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Radiotherapy for Ledderhose disease: Results of the LedRad-study, a prospective multicentre randomised double-blind phase 3 trial

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Highlights

- First randomised controlled trial to investigate the efficacy of radiotherapy for Ledderhose disease.
- Radiotherapy for Ledderhose disease results in pain reduction in majority of patients.
- Quality of life improves after radiotherapy for Ledderhose disease and is comparable to the reference population.
- Side effects after radiotherapy for Ledderhose disease are limited.
- The most demanding walking situation for patients with Ledderhose disease, barefoot speed walking, significantly improves after radiotherapy.

Abstract

Background and purpose

Radiotherapy is considered a treatment option for Ledderhose disease. However, its benefits have never been confirmed in a randomised controlled trial. Therefore, the LedRad-study was conducted.

Materials and methods

The LedRad-study is a prospective multicentre randomised double-blind phase three trial. Patients were randomised to sham-radiotherapy (placebo) or radiotherapy. The primary endpoint was pain reduction at 12 months after treatment, measured with the Numeric Rating Scale (NRS). Secondary endpoints were pain reduction at 6 and 18 months after treatment, quality of life (QoL), walking abilities and toxicity.

Results

A total of 84 patients were enrolled. At 12 and 18 months, patients in the radiotherapy group had a lower mean pain score compared to patients in the sham-radiotherapy group (2.5 versus 3.6 ($p = 0.03$) and 2.1 versus 3.4 ($p = 0.008$), respectively). Pain relief at 12 months was 74% in the radiotherapy group and 56% in the sham-radiotherapy group ($p = 0.002$). Multilevel testing for QoL scores showed higher QoL scores

in the radiotherapy group compared to the sham-radiotherapy group ($p < 0.001$). Moreover, patients in the radiotherapy group had a higher mean walking speed and step rate with barefoot speed walking ($p = 0.02$). Erythema, skin dryness, burning sensations and increased pain were the most frequently reported side effects. These side effects were generally graded as mild (95%) and the majority (87%) were resolved at 18 months follow-up.

Conclusion

Radiotherapy for symptomatic Ledderhose disease is an effective treatment resulting in a significant pain reduction, improvement of QoL scores and bare feet walking abilities, in comparison to sham-radiotherapy.

