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CLINICAL PROGNOSTIC FACTORS IN PATIENTS WITH ADVANCED STAGE OF PROSTATE CANCER

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Objectives: To determine the prognostic factors that could predict patient outcome in patients with advanced stage prostate cancer.

Patients and Methods: In this study we retrospectively evaluated the medical record data of 222 patients with advanced stage prostate cancer treated by hormonal therapy (either castration or total androgen blockade (TAB)). All pre- and post- treatment data records were evaluated with respect to patient age, prostate and tumor size, tumor grade, stage, PSA, alkaline and acid phosphatase and the number of bone lesions. The response to the hormonal treatment was evaluated either early (12 months after treatment) or late (over all follow-up visits until the last visit or death). Descriptive statistics, student T test, multivariate and Kaplan Meier's curve were used for data analysis.

Results: Within 12 months of treatment 70% of the cases showed an improvement with a significant decrease of their pre-treatment values after hormonal therapy. Patient age, tumor stage, the number of bone lesions, serum alkaline and acid phosphatase levels in the pre-treatment data were significantly independent predictors of the overall survival outcome (p= 0.0015, 0.002, 0.001, 0.0002 and 0.028, respectively), while the pre-treatment PSA serum level, tumor grade and the type of hormonal treatment used (either castration or TAB) were no predictors of patient outcome (p= 0.18, 0.82 and 0.47, respectively). Importantly, the PSA serum level and the number of bone lesions in the first 12 months of patient follow-up were significant predictors of the overall disease survival status (p=0.001 and 0.028, respectively). The mean follow-up period of alive cases was 39.42 months ranging from 6 – 171 months. Of the 222 cases 110 (51.6%) had overall disease progression during a mean of 59.4 months, while mortality was reported in 118 cases (53.2%) in the course of a mean of 59.9 months.

Conclusion: The pre-treatment patient age, tumor stage, serum alkaline and acid phosphatase, as well as the post-treatment PSA level and the number of bone lesions were significant independent predictors of the overall patient outcome in patients with advanced stage prostate cancer. However, a survival analysis in relation to the treatment type did not reveal a statistically significant difference between the outcomes of castration and TAB.

Key Words prostate cancer, castration, total androgen blockade (TAB)

INTRODUCTION

Castration has been the gold standard for managing metastatic cancer of the prostate (CaP) ever since Huggins and Hodges demonstrated its androgen dependence.[1] Although 60% to 80% of patients with advanced CaP improve following castration, there is an inevitable progression to an androgen-independent state. The concept of total androgen blockade (TAB) dates back to the report published in 1945 by Huggins and Scott.[2] However, this approach continues to be controversial even after decades of randomized, controlled trials. Accordingly, the appropriate selection of patients for treatment should be done on the basis of a range of prognostic factors, to identify the subgroup that would respond well to endocrine therapy and those patients that may benefit from combination therapy. In judging the effects of endocrine treatment, it is crucial to realize that the natural course and the

Table 1: Descriptive Statistics of the Pre-Treatment Data

Data	Mean	Median	Range
Age (years)	70.6	71	47 - 88
Prostate size (cc)	55	50	15 – 150
Tumor size (cc)	4.6	4.5	1 – 20
PSA (ng/ml)	79.4	69	2 – 1314
Alkaline phosphatase (U/L)	314	111	38 – 3673
Acid phosphatase (U./L)	67	10.6	1.2 – 2270
Bone lesion	7.2	5	0 - 20

Table 2: Early and Late Response to Hormonal Ablation

Status	Early		Late	
	No.	%	No.	%
Improvement	153	68.9%	79	43.0%
Progression	28*	12.6%	81	44.0%
Stable	41	18.5%	24	100.0%
Total	222	100%	184	100%

* All early progressed cases died within 12 months

course of the treated disease are governed by very powerful prognostic factors.[3] Some of these factors are directly tumor-related, such as the extent of the primary tumor (T category), the estimated total tumor mass which can be judged by the extent of metastases on bone scans or by tumor markers such as PSA, PAP, or alkaline phosphatase. Other prognostic factors are only indirectly tumor-related but by no means less powerful. A major problem concerning the evaluation of response and progression in metastatic prostate cancer lies in the fact that the most frequent metastatic sites - lymph nodes and bone - are usually not measurable but only evaluable. Considering the relative value of each individual parameter available for response and progression and the lack of measurable disease in the follow-up of prostate cancer patients, the EORTC GU Group has now decided not to attempt any longer to use computation of the different parameters for response and progression. The individual parameters are now used alone, such as pain, quality of life, performance status, PSA, new bone lesions and soft tissue metastases[4].

