



Long-term effect and prognostic factors of a low-dose radiotherapy of painful plantar calcaneal spurs

A retrospective unicenter study

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Abstract

Purpose To estimate the long-term effect of low-dose radiotherapy of painful plantar calcaneal spurs, and to verify possible prognostic factors.

Patients and methods In this retrospective unicenter study, electronic patient files of patients with painful plantar calcaneal spurs treated with low-dose radiotherapy between July 2009 and February 2020 were reviewed. The low-dose radiotherapy consisted of a total dose of 3.0 Gy given with a fraction dose of 0.5 Gy three times a week. The pain reduction was estimated using a patient questionnaire with a visual analogue scale. Kaplan–Meier statistics and Cox regression analysis were used for the statistical analysis.

Results Altogether, 864 heels of 666 patients were reviewed. The probability of an insufficient pain control 10 years after low-dose radiotherapy was 45.9% (95% confidence interval 39.4–52.4%) in the subset of patients with a minimum follow-up of 3 months (582 heels of 467 patients). Patients with an unsatisfactory pain reduction 3 months after low-dose radiotherapy were offered a re-irradiation. Forty percent of the patients who received a re-irradiation developed good pain reduction.

Occurrence of an initial aggravation of pain during or within 3 months after low-dose radiotherapy ($p=0.005$), and treatment of bilateral painful plantar calcaneal spurs ($p=0.008$) were identified as significant unfavorable prognostic factors on univariate analysis. On multivariate analysis, the initial aggravation of pain remained as independent significant prognostic factor ($p=0.01$). No clear radiation toxicity was observed.

Conclusions Low-dose radiotherapy is a safe and effective treatment option for patients with painful plantar calcaneal spurs. An initial aggravation of pain during or within 3 months after radiotherapy was identified as unfavorable prognostic factor for the treatment outcome. Re-irradiation of patients with an unsatisfactory pain reduction after low-dose radiotherapy is effective and should be offered to patients.

Keywords Heel · Plantar fasciitis · Benign disease · Pain relief · Radiation effects · Treatment outcome

Plantar calcaneal spurs (PCS) are a bony outgrowth from the calcaneal tuberosity [1]. Functional and structural stress as well as the individual's genetic predisposition to forming bone have been discussed as influencing factors for the de-

velopment of PCS [2]. PCS are frequently associated with plantar fasciitis (PF) and plantar heel pain (PHP) [3]. The association between PCS, PF and PHP is complex. It has been well recognized that a considerable proportion of pa-

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tients with PCS are asymptomatic [4]. In patients with PHP, PF or PF combined with PCS is a frequent finding, whereas isolated PCS is rare [3]. However, patients with PCS had more pain compared to a control group, even when patients with PF were excluded [4]. Anatomical and radiological studies have shown that PCS are not located within the plantar fascia but deep to it [1, 5], suggesting a different etiology for PCS and PF [2]. The prevalence of painful PCS is associated with increasing age and obesity and has been estimated to amount to 6.8% in patients with a mean age of 53.5 years [4]. Chronic PHP is associated with physical and mental impairment, more anxiety and depression, and reduced general health-related quality of life [6–8]. Due to its relatively high prevalence it represents an important economic burden to health services [9].

Painful PCS are usually treated conservatively. Conservative treatment options include insole or orthopedic shoe modifications, physical therapy, dry needling, oral nonsteroidal anti-inflammatory drugs (NSAID), local injections with corticosteroids or platelet-rich plasma, low-level laser therapy, and extracorporeal shock wave therapy. No clear consensus has emerged which treatment is the most effective for the management of chronic PHP [10–13].

