

**A prospective study of active surveillance for untreated, localised prostate cancer**

C C Parker<sup>1</sup>, A R Norman<sup>2</sup>, N Van As<sup>1</sup>, A Horwich<sup>1</sup>, R A Huddart<sup>1</sup>, V S Khoo<sup>2</sup>, A Thompson<sup>2</sup>, D P Dearnaley<sup>1</sup>

<sup>1</sup>Institute of Cancer Research, Sutton, Surrey, United Kingdom; <sup>2</sup>Royal Marsden NHS Foundation Trust, Sutton, Surrey, United Kingdom

**Introduction:** Active surveillance is a relatively new approach to the management of localised prostate cancer, designed to avoid 'unnecessary' treatment. Radical treatment is targeted to those with signs of disease progression during close monitoring. We present the initial clinical outcomes of a prospective, NCRI-funded study of active surveillance.

**Methods:** Eligible patients had histologically-proven prostatic adenocarcinoma (T1/2a, Gleason score  $\leq 7$  with primary grade  $\leq 3$ , percentage positive biopsies  $\leq 50\%$ , and PSA  $< 15$  ng/ml). Monitoring comprised serum PSA measurement every 1-3 months, with repeat prostate biopsy at 18-24 months. Indications for radical treatment were PSA doubling time  $< 4$  years, or histologic progression (primary Gleason grade  $\geq 4$  or  $> 50\%$  positive cores).

**Results:** 307 men have been recruited since 2002, with median follow-up of 2.5 years. Median age was 67 years, and median initial PSA, 6.5 ng/ml. Median PSA velocity was 0.35 ng/ml/yr. To date, 64 patients have had radical treatment (of whom 2 have developed biochemical failure), 16 have changed to traditional watchful waiting because of increasing co-morbidity, and 227 (74%) remain on surveillance. No patient has developed metastatic disease or died of prostate cancer. Updated results will be presented.

**Conclusions:** Active surveillance of favourable-risk localized prostate cancer is feasible, with encouraging short-term outcomes. Most patients on surveillance will avoid radical treatment (and its adverse effects). The biorepository associated with this study is a valuable resource for translational studies to identify biomarkers of prostate cancer behaviour. Phase III trials will compare the long-term outcomes of active surveillance with those of radical treatment.