7%)	
Male	14 (23.3%)	13 (20.3%)	
Body mass index			.336
Mean	34	33.1	
Range	21.9-48	21.3-43.8	
Occupation			.313
Standing	54 (90%)	61 (95.3%)	
Sitting	6 (10%)	3 (4.7%)	
Cigarette smoker			.886
Yes	9 (15%)	8 (12.5%)	
No	51 (85%)	56 (87.5%)	
No. of locations of spur (%)			.614
Plantar	41 (68.3%)	42 (65.6%)	
Dorsal	9 (15%)	11 (17.2%)	
Both	10 (16.7%)	11 (17.2%)	
Duration of pain (mo)			.018
Mean	18.6	14	
Range	6-48	6-48	
≤6 months	12 (20%)	22 (34.3%)	
>6 months	48 (80%)	42 (65.6%)	
Localization of pain			.413
Right	17 (28.3%)	21 (32.8%)	
Left	19 (31.7%)	22 (34.4%)	
Right = left	4 (6.7%)	5 (7.8%)	
Right > left	12 (20%)	9 (14.1%)	
Right < left	8 (13.3%)	7 (10.9%)	
Extension of pain			.169
None	17 (28.3%)	8 (12.5%)	
Sole of foot	14 (23.3%)	20 (31.3%)	
Calf	22 (36.7%)	26 (40.6%)	
Sole of foot and calf	7 (11.7%)	10 (15.6%)	
Start of pain			.545
Unknown	5 (8.3%)	6 (9.4%)	
Sudden	28 (46.7%)	26 (40.6%)	
Insidious	27 (45%)	32 (50%)	
Impact of pain on quality of life			.923
No impact	9 (15%)	10 (15.6%)	
Leisure	1 (1.7%)	6 (9.4%)	
Work	30 (50%)	24 (37.5%)	
Leisure and work	20 (33.3%)	24 (37.5%)	
Effects on daily work			.087
Able to work	40 (66.7%)	33 (51.6%)	
Unable to work	19 (31.7%)	29 (45.3%)	
No occupancy	1 (1.7%)	2 (3.1%)	
Effects on leisure or sports			.295
Unlimited	-	1 (1.6%)	
Limited	6 (10%)	7 (10.9%)	
Impossible	1 (1.7%)	4 (6.3%)	
No sports	53 (88.3%)	52 (81.3%)	

(continued)

Table 1 (continued)

Characteristic	Radiation therapy group	PG steroid group	P
Previous therapy			.246
Ice/heat	6 (10%)	7 (10.9%)	
Extracorporeal shock wave	12 (20%)	14 (21.9%)	
Oral medication	9 (15%)	8 (12.5%)	
Injection	21 (35%)	17 (26.6%)	
Insole support	9 (15%)	12 (18.7%)	
Ultrasound application	3 (5%)	6 (9.4%)	
Test			.883
Standing on toes	9 (15%)	8 (12.5%)	
Walking on toes	11 (18.3%)	10 (15.6%)	
Standing on heel	13 (21.7%)	15 (23.4%)	
Walking on heel	27 (45%)	31 (48.5%)	
VAS			.009
Mean	7.6	6.9	
Minimum	4	4	
Maximum	10	10	
Median	8	7	
Five-level function score			.001
Mean	41.6	48.4	
Minimum	20	30	
Maximum	70	85	
Median	40	50	

Abbreviations: PG = palpation guide; VAS = visual analog scale.

$P=.001$, respectively). These data are summarized in [Table 1](#).

The mean differences in VAS scores after 3 months was 2.8 in the radiation therapy arm and 4.6 in the PG steroid injection group. Therefore, patients in the radiation therapy arm had superior results ($P<.001$). A similar result was observed upon evaluation of the 5-level function scores: the mean difference was 78.3 in the radiation therapy arm and 60 in the PG steroid injection group ($P<.001$). Treatment outcome after radiation therapy was significantly better than treatment outcome after PG steroid injection ([Table 2](#)).

The mean differences in VAS scores after 6 months compared with the values before radiation therapy was 2.7 in the radiation therapy arm and 4.6 in the PG steroid injection group, resulting in superior results after radiation therapy ($P<.001$). A similar result was observed when evaluating the 5-level function: the mean difference amounted to 78.7 in the radiation therapy and 59 in the PG steroid injection group ($P<.001$) ([Table 2](#)).

