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RESEARCH ARTICLE

EFFICACY OF EXTERNAL BEAM RADIOTHERAPY FOR THE MANAGEMENT OF REFRACTORY PLANTAR FASCIITIS: A PROSPECTIVE STUDY

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ABSTRACT

Purpose: To evaluate the efficacy of external beam radiotherapy for the management of refractory plantar fasciitis and to assess radiation induced side effects, including malignancy.

Material and Method: The study was carried out in Department of Radiotherapy, PGIMS, Rohtak (India), on 36 diagnosed cases (56 heels) of plantar fasciitis. These diagnosed patients of plantar fasciitis having pain, refractory to medical treatment, were accrued for and given external beam radiation therapy (EBRT) during 2005-08. The dose of EBRT was 6 Gy in 6 fractions over 2 weeks (1Gy per fraction, 3 fractions per week), given on Telecobalt. Assessment was made for response – at completion of radiotherapy, after six months and one year following radiotherapy. Response was evaluated using Objective (Calcaneodynia) pain score and Subjective (von Pennewitz) pain score. Acute skin reactions were noted at completion of radiotherapy. Late event as radiation induced malignancy was noted after at least 6 years following treatment.

Results: Six months following EBRT, complete/ excellent response (CR) was observed in 62.5% heels, both by objective and subjective scores. Partial/ good response (PR) was 16.1% on objective score and 23.3% on subjective score, minor/ fair response (MR) was 12.5% & 7.1% and no/poor response (NR) was 8.9% and 7.1% respectively. One year after radiotherapy, Calcaneodynia objective score revealed CR, PR, MR and NR respectively were 80.4%, 7.1%, 8.9% and 3.6%. No progressive disease was found in any of the heels treated with radiotherapy during treatment or follow-up. No significant acute skin reaction was observed. None of the patients has reported with radiation induced or second malignancy so far.

Conclusion: External beam radiotherapy offers very good treatment option for management of plantar fasciitis pain refractory to medical treatment. EBRT may be offered to patients, particularly older, without the historical fear of radiation induced malignancy. Though, equally effective in young patients, conclusive words regarding risk of long term side effects still need longer follow up.

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INTRODUCTION

Epidemiology

Plantar fasciitis, inflammation of plantar fascia, is the most common cause of inferior heel pain. The condition is seen between the ages of 8 to 80 years, but is common in middle aged women and male runners. The common risk factors for plantar fasciitis include: sudden gain in body weight, obesity, unaccustomed walking or running, shoes with poor cushioning, increase in running distance or intensity, change in the walking or running surface and tightness of achilles tendon (Singh *et al*., 1997). The condition was first described in 1900 by Plettener (Plettner, 1990). Anglo-American countries use the term plantar fasciitis. Another term 'heel spur syndrome' derived from the German word "Kalkanneus sporn" for calcaneal spur, is also used synonymously. The prevalence of this disorder ranges from 8% to 10% in general population (Bulstrode, 2002). Reliable population based data of this disorder in India is not available.

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Clinical presentation

Patients present with heel pain. Physical examination in a patient with plantar fasciitis shows localized tenderness on the antero-medial aspect of the heel, elicited by a firm finger pressure to localize the point of maximum tenderness. Associated mild swelling is a common finding. Tightness of the Achilles tendon (dorsiflexion at the ankle limited by 50 or more) is found in 78% of patients (Keilholz, 1998). Plantar fasciitis is usually unilateral, but up to 30% cases have bilateral presentation (Roxas, 2005). Lateral view radiograph shows the pointed bone lesion at the tuberculum medial calcanei, which is a "tractional osteophyte" at the insertion of the plantar fascia. Also, sclerosis & thickening of the periosteum at the calcaneum and a wide plantar fat pad may be seen. In acute phase, ultrasound shows edema of the plantar aponeurosis as decreased echogenicity. Chronic stress leads to thickening of the plantar fascia, with intermediate echoes.

Scintigraphy shows pathological uptake at the insertion of the plantar aponeurosis, even when the X-ray is normal. It has highest sensitivity for detection of fasciitis in the acute phase. Magnetic resonance imaging (MRI) is recommended for its high soft tissue contrast and anatomic resolution, resulting in high sensitivity and specificity. Blood count and erythrocyte sedimentation rate is recommended in patients with bilateral disease or an atypical clinical picture.

Differential diagnosis

Other causes of heel pain should be ruled out to make diagnosis of plantar fasciitis (Table 1).

