

A Patient's Guide to High Intensity Focused Ultrasound (HIFU) for Prostate Cancer

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This booklet is intended to help you understand your prostate and what your operation will involve

This is a booklet for men who are either considering treatment, or are being treated, for prostate cancer by HIFU (High Intensity Focused Ultrasound). It also provides useful advice and information for their families. It is best read in conjunction with the more general booklet in this series, *A Patient's Guide to Prostate Cancer*, which provides an overview of the subject and introduces terms used in this booklet. This booklet may have already been given to you, or it may be viewed and downloaded from the website: www.prostatecancercentre.com

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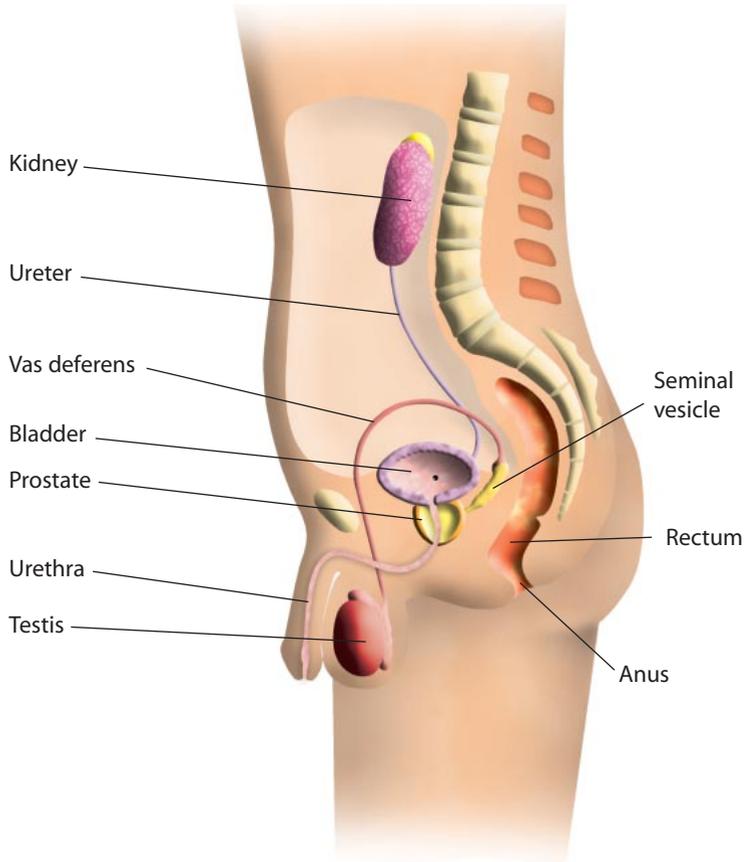
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Introduction

Anatomy.



HIFU: high intensity focused ultrasound

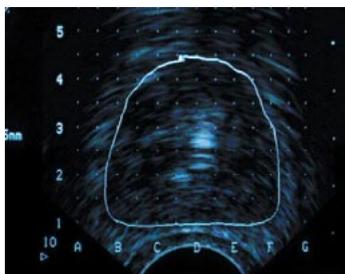
HIFU is a procedure designed to treat localised prostate cancer using high intensity focused

ultrasound (HIFU). A rectal probe generates high intensity ultrasound waves which travel through the rectal wall and are focused in the prostate. This focusing produces intense heat and provokes the destruction of the tissue inside the targeted zone, with minimal effect to surrounding tissues. The treatment typically takes 3 hours to perform, usually under a general anaesthetic. The technique is very new in the field of prostate cancer treatments and is still under research, with little long-term data to verify its effectiveness. However, for some patients, especially those with recurrent localised prostate cancer following radiotherapy, it may offer a useful second-line option.

History of HIFU

The initial work in devising a machine that could focus high intensity ultrasound waves at the prostate began in the late 1980s, following the development of transrectal ultrasound probes. Much of the early research was carried out in France, and the device received a CE mark approximately ten years later.

Whilst further studies have been requested from America, to demonstrate the effectiveness of the device before it receives FDA approval, many patients have already been treated in Europe.



Ultrasound image of the prostate gland.

