

Treatment of basal cell carcinoma with HeberFERON®: clinical study

Abstract

Objective: To evaluate the effectiveness of HeberFERON® in the treatment of basal cell carcinoma (BCC) in patients treated at the “Dr. Juan Bruno Zayas Alfonso” General Teaching Hospital.

Methods: An observational, descriptive and longitudinal study was conducted in patients with facial BCC treated with HeberFERON®. Sociodemographic variables, tumor characteristics, response to treatment and adverse effects were analyzed.

Results: 20 patients were included, predominantly male (55%) and the age group 60 years or older (65%). The nodular type was the most frequent (40%) and the most common location was the nasal region (48.1%). 70% of patients had a complete response to treatment. The most frequent adverse reactions were arthralgia (28.1%), general malaise (25.2%) and fever (20.0%).

Conclusion: HeberFERON® is an effective therapeutic alternative for BCC, reducing the need for surgery and preserving facial aesthetics.

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Introduction

Basal cell carcinoma (BCC) is a skin neoplasm of limited malignancy, slow growth and little capacity to give metastases, originating in the epidermal cells of the hair follicles or the basal cells of the epidermis.¹ It is the most frequent malignant skin tumor, representing approximately 70% of all non-melanomatous skin cancers (NMSC).²

Despite being a tumor of low malignancy, it has a high incidence, which from the point of view of morbidity, makes it an important health problem.³ It occurs more frequently in the male sex, with a ratio of 2:1, presumably related to greater sun exposure for occupational reasons.⁴ However, there are reports in which a slight predominance of the female sex over the male is observed.³

It has been determined that the etiology is multifactorial, where both constitutional and environmental factors can play a role.⁵

Treatment is aimed at removing or destroying the entire tumor. There are various therapeutic modalities, surgical and non-surgical, including: conventional surgery, Mohs micrographic surgery, curettage and electrodesiccation, cryosurgery, CO2 laser, radiotherapy, photodynamic therapy, and pharmacological treatments with Imiquimod and 5-Fluorocil.⁶ Surgery is considered the treatment of choice for BCCs for two main reasons; it allows for the highest percentages of cures compared to other treatments and facilitates histological control of tumor margins.⁷

When multiple BCCs are present, their removal with invasive methods becomes impractical; In these cases, one of the recommended treatments is the use of interferons, an immunotherapy that can be administered parenterally for a long time to control the disease.⁸ Interferons are a family of naturally synthesized glycoproteins that express antiviral, immunomodulatory and antitumor capacity. There are three main classes of interferon: type I (interferon alpha and interferon beta) and type II (interferon gamma). By binding to specific receptors, interferons initiate a series of intracellular events through the Jak-stat signaling pathway.⁹

The mechanisms by which interferon induces tumor regression are not yet fully understood. However, immunohistochemical analysis of post-treatment biopsies has shown a marked increase in the number of T lymphocytes, with a slight predominance of CD4+ T lymphocytes, suggesting that immune modulation is important. It has been observed in vitro that interferon alpha and granulocyte- monocyte colony-stimulating factor (gm-csf) induce the transformation of monocytes into dendritic cells with the ability to induce T-lymphocyte activation with great anti-tumor activity.¹⁰

The use of HeberFERON® is indicated in the perilesional (intradermal) or intralesional treatment of basal cell carcinoma previously confirmed by biopsy. It can be used as an alternative or adjuvant treatment for other procedures (surgical or not) as well as in lesions of any size, of any clinical subtype and in any location, high risk (H zone of the face) or locally advanced (lesions difficult to treat due to local invasion and/or proximity to vital structures such as eyes and brain). HeberFERON® is 5 to 10 times more potent than IFNs alone, promotes a faster and longer clinical response with an excellent safety profile; It reduces the rate of appearance of new lesions and recurrences, provides 98.6% disease control (RC+PR+PE), can be used pre-surgical, to reduce tumor size; after surgery to prevent recurrence; or as a first option in non-surgical, or recurrent tumors, or for cosmetic reasons.¹¹

Methodology

An observational, descriptive and longitudinal study was conducted at the “Dr. Juan Bruno Zayas Alfonso” General Teaching Hospital between May 2018 and May 2020. Patients over 18 years of age with a diagnosis of facial BCC confirmed by biopsy were included.

HeberFERON® was administered intralesionally in alternating doses for three weeks. Response to treatment was assessed by dermatoscopy at 16 weeks, classifying it as complete response, partial response or disease progression.

Sociodemographic variables, type of lesion, location, size, adverse effects and therapeutic response were recorded.

Results

Twenty patients were included, with a predominance of males (55%) and the age group 60 years or older (65%). The nodular histological subtype was the most frequent (40%), followed by superficial (25%) and sclerodermiform (35%). The nasal region was the most common location (48.1%).

After 16 weeks of treatment, 70% of patients had a complete response and 30% a partial response. The most frequent adverse reactions were arthralgia (28.1%), malaise (25.2%) and fever (20.0%), which were mild and transient.

Patients with lesions smaller than 4 cm had a better response to treatment.

Discussion

HeberFERON® has proven to be an effective therapeutic option for the treatment of BCC, avoiding in many cases the need for surgery and its potential aesthetic sequel. In this study, a complete response rate of 70% was obtained, similar to that reported in previous research.

The mechanism of action of HeberFERON® combines immunomodulatory and antiproliferative effects that contribute to tumor reduction. It has been observed that patients with lesions smaller than 4 cm respond better to treatment, suggesting that its early application could optimize clinical results.

Although adverse reactions occurred, they were mild and did not require discontinuation of treatment, which reinforces the safety of its use.

Conclusions

Treatment of basal cell carcinoma with HeberFERON® proved to be effective, achieving a high rate of tumor remission without the need for surgical procedures. Its safety and effectiveness profile make it a viable alternative for lesions in areas of high aesthetic impact. Its application is recommended in selected cases to maximize its benefits.

Acknowledgments

None

Conflicts of interest

The authors have no conflicts of interest to declare.

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