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Topical Cream Curaderm^{bec5} Treats a Recalcitrant Basal Cell Carcinoma

Batsev AF[1], Dobrokhotova VZ[1] and Cham BE[2]*

[1]*N.N. Blokhin Russian Cancer Research Center of Russian Academy of Medical Sciences, Moscow, Russian Federation*

[2]*Australasian Medical Research, Port Vila, Republic of Vanuatu*

***Corresponding author:** *Bill Cham, Australasian Medical Research, Port Vila, Republic of Vanuatu, Tel: +678-7750987, E-mail: bill.cham@gmail.com*

Abstract

Solasodine rhamnosides, solamargine and solasonine, are antineoplastics with high affinity, high efficacy and low toxicity as shown in cell culture, animal and human studies. The mode of action is by apoptosis and is accompanied by a high order of specificity. This specificity towards cancer cells is ideal for treating skin cancers. Previous studies show that solasodine rhamnosides in a topical cream formulation Curaderm^{BEC5} is a highly regarded therapy for nonmelanoma skin cancers. A case is reported which indicate that Curaderm^{BEC5} is clinically effective for the treatment of a large basal cell carcinoma on the nose of a patient that had been treated unsuccessfully on three previous separate occasions by surgery, radiation therapy and photodynamic therapy.

Keywords

Nonmelanoma skin cancers, Solamargine, Solasonine, Curaderm, Surgery, Radiation, Photodynamic therapy

Introduction

Skin cancer is the most common form of human cancer resulting in over 10,000 deaths annually in the USA. The incidence of skin cancer is higher than all other cancers combined. Approximately 80% of all skin cancers are basal cell carcinomas (BCCs), approximately 16% are squamous cell carcinomas (SCCs) and 4% are melanomas.

Treatment for nonmelanoma skin cancers (NMSC) depends on the size and location of the cancer, whether it is BCC or SCC, and age and overall health. The goals of treatment for NMSC are to remove the entire skin cancer and a margin of skin tissue around the cancer to reduce the chance of recurrence and to preserve nearby skin tissue that is free of cancer and minimize scarring after treatment.

Current treatment options include [1] excision of the skin cancer along with some healthy skin boarder, [2] Mohs micrographic surgery removes the skin cancer one layer at a time, checking each layer for cancer cells after it is removed, [3] radiation therapy uses x-rays or other types of radiation to kill cancer cells, [4] cryosurgery destroys the skin cancer by freezing it with liquid nitrogen, [5] curettage and electrosurgery uses a spoon-shaped instrument (curette) to scrape off the skin cancer, and electrosurgery controls the bleeding and destroys any remaining cancer cells.

For BCC, additional options are available, including photodynamic therapy, laser surgery, topical creams such as topical fluorouracil (5-Fu), and topical imiquimod. The advantages and limitations of these treatment options have previously been described [1-3].

However, most of the above treatments lack specificity. This deficiency translates to these treatments not being completely effective in all patients for various reasons, such as, insufficient excision margins. This is a major shortcoming with current therapies.

Solasodine rhamnosides are secondary metabolites of plants and protect against bacteria, viruses, fungi, insects and animals. They are found mainly in Solanaceae and Liliaceae. Recent reports indicate that solasodine rhamnosides can induce apoptosis in cancer cells. Thus, several studies have shown positive clinical and histological effects of topical application of solasodine rhamnosides to skin cancer [1-11]. In this paper, we present a case report of a patient with a large recalcitrant BCC on the nose.

Case Report

A 78 year old woman was referred for consultation because she had a 2-cm large and several mm deep tumour on the tip of her nose (Figure 1(a)). The patient had a history of BCC treated by surgical removal followed by laser and photodynamic therapies. Histological analyses of a biopsy showed the recurrence of the BCC.

The patient who had this relapsed BCC elected to treat the lesion with the cream formulation Curaderm^{BEC5}. The cream formulation Curaderm^{BEC5} is registered in the Russian Federation and in several countries and is available to patients. Curaderm^{BEC5} contains the glycoalkaloids BEC consisting mainly of solamargine and solasonine [1-11] at 0.005% as a topical cream formulation. The cream was applied 2-4 times daily under occlusive dressing (micropore paper tape) until the lesion had clinically regressed. The patient experienced some transient minor stinging that lasted for up to 15 minutes after application of the cream to the lesion. The patient was followed up after 10 weeks after completion of therapy.

Figure 1(a) shows the extent of the BCC after failed previous therapies but just before treatment with Curaderm^{BEC5}. The lesion responded rapidly to the treatment and appeared larger at 2 weeks of treatment (Figure 1(b)).

