Patient-reported real-world treatment patterns for melanoma in the UK measured using a digital 'bring your own device' platform

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BACKGROUND

Melanoma

Melanoma is an aggressive form of skin cancer that originates from melanocytes in the basal layer of the epidermis.[1]

Melanoma is the fifth most common cancer in the UK, with 15,906 new cases registered in 2015.[2]

The incidence is rising, especially in older adults – just over half of melanoma cases each year are in people aged 65 years and over.[2]

However, melanoma also occurs relatively frequently in younger people (in contrast to most types of cancer): just under a third of melanomas in the UK between 2013 and 2015 were in patients aged younger than 50 years.[2]

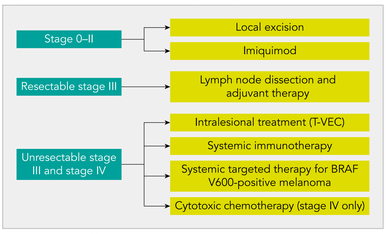
New treatments in melanoma are gradually transforming the disease into a chronic condition:

- for advanced disease stages, the median survival has significantly increased (from 9 months in stage 4 patients with limited treatment options,[3] to a 3-year survival rate of up to 58%, with a proportion of them living to 5-10 years.[4]
- in the early setting, adjuvant therapy is taking a prominent place in the therapeutic landscape, with many patients with normal life expectancies being exposed to treatments with potential side effects (some long-term or irreversible).[5]

Treatment guidelines

The treatment of melanoma varies depending on the stage of the disease (see Figure 1).[6]

Figure 1: NICE melanoma treatment pathway



Abbreviations: T-VEC, talimogene laherparepvec

The value of real-world data

Real-world data are vital to understand the impact of a chronic condition such as melanoma, and its treatment, on patients' lives, symptoms, functioning, work and other forms of productivity and daily activities, such as caring for a family.

The NICE methods guide[7] recommends collection of real-world data as a condition of entry into the revised Cancer Drugs Fund (CDF), to address uncertainty in technology appraisal.

In the real-world setting, data can be collected from a broader range of patients than is encountered in clinical trials, including those with co-morbidities and across all age ranges.

In the UK, melanoma patients are registered at the population level by one of the four National Cancer Registries and numerous regional melanoma registries; however, none of the existing registries collected health-related quality of life (HRQL) or patient-reported outcomes (PRO) data. Furthermore, the CDF requires data collect over 24 months, which is often insufficient time to develop and extract data from a de novo registry, particularly using paper-based data capture.

The MyRealWorld™ Melanoma Registry

The Melanoma Registry has been developed in collaboration with the patient advocacy organization Melanoma UK and the Royal Marsden NHS Foundation Trust (London).

The registry records patients' demographics, treatment patterns (including current and previous treatments, where they live/are treated, and frequency of consultations), adverse events, Eastern Cooperative Oncology Group (ECOG) performance status, diet and exercise, as well as monthly PRO data:

- patients complete the EQ-5D-5L, EORTC QLQ-C30 and a melanoma-focused subset of the PRO-CTCAE using the study app on their mobile devices ('bring your own device' technology);
- development of the app was informed by feedback from patients and Melanoma UK;
- patients with any type or stage of melanoma are recruited in collaboration with Melanoma UK;
- the registry was launched at the end of October 2017;
- ethical approval has been obtained;
- informed consent is obtained electronically via the study app;
- the study is fully GDPR compliant;
- the study protocol has been registered with clinicaltrials.gov:
  - ID NCT03379454;
  - study title: The impact of melanoma and drug treatment in the real world.

Patient recruitment & inclusion criteria

Patients are recruited in collaboration with Melanoma UK.

The patient inclusion criteria are broad to ensure that a wide selection of people is recruited:

- resident in UK; with NHS (or CHI) number;
- current or previous diagnosis of melanoma;
- age ≥18 years;
- willing to use their own smartphone or tablet.

Study objective

The aim of the present study was to conduct an analysis of the data recorded in the registry in order to:

- examine patient-reported treatment patterns for melanoma in UK real-world practice, including choice of treatment, and application of treatment guidelines, in close to real-time.

METHODS

Our methodology comprised two steps:

- analysis of the data collected through the app;
- scoping literature search on PubMed, to understand the current published guidelines.

RESULTS

Main treatment hospitals/clinics

Ninety one main treatment hospitals/clinics were reported by participants, the most frequently reported of which are listed in Table 1.

The wide spread of reported hospitals in our study suggests that our findings are a good representation of typical treatment patterns in the NHS.

Table 1

Hospital/clinic
The Christie (North West)
Royal Marsden (London)
Nottingham University Hospitals NHS Trust (East Midlands)
St. Helen's and Knowsley Hospitals NHS Trust (North West)
Clatterbridge Cancer Centre NHS Foundation Trust (North West)
Newcastle-upon-Tyne Hospitals NHS Foundation Trust (North East)
University Hospitals Bristol NHS Foundation Trust (South West)

Note: The results presented here are based on 146 registry participants who provided main treatment hospital/clinic data from a total sample of 396 participants recruited at the time of the data cut.

