

**Incidence, mortality and medical costs of patients hospitalized
with melanoma in Spain: a retrospective multicentre
observational study**

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Abstract

Objective: This study aimed to update and analyze the in-hospital incidence and in-hospital mortality of melanoma in Spain, to evaluate any temporal trends in both measures and to quantify the direct medical costs of specialized care that are associated to this malignancy.

Methods: Anonymized specialized care admission records registered between 1 Jan 2011 and 31 Dec 2017 were extracted from a Spanish nationwide hospital discharge database.

Results: Records included corresponded to 16,657 patients, of which 50.62% were male. In nearly 38% of all admissions secondary malignant tumors were registered, principally tumors in the lymph nodes. In-hospital incidence of melanoma was 67.5 and 58.2 per 100,000 males and females, respectively, in the study period (2011-2017), with a decreasing tendency measured after the year 2014. Mortality increased with patients' age and over time in patients over 75 years of age. In-hospital mortality was 7.73% for males and 5.29% for female patients, and was principally associated to metastatic tumors, principally in the lungs, liver and brain. Mean length of hospital stay was 4.36 days, with a readmission rate of 6.93% and a 15.70% of urgent admissions. The mean annual direct medical cost per patient was €4,175, increasing between 2014 and 2017.

Conclusions: The increasing in-hospital incidence of melanoma appeared to reverse in 2014, as did the increasing mortality rate measured in older males. The shift in melanoma in-hospital incidence could respond to the increasing trend to treat patients in primary care settings. Further studies will be required to confirm these trends in order to adapt the healthcare system.

Keywords: Melanoma; Skin Neoplasms; Incidence; Mortality; Spain.

Short title: Incidence, mortality and medical costs of melanoma in Spain

Word count: 4246

Introduction

In the European population, the annual incidence of melanoma varies from 3 to 35 per 100,000 persons south to north of the continent [1]. Spain has one of the lowest melanoma incidence and mortality rates in Europe; however, data suggests an increase in both rates during the past decade [2,3]. The Spanish Society of Medical Oncology estimated a 5-year prevalence of melanoma of 1.8% in males and 3.0% in females in 2018 [4]. In the Spanish region of Catalonia, the incidence of cutaneous malignant melanoma was projected to increase between 2015 and 2019, up to 11 per 100,000 males and 23 per 100,000 females [5]. On the contrary, mortality appeared to be stabilizing in the same period [5].

Upon diagnosis, melanoma is staged according to the histopathological features of the tumor and other characteristics, as thickness and presence or absence of ulceration [6]. In many cases, this first classification is followed by the biopsy of the lymph nodes to evaluate the presence of secondary melanoma cells (sentinel lymph node biopsy) [6,7]. Previous evaluations indicate the need to promote early detection in order to reduce mortality, as well as the early detection of secondary tumors [1].

The evaluation of updated incidence and mortality data in hospital settings, obtained from patient records, has been proven useful to assist healthcare and resource allocation decisions [8,9]. In addition, few data are available on the costs of melanoma from the healthcare system perspective in Spain. Previous evaluations in Europe suggest a direct cost per patient that may range between the €923 estimated in Sweden and the €9,829 calculated in Denmark [10].

The objective of this study was to update and analyze the in-hospital incidence and mortality of melanoma in Spain, to evaluate any temporal trends in both measures and to quantify the medical costs of specialized care associated to this malignancy.

Methods

Study design and setting

A retrospective multicentre observational study was set to review admission files from specialized care facilities in which malignant melanoma was registered as the admission motive between 1 Jan 2011 and 31 Dec 2017. Records of hospital admissions (inpatient and outpatient) were obtained from the Spanish discharge database for Hospitalization and Specialized Care, which covers around 90% of hospitals in the country, via the Spanish Ministry of Health [11]. Additionally, complementary data was obtained to extend in-hospital incidence and mortality analyses back to the year 1999.

Data extraction

Within the database, specialized care records are codified with the International Classification of Diseases, ninth and tenth Revision, Clinical Modification codes (ICD-9-CM and ICD-10-CM). Thus, the ICD-9-CM codes corresponding to melanoma were used to claim files up to 2015 and ICD-10-CM codes identified files after 2016 (Table 1).