Low-dose external beam radiotherapy (LD-EBRT) is commonly applied when other treatment options failed [14–16]. The efficacy of LD-EBRT was proven by a randomized study comparing a radiation regimen with a very low dose (total dose 0.6 Gy, fraction dose 0.1 Gy, 2 fractions per week) with a standard dose radiation regimen (total dose 6.0 Gy, fraction dose 1.0 Gy, 2 fractions per week). Three months after therapy, patients in the standard dose group exhibited significantly better visual analogue scale values, calcaneodynia scores and quality of life scores compared to the very low-dose group. Twelve months after therapy, about 64% of the patients in the very low-dose group received a second treatment series due to insufficient treatment results compared to 17% in the standard dose group [17].

Two randomized dose optimization studies showed that a radiation regimen using a total dose of 3.0 Gy, fraction dose 0.5 Gy, 2 fractions per week was as effective as the radiation regimen using a total dose of 6.0 Gy, fraction dose 1.0 Gy, 2 fractions per week, thus defining the new clinical treatment standard with a total dose of 3.0 Gy, fraction dose 0.5 Gy, 2 fractions per week as the minimum effective dose [18–20]. A randomized study comparing LD-EBRT with local corticosteroids injections showed significantly better results with LD-EBRT three months after treatment [21].

A large body of retrospective studies supports the efficacy of LD-EBRT of the treatment of PHP. Several risk factors potentially associated with treatment failure have been described, such as longer history of pain before LD-EBRT [16, 22–24], older age of patients [16, 23, 24], higher num-

ber of LD-EBRT-series required [16, 23], and larger size of the PCS [24].

However, data with long-term outcome after LD-EBRT are scarce. The purpose of this study was to estimate the long-term effect of LD-EBRT of painful PCS, and to verify possible prognostic factors.

Patients and methods

Patients

In this retrospective unicenter study, electronic patient files of patients treated with LD-EBRT for painful plantar heel spurs between July 2009 and February 2020 were reviewed. Data were entered into a custom-made database (MS Access [Microsoft, Redmond, WA, USA]) and transferred to statistic programs for statistical analysis (Statistica [TIBCO, Palo Alto, CA, USA], MedCalc [MedCalc Software Ltd, Ostend, Belgium]). Patients with a previous LD-EBRT for painful PCS were excluded from the analysis.

The diagnosis of painful PCS was made by referring orthopedic or general physicians and was in most patients confirmed by imaging. Most patients received multiple conservative treatments before referral to radiotherapy.

The LD-EBRT consisted of a total dose of 3.0 Gy given with a fraction dose of 0.5 Gy three times a week. Some patients treated before 2016 received a total dose of 6.0 Gy given with a fraction dose of 1.0 Gy three times a week (Table 1).

Patients were routinely evaluated at the last day of LD-EBRT and 3 months after LD-EBRT. Since 2015, all patients received a questionnaire at each visit with a Visual Analog Scale (VAS) for estimating the pain reduction after LD-EBRT (0–100%) and the question if they experienced a temporary aggravation of the pain during or within 3 months after LD-EBRT (yes or no). The questionnaire was filled out and signed by the patient, electronically scanned, and attached to the electronic patient file. The percent pain reduction and initial aggravation of pain of patients treated before 2015 was often stated in the “end of treatment reports” and “3-month follow-up reports”. Long-term follow-up data were obtained by visits of many patients for LD-EBRT for other indications and by contacting the remaining patients by telephone.

The local institutional review board declared that the ethical approval can be waived for this retrospective study.

Radiation technique

Patients were positioned feet first on the radiation treatment couch, lying sideways with the medial side of the foot facing up. For the right foot, the patients laid on the right side

Table 1 Patient and treatment characteristics of patients treated with low-dose radiotherapy for painful plantar heel spurs