Overall, 93 patients were event-free during the follow-up period. With a total number of 25% (31) events (second treatment requirement), 1-year event-free probability of radiation therapy arm was 95%, whereas the event-free probability in the PG steroid arm was 90.2% according to Kaplan-Meier analysis ([Fig. 3](#)). The time interval required for the second treatment ranged from 4 months to 15.2 months (mean, 9 months) after radiation therapy and

Table 2 Comparison of pain data after 3 months and 6 months

Measurement	Value	RT group for 3 month	PG steroid group for 3 month	<i>P</i>	RT group for 6 month	PG steroid group for 6 month	<i>P</i>			
VAS	Mean	2.8	4.6	<.001	2.7	4.6	<.001			
	Minimum	0	0		0	0				
	Maximum	9	10		10	10				
	Median	2	5		2	5				
Five-level function score	Mean	78.3	60	<.001	78.7	59	<.001			
	Minimum	30	6		35	0				
	Maximum	100	100		100	100				
	Median	85	57.5		80	60				
	Excellent	24 (40%)	10 (15.6%)		23 (38.3%)	10 (15.6%)				
	Good	24 (40%)	12 (18.8%)		23 (38.3%)	14 (21.9%)				
	Moderate	12 (20%)	32 (50%)		13 (21.7%)	29 (45.3%)				
	Poor	-	10 (15.6%)		1 (1.7)	11 (17.2%)				
	Modified von Pannewitz pain score	Complete response	23 (38.3%)		10 (15.6%)	<.001		21 (35%)	10 (15.6%)	<.001
	Partial response	17 (28.3%)	6 (9.4%)		20 (33.3%)			8 (12.5%)		
Minor response	11 (18.3%)	22 (34.4%)	12 (20%)	20 (31.3%)						
No change	8 (13.3%)	20 (31.3%)	6 (10%)	20 (31.3%)						
Increased pain	1 (1.7)	6 (9.4%)	1 (1.7%)	6 (9.4%)						

Abbreviations: PG = palpation guide; RT = radiation therapy; VAS = visual analog scale.

from 3.1 months to 14.1 months (mean, 6.4 months) after PG steroid injection. The time interval for the second treatment was significantly longer in the radiation therapy group than in the PG steroid injection group ($P=.045$).

In 1 patient in the PG steroid injection arm, acute infection was observed at the injection site. The patient was treated with antibiotic therapy. Acute side effects or long-term toxicity did not occur in the radiation therapy arm.

In univariate and multivariate analyses, age (≤ 50 or >50 years), sex, BMI, pain onset (≤ 6 months or >6 months), and treatment group were investigated as prognostic factors for pain relief. Results of the univariate analyses indicated that only age was considered a significant prognostic factor ($P=.015$). None of these factors was statistically significant in multivariate analyses. Results of univariate and multivariate analyses are shown in Table 3.

Discussion

Up to 10% of adults will suffer heel pain during their lifetime, and plantar fasciitis causes approximately 80% of all heel pain (22). Plantar fasciitis commonly presents as sharp, stinging pain. It develops upon initially straining the planter aponeurosis, followed by development of persistent inflammatory reactions (23). The pain is worse during weight-bearing activities such as walking, jogging, and lifting (24). Treatment of the heel spurs is primarily nonsurgical, including use of nonsteroidal anti-inflammatory drugs, ultrasound diathermy, physical therapy, night splinting, corticosteroid injection, and shock-wave therapy (6-9).

The aim of this study was to compare the analgesic effects of radiation therapy with that of PG steroid injections. Furthermore, this trial was randomized but not blinded to the patient or physician. There was a clear superiority of

radiation therapy treatment over PG steroid injection in terms of pain relief as well as quality of life. The improvement persisted for at least several months after therapy.