In-hospital incidence and mortality were calculated from data obtained via the Unit of Health Care Information and Statistics in the Spanish Ministry for the period 1999-2017 [12].

Admission data did not contain any parameters identifying healthcare centres and medical history, which are re-coded within the database maintaining records anonymised, in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki. This research did not involve human participants and there was no access to identifying information.

Study variables

Admission files contain raw data registered on admission, including patients' sex and age, hospital location (Spanish region), date of admission, type of admission, date of discharge, type of discharge (including death), service that discharged the patient, length of stay, readmission rate, admission motive, secondary diagnoses registered during the admission, medical procedures performed and cost of the admission.

Data analysis

Single-patient data for the characterization of the population was extracted based on the first admission per patient. In-hospital incidence was calculated as the annual number of cases of melanoma in Spanish hospitals within the total population. In-hospital mortality was calculated as the annual percentage of deaths registered per number of patients admitted. Direct medical costs were calculated based on the standardized average expenses of admissions and medical procedures determined by the Spanish Ministry of Health, indicated in the database. Medical costs included all expenses related to specialized care admissions: examination, medication, surgery, diet, personnel, medical equipment and resources corrected per groups of patients. All costs were adjusted for inflation to 2017 values.

Frequencies and percentages are presented for dichotomous variables and mean and standard deviation or data range were calculated for quantitative variables. Normality was tested with the Kolmogorov-Smirnov test. Patients were divided in 4 age groups excluding those under 20 years of age due to the small number of individuals. To assess the association of secondary conditions with in-hospital mortality, odd ratios (OR) with 95% confidence interval (CI) were used, with the group of patients non-deceased during the hospitalization as the reference group. A Cochran-Armitage trend test was performed to assess temporal trends in the incidence, mortality and length of stay. Two-tailed T-student or one-way analysis of variance were used as appropriate to compare mean length of stay and cost between patient groups. In all cases, a $p < 0.05$ considered statistically significant. Data presentation is mainly descriptive. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 20.0. Released 2011 (IBM Corporation, Armonk, NY, USA) and Microsoft Excel© Professional Plus 2010 (Microsoft Corporation, Redmond, WA, USA).

Results

Patient characteristics

The files extracted from the specialized care database corresponded to 14,464 patients diagnosed with a melanoma between 2011 and 2017 (Table 2). The percentage of male and female patients varied with tumor location; the majority of patients with a tumor of the scalp or neck or tumor of ear/external auricular canal were males, whereas most of the patients with a melanoma of a lower limb were females.

Secondary diagnoses registered during the admission, included in specialized care admission records, were used to evaluate disease comorbidity. In 37.94% of admissions of patients with melanoma, secondary malignant tumors were registered, principally in the lymph nodes (Table 3). Other chronic conditions as hypertension (26.82%), hypercholesterolemia (15.36%) and diabetes (11.62%) were registered frequently in this patient population.

Incidence and mortality

The in-hospital incidence of melanoma over the period of study (2011-2017) was 67.5 and 58.2 per 100,000 males and females, respectively. When considering a wider time period, a slow increasing tendency was observed in the incidence of melanoma in males between 1999 and 2014 ($p < 0.001$), slightly decreasing after 2014 ($p = 0.038$) (Figure 1A). For females, in-hospital incidence appeared stable over the same time period ($p = 0.056$).

In-hospital mortality rate increased with patients' age in both males and females, reaching the 10.60 per 100,000 persons over 75 years of age ($p < 0.001$) (Figure 2). Overall, mortality remained stable over time ($p = 0.996$) only increasing in males over 75 years of age ($p < 0.001$) (Figure 2A). No fluctuations were measured in the in-hospital mortality rate evaluated within the database (2011-2017), which was 7.73% for males and 5.29% for female patients.