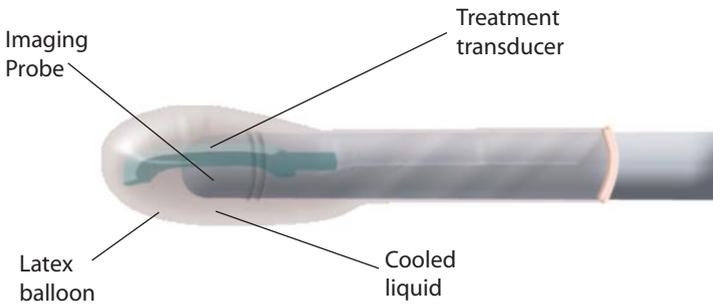
The Device

The HIFU device consists of a number of components:

- A table for the patient to lie on during the treatment.



- An ultrasound imaging system, which allows the visualisation of the prostate by the urologist.



- A transrectal device, consisting of the imaging probe and the treatment transducer, which emits the focused ultrasound. These two elements are placed in a latex balloon filled with cooled liquid.



- A computer, which controls and aims the high intensity beam according to the treatment plan established by the urologist.

There are a number of devices connected to the equipment and measures taken, to ensure the

patient's safety and to optimise the treatment:

- Continuous control of the treatment probe's position in relation to the rectal wall, to avoid damage to the rectum.
- A patient movement detector, to ensure that the patient lies still and the prostate stays in target.
- Constant monitoring of the rectal temperature, to avoid heating and damaging the rectum.
- Constant control of the power delivered to the patient, avoiding surges that may cause damage to structures surrounding the target zone.

How is HIFU Performed?

Preparation

You may be hospitalised the evening before the procedure. You will be given an enema for colorectal preparation approximately two hours before treatment.



The procedure

The treatment is performed under anaesthesia and is executed with the patient lying in a right lateral position. Strict immobility is necessary during the

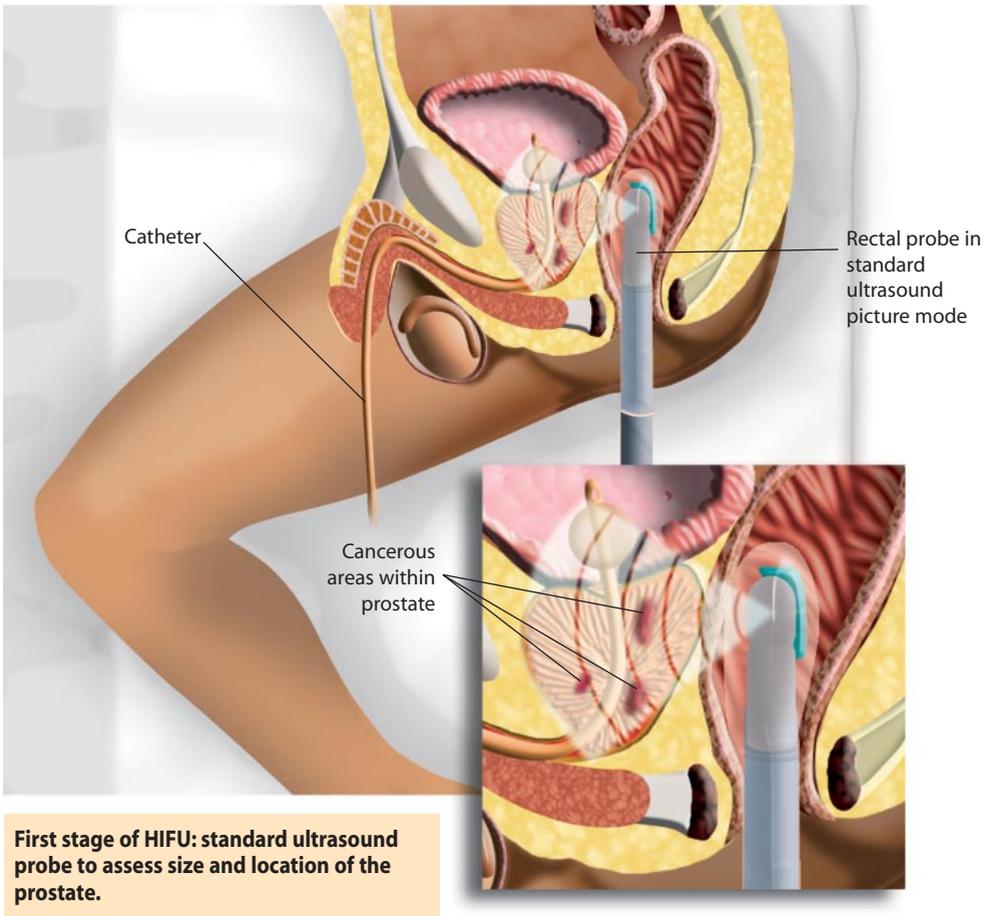


treatment, which can last at least three hours – hence the appeal of a general anaesthetic.

