Clinical (Non-Histological) Diagnosis of Advanced Prostate Cancer: Evaluation of Treatment Outcome After Androgen Deprivation Therapy

Introduction and Objective: Transrectal prostate biopsy may cause significant morbidity and even mortality despite antibiotic prophylaxis, especially with the recent emergence of highly resistant bacterial strains. Numerous studies have shown a strong association between serum prostate specific antigen (PSA) and tumour burden in men with adenocarcinoma of the prostate (ACP). The aim of this study was to evaluate the reliability of a non-histological diagnosis of ACP based on serum PSA and clinical features.
Materials and Methods: Androgen deprivation therapy (ADT) was used in 825 (56%) of 1467 men with ACP treated January 1996 through December 2007 at our institution, a university hospital serving a predominantly low-income population. The diagnosis of ACP was made histologically in 607 (73.6%) and clinically alone in 218 (26.4%) based on serum PSA >60 ng/ml and/or clinical T3-4 tumor and/or imaging evidence of metastases. We compared two randomly selected groups with a clinical only (n=90) versus histological diagnosis of ACP (n=96). Statistical analysis was performed with Fisher's exact test for contingency tables and Mann-Whitney test for non-parametric data. Values are expressed as mean (range).
Results: The group with a clinical (non-histological) diagnosis of ACP compared to the group with a histological diagnosis had a significantly greater proportion with retention, skeletal pain, paraparesis, stage T3-4 M1 cancer and higher PSA at presentation, higher PSA nadir, shorter time to PSA nadir and shorter time to PSA relapse after ADT. There were no significant differences in the proportions with PSA decrease and PSA relapse, duration of followup or patient survival at last followup. The results are shown in the Table.

	Clinical diagnosis		**Histological diagnosis**		
	n=90	**%**	**n=96**	**%**	**p-value**
Age (years)	69.4 (40.5-96.4)		68.5 (46.5-89.2)		
Clinical presentation					
Urinary retention	22	24.4	10	10.4	0.012
Skeletal pain	41	45.6	14	14.6	<0.001
Paraparesis/paraplegia	10	12.1	2	2.1	0.016
Clinical stage					
T1-2	5	5.6	49	51	
T3-4	84	93.4	47	49	<0.001
M0	6	6.7	26	27.1	
M1	46	51.1	19	19.8	<0.001
PSA at diagnosis (ng/ml)	3750.1 (33.8-157630)		295.4 (2.4-14390)		<0.001
Followup (months)	26.1 (0.6-159.7)		26.8 (9.3-61.1)		
Patients with PSA decrease after ADT	86	95.6	96	100	
Nadir PSA (ng/ml)	36.3 (0-453.0)		3.0 (0-70.2)		<0.001
Time to nadir PSA (months)	9.7 (0.5-50.9)		17.8 (1.6-86.8)		<0.001
Patients with PSA relapse after ADT	63	70.0	65	67.7	
PSA at relapse (ng/ml)	252.5 (0.5-2330)		20.7 (0.2-253)		<0.001
Time to PSA relapse (months)	18 (1.6-65)		43.3 (2.5-97.5)		<0.001
Patients alive at last follow-up	82	91.1	92	95.8	

Conclusions: A clinical (non-histological) diagnosis of advanced ACP can be made reliably, based on serum PSA and clinical features. This avoids the cost, discomfort and possibly serious complications of transrectal prostate biopsy, without compromising treatment outcome of ADT.