UROLOGICAL SOCIETY
OF AUSTRALIA
AND NEW ZEALAND

Position Statement on Focal Therapy for Prostate Cancer

Prostatic focal therapy is an emerging treatment strategy for men diagnosed with prostate cancer. It works on the assumption that the largest focus of cancer in the prostate (the "index lesion") is predominantly responsible for the risk of cancer recurrence, and that this lesion can reliably be imaged, biopsied and specifically treated. It also assumes that targeting this lesion for focal treatment may lead to equivalent long term cancer survivals compared with whole gland therapies e.g. surgery or radiotherapy with less side effects, and that if unsuccessful that salvage (or additional) therapies can be introduced safely, without compounding side effects . To date, these assumptions are unproven and as such focal therapy of prostate cancer cannot be considered standard of care.

A review of the current medical literature has demonstrated the following limitations:

1. Uncertainty regarding identification of the index lesion – whilst multi-parametric MRI of the prostate has the promise to improve cancer identification within the prostate, it also has the potential to miss significant cancers (see USANZ position statement on MRI prostate);
2. Current technology does not allow for precise co-localisation of a lesion seen on MRI prostate to the ultrasound image used at the time of prostate biopsy , hence there is the potential for error in both the diagnosis of a cancer (with regards to its size , position and potential biological aggression) and its subsequent focal treatment;
3. Focal therapies energy modalities to destroy the prostate cancer cells that have been investigated to date include cryotherapy, high intensity focused ultrasound, photodynamic therapy; laser induced interstitial thermotherapy and irreversible electroporation. Although promising, few focal therapy reports have systematically reported quality of life outcomes using validated tools and as such side effects of these treatments are largely unknown;
4. Cancer control rates following focal therapies are largely unknown compared to standard whole gland therapies, and those that are available are immature, with short follow up;
5. The feasibility , efficacy and safety of whole gland therapies e.g. surgery , in order to salvage failed focal therapy is unknown;
6. The impact of leaving the non-index lesions untreated is unknown;
7. There are significant challenges in determining how to monitor patients following focal therapy e.g. PSA alone, and/or repeat biopsy. There is no formal definition as to what constitutes treatment failure;
8. Focal therapy is unsuitable for men with aggressive cancers , or those with larger cancers found in both lobes of the prostate;
9. Focal therapy should not be viewed as a substitute for active surveillance and men with small, low risk cancers should be reassured that their risk of cancer death over a 10-15 year time frame is extremely low, and that having regular monitoring and no immediate treatment in these circumstances is safe and should be encouraged;
10. Not all focal therapy treatment protocols are standardized; some centres treat half the prostate, some only focal areas within the prostate, and the implications of these differences remain unclear regarding the outcomes of treatment.

Due to the lack of long-term data on focal therapy regarding the ability to accurately target a lesion, on the long-term cancer control, on the side effects of treatment , and on the ability to provide safe salvage options should treatment failure occur – USANZ believes that focal therapy for prostate cancer remains an experimental technique.

As USANZ strongly encourages clinical research that may advance knowledge, USANZ recommends that patients could consider undergoing this treatment as part of a formal clinical trial, with appropriate ethics committee approval, consent process and with strict reporting requirements regarding outcomes and safety profile. Cost implications for patients must also be discussed with full disclosure as clinical trials should not impose a fee on the patient.

The lack of clear evidence of its superiority (or even equivalence) to standard therapies, and the potential risks in cancer outcomes and side effects need to be clearly stated and understood by patients.

USANZ concludes that at this stage focal therapy remains an experimental technique and is not standard of care. Therefore if a practicing urologist does not offer focal therapy as a treatment option, patients should be reassured that this is entirely appropriate.

USANZ is committed to providing evidence based information to its members, to other health professionals and to the public, and will update this position statement as additional data emerges regarding this treatment option.