The factors associated with in-hospital mortality were evaluated by analyzing the disease comorbidities found in patients with melanoma and deceased during the hospitalization. Secondary malignant neoplasms were more frequent in this group (OR=18.54; 95%CI 15.46-22.14), diagnosed in more than 100% of admissions on average, considering that

the same patient could be diagnosed with more than one tumor. In 43.61% of admissions lung tumors were detected, 32.84% registered hepatic tumors, 32.03% tumors in the brain and spinal cord, 31.76% in the lymph nodes and 21.53% tumors of the bone and bone marrow. Heart disease, acute respiratory failure, nephritis and nephrotic syndrome and anemia were also more frequent in this patient group, diagnosed in 16.96% (OR=2.29; 95%CI 1.84-2.85), 14.13% (OR=75.01; 95%CI 48.14-116.86), 13.73% (OR=6.98; 95%CI 5.43-8.97) and 12.38% (OR=6.28; 95%CI 4.86-8.12) of admissions, respectively. The deceased patients had a mean age of 65.97 (16.56) years.

Use of healthcare resources and medical costs

Mean length of hospital stay was of 4.36 days over the study period, with a readmission rate of the 6.93%. The percentage of urgent admissions, mean length of hospital stay and readmission rate in specialized care varied with the tumor nature and location (Table 4). All three variables showed the highest values in melanomas with no specified site.

The analysis stratified per year showed a LOHS that significantly declined over time (2011 vs. 2017, $p < 0.001$) (Figure 3A). LOHS appeared associated with patients' age, with statistical significance in this variable when comparing patients under 44 years of age and those over 75 years ($p = 0.001$).

Up to 66.83% of admissions of patients with melanoma were registered in surgery services. Patients with melanoma were also registered in dermatology and oncology services in 15.34% and 6.53% of admissions, respectively.

In addition, the most common medical procedures were analyzed. Interestingly, 54.11% of hospital admissions in patients with melanoma were related to the excision of lymph

nodes, and the radical excision of skin lesions was registered in 51.42% of admissions (Table 5).

This use of resources and medical needs corresponded to a mean annual direct medical cost per patient of €4,175 for patients with melanoma over the study period; cost per admission ranged from €1,302 to €116,052 between 2011 and 2017. Annual costs per patient decreased between 2011 and 2014 and increased again from 2014 to 2017.

Annual costs were higher in patients over 75 years of age vs. those under 44 ($p=0.003$). Additionally, the presence of metastatic tumors increased the mean LOHS to 7.89 days ($p<0.001$) and the mean admission cost to €5,486 ($p<0.001$). These variables increased to 6.23 days and €4,809 in patients with heart disease, 10.30 days and €5,837 in patients with anemia, 7.16 days and €6,132 in patients with nephritis and nephrotic syndrome and 10.74 days and €7,546 in patients with acute respiratory failure. The database registered an average of 1,100 patients attended per year, representing a total annual direct medical cost of specialized care of €9,934,321.

Discussion

The incidence of melanoma in Spain is one of the lowest in the European Union; however, previous evaluations described a changing situation, with an incidence that appeared to be rapidly increasing [5,13]. This study aimed to update in-hospital incidence and mortality trends in the country and to analyze disease demographics and medical costs taking into account patient characteristics and care needs.

Comparably to previous evaluations, the in-hospital incidence of melanoma in males as registered in this database showed an increase between 1999 and 2014, however, it

appeared to decrease after 2014. For females, incidence was stable over the study period. Both incidence and mortality rates showed a remarkable cohort effect. Interestingly, the incidence of malignant neoplasms of skin increased from 95 to 169 per 10,000 persons in primary care centers between 2011 and 2017, according to data from the Spanish Ministry of Health, which could be interpreted as an increase in the portion of patients treated in primary care centers versus specialized care [14]. The major in-hospital incidence rates were found in the age group of 45 to 64 years, whereas in-hospital mortality was the highest in the group over 75 years of age. Recent evaluations suggested a decrease in mortality in this last group, yet, in this study such decrease appears associated to mortality in men between 65 and 74 years [15,16]. In-hospital mortality was more elevated in males than in females, especially in patients over 65 years of age, which could be indicative of a better prognosis of the disease in women, as previously described in Spain [17].

