

33

A RANDOMIZED TRIAL COMPARING ZOLADEX 3.6 MG DEPOT WITH STILBOESTROL 3MG/DAY IN ADVANCED PROSTATE CANCER: PATIENT CHARACTERISTICS, RESPONSE AND TREATMENT FAILURES.

L.A. Emtage, C. Trethowan, C. Hilton, D.G. Arkell, D.M.A. Wallace, M.A. Hughes, D. J. Farrar, C. Young, M. Jones, A.M. Hay, A.R.E. Blacklock, A.D. Rowse, G.R.P. Blackledge. For the West Midlands Urology Research Group at the CRC Clinical Trials Unit, Birmingham, UK.

A randomized study comparing Zoladex(Z) 3.6mg depot with stilboestrol(D) 3mg/day was initiated in August 1985. 186 patients with histologically confirmed prostate cancer T3 or greater, or any T, M1 have been entered up to the end of January 1987; 91 to Z, 95 to D.

Median follow-up is 9 months, and the response rate at six months (CR+PR) for Z is 51% and 28% for D ($p<0.05$). Subjective responses are 59% for Z and 63% for D. Progression has occurred in 3 patients on Z and 4 on D. Two minor and three major increases in bone pain were found after the first Z treatment, but none of these required treatment withdrawal.

Nine patients on D required withdrawal due to severe cardiovascular adverse reaction, compared to none on Z. Two patients with extensive vertebral metastatic disease developed spinal cord compression within the first month of treatment; one in each treatment group. Both responded to radiotherapy and steroids, and are still in the study. This gives an overall major complication rate for Z of 1.1% and 10.5% for D ($p<0.01$).

The study has shown that Z is equivalent to D in achieving subjective response in advanced prostate cancer, but is significantly superior to D in causing no serious complications warranting treatment withdrawal.

34

SERUM TESTOSTERONE AT BASELINE RELATES TO PERFORMANCE STATUS IN PATIENTS WITH ADVANCED PROSTATE CANCER

L.A. Emtage¹, C. Trethowan¹, G. Holder², G.R.P. Blackledge¹
1. Clinical Trials Unit, Queen Elizabeth Hospital, Birmingham; 2. Midland Hospital for Women, Birmingham, U.K.

121 men entered to a multicentre randomised trial comparing zoladex 3.6mg depot with DES 3mg/day were studied. Comparison was made between serum testosterone and other subjective and objective assessments of the disease. Testosterone assays were carried out at one regional endocrine laboratory at the time of randomisation. We used the laboratory lower limit of normal for testosterone of 11 nmol/l to split the patients into normal and low groups. These were compared with WHO performance score, urine flow score, presence or absence of bone pain, age ($>70, <70$), T category (T2 or less, $>T2$), M status (M0, M1) and WHO tumour grade. Testosterone levels were significantly lower in those with cancer-related debility. In those who were fully active, 29/88 (33%) had a low testosterone, whereas in the poor performance group there were 20/33 (61%) low testosterone (chi-square = 7.61, DF=1, $p=0.0058$). Analyses of the other variables showed no relationship with normal and low testosterone. Testosterone is a useful biochemical marker of performance status in untreated advanced prostate cancer.

35

SYSTEMATICAL ASSOCIATION OF PAP AND PSA SERUM DETERMINATION TO BONE SCINTIGRAPHY IN 283 PROSTATE CANCER

F. FINCKER, R. SAUVAN, J. PASQUIER, (IPC MARSEILLE)

Our study comprised 283 patients (mean age 71,5 yr, range 52-89 yr) who had a prostate cancer at various individual stage.

PAP and PSA were determined in all patients by specific radioimmunoassay on fresh serum. Bone scintigraphy was classified in 7 groupes according to skeletal metastasis involvement.

Our purpose was to study if PAP and PSA marker can predict the presence of metastatic disease. The cut of level was set to 3ng/ml for PAP and to 10ng/ml for PSA.

	PAP+	PSA+	PAP+ and/or PSA+
SPECIFICITY	0.90	0.79	0.75
SENSITIVITY	0.53	0.69	0.73

The specificity of PSA is appreciably reduced by the patients without radical prostatectomy who have normal scintigraphy and positive PSA level (14/35).

The combinaison of both markers increases the sensivity up to 73% with a little loss of specificity.

We show that sensivity from PSA increased more than PAP with the skeletal involvement.

Our conclusion is that PSA determination must be used in the follow up control of patient with prostate cancer whether in combinaison with PAP or alone if only one marker is asked.

36

BUSERELIN AND FLUTAMIDE VERSUS SUBCAPSULAR ORCHIECTOMY AND FLUTAMIDE IN STAGE C AND D PROSTATIC CANCER: A COST BENEFIT RATIO ANALYSIS

A. Franzini; G. Alfano; C. Antolini; C. M. Borghi; F. Cicchetti; P. Viganò.

U.S.S.L. 66 OSPEDALE BASSINI DIV. DI UROLOGIA CINISELLO BALSAMO via Gorki 50 (MI) ITALIA
Complete androgenic suppression is considered the therapy of choice in several urologic centres. Testicular androgenic suppression can be provided both by L.H.R.H. analogues and by subcapsular orchiectomy. In this work we analysed the economical cost of surgical and medical androgenic suppression and found that in our unit subcapsular orchiectomy, performed in day hospital and local anaesthesia, cover the cost of a 8 weeks course of therapy with Buserelin and 18 weeks when testicular prosthesis implant is considered. Flutamide cost is unchanged in both protocols and has not been considered. Morbidity of this simple surgery is very low and was not considered in this study. We think that surgery has real cost advantage and that Buserelin can be administered only when surgery is refused for any reason, usually psychological distress, or anyway contraindicated.