



# REAL-WORLD EVIDENCE OF HIGH-COST DRUGS FOR METASTATIC MELANOMA: EFFECTIVENESS, COMPLIANCE TO CLINICAL PRACTICE GUIDELINES AND ECONOMIC EVALUATION

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## BACKGROUND

In Italy melanoma is the second most common cancer among men and the third in women. Invasive malignant melanoma accounts for about 1% of all skin cancers, but it is the most deadly. Targeted therapy and immunotherapy have changed the management of metastatic melanoma. Chemotherapy is less effective, but it is still a treatment option.

## PURPOSE

To analyse drug effectiveness for metastatic melanoma in our hospital, to assess compliance to clinical practice guidelines and to perform an economic evaluation.

## MATERIAL AND METHODS

We analysed all patients with metastatic melanoma treated from 1 May 2016 to 30 April 2018 and which drugs were administered. Patients were stratified by age, gender, line of therapy, Eastern-Cooperative-Oncology-Group (ECOG) performance status (PS) and type of cancer treatment (targeted therapy-immunotherapy).

We assessed progression-free survival (PFS) and overall survival (OS) with the Kaplan–Meier method.

We assessed compliance to Italian clinical practice guidelines and we analysed the drug costs.

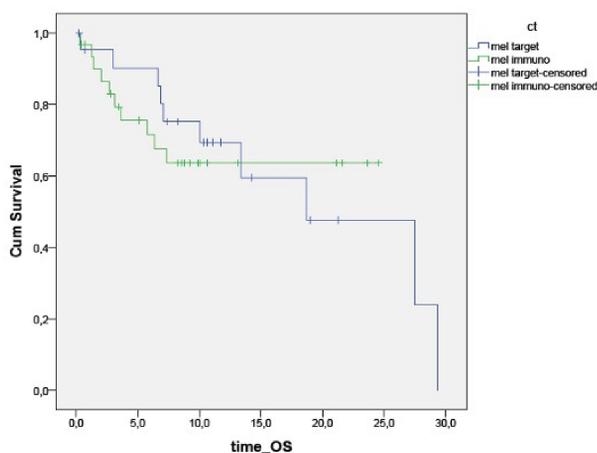
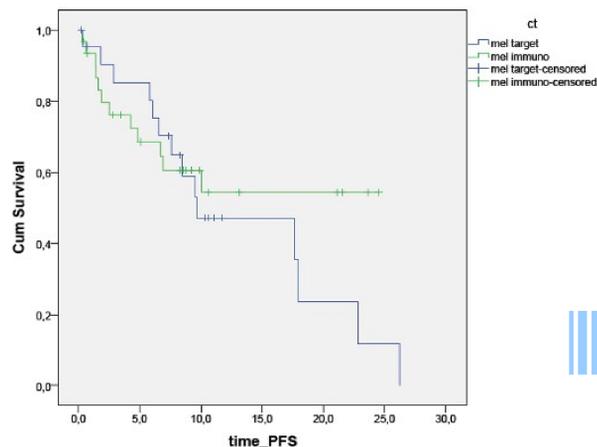
## RESULTS

Fifty-three cases of metastatic melanoma were found. The mean age was 66, 58% were older than 65 years and 55% were male. Median PFS was 17.7 months and median OS was 27.5 months.

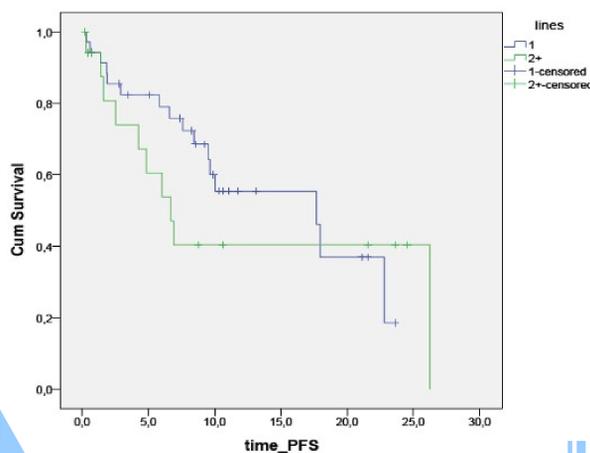
Fifty-eight per cent were treated with immunotherapy (nivolumab or pembrolizumab) and 42% with targeted therapy (dabrafenib+trametinib or vemurafenib+cobimetinib)

In the targeted therapy group, median PFS was 9.6 months and median OS was 18.6 months.