The 16,657 patients depicted in this study, with a mean age of 61.41 years, registered frequent diagnoses of hypertension, hypercholesterolemia and diabetes, which seemingly derive from their old age. According to the data from the Spanish Ministry of Health, 19.8% of the Spanish population suffered from hypertension in 2017, 17.9% had hypercholesterolemia and 7.8% diabetes, while these percentages were 29.82%, 30.77% and 11.77% in the population between 55 and 64 years of age the same year [12]. In addition, the fact that the selected patients were attended in specialized care centers could be associated with a more severe condition.

Overall, in 37.94% of hospital admissions a secondary tumor was registered; in 13.94% of the cases this was a tumor of the lymph nodes. Secondary tumors were the principal factor associated with in-hospital mortality. In this case, patients presented lung, liver and brain tumors.

Data indicates that most secondary melanomas occur within the first two years after the first diagnosis of a melanoma, indicating the usefulness of life-long, regular dermatologic and oncologic examinations [18]. Current diagnostic protocols include dermoscopy, imaging techniques and biopsy, and the evaluation of lymph node involvement is one of the first steps to determine prognosis and therapeutic strategies [1,19]. Diagnostic procedures were not registered in great frequencies in this population, seemingly due to the large variability in the nature and location of the tests. The excision of lymph nodes was registered in 54.11% of admissions in this patient population. Overall, the radical and local excision of skin lesions were the predominant procedures in hospital settings.

These care needs were associated to a mean annual direct medical cost of specialized care of €4,175 per patient over the study period. This cost would be within the cost range obtained for other European regions [10]. Disease stage and tumor characteristics have been previously associated to cost increases, but this connection cannot be assessed in this database [20]. Herein, costs were directly associated with patients' age, with the highest costs per patient found in those over the 75 years of age, seemingly due to the prevalence of comorbid diseases in this group.

Over the study period, annual direct medical costs per patient displayed a decreasing tendency between 2011 and 2014, reversed between 2014 and 2017. The decrease

registered between 2011 and 2014 coincides with the economic crisis in Spain, when healthcare costs were considerably reduced [12].

On the other hand, a previous cost evaluation in Spain using unit costs estimated a cost of the first phase of the diagnostic process of around €1,180; the cost of the subsequent diagnostic and therapeutic process was of €6,977 without lymph node involvement, and could reach the €131,638 in patients with distant metastasis [21]. Similarly, mean hospitalization costs were €6634, €6950 and €3449 in France, Germany and the UK, respectively [22]. In addition to these evaluations, further studies should take into account indirect costs to estimate the total burden of melanoma, which ranged between the €129 to the €4,441 in France and Germany, respectively [22].

A number of limitations may have influenced the results of this study. The codification system used in the database impeded the differentiation between melanoma stages. The analysis of disease incidence and mortality is limited to hospital settings. Finally, patient characteristics respond to the group of hospitalized patients and cannot be extrapolated to the entire population. In addition, indirect medical costs and non-medical costs should be taken into account in further evaluations.

Conclusions

The in-hospital incidence of melanoma as registered in this discharge database displayed a decreasing tendency after the year 2014, this decrease could respond to an increasing tendency to treat patients in primary care settings. Mortality was overall stable, only increasing in older males, a tendency that was too reversed after 2014. Further studies will be required to confirm these trends in order to adapt the healthcare system. Early

detection of tumors, especially secondary tumors, should decrease hospitalization times and mortality, reducing, in turn, medical costs.

Transparency section

Declaration of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of financial and other interest

The authors declare that they have no competing interests.

Data availability statement

Data sharing is restricted due to legal stipulations, yet the data that support the findings of this study is fully available from the Spanish Ministry of Health via the Unit of Health Care Information and Statistics (Spanish Institute of Health Information) for researchers who meet the criteria for access to confidential data at:

<https://www.mscbs.gob.es/estadEstudios/sanidadDatos/home.htm>

Author contributions

JD contributed to the investigation by analyzing and interpreting the burden associated to melanoma and other skin neoplasms in Spain and was a major contribution in the intellectual content revision. AM analyzed the current situation of melanoma and skin neoplasms in Spain, interpreted the statistical data and was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1 International Classification of Diseases, Clinical Modification (ICD-CM) codes used for data extraction.

