

# High-intensity focused ultrasound for prostate cancer

## 1 Guidance

- 1.1 Current evidence on the safety and efficacy of high-intensity focused ultrasound (HIFU), as measured by reduction in prostate-specific antigen (PSA) levels and biopsy findings, appears adequate to support the use of this procedure for the treatment of prostate cancer provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 The effects of HIFU for prostate cancer on quality of life and long-term survival remain uncertain. Clinicians should therefore ensure that patients understand the uncertainties and the alternative treatment options. Use of the Institute's *Information for the public* is recommended.
- 1.3 Interpretation of the data was difficult because it was not clear from the literature when the procedure was used for primary or for salvage treatment. Further research and audit should address clinical outcomes, long-term survival and indications for treatment (differentiating between the use of the procedure for primary and for salvage treatment).

## 2 The procedure

### 2.1 Indications

- 2.1.1 High-intensity focused ultrasound (HIFU) may be used to treat carcinoma of the prostate, either as a primary or salvage therapy.
- 2.1.2 Treatment options depend on the stage of the cancer. Current primary treatments for localised prostate cancer include 'watchful

waiting', radiotherapy and radical prostatectomy. Metastatic prostate cancer is usually treated with hormone therapy.

- 2.1.3 Treatment options for locally recurrent prostate cancer after radiotherapy are limited and include salvage radical prostatectomy, salvage cryotherapy and salvage brachytherapy.

### 2.2 Outline of the procedure

- 2.2.1 HIFU for prostate cancer is carried out under a spinal or general anaesthesia. An endorectal probe incorporating an ultrasound scanner and a HIFU treatment applicator is inserted. The probe emits a beam of ultrasound, which is focused to reach a high intensity in the target area. Absorption of the ultrasound energy creates an increase in temperature, which destroys tissue. A cooling balloon surrounding the probe protects the rectal mucosa from the high temperature. A urethral or suprapubic catheter is used after the procedure.
- 2.2.2 Transurethral resection of the prostate may be carried out immediately before the HIFU treatment, to reduce the volume of the prostate and minimise the amount of necrotic debris left after the procedure. HIFU treatment can be repeated if necessary.

### 2.3 Efficacy

- 2.3.1 The evidence was based on case series and the main outcomes reported were negative biopsy rates and PSA nadir levels. Some studies reported disease-free survival rates but the criteria used to define disease varied. A systematic review, including eight case series, reported a negative biopsy rate of

# Interventional Procedure Guidance 118

## This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

60% (37/62) in one study with follow up not specified, and 80% (75/94) in a study with 3-year follow up. In three further studies in the review, the proportion of patients without clinical or biochemical evidence of disease ranged from 56% (28/50) at 24 months to 66% (67/102) at 19 months.

2.3.2 Three additional case series reported negative biopsy rates between 87% (251/288) in a study with mean follow up of 13 months and 93% (128/137) in a study with mean follow up of 22.5 months. One of these studies, which included 146 patients, also reported disease-free survival rates of 54% or 71.5%, depending on the criteria used to define disease-free status. For more details, refer to the Sources of evidence.

2.3.3 The Specialist Advisors considered that long-term data are needed to establish whether the procedure reduces prostate-cancer-specific mortality.

## 2.4 Safety

2.4.1 Urinary tract infections and stress incontinence were the most commonly reported complications, affecting between 4% (6/137) and 48% (46/96) and between 8% (9/111) and 23% (23/102) of patients in two case series. Recto-urethral fistula was reported in 0.7% (1/137) and 3% (3/111) of patients. Four studies reported rates of impotence after the procedure between 24% (75/315) and 100% (62/62) but the proportion of men who were potent before treatment was inadequately reported. Other complications included prolonged urinary retention, urge incontinence, urgency, bladder neck stenosis, urethral stenosis, urethritis, prostatic abscess, epididymitis, asymptomatic rectal burns and chronic pelvic pain. For more details, refer to the Sources of evidence.

2.4.2 The Specialist Advisors listed urinary incontinence, rectal fistula, bowel perforation and erectile dysfunction as potential adverse events but noted that HIFU appears to be safer than alternative radical treatments for prostate cancer. Two Specialist Advisors noted that there were concerns regarding control of local heating and limiting sound energy to the target area.

## 2.5 Other comments

2.5.1 In recommending that further research and audit should address long-term survival, it is noted that prostate cancer patients frequently die from unrelated causes.

2.5.2 Most of the evidence related to localised prostate cancer.

## 3 Further Information

3.1 The Institute has issued guidance on urological cancer services ([www.nice.org.uk/page.aspx?o=36469](http://www.nice.org.uk/page.aspx?o=36469)), which includes prostate cancer. The Institute has also issued interventional procedures guidance on laparoscopic radical prostatectomy ([www.nice.org.uk/IPG016guidance](http://www.nice.org.uk/IPG016guidance)), and is preparing guidance on salvage cryotherapy for recurrent prostate cancer. For more details see [www.nice.org.uk/ip\\_130](http://www.nice.org.uk/ip_130)

Andrew Dillon  
Chief Executive  
March 2005

## Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from [www.nice.org.uk/IPG118publicinfo](http://www.nice.org.uk/IPG118publicinfo).

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

*Interventional procedure overview of high intensity focused ultrasound for prostate cancer*, March 2004.

Available from: [www.nice.org.uk/ip230overview](http://www.nice.org.uk/ip230overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0839. *Information for the public* can be obtained by quoting reference number N0840 for the English version and N0841 for a version in English and Welsh.

The distribution list for this guidance is available at [www.nice.org.uk/IPG118distributionlist](http://www.nice.org.uk/IPG118distributionlist)

Published by the National Institute for Clinical Excellence, March 2005 ISBN: 1-84257-905-3

© National Institute for Clinical Excellence, March 2005. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is allowed without the express written permission of the National Institute for Clinical Excellence.

National Institute for Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA, website: [www.nice.org.uk](http://www.nice.org.uk)

N0839 1P 20k Mar 05 (ABA)