

EFFECTIVENESS AND SAFETY OF BRAF/MEK INHIBITORS IN ADVANCED OR METASTATIC MELANOMA IN TWO TERTIARY HOSPITALS

Mejías Trueba M¹, Ciudad Gutiérrez P¹, Montecatine Alonso E², Acosta García H¹
¹Hospital Universitario Virgen del Rocío, Hospital Pharmacy, Seville, Spain.
²Hospital Universitario de Jerez, Hospital Pharmacy, Cádiz, Spain.

BACKGROUND AND IMPORTANCE

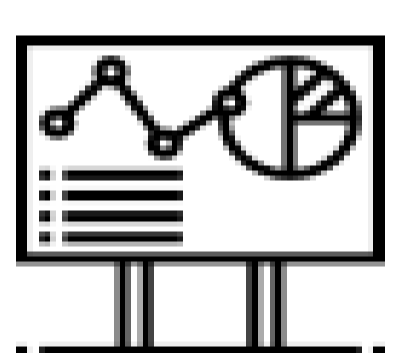
Dabrafenib/trametinib and vemurafenib/cobimetinib: increased significantly Progression-Free Survival (PFS) and Overall Survival (OS) in patients with advanced or metastatic melanoma with BRAF mutations, in phase 3 Clinical Trials.

OBJECTIVE

To assess the effectiveness and safety of vemurafenib/cobimetinib and dabrafenib/trametinib, in patients with locally advanced or metastatic melanoma in real life.

MATERIAL AND METHODS:

- Design: retrospective, multicenter, observational study.
- Treatment: vemurafenib/cobimetinib or dabrafenib/trametinib in patients with BRAF-mutated melanoma.
- Variables collected: sex, age, stage, Performance Status (PS), previous treatments, duration of treatment and response, dose received and dose adjustments.
- Variables evaluated: PFS, OS, adverse events (AE), withdrawal rate and reason for it.



RESULTS:

Vemurafenib/cobimetinib (n=20), dabrafenib/trametinib (n=13), dabrafenib (n=1), both drugs (n=8) --> 38 patients analyzed, 4 loss of follow-up.



15 Women

Effectiveness and safety:



42 patients analyzed



Median 62.4 years old

- **Vemurafenib/trametinib:** median PFS 9.71 (IC95%:5.77-NA); median OS 18.5 (IC95%:11.9-NA). Median duration of treatment: 99 (IR:20-243).
- 100% AE --> 85.2% dermatological and 74.1% gastrointestinal, mainly. 26% withdrawal treatment.
- **Dabrafenib/cobimetinib:** median PFS 10.1 (IC95%:7.7-NA); median OS was not reached. Median duration of treatment: 198 (IR:73-632).
- 94.7% AE --> 52.6% dermatological, 68.4% gastrointestinal and 57.9% low-grade fever/discomfort. 15.8% withdrawal treatment



81% metastatic melanoma



1st line: 71.4%
vemurafenib/cobimetinib
14.3% dabrafenib/trametinib

	Vemurafenib/cobimetinib	Dabrafenib/ trametinib
Complete response	14.8%	26.3%
Partial response	33.3%	26.3%
Stable disease	7.4%	15.8%
Progress	11.1%	15.8%
Not assessable	33.3%	15.8%



CONCLUSION:

-The effectiveness observed in our patients was slightly **lower** than that seen in the pivotal CT (COBRIM-b) in vemurafenib/cobimetinib patients. It was **similar** to that seen in pivotal CTs (COMBI-v and COMBI-d) in patients treated with dabrafenib/trametinib.

The **toxicity profile** of both drugs is **similar** to pivotal CTs' results. Dabrafenib/trametinib was better tolerated than vemurafenib/cobimetinib.