CO146

Treatment use and overall survival of Patients with Unresectable/ Metastatic Melanoma in Colombia: A real world study.

Reyes Sanchez, JM[1], Bolaños-López, J[2], Bello, C[2], Rubio, AC[1], Gonzalez, FJ[2], Toro A[2], Chen K[3], Arciniegas, J[1], Alarcon BA[1], Garcia M[1]

[1]Pfizer, Colombia; [2]Centro de Biociencias Sura, Colombia; [3]Pfizer, USA.

BACKGROUND

- Melanoma, a malignant tumor of melanocytes, is a characteristically aggressive cancer that most commonly affects the skin, and other sites such as mucosa, intestines, the brain, or the uvea rarely involve[1].
- About 90% of melanomas are diagnosed as primary tumors without any evidence of metastasis at the time of diagnosis[2]. Before targeted and immunotherapies became available, chemotherapy was the only systemic treatment that could be offered to Stage IV melanoma patients, however, currently chemotherapy may only be considered as last treatment option in patients with resistance to immunotherapies[3].
- The initial immunotherapy approved by INVIMA (the Colombian food and drug regulation agency) was reported in 2016, and after that several systemic therapies have been approved for melanoma treatment to the present day.

OBJECTIVE

- This study aimed to measure treatment use and overall survival (OS) of Colombian patients with unresectable/metastatic melanoma between 2015 to 2022.

METHODS

- A descriptive, retrospective, longitudinal cohort study was conducted in patients with the diagnosis of unresectable (Stage III) and metastatic (Stage IV) melanoma in the Colombian population using electronic health record and pharmacy claims databases of a Health Management Organization (HMO).
- Eligible study patients were those had a confirmed unresectable or metastatic melanoma diagnosis given by the International Classification of Diseases, tenth version (ICD-10) codes for melanoma (code C43.x or D03.x) and started treatment during January 2015 and December 2021.
- Index date was defined as the first date or initial record of unresectable or metastatic melanoma diagnosis.
- Patients were followed from the index date until death, discontinuation of HMO insurance (patient loss), 5-year follow-up, or the end of the observation period (31 December 2022).
- The primary study objective was to examine treatment regimens in each line of therapy (LOT), the year of treatment regimens initiation, the number of LOT received, and treatment sequences (Sequence of successive therapies for unresectable/metastatic melanoma up to the third LOT).
- The second objective is the OS from the diagnosis. This OS was defined since the index date during the observation period to the date of death from any cause. Patients who are still alive at the end of follow-up or who are lost to follow-up will be censored at the last date they were known to be alive.
- Time to event for death (overall survival) was evaluated using the Kaplan-Meier method. A univariate Cox regression analysis was used to evaluate covariables such as demographic (age, sex) and clinical characteristics (Charlson comorbidity score, stage at diagnosis, number of metastases, histology, previous treatment, etc.) about the OS.

RESULTS

- 156 patients with unresectable/metastatic melanoma were included in the study. The mean of follow-up were 25.9 months (Standard deviation [SD] 23.9). The mean of age is 56.7 months (SD 16.4). Most of the patients were in IV stage which 10.8% of patients had metastasis in brain and 8.1% in lung (Table 1).

RESULTS (cont)

- The most frequent therapy used as first line were immunotherapy (84.7%), excluding the patients without information of treatment. In these group of patients, nivolumab in monotherapy (57.6%) and nivolumab combined with ipilimumab (28.2%) were the most prescribed. Targeted therapy was used in 10.8% as first line, and 33.3% in second line. 28.8% of patients were not treated with any treatment. In second line, the immunotherapy was used in 28.6% and increased the targeted therapy increased to 19.1% while patients with no data about treatment increased to 47.6%. The patients that refer No data could be dead in previous line, receive palliative treatment or loss during the follow-up (Figure 1).
- The median of overall survival of the total population was 67.8 months (95% Interval confidence IC 37.4 - no available [NA]) (Figure 2).
- The patients older 60 years presented a median OS 35.7 months (95% IC 23.3 - NA) while younger patients did not achieve median (HR 2.1 95% CI 1.2-3.6).
- When the number of metastases increases, the OS decrease. Comparing no metastasis, HR for 1 metastasis was 2.5 (95% IC 1.3-4.8) and for 2 metastasis 3.9 (95% IC 1.7-8.8) (Table 2).
- Likely to number of metastases, the increased of risk of comorbidities using Charlson score were increased Overall survival. When the Charlson score is 5 -10 compared to less than 5, HR was not statistically significant (1.5 [95% CI 0.6 – 3.7]), however greater scores were statistically significant (Charlson score 10-15, HR 3.4 [95% CI 1.5-7.8]; >15. HR 8.3 [95% IC 2.4-28.3]) (Table 2).
- High lactate dehydrogenase levels decrease the OS compared to normal lactacte dehydrogenase (HR 3.6 [95% IC 1.5 – 8.6]) (Table 2).
- Overlapping sites of primary cancer had less OS than other localization with 26 months (95% IC 16.6 – NA) and HR 2.6 (95% IC 1.5 – 4.5) compared to other sites. (Table 2).