A probe is placed in the rectum. This probe has a dual function: to provide the conventional ultrasound images of the prostate and also to emit the high intensity ultrasound waves that will destroy the gland.

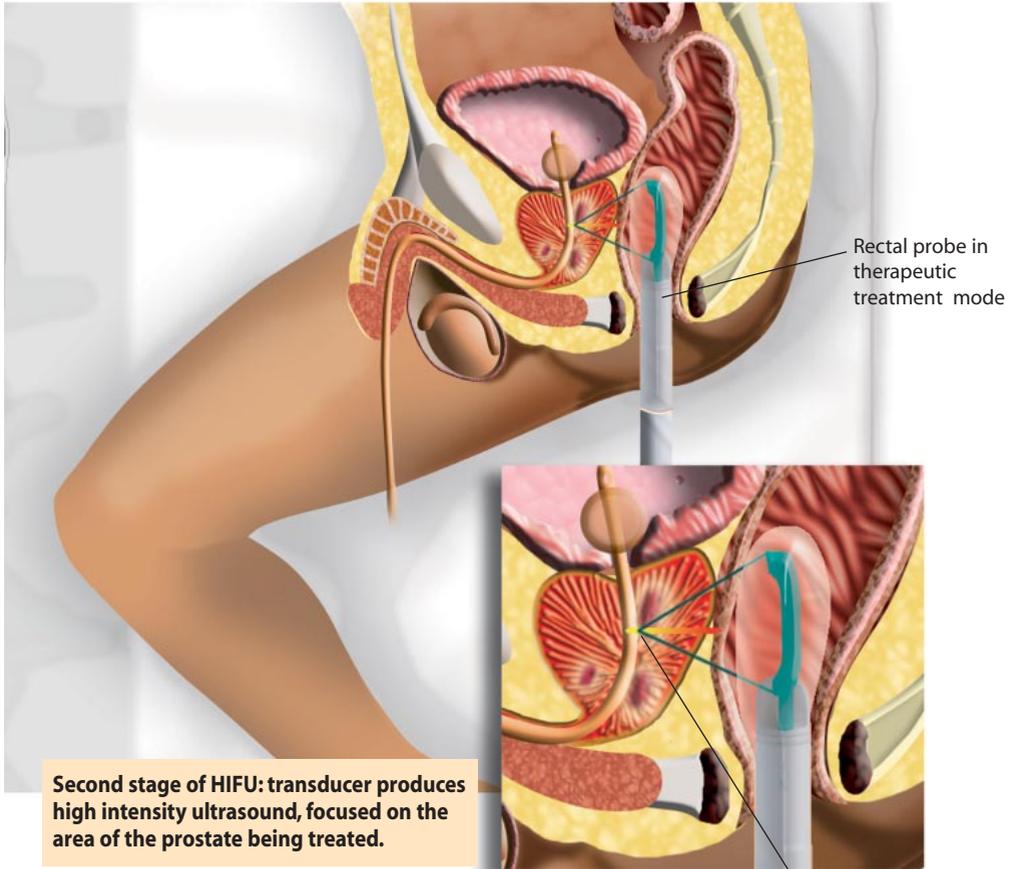
Initially, the shape and size of the prostate are calculated and processed as the target area to be treated. As cancerous prostate tissue typically has the same appearance on ultrasound as normal benign tissue, it is not possible to accurately treat just the cancerous parts of the gland. As the intention is to cure you of your disease, the entire prostate gland needs to be targeted and treated.

From studies in patients who have undergone a radical prostatectomy, it is clear that there are commonly seven or more separate regions within the prostate gland where the cancerous tissue can be identified.

