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Radiotherapy for calcaneodynia

Results of a single center prospective randomized dose optimization trial

Calcaneodynia commonly causes inferior heel pain and occurs in up to 10% of the population [4]. The condition affects active and sedentary adults of all ages. Plantar fasciitis is more likely to occur in obese people, who spend most of the day on their feet. Experts believe that the pain is mainly caused by acute or chronic injury to the origin of the plantar fascia from cumulative overload stress [1, 4]. Most interventions used to manage calcaneodynia have not been studied adequately; however, shoe inserts, stretching exercises, steroid injection, and custom-made night splints may be beneficial. Extracorporeal shock wave therapy may effectively treat a number of patients with chronic heel pain but is ineffective in others [36, 40]. Limited evidence suggests that casting or surgery may be beneficial when conservative measures fail [4].

For decades, radiotherapy has been successfully applied in the treatment of benign hyperproliferative and degenerative diseases [7, 8, 9, 18, 20] including calcaneodynia [11, 21], and encouraging results of approximately 13,000 patients had been published (see **Tab. 3**). Nevertheless, an optimal radiotherapy regimen still is not clear and under current discussion [30]. Fraction doses of 0.5–1.0 Gy and total doses of 3–6 Gy are generally accepted [11, 21]. Modulations of a plethora of immunological processes by low and intermediate doses of X-ray have been identified with preclinical in vitro and in vivo model systems during recent years [26]. A discontinuous dose dependency for the induction of an anti-inflammatory phenotype of immune cells has mostly been observed with a maximum effect in the dose range between 0.3 and 0.7 Gy [25]. The present prospective and randomized trial was initiated to determine the optimal single dose in terms of efficacy and radiation protection, as previously conducted for benign painful elbow syndrome [23].

Patients and methods

Between February 2006 and April 2010, a total of 499 consecutive patients with calcaneodynia were treated at Erlangen University Hospital. Of these, 20 refused study participation and 22 patients could not be included into the analysis because of incomplete data (**Fig. 1**). At the time of radiotherapy, the median age of the remaining 457 evaluable patients was 55 years (range 27–86 years). All patients participated in our comprehensive dose optimization trial with a total of more than 1,000 patients recruited. Informed consent was obtained from all patients. Additional information on patient and treatment characteristics may be found in **Tab. 1**.

Treatment

All patients received radiotherapy in orthovoltage technique (Siemens Stabilipan, 250 kV, 15 mA, 1 mm Cu-filter, focus–skin distance 40 cm) usually with a

Tab. 1 Patient and treatment characteristics

	0.5 Gy	1.0 Gy	p value
Cases [n/N (%)]	217/457 (47.5)	240/457 (52.5)	–
Gender [n/N (%)]			
Male	54/217 (25)	65/240 (27)	0.593
Female	163/217 (75)	175/240 (73)	
Lateralization [n/N (%)]			
Right shoulder	114/217 (53)	114/240 (48)	0.282
Left shoulder	103/217 (47)	126/240 (52)	
Pain duration [months ± SD]	12.7±17.5	13.0±21.1	0.788
Pretreatments [number ± SD]	2.5±1.3	2.5±1.2	0.938
Age [years ± SD]	57.3±11.9	54.4±11.0	0.022
RT series [n/N (%)]			
One	26/217 (12)	26/240 (11)	0.699
Two	191/217 (88)	214/240 (89)	
Total dose			
Median [Gy]	6.0	12.0	<0.001

SD standard deviation, RT radiotherapy.