Etio-pathology

Proposed mechanism of chronic degenerative/reparative process secondary to stress over load explains why the syndrome is found in both overweight and active individuals. Reactive bone formations occur as part of regressive changes in insertion tendons. The plantar heel spur grows into the plantar fascia along the traction and pressure lines of the calcaneus. On histological examination one can find degenerative signs, collagen necrosis and angiofibroblastic proliferations (Rödel *et al*., 2007; Hildebrandt *et al*., 1998).

Treatment

Various treatment options available for plantar fasciitis can be grouped into non-surgical and surgical treatments. Excluding external beam radiotherapy (EBRT), nonsurgical treatment includes exercise for stretching the Achilles tendon, oral anti-inflammatory drugs; local measures (hot and cold baths), orthoses, iontophoresis and adjunctive treatments options (night splints, vascico-elastic heel cup and rubber heel cups). For recalcitrant cases, treatment options are injections of lignocaine plus corticosteroids, customized orthotic devices, strapping of the foot or total contact (below knee) cast (Roxas, 2005). Other non-surgical methods are- extracorporeal shock wave therapy, laser treatment, microwave, ultrasound applications, magnetic insoles and exposure to an electron-generating device are also used to treat plantar fasciitis but long term outcome data are yet to come for most of these methods.[5] None has yet demonstrated a clear superiority over the other with convincing results (Crawford, 2002). Surgical intervention should be considered only for intractable pain which has not responded to 12 months of proper conservative treatment.

Radiotherapy for plantar fasciitis

Since, Sir Wilhelm Conrad Roentgen discovered X-rays in 1895, radiation therapy has been given successfully to patients suffering from a wide variety of benign diseases, including plantar fasciitis, though reserved only for patients who are refractory to standard treatments. In 1995 the German Working Group on "Radiotherapy for Benign Diseases" was founded together with the German Radiation Oncology Society. In 1996 a national conference on RT for benign diseases was held and treatment guidelines were anticipated. In 1997 the consensus process started, and in 1999 it was finalized.

As the total radiation dose in benign disease is much less than that given in malignancies; the radiobiological mechanisms postulated to be involved in its therapeutic effect are different. These mechanisms include anti-proliferative, immune modulator, anti-inflammatory and functional (Rödel , 2007; Hildebrandt, 1998). Lack of understanding of the mechanisms of action of radiotherapy in benign diseases and awareness of the potential risks probably contributed to the marked reduction of cases treated by radiotherapy. Recent studies show very encouraging results of radiation therapy in plantar fasciitis (Crawford, 2002; Schafer *et al*., 1995; Glatzel, 2001; Heyd *et al*., 2007; Mucke *et al*., 2007; Micke *et al*., 2001; Mucke *et al*., 2003; Schneider *et al*., 2002; Heyd *et al*., 2001; Seegenschmiedt *et al*., 1996; Thomas *et al*., 2001; Micke *et al*., 2002; Micke *et al*., 2004). Plantar fasciitis behaves in a far from benign way and has extremely morbid and unpleasant behavior that leads to change in routine life of patients. These patients seriously deserve our efforts to minimize their sufferings and to establish a clear-cut role of radiation therapy in management of plantar fasciitis.

Secondary malignancy: The fear factor

Despite a perceived worry that a low dose radiation used to treat a benign disease could induce malignancy, no secondary malignancies due to radiations in benign diseases were observed during the reported follow-up of nearly 31 years (range22-36 years) (Surenkok *et al*., 2006). The calculated mean carcinogenesis risk is 1.3% for radiation treatment in plantar fasciitis, and no secondary cancer has been clinically observed with minimum 5-year and maximum 29-year follow-up (mean 11.9 years). It has also been observed that benign disease treatment with low dose radiations up to 15 Gy shows no evidence of secondary malignancy (Rath, 2002).

MATERIALS AND METHODS

Patients

The study was carried out in Department of Radiotherapy, PGIMS, Rohtak (India), on 36 diagnosed cases (56 heels) of plantar fasciitis after approval of Institute's Ethical Committee. These diagnosed patients of plantar fasciitis having pain, refractory to medical treatment, were accrued for and given external beam radiation therapy (EBRT) during 2005-08. The dose of EBRT was 6 Gy in 6 fractions over 2 weeks (1Gy per fraction, 3 fractions per week), given on telecobalt. Patients who had received radiation therapy to foot due to any reasons were excluded from the study.