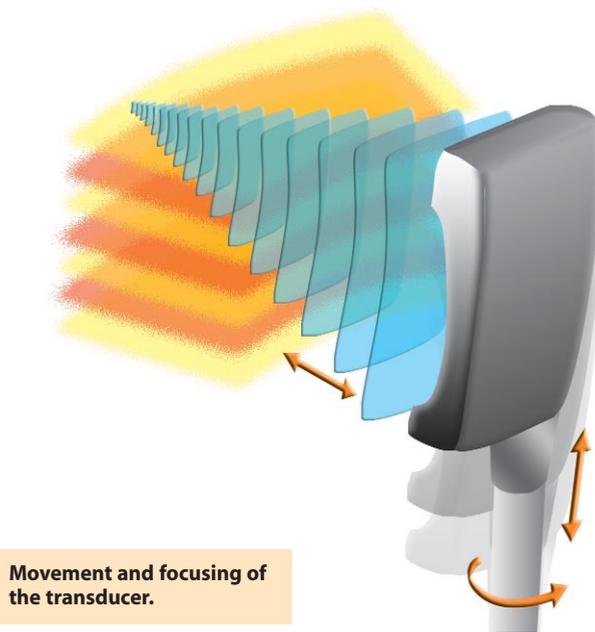


At the point where the beam of high intensity convergent ultrasound is focused (focal point), the rapid and intense absorption of the ultrasound

energy creates a sudden elevation of the temperature to 100°C, which destroys the cells located in the targeted zone.



The targeted zone destroyed by each pulse is oval-shaped and measures up to 24mm in height by less than 2mm in diameter. By repeating the pulses, and moving the focal point between each pulse, it is possible to destroy the prostate gland. Little damage occurs to the rectal wall by these pulses, as the beam is not focused on this tissue.



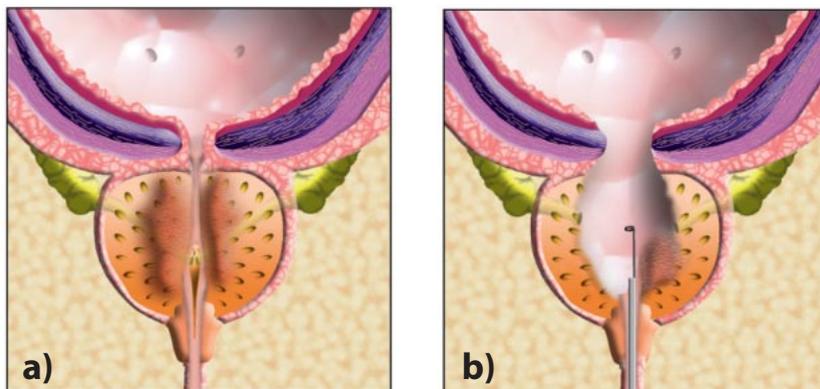
Movement and focusing of the transducer.

The treatment duration varies according to the prostate volume and may take approximately 3 hours.

Swelling of the prostate appears immediately after the treatment, due to the effective burning of the gland. This swelling or oedema compresses the urethra and can make it difficult or impossible to pass urine initially. A temporary urinary catheter is inserted into the bladder, either through the urethra (water pipe) or through the lower abdomen (supra pubic). This allows the elimination of urine until the oedema recedes, which generally takes 3-8 days.

Sometimes, for larger prostate glands, as well as to help reduce the need for prolonged post-treatment catheterisation, a 'mini' transurethral resection of the prostate, or TURP, can be done before or immediately after the treatment with HIFU (during

the same anaesthesia). This procedure removes the central, obstructing portion of the prostate and is most commonly performed in men with benignly enlarged glands, to improve their urinary symptoms.



TURP. a) before operation.
b) removal of obstructing tissue, using a hot wire loop.

Such a dual procedure is mainly performed with HIFU in patients presenting with signs of prostatic obstruction (weak urinary stream, frequent nocturnal urination, residual urine volume in the bladder). Naturally, combining treatments can increase the post-operative complications. In particular, a TURP will usually affect the ejaculatory function of the patient, causing the ejaculate to enter the bladder at the point of orgasm, rather than being produced from the penis. The ability to obtain an erection can also occasionally be affected. For more information on TURP, please read *A Patient's Guide to TURP – Your Prostate Operation*, which should be available at your hospital or may be viewed and downloaded from the internet at: www.prostatecancercentre.com

After the procedure

Patients are normally able to eat and drink by the evening of the treatment day, and the urinary catheter is generally removed 3-4 days after the session. Discharge from hospital usually takes place the day after the urinary catheter removal, once your doctor is happy that you are reliably able to empty your bladder. Occasionally, patients can go home with a catheter in place, to return for its removal at a later date.

A prophylactic antibiotic, such as ciprofloxacin, may be prescribed for the following few weeks, to prevent the occurrence of a urinary infection.

