

**COMMUNICATION**

# Melanoma outcomes in resource-limited oncology systems: Lessons from Albania in the era of global cancer health disparities

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## Abstract

The rapid introduction of checkpoint inhibitors and BRAF/MEK-targeted therapies has transformed melanoma into one of oncology's most curable malignancies. However, access to these agents remains profoundly unequal across regions. This study evaluates treatment outcomes for patients with non-metastatic melanoma (NMM) in Albania over a decade, highlighting how limited access to innovative treatments constrains survival improvements compared to Western European nations such as France and Germany. A retrospective analysis was conducted of 152 Albanian patients with NMM treated between 2011 and 2021 at the University Hospital Mother Theresa. Demographic, clinical, and therapeutic variables were extracted from medical records. Patients receiving surgery plus adjuvant or systemic therapy were included. Outcomes included overall survival (OS), disease-free survival (DFS), and relapse rates. BRAF mutation was present in 26.3% of patients. All patients underwent surgery; 84.9% received adjuvant systemic therapy. The predominant regimen was interferon-based immunotherapy (48.8%), followed by chemotherapy (23.3%) and targeted therapy (20.2%). No patients received checkpoint inhibitors during the study period, as anti-CTLA-4 and anti-PD-1 therapies were not approved in Albania. Relapse occurred in 57.2% of patients, with a mean relapse time of 1.6 years. Median DFS was 3.1 years and median OS 8.7 years, with a 10-year OS rate of 86.8%. Compared with published European data, Albanian patients experienced shorter DFS (3.1 vs. 5–6 years) and higher relapse rates, consistent with limited access to modern therapies. This study illustrates how systemic inequities in drug access perpetuate survival disparities across Europe. Thus, policies enabling equitable access to innovative cancer treatments are essential to translate scientific progress into population-level benefit.

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**Citation:** Bardhi K, Nina H, Tsimafeyeu I. Melanoma outcomes in resource-limited oncology systems: Lessons from Albania in the era of global cancer health disparities. *Cancer Plus*. 2026;8(2):026070009. doi: 10.36922/CP026070009

**Received:** February 10, 2026

**Revised:** March 8, 2026

**Accepted:** March 24, 2026

**Published online:** May 15, 2026

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**Keywords:** Melanoma; Health disparities; Immunotherapy access; Targeted therapy; Albania; Oncology policy

## 1. Introduction

The last decade has witnessed an extraordinary transformation in melanoma management.<sup>1</sup> Once considered nearly uniformly fatal in advanced stages, the introduction of immune checkpoint inhibitors and BRAF/MEK-targeted therapies has yielded five-year survival rates exceeding 70% for resected stage III and IV disease in high-income settings.<sup>2</sup> These advances have turned melanoma into a model of precision oncology and immunologic cure.

However, the benefits of these innovations are unevenly distributed. Access to checkpoint inhibitors (anti-CTLA-4, anti-PD-1)<sup>3,4</sup> and targeted combinations remains limited in several lower- and middle-income European countries. This gap in drug availability, reimbursement, and clinical infrastructure contributes to persistent survival disparities across the continent.

Albania provides a unique case study. Despite being geographically close to Western Europe, it continues to face systemic barriers to integrating new therapies due to economic constraints and delayed regulatory adoption. While melanoma incidence remains relatively low, outcomes lag significantly behind those in countries like France and Germany, where national health systems provide universal access to modern adjuvant and metastatic regimens.

The present study evaluates the real-world outcomes of Albanian patients with non-metastatic melanoma treated between 2011 and 2021—an era characterized by global innovation but local limitation. By comparing these results with international benchmarks, this study aims to demonstrate how restricted therapeutic access translates into measurable survival inequities, aligning with the mission of the science of cancer health disparities to bridge the gap between scientific progress and real-world benefit.

## 2. Methods

### 2.1. Study design and population

A retrospective multicenter cohort analysis was performed including patients diagnosed with non-metastatic melanoma (NMM) across Albanian regions from January 2011 to December 2021. Data were collected at the Oncologic Service of the University Hospital Mother Theresa in Tirana. Eligible patients were  $\geq 18$  years old, had histologically confirmed stage II–III melanoma, and received multimodal therapy including surgery and systemic adjuvant or post-progression treatment.

Patients treated exclusively with surgery or those with metastatic disease at diagnosis were excluded.

### 2.2. Data collection and variables

Clinical variables included sex, age, melanoma subtype, stage, and *BRAF* mutation status. Treatment modalities, including surgery, immunotherapy, chemotherapy, targeted therapy, and radiotherapy, were recorded. Outcomes assessed were overall survival (OS), disease-free survival (DFS), and time to relapse.