An informed consent was taken before any intervention. Patient's characteristics are shown in Table 2.

Pretreatment evaluation

Pretreatment evaluation of the patients included history, general physical examination and complete systemic examination. The assessment of patients was done by the scores proposed by the German cooperative group for benign disease (GCG-BD) / Calcaneodynia score (Appendix A). Treatment success was defined as pain free and substantial pain improvement by using above mentioned pain scores and also by subjective von Pennewitz pain score (Appendix B).

Methodology

Prior approval of ethical board of institute was sought to carry out the study. Each case of plantar fasciitis was treated on Telecobalt machine. External beam radiotherapy (EBRT) given was total of 6 Gy in 6 fractions (1Gy / Fraction), 3 fractions per week (alternate days) to each heel. The target volume included the lower part of calcaneum, the calcaneal origin and major part of the plantar fascia with in the treatment portal (Figure 1). Irradiation was carried out by two lateral opposing fields after individualization.

Observations

Assessment was made for response – at completion of radiotherapy, after six months and one year following radiotherapy. Response was evaluated using Objective (Calcaneodynia) pain score and Subjective (von Pennewitz) pain score. Zero score meant maximum pain where as score of 100 meant no pain. Acute skin reactions (as per RTOG criteria) were noted at completion of radiotherapy. Late event as radiation induced malignancy was noted at least 6 years following treatment. The data thus collected has been subjected to statistical analysis.

Quality assurance

The study was carried out, only after the protocol was approved by the institution's ethics review board. Senior radiation oncologists in the department reviewed the records and also conducted examination of the patients at random, to verify the findings.

Study design

Study design is shown in Figure 2.

RESULTS

A. Response to radiotherapy: Table III, Table IV and Figure 3 show response to radiotherapy

Even on completion of radiotherapy, 87.5% heels responded, though most (78.6%) were minor response, only 8.9% partial response and none with complete response; as assessed by objective score. Six months following EBRT, complete/ excellent response (CR) was observed in 62.5% heels, both by objective and subjective scores. Partial/ good response (PR) was 16.1% on objective score and 23.3% on subjective score, minor/ fair response (MR) was 12.5% & 7.1% and no/poor response (NR) was 8.9% and 7.1% respectively.

One year after radiotherapy, Calcaneodynia objective score revealed CR, PR, MR and NR respectively as 80.4%, 7.1%, 8.9% and 3.6%. No progressive disease was found in any of the heels treated with radiotherapy during treatment or follow-up. As evident from table 4, Calcaneodynia pain score continuously improved by the end of radiation treatment and over the course of follow up of one year.

Comparative observations- subgroup analysis

For the comparison of response, von Pennewitz pain score was used.

A 1. Relation to age

Table V shows age group wise response. There was progressively better response observed with increasing age. After 1 year of radiotherapy, patients of age more than 40 years showed complete response in 93.3% (14/15 heels) cases compared to 75.6% (31/41 heels) cases of age 40 years or lesser (Figure 4).

A 2. Relation to gender

No statistically significant relation between sex and treatment response, though slightly better outcomes were observed in females. After 1 year of radiotherapy, female patients showed complete response in 82.4% (28/34 heels) cases compared to 77.3% (17/22 heels) in males.

A 3. Relation to duration of pain prior to radiotherapy

After 1 year of radiotherapy, heels with pain duration below 12 months showed better complete response- 85.0% (17/20 heels) compared to those with pain duration of 12 months or more- 77.8% (28/36 heels).

Skin reactions

No skin reactions were observed in any of the patients during and after radiation treatment and up to a follow-up period of six months.

Secondary malignancy

More than 6 years since radiotherapy and none of the patients have reported with radiation induced or second malignancy so far.

DISCUSSION

Although, plantar fasciitis is benign disease, the morbidity associated with it is no less than that of malignancy. Many patients find it highly debilitating resulting in alteration of lifestyle and/ or even change of occupation. This study, among the very few prospective studies (Schneider *et al*., 2002; Heyd *et al*., 2001), addresses the issue of efficacy assessment by objective pain scale and after effects of radiotherapy use for the management of medical treatment refractory plantar fasciitis/ painful heel spur. On completion of radiotherapy, we observed objective response in 87.5% heels, though most (78.6%) were minor response, only 8.9% partial response and none with complete response. Promising long lasting results were achieved. One year after radiotherapy, Calcaneodynia objective score revealed CR, PR, MR and NR respectively as 80.4%, 7.1%, 8.9% and 3.6%.

