



ORIGINAL ARTICLE

Health-Related Quality of Life in Patients with Locally Advanced or Metastatic Basal Cell Carcinoma Treated with Vismodegib and Treatment-Related Adverse Events: A Study at University Hospital of Oran, Algeria.

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ABSTRACT

Objective: The objective of our study was to evaluate the health-related quality of life (HRQoL) in patients with locally advanced or metastatic basal cell carcinoma (BCC) using the Dermatology Life Quality Index (DLQI) after six months of treatment with vismodegib and to describe the adverse events (AEs). **Materials and Methods:** A prospective, monocentric study was conducted over a one-year period in the Department of Dermatology and Venereology, in collaboration with the Pharmacovigilance Department at EHU-Oran, Algeria. The study included all adult patients treated with vismodegib for locally advanced or metastatic BCC at the day hospital to assess HRQoL using the DLQI after six months of treatment and to describe the associated AEs. **Results:** Three male patients with histologically confirmed BCC—two with locally advanced BCC and one with metastatic BCC—were included in the study. The median age of the participants was 64 years. The BCC lesions were located on the auricle, face, and back, with the metastatic patient experiencing pulmonary and osseous metastases. The DLQI was assessed both before the initiation of treatment and after six months of vismodegib therapy. The mean DLQI score decreased from an initial average of 9 to 0.33. Reported AEs included muscle spasms, fatigue, alopecia, loss of appetite, and creatine phosphokinase elevation. **Conclusion:** This study highlights a significant improvement in HRQoL among patients treated with vismodegib, as evidenced by the reduction in DLQI scores over six months.

Keywords: BCC, HRQoL, DLQI, Vismodegib, Adverse events.

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1. INTRODUCTION

Basal cell carcinoma (BCC) is the most common form of non melanoma skin cancer (NMSC), accounting for over 90% of all NMSC cases. It is particularly prevalent among fair-skinned populations, representing 65% of epithelial tumors. Approximately 80% of BCC cases occur in the head and neck region. BCC originates from the basal cells of the epidermis and the pilosebaceous unit(1-3). This type of cancer typically manifests in adulthood, especially from the fifth decade of life, and is characterized as a slow-growing tumor(4). While BCC rarely results in death or metastasis, some cases can progress to an advanced or, in rare instances, metastatic stage. Nonetheless, it can still lead to significant morbidity due to its locally destructive nature(5-6).The incidence of BCC is continuously increasing worldwide, with the highest rates reported in Australia and the lowest observed in Africa(7).Risk factors for BCC include genetic and phenotypic predispositions, intermittent intense sun exposure, chronic exposure to arsenic, certain autoimmune conditions, immunosuppression, and secondary effects from various therapies, such as psoralen plus ultraviolet A (PUVA) phototherapy and

ionizing radiation(8-9).At the genetic level, the primary driver of the condition is the overactivation of the Hedgehog (Hh) signaling pathway, typically resulting from inactivating mutations in the negative regulator PTCH1 or, less frequently, from activating mutations in the positive regulator Smoothened homologue (SMO) (10).

The Hh signaling pathway plays a crucial role as a key regulator of patterning and growth during embryogenesis; it is mostly inactive or poorly active in adults. Dysfunction or aberrant activation of the Hh signaling pathway is associated with developmental deformities and cancers, such as sporadic BCC(11).Surgery is the primary treatment for BCC, aimed at achieving complete tumor resection and reconstructing the defect using the most effective repair techniques to ensure optimal aesthetic results. Some cases may progress to an advanced or, rarely, a metastatic stage. In such instances, non-surgical treatments such as cryotherapy, adjuvant radiotherapy, and targeted therapy may be necessary(4-5).Vismodegib is a novel, first-in-class oral small molecule inhibitor of the Hh pathway. It received approval from the United States Food and Drug Administration (FDA) in January 2012. In July 2013, the European Medicines Agency (EMA) also approved vismodegib for the treatment of adult patients with symptomatic locally advanced or metastatic BCC who are not candidates for surgery or radiotherapy(12-13).

