

CLINICAL INVESTIGATION

Benign disease

RADIOTHERAPY IN PAINFUL HEEL SPURS (PLANTAR FASCIITIS)—RESULTS OF A NATIONAL PATTERNS OF CARE STUDY

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Purpose: After a general patterns of care study, the German Cooperative Group on Radiotherapy for Benign Diseases conducted a multicenter cohort study to analyze radiotherapy (RT) in painful heel spur syndrome (HSS).

Methods and Materials: In 2001, a patterns of care study was conducted in all German RT institutions using a standardized structured questionnaire. Patient accrual, patient number, pretreatment, pain record, treatment indications, RT technique, and target volume concepts for painful HSS were assessed. In addition, the functional and subjective outcomes were evaluated.

Results: Of the institutions, 146 (79.3%) returned the questionnaire: 10 (6.8%) reported no clinical experience with RT for HSS, and 136 (93.2%) treated 3621 patients annually, a median of 23 cases/institution. The indications for treatment were chronic or therapy refractory pain. The total dose ranged between 2.5 and 18.75 Gy (median 6), and single fractions ranged between 0.3 and 1.5 Gy (median 1). Of the responding institutions, 44.9% applied two fractions and 37.5% three fractions weekly. RT was delivered with orthovoltage units (38.2%), linear accelerators (53.7%), ⁶⁰Co units (5.1%), or other treatment units (3%). Seventy-six institutions presented their retrospective clinical evaluation in a total of 7947 patients. Pain reduction for at least 3 months was reported in 70%, and persistent pain reduction was reported in 65% of the treated patients. In 19 institutions, a second RT series was applied for inadequate pain response or early pain recurrence. No radiogenic acute or chronic side effects were observed.

Conclusion: The study comprised the largest number of cases reported of RT for painful HSS. Despite variations in the daily RT practice, this national patterns of care study represents a very large number of painful and refractory HSS cases that were treated effectively with RT. © 2004 Elsevier Inc.

Heel spur syndrome, Insertion tendinopathy, Plantar fasciitis, Radiotherapy, Patterns of care study, Benign disease.

INTRODUCTION

The term “heel spur syndrome” (HSS) derives from Plettner (1) in 1900, who coined the German term “Kalkaneussporn” (or calcaneal spur). His first radiologic study (1) described an exostotic plantar bone formation at the insertion of the plantar fascia and muscles, which resulted in the term “plantar heel spur.” In contrast, the exostosis at the insertion of the Achilles tendon was termed “dorsal” heel spur or “Haglund exostosis.” The latter disorder develops less often and often remains asymptomatic. Plantar and dorsal heel spurs can develop in the same individual, and bilateral manifestations are often observed (2). Today, the phrases “painful

heel spur” and “HSS” encompass different entities and terms, which have been synonymously used: plantar or dorsal heel spur, Haglund exostosis, calcaneal spur, achilodynia, and calcaneodynia (3). Anglo-American countries also use the term “plantar fasciitis” for HSS (4).

The prevalence of HSS ranges from 8% to 10% (5). Data on the gender ratio vary considerably (6). Usually, patients are >40 years old. In most cases, the spurs measure 4–6 mm, but shorter and longer dimensions are possible. No strong correlation exists between spur size and the extent and strength of pain. Typically, the pain is stinging and occurs under the heel or at the insertion of the Achilles

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tendon. It can be an extensive heel pain that may radiate into the leg or forefoot. This pain leads to a marked impairment of gait and mobility. Often, a local tenderness at the medial and distal aspect of the tuber calcanei is observed (4). The chronic damage to the insertion of the plantar aponeurosis and the small foot muscles owing to the increased strain plays an important role in the etiology of the disorder. The increased strain is supposed to be the result of a foot deformity (e.g., splay-foot), obesity, or specific sports activities (7–9). The chronic damage is followed by a decreased elasticity of the insertional cartilage. Gaps in the impaired cartilage are invaded by mesenchymal cells, which later form scar tissue. After the invasion of neovascular vessels, the scar slowly ossifies, which may lead to the development of the typical bony spurs at the insertion zone (5).

Similar to the therapy of osteoarthritis, various treatments have been proposed for HSS, primarily including rest and decrease of body weight (10), orthopedic shoe modifications, orthoses or heel pads (11, 12), different types of physical therapies (13, 14), and local electrophysical measures, including cold or heat applications or local infiltration with corticoid crystal suspensions and anesthetics (15, 16). In addition, systemic nonsteroidal antiinflammatory drugs, iontophoresis, and laser, microwave, and ultrasound applications are often used (17–22).

Recently, extracorporeal shock wave therapy (ESWT) has generated great promise (23–25), but long-term outcome data are to come for most of these methods. Different surgical techniques have been proposed and are in use for the more complicated cases and those with a chronic pain syndrome (26–28). Despite this variety of treatment options, none has yet demonstrated a clear superiority with convincing results (17, 29, 30).

Radiotherapy (RT) for painful HSS or other musculoskeletal degenerative and inflammatory disorders has been well established in Germany and other countries of Central and Eastern Europe (31) for about 100 years (32), with very good treatment results (33, 34). Nevertheless, only few reports exist with a statistically significant high level of evidence (35). Northern European and Anglo-American countries regard RT for nonmalignant disorders with great skepticism (36, 37). Thus, the implementation of treatment guidelines and suitable tools for quality assurance are crucial for additional promotion of this treatment (38, 39).

Patterns of care studies (PCSs) provide an important instrument for the definition and evaluation of treatment standards and quality assurance; thereby, practice standards, treatment guidelines, and accomplishments can be assessed continuously (31, 40–43). After a general PCS about RT for benign disease with >20,000 patients treated in Germany annually (44), the German Cooperative Group on Radiotherapy for Benign Diseases (GCG-BD) initiated a disease-specific PCS on RT for painful HSS in Germany.

MATERIALS AND METHODS

In 2001, the Patterns of Care Study in Benign Diseases Panel (Appendix A) of the GCG-BD of the German Society for Radiation Oncology developed a structured standardized questionnaire (Appendix B) and mailed it to all RT departments in Germany with the aim to identify their institutional experience with RT for painful HSS.