### 2.3. Statistical analysis

Descriptive statistics were used for demographic and

treatment data. Survival outcomes were estimated by Kaplan–Meier analysis using STATA 13.0 (StataCorp LP, Texas, USA). Differences between subgroups were evaluated with log-rank and chi-square tests. Comparative benchmarks were derived from published registries and national melanoma datasets from France (Institut National du Cancer, 2021) and Germany (Robert Koch Institute, 2020).

## 3. Results

### 3.1. Patient demographics

A total of 152 patients were included in this analysis (Table 1). The cohort comprised 86 males (56.6%) and 66 females (43.4%). The mean diagnostic age was  $54.7 \pm 12.9$  years (mean  $\pm$  SD), with 55.9% aged  $\geq 61$  years. Most patients (69.7%) presented with stage III disease, while 30.3% were diagnosed at stage II. *BRAF* mutations were identified in 26.3% of patients ( $n = 41$ ).

### 3.2. Treatment patterns

All patients underwent complete surgical excision. Systemic therapy was administered in 129 patients (84.9%) post-surgery and in 23 patients (15.1%) after disease progression (Table 2). No patients received checkpoint inhibitors, as anti-CTLA-4 and anti-PD-1 agents were unavailable in Albania.

Interferon-based immunotherapy (48.8%) was the most common adjuvant approach, followed by chemotherapy (23.3%) and targeted therapy (20.2%). Combined regimens were rare (7.6%), reflecting drug unavailability and cost barriers. Targeted therapy was typically limited to single-agent *BRAF* inhibition, without MEK co-administration.

### 3.3. Outcomes

At a median follow-up of 10.5 years, median OS was 8.7 years (95% CI: 8.27–9.27). The 10-year OS rate was 86.8%. Figure 1 illustrates OS among patients with stage II and III melanoma. Median DFS across the cohort was 3.1 years (95% CI: 2.64–3.76). Disease relapse occurred in 87 patients (57.2%), of which most encountered relapse within two years of surgery (mean  $1.6 \pm 2.1$  years).

Patients receiving targeted therapy had longer DFS compared with those treated with chemotherapy (median 3.1 vs. 2.7 years,  $p = 0.04$ ). *BRAF*-positive patients relapsed earlier (1.09 vs. 1.78 years,  $p = 0.03$ ), reflecting incomplete access to dual *BRAF*/MEK inhibition.

## 4. Discussion

This study provides a decade-long real-world snapshot

**Table 1. Sociodemographic and clinical characteristics of patients**

<b>Total number of patients, <i>n</i> (%)</b>	<b>152 (100)</b>
Sex, <i>n</i> (%)	
Female	66 (43.4)
Male	86 (56.6)
Age (years), median	
All patients	59.5
Female	57.2
Male	61.3
Age at diagnosis (years), median	
Female	52.7
Male	56.2
Stage, <i>n</i> (%)	
II	46 (30.26%)
III	106 (69.74%)
T, <i>n</i> (%)	
Tx	9 (5.92%)
T1	2 (1.32%)
T2	8 (5.26%)
T3	55 (36.18%)
T4	78 (51.32%)
N, <i>n</i> (%)	
Nx	14 (9.2%)
N0	48 (31.58%)
N1	39 (25.66%)
N2	21 (13.82%)
N3	30 (19.74%)

of melanoma outcomes in Albania—an oncology system navigating the intersection of scientific progress and limited access. While survival in early melanoma depends primarily on surgical adequacy, durable remission in high-risk stage II–III disease increasingly requires adjuvant immunotherapy or targeted therapy. Albania's lack of approved checkpoint inhibitors during the study period thus constrained the potential for outcome improvement.

#### 4.1. The innovation access gap

Between 2011 and 2021, melanoma management

underwent a global revolution. The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) approvals of ipilimumab (2011), pembrolizumab (2014), nivolumab (2014), and dabrafenib/trametinib (2013) redefined standards of care. France and Germany incorporated these regimens into national formularies within one year of approval. By contrast, Albania approved pembrolizumab only in 2021 and continues to face a lack of routine reimbursement for dual BRAF/MEK therapy. Table 3 summarizes this temporal access lag.

Benchmarking against European data highlights the treatment gap. In France, adjuvant pembrolizumab and nivolumab achieved three-year recurrence-free survival (RFS) rates of 71–75% in stage III melanoma (KEYNOTE-054, CheckMate-238). German registry data report a median DFS of 5.8 years and 10-year OS exceeding 90% for comparable populations.

By contrast, Albanian DFS (3.1 years) and relapse rate (57%) remain comparable to pre-immunotherapy-era outcomes in Western countries (circa 2005; see ref.<sup>5</sup>). These results demonstrate how access barriers translate directly into delayed survival progress.

