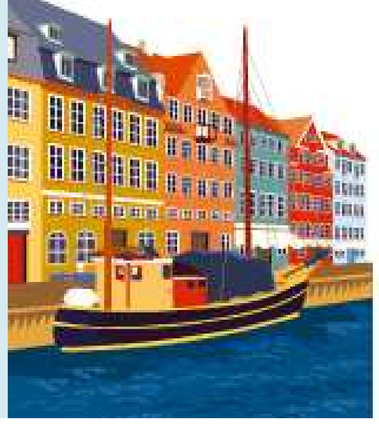

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DOCETAXEL, ABIRATERONE AND ANDROGEN DEPRIVATION THERAPY: EFFICACY AND SAFETY ANALYSIS

A. MAGDALENA PÉREZ 1, J. PEÑA HERNÁNDEZ 1, C. MELIÁN CABRERA 2, J. ESQUIVEL NEGRÍN 1, P. FUMERO CRUZ 1, I. GONZÁLEZ PERERA 1, M.M. PIÑERO GONZÁLEZ 2, C.L. DÍAZ DÍAZ 1, S. GONZÁLEZ SUÁREZ 1, M. GARCÍA ALONSO 3, M.P. DÍAZ RUIZ 1.

(1)Hospital Pharmacy Service of University Hospital of Our Lady of Candelarial
(2)Hospìtal Pharmacy Service of University Hospital of Gran Canaria Doctor Negrin
(3)Oncology Medical Service of University Hospital of Our Lady of Candelaria

AIM AND OBJETIVES:

To analyze the safety and efficacy profile of the triple therapy:Abi+Doc+ADT in patients with high-volume HSmPC.

MATERIALS AND METHODS:

Retrospective, observational, multicenter study conducted between November 2021-September 2024 in patients with high-volume HSmPC who received Abi+Doc+ADT after off-label approval.

Evaluated efficacy variables included: number of cycles, progression-free survival(PFS), percentage of response by PSA considering progression as three consecutive increases(PEACE-1 criteria) and type of radiological response according to RECIST v1.1 criteria.

For safety: previous and subsequent comorbidities, addition of medications during treatment, interactions between home and oncology medications, and the development of adverse reactions(ARs) were recorded according to CTCAE v5.0 criteria.

Statistical analysis was performed using Jamovi software.

RESULTS:

30 patients

18+ Median age 63(54-85)

ECOG 0-1

83.3% patients received 6 cycles of docetaxel

Treatment was discontinued in 5 patients(2 due to progression, 2 due to docetaxel intolerance, and 1 due to pneumonia requiring hospitalization).

Based on **PSA values**, 22(73,3%) responded.

One-year PFS was 88% (76%-100%, 95% CI), and the median PFS was not reached.

Radiological response rate was 60%, with 6 complete responses(20%), 8 partial response(26,7%), 4 stable disease(13,3%), and 4 patients with progression

70% had **pre-existing comorbidities**: hypertension(33.3%), dyslipidemia(33.3%) and type 2 diabetes mellitus(16.7%).

Six patients(20%) developed **lipid profile alterations**, but no treatment modifications were necessary.

Pharmacological interactions with abiraterone(40%):mainly increased risk of statin-induced myotoxicity, but no cases were reported.

ARs in 21 patients(70%): 7 asthenia and 5 gastrointestinal. Of these, 14(46,7%) were grade 1-2. Only 7 patients(23.3%) had ARs related to abiraterone and treatment was discontinued in one case due to atrial fibrillation. No further clinical actions were required in the remaining cases.

CONCLUSION AND RELEVANCE:

Our experience suggests that Abi+Doc+ADT is an effective therapy with promising results for patients with high-volume HSmPC.

Our study (2,8 years of follow-up) needs to evaluate whether the median PFS resembles that of the trial (4,46 years).

It is a safe treatment, as most ARs were low-grade, manageable and the interactions were not clinically significant.

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