Table 1. Differential Diagnosis of Heel Pain

Neurological causes (entrapment syndromes)	Radiating burning pain, numbness and tingling, especially at night
Tarsal tunnel syndrome	Diffuse symptoms over plantar surface
Medial calcaneal branch of the posterior tibial nerve entrapment	Medial and plantar heel symptoms
Abductor digiti quinti nerve entrapment	Burning pain in heel pad area
Skeletal causes	Bony point tenderness
Calcaneal stress fracture activity	Pain with weight-bearing, worsens with prolonged weight-bearing
Paget's disease	Bowed tibias, kyphosis, headaches
Tumor	Deep bone pain, constitutional symptoms late in the course
Calcaneal apophysitis (Severe's disease)	Posterior heel pain in adolescents
Soft tissue causes	Diffuse pain
Fat pad syndrome	Atrophy of heel pad
Heel bruise	History of acute impact injury
Bursitis	Usually retrocalcaneal, swelling and erythema of posterior heel
Plantar fascia rupture	Sudden acute, knife-like pain, ecchymosis
Tendonitis	Pain with resisted motions
Plantar fasciitis	Pain which is worst on first weight bearing in the morning

Table 2. Patient characteristics (N= 36) Heels= 56

Characteristics		Number (%)
Age (years)		
	Range	22 to 59 years
	Mean	37.9 years
Gender		
	Males	16 (44.4%)
	Females	20 (55.6%)
Social background		
	Rural	17 (47.2%)
	Urban	19 (52.8%)
Duration of pain (Month)		
	< 12 months	15 (41.7%)
	≥ 12 months	21 (58.3%)
	Range	8 – 35 months
	Mean	19 months
Lateralization of pain		
	Left	6 (16.6%)
	Right	10 (27.8%)
	Bilateral	20 (55.6%)
Prior treatment taken		
	Fomentation (Ice/Heat)	36 (100%)
	Physiotherapy	36 (100%)
	Ultrasound/ Microwave	24 (66.7%)
	Analgesics (Oral / Inj)	36 (100%)
	Analgesics + Steroids	22 (61.1%)
	Orthotic devices (Splint/Fixation/Shoe adjustment)	24 (66.7%)
	Surgery	Nil
Calcaneodynia Pain score (Maximum pain = 0, No pain = 100)		
	<20	Nil
	21-25	14 (25.0%)
	26-30	19 (33.9%)
	31-35	20 (35.7%)
	36-40	03 (5.4%)
	>40	Nil
	Mean	30 ± 3.77
	Range	25 – 39

Table 3. Response to radiotherapy as per standard pain scores (N=36, Heels=56)

Response	End of RT		6 Months post radiotherapy				1 year post radiotherapy	
	CPS		CPS		*VPS*		CPS	
	Number	%	Number	%	*Number*	*%*	Number	%
CR	00	-	35	62.5	*35*	*62.5*	45	80.4
PR	05	8.9	09	16.1	*13*	*23.3*	04	7.1
MR	44	78.6	07	12.5	*04*	*7.1*	05	8.9
NR	07	12.5	05	8.9	*04*	*7.1*	02	3.6
PD	00	-	00	-	*00*	-	00	-

CR=Complete response, PR=Partial response, MR=Minor response, NR= No response, PD= Progressive disease
CPS = Calcaneodynia pain score, VPS = Von pennewitz pain score

Table 4. Response as per Calcaneodynia Pain score (N=36, Heels=56)

Statistics	Pre-RT	End of RT	6 months	1 year
Mean ± Standard deviation	30±3.77	50.84±11.23	80.71±18.44	88.29±15.45
Range of pain score	25 – 39	29 – 78	32 – 96	36 – 98

Table 5. Age group wise response (N=36, Heels=56)

Age group (Years)	No. of Heels	CR (%) at 1 year	< CR (%) at 1 year
21-30	12	07 (58.3)	05 (41.7)
31-40	29	24 (82.8)	05 (17.2)
41-50	7	06 (85.7)	01 (14.3)
51-60	8	08 (100)	00
Overall	56	45 (80.4)	11 (19.6)

