

First Real-World Evidence of Immunotherapy in the Brazilian Public Health System: A Retrospective Study in Melanoma Patients Treated with Pembrolizumab



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Pereira CAD, Gonçalves GM, Serrano SV, Souza LC, Alves AFA, Carvalho CEB, Vazquez VL
Fundação Pio XII - Barretos - SP - Brazil

Barretos Cancer Hospital, São Paulo, Brazil



A Mission to Provide Cancer Care

With over 30 years of history, and international recognition for its excellence in technology and humanized care, the Barretos Cancer Hospital currently serves more than 30000 cancer patients from all regions of Brazil. The Barretos Cancer Hospital has 5,300 qualified employees who work on the mission of providing high-quality cancer diagnosis for patients of the Brazilian Public Health System, supported by Prevention, Teaching and Research Programs.

Objectives

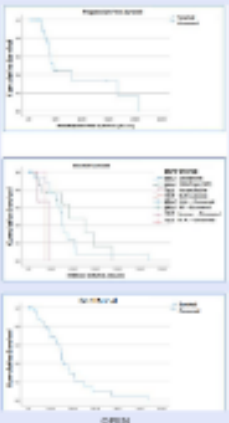
Pembrolizumab is a PD-1 antibody-mediated inhibitor approved for metastatic melanoma (MM) treatment, with previous evidence of increasing patient survival. The use of immunotherapy was not yet a reality in the Brazilian public health system and there is no data on clinical trials regarding the efficacy of pembrolizumab in MM patients. The objective of this retrospective study was to assess the effectiveness of pembrolizumab in MM patients in a Brazilian, oncologic, philanthropic hospital.

Methods

Among 303 patients diagnosed with MM between 2017 and 2020, 42 received at least one course of treatment with pembrolizumab. Demographic and clinical characteristics of patients and treatment outcomes were extracted from the hospital-based registry and analyzed by SPSS 20.0.

Progression-free survival (PFS) and overall survival (OS) were analyzed. Correlations were performed for PFS and OS using gender, age, presence of brain metastases, number of metastatic sites, time of diagnosis, body mass index.

Figures



Progression-free survival

Overall survival

Best supportive care

Results

The baseline profile of patients was: 55.0% were under 60 years of age at diagnosis; 54.8% were males and 45.2% were female; 55.0% of patients received pembrolizumab before first therapy and 45.0% had more than 2 different metastatic sites.

The median OS and PFS of pembrolizumab-treated patients were 14.8 and 3.2 months, respectively. Among patients with BRAF V600E mutant, median OS was 14.3 months vs 16.1 months in BRAF wild-type patients (p=0.647).

The median OS was 11.2 months among male and female treated in female (p=0.028). No statistical difference was detected in five subgroups.

Findings in our study differed in several ways from both pooled data from MM patients in a

Conclusion

This study provides real-world evidence on the effectiveness of pembrolizumab in MM patients in Brazil, confirming the clinical benefits of immunotherapy in the public health system, which is currently the available standard of care treatment for MM despite not being effective in prolonging patient survival.

We acknowledge several limitations that should be

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A MISSION TO PROVIDE CANCER CARE

With over 58 years of history, and international recognition for its excellence in technology and humanized care, the Barretos Cancer Hospital annually serves more than 10.000 cancer patients from all regions of Brazil. The Barretos Cancer hospital has 5,300 qualified employees who work on the mission of promoting health care in cancer diseases for patients of the Brazilian Public Health System, supported by Prevention, Teaching and Research Programs¹.

OBJECTIVES

Pembrolizumab is a PD-1 antibody-mediated inhibitor approved for metastatic melanoma (MM) treatment, with proven evidence of increasing patient survival.