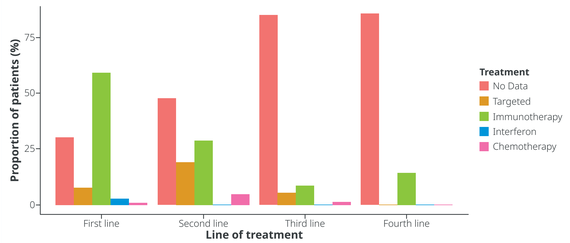
Table 1. Clinical and demographic characteristics of patients with unresecable and metastasis melanoma colombian patients

	Total 156
Age Mean (sd)	56.7 (16.4)
AJCC Stage	
IIIB	29 (18.6)
IIIC	40 (25.6)
IIID	4 (2.6)
IV	83 (53.2)
Historical of surgical resection	29 (18.6)
Metastasis	
Brain	12 (10.8)
Lung	9 (8.1)
Liver	3 (2.7)
Lymph nodes	2 (1.8)
Bone	1 (0.9)
Distant skin	0 (0)
Other	84 (75.7)
Number of metastasis	
0	65 (41.7)
1	72 (46.2)
2	18 (11.5)
≥3	1 (0.6)
Melanoma localization	
Lower limb	28 (18.4)
Trunk	24 (15.8)

RESULTS (cont)

	Total 156
Overlapping	9 (5.9)
Other parts of face	8 (5.3)
Scalp and neck	8 (5.3)
Upper limb	8 (5.3)
Lip	2 (1.3)
Ear and external auricular canal	1 (0.7)
Eyelip	0(0)
Unknown	64 (42.1)
LDH	
Elevated	8 (5.1)
Normal	116 (74.4)
Not assessed	32 (20.5)

Figure 1. Treatment patterns of unresectable/metastatic melanoma in Colombian patients



No Data. It refers to patients that could death in the previous line, or change to palliative treatment, or loss administrative patients.

Figure 2. Overall survival of unresectable/metastatic melanoma in Colombian patients

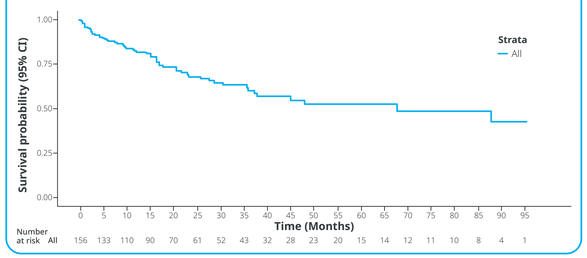


Table 2. OS and univariable analysis of different clinical and demographic variables

	n	Median	LCL	UCL	HR	LCL, UCL	P Value
Age							
≤60	91	NA	67,8	NA	Ref		
>60	65	35,7	23,3	NA	2,07	1,20-3,59	0,009
Sex							
Female	72	67,8	37,4	NA	Ref		
Male	84	88,1	35,7	NA	0,88	0,52-1,52	0,7
No Metastasis							
0	65	88,1	47,9	NA	Ref		
1	72	37,8	23,3	NA	2,47	1,26-4,84	0,008
2	19	23	12	NA	3,9	1,72-8,84	0,001
Charlson score							
0-4	43	NA	47,93	NA	Ref		
5-9	57	88,1	37,82	NA	1,5	0,62-3,67	0,4
10-14	51	27,8	16,56	NA	3,37	1,46-7,77	0,004
>=15	5	15,1	1,68	NA	8,25	2,41-28,3	<0,001
LDH							
Normal	119	88,1	45,1	NA	0,28	0,12-0,68	0,005
High	8	14,2	12	NA	Ref		
Localization of CA							
Lip	8	45,1	23,3	NA	0,28	0,12-0,68	0,005
Eyelid	6	NA	15,1	NA	0,96	0,23-3,94	>0,9
Ear and external auricular canal	3	NA	NA	NA	NA	NA	NA
Other parts of the face	25	26	15,1	NA	1,8	0,97-3,31	0,061
Scalp and neck	13	NA	26	NA	0,55	0,17-1,78	0,3
Trunk	42	88,1	NA	NA	0,83	0,44-1,59	0,6
Upper limb	28	67,8	37,4	NA	0,68	0,32-1,44	0,3
Lower limb	52	NA	35,7	NA	0,76	0,43-1,36	0,4
Overlapping sites	35	26	16,6	NA	2,55	1,45-4,49	0,001
Unspecified	45	67,8	35,7	NA	1,4	0,66-2,99	0,4
Previous surgical							
No	126	67.4	37.8	NA	Ref		
Yes	30	37.4	28.6	NA	0.8	0.39-1.64	0.5

CONCLUSION

- The OS observed in unresectable/metastatic melanoma in Colombian patients was affected by demographic and clinical characteristics of patients. The immunotherapy is main driver of treatment of patients with stage of melanoma.

REFERENCE

1. Siegel RL, Miller KD, Wagle NS, Jemal A. Cancer statistics, 2023. CA Cancer J Clin. 2023;73(1):17-48. doi:10.3322/caac.21763
2. Garbe C, Amaral T, Peris K, et al. European consensus-based interdisciplinary guideline for melanoma. Part 1: Diagnostics: Update 2022. Eur J Cancer. 2022;170:236-255. doi:10.1016/j.ejca.2022.03.008
3. Garbe C, Amaral T, Peris K, et al. European consensus-based interdisciplinary guideline for melanoma. Part 2: Treatment - Update 2022. Eur J Cancer. 2022;170:256-284. doi:10.1016/j.ejca.2022.04.018.

Financial disclosure: This study was sponsored by Pfizer S.A.S. Poster presented in ISPOR International, Atlanta May 5-8 2024.