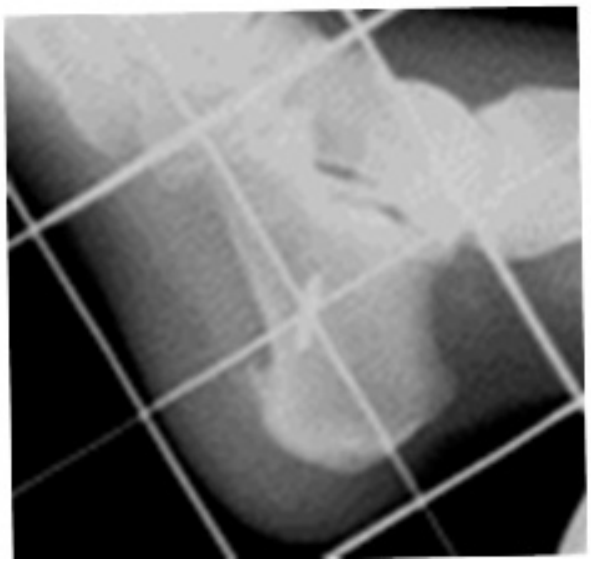

Figure 1. Treatment Portal

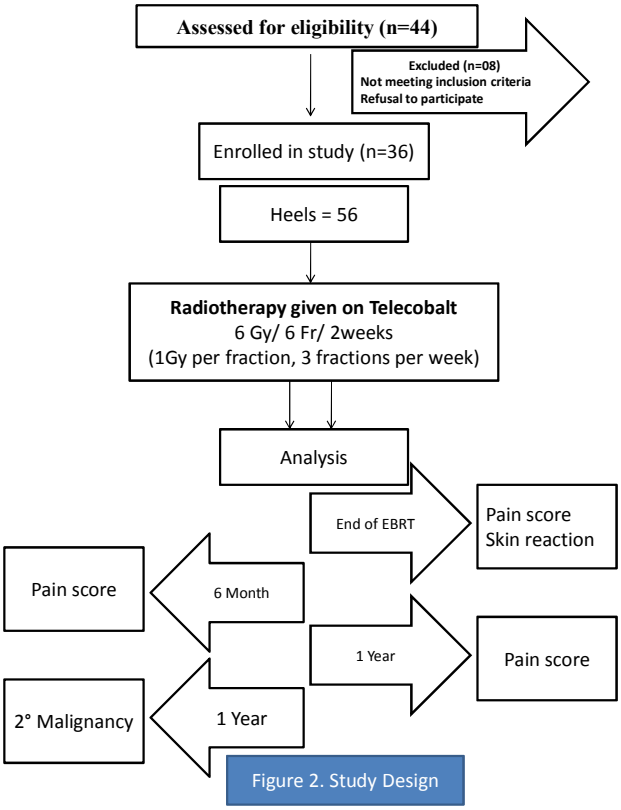

Figure 2. Study Design

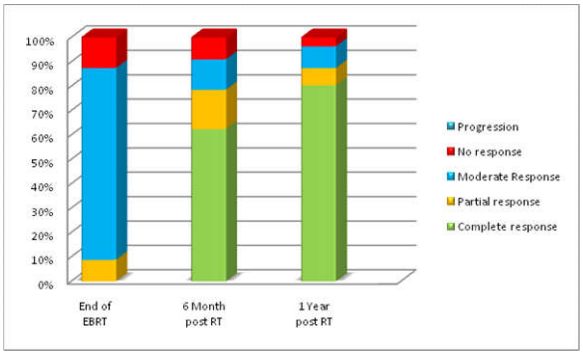

Figure 3. Response to radiotherapy as assessed by Calcaneodynia pain score (heels = 56)