Characteristic	Total		Subgroup for survival analysis ^a	
	<i>n</i>	%	<i>n</i>	%
<i>Patients</i>	666	–	467	–
<i>Heels</i>	864	–	582	–
<i>Gender</i>				
Female	449	67.4	323	69.2
Male	217	32.6	144	30.8
<i>Age (years)</i>				
Mean	56.9	–	57.5	–
Minimum–maximum	20–95	–	20–91	–
<i>Body mass index (BMI)</i>				
Normal weight	47	8.1	35	7.6
Overweight	225	38.9	182	39.3
Class I obesity	200	34.6	162	35.0
Class II obesity	63	10.9	53	11.4
Class III obesity	43	7.4	31	6.7
<i>Radiation regimen</i>				
6 × 0.5 Gy	785	90.9	506	86.9
6 × 1.0 Gy	79	9.1	76	13.1
<i>Laterality of RT</i>				
Bilateral (concomitantly)	123	18.5	80	17.1
Right and left heel sequentially	79	11.9	72	15.4
Right heel	223	33.5	157	33.6
Left heel	241	36.2	158	33.8
<i>Initial aggravation of pain (heels) ^c</i>				
Yes	340	46.8	219	47.3
No	387	53.2	244	52.7
<i>Re-RT (heels) ^b</i>				
No Re-RT	572	66.2	421	72.3
Re-RT 1	238	27.5	136	23.4
Re-RT 2	48	5.6	19	3.3
Re-RT 3	6	0.7	6	1.0
<i>History of pain before RT (months) (heels)</i>				
< 6	285	40.7	190	42.9
6–12	242	34.5	155	35.0
> 12	174	24.8	98	22.1

RT radiotherapy

^a Patients with a minimum follow-up time of 3 months

^b Re-irradiation (Re-RT) 3 months after previous RT

^c Episode of aggravation of pain during RT and shortly afterwards (< 3 months)

and for the left foot on the left side. The foot was supported with a standard wedge cushion for exact and straight positioning. The field size was chosen to cover the pain area, the heel (whole calcaneus) and the insertion of the Achilles tendon with at least an extra margin of about 2 cm. For most patients, a field size of 12 cm × 12 cm was used. The upper part of the ankle joint was blocked using individual blocks or multileaf collimator (MLC). The foot positioning, field size, isocenter, and blocking was controlled and documented with either computed radiographs images, kV on-board imaging system (OBI), or an electronic portal imag-

ing device (EPID). Radiation therapy was performed using a 6 MV photon beam of linear accelerators (Siemens MXE and Varian iX) via anterior/posterior opposed (AP/PA) pair treatment fields. The dose was prescribed to the isocenter point. The planning target volume was covered by the 95% isodose for most patients and not less than by the 90% isodose for all patients.

Table 2 Effect of re-irradiation (Re-RT) 3 months after the LD-EBRT (1st RT) on the pain reduction

1st RT Pain reduction	<i>n</i>	Re-RT			Improvement ^a	
		0–24%	25–74%	75–100%	<i>n</i>	%
0–24%	17	9	2	6	6/17	35
25–74%	29	2	8	19	19/29	66
75–100%	11	0	2	9	9/11 ^b	–18
Total improvement					23/57	40

LD-EBRT low-dose external beam radiotherapy, Re-RT re-irradiation

^a Improvement is defined as a change of the pain reduction from <75% to 75–100%

^b Three of nine patients with a pain reduction between 75% and 99% reported a complete pain reduction after Re-RT (33%)

Table 3 Univariate analysis of factors with possible impact on the pain control after LD-EBRT of painful plantar heel spurs (Kaplan–Meier analysis)

Factor	<i>n</i>	Mean (months)	95% CI of the mean		<i>p</i> -value
<i>Age (years)</i>					0.59
≤ Mean	306	75	67	82	–
> Mean	276	73	65	81	–
<i>Gender</i>					0.48
Male	181	71	60	82	–
Female	401	74	68	81	–
<i>Body mass index</i>					0.95
Normal weight	47	65	43	86	–
Obesity	306	73	65	80	–
Overweight	225	75	66	84	–
<i>Radiation regimen</i>					0.96
6 × 0.5 Gy	506	72.6	66.1	79.0	–
6 × 1.0 Gy	76	74.8	61.3	88.4	–
<i>Laterality of RT</i>					0.009
Bilateral (concomitant)	155	61	50	72	–
Unilateral	427	79	72	85	–
<i>Initial aggravation of pain</i>					0.005
Yes	219	70	60	80	–
No	244	76	67	86	–
<i>Re-RT</i>					0.79
No Re-RT	421	73	67	80	–
1–3 Re-RTs	161	77	65	88	–
<i>History of pain before LD-EBRT (months)</i>					0.65
< 6	190	66	52	80	–
6–12	155	68	54	81	–
> 12	98	73	60	86	–