In this systematic approach, patient accrual, total patient number, number and type of pretreatments, pain record, treatment indication, RT, and target volume concept for each institution were analyzed. In addition, the functional and subjective outcome results of all participating institutions, which consistently used scores with subjective and objective parameters, were analyzed from published, as well as unpublished, clinical data. In the case of unclear or incomplete data acquisition, interviews or visits to the institutions were used to acquire the appropriate institutional and clinical information. The relatively high response rate (146 institutions [79.3%]) allowed an extensive and representative data analysis for Germany. The records of 7947 patients were prospectively evaluated to obtain the clinical outcome data. The reported follow-up period for these patients was a median of 28 months (range 3–335).

The statistical description of all relevant parameters included the median, mean, standard deviation, and range for all continuous variables, and the absolute and relative values for all categorical variables. The differences between the frequencies of the groups were analyzed with Fisher's exact test and the chi-square test. The mean values of the group frequencies were analyzed with Student's *t* test. All statistical analyses were performed using the commercially available program package, Statistical Package for Social Sciences, version 10.0.7 (SPSS, Chicago, IL).

Because only a few institutions (14.5%) used validated pain scores (e.g., the modified score of Rowe *et al.* [45]) or the score proposed by the GCG-BD (46) (Appendices C and D), for practical reasons, the outcome analysis was based on the 5-item pain scale first described by the German radiologist Günter von Pannowitz (47). He used five categories of response: pain free, substantial pain improvement, moderate pain improvement, pain unchanged, and worse pain (Appendix E). Treatment success was defined as (pain free plus substantial pain improvement).

As suggested by Hanks *et al.* (43) and Coia and Hanks (48), this PCS was structured and analyzed according to the model for quality assessment set up by Donabedian (49, 50) in three major components: structure, process, and outcome. To determine the interrelationship between these factors, a multivariate analysis was performed by analysis of variance.

RESULTS

Structural data

Of the 146 institutions participating in the survey, 36 were university hospitals (24.6%), 81 were community hos-

Table 1. Type and distribution of participating institutions

Hospital type (146/184; 79.3%)	<i>n</i> (%)
University hospitals	36 (24.6)
Community hospitals	81 (55.5)
Private institutions	29 (19.9)

pitals (55.5%), and 29 were private RT institutions (19.9%) (Table 1). Ten (6.8%) reported no experience with RT for painful HSS. Therefore, the current analysis was based on the answers of the remaining 136 institutions (93.2%). For the baseline year, 2001, the participating institutions reported a total of 3,621 patients treated annually. The median number of patients per institution was 23 (range 1–242). The referral for RT came primarily from orthopedic surgeons ($n = 82$; 60.3%), followed by general practitioners ($n = 45$; 33.1%) and other disciplines ($n = 9$; 6.6%; e.g., surgeons).

The therapeutic measures used before RT (several answers possible) were shoe modifications ($n = 72$), oral medication with nonsteroidal antiinflammatory drugs ($n = 70$), local injections with corticosteroids or local anesthetics ($n = 69$), various physiotherapeutic measures ($n = 59$), ESWT ($n = 47$), surgical interventions ($n = 44$), and other treatments ($n = 10$). Most patients referred for RT had undergone extensive pretreatments, predominantly with two

to three types of therapy ($n = 58$; 42.6%). In 7 institutions (5.1%) only, RT was given as the primary treatment. All results are summarized in Fig. 1.

In 73 institutions (53.7%), the technical equipment used for RT consisted of linear accelerators (median energy 6 MeV, range 4–9); in 52 institutions (38.2%), orthovoltage units (60–200 kV) were used; and in 7 (5.1%), ^{60}Co machines and in 4 (3%) other treatment units (e.g., ^{137}Cs) (Fig. 2).

Process data

The main area of maximal pain indicated by the patients was the plantar region (80%), followed by the dorsal region (14%) or both areas of the heel (6%). The typical indication for the use of RT was “chronic heel pain” in 100 institutions (73.5%), “acute pain” and “both pain types during a period of 6–8 weeks” or “therapy refractory pain after more than two unsuccessful treatment attempts” in 36 institutions (26.5%). In addition to the typical clinical symptoms, almost one-half of the RT institutions (49.2%; $n = 67$) demanded a minimal period of pain symptoms of at least 6 months. However, only 41 institutions (30.1%) considered an imaging or radiologic finding to be indispensable before the indication and use of RT.

A broad range of RT dose and fractionation concepts were applied. The total RT dose ranged from 2.5 to 18.75 Gy (median 6; Fig. 3); the single RT dose fraction ranged from 0.3 to 1.5 Gy (median 1.0). A total of 40 institutions (33.1%) used

