ABIRATERONE OFF LABEL USE IN COMBINATION WITH DOCETAXEL AND ANDROGEN DEPRIVATION THERAPY IN PATIENTS WITH METASTASIC HORMONE SENSITIVE PROSTATE CANCER: A REAL WORLD EXPERIENCE

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BACKGROUND AND IMPORTANCE

Initial therapy for males with metastasic hormonosensitive prostate cancer (mHSPC) consist of combination of oral antiandrogens (abiraterone, apalutamide or enzalutamide) or docetaxel with androgen deprivation therapy (ADT). Recently, combinations of ADT with docetaxel plus a second systemic agent (abiraterone or darolutamide) have been show to improve survival over ADT plus docetaxel alone.

AIM AND OBJECTIVES

To **compare the efficacy profile, safety and clinical** follow up of patients with synchronous mHSPC treated with triplet therapy (TT)(**docetaxel+TDA+abiraterone**) **versus** patients treated only with **abiraterone plus TDA** (doublet therapy)(DT) due to inegibility to docetaxel or diagnosis mHSPC before approval of triplet therapy protocol with abiraterone off label at hospital.

MATERIAL AND METHODS

Retrospective observational study

Patients with mHSPC who initiated TT and DT in a third level hospital.

The clinical data cut-off date established was 3 August 2024. All patients had a minimal follow up of 6 months.

Variables collected

- **Stage**
- **Burden and risk disease**
- **PSA evolution**
- **Toxicity**
- **Progression free survival.**

RESULTS

A total of **31 patients** (67±6 years)were included.16 patients were treated with TT and 15 patients with DT. All patients had synchronous mHSPC with high disease burden and high risk disease.

At diagnosis, bone metastasis were predominant in both groups.

Visceral metastasis were present in 31,2% of patients in triple therapy group (TTG) versus none in double therapy group (DTT).

The median pre-treatment PSA level in TTG was 378,4 (9,3-1000) ng/ml versus 149,2 (4.8-756,4)ng/ml in the DTG.

At 3 months,**100% of patients achieved >90% reduction in baseline PSA in the TTG** versus 93,3% in the DTG.

At data cut off, median time treatment in TTG was 13,4±4 months versus 11,1±5 months in DTG. **93,7% of patients had no disease progression in the TTG** versus 53,3% in the DTG.

There were no deaths in the TTG compared to 20% of patients in DTG due to progression disease.Only one patient in each group had treatment interruption and doses reduction due to toxicity to abiraterone.

CONCLUSION

- **Abiraterone plus docetaxel and TDA** in real-world setting demonstrates a **better efficacy** profile compared to abiraterone plus TDA despite patients in TTG had higher baseline PSA levels and a high percentage of patients with visceral metastases.
- **Abiraterone plus docetaxel and TDA** proves a **favourable safety** profile in agreement with previous data published.

4CPS-033

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