LD-EBRT low-dose external beam radiotherapy, Re-RT re-irradiation, CI confidence interval

Statistical analysis

Descriptive statistics of patient groups are presented in Table 1 and 2. Follow-up time was defined as the time between the first day of the last LD-EBRT and last contact to the center (visit or telephone call). For the statistical analysis, the degree of the pain reduction was arbitrarily categorized into “no or low” (0–24% pain reduction), “moderate” (25–74% pain reduction), and “good” (75–100% pain reduction). The probability of an insufficient pain control, defined as a pain reduction of less than 75%, and the univariate

analysis of possible prognostic factors were assessed using the Kaplan–Meier method. Patients with a follow-up time of less than 3 months were excluded from the Kaplan–Meier analysis. The probability of an insufficient pain control was defined as the time from the start of the last LD-EBRT until a pain reduction of less than 75%. Patients with a good pain response were censored at their last contact to the center. Statistical difference between groups was evaluated using the two-sided log-rank test (Table 3). The simultaneous influence of factors significant on univariate analysis was assessed using Cox proportional hazards regression analysis.

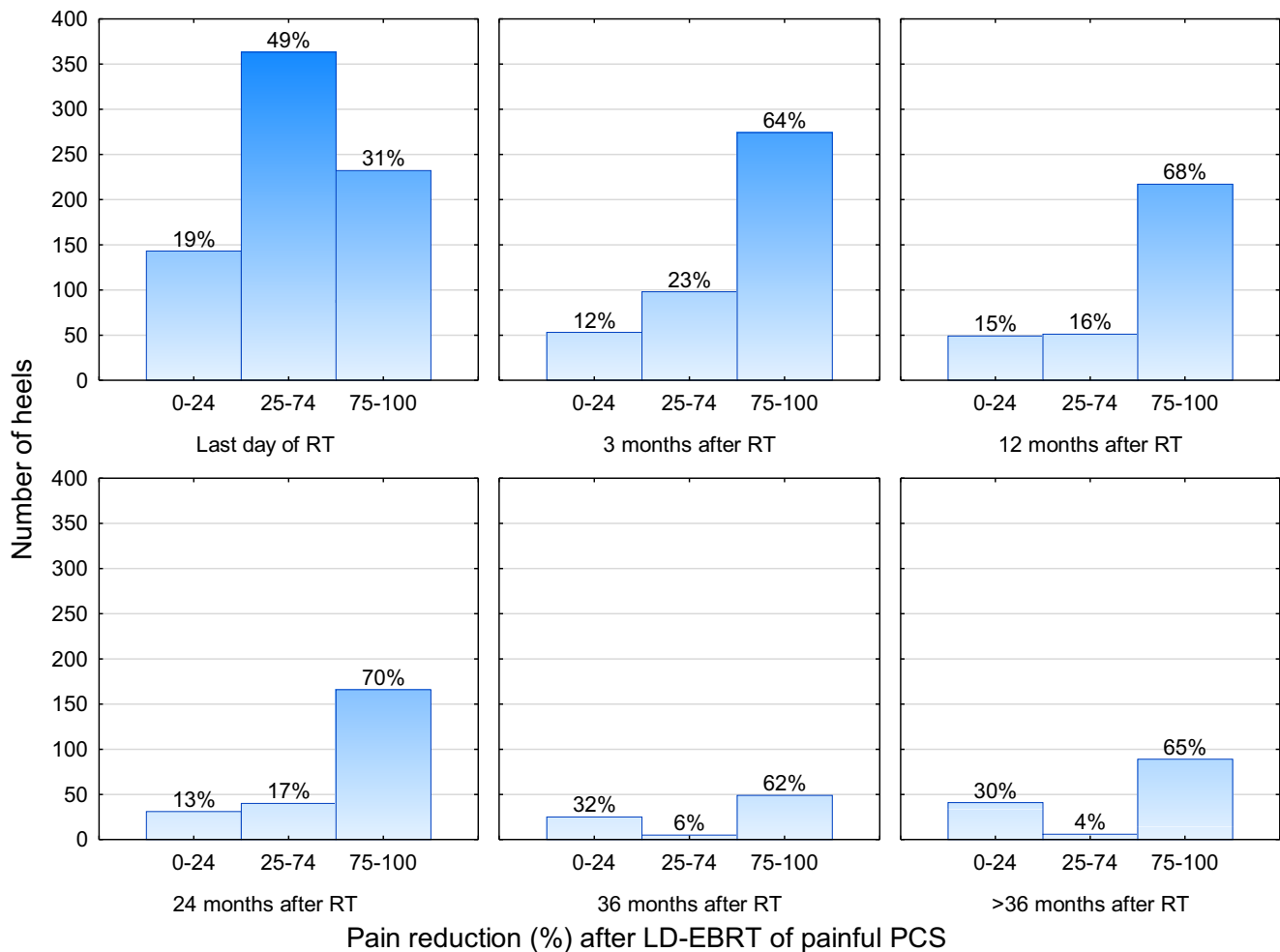


Fig. 1 Pain reduction at different times after low-dose external beam radiotherapy (LD-EBRT) for painful plantar calcaneal spurs (PCS)

The regression coefficients were estimated by the maximum likelihood method and model selection was performed by a stepwise strategy using the likelihood ratio test.

Results