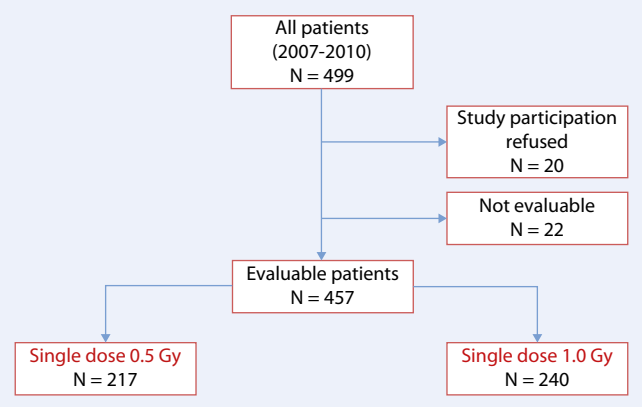

Fig. 1 ▲ Consort diagram

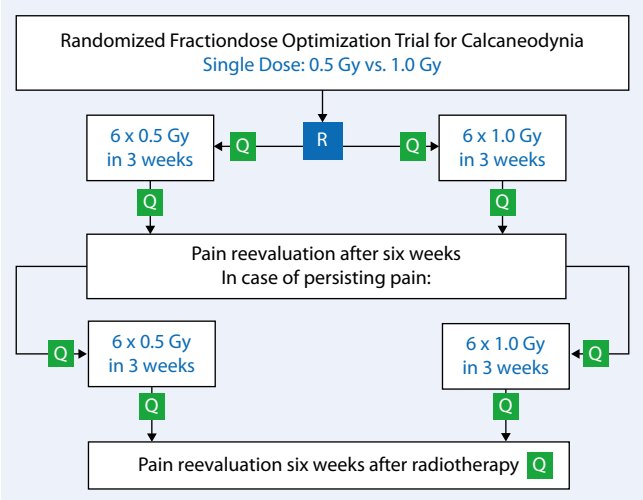

Fig. 2 ▶ Study design. *R* randomization, *Q* questionnaire

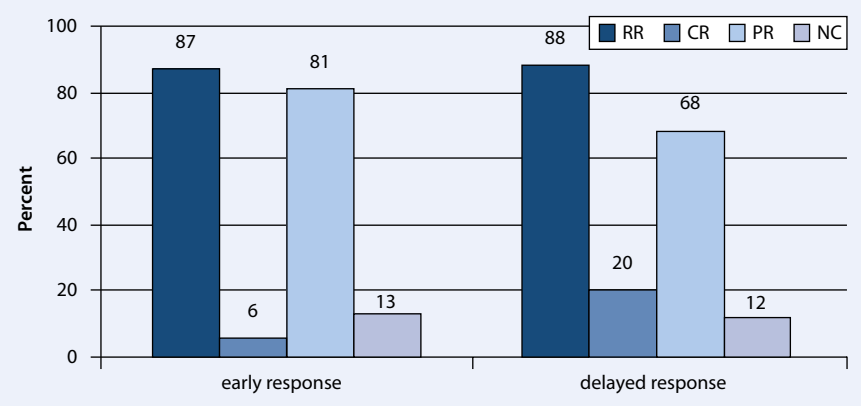

Fig. 3 ▲ Overall response rates based on the comprehensive pain score (*CPS*). *RR* response rate, *CR* complete response, *PR* partial response, *NC* no change

single field of 6×8 cm directly positioned on the plantar calcaneus. One radiotherapy series consisted of six single fractions delivered in 3 weeks with an interfractional radiation-free interval of at least 2 days. In case of no or insufficient partial remission of pain, 6 weeks after the end of the first series and second radiation series was performed (**Fig. 2**). In case of complete remission of pain after the first treatment, the second series was abandoned. Patients were randomly assigned to receive either single doses of 0.5 or 1.0 Gy throughout the complete treatment.

Endpoint and statistics

The endpoint of this clinical trial was pain reduction. Pain levels were measured with a standardized questionnaire immediately before and after each radiation series and during a follow-up visit 6 weeks after completion of radiotherapy. Pain level was determined using a graphical visual analogue scale (VAS) with levels from 0 (no pain) to 100 (maximum conceivable pain) and a modified von Pannewitz pain score [38] adapted from Seegenschmiedt and Keilholz [33]. With this score the treatment response was evaluated with regard to pain symptoms grouped into five categories (pain at strain, pain at night, persistent pain during daytime, pain at rest, and morning stiffness) and four grades (none: 0 points, mild: 1 point, moderate: 2 points, severe: 3 points). The points of the five categories were added to a comprehensive pain score result with values ranging from 0–15. Treatment results were judged as complete response (CR) with a score of 0 points, as partial response (PR) with a score >0 and better than the baseline score, and as no change (NC) with score values equal or higher than the baseline score.