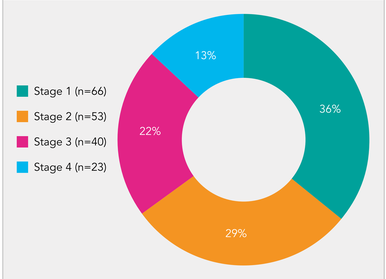
423 participants are currently registered.

Patient demographics

Participants were split across melanoma stages (Figure 2).

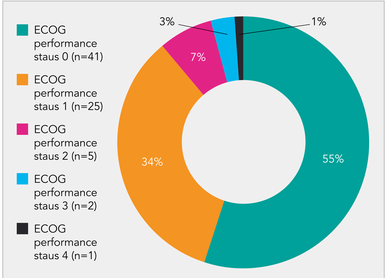
Most participants reported an ECOG performance status of 0 or 1 (Figure 3), indicating fully active or restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, respectively.

Figure 2: Current melanoma stage (n=187)



Note: 5 participants were excluded as their stage was either unknown or ocular melanoma/uveal (metastatic)

Figure 3: Latest ECOG performance status (n=187)



Note: 113 participants were excluded as ECOG performance status was unknown

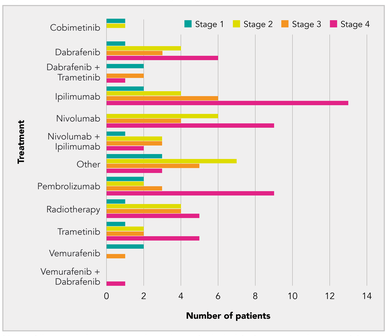
Note: The results presented here are based on 187 registry participants who provided treatment patterns data and melanoma stage from a total sample of 396 participants recruited at the time of the data cut.

Treatment by stage

The most frequently reported treatments were ipilimumab, nivolumab and other – which made up 18%, 14% and 13% of all reported treatment periods respectively (Figure 4).

In most instances, stage 4 participants were the largest group in each reported treatment – for example 56% of pembrolizumab and 52% of ipilimumab reports were by stage 4 participants.

Figure 4: Treatments received by stage (n=146)



Note: All reported treatments have been included in instances where participants reported more than one treatment; 81 participants were excluded as either no treatment was reported and/or no stage or ocular melanoma was reported

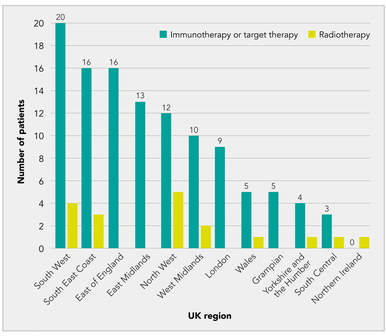
Note: The results presented here are based on 146 registry participants who provided treatment patterns data and melanoma stage from a total sample of 396 participants recruited at the time of the data cut.

Treatment by region

Immunotherapy or targeted therapy was most common in South East Coast (70% of participants), East of England (64% of participants) and South West (56% of participants) regions (Figure 5).

Radiotherapy was more common in North West (15% of participants) and South West (11% of participants) regions, but was not used to treat any participants in the East of England and East Midlands regions.

Figure 5: Treatment instance by region (n=133)



Note: Differences in treatments between regions do not take into account other variables (e.g., age, disease stage, ECOG performance status); 75 participants were excluded who reported either 'no treatment' or 'other treatment'; 1 participant is counted twice as they reported two different regions

Note: The results presented here are based on 133 registry participants who provided both location and treatment patterns data from a total sample of 396 participants recruited at the time of the data cut.

DISCUSSION AND CONCLUSIONS

Treatment of melanoma in the UK real-world setting broadly follows published guidelines, with use of immunotherapies and targeted therapies reported mostly by stage 3 and 4 participants.

The value of this dataset is that it comes directly from melanoma patients, in real-time. However, this makes it open to potential errors. 30% of stage 2 participants, for example, reported having received nivolumab, despite the fact that this immunotherapy is unlikely to have been recommended to stage 2 patients per published guidelines. Such results may indicate that these participants have progressed to a more severe stage of melanoma (one in which immunotherapies and targeted therapies would be recommended as a treatment) but have not updated their stage profile in the study app for some reason.

While the results from the dataset presented here should be interpreted with caution, the registry is ongoing and improvements to the design of the app are being implemented with input from patients to ensure that it better captures real-world practice. Such improvements will enable gaps in care to be identified and addressed.

In the future, the registry will also allow real-time exploration of changes in the treatment landscape (e.g., the introduction of dabrafenib with trametinib in October 2018, and encorafenib with binimetinib in February 2019).

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