Altogether, 864 heels of 666 patients were analyzed. The patient and treatment characteristics are presented in Table 1. Most patients received multiple conservative treatments before referral to LD-EBRT which may explain the relatively high proportion of patients with a history of pain before LD-EBRT of equal or greater than 6 months (Table 1). Compared to published data of the German population [25], the body mass index (BMI) of this patient cohort appeared to be much higher (Table 1). This is in accordance with the fact that increasing BMI represents a risk factor for the development of PCS, PF and PHP [2]. Many patients reported a temporary episode of a slight to strong aggravation of the pain at the evaluation at the end of LD-EBRT or

3 months after LD-EBRT. This observation is referred to “Initial aggravation of pain” in this analysis. Fig. 1 shows that the proportion of patients with good pain reduction was considerably higher 3 months after LD-EBRT compared to at the last day of LD-EBRT, suggesting that in many patients the pain reduction needed some time to develop. For this reason, the analysis of the pain reduction and the analysis of possible prognostic factors were performed in the subgroup of patients with a minimum follow-up time of 3 months (582 heels of 467 patients). The median follow-up time was 16 months (3–125 months). The proportion of patients with complete pain response (100%) in Fig. 1 was 5, 20, 47, 49, 49 and 53% at the end of LD-EBRT, 3, 12, 24, 36 and >36 months after LD-EBRT. The total number of patients were used for the analysis of patient and treatment characteristics, in particular the initial aggravation of pain and treatment response.

Efficacy of re-irradiation

At the first follow-up visit 3 months after LD-EBRT, patients desiring a stronger pain reduction were offered a re-irradiation (Re-RT) with the same total dose and fractionation regimen. Thirty-two percent of patients with a pain reduction of 0–24%, 31% with a pain reduction of 25–49%, 30% with a pain reduction of 50–74%, and 21% with a pain reduction of 75–100% three months after LD-EBRT opted for and received a Re-RT. Some patients received multiple Re-RTs (Table 1).