Corticosteroid injection in the heel for pain relief is considered if other conservative modalities fail. PG injection is an effective and common treatment (25). In all studies to date, regardless of the method used, VAS values are improved by steroid injection: 5.4 to 2.4 (range, 3.3-7.5 and 0.8-4.8, respectively) for PG steroid injection (26), 6.4 to 2.2 (range, 3.7-9.1 and 0.7-4.7, respectively) for PG steroid injection (5), and 59.7 to 18.2 (range, 48-71.5 and 5.5-30.9, respectively) for PG steroid injection (19). In another study, there were statistically significant differences between the preinjection and follow-up VAS values. Genç

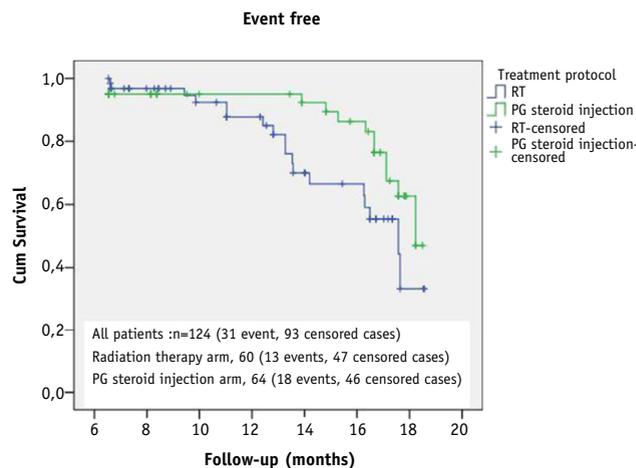


Fig. 3. Kaplan-Meier curve for pain control used for all patients. Cum = cumulative; PG = palpation guide; RT = radiation therapy.

Table 3 Univariate and multivariate analyses of prognostic factors

Variable	No. of patients	Univariate analyses		Multivariate analyses	
		Event-free probability (follow-up, mo)	<i>P</i>	Hazard Ratio (95% CI)	<i>P</i>
Age (y)					
≤50	52	22.5% (17.8)	.015	0.45 (0.20-1.02)	.053
>50	72	59% (18.6)			
Sex			.326		
Male	27	43% (18.6)		0.83 (0.27-2.56)	.751
Female	97	45.3% (18.5)			
BMI			.784		.948
<25	3	66.7% (17.6)		0.52 (0.05-5.47)	.584
25-29.9	26	33.7% (18.5)		0.56 (0.06-5.13)	.612
30-39.9	23	47% (18.6)		0.65 (0.06-7.18)	.725
>40	12	29.6% (18.5)			
Duration of pain (mo)					
≤6	36	16.8% (17.6)	.244	0.84 (0.33-2.09)	.702
>6	88	47.2% (18.6)			
Treatment scheme					
Radiation therapy	60	47% (18.5)	.065	1.89 (0.88-4.04)	.102
PG-steroid injection	64	33.3% (18.6)			

Abbreviations: BMI = body mass index; PG = palpation guide.

et al (25) found that with PG steroid injections, plantar fascia thickness and mean VAS values decreased significantly 6 months after steroid injection. In the present study, there were statistically significant differences between the preinjection and follow-up VAS values. A response rate of 59.4% was obtained at the 6-month follow-up in the PG steroid injection arm.

Application of radiation therapy in benign disorders has been used for nearly 100 years in central Europe. Patients with plantar fasciitis constitute an important proportion of patients undergoing radiation therapy. A recent randomized trial published by Niewald et al (18) compared a standard radiation therapy dose with a very low dose. In terms of pain relief and quality of life, those authors showed the superiority of the standard dose over the low dose. Thus, it can be assumed that administration of 6 Gy, as used in our study, is a sufficient dose. In the radiation therapy arm, response rates of 84.9% were obtained at the 6-month follow-up examination. Our results are comparable to previous data that reported response rates ranging from 65% to 100%. In another study that included 3472 patients, complete pain relief was noted in 53.2% of patients and partial pain relief in 30.9%, and 15.9% of patients were unchanged (27). In the current study, 35% of patients in the radiation therapy arm had complete responses, 33.3% had partial responses, 20% had minor responses, and 10% were unchanged. In the PG steroid injection arm, 15.6% of patients had complete responses, 12.5% had partial responses, 31.3% had minor responses, and 31.3% were unchanged. In the radiation therapy arm, we observed a significantly increased rate of patients who responded to treatment, which was significantly in favor of radiation therapy. Ott et al (28) reported mean VAS pain values 6 weeks after completion of their study in the 1.0-Gy treatment group was 28.9. With the use of standard dose, Niewald et al (18) found a mean difference in VAS scores of

−43.39 after 3 months compared with the values before radiation therapy. Moreover, another study reported the mean VAS pain value after completion of radiation therapy was 2.15 (29). In the current study, the mean VAS pain values 3 months after completion of the study treatment were 2.8 for radiation therapy arm and 4.6 for the PG steroid arm. These results are statistically significant in favor of radiation therapy.