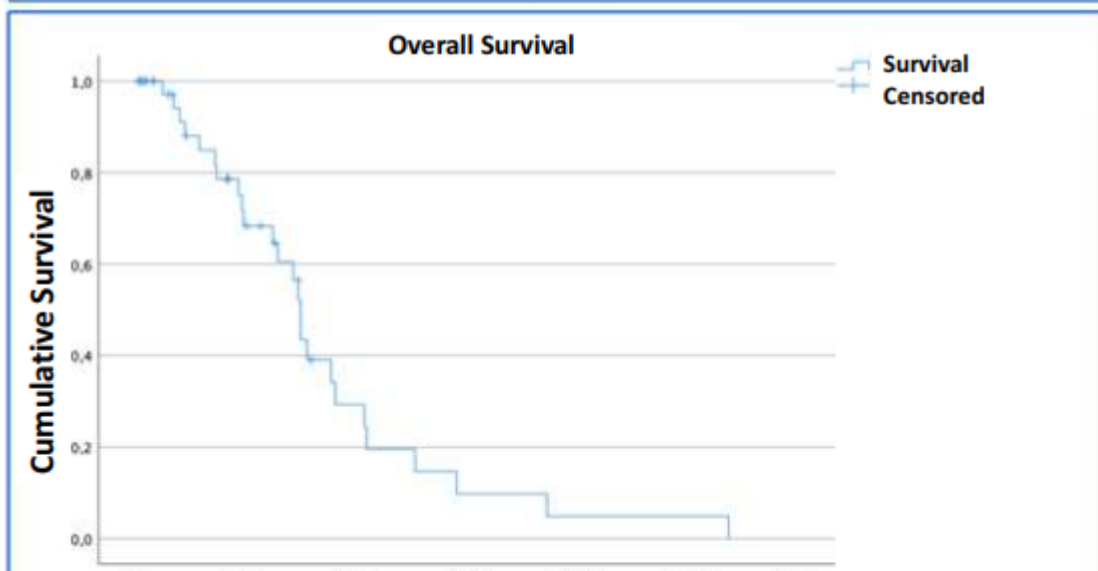
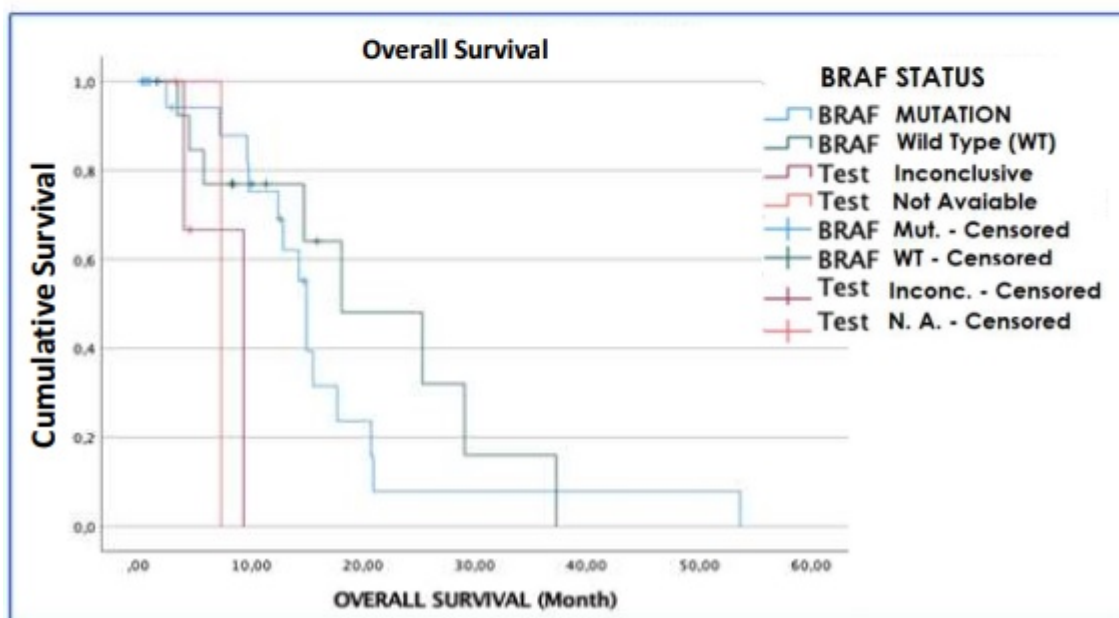
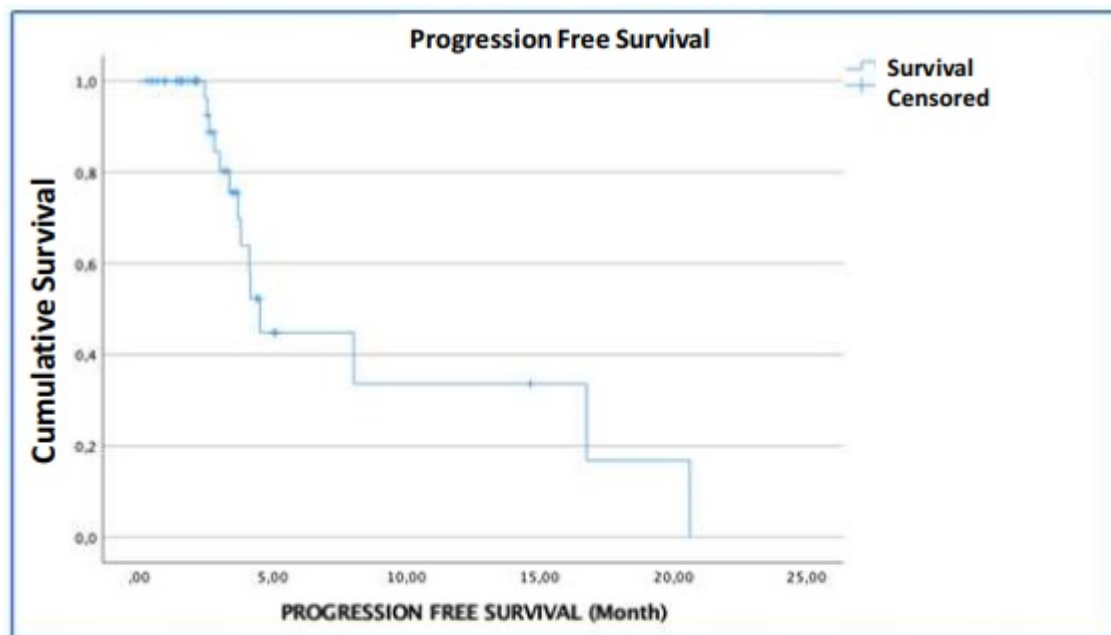
The use of Immunotherapy use is not yet a reality in the Brazilian public health system and there is no data outside clinical trials regarding the efficacy of pembrolizumab in MM patients. The objective of the present study was to assess the effectiveness of pembrolizumab in MM patients in a Brazilian, oncologic, philanthropic hospital.