The implications are profound: in systems without timely access to these innovations, survival stagnates even when clinical expertise and surgical standards are high.

#### 4.2. Real-world consequences

The Albanian 10-year OS rate (86.8%) superficially resembles outcomes from European registries; however, this apparent parity reflects the predominance of stage II–III cases without accounting for relapse dynamics. The 57% relapse rate and median DFS of 3.1 years signal early disease recurrence due to inadequate adjuvant protection. By comparison, relapse occurs in fewer than 30% of similar patients in France or Germany.

Chemotherapy and interferon, the backbone of Albanian adjuvant therapy, have long been shown to yield modest benefits and significant toxicity. In landmark trials, interferon prolonged DFS by only 0.8 years versus observation, while adjuvant nivolumab reduced relapse risk by 35% compared to ipilimumab. These efficacy gaps manifest as tangible survival disparities when innovation diffusion is delayed.

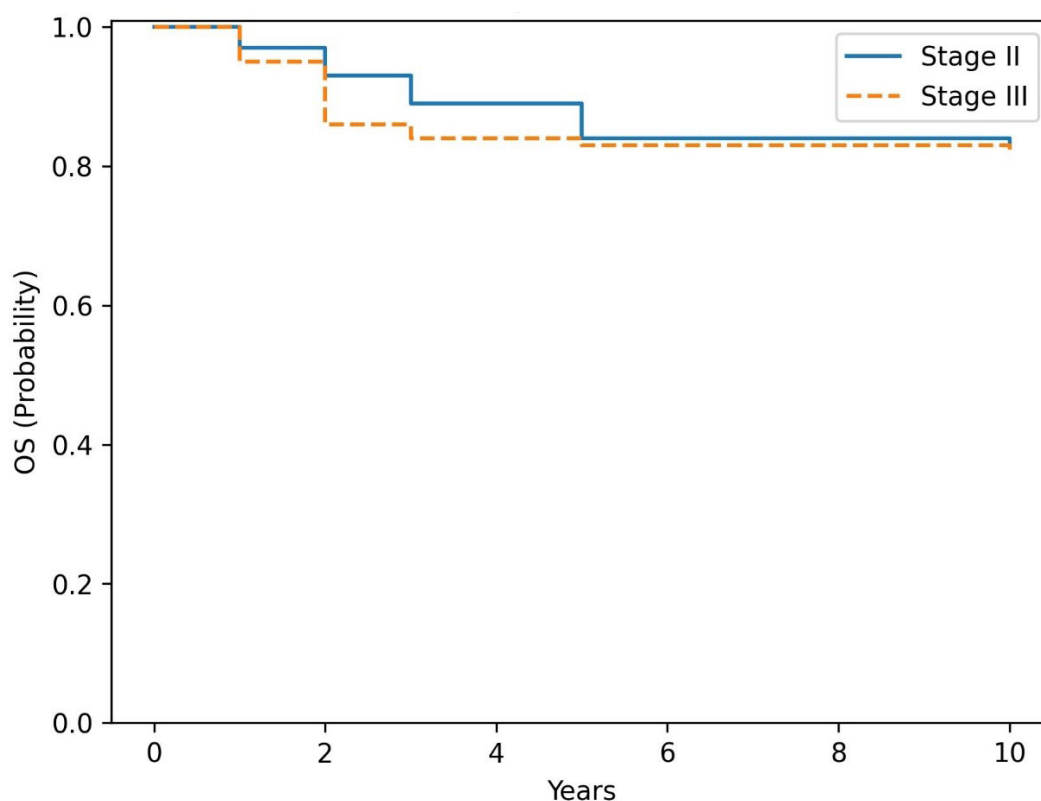
#### 4.3. Systemic barriers beyond drugs

The limitations extend beyond pharmacologic access. Albania lacks a comprehensive national cancer registry and a structured referral network for molecular testing. Only 27% of patients in this cohort were tested for BRAF status, compared to >90% in France and Germany. Centralized

**Table 2. Distribution of patients receiving different types of systemic therapy**

	No. of patients receiving systematic therapy as adjuvant treatment, <i>n</i> (%)	No. of patients receiving systematic therapy after disease progression, <i>n</i> (%)
Systemic therapy	129 (84.9)	23 (15.1)
Immunotherapy (IFN-based)	63 (48.8)	8 (34.8)
Chemotherapy	30 (23.3)	86 (56.6)
Targeted therapy	26 (20.2)	4 (17.4)
Combined therapy	10 (7.6)	-

Abbreviation: IFN: Interferon.