Crawford et al (30) demonstrated that steroid injection relieved heel pain after 1 month, which did not persist at the 3-month follow-up. That study therefore concluded that steroid injections provide only short-term relief. In our study, there were no differences between the 2 arms regarding the need for secondary treatment. However, the duration until the second treatment was significantly shorter in the injection arm. PG injection might have been the cause of inaccurately guided injections. In addition, repeated corticosteroid injections tend to cause fat pad atrophy and plantar fascia rupture (31). However, in our study, no patients who underwent steroid injections experienced fat pad atrophy and plantar fascia rupture.

The possible carcinogenic risks of radiation therapy have been investigated in many trials, and it has been determined that the risk is not as high as originally feared (32, 33). Radiation therapy fields used to treat plantar fasciitis are too small and the total doses are much lower than those used for malignant disease. We observed no acute and or long-term side effects in this study in the radiation therapy arm.

In our analyses of prognostic factors that predict pain relief, age was determined to be statistically significant based on univariate analysis. No factors were significant in the multivariate analyses. Sex, BMI, pain onset ≤6 months versus >6 months, and treatment modality were not significant prognostic factors for pain relief. In a study by

Hermann et al (34), age, length of heel spur ≤ 6.5 mm, and onset of pain <12 months before radiation therapy were prognostic factors that affected pain relief. In another study, multivariate analyses indicated that age, prior treatment, and high-voltage photons were prognostic factors for pain relief (32).

Conclusions

Our prospective study provides high-level evidence that demonstrates radiation therapy yields pain relief in patients with plantar fasciitis compared to PG steroid injection.