During this period, you might experience some discomfort, mild bleeding in the beginning of passing urine, frequent and sometimes urgent urination and urine leakage or incontinence with exertion. Over the next few weeks, necrotic debris from the prostate will be passed in the urine. If debris or blood are seen in the urine, it is important to maintain a high fluid intake. Caffeinated drinks should be avoided, as they may increase urinary frequency or urgency.

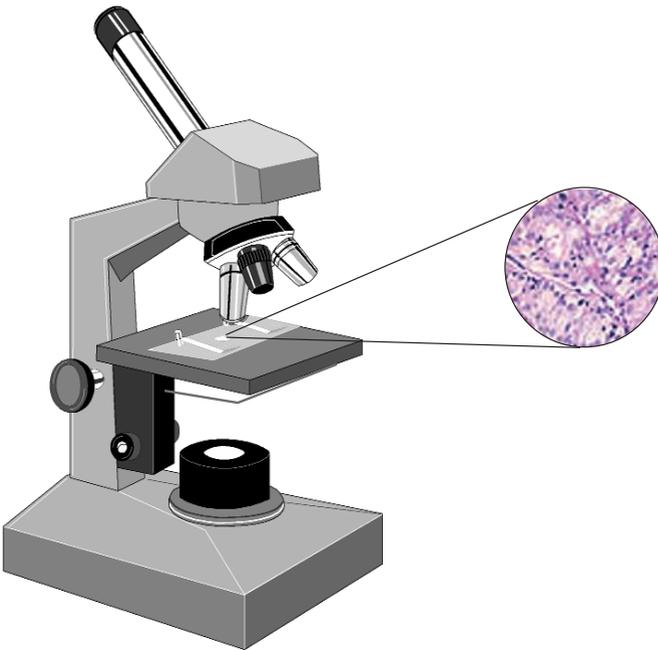


Infections with fever are rare, but possible, and if you feel generally unwell, you should contact your doctor immediately for an appropriate antibiotic.

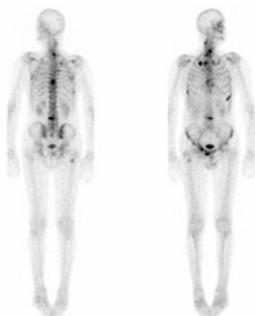
Follow-up visits after the treatment

Some 3-6 months after your treatment, control biopsies may be performed under local anesthesia: if they are negative, regular checking of your PSA every three months for the first year, then six-monthly thereafter, is sufficient.

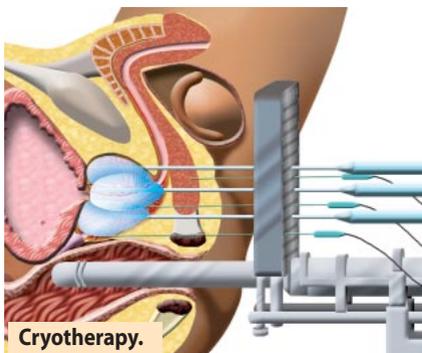
If a residual cancerous zone is detected on biopsy (in about 10% of cases), a second treatment can be conducted 6 months after the initial session, or an alternative therapy may be considered.



Whole body bone scan, showing cancers (black) that have spread to the bones.



Radiotherapy.



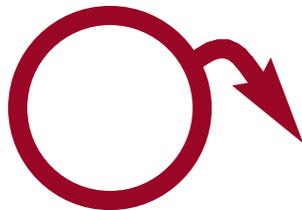
If the biopsies are negative, but your PSA rises, imaging is required to identify whether the prostate cancer has spread to your pelvic lymph glands or your bones. If so, hormone therapy may be the next treatment to consider. If the tumour appears still confined to your prostate, external beam radiotherapy or prostate cryotherapy may be treatment options, if they have not been used previously. However, as many urologists feel that HIFU should only be used in patients who have failed an initial first-line therapy such as prostate brachytherapy or radiotherapy, your individual treatment history will affect the options available.