Adverse events (AEs) are believed to be mechanistically related to the inhibition of the Hh pathway. These AEs can significantly interfere with patients' quality of life (QOL), leading to treatment interruptions and discontinuation, which may hinder the intended therapeutic effect. Therefore, implementing appropriate strategies for the prevention and management of AEs is essential to ensure that patients can continue to receive and benefit from hedgehog pathway inhibitors (HPI) treatment. Patient education is crucial for effectively managing these AEs and preventing treatment discontinuation(14-15). A delay in diagnosis and treatment is one factor that can contribute to the progression of locally advanced BCC. However, when detected early, even high-risk BCC can be effectively treated, providing an opportunity for behavioral change and improved health-related quality of life (HRQoL)(16-2).HRQoL refers to an individual's perception of how illness and its treatment affect the physical, psychological, and social aspects of their life. It plays a significant role in dermatology(17).

The objective of this study was to assess HRQoL in patients with locally advanced or metastatic BCC using the Dermatology Life Quality Index (DLQI) after six months of treatment with vismodegib, and to describe the associated AEs.

2. MATERIALS AND METHODS

This prospective study was conducted over a one-year period, from October 2023 to October 2024, within the department of dermatology and venereology, in collaboration with the pharmacovigilance department, at the University Hospital Establishment of November 1st, 1954, in Oran, Algeria. The approved therapeutic regimen for vismodegib was 150 mg per day. The study included all adult patients receiving treatment in a day hospital setting for locally advanced or metastatic BCC who were administered vismodegib.

All patients included in this case series were male. This reflects the small sample size and the incidental distribution of patients presenting during the study period, rather than a selection based on sex.To evaluate the impact of vismodegib on patients' HRQoL, a brief, self-administered, and validated DLQI questionnaire was utilized. The DLQI comprises 10 items, each rated on a scale from 0 (not at all) to 3 (very much), with intermediate scores of 1 (a little) and 2 (a lot). The questionnaire assesses six key domains: (1) symptoms and feelings, (2) daily activities, (3) leisure, (4) work and school, (5) personal relationships, and (6) treatment. The total DLQI score ranges from 0 to 30, with higher scores indicating a greater impairment of HRQoL. In normal populations, mean DLQI scores typically range from 0 to 0.5 (18-19-20-21).

Patients completed the DLQI questionnaire both before initiating treatment and after six months of vismodegib therapy to assess its specific impact on their HRQoL (Fig. 01).

Inclusion Criteria

All patients with locally advanced or metastatic BCC who received treatment with vismodegib in the dermatology department during the study period were included. Due to the very limited availability of vismodegib—provided to the hospital as restricted-quantity samples because of its particularly high cost—and in the absence of an equivalent therapeutic alternative, all patients treated with vismodegib were systematically included in the study.

Exclusion Criteria

No exclusion criteria were applied. Given the small number of eligible patients and the restricted access to this costly treatment, no patient receiving vismodegib was excluded from the study.

DERMATOLOGY LIFE QUALITY INDEX (DLQI)

Hospital No: Date:
Name: Score:
Address: Diagnosis:

The aim of this questionnaire is to measure how much your skin problem has affected your life
OVER THE LAST WEEK. Please tick (✓) one box for each question.

1. Over the last week, how itchy, sore, painful or stinging has your skin been?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	
2. Over the last week, how embarrassed or self conscious have you been because of your skin?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	
3. Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐
4. Over the last week, how much has your skin influenced the clothes you wear?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐
5. Over the last week, how much has your skin affected any social or leisure activities?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐
6. Over the last week, how much has your skin made it difficult for you to do any sport?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐
7. Over the last week, has your skin prevented you from working or studying?	Yes ☐	
	No ☐	Not relevant ☐
If "No", over the last week how much has your skin been a problem at work or studying?	A lot ☐	
	A little ☐	
	Not at all ☐	
8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐
9. Over the last week, how much has your skin caused any sexual difficulties?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐
10. Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	Very much ☐	
	A lot ☐	
	A little ☐	
	Not at all ☐	Not relevant ☐

Please check you have answered EVERY question. Thank you.