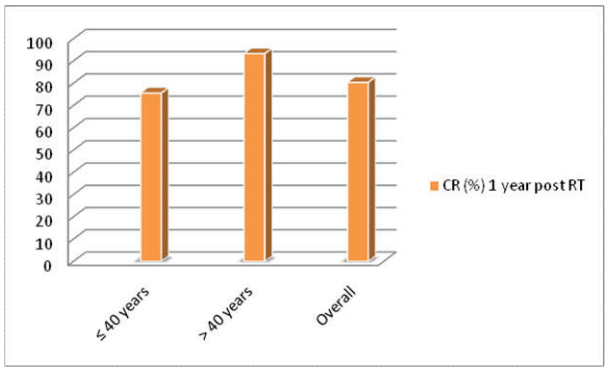

Figure 4. Age group wise CR (%) - 1 year post Radiotherapy

No progressive disease was found in any of the heels treated with radiotherapy during treatment or follow-up. Calcaneodynia pain score continuously improved by the end of radiation treatment and over the course of follow up of one year. Muecke *et al*. (2003) retrospectively analyzed 117 patients (136 heels) treated between 1996 and 2000 with low-dose radiotherapy (RT) for painful heel spurs. Low-dose radiotherapy was performed twice a week with 6-MV photon, 10 fractions of 0.5 Gy, to a total dose of 5 Gy. As early as on completion of radiotherapy, 27 patients (23.1%) were free of pain when evaluated using the von Pannewitz score. Schneider O, *et al*[15] in a prospective study over 74 patients, using EBRT in total dose of 5 Gy in 7 fractions, given twice a week, reported subjective pain relief in 84.5 % cases, 6 weeks after radiotherapy.

Glatzel *et al*. (2001) in a retrospective analysis using orthovoltage radiotherapy, 6 x 1 Gy within 2 weeks reported complete pain relief in 63% cases within 6 weeks on an average after completion of treatment. Results of the study concluded high efficacy of radiotherapy of painful heel spur, total dose of 6 Gy to be sufficient in most of the cases. In this study, approximately three fourth heels (73.2%) belonged to patients below 40 years. Mean age at presentation was 37.9 years with a standard deviation (SD) of 10.069 years and range of age was from 22 – 59 years. Study by Mucke *et al*. (2003) shows median age was 58 with a range from 30 to 84 years. Studies by Schneider, *et al*. (2002) showed that mean age was 55 years. Also that older patients (>50 years) showed a significantly better pain relief (37.1 % vs. 11.1 %; $p<0.01$), 6 weeks post-radiotherapy. Present study also confirms that older patients (>40 years) showed better pain relief (CR- 93.3% vs. 75.6%), 1 year post-radiotherapy. After 1 year of radiotherapy, heels with pain duration below 12 months showed better complete response- 85.0% (17/20 heels) compared to those with pain duration of 12 months or more- 77.8% (28/36 heels). Study by Micke *et al*. (Micke *et al*., 2004) Seegenschmiedt MH *et al*. (1996) and Muecke *et al*. (2003) also found duration of pain prior to radiotherapy as prognostic factor and considered radiotherapy as early primary approach rather than last resort. Schneider *et al*. (2002) observed no such relation.

Conclusion

External beam radiotherapy offers very good treatment option for management of plantar fasciitis pain refractory to medical treatment. EBRT may be offered to patients, particularly older, without the historical fear of radiation induced malignancy. Though, equally effective in young patients, conclusive words regarding risk of long term side effects still need longer follow up.

Availability of Data and Materials: Please contact author for data requests

List of abbreviations: Mentioned with main text

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Appendix A- Calcaneodynia score

Criteria	Extent of symptoms/ Alteration	Points
1. Pain symptoms	S = Pain at Strain	6 / 4 / 2 / 0
	N = Pain during night time	6 / 4 / 2 / 0
(Total : 30%)	D = Pain during day (continuously)	6 / 4 / 2 / 0
	R = Pain at rest (following any kind of strain)	6 / 4 / 2 / 0
Per single criterion	I = Pain at initiation of movement/ morning stiffness	6 / 4 / 2 / 0
	None- 6, Slight- 4, Moderate- 2, Severe- 0	
		Sum 1
2.Use of appliances	No appliances	15
	Orthopedic shoe, Insoles, Heel cushion	10
(Total : 15%)	One cane or crutch	05
	Two canes or crutches	00
		Sum 2
3.Professional activities	No limitation, maximum professional strain possible	20
	Slight limitation, normal professional work possible	10
(Total : 20%)	Moderate limitation, reduced professional activity	05
	Severe limitation, daily professional work impossible	00
		Sum 3
4.Daily/ Leisure activities	No limitation of daily and leisure activities and sports	15
	Slight limitation/ reduced leisure activities and sports	10
(Total : 15%)	Moderate limitation/ no leisure activities and sports	05
	Complete limitation of any daily and leisure activity	00
		Sum 4
5.Gait / Limp	No limp, normal walking possible without limitation	20
	Slightly altered gait, limp after walking >1km (2 blocks)	10
(Total : 20%)	Moderately altered gait, limp after walking <1km (2 blocks)	05
	Severely altered gait, normal walking is impossible	00
		Sum 5
Sum 1 + Sum 2 + Sum 3 + Sum 4 + Sum 5		TOTAL SCORE

Appendix B. Von Pannewitz pain scale for evaluation of benign disease

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

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