For more information on external beam radiotherapy, prostate cryotherapy or brachytherapy, please read *A Patient's Guide to External Beam Radiotherapy*, *A Patient's Guide to Prostate Cancer*, *A Patient's Guide to Cryotherapy*, and/or *A Patient's Guide to Prostate Brachytherapy*, which should all be available at your hospital or may be viewed and downloaded from the internet at: www.prostatecancercentre.com

Side-effects with HIFU

The main side-effects with HIFU, when used to cure patients with prostate cancer, are as follows:

- Difficulty in passing urine, which requires all patients to be initially catheterised following the treatment, before the swollen prostate reduces in size, which may take a week or more.
- Urinary frequency, urgency and burning, which may be aggravated by drinking caffeinated drinks post-procedure.
- Rectal burning and bleeding, which is most common in patients treated with multiple HIFU sessions.
- Urinary leakage or incontinence occurring with physical exertion is seen in 1 in 20 patients, but will often settle in time with the help of pelvic floor exercises.
- Impotence (the inability to get an erection), which is a common side-effect in HIFU patients, occurring in more than 70% of cases, as the tiny nerves supplying the erectile tissues of the penis lie on the outer surface of the prostate gland and may be damaged during treatment.
- When a TURP is performed in conjunction with HIFU, patients will normally experience a

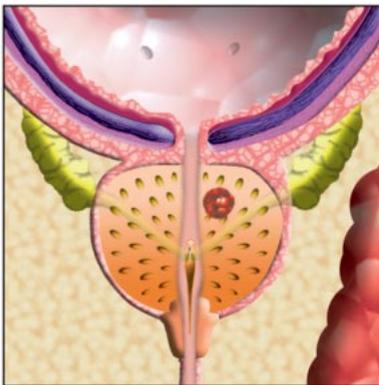


retrograde or internal ejaculation at the time of orgasm, as the part of the prostate that is removed causes the ejaculate to be released into the bladder, rather than being produced from the penis. This effect is usually permanent, but is not harmful.

Who is best treated by HIFU?

Due to the lack of long-term clinical data regarding the effectiveness of HIFU in the treatment of prostate cancer, many urologists believe that HIFU should not be used as a first-line option. Indeed, due to this lack of data, the treatment has not yet received a licence to be offered in the USA. Currently, existing treatments, such as radical prostatectomy and brachytherapy, have a proven effectiveness and appear to offer higher chances of long-term cure, with better side-effect profiles. However, clinical trials have begun in Europe, which will hopefully demonstrate the value of HIFU.

HIFU is only an option for localised prostate cancer (Stage 1 or 2), as little of the surrounding tissue is



Stage 1 cancer in prostate.



Stage 2 cancer in prostate.

treated. It may be best reserved for patients who have already been treated by either radiotherapy or cryotherapy, in whom the cancer has recurred within the gland.

Researchers are investigating whether treating just part of the prostate, rather than the whole gland, may be effective in suppressing the disease and PSA, even though it is known that the cancer is normally multifocal and spread through the prostate at the time of diagnosis. The thought behind such a treatment strategy is that multiple further treatments in the future can be given if and when required. Such an untested approach to the treatment of prostate cancer should be regarded with caution, as the risk of significant side-effects increases with multiple HIFU sessions, and the chance of the cancer spreading from the prostate between treatments remains a real possibility.

Summary

HIFU is a novel therapy, using complex computer-assisted equipment to treat prostate cancer. It usually requires a 2-3 hour anaesthetic to perform, and patients are catheterised for a short while after treatment. Whilst the science and concept is inviting, detailed studies have yet to show its long-term effectiveness, which is critical in assessing a prostate cancer treatment, and the side-effects associated with this treatment can be significant.

Useful website addresses and support networks

CancerBACUP

'Helping people live with cancer.'

www.cancerbacup.org.uk

CancerSupport UK

'Coping with cancer at home.'

www.cancersupportuk.nhs.uk

PCaSO

'To improve the diagnosis, treatment, care and support to those troubled by this cancer.'

www.pcaso.com

The Continence Foundation

'For people with bladder and bowel problems.'

www.continence-foundation.org.uk

The Prostate Cancer Charity

'Prostate cancer is our sole concern.'

www.prostate-cancer.org.uk

The Sexual Dysfunction Association

'To help sufferers of impotence (erectile dysfunction) and their partners.'

www.impotence.org.uk

The Prostate Cancer Centre

'Providing a single point of referral to specialists at the forefront of the treatment of localised prostate cancer.'

www.prostatecancercentre.com

Mr John Davies - Cryotherapy and high intensity focused ultrasound (HIFU).

Mr Christopher Eden - Laparoscopic radical prostatectomy.

Professor Stephen Langley - Brachytherapy.

The Prostate Project

'A local charity promoting male health.'

www.prostateproject.org

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