Among men with prostate cancer, PSA has been considered one of the strongest prognostic factors. The higher the PSA the more advanced the disease and the poorer the survival with any treatment option.[5-7] The association between PSA and disease survival is becoming apparent, although long-term data are as yet insufficient to support the use of PSA as a surrogate end point.

The histological grade of the tumor has provided a guide to disease prognosis. A poorly differentiated tumor is related to a more aggressive disease and perhaps a poorer survival. The grade and ploidy of the primary tumor are important predictors of cancer behaviour.[8] Advanced local disease is more frequently of high grade and associated with pelvic lymph node spread.

The extent of metastatic disease on the pre-treatment bone scan has been shown in several studies to have a prognostic significance. Many authors have found a statistically significant difference in the survival rates of patients with few, many or intermediate bone lesions.[9-11]

The aim of this study was to determine the independent clinical prognostic factor(s) that could predict patients' outcome in advanced stage prostate cancer.

Table 3: Comparative Analysis Between the Mean Pre- and Post-Treatment Data

	Pre-Treatment	Post-Treatment	P-Value
PSA (ng/ml)	79.44	7.48	0.000
Alkaline phosphatase (U/L)	313.81	208.7	0.12
Acid phosphatase (U/L)	66.69	14.57	0.26
Number of bone lesions	7.23	3.05	0.000
Prostate size (gm)	55	23	0.000
Tumor size (cc)	4.61	1.41	0.000

PATIENTS AND METHODS

A retrospective evaluation was made for 222 patients who underwent hormonal ablation therapy for advanced-stage prostate cancer between 1990 and 2000 (stage C= 32, D1= 17, and D2= 173 cases).

All pre-treatment data records were evaluated with regard to the patients' age, prostate and tumor size, tumor grade, stage, PSA level, serum alkaline, acid phosphatase and the number of bone lesions. The type of treatment that the patients received was also taken into consideration whether castration alone (n= 98) or TAB (n= 124). All patients who received TAB started a non-steroidal antiandrogen therapy 1 – 3 days post orchiectomy.

The post-treatment evaluation was divided into two parts. Part 1 included the response to treatment in the first 12 months assessed by PSA and bone scan. Part 2 included all available data such as PSA, bone scan, TRUS (prostate and tumor size) as well as alkaline and acid phosphatase until death or the last follow-up visit.

Taking into account the aforementioned criteria, we evaluated the initial and late response as follows:

As for the initial response, an improvement was considered when 50% or more of all pre-treatment parameters had declined during the first 12 months of follow-up. The disease was regarded as stable when all pre-treatment parameters decreased by less than 50% or when no changes were noted. Disease progression was confirmed by a continuous rise of the serum PSA level and an increase of the number of bone lesions on bone scan.

The late response was recorded according to the available follow-up data obtained at the patient's last visit, using the same criteria as above and the overall survival.

Statistical evaluation of all pre- and post-treatment data was initially performed by Chi-square, student t-test and the Anova single factor methods in order to obtain the significance ($P=<0.05$) of treatment results according to the type of treatment. The Chi-square test was used in the comparative analysis of the data using the number of patients and in the cross correlation analysis between all pre-treatment data values to predict the association between these parameters (i.e. the correlation between serum PSA level and the number of bone lesion). The Anova single factor method was used to confirm these results based on values from patients who had a complete set of pre- and post- treatment data. The mean, median and range of the data were obtained by descriptive statistical methods.

All the data were analyzed using the Cox proportional hazard model in relation to the disease status (overall survival and mortality) with its significance $P= <0.05$. The overall survival and the time elapsed until disease progression were analyzed using the Kaplan Meier curve and its significance was assessed by the Log-Rank test ($p=<0.05$).

RESULTS

The pre-treatment data were analyzed and the results are summarized in Table 1.

The correlation analysis of the pre-treatment values revealed that the PSA serum level was significantly related to the number of

Table 4: Early and Late Response to Treatment According to the Treatment Type

Status	Castration				TAB			
	Early		Late		Early		Late	
	No.	%	No.	%	No.	%	No.	%
Improvement	67	68.4%	38	45.0%	83	67.0%	46	44.0%
Progression*	14	14.3%	32	38.0%	19	15.3%	45	43.0%
Stable	17	17.3%	14	17.0%	22	17.7%	14	13.0%
Total	98	100%	84	100%	124	100%	105	100%

* All early progressed cases died within 12 months.