Methods

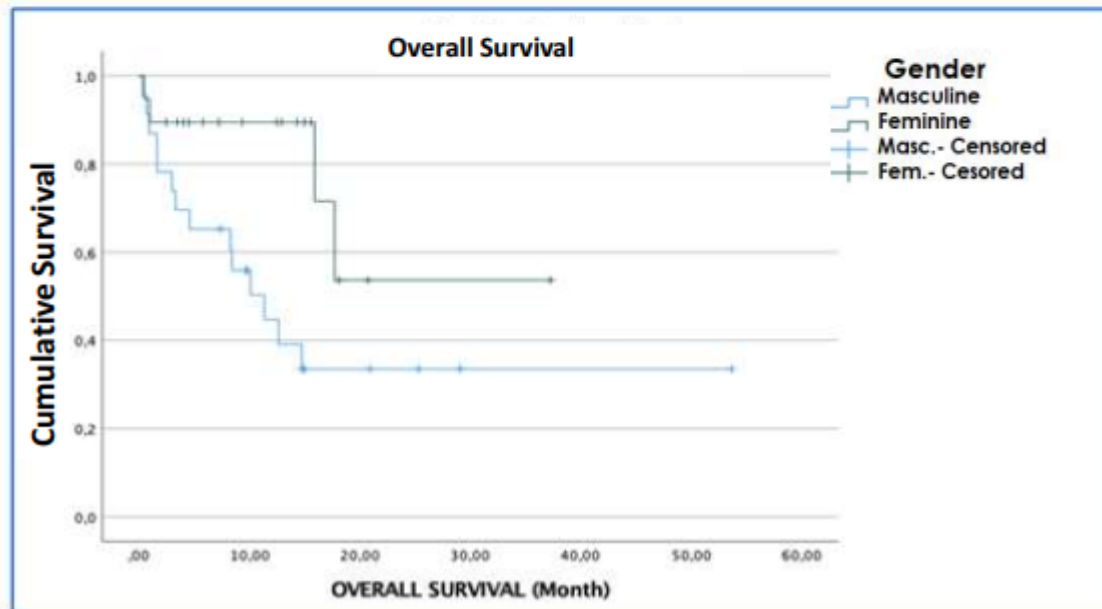
Among 155 patients diagnosed with MM between 2017 and 2020, 42 received at least one course of treatment with pembrolizumab. Demographic and clinical characteristics of patients and treatment outcomes were extracted from the hospital-based registry and analyzed by SPSS 20.0.

