

Chapter 04 / Capítulo 04

Advanced Prostate Adenocarcinoma and Androgen Deprivation Therapy. Clinical Outcomes, Risk Stratification, and Therapeutic Results

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Field study: design, criteria, variables, and instruments

Study design and methodological framework

The empirical analysis developed in this volume was based on a descriptive observational study structured under a cross-sectional design. This approach allowed us to examine the clinical behavior of patients diagnosed with advanced prostate adenocarcinoma who were undergoing total androgen deprivation and were treated at the Urology Department of the Joaquín Albarrán Domínguez Clinical Surgical Teaching Hospital during an observational period of several years.

The choice of an observational design corresponded to the nature of the phenomenon studied. The central interest was not to intervene in therapeutic variables but to describe clinical patterns, evolutionary trajectories, and diagnostic characteristics as they manifested themselves in routine healthcare practice. The descriptive nature of the study allowed us to characterize the expression of the variables of interest within the defined institutional context, preserving the complexity inherent in the real clinical environment.

The cross-sectional design facilitated the integration of clinical information corresponding to a defined time interval, offering a structured view of patient evolution under comparable therapeutic conditions. This approach made it possible to examine biochemical indicators, clinical parameters, and functional dimensions relevant to the follow-up of advanced prostate cancer patients.

Study population

The reference population consisted of all patients diagnosed with prostate adenocarcinoma treated at the hospital during the period analyzed. A total of 234 patients with a confirmed diagnosis of prostate adenocarcinoma were identified during an observational period of several years.

This population included patients with different stages of the disease, diverse clinical trajectories, and heterogeneous therapeutic regimens. From this group, a specific sample was selected, aimed at capturing only those cases that met clinical and therapeutic characteristics compatible with the study objectives.

Sample selection

The final sample consisted of 73 patients who met the previously defined selection criteria. This process allowed us to define a homogeneous group in terms of age, clinical stage, and therapeutic strategy, favoring the analytical consistency of the study.

The definition of the sample corresponded to the need to examine the behavior of advanced prostate adenocarcinoma under a specific therapeutic regimen: total androgen deprivation. This selection reduced the variability derived from alternative treatments or noncomparable clinical stages.

Inclusion criteria

Patients over 50 years of age with a confirmed diagnosis of advanced prostate adenocarcinoma were included in the study. Similarly, only those individuals who were undergoing clinical follow-up through the outpatient clinic of the Joaquín Albarrán Domínguez Hospital and who had received treatment based on total androgen blockade were considered.

The inclusion of patients in outpatient follow-up ensured the availability of systematic clinical information, serial biochemical parameters, and consistent evolutionary evaluation. Therapeutic homogeneity allows for the analysis of clinical response within a comparable hormonal intervention framework.

Exclusion criteria

Patients with a history of autoimmune diseases, previous malignant neoplasms, or prostate diagnoses other than invasive adenocarcinoma, such as prostatic intraepithelial neoplasia or focal glandular atypia, were excluded. This decision was made to avoid potential confounding factors that could interfere with the interpretation of clinical progression or response to hormone therapy.

Likewise, patients with neurological or psychological conditions that prevented adequate understanding or response to the clinical assessment instruments used were not included. This criterion preserved the consistency of the information obtained, particularly in relation to functional and quality of life variables.

Methods, techniques, and procedures for obtaining information.

To achieve the proposed objectives, information was collected through statistical records, medical records, and pathological anatomy reports, which were compiled in the data collection form (Appendix I), where all the variables of interest for the research were recorded.

With the information provided in the instrument, we classify patients by risk, which is very low, low, intermediate favorable and unfavorable, high, and very high, in addition to identifying the stage of their disease at the time of diagnosis and when it progresses to advanced stages, thus forming the sample to be used in our research. We based our classification on PSA levels, Gleason score, histopathological grade, digital rectal examination, abdominal and bladder-prostate ultrasound, complete blood count, and blood chemistry. Through the histological study of the Trucut biopsy, we were unable to stage patients in T3 and T4, as the sample size was insufficient for analysis. However, in the presence of stony, fixed, asymmetrical prostates with irregular edges or upon physical examination of lymphedema in the lower limbs due to the presence of inguinal adenopathies, as well as ultrasound findings of ureterohydronephrosis secondary to trigone infiltration, these findings were characteristic of stages T3 and T4.

Written informed consent was obtained from the patients to participate in the study, and each participant was interviewed to explain the principles of treatment, follow-up, and symptoms for better identification of recurrence. The health status of the participants after the start of anti-androgen treatment was investigated, with reference to symptoms such as decreased sexual desire, hot flashes, bone pain, gynecomastia, and mastodynia. In addition, the progression of the stages was monitored via review and detection of increases in PSA, alterations in testosterone, the appearance of bone metastases, and physical examination to detect the presence of lymphedema and inguinal adenopathies.

Table 4.1 shows the operationalization of the variables. For each variable, the definition and scales are presented to facilitate understanding of the analysis.

Table 4.1. Operationalization of variables

Variable	Definition	Scale used
Age	Years of age at the start of the study were considered, grouped by category	Less than 50 50-54 55-59 60-64 65-69 70 and over
Total androgen blockade	- Patients who are unlikely to undergo surgery or those who refuse surgery. - Patients who have undergone surgery	Pharmacological Surgical
Appearance of signs of progression	Depending on the appearance of signs of progression in patients	Local invasion Distant metastasis Hormone resistance
Prostate Surface Antigen	Prognostic parameter to establish treatment effectiveness, at the time of diagnosis and every 3 months	According to patient values. < 4 ng/ml in metastatic disease <0,5 ng/ml in controlled disease.
Testosterone	Prognostic parameter to establish treatment effectiveness, depending on castration concentration. Hormone resistance	According to patient values. Normal value: < 20 ng/dl
Hemoglobin	Prognostic parameter for establishing treatment effectiveness	According to patient values. Normal value: < 13 g/l
Creatinine	Prognostic parameter for establishing treatment effectiveness depending on renal function	Based on patient values. Normal value: < 113 mmol/L
Liver enzymes	Prognostic parameter for establishing treatment effectiveness depending on liver function	According to patient values. Normal value: Glutamic pyruvic transaminase. 5-40 U/L (GPT or ALT) Glutamic oxaloacetic transaminase. 7-56 U/L (GOT or AST)
Degree of cellular differentiation	Histological study result	Differentiated Moderately differentiated Undifferentiated
Gleason classification	Assigning a score based on greater or lesser differentiation and glandular histology	From 1 to 10
Risk classification	Based on physical examination, histological results, and complementary tests	Low Very low Favorable intermediate Intermediate unfavorable High

Bioethical considerations

During this research, the standards for medical research involving humans established in the Declaration of Helsinki were followed, which set out four basic ethical principles: respect for

persons, beneficence, nonmaleficence, and justice.

This research was endorsed by the Research Ethics Committee and the Scientific Council of the Joaquín Albarrán Domínguez Clinical-Surgical Teaching Hospital.

The surveys were anonymous and were administered after informed consent was obtained, making it clear that the respondents' data would not be disclosed to third parties and would only be handled by the research participants, who undertook not to disclose any data that would allow the respondents to be identified.

The results of the evaluation of the instruments were collected in a database, which was kept under the care of the person responsible for the research.

Each patient was asked to participate after the objectives of the study and the procedures that would be followed if they agreed to collaborate were explained. They were told that they were completely free to refuse to participate, without any consequences for their present and/or future medical care, as this was their right. This was done in conjunction with the informed consent document, and only if they agreed to participate in the research did they sign it as proof of their desire to do so.