Table 5: Cox Proportional Hazard Model for Prognostic Factors in all Studied Cases

Variables	Coefficient	Standard Deviation	95% Confidence Interval Low – High	P Value
Age	0.0568	0.0179	0.0219 - 0.0916	0.0015
Tumor size	-0.0736	0.0606	0.1917 - 0.0444	0.2240
Tumor grade	-0.0523	0.2396	-0.5196 - 0.4149	0.8272
Tumor stage	1.0383	0.3373	0.3805 – 1.6961	0.0021
Pre-treatment PSA	0.0022	0.0017	-0.0011 – 0.0055	0.1843
Alkaline phosphatase	0.0036	0.0010	0.0017 – 0.0054	0.0002
Acid phosphatase	0.0049	0.0022	0.0005 – 0.0092	0.0286
Bone lesion	0.0724	0.0226	0.0283 – 0.1164	0.001
Kind of treatment	-0.1510	0.2106	-0.5617 – 0.2596	0.4732
First year PSA	0.0213	0.0065	0.0086 – 0.0339	0.0010
First year bone scan	0.0886	0.0404	0.0097 – 0.1647	0.0285

bone lesions and the tumor size (p=0.02 and p=0.04, respectively). However, it had no relation to the tumor grade or prostate size (p= 0.87 and p=0.76, respectively). Similarly, alkaline and acid phosphatase were significantly related to the number of bone lesions (p= 0.000 and p=0.00, respectively). Moreover, all patients with a serum alkaline phosphatase value doubling the normal level (90 –110u/L) had bone lesions on bone scan. On the other hand, alkaline phosphatase was not significant ly correlated to the PSA level, tumor grade and size, and prostate size (P=0.13, 0.7, 0.31 and 0.38, respectively). Similarly, acid phosphatase had no relation to the PSA level, prostate size, tumor size and grade (p=0.09, 0.08, 0.68 and 0.85, respectively), while it was significantly related to the alkaline phosphatase level (p=0.004). Importantly, we observed that the tumor grade was correlated significantly to the tumor size (p=0.039).

The mean follow-up period of alive cases was 39.42 months (median 29 months) ranging from 6 – 171 months. Of the 222 cases 110 (51.6%) had an overall disease progression within a mean time of 59.4 months (median 42 months), while mortality was reported in 118 (53.2%) of the 222 cases within a mean time of 59.9 months (median 48 months).

Table 6: Survival Outcome in Relation to Treatment Type

	Castration	TAB	Log-Rank
Mean survival (months)	60.28	48.78	0.55 (GI/GII)
Median survival (months)	56.00	42.00	
Mean follow-up (months)	38.80	36.40	

When evaluating the response to hormonal therapy we found that 153 cases (68.9%) experienced some initial improvement in the first 12 months of treatment. In 41 cases (18.5%) the disease remained stable, while 28 cases (12.6%) showed progression of the disease up to mortality within 3 to 12 months (Table 2). In the latter cases, the PSA level was continuously rising with a simultaneous increase in the number of bone lesions.

In general, all pre-treatment values significantly decreased after hormonal ablation therapy. There were statistically significant differences between the pre- and post-treatment data. However, the serum acid and alkaline phosphatase levels showed no significant changes in the post-treatment values (Table 3).

Moreover, the comparative analysis of the total initial and late responses to the treatment type revealed no statistically significant differences (p=0.99 and 0.88, respectively) (Table 4).

The multivariate analysis was used in order to predict the prognostic factors of all previous parameters in relation to the disease status (overall survival and mortality). We found that the pre-treatment values of patient age, tumor stage, number of bone lesions, serum alkaline and acid phosphatase were significantly related to the overall survival (p=0.0015, 0.0021, 0.001, 0.0002 and 0.028, respectively). However, the pre-treatment PSA serum level, tumor grade and the kind of hormonal treatment were not found to be predictors of the patients' outcome (Table 5).

Importantly, the PSA serum level and the number of bone lesions in the first 12 months of follow-up were significant predictors of the overall disease survival status (p=0.001 and 0.028, respectively).

It is worth to be mentioned that, when analyzing the overall survival rate in relation to the treatment type, we did not observe any statistically significant differences (Table 6). Moreover, there was no statistically significant difference between castration and TAB regarding the overall survival outcomes if correlated to the tumor stage.

