

Dupuytren's Disease and Radiotherapy

NICE have indicated in a recent document that their guidelines on radiotherapy for Dupuytren's Disease were published after consultation with the BSSH. This is incorrect. Although individuals were approached who are members of the BSSH, the BSSH itself was not formally consulted. Consequently, the views published do not reflect the views of the BSSH.

This matter was the subject of a formal complaint by the Society to NICE and as the result of this, the way in which advice is sought by NICE from professional bodies has been changed.

Radiotherapy has really only been used for patients with nodules in the palm. Many would argue that these patients do not need treatment. They may never need any form of treatment, as in a substantial proportion, the disease will not progress and the nodules may even regress.

Many of these patients may therefore be getting unnecessary treatment in the form of radiotherapy, and this would be considered by many to be unethical, particularly if carried out for profit.

Radiotherapy is commonly used for treating cancer and has its own problems:-

- dryness of the hand due to destruction of the sweat glands in the skin
- desquamation (flaking)
- itching/pain/burning (most patients)
- scarring and fibrosis of the structures within the hand which may render subsequent surgery difficult and hazardous
- The possibility of radiation induced cancers in the hand

Not all cases of palmar Dupuytren's nodules progress. This is accepted and well known and well documented in the standard texts.

The use of radiotherapy in these cases may therefore be inflicting unnecessary treatment with attendant risk and side effects on patients.

The British Society for Surgery of the Hand would not currently advocate radiotherapy for treatment of Dupuytren's nodules in the palm.

With regard to the Interventional Procedures Overview (IP 780) published by NICE, the BSSH have several concerns, which are listed below.

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1. There is confusion about the source of advice received from radiotherapists.

No radiotherapists are mentioned in the version of IP 780 (...47993.pdf) linked from the guidance webpage. The document states that it was prepared in January 2010. Readers of this document on radiotherapy treatment would be puzzled by the omission of advice from radiotherapists.

However, while searching the web for documents related to the guidance, we discover another version of IP 780 (...49553.pdf), also "prepared in January 2010", in which the names of two radiotherapy advisers are given. They are Mr J Glees (Royal College of Radiologists), Miss M Spittle (Royal College of Radiologists). We note that they work at the Parkside Oncology Clinic, where private radiotherapy treatment of benign conditions including Dupuytren's contracture is available. IP 780 indicates (p 12) that the notification of this procedure to NICE indicated that there is at least one centre wishing to provide it. Was this the Parkside Clinic, and if so is it appropriate to ask for radiotherapy advice only from those who wish to provide the service?

2. The evidence analysed in IP 780 does not support efficacy of radiotherapy in Dupuytren's disease.

IP780 records the databases searched, quoting 'No language restriction was applied to the searches' but on page 3 *'Non-English –language articles were excluded unless they were thought to add substantively to the English-language evidence base'*. The process by which this was decided is not outlined but it is not clear that other language articles were reviewed.

Our reading of the literature suggests that radiotherapy for benign conditions is a largely German phenomenon. Radiotherapy for Dupuytren's disease is not, as far as we are able to ascertain, available in the National Health Service and is not supported by any British publication (we do not regard Finney 1953 as support).

Radiotherapy for benign conditions is controversial. Placebo-controlled trials are lacking in this field and most of the work is based on case series or "patterns of care" studies.

These deficiencies are acknowledged in a paper by Seegenschmiedt and others arising out of a consensus meeting in Nice in 2007 (Radiotherapy of non-malignant disorders: where do we stand? Leer JW, van Houtte P, Seegenschmiedt H. *Radiother Oncol.* 2007. 83(2):175-7.). The consensus was that radiotherapy for Dupuytren's disease should be category B (evidence controversial, treatment only in the context of a clinical trial) for patients with early disease (nodules and cause without contracture). For more advanced cases, the consensus was Category C (insufficient evidence, those who do it should stop). We find it odd that NICE takes a more permissive view than the proponents themselves.

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IP 780 quotes four studies.

- a) The Seegenschmiedt (2001) paper is described as a randomised controlled trial but it is in fact a comparison of two treatment regimes; there is no control group to assess the effect of radiotherapy against the natural history of the disease without treatment.
- b) Pohl (2002) is an abstract of a presentation at a conference and appears to contain the same patients as the Seegenschmiedt (2001) paper.
- c) Keilholz (1996) was a retrospective case series, without controls, with 63% follow-up at six years. 7/142 hands "progressed to failure".
- d) Finney (1953) studied only 25 cases. There were no controls.

The 49553.pdf version of IP 780 quotes Betz et al (2010), which is a longer term study from Keilholz's unit. The disease progressed in 31% of 208 hands, i.e. what one would expect from the natural history of the disease.

IP 780 omits reference to Weinzierl et al (Lack of effectiveness of alternative non-surgical treatment procedures of Dupuytren contracture. *Chirurg.* 1993 Jun;64(6):492-4) which states that the results after seven years follow-up did not differ clearly from the spontaneous course of Dupuytren's contracture grade 1. Falter et al (1991) from Munchen-Bogenhausen (Falter E, Herndl E, Mühlbauer W. Dupuytren's contracture. When operate? Conservative preliminary treatment? *Fortschr Med.* 1991 Apr 5;109(10):223-6) go further, stating "Conservative therapy has no influence on the course of the condition, while radiotherapy is inadmissible on account of its side effects."

3. IP 780 ignores the evidence on the natural history of early Dupuytren's disease

Millesi reported that the rate of progression was 9% at one year, 22% after three years and 39% after five years. (Millesi H, 1965. Zur Pathogenese und Therapie der Dupuytren'schen Kontraktur. *Bruns Beitr. Klin. Chir.* 198,1-25)

In a study of 59 patients with nodules of Dupuytren's disease with average follow-up 8.7 years, only five cases had progressed to the point where surgical treatment would be considered. The nodules resolved in seven cases (Reilly RM, Stern PJ, Goldfarb CA. (2005). A retrospective review of the management of Dupuytren's nodules. *Journal of Hand Surgery*, 30A: 1014-1018.).

A study in Iceland, where Dupuytren's disease is highly prevalent, found that 26 of 75 men (35%) examined in 1981/82 had developed contractures or required surgery 18 years later (Gudmundsson KG, Arngrimsson R, Jonsson T. (2001). Eighteen years follow-up study of the clinical manifestations and progression of Dupuytren's disease. *Scand J Rheumatol*, 30: 31-34.).

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The studies indicate that only a minority of patients with early Dupuytren's disease develop a contracture.

4. We are concerned that the guidance would encourage inappropriate radiotherapy treatment of a condition that is believed to affect approximately 10% of older British men.

The British Society for Surgery of the Hand considers it inappropriate that guidance should have been issued without a balanced analysis of available data. We would advise that there is little evidence of efficacy and that radiotherapy is permitted only in the context of a controlled randomised trial that includes a placebo arm.

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Honorary Secretary BSSH 2010-12