The effect of the Re-RT is summarized in Table 2. Of 57 patients with a pain evaluation 3 months after LD-EBRT and 3 months after Re-RT, the number of patients with a pain reduction of 75–100% increased from 11 to 34 three months after Re-RT. Of 9 patients with a good but not complete pain reduction after LD-EBRT, 3 patients developed a complete pain reduction after Re-RT. Of 10 patients with available data 3 months after Re-RT and 3 months after a second Re-RT, the number of patients with 75–100% pain reduction increased from one to seven after the second Re-RT.

Pain control and prognostic factors

Fig. 2 demonstrates the probability of an insufficient pain control after LD-EBRT. The probability of an insufficient pain control at 10 years was 45.9% (95% confidence interval [CI] 39.4–52.4%). The mean time to an insufficient pain control was 74 months (95% CI 68–80 months). Of heels with a good pain reduction 3 months after the last LD-EBRT ($n=418$) only 50 developed a failure during the follow-up period (12.0%).

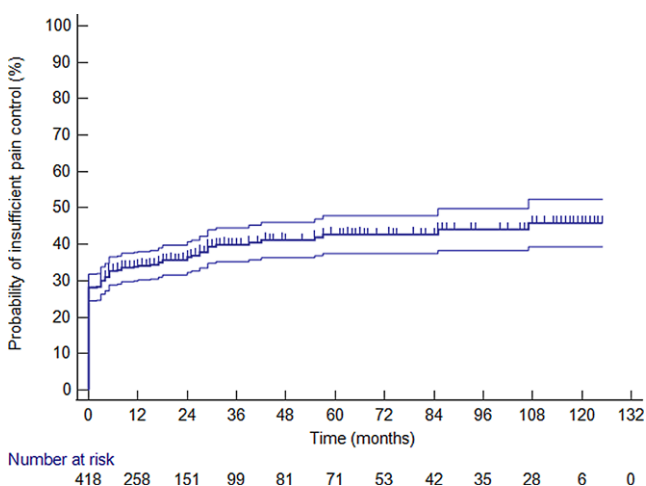


Fig. 2 Probability of an insufficient pain control after low-dose external beam radiotherapy (LD-EBRT) of 582 plantar heel spurs of 467 patients (Kaplan–Meier analysis). The vertical lines represent censored events, the upper and lower line the 95% confidence interval

On univariate analysis, the factors “initial aggravation of pain” and “laterality of RT” revealed a statistically significant impact on the probability of an insufficient pain control (Table 3). Specifically, experience of an “initial aggravation of pain” (Fig. 3) and “bilateral RT” (Fig. 4) were both associated with an insufficient pain control. On multivariate analysis, only “initial aggravation of pain” remained as statistically significant independent risk factor (Table 4).

Acute and late radiation reactions

Apart from the initial increase in pain during and shortly after LD-EBRT, toxicity clearly attributable to acute or late radiation reactions was not observed in any patient.

Discussion

Our retrospective unicenter analysis of a homogenous patient collective with painful PCS showed a good long-term pain control after LD-EBRT. The probability of insufficient pain control of 45.9% at 10 years ($n=582$) observed in our study is in excellent agreement with the overall 8-year event-free probability of 60.9% ($n=502$) found in the large retrospective multicenter study by Muecke et al. [16]. Other retrospective studies with long-term follow-up times equal or greater than 40 months showed good pain reduction in 52.9% ($n=68$) [23], 58% ($n=18$) [26], and 61.4% ($n=171$) [27] of the investigated heels.

We observed that in many patients the pain reduction needed some time to develop, and that therefore the pain evaluation 3 months after LD-EBRT was more representative for the long-term effect than the pain evaluation at the last day of the LD-EBRT (Fig. 1). The same observation