Continuous treatments show the progress of the lesion at 5 weeks (Figure 1(c)), 8 weeks (Figure 1(d)), 14 weeks (Figure 1(e)), after commencement of therapy. Treatment was stopped at 14 weeks. Figure 1(f) shows the treated area 7 weeks and Figure 1(g) 10 weeks after completion of therapy.

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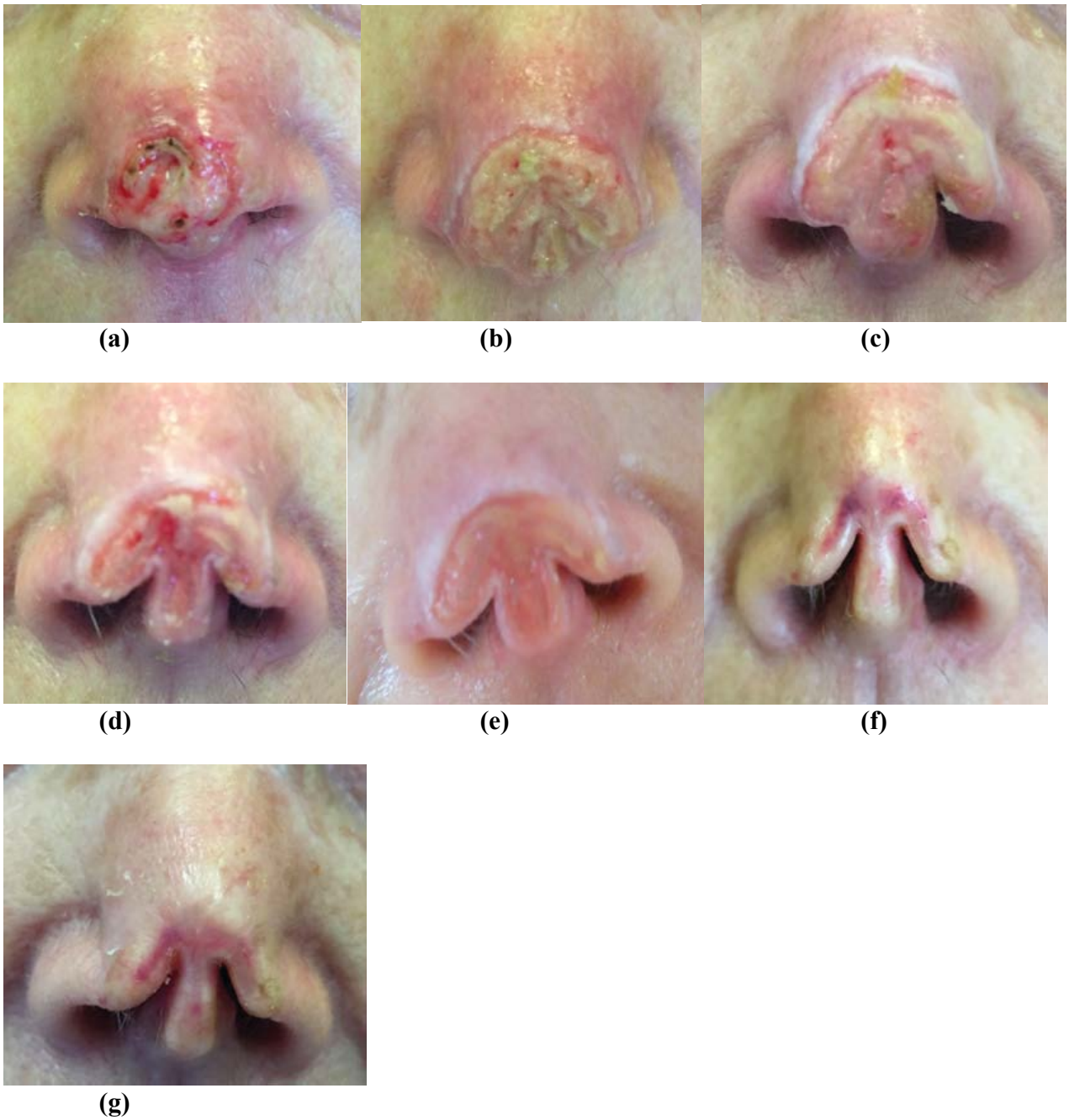

Figure 1: A large infiltrating refractory BCC which recurred after three failed attempts by widely accepted therapies; (**a**) immediately before commencement with Curaderm^{BEC5} therapy; (**b**) 2 weeks; (**c**) 5 weeks; (**d**) 8 weeks and (**e**) 14 weeks during Curaderm^{BEC5} therapy. Treatment stopped at 14 weeks of therapy. Appearances of treated lesions (f) 7 weeks and (g) 10 weeks after cessation of treatment.