Data management and statistics were carried out with IBM SPSS Statistics for MS Windows (SPSS Inc., Chicago, IL, USA), release 19. For statistical comparisons between groups the Mann–Whitney U test and Pearson's χ^2 test were used.

Results

The gender distribution of the 457 evaluated patients was 26% (119/457) male and 74% (338/457) female. In 50% (228/457) the right and in 50% (229/457) the left calcaneus has been involved. The mean pretherapeutic history of pain for all patients was 12.9±19.5 months. During the study, 89% of the patients (405/457) received two radiation series and 11% (52/457) just one because of CR. The evaluable 457 patients were randomly assigned in 47.5% (217/457) to the 0.5 Gy and in 52.5% (240/457) to the 1.0 Gy arm. With exception of a slightly older age in the 0.5 Gy arm (57.3±11.9 vs. 54.4±11.0; p=0.022) no significant differences regarding patients' characteristics were found (**Tab. 1**).

The mean VAS pain values immediately before treatment initiation (baseline values) for the 0.5 and 1.0 Gy groups were 65.5±22.1 and 64.0±20.5 (p=0.188). The mean baseline comprehensive pain score was rated with 10.1±2.7 and 10.0±3.0 (p=0.783), respectively. The mean VAS pain values immediately after the last radiation fraction (early response) for the 0.5 and 1.0 Gy groups were 34.8±24.7 and 39.0±26.3 (p=0.122). The mean compre-

hensive pain score was rated with 5.6±3.7 and 6.0±3.9 (p=0.336), respectively. The mean VAS pain values 6 weeks after completion of the study treatment (delayed response) for the 0.5 and 1.0 Gy groups were 25.1±26.8 and 28.9±26.8 (p=0.156). The mean comprehensive pain score was rated with 4.0±4.1 and 4.3±3.6 (p=0.257), respectively.

The overall response rate (CR+PR) for all patients was 87% for early response and slightly increased to 88% for delayed response (see **Fig. 3**). In detail, CR, PR, and NC rates were 6%, 81%, 13%, and 20%, 68%, and 12%, respectively (p<0.001).

The overall response rate for patients with 0.5 Gy was 86% for early response and 86% for delayed response. In detail, CR, PR, and NC rates were 8%, 78%, 14%, and 25%, 62%, and 14%, respectively. The overall response rate for patients with 1.0 Gy was 87% for early response and increased to 90% for delayed response. In detail, CR, PR, and NC rates were 3%, 83%, 13%, and 15%, 75%, and 10%, respectively. No statistically significant differences between the two single dose trial arms for early (p=0.216) and delayed response (p=0.080) were found. In summary, in both the VAS and CPS analysis no significant differences regarding early and delayed responses were found between the two trial arms (**Tab. 2** and **Fig. 4**). Due to the low dose applied, no severe side effects were observed in the 457 patients evaluated.

Discussion

Between 1924 and 2012 the results after radiotherapy for calcaneodynia have been reported in more than 13,000 patients (**Tab. 3**). The mean overall response rate (CR+PR) of all published patients was 85% (range 61–100%) and is in agreement with the results of our trial with early and delayed response rates of 87 and 88%, respectively. It is an important finding of our trial that the response rate (especially CR) significantly improved (**Fig. 3**) from the end of the treatment (early response) to the follow-up examination 6 weeks after completion of radiotherapy (delayed response). In the historical collective (**Tab. 3**) the mean overall complete and partial re-

Abstract · Zusammenfassung

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Radiotherapy for calcaneodynia. Results of a single center prospective randomized dose optimization trial

Abstract

Purpose. The aim of this work was to compare the efficacy of two different dose fractionation schedules for radiotherapy of patients with calcaneodynia.