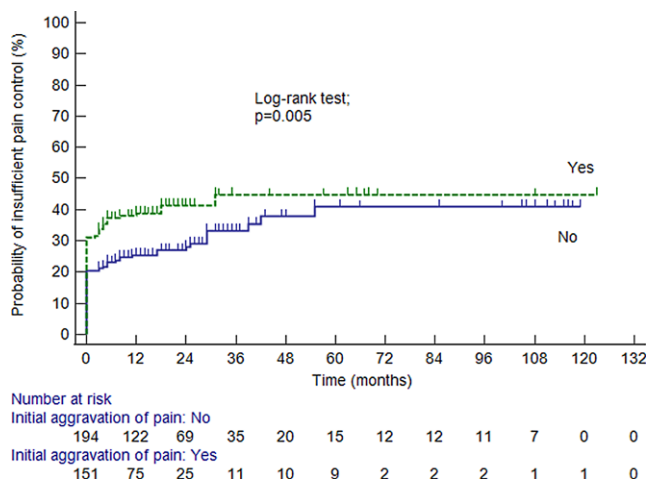


Fig. 3 Probability of an insufficient pain control in patients with or without an initial aggravation of pain after low-dose external beam radiotherapy (LD-EBRT) of painful heel spurs (Kaplan–Meier analysis)

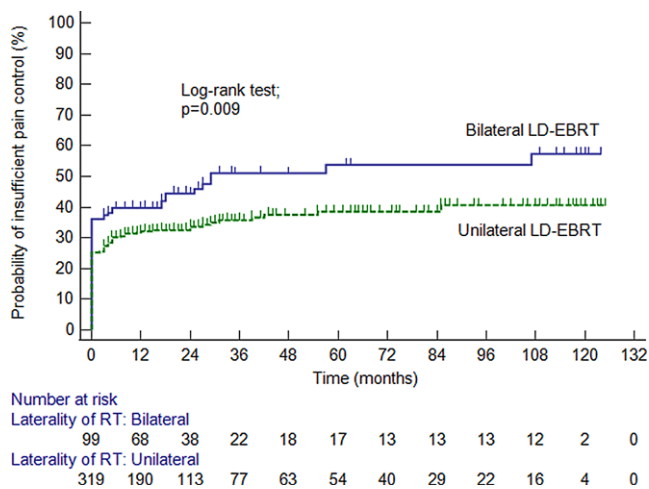


Fig. 4 Probability of insufficient pain control after bilateral or unilateral low-dose external beam radiotherapy (LD-EBRT) of painful plantar heel spurs

has been reported by other study groups [20, 28–30]. In agreement with other reports [17, 30], patients who developed a good pain response after LD-EBRT also exhibited a good long-term prognosis. Heyd et al. [30] reported a failure rate of 7.3% of 205 heels after a follow-up period of 48.4 months (this study: 12.0%).

A new and interesting finding of our study is the prognostic relevance of the occurrence of a temporary aggravation of pain within 3 months after LD-EBRT (“initial aggravation of pain”). This phenomenon was significant on uni- and multivariate analysis (Table 3, 4; Fig. 3). An initial aggravation of pain during LD-EBRT of painful PCS has also been described by other study groups, but its possible impact on the outcome results has not been investigated [17, 18]. Surprisingly, the initial aggravation of pain was associated with a significantly reduced probability of pain control. Commonly, an aggravation of pain is interpreted as a sign of response to the LD-EBRT, promising a favorable effect. The initial aggravation of pain during or within 3 months after LD-EBRT as well as the delayed development of the pain reduction are most probably related to specific radiobiological effects of the LD-EBRT.

The critical radiobiological effect of a radiotherapy of malignant tumors is the production of DNA double-strand

Table 4 Multivariate Cox regression analysis of factors significant for the pain control on univariate analysis

Factor	PE	p-value	HR	95% CI of HR	
Initial aggravation of pain (Yes)	0.20	0.01	1.50	1.09	2.06
Laterality of LD-EBRT (Bilateral)	0.15	0.08	1.35	0.96	1.88