Neoplasm nature and location	ICD-9-CM	ICD-10-CM
Malignant melanoma	-	-
Lip	172.0	C43.0
Eyelid, including canthus	172.1	C43.10, C43.11, C43.12
Ear and external auricular canal	172.2	C43.20, C43.21, C43.22
Nose or unspecified part of face	172.3	C43.30, C43.31, C43.39
Scalp and neck	172.4	C43.4
Other part of trunk	172.5	C43.51, C43.52, C43.59
Upper limb, including shoulder	172.6	C43.60, C43.61, C43.62
Lower limb, including hip	172.7	C43.70, C43.71, C43.72
Other and unspecified sites of skin	172.8, 172.9	C43.8, C43.9

Table 2 Characteristics of the patients included in the study.

Neoplasm nature and location	Admissions, N	Patients, N	Males, %	Age, years (SD)
Malignant melanoma	16,657	14,464	50.62	61.41 (16.59)
Lip	56	47	65.96	66.04 (14.11)
Eyelid, including canthus	181	157	43.95	70.92 (14.25)
Ear and external auricular canal	362	328	67.68	62.32 (17.10)
Nose or unspecified part of face	1,480	1,274	48.67	70.47 (15.43)
Scalp and neck	1,054	902	67.52	62.16 (17.90)
Other part of trunk	4,941	4,400	61.02	57.10 (15.59)
Upper limb, including shoulder	2,360	2,135	43.84	60.37 (15.89)
Lower limb, including hip	4,479	3,860	34.69	62.85 (16.74)
Other and unspecified sites of skin	1,744	1,361	59.52	62.45 (16.00)

Table 3 Comorbidities registered in more than 1% of admission of patients with melanoma.

Secondary diagnoses	Admissions, %
Secondary malignant neoplasm	37.94
Lymph nodes	13.95
Lung	5.39
Liver	3.94
Brain and spinal cord	3.67
Bone and bone marrow	2.67
Unspecified essential hypertension	26.82
Hypercholesterolemia and hyperlipidemia	15.36
Diabetes	11.62
Heart disease	8.30
Tobacco use disorder	5.67
Depressive disorders and anxiety	3.85
Thyroid gland disorders	3.82
Chronic obstructive pulmonary disease	3.66
Overweight and obesity	3.20
Benign localized hyperplasia of prostate	3.25
Nephritis and nephrotic syndrome	3.01
Anemia	2.78
Osteoarthritis	2.54
Enlargement of lymph nodes	1.76
Liver disorders	1.69
Bacterial infection	1.24
Hypertensive chronic kidney disease	1.16
Acute respiratory failure	1.07

Table 4 Nature of specialized care admissions in patients with melanoma

Neoplasm nature and location	Urgent admissions, %	Mean LOHS, days	Readmission rate, %
Malignant melanoma	15.70	4.36	6.93
Lip	19.64	4.93	11.36
Eyelid, including canthus	10.50	3.78	9.77
Ear and external auricular canal	9.67	3.22	5.26
Nose or unspecified part of face	12.09	4.01	8.17
Scalp and neck	13.47	3.76	6.93
Other part of trunk	9.51	3.52	5.52
Upper limb, including shoulder	9.36	3.06	4.94
Lower limb, including hip	11.10	5.22	6.70
Other and unspecified sites of skin	59.69	7.18	12.88

Table 5 Medical procedures registered in more than 1% of hospital admissions of patients with malignant melanoma.

Medical procedures	Admissions, %
Excision of lymph node	54.11
Radical excision of skin lesion	51.42
Other local excision or destruction of lesion or tissue of skin and subcutaneous tissue	21.58
Attachment of pedicle or flap graft	21.12
Biopsies	17.90
Injection or infusion of other therapeutic or prophylactic substance	17.57
Computerized axial tomography	14.40
Scan of lymphatic system	14.30
Diagnostic ultrasound	2.43
Electrocardiogram	2.01
Magnetic resonance imaging	1.48
Injection or instillation of radioisotopes	1.44

Figures

Figure 1 In-hospital incidence of melanoma 100,000 persons in males (A) and females (B) in Spain stratified by age (1999- 2017).