**Figure 1.** Overall survival of stage-stratified patients in a decade**Table 3. Timeline of regulatory approval and clinical availability of key melanoma therapies in Europe and Albania (2011–2023)**

Therapy	Year of approval by EMA	Implementation by France/Germany	Albania implementation
Ipilimumab (CTLA-4)	2011	2012	Not available
Pembrolizumab (PD-1)	2014	2015	2021
Dabrafenib/Trametinib	2013	2014	Partial, private sector only
Nivolumab	2015	2016	Not reimbursed
Relatlimab/Nivolumab combo	2022	2023	Not available

Abbreviation: EMA: European Medicines Agency.

drug procurement further delays adoption of EMA-approved medicines. These systemic challenges illustrate how disparities in infrastructure amplify the effects of economic inequity.

#### 4.4. Policy lessons from France and Germany

France and Germany provide contrasting examples of equitable oncology governance. Both countries integrated melanoma immunotherapies through early health technology assessments, expanded molecular diagnostics, and national reimbursement schemes. French regional cancer networks (INCa) ensure uniform access to innovations regardless of geography, while Germany's statutory health insurance mandates coverage for all EMA-approved therapies within three months of authorization.<sup>6,7</sup> These policies transformed melanoma from a fatal disease into a manageable chronic disease within five years—an outcome that has yet to be realized in Albania.

#### 4.5. Implications for cancer health disparities research

This analysis exemplifies a broader principle: innovation without equity perpetuates disparities. The science of cancer health disparities must expand beyond ethnicity and socioeconomic status to encompass innovation access—the right of all patients to benefit from scientific progress. Albania's experience underscores that geographic inequality within Europe can mirror global North–South divides. As next-generation agents emerge, equitable adoption mechanisms will determine whether progress translates into population-level benefit or remains confined to affluent systems.

### 5. Conclusion

The experience of melanoma care in Albania offers a striking example of how the benefits of scientific progress can remain out of reach when innovation is not matched by equitable access. Over the last decade, oncology has entered a new era in which advanced immunotherapies and molecularly targeted combinations have transformed melanoma from a highly lethal disease into one with durable remission and long-term survival for many patients.<sup>8,9</sup> Yet, as this study demonstrates, those breakthroughs have not reached all populations equally.

Despite commendable local expertise and consistent surgical management, Albanian patients with non-metastatic melanoma continue to face significantly shorter disease-free intervals and higher relapse rates compared with their counterparts in Western Europe. These differences are not the result of biology or clinical practice alone but are largely shaped by systemic inequities in the availability and reimbursement of novel therapies. The

absence of immune checkpoint inhibitors and combined BRAF/MEK inhibitors during the study period created a treatment gap that modern clinical knowledge could not bridge.

In France and Germany, early national adoption of pembrolizumab, nivolumab, and targeted therapy combinations has redefined the standard of care, reducing recurrence risk by nearly half and substantially extending survival. In contrast, Albanian clinicians have had to rely on interferon and chemotherapy—agents once considered cutting-edge but now regarded as obsolete. This stark difference underscores how innovation without accessibility perpetuates health disparities, even within the same continent. Unfortunately, the situation has not changed substantially since then and the aim of this article is to highlight this persistent challenge and draw attention to the need for improved access to modern therapies.

Closing this divide requires more than new drugs; it calls for policy reform, international collaboration, and infrastructure development. Fast-track regulatory pathways, inclusion in European procurement mechanisms, and investment in diagnostic capacity would allow smaller nations to integrate evidence-based treatments more rapidly. In parallel, national cancer registries and public funding for molecular testing are essential to ensure equitable implementation of precision medicine.

Ultimately, the Albanian experience reminds us that the progress of oncology must be measured not only by scientific discovery but by its reach. Until every patient, regardless of geography or national income, can benefit from the same therapeutic advances, the promise of modern melanoma treatment remains incomplete. True success will come when scientific innovation and social equity advance hand in hand, transforming disparities into shared progress across all health systems.

### Acknowledgments

The authors acknowledge the contributions of clinical staff at the University Hospital Mother Theresa and thank the Bureau for Cancer Research (BUCARE) for methodological support.

### Funding

None.

### Conflict of interest

The authors declare that they have no competing interests.

### Author contributions

*Conceptualization:* Katerina Bardhi, Helidon Nina

*Data curation:* Katerina Bardhi, Helidon Nina

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## Ethics approval and consent to participate

This retrospective study involving human participants was approved by the Mother Theresa University Hospital, Tirana, Albania (No. 01012011). The study used de-identified clinical data collected as part of routine care; therefore, the requirement for written informed consent was waived by the ethics committee in accordance with institutional policies and the Declaration of Helsinki.

## Consent for publication

Not applicable.

## Availability of data

Data are not publicly available due to local privacy regulations.

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