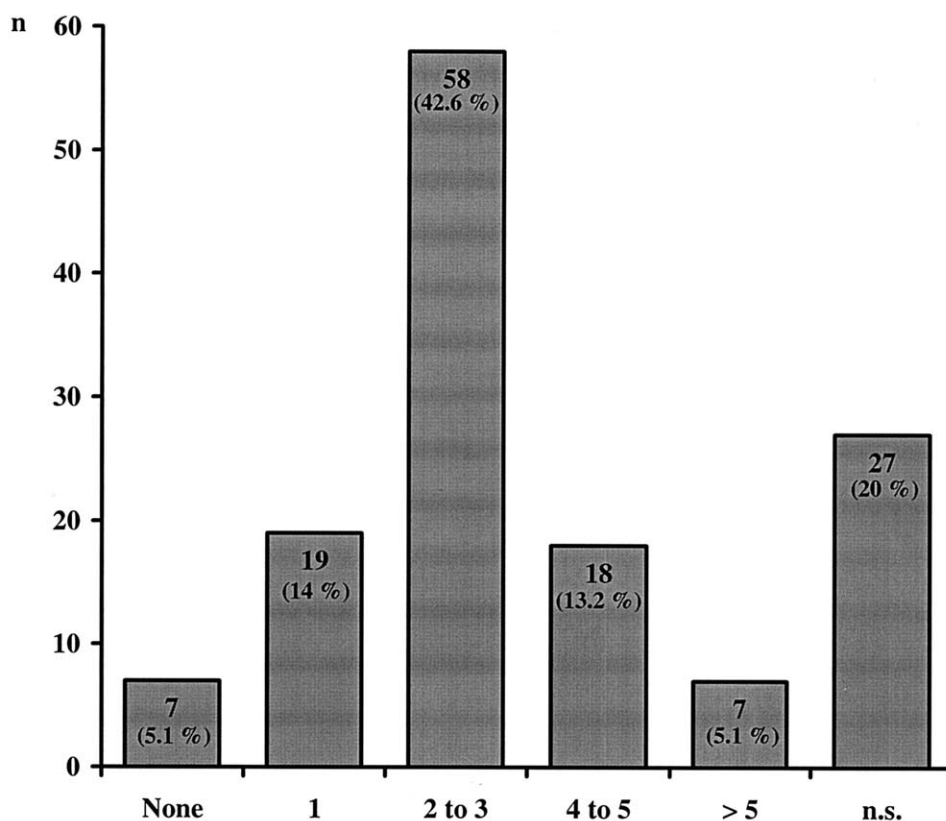


Fig. 1. Number of treatment attempts before initiation of RT. n.s. = not stated.

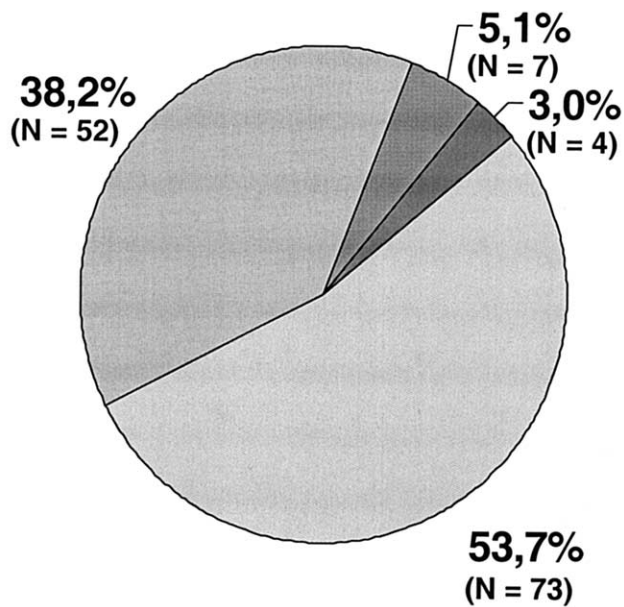


Fig. 2. Technical equipment used for RT for painful heel spurs. Linear accelerator, 53.7% ($n = 73$); orthovoltage, 38.2% ($n = 52$); ⁶⁰Co, 5.1% ($n = 7$); other, 3.0% ($n = 4$).

0.5 Gy and 67 (55.4%) 1.0 Gy as a standard daily single dose. Most institutions delivered two to three RT fractions weekly: 61 (44.9%) used two fractions and 51 (37.5%) three fractions

weekly (Fig. 4). In two-thirds of cases ($n = 90$), patient positioning and RT setup was performed clinically without treatment planning and localization at a simulator. The large majority of institutions (89.7%) prescribed the dose to a specified tissue depth, mostly the mid-plane of the heel; only a few centers (11.3%) used the "surface dose" for dose specification. Nearly all institutions (95.6%) indicated a second RT series would be done if the pain response was inadequate or early pain recurrence developed within 6–8 weeks after the first RT series.

All institutions reported quite different concepts for coverage of the target volume (Fig. 5): 58 (42.6%) included the lower part of the calcaneus, the calcaneal insertion, and a major part of the plantar fascia within the treatment portal; 27 (19.9%) included the dorsal part of the calcaneus and the insertion and lower parts of the Achilles tendon; 44 (32.4%) used a smaller field with the calcaneus and both insertion zones; and a very small group ($n = 7$) of institutions and radiotherapists (5.1%) used a large field that included major parts of the plantar fascia and the Achilles tendon. Irradiation was applied via a single plantar or dorsal field in 85 institutions (62.5%) or by two lateral opposing fields in 51 institutions (37.5%).

Outcome data

A total of 76 institutions provided detailed data for clinical evaluation of treatment outcome. The clinical data since