References

1. Michetti ML, Jacobs SA. Calcaneal heel spurs: Etiology, treatment, and a new surgical approach. *J Foot Surg* 1983;22:234-239.
2. McCarthy DJ, Gorecki GE. The anatomical basis of inferior calcaneal lesions. A cryomicrotomy study. *J Am Podiatry Assoc* 1979;69:527-536.
3. Micke O, Ernst-Stecken A, Mücke R, et al. Calcaneodynia: Plantar and dorsal heel spur/heel spur syndrome. In: Seegenschmiedt MH, Makoski HB, Trott KR, et al., editors. *Radiotherapy for Nonmalignant Disorders*. Berlin: Springer; 2008:295-315.
4. Schroeder BM. Diagnosis and treatment of heel pain. *Am Fam Physician* 2002;65:1686-1688.
5. Yucel I, Yazici B, Degirmenci E, et al. Comparison of ultrasound-, palpation-, and scintigraphy-guided steroid injections in the treatment of plantar fasciitis. *Arch Orthop Trauma Surg* 2009;129:695-701.
6. Akfirat M, Sen C, Gunes T. Ultrasonographic appearance of the plantar fasciitis. *Clin Imaging* 2003;27:353-357.
7. Dasgupta B, Bowles J. Scintigraphic localisation of steroid injection site in plantar fasciitis. *Lancet* 1995;346:1400-1401.
8. Evans A. Podiatric medical applications of posterior night stretch splinting. *J Am Podiatr Med Assoc* 2001;91:356-360.
9. Hammer DS, Adam F, Kreutz A, et al. Ultrasonographic evaluation at 6-month follow-up of plantar fasciitis after extracorporeal shock wave therapy. *Arch Orthop Trauma Surg* 2005;125:6-9.
10. Barrett SL, Day SV. Endoscopic plantar fasciotomy: Two portal endoscopic surgical techniques—Clinical results of 65 procedures. *J Foot Ankle Surg* 1993;32:248-256.
11. Hildebrandt G, Seed MP, Freemantle CN, et al. Mechanisms of the antiinflammatory activity of low-dose radiation therapy. *Int J Radiat Biol* 1998;74:367-378.
12. Schae D, Marples B, Trott KG. The effect of low dose X irradiation on the oxidative burst in stimulated macrophages. *Int J Radiat Biol* 2002;78:567-576.
13. Hildebrandt G, Maggiorella L, Rödel F, et al. Mononuclear cell adhesion and cell adhesion molecule liberation after X-irradiation of activated endothelial cells in vitro. *Int J Radiat Biol* 2002;78:315-325.
14. Trott KR, Kamprad F. Radiobiological mechanism of antiinflammatory radiotherapy. *Radiother Oncol* 1999;51:197-203.
15. Miszczyk L, Jochymek B, Wozniak G. Retrospective evaluation of radiotherapy in plantar fasciitis. *Br J Radiol* 2007;80:829-834.
16. Seegenschmiedt MH, Keilholz L, Katalinic A, et al. Radiotherapy of plantar heel spurs: Indications, technique, clinical results at different dose concepts. *Strahlenther Onkol* 1996;172:376-383.
17. Heyd R, Tselis N, Ackermann H, et al. Radiation therapy for painful heel spurs: Results of a prospective randomized study. *Strahlenther Onkol* 2007;183:3-9.
18. Niewald M, Seegenschmiedt MH, Micke O, et al. Randomized, multicenter trial on the effect of radiation therapy on plantar fasciitis (painful heel spur) comparing a standard dose with a very low dose: Mature results after 12 months' follow-up. *Int J Radiat Oncol Biol Phys* 2012;84:455-462.
19. Kane D, Greaney T, Shanahan M, et al. The role of ultrasonography in the diagnosis and management of idiopathic plantar fasciitis. *Rheumatology (Oxford)* 2001;40:1002-1008.
20. Porter MD, Shadbolt B. Intralesional corticosteroid injection versus extracorporeal shock wave therapy for plantar fasciopathy. *Clin J Sport Med* 2005;15:119-124.
21. Rennie D. CONSORT revised—Improving the reporting of randomized trials. *JAMA* 2001;285:2006-2007.
22. Young C. In the clinic. Plantar fasciitis. *Ann Intern Med* 2012;156:1-16.
23. Schepsis AA, Leach RE, Gorzyca J. Plantar fasciitis. *Clin Orthop* 1991;266:185-196.
24. Barry LD, Barry AN, Chen Y. A retrospective study of standing gastrocnemius-soleus stretching versus night splinting in the treatment of plantar fasciitis. *J Foot Ankle Surg* 2002;41:221-227.
25. Genc H, Saracoglu M, Nacir B, et al. Long-term ultrasonographic follow-up of plantar fasciitis patients treated with steroid injection. *Joint Bone Spine* 2005;72:61-65.
26. Tsai WC, Hsu CC, Chen CP, et al. Plantar fasciitis treated with local steroid injection: Comparison between sonographic and palpation guidance. *J Clin Ultrasound* 2006;34:12-16.
27. Micke O, Seegenschmiedt MH. German Cooperative Group on Radiotherapy for Benign Diseases. Radiotherapy in painful heel spurs (plantar fasciitis). Results of a national patterns of care study. *Int J Radiat Oncol Biol Phys* 2004;58:828-843.
28. Ott OJ, Jeremias C, Gaipf US, et al. Radiotherapy for calcaneodynia. Results of a single center prospective randomized dose optimization trial. *Strahlenther Onkol* 2013;189:329-334.
29. Koca T, Aydın A, Sezen D, et al. Painful plantar heel spur treatment with Co-60 teletherapy: Factors influencing treatment outcome. *Springerplus* 2014;3:1-4.
30. Crawford F, Atkins D, Young P, et al. Steroid injection for heel pain: Evidence of short-term effectiveness. A randomized controlled trial. *Rheumatology (Oxford)* 1999;38:974-977.
31. Kane D, Greaney T, Bresnihan B, et al. Ultrasound guided injection of recalcitrant plantar fasciitis. *Ann Rheum Dis* 1998;57:383-384.
32. Muecke R, Micke O, Reichl B, et al. Demographic, clinical and treatment related predictors for event-free probability following low-dose radiotherapy for painful heel spurs—A retrospective multicenter study of 502 patients. *Acta Oncol* 2007;46:239-246.
33. Surenkok S, Dirican B, Beyzadeoğlu M, et al. Heel spur radiotherapy and radiation carcinogenesis risk estimation. *Radiat Med* 2006;24:573-576.
34. Hermann RM, Meyer A, Becker A, et al. Effect of field size and length of plantar spur on treatment outcome in radiation therapy of plantar fasciitis: The bigger the better? *Int J Radiat Oncol Biol Phys* 2013;87:1122-1128.