Progression free survival (PFS) and overall survival (OS) were analyzed. Cox regression was performed for PFS and OS using gender, age, presence of brain metastases, number of metastatic sites, lines of therapy, body mass index and BRAF status as covariates.

FIGURES



OVERALL SURVIVAL (Month)



RESULTS

The baseline profile of patients was: 59.5% were under 60 years of age at diagnosis; 54.8% were males and 54.8 were BRAF V600E-mutant; 64.3% of patients received pembrolizumab as first line therapy and 42.9% had more than 4 different metastasis sites.

The median OS and PFS of pembrolizumab treated patients were 14.9 and 4.5 months, respectively. Among patients with BRAF V600E-mutant, median OS was 14.9 months vs 18.1 months in BRAF wild-type patients ($p=0.047$).

The median OS was 11.3 months among male and was not reached in female ($p=0.028$). No statistical difference was detected in the other covariates.

Findings in our study differed in several ways from both pooled data from MM patients in a pembrolizumab clinical trial (KEYNOTE-006)² and US real-world experience³. In general, our OS and PFS median were lower. In addition, previous studies show no difference recorded in BRAF mutation status³ or the results favors greater OS for the BRAF V600E - mutant patient.

CONCLUSION

This study provides real-world evidence on the effectiveness of pembrolizumab in MM patients in Brazil, confirming the clinical benefits of immunotherapy in the public health system, in which dacarbazine is currently the available standard of care treatment for MM despite not being effective in prolonging patient survival.

We acknowledge several limitations that should be considered in interpreting our findings justified because we have a smaller sample size and follow up. On the other hand, this study has several strengths, including the use of real-world data of Brazilian public health system. These findings support effectiveness of pembrolizumab in the real-world clinical setting for a heterogeneous MM patient population.

The Barretos Cancer Hospital remains with the mission of diagnosing and treating patients with the best health resource, in a qualified and humanized way.

DISCLOSURES

Participation in clinical trials as investigator or subinvestigator: Roche, Novartis, MSD, Bristol, Abbvie, J&J

Participation as Speaker in medical education events: Roche, Novartis, MSD, Bristol

ABSTRACT

FIRST REAL-WORLD EVIDENCE OF IMMUNOTHERAPY IN THE BRAZILIAN PUBLIC HEALTH SYSTEM: A RETROSPECTIVE STUDY IN MELANOMA PATIENTS TREATED WITH PEMBROLIZUMAB

OBJECTIVES: Pembrolizumab is a PD-1 antibody-mediated inhibitor approved for metastatic melanoma (MM) treatment with proven evidence of increasing patient survival. Immunotherapy use is not yet a reality in the Brazilian public health system and there is no data outside clinical trials regarding the efficacy of pembrolizumab in MM patients. The objective of the present study was to assess the effectiveness of pembrolizumab in MM patients in a Brazilian, oncologic, philanthropic hospital.

METHODS: Among 155 patients diagnosed with MM between 2017 and 2020, 42 received at least one course of treatment with pembrolizumab. Demographic and clinical characteristics of patients and treatment outcomes were extracted from the hospital-based registry and analyzed by SPSS 20.0. Progression-free survival (PFS) and overall survival (OS) were analyzed. Cox regression was performed for PFS and OS using gender, age, presence of brain metastases, number of metastatic sites, lines of therapy, body mass index and BRAF status as covariates.

RESULTS: The baseline profile of patients was: 59.5% were under 60 years of age at diagnosis; 54.8% were males and 54.8% were BRAF V600E-mutant; 64.3% of patients received pembrolizumab as first line therapy and 42.9% had more than 4 different metastasis sites. The median OS and PFS of pembrolizumab-treated patients were 14.9 and 4.5 months, respectively. Among patients with BRAF V600E-mutant, median OS was 14.9 months vs 18.1 months in BRAF wild-type patients ($p=0.047$). The median OS was 11.3 months among male and was not reached in female ($p=0.028$). No statistical difference was detected in the other covariates.

CONCLUSIONS: This study provides the first real-world evidence on the effectiveness of pembrolizumab in MM patients in Brazil, confirming the clinical benefits of immunotherapy in the public health system, in which dacarbazine is currently the available standard of care treatment for MM despite not being effective in prolonging patient survival.

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