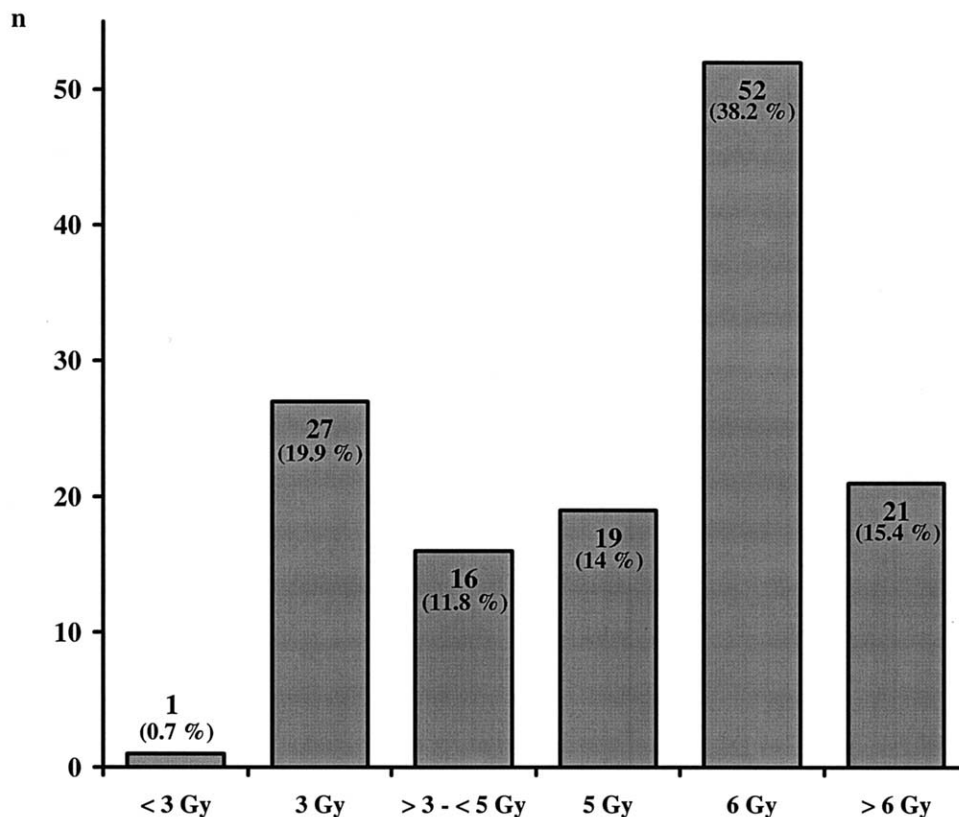


Fig. 3. Different concepts for total dose.

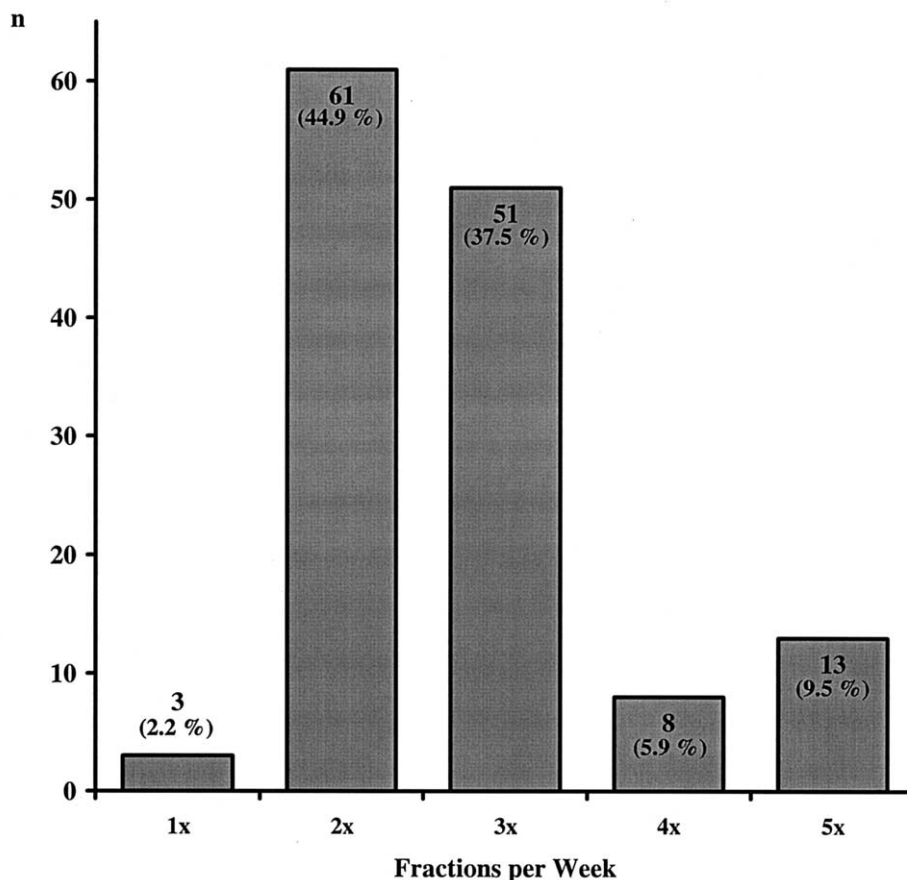


Fig. 4. Different fractionation concepts.

1960 and the treatment results for 7947 patients irradiated for painful HSS are reported. The reported follow-up period for these patients amounted to a median 28 months (range 3–335).

A total of 65 (85.5%) of the above-mentioned institutions used subjective pain scores for the evaluation of clinical outcome (e.g., the pain scale first described by the German radiologist von Pannwitz [47] who used five categories of response [Appendix E]). In contrast, only 11 institutions (14.5%) used orthopedic functional scores, including both subjective and objective response criteria (e.g., the modified score of Rowe *et al.* [45]), or the score proposed by the GCG-BD (46) (Appendices C and D).

Complete pain relief for >3 months was reported in a median of 70% (range 25–100%) of all treated patients and persisting pain relief for a minimum of 12 months in a median of 65% (range 19–99%). A median of 15% of all treated patients had no symptomatic improvement (range 5–50%). In a median of 19% cases, a second RT series was required for inadequate pain relief or early pain recurrence, and in a median of 3% of all treated cases a third RT series was necessary. All participating institutions reported no RT-related side effects. In particular, no secondary malignancies were observed during the reported follow-up period, with a maximal follow-up of nearly 28 years.

Of all radiation oncologists in this national survey, 95%

considered RT for painful HSS as a worthwhile and necessary treatment indication.

The multivariate analysis of all patients included in the analysis revealed a pain history of <6 months vs. a pain history of ≥6 months to be a statistically significant ($p < 0.05$) prognostic factor indicating a successful treatment outcome. Other favorable prognostic parameters were fewer than two previous treatment attempts vs. two or more pretreatments, and one RT series vs. two or three RT series. In contrast, no statistically significant dose–response relationship was found and no significant statistical correlation was observed between fractionation, treatment equipment, or target volume definition and the treatment success of RT. In addition, a statistical correlation with the type of pretreatment could not be established, although a trend toward a worse outcome after surgery was noted. A complete overview of all results of the multivariate analysis is given in Table 2.