Patients and methods. Between February 2006 and April 2010, 457 consecutive evaluable patients were recruited for this prospective randomized trial. All patients received radiotherapy using the orthovoltage technique. One radiotherapy series consisted of 6 single fractions/3 weeks. In case of insufficient remission of pain after 6 weeks a second radiation series was performed. Patients were randomly assigned to receive either single doses of 0.5 or 1.0 Gy. Endpoint was pain reduction. Pain was measured before, immediately after, and 6 weeks after radiotherapy using a visual analogue scale (VAS) and a comprehensive pain score (CPS).

Results. The overall response rate for all patients was 87% directly after and 88% 6 weeks after radiotherapy. The mean VAS values before, immediately after, and 6 weeks after treatment for the 0.5 and 1.0 Gy groups were 65.5±22.1 and 64.0±20.5 (p=0.188), 34.8±24.7 and 39.0±26.3 (p=0.122), and 25.1±26.8 and 28.9±26.8 (p=0.156), respectively. The mean CPS before, immediately after, and 6 weeks after treatment was 10.1±2.7 and 10.0±3.0 (p=0.783), 5.6±3.7 and 6.0±3.9 (p=0.336), 4.0±4.1 and 4.3±3.6 (p=0.257), respectively. No statistically significant differences between the two single dose trial arms for early (p=0.216) and delayed response (p=0.080) were found.

Conclusion. Radiotherapy is an effective treatment option for the management of calcaneodynia. For radiation protection reasons, the dose for a radiotherapy series is recommended not to exceed 3–6 Gy.

Keywords

Calcaneodynia · Pain · Radiotherapy · Plantar fasciitis · Randomized trial

Strahlentherapie bei Calcaneodynie. Ergebnisse einer monoinstitutionalen, prospektiven, randomisierten Dosisoptimierungsstudie

Zusammenfassung

Ziel. Vergleich der Effektivität zweier Dosis-Fraktionierungskonzepte bei der Strahlentherapie von Patienten mit Calcaneodynie.

Patienten und Methoden. Zwischen 2006 und 2010 wurden 457 auswertbare Patienten in diese prospektive und randomisierte Studie eingeschlossen. Alle Patienten erhielten die Bestrahlung in Orthovolt-Technik. Eine Bestrahlungsserie bestand aus 6 Einzelfraktionen/3 Wochen. Bei ungenügendem Ansprechen der Schmerzsymptomatik nach 6 Wochen wurde eine zweite Bestrahlungsserie durchgeführt. Die Patienten wurden auf die beiden Studienarme randomisiert und erhielten je nach Ergebnis Einzeldosen von 0,5 bzw. 1,0 Gy. Der Endpunkt der vorliegenden Analyse war die Schmerzreduktion. Die Schmerzintensität wurde vor, unmittelbar nach sowie 6 Wochen nach der Strahlentherapie mittels visueller Analogskala (VAS) und einem umfassenden Schmerzscore (CPS) gemessen.

Ergebnisse. Die Gesamtansprechrate aller Patienten betrug 87% direkt nach und 88% 6 Wochen nach Bestrahlung. Die mittleren VAS-Werte vor, nach und 6 Wochen nach der Strahlentherapie waren für die 0,5-Gy- und die 1,0-Gy-Gruppe jeweils 65,5±22,1 und 64,0±20,5 (p=0,188), 34,8±24,7 und 39,0±26,3 (p=0,122) sowie 25,1±26,8 und 28,9±26,8 (p=0,156). Die mittleren Schmerzscore-Werte betrugen vor, nach und 6 Wochen nach der Strahlentherapie jeweils 10,1±2,7 und 10,0±3,0 (p=0,783), 5,6±3,7 und 6,0±3,9 (p=0,336) sowie 4,0±4,1 und 4,3±3,6 (p=0,257). Es konnten keine statistisch signifikanten Unterschiede im Therapieansprechen (CPS) zwischen den beiden Studienarmen unmittelbar nach (p=0,216) und 6 Wochen nach Strahlentherapie (p=0,080) festgestellt werden.

Schlussfolgerung. Die Strahlentherapie ist eine effektive Maßnahme in der Behandlung der Calcaneodynie. Aus Strahlenschutzgründen wird empfohlen, eine Gesamtdosis von 3–6 Gy pro Bestrahlungsserie nicht zu überschreiten.