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Figure 1. Dermatology Life Quality Index (DLQI).

Ethical statement: This study was conducted in accordance with ethical standards. The protocol was approved by the Scientific Council of Establishment Hospital University of Oran (EHU-O). Participants provided informed consent before answering the DLQI questionnaire.

3. RESULTS:

Three male patients with histologically confirmed BCC—two with locally advanced BCC and one with metastatic BCC—were included in a monocentric prospective study. The median age of the participants was 64 years, ranging from 62 to 69 years. Their demographic, clinical, and dermatological characteristics are presented in table 1. The BCC lesions were located on the auricle, face, and back, with the latter patient experiencing pulmonary and osseous metastases. All three patients completed the DLQI questionnaire at their baseline visit and again after six months of treatment. The DLQI was assessed both before the initiation of treatment and after six months of vismodegib therapy. Baseline DLQI scores ranged from 7 to 12, with the highest score recorded in the patient with facial BCC (Fig. 2).

Table 1. Demographic, Clinical, and Dermatological Characteristics of the Patients.

Parameter	Patient 1	Patient 2	Patient 3
Age (years)	62	61	69
Sex	M	M	M
Location of basal cell carcinoma	Face	Auricle	Back
Initial lesion size (cm)	10cm	4cm	13cm
Histological subtype	Nodular subtype	Not specified	Nodular subtype
Duration before treatment	28 years	4 years	12 years
Comorbidities	None	None	Hypertension (HTA)
Concomitant / Prior treatments	None	Prior: excision + flap repair (auricle) Concomitant: - Adenosine triphosphate disodium trihydrate - Cholecalciferol	Prior: Chemotherapy (prior to Vismodegib)
Skin phototype(Fitzpatrick)	III	V	II
Dermatological history	None	None	None

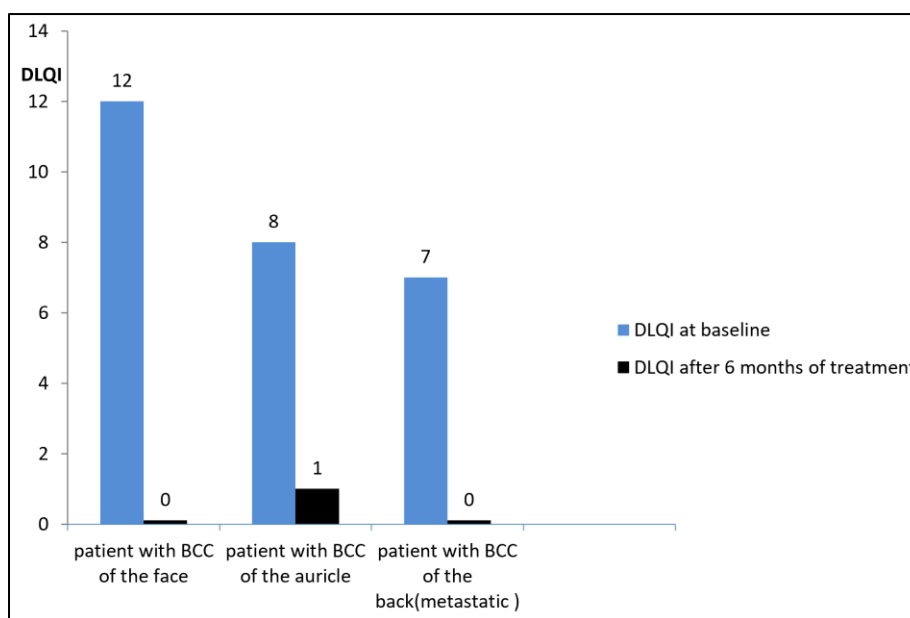


Figure 2. DLQI values at baseline and after 6 months of treatment with vismodegib in patients with locally advanced or metastatic BCC classified according to BCC location.