DISCUSSION

Since their first implementation in the United States in 1973, the PCS has been established as a valuable tool for periodic evaluation of RT practice (48, 51). Its primary function is, as the founder Simon Kramer (52) stated, “to

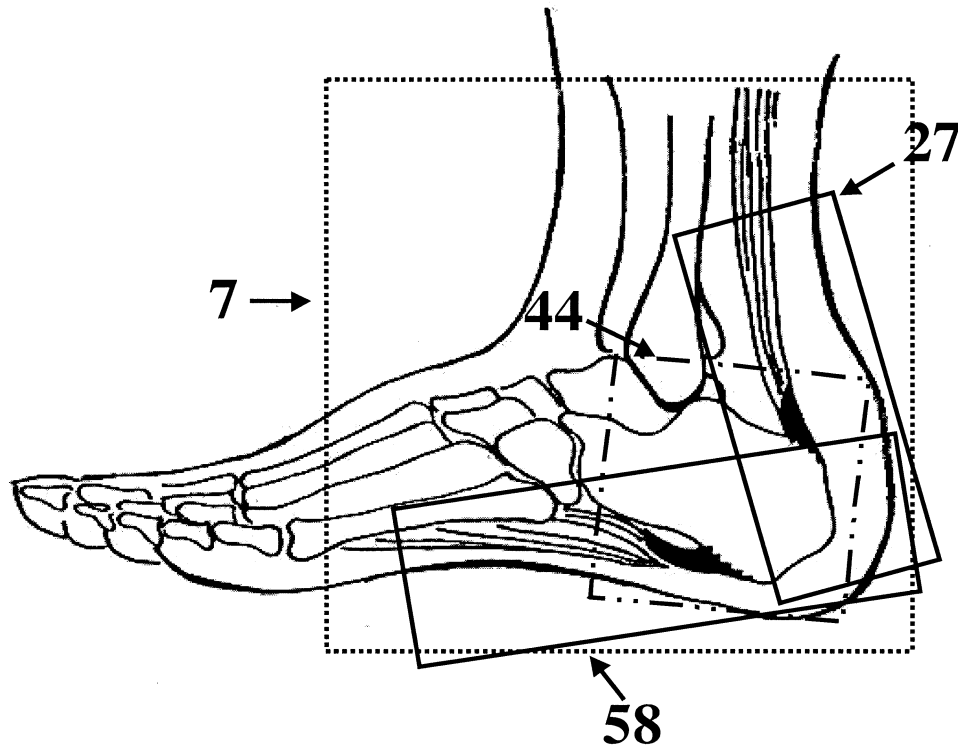


Fig. 5. Different target volume concepts.

improve the quality and accessibility of radiation care in the United States. To this end the PCS seeks to establish how and by whom radiation therapy is being practiced in the United States and to evaluate the factors [that] affect the levels of care presently being delivered.” Since these early steps, the evaluation of the quality of care has become a most critical issue in medical practice, and it is particularly important in the multidisciplinary management of cancer patients (53, 54). The method of PCS was successfully transported to many other countries outside the United States; for example, Japan (42, 55). Nevertheless, for a long period, most PCSs were restricted to the management of malignant diseases (40, 52, 54, 56–58).

Obviously, the use of RT for nonmalignant disorders should be performed under the same conditions in terms of quality assurance and standards of care as for malignant diseases (38), although nonmalignant disorders do not carry the same fatalities as most malignancies. Nevertheless, even nonmalignant diseases can lead to a significant restriction in quality of life, as well as large socioeconomic damage (39). Thus, a major scope of the national GCG-BD was to establish a valuable instrument of PCS in the area of nonmalignant disorders. So far, one general national survey on nonmalignant diseases (44) and four PCSs on specific indications (59–62) have been performed in Germany—a country with a very long-standing tradition and well-evolved experience in the treatment of nonmalignant diseases (32, 63). The current PCS focused on RT for painful HSS, one of the most frequent indications for RT, representing 11% in the general survey in Germany (44). PCSs analyze the patient with regard to technical and interpersonal components

with three criteria: structure, process, and outcome (48, 49, 64). Understanding the relationships of these three factors leads to the measurement of quality in any specialty (43).

Structure data

The structural analysis revealed that experience in using RT for painful HSS is widespread (81%). The distribution of academic vs. nonacademic institutions of about 1:4 is similar to that described in the former general PCS (44, 60) and in other PCSs on malignant disorders (42, 65, 66). The reasons for this higher prevalence of RT use in HSS in nonacademic institutions could be that most RT patients in Germany are treated in nonacademic institutions and that academic institutions focus more on the treatment of malignant diseases with specialized techniques (e.g., brachytherapy, intensity-modulated RT, stereotactic RT) or on the setting of multimodality therapies (44).

The referral for RT came primarily from orthopedic surgeons in private practice; they should be the major partners for communication about the interdisciplinary treatment of these patients. Most patients referred for RT had been heavily pretreated with two, three, or even more unsuccessful treatment attempts. Primarily, shoe modifications, oral nonsteroidal antiinflammatory drugs, local injections with corticosteroids or anesthetics, physiotherapy, and ESWT were applied. In our opinion, these therapy options should always be discussed and explained to the patient, and all conventional measures should be exhausted before initiating RT as a “salvage treatment.” However, the multivariate analysis of this PCS demonstrated that a greater number of

Table 2. Results of multivariate outcome analysis

Factor	Outcome (treatment success)	Relative risk	<i>p</i>
Pain history (mo)			
<6	82	1	0.001
≥6	62	1.33	
Pretreatments (<i>n</i>)			
<2	93	1	<0.001
≥2	68	1.4	
First (prior) treatment modality			
Shoe modifications	79	1.16	NS
Oral medications	77	1.15	NS
Local injections	75	1.13	NS
Physiotherapeutic measures	80	1.16	NS
ESWT	72	1.1	NS
Surgical intervention	66	1	0.1
Other	78	1.15	
RT series (<i>n</i>)			
1	89	1.28	0.005
2–3	70	1	
Dose (Gy)			
<5	77	1	NS
≥5	80	1.03	
Fractions/wk (<i>n</i>)			
≤2	78	1	NS
>2	79	1.01	
Treatment equipment			
Linear accelerator	78	1.02	NS
Orthovoltage	81	1.06	NS
⁶⁰ Co/other	76	1	
Target volume			
Large	76	1	NS
Small	82	1.08	

Abbreviations: ESWT = extracorporeal shock wave therapy; NS = not statistically significant ($p > 0.05$).

pretreatments and a longer pain history were related to a significantly worse treatment outcome. These findings should challenge the GCG-BD to introduce RT much earlier in the treatment of painful HSS.