DISCUSSION

While prostate cancer is known to be the second leading cause of death in North America, the incidence of prostate cancer in Egyptians is unknown. However, the incidence of newly discovered prostate cancer is increasing annually. Approximately 30 to 40% of the newly diagnosed cases either have clinical evidence of metastases or unsuspected micrometastases at the time of diagnosis. Nevertheless, prostate cancer among Africans represents only 8.2% of all diagnosed tumors in men.[12]

The hormonal treatment of prostate cancer has changed rapidly in the last few years, while castration remains the first-line gold standard treatment of advanced prostate cancer. Total androgen blockade (TAB) has been the focus of clinical research for more than 20 years and remains an option in the treatment of advanced prostate cancer.

Primary endocrine therapy can temporarily arrest the growth or dissemination of prostate cancer. Such treatment will not cure patients, as it is only palliative. Thus, the disease will inevitably recur as hormone independent within a relatively short period.

Our study retrospectively evaluated 222 patients who underwent androgen ablation therapy for advanced-stage prostate cancer. The mean follow-up period was 39 months, ranging from 6 – 171 months with a mortality rate of 53.2% (118/222). In 25% of our patients advanced-stage prostate cancer was diagnosed during their routine check-up visits; this incidence is quite similar to that reported in the literature.[13,14] The follow-up period in our study was similar to the largest meta-analysis of 22 trials, which had a median follow-up of 40 months and 57% mortality.[15]

Many studies have attempted to evaluate the pre-treatment prognostic predictors that could have a relation to patient survival outcomes in advanced-stage disease. The EORTC GU Group stated that the individual parameters (pain, quality of life, performance status, PSA, bone lesions, and soft tissue metastasis) were good predictors of patient outcome for such disease stage.[16]

In this study, we evaluated some of the pre-treatment data with regard to patient age, PSA, tumor size and grade, alkaline, acid phosphatase, number of bone lesions and the kind of hormonal treatment in relation to the overall survival using the multivariate analysis. Evans et al., in 1996, reported that in patients with metastatic disease the age was a strong predictor of survival.[17] This supports our findings, which indicate that patient age was significantly correlated to overall survival.

Most prior studies considered the pre-treatment PSA level a good prognostic indicator. However, we found that the PSA level had no relation to the overall survival, and 18% of our cases had a serum PSA level of < 20 ng/ml despite the higher stage disease. The same observation was made by other authors using the same statistical methods[18,19,20].

The extent of metastatic disease on pre-treatment bone scan has been reported by many researchers[8-10,21] to be an independent predictor of poor outcome. Our findings are in agreement with these studies, which demonstrated that the number of bone lesions was a strong independent predictor of poor survival.

Tumor grade and stage were reported to be prognostic factors in organ-confined disease. In our results only tumor stage but not grade was significantly associated with a poor prognosis in advanced-stage disease.

The serum alkaline phosphatase level is considered an important prognostic variable predicting the outcome in advanced-stage prostate cancer, as observed also in our study.[20,22] However, the serum alkaline phosphatase level was normal in 50 to 51% in our cases. Even with that, there was a strong correlation between the serum alkaline phosphatase level and the presence or absence of bone lesions. In fact, all cases that had a doubling of normal alkaline phosphatase levels had bone metastases.

Interestingly, the post-treatment serum PSA level and the number of bone lesions on the bone scan seen during the first 12 months of follow-up were strong independent predictors of overall survival. This observation was also made by other authors.[18] Despite these interesting findings, a regular follow-up of the other post-treatment data, such as serum alkaline and acid phosphatase, prostate and tumor size of our patients are lacking because the patients in question were followed-up on an individual basis.

The overall response rate to hormonal therapy observed in our study is comparable to that in the literature. De Voogt et al.,[23] in 1989 and Vogelzang et al.,[24] in 1995, reported that the overall response rate to hormonal therapy in advanced-stage prostate cancer ranged between 60% and 80%. In our study, the overall improvement at initial and late response ranged from 69% to 88% and 43% to 56%, respectively.

Although, orchiectomy has been recognized as the ideal hormonal therapy for stage D2 prostate cancer, medical castration has been reported to be an effective alternative option.[24-26] Stage D2 patients comprised 80% of our study population. The overall response rates in this group of patients ranged from 86% to 62% for early and late response, respectively. The 5-year overall survival was 30%. Other authors reported that the overall objective response rate in stage D2 cases was 98% and the 5-year cause-specific mortality rate was 15%.[27]

The majority of the 222 cases studied had undergone castration alone either with (N=124) or without (N=98) non-steroidal antiandrogen. In the comparative analysis of all the pre-treatment data, we observed no significant differences between both treatment groups, indicating a good similarity of the groups prior to therapy.