Schlüsselwörter

Calcaneodynie · Schmerz · Strahlentherapie · Fasciitis plantaris · Randomisierte Studie

Tab. 2 Response rates and single fraction dose

	Cases[a] [n]	RR [%]	CR [%]	PR [%]	NC [%]	p value
Direct after RT						
0.5 Gy	189	86	8	78	14	0.216
1.0 Gy	204	87	4	83	13	
6 weeks after RT						
0.5 Gy	102	86	24	62	14	0.080
1.0 Gy	110	90	15	75	10	

RR response rate, CR complete response, PR partial response, NC no change. [a]Number of cases accessible for evaluation.

Tab. 3 Results after radiotherapy for calcaneodynia

Author [Reference]	Year	Cases (n)	RR [%]	CR [%]	PR [%]	NC [%]
Richarz [24]	1924	5	100	80	20	–
von Pannewitz [39]	1933	88	92	–	–	–
Cocchi [3]	1943	6	83	33	50	–
Mitrov and Harbov [16]	1967	1,520	88	50	38	12
Zschache [41]	1972	49	86	12	74	14
Mantell [13]	1978	26	65	53	12	35
Basche et al. [2]	1980	102	90	32	58	10
Sautter-Bihl et al. [28]	1993	15	80	60	20	20
Schäfer et al. [29]	1995	21	67	58	8	33
Seegenschmiedt et al. [34]	1996	72 98	100 95	67 72	33 23	– 5
Oehler and Hentschel [22]	2000	258	88	81	7	12
Schreiber and Böhnlein [32]	2000	87	86	67	29	14
Glatzel and Bäsecke [5]	2001	161	89	63	26	11
Mücke et al. [17]	2003	136	90	75	15	10
Micke and Seegenschmiedt [14]	2004	7,947	70	–	–	–
Schneider et al. [31]	2004	161	89	18	64	18
Heyd et al. [10]	2006	305	85	44	41	15
Surenkok et al. [35]	2006	20	100	–	–	–
Miszczyk et al. [15]	2007	623	86	48	38	14
Mücke et al. [19]	2007	502	61	–	–	–
Heyd et al. [11]	2007	130	84	51	33	16
Hajtmanová et al. [6]	2010	273	75	–	–	–
Ott et al. (this study)	2012	456	88	20	68	12
Summary/average		13,061	85	52	35	16

RR response rate, CR complete response, PR partial response, NC no change.

sponse rates were 52% (range 12–80%) and 35% (range 7–74%) which is different from our trial (early response 6% and 81%; delayed response 20% and 68%), which may be a tribute to the more standardized, strict and transparent rating of CR and PR rates on the basis of the CPS in our trial compared the majority of the publications from the past.

The comparison between the two study arms (0.5 vs. 1.0 Gy) of our randomized trial resulted in no significant differences considering the analysis with the VAS and the CPS at any time, which supports the biological hypothesis that single doses of 0.5 Gy are equally effective compared to single doses of at least 1.0 Gy [25].

Heyd et al. [11] reported on a comparable trial on 130 patients with painful heal spurs that were randomized to receive either single doses of 0.5 Gy to a total dose of 3.0 Gy/3 weeks (low-dose group; n=65) or single doses of 1.0 Gy to a total dose of 6.0 Gy/3 weeks (high-dose group; n=65). In 18% (24/130) of cases of the high-dose group and 13% (17/130) of cases of the low-dose group, a second radiotherapy series was given. At the 6-month follow-up, radiotherapy led to a highly significant reduction of pain symptoms in both groups. The comparison between the trial arms revealed no statistically significant difference of response to radiotherapy between both groups.