The applied technical equipment described in this PCS was predominated by linear accelerators with low energies between 4 and 9 MeV, which were used in more than one-half of the institutions. This finding stands in contrast with the clinical data of 16 clinical studies extracted from a literature review (published between 1933 and 2002) summarizing the data from 3,472 patients (67). In that study, nearly three-fourths of all institutions used orthovoltage treatment units. The use of linear accelerators may have some economic disadvantages, because the reimbursement for machine costs and personal required for the labor-intensive linear accelerators is very low for nonmalignant disorders. However, this practice contradicts an old paradigm that orthovoltage with its higher bone and soft-tissue absorption should be superior in outcome compared with linear accelerator photons (68). However, so far no biologic *in vitro*, *in vivo* (69), or clinical outcome data exist (70–72)

to support this theoretical assumption, and the multivariate analysis of this PCS could not detect a relationship between the use of different treatment units and clinical outcome.

Process data

The indication for treatment of painful HSS is primarily cases refractory to conventional treatment. This coincides with recently established treatment guidelines that recommend the use of RT in treatment refractory inflammatory degenerative tendinopathy (38). Refractory HSS represents most of the indications reported in the literature (6, 34, 35, 73). However, it is known that a long pain history and more treatment attempts before RT may lead to less success with regard to pain response (6, 34, 71, 72). This observation has been confirmed by the multivariate analysis of our national PCS. When the first RT series has failed, implementation of a second RT series is very common. Our multivariate analysis confirmed that patients who undergo a second RT series respond worse, not because of this second treatment series, but rather because of their chronic and refractory pain process (74). Nevertheless, in general, a long-term pain control rate of >70% can be expected (75). In our PCS, the standardized RT dose concepts revealed a large variation, with total doses between 3 and 6 Gy and single doses between 0.5 and 1 Gy. Usually, two or three fractions weekly were applied. This is also the most common regimen reported in the literature (67).

To date, in this PCS, no dose–response relationship could be established (35, 76). Multivariate analysis showed no also correlation between dose and treatment outcome. Thus, the next task is a prospective clinical trial assessing a possible dose reduction without loss of efficacy.

In the national practice, the target volume concepts exhibited considerable variations that did not translate into different treatment outcomes. To date, a clear consensus exists about the inclusion of the calcaneal insertion of the plantar fascia or the Achilles tendon depending on the irradiation of the painful plantar or dorsal insertion zones. Apparently, larger treatment portals did not interfere with the treatment response, but from the standpoint of quality assurance, portals that are too small should be avoided, and a standardization of the daily practice and setup of portals would be mandatory in controlled clinical studies.

Outcome

Outcome analysis in the context of PCS is an important tool to set up a national benchmark on treatment outcome, which should be expected, after RT in a specific disorder (40, 43, 48). To date, the national PCS on painful HSS has collected the largest number of cases (7,947 patients from 76 institutions) ever reported on the use of RT for painful HSS. Nevertheless, only a minority of the institutions used modern functional orthopedic scores for evaluation, which include both subjective and objective criteria. This strengthens the continuous efforts of the GCG-BD to establish modern and orthopedic scores in the daily clinical practice of radiotherapists (77). It would allow interdisciplinary (e.g., orthopedic and radiotherapeutic)

Table 3. Overview of literature results of RT for painful heel spurs

Author	Patients (n)	Heels (n)	RT	Response rate* (%)	CR (%)	PR (%)	NC (%)
von Pannewitz, 1933 (63)	88	88	OV	92			
Mitrov and Harbou, 1967 (81)	1520	1520	OV	88	50	38	12
Zschache, 1972 (82)	49	49	OV	86	12	74	14
Mantell, 1978 (83)	17	26	240–300 kV	65	53	12	35
Basche <i>et al.</i> , 1980 (84)	102	102	120 kV	90	32	58	10
Sautter-Bihl <i>et al.</i> , 1993 (85)	15	15	HV	80	60	20	20
Schäfer <i>et al.</i> , 1995 (73)	18	21	⁶⁰ Co	67	58	8	33
Seegenschmiedt <i>et al.</i> , 1996 (35)	141	72 at 12 Gy 98 at 3–5 Gy	200–250 kV	100	67	33	0
Oehler <i>et al.</i> , 2000 (86)	212	258	OV	88	81	7	12
Koeppen <i>et al.</i> , 2000 (76)	673	673	250 kV	78	13	65	22
Scheiber <i>et al.</i> , 2000 (87)	70	87	6 MV	86	67	29	14
Heyd <i>et al.</i> , 2001 (6)	105	127	6 MV	88	46	42	12
Glatzel <i>et al.</i> , 2001 (34)	141	161	175 kV	89	63	26	11
Mücke <i>et al.</i> , 2001 (71)	117	136	6 MV	90	75	15	10
Schlehuber <i>et al.</i> , 2001 (72)	63	63	6 MV	67	33	34	33
Schneider <i>et al.</i> , 2002 (74)	141	161	OV	89	69	20	11
Present study	7947		HV, MV, OV, ⁶⁰ Co	70			15

Abbreviations: RT = radiotherapy; CR = complete response, complete pain relief, pain free; PR = partial response, partial pain relief, substantial improvement; NC = no change, unchanged pain; OV = orthovoltage; HV = high voltage; MV = megavoltage.