PE parameter estimate, HR hazard ratio, CI confidence interval, LD-EBRT low-dose external beam radiotherapy

breaks, leading to mitotic cell death [31]. In conventional RT of malignant tumors often total doses of 30–70 Gy with fraction doses of 1.8–3.0 Gy are applied. In contrast, the critical radiobiological effect of LD-EBRT using total doses of 3.0 Gy or 6.0 Gy with fractions doses of 0.5 Gy or 1.0 Gy is completely different. LD-EBRT has been shown to modulate several immunological pathways as well as activities of endothelial cells, mono- and polymorphonuclear leukocytes, and macrophages [32]. However, the precise mechanism of the pain reducing effect of LD-EBRT is not yet fully understood. Why an initial aggravation of pain may be associated with a reduced pain reduction during the follow-up is unclear. It can be speculated that an enhanced radiobiological response to LD-EBRT with a temporary aggravation of pain may indicate a more vulnerable tissue with less healing potential. Future studies have to investigate this observation.

Another risk factor significant on univariate analysis and with a p-value of 0.08 on multivariate analysis was the concomitant treatment of both heels at the same time in contrast to treating only one heel or both heels sequentially. This factor has not been examined in other studies to our knowledge. Bilateral LD-EBRT was associated with an unfavorable outcome in our study. The occurrence of bilateral painful PCS at the same time may indicate a more advanced stage of the syndrome associated with lower treatment success. A genetic predisposition has been discussed as part of the etiology of PCS [2]. It can be speculated that bilateral PCS are more common in patients with a genetic predisposition and that these patients may develop stronger symptoms which are more difficult to treat.

Gender, age, body mass index (BMI), number of Re-RTs, and history of pain before LD-EBRT had no statistical impact of the survival with good pain reduction in our study. Conflicting results have been reported about the impact of age [16, 18, 21–24, 33], history of pain before LD-EBRT [15, 16, 18, 21–24, 33], and number of LD-EBRT series [15–17, 23, 30, 34, 35] on the treatment outcome. In agreement with our study, no study has found an impact of the gender [16, 18, 22, 24, 33] or body mass index [21] on the treatment outcome.

Our data showed that patients with an insufficient pain control (<75%) 3 months after LD-EBRT have a good (approximately 40%) chance to improve their results (pain reduction ≥75%) with a re-irradiation. Likewise, patients with an insufficient pain control after the first Re-RT again had a good chance of similar magnitude to improve their results with a second Re-RT. Patients, who finally developed a good pain reduction showed a good long-term prognosis, and the number of Re-RTs had no unfavorable impact on the probability of an insufficient pain control in our study. Hautmann et al. examined 101 heels after Re-RT for painful heel spur syndrome [34]. A significant pain reduction of was ob-

served during the follow-up period of 2 years. A good pain reduction after Re-RT evaluated at different follow-up times was also reported by several other study groups [16–18, 30, 33].

We would like to mention the limitations of our study. Due to the retrospective study design, a selection bias through the referring physicians cannot be excluded with certainty. There are some missing data of the patient and treatment characteristics which may cause a bias. The study parameter “pain reduction” was patient assessed and not based on objective measurements. Patients may rate the extent of pain differently. The initial aggravation of pain was evaluated as bivariate variable (“yes” or “no”) at the end of LD-EBRT and 3 months after LD-EBRT. It is not possible to differentiate between a radiation induced aggravation of pain or a possible aggravation of pain as part of the natural course of the disease. Concomitant LD-EBRT of both heels was a significant prognostic factor on univariate analysis. It cannot be excluded that patient with bilateral painful PCS tend to be more sensitive to pain because of the probably more reduced quality of life due to the bilateral disease.

Conclusion

Low-dose external beam radiotherapy (LD-EBRT) is a safe and effective treatment option with a good long-term pain reduction in patients with painful plantar calcaneal spurs (PCS). An initial aggravation of pain during or shortly after LD-EBRT as well as the occurrence of bilateral painful PCS at the same time were identified as unfavorable prognostic factors for the treatment outcome. Re-irradiation of patients with an insufficient pain control after LD-EBRT is effective and should be offered to patients.

Conflict of interest V. Rudat, N. Tontcheva, G. Kutz, T.O. Orovighose and E. Gebhardt declare that they have no competing interests.

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