

## **RADIOTHERAPY FOR PRIMARY OR RECURRENT MORBUS LEDDERHOSE: 12 YEAR LONG-TERM OUTCOME OF A PROSPECTIVE PHASE 2 TRIAL.**

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### **PURPOSE:**

Long-term outcome analysis of a prospective phase 2 study to analyze the use of radiotherapy (RT) for Morbus Ledderhose (ML) to prevent disease progression.

### **METHODS:**

From 1997 to 2009 over 143 patients with ML have been referred to our clinic with symptomatic and progressive ML to receive RT for prevention of disease progression. As of 12 / 2009, 138 pts (71 M; 67 F) have been evaluated for at least 1 years follow-up (FU; median: 6 years). 54 patients had one foot (28 R, 26 L) affected and 84 had bilateral affliction; thus, a total of 222 feet were afflicted and additional 54 feet were uninvolved and observed in long-term FU. While 47 (34%) patients (94 feet) with 67 affected feet, but only minimal symptoms served as control without RT, 91 (66%) patients and 126 feet received RT for primary (n = 66) or recurrent ML. Of the 138 pts, 68 had Morbus Dupuytren (MD) or knuckle pads (n = 8), keloids (n = 11), diabetes mellitus (n = 12), epilepsy (n = 2), liver disorders (n = 7), foot trauma (n = 13), and 39 patients reported nicotine abuse. Time from first observation to first consultation was 12 months. RT was applied with 10 x 3Gy in two RT series of 5 x 3Gy separated by 8 weeks and delivered using 125 to 150 kV photons, lead rubber shielding and superflab bolus for individual set-up. ML was classified in 4 grades; the clinical evaluation (toxicity, efficacy) was performed at 3 months and 1 year after RT and every year thereafter.

### **RESULTS:**

Acute and late side-effects were minimal: 26 and 6 feet developed CTC grade 1 and 2 skin changes; chronic side-effects (mostly dry skin within the RT portal) were observed in 20 feet. At last FU, clinical disease progression was observed in 11 of 126 (9%) feet; 56 (44%) had stable disease and 59 (47%) showed objective remission of disease. 24 of 62 feet with cords. Moreover, total relief or reduction of symptoms was also pronounced in the RT group: 18 of 22 feet with itching, 48 of 62 with tension sensation, 74 / 100 with pressure sensation, 71 / 86 with pain during walking and 32 / 47 with pain at rest. In contrast, in the control group without RT, 23 of 67 (34%) feet progressed and required treatment, 34 (61%) remained stable and 10 (15%) had a spontaneous remission or reduction of symptoms without treatment.

### **CONCLUSION:**

External beam RT is effective and improves long-term outcome for progressive ML; RT is well tolerated and reduces or avoids otherwise necessary surgical procedures. As no primary treatment is available sofar, RT appears to be the treatment of choice when symptoms progress and affect daily quality of life and invasive procedures are to be avoided.