* CR plus PR rates.

comparisons, interobserver, as well as inter-institutional, comparisons, and outcome analysis for painful HSS (39). The overall subjective treatment results revealed complete pain relief for >3 months in 70% of patients and persisting pain relief in 65% of patients. Only 19% required a second RT series. These results are very encouraging compared with the results of conventional treatment (17, 78–80). Our clinical data were compared with data from a literature review encompassing 16 studies with a total of 3472 patients (6, 34, 35, 63, 71–74, 76, 81–87). The response rates (complete and partial) varied between 67% and 100% (median 80%), in the same range as our PCS demonstrated. Only a few studies had a prospective design (6, 35, 74). The studies and outcome data are summarized in Table 3. Thus, despite large experience, limited evidence-based outcome data on the use of RT in painful HSS exist. In addition, the exact radiobiologic mechanisms of the effect of ionizing radiation on HSS have been incompletely investigated and understood (88, 89). However, cell death and inhibition of proliferation as seen during cancer treatment are not expected to be involved in the response to these low doses (90). Older theories described an influence on the vascular endothelium with improved tissue perfusion; destruction of inflammatory cells (especially lymphocytes) with release of cytokines and proteolytic enzymes; modulation of the vegetative nervous system; alteration of the tissue pH; and increased membrane permeability (91–94). Recent studies showed that effects of low-dose ionizing radiation also exist on the molecular and cellular level involving adhesion molecules, apoptosis, cytokine expression, and inflammation cascade (69, 95–103). A new and very interesting hypothesis is the inhibition of oxidative burst formation in human phagocytic cells (90, 104). Most likely, radiation acts, not through a single mechanism, but through a complex interaction of different

effects. As already shown by von Pannewitz (63) in a rabbit arthritis model in 1933, low-dose RT is able to reduce the inflammatory reaction, but not the morphologic changes, of the joints. These findings may explain why a longer pain history or more pretreatment attempts were associated with a worse outcome. A longer course of disease, which is mostly accompanied by a larger number of unsuccessful treatment attempts, may lead to morphologic changes that cannot be reversed by RT (74).

The most important competing treatment option is ESWT. Recently, encouraging results in HSS were demonstrated. Pain relief was achieved in up to 80% (24). Similar to RT, the biologic mechanisms are poorly understood (105). Moreover, ESWT has not always shown convincing outcome data in controlled clinical trials (106).

All participating institutions reported no RT-related acute and chronic side; in particular, no radiation-associated malignancies were reported with a median follow-up of 28 months and a maximum of 335 months. This confirms other reports describing or calculating a low carcinogenesis risk after RT for nonmalignant disorders (107–109). It is not unexpected that the vast majority of all German radiotherapists asked in this national survey judged RT for painful heel spur to be a worthwhile treatment indication.

CONCLUSION

This PCS comprised the largest number of cases reported of RT for painful HSS. RT provides an excellent alternative for patients with refractory pain or contraindications to conventional therapy. Despite some variations of the routine RT practice, this national PCS presents a very large number of painful HSS treated effectively by RT. The results of this

national PCS will lead the GCG-BD to the following tasks: (1) the standardization of RT practice for painful HSS; (2) the establishment of validated orthopedic scores, including subjective

and objective criteria in clinical routine and controlled clinical practice; and (3) the initiation of prospective clinical studies assessing dose reduction without loss of effectiveness.

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APPENDIX A

The members of the Patterns of Care Study in Benign Disease Panel are as follows: M. H. Seegenschmiedt (Chairperson and Coordinator), Alfried Krupp Krankenhaus, Essen, Germany; O. Micke (Co-Chairperson and Secretary), Münster

University Hospital, Münster, Germany; F. Bruns, Hannover University Hospital, Hannover, Germany; U. Schäfer, Münster University Hospital, Münster, Germany; and H.-Br. Makoski, Staedtische Kliniken, Duisburg, Germany.

Members of Patterns of Care Study in Benign Diseases Panel

Investigator	Institution
M. H. Seegenschmiedt (Chairman & Coordinator of the Group)	Alfried Krupp Krankenhaus, Essen, Germany
O. Micke (Co-Chairman & Secretary)	Münster University Hospital, Münster, Germany
F. Bruns	Hannover University Hospital, Hannover, Germany
U. Schäfer	Münster University Hospital, Münster, Germany
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APPENDIX B

Questionnaire sent out by German Cooperative Group on Radiotherapy for Benign Diseases for patterns of care study on radiotherapy for heel spur syndrome/plantar fasciitis/calcaneodynia.

German Cooperative Group on Radiotherapy for Benign Diseases (GCG-BD)
Radiotherapy (RT) in Heel Spur Syndrome (HSS)/Plantar Fasciitis/Calcaneodynia
General Institutional Data:

[..] = Please mark [X] !

Institution: [] University Hospital [] Community Hospital
 [] Private Institution [] Other:

Address (Stamp):

.....

.....

Contact person :

Experience with radiotherapy (RT) for heel spur syndrome / plantar fasciitis : [] Yes [] No

If yes, please provide further information : Average number of cases per year :

Reference to RT: [] General Practitioner (Number): [] Orthopedist (Number):
 (Please mark!) [] Other Disciplines (Number):
 Please specify:

Pain Localization: [] plantar (Number): [] dorsal (Number):
 (Please mark!) [] Other (Number):
 Localization (please specify):

Which number of pretreatments is most frequently documented?

(Please mark only one!) [] none [] 1 Tx [] 2-3 [] 3-5 [] > 5 Therapies

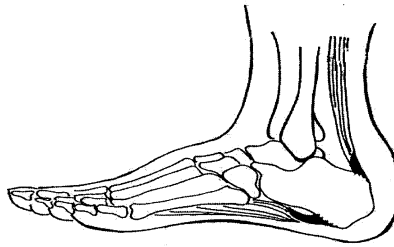
Which treatments were regularly documented ? [] Surgical intervention (s) [] Physical Therapy:
 [] Shoe modifications [] Local injections
 [] Oral Medication (Pain Medication, NSAR) [] Shock Waves (ESWT)
 (Please mark!) [] Other (please specify):

Which indications for RT do use ? [] Acute Pain [] Chronic pain for weeks
 [] Therapy refractory Pain after (Number) pretreatments
 [] Other Indications :

Information on RT:

Target Volume Concept: Whole back foot Whole Calcaneus
 (Please mark!) Other (please specify):

Please outline the corresponding field extension!