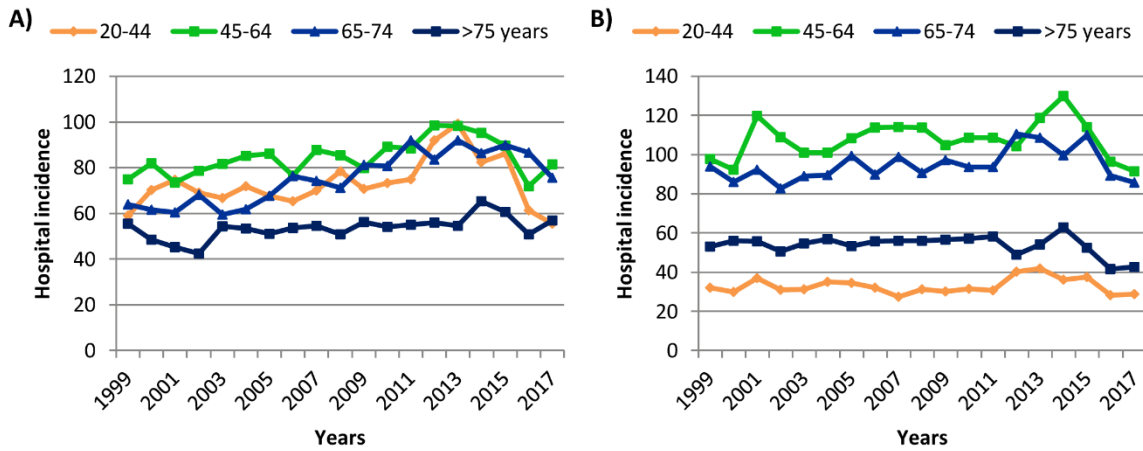


Figure 2 In-hospital mortality rate of melanoma per 100,000 persons in males (A) and females (B) stratified by age (1999-2017).

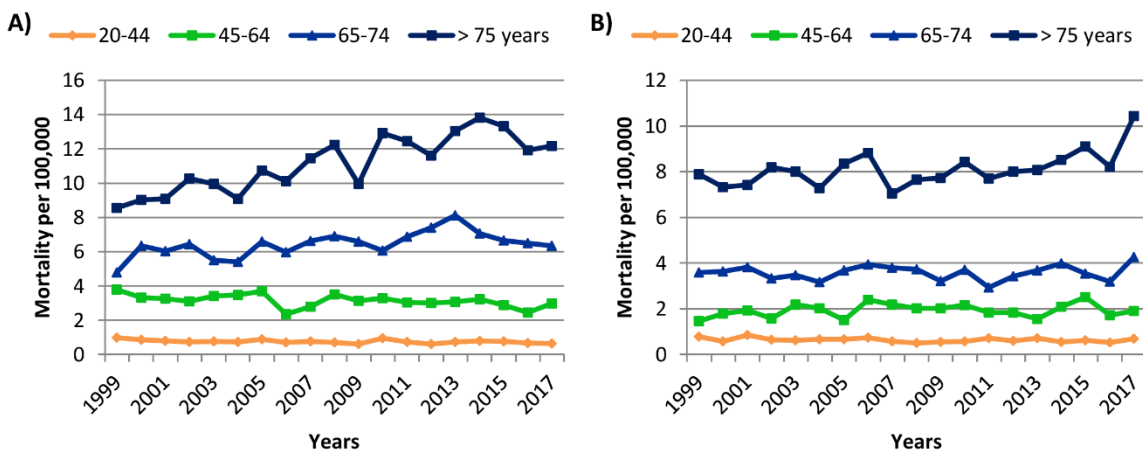


Figure 3 (A) Length of hospital stay (LOHS) and (B) cost per patient stratified by age (2011-2017).