The mean DLQI score decreased from an initial value of 9 to 0.33 after six months of treatment (table 2).

Table 2. Evolution of mean DLQI before and after 6 months of vismodegib treatment.

	N	Minimum	Maximum	Mean
Score DLQI before treatment	3	7,00	12,00	9,00
Score DLQI after 6 months of treatment	3	0,00	1,00	0,33

AEs reported included muscle spasms, fatigue, alopecia, loss of appetite, and creatine phosphokinase (CPK) elevation. All patients had muscle spasms of varying intensity; two patients reported fatigue, and two presented alopecia. One patient experienced CPK elevation, and one had loss of appetite (Fig. 3).

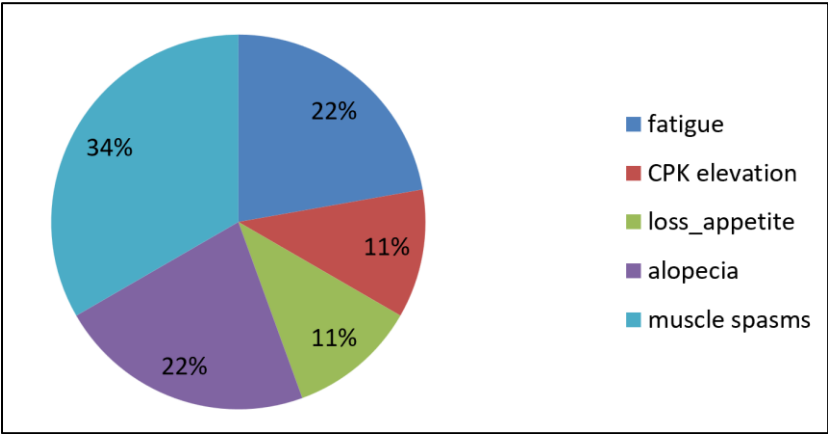


Figure 3. Distribution of AEs in patients with locally advanced or metastatic BCC treated with vismodegib.

All patients received oral vismodegib at a dosage of 150 mg once daily, administered continuously in 28-day cycles over six months. During the follow-up, all patients showed stable CPK values within normal limits, except for one patient. In this patient, the initial CPK level was 83.2 U/L, which increased to 308 U/L after the fourth cycle of vismodegib. However, due to the occurrence of severe muscle spasms as an adverse effect and CPK elevation, and following the advice of the rehabilitation specialist, treatment was interrupted for 21 days, and the patient received adenosine triphosphate disodium trihydrate (30 mg) for 15 days as a muscle relaxant, along with cholecalciferol supplementation (200,000 IU) for three months. When the CPK level decreased to 78 U/L, vismodegib was resumed on an intermittent regimen, one capsule every other day(150 mg/48 h) (Table 3). The patient’s CPK was then 114 U/L.

Table 3. Administration schedule of vismodegib in patients with locally advanced or metastatic BCC during 6 months of treatment.

Administration schedule of vismodegib	number of patients
Continuous treatment (150mg/24h)	02
Intermittent treatment (150mg/48h) after 4 cycles.	01

4. DISCUSSION:

The study population consisted exclusively of adults, which aligns with existing literature on BCC. That said, the very small sample size limits the generalizability of our findings (3-22). However, since all patients in our study were male, we cannot determine gender predominance. Nevertheless, the majority of published studies indicate a higher prevalence of BCC in males(22-23-24).Consistent with prior research, the most AEs associated with vismodegib treatment in our cohort included fatigue, CPK elevation, loss of appetite, muscle spasms, and alopecia (25-26-27). Notably, while most AEs manifested early in treatment, alopecia emerged as a delayed side effect, a finding corroborated by Kate Fife et al.(27). In one case, treatment was interrupted after the fourth month for 21 days. Subsequently, an intermittent regimen was introduced to alleviate severe muscle spasms while maintaining therapeutic efficacy and preventing further treatment discontinuation (28).