Discussion

Solasodine rhamnosides preferentially interact with cancer cells only, but not normal cells and subsequently cause apoptosis only in cancer cells. This phenomenon is due to identified and characterized specific receptors, found on cancer cells only [1], which bind and internalize the solasodine rhamnosides leading to interaction with lysosomes and mitochondria. Subsequently, these cells commit suicide (apoptosis) by triggering intrinsic and extrinsic apoptotic pathways by up-regulating the expression of external death receptors such as tumour necrosis factor receptor 1 (TNF1), Fas receptor, TNF-1 associated death domain and Fas associated death domain. The solasodine rhamnosides enhance the intrinsic ratio of Bax to Bcl-2 by up-regulating Bax and down regulating Bcl-2 and Bcl-x expressions. These effects result in activation of the enzymes Caspase -8, -9 and -3 leading to apoptosis in cancer cells [1,2].

Open studies and double blind placebo controlled clinical trials have shown that solasodine rhamnosides in a cream formulation Curaderm^{BEC5} is very effective for treating NMSC [1-11]. The main feature of Curaderm^{BEC5} therapy over other therapies is the specificity towards cancer cells, which translates to low recurrences of the cancers and the impressive cosmetic outcomes.

A flaw with Curaderm^{BEC5} therapy is the duration of treatment period, which ranges from 2 weeks to 14 weeks, depending on the size and type of the skin cancer. However, this must be viewed in the proper context. Topical cream and gel formulations for the treatment of less serious conditions such as actinic keratoses require treatment periods in the same range as with Curaderm^{BEC5} for the more serious NMSC. In addition, the impressive cosmetic end results with Curaderm^{BEC5} therapy far outweigh the inconvenience of the treatment duration period [1-11].

The case presented here is a large and anatomically difficult to treat BCC. Treatment with Curaderm^{BEC5} resulted initially in an increase in size of the BCC indicating the removal of cancer cells that were initially not observable with the bare eye. Continual treatment afforded reduction in size until the BCC was clinically completely eliminated. During this process the eliminated cancer cells were being

replaced with normal skin cells indicating specificity of Curaderm^{BEC5} for cancer cells. It has been reported that in some instances the initial increase in size with Curaderm^{BEC5} therapy could be as high as double the initial lesion size [3].

Therapy with Curaderm^{BEC5} is self-titrating, treatment is only stopped after the entire lesion has been replaced with normal skin and this depends on the type, size and depth of the lesion on the skin. Hence small BCC lesions can take one week of treatment and large lesions may take up to 14 weeks treatment. Treatment is only stopped when complete clinical regression is observed. These treatments criteria have resulted in no recurrences for over 5 year's follow-up periods [1]. These observations are only possible because of the specificity of the solasodine rhamnosides in Curaderm^{BEC5} towards cancer cells. With the case presented here, Curaderm^{BEC5} therapy required 14 weeks of treatment. The BCC was initially 2 cm in diameter and had undergone three failed therapies including surgery, laser and photodynamic therapies.

Considering the history and the previous three failed therapies for this lesion, the cosmetic outcome is limited because of by the three previous failed therapies. The alternative treatment for this patient was prosthesis.

Large BCCs without other previous therapies when treated with Curaderm^{BEC5} have resulted in excellent cosmetic outcomes [1-11]. Functionality of skin cancer affected areas has also been restored with Curaderm^{BEC5} therapy [11].

Recently it was reported that Curaderm^{BEC5} therapy was effective in patients with BCCs that had previously undergone a failed treatment with either surgery, radiation therapy, photodynamic therapy, cryosurgery or imiquimod cream [9]. This is the first reported case whereby three different therapies had failed on the same BCC and that Curaderm^{BEC5} was successful in its removal.

The follow-up period for the case presented here is currently 10 months with no signs of recurrence. Patients who have been treated with Curaderm^{BEC5} for BCCs and SCCs and have been followed up for 5 years have not shown recurrences [1-9].

Conclusion

Solasodine rhamnosides, such as solamargine and solasonine, have been shown to induce apoptosis with high specificity towards skin cancer cells. This study presents a case report where treatment with solasodine rhamnosides (Curaderm^{BEC5}) resulted in regression of a BCC on the nose, which had recurred after three failed attempts by widely accepted therapies. These data confirm promising effects of solasodine rhamnosides in the treatment of refractory BCCs.

Author Contributions

A.F. Batsev and V.Z. Dobrokhotova supervised the treatment of the patient. B.E. Chamanalysed and interpreted the patient data and was a major contributor in writing the manuscript.

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