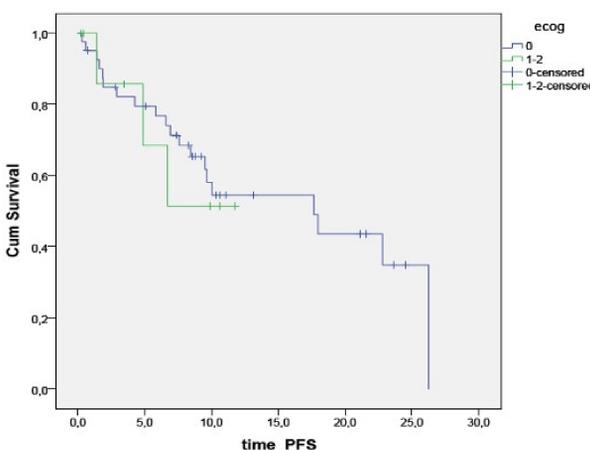
Median PFS and OS in the immunotherapy group were not reached.



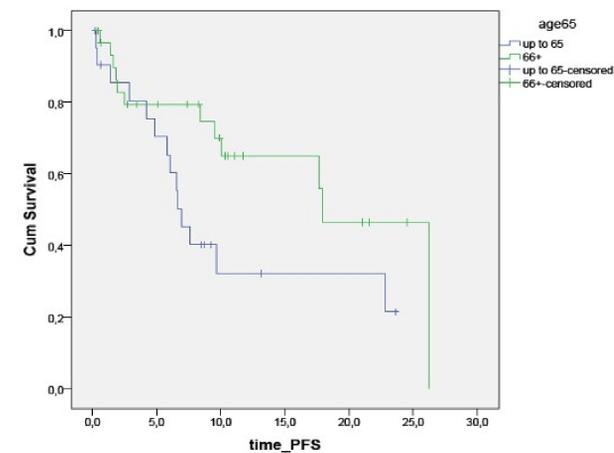
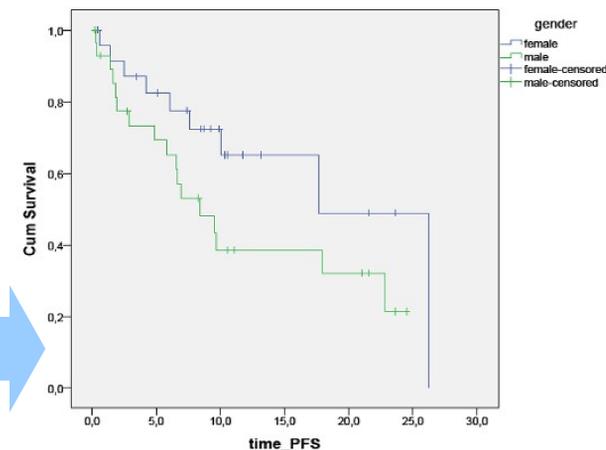
Sixty-six per cent were first-line treatments (median PFS 17.6 months, median OS 29.3 months). Beyond first-line therapy median PFS was 6.7 months and median OS was 7.3 months.



Seventy-seven per cent had baseline PS of 0. PS was identified as an important prognostic factor for PFS and OS.



Female gender and age older than 65 were significant predictors for PFS and OS benefit.



We identified only one case of non-compliance to clinical practice guidelines.

The cost of the drug combination vemurafenib+cobimetinib was higher than the cost of dabrafenib+trametinib. Pembrolizumab was less expensive than nivolumab.

## CONCLUSION

Our analysis suggests a high level of compliance with clinical practice guidelines.

Dabrafenib+trametinib was a cost-effective regimen in BRAF-mutated patients requiring rapid intervention to avoid disease progression.

Immunotherapy should be the treatment of choice in order to achieve long-term disease control.



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