Regarding HRQoL, the patient with facial BCC exhibited the highest baseline DLQI score, consistent with findings reported by Villani et al. and Jette Skiveren et al. (29-30). BCC significantly impacts patients’ QoL, not only due to the tumor itself but also as a result of therapeutic interventions and their associated AEs(31). However, data regarding HRQoL outcomes in patients with advanced BCC treated with vismodegib remain limited. Our findings demonstrate that vismodegib therapy improves HRQoL in patients with locally advanced or metastatic BCC. Although similar findings have been reported in larger studies using the DLQI and other assessment tools, these comparisons are descriptive and limited by the small sample size(29,32,33).

The STEVIE Phase 2 study (NCT01367665), led by Johan Hansson and colleagues, evaluated the safety of vismodegib and its impact on HRQoL in 730 patients with locally advanced or metastatic BCC who were not candidates for surgery or radiotherapy. Patients

completed the Skindex-16 and the MD Anderson Symptom Inventory (MDASI) at baseline and at follow-up visits. Both tools showed improvements in HRQoL during treatment with vismodegib (32). Similarly, Gualdi et al. evaluated HRQoL in 10 patients with locally advanced BCC treated at the ASST Spedali Civili of Brescia using the Pictorial Representation of Illness and Self Measure (PRISM) test. The results, expressed as the Self-Illness Separation (SIS) score, showed significant improvements in HRQoL over the course of treatment (33).

In our study, the DLQI was employed to assess HRQoL before and after six months of treatment, demonstrating a significant decrease in DLQI scores. The DLQI has been extensively used in HRQoL assessments for patients, with prior studies confirming that a lower DLQI score indicates improved HRQoL (20).

A 2019 study by Villani et al., involving 48 patients with advanced or multiple basal cell carcinomas treated at the Non-Melanocytic Skin Cancer Unit of the University of Naples Federico II, Italy, demonstrated a notable improvement in QoL. DLQI scores significantly decreased from 5.7 at baseline to 0.4 after six months of vismodegib therapy (29). Other studies evaluating surgical and radiotherapy options for BCC have also documented similar reductions in DLQI scores, reinforcing the findings of our study. For instance, Rhee et al. conducted a prospective study with 121 patients who had NMSC of the head and neck and underwent Mohs surgery. They found a reduction in DLQI scores, from 2.4 ± 2.7 at baseline to 1.7 ± 2.9 four months after surgery (34). Blackford et al. found that DLQI scores declined from 5.3 ± 4.1 at baseline to 1.3 ± 2.1 three months post-surgery (35). Additionally, in a study by Çetinarslan et al., patients with BCC showed a significant reduction in DLQI scores, from 6.37 ± 6.28 to 3.96 ± 5.14 three months post-surgery. Although the study also included patients with SCC, the results for BCC are directly relevant to our analysis (36). Similarly, a 2012 study by Jette Skiveren et al. involving 25 patients with advanced BCC undergoing X-ray therapy demonstrated a reduction in DLQI scores from 1.2 ± 1.5 at baseline to 0.4 ± 0.9 post-treatment, indicating an improvement in HRQoL (30).

After six months of treatment, the mean DLQI score significantly decreased from 9 to 0.33. Although based on a very small sample, this trend is in line with the improvement reported by Villani et al. in a larger cohort (29). These findings underscore vismodegib's effectiveness in enhancing the HRQoL of patients with locally advanced or metastatic BCC, thereby contributing to the growing body of evidence supporting its therapeutic benefits.

Limitations

Several limitations should be acknowledged, including the small sample size, which may introduce bias and limit generalizability, as well as the short study duration, which may not fully capture long-term effects. Additionally, some researchers argue that the DLQI may not be sufficiently specific for assessing HRQoL in BCC patients, indicating the need for more targeted evaluation tools.

5. CONCLUSION

Our study demonstrates that a six-month treatment with vismodegib significantly improves HRQoL in patients with locally advanced or metastatic BCC, despite the occurrence of AEs. The reduction in DLQI scores underscores its positive impact; however, careful management of side effects remains essential to ensure treatment adherence.

Competing interests: The authors declare that they have no competing interest.

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