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Bicalutamide

A Viewpoint by Chris J. Tyrrell

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Adjuvant therapy is widely accepted in several malignancies (e.g. breast and colorectal cancer) with the aim of reducing the risk of distant metastases and improving the long-term cure rate. Prostate cancer also has a high metastatic rate, although it has a long natural history, and is therefore a further good candidate for systemic prophylaxis following primary radical treatment. Traditional hormone therapy has been castration, either surgically or medically, which has not been an acceptable form of adjuvant therapy in patients with no detectable disease. The development of bicalutamide with its once-daily tablet formulation provides hope that such therapy might be tolerated and might give rise to improvements in survival in a similar way to tamoxifen in postmenopausal oestrogen-receptor positive breast cancer. The Early Prostate Cancer (EPC) programme in over 8 000 patients has been set up to test this hypothesis.

In the first planned analysis of the EPC programme, after a median follow-up of 3 years (minimum 2 years), there is no survival data, with >90% of patients still alive and a disease specific death rate of <3%. The reduction, however, in objective progression (metastatic spread) is impressive. There is a 42% reduction in metastatic conversion in those receiving bicalutamide. This risk reduction is exactly the same in those receiving radical prostatectomy and in patients receiving radical radiation treatment suggesting that metastatic conversion might be independent of the mode of treatment of the primary. A planned bone scan carried out in all patients at 96 weeks revealed a 30% reduction in positivity, even in patients who were asymptomatic and apparently well. Any impact on survival is likely to take at least 5 years and probably 10 years before it is fully realised.

These results are better than were achieved by tamoxifen in postmenopausal breast cancer at a similar stage in its adjuvant trial programme. This programme is large enough to analyse sub groups of patients to define the precise risk based on parameters such as Gleason score, baseline prostate specific antigen (PSA) and T stage. As expected, patients with a high PSA at baseline and high Gleason score have a higher rate of metastatic progression and might therefore have a greater potential benefit from adjuvant treatment. These trials are ongoing with subsequent analyses due in 2003 which should provide more definitive data and are eagerly awaited. ▲