

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Radiation therapy for early Dupuytren's disease

1 Guidance

- 1.1 Evidence on the safety of radiation therapy for early Dupuytren's disease is limited in quantity but does not raise any serious safety concerns. The evidence on efficacy is limited in quantity and there is uncertainty about the natural history of early Dupuytren's disease, which makes evaluation of the effect of the procedure difficult. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake radiation therapy for early Dupuytren's disease should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy, the unpredictability of progression of early Dupuytren's disease, and that there is a theoretical risk of malignancy in the long term after any type of radiation therapy. Clinicians should provide patients with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG368publicinfo).
 - Audit and review clinical outcomes of all patients having radiation therapy for early Dupuytren's disease (see section 3.1).
- 1.3 Further research would be useful, particularly comparing the long-term efficacy of radiation therapy against the natural history of Dupuytren's disease. Both short- and long-term safety outcomes, such as dry hands and development of neoplastic disease, should be reported.

2 The procedure

2.1 *Indications and current treatments*

2.1.1 Dupuytren's disease is a benign, slowly progressive condition of unknown origin, characterised by connective tissue thickening in the palm of the hand, forming nodules and cords, which leads to difficulty in extending the fingers. Symptoms include reduced range of motion, reduced hand function and pain. Most patients are affected in both hands.

2.1.2 Treatments aim to restore hand function and/or prevent progression. These include needle fasciotomy in earlier stages and open surgical correction in later stages when secondary changes to tendons and joints have developed.

2.2 *Outline of the procedure*

2.2.1 The aim of this procedure is to prevent or postpone the need for surgical intervention. The mechanism of action of radiation therapy is unclear, but it is thought to affect the development and growth rate of fibroblasts within the palmar fascia.

2.2.2 Radiation therapy is delivered to the nodules and cords that have formed in the hands and is given over several consecutive days, until the planned radiation dose (usually about 15 Gy in 5 fractions) has been delivered. In severe disease, particularly if there is contracture of the proximal interphalangeal joint, more than 1 course of treatment may be used, with each course being separated by a few weeks.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/guidance/IP/780/overview

2.3 Efficacy

- 2.3.1 A randomised controlled trial (RCT) of 129 patients (198 hands) treated by 30 Gy or 21 Gy of radiation reported that objective symptom assessment (number and consistency of cords and nodules, and degree of extension deficit) showed regression in 56% (53/95) and 53% (55/103) of hands respectively at 1-year follow-up (no significant difference reported between groups). The same trial reported that subjective symptom assessment (not otherwise defined) showed regression of Dupuytren's disease in 65% (41/63) and 53% (35/66) of patients respectively at 1-year follow-up (significance between groups not stated).
- 2.3.2 A case series of 135 patients (208 hands) reported complete symptom relief in 16% (14/87) of patients; good symptom relief in 18% (16/87); minor symptom relief in 32% (28/87); no change in 14% (12/87); and worsening symptoms in 20% (17/87) of patients at median 13-year follow-up.
- 2.3.3 This case series of 135 patients (208 hands) reported stable disease in 59% (123/208) of hands and progression in 31% (65/208) of hands at median 13-year follow-up.
- 2.3.4 A case series of 25 patients reported full functional recovery in 32% (8/25) of patients, with maximum benefit achieved at 6 months. At final follow-up (range 2 to 10 years) 75% of patients had symptom improvement (not otherwise defined).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as correction of contracture, restoration of hand function and avoidance of recurrence requiring surgery. They expressed uncertainty about the procedure's efficacy for nodular disease, which is commonly asymptomatic and may not progress.

2.4 Safety

- 2.4.1 The RCT of 129 patients (198 hands) treated by 30 Gy or 21 Gy of radiation reported chronic toxicity events in 16% (15/95) and 11% (11/103) of hands

respectively at 3-month follow-up (significance not stated). These included skin dryness, increased desquamation, mild skin atrophy and slight subcutaneous fibrosis requiring ointments. Alteration of temperature and pain sensation was reported in 4% (8/198) of hands, although it is unclear to which treatment group this applied (minimum follow-up 1 year).

2.4.2 In a subset of 110 patients (168 hands) from the RCT of 129 patients, no significant difference was reported in the rate of acute skin changes between patients treated by 30 Gy (13% [10/78]) and 21 Gy (18% [16/90]) (significance and follow-up not stated).

2.4.3 The case series of 135 patients (208 hands) reported mild skin atrophy with occasional telangiectasia in 7% (14/208) of hands, and minor skin dryness and increased desquamation in 23% (47/208) of hands at median 13-year follow-up.

2.4.4 The Specialist Advisers considered the long-term potential for developing radiation-induced cancer to be a theoretical adverse event.

2.5 Other comments

2.5.1 NICE received 20 completed questionnaires from patients treated by the procedure. Photosensitivity was reported by 1 patient.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), which will be available when the guidance is published.
- 3.2 NICE published interventional procedures guidance on needle fasciotomy for Dupuytren's contracture in 2004, available from www.nice.org.uk/IPG43

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See <http://www.nice.org.uk/guidance/IPG368/publicinfo>