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High Intensity Focused Ultrasound

HIFU

Introduction

High Intensity Focused Ultrasound (HIFU) works by generating small areas of energy about the size of a grain of rice. The release of this energy within the prostate causes the tissue to heat up. This change in temperature destroys the prostate cells and any cancerous cells in the area. The small treatment areas can be very carefully located within the prostate, thereby avoiding the delicate organs that lie next to the prostate gland.

HIFU therapy for prostate cancer has been in use for 6-7 years. HIFU appears to be effective at controlling prostate cancer. Reports have shown that HIFU therapy was effective at controlling prostate cancer in 80% to 95% of men treated up to five years after the patient received the treatment. Studies have shown that HIFU therapy is at least as safe as other treatments for early prostate cancer and may have fewer side effects in terms of incontinence, impotence, blood loss and damage to the bowel and bladder. HIFU actually treats lower urinary tract symptoms.

If you have prostate cancer that, to the best of our knowledge, appears confined to your prostate gland and should your prostate be of suitable size (<50g), HIFU therapy is a possible treatment option as an alternative to the standard therapies for early prostate cancer - these are radical prostatectomy or radiation therapy either by external beam or brachytherapy. It is also possible that you may have been offered something called active surveillance or hormonal therapy as well. If your prostate is larger than 50g it is possible to have some laser therapy prior to HIFU to decrease the size of the prostate to make the treatment viable.

HIFU Treatment

Most men will be able to have their treatment and go home the next morning. Occasionally, it is possible to leave two to three hours later, provided there is someone else at home and suitable transport can be arranged.

What do I have to do?

The day before your HIFU therapy you will be asked to avoid solid food if possible and drink plenty of fluid. In the afternoon, on the day before the HIFU treatment you will be asked to take a sachet of powder, which is a laxative. You should take this with plenty of water (1-2 jugs over 4 hours)

You will need to fast (i.e. no food or drink) for 6 hours prior to the procedure – you will be given a fasting time at the time of admission (or on occasions 1-2 days prior to your admission)

Day of Treatment - HIFU

On the day of your treatment an anaesthetist will come to see you. He or she will explain the options available to you and make sure that your preferred option is both appropriate and safe for you. The anaesthetist will

answer any questions you may have in relation to the anaesthetic. A general anaesthetic is the preferred option, which puts you into a deep sleep. You will then receive the HIFU therapy. The sound energy that HIFU uses to destroy cancer cells is created within a probe, similar in size to the one used when you had your prostate biopsies taken. This is placed into the rectum. Once this has been done your therapy is planned with the help of a computer. The HIFU treatment once a satisfactory plan has been achieved. This normally takes between 2-3 hours. The device that is used is the Sonablate 500. It uses a high-energy focused ultrasound beam, which is directed across the wall of the rectum into the prostate to heat and destroy a very precise volume of tissue at its focus.

After the treatment, a urinary catheter (a tube that drains urine from the bladder) is placed in the bladder. Once this has been done your anaesthetist *will* wake you up.

You will then be taken to the recovery room and then to the ward. At this point you will be given something to drink and eat if you feel hungry. Most people will be advised to remain overnight in hospital, but it is quite safe for you to go home the same day – if you feel comfortable enough.

Before you go home you will be taught all about your catheter and how to look after it. You will be given some mild painkillers and a short course of antibiotics to take home with you. You *will* also be given a number to contact if you have any problems once at home.

Post-Operative Care

An appointment will be made for you to come back to the *Urology Sydney* rooms to have your catheter removed 7-10 days after the HIFU therapy. This is a simple procedure that is usually not painful. Once the catheter has been removed you will be encouraged to drink. Once your bladder is full you will be asked to try and pass urine. Once you have done so we will check that your bladder has emptied adequately by using a hand held bladder scanner. If you are unable to pass water, a new catheter will be placed and you will be invited back a week later to have it removed.

If at the second attempt at catheter removal, you are still unable to pass urine two things may happen. The first would involve teaching you the technique of Clean Intermittent Self Catheterisation or CISC. Although this may sound difficult to perform, it is quite straight forward and most people learn it very quickly. It involves you passing a small slippery catheter into the bladder and by doing so allowing the bladder to empty. You would only do this when you needed to. With time your bladder would start to work again and your need for CISC would become less and less.

If a man cannot re-establish normal bladder emptying a cystoscopy (using a telescope to look into the bladder) will be carried out to investigate the cause. This is necessary in about 10% of HIFU patients. At the time a small procedure may be performed in order to promote normal bladder emptying. This might involve releasing some scar tissue in the prostate (formed as a result of the HIFU therapy) or cutting through the bladder neck in order to allow more efficient bladder emptying. Very occasionally some dead tissue or debris within the prostate would have to be removed. These procedures can be done using a telescope and should require no more than a one-night stay in hospital.

How do I know if HIFU has been successful?
The HIFU therapy will be assumed to have been effective unless one or both of the following occur. Firstly, if prostate biopsies (scheduled at 6 months and at 3 years) show prostate cancer cells. Second, if three consecutive rises in PSA (prostate cancer blood test) occur. If the PSA level rises on three successive occasions you will be offered further prostate biopsies, even if previous biopsies did not reveal cancer. If these biopsies or either of the scheduled biopsies (6 months and 3 years) show prostate cancer cells the HIFU treatment will be deemed to have failed. Your suitability for further treatment will be assessed. These are often called salvage treatments or salvage therapies. Further treatments that might be considered include:

1. Repeat HIFU therapy
2. Radiotherapy
3. Hormonal manipulation
4. Cryotherapy
5. Surgery - rarely

What are the alternatives?
At the time of diagnosis, prostate cancer may be confined to the prostate itself, or may have spread to other sites within the body. If prostate cancer is confined to the prostate, it may be possible to cure it. The types of treatment that aim to cure prostate cancer when it is confined to the prostate include the following:

- HIFU
- Surgery (radical prostatectomy)
- External beam radiotherapy
- Brachytherapy (small implanted radioactive seeds)

All these treatments can fail to cure prostate cancer. There are two main reasons why this may happen. First, the cancer within the prostate was not properly treated. In other words some of the cancer cells survived. Second, although the prostate cancer was thought to be confined to the prostate this was not the case. Some cancerous cells had spread to other areas and were therefore unaffected by the surgery, radiotherapy, or HIFU.

The cure rates reported after surgery and radiotherapy are between 80-85% at 10 to 15 years. What this means is that 80 to 85% of men receiving either treatment had no evidence of prostate cancer whilst they were being monitored. Although the HIFU results are similar to this in the short term we do not know whether the HIFU cure rates will stay at this level for 10 to 15 years.

All of the treatment options for prostate cancer mentioned above have possible side effects. The frequency of these complications / side effects varies slightly between treatment types, but the most significant are incontinence, impotence, infection, damage to the bowel and death. In order to help you compare the complication rates for a man having radical prostatectomy (surgery) are as follows: urinary incontinence requiring a pad - 5%; impotence or inability to get or maintain an erection - 70%; infection -5%; bowel damage - 2%. Patients receiving radiation therapy have slightly different complications. These include radiation injury to the

bladder and bowel. In most cases this gets better with time though in some men it can be long lasting.

Although the long-term results of HIFU are not known the side effects that occur as a result of treatment are well known. These results come from a number of studies that analysed the side-effects that occurred in groups of men treated in Europe. In general the men were very similar to those reading this information sheet.

In general urinary incontinence is not a big problem with HIFU. Studies show that few if any men had incontinence requiring pads, though 5% of men may experience dribbling of urine that was not considered troublesome. HIFU does require a catheter for up to 10 days after the therapy. This can cause its own problems of infection, blockage, bleeding. This will occur in about 10% of men. Some men will not be able to pass water once the catheter has been removed. Should this occur a new catheter will be placed and removal planned a week later. The options available to men if they are unable to pass urine normally after a second catheter is removed are outline above.

All prostate cancer treatments affect men's ability to get and maintain erections. HIFU appears to be less detrimental to erectile function compared to other treatments. In the studies reviewed, between 45% and 70% of men reported preservation of erections sufficient for penetration. HIFU does not require blood transfusion, is not associated with any requirement for emergency surgery and there have been no treatment related deaths reported.

One of the key areas with regard to the safety of HIFU relates to rectal injury. Whilst cases of rectal injury were reported in the early experience of HIFU, recent reports show this event to be rare (less that 1%). Studies that have been published recently (2004) confirm rates of less than 1%. In one study of 148 men only one rectal injury occurred. This was in a man who had previous rectal surgery and long standing anal infection. There is no evidence that HIFU can lead to the spread of a tumour.

No other direct complications of the treatment have been recognised, but you would be strongly urged to mention any symptoms that you experience to your GP or myself.

Patients that have failed radiation therapy (external beam radiotherapy or seed implant brachytherapy)

Patents who have failed radiotherapy have little in the way of potentially curative treatment options as no further radiotherapy can be given safely and surgery has a very high complication and side effect rate. Patients who are carefully restaged after radiation therapy with scans of the bones and pelvis, who have cancer in the prostate and not in the seminal vesicles on re-biopsy may be potential candidates for salvage therapy with HIFU with potential biochemical free progression rates of 60% at five years. Clearly salvage HIFU post radiation therapy failure has a higher complication rate in terms of incontinence, impotence and rectal injury, therefore careful treatment is required.