Treatment planning concept: Radiological simulation/localization
 Clinical set-up treatment unit

RT-Concept: Total dose: Gy Single dose: Gy
 Fractions / week: 2x 3x 5x Other x
 Dose specification :

RT-Equipment: Orthovoltage: kV Cobalt-60 Linac: (MV)
 Other:

Clinical Evaluation

Number of patients / cases (total) : since year

Use of
Pain scores ? No Yes If yes, which ?
Functional scores ? No Yes If yes, which ?

Treatment results? Pain ↓ for at least 3 Months: (Number) (Percentage)
 Pain ↓ for at least 12 Months: (Number) (Percentage)
 Continuous pain relief: (Number) (Percentage)
 No improvement: (Number) (Percentage)
 2. RT-Series necessary: (Number) (Percentage)
 3. RT-Series necessary: (Number) (Percentage)

Radiogenic side effects ? No Yes: (Number) (Percentage)
 If yes, which ?

Publications and/or Abstracts No Yes If yes, which ? (Source, possibly send copy!)

Personal Estimation:

Personally, I consider the RT for painful heels as
 very worthwhile worthwhile less worthwhile not worthwhile

APPENDIX C

Form to use when determining heel pain score according to criteria suggested by German Cooperative Group on Radiotherapy for Benign Diseases.

Heel Pain (Calcaneodynia)

Patient **Date of Birth**

Address

	Plantar Heel Spur	Dorsal Heel Spur	Achillodynia		
Pain	only right (R)	only left (L)	R > L	R < L	R = L
- Direction	no direction	to the sole and forefoot	in the calf lower leg	both directions	
- Onset	creeping / chronic	acute / sudden	not to explain		
- Time / Type	onset of strain	permanent at daytime	at rest	at night	
	Grade:	
- Release	w/o strain	while standing	while walking	while jumping	
	Grade:	
- Additional complaints:				

Effects on Profession / Sports only **profession** only **sports** **both**

Practiced **Profession** :

able to work **unable** to work **no profession** before treatment

Practiced **Sport**:

fully able to practice **restricted** practice **not able to practice**

Pretreatment (Please mark appropriate fields !) from / to /

	Physical Measures	Orthopedic Measures
	Cold / Heat Applications	External Stabilization Aid
	Ultrasound / Lithotripsy	Shoe Inlays / Insoles
	Microwaves / Electric Currents	Other Cushion / Padding
	Medication / Injections	Surgical Measures
	Oral Meds.:	Which:
	Injections :	

Functional Tests Toe Stand Toe Walking Heel Stand Heel Walking
(✓ = possible)

Calcaneodynia - Score

Applicable for the following disease entities: **Plantar Heel Spur / Achillodynia**

Evaluation: before RT ; during RT ; Weeks / Months / Years after RT

Criteria	Extent of Symptoms / Alteration	Points
1. Pain Symptoms (total: 30%) per single criterion:	S = Pain at Strain	6 / 4 / 2 / 0
	N = Pain during Night Time	6 / 4 / 2 / 0
	D = Pain during Day Time (continuously)	6 / 4 / 2 / 0
	R = Pain at Rest (following any kind of strain)	6 / 4 / 2 / 0
	I = Pain at Initiation of Movement / Morning Stiffness	6 / 4 / 2 / 0
	none = 6 ; slight = 4 ; moderate = 2 ; severe = 0 points	
	⇒	
2. Use of Appliances (total: 15%)	No Appliances	15
	Orthopedic shoe, Insoles, heel cushion	10
	One cane or crutch	5
	Two canes or crutches	0
	⇒	
3. Professional Activities (total: 20%)	No limitation, maximum professional strain possible	20
	Slight limitation, normal professional work possible	10
	Moderate limitation, reduced professional activity	5
	Severe limitation, daily professional work impossible	0
	⇒	
4. Daily / Leisure Activities (total: 15%)	No limitation of daily and leisure activities and sports	15
	Slightly limitation / reduced leisure activities and sports	10
	Moderate limitation / no leisure activities and sports	5
	Complete limitation of any daily and leisure activities	0
	⇒	
5. Gait / Limp (total: 20%)	No limp, normal walking is possible without a limitation	20
	Slightly altered, limp after walking > 1 km (2 blocks)	10
	Moderately altered, limp after walking < 1 km (2 blocks)	5
	Severely altered, normal walking is impossible	0
	⇒	
Total Score	Sum of the single scores 1 + 2 + 3 + 4 + 5 ⇒	

modified from: Heyd et al.: Radiology (2001) and Seegenschmiedt et al.: Radiology (1996)

Subjective estimation of the overall quality of life by the individual (X):

[-----i-----i-----i-----i-----i-----i-----i-----i-----i-----i-----]

.....
Date

.....
Physician-Signature

APPENDIX DHeel score as determined by criteria of Rowe *et al.* 1963

(45)

Criteria	Response level	Score*
Pain	None	30
	Mild	20
	Moderate	10
	Severe	0
Use of appliances	None	15
	Insoles, heel pads	10
	One cane or crutch	5
	Two canes or crutches	0
Work	No limitation, heavy work possible	20
	Slight limitation, heavy work possible	10
	Severe limitation, daily work not possible	0
Daily activities	Normal, no limitation of daily activities	15
	Mild limit	10
	Moderate limit	5
	Complete limit	0
Gait	No limp, normal walking possible without limit	20
	Mild, pain and limp after a distance >1 kilometer	10
	Moderate, pain and limp after a distance <1 kilometer	5
	Severe, normal walking not possible	0

*Excellent = 90–100 points; good = 70–85 points; fair = 40–69 points; and poor = 0–39 points.

APPENDIX E

Pain scale for evaluation of benign diseases according to von Pannewitz (47)

Score	Response*	Description
1	Complete response	pain free
2	Partial response	Substantial pain improvement
3	Minor response	Moderate pain improvement
4	No change	Pain unchanged
5	Progressive disease	Worse pain

*Treatment success determined by addition of complete and partial responses.