Mücke et al. [19] reported on a retrospective analysis of 502 cases with calcaneodynia after a median follow-up of 26 months. In 341 patients (68%), radiotherapy was performed twice a week with a single 6–10 MV photon field, in 161 patients (32%) three times a week with a single 175-kV x-ray field. With 6 MV, ten fractions of 0.5 Gy were applied in 100 patients, five to six fractions of 1.0 Gy were applied in 140 patients. With 10 MV, five fractions of 1.0 Gy were applied in 101 patients. In all patients treated with 175 kV x-rays, six fractions of 1.0 Gy were given. Patients treated with a second RT series received the same single and total dose as in the first RT series. Pain measurement was performed with the von Pannewitz score [38] and 61% of the treated patients were still satisfied with the therapeutic effect of the radiation treatment. In an univariate subgroup analysis to determine prognostic factors for pain control single doses of 0.5 Gy led to better event-free probability compared to 1.0 Gy (86.2% vs. 55.1%; p=0.009). But the advantage for single doses of 0.5 Gy remained no longer significant in multivariate analysis.

Another analysis of Seegenschmiedt et al. [34] compared the clinical effect of three different dose concepts in the radiotherapeutic treatment of painful heel spurs: group A (n=72) received 12 Gy total radiation dose in 3 fractions/week and 2 series (6×1 Gy/series) separated by 6 weeks; group B (n=98) received 3 Gy total radiation dose in 10 fractions of 0.3 Gy (n=50) or 10 fractions of 5 Gy (n=48) with conventional fractionation in 1 series. Radiotherapy was very effective: at last follow-up 67% (group A) and 71% (group B) remained completely free of pain. The CR rate was not different between the 3 radiation concepts. However, significant differences were observed with regard to PR rates. More favorable results were achieved in patients receiving a 5 Gy or 12 Gy total dose, while patients with a 3 Gy total dose had significantly worse results. Compared to our trial, the much higher CR rates (67–71% vs. 20%) raise expectations that the rate

Fig. 4 ▲ Visual analogue scale (*VAS*) results and single fraction dose. *RT* radiotherapy

of complete responders may further increase over time.

Although an adequately powered placebo-controlled trial is lacking to formally prove the efficacy of the radiotherapy of selected benign degenerative painful diseases and may perhaps never be performed due to ethical reasons, the huge body of evidence (see **Tab. 3**) demonstrates low-dose radiotherapy as a very effective tool in the symptomatic treatment of calcaneodynia, especially in patients who did not persistently benefit from other non-radiation conservative therapies. Despite tumor induction by ionizing radiation still being critically discussed [37], no significant numbers of patients with radiotherapy-associated tumors have been published. Nevertheless, additional civilizatoric ionizing irradiation should be avoided whenever possible. Therefore, we currently prefer to use single doses of 0.5 Gy according to the results of our trial which did not reveal any disadvantage for the patients treated with the lower dose protocol at any time of evaluation. Of course, longer follow-up data is necessary and will be presented to provide a conclusive recommendation for the radiation treatment of calcaneodynia. From the radiation protection view, together with Heyd et al. [11] our trial still supports the hypothesis that radiotherapy with lower single doses of 0.5 Gy might be equally effective to single doses of 1.0 by substantially decreasing the potential radiation risk. Preclinical experiments have proven that predominantly 0.5 Gy of ionizing irradiation is superior to 1.0 Gy in inducing an anti-inflammatory phenotype of endothelial cells, granulocytes, and macrophages [12, 27]. Current work aims to identify how the immune status in the peripheral blood of patients treated with 0.5 Gy in comparison to 1.0 Gy is modulated by low dose radiation therapy. The radiation dose with the highest efficacy for induction of anti-inflammation and pain relief in patients with calcaneodynia, concomitant with the most possible dose reduction, should be identified in the future.

Conclusion

On the basis of approximately 13,000 retro- and prospectively published patients with calcaneodynia, radiotherapy proved to be a highly effective option for pain control. In our prospective randomized trial in both the VAS and CPS analysis, no significant differences between the two trial arms was revealed, which supports the biological hypothesis that single doses of 0.5 Gy are at least as effective compared to 1.0 Gy. Longer follow-up is necessary to provide a conclusive dose recommendation for the radiation treatment of calcaneodynia, and until then both single doses of 0.5 and 1.0 Gy and total doses of 3–6 Gy per series should be regarded as the dose standard.

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Conflict of interest. On behalf of all authors, the corresponding author states that there are no conflicts of interest.

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