From that point, we started to evaluate the post-treatment response in relation to the treatment type. Despite the good responses observed, no statistically significant differences were found between both treatment types. With a mean follow-up period of 36 and 38 months, overall survival was 60 and 49 months for castration and TAB, respectively. A recent prospective randomized study by Eisenberger et al.[20] which included 1387 cases with advanced-stage prostate cancer supports our results. They also failed to demonstrate or to confirm previous results reported by Crawford et al.[19] showing a 25% improvement in the median survival among patients treated by TAB in comparison to medical castration alone. Lastly, they suggested that it might be worthwhile to reassess the relative merits of medical or surgical castration in combination with antiandrogens. They suggested that the benefit of MAB in a patient with advanced prostate cancer is negligible[20].

We are aware of the fact that study has some methodological limitations. It is a retrospective review of non-consecutive patients from different geographic, socioeconomic and medical backgrounds leading to some selection bias. In addition, the data obtained from the medical chart-review was occasionally incomplete. Nevertheless, our study contained a very respectable number of patients and employed appropriate complex statistical methods including multivariate analyses. Furthermore, our results confirm what has already been suggested in the literature, namely, that TAB offers little, if any, clinical benefit over castration alone in patients with advanced prostate cancer.

In conclusion, in patients with advanced - stage prostate cancer, pre-treatment patient age, tumor stage, serum alkaline and acid phosphatase, one year post-treatment PSA level and the number of bone lesions were significant independent predictors of the overall patient outcome. However, the treatment type had no effect on the overall survival outcome.

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RESUME

Facteurs Pronostiques Cliniques chez les Patients Atteints de Cancer Prostatique Avancé

Objectifs: De déterminer les facteurs pronostiques prédictifs de l'évolution du cancer prostatique chez nos patients atteints de cancer avancé de la prostate. **Patients et Méthodes**: Dans cette étude nous avons rétrospectivement évalué les données médicales de 222 patients atteints de cancer avancé de la prostate traités par thérapie hormonale (castration ou blocage androgènique total (BAT)). Toutes les données pré et post ont été évaluées en ce qui concerne l'âge des patients, la taille de la prostate et de la tumeur, le score histologique de la tumeur, le stade clinique, le PSA, la phosphatase alkaline et acide et le nombre de lésions osseuses. La réponse au traitement hormonal a été évaluée aussi bien tôt (12 mois après traitement) ou tard (à la dernière visite ou mort). Des statistiques descriptives, les tests T de Student, multivariable et de Kaplan Meier ont été employées pour l'analyse des données. **Résultats**: Pendant les 12 premiers mois du traitement, 70% des cas ont montré une amélioration avec une régression significative de leurs tumeurs. L'âge des patients, le stade de la tumeur, le nombre de lésions osseuses, les niveaux de phosphatase alcalines et acides sériques préopératoires étaient des facteurs prédictifs de survie indépendants et significatifs (p = 0.0015, 0.002, 0.001, 0.0002 et 0.028, respectivement), tandis que le taux sérique de PSA pré thérapeutique, le grade de la tumeur et le type de traitement hormonal utilisé (castration ou BAT) n'étaient pas significativement prédictifs de l'évolution des patients (p = 0.18, 0.82 et 0.47, respectivement). Essentiellement, le niveau de PSA et le nombre de lésions osseuses pendant les 12 premiers mois de suivi étaient des facteurs prédictifs significatifs du statut global de survie de la maladie (p=0.001 et 0.028, respectivement). La période moyenne de suivi des cas vivants était de 39.42 mois s'étendant de 6 - 171 mois. Parmi les 222 cas 110 cas (51.6%) ont eu une progression de la maladie pendant un intervalle de temps moyen de 59.4 mois, alors que la mortalité était de 118 cas (53.2%) pendant un intervalle moyen de temps de 59.9 mois. **Conclusion**: L'âge du patient, le stade de la tumeur, le taux sérique de phosphatase alcaline et acide, comme le taux de PSA pré thérapeutique et le nombre de lésions osseuses étaient des facteurs prédictifs indépendants et significatifs de l'évolution du cancer chez les patients présentant un cancer avancé de la prostate. Cependant, une analyse de survie par rapport au type de traitement n'a pas indiqué une différence statistiquement significative entre les résultats de la castration et le BAT.

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