PATIENT INFORMATION SHEET

Focal Therapy of Prostate Cancer

A number of options have developed over the last 5-10 years for the treatment of prostate cancer where the significant cancer is in one part of the prostate only and where a man does not either not want to risk the side effects of radical therapy for intermediate risk cancers or does not like the idea of active monitoring for lower risk disease. It should be stressed that radical prostatectomy and radical radiotherapy remain the standards in this area and that for men with low risk disease, active monitoring is the initial option of choice.

We have been involved in the research of a number of options including electroporation of the prostate, photodynamic treatment of the prostate and cryotherapy (freezing). At present, my favoured approach for most men is cryotherapy although electroporation remains an option. Another commonly used option is HIFU (high intensity focussed ultrasound.

At present I have greater experience with cryotherapy although electroporation is also used; for this ee await the long termresults of a large, European study of electroporation in which I am the UK investigator, to have a better feel for the overall cancer cure rate.

For both options, the management is roughly the same and I hope this information sheet will be helpful. Attached is the latest (rather out of date) NICE guidance on focal therapy.

You will have had a multiparametric prostate MRI scan and MRI guided biopsies, usually with systematic biopsies carried out as well. In my practice, as you know, we encourage patients to seek both radiotherapy and surgical opinions although some men do not wish to do this.

Essentially, the majority of cancers which are treated are cured by both cryotherapy and electroporation with our data in cryotherapy suggesting that around 80-85% of treated tumours do not show a recurrence over a 5-8 year period. We do not have large scale randomised studies here (a study we tried to set up for cryotherapy versus active

monitoring in radiation failures with cryotherapy, failed to recruit as patients would not be randomised to the active monitoring study).

On the day of the operation, you will be admitted to hospital and a light general anaesthetic is given with antibiotics. For both cryotherapy and electroporation, a probe is put into the back passage and the prostate is measured and visualised with ultrasound. Treatment needles are then inserted into the prostate based on the preplanning and usually we aim to treat the cancer with a small margin. We will have discussed with you beforehand the possibility of preserving erectile function. In general, with cryotherapy erectile function will dip a bit following the procedure but recover over a year or two and with electroporation, we do not really know the long-term nerve recovery rate situation but certainly the reported erectile dysfunction is lower than with radical therapy.

With cryotherapy, the treatment area of the prostate is frozen with the aim of freezing down to -40°C and then the treatment area is thawed with another treatment cycle being given. The urethra (water pipe) is warmed with a catheter to try to reduce the risk of necrosis (death) of the lining of the urethra which can be an unpleasant problem (if it does occur it will usually recover, albeit after a number of weeks or months.) With electroporation, we gage the voltage required to adequately treat the target area and then a treatment cycle is given. The difference between the two treatments is that cryotherapy disrupts the cancer cells and intracellular bodies by causing ice crystal formation which ruptures the cells and also causes a degree of apoptosis (cell death) around the treated area whereas electroporation causes small holes to be punched into the cell membranes and this again causes cell death.

Following the procedure, you will be woken up and will have a catheter in the bladder. Most men can go home on the day of the procedure and you will be given antibiotics with a date for removal of the catheter 5-8 days following the operation. We then get a limited MRI scan after a few weeks to assess the area killed by treatment. PSA testing is carried out after three months with a multiparametric MRI scan six months later.

What side effects can happen?:

The risk of major side effects with focal therapy is small but not zero. A number of men find it difficult to pass urine again after the operation and this is a greater risk in men who have benignly swollen prostate which is causing a blockage prior to the procedure. From the point of view of this, if men cannot void or have difficulty voiding afterwards, we may need to carry out a small laser or TURP operation but the risk of this is only about 1 in 30.

Incontinence is very rare and if it does occur in the early days due to chlling of the sphincter muscle, it will usually resolve in a few months. I don't, so far, have any patients following focal therapy who required an artificial urinary sphincter but do have several who had full gland cryotherapy for cancer recurrence following radiotherapy.

Erectile dysfunction is something which can be predicted on an individual basis and this will have been discussed with you. It is my practice to give men daily tadalafil in the first 3-6 months following surgery to assist with the erections.

Pain is not usually a major issue and most men take no more than a Nurofen level painkiller for a few days, but some men do have pelvic pain which can persist for a number of weeks or months following. This will nearly always completely resolve without specific treatment.

There is a small risk of rectal injury following any prostate focal therapy and the risk of this is certainly less than 1% but not zero. Were this to happen, then a repair would be necessary, possibly with a covering colostomy for a number of weeks. However the rectal protection technique we have developed has massively reduced this risk, allowing a safety cushion of 1.5 cm or more between the iceball and the rectal wall.

Following the focal therapy, follow-up is be along the same lines as you have already discussed for the active monitoring options.

I hope this is helpful and if you have any specific questions, please do let me know. The NICE guidance is attached, and have in the past submitted my data to the international

COLD registry which is the largest database of prostate cryotherapy cases in the world. My data is now going into the European Focal Registry. If you wish more information on other options then the Prostate Cancer